Medical Technology Assessment Directory: A Pilot Reference to Organizations, Assessments, and Information Resources

Council on Health Care Technology
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Medical Technology Assessment Directory

A Pilot Reference To Organizations, Assessments, and Information Resources

Clifford Goodman, Editor

Council on Health Care Technology
Institute of Medicine

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NOTICE: This *Directory*, a project of the Council on Health Care Technology of the Institute of Medicine, fulfills in part the provision in Section 309 of Public Law 98-551 that the council serve as a clearinghouse for information on health care technologies and assessments.

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The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an advisor to the federal government and its own initiative in identifying issues of medical care, research, and education.

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INFORMATION PANEL OF THE COUNCIL ON HEALTH CARE TECHNOLOGY

Project Staff

COUNCIL ON HEALTH CARE TECHNOLOGY

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ACKNOWLEDGMENTS

A novel effort to assemble information from diverse sources, this *Directory* called for a blend of experience, original thinking, and resolve. We wish to acknowledge those who contributed these qualities to the project.

We are grateful to the members of the Information Panel for lending their experience in health plan and facility management, medicine, bioengineering, health care product development, third party payment, medical informatics, and national health policy to building a technology assessment information capacity. Of import to meeting this, the first charge of the congressional mandate for the council, is the members' ability to coalesce their sectorial interests into a group effort of needs assessment, systems design, product development, strategic planning, and marketing.

Pamela Simerly deserves special recognition for her skill and perseverance in helping to plan the project, and in assembling, reviewing, and processing information used for the assessment program profiles. Leslie Hardy collected and organized descriptive information for many of the entries in the information and data resources part of the *Directory*. Wallace Waterfall and James Gormley provided advice on editorial matters and layout.

Peter Goldschmidt's knowledge of information systems, medicine, and management made him a worthy consultant to the project. He brought systematic thinking and thoroughness to matters ranging from reviewing for relevance thousands of assessment report citations to setting the project within a long range plan. Grace McCarn provided insightful consultation regarding the needs and capabilities of the medical information community relevant to this project, including technical aspects of such matters as indexing, production, and market placement.

Since the early stages of the project, we have sought counsel from leading institutions in management of health care information systems. The staff of the National Library of Medicine has been consistently forthcoming with constructive advice. NLM's Betsy Humphreys coordinated planning sessions with key library staff to share technological expertise and to formulate strategies for development of a broadly integrated technology assessment information base. The review undertaken by NLM staff of the *Directory* provides encouraging evidence of the utility of this body of information. Guidance concerning the design and implementation of information bases for the health community was provided by Eloise Foster and staff of the American Hospital Association Resource Center and by LeRoy Walters and staff of the Kennedy Institute of Ethics, Georgetown University.

We are very pleased with the work of the TRITON Corporation, which was responsible for assembling the information base of assessment program profiles and report citations, indexing of citation records, and preparing camera-ready copy of the *Directory*. Meriting special recognition are Patricia President, who coordinated all aspects of the contractor's effort, and Linda Malcom, who had a key role in indexing a disparate and technical body of literature. This resourceful and adaptive group also included Patricia Chang and Karen Inscoe, who were responsible for programming and data entry, and corporate officer Edsel Billingy.

Finally, we thank the people associated with the organizations described in the *Directory* who completed surveys and forwarded other material incorporated here. Many of these individuals are shown as contact persons for the profiled assessment programs and the resource organizations in the *Directory*.

LAWRENCE C. MORRIS
CHAIRMAN, INFORMATION PANEL
CLIFFORD S. GOODMAN
STAFF OFFICER

FOREWORD

The *Medical Technology Assessment Directory* is the first major published work of the Council on Health Care Technology. The *Directory* is an introductory vehicle that organizes recent and current assessment information from a broad though not comprehensive selection of assessment programs and related activities. With this edition, the council makes an overture to those with interests in medical technology assessment to become partners in building a wider and more integrated information network. How users respond to the *Directory* will help to determine which among a variety of ways this information capacity will evolve.

The council was mandated by the U.S. Congress in the Health Promotion and Disease Prevention Amendments of 1984 (P.L. 98-551) and by technical amendments made in 1985 (P.L. 99-117). The purpose of the council is to promote the development and application of technology assessment in health care and to review health care technologies for their appropriate use.

Provision for the council in P.L. 98-551 was the culmination of two streams of activity conducted under the auspices of the Institute of Medicine, National Academy of Sciences. The first was the initiative to create an entity, supported jointly by the private and public sectors, to enhance the assessment of medical technology. The second was a comprehensive study of the state of medical technology assessment.

In December 1982, the Institute of Medicine established the Committee to Plan a Private/Public Sector Entity to Assess Technology in Medical Care under the chairmanship of Jeremiah Barondess. The committee was charged with developing a plan for a technology assessment organization that would be based in the private sector but supported by both government and non-governmental parties[1]. This initiative grew out of an exploratory meeting convened by the Institute on June 16, 1982, in response to growing concerns in both the public and private sectors about the proliferation of technologies in medical care. These concerns were characterized by pressures to eliminate technologies that may be obsolete, harmful, or ineffective; desires to affirm the benefits of other technologies; and stringencies of the need to slow the growth of costs while maintaining and improving the quality of American medical care.

The committee completed its work on June 30, 1983. The final report, published in November 1983, recommended the creation of a medical technology assessment consortium within the Institute of Medicine. The consortium was conceived of as seeking support divided approximately evenly between governmental and non-governmental resources. It was not intended as a competitor or as a replacement for any existing entity involved in assessing medical technologies. Rather, it was to be complementary and facilitative of the efforts of others involved in responsible assessments. As a first step, the consortium was to establish and maintain an information clearinghouse for medical technology assessment. This clearinghouse function would help to build a communication network among the principal parties to technology assessment, including other technology assessment entities, third party payers, major health care providers, and others; serve to reduce unneeded or unrecognized redundancies in evaluation; establish a source of information on completed and ongoing assessments; provide a forum for all the parties at interest in the development and validation of technologies; and facilitate the dissemination of information on medical technology assessments.

Subsequent to legislation enacting the ideas in the committee's report, the Council on Health Care Technology was formed in March 1986. At its first meeting in April 1986, the council created the Information Panel to plan and establish the clearinghouse. This *Directory* is the Information Panel's first substantive product.

Another Institute committee, the Committee for Evaluating Medical Technologies in Clinical Use, under the chairmanship of Frederick Mosteller, was charged with examining the state of medical technology assessment. This study was begun following a 1980 Institute conference on linking the clinical use of biomedical technologies and the collection of evaluative data. Major areas addressed in the committee's 1985 study report, *Assessing Medical Technologies*[2], included the scope of medical technology assessment in the U.S., methods of assessment, effects of clinical evaluation on the diffusion of medical technology, the relationship of assessment and reimbursement policy, assessment activities in other countries, and papers on such topics as clinical trials, cost-effectiveness, and values and preferences in health care delivery. Also included were detailed profiles of 20 technology assessment programs in the U.S. and topics of their respective assessment reports. The work on the scope of medical technology assessment and the program profiles constituted important groundwork for this *Directory* , just as the entire study report has been a touchstone for the deliberations of our council.

On behalf of the Council on Health Care Technology, I trust you will find the *Directory a* useful working document. The council plans to expand and update the *Directory* periodically, and intends to make its information base available in a machine readable format. If you think that your organization, or another organization, has an assessment program that ought to be incorporated in an updated *Directory*, please let us know. We welcome your comments.

WILLIAM N. HUBBARD

JR., CHAIRMAN

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PREFACE

During the last decade, various sectors of the health care enterprise have taken a converging interest in determining the safety, effectiveness, cost-effectiveness, and social, ethical, and legal impacts of health care technologies. Each of these sectors—physicians and other health professionals, patients and other consumers, biomedical researchers, health product makers, third party payers, health plan managers, institutional administrators, academicians, public policy makers, and others—tends to rely on some familiar, though different, set of literature and information sources in an attempt to meet assessment needs.

Although more of the health care community has taken explicit interest in medical technology assessment, there remain inadequacies in the supply of good assessment information and the manner in which existing information is organized and made available to those who need it. I have learned as a committee member for the Institute of Medicine study *Assessing Medical Technologies* and from the perspective of a health care payer that the demand for assessment information is outstripping the aggregation of well conducted clinical trials, authoritative group judgments, surveillance studies, and other inquiries concerning medical technologies. Therefore, as we encourage an increase in competent assessment activity, we seek to assemble what good assessment findings there are, both from our traditional sources and from sources that are new to us. As the emerging field of medical technology assessment becomes the shared province of multiple health industry sectors, each one stands to benefit by gaining familiarity with and access to new information resources. Further, we seek to identify a coherent body of assessment literature from which all of us may benefit.

In authorizing the Council on Health Care Technology, Congress specified establishment of a clearinghouse on medical technology assessment information. The *Medical Technology Assessment Directory* is the first major step toward fulfilling this purpose. It encompasses programs that produce medical technology assessments, information and data resources, and other organizations to which inquiries about medical technology can be directed. An important contribution of the *Directory* is to make a first attempt at organizing certain valuable "gray" or "fugitive" literature, i.e. technology assessments not published in widely circulated peer reviewed medical journals or accessible through the better known citation bases such as the National Library of Medicine's (NLM) MEDLARS (Medical Literature Analysis and Retrieval System). Thus, this *Directory* describes relevant mainstream information sources, and complements them with its collection of pertinent gray literature.

Assessments cited in this first edition of the *Directory* are limited to those produced by organizations with an ongoing medical technology assessment program. Future versions, whether in hard-copy or machine readable format, will expand coverage to include more and different sources of literature. For purposes of indexing the assessment report citations, we have used NLM's MeSH (Medical Subject Headings) terms wherever possible. In the technology thesaurus particularly, we have begun to craft a controlled vocabulary that builds upon MeSH terms to make the indexing as relevant as practical to the technology assessment community.

The *Directory* is intended to be a resource to the wider technology assessment community. We hope that this edition, with alphabetical listings of organizations, contact information, descriptions of activities, list of defined acronyms, indexes, and a thesaurus of technology terms designed to lead different types of users to assessments of interest, will be a worthy guide to this multidisciplinary field. Because it assembles and organizes

a strong sample of assessment activity rather than being an exhaustive compendium, we view it as a prototype for a more comprehensive, adaptive information base for medical technology assessment.

The *Directory* is the first substantive product of the council's Information Panel. In future months and years, the Information Panel plans to work with the NLM to augment the Library's MeSH vocabulary and certain files of organizational based information, produce access guides to standard literature sources, enhance and update the *Directory*, institute clearinghouse services, and establish online access to the *Directory* information base. We hope that the *Directory* will enhance communication in the assessment community, and will prompt greater participation in development of our clearinghouse activities.

LAWRENCE C. MORRIS

CHAIRMAN, INFORMATION PANEL

CONTENTS

INTRODUCTION

This introduction to the *Medical Technical Assessment Directory: A Pilot Reference to Organizations, Assessments, and Information Resources* describes the purpose of the *Directory*, its major parts, its scope and limitations, how it was compiled, and activities planned to follow up this work, including ties with the National Library of Medicine and the World Health Organization.

PURPOSE OF THE DIRECTORY

The *Medical Technology Assessment Directory* is the first substantial published guide to the field of medical technology assessment. It is intended to better define the substance of medical technology assessment, and to crystallize the emerging network of organizations, institutions, and individuals that generate and use technology assessments. The *Directory* is a reference to medical technology organizations, assessments, and information and data resources. It covers activities in the U.S. and certain other countries, including those of government agencies, private companies and associations, and research and educational institutions. It represents the first indexed bibliographic compilation devoted to medical technology assessments produced, in progress, or planned by a broad set of assessment programs spanning the public and private sectors. The *Directory* was developed to increase access to valuable health care technology assessment information, much of which is found outside standard published sources.

This is a product of the Information Panel of the Council on Health Care Technology. One of four panels of the council, the role of the Information Panel is to oversee the development and operation of an information clearinghouse for health care technologies and health care technology assessments, as called for in the congressional mandate for the council. Although the various constituencies of the council have different sets of needs regarding technology assessment, nearly all have expressed a desire for the council to collect, organize, and disseminate technology assessment report information.

As implied by the term "Pilot" in its subtitle, the *Directory* takes a leading step toward a more comprehensive capacity for information services in medical technology assessment. Though it has immediate utility in its own right, the *Directory* is an experimental compilation of information in an emerging field. The assessment report citations and other categories of information included here represent a cross-section of the field, and cover assessment activity of the recent several years of a selection of programs in the U.S. and abroad. One of the major functions of the *Directory* is to act as a hardy-copy precursor of a computerized technology assessment information base. The development and testing of the *Directory* will help guide the Information Panel's clearinghouse plans.

With its extensive descriptions and contact information, the *Directory* provides ready access to assessment people, programs, and resources. It is intended for users who wish to identify available assessments and contact people currently conducting assessments of a particular technology before making a decision on medical practice, coverage, reimbursement, acquisition, or standard-setting.

Private and government third party payers, HMOs, and self-insured employers currently reviewing technologies for coverage or inclusion in their health plans may use the *Directory* to locate assessments of these technologies by regulatory bodies and physicians' groups. Physicians seeking medical consensus regarding appropriate use of technologies

may find guidance from assessments indexed here. Pharmaceutical and health device and equipment makers may use the *Directory* as a reference to the processes and scope of activity of programs that are likely to assess their products. Procurement decisions for health care facilities may be more informed by reviewing assessments of devices and equipment, and by consulting organizations currently assessing new technologies. Assessors seeking information concerning such areas as postmarketing surveillance, drug utilization, or new product development may use the *Directory* to locate appropriate resources.

The *Directory* may help to advance the field in many other ways. Organizations that conduct or are considering initiating assessment activities may discern ways of strengthening their programs by examining the attributes of profiled programs. By identifying, describing, and providing contact information for assessment organizations, the *Directory* should raise the level of, and render more efficient, communication in the assessment community. Knowing the types of technologies generally assessed by programs, as well as methods used and other program characteristics, those seeking assessment information may prompt appropriate programs to undertake assessments to address specific needs. Those in the academic, research, and public policy sectors who study the field of technology assessment may contrast and compare assessment processes and consider how better to set assessment priorities and otherwise strengthen the assessment enterprise. Thus, the Council on Health Care Technology and others may use the *Directory* information base to review the capacity and products of technology assessment and to discern trends, gaps, and redundant efforts in the field.

Given that this edition could not be a comprehensive rendering of medical technology assessment and that this is an emerging field, wide dissemination of the *Directory* is crucial for building and updating its information base. The council hopes that, by reviewing the *Directory* , assessment programs and other resource organizations not already included will recognize that they conduct activities similar to certain of those described here, and will contact the council about being included in forthcoming editions.

GRAY LITERATURE FOR ASSESSMENT

Certainly an important step in carrying out most assessments of medical technologies is searching an information base covering the relevant peer reviewed literature in health and biomedicine. Perhaps the foremost example of such an information base is the online bibliographic citation base MEDLINE, a major component of the National Library of Medicine's MEDLARS system. MEDLINE is one of more than 70 information and data resources described in Part 3 of the *Directory*. It contains all of the citations published in *Index Medicus*. MEDLINE covers more than 5 million articles from some 3,200 biomedical journals, out of the more than 25,000 cataloged by the library.

Yet, given the rapid evolution of health care's technological portfolio and the breadth of assessment perspectives on medical technologies, valuable technology assessment information may be found outside the mainstream of published periodical literature available from traditional sources. This "gray" or "fugitive" literature is found in industry and government monographs, regulatory documents, professional association reports and guidelines, market research reports, policy and research institute studies, spot publications of special panels and commissions, conference proceedings, online services, and other sources.

Although users of the gray literature must consider that much of it has not been subject

to the quality screen of peer review, it often has great utility for assessment given its scope beyond traditionally selected sets of journal literature and a currency not subject to the lag time of peer review. The border between gray and standard literature is not distinct; what is gray and what is standard may differ according to one's familiarity with and access to various sources. To be sure, some gray literature eventually passes into the standard literature. Many of the assessment reports generated by organizations profiled in this *Directory*, such as the American College of Physicians Clinical Efficacy Assessment Project, American Medical Association Diagnostic and Therapeutic Technology Assessment Program, and the National Institutes of Health Consensus Development Program, do appear in the peer reviewed literature, though months or perhaps one or two years after initial release in some gray form.

Conducting a good assessment may depend not only upon awareness of key gray literature sources, but one's ability to access them. Desired reports may be available through press releases, journal articles, or books; provided free of charge or at a fee; made available in open libraries or held as proprietary. For instance, the comparative medical device and equipment assessments published by the independent evaluator ECRI are not made available to open libraries such as the National Library of Medicine (NLM), but only to subscribing hospitals, HMOs, and other institutions because ECRI's revenues could be eroded by free or low-cost (e.g., by photocopying) access to its publications. Many of the Food and Drug Administration's (FDA) technical reports on drugs and devices are available only upon request from the FDA or from the National Technical Information Service. Certain reports on emerging and new medical technologies generated by market research firms are publicly available, though at costs ranging from a few hundred to tens of thousands of dollars.

Rather than devoting considerable effort to already organized and indexed assessment reports appearing in the peer reviewed journal literature, much of the *Directory* is addressed to gray sources, including many of the profiled assessment programs and the information and data resource descriptions. Thus, this *Directory* is the first attempt to organize gray literature sources in the field of medical technology assessment.

MAJOR PARTS OF THE DIRECTORY

Part 1 of the *Directory* includes profiles of 68 assessment programs and a total of approximately 3,200 citations of their respective assessment reports. These assessment programs are located in a variety of public and private sector organizations, including professional, scientific, and industry associations, biomedical research institutions, educational institutions, government advisory bodies, regulatory agencies, third party payers, policy institutes, and for-profit corporations. The profiled programs are primarily from the United States; among other countries represented are Canada, the Netherlands, Sweden, and the United Kingdom. These are ongoing programs that generate medical technology assessments. For the purposes of this *Directory* , a medical technology assessment is a study or inquiry, the object of which is to provide information regarding the effects of a technology that is intended to maintain or improve health, or be used as part of an intervention for such purpose, whether or not the study evaluates these effects directly.

Using a common multidimensional framework, these categorical profiles represent a systematic characterization of a diverse community of assessors. This framework was adapted from the one used to profile 20 assessment programs in the 1985 Institute of Medicine study *Assessing Medical Technologies*. The profiles address the purpose, types of technology assessed, topic selection, assessment methods, properties assessed, report

dissemination, budget, contact information, and other characteristics of each program. Each profile is followed by a listing of bibliographic citations of the program's recent assessment reports (over approximately the last five years). Following the profiles is a subject index to the citations. Each of the assessment report citations is indexed using from one to five terms. For instance, a report titled "Dialysis treatment for end stage renal disease (outpatient)" is indexed under the terms *Dialysis; Kidney failure, Chronic*; and *Outpatients*.

Part 2 has two major sections: a technology thesaurus and a cross-listing of the assessment report citations by technology. The technology thesaurus was developed for this *Directory* to help users search for assessment reports by technology topic. It was generated based upon the technologies appearing in the titles of the assessment report citations. Where appropriate, it uses the NLM's MeSH (Medical Subject Headings) vocabulary terms. To enhance searching by all types of users, the 1,200-term thesaurus includes many synonyms, acronyms, and cross-references, and indicates broader and narrower terms to help clarify relationships among technology terms.

The cross-listing arranges the assessment report citations by technology, e.g., *Apnea monitoring, Coronary artery bypass grafting*, and *Infusion pumps*, so that all citations for each type of technology may be viewed together. Under any particular technology heading, the citations are listed in reverse chronological order to provide the newest information first. This listing is analogous to printouts of computer searches for citations involving particular technologies. In addition to bibliographic information, most citations note the general type of assessment method used, e.g., clinical trial, group judgment, and information synthesis. Because not all of the 3,200 assessment report citations have a technology term in their titles, Part 2 contains about 2,500 citations arranged by technology. Of course, the subject index to report citations at the end of Part 1 uses technology and other terms to index all 3,200 citations with respect to their source assessment programs.

It is important for users to take advantage of the technology thesaurus for searching the cross-listing of assessment report citations by technology. Unless a report citation has more than one technology in its title, it is shown only once in the cross-listing, usually appearing under its most specific technology term. For citations listed in this section, distinctions generally are made between procedures and the equipment used for them. For example, headings include *Computed tomography* as well as *Computed tomography scanners*, and *Fetal monitoring* as well as *Fetal monitors*.

Part 3 describes 73 public and private sector information and data resources that may be of value for assessing medical technologies. Arranged alphabetically by name of resource, these are of many types, including online citation bases and services; data files; compendiums, inventories, and directories; market research reports; and others. Each is described in terms of source, subject, content, compilation, and access information. The resource descriptions are preceded by a categorical chart indicating for each resource its file type (directory, bibliographic information, data set, etc.), format (hard copy, online, etc.), and degree of access (public or limited). At the end of this part is a subject index to the information and data resources.

Part 4 provides 300-word descriptions and contact information for 72 organizations that are active in affairs related to medical technology and are stakeholders in medical technology assessment. These include medical societies, scientific organizations, industry associations, and others. Although most of these organizations do not generate technology assessment reports on a regular basis, they have memberships concerned with medical technologies, conduct relevant meetings and symposiums, publish conference

proceedings and other documents of note, establish standards for technologies, or are active in government, regulatory, or other policy affairs relevant to the field. At the end of this part is a subject index to these organizations.

Part 5 includes an alphabetical listing with addresses and telephone numbers for all organizations described in the *Directory*, as well as a page index to the organizations. Among the appendices to the *Directory* are a description of the council, rosters of council and panel members, a listing of organizations that have contributed financial support to the council, and the survey form used to collect information for the 68 profiles in Part 1.

SCOPE AND LIMITATIONS

This *Directory* covers many of the major national level assessment activities in the U.S. and certain significant ones from around the rest of the world. Its immediate utility as a hard-copy reference notwithstanding, the *Directory* is not a complete guide to the field or an all-encompassing information base. The set of 68 profiled programs and their 3,200 assessment report citations in Part 1, the listing of 2,500 of the assessment report citations by technology in Part 2 , the 73 information and data resources in Part 3, and the 72 organizational resources in Part 4 are illustrative, not exhaustive, of the scope of technology assessment activities in the U.S. and on the international scene. The *Directory* does represent an important step toward a more comprehensive resource, as a foundation and a template for building an online medical technology assessment information base and related services.

Types of assessment programs and other assessment resources are variously represented in the *Directory*. That an assessment program or other resource is not described in the *Directory* implies nothing about its value. Rather, the breadth of the sample of those included in this first edition helps to suggest how the *Directory* information base might be expanded. For instance, of the various bureaus, institutes, divisions, and other components of the National Institutes of Health that conduct clinical trials or other assessment activities, just three are profiled here. Seventeen of the 24 member organizations of the Council of Medical Specialty Societies (CMSS) provided information for the assessment program profiles or resource organization descriptions in the *Directory*; other CMSS members may also be appropriate for addition to the information base.

Eleven university based programs are profiled; there are others worthy of note. A recent publication of the American College of Radiology noted more than 50 U.S. and international societies in the field of radiology alone; certainly, some of these organizations generate technology assessment documents or engage in other activities relevant to technology assessment.

A survey of existing inventories of health care data sets conducted for the Methods Panel of the council by intern Norma Gavin identified more than 260 data sets that meet minimum provisional criteria for inclusion in a proposed inventory of data sources for health care technology assessment. Although the data sets were identified too late in 1987 to be categorically described in this volume, that survey suggests how the set of information and data resources in Part 3 of the *Directory* could be expanded and its contents more thoroughly elucidated.

Inclusion in the *Directory* of descriptions of any assessment programs, information or data resources, or other organizations does not imply any judgment on behalf of the council, Information Panel, or staff as to the quality of those assessment resources. Similarly, inclusion of any assessment report citations in the *Directory* implies no judgment

as to the validity, utility, or other aspect of the quality of the assessment reports. The bulk of the content of the *Directory* was self reported by assessment programs and other resource organizations, and this information was not independently or systematically verified. Compilation of the *Directory* was largely limited by staff awareness of assessment activities, availability of information about these, and limitations of time, personnel, and other resources available for this edition.

The technology thesaurus in Part 2 was generated based upon the technologies appearing in the titles of the assessment report citations of the 68 profiled programs. Therefore, the 1,200-term thesaurus does not encompass all medical technologies, although it may be readily augmented with additional technology terminology. The technology heading under which an assessment report citation is listed in Part 2 does not imply that the technology has been found to be safe, effective, or otherwise appropriate for the use implied by that heading. That a report citation is listed under a particular heading implies only that the technology that is the subject of that citation may have been assessed for the application represented by that heading. For instance, a particular drug may be listed under *Antineoplastics* and under *Antiarthritics*. Assessed as an antineoplastic, the drug may have been determined by a regulatory or other organization to be safe, effective, cost-effective, etc. Assessed as an antiarthritic, the drug may or may not have been found to possess one or more of these qualities. Nevertheless, it would be listed under both headings because the report citations indicate that it was assessed for both applications, regardless of the assessment findings, not because the drug was determined to be appropriate for those uses.

COMPILATION OF THE DIRECTORY

Information for the *Directory* was compiled largely from three surveys. The assessment program profiles and report citation listings of Parts 1 and 2 are based primarily upon responses to a survey of organizations with ongoing medical technology assessment programs. Many of the descriptions in Part 3 were written from responses to a survey of organizations that compile or make available data or information relevant to medical technology assessment. The organizational resources descriptions in Part 4 were drawn largely from a request for brief descriptions of professional, industry, and other organizations having interests in technology assessment.

Council staff reviewed and edited all returned survey forms. No attempt was made to verify with third parties the information provided by the organizations. Staff did not assess the quality of assessment programs, information and data resources, organizational resources, or assessments listed in the *Directory*.

Organizations known or thought to have an ongoing medical technology assessment program were identified initially from council staff files in October 1986. Additional organizations were identified by those organizations surveyed initially and by further council staff work. More than 80 organizations were sent the survey instrument, which is shown in the appendices. This survey was not applicable to organizations that may have conducted medical technology assessments but did not have an ongoing program; that cataloged, indexed, or evaluated assessments but did not produce them; or that conducted assessments but generally did not make results available outside of the organization. Due to resource constraints and because this was not an effort to assemble a library, the survey requested bibliographic citations of assessment reports and sample reports, rather than complete sets of reports from all programs.

Most of the surveys were returned to council staff fully or partially completed. In several cases, council staff and program contacts determined that a program did not constitute an ongoing assessment program, but was appropriate for inclusion in Part 4 or another part of the *Directory*. Surveys were returned to several organizations with requests for additional information or more thorough responses to portions of the survey; often such requests were for more complete citations for assessment reports. Council staff also used telephone or face-to-face interviews with assessment program staff, as well as reports and other literature submitted by the programs, to complete the surveys. Following editing by council staff and further preparation by the contractor, these descriptions were forwarded to the contact persons at each assessment program with a request to verify their factual content or make other suggestions and to return these to council staff by a deadline date, or to expect no modifications if no response was received by that date.

Staff and consultants reviewed the lists of assessment report citations provided by the programs and deleted those that did not meet the criteria of a medical technology assessment report. For purposes of deciding whether or not a report should be listed in the *Directory* , the title had to contain or suggest one or more medical technologies, or imply the consideration of medical technologies, e.g., the management of cervical cancer. Further, it had to either state or imply technology assessment, or one or more properties or attributes of a technology that could be determined by an assessment, e.g., safety, efficacy, ethical implications, or state or imply an evaluation; or be or appear to be guidelines issued by a professional body or its equivalent known by staff to conduct assessments. Staff deleted, for example, assessments of the health effects of Agent Orange because it was neither intended to be nor has it been used as a medical technology. On the other hand, staff retained in the listing assessments of the detrimental consequences of medical technologies, such as the risk of birth defects among nurse anesthetists.

Staff tended to be inclusive in determining what constituted assessment reports for listing with program profiles in Part 1. The primary reasons for this leniency were that decisions were necessarily based on limited information, i.e. report titles rather than full reports; that as a first effort, this *Directory* ought not severely circumscribe this body of literature; and that users might gain a better understanding of programs' scope by viewing fuller portfolios of their reports.

Somewhat stricter criteria were applied for including reports in the list of assessment report citations by technology in Part 2. In instances where titles were ambiguous in this regard and where full reports were on file with council staff, these reports were reviewed to determine whether they constituted assessment reports. However, staff did not make special requests to acquire reports for this purpose.

Edited survey forms were sent to TRITON Corporation, a contractor retained by the council. Using the surveys, TRITON prepared uniform descriptions, or "profiles," of ongoing medical technology assessment programs and created a record for each of their assessment report citations. Each profile has approximately 20 descriptors such as program name, address, telephone, contact person, purpose, methods, reports, etc. Descriptions were edited for consistency and to ensure, as far as possible, uniformity in detail. In creating database records for assessment citations, TRITON followed *Index Medicus* style. The base of citation records was used for two purposes: for generating the coded list of citations following each profile in Part 1, and for generating the listing of assessment report citations by technology in Part 2.

TRITON indexed each assessment report citation using from one to five subject

headings, including but not limited to technology terms. Of necessity, TRITON had to rely exclusively on titles to index assessment reports. The subject headings used for indexing are taken primarily though not entirely from the National Library of Medicine's controlled biomedical vocabulary MESH. The departure from MeSH terms occurred most often for terms related to technologies. The index to the citations appears at the end of Part 1, and is coded to citations appearing after their respective assessment programs.

The technology thesaurus that appears at the beginning of Part 2 was developed in order to arrange the listing of assessment report citations by technology that follows it. The technology thesaurus terms used as headings for Part 2 constitute, largely, a subset of the indexing terms used in Part 1, i.e., those that identify technologies. As noted above, technology terms accounted for most of the instances where indexing departed from MESH. If MeSH did not contain a subject heading appropriate for a technology used in an assessment report citation title, one was designated based on usage in the medical technology assessment literature as determined by staff, consultants, and TRITON. In some instances, MeSH did not include a term for a particular technology. In others, the closest MeSH term may have been too broad or too narrow to adequately identify a technology, or one not commonly used or perhaps not readily recognized by users who do not have a particular medical or scientific expertise. Linkages to MeSH are retained wherever possible with the use of synonyms, acronyms, cross-references, and broader and narrower terms that are used in MESH.

Information and data resources described in Part 3 were identified by council staff and by respondents who completed surveys for this part. About half of the descriptions of information and data resources in Part 3 were based entirely or in part on survey responses. The remainder of the descriptions was derived by staff from literature and samples received from the source organizations and telephone interviews. The copy for Part 3 that was submitted to TRITON was generated by staff.

The organizational resource descriptions in Part 4 were derived primarily from requests for narratives of 300 words or less made to organizations identified by council staff and suggested to staff by certain of these organizations. Following editing by council staff, drafts of these descriptions were forwarded to the contact persons at each organization with a request to verify their factual content or make other suggestions and to return these to council staff by a deadline date, or to expect no modifications if no response was received by that date. The copy for Part 4 that was forwarded to TRITON was generated by staff. TRITON submitted final, camera-ready copy of the *Directory* to council staff, who turned it over to the National Academy Press for printing.

PLANS OF THE INFORMATION PANEL

The Information Panel plans to develop technology assessment information products beyond this first edition of the *Directory*. Among the major proposed areas of activity are wide dissemination of the *Directory* , working with the NLM to augment the Library's MeSH vocabulary and DIRLINE (Directory of Information Resources Online) file with new information from the *Directory*, producing access guides to standard literature sources, enhancing and updating the *Directory*, instituting clearinghouse services, and establishing online access to a technology assessment information base.

Users of the *Directory* will be surveyed regarding its utility and format, and will be asked for suggestions for improvement. Additional responses will come in the form of

number and distribution of sales, book reviews, and other user feedback. The Information Panel will take account of user responses in formulating its plans for further development of the *Directory* information base and related efforts.

The Information Panel plans a joint vocabulary project with the NLM to better index and thereby improve access to technology assessment information. The vocabulary effort began with the indexing of assessment report titles for the *Directory* and preparation of the technology thesaurus. From this project, the Information Panel may better determine the topical scope of the technology assessment literature, as well as the capacity of the NLM's MeSH vocabulary for indexing technology assessment topics. Instances in which current MeSH terms are found inappropriate for indexing technology assessment report titles in the *Directory* provide opportunities for augmenting MeSH with the intention of improving its utility for searching MEDLINE for assessment related information. Because the *Directory* indexes many report citations drawn from gray literature sources, it may provide a means for identifying newer terms that have not yet entered the lexicon of more traditional sources.

The vocabulary project would establish a framework for, and could begin mapping, certain existing terminology sets such as MESH, ECRI device codes, ICD-9-CM (*International Classification of Diseases, 9th Revision, Clinical Modification*) and CPT-4 (*Current Procedural Terminology, 4th Edition*) procedure codes, and DRG (diagnosis-related group) terms to the technology topics used in the *Directory*. The mapping of vocabulary terms is consistent with the mission of the Library's Unified Medical Language System project.

Information gathered in compiling the *Directory* will be used to add, update, and modify organizational descriptions in the NLM's DIRLINE file. A component of MEDLARS, DIRLINE is accessible for all users of MEDLARS and certain commercial databases. It contains descriptive information on many organizations and resource centers in the health field. Users interested in particular subjects may enter appropriate keywords to locate information about organizations active in those areas. Adding to DIRLINE descriptive information from the *Directory* about organizations involved in technology assessment will provide broad online access to it through MEDLARS, and any services that download DIRLINE from MEDLARS.

Whereas the *Directory* deals primarily with technology assessments generated by specific assessment organizations and found to a large extent in the gray literature, the Information Panel is planning access guides that would address retrieval of technology assessment information from existing citation bases and other sources. Some of these sources, such as BIOETHICSLINE, MEDLINE, and the National Technical Information Service, are noted in the information and data resources part of this *Directory*. The purpose of these guides would be to help users extract valuable medical technology assessment information from sources that are not specifically devoted to the field or are structured in ways that are not amenable to searching for this information. The guides would describe these sources in greater detail, explain what subfiles or other aspects of each may be useful for assessment purposes, indicate how to access them, and provide examples of assessment searches.

The *Directory* information base may be developed in several major ways. Profiles of programs entered in the first edition may be updated and their new assessments indexed. Additional assessment programs may be profiled and their assessments indexed, and the technology thesaurus updated accordingly. Based upon the information and data resources in Part 3, an expanded, more detailed inventory of data sets for technology assessment could be developed using more quantitative and qualitative

descriptors. This inventory would be guided in part by the survey work on data sets described above.

Of particular interest to both the Evaluation Panel and Information Panel of the council is strengthening the information base to enable tracking of new and emerging medical technologies. Such information has value to different sectors of the health care enterprise. It can be used to anticipate assessment needs and prepare timely and well informed assessments, e.g., at the time of market entry of a new drug or device, or when a reimbursement claim is made for a new procedure. Further, it may be useful for remaining apprised of the state-of-the-art in medical practice, planning clinical services, making resource allocation decisions to foster development and diffusion of promising technologies, charting trends in health care product and practice innovation, and identifying investment opportunities. Sources that might be monitored for information concerning emerging and new technologies might include status reports of biomedical research projects, patent information, medical and bioengineering conference proceedings, medical and scientific bibliographic information bases, future-oriented surveys and monographs, market research reports, financial investment sources, product development databases, annual and quarterly reports of health care product companies, news services, FDA approval documents for new drugs and devices, and health insurance claims data. Although this edition of the *Directory* has descriptions of certain information sources that fall into these categories, development of the information base could emphasize addition of information sources, indexing, and retrieval means to help meet needs for intelligence about new and emerging technologies.

The Information Panel is considering implementing selected clearinghouse services with expanded staff or under contract. Initial clearinghouse services may be established based upon the *Directory* and continued updating of its information base, and access to MEDLINE and other online information sources. With these resources, the council could begin to respond to certain types of assessment related inquiries received via written correspondence, telephone, or electronic mail. Staff assigned to this activity could also conduct special searches or generate assessment report bibliographies on topics of current interest for broad distribution. These services would be initiated on an experimental basis, and the demand for them monitored carefully. Commitments to phone answering and conducting searches would have to be adjusted according to demand and availability of resources.

The Information Panel will continue to study the feasibility of providing computer access to technology assessment information. Computer access may entail use of central information bases and distribution of the *Directory*, its updates, and related products via optical or magnetic disks. The panel has determined that appending a technology assessment information base to an existing online system would be preferable to initiating a new stand-alone system. The panel will take account of what is learned from the response to the *Directory* and other current efforts, consult with the NLM and other information base authorities, and plan accordingly.

Providing computer access to the technology assessment information base will be furthered by implementing other of the Information Panel's plans. Together, the *Directory* and access guides will account for much of the gray literature and other online and traditional sources that could be integrated in an online system. Augmenting DIRLINE and MeSH will help to make NLM's MEDLARS more useful to users concerned with technology assessment. Response to the *Directory*, which represents a hard-copy analog of certain aspects of an online system, and access guides will inform

the Information Panel about the desirable content and format of assessment information compilations. Clearinghouse services would enhance the council's ability to meet, and learn more about, user needs.

NLM's review of the *Directory*, described below, and other council efforts will provide insight into the extent to which an online technology assessment information base may be linked with the MEDLARS system. One venue for such a link would be to append the *Directory* information base to the HEALTH (HEALTH Planning and Administration) file of MEDLARS, which covers citations on nonclinical aspects of health care delivery such as facilities planning and administration, manpower, insurance, financial management, regulation, and quality assurance. HEALTH is compiled primarily by the American Hospital Association using selections from MEDLINE and augmented by a variety of sources not indexed by NLM. Thus, HEALTH stands as a model of an online base formed from published literature sources as well as certain gray literature sources.

Ties with the National Library of Medicine

In devising the clearinghouse plan and developing this *Directory*, the Information Panel and staff have worked closely with the NLM to develop an information base that complements NLM resources. As indicated above, of particular interest are the extent to which the *Directory* information base identifies new indexing terminology, adds to what is known concerning descriptions of organizations that are significant in biomedical affairs, and identifies valuable sources of literature not indexed by NLM. Pursuant to these interests, NLM staff members have reviewed pertinent portions of an early draft of the *Directory* to gain preliminary measures of these characteristics of the *Directory* information base.

The NLM review indicates that the technology thesaurus terms derived from the assessment reports cited in the draft *Directory* provide some 40 potential new MeSH headings and nearly 400 potential entry terms, i.e. new synonyms for cross-references in MeSH. NLM also reviewed more than 2,500 of the assessment reports citations to determine what proportion were owned and/or indexed by the library. (Approximately 1,000 of the 3,500 report citations in the draft *Director*), were not reviewed because they were assessments in progress, were more than five years old, or were then incomplete citations.) Of the citations reviewed from the draft *Directory*, NLM found that 23 percent were owned and indexed by NLM. Of the remaining 77 percent, about half were owned but not indexed by NLM, and half were neither owned nor indexed by NLM. Since NLM was given the preliminary draft of the *Directory*, some assessment report titles were added, and a few hundred were deleted as irrelevant to medical technology assessment. Also, a few program profiles were added to the *Directory*, and the technology thesaurus was revised. These modifications would not appreciably affect the findings of the NLM review.

NLM compared approximately 190 organizational descriptions from the profile, information and data resources, and organizational resources parts of the draft *Directory* with DIRLINE records to determine the extent to which those in the *Directory* might be used to augment DIRLINE. NLM found that about 28 percent of the organizational descriptions in the *Directory* had directly comparable records in DIRLINE. Another 28 percent of the descriptions were entirely new to DIRLINE. Of the remaining 44 percent of the draft *Directory* descriptions, half were represented only at a more general level in DIRLINE. The rest of the *Directory* organization descriptions were mentioned in DIRLINE records but had no DIRLINE record of their own, were described only in

part in DIRLINE records, or were part of larger organizations for which the DIRLINE records did not describe the part included in the *Directory*. Thus, most of the organization descriptions in the draft *Directory* are suitable for augmenting DIRLINE. Some 20 organizational descriptions have been added to various parts of the *Directory* since the preliminary draft was given to NLM.

NLM's review provides some insight into the extent to which the *Directory* information base may be used to complement existing NLM and other major resources for technology assessment, and will help to plan a appropriate strategy for providing this information online.

International Ties

The Information Panel seeks to incorporate valuable sources of international information on technology assessment into the *Directory* information base. This first edition of the *Directory* includes profiles and assessments of 14 programs outside of the U.S., as well as descriptions of other European and international organizations and information resources of interest to the assessment community. This represents only a sample of international sources of potential value to users in the U.S. and abroad.

Although the information concerning assessment activities in other countries was provided directly to council staff for this *Directory* , other organizations in particular countries or certain international agencies could collect such information to be shared with the *Directory* information base. In particular, the Information Panel has been planning certain of its efforts with the European Office of the World Health Organization (WHO), which has among its charges to act as a health technology assessment information clearinghouse for its member countries.

In 1987, WHO established a collaborative effort with the University of Linköping in Sweden, known as WHO/LINFO, to further this charge. The first project of WHO/LINFO is to assemble a technology assessment information base, modeled in part after this *Directory*. The Information Panel and WHO/LINFO have agreed to coordinate their efforts by using similar information collection, indexing, and display formats to facilitate exchange of assessment information and to avoid duplicative work. As compilation of the council's *Directory* was launched prior to that of WHO/LINFO, WHO/LINFO was able to use a modified version of the council's *Directory* profile survey to collect information about European organizations involved in assessment. Further, the council is sharing the technology thesaurus used to index the assessment report citations in the *Directory* so that WHO/LINFO may consider using similar terminology to index assessments of its participating programs. Plans concerning responsibility for ongoing collection of assessment information from European and other international sources and related collaboration will be made subject to response to the *Directory* and WHO/LINFO products.

GUIDE TO DIRECTORY'S CONTENTS

The *Directory* includes the following five major parts, described below:

- Part 1: Assessment Program Profiles and Report Citations
- Part 2: Assessment Report Citations Listed by Technology
- Part 3: Information and Data Resources
- Part 4: Organizational Resources
- Part 5: Index to Organizations.

PART 1: ASSESSMENT PROGRAM PROFILES AND REPORT CITATIONS

This part has two major sections. First are the profiles of 68 medical technology assessment programs, with citations of their approximately 3,200 completed, ongoing, and planned assessments. Second is a subject index to the citations, to be used for locating citations on particular subjects among the profiles.

Profiles and Citations

The profiles are of ongoing programs that generate medical technology assessments. For the purposes of this *Directory*, a medical technology assessment is a study or inquiry, the object of which is to provide information regarding the effects of a technology that is intended to maintain or improve health, or be used as part of an intervention for such purpose, whether or not the study evaluates these effects directly.

Most of the information for the assessment program profiles was drawn from the survey of organizations with an ongoing medical technology assessment program, reproduced in Appendix C. Entries for the information categories in each profile include responses to checklists and other questions on the survey. The survey shows these checklists and questions, as well as definitions of terms where necessary. The level of detail in the information categories across the profiles varies. Although staff worked with some assessment program representatives to complete responses to the survey, certain information was unavailable from programs.

The assessment program profiles are listed alphabetically by name of parent organization, and are arranged according to the following common format.

Parent organization and assessment program name, address, and telephone number.

Contact person(s): name, title, address, telephone number if different from the above, telex, telefax, and other numbers.

Overview provides a brief description of the parent organization's purpose, and the assessment program's purpose and origins.

Primary intended users describes the intended audience of the program's assessments. Taken from the checklist of more than 20 categories of primary intended users on page 4 of the survey in Appendix C, examples of these are: general public, patients, physicians, acute facility administrators, long-term care facility administrators, health product manufacturers, health/medical professional associations, third party payers, government regulators, biomedical researchers, and specified others.

Technologies lists the general categories of technology usually assessed by the program. The first listed, in italics, is the one assessed most often. The categories, shown and defined on page 4 of the survey, are: drug, device, medical or surgical procedure, support system, organizational or administrative system, and specified others.

Intervention lists the types of technological intervention normally assessed by the program. The first listed, in italics, is the one assessed most often. The types, shown and defined on page 5 of the survey, are: prevention, diagnosis, treatment, rehabilitation, and specified others.

Stage lists the stages in the life-cycle of technologies at which the program normally conducts its assessments. The first listed, in italics, is the stage assessed most often. The stages, shown and defined on page 5 of the survey, are: emerging, new, established or widespread practice, obsolete, and specified others.

Properties lists the properties or attributes of a technology that the program normally assesses. The first listed, in italics, is the property or attribute usually emphasized. The properties or attributes of technologies assessed, shown and defined on page 5 of the survey, are: safety, efficacy, effectiveness, cost, cost-benefit, cost-effectiveness, service requirements, acceptance/adoption level, system impact, economic implications, and ethical, legal, social implications.

Selection process describes how the program generally selects technologies for assessment. As posed on pages 9 and 10 of the survey, this may encompass who can request that an assessment be conducted, how requests for assessment are made, how and by whom assessment priorities are set, and what provisions are made for reassessing technologies.

Methods lists the broad categories of assessment methods that the program normally employs to conduct an assessment. The first listed, in italics, is the method the program relies on primarily, or exclusively if no other method is listed. The categories of assessment methods, shown and defined on page 6 of the survey, are: information syntheses, expert opinion, group judgment, modeling, cost analyses, epidemiological and other observational methods, clinical trials, and bench testing. This section also includes supplemental descriptive information encompassing: how the assessment process is conducted and by whom, the approximate (average or range of) turnaround time from selection of assessment topic to report of findings, and approximate cost per assessment.

Assessors describes the types of expertise of a program's assessors.

Assessment reports include lists the types of items generally included or addressed in a program's assessment reports. Taken from the checklist of more than 20 items listed on page 6 of the survey, examples of these are: abstract, purpose of assessment, who sponsored assessment, who conducted assessment, description of technology, how the technology works, properties assessed, sources of data/information, methods for analyzing/synthesizing data/information, limitations of findings, regulatory agency approval status, coverage/reimbursement status, and specified others.

Dissemination lists the means by which a program disseminates its assessment findings. The first listed, in italics, is the one relied on primarily. The general types of dissemination means, shown on page 6 of the survey, are: printed reports (excluding journal articles); journal articles; advisories to members/constituents;

press conferences/news releases; TV/radio broadcasts, video products; clearinghouse, data/citation bases, online services; other (specify). This section also includes supplemental information encompassing: types of assessment products, details of how assessment results are disseminated, and how to acquire copies of assessment reports.

Budget gives the program's annual budget in U.S. dollars for calendar 1986 unless specified otherwise, and the percentage from type of source. These sources, shown on page 7 of the survey, are: parent organization; government grants/ contracts; foundations and other private grants; sponsors/members dues contributions; sales of assessments, consultant services, etc.; and specified others.

Use describes how assessments are used by the parent organization, who else uses them and for what purpose (and how the program knows this); documented use of assessment reports and their impact, including citation of published documents; and citations in the published literature to the program or its assessments.

Program evaluation describes the evaluations that have been conducted of the program, who did them, evaluation results, and how evaluation results have been used to improve the program.

Related activities describes additional information about the technology assessment activities of the program not covered elsewhere in a profile.

Completed Reports are listed in reverse chronological order and then in alphabetical order by author and title. For most of the profiles, the citations cover assessments generated since 1980. The completeness of bibliographic citations varies. To the extent possible, the citations are in *Index Medicus* style. If an organization sponsoring the technology assessment is not the author of the report, the organization name is enclosed within brackets. Reports issued by programs of the U.S. Government often are available from the U.S. Government Printing Office or the National Technical Information Service. Where provided by assessment programs, order numbers are included in the bibliographic citation. The report code preceding each citation (consisting of a two letter prefix and a number) is used to link the report to the index to report citations at the end of Part 1. Information in brackets following the citation indicates the type of method(s) used by the program to conduct its assessments.

Ongoing Assessments are listed in chronological order (based on expected completion date), earliest first and then in alphabetical order by author and title. The citation provides the expected date of the report, if the program provided one. Assessments for which the program did not provide a completion date are listed alphabetically by author and title after those for which it provided a completion date. Some of the ongoing assessments have been completed and made available by the time of publication of this *Directory*. Not all programs provided information about ongoing assessments.

Planned Assessments lists assessments the program expects to conduct by author and title. Some of the planned assessments may have been completed and made available by the time of publication of the *Directory.* Not all programs provided information about ongoing assessments.

Not all reports generated by the 68 programs are cited in the *Directory.* In most instances, reports dated prior to 1980 are excluded, although for certain smaller programs earlier reports are retained. The scope of activity of certain of the 68

programs does not neatly or consistently coincide with medical technology assessment. In other cases, an understanding of a program's activity does indicate that it conducts assessments of medical technologies, but pertinent report titles are not written in a manner reflecting this. Many report titles produced by certain programs mention no medical technology and/or do not indicate that an assessment was involved.

In general, to appear in the *Directory*, report citations must, in at least a broad sense, mention or imply an assessment of one or more technologies. For example, a report title reading "Evaluation of... "qualifies, as do titles mentioning one or more attributes or properties of an assessment such as safety, effectiveness, cost-effectiveness, or economic, ethical, legal, or social implications, or such related extensions as market analysis or analysis of variation in clinical practice. Reports that are "Guidelines for..." or "Standards for... "are also listed, although some are, strictly speaking, model practices or criteria developed based upon assessment findings.

Assessments of the effects of environmental hazards, substances, and interactions neither intended nor used as medical technologies are excluded from the *Directory*. However, interventions to prevent, diagnose, or treat the effects of these are considered medical technologies. Assessments of certain natural processes, e.g., breast feeding, are included because other interventions (e.g., infant formula, in this case) create the possibility of alternative modalities. Excluded specifically are documents describing regulatory requirements. Examples of reports generated by assessment programs but excluded from the *Directory* because they are not about medical technologies or assessments of technologies are: "Carcinogen regulation," "Effects of toxic chemicals on the reproductive cycle," "Health effects of smokeless tobacco," "Health effects of Agent Orange and dioxin contaminants," and "Smoking related deaths and financial costs."

Because the conduct and utility of technology assessments depends on the availability of suitable methods for this purpose, assessments of methods are considered within the scope of the *Directory*. Examples of reports about assessments of methods are "Assessment of double-blindness at the conclusion of the Beta-Blocker Heart Attack Trial," "Postmarketing surveillance of prescription drugs," and "The impact of randomized clinical trials on health policy and medical practice."

In certain instances where council staff was aware by discussion with assessment program representatives and familiarity with program reports, citations were included that had short titles not indicating that report content did address assessments of technologies. This is the case, for example, for certain citations of the American College of Obstetricians and Gynecologists Committee on Technical Bulletins. Reports with such titles as "Carcinoma of the endometrium," "Hemorrhagic shock," and "Osteoporosis" deal with the management of these conditions or alternative technologies for diagnosis or treatment of them, and therefore were retained in the listing of citations following the program profile in Part 1 of the *Directory*. Similarly, reports of the NIH Consensus Development Program titled "Travelers' diarrhea," "Osteoporosis," and "Health implications of obesity" are included in Part 1. Instances such as these are exceptions, however, and staff did not seek on a systematic basis to determine report content beyond what could be discerned from titles. Further, because titles such as these do not name a specific technology, they are not included in the listing of assessment report citations by technology in Part 2.

Index to Report Citations

At the end of Part 1 is an index to report citations. The index has approximately 1,900 subject terms, e.g., *Aspirin, Decubitus ulcer, Monoclonal antibodies*, and *Urinary calculi*.

These terms were compiled by indexing the titles of the assessment reports generated by the programs profiled in Part 1. Each assessment report citation is indexed using from one to five terms. The indexing terms are listed alphabetically, each followed by one or more relevant assessment report codes. Each code has a two letter prefix indicating an assessment program in Part 1, and a number indicating the report's placement in the program's list of citations. For instance, the term *Decubitus ulcer* is followed by the codes AG49, CB10, CB13, NC74, NC104, NC122, and ND19. A list of prefixes and their respective programs is shown immediately preceding this subject index.

Because each assessment report citation is indexed with from one to five terms, a particular report citation may be shown under more than one term in the index to report citations at the end of Part 1. For instance, the report code NC2, corresponding to the NCHSR Office of Health Technology Assessment report "Apheresis in the treatment of systemic lupus erythematosus (SLE)," is listed under *Apheresis* and under *Lupus erythematosus, Systemic*.

This index includes technology terms (e.g., *Dental sealants, Magnetic resonance imaging*, and *Tonometry*) as well as non-technology terms (e.g., *Esophagus, Fetus*, and *Thrombophlebitis*). For non-technology terms, the subject index to report citations relies primarily upon the National Library of Medicine's (NLM) MeSH (Medical Subject Headings) terminology. For technology terms, this index relies primarily upon the terms developed for the technology thesaurus in Part 2, which includes some MeSH terms.

PART 2: ASSESSMENT REPORT CITATIONS LISTED BY TECHNOLOGY

This part has two major sections: a technology thesaurus and a cross-listing of the assessment report citations by technology. These two sections are directly related in that the listing of assessment report citations by technology is arranged according to the terminology set forth in the technology thesaurus.

Technology Thesaurus

The technology thesaurus was developed for the *Directory* to help users search for assessment reports by technology topic. It was generated based upon the technologies appearing in the titles of the assessment report citations shown in Part 1. Where appropriate, it uses the NLM's MeSH vocabulary terms. To enhance searching, the 1,200-term thesaurus includes many synonyms, acronyms, and cross-references, and indicates broader and narrower terms to lead users to desired citations and to help clarify relationships among technology terms.

Technologies are listed at the most specific level suggested by terms used in report titles, usually the name or class of a drug, procedure, device, etc. In general, drugs are listed by generic name, and procedures, devices, etc. are listed by class, e.g., *Radiographic equipment*, in preference to individual brands or models. Thus, assessments of all brands of hydrophilic contact lenses are listed together.

The technology thesaurus lists a technology's synonyms, including abbreviations as well as alternative terms. For each synonym, the thesaurus indicates the listing term under which pertinent citations are shown, using **SEE** (*listing term*). For each listing term, the thesaurus indicates terms from which the user may have been referred using **x** (e.g., from a **SEE** (*listing term*)); indicates which terms are broader than the listing term, using **BT**; and which terms are narrower than the listing term, using **NT**; and indicates related terms, using **SEE ALSO** (*related term*). With respect to **BTs** and **NTs**, each indicates only one level broader or narrower. However, by referring to the next **BT** or **NT**, a user can find other terms yet broader or narrower.

Because a technology may have more than one type of application, or may be classified along a number of dimensions, two or more **BTs** may be shown for a given technology:

For example, *Ibuprofen* has as broader terms *Antipyretics* and *Nonsteroidal anti-inflammatory analgesics*, so that a user looking under either of these broader terms would be referred to assessment report citations concerning ibuprofen. *Laser angioplasty* has as broader terms *Angioplasty* and *Laser surgery*, so that a user seeking citations about means for performing angioplasty, or about applications of laser surgery, would be referred to assessment citations concerning laser angioplasty. Where assessment report citations exist of both a device and its use in practice, each is referred to the other. For example, *Fetal monitors* suggests **SEE ALSO** *Fetal monitoring*, and vice-versa.

Designation of broader or narrower terms is not intended to be complete according to some established framework, although a hierarchically arranged framework of technology terms is conceivable. The extent to which portions of such a framework appear here reflects only the need to accommodate the terms drawn from the assessment report citations included in the *Directory*.

MeSH terms are used in preference to other terms, unless a MeSH term appears to vary substantially from common usage. Thus, pertinent assessment citations are listed under *Coronary artery bypass grafting* in the *Directory* instead of the corresponding MeSH term *Aortocoronary bypass; Beta blockers* is used instead of the MeSH term *Adrenergic beta receptor blockaders*; and *Computed tomography* is used instead of the MeSH term *Tomography, X-ray computed*. Nevertheless, such MeSH terms are shown as synonyms so that users using these as "entry terms" will be referred to the term under which pertinent assessments are listed, so that linkages with MeSH are retained. Word form variations are consistent with the basic term, e.g., *Computed tomography scanners.* Technologies are listed by full name, in preference to an abbreviation, except where an abbreviation is used more commonly or the full name is unwieldy, e.g., *APACHE* instead of *Acute Physiology and Chronic Health Evaluation*, and *BCG vaccine* instead of *Bacillus Calmette-Guérin strain of Mycobacterium bovis*.

Assessment Report Citations by Technology

The cross-listing of assessment report citations listed by technology arranges the citations under technology terms from the thesaurus, e.g., *Cataract extraction, Heart valve prosthesis*, and *Propranolol,* so that all citations for each type of technology may be viewed together.

Citations listed are those in which the title includes one or more identifiable medical technologies. For example, a report titled "Evaluation of nadolol in treatment of hypertension" is listed under *Nadolol*. Under any particular technology heading, the citations are listed in reverse chronological order, and then in alphabetical order by author and title. In addition to bibliographic information, most citations note, in brackets at the end of the citation, the general type of assessment method used, e.g., clinical trial, group judgment, and information synthesis. Because not all of the 3,200 assessment report citations shown with the assessment program profiles in Part 1 have a technology term in their titles, Part 2 contains a subset of these, i.e. about 2,500 citations.

Given its synonyms, acronyms, cross-references, and broader and narrower terms, referring to the technology thesaurus first is the best way to search the listing of assessment report citations by technology in Part 2. Unless a report citation has more than one technology in its title, it is shown only once in the technology listing, usually appearing under its most specific technology term.

Where a title indicates that two or more specific medical technologies are assessed either individually or one in comparison to the other, the citation is listed under both terms. If two or more technologies appear to be used in combination, e.g., "Protein-calorie therapy in combination with anabolic steroids in alcoholic hepatitis," the citation is listed only once under the combined term, in this instance, *Protein-calorie therapy with anabolic steroids*. If a title is ambiguous in this respect, the report is listed under each of the medical technologies mentioned.

For citations listed in this section, distinctions generally are made between procedures and the equipment used for them. For example, headings include *Computed tomography* as well as *Computed tomography scanners*, and *Fetal monitoring* as well as *Fetal monitors*.

Where a report involves a technology to address consequences of a previously applied technology, the active technology is indexed. For instance, the title "Prevalence and pathogenesis of cholesterol gallstones in Halifax: prevention of recurrence by diet changes after medical dissolution therapy" is listed under *Diet therapy*, rather than under a technology for medical dissolution of cholesterol gallstones.

PART 3: INFORMATION AND DATA RESOURCES

This part describes 73 public and private sector information and data resources that may be useful in conducting medical technology assessments. Included are a categorical chart of all of the resources, the 73 resource descriptions, and a subject index to the resources.

At the beginning of Part 3, a categorical chart indicates which of three types of descriptors characterizes each resources. These are:

File type
directories/compendiums
bibliographic information/abstracts
reports/texts/references
data sets
news bulletins

Format
hard copy/print/microfiche
online computer
machine-readable/disk/magnetic tape

Access
public
limited.

An information or data resource may be characterized by more than one descriptor for each of the three main types. For instance, a resource may have bibliographic as well as full text files, may appear in hard copy as well as online format, or may have both public and limited access files.

The descriptions of each of the 73 information and data resources are arranged alphabetically by name of resource. Each is described according to the following common format.

Name of information or data resource.

Source gives the name, address, and telephone number of the organization that produces or makes available the information or data.

Subject indicates the general subject matter covered by the information or data resource.

Content describes the information or data contained in the resource, such as scope of coverage, file format, and descriptions of subfiles.

Compilation describes how the information or data resource is assembled, such as primary sources, when compilation began, and how often the resource is updated.

Access describes how to acquire the information or data, including subscription and use charges, limitations to public access, need for computer hook-up, etc.

At the end of Part 3 is a subject index for identifying information and data resources relevant to particular topics, e.g., market research.

PART 4: ORGANIZATIONAL RESOURCES

This part provides brief descriptions and contact information for 72 organizations that are active in affairs related to medical technology and are stakeholders in medical technology assessment. Although most of these organizations do not generate technology assessment reports on a regular basis, they have memberships concerned with medical technologies, conduct relevant meetings and symposiums, publish conference proceedings and other documents of note, establish standards for technologies, or are active in government, regulatory, or other policy affairs relevant to the field.

The organizational descriptions are arranged alphabetically by organization name. Each includes name, address, and telephone number of the organization; contact person(s), and a narrative description of the organization in 300 words or less, including discussion of medical technology related activities. At the end of Part 4 is a subject index for identifying organizations involved in particular areas, e.g., biomedical engineering.

PART 5: INDEX TO ORGANIZATIONS

This part includes an alphabetical listing with addresses and telephone numbers for all organizations described in the *Directory*, as well as a page index to the organizations.

WAYS TO USE THE DIRECTORY

DO YOU WANT TO SEE IF AN ORGANIZATION IS LISTED, OR WHAT IT DOES?

Check the index to organizations in Part 5 to find the pages on which organizations are described in the *Directory*.

DO YOU WANT TO FIND ASSESSMENT REPORTS ON A SPECIFIC TECHNOLOGY?

Check the technology thesaurus at the beginning of Part 2 on page 313. The thesaurus will inform you whether reports are listed under the technology term that you have in mind, or under a synonym or related term. Once you have located the appropriate term, you can find the pertinent report citations under that heading in Part 2.

YOU MAY BE INTERESTED IN REPORTS THAT HAVE TITLES REFERRING TO TECHNOLOGY TERMS THAT ARE BROADER OR NARROWER THAN THE ONE YOU HAVE IN MIND.

For example, if you are interested in reports about beta-blockers, you will find reports under the heading *Beta-blockers*. But, as the thesaurus indicates, additional reports are to be found under more specific names for beta-blockers, such as *Propranolol*. Except for cases in which more than one technology is shown in the title of a report citation, a citation is listed only once in Part 2, i.e. under the most specific technology heading. So, it is important to refer to the thesaurus first to get the most out of the listing of assessment report citations by technology in Part 2.

DO YOU WANT TO FIND REPORTS INDEXED BY NON-TECHNOLOGY TERMS SUCH AS COST BENEFIT ANALYSIS, PARTICULAR DISEASES, OR OTHER SUBJECTS?

Check under the desired term in the index to report citations at the end of Part 1, and use the report codes found there to look up the assessments in the indicated program profiles. Each code under that term has a two letter prefix indicating the assessment program in Part 1, and a number indicating the report's placement in the program's list of citations. A list of prefixes and their respective programs is shown immediately preceding this subject index.

Under *Cost benefit analysis*, you would find the reference numbers BA2, CP3, CU62, etc., which correspond to the numbered assessment report citations following the profiles on Battelle Memorial Institute, College of American Pathologists, Congress of the United States Office of Technology Assessment, etc. Similarly, under *Asthma*, you would find AC110, MG14, and ND86; under *Breast neoplasms* are AE15, AH4, AH6, etc.; under *Hypertension* are AG25, BA1, HN28, etc., and under *Postmarketing surveillance* are CU56, HN79, MG9, and MG10.

Because each assessment report citation is indexed with from one to five terms, a particular report citation may be shown under more than one term in the index to report citations at the end of Part 1. For instance, the 1987 report by the Medical Technology and Practice Patterns Institute, "Dialysis treatment for end stage renal disease (outpatient)," is indexed under the terms *Dialysis; Kidney failure, Chronic*; and

Outpatients. This means that the code for that report, MT6, is shown under each of these three terms.

For non-technology terms such as asthma, cost benefit analysis, or hypertension, the subject index to report citations relies primarily upon MeSH terminology. The actual titles of the the aforementioned three reports indexed under *Cost benefit analysis*, i.e. BA2, CP3, and CU62, include the phrases "cost-effectiveness analysis, "cost-effective," and "Allocating costs and benefits," respectively. *Cost benefit analysis* is the MeSH indexing term assigned for these. For technologies such as beta-blockers, coronary artery bypass grafting, or chorionic villi sampling, this index relies primarily upon the terms developed for the technology thesaurus in Part 2, which includes some MeSH terms. Searching for reports by technologies is best done using the technology thesaurus at the beginning of Part 2 because it shows cross-references, synonyms, and related terms.

DO YOU WANT TO FIND REPORTS THAT ADDRESS MORE THAN ONE SUBJECT?

This involves locating the set of reports common to the multiple subjects of interest. For instance, to find reports that address both cost benefit analysis and cervical cancer screening, note the reports listed under *Cost benefit analysis* in the subject index at the end of Part 1. Next, determine if any of these reports is also listed under *Cancer screening—Cervical* in the index at the end of Part 1 or the listing of assessment report citations by technology in Part 2. Remember that the thesaurus at the beginning of Part 2 is the best guide in the *Directory* for locating reports by their technology subjects. Among the reports found under both *Cost benefit analysis* and *Cancer screening—Cervical* is a report from the Congress of the U.S. Office of Technology Assessment, "Allocating costs and benefits in disease prevention: an application to cervical cancer screening."

This manual approach of looking under two or more subject headings is necessary given that the *Directory* information base is available only in hard-copy format at the time of printing this first edition. In a computer format, the "and/or" operations of Boolean algebra could be used more readily for searching reports involving such constraints as multiple subjects.

DO YOU WANT TO OBTAIN A TECHNOLOGY ASSESSMENT REPORT?

Check the subject index to assessment report citations at the end of Part 1 or the listing of assessment report citations by technology in Part 2 to find out which assessment program produced it. Find the program's profile in the alphabetical listing of assessment programs in Part 1, and see the section on *Dissemination* for ordering information. The program's address, telephone number, and other contact information are shown at the beginning of the profile.

DO YOU WANT TO GET IN TOUCH WITH AN ORGANIZATION THAT DEALS WITH A CERTAIN TOPIC?

Use the subject indexes to the different parts of the *Directory* to identify organizations active in certain areas. The index to report citations at the end in Part 1 and the listing of assessment report citations by technology in Part 2 may be used to identify profiled assessment programs, arranged alphabetically in Part 1, by the topics of their assessment reports. The information and data resources in Part 3 and the organizational resources in Part 4 are indexed by subject at the ends of those parts. For instance, under

the heading *Market research* in the index to information and data resources in Part 3 are listed IMS Audits, Scrip, Market/Technology Reports (Biomedical Business International), and other resources. Under the heading *Biomedical engineering* in the index to organizational resources in Part 4 are listed the Alliance for Engineering in Medicine and Biology, American Society of Mechanical Engineers, RESNA—Association for the Advancement of Rehabilitation Technology, Institute of Electrical and Electronics Engineers, and the International Federation for Medical and Biological Engineering. Contact information and descriptions of these are arranged alphabetically.

GLOSSARY OF ACRONYMS

AABB	American Association of Blood Banks
AAD	American Academy of Dermatology
AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
AAMI	Association for the Advancement of Medical Instrumentation
AAMSI	American Association for Medical Systems and Informatics
AAN	American Academy of Neurology
AAO	American Academy of Ophthalmology
AAOHNS	American Academy of Otolaryngology-Head and Neck Surgery
AAOS	American Academy of Orthopaedic Surgeons
AAP	American Academy of Pediatrics
AAPMR	American Academy of Physical Medicine and Rehabilitation
AATB	American Association of Tissue Banks
ACC	American College of Cardiology
ACEP	American College of Emergency Physicians
ACG	American College of Gastroenterology
ACNP	American College of Nuclear Physicians
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society or American College of Surgeons
ACT	American Council on Transplantation
ADA	American Dental Association or American Diabetes Association
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
ADM	alcohol, drug abuse, and mental health
AEMB	Alliance for Engineering in Medicine and Biology
AGS	American Geriatrics Society
AHA	American Hospital Association or American Heart Association
AHCI	American Health Care Institute
AHSR	Association for Health Services Research
AIUM	American Institute of Ultrasound in Medicine
AMA	American Medical Association
AMCRA	American Medical Care and Review Association
AMPRA	American Medical Peer Review Association
AAMRC	American Medical Review Research Center
ANSI	American National Standards Institute
AP	Associated Press
APA	American Psychiatric Association
APHA	American Public Health Association
ARA	American Rheumatism Association
ASA	American Society of Anesthesiologists
ASCP	American Society of Clinical Pathologists
ASCPT	American Society for Clinical Pharmacology and Therapeutics

ASGE	American Society for Gastrointestinal Endoscopy
ASIM	American Society of Internal Medicine
ASPEN	American Society of Parenteral and Enteral Nutrition
ASTM	American Society of Testing and Materials
ASTP	American Society of Transplant Physicians
ASTS	American Society of Transplant Surgeons
AUA	American Urological Association
AZT	azidothymidine
BCBS	Blue Cross and Blue Shield
BCDSP	Boston Collaborative Drug Surveillance Program
BDDD	Division of Birth Defects and Developmental Disabilities (CDC)
BERC	Bureau Eligibility, Reimbursement and Coverage (HCFA)
BMEDSS	Biomedical Engineering Decision Support Services
BRS	Bibliographic Retrieval Service
CABG	coronary artery bypass grafting
CAMMD	Canadian Association of Manufacturers of Medical Devices
CAP	College of American Pathologists
CASSIS	Classification and Search Support Information System (Patent and Trademark Office)
CAT	computerized axial tomography
CBO	Centraal Begeleidingsorgaan voor de Intercollegiale Toetsing (The Netherlands)
CCC	Copenhagen Collaborating Center (WHO)
CDB	Center for Drugs and Biologics (FDA)
CDC	Centers for Disease Control
CDRH	Center for Devices and Radiological Health (FDA)
CEAP	Clinical Efficacy Assessment Project (ACP)
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CHA	Center for Health Affairs (Project HOPE)
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services
CHID	Combined Health Information Database
CHPE	Center for Health Promotion and Education (CDC)
CHPRE	Center for Health Policy Research and Education (Duke University)
CMA	California Medical Association
CMSS	Council of Medical Specialty Societies
CMT	Center for Medical Technology Assessment (Linköping University)
COMPASS	Computerized On-Line Medicaid Pharmaceutical Analysis and Surveillance System (Health Information Designs, Inc.)
CPHA	Commission on Professional and Hospital Activities
CPT-4	Current Procedural Terminology, 4th Edition
CRISP	Computer Retrieval of Information on Scientific Projects (NIH)
CSDD	Center for the Study of Drug Development (Tufts University)
CSS	Council of Subspecialty Societies
CT	computed tomography
CVS	chorionic villi sampling
DATTA	Diagnostic and Therapeutic Technology Assessment Program (AMA)

DCCC	Duke Comprehensive Cancer Center Database
DEN	Device Experience Network (FDA)
DHHS	U.S. Department of Health and Human Services
DHSS	Department of Health and Social Security (United Kingdom)
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information (Germany)
DIRLINE	Directory of Information Resources Online (NLM)
DOD U.S.	Department of Defense
DPPR	Drug Product Problem Reporting System (FDA, USP)
DRG	diagnosis-related group or Division of Research Grants (NIH)
DURbase	Drug Utilization Review base (Health Information Designs, Inc.)
EBRI	Employee Benefit Research Institute
ECRI	formerly Emergency Care Research Institute
ECRI/HDP ECRI	Health Devices Program
ECRI/TAP ECRI	Technology Assessment Program
EHLS	Division of Environmental Health Laboratory Sciences (CDC)
EMBASE	Excerpta Medica Database (Elsevier)
EPA	Environmental Protection Agency
ERIC	Educational Resources Information Center
ESRD	end stage renal disease
FAHS	Federation of American Health Systems
FDA	Food and Drug Administration
GHAA	Group Health Association of America
GHC	Group Health Cooperative of Puget Sound
GPIA	Generic Pharmaceutical Industry Association
GPO U.S.	Government Printing Office
GWUMC	George Washington University Medical Center
HANES	National Health and Nutrition Examination Survey (NCHS)
HBP	high blood pressure
HCFA	Health Care Financing Administration (DHHS)
HECLINET	Health Care Literature Information Network (DIMDI)
HHS U.S.	Department of Health and Human Services
HIAA	Health Insurance Association of America
HIMA	Health Industry Manufacturers Association
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
HSR & D	Health Services Research and Development Service (VA)
IAF	Institute for Alternative Futures
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
IDE	investigational device exemption (FDA)
IEEE	Institute of Electrical and Electronics Engineers
IFMBE	International Federation for Medical and Biological Engineering
IFTF	Institute for the Future
IFVHSF	International Federation of Voluntary Health Service Funds

IHPS	Institute for Health Policy Studies (UCSF)
IMPAC	Information for Management Planning Analysis and Coordination (NIH)
IND	investigational new drug (FDA)
IOM	Institute of Medicine (NAS)
IRCS	International Research Communications System (Elsevier)
ISTAHC	International Society of Technology Assessment in Health Care
MDR	Medical Device Reporting regulation (FDA)
MEDITEC	Medizinische Technik
MEDLARS	Medical Literature Analysis and Retrieval System (NLM)
MEDLINE MEDLARS	online (NLM)
MeSH	Medical Subject Headings (NLM)
MHA	Maryland Hospital Association
MHRST	Medical and Health Related Sciences Thesaurus (NIH)
MRC	Medical Research Council (Canada)
MTPPI	Medical Technology and Practice Patterns Institute
NAHDO	National Association of Health Data Organizations
NAM	National Association of Manufacturers
NAS	National Academy of Sciences
NASA	National Aeronautics and Space Administration
NCEP	National Cholesterol Education Program
NCHS	National Center for Health Statistics
NCHSR/HCTA	National Center for Health Services Research and Health Care Technology Assessment
NCI	National Cancer Institute
NCQHC	National Committee for Quality Health Care
NDA	new drug application (FDA)
Nd:YAG	Neodymium: yttrium aluminum garnet
NEMA	National Electrical Manufacturers Association
NEMT	Nordic Evaluation of Medical Technology
NHC	National Heart Council
NHLBI	National Heart, Lung, and Blood Institute
NHRDP	National Health Research and Development Program (Canada)
NHS	National Health Service (United Kingdom)
NHSPPS	National Health Services and Practice Patterns Survey
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NICHD	National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health (PHS, DHHS)
NIMH	National Institute of Mental Health
NINCDS	National Institute of Neurological and Communicative Disorders and Stroke
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NMR	nuclear magnetic resonance
NSEP NHLBI	Smoking and Education Program
NTIS	National Technical Information Service

OASH	Office of the Assistant Secretary for Health (DHHS)
ODPHP	Office of Disease Prevention and Health Promotion (DHHS)
OHTA	Office of Health Technology Assessment (NCHSR)
OMAR	Office of Medical Applications of Research (NIH)
ONHIC ODPHP	National Health Information Center
OPE	Office of Planning and Evaluation (NIH)
OPTN	Organ Procurement and Trans-plantation Network (UNOS)
ORD	Office of Research and Demonstrations (HCFA)
OSHA	Occupational Safety and Health Administration
OTA	Office of Technology Assessment (U.S. Congress)
PAHO	Pan American Health Organization
PDQ	Physician Data Query (NCI)
PHS	U.S. Public Health Service (DHHS)
PMA	Pharmaceutical Manufacturers Association
PPRC or PhysPRC	Physician Payment Review Commission
PPS	Medicare Prospective Payment System
PRO	professional review organization
ProPAC	Prospective Payment Assessment Commission
PRP	Medical Device and Laboratory Product Problem Reporting Program (FDA, USP)
PTO	U.S. Patent and Trademark Office
R&D	research and development
RESNA	Association for the Advancement of Rehabilitation Technology, formerly Rehabilitation Engineering Society of North America
RCT	randomized (controlled) clinical trial
RFA	request for application
RFP	request for proposal
RPA	Renal Physicians Association
RTECS	Registry of Toxic Effects of Chemical Substances (NIOSH, NLM)
SBA	Summary Basis of Approval (FDA)
SEER	Surveillance, Epidemiology, and End Results Program (NCI)
SIC	Standard Industrial Classification
SMD	Society for Medical Decision Making
SNM	Society of Nuclear Medicine
SNIVT	Society of Non-Invasive Vascular Technology
SPO	Special Projects Office (VA)
SPRI	Swedish Planning and Rationalization Institute of the Health Services
SPRILINE	Swedish Planning and Rationalization Institute of the Health Services line
SREPCIM	Society for Research and Education in Primary Care Internal Medicine
SSED	Summaries of Safety and Effectiveness Data (FDA)
TAF	Technology Assessment and Forecast Program (PTO)
TDC	Technical Data Center (OSHA)
TNO	Medical Technology Unit, Netherlands Organization for Applied Scientific Research
UCSF	University of California at San Francisco
UHC	University Hospital Consortium
UNOS	United Network for Organ Sharing
USDA	U.S. Department of Agriculture

USDHHS	U.S. Department of Health and Human Services
VA	Veterans Administration
WHO	World Health Organization
YAG	yttrium aluminum garnet

PART 1 ASSESSMENT PROGRAM PROFILES AND REPORT CITATIONS

PART 1

ASSESSMENT PROGRAM PROFILES AND REPORT CITATIONS

This part has two major sections. Beginning on page 3 are profiles of 68 medical technology assessment programs, with citations of their approximately 3,200 completed, ongoing, and planned assessments. The assessment program profiles are listed alphabetically by name of parent organization.

Following the profiles, beginning on page 254, is a subject index to report citations, to be used for locating citations on particular subjects among the profiles. The index has approximately 1,900 subject terms. These terms are listed alphabetically, each followed by one or more relevant assessment report codes. Each code has a two letter prefix indicating an assessment program and a number indicating the report's placement in the list of citations at the end of the program's profile earlier in Part 1. A list of prefixes and their respective programs is shown on page 252, immediately preceding the subject index.

AMERICAN ACADEMY OF NEUROLOGY PRACTICE COMMITTEE

2221 University Avenue SE, Suite 335
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612-623-8115

Contact: Richard P. Hames, Director, Division of Medical Services and Communications; William H. Stuart M.D., 105 Collier Rd. NW, Suite 1030, Atlanta, GA 30309, 404-351-2270; or John P. Conomy M.D., Department of Neurology, Cleveland Clinic Foundation, 9500 Euclid Ave., Cleveland, OH 44106, 216-444-5555.

Overview: The American Academy of Neurology (AAN) is a 9,000-member medical specialty society founded in 1948. The Academy's major objectives are to stimulate the growth and development of the specialty of clinical neurology and clinical neurologists. The AAN Practice Committee assesses the clinical effectiveness of drugs, devices, and procedures involving the neurosciences.

Purpose: To review and evaluate clinical, procedural, and technological requests for opinion received by the Academy.

Primary intended users: Providers, generally; physicians; health/medical professional associations; third party payers; government regulators.

Technologies: *Medical or surgical procedure*, drug, device.

Intervention: *Treatment*, diagnosis, rehabilitation.

Stage: *New*, established or widespread practice, obsolete.

Properties: *Effectiveness*; safety; efficacy; cost; service requirements; acceptance/adoption level; ethical, legal, social implications.

Selection process: Individual practitioners in neurology and neurosurgery, medical organizations, and third party payers can request that an assessment be conducted. All requests must be in writing and sent to the Academy office. Requests are submitted to the Practice Committee for opinion and inclusion on the agenda. The Practice Committee does not set assessment topic priorities. The Committee, acting as a group, assesses all questions submitted to it, although the Committee has rejected such complicated topics as organ transplantation.

Methods: *Group judgment*, expert opinion.

The Practice Committee receives reports from several subcommittees that are, in most cases, chaired by a Practice Committee member. The subcommittees consider the procedure/treatment question and exercise one of two options: 1) develop recommendation for full committee as to whether the treatment/procedure is established, investigational, unacceptable, or indeterminate (as defined in accordance with the American Medical Association (AMA) Diagnostic and Therapeutic Technology Assessment plan); or 2) defer recommendation pending further research/study by subcommittee members. At each of the four regularly scheduled meetings per year the Practice Committee reviews and acts on the recommendations of the subcommittees. Practice Committee actions are then submitted to the Academy Executive Board as information items.

The following statement is incorporated into every response to a request for opinion: "This response is provided as a service of the American Academy of Neurology. It is based on current scientific and clinical information through (date of evaluation), and does not represent endorsement by the AAN of particular diagnostic and therapeutic procedures or treatment."

When major questions or issues confront the Committee, such as the use of magnetic resonance imaging as a diagnostic procedure, a wider consensus is sought. Working with the Council of Medical Specialty Societies (CMSS), the AMA, and other organizations, a consensus panel is convened and a position paper developed on the technology in question.

The turnaround time from selection of assessment topic to reporting of findings ranges from 1 week to 6 months.

Assessors: The Practice Committee is composed of 16 members from across the country who represent the interests and concerns of the practitioner.

Assessment reports include: Who sponsored/commissioned/ supported the assessment; stage of life-cycle of technology when assessed; recommendations for practice, future assessments, technology development, research.

Dissemination: Assessment results are disseminated through the minutes of the Practice Committee and through correspondence with other medical organizations and practitioners. The Academy office maintains a listing of Practice Committee decisions and responds to inquiries about procedures/treatment. The Council of Medical Specialty Societies also distributes Practice Committee assessments.

Budget: The assessment program is not budgeted as a separate activity. The approximate cost per assessment is not known.

Use: The Academy disseminates assessment results to its membership. Based on inquires received, third party payers rely on Practice Committee opinions in making reimbursement decisions.

Completed Reports

AA1 American Academy of Neurology, Practice Committee. Extracranial-intracranial bypass surgery for treatment or prevention of stroke. 1986 Feb. [Expert opinion, Group judgment]

AA2 _____ Hyperbaric oxygen therapy for treatment of senility, multiple sclerosis, and cerebral edema. 1986 Feb. [Expert opinion, Group judgment]

AA3 _____. Apheresis (therapeutic) in the treatment of Guillain-Barré Syndrome. 1985 Jun. [Expert opinion, Group judgment]

AA4 _____. Apheresis in treatment of systemic lupus erythematosus. 1985 Jun. [Expert opinion, Group judgment]

AA5 _____. Percutaneous transluminal angioplasty (PTA). 1985 Feb. [Expert opinion, Group judgment]

AA6 _____ Topographic mapping. 1985. Feb. [Expert opinion, Group judgment]

AA7 _____. Apheresis in treatment of chronic relapsing polyneuropathy. 1984 Feb. [Expert opinion, Group judgment]

AA8 _____. Autopsies on patients with slow virus diseases. 1984 Nov. [Expert opinion, Group judgment]

AA9 _____. EEG guidelines for epileptic mentally retarded. 1984 Nov. [Expert opinion, Group judgment]

AA10 _____. Electromyographic biofeedback in treatment of hyperactivity. 1984 Feb. [Expert opinion, Group judgment]

AA11 _____. Electronystagmography. 1984 Jun. [Expert opinion, Group judgment]

AA12 _____. Functional integration in the alleviation of chronic muscular pain and spasticity. 1984 Feb. [Expert opinion, Group judgment]

AA13 _____. Nuclear magnetic resonance. 1984 Feb. [Expert opinion, Group judgment]

AA14 _____. Sterotactic cingulatomy. 1984 Nov. [Expert opinion, Group judgment]

AA15 _____. Amyotrophic lateral sclerosis—injected modified neurotoxin for treatment. 1983 Feb. [Expert opinion, Group judgment]

AA16 _____. Edinburgh Masker for stuttering. 1983 Jun. [Expert opinion, Group judgment]

AA17 _____ Histamine desensitization for cluster headache. 1983 Jun. [Expert opinion, Group judgment]

AA18 _____. Melodic intonation therapy for aphasia. [Expert opinion, Group judgment]

AA19 _____. Modified neurotoxin in the treatment of ALS. 1983 Jun. [Expert opinion, Group judgment]

AA20 _____. Plasmapheresis in treatment of multiple sclerosis. 1983 Feb. [Expert opinion, Group judgment]

AA21 _____. Plasmapheresis in treatment of myasthenia gravis. 1983 Feb. [Expert opinion, Group judgment]

AA22 _____. Somatosensory evoked response. 1983 Nov. [Expert opinion, Group judgment]

AA23 _____. Trancutaneous electrical nerve stimulation for treatment of acute pain for ambulatory patients. 1983 Nov. [Expert opinion, Group judgment]

AA24 _____ Twenty-four hour EEG ambulatory monitoring. 1983 Jun. [Expert opinion, Group judgment]

AA25 _____. Biofeedback for headaches. 1982 Jun. [Expert opinion, Group judgment]

AA26 _____. Carotid infusion of BCNU for glioblastoma multiforme. 1982 Jun. [Expert opinion, Group judgment]

AA27 _____. Cerebellar stimulator implantation for cerebral palsy. 1982 Oct. [Expert opinion, Group judgment]

AA28 _____. Cerebellar stimulator implantation. 1982 Jun. [Expert opinion, Group judgment]

AA29 _____. Cochleostomy with neurovascular transplant in treatment of Ménière's Disease. 1982 Oct. [Expert opinion, Group judgment]

AA30 _____. EEG monitoring—ambulatory. 1982 Apr. [Expert opinion, Group judgment]

AA31 _____. EEG monitoring during open-heart surgery and immediate post-operative period. 1982 Oct. [Expert opinion, Group judgment]

AA32 _____. Negative pressure respirators for home use in chronic neuromuscular disease. 1982 Oct. [Expert opinion, Group judgment]

AA33 _____. Spinal cord stimulation for treatment of cerebral palsy. 1982 Jun. [Expert opinion, Group judgment]

AA34 _____. Taste and smell clinics. 1982 Jun. [Expert opinion, Group judgment]

AA35 _____. Acupuncture. 1981 Jul. [Expert opinion, Group judgment]

AA36 _____. Apheresis for multiple sclerosis. 1981 Jul. [Expert opinion, Group judgment]

AA37 _____. EEG interpretation and brain stem evoked response. 1981 Jul. [Expert opinion, Group judgment]
AA38 _____. Electrical nerve stimulation of post-surgical pain. 1981 Apr. [Expert opinion, Group judgment]
AA39 _____. Electrical stimulation for treatment of Bell's Palsy. 1981 Apr. [Expert opinion, Group judgment]
AA40 _____. Electrical stimulation for treatment of facial nerve palsy. 1981 May. [Expert opinion, Group judgment]
AA41 _____. Histamine therapy for Ménière's Disease. 1981 Jul. [Expert opinion, Group judgment]
AA42 _____. Prolotherapy. 1981 Jul. [Expert opinion, Group judgment]
AA43 _____. Visual evoked potentials. 1981 Jul. [Expert opinion, Group judgment]
AA44 _____. Biofeedback treatment for migraine headache. 1980 Apr. [Expert opinion, Group judgment]
AA45 _____. Continuous EEG monitoring during surgery. 1980 Apr. [Expert opinion, Group judgment]
AA46 _____. Intracranial pressure monitors. 1980 Oct. [Expert opinion, Group judgment]
AA47 _____. Neurosonology. 1980 Mar. [Expert opinion, Group judgment]
AA48 _____. Spinal stimulation for multiple sclerosis. 1980 May. [Expert opinion, Group judgment]
AA49 _____. Transfer factor treatment in multiple sclerosis. 1980 Apr. [Expert opinion, Group judgment]
AA50 _____. Ultrasonic arteriography. 1980 May. [Expert opinion, Group judgment]

AMERICAN ACADEMY OF OPHTHALMOLOGY OPHTHALMIC PROCEDURES ASSESSMENT PROGRAM

PO Box 7424
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415-561-8500

Contact: Lea Gamble, Director Health Policy Research; or David L. Guyton, M.D., Chairman, Committee on Ophthalmic Procedures Assessment, Wilmer Ophthalmological Institute, the Johns Hopkins Hospital, Baltimore, MD 21205, 301-955-8314.

Overview: The American Academy of Ophthalmology (AAO) is a professional association composed of over 14,000 physicians trained in the specialty of ophthalmology. It offers a wide range of membership services including continuing education programs, public and professional information materials, and scientific meetings. The Ophthalmic Procedures Assessment Program is the medical technology assessment program of the AAO.

Purpose: To present state-of-the-science information about ophthalmic technologies that will help Academy members make informed decisions about patient care.

Primary intended users: Physicians, third party payers, government regulators.

Technologies: *Medical or surgical procedure*, drug, device.

Ophthalmology-related orphan drugs and products, diagnostic and therapeutic devices, and medical and surgical procedures are assessed.

Intervention: *Treatment*, diagnosis.

Stage: *New*, emerging, established or widespread practice.

Sufficient information must be available in the scientific literature to develop assessments.

Properties: *Safety, effectiveness*, efficacy.

Comprehensive assessments usually follow this format: definition of terms, including development of technique or procedure, extent of current use; clinical implementation, including indications for use, comparison to conventional methods, advantages/ disadvantages, patient population most likely to benefit, and effectiveness; safety; qualifications necessary to use technique; and current research and summary.

Selection process: Academy members, public and private third party payers, and government agencies can request that assessments be conducted. Requests will also be accepted from other sources. Usually requests for assessments are written inquiries asking the Academy's position/opinion on a certain technology. Inquiries from individuals and private third party payers are frequently received over the telephone, but the AAO requires that a written request be submitted. The Committee on Ophthalmic Procedures Assessment sets priorities. Technologies to be assessed must be within the scope of ophthalmology, and sufficient scientific information on which to base a decision must be available. If new information is available that substantially changes information contained in an assessment, a reassessment of the technology will be initiated.

Methods: *Information syntheses, group judgment*, expert opinion, epidemiological and other observational methods.

The scientific literature in refereed journals is reviewed and expert opinion and group judgment is sought in order to reach consensus. After a decision to evaluate a technology has been made, the following four steps are followed: 1) an expert is identified who develops a draft with references; 2) the draft is reviewed by other experts, generally AAO members, the Committee, staff, and legal counsel; 3) if substantial changes are needed, a revised draft is recirculated to all reviewers and, generally, a conference call is held to discuss differences in interpretation of findings in the literature; and 4) once a draft is acceptable to the reviewers, it is submitted to the Academy's Board of Directors for approval.

For noncontroversial technologies, the average turnaround time from selection of assessment topic to reporting of findings is 6 to 9 months. For controversial technologies the turnaround time can extend into years.

Assessors: The Committee is composed of three Academy members, staffed by the Academy's Office of Health Policy Research, and assisted by the membership of the Academy. Academy members participate as reviewers, as in-depth consultants, or by preparing the original draft assessment. A total of 400 Academy members, covering 40 technical areas, have agreed to participate, in some capacity, in the assessment effort. These members participate voluntarily and without remuneration. When appropriate, experts from related fields are consulted.

Assessment reports include: Who conducted the assessment; description of the technology; properties assessed; sources of data/information; findings or conclusions; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology.

Dissemination: *Printed reports; journal articles;* press conferences/news releases, TV/ radio broadcasts, video products.

The Academy prints the assessment reports, and notices of completed assessments appear in the AAO membership newsletter. The assessments are published in the AAO's scientific journal, displayed at the AAO annual meeting, and are mailed to specific organizations and interested individuals. The Academy's Order Department accepts telephone and written requests for assessment reports. Copies are provided free of charge.

Budget: $7,500. Funding source: 100 percent sponsors/members dues, contributions.

Use: Assessment reports are considered an educational service to the members and are provided in response to inquiries from the media, third party payers, and the public. Private and public third party payers use them to make policy decisions about coverage. Their purpose for requesting an assessment is generally stated.

Related activities: At the 1986 AAO annual meeting, the Committee on Ophthalmic Procedures Assessment sponsored a special scientific session entitled, "Radial Keratotomy in Perspective." The purpose of this session was to have opthalmologists representing a range of opinions address key questions about the procedure.

Completed Reports

AB1 American Academy of Ophthalmology. Epikeratophakia procedures for the correction of severe hyperopia, myopia, and keratoconus. San Francisco, CA: American Academy of Ophthalmology, expected completion October 1987. [Information syntheses, Expert opinion]

AB2 _____. Punctal occlusion for the dry eye. San Francisco, CA: American Academy of Ophthalmology, 1987. [Information syntheses, Expert opinion]

AB3 _____. Punctoplasty for siccakeratitis. San Francisco, CA: American Academy of Ophthalmology, expected completion June 1987. [Information syntheses, Expert opinion]

AB4 _____. Radial keratotomy for myopia. San Francisco, CA: American Academy of Ophthalmology, expected completion October, 1087. [Information syntheses, Expert opinion]

AB5 _____. Cataract surgery in the 1980's. San Francisco, CA: American Academy of Ophthalmology, 1987. [Information syntheses, Expert opinion]

AB6 _____. Keratophakia and keratomileusis: safety and effectiveness. San Francisco, CA: American Academy of Ophthalmology, 1986. [Information syntheses, Expert opinion]

AB7 _____. Thymoxamine: the need for orphan drug status. San Francisco, CA: American Academy of Ophthalmology, 1986. [Information syntheses, Expert opinion]

AB8 _____. Botulinum toxin therapy of eye muscle disorders: safety and effectiveness. San Francisco, CA: American Academy of Ophthalmology, 1984. [Information syntheses, Expert opinion]

AB9 Committee on Ophthalmic Procedures Assessment. [American Academy of Ophthalmology] Carbon dioxide laser surgery in head and neck surgery. San Francisco, CA: American Academy of Ophthalmology, 1984. [Information syntheses, Expert opinion]

AB10 _____. [American Academy of Ophthalmology] Cyanoacrylate tissue adhesive. San Francisco, CA: American Academy of Ophthalmology, 1984. [Information syntheses, Expert opinion]

AB11 _____. [American Academy of Ophthalmology] Therapeutic contact lenses for recurrent corneal erosion. San Francisco, CA: American Academy of Ophthalmology, 1984. [Information syntheses, Expert opinion]

AB12 Keltner JL. [American Academy of Ophthalmology] Academy recommendation: automated perimetry. Ophthalmology 1984;91:51-56. [Information syntheses, Expert opinion]

AB13 Trokel S. [American Academy of Ophthalmology] Academy recommendation: ophthalmic neodymium YAG lasers: safety and effectiveness. Ophthalmology 1984;91:539-42. [Information syntheses, Expert opinion]

AB14 American Academy of Ophthalmology. Laser trabecular surgery for open-angle glaucoma. San Francisco, CA: American Academy of Ophthalmology, 1983. [Information syntheses, Expert opinion]

AMERICAN ACADEMY OF PEDIATRICS

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Overview: The American Academy of Pediatrics (AAP) is a professional association composed of pediatricians and pediatric medical and surgical subspecialists. The Academy promotes optimal physical, mental, and social health for infants, children, adolescents, and young adults. It provides a range of services including advocacy for children and pediatrics, health systems delivery research, public information and education, continuing medical education, and analyses and review of child health policy issues. The Academy's technology assessment activities are an integral part of the information gathering and advisory functions of the numerous AAP Committees.

Purpose: The AAP Committees keep abreast of developments in the field and advise the membership and Executive Board on topics within the committees' areas of expertise.

Primary intended users: General public; physicians; health/medical professional associations; government regulators; public policy-makers, legislators; policy research organizations; liability, malpractice insurers.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system.

Intervention: Prevention, diagnosis, treatment, rehabilitation.

Stage: Emerging, new, established or widespread practice.

Properties: Safety; efficacy; effectiveness; service requirements; system impact; ethical, legal, social implications.

Selection process: Topic suggestions can come from any source. Usually, assessment topics are suggested by committee members, AAP members, or through other organizational requests. The AAP accepts telephone and written requests and occasionally relies on formal contracts. For example, the Food and Drug Administration contracted

with the AAP for advice relative to infant formulas and drugs. AAP staff screen the requests and then the appropriate committee considers the question. Assessment topic priorities are set by the individual committee and the Academy.

Methods: Information syntheses, expert opinion, group judgment.

The assessment method varies from committee to committee and by issue, although all committees generally rely on a type of group judgment. For statements, committees usually proceed in the following manner: 1) general discussion of issue; 2) preparation of first draft by committee member; 3) extensive review and preparation of bibliography by same member (in some cases, this information is reviewed by outside consultants); 4) presentation of second draft and discussion by committee; and, 5) revision of draft, if necessary. All reports must be approved by the Executive Board of the AAP.

The average turnaround time from selection of assessment topic to reporting of findings ranges from 4 months to 1 year.

Assessors: AAP has committees in such areas as adolescence, bioethics, drugs, fetus and newborn, hospital care, infectious diseases, nutrition, radiology, and surgery. Each committee consists of experts in the topic area. Committees can also bring in consultants for additional expertise on particular reports.

Dissemination: Printed reports; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts.

Committees issue reports with the assessment findings. For smaller scale projects a note is made in the minutes or a recommendation given to the AAP Executive Board. AAP Committee statements are published in *Pediatrics* or information may appear in *AAP News*. Occasionally, letters are sent to government agencies such as the Environmental Protection Agency or the Consumer Product Safety Commission. Some reports are distributed directly to the AAP members, such as the *Report of the Committee on Infectious Diseases* (the "Red Book").

Budget: Not provided.

Related activities: The AAP publishes a quarterly newsletter, *Child Health Financing Report*, which contains the latest information about child health financing for privately insured children and those covered by Medicare. The Academy also sponsors an annual meeting, educational programs, and continuing education courses.

Completed Reports

AC1 American Academy of Pediatrics, Committee on Hospital Care. Emergency services. Pediatrics (To be published).

AC2 _____, Committee on Hospital Care. Guidelines for air and ground transportation. Pediatrics (To be published).

AC3 _____, Committee on Hospital Care. Quality assurance of hospital care of children. Pediatrics (To be published).

AC4 _____, Committee on Practice and Ambulatory Medicine. Screening for vision problems. Pediatrics (To be published).

AC5 _____, Committee on Accident and Poison Prevention. Revised first aid for the choking child. Pediatrics 1986 Jun.

AC6 _____, Committee on Child Health Financing. Medicaid policy statement. Pediatrics 1986 May.

AC7 _____, Committee on Disabilities. Screening for developmental disabilities. Pediatrics 1986 Sep.

AC8 _____, Committee on Disabilities. Transition of severely disabled children from hospital or chronic care facilities to the community. Pediatrics 1986 Sep.

AC9 _____, Committee on Early Childhood, Adoption, and Dependent Care. Oral and dental aspects of child abuse and neglect. Pediatrics 1986 Sep.

AC10 _____, Committee on Nutrition. Prudent lifestyle for children: dietary fat and cholesterol. Pediatrics 1986 Sep.

AC11 _____, Committee on Practice and Ambulatory Medicine. Vision screening and eye examination in children. Pediatrics 1986 Jun.

AC12 _____, Committee on Research. Guidelines for the Pediatric Cancer Center and the role of such centers in diagnosis and treatment. Pediatrics 1986 Jun.

AC13 _____, Committee on School Health. CPR training in the school. AAP News 1986 Jan.

AC14 _____, Committee on School Health. School attendance of children and adolescents with human T lymphotropic virus III/lymphadenopathy-associated virus infection. Pediatrics 1986 Mar.

AC15 _____, Committee on School Health. School health examinations. AAP News 1986 Feb.

AC16 _____, Committee on Infectious Diseases. Prevention of hepatitis B virus infections. Pediatrics 1985 Feb.

AC17 _____, Committee on Bioethics. Proposed guidelines on genetic engineering. Pediatrics 1985 Jun.

AC18 _____, Committee on Disabilities. Assisting disabled children. Pediatrics 1985 Jun.

AC19 _____, Committee on Disabilities. Provision of related services for children with chronic disabilities. Pediatrics 1985 Apr.

AC20 _____, Committee on Drugs. "Inactive" ingredients in pharmaceutical products. Pediatrics 1985 Oct.

AC21 _____, Committee on Drugs. Behavioral and cognitive effects of anticonvulsant therapy. Pediatrics 1985 Oct.

AC22 _____, Committee on Drugs. Guidelines for the elective use or conscious use of sedation, deep sedation, and general anesthesia in pediatric patients. Pediatrics 1985 Aug.

AC23 _____, Committee on Environmental Hazards. Smokeless tobacco—a carcinogenic hazard to children. Pediatrics 1985.

AC24 _____, Committee on Fetus and Newborn. High risk newborn care. Pediatrics 1985 Jul.

AC25 _____, Committee on Fetus and Newborn. Home phototherapy. Pediatrics 1985 Jul.

AC26 _____, Committee on Fetus and Newborn. Vitamin E and the prevention of retinopathy of prematurity. Pediatrics 1985 Aug.

AC27 _____, Committee on Hospital Care. Child life programs for hospitalized children. Pediatrics 1985 Sep.

AC28 _____, Committee on Hospital Care. Guidelines for pediatric intensive care units. Pediatrics 1983 Sep.

AC29 _____, Committee on Infectious Diseases. Hemophilus type b polysaccharide vaccine. Pediatrics 1985 Aug.

AC30 _____, Committee on Infectious Diseases. Recommendations for using pneumococcal vaccine in children. Pediatrics 1985 Jun.

AC31 _____, Committee on Infectious Diseases. Recommendations for using pneumococcal vaccine in children. Pediatrics 1985 Jun.

AC32 _____, Committee on Nutrition. Nutritional needs of low-birth-weight infants. Pediatrics 1985 May.

AC33 _____, Committee on Nutrition. Use of oral fluid therapy and posttreatment feeding following enteritis in children in a developed country. Pediatrics 1985 Feb.

AC34 _____, Committee on Practice and Ambulatory Medicine. Computers in your practice. Pediatrics 1985 Jul.

AC35 _____, Committee on Practice and Ambulatory Medicine. High risk newborn care. Pediatrics 1985 Jul.

AC36 _____, Committee on School Health. Health education and schools. Pediatrics 1985 Jun.

AC37 _____, Committee on Screening Genetics. Maternal phenylketonuria. Pediatrics 1985 Aug.

AC38 _____, Committee on Adolescence. A policy reference guide to the AAP's Council Committee and Executive Board statements. 1984.

AC39 _____, Committee on Drugs. Ethanol in liquid preparations intended for children. 1984.

AC40 _____, Committee on Drugs. Antimicrobial prophylaxis in pediatric surgical patients. Pediatrics 1984 Sep.

AC41 _____, Committee on Infectious Diseases. Antimicrobial prophylaxis in pediatric surgical patients. Pediatrics 1984 Sep.

AC42 _____, Committee on Infectious Diseases. Pertussis vaccine. Pediatrics 1984 Aug.

AC43 _____, Committee on Nutrition. Imitation and substitute milks. Pediatrics 1984 Jun.

AC44 _____, Committee on Research. Fetal research. Pediatrics 1984 Sep.

AC45 _____, Committee on School Health. Administration of medication in school. Pediatrics 1984 Sep.

AC46 _____, Committee on School Health. Alcohol abuse education in schools. Pediatrics 1984 Sep.

AC47 _____. Committee on School Health. Guidelines for urgent care in schools. Pediatrics 1984 Jul.

AC48 _____, Committee on School Health. Heat stress and school closings. Pediatrics 1984 Aug.

AC49 _____, Committee on Sports Medicine. Health appraisal guidelines for day camps and residence camps. Pediatrics 1984 Jun.

AC50 _____, Committee on Nutrition. The use of whole cow's milk in infancy. Pediatrics 1983 Aug.

AC51 _____, Committee on Adolescence. Rape and the adolescent. Pediatrics 1983 Nov.

AC52 _____, Committee on Adolescence. The role of the pediatrician in substance abuse counseling. Pediatrics 1983 Aug.

AC53 _____, Committee on Bioethics. Treatment of critically ill newborns. 1983.

AC54 _____ Committee on Drugs. Growth hormone in treatment of children with short stature. 1983.

AC55 _____, Committee on Drugs. "Look-alikes." Pediatrics 1983 Aug.

AC56 _____, Committee on Drugs. Benzyl alcohol. toxic agent in neonatal units. Pediatrics 1983 Sep.

AC57 _____, Committee on Drugs. Dimethyl sulfoxide (DMSO). Pediatrics 1983 Jan.

AC58 _____, Committee on Drugs. New therapy for severe cystic acne. Pediatrics 1983 Aug.

AC59 _____, Committee on Drugs. Valproate teratogenicity. Pediatrics 1983 Jun.

AC60 _____, Committee on Early Childhood, Adoption, and Dependent Care. Gonorrhea in prepubertal children. Pediatrics 1983 Apr.

AC61 _____, Committee on Fetus and Newborn. Benzyl alcohol: toxic agent in neonatal units. Pediatrics 1983 Sep.

AC62 _____, Committee on Nutrition. Soy-protein formulas: recommendations for use in infant feeding. [1983]

AC63 _____, Committee on Nutrition. Commentary on parenteral nutrition. Pediatrics 1983 Apr.

AC64 _____, Committee on Nutrition. Toward a prudent diet for children. Pediatrics 1983 Jan.

AC65 _____, Committee on Research. Reducing the toll of injuries in childhood requires support for a focused research effort. Pediatrics 1983 Nov.

AC66 _____, Committee on Sports Medicine. Sports and the child with epilepsy. Pediatrics 1983 Dec.

AC67 American Academy of Pediatrics, Committee on Fetus and Newborn. Criteria for early infant discharge and follow-up evaluation. Pediatrics 1982 Dec.

AC68 _____, Committee on Disabilities. The Doman-Delacato treatment of neurologically handicapped children. Pediatrics 1982 Nov.

AC69 _____, Committee on Drugs. Psychotropic drugs in pregnancy and lactation. Pediatrics 1982 Feb.

AC70 _____, Committee on Drugs. Valproic acid: benefits and risks. Pediatrics 1982 Aug.

AC71 _____, Committee on Hospital Care. Preoperative chest radiographs. Pediatrics 1983 May.

AC72 _____, Committee on Infectious Diseases. Aspirin and Reye syndrome. Pediatrics 1982 Jun.

AC73 _____, Committee on Nutrition. Promotion of breast feeding. 1982.

AC74 _____, Committee on Research. Guidelines for health supervision of pediatric visits as recommended by the American Academy of Pediatrics Committee on Practice and Ambulatory Medicine. News and Comment 1982 May.

AC75 _____, Committee on Screening Genetics. New issues in newborn screening for phenylketonuria and congenital hypothyroidism. Pediatrics 1982 Jan.

AC76 _____, Committee on Sports Medicine. Risks in long distance running for children. Pediatrics 1982 Jun

AC77 _____, Committee on Nutrition. Nutritional aspects of obesity in infancy and childhood. Pediatrics 1981 Dec.

AC78 _____, Committee on Nutrition. Breast feeding and contraception. 1981

AC79 _____, Committee on Nutrition. Breast feeding and contraception. 1981.

AC80 _____, Committee on Nutrition. Plant fiber intake in pediatric diet. 1981.

AC81 _____, Committee on Nutrition. Sodium intake for infants in the U.S., 1981.

AC82 _____, Committee on Nutrition. Nutrition and lactation. Pediatrics 1981 Sep.

AC83 _____, Committee on Adolescence. Contraception for the adolescent. Pediatrics 1980 Mar.

AC84 _____, Committee on Drugs. Anticonvulsants and pregnancy. Pediatrics 1980 Feb.

AC85 _____, Committee on Drugs. Medroxyprogesterone acetate (Depo-Provera). Pediatrics 1980 Mar.

AC86 _____, Committee on Drugs. Naloxone use in newborns. Pediatrics 1980 Mar.

AC87 _____, Committee on Nutrition. Vitamins and mineral supplement needs. 1980.

AC88 _____, Committee on Nutrition. Encouraging breast-feeding. Pediatrics 1980 Mar.

AC89 _____, Committee on Nutrition. Human milk banking. Pediatrics 1980 Apr.

AC90 _____, Committee on Nutrition. On the feeding of supplemental foods to infants. Pediatrics 1980 Jun.

AC91 _____, Committee on Radiology. Comparison radiographs of extremities in childhood: recommended usage. Pediatrics 1980 Mar.

AC92 _____, Committee on Radiology. Excretory urography for evaluation of enuresis. Pediatrics 1980 Mar.

AC93 _____, Committee on Screening Genetics. Prenatal diagnosis for pediatricians. Pediatrics 1980 Jun.

AC94 _____, Committee on Adolescence. Pregnancy and abortion counseling. Pediatrics 1979 Jun.

AC95 _____, Committee on Disabilities. Current approaches to evaluation and management of children with myelomeningocele. Pediatrics 1979 Apr.

AC96 _____, Committee on Sports Medicine. Accidental hypothermia. Pediatrics 1979 Jun.

AC97 _____, Committee on Drugs. Camphor: who needs it? Pediatrics 1978 Sep.

AC98 _____, Committee on Drugs. Commentary on anthelmintics. Pediatrics 1978 Aug.

AC99 _____, Committee on Drugs. Effect of medication during labor and delivery on infant outcome. Pediatrics 1978 Sep.

AC100 _____, Committee on Drugs. PUVA: a caution. Pediatrics 1978 Aug.

AC101 _____, Committee on Drugs. Treatment of congenital hypothyroidism. Pediatrics 1978 Sep.

AC102 _____, Committee on Drugs. Unapproved uses of approved drugs: the physician, the package insert, and the FDA. Pediatrics 1978 Aug.

AC103 _____, Committee on Drugs. Use of codeine-and dextromethorphan-containing cough syrups in pediatrics. Pediatrics 1978 Jul.

AC104 _____, Committee on Nutrition. Juice in ready-to-use bottles and nursing bottle caries. 1978.

AC105 _____, Committee on Nutrition. Breast-feeding. Pediatrics 1978 Oct.

AC106 _____, Committee on Radiology. Radiation of pregnant women. Pediatrics 1978 Jan.

AC107 _____, Committee on Radiology. Water-soluble contrast material. Pediatrics 1978 Jul.

AC108 _____, Committee on Nutrition. Nutritional aspects of vegetarianism, health foods and fad diets. Pediatrics 1977 Mar.

AC109 _____, Committee on Screening Genetics. Screening school children for urologic disease. Pediatrics 1977 Aug.

AC110 _____, Committee on Drugs. Adverse reactions to iodide therapy of asthma and other pulmonary diseases. Pediatrics 1976 Feb.

AC111 _____, Committee on Drugs. Generic prescribing. Pediatrics 1976 Feb.

AC112 _____, Committee on Nutrition. Commentary on breast-feeding and infant formulas, including proposed standards for formulas. Pediatrics 1976 Feb.

ACl13 _____, Committee on Bioethics. AAP code of ethics for the use of fetuses and fetal material for research. 1975

AC114 _____, Committee on Fetus and Newborn. Report of the Ad Hoc Task Force on Circumcision. Pediatrics 1975 Oct.

AC115 _____, Committee on Disabilities. Early identification of children with learning disabilities: the preschool child. Pediatrics 1973 Nov.

AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION TASK FORCE ON ASSESSMENT OF DIAGNOSTIC AND THERAPEUTIC CARDIOVASCULAR PROCEDURES

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Overview: The American College of Cardiology (ACC) is a professional medical society composed of physicians and scientists. Its mission is to ensure optimal care for persons with cardiovascular disease or the potential for developing cardiovascular disease and to contribute to the prevention of cardiovascular disease through educational and socioeconomic activities. The American Heart Association (AHA) is a voluntary health agency supported by public contributions and the donated time of volunteers. Its mission is to reduce premature death and disability from cardiovascular disease and stroke. The Task Force on the Assessment of Diagnostic and Therapeutic Cardiovascular Procedures is a technology assessment program jointly sponsored by the AHA and the ACC.

Purpose: To define the role of noninvasive and invasive diagnostic and therapeutic procedures in the diagnosis and management of cardiovascular disease.

Primary intended users: Physicians.

Technologies: Medical or surgical procedure.

Specifically, diagnostic and therapeutic cardiovascular procedures are assessed.

Intervention: Diagnosis, treatment.

Stage: Established or widespread practice.

Properties: Effectiveness, indications/contraindications.

Selection process: Members of the American College of Cardiology or the American Heart Association can submit, in writing, requests for assessments to the Chairman of the ACC/AHA Task Force. The Task Force meets at least twice a year to discuss possible future assessments. Recommendations are forwarded to the officers of the

American College of Cardiology and the American Heart Association. The possibility of updating published assessment reports is currently under discussion.

Methods: Information syntheses, expert opinion, group judgment.

As part of the assessment process a series of committee meetings are held. As the assessment report develops, information is shared, via mail, between Task Force members. The approximate turnaround time from selection of assessment topic to reporting of findings is 18 months.

Assessors: Task Force members are physicians who specialize in cardiovascular medicine.

Assessment reports include: The purpose of the assessment, who sponsored/commissioned/supported the assessment, who conducted the assessment, description of the technology.

Dissemination: Journal articles.

Reports are published simultaneously in the *Journal of the American College of Cardiology* and *Circulation*. Copies of the assessment reports can be obtained by contacting the headquarters offices of the American College of Cardiology or the American Heart Association.

Budget: $25,000. The approximate direct costs per assessment ranges from $10,000 to $15,000. Volunteer time committed to this effort is significant and is not calculated in this amount. Funding source: 50 percent American College of Cardiology, 50 percent American Heart Association.

Use: The Task Force assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Related activities: Services available to ACC members include a government relations department that promotes cardiovascular issues, the *Cardiology* and *Affiliates in Training* newsletters, an endowments program, professional awards programs, and continuing education opportunities.

The 14 Scientific Councils of the AHA generate state-of-the-art and position papers concerning specific areas of cardiovascular disease such as arteriosclerosis, cardiovascular radiology, cardiovascular surgery, and thrombosis. The Association provides approximately $50 million annually for scientific research and additional support for public education programs. The AHA advocates legislation for research and education in the field.

Completed Reports

AD1 O'Rourke RA, Chatterjee K, Dodge HT, et al. [American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures] Guidelines for clinical use of cardiac radionuclide imaging. J Am Coil Cardiol 1986 Dec;8:1471-83. [Group judgment]

AD2 Schlant RC, Blomqvist CG, Brandenburg RO, et al. [American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures] Guidelines for exercise testing. J Am Coil Cardiol 1986;8:725-738. [Group judgment]

AD3 Frye RL, Collins JJ, DeSanctis RW, et al. [American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures] Guidelines for permanent cardiac pacemaker implantation. J Am Coll Cardiol 1984;4:434-49. [Group judgment]

Ongoing Assessments

AD4 American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures. Guidelines for ambulatory electrocardiographic monitoring. Ongoing. [Group judgment]

AD5 _____. Guidelines for clinical intracardiac electrophysiologic studies. Ongoing. [Group judgment]

AD6 _____. Guidelines for coronary angiography. Ongoing. [Group judgment]

AD7 _____. Guidelines for percutaneous transluminal coronary angioplasty (PTCA). Ongoing. [Group judgment]

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS COMMITTEE OPINIONS

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Overview: The American College of Obstetricians and Gynecologists (ACOG) is a not-for-profit, professional organization comprised of more than 26,000 physicians trained in the specialty of obstetrics and gynecology. The purpose of the organization is to promote and maintain high standards for women's health care by providing quality continuing education for its members and establishing patient care standards. ACOG is governed by an Executive Board composed of seven selected officers from the membership and ten District representatives. The Committee Opinions program is one of two technology assessment programs sponsored by the College.

Purpose: To provide members and other interested parties with state-of-the-art information on the clinical application of new technologies.

Primary intended users: Physicians, third party payers, public policy-makers, legislators.

Technologies: *Medical or surgical procedure*, drug, device.

The committees assess new devices, equipment, and other therapeutic modalities for the treatment of reproductive disorders in women.

Intervention: *Treatment*, diagnosis.

Stage: *New*, emerging, established or widespread practice.

Technologies are assessed as they are being applied to clinical practice.

Properties: *Effectiveness*, safety, service requirements.

Selection process: Within the ACOG structure, the Executive Board, Health Care Commission, or individual members can request that an assessment be conducted. The College also receives requests from third party carriers and government agencies. Only written requests are accepted. Assessment topic priorities are set by the Executive Board, Health Care Commission, and the committee to whom the request is referred. All existing opinions/statements are reviewed within 18 to 94 months from date of publication for relevance and accuracy.

Methods: *Information syntheses*, expert opinion, group judgment.

A subject is selected and referred to a committee. The committee elects a member to review the literature and draft a preliminary report citing literature references. The committee discusses the preliminary draft, achieves consensus on areas of controversy, and submits a revised report to an expert panel for review and comment. Information from reviewers is synthesized and a final report prepared for review by the Health Care Commission and Executive Board prior to publication. At any step along the way, when agreement is in doubt, the advice of further technical experts may be sought.

The turnaround time from selection of the assessment topic to publication of the findings ranges from 18 to 24 months.

Assessors: Committee members represent the academic and the clinical practice communities, are geographically dispersed, and reflect a wide range of practice settings. Panel experts are chosen because of their recognized authority in the chosen subject. The Health Care Commission and the Executive Board members are academicians, clinical practice generalists, and subspecialists.

Assessment reports include: Description of the technology; sources of data/information; findings or conclusions; how the technology works, including theory, principles; whether the technology is experimental, investigational, or considered acceptable clinical practice.

Dissemination: *Advisories to members/constituents*, printed reports.

Assessments are published as committee opinions and are disseminated to the College membership as an insert in the monthly ACOG newsletter. The reports are available upon request to all other interested parties.

Budget: $15,000. Currently, the assessment activity is considered part of the charge of the obstetric and gynecologic standing committees and is not identified separately within the committee budget. Therefore, the approximate cost per assessment is not known. Approximately $15,000 is allocated for printing and distribution of the reports to the membership. Funding source: 100 percent parent organization.

Use: When appropriate, the report conclusions are conveyed in other documents prepared by the ACOG (such as educational resources) and used in responding to individuals and organizations requesting specific information. Third party carriers use the reports for insurance purposes and to determine if the technology is viewed as clinically applicable. Members use the reports to determine if the state-of-the-art of the technology is appropriate for application to their practices.

The publications *ACOG Standards for Obstetric-Gynecologic Services, Guidelines for Perinatal Care*, and *Precis*, a compendium of current information in the specialty, reflect committee opinions where applicable. New editions of these publications appear every 3 years.

Related activities: The College produces a scientific, refereed journal that primarily reports research and the results of controlled clinical studies. These reports, along with those published in similar journals, provide the data with which committees form their opinions. The College also issues *Technical Bulletins* (see separate profile on ACOG Committee on Technical Bulletins), conducts an annual scientific meeting with symposia on new information in the specialty, and offers free-standing postgraduate courses on a variety of topics, many of which convey information on technologic advances and, where applicable, committee opinions.

The College also provides a contraceptive slide rule for lay persons which spells out the risks/benefits, advantages/disadvantages, cost, and mortality rates for various forms of contraceptives.

Completed Reports

AE1 American College of Obstetricians and Gynecologists, Committee Opinion. Clinical use of bromocriptine. Pending. [Information syntheses]
AE2 _____. Teratogenicity of steroids. Pending. [Information syntheses]
AE3 _____. Ultrasonography in the monitoring of follicular growth. Pending. [Information syntheses]
AE4 _____. Hysteroscopy. Revised 1986 Jan. [Information syntheses]
AE5 _____. The use of cryosurgery in the treatment of CIN. Revised 1986 Nov. [Information syntheses]
AE6 _____. Contraception for women in their later reproductive years. 1985 Dec. [Information syntheses]
AE7 _____. Current role of electronic heart rate monitoring in labor. Revised 1985 Jul. [Information syntheses]
AE8 _____. Endometrial sampling. 1985 Jun. [Information syntheses]
AE9 _____. Prophylactic use of antibiotics with abdominal hysterectomy. [Information syntheses]
AE10 _____. Anticonvulsants and pregnancy. Revised 1984 Jul. [Information syntheses]
AE11 _____. Carbon dioxide laser. Revised 1984 Apr. [Information syntheses]
AE12 _____. Fetoscopy. Revised 1984 Jul. [Information syntheses]
AE13 _____. Human in vitro fertilization and embryo placement. 1984 Apr. [Information syntheses]
AE14 _____. Microsurgery. 1984 Apr. [Information syntheses]
AE15 _____. Needle aspiration cytology in the evaluation of breast lesions. 1984 Jun. [Information syntheses]
AE16 _____. Breast-feeding and contraception. 1981 May. [Information syntheses]
AE17 _____. ACOG statement on periodic cancer screening for women. 1980 Jun. [Information syntheses]
AE18 _____. ACOG statement on mammography. 1979 Sep. [Information syntheses]

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS COMMITTEE ON TECHNICAL BULLETINS

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Overview: The American College of Obstetricians and Gynecologists (AGOG) is a not-for-profit, professional organization comprised of more than 26,000 physicians trained in the specialty of obstetrics and gynecology. The purpose of the organization is to promote and maintain high standards for women's health care by providing quality continuing education for its members and establishing patient care standards. AGOG is governed by an Executive Board composed of seven elected officers from the membership and ten District representatives. The Committee on Technical Bulletins is one of two technology assessment programs sponsored by the College.

Purpose: To provide practicing physicians with timely information on the latest proven techniques of clinical practice in the specialty.

Primary intended users: Physicians.

Technologies: *Medical or surgical procedure*, drug, device.

The Committee assesses the management of specific reproductive disorders, treatment therapies, and the application of new technologies.

Intervention: *Treatment*, prevention, diagnosis.

Stage: *Established or widespread practice*, new.

Technologies are assessed when they are determined to have widespread applicability in clinical practice.

Properties: *Effectiveness*, service requirements, acceptance/adoption level.

Selection process: The Committee on Technical Bulletins is responsible for surveying current clinical knowledge to determine the need to address new topics or to update existing *Bulletins*. Topics can also be suggested by the Learning Resources and the Health Care Commissions, other standing committees, the Executive Board, and individual members. Requests for assessments are made by Committee consensus and are submitted in writing. Assessment topic priorities are set by the Committee in consultation with the Learning Resources Commission.

Technical Bulletins generally are reviewed for relevance and accuracy within 3 years from date of publication unless new information requires earlier attention.

Methods: *Expert opinion*, group judgment.

Once a topic is selected by the Committee on Technical Bulletins, an expert on the topic is chosen to prepare a manuscript. The Committee reviews the author's draft and achieves consensus on areas of disagreement between members and the author. A revised draft is submitted to the Learning Resources Commission. Information from the reviewers is synthesized, consensus is reached regarding any further unresolved matters, and a final report is prepared for review by the Executive Board prior to publication.

The turnaround time from selection of the topic to the publication of findings averages between 18 to 24 months.

Assessors: Committee members are geographically dispersed and are representatives of the academic and clinical practice communities. Authors are recognized authorities in the topics selected. The Learning Resources Commission and the Executive Board members are academicians, clinical practice generalists and subspecialists.

Assessment reports include: Description of the technology; sources of data/information; findings or conclusions; how the technology works, including theory, principles.

Dissemination: *Printed reports*, advisories to members/constituents.

Assessments are published as *Technical Bulletins* and the results are disseminated to the College membership as an insert in the monthly ACOG newsletter. Requests for copies of the *Technical Bulletins* should be directed to the ACOG Distribution Center at the Washington, DC address.

Budget: $95,000. The approximate cost per assessment is $5,000 exclusive of Committee budget. Funding source: 100 percent parent organization.

Use: The College uses the *Technical Bulletins* to keep members informed regarding accepted clinical management techniques. Insurers report that they have introduced the *Bulletins* as evidence in malpractice suits, by both plaintiffs and defendants. Trial lawyers have also used the *Bulletins*.

The publications *ACOG Standards for Obstetric-Gynecologic Services, Guidelines for Perinatal Care*, and *Precis*, a compendium of current information in the specialty, reflect, where applicable, the findings of *Technical Bulletins*. New editions of these publications appear every 34 years.

Program evaluation: The ACOG Division of Education periodically asks participants and members attending courses and annual meetings to evaluate the usefulness of educational offerings. *Technical Bulletins* consistently have been rated high by respondents.

Related activities: ACOG produces a scientific, refereed journal that primarily reports research and the results of controlled clinical studies. The College also issues committee opinions (see separate profile on ACOG Committee Opinions), conducts an annual scientific meeting with symposia on new information in the specialty, and offers freestanding postgraduate courses on a variety of topics, many of which convey information on technologic advances.

The College also provides a contraceptive slide rule for lay persons that spells out the risks/benefits, advantages/ disadvantages, cost, and mortality rates for various forms of contraceptives.

Completed Reports

AF1 American College of Obstetricians and Gynecologists, Committee on Technical Bulletins. Antimicrobial therapy for gynecologic infections. 1986 Oct. (Technical bulletin no. 97). [Expert opinion]

AF2 _____. Estrogen replacement therapy. 1986 Jun. (Technical bulletin no. 93). [Expert opinion]

AF3 _____. Management of diabetes mellitus in pregnancy. 1986 May. (Technical bulletin no. 92). [Expert opinion]

AF4 _____. Management of isoimmunization in pregnancy. 1986 Jan. (Technical bulletin no. 90). [Expert opinion]

AF5 _____. Management of preeclampsia. 1986 Mar. (Technical Bulletin no. 91). [Expert opinion]

AF6 _____. Management of the breech presentation. 1986 Aug. (Technical bulletin no. 95). [Expert opinion]

AF7 _____. Genitourinary fistula. 1985 Jan. (Technical bulletin no 83). [Expert opinion]

AF8 _____ Gonorrhea and chlamydia infections. 1985 Nov. (Technical bulletin no. 89). [Expert opinion]

AF9 _____. Management of endometriosis. 1985 Mar. (Technical bulletin no. 85). [Expert opinion]

AF10 _____. Blood component therapy. 1984 Jul. (Technical bulletin no. 78). [Expert opinion]

AF11 _____. Carcinoma of the endometrium. 1984 Mar. (Technical bulletin no. 75). [Expert opinion]

AF12 _____. Carcinoma of the vulva. 1984 Jun. (Technical Bulletin no. 77). [Expert opinion]

AF13 _____. Cervical cytology: evaluation and management of abnormalities. 1984 Oct. (Technical bulletin no. 81). [Expert opinion]

AF14 _____. Prevention of Rho(D) isoimmunization. 1984 Aug. (Technical bulletin no. 79). [Expert opinion]

AF15 _____. Septic shock. 1984 Mar. (Technical bulletin no. 75). [Expert opinion]

AF16 _____. Hemorrhagic shock. 1984 Dec. (Technical bulletin no. 82). [Expert opinion]

AF17 _____. Automobile passenger restraints for children and pregnant women. 1983 Dec. (Technical bulletin no. 74). [Expert opinion]

AF18 _____. Cancer of the ovary. 1983 Oct. (Technical bulletin no. 73). [Expert opinion]

AF19 _____ Diagnosis and management of invasive cervical carcinomas. 1983 May. (Technical bulletin no. 69). [Expert opinion]

AF20 _____. Dysmenorrhea. 1983 Mar. (Technical bulletin no. 68). [Expert opinion]

AF21 _____. Epidemiology and diagnosis of breast disease. 1983 Sep. (Technical bulletin no. 71). [Expert opinion]

AF22 _____. Osteoporosis. 1983 Oct. (Technical bulletin no. 72). [Expert opinion]

AF23 _____. Anesthesia for cesarean section. 1982 May. (Technical bulletin no. 65). [Expert opinion]

AF24 _____. Dysfunctional uterine bleeding. 1982 Sep. (Technical bulletin no. 66). [Expert opinion]

AF25 _____. Immunization during pregnancy. 1982 May. (Technical bulletin no. 64). [Expert opinion]

AF26 _____. Prenatal detection of neural tube defects. 1982 Oct. (Technical bulletin no. 67). [Expert opinion]

AF27 _____. Diagnostic ultrasound in obstetrics and gynecology. 1981 Oct. (Technical bulletin no. 63). [Expert opinion]

AF28 _____. Neonatal metabolic diseases. 1981 Jan. (Technical bulletin no. 60). [Expert opinion]

AF29 _____. Rubella—a clinical update. 1981 Jul. (Technical bulletin no. 62). [Expert opinion]

AF30 Management of gestational trophoblastic neoplasia. 1980 Dec. (Technical bulletin no. 59). [Expert opinion]

AF31 _____. Pregnancy, work, and disability. 1980 May. (Technical bulletin no. 58). [Expert opinion]

AF32 _____. Cigarette smoking and pregnancy. 1979 Sep. (Technical bulletin no. 53). [Expert opinion]

AF33 _____. Diagnosis and management of missed abortion and antepartum fetal death. 1979 Nov. (Technical bulletin no. 55). [Expert opinion]

AF34 _____. Methods of midtrimester abortion. 1979 Dec. (Technical bulletin no. 56). [Expert opinion]

AF35 _____. Induction of labor. 1978 May. (Technical bulletin no. 49). [Expert opinion]

AF36 _____. Sexually transmitted diseases (STD): other than gonorrhea and syphilis. (Technical bulletin no. 51). 1978 Jul. [Expert opinion]

AF37 _____. Classification and staging of malignant tumors in the female pelvis. 1977 Jun. (Technical bulletin no. 47). [Expert opinion]

AF38 _____. Communication of sexual problems in office gynecology. 1977 Apr. (Technical bulletin no. 45). [Expert opinion]

AF39 _____. Intrapartum fetal monitoring. 1977 Jan. (Technical bulletin no. 44). [Expert opinion]

AF40 _____. Prevention of hospital-acquired urinary tract infections in gynecology patients. 1977 May. (Technical bulletin no. 46). [Expert opinion]

AF41 _____. Fetal blood sampling. 1976 Oct. (Technical bulletin no. 42). [Expert opinion]

AF42 _____. Oral contraception 1976 Jul. (Technical bulletin no. 41). [Expert opinion]

AF43 _____. Prevention of Tay-Sachs disease: carrier identification and genetic counseling. 1976 Jan. (Technical bulletin no. 34). [Expert opinion]

AF44 _____ Urinary incontinence in the female. 1979 Feb. (Technical bulletin no. 36). [Expert opinion]
AF45 _____. Fetal heart rate monitoring. 1975 Jun. (Technical bulletin no. 32). [Expert opinion]

AMERICAN COLLEGE OF PHYSICIANS CLINICAL EFFICACY ASSESSMENT PROJECT

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Overview: The American College of Physicians (ACP) is a national medical society with a membership of over 63,000 internists and related subspecialists. It works to uphold health care standards through its activities in continuing education, health policy analysis, quality assurance, and medical technology assessment. The Clinical Efficacy Assessment Project (CEAP) is an expansion of the College's participation in the Blue Cross and Blue Shield Association's Medical Necessity Project beginning in 1976, which identified outmoded tests in order to curtail reimbursement for unnecessary medical procedures. Recognizing the need for complete and accurate technology assessment on a continuing basis, the ACP expanded the program in 1981 with a 3-year grant from the John A. Hartford Foundation of New York City. In 1984, the CEAP became a fully funded activity of the College. Beginning in 1986, ACP has accepted contributions to the CEAP from interested individuals and organizations.

Purpose: To help physicians practice high-quality, more efficient, and cost-effective medicine. CEAP recommendations are intended to provide physicians with current information and guidelines regarding the use of tests, procedures, and therapies and the rationale for such recommendations founded on both the literature and broad-based expert opinion.

Primary intended users: Providers, generally; physicians; other care givers; health/ medical professional associations; third party payers; government regulators; public policy-makers, legislators; policy research organizations.

Technologies: *Medical or surgical procedure*, drug, device, organizational or administrative system.

Intervention: *Diagnosis*, prevention, treatment, rehabilitation.

Stage: *Established or widespread practice*, new, obsolete.

Properties: *Efficacy*, safety, effectiveness, cost, service requirements.

Selection process: The Clinical Efficacy Assessment Subcommittee identifies potential technologies for CEAP evaluations by reviewing policy needs, practitioner opinion, academic opinion, recent journal articles, and professional meetings focusing on emerging technologies. Recommendations and requests also are received from other ACP committees as well as outside organizations. In selecting technologies to be evaluated, the Clinical Efficacy Assessment Subcommittee examines the following attributes:

1) degree of interest to practitioners of internal medicine, whether or not internists are directly responsible for its application; 2) potential for wide application, or prevalence of current usage; 3) potential for significant benefit if widely applied; and 4) potential for risk if widely applied, particularly in relation to potential benefit.

The Subcommittee will consider requests from College members and others for reevaluation of a statement if the request contains compelling documentation. Staff also solicit advice from the Council of Subspecialty Societies, the Council of Medical Societies, and other experts as to the availability of new information on a technology. If substantive, new information is available, the Subcommittee will consider reassessment.

Methods: *Information syntheses*, expert opinion, group judgment, cost analyses.

Notice of a pending CEAP evaluation is published in *Annals of Internal Medicine, ACP Observer, New England Journal of Medicine*, and the *International Journal of Technology Assessment in Health Care*. The notices invite comments from interested parties. For special or major evaluations, other specialty journals may be asked to publish notices of CEAP evaluations.

ACP staff, in consultation with the CEA Subcommittee, select the appropriate member societies of the Council of Subspecialty Societies (CSS) and Council of Medical Societies (CMS) to review the technology in question. These societies are asked to provide opinion and data on the safety, efficacy, effectiveness, and cost of the technology, as well as to identify other experts (proponents, opponents, and those who are neutral on the topic) to provide information on the technology.

Consultants undertake a comprehensive review of the scientific literature. Assessments of other organizations are reviewed and, when possible and necessary, information regarding ongoing clinical trials is obtained. A synthesis of this information, the comments from persons responding to the published notices, and the opinions of the CSS/CMS members and other experts form the scientific base of the CEAP evaluation.

Consultants assess a technology by the method best suited to the topic. The methods include, but are not limited to, data synthesis, meta-analysis, clinical decision analysis, and consensus development. At times, a combination of methods is used. When possible, risk-benefit and cost-effectiveness analyses are performed.

The approximate turnaround time from selection of assessment topic to reporting of findings is 9 months to 1 year.

Assessors: Physicians trained in clinical epidemiology, statistics, economics, decision analysis, and technology assessment are commissioned to conduct CEAP evaluations. These physicians are selected from candidates suggested by the CEAP Subcommittee, members of the Technology Assessment Committee of the Society for Research and Education in Primary Care Internal Medicine (SREPCIM), and others. When the evaluation of a specific topic requires special expertise, the principal consultant is asked to collaborate with a qualified content expert in the assessment of the topic.

Assessment reports include: Abstract; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of lifecycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/ synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice,

future assessments, technology development, research; how the technology works, including theory, principles.

CEAP statements have five components: 1) a general description of the technology, its uses, potential uses, and rationale; 2) an overview of the safety of the technology; 3) a review of the technology's efficacy; 4) information on its cost; and 5) appropriate conclusions and recommendations. Areas requiring further research also are summarized. Key points in the statement refer to the appropriate published literature and the effective date of the literature review is noted. A detailed and referenced background paper that supports and provides the rationale for the CEAP statement and recommendations also is developed. Whereas the CEAP statement follows a standard format, the background paper may be prepared in the style best suited to the analysis of the subject.

Dissemination: CEAP statements become position papers of the American College of Physicians upon approval by the Board of Regents. The position and background papers are submitted to *ACP Observer* and to *Annals of Internal Medicine* for publication. If the *Annals* declines to publish the position paper, it is published in full in *ACP Observer* . If the *Annals* accepts the position paper for publication, an abstract will be published in *ACP Observer*. Thus, all College members and many others receive all CEAP statements through these publications. Background papers that are not published in *Annals* remain the property of their authors and may be submitted to other journals for publication. In addition, the *International Journal for Technology Assessment in Health Care* has been given permission to republish abstracts of all ACP position papers.

Single copies of CEAP statements are available free of charge from the College. A three-ring binder *Clinical Efficacy Reports*, containing the full collection of CEAP statements is available from ACP.

In 1987, ACP published the manual *Common Diagnostic Tests: Use and Interpretation*, available from the ACP publications department. The purpose of this manual is to help physicians determine when diagnostic tests are likely to make desirable differences in patient care. Based on a critical review of published articles, the manual provides recommendations for using selected tests in cardiopulmonary medicine, hematology, infectious diseases, oncology, and other diagnostic applications. The manual calls for additional research for tests for which the published literature is insufficient for making well founded recommendations. The manual chapters are derived from papers commissioned by the Blue Cross and Blue Shield Association for its Medical Necessity Project. These were reviewed through the CEAP process, approved by the ACP, and published in the *Annals of Internal Medicine*. The appendices are texts of the Blue Cross and Blue Shield Medical Necessity guidelines.

Budget: $150,000. If the total program budget is divided by the number of assessments per year, the cost is $10,000.

Approximate consultant cost per assessment is $3,500. Funding sources: 95 percent parent organization; 5 percent foundations, other private grants.

Use: CEAP statements are used by third party payers, training directors in residency programs, and as an educational service to college members as evidence of its commitment to quality care.

The establishment of the Association of Ambulatory Cardiac Catheters (AACC) was a direct result of a CEAP paper. The AACC is now organizing quality assurance activities with the objective of receiving JCAH accreditation for freestanding units. The CEAP endoscopy papers were cited in the 1985 presidential address to the American Gastroenterology Association.

CEAP is described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies* . Washington, DC: National Academy Press, 1985.

Program evaluation: As part of its grant award, the John A. Hartford Foundation stipulated and funded an evaluation of the CEAP. In 1983, the Blue Cross and Blue Shield Association conducted the evaluation which included a questionnaire that was sent to all major third party payers and government agencies. Recipients were asked about their knowledge of the CEAP, if the reports were relevant, and if the CEAP reports were used for educational and policy-setting purposes. Findings indicated that CEAP reports were used for educational and policy-setting purposes. The program was not modified as a result of the evaluation, but the mailing list was expanded.

Completed Reports

AG1 American College of Physicians, Clinical Efficacy Assessment Project. A comparative assessment of coronary artery bypass surgery and percutaneous transluminal coronary angioplasty. Expected completion 1988. [Information syntheses]

AG2 _____ Allergy testing. Expected completion 1988. [Information syntheses]

AG3 _____. Chemical aversion therapy in the treatment of alcoholism, expected completion 1988. [Information syntheses]

AG4 _____. Clinical ecology, expected completion 1988. [Information syntheses]

AG5 _____ Exercise thallium scanning, expected completion 1988. [Information syntheses]

AG6 _____. How to study the carotid arteries, expected completion 1988. [Information syntheses]

AG7 _____. How to study the gallbladder, expected completion 1988. [Information syntheses]

AG8 _____. Intravenous pyelography, expected completion 1988. [Information syntheses]

AG9 _____ Laboratory evaluation of the patient after myocardial infarction, expected completion 1988. [Information syntheses]

AG10 _____. Preoperative pulmonary function tests, expected completion 1988. [Information syntheses]

AG11 _____. Rehabilitation of the myocardial infarction patient, expected completion 1988. [Information syntheses]

AG12 _____. Bone mineral densitometry, 1987. [Information syntheses]

AG13 _____. Magnetic resonance imaging of the brain and spine, 1987. [Information syntheses]

AG14 _____. Methotrexate for rheumatoid arthritis, 1987. [Information syntheses]

AG15 _____. Parenteral nutrition, 1987. [Information syntheses]

AG16 _____. A comparative assessment of standard and computed tomography in the evaluation of neoplasms of the chest. 1986. [Information syntheses]

AG17 _____. Automated ambulatory blood pressure monitoring. Ann Intern Med 1986; 104:275-8. [Information syntheses]

AG18 _____. Cardiokymography. ACP Observer 1986 Jan:8,10. [Information syntheses]

AG19 _____. Congestive heart failure and thoracentesis, 1986. [Information syntheses]

AG20 _____. Pneumococcal vaccine. Ann Intern Med 1986;104:118-120

AG21 _____. The diagnostic spinal tap. Ann Intern Med 1986;104:880-5,840-8. [Information syntheses]

AG22 _____. Apheresis in chronic inflammatory demyelinating polyneuropathy and in renal transplantation. Ann Inter Med 1985; 103:630-3. [Information syntheses]

AG23 _____. Biofeedback for gastrointestinal disorders. Ann Intern Med 1985;103:291-3,240-44. [Information syntheses]

AG24 _____. Biofeedback for headaches. Ann Intern Med 1985; 102:128-31. [Information syntheses]

AG25 _____. Biofeedback for hypertension. Ann Intern Med 1985; 102:709-15. [Information syntheses]

AG26 _____. Biofeedback for neuromuscular disorders. Ann Intern Med 1985; 102:854-8. [Information syntheses]

AG27 _____. Colonoscopy: management of colorectal neoplasia. 1985. [Information syntheses]

AG28 _____. Diagnostic thoracentesis and pleural biopsy. Ann Intern Med 1985;103:799-802. [Information syntheses]

AG29 _____. Esophagogastroduodenoscopy (EGD). [Information syntheses]

AG30 _____. Lithotripsy. Ann Intern Med 1985; 103:626-9. [Information syntheses]

AG31 _____. Screening for breast cancer. Ann Intern Med 1985; 103:143-6,79-85. [Information syntheses]

AG32 _____. The safety and efficacy of ambulatory cardiac catheterization in the hospital and free standing setting. Ann Intern Med 1985:103;294-8. [Information syntheses]

AG33 _____. Thrombolysis for evolving myocardial infarction. Ann Intern Med 1985;103:463-9. [Information syntheses]

AG34 _____. Apheresis in chronic severe rheumatoid arthritis. 1984. [Information syntheses]

AG35 _____. Clinical usefulness of hemoglobin A1C measurements. Ann Intern Med 1984;101:710-3. [Information syntheses]

AG36 _____. Efficacy of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic retrograde sphincterotomy (ERS). 1984. [Information syntheses]

AG37 _____. Endocardial electrical stimulation. Ann Intern Med 1984; 100:452-4. [Information syntheses]

AG38 _____. Endoscopic injection sclerotherapy. Ann Intern Med 1984;100:608-10. [Information syntheses]

AG39 _____. Ergonovine provocative testing. Ann Intern Med 1984; 100:159-2. [Information syntheses]

AG40 _____. Heparin infusion pumps. Ann Intern Med 1984;100:305-6. [Information syntheses]

AG41 _____. Hepatitis B vaccine. Ann Intern Med 1984; 100:149-50. [Information syntheses]

AG42 _____. Radiologic methods to evaluate bone mineral content. Ann Intern Med 1984;100:108-11. [Information syntheses]

AG43 _____. 13C and 14C glycocholate tests. 1983. [Information syntheses]

AG44 _____. 13C and 14C glycocholate, H2 breath, 13C trioctanoin, and 14C triolein breath tests. 1983. [Information syntheses]

AG45 _____. 14C xylose breath test. 1983. [Information syntheses]

AG46 _____. Home blood glucose monitoring. Ann Intern Med 1983;99:272-4. [Information syntheses]

AG47 _____. Hyperbaric oxygen therapy: acute, traumatic peripheral ischemia. 1983. [Information syntheses]

AG48 _____. Hyperbaric oxygen therapy: chronic vascular insufficiency. 1983. [Information syntheses]

AG49 _____. Hyperbaric oxygen therapy: decubitus ulcers. 1983. [Information syntheses]

AG50 _____. Hyperbaric oxygen therapy: senility. [Information syntheses]

AG51 _____. Lactulose H2 breath test. 1983. [Information syntheses]

AG52 _____. Management of diabetes mellitus: computerized insulin infusion pumps. Ann Intern Med 1983;99::272-4. [Information syntheses]

AG53 _____. Management of diabetes mellitus: external infusion pumps. Ann Intern Med 1983;99:272-4. [Information syntheses]

AG54 _____. Management of diabetes mellitus: pancreatic transplants. Ann Intern Med 1983;99:272-4. [Information syntheses]

AG55 _____. Percutaneous transluminal angioplasty: carotid, vertebral, and subclavian arteries. Ann Intern Med 1983;99:864-9. [Information syntheses]

AG56 _____. Percutaneous transluminal angioplasty: coronary arteries. Ann Intern Med 1983;99:864-9. [Information syntheses]

AG57 _____. Percutaneous transluminal angioplasty: iliac, femoral, and popliteal arteries. Ann Intern Med 1983;99:864-9. [Information syntheses]

AG58 _____. Percutaneous transluminal angioplasty: renal arteries. Ann Intern Med 1983;99:864-9. [Information syntheses]

AG59 _____. The dexamethasone suppression test. Ann Intern Med 1983;100:307-8. [Information syntheses]

AG60 _____. The H2 breath test. 1983. [Information syntheses]

AG61 _____. Antilymphocyte (ALG) and antithymocyte (ATG) globulin in renal transplantation. 1982. [Information syntheses.

AG62 _____. Bentonite flocculation test. 1982. [Information syntheses]

AG63 _____. DNA antibody test. 1982. [Information syntheses]

AG64 _____. Immunotherapy of cancer. 1982. [Information syntheses]

AG65 _____. Kunkel test (total serum gammaglobulin). 1982. [Information syntheses]

AG66 _____. Phonocardiography. 1982. [Information syntheses]

AG67 _____. 24-hour sphygmomanometry. 1981. [Information syntheses]

AG68 _____. 25 hydroxyvitamin D level. 1981. [Information syntheses]

AG69 _____. Cytotoxic food testing. 1981. [Information syntheses]

AG70 _____. Gastric analysis by the capsule method (Heidelberg). 1981. [Information syntheses]

AG71 _____. Human tumor cell drug sensitivity assay in the treatment of solid tumors. 1981. [Information syntheses]

AG72 _____. Hyperbaric oxygen therapy: actinomycosis. 1981. [Information syntheses]

AG73 _____. Hyperbaric oxygen therapy: arthritis. 1981. [Information syntheses]

AG74 _____. Hyperbaric oxygen therapy: osteomyelitis. 1981. [Information syntheses]

AG75 _____. Intracutaneous titration. 1981. [Information syntheses]

AG76 _____. Intravenous histamine therapy. 1981. [Information syntheses]

AG77 _____. Management of histapenia. 1981. [Information syntheses]

AG78 _____. Radioallergosorbent technique (RAST). 1981. [Information syntheses]

AG79 _____. Ultrasonic arteriography, B mode. 1981. [Information syntheses]

AG80 _____. Ultrasonic arteriography, B-scan and Doppler ultrasound. 1981. [Information syntheses]

AG81 _____ Hemodialysis for the treatment of schizophrenia. 1980. [Information syntheses]

AG82 _____. Urine autoinjection. 1980. [Information syntheses]

AG83 _____. Whole body hyperthermia for cancer patients. 1980. [Information syntheses]

AMERICAN COLLEGE OF RADIOLOGY TASK FORCE ON BREAST CANCER

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Contact: Marie Zinninger, M.S.N., Coordinator; Gerald Dodd, M.D., Chairman, Task Force on Breast Cancer.

Overview: The American College of Radiology (ACR) serves radiologists with programs addressing the practice of radiology and the delivery of comprehensive radiological health services. The purposes of the ACR are to advance the science of radiology, improve radiologic service to the patient, study the economic aspects of the practice of radiology, and encourage improved and continuing education for radiologists and allied professional fields.

The ACR has more than 20,000 members and fellows in diagnostic and therapeutic radiology, radiologic physics, and related disciplines. ACR members participate in commissions and committees that prepare publications and conduct programs directed

to meeting member needs. These include quality assurance, practice and accreditation, management consulting, professional placement, self-evaluation, continuing education, manpower, practice management, and the development and conduct of special scientific courses needed in the field. The subject of this profile is the ACR Task Force on Breast Cancer.

Purpose: To coordinate the activities of various ACR committees concerned with mammography and breast cancer. These include the Committee on Breast Cancer, Committee on Breast Imaging, Committee on Mammography Equipment, the Committee on Mammography Accreditation of the Commission on Radiologic Practice, and the ACR/American Cancer Society Joint Committee on Mammography. Issues addressed by the Task Force include education of radiologists and referring physicians, mammography policy statements and guidelines, mammography quality assurance, and liaison with other national medical organizations such as the American Cancer Society.

Primary intended users: Physicians; patients; health/medical professional associations; voluntary associations, organizations.

Technologies: *Medical or surgical procedure*, device.

Intervention: *Diagnosis*, prevention.

The major emphasis of the program is on early detection of breast cancer.

Stage: Established or widespread practice.

Properties: *Safety; effectiveness*; cost; ethical, legal, social implications.

Selection process: ACR assessments are requested by such outside organizations as the Office of Health Technology Assessment, American Cancer Society (ACS), Blue Cross and Blue Shield Association, the Conference of Radiation Control Programs Directors, Inc., and other sources. In addition, they may be requested by ACR members and other physicians, and by the ACR committees cited above that work with the Task Force. Assessment priorities are normally set by the Task Force.

Methods: *Group judgment*, information syntheses, expert opinion, cost analyses, epidemiological and other observational methods.

Assessments are generally initiated by the Committee on Breast Cancer, Committee on Breast Imaging, Committee on Mammography Equipment, Committee on Mammography Accreditation, or ACR/ACS Joint Committee on Mammography, as appropriate. Reports are often drafted jointly by committee members and staff.

When a consensus is reached at the committee level, it is forwarded to the Task Force for review and approval. The Task Force normally meets twice a year, though it may meet more often as needed. Upon Task Force approval, reports are submitted to the ACR Board of Chancellors for acceptance. The final endorsement comes at the ACR annual meeting where the ACR Council of approximately 175 physicians acts upon a resolution. Average turnaround time for assessments is approximately one year.

As guidelines are based on current available information, they are to be revised as more is learned about the control of breast cancer. Thus, in 1986 the Task Force issued

supplementary statements to the 1982 policy statement on mammography; these supplementary statements addressed the capabilities and limitations of mammography in the detection and diagnosis of breast cancer and performance guidelines for mammography.

Assessors: The Task Force on Breast Cancer has 14 members. Of these, 12 are physicians and 2 are radiological physicists. There are 10-12 members on each of the committees; members are gynecologists, surgeons, radiation oncologists, internists, pathologists, family practitioners, and members of other organizations such as the American Cancer Society and National Cancer Institute.

Assessment reports include: Purpose of the assessment; relationship of the assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; sources of data/information; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles.

Dissemination: *Printed reports*; advisories to members/constituents; press conference/ news releases, TV radio broadcasts, video products; clearinghouses.

Individual Task Force policy statements are available from the ACR at no charge. Policy statements also appear in the newsletter *ACR Bulletin*. The ACR *Mammography Resource Kit* includes the policy statements on mammography, as well as reprints of other organizations' statements on mammography, order forms for public service announcements, information about mammography training programs, mammography bibliography, audiovisual materials on mammography, protocol information for patients, and related educational and reference materials. The kit is available upon written request to ACR members at no charge and to others for $25.

Use: Portions of ACR policy statements on mammography appear in publications of the National Cancer Institute, American Cancer Society, and other organizations. ACR policy statements on mammography help form the basis for recommended mammography guidelines issued by medical specialty organizations such as the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians. ACR mammography guidelines are also cited in guidelines and suggested state regulations offered by the Conference of Radiation Control Program Directors, used by many state radiation control programs.

ACR policy statements have been cited in assessments by the Blue Cross and Blue Shield Association, the Office of Health Technology Assessment, and other agencies. For example, ACR opinions have been used in the Blue Cross and Blue Shield Association Medical Necessity guidelines on bronchoscopy (1977), angiocardiography (1977), angiography (1977), diagnostic imaging (1984), and routine preoperative and general hospital admission chest x-rays (1987).

ACR opinions have also been cited in the National Council on Radiation Protection and Measurements Report No. 85, *Mammography: A User's Guide* (1986); State of New York Department of Health memorandum *Quality Assurance Programs for Providers of Mammography Services* (1987); and the Food and Drug Administration Center for Devices and Radiological Health *Mammographic Phantom Evaluation Project Report* (1983).

Articles written by Task Force members on topics related to mammography policy statements appear in the published periodical literature and in texts. Examples are the following:

McClelland, R, Feig SA. Guidelines for mammography. In Feig SA, McClelland R, eds. *Breast carcinoma: current diagnosis and treatment*. New York: ACR and Masson, 1983:365-69.

Bird RE, McClelland R. How to initiate and operate a low-cost screening mammography center. *Radiology* 1986; 161 (2):43-47.

Budget: The Task Force operations budget is approximately $26,000. This amount does not include the value of the time volunteered to the Task Force by the member radiologists, physicists, and other professionals; it also does not include costs for the other committees involved in generating statements.

Related activities: The Task Force on Breast Cancer coordinates and cosponsors with the American College of Pathologists, ACS, and American Society for Therapeutic Radiology and Oncology a biennial National Conference on Breast Cancer. The ACR and the ACS have a liaison committee to support the ACS Breast Cancer Detection Awareness Program to educate asymptomatic women and their physicians in the importance of breast cancer detection, including screening mammography.

The ACR Mammography Accreditation Program, directed by the ACR Committee on Practice Accreditation and assisted by the Task Force on Breast Cancer, provides voluntary peer review and evaluation services of mammography facility staff qualifications, equipment, quality control and quality assurance programs, image quality and breast dose. Facilities meeting the criteria of the Mammography Accreditation Program are given a 3-year accreditation, a certificate for each approved mammography unit, and a listing on the ACS referral list of approved mammographic centers.

The Patterns of Care Study of cancer treatment, which has been supported by the National Cancer Institute and conducted by ACR since 1971, has conducted surveys of structure, process, and outcomes for a national sample of radiation treatment facilities. As part of the study, ACR assembled review committees of radiation therapists to reach consensus in the form of decision trees for the management of ten disease types in which radiation therapy is involved. The ACR Practice Accreditation Program in Radiation Oncology, which evolved from the Patterns of Care Study, provides a voluntary quality assurance service for radiation therapy facilities. This program involves individual facility visits modeled in order to provide feedback to radiation therapists on their practice relative to regional and national norms established through the Patterns of Care Study.

Based on site visits by teams of selected ACR member surveyors, the ACR Practice Survey Program is a voluntary review and evaluation service offered to diagnostic radiologists in a variety of practice settings. Both accreditation and consultative surveys are available.

Additional ACR publications related to technology assessment include the following.

ACR policy statements on computed tomography, imaging center guidelines, magnetic resonance, and obstetrical/ ultrasound examination guidelines.

Acceptance testing protocols: a systematic approach to evaluation of radiology equipment. 1983.

Imaging equipment compendium: a comparative reference of equipment characteristics. 1983. 1985 update, supplement.
List of MR sites.
Planning guides for radiologic installations.
Proceedings of the Eighth Conference on Computer Applications in Radiology. 1984.

Completed Reports

AH1 American College of Radiology, Task Force on Breast Cancer. Policy statement on oscillating grids for mammography equipment. Expected 1987. [Group judgment]
AH2 _____. Resolution no. 1: supplementary mammography statement. 1986 Sep. [Group judgment]
AH3 _____. Resolution no. 2: mammography performance guidelines. 1986 Sep. [Group judgment]
AH4 _____. Policy statement: breast cancer screening centers. 1985. [Group judgment]
AH5 _____. Policy statement on sonography for the detection and diagnosis of breast disease. 1984. [Group judgment]
AH6 _____. Policy statement on thermography for the detection of breast cancer. 1983 Sep 28. [Group judgment]
AH7 _____. Statement of the preservation of mammograms. 1983. [Group judgment]
AH8 _____. Policy statement: guidelines for mammography. 1982 Sep 22. [Group judgment]

AMERICAN DENTAL ASSOCIATION COUNCIL ON DENTAL MATERIALS, INSTRUMENTS, AND EQUIPMENT

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Chicago, IL 60611
312-440-2507
Contact: Dr. P.L. Fan, Associate Secretary.
Overview: The American Dental Association (ADA) is a professional association that provides a variety of services to assist its members practice dentistry and deliver health care to the public. The ADA's objectives include encouraging the improvement of the public's health, promoting the art and science of dentistry, and representing the interests of the dental profession and the public that it serves. The Council on Dental Materials, Instruments, and Equipment is one of two technology assessment programs sponsored by the ADA; the other being the Council on Dental Therapeutics. The Council was established in 1966 to centralize the ADA's activities in the standardization and evaluation of dental materials, instruments, and equipment. This activity had been initiated by the Association in 1928 at the National Bureau of Standards.

The Council performs its duties through its Specification Program, Evaluation Programs (which include the Certification Program, the Acceptance Program and the Recognition Program), Complaint Report Program, and Status Report Program. This profile focuses on the Acceptance Program component. Additional information on other Council activities can be found in the Council's textbook, *Dentists' Desk Reference: Materials, Instruments and Equipment*.

Purpose: To evaluate materials, instruments, and equipment for which evidence of safety and usefulness has been established by biological, laboratory, or clinical evaluations and for which physical standards or specifications do not exist.

Primary intended users: General public, patients, health product manufacturers, dentists.

Technologies: Device.

The following are examples of product areas presently covered by the Council's Acceptance Program: alloys for cast dental restorative and prosthetic devices, autoclave sterilizers, composite resin materials for occlusal restorations, crown and bridge resins, electrosurgical devices; x-ray equipment, denture adherents, denture cleansers, endosseous implants, glass ionomer cements, denture cleaning devices, nitrous oxide/oxygen sedation machines and devices, oral irrigating devices, orthodontic bracket attachment materials, powered oral hygiene devices, precision attachments, processing devices for radiographic film; scaling/stain removal devices, and visible radiation emitting devices.

Intervention: *Treatment*, prevention, diagnosis.

Stage: *New*, emerging, established or widespread practice.

Properties: *Effectiveness*, safety, efficacy.

Selection process: Commercial products are evaluated at the request of the manufacturer or distributor, or at the Council's initiative. All submissions and other information are sent in writing to the Council. Only complete submissions will be accepted; partial submissions will be returned. Each submission must include a summary report covering all information on safety and efficacy of the material, instrument, or item of equipment.

Submissions normally include the following: name and use of item; patent number relating to product; composition, physical, and chemical properties of dental materials; materials used in construction and method of operation of a device; and evidence of safety and usefulness of the product based on in vitro, biological, and clinical evaluations. Evidence of safety and usefulness of the product may be in the form of published reports or unpublished information obtained from appropriate scientific studies using in vitro, biological, and clinical observations.

Methods: Information syntheses, expert opinion, group judgment, bench testing.

The Council evaluates the information available and arrives at a decision, classifying the product as "acceptable," "provisionally acceptable," or "unacceptable." Products classified as "acceptable" usually retain that status for 3 years. Acceptance is renewable and may be reconsidered at any time. If there is a change in manufacturer or distributor of the product, the acceptance automatically expires.

"Acceptable" products are listed in *Dentists' Desk Reference: Materials, Instruments and Equipment*. The manufacturer or distributor may use the Seal of Acceptance and the Council's authorized statement.

"Provisionally acceptable" products consist of those that lack sufficient evidence to justify classification as "acceptable," but for which there is reasonable evidence of safety

and usefulness including clinical feasibility. The Council may authorize the use of a suitable statement to specifically define the area of usefulness. Products in this classification category are reviewed each year and ordinarily are not continued for more than 3 years.

"Unacceptable" products are those that are obsolete, markedly inferior, useless, or dangerous to the health of the user.

Dissemination: Acceptable products are listed in the ADA publication *Dentists' Desk Reference: Materials, Instruments and Equipment* and in the *Journal of the American Dental Association*. See for example, Product listing: classified dental materials, instruments, and equipment. *J Am Dent Assoc* 1986 Dec;113:1013-1015.

Budget: Not available. Funding source: 100 percent parent organization. Evaluators and consultants donate their time.

Use: The information is used by the ADA membership and the public.

Related Activities: The Council's Certification Program evaluates products and classifies them as "certified" when they meet formal certification requirements. The results of the Certification Program are also published in the *Journal of the American Dental Association*.

Completed Reports

AJ1 American Dental Association, Council on Dental Materials, Instruments and Equipment. Dentin bonding systems: an update. J Am Dent Assoc 1987; 114:91-95.

AJ2 _____. Dental endosseous implants. J Am Dent Assoc 1986; 113:949-950.

AJ3 _____. Posterior composite resins. J Am Dent Assoc 1986;112:717-709.

AJ4 _____. Posterior composite resins: an update. J Am Dent Assoc 1986; 113:950-952.

AJ5 _____. The effects of blue light on the retina and the use of protective filtering glasses. J Am Dent Assoc 1986; 112:533-535.

AJ6 _____. Recent developments in materials and process for ceramic crowns. J Am Dent Assoc 1985; 110:548-549.

AJ7 _____. Report on base metal alloys for crown and bridge applications: benefits and risks. J Am Dent Assoc 1985;111:479-483.

AJ8 _____. Status report on professional scaling and stain-removal devices. J Am Dent Assoc 1985; 111:801-802.

AJ9 _____. Visible light-cured composites and activating units. J Am Dent Assoc 1985;110:100-103

AJ10 _____, Council on Dental Research, and Council on Dental Therapeutics. Hydroxylapatite, beta tricalcium phosphate, and autogenous and allogenic bone for filling periodontal defects, alveolar ridge augmentation, and pulp capping. J Am Dent Assoc 1984; 108:822-831.

AJ11 _____, Council on Dental Therapeutics. Patch tests for sensitivity to mercury or nickel. J Am Dent Assoc 1984; 108:381.

AJ12 _____. Classification system for cast alloys. J Am Dent Assoc 1984; 109:766.

AJ13 _____. Mouth protectors and sports team dentists. J Am Dent Assoc 1984;109:84-87.

AJ14 _____. Recommendations in dental mercury hygiene, 1984. J Am Dent Assoc 1984;109:617-619.

AJ15 _____. Recommendations in radiographic practices, 1984. J Am Dent Assoc 1984; 109:764-765.

AJ16 _____. Reported sensitivity to glass ionomer luting cements. J Am Dent Assoc 1984; 109:617-619.

AJ17 _____. Resin dental bonding systems. J Am Dent Assoc 1984; 108:240-241.

AJ18 _____. Status report on enamel bonding of composites, preformed laminate, and laboratory fabricated resin veneers. J Am Dent Assoc 1984; 109:762-764.

AJ19 _____. Denture cleansers. J Am Dent Assoc 1983;106:77-79.
AJ20 _____. Pit and fissure sealants. J Am Dent Assoc 1983; 107:465.
AJ21 _____. Safety of dental amalgam. J Am Dent Assoc 1983;106:519-520.
AJ22 _____. Status report on amalgamators. J Am Dent Assoc 1983; 107:639-640.
AJ23 _____. Status report on posterior composites. J Am Dent Asso 1983; 107:71-75.
AJ24 _____. Status report: the periodontal ligament injection. J Am Dent Assoc 1983; 106:222-224.
AJ25 _____. Biological effects of nickel-containing dental alloys. J Am Dent Assoc 1982;104:501-505.
AJ26 _____. Biological effects of radiation from dental radiography. J Am Dent Assoc 1982; 105:275-281.
AJ27 _____. High copper-content amalgam alloys. J Am Dent Assoc 1982;105:1077-1080.
AJ28 _____. Recommendations for radiographic darkrooms and darkroom practices. J Am Dent Assoc 1982; 104:636-637.
AJ29 _____. State of the art and science of bonding in orthodontic treatment. J Am Dent Assoc 1982;105:844-850.
AJ30 _____. Status report on beta titanium orthodontic wire. J Am Dent Assoc 1982;105:684-685.
AJ31 _____. Status report on microfilled composite restorative resins. J Am Dent Assoc 1982-105:488-492.
AJ32 _____. Status report on precious metal scrap. J Am Dent Assoc 1982;105:1080-1081.
AJ33 _____. Status report: dental visible light-curing units. J Am Dent Assoc 1982; 104:505.
AJ34 _____. A status report on resilient denture base materials. J Am Dent Assoc 1981; 103:450-451.
AJ35 _____. ADA Council issues updated mercury hygiene measures recommended. ADA News 1981 Sep 7.
AJ36 _____. Classification and definition of alloys used for casting substrates for porcelain veneering. J Am Dent Assoc 1981;103:755-757.
AJ37 _____. Council update on "adhesion" and "adhesive" materials. J Am Dent Assoc 1981;103:252-253.
AJ38 _____. Current status of sterilization instruments, devices, and methods for the dental office. J Am Dent Assoc 1981; 102:683-689.
AJ39 _____. How to improve shade matching in the dental operatory. J Am Dent Assoc 1981;102:209-210.
AJ40 _____. Porcelain-metal alloy compatibility: criteria and test methods. J Am Dent Assoc 1981;102:71-72.
AJ41 _____. Recommendations in radiographic practices. J Am Dent Assoc 1981; 103:103-104
AJ42 _____. The desirability of using radiopaque plastics in dentistry: a status report. J Am Dent Assoc 1981;102:347-349.
AJ43 _____. Council position on nitrous oxide scavenging and monitoring devices. J Am Dent Assoc 1980;101:62.
AJ44 _____. Council reevaluates position on dental endosseous implants. J Am Dent Assoc 1980;100:247.
AJ45 _____. Prevention of problems with removable partial dentures. J Am Dent Assoc 1980; 100:919-921.
AJ46 _____. Status report on low-gold-content alloys for fixed prostheses. J Am Dent Assoc 1980; 100:237-240.

AMERICAN DENTAL ASSOCIATION COUNCIL ON DENTAL THERAPEUTICS

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Contact: Kenneth H. Burrell, Secretary.

Overview: The American Dental Association (ADA) is a professional association that provides a variety of services to assist the profession in delivering health care to the

public. The ADA's objectives include encouraging the improvements of the public's health, promoting the art and science of dentistry, and representing the interests of the members of the dental profession and the public that it serves. The Council on Dental Therapeutics is one of two technology assessment programs sponsored by the ADA; the other being the Council on Dental Materials, Instruments, and Equipment. The Council supplies reliable information and confers a seal of acceptance, provisional acceptance, and unacceptance on recently developed dental products.

Purpose: To study, evaluate, and disseminate information on 1) the proper use of dental therapeutics, their adjuncts, and dental cosmetic agents offered to the public or profession; and 2) aspects of the dental practice environment related to the health of dentists, dental auxiliaries, and the public.

Primary intended users: General public, patients, dentists.

Technologies: Drug, medical or surgical procedure.

Examples of technologies evaluated by the Council are: topical fluoride preparations, analgesics, antianxiety agents, anticholinergic drugs, antihistamines for control of allergic reactions, artificial salivas, astringents for gingival retraction, chemical disinfecting/ sterilizing agents, corticosteroids, fluoride dentrifices, fluoride mouthrinses, formocresol preparations, hand antiseptics, hemostatic agents, hypochlorite substances, inhalation anesthetics, local anesthetics, muscle relaxants, nutritional supplements, oral antiseptics, periodontal dressings, pharmaceutical aids, phenolic compounds, respiratory stimulants, root canal calcium chelating agents, sedatives and hypnotics, sterilizing agents, topical protectants, vasoconstrictors, and zinc oxide preparations.

Intervention: Prevention, diagnosis, and treatment.

Stages: *New*, emerging, established or widespread practice.

Properties: Safety, efficacy, effectiveness.

The Council also considers if the products meet standards of acceptance with respect to composition, advertising, and labeling.

Selection process: Commercial products are evaluated at the request of a manufacturer or distributor, or at the Council's initiative. Any firm may submit appropriate products to the Council for the consideration of acceptance. Communications must be submitted in writing through the Secretary of the Council.

The Manufacturers normally submit the following types of information: product name, composition, physical and chemical properties of product; evidence of safety and effectiveness; government regulations related to the product; and promotional materials.

Methods: Information syntheses, expert opinion, group judgment, bench testing.

The steps required for the review of products in the Council's acceptance program depend on several factors. For example, if a product is essentially the same as an existing accepted product and does not require chemical analysis by the Council's laboratory or review by consultants, the process will require fewer steps.

After consideration of a product has been completed, the Council classifies the product as "accepted," "provisionally accepted," or "unaccepted." Products are generally accepted for three years. Acceptance is renewable and may be reconsidered at any time. If there is a change in the product's manufacturer or distributor, the acceptance automatically expires.

"Accepted" products include those for which there is adequate evidence of safety and effectiveness. They may use the Council's "Seal of Acceptance" and/or an authorized statement, unless otherwise provided. "Provisionally accepted" products include those for which there is reasonable evidence of safety and effectiveness, but which lack sufficient evidence of dental effectiveness to justify being accepted. These products meet other qualifications and standards established by the Council. "Unaccepted" products include those for which the Council has determined that there is no substantial evidence of effectiveness, or that a question of safety exists.

Dissemination: Accepted products are listed in *Accepted Dental Therapeutics* and may be described in suitable reports in the *Journal of the American Dental Association* See for example, Product listing: accepted therapeutic products. *J Am Dent Assoc* 1986 Dec; 113:1018-1023. When it is in the best interest of the public or the profession, the Council may submit reports on unaccepted products for publication in the *Journal of the American Dental Association*.

Budget: Not available. Funding source: 100 percent parent organization. Evaluators and consultants donate their time.

Use: The information is used by the ADA membership and the public.

Completed Reports

AK1 American Dental Association, Council on Dental Therapeutics, Council on Dental Materials, Instruments, and Equipment. The use of root canal filling materials containing paraformaldehyde: a status report. J Am Dent Assoc 1987 Jan;114:95.

AK2 _____. American Dental Association, Council on Dental Therapeutics. Acceptance of Promise with Fluoride and Sensodyne-F toothpastes for sensitive teeth.] Am Dent Assoc 1986;113:673-5.

AK3 _____. Guidelines for acceptance of chemotherapeutic products for the control of supragingival dental plaque and gingivitis. J Am Dent Assoc 1986;112:529-32.

AK4 _____. Recommendations for evaluating agents for the reduction of dentinal hypersensitivity. J Am Dent Assoc 1986; 112:709-10.

AK5 _____, Council on Prosthetic Services and Dental Laboratory Relations. Guidelines for infection control in the dental office and the commercial dental laboratory. J Am Dent Assoc 1985; 110:969-72.

AK6 _____. Acceptance of OMNI-II disinfectant for instruments and equipment. J Am Dent Assoc 1985;110.

AK7 _____. Acceptance of Sensodyne toothpaste for sensitive teeth. J Am Dent Assoc 1985; 110.

AK8 _____. Prevention of bacterial endocarditis: a committee report of the American Heart Association. J Am Dent Assoc 1985;110.

AK9 _____. Herpes simplex virus disease: implications for dental personnel. J Am Dent Assoc 1984; 108:381-2.

AK10 _____, Council on Dental Research and Council on Dental Therapeutics. Report of symposium: root surface caries. J Am Dent Assoc 1983; 106.

AK11 American Dental Association. Report of the President's Conference on the examination, diagnosis, and management of temporomandibular disorders. J Am Dent Assoc 1983;106:75-7.

AK12 American Dental Association, Council on Dental Therapeutics. Evaluation of Denquel Sensitive Teeth toothpaste. J Am Dent Assoc 1982; 105.

AK18 _____. Council accepts Aim with sodium monofluorophosphate. J Am Dent Assoc 1980;101:822.

AK14 _____. Council accepts dilution claims for Sporicidin. J Am Dent Assoc 1980; 100:918.

AK15 _____. Office emergencies and emergency kits. J Am Dent Assoc 1980;101.

AMERICAN DIABETES ASSOCIATION

1660 Duke Street
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703-549-1500

Contact: Richard Kahn, Ph.D., Assistant Executive Vice President.

Overview: The American Diabetes Association (ADA) is a not-for-profit membership association that promotes efforts to prevent and cure diabetes and works to improve the well-being of people with diabetes and their families. It provides professional education programs, patient information materials/programs, research grant awards, and public awareness about diabetes. ADA's technology assessment activities include sponsoring consensus conferences, developing position papers, and publishing review articles.

Purpose: To provide health professionals and the public with accurate and comprehensive information about technologies relevant to diabetes.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; reporters, writers, news media; information/ computer industry; labs, blood banks; public policy-makers, legislators; policy research organizations.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system.

Intervention: Diagnosis, treatment, rehabilitation.

Stage: New, established or widespread practice.

Properties: Safety; efficacy; effectiveness; cost; cost-benefit; cost-effectiveness; service requirements; acceptance/ adoption level; system impact; economic implications; ethical, legal, social implications.

Selection process: ADA board members and officers, professional members, and other agencies and institutions can request that an assessment be conducted. Written requests are submitted to the volunteer leadership or senior staff. The volunteer leadership sets the assessment topic priorities.

Methods: Information syntheses, expert opinion, group judgment, cost analyses.

The assessment process is conducted in committee meetings, symposia, and conferences. The approximate turnaround time from selection of assessment topic to reporting of findings is 6 months.

Assessors: The assessors have expertise in a wide variety of areas related to diabetes including medicine, nutrition, exercise, law, and public health.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/ information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; coverage/ reimbursement status of the technology.

Dissemination: Printed reports; journal articles; advisories to members/constituents; press conferences/news releases; TV/radio broadcasts, video products.

The ADA accepts telephone and written requests for copies of assessment reports.

Budget: $100,000. The approximate cost per assessment ranges from $1,000 to $50,000. Funding sources: 5 percent government grants/contracts; 15 percent foundations, other private grants; 80 percent sponsors/members dues, contributions.

Use: The ADA uses the assessment reports and position statements as a guide for new program development and as an authoritative source of information. Reports are cited in government documents, newspaper articles, lay public magazines, and other publications.

Related activities: The ADA conducts an annual scientific session at which hundreds of original research reports are presented. The Association sponsors an annual postgraduate course, a research symposium, and other conferences intended to disseminate new information or to provide a forum for discussing important topics related to diabetes.

Completed Reports

AL1 American Diabetes Association, Consensus Development Panel. Consensus statement on self-monitoring of blood glucose. Diabetes Care 1987; 10:95-99. [Expert opinion, Group judgment]

AL2 American Diabetes Association, Task Force of the Council on Nutrition Sciences and Metabolism. Position statement on use of noncaloric sweeteners. 1987. [Expert opinion, Group judgment]

AL3 American Diabetes Association. Nutritional recommendations and principles for individuals with diabetes mellitus. Diabetes Care 1087;10:126-132. [Expert opinion, Group judgment]

AL4 American Diabetes Association and the Centers for Disease Control, Task Force on Financing Quality Health Care for Persons with Diabetes. Third-party reimbursement for diabetes outpatient education. 1986. [Expert opinion, Group judgment]

AL5 American Diabetes Association. Position statement on polydextrose. 1986. [Expert opinion, Group judgment]

AL6 _____. Bedside blood glucose monitoring in hospitals. Diabetes Care 1986;9:89. [Expert opinion, Group judgment]

AL7 _____ Gestational diabetes mellitus. Diabetes Care 1986;9:430-431. [Expert opinion, Group judgment]

AL8 _____. Continuous subcutaneous insulin infusion. Diabetes 1985;34:946. [Expert opinion, Group judgment]

AL9 _____. Office guide to diagnosis and classification of diabetes mellitus and other categories of glucose intolerance. Diabetes Care 1981;4:335. [Expert opinion, Group judgment]

AL10 Olefsky JM, Crapo P. [American Diabetes Association] Fructose, xylitol, and sorbitol. Diabetes Care 1980;3:390-393. [Expert opinion, Group judgment]

AMERICAN GASTROENTEROLOGICAL ASSOCIATION PATIENT CARE COMMITTEE

c/o John Balint, M.D.
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Contact: John Balint, M.D.

Overview: The American Gastroenterological Association (AGA) is a professional society for gastroenterologists concerned with patient care education, research, and public policy.

Purpose: To evaluate the safety and efficacy of new diagnostic and treatment modalities in digestive diseases and to develop effective and affordable methodologies for data collection.

Primary intended users: Patients; physicians; acute facility administrators; health product manufacturers; health/ medical professional associations; third party payers; government regulators; biomedical researchers; public policy-makers, legislators.

Technologies: *Device*, drug, medical or surgical procedure.

Specifically, endoscopic instrumentation for diagnosis and treatment, new imaging technology, and nutritional support systems are assessed.

Intervention: *Treatment*, diagnosis.

Stage: *New*, emerging, established or widespread practice.

Properties: *Effectiveness*, safety, cost-benefit, cost-effectiveness, acceptance/adoption level.

Selection process: Anyone can request that an assessment be conducted. Generally, Committee members initiate a request, although the Committee will respond to requests from any organization. The Committee sets assessment topic priorities and decides on the most appropriate response to a request.

Methods: *Information syntheses*, expert opinion, group judgment, epidemiological and other observational methods.

Committee members conduct the assessment process and are assigned specific tasks to complete. Assessments are based largely on literature reviews, although, the Committee wants to develop questionnaire methods for prospective evaluations. The turnaround time from selection of assessment topic to reporting of findings ranges from 6 months to 2 years.

Assessors: The Patient Care Committee consists of practicing gastroenterologists, surgeons, endoscopists, and pediatric gastroenterologists.

Assessment reports include: The purpose of the assessment; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; and recommendations for practice, future assessments, technology development, research.

Dissemination: Printed reports, journal articles.

Assessment results are published in the journal *Gastroenterology* and are presented at AGA meetings. Copies of the assessments can be requested from the Patient Care Committee.

Budget: Not available. The approximate cost per assessment is not known. In general, Committee members donate their time. Funding source: 100 percent parent organization.

Related activities: The Patient Care Committee sponsors symposia at their annual meeting that are designed to help the practicing gastroenterologist evaluate and properly use diagnostic and treatment modalities.

Completed Reports

AM1 Sitzman JV, Pitt HA. [American Gastroenterological Association, Patient Care Committee] Guidelines for total parenteral nutrition. Gastroenterology 1987 (in press).

AM2 Kreek MJ, Balint JA. [American Gastroenterological Association, Patient Care Committee] "Skinny needle" cholangiography: results of a pilot study of a voluntary prospective method for gathering risk data on new procedures. Gastroenterology 1980;78:598-604. [Information syntheses]

Ongoing Assessments

AM3 American Gastroenterological Association, Patient Care Committee. Diagnostic procedures in jaundice. Ongoing.

AM4 American Gastroenterological Association, Patient Care Committee. Diagnostic procedures in noncardiac chest pain. Ongoing.

AMERICAN HOSPITAL ASSOCIATION HOSPITAL TECHNOLOGY SERIES PROGRAM

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Contact: Henry C. Alder, Director; Suzanna Pribyl, Manager, Technology Policy and Planning; or Susan A. Frankel, Manager, Marketing and Publications.

Overview: The American Hospital Association (AHA) is a trade association that represents member hospitals, providing advocacy, policy development, publications, data services, educational programs, and special projects. Its Hospital Technology Series Program, initiated in 1982, is a health care technology evaluation and information dissemination program for hospital administrators.

Purpose: To assist hospital administrators in making prudent and informed management decisions regarding new and existing technologies to support clinical services planning activities.

Primary intended users: Providers, generally; acute facility administrators; long-term care facility administrators.

Technologies: Device, support system.

The Program deals primarily with service implications of technological advances on the planning and delivery of clinical services from the hospital perspective. The Program generally does not evaluate procedures, although they are discussed insofar as they bear upon strategic equipment and service choices.

Intervention: Diagnosis, treatment.

Properties: *Service requirements, system impact*, efficacy, effectiveness, cost, cost-benefit, cost-effectiveness, acceptance/adoption level, economic implications.

Evaluations also consider manufacturer issues, such as vendor stability, the capacity for technologies to be upgraded, and other compared attributes of competing technologies. Although evaluations do not include brand name ratings, they sometimes provide brand-specific information, such as cost and installation information and service support arrangements. Specifically, evaluations are most concerned with the following: 1) cost and organizational implications, 2) installation costs, 3) staffing and training requirements, 4) probable number of patients affected, 5) effects on other hospital resources, and 6) effectiveness (not patient outcomes, but effects on the use of hospital resources, such as inpatient versus outpatient stay and average length of stay).

Selection process: Program staff select subjects for assessment after reviewing their importance to hospital management, especially their impact on costs. Technologies are reassessed based on new information and the perceived needs of hospitals. Reassessments follow the same format as the original assessments.

Methods: Information syntheses, expert opinion, cost analyses.

Evaluations consist of syntheses of the literature, focused interviews with manufacturers and users, and compilations of reported experience by users in such areas as negotiating purchase contracts and common mistakes made in implementation.

The approximate turnaround time from selection of assessment topic to reporting of findings is 6 months.

Assessors: The evaluations are conducted or directed by staff of the Division of Clinical Services and Technology who have expertise in hospital and business administration, health care administration, and clinical engineering. Outside consultants with medical and scientific expertise are also employed.

Assessment reports include: Who conducted the assessment; description of the technology; properties assessed; results; findings or conclusions; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; procurement/deployment information; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: *Printed reports*, journal articles, advisories to members/constituents.

Evaluation findings are reported in *Guideline Reports* issued approximately 4 times a year and disseminated to member hospitals. Selected *Guideline Reports* are summarized in *Hospitals* magazine. They may be obtained as part of a subscription to the *AHA Hospital Technology Series* or ordered separately for a nominal fee.

In addition to *Guideline Reports* the *AHA Hospital Technology Series* includes the following:

Executive Briefing; an overview of major developments affecting hospitals' use of technology in the delivery of patient care; directed to hospitals' chief executive officers and distributed monthly.

Technology Scanner; a collection of categorized summaries of articles relevant to hospital technology, drawn from more than 80 medical and technical journals. Directed to hospital administrators and distributed monthly.

Special Reports; brief updates on current technological issues.

Budget: $368,000. Funding sources: 100 percent sales of subscriptions and reports.

Use: Approximately 1,700 hospitals subscribe to the *Hospital Technology Series*.

Related activities: The AHA's Division of Clinical Services and Technology also produces *Medi Trends*, an environmental assessment of clinical services focusing on medical technology.

Completed Reports

AN1 American Hospital Association, Hospital Technology Series Program. Positron emission tomography. 1987. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN2 _____. Radiation therapy planning. 1987. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN3 _____. Topographic brain mapping. 1987. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN4 _____. Cine-CT: progress and opportunities. 1986. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN5 _____. Implementing laser technology in the community hospital. 1986. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN6 _____. Purchasing a satellite receiving earth terminal. 1986. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN7 _____. Lithotripters. 1985. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN8 _____. NMR—issues for 1985 and beyond. 1985. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN9 _____. Picture archiving and communication systems. 1985. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN10 _____. A medical device recall and reporting system. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN11 _____. Adult volume ventilators. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN12 _____. Bar coding technology—applications in health care. 1984. (Guideline report)

AN13 _____. Computerized tomographic scanners. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN14 _____. Echocardiography. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN15 _____. Equipment acquisition under prospective payment. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN16 _____. Microcomputers in hospitals. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN17 _____. Trends in nuclear medicine. 1984. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN18 _____. Materials management information systems. 1983. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN19 _____. Medicare technology assessment. 1983. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN20 _____. Nuclear magnetic resonance (NMR). 1983. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN21 _____. Automated indirect blood pressure measurement devices. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN22 _____. Automated infusion devices. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN23 _____. Autotransfusion units. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN24 _____. Buying and selling used medical equipment. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN25 _____. Clinical laboratory information systems. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN26 _____. Computerized arrhythmia monitoring systems. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN27 _____. Digital subtraction angiography. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN28 _____. Ethylene oxide sterilization. 1982. (Guideline report) [Information synthesis, expert opinion, Cost analyses]

AN29 _____. Evaluation methods for intensive care units. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN30 _____. Medicare technology assessment. 1982. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AN31 _____. Medicare technology assessment. 1981. (Guideline report) [Information syntheses, Expert opinion, Cost analyses]

AMERICAN MEDICAL ASSOCIATION COUNCIL ON SCIENTIFIC AFFAIRS

535 North Dearborn Street
Chicago, IL 60610
312-645-5335

Contact: William R. Hendee, Ph.D., Secretary; or Vicki Grosso, Council and Committee Coordinator.

Overview: The American Medical Association (AMA) is a professional association that provides a wide range of services and products to advance the field of medicine. The Council on Scientific Affairs was formed in 1976 by the AMA.

Purpose: To provide accurate, balanced, and up-to-date information on medical technology to the practicing medical community and to communicate the concerns and opinions of physicians to the health care community.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; public policy-makers, legislators.

Technologies: *Medical or surgical procedure*, drug, device.

Intervention: *Diagnosis, treatment*, prevention, rehabilitation.

Stage: Emerging, new, established or widespread practice, obsolete.

Properties: *Safety, effectiveness*, efficacy.

Selection process: Any responsible party may request an assessment. Requests are made to the Secretary or Council members. The members of the Council then set the priorities for assessment.

Methods: *Group judgment*, information syntheses, expert opinion.

Issues of importance to the practicing medical community are identified. Often expert panels are organized and charged with addressing pertinent issues. Reports are developed by the panel and submitted to the Council for approval. In other cases, issues are analyzed by staff. Reports are developed and reviewed by three or four consultants. They are then submitted to the Council for approval. The approximate turnaround time from selection of assessment topic to reporting of findings is 6 to 12 months.

Assessors: The Council has access to experts in all areas of medicine.

Assessment reports include: Abstract; the purpose of the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; sources of data/information; results; findings or conclusions; limitations of findings;

implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology.

Dissemination: Printed reports; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

The reports are 20-25 pages in length with an initial synopsis. The results are disseminated through the *Journal of the American Medical Association (JAMA)* or the popular press. Copies of the assessment reports may be obtained from *JAMA* or by requesting reprints.

Budget: $613,782. The cost per assessment varies. Funding source: 100 percent parent organization.

Use: The AMA uses the assessment reports as a source of information for physicians to incorporate in their decision-making processes.

Completed Reports

AO1 American Medical Association, Council on Scientific Affairs. Drugs and athletes—Progress Report. 1986. [Group judgment]

AO2 _____. Glucocorticoid-induced osteonecrosis. 1986. [Group judgment]

AO3 _____. Herpes simplex and school children. 1986. [Group judgment]

AO4 _____. Lasers in medicine and surgery. JAMA 1986 Aug 15;256(7):900-907. [Group judgment]

AO5 _____. OTC diet preparations containing phenylpropanolamine (Resolution 100, I-85). 1986. [Group judgment]

AO6 _____. Preventing death and disability from fires by the new rapid response automatic sprinklers and smoke detectors (Resolution 2, A-85). 1986. [Group judgment]

AO7 _____. Safe use of radioactive materials in medical practice (Resolution 66, A-85). 1986. [Group judgment]

AO8 _____. Statement on liver transplantation. 1986. [Group judgment]

AO9 _____. The Heimlich maneuver interim report (Resolution 52, I-85). 1986. [Group judgment]

AO10 _____. Use of immunosuppressants in organ transplantation. 1986. [Group judgment]

AO11 _____. AMA diagnostic and treatment guidelines concerning child abuse and neglect. JAMA 1985 Aug 9;254 (6):796-800. [Group judgment]

AO12 _____. Aspartame: review of safety issues. JAMA 1985 Jul 18;254:400-402. [Group judgment]

AO13 _____. Autopsies: interim report (Substitute Resolution 11, A-84). 1985. [Group judgment]

AO14 _____. Current status of therapeutic plasmapheresis and related techniques. JAMA 1985 Feb 8;253:819-825. [Group judgment]

AO15 _____. Dementia. 1985 [Group judgment]

AO16 _____. Drugs and athletes—interim report. 1985. [Group judgment]

AO17 _____. Guidelines for handling parenteral antineoplastics. JAMA 1985 Mar 15;253:1590-1592. [Group judgment]

AO18 _____. Guidelines for reporting estimates of probability of paternity. JAMA 1985 Jun 14;253:3298. [Group judgment]

AO19 _____. Harmful effects of UVA and UVB light. 1985. [Group judgment]

AO20 _____. SI units for clinical laboratory data. JAMA 1985 May 3;253:2553-2554. [Group judgment]

AO21 _____. Saccharin: review of safety issues. JAMA 1985 Nov 8;254(18):2622-2624. [Group judgment]

AO22 _____. Scientific status of refreshing recollection by the use of hypnosis. JAMA 1985 Apr 5;253:1918-1923. [Group judgment]

AO23 _____. The use of cardiac pacemakers in medical practice. JAMA 1985 Oct 11;254 (14) 1952-1954. [Group judgment]

AO24 _____. Vitamin preparations as dietary supplements and as therapeutic agents. 1985. [Group judgment]

AO25 _____. Xenografts: Review of the literature and current status. JAMA 1985 Dec 20;254(23):3353. [Group judgment; Information syntheses]

AO26 _____. Caffeine labeling. JAMA 1984 Aug 10;252:803-806. [Group judgment]

AO27 _____. Chelation therapy. 1984. [Group judgment]

AO28 _____. Combined modality approaches to cancer therapy. JAMA 1984 May 11;251:2398-2407. [Group judgment]

AO29 _____. Early detection of breast cancer. JAMA 1984 Dec 7;252:3008-3011. [Group judgment]

AO30 _____. Nicotine chewing gum for cessation of smoking. 1984. [Group judgment]

AO31 _____. Percutaneous transluminal angioplasty. JAMA 1984 Feb 10;251:764-768. [Group judgment]

AO32 _____. Prescription Abuse Data Synthesis (PADS) Project and the AMA prescription drug abuse activity. 1984. [Group judgment]

AO33 _____. The acquired immunodeficiency syndrome. JAMA 1984 Oct 19;252:2037-2043. [Group judgment]

AO34 _____. A guide to the hospital management of injuries arising from exposure to or involving ionizing radiation. 1983. [Group judgment]

AO35 _____. AMA's role in technology assessment (Resolution 131 (A-83). 1983. [Group judgment]

AO36 _____. Calcium channel blocking agents. JAMA 1983 Nov 11;250:2522-2524. [Group judgment]

AO37 _____. Choking: the Heimlich maneuver (abdominal thrust) vs. back blows. 1983. [Group judgment]

AO38 _____. Cochlear implants. JAMA 1983 Jul 15;250:391-392. [Group judgment]

AO39 _____. Dietary and pharmacologic therapy for the lipid risk factors. JAMA 1983 Oct 14;250:1873-1879. [Group judgment]

AO40 _____. Effects of competition in medicine. JAMA 1983 Apr 8;249:1864-1868. [Group judgment]

AO41 _____. Estrogen replacement in the menopause. JAMA 1983 Jan 21;249:359. [Group judgment]

AO42 _____. Exercise programs for the elderly. 1983. [Group judgment]

AO43 _____. In-utero fetal surgery: (Resolution 73 (I-81). JAMA 1983 Sep 16;250:1443-1444. [Group judgment]

AO44 _____. Maternal alcohol use. JAMA 1983 May 13;249:2517-2521. [Group judgment]

AO45 _____. Medical evaluations of healthy persons. JAMA 1983 Mar 25;249:1626-1633. [Group judgment]

AO46 _____. Methaqualone, abuse limits its usefulness. JAMA 1983 Dec 9;250:3052. [Group judgment]

AO47 _____. Nonsmoking in hospitals. 1983. [Group judgment]

AO48 _____. Pharmaceutical dissolution of gallstones. JAMA 1983 Nov 4;250:2373-2374. [Group judgment]

AO49 _____. Update on venereal disease. 1983. [Group judgment]

AO50 _____. AMA involvement in prevention and treatment of child abuse and neglect (Substitute Resolution 75, A-81). 1982. [Group judgment]

AO51 _____. Addition of thiamine to alcoholic beverages (Resolution 140, A-81). 1982. [Group judgment]

AO52 _____. Continuous ambulatory peritoneal dialysis. JAMA 1982 Nov 12;248:2340. [Group judgment]

AO53 _____. Dimethyl sulfoxide. JAMA 1982 Sep 17;248:1369. [Group judgment]

AO54 _____. Drug abuse related to prescribing practices. JAMA 1982 Feb 12;247:864. [Group judgment]

AO55 _____. Genetic counseling and prevention of birth defects. JAMA 1982 Jul 9;248:221. [Group judgment]

AO56 _____. Health care needs of a homosexual population. JAMA 1982 Aug 13;248:736. [Group judgment]

AO57 _____. Infant formula marketing (Resolution 155, A-81). 1982. [Group judgment]

AO58 _____. Maternal serum a-fetoprotein monitoring. JAMA 1982 Mar 12;247:1478. [Group judgment]

AO59 _____. Pneumococcal, influenza and hepatitis-B vaccine (Resolution 75, A-82). 1982. [Group judgment]

AO60 _____. Acupuncture. 1981. [Group judgment]

AO61 _____. Electronic fetal monitoring. JAMA 1981 Nov 20;246:2370. [Group judgment]

AO62 _____. Evalution of iridology. 1981. [Group judgment]

AO63 _____. Hypnotic drugs and treatment of insomnia. JAMA 1981 Feb 20;245:749. [Group judgment]

AO64 _____. Indications and contraindications for exercise testing. JAMA 1981 Aug 28;246:1015. [Group judgment]

AO65 _____. Marijuana, its health hazards and therapeutic potentials. JAMA 1981 Oct 16;246:1823. [Group judgment]

AO66 _____. Medical care for indigent and culturally displaced obstetrical patients and their newborns. Committee on Maternal and Child Health. JAMA 1981 Mar 20;245:1159. [Group judgment]

AO67 _____. Organ donor recruitment. JAMA 1981 Nov 13;246:2157. [Group judgment]

AO68 _____. Physician-supervised exercise programs in rehabilitation of patients with coronary heart disease. JAMA 1981 Apr 10;245:1463. [Group judgment]

AO69 _____. Prescription of tranquilizers and antidepressants for women (Board of Trustees report X, I-80). 1981. [Group judgment]

AO70 _____. Health care technology assessment—1980. 1980. [Group judgment]

AO71 _____. Hypoglycemic treatment, guidelines for the non-insulin-dependent diabetic. JAMA 1980 May 23-30;243:2078. [Group judgment]

AO72 _____. Importance of diagnostic computerized tomographic scanning. 1980. [Group judgment]

AO73 _____. Infant nutrition (Resolution III, I-78.) 1980. [Group judgment]

AO74 _____. Marijuana in the 80's. 1980. [Group judgment]

AO75 _____. Progress in adoption of SI units. 1980. [Group judgment]

AO76 _____. The nutritive quality of processed foods: general policies for nutrient additions. 1980. [Group judgment]

AMERICAN MEDICAL ASSOCIATION DIAGNOSTIC AND THERAPEUTIC TECHNOLOGY ASSESSMENT

535 North Dearborn Street
Chicago, IL 60610
312-645-4530

Contact: William T. McGivney, Ph.D., Director; or Andrea L. Schneider, Program Administrator. Telex 910-221-0300.

Overview: The American Medical Association (AMA) is a professional association that provides a wide range of services and products to advance the field of medicine. The Diagnostic and Therapeutic Technology Assessment program (DATTA) was established by the AMA in 1982.

Purpose: To provide accurate, balanced, and up-to-date information on medical technology to the practicing medical community; and to communicate the concerns and opinions of physicians to other constituents of the health care community.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; public policy-makers; legislators.

Technologies: *Medical or surgical procedure*, drug, device.

Intervention: *Diagnosis, treatment*, prevention, rehabilitation.

Stage: *New*, emerging, established or widespread practice, obsolete.

Properties: *Safety, effectiveness*, efficacy.

Selection process: Any responsible party may request that an assessment be conducted. Written requests should be submitted to the Director. The DATTA Subcommittee, Director, and AMA Executive staff set assessment topic priorities. The need to reassess the technologies is considered periodically.

Methods: *Expert opinion*, information syntheses.

DATTA formulates questions to examine the safety and effectiveness of a technology when applied for very specific indications. Individuals with expertise in the topic are selected from a reference panel and asked (by mail) to rate the safety and effectiveness of the technology as established, investigational, or unacceptable. Panelists are encouraged to provide supporting data and relevant considerations. The evaluations of the panelists are collated, compiled, and synthesized with an extensive analysis of the biomedical literature. The approximate turnaround time from selection of topic to reporting of findings is 120 days.

Assessors: DATTA is operated by AMA staff under direction of a subcommittee of the AMA Council on Scientific Affairs. Staff selects panelists for each assessment from a reference panel of 1,000 physicians appointed by the Council on Scientific Affairs. Panelists represent a broad spectrum of specialties and subspecialties.

Assessment reports include: Description of the technology; stage of life-cycle of technology when assessed; properties assessed; sources of data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles.

Dissemination: Printed reports; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

The assessment reports contain an initial synopsis and are usually 8 to 10 pages in length. DATTA results are usually published in the *Journal of the American Medical Association*, disseminated in the popular press, and are distributed to certain individuals and organizations on a mailing list. Individual copies of DATTA reports may be obtained from the AMA. Subscriptions to the DATTA series, including new and past reports and the newsletter *AMA Tech*, are available from the AMA.

Budget: $380,000. The approximate cost per assessment is $15,000. Funding source: 100 percent parent organization.

Use: The AMA uses the assessment reports as a source of information for physicians to use for decision-making purposes. They are also used by third party payers, group practices, specialty societies, individual patients, public policy-makers. Articles describing the program include the following citations:

Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Monaco GP, Burke RL. Insurance as gatekeeper—part two: policy obstacles in unproven methods litigation. *Forum* 1985;spring.

Petitti DB. Competing technologies, implications for the cost and complexity of medical care. *New Engl J Med* 1986 Dec 4.

Rose M, Leibenluft RF. Antitrust implications of medical technology assessment. *New Engl J Med* 1986 Jun 5.

The following assessment reports of the Office of Health Technology Assessment (National Center for Health Services Research and Health Care Technology Assessment) reference DATTA statements:

1983

Anti-gastroesophageal reflux implantation

Diathermy as a physical therapy modality

Fully automated ambulatory blood pressure monitoring of hypertension

1984

Ambulatory electroencephalographic (EEG) monitoring

External open-loop pump for the subcutaneous infusion of insulin in diabetes

Implantable pump for chronic heparin therapy Streptokinase infusion for acute myocardial infarction

Transplantation of the pancreas

1985

Apheresis in the treatment of guillian-barre syndrome

Extracorporeal shock wave lithotripsy (ESWL) procedure for treatment of kidney, stones

Patient selection criteria for percutaneous transluminal coronary angioplasty of a stenotic lesion in a single coronary artery

Percutaneous ultrasound procedures for the treatment of kidney stones

Reassessment of cardiokymography (No longer valid)

Transurethral ureteroscopic lithotripsy procedures for the treatment of kidney stones

Completed Reports

AP1 American Medical Association, Diagnostic and Therapeutic Technology Assessment. Ablation of accessory pathways in Wolff-Parkinson-White Syndrome. Mar 31, 1986. [Expert opinion, Information syntheses]

AP2 _____. Angelchik antireflux prosthesis treatment of gastroesophageal reflux. JAMA 1986 Sep 12. [Expert opinion, Information syntheses]

AP3 _____. Autologous bone marrow transplantation. JAMA 1986 Jul 4. [Expert opinion, Information syntheses]

AP4 _____. BCG immunotherapy in bladder cancer. Mar 31, 1986. [Expert opinion, Information syntheses]

AP5 _____. Cardiac rehabilitation services. Jul 16, 1986. [Expert opinion, Information syntheses]

AP6 _____. Garren gastric bubble for morbid obesity. JAMA 1986 Dec 19. [Expert opinion, Information syntheses]

AP7 _____. Mammographic screening for breast cancer. Oct 19, 1986. [Expert opinion, Information syntheses]

AP8 _____. Microsurgical reconstruction for brachial plexus injury. Jul 16, 1986. [Expert opinion, Information syntheses]

AP9 _____. Continuous arteriovenous hemofiltration (CAVH) for fluid removal. JAMA 1985 Mar 1. [Expert opinion, Information syntheses]

AP10 _____. Diagnostic intraoperative ultrasound. JAMA 1985 Jul 12. [Expert opinion, Information syntheses]

AP11 _____. Endoscopic electrocoagulation for gastrointestinal hemorrhage. JAMA 1985 May 11. [Expert opinion, Information syntheses]

AP12 _____. Endoscopic laser photocoagulation for gastrointestinal hemorrhage. JAMA 1985 May 11. [Expert opinion, Information syntheses]

AP13 _____. Endoscopic thermal coagulation for gastrointestinal hemorrhage. JAMA 1985 May 11. [Expert opinion, Information syntheses]

AP14 _____. Endoscopic topical therapy for gastrointestinal hemorrhage. JAMA 1985 May 11. [Expert opinion, Information syntheses]

AP15 _____. Enhanced computed tomography in head trauma. JAMA 1985 Dec 20. [Expert opinion, Information syntheses]

AP16 _____. Non-invasive extracorporeal lithotripsy for disruption of kidney stones—Update. Feb 15, 1985. [Expert opinion, Information syntheses]

AP17 _____. Sperm penetration assay in identifying male infertility. JAMA 1985 Oct 11. [Expert opinion, Information syntheses]

AP18 _____. Sterotactic cingulatomy treatment for psychiatric disorders. JAMA 1985 Nov 15. [Expert opinion, Information syntheses]

AP19 _____. Apnea monitoring for 24-hour surveillance of newborns at risk for sudden infant death syndrome. JAMA 1984 Jan 27. [Expert opinion, Information syntheses]

AP20 _____. Bone marrow transplantation in childhood leukemia. JAMA 1984 Apr 27. [Expert opinion, Information syntheses]

AP21 _____. Cardiokymography for (non-invasive) cardiological diagnosis. JAMA 1984 Feb 24. [Expert opinion, Information syntheses]

AP22 _____. Diaphanography (transillumination of the the breast) for cancer screening. JAMA 1984 Apr 18. [Expert opinion, Information syntheses]

AP23 _____. Endoscopic transurethral nephrolithotomy for disruption of kidney stones. JAMA 1984 Dec 21. [Expert opinion, Information syntheses]

AP24 _____. Gastric restrictive surgery for morbid obesity. JAMA 1984 Jun 8. [Expert opinion, Information syntheses]

AP25 _____. Hyperthermia treatment for cancer—Update. Sep 17, 1984. [Expert opinion, Information syntheses]

AP26 _____. Implanted electrospinal stimulator for scoliosis. JAMA 1984 May 25. [Expert opinion, Information syntheses]

AP27 _____. Percutaneous nephrolithotomy for kidney stone removal. JAMA 1984 Dec 2. [Expert opinion, Information syntheses]

AP28 _____. 24-hour ambulatory EEG monitoring for diagnosing seizure disorders. JAMA 1983 Dec 23. [Expert opinion, Information syntheses]

AP29 _____. Biofeedback for managing vascular and tension headaches. JAMA 1983 Nov 14. [Expert opinion, Information syntheses]

AP30 _____. CO2 laser for the treatment of gynecologic malignancies. JAMA 1983 Aug 5. [Expert opinion, Information systheses]

AP31 _____. Chelation therapy (with EDTA) for atherosclerosis. JAMA 1983 Aug 5. [Expert opinion, Information syntheses]

AP32 _____. Cranial electrostimulation for treatment of anxiety and/or depression. JAMA 1984 Feb 24. [Expert opinion, Information syntheses]

AP33 _____. Diathermy for treating musculoskeletal conditions. JAMA 1983 Jul 22-29. [Expert opinion, Information syntheses]

AP34 _____. Implantable infusion pump for continuous drug therapy. JAMA 1983 Oct 14. [Expert opinion, Information syntheses]

AP35 _____. Mandatory EKG prior to elective surgery. JAMA 1983 Jul 29. [Expert opinion, Information syntheses]

AP36 _____. Quantitative EEG (fast Fourier transform analysis) operative monitoring of cerebrovascular status. JAMA 1983 Jul 15. [Expert opinion, Information syntheses]

AP37 _____. Radial keratotomy for the treatment of myopia. JAMA 1983 Jul 15. [Expert opinon, Information syntheses]

AP38 _____. Thermography (electronic and liquid crystal) for diagnosing low-back pain. Ongoing. [Expert opinion, Information syntheses]

AMERICAN MEDICAL ASSOCIATION DRUG EVALUATIONS

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Contact: Donald R. Bennett, M.D., Ph.D., Director; or Marilyn A. Mayo, Assistant to the Director. Telex 910-221-0300.

Overview: The American Medical Association (AMA) is a professional association that provides many services and products to advance the field of medicine. The AMA Drug Evaluations section was established in 1971, however, the Department of Drugs has been a part of the AMA for 75 years. Every 2 to 3 years it publishes the reference book *Drug Evaluations*; the sixth edition was published in 1986.

Purpose: To provide physicians and other health care professionals with up-to-date, objective information on the clinical use of drugs and to serve as a reference source for practical, comparative, evaluative information on drug therapy.

Primary intended users: Providers, generally; physicians; health product manufacturers; health/medical professional associations; public policy-makers, legislators.

Technologies: Drug.

Intervention: Treatment.

Stage: Emerging, new, established or widespread practice, obsolete.

Properties: Safety, efficacy, effectiveness.

Selection process: Assessment topics are identified primarily by AMA scientific staff review of current drug utilization. Occasionally, requests are received from physicians. The requests are submitted to the Director who sets priorities in consultation with the Drug Evaluations editor and scientific staff.

Methods: Information syntheses, expert opinion.

The staff of the AMA Department of Drugs prepares chapters based on the current scientific literature. The chapters are reviewed by consultants and the medical staffs of the appropriate pharmaceutical manufacturers. Following consensus revision, the chapters are reviewed by designees or members of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). For the sixth edition, more than 500 distinguished consultants contributed their comments to the draft versions. Thus, this publication is a joint scientific contribution to the field of applied therapeutics by the AMA, a large consultant body, and the ASCPT. The consultants have expertise in pharmacology and therapeutics. A new edition of *Drug Evaluations* is produced every 2 to 3 years.

Assessors: AMA professional staff, medical staff of pharmaceutical manufacturers, and expert consultants in pharmacology and therapeutics participate in the assessments.

Assessment reports include: Description of the technology; stage of life-cycle of technology when assessed; properties assessed; sources of data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles. The text describes approximately 2,000 drugs.

Dissemination: The text is sold by the AMA directly and by a commercial publisher.

Budget: The cost of producing each text is $1,500,000; this averages $500 for each drug evaluation. Funding source: 100 percent parent organization.

Use: *Drug Evaluations* provides physicians information on comparative drug therapy to improve their prescribing practices. There are numerous citations in the biomedical literature to this text.

Completed Reports

AQ1 American Medical Association. Drug evaluations. Philadelphia: Saunders, 1986. [Information syntheses, Expert opinion]

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY COMMITTEE ON TECHNOLOGY ASSESSMENT

13 Elm Street
Manchester, MA 01944
617-927-8330

Contact: William T. Maloney, Executive Director; or John H. Bond Jr., M.D., Chairman, Veterans Administration Hospital, 54th St. and 48th Ave. South, Minneapolis, MN 55417,612-725-6767.

Overview: The purposes of the American Society for Gastrointestinal Endoscopy (ASGE) are 1) to further knowledge of gastrointestinal disease through the use of endoscopic techniques in clinical practice and research; 2) to establish and maintain the highest standards of practices for the diagnostic and therapeutic use of gastrointestinal endoscopic methods; 3) to provide guidelines for training programs and to further the teaching of gastrointestinal endoscopy; 4) to assist all those involved with health care as it relates to gastrointestinal endoscopy; and 5) to facilitate development of improved instruments of gastrointestinal endoscopy.

The Society has 3,840 members. Its activities include educational, audiovisual, scientific, and research programs, as well as publication of a bimonthly journal *Gastrointestinal Endoscopy* and guidelines and statements on training and practice.

Various activities relating to technology assessment were organized under the direction of a five-member Committee on Technology Assessment in May 1986. The Society functions as an information source, and is capable of offering expert and consensus opinions and other assistance in matters that relate to gastrointestinal endoscopic technology.

Purpose: To explore and define technology issues that apply to gastrointestinal endoscopy.

Primary intended users: Providers, generally; physicians.

Technologies: Device, medical or surgical procedure.

Interest is focused primarily on the use in clinical practice of emerging and established gastrointestinal endoscopic procedures and other technical procedures that relate to endoscopy. The Society is also concerned with the development and assessment of new instruments and techniques as well as innovative uses of existing methods and instruments.

Intervention: *Diagnosis, treatment*.

Stage: Emerging, new, established or widespread practice, obsolete.

Existing and established endoscopic methods and related instruments are assessed. Emerging procedures and instruments are also assessed, especially those that appear likely to be adopted by large numbers of physicians who use endoscopy.

Properties: *Safety, efficacy, effectiveness*, cost-effectiveness.

Emphasis is on the correct use of endoscopic instruments and techniques with respect to accepted indications and contraindications, safety considerations, effectiveness, and cost-effectiveness, and on training in endoscopic procedures.

Selection process: The ASGE Governing Board directs the activities of the Technology Assessment Committee. In some instances the Board directs that specific questions be reviewed while in other cases, committees may recommend areas for study that they consider important or controversial. The Society solicits the views of its members, usually by means of questionnaires and surveys, to identify problem areas.

All ASGE statements on the use of endoscopic procedures are updated periodically, and out-of-date statements are withdrawn.

Methods: *Group judgment*, information syntheses, expert opinion, cost analyses.

The Society has several assessment procedures, including information gathering and syntheses. In this process, published information is reviewed, the opinions of expert consultants are solicited, and conclusions are formulated by a panel of experienced endoscopists.

The ASGE conducts prospective studies of various problems pertaining to the use of endoscopy in which members submit data according to a protocol. One of the most useful has been the National ASGE Survey on Upper Gastrointestinal Bleeding (Silver-stein FE, et al. *Gastrointest Endosc* 1981;27:73-103) which included the participation of 277 members.

A comprehensive review of a specific technology requires about 9 to 12 months, although this is highly variable and depends on the complexity of the problem.

Assessors: Society members who participate in technology assessment have extensive clinical experience in endoscopy. They are usually acknowledged experts in specific

areas of endoscopy as well as established investigators who have made significant contributions to the field in its technical and clinical aspects.

Assessment reports include: Description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: Printed reports, journal articles.

The conclusions that result from a review process may be formulated as a guideline statement with recommendations directed to Society members and the medical community at large. Statements, recommendations, and reviews are usually published as pamphlets or monographs, which are available free from the Manchester office.

Budget: Not provided. The approximate cost of an assessment, based on the number of meetings to generate a report, is $5,000 to $25,000. A complex review of a broad area or an intricate problem that requires considerable discussion might require greater funding.

Use: The ASGE uses the assessments to promote high standards of practice, patient care, and training in matters that pertain to endoscopy. Although the work of the ASGE as a professional society is primarily directed toward practicing physicians, it is also available to health care institutions, government agencies, certifying bodies, organizations that regulate health care delivery, and virtually any organization with legitimate interests in health care. It is also available to the general public. It is the ASGE's impression that some of these groups have used its reports, but this usage is not tracked.

Related activities: The results and conclusions of investigative work sponsored by the ASGE and relating, at times, to technology assessment are usually presented in open forums such as the plenary session of the Society and in the Society's journal, *Gastrointestinal Endoscopy*.

Completed Reports

AS1 Boyce HW. Treatment of esophageal stenosis. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS2 Fleischer DE. Esophageal cancer: laser treatment. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS3 Jensen DM. Gastrointestinal angiomata: current diagnosis and treatment. In: American society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS4 Johnston JH. Ulcer hemorrhage heater probe treatment. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS5 Kozarek RA. Balloon dilation. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information synthesis, Expert opinion, Group judgment, Cost analyses]

AS6 Mellow MH. Endoscopic laser treatment of colon cancer. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS7 Overholt BF. Ulcer hemorrhage—laser treatment. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS8 Papp JP. Control of upper gastrointestinal bleeding by monopolar electrocoagulation. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS9 Ponsky JL. Percutaneous endoscopic gastrostomy and jejunostomy. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information synthesis, Expert opinion, Group judgment, Cost analyses]

AS10 Protell RL. Ulcer hemorrhage—bicap probe treatment. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information sytheses, Expert opinion, Group judgment, Cost analyses]

AS11 Silvis SE. Endoscopic retrograde sphincterotomy (ERS). In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses; Expert opinion, Group judgment, Cost analyses]

AS12 Sivak MV. Sclerotherapy of esophageal varices. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS13 Wayne JD. Colonoscopic polypectomy. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS14 Webb WA. Esophageal and gastric foreign bodies: endoscopic removal. In: American Society for Gastrointestinal Endoscopy, Committee on Technology Assessment. Therapeutic gastrointestinal endoscopy: an information resource manual. 1987. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

AS15 American Society for Gastrointestinal Endoscopy. Appropriate use of gastrointestinal endoscopy. 1986 Jun.

AS16 _____. Flexible sigmoidoscopy. Revised 1986 Mar.

AS17 _____. Standards of practice for gastrointestinal endoscopy. Revised 1986 Mar.

AS18 _____. Statement of endoscopic training. Revised 1986 Mar.

AS19 _____. The role of colonoscopy in the management of patients with colonic polyps. Revised 1986 May.

AS20 _____. The role of colonoscopy in the patients with inflammatory bowel diseases. Revised 1986 May.

AS21 _____. The role of endoscopy in the management of esophagitis. Revised 1986 Mar.

AS22 _____. The role of endoscopy in the management of the patient with peptic ulcer disease. Revised 1986 Mar.

AS23 _____. The role of endoscopy in the management of upper gastrointestinal hemorrhage. Revised 1986 Mar.

AS24 _____. The role of endoscopy in the patient with lower gastrointestinal bleeding. 1986 May.

AS25 _____. The role of endoscopy in the surveillance of premalignant conditions of the upper gastrointestinal tract. Revised 1986 Mar.

BATTELLE MEMORIAL INSTITUTE

Battelle Human Affairs Research Centers
4000 NE 41 St Street
Seattle, WA 98105
206-525-3130
Battelle Medical Technology Assessment Program
2030 M Street NW
Washington, DC 20036
202-785-8400

Contact: Roger W. Evans, Ph.D., Senior Research Scientist, Human Affairs Research Centers; Bryan R. Luce, Ph.D., Director, Medical Technology Assessment Program.

Overview: The Battelle Memorial Institute is a nonprofit organization devoted to the advancement and use of science and technology. The Battelle Human Affairs Research Centers is a component of the Pacific Northwest Division of Battelle Memorial Institute. Assessments of health care technologies are undertaken by the Health and Population Study Center in Seattle, and by the Medical Technology Assessment Program (MEDTAP) in Washington, DC.

Purpose: To assess medical technologies.

Primary intended uses: General public; patients; providers, generally; physicians; acute facility administrators; health product manufacturers; health/medical professional associations; health industry associations; employers; third party payers; government regulators; reporters, writers, news media; public policy-makers, legislators.

Technologies: *Drug, device*, medical or surgical procedure, support system, organizational or administrative system.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice.

Properties: *Cost-effectiveness*; effectiveness; cost; service requirements; acceptance/adoption level; economic implications; ethical, legal, social implications; health status effects; reimbursement implications.

Selection process: Anyone can request that an assessment be conducted; requests do not follow a specific format. All assessments are done through either a contract or grant. Generally the sponsor, whether it is industry or government, sets assessment topic priorities.

Methods: *Cost analyses*, information syntheses, expert opinion, group judgment, modeling, epidemiological or other observational methods, prospective economic clinical trials/studies, retrospective cost-effectiveness studies, quality of life questionnaires, cost of illness simulation techniques.

The assessment process varies depending upon the issue addressed. The turnaround time from selection of assessment topic to reporting of findings averages 1 year but ranges from 4 months to 3 years.

Assessors: The assessors have expertise in conducting cost effectiveness research, quality of life/health status measurement, and prospective economic clinical studies.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: Printed reports, journal articles.

Copies of assessments may be obtained by writing to: Battelle Human Affairs Research Centers or to Battelle MEDTAP. For the National Heart Transplantation Study and the National Kidney Dialysis and Kidney Transplantation Study, Battelle printed a total of some 80 Update Series reports on various aspects of these major studies. All are available from Battelle; some have been published in journals. Due to agreements with its clients, Battelle MEDTAP is unable to provide a complete list of ongoing assessments.

Budget: $200,000. The cost per assessment ranges from $40,000 to $3,000,000. Funding source: 100 percent private industry contracts.

Use: Most assessments are used for health policy and reimbursement decisions or marketing purposes. The Battelle National Heart Transplant Study was particularly important in assisting the Health Care Financing Administration and the Secretary of the U.S. Department of Health and Human Services in formulating Medicare reimbursement policy.

Battelle's assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Completed Reports

BA1 Luce BR, Ellrodt AG, Camaeron JM, Reidinger M. [Battelle Medical Technology Assessment Program] Managing acute hypertension: cost considerations. Am J Emer Med 1986;6(supplement):31-34. [Cost analyses]

BA2 Health Industry Manufacturers Association. [Battelle Medical Technology Assessment Program] A guide to cost-effectiveness analysis for medical device and diagnostic manufacturers. Washington, D.C.: Health Industry Manufacturers Association, 1985. (HIMA Report Number B5-2, HIMA Research Report Series Number 3). [Cost analyses]

BA3 Battelle Human Affairs Research Centers. National Heart Transplantation Study, Final Report to the Health Care Financing Administration. 1984.

BA4 Battelle Human Affairs Research Centers. National Kidney Dialysis and Kidney Transplantation Study, Final Report submitted to the Health Care Financing Administration. 1984.

Ongoing Assessments

BA5 Battelle Human Affairs Research Centers. Cost-effectiveness of cyclosporine as primary immunosuppressive therapy for kidney transplantation recipients, sponsored by the Health Care Financing Administration. Ongoing.

BA6 Battelle Medical Technology Assessment Program. Cost-effectiveness of the implantable cardiac defibrillator. Ongoing.

BLUE CROSS AND BLUE SHIELD ASSOCIATION MEDICAL NECESSITY PROGRAM

676 North St. Clair Street, 11th Floor
Chicago, IL 60611
312-440-5577

Contact: Susan Gleeson, Executive Director, Technology Management Department; David Tennenbaum, Manager, Medical Necessity Program 312-440-6155.

Overview: The Blue Cross and Blue Shield Association represents member Blue Cross and Blue Shield plans and advises them on health care insurance issues. As an association, it provides medical, financial, and administrative consultation and technical assistance to member plans.

The identification of obsolete procedures by Blue Cross and Blue Shield plans began in 1975 with the California Blue Shield Medical Policy Committee. The Medical Necessity Program was begun in 1976 under the National Association of Blue Shield Plans (which merged in 1978 with the Blue Cross Association to form the Blue Cross and Blue Shield Association), representing one of the first national private initiatives to assess medical technology for coverage purposes. Since its inception, the Program has worked in cooperation with such organizations as the American College of Physicians, the American College of Radiology, and the American College of Surgeons. As a result of its participation in the Medical Necessity Program, the American College of Physicians established the Clinical Efficacy Assessment Project.

Purpose: To provide advice to member Blue Cross and Blue Shield plans on the clinically appropriate uses of existing medical technologies.

Primary intended users: Physicians, medical policy staff, Blue Cross and Blue Shield plans.

Technologies: *Medical or surgical procedure*, device.

Intervention: *Diagnosis*, treatment, rehabilitation.

Stage: *Established or widespread practice*, obsolete.

Properties: *Effectiveness*, efficacy, medical necessity.

Selection process: Blue Cross and Blue Shield plans submit requests for assessments to Program staff. The staff sets assessment topic priorities in consultation with a Medical Advisory Panel comprised of medical directors from selected Blue Cross and Blue Shield plans. Technologies are reassessed when an ongoing review of new clinical evidence suggests this is warranted.

Methods: *Information syntheses*, expert opinion.

The Program commissions experts on the respective assessment topics to develop comprehensive literature review articles. A Medical Necessity Program conference may be held where national medical organization representatives review the commissioned articles. Draft clinical guidelines based on the articles are also reviewed. Final guidelines are then developed by Program staff in consultation with the commissioned experts. Recently, several medical necessity topics have been assessed by the Clinical Efficacy Assessment Subcommittee of the American College of Physicians.

The approximate turnaround time from selection of assessment topic to reporting of findings is 1 year.

Assessors: Both external consultants and internal staff have medical, clinical, and research expertise including data analysis and interpretation.

Assessment reports include: Who conducted the assessment; description of the technology; properties assessed; results; findings or conclusions; recommendations for practice, future assessments, technology development, research.

Dissemination: *Advisories to members/constituents*; printed reports; journal articles; press conferences/news releases, TV/radio broadcasts.

The Association distributes *Medical Necessity Program Guidelines* to Blue Cross and Blue Shield plans. The plans generally publicize the *Guidelines* and distribute them to providers in their service area. *Guidelines* can be obtained from the Association upon request. The literature review articles are published by the authors in medical peer-reviewed journals.

Budget: $350,000. Funding source: 100 percent parent organization.

Use: The literature review articles and *Medical Necessity Guidelines* constitute clinical advice to the plans, which use them in establishing their medical policies. Organizations such as the American College of Physicians have endorsed many Medical Necessity Program products. *Guidelines* are often used by health care institutions' utilization review and quality assurance programs.

The Program is cited in the following documents:

Government Accounting Office. *OPM should promote medical necessity programs for federal employees' health insurance*. 1980 Jul 29.

Greenberg G and Derzon RA. Determining health insurance coverage of technology: problems and options. *Med Care* 1981;19(10):967-78.

Institute of Medicine, Committee for Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Lewin and Associates. *A forward plan for Medicare coverage and technology assessment*. 1986 Dec.

Completed Reports

BC1 Blue Cross and Blue Shield, Medical Necessity Program. Activated partial thromboplastin time and prothrombin time. 1987. [Information syntheses]

BC2 _____. Arterial blood gas analysis. 1987. [Information syntheses]

BC3 _____. Biochemical profiles in ambulatory screening and preadmission testing of adults. 1987. [Information syntheses]

BC4 _____. Blood cultures. 1987. [Information syntheses]
BC5 _____. Blood urea nitrogen concentration and serum creatinine concentration. 1987. [Information syntheses]
BC6 _____. Carcinoembryonic antigen. 1987. [Information syntheses]
BC7 _____. Cardiac enzyme assays in the diagnosis of myocardial infarction. 1987. [Information syntheses]
BC8 _____. Complete blood count and leukocyte differential count. 1987. [Information syntheses]
BC9 _____. Erythrocyte sedimentation rate. 1987. [Information syntheses]
BC10 _____. Routine preoperative and general hospital admission chest x-rays. 1987. [Information syntheses]
BC11 _____. Routine preoperative and general hospital admission electrocardiograms. 1987. [Information syntheses]
BC12 _____. Serum electrolytes and serum osmolality. 1987. [Information syntheses]
BC13 _____. Syphilis tests. 1987. [Information syntheses]
BC14 _____. Throat cultures and rapid test for diagnosing group A streptococcal pharyngitis. 1987. [Information syntheses]
BC15 _____. Urinalysis, urine culture, and other tests in the diagnosis of women with acute dysuria. 1987. [Information syntheses]
BC16 _____. Anticoagulant therapy in the myocardial infarction patient. 1985. [Information syntheses]
BC17 _____. Cardiac exercise stress test. 1985. [Information syntheses]
BC18 _____. Cardiokymography. 1085. [Information syntheses]
BC19 _____. Coronary angiography and cardiac catheterization. 1985. [Information syntheses]
BC20 _____. Doppler flow velocity study. 1985. [Information syntheses]
BC21 _____. Echocardiogram. 1985. [Information syntheses]
BC22 _____. Electrocardiogram. 1985. [Information syntheses]
BC23 _____. Intensive cardiac care unit. 1985. [Information syntheses]
BC24 _____. Outpatient cardiac rehabilitation. 1985. [Information syntheses]
BC25 _____. Permanent cardiac pacemakers. 1985. [Information syntheses]
BC26 _____. Serum lipoprotein evaluation. 1985. [Information syntheses]
BC27 _____. Vectorcardiogram. 1985. [Information syntheses]
BC28 _____. CT scan in the evaluation of headaches, cerebrovascular disease and dementia. 1984. [Information syntheses]
BC29 _____. Chest x-ray examinations. 1984. [Information syntheses]
BC30 _____. Diagnostic imaging in the evaluation of breast disease. 1984. [Information syntheses]
BC31 _____. Head CT scan and ultrasound in the pediatric patient. 1984. [Information syntheses]
BC32 _____. Outmoded radionuclide imaging procedures. 1984. [Information syntheses]
BC33 _____. Radionuclide bone scan and x-ray of bones in the evaluation of bone metastases. 1984. [Information syntheses]
BC34 _____. Radionuclide brain scan in the evaluation of adult intracranial disease. [Information syntheses]
BC35 _____. Ultrasound and x-ray pelvimetry in maternity care. 1984. [Information syntheses]
BC36 _____. Upper gastrointestinal fluoroscopic study. 1984. [Information syntheses]
BC37 _____. Routine admission testing—medical admissions. 1983. [Information syntheses]
BC38 _____. Routine admission testing—surgical admissions. 1983. [Information syntheses]
BC39 _____. Diagnostic studies for respiratory patients: arterial blood gas analysis. 1982. [Information syntheses]
BC40 _____. Diagnostic studies for respiratory patients: pulmonary function tests. 1982. [Information syntheses]
BC41 _____. Oxygen therapy. 1982. [Information syntheses]
BC42 _____. Respiratory therapy: aerosol therapy. 1982. [Information syntheses]
BC43 _____. Respiratory therapy: incentive spirometry. 1982. [Information syntheses]
BC44 _____. Respiratory therapy: intermittent positive pressure breathing. 1982. [Information syntheses]
BC45 _____. Respiratory therapy: postural drainage. 1982. [Information syntheses]

BLUE CROSS AND BLUE SHIELD ASSOCIATION TECHNOLOGY EVALUATION AND COVERAGE PROGRAM

676 North St. Clair, 11th Floor
Chicago, IL 60611
312-440-5577

Contact: Susan Gleeson, Executive Director, Technology Management Department.

Overview: The Blue Cross and Blue Shield Association represents member Blue Cross and Blue Shield plans and advises them on health care insurance issues. As a trade association, it provides medical, financial, and administrative consultation and technical assistance publications. Its Technology Evaluation and Coverage (TEC) Program was formally established in 1985, having evolved from activities originally begun under the National Association of Blue Shield Plans in the late 1960s.

Purpose: To provide advice to member Blue Cross and Blue Shield plans to assist them in determining the eligibility for coverage of new and emerging technologies.

Primary intended users: Blue Cross and Blue Shield plans.

Technologies: Device, medical or surgical procedure, support system.

Intervention: *Treatment*, diagnosis.

Stage: *New*, emerging.

Properties: *Effectiveness*, safety, efficacy, cost, cost-effectiveness, service requirements.

In order to be recommended as eligible for coverage: (1) a technology must have final approval from the appropriate government regulatory agency, e.g., Food and Drug Administration; (2) scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; (3) the technology must improve the net health outcome; (4) the technology must be as beneficial as any established alternative; and (5) the improvement must be attainable outside the investigational settings.

Methods: *Information syntheses*, expert opinion, group judgment, cost analyses.

TEC staff or commissioned experts review and synthesize the published literature. Responses to specific assessment criteria underlie and define the process. A Medical Advisory Panel appointed by the Association monitors the validity of the process and outcome.

Approximate turnaround time from selection of assessment topic to reporting of findings is 3 to 6 months.

Assessors: The Medical Advisory Panel includes seven physicians who are medical directors of Blue Cross and Blue Shield plans, as well as non-voting outside experts. Assessors have expertise in the medical, clinical, ethics, and research fields, including data analysis and interpretation.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; description of the technology; properties assessed;

procedure used for the assessment; sources of data/information; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles.

Dissemination: *Advisories to members/constituents*, printed reports.

Advisory bulletins, newsletters, and reports are distributed to member plans. TEC evaluations are available only from the Blue Cross and Blue Shield Association and are normally made available only to member Blue Cross and Blue Shield plans.

Budget: $600,000. Funding source: 100 percent parent organization.

Use: The Association uses the reports only to provide advice to member plans. The coverage recommendations associated with each report, however, appear to be rapidly communicated among affected providers and other health insurance carriers.

One example of outside use is the citation of the Association's document, *Extracorporeal shock wave lithotripsy: clinical assessments, utilization and cost projects*, May 1985 in a publication issued by the Congressional Office of Technology Assessment: *Effects of federal policies on extracorporeal shock wave lithotripsy*, 1985.

The Program is cited in the following documents:

Greenberg G and Derzon RA. Determining health insurance coverage of technology: problems and options. *Med Care* 1981;19(10):967-78.

Institute of Medicine, Committee for Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Lewin and Associates. *A forward plan for Medicare coverage and technology assessment*. 1986 Dec.

Completed Reports

BS1 Blue Cross and Blue Shield Association, Technology Evaluation and Coverage Program. Absorptiometry, dual photon for osteoporosis monitoring. 1986. [Information syntheses]

BS2 _____. Absorptiometry, single and dual photon. 1986. [Information syntheses]

BS3 _____. Ambulatory uterine monitoring. 1986. [Information syntheses]

BS4 _____. Angelchik antireflux prosthesis. 1986. [Information syntheses]

BS5 _____. Automated and semi-automated ambulatory blood pressure monitoring. 1986. [Information syntheses]

BS6 _____. Automatic implantable cardioverter defibrillator. 1986. [Information syntheses]

BS7 _____. Bone marrow transplantation, allogeneic. 1986. [Information syntheses]

BS8 _____. Bone marrow transplantation, autologous. 1986. [Information syntheses]

BS9 _____. Chorionic villi sampling. 1986. [Information syntheses]

BS10 _____. Collagen implants. 1986. [Information syntheses]

BS11 Continuous arteriovenous hemofiltration. 1986. [Information syntheses]

BS12 _____. Continuous passive motion device. 1986.

BS13 _____ Corneal endothelial cell microscopy. 1986. [Information syntheses]

BS14 _____. Electrical bone growth stimulation. 1986. [Information syntheses]

BS15 _____. Electrical nerve stimulation (implantable spinal cord stimulator). 1986. [Information syntheses]

BS16 _____. Electrical nerve stimulation of the ear. 1986. [Information syntheses]

BS17 _____. Epidural analgesia therapy. 1986. [Information syntheses]

BS18 _____ Epikeratophakia. 1986. [Information syntheses]
BS19 _____. Extracranial-intracranial artery bypass surgery. 1986. [Information syntheses]
BS20 _____. Gastric bubble. 1986. [Information syntheses]
BS21 _____. Home phototherapy for neonatal jaundice. 1986. [Information syntheses]
BS22 _____. Hyperthermia, local. 1986. [Information syntheses]
BS23 _____. Implantable infusion pump. 1986. [Information syntheses]
BS24 _____. In vitro fertilization. 1986. [Information syntheses]
BS25 _____. Iontophoresis. 1986. [Information syntheses]
BS26 _____. Isolated limb perfusion. 1986. [Information syntheses]
BS27 _____. Lacate infusion for panic disorder. 1986. [Information syntheses]
BS28 _____. Nasal continuous positive airway pressure. 1986. [Information syntheses]
BS29 _____. Nd:YAG laser—gastrointestinal bleeding. 1986. [Information syntheses]
BS30 _____. Nd:YAG laser—posterior capsulotomy. 1986. [Information syntheses]
BS31 _____. Nd:YAG laser—tracheo-bronchial obstruction. 1986. [Information syntheses]
BS32 _____. Psoralens and ultraviolet A (PUVA). 1986. [Information syntheses]
BS33 _____. SIDS (home apnea monitoring of siblings). 1986. [Information syntheses]
BS34 _____. Signal averaged ECG. 1986. [Information syntheses]
BS35 _____. Sperm penetration assay. 1986. [Information syntheses]
BS36 _____. Videofluoroscopic evaluation in speech pathology. 1986. [Information syntheses]

BRANDEIS UNIVERSITY HEALTH POLICY CENTER ORGAN PROCUREMENT PROJECT

415 South Street
Waltham, MA 02254
617-736-3900

Contact: Jeffrey Prottas, Senior Research Associate; or Helen Levine Batten, Research Associate.

Overview: The Brandeis University Health Policy Center studies, develops, and demonstrates aspects of national health policy. The Organ Procurement Project first conducted an evaluation of the organ procurement system in 1983. Surveys of key medical professionals, donor families, and the general public were undertaken in 1984-1986. Currently, a study of the causes of failure to transplant organs and a reevaluation of the organ procurement system are in progress.

Purpose: To improve the supply and distribution of cadaveric organs.

Primary intended users: General public; health/medical professional associations; government regulators; public policy-makers, legislators.

Technologies: *Organizational or administrative system*, support system.

Intervention: Administration.

Stage: *Established or widespread practice*, emerging, new.

Properties: *Service requirements*; cost-effectiveness; economic implications; ethical, legal, social implications.

Methods: Epidemiological and other observational methods.

Case studies, survey research, and cost-data analysis are the methods used to conduct assessments. The turnaround time from selection of assessment topic to reporting of findings varies.

Assessors: The assessors have extensive experience and expertise in organ procurement and medical sociology.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: *Printed reports*, journal articles.

Copies of assessment reports are available upon request.

Budget: The budget and cost per assessment varies. Funding source: 100 percent parent organization.

Use: The assessment reports are used to further the development of national health policy.

Completed Reports

BU1 Batten HL, Prottas JM. [Brandeis University, Health Policy Center, Organ Procurement Project] Kind strangers: families of organ donors. Health Affairs, forthcoming. [Epidemiological and other observational methods]

BU2 Prottas JM, Batten HL. [Brandeis University, Health Policy Center, Organ Procurement Project] Attitudes and incentives in organ procurement: report to the Health Care Financing Administration. 1986 Apr. [Epidemiological and other observational methods]

BU3 Prottas JM. [Brandeis University, Health Policy Center, Organ Procurement Project] Organ procurement in Europe and the United States. Milbank Mem Fund Q 1985;63(1):94-126. [Epidemiological and other observational methods]

BU4 Prottas JM. [Brandeis University, Health Policy Center, Organ Procurement Project] The structure and effectiveness of the U.S. procurement system. Inquiry 1985;22(4)365-376. [Epidemiological and other observational methods]

BU5 Prottas JM. [Brandeis University, Health Policy Center, Organ Procurement Project] Encouraging altruisms: public attitudes and the marketing of organ donation. Milbank Mem Fund Q 1983;61:278-2306. [Epidemiological and other observational methods]

BU6 Prottas JM. [Brandeis University, Health Policy Center, Organ Procurement Project] Obtaining replacements: the organizational framework of organ procurement. J Health Polit Policy Law 1983;8(2):235-250. [Epidemiological and other observational methods]

CALIFORNIA MEDICAL ASSOCIATION MEDICAL PRACTICE OPINION PROGRAM

PO Box 7690
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415-863-5522

Contact: Robert Sparacino, Manager, Department of Specialty Sections and Scientific Programs.

Overview: The California Medical Association (CMA) is a not-for-profit, voluntary professional medical association whose members number almost 34,000. Its principal services include legislative advocacy, insurance programs, peer review, financial management, continuing medical education, socioeconomic research and reports, and administration of accreditation and licensing programs for hospitals. The Medical Practice Opinion Program began in 1972 and since its inception, approximately 350 opinions have been issued.

Purpose: To provide CMA's members, its component medical societies, and other interested organizations with objective, authoritative, scientific opinion on questions of medical practice in California. The opinions offered are based on training, experience, and literature reviewed by specialists. The opinions are advisory only and are not intended to be interpreted as directives, instructions, or policy statements. Opinions are always subject to revision as dictated by new information.

Primary intended users: General public; physicians; health/medical professional associations; health industry associations; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations.

Technologies: Drug, device, medical or surgical procedure.

Intervention: Diagnosis, treatment.

Stage: *New*, emerging, established or widespread practice, obsolete.

Properties: Acceptance/adoption level, safety, effectiveness, limitations of use.

Selection process: CMA members, component medical societies, voluntary/professional medical associations, government agencies, third party payers or any other organization with a vital interest in a subject may pose a question for review. Requests must be submitted in writing and include background material that describes the technology in question.

Staff, in collaboration with the chairmen of CMA's 24 advisory panels and the chairman of the Commission on Quality Care Review, set the assessment topic priorities. Topics are generally addressed in the order received. An issue that demands immediate attention is processed promptly.

All opinions are reviewed annually by the appropriate advisory panels and the Commission on Quality Care Review. Some subjects warrant review within that annual interval.

Methods: *Group judgment*, expert opinion, information syntheses.

Following approval of the question by the appropriate advisory panel chairman, staff prepares a questionnaire with background material that typically includes policy or position statements from state/national organizations; testimonials from physicians who are known to be expert in the field; and a selection of recent, pertinent journal articles.

Advisory panel members review the material and submit their opinions individually; these opinions are the foundation of the consensus opinion. Some questions involve more than one panel. Staff prepare the consensus opinion which is subject to the review and approval of the panel chairmen, the panel members and, finally, the Commission on Quality Care Review. Once approved, the opinion is sent to the original inquirer and then published in *The Western Journal of Medicine* , the official scientific publication of California and eight other western state medical associations and five research societies.

The approximate turnaround time from selection of assessment topic to reporting of findings is 4 months. Complex questions involving multiple panels usually take longer.

Assessors: Officers of the state's principal specialty societies, California medical school department chairmen, and representatives of CMA's 24 specialty sections comprise the membership of each advisory panel, which includes an equal number of private practicing physicians and full-time medical school faculty physicians.

Assessment reports include: The purpose of the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; implications of findings for practice; how the technology works, including theory, principles; regulatory agency approval status.

Dissemination: Printed reports; journal articles; advisories to members/constituents.

Copies of medical practice opinions can be obtained by calling or writing the CMA Department of Specialty Sections and Scientific Programs, in the Division of Scientific and Educational Activities.

Budget: $15,000. Funding source: 100 percent sponsors/members dues, contributions.

Use: The CMA provides the opinions to its members and component medical societies as a member service and will share them with persons or organizations outside its immediate membership as a public service.

Generally, health associations, government agencies, and insurance companies most frequently initiate CMA's review of new technologies. The opinions assist these organizations in formulating their own views on the scientific standing of new medical or surgical procedures.

Program evaluation: Internal monitoring of the program is performed by the Commission on Quality Care Review and the Scientific Board's 24 advisory panels. However, no formal evaluation of the program has been conducted.

Completed Reports

CA1 California Medical Association, Medical Practice Opinion Program. Arthroscopic stapling of an unstable shoulder. 1985 Sep. (Medical Practice Opinion #335) [Group judgment]

CA2 _____. Diagnosis of obstructive sleep apnea in children. 1987 Feb. (Medical Practice Opinion #346) [Group judgment]

CA3 _____. Hubbard method of detoxification. 1987 Apr. (Medical Practice Opinion #347) [Group judgment]

CA4 _____. Topographic brain mapping. 1987 Mar. (Medical Practice Opinion #345) [Group judgment]

CA5 _____. Ambulatory monitoring of uterine activity. 1986 Jul. (Medical Practice Opinion #342) [Group judgment]

CA6 _____. Contralateral breast surgery following mastectomy. 1986 Feb. (Medical Practice Opinion #338) [Group judgment]

CA7 _____. Epikeratophakia in children. 1986 Dec. (Medical Practice Opinion #344) [Group judgment]

CA8 _____. Gastric bubble for treatment of obesity. 1986 Aug. (Medical Practice Opinion #343) [Group judgment]

CA9 _____. Hospital admission following rigid esophagoscopy. 1986 Jul. (Medical Practice Opinion #339) [Group judgment]

CA10 _____. Sleep studies for obstructive sleep apnea. 1986 Feb. (Medical Practice Opinion #340) [Group judgment]

CA11 _____. Vertebral artery surgery. 1986 Sep. (Medical Practice Opinion #341) [Group judgment]

CA12 _____. Acoustic impedance testing in school screening. 1985 Sep. (Medical Practice Opinion #325) [Group judgment]

CA13 _____. Anticholinergic drugs for nicotine addiction. 1985 May. (Medical Practice Opinion #322) [Group judgment]

CA14 _____. Assistant surgeon at cataract surgery. 1985 May. (Medical Practice Opinion #324) [Group judgment]

CA15 _____. Assistant surgeon at elective abdominal tubal ligation. 1985 Nov. (Medical Practice Opinion #333) [Group judgment]

CA16 _____. Chorionic villus biopsy. 1985 Sep. (Medical Practice Opinion #328) [Group judgment]

CA17 _____. Cytoxan therapy for multiple sclerosis. 1985 Oct. (Medical Practice Opinion #329) [Group judgment]

CA18 _____. Discography for cervical and lumbar disorders. 1985 Feb. (Medical Practice Opinion #317) [Group judgment]

CA19 _____. Early detection of lung cancer. 1985 Dec. (Medical Practice Opinion #337) [Group judgment]

CA20 _____. Echocine for diagnosis of sinusitis. 1985 Jun. (Medical Practice Opinion #318) [Group judgment]

CA21 _____. Extracorporeal shock-wave lithotripsy. 1985 Sep. (Medical Practice Opinion #32) [Group judgment]

CA22 _____. In vitro fertilization. 1985 Jun. (Medical Practice Opinion #278) [Group judgment]

CA23 _____. Indications for tonsillectomy. 1985 Dec. (Medical Practice Opinion #326) [Group judgment]

CA24 _____. Intraosseous pressure measurement. 1985 Oct. (Medical Practice Opinion #334) [Group judgment]

CA25 _____. Laser irradiation for pain of Charcot-Marie-Tooth disease. 1985 May. (Medical Practice Opinion #321) [Group judgment]

CA26 _____. Laser therapy for plantar warts. 1985 May. (Medical Practice Opinion #320) [Group judgment]

CA27 _____. Magnetic resonance imaging. 1985 Sep. (Medical Practice Opinion #277) [Group judgment]

CA28 _____. Microsurgery in the treatment of infertility. 1985 Aug. (Medical Practice Opinion #308) [Group judgment]

CA29 _____. Neurostimulation for urethral sphincter spasticity. 1985 Dec. (Medical Practice Opinion #336) [Group judgment]

CA30 _____. Permanent eyeliner. 1985 Nov. (Medical Practice Opinion #332) [Group judgment]

CA31 _____. Radial keratotomy for myopia. 1985 Apr. (Medical Practice Opinion #244) [Group judgment]

CA32 _____. Reconsideration of percutaneous and transluminal coronary angioplasty. 1985 Feb. [Group judgment]

CA33 _____. Stereotactic heavy-ion irradiation for arteriovenous malformations. 1985 Sep. (Medical Practice Opinion #316) [Group judgment]

CA34 _____. Suction lipectomy. 1985 Dec. (Medical Practice Opinion #286) [Group judgment]

CA35 _____. Transmission of disease via mouth to mouth resuscitation. 1985 June. (Medical Practice Opinion #323) [Group judgment]

CA36 _____. Treatment of rheumatoid arthritis with flagyl. 1985 Oct. (Medical Practice Opinion #330) [Group judgment]

CA37 _____. Treatment of rheumatoid arthritis with sex hormones. 1985 Oct. (Medical Practice Opinion #331) [Group judgment]

CA38 _____ YAG laser for posterior lens capsules. 1985 Apr. (Medical Practice Opinion #319) [Group judgment]

CA39 _____. Assistant surgeon for arthroscopic procedures. 1984 Apr. (Medical Practice Opinion #239) [Group judgment]

CA40 _____. Assistant surgeon for septorhinoplasty. 1984 Jan. (Medical Practice Opinion #307) [Group judgment]

CA41 _____. Aversion therapy for alcoholism. 1984 Feb. (Medical Practice Opinion #311) [Group judgment]

CA42 _____. Biochemical biopsy. 1984 Nov. (Medical Practice Opinion #285) [Group judgment]

CA43 _____. Cardiac pacemakers. 1984 Mar. (Medical Practice Opinion #291) [Group judgment]

CA44 _____. Computed tomography—multiplanar reconstruction. 1984 Nov. (Medical Practice Opinion #310) [Group judgment]

CA45 _____. Cranial electrotherapy stimulation. 1984 Nov. (Medical Practice Opinion #315) [Group judgment]

CA46 _____. Cytotoxic testing for food allergy. 1984 Feb. (Medical Practice Opinion #265) [Group judgment]

CA47 _____. Heart-lung transplantation. 1984 Sep. (Medical Practice Opinion #309) [Group judgment]

CA48 _____. Immunotherapy for melanoma. 1984 Feb. (Medical Practice Opinion #305) [Group judgment]

CA49 _____. Immunotherapy for treatment of cancer. 1984 Jul. (Medical Practice Opinion #204) [Group judgment]

CA50 _____. Intradermal provocative titration/diagnosis of food allergy. 1984 Feb. (Medical Practice Opinion #293) [Group judgment]

CA51 _____. Kinetic therapy for lumbago. 1984 Nov. (Medical Practice Opinion #312) [Group judgment]

CA52 _____. Radioallergosorbent test (RAST) 1984 Dec. (Medical Practice Opinion #255) [Group judgment]

CA53 _____. Rinkel serial intracutaneous titration/diagnosis. 1984 Feb. (Medical Practice Opinion #295) [Group judgment]

CA54 _____. Sublingual challenge technique/diagnosis of food allergy. 1984 Feb. (Medical Practice Opinion #294) [Group judgment]

CA55 _____. Temporomandibular joint procedure. 1984 Feb. (Medical Practice Opinion #270) [Group judgment]

CA56 _____. Tuberculosis surveillance program for hospital employees. 1984 Oct. (Medical Practice Opinion #304) [Group judgment]

CA57 _____. Use of sclerosant injections for neck, back and lower extremity pain. (Medical Practice Opinion #313) [Group judgment]

CA58 _____. Video electroencephalographic monitoring. 1984 Nov. (Medical Practice Opinion #314) [Group judgment]

CA59 _____. Barbiturate coma. 1983 Feb. (Medical Practice Opinion #280) [Group judgment]

CA60 _____. Bilio-pancreatic bypass surgery for obesity. 1983 Mar. (Medical Practice Opinion #284) [Group judgment]

CA61 _____. Biofeedback. 1983 Aug. (Medical Practice Opinion #240) [Group judgment]

CA62 _____. Collagen implant. 1983 Apr. (Medical Practice Opinion #283) [Group judgment]

CA63 _____. Computerized tomography for lumbar spine. Feb 1983. (Medical Practice Opinion #282) [Group judgment]

CA64 _____. Continuous passive motion for stiffening conditions. 1983 Mar. (Medical Practice Opinion #306) [Group judgment]

CA65 _____. Endothelial cell counts. 1983 Sep. (Medical Practice Opinion #303) [Group judgment]

CA66 _____. Ericsson sex selection method. 1983 Sep. (Medical Practice Opinion #298) [Group judgment]

CA67 _____. Hyperbaric oxygen therapy. 1983 Sep. (Medical Practice Opinion #243) [Group judgment]

CA68 _____. Hyperthermia treatment for cancer. 1983 Oct. (Medical Practice Opinion #296) [Group judgment]

CA69 _____. Interferon for the treatment of cancer. 1983 Sep. (Medical Practice Opinion #299) [Group judgment]

CA70 _____. Interferon for the treatment of infectious diseases. 1983 Sep. (Medical Practice Opinion #300) [Group judgment]

CA71 _____. Intravenous streptokinase after myocardial infarction. 1983 June. (Medical Practice Opinion #287) [Group judgment]

CA72 _____. Laser photoradiation therapy for carcinoma. 1983 Feb. (Medical Practice Opinion #279) [Group judgment]

CA73 _____. Liver transplantation. 1983 Sep. (Medical Practice Opinion #297) [Group judgment]

CA74 _____. Nissen's fundoplication—gastric reservoir reduction for morbid obesity. 1983 May. (Medical Practice Opinion #290) [Group judgment]

CA75 _____. Noninvasive muscle stimulators for prevention of muscle atrophy. 1983 Jul. (Medical Practice Opinion #292) [Group judgment]

CA76 _____. Palatopharyngoplasty for the treatment of snoring. 1983 Dec. (Medical Practice Opinion #301) [Group judgment]

CA77 _____. Rectal mucosal replacement. 1983 Nov. (Medical Practice Opinion #288) [Group judgment]

CA78 _____. Stapedectomy for otosclerosis. 1983 Sep. (Medical Practice Opinion #302) [Group judgment]

CA79 _____. Thrombolytic therapy for pulmonary embolism. 1983 Feb. (Medical Practice Opinion #281) [Group judgment]

CA80 _____. Assistant surgeon for laser iridotomy. 1982 Jul. (Medical Practice Opinion #272) [Group judgment]

CA81 _____. Bone densitometry. 1982 Nov. (Medical Practice Opinion #254) [Group judgment]

CA82 _____. Challenge food testing for depression. 1982 Feb. (Medical Practice Opinion #257b) [Group judgment]

CA83 _____. Challenge food testing for respiratory disorders. 1982 Feb. (Medical Practice Opinion #257c) [Group judgment]

CA84 _____. Challenge food testing for rheumatoid arthritis. 1982 Feb. (Medical Practice Opinion #257a) [Group judgment]

CA85 _____. Constant blood pressure monitoring. 1982 Aug. (Medical Practice Opinion #275) [Group judgment]

CA86 _____. Human tumor stem cell assay. 1982 Jul. (Medical Practice Opinion #273) [Group judgment]

CA87 _____. Intraarterial BCNU chemotherapy. 1982 Oct. (Medical Practice Opinion #276) [Group judgment]

CA88 _____. Methylethylketone damage of the immune system. 1982 Nov. (Medical Practice Opinion #261) [Group judgment]

CA89 _____. Needleless insulin injection. 1982 Dec. (Medical Practice Opinion #274) [Group judgment]

CA90 _____. Plasmapheresis for rheumatoid arthritis. 1982 Aug. (Medical Practice Opinion #263) [Group judgment]

CA91 _____. Plasmapheresis for six conditions. 1982 Sep. (Medical Practice Opinion #249) [Group judgment]

CA92 _____. Sleep disorder therapy. 1982 Dec. (Medical Practice Opinion #271) [Group judgment]

CA93 _____. Thermography for spinal problems. 1982 Jul. (Medical Practice Opinion #269) [Group judgment]

CA94 _____. Transcutaneous electrical nerve stimulation. 1982 Jul. (Medical Practice Opinion #82) [Group judgment]

CA95 _____. Viral and bacterial vaccines for arthritis. 1982 Jun. (Medical Practice Opinion #268) [Group judgment]

CA96 _____. Anesthesia by hypnosis. 1981 Aug. (Medical Practice Opinion #250) [Group judgment]

CA97 _____. Cochlear implant for deafness. 1981 Aug. (Medical Practice Opinion #178) [Group judgment]

CA98 _____. DMSO. 1981 Jan. (Medical Practice Opinion #248) [Group judgment]

CA99 _____. Esterine for treatment of rheumatoid arthritis. 1981 Dec. (Medical Practice Opinion #253) [Group judgment]

CA100 _____. Heart transplants. 1981 Dec. (Medical Practice Opinion #252) [Group judgment]

CA101 _____. High gastric bypass for morbid obesity. 1981 Feb. (Medical Practice Opinion #246) [Group judgment]

CA102 _____. Intermittent positive pressure breathing. 1981 Aug. (Medical Practice Opinion #259) [Group judgment]

CA103 _____. Paper radioallergosorbent test (PRAST) 1981 Aug. (Medical Practice Opinion #256) [Group judgment]

CA104 _____. Plasmapheresis treatment of multiple sclerosis. 1981 Dec. (Medical Practice Opinion #212) [Group judgment]

CA105 _____. Singer-Blom valve operation. 1981 Jul. (Medical Practice Opinion #262) [Group judgment]

CA106 _____. Stat-tek glucose analyzer for diabetes. 1981 Aug. (Medical Practice Opinion #260) [Group judgment]

CA107 _____. Clinical ecology. 1980 Dec. (Medical Practice Opinion #264) [Group judgment]
CA108 _____. Injections of universal bacterial antigen. 1980 Jan. (Medical Practice Opinion #210) [Group judgment]
CA109 _____. Microsurgical lumbar discectomy. 1980 Feb. (Medical Practice Opinion #238) [Group judgment]

CBO (CENTRAAL BEGELEIDINGSORGAAN VOOR DE INTERCOLLEGIALE TOETSING) NATIONAL ORGANIZATION FOR QUALITY ASSURANCE IN HOSPITALS CONSENSUS DEVELOPMENT PROGRAM

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Overview: CBO is an independent foundation established in 1979 by the National Specialists Organization in the Netherlands and the Dutch Association of Medical Directors of Hospitals. The Board of Trustees consists of representatives of those organizations, the National Hospital Association, the Society of Dutch Sick Funds, the Society of Private Insurance Companies, the Royal Netherlands Medical Association, and the Ministry of Welfare, Health and Culture. CBO is a World Health Organization Collaborating Center for Quality Assurance in Health Care. This profile describes the CBO consensus development program.

Purpose: To develop statements that facilitate a uniform approach among hospital clinicians in dealing with patient problems of national concern.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators.

Technologies: *Medical or surgical procedure*.

Intervention: *Diagnosis, treatment*, prevention, rehabilitation.

Stage: *Established or widespread practice*.

Properties: *Safety, effectiveness*, service requirements, acceptance/adoption level.

Selection process: CBO selects the assessment topics from suggestions made by the hospitals. Topics may be reassessed when consensus statements are out of date, e.g., are 5 or more years old, or when the findings of consensus efforts are inconclusive. Blood transfusion therapy is the first topic to be reassessed.

Methods: *Group judgment, expert opinion*.

Panels consisting of 6 to 20 experts are given 6 to 18 months to produce a draft consensus report. The draft report contains 2- to 4-page papers individually authored by the panelists and a draft consensus statement consisting of as many as 30 numbered statements on the topic generated by the panelists. The report is put into a booklet and

circulated to a larger group of health care workers interested in the topic. This larger group—usually between 100 to 150 people, but sometimes more—convenes for a 1-day meeting to review the draft report with the panelists. Following this meeting, the panel completes a final consensus statement in narrative form.

Assessors: Consensus panels are usually composed of physician specialists relevant to the topic (e.g., neurosurgeons, radiologists, and dermatologists); a few panels have included other types of personnel (e.g., laboratory technicians for blood transfusion therapy panel, nurses for treatment of bedsores panel, and epidemiologists for follow-up colorectal cancer panel).

Assessment reports include: The first five assessment reports appeared in narrative form only. All subsequent statements have appeared first as draft statements in booklet form that include table of contents, list of participants, introductory paragraph, the short papers individually authored by the panelists, and the draft numbered consensus statements. The final statements are narratives distilled from the draft booklets. Final statements may reflect disagreements among panel members.

Dissemination: The draft consensus statements in booklet form and the final statements are available from the CBO. The final statements are also published approximately 1 year following their release in the *Netherlands Tydschrift voor Geneeskunde* (Dutch Journal of Medicine). Only one report, on melanoma of the skin (1984) has been translated into English; all others are in Dutch.

Budget: The entire CBO budget is approximately $900,000, some $135,000 of which is devoted to consensus activities. CBO is funded from levies applied to Dutch hospitals based on their number of beds.

Use: CBO has attempted to gauge the impact of some consensus statements. CBO staff have worked with hospital quality assurance committees to determine whether consensus guidelines on melanoma of the skin and blood transfusion therapy have been incorporated into quality assurance criteria and practices.

Related activities: CBO is devoted to enhancing quality assurance in Dutch hospitals. It assesses and works to improve the quality of procedures in specific hospitals, assists in setting criteria for quality assurance, and provides a second-opinion service. CBO also offers assistance to other organizations in assessing new technologies, developing information systems, and developing clinical protocols. Because of statutory limitations, CBO is not engaged in research.

Completed Reports

CB1 CBO (Centraal Begeleidingsorgaan voor de Intercollegiale Toetsing) Consensus Development Program. Diagnosis of atopic syndrome. 1987. [Dutch language only] [Group judgment, Expert opinion]

CB2 _____. Follow-up colorectal cancer. 1087. [Dutch language only] [Group judgment, Expert opinion]

CB3 _____. Hemophilia. 1987. [Dutch language only] [Group judgment, Expert opinion]

CB4 _____. Hypercholesterolemia. 1987. [Dutch language only] [Group judgment, Expert opinion]

CB5 _____. Prevention of herpes neonatorum. 1987. [Dutch language only] [Group judgment, Expert opinion]

CB6 _____. Suspect lymph nodules in the neck. 1987. [Dutch language only] [Group judgment, Expert opinion]

CB7 _____. Total hip prostheses. 1987. [Dutch language only] [Group judgment, Expert opinion]
CB8 _____. Diagnosis of deep venous thrombosis. 1986. [Dutch language only] [Group judgment, Expert opinion]
CB9 _____. Non-scrotal testis. 1986. [Dutch language only] [Group judgment, Expert opinion]
CB10 _____. Treatment of bedsores. 1986. [Dutch language only] [Group judgment, Expert opinion]
CB11 _____. Foot problems of diabetic patients. 1985. [Dutch language only] [Group judgment, Expert opinion]
CB12 _____. Osteoporosis. 1985. [Dutch language only] [Group judgment, Expert opinion]
CB13 _____. Prevention of bedsores. 1985. [Dutch language only] [Group judgment, Expert opinion]
CB14 _____. Solid solitary thyroid nodule. 1985. [Dutch language only] [Group judgment, Expert opinion]
CB15 _____. Melanoma of the skin. 1984. [Group judgment, Expert opinon]
CB16 _____. Severe brain damage. 1984. [Dutch language only] [Group judgment, Expert opinion]
CB17 _____. Thrombocytes transfusion policy. 1984. [Dutch language only] [Group judgment, Expert opinion]
CB18 _____. Mammography policy. 1983. [Dutch language only] [Group judgment, Expert opinion]
CB19 _____. Traumatic lesions of the back. 1983. [Dutch language only] [Group judgment, Expert opinion]
CB20 _____. Blood transfusion therapy. 1982. [Dutch language only] [Group judgment, Expert opinion]

COLLEGE OF AMERICAN PATHOLOGISTS SURVEYS PROGRAM

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Contact: William E. Williamson, Director Laboratory Improvement Programs.

Overview: The College of American Pathologists is a professional association dedicated to serving the needs of its members in the fields of pathology, medicine, and patient care. With over 10,000 members, its services include periodicals, educational programs, Professional Affairs Assistance, and other programs.

The College's Surveys Program is an ongoing assessment of laboratory technology that provides subscribing laboratories with an evaluation of their own accuracy and precision. This Program began with circulation of samples to assess the technology in limited areas of clinical chemistry and hematology. Over the past 25 years the program has grown to over 50 surveys, assessing the technology of virtually all areas of laboratory medicine. The program currently provides technology assessment information to over 12,000 participating laboratories in the United States and several foreign countries.

Purpose: To assess laboratory technology and to provide individual subscribing laboratories with these assessments as well as evaluations of their own accuracy and precision.

Primary intended users: Labs, blood banks.

Technologies: *Device*, medical or surgical procedure, support system.

Laboratory methods, systems, and instrument performance are assessed.

Intervention: *Diagnosis*, treatment.

Stage: *Established or widespread practice*, new, obsolete.

Properties: Safety, effectiveness, acceptance/adoption level.

The Program assesses the laboratories for safety and effectiveness with respect to accuracy and precision of results. Based on performance, assessments provide mechanisms for determining acceptance and level of technology.

Selection process: Any medical laboratory may request that an assessment of its performance be conducted and compared with its peers. Since this is a voluntary program, laboratories need only to subscribe to the surveys in which they wish to participate. Assessment topics are determined and prioritized by CAP committees of experts in the laboratory discipline involved in the technology assessment.

Methods: Bench testing.

Unknown simulated patient samples (e.g., blood products, spinal fluid, urine) are sent quarterly to participating laboratories. Laboratories are given a certain amount of time to analyze samples for specified constituents and return data for computer analysis of performance.

Selection of assessment topics (simulated patient sample content) is determined 18 months prior to the surveys. However, the actual turnaround time for the assessment process, from the standpoint of the participant, is approximately 8 weeks from receipt of samples for analysis to reporting of findings.

Assessors: The expert committees that operate the various assessment programs are made up of pathologists and doctoral scientists with expertise in the given area of technology assessment.

Assessment reports include: The assessment's intended audience; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; where technology is in use.

Dissemination: *Printed reports*, journal articles, advisories to members/constituents.

Assessment products include CAP Surveys Program quarterly summary reports, CAP conference proceedings, articles in *Archives of Pathology and Laboratory Medicine* and the quarterly CAP newsletter, *Summing Up*. The summary reports are mailed to participating laboratories listing their own results and summarizing the results of all participants.

Generally, summary reports are available only to participants. Conference proceedings and *Summing Up* can be purchased from CAP. Selected studies are published in the scientific literature.

Budget: $15,000,000. Funding source: 85 percent sponsors/members dues, contributions; 15 percent parent organization.

Use: The CAP uses the assessments to monitor the state of the art. Members of the expert committees also use the assessments as the basis for articles in professional journals.

Scientific professionals may use the reports for the noncommercial purpose of scientific or educational advancement as defined in the CAP copyright. Generally permission is requested prior to publication. Government and regulatory agencies also use the results to establish compliance and regulatory requirements.

Program evaluation: Various Federal agencies assess the Program to determine compliance with Federal Equivalency Requirements.

The CAP evaluated the Surveys Program in 1981 as the result of a database conference it sponsored that was attended by representatives of clinical laboratories, the diagnostic industry, and government. The conference participants requested the evaluation because they regarded the CAP database as an important resource for the advancement of technology in the clinical laboratory field.

The College funded the evaluation, which consisted of compiling data from its clinical laboratory improvement programs for the years 1970 to 1980. The resulting compendium, *Data ReCap 1970-1980: A Compilation of Data from the College of American Pathologists Clinical Laboratory Improvement Program*, was published in 1981 and documented laboratory performance over the decade and the state of the art in 1980.

Related activities: The quarterly newsletter *Summing Up* highlights various areas of technology assessment based upon the surveys performance. Annual conferences are sponsored by the various expert committees of the Surveys Program which, based upon the technology assessments, focus on the relevance of clinical laboratory testing to patient care. These conferences periodically review and redefine analytical goals based upon the performance assessments of the Surveys Program. As new specialized technologies emerge, new committees are formed to monitor and assess performance.

Completed Reports

CP1 Howanitz PJ, ed. Quality assurance in physician office, bedside, and home testing. Skokie, IL: College of American Pathologists. Expected 1987. [Expert opinion, Bench testing]

CP2 Triplett DA, ed. Advances in coagulation testing: interpretation and application. Skokie, IL: College of American Pathologists. Expected 1987. [Expert opinion, Bench testing]

CP3 Smith JW, ed. The role of clinical microbiology in cost-effective health care. CAP Conference/1984. Skokie, IL: College of American Pathologists, 1985. [Expert opinion, Bench testing]

CP4 Rippey JH, Nakamura RM, eds. Diagnostic immunology: technology assessment and quality assurance. CAP Conference/1983. Skokie, IL: College of American Pathologists, 1984. [Expert opinion, Bench testing]

CP5 Homburger HA, ed. Clinical and analytical concepts in enzymology. CAP Conference/1982. Skokie, IL: College of American Pathologists, 1983. [Expert opinion, Bench testing]

CP6 Polesky HF, Walker RH, eds. Safety in transfusion practices. CAP Conference/Aspen 1980. Skokie, IL: College of American Pathologists, 1981. [Expert opinion, Bench testing]

CP7 Sommers HM, ed. Clinical relevance in microbiology. CAP Conference/Aspen 1979. Skokie, IL: College of American Pathologists, 1981. [Expert opinion, Bench testing]

CP8 Triplett DA, ed. Standardization of coagulation assays: an overview. CAP Conference/Aspen 1980. Skokie, IL: College of American Pathologists, 1981. [Expert opinion, Bench testing]

CP9 Keitagaes PW, Nakamura RM, eds. Diagnostic immunology: current and future trends. CAP Conference/Aspen 1978. Skokie, IL: College of American Pathologists, 1980. [Expert opinion, Bench testing]

CP10 Koepke JA, ed. Differential leukocyte counting. CAP Conference/Aspen 1977. Skokie, IL: College of American Pathologists, 1978. [Expert opinion, Bench testing]

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT HEALTH PROGRAM

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202-228-6590

Contact: Clyde J. Behney, Program Manager for Health.

Overview: The Office of Technology Assessment (OTA) is a nonpartisan analytical support agency that serves the U.S. Congress. The Office was authorized in 1972, funded in late 1973, and began full operations in 1974. The Health Program was established in 1975.

OTA has three operating divisions: the Energy, Materials, and International Security Division; the Science, Information and Natural Resources Division; and the Health and Life Sciences Division. Within the Health and Life Sciences Division are three programs: the Food and Renewable Resources Program; the Biological Applications Program; and the Health Program. This profile deals primarily with assessment activities of the Health Program.

OTA is governed by a 12-member bipartisan Congressional board of six senators and six representatives. The board is advised by an Advisory Council of 10 public members eminent in science, technology, and education, appointed by the board. The Comptroller General of the United States and the director of the Congressional Research Service of the Library of Congress are also members. The OTA director is appointed by the board and serves as a nonvoting member.

Purpose: To help Congress anticipate and plan for the consequences of technological applications, and to examine the ways, expected and unexpected, in which technology affects people's lives. The OTA clarifies for Congress both the range of policy options and the potential impacts of adopting each option, but it makes no formal recommendations. The OTA also provides advice to Congressional committee members and staff, presents testimony at hearings, and conducts workshops with committees. Although the OTA is responsible to the needs of the Congress and its products are designed for use by the Congress, they have a wider applicability as well.

Primary intended users: Legislators, government regulators, public policy-makers.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system, personnel.

The OTA focuses its evaluation efforts on broad policy technological issues or on case studies from which further research questions or generalizable lessons can be gained.

Intervention: Prevention, diagnosis, treatment, rehabilitation.

Stage: *New, established or widespread practice*, emerging, obsolete.

Properties: *Safety; efficacy; cost-effectiveness*; effectiveness; cost; acceptance/adoption level; system impact; economic implications; ethical, legal, social implications.

The scope of OTA assessments is quite broad, reflecting the extent to which legislative policy issues are influenced by technological developments.

Selection process: Under OTA statute, studies may be initiated by a request from a Congressional committee chairman. The OTA will also respond formally to requests for information from any member of Congress or any Congressional committee. OTA staff members screen the proposed study to determine what resources and time it might require and what modifications it might need to suit the OTA's resources and Congressional needs. The staff then presents a formal study proposal to the OTA Board, which makes the final decision on whether to undertake it.

Methods: *Information syntheses*, expert opinion, modeling, cost analysis.

The OTA generally does not support original research, but synthesizes existing knowledge from the medical and health policy literature with the help of expert advisors.

The OTA staff develops an initial draft with advice from an expert advisory panel appointed for each main report. The draft is then circulated for review and comment to groups and experts both in the government and in the private sector. Advisory panel assistance includes review and comment, although its consensus is not sought for report content or findings and reports are not formally approved by the panel. OTA staff are responsible for drafting the final report. Case studies of specific technologies have been used often in conjunction with reports dealing with broad issues such as studies of cost-effectiveness and cost-benefit analyses of technologies. Such case studies usually are prepared by experts under commissions from the OTA and occasionally by OTA staff.

The bulk of OTA's work involves comprehensive, in-depth assessments that may take 18 months or more to complete. It is also provides shorter responses to meet Congressional needs, largely based on information in past and current assessments. OTA can structure longer-range assessments so that the results, in various stages, can be sent to Congress in the form of interim reports.

Assessors: OTA multidisciplinary staff teams plan, direct, and draft all assessments. Staff members have expertise in such areas as medicine, law, sociology, epidemiology, statistics, public health, public policy, and biology. The Health Program has about 13 permanent staff and 12 to 14 other in-house staff on temporary appointments. Outside contract work is usually for special material to be included in OTA reports. OTA uses expert advisory panels as a way of ensuring that reports are objective, fair, and authoritative. The Health Program is advised regarding overall planning by a standing 15-member Health Program Advisory Committee composed of experts in a variety of fields relevant to health care technology assessment. This committee generally is not involved directly in specific studies. The staff rely extensively on the broad technical and professional resources of the private sector, including universities, research organizations, industry, and public interest groups.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/ supported the assessment; who conducted the assessment; description of the technology; stage of lifecycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; where technology is in use.

Dissemination: *Printed reports*; journal articles; press conferences/news releases; TV/ radio broadcasts, video products; briefings to Congressional committees and staff.

Reports approved by the OTA Director are sent to the Technology Assessment Board and to the requesting Congressional committee(s). Summaries are also sent to all members of Congress and then the report and summary are released to the public. Summaries of all OTA reports are available free of charge from the OTA. OTA studies are also available from the U.S. Government Printing Office or the National Technical Information Service.

Budget: $1.6 million (fiscal year 1987). The approximate cost per assessment is $400,000 to $700,000. Funding source: 100 percent parent organization.

Use: OTA reports have generally been well-received by Congress and the various sectors of the health care industry. Because of the nature of congressional decisions, it is difficult to attribute legislative change or other congressional actions to any one factor. However, in several instances Congress has based funding and policy decisions on OTA report findings.

The OTA Health Program is described in: Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Related activities: The OTA was mandated by Congress to select and appoint the members of the Prospective Payment Assessment Commission (ProPAC), which advises the Secretary of DHHS regarding the hospital prospective payment system used for Medicare. The OTA acts as an observer and evaluator of ProPAC, reports annually to Congress on the functioning of the Commission, and appoints replacement commissioners each year. The OTA has similar responsibilities for the Physician Payment Review Commission.

Completed Reports

CU1 Congress of the United States, Office of Technology Assessment. Assessing the quality of medical care. Washington, D.C.: U.S. Government Printing Office. To be completed in Spring 1988.

CU2 _____. Diagnostic and predictive medical tests. Washington, D.C.: U.S. Government Printing Office. To be completed in Spring 1988.

CU3 _____. Drug labeling in developing countries. Washington, D.C.: U.S. Government Printing Office. To be completed in Winter 1988/89.

CU4 _____. Nontraditional methods of cancer management. Washington, D.C.: U.S. Government Printing Office. To be completed in Summer 1988.

CU5 _____. Carcinogen regulatory policy. Washington, D.C.: U.S. Government Printing Office. To be completed Spring 1987.

CU6 _____. Clinical staffing issues in the Indian Health Service. Washington, D.C.: Office of Technology Assessment. Special report. To be released in Spring 1987.

CU7 _____. Effectiveness and costs of ambulatory tocodynamometry. Washington, D.C.: U.S. Government Printing Office. To be completed in Spring 1987.

CU8 _____. Immuno-augmentative therapy. Washington, D.C.: U.S. Government Printing Office. To be completed in Winter 1987/1988.

CU9 _____. Mammography screening for the Medicare population. Washington, D.C.: Office of Technology Assessment. To be completed in Summer 1987.

CU10 _____. Mental health services for children. Washington, D.C.: U.S. Government Printing Office, January 1987.

CU11 _____. Review of study comparing inpatient hospital costs in the Veterans Administration to those in non-VA facilities. Washington, D.C.: Office of Technology Assessment. To be completed in February 1987.

CU12 _____. Technology and child health. Washington, D.C.: U.S. Government Printing Office. To be completed in Spring 1987.

CU13 _____. Extracorporeal shock-wave lithotripsy. Washington, D.C.: U.S. Government Printing Office, May 1986. (Health technology case study series #36)

CU14 _____. Indian health care. Washington, D.C.: U.S. Government Printing Office, April 1986.

CU15 _____. Nurse practitioners, certified nurse-midwives, and assistants: a policy analysis. Washington, D.C.: U.S. Government Printing Office, December 1986. (Health technology case study series #37)

CU16 _____. OTA's second report on the Prospective Payment Assessment Commission (special report). Washington, D.C.: Office of Technology Assessment, March 1986.

CU17 _____. Passive smoking in the workplace: selected issues. Washington, D.C.: Office of Technology Assessment, May 1986.

CU18 _____. Payment for physician services: strategies for Medicare. Washington, D.C.: U.S. Government Printing Office, February 1986.

CU19 _____. Technologies for detecting heritable mutations in human beings. Washington, D.C.: U.S. Government Printing Office, September 1986.

CU20 _____. Blood policy and technology. Washington, D.C.: U.S. Government Printing Office, January 1985.

CU21 _____. Evaluation of HCFA's Part A data base. Washington, D.C.: Office of Technology Assessment, July 1985.

CU22 _____. Medical devices and the Veterans Administration. Washington, D.C.: U.S. Government Printing Office, February 1985.

CU23 _____. Medicare's prospective payment system: strategies for evaluating cost, quality, and medical technology. Washington, D.C.: U.S. Government Printing Office, October 1985.

CU24 _____. OTA's first report on the Prospective Payment Assessment Commission (special report). Washington, D.C.: Office of Technology Assessment, March 1985.

CU25 _____. Preventing illness and injury in the workplace. Washington, D.C.: U.S. Government Printing Office, April 1985.

CU26 _____. Replacing the Rosebud Sioux Hospital: number of beds and whether a surgical suite is needed. Washington, D.C.: Office of Technology Assessment, August 1985.

CU27 _____. Review of the Public Health Service's response to AIDS. Washington, D.C.: U.S. Government Printing Office, February 1985.

CU28 _____. Status of biomedical research and related technology for tropical diseases. Washington, D.C.: U.S. Government Printing Office, September 1985.

CU29 _____. Technologies for managing urinary incontinence. Washington, D.C.: U.S. Government Printing Office, July 1985. (Health technology case study series #33)

CU30 _____. The cost effectiveness of digital subtraction angiography in the detection of cerebrovascular disease. Washington, D.C.: U.S. Government Printing Office, May 1985. (Health technology case study series #34)

CU31 _____. The effectiveness and costs of continuous ambulatory peritoneal dialysis. Washington, D.C.: U.S. Government Printing Office, September 1985. (Health technology case study series #35)

CU32 _____ The hemodialysis equipment and disposables industry. Washington, D.C.: U.S. Government Printing Office, December 1984. (Health technology case study series #32)

CU33 _____. Federal policies and the medical devices industry. Washington, D.C.: U.S. Government Printing Office, October 1984.

CU34 _____. Intensive care units: costs, outcome, and decisionmaking. Washington, D.C.: U.S. Government Printing Office, October 1984. (Health technology case study series #28)

CU35 _____. Medical technology and costs of the Medicare program. Washington, D.C.: U.S. Government Printing Office, July 1984.

CU36 _____. Nuclear magnetic resonance imaging technology: a clinical, industrial, and policy analysis. Washington, D.C.: U.S. Government Printing Office, September 1984. (Health technology case study series #27)

CU37 _____. The Boston elbow. Washington, D.C.: U.S. Government Printing Office, November 1984. (Health technology case study series #29)

CU38 _____. The contact lens industry. Washington, D.C.: U.S. Government Printing Office, December 1984 (Health technology case study series #31)

CU39 _____. The health effects of fish oil. Washington, D.C.: Office of Technology Assessment, February 1984.

CU40 _____. The market for wheelchairs: innovations and public policy. Washington, D.C.: U.S. Government Printing Office, November 1984. (Health technology case study series #30)

CU41 _____. The use of immunosuppressive drugs in kidney transplantation. Washington, D.C.: Office of Technology Assessment, March 1984.

CU42 _____. Update of Federal activities regarding the use of pneumococcal vaccine. Washington, D.C.: U.S. Government Printing Office, May 1984.

CU43 _____. Assistive devices for severe speech impairments. Washington, D.C.: U.S. Government Printing Office, December 1983. (Health technology case study series #26)

CU44 _____. Diagnosis-related groups (DRGs) and the Medicare program: implications for medical technology, Washington, D.C.: U.S. Government Printing Office, July 1983.

CU45 _____. Quality and relevance of research and related activities at the Gorgas Memorial Laboratory. Washington, D.C.: U.S. Government Printing Office, August 1983.

CU46 _____Technology and learning disabilities. Washington, D.C.: U.S. Government Printing Office, December 1983. (Health technology case study series #25)

CU47 _____. The effectiveness and costs of alcoholism treatment. Washington, D.C.: U.S. Government Printing Office, March 1983. (Health technology case study series #22)

CU48 _____. The impact of randomized clinical trials on health policy and medical practice. Washington, D.C.: U.S. Government Printing Office, August 1983.

CU49 _____. The safety, efficacy, and cost effectiveness of therapeutic apheresis. Washington, D.C.: U.S. Government Printing Office, July 1983. (Health technology case study series #23)

CU50 _____. Variations in hospital length of stay: their relationships to health outcomes. Washington, D.C.: U.S. Government Printing Office, August 1983. (Health technology case study series #24)

CU51 _____. Assessment of four common X-ray procedures. Washington, D.C.: U.S. Government Printing Office, April 1982. (Health technology case study series # 19)

CU52 _____. Cardiac radionuclide imaging and cost-effectiveness. Washington, D.C.: U.S. Government Printing Office, May 1982. (Health technology case study series #13)

CU53 _____. MEDLARS and health information policy. Washington, D.C.: U.S. Government Printing Office, September 1982.

CU54 _____. Mandatory passive restraint systems in automobiles. Washington, D.C.: U.S. Government Printing Office, September 1982. (Health technology case study series #20)

CU55 _____. Medical technology under proposals to increase competition in health care. Washington, D.C.: U.S. Government Printing Office, October 1982.

CU56 _____. Postmarketing surveillance of prescription drugs. Washington, D.C.: U.S. Government Printing Office, November 1982.

CU57 _____. Selected telecommunications devices for hearing-impaired persons. Washington, D.C.: U.S. Government Printing Office, December 1982. (Health technology case study series #21)

CU58 _____. Strategies for medical technology assessment. Washington, D.C.: U.S. Government Printing Office, September 1982.

CU59 _____. Technology and handicapped people. Washington, D.C.: U.S. Government Printing Office, May 1982.

CU60 _____. Technology transfer at the National Institutes of Health. Washington, D.C.: U.S. Government Printing Office, March 1982.

CU61 _____. The artificial heart: cost, risks, and benefits. Washington, D.C.: U.S. Government Printing Office, May 1982. (Health technology case study series #9)

CU62 _____. Allocating costs and benefits in disease prevention: an application to cervical cancer screening. Washington, D.C.: U.S. Government Printing Office, May 1981. (Health technology case study series #7)

CU63 _____. Assessing selected respiratory therapy modalities: trends and relative costs in the Washington, D.C. area. Washington, D.C.: U.S. Government Printing Office, July 1981. (Health technology case study series #12)

CU64 _____. Benefit and cost analysis of medical interventions: the case of cimetidine and peptic ulcer disease. Washington, D.C.: U.S. Government Printing Office, September 1981. (Health technology case study series #11)

CU65 _____. Cost-benefit/cost-effectiveness of medical technologies: a case study of orthopedic joint implants. Washington, D.C.: U.S. Government Printing Office, September 1981. (Health technology case study series #14)

CU66 _____. Cost-effectiveness of automated multichannel chemistry analyzers. Washington, D.C.: U.S. Government Printing Office, April 1981. (Health technology case study series #4)

CU67 _____. Cost-effectiveness of influenza vaccination. Washington, D.C.: U.S. Government Printing Office, December 1981.

CU68 _____. Elective hysterectomy: costs, risks and benefits. Washington, D.C.: U.S. Government Printing Office, October 1981. (Health technology case study series #15)

CU69 _____. Formal analysis, policy formulation, and end-stage renal disease. Washington, D.C.: U.S. Government Printing Office, April 1981. (Health technology case study series #1)

CU70 _____. Periodontal disease: assessing the effectiveness and costs of the Keyes technique. Washington, D.C.: U.S. Government Printing Office, May 1981. (Health technology case study series #5)

CU71 _____. Policy implications of computed tomography (CT) scanners: an update. Washington, D.C.: U.S. Government Printing Office, January 1981.

CU72 _____. Screening for colon cancer. Washington, D.C.: U.S. Government Printing Office, April 1981. (Health technology case study series #3)

CU73 _____. Surgery for breast cancer. Washington, D.C.: U.S. Government Printing Office, October 1981. (Health technology case study series # 17)

CU74 _____. Technologies for determining cancer risks from the environment. Washington, D.C.: U.S. Government Printing Office, June 1981.

CU75 _____. The cost-effectiveness of bone marrow transplant therapy and its policy implications. Washington, D.C.: U.S. Government Printing Office, May 1981. (Health technology case study series #6)

CU76 _____. The cost-effectiveness of upper gastrointestinal endoscopy. Washington, D.C.: U.S. Government Printing Office, May 1981. (Health technology case study series #8)

CU77 _____. The costs and effectiveness of neonatal intensive care. Washington, D.C.: U.S. Government Printing Office, August 1981. (Health technology case study series #10)

CU78 _____. The costs and effectiveness of nurse practitioners. Washington, D.C.: U.S. Government Printing Office, July 1981. (Health technology case study series #16)

CU79 _____. The feasibility of economic evaluation of diagnostic procedures: the case of CT scanning. Washington, D.C.: U.S. Government Printing Office, April 1981. (Health technology case study series #2)

CU80 _____. Compensation for vaccine-related injuries. Washington, D.C.: U.S. Government Printing Office, November, 1980.

CU81 _____. Methodological issues and literature review. Washington, D.C.: U.S. Government Printing Office, September 1980. (Background paper #1 of the Series on implications of cost-effectiveness analysis of medical technology)

CU82 _____. The efficacy and cost effectiveness of psychotherapy. Washington, D.C.: U.S. Government Printing Office, October 1980. (Health technology case study series #18)

CU83 _____. The implications of cost-effectiveness analysis of medical technology. Washington, D.C.: U.S. Government Printing Office, August 1980.

CU84 _____. The management of health care technology in ten countries. Washington, D.C.: U.S. Government Printing Office, October 1980. (Background paper #4 of the Series on implications of cost-effectiveness analysis of medical technology)

CU85 _____. A review of selected federal vaccine and immunization policies. Washington, D.C.: U.S. Government Printing Office, September 1979.

CU86 _____. Computer technology in medical education and assessment. Washington, D.C.: U.S. Government Printing Office, September 1979.

CU87 _____. Assessing the efficacy and safety of medical technologies. Washington, D.C.: U.S. Government Printing Office, September 1978.

CU88 _____. Policy implications of computed tomography (CT) scanners. Washington, D.C.: U.S. Government Printing Office, August 1978.

CU89 _____. Cancer testing technology and saccharin. Washington, D.C.: U.S. Government Printing Office, October 1977.

CU90 _____. Policy implications of medical information systems. Washington, D.C.: U.S. Government Printing Office, November 1977.

CU91 _____. Development of medical technology: opportunities for assessment. Washington, D.C.: U.S. Government Printing Office, August 1976.

CU92 _____. Drug bioequivalence. Washington, D.C.: U.S. Government Printing Office, July 1974.

DUKE UNIVERSITY CENTER FOR HEALTH POLICY RESEARCH AND EDUCATION

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Overview: The Center for Health Policy Research and Education (CHPRE) was created in 1980 with a core grant from the Duke Endowment. From the start, it has focused on the development and application of methods to assess health technologies. It also works to analyze particular health practices and to educate policy makers. Its products are technology assessment methods, assessments, and educational programs.

Purpose: To develop methods of technology assessment, to improve health by evaluation of particular health practices, and to educate policy makers.

Primary intended users: Providers, generally; physicians; acute facility administrators; health product manufacturers; health/medical professional associations; health industry associations; employers; third party payers; government regulators; voluntary associations, organizations; public policy-makers, legislators.

Technologies: Drug, device, medical or surgical procedure.

Assessments have focused on the impact of technologies on individuals as well as on populations.

Intervention: *Prevention, treatment*, diagnosis, rehabilitation.

Stage: Emerging, new, established or widespread practice, obsolete.

The program is concerned with controversial technologies at any stage.

Properties: *Efficacy, cost-effectiveness*, safety, effectiveness, cost, system impact, economic implications.

Selection process: Any organization may request that an assessment be conducted, including third party payers; state, federal, and international governments; hospitals; health maintenance organizations; professional societies; health industries; trade associations; and venture capitalists.

Assessment topic priorities are set by the Center staff. Major criteria are: 1) a request from a major organization currently facing a decision about the technology; 2) the importance (magnitude of the health and economic impact) of the health problem and the expected difference made by the technology; 3) the degree of uncertainty or

controversy about the technology; and 4) the existence of methodological issues (anticipated difficulty and novelty of the analysis).

Reassessments are performed at the request of an organization or when new information becomes available that could modify the results of an active assessment (an assessment still being used for decisions).

Methods: *Information syntheses*; expert opinion; group judgment; modeling; cost analyses.

Existing information is analyzed to estimate the effect of the technology on important health and economic outcomes. Typically, quantitative methods are used to interpret and synthesize the information, and to estimate effects that have not been or can not be observed experimentally (e.g., life expectancy and population effects). To the greatest extent possible, analyses rest on empirical observations. When unavoidable, expert judgments are formally incorporated into the assessment.

Assessments are typically performed in eight steps: 1) problem formulation (performed in conjunction with the requesting organization); 2) information gathering; 3) model development; 4) analysis; 5) preparation of drafts; 6) cycles of external review and revision; 7) approval; and 8) final report.

Turnaround time from selection of assessment topic to reporting of findings depends on the time constraints of the requesting organization, prior familiarity with the assessment problem, and the review process. The time ranges from 1 week to 2 years; the average is 6 months.

Assessors: Assessors are experts in medicine, statistics, mathematics, operations research, computer science, and law.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: Printed reports, journal articles, advisories to members/constituents.

Assessment results are also disseminated by the requesting organizations through their own channels. Copies of assessment reports are available upon request or in the open scientific literature.

Budget: $1,000,000. Assessments cost CHPRE from $3,000 to $60,000; charges have ranged from no charge to $45,000. Funding sources: 10 percent parent organization; 30 percent government grants/contracts; 60 percent foundations, other private grants.

Use: Duke University does not formally use the assessment reports. The requesting organizations have used the results to help set third party coverage policies, to design practice standards, to draft legislation, to develop recommendations for national policy, and to design national health programs. The use of assessments is usually known

because CHPRE staff works with the requesting organization through the implementation stage. In addition, assessment authors are frequently invited to speak on their topics.

Examples of use include the following: 1) publication by the American Cancer Society of the *ACS Guidelines on the Cancer-Related Health Checkup*; 2) publication by the World Health Organization of *Control of Oral Cancer in. Developing Countries*; 3) adoption by the National Cancer Institute of a computer program for *Setting National Cancer Control Priorities for the Year 2000* and 4) acceptance by the Minister of Health, Chile, of recommendations for cancer control priorities.

Program evaluation: In 1986, the Hartford Foundation evaluated CHPRE at the end of a 3-year grant that funded the development and application of a new set of assessment methods. An independent consultant to the Foundation read project reports and background material and visited the Center for 1 day. The evaluation's findings were positive. Following the evaluation, the Center received a second grant from the Foundation to continue development of the assessment method.

Related activities: Computer software is being prepared to enable others to use some of the quantitative technology assessment methods developed at the Center. CHPRE plans to offer several I-day seminars to acquaint researchers and policy-makers with technology assessment methods developed by the Center.

Completed Reports

DC1 Adar R, Critchfield GC, Eddy DM. [Duke University, Center for Health Policy and Education] A confidence profile analysis of the results of percutaneous transluminal angioplasty in the treatment of ischemic femoropopliteal artery disease, expected publication 1988. [Information syntheses]

DC2 Critchfield GC, Eddy DM. [_____] A confidence profile analysis of the effectiveness of disulfiram in the treatment of chronic alcoholism. Med Care, submitted for publication. [Information syntheses]

DC3 Critchfield GC, Eddy DM. [_____] Screening for osteoporosis, expected publication 1988. [Information syntheses]

DC4 Eddy DM, Hasselblad V, McGivney W, Hendee W. [_____] The value of mammography screening for women age 40-49, submitted for publication. [Information syntheses]

DC5 Eddy DM. [_____] Screening by mammography for women over age 65, reassessment, expected publication 1988. [Information syntheses]

DC6 _____. [_____] Screening for breast cancer, reassessment, expected publication 1988. [Information syntheses]

DC7 _____. [_____] Screening for cervical cancer, reassessment, expected publication 1988. [Information syntheses]

DC8 _____. [_____] Screening for colorectal cancer, reassessment, expected publication 1988. [Information syntheses]

DC9 _____. [_____] Screening for glaucoma, reassessment, expected publication 1988. [Information syntheses]

DC10 _____. [_____] Screening for lung cancer, reassessment, expected publication, 1988. [Information syntheses]

DC11 Gavin NI, Hasselblad V, Eddy DM. [_____] The role of adjuvant tamoxifen treatment of postmenopausal women with stage II breast cancer, expected publication 1988. [Information syntheses]

DC12 Hasselblad V. [_____] Analysis of the prevention of mental retardation by screening for maple syrup urine disease, expected publication 1988. [Information syntheses]

DC13 Brandeau ML, Eddy DM. [_____] The workup of the asymptomatic patient with a positive fecal occult blood test. Med Decis Making 1987;7:32-46. [Information syntheses]

DC14 Eddy DM, Wolpert RL, Rosenberg ML. [_____] Estimating the effectiveness of interventions to prevent youth suicides: a report to the Secretary's Task Force on Youth Suicide. 1987. [Information syntheses]

DC15 Eddy DM, Nugent FW, Eddy JF, et al. [_____] Screening for colorectal cancer in a high-risk population: results of a mathematical model. Gastroenterology, 1987;92:682-692. [Information syntheses]

DC16 Eddy DM. [_____] The use of confidence profiles to assess tissue-type plasminogen activator. In: Califf RM, Wanger GS, eds. Acute coronary care. Boston: Martinus Nijhoff Publishing, 1987. [Information syntheses]

DC17 _____. [_____] Priorities for cancer control in Chile. Report prepared for the World Health Organization. 1986. [Information syntheses]

DC18 _____. [_____] Priorities for cancer control in India. Report prepared for the World Health Organization. 1986. [Information syntheses]

DC19 _____. [_____] The effectiveness, cost, & cost-effectiveness of breast cancer screening with annual mammography & breast physical exam. for women over 65. Report prepared for Committee on Ways & Means, Subcommittee on Health, U.S. House of Representatives. 1986 Jan 7. [Information syntheses]

DC20 Eddy JF, Eddy, DM. [_____] The value of corneal endothelial cell microscopy for cataract surgery. Report prepared for the Blue Cross and Blue Shield Association. 1986. [Information syntheses]

DC21 Eddy DM. [_____] Priorities for cancer control in Chile. Report prepared for the World Health Organization. 1985. [Information syntheses]

DC22 _____. [_____] Priorities for cancer control in India. Report prepared for the World Health Organization. 1985. [Information syntheses]

DC23 A WHO Meeting [_____] Control of oral cancer in developing countries. Bull WHO 1984;62:817-830. [Information syntheses]

DC24 _____. [_____] The economic impact of cancer and cancer prevention in private industry. Report prepared for the American Cancer Society. 1984. [Information syntheses]

DC25 Eddy DM, Eddy JF, Sanders LE. [_____] Surgical treatment of obesity. Evidence of effectiveness and risks. Report prepared for the North Carolina Blue Cross and Blue Shield Association. 1983. [Information syntheses]

DC26 Eddy DM, Sanders L, Eddy J. [_____] The value of screening for glaucoma with tonometry. Surv Ophthalmol 1983;28:194-205. [Information syntheses]

DC27 Eddy DM. [_____] Appropriateness of cervical cancer screening. Gynecol Oncol 1981;12:S 168-187. [Information syntheses]

DC28 _____. [_____] Screening for colon cancer: a technology assessment. 1981. (Office of Technology Assessment background paper #2: case studies of medical technologies) [Information syntheses]

DC29 _____. [_____] Guidelines for the cancer-related checkup: recommendations and rationale. CA-A Cancer J Clin 1980;30:193-240. [Information syntheses]

ECRI HEALTH DEVICES PROGRAM

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Overview: ECRI, formerly the Emergency Care Research Institute, is an independent not-for-profit corporation that works to improve the quality of patient care. It provides a wide range of services dealing with health care technology including research, evaluation, assessment, consulting, environmental testing, and publications development. The Health Devices Program (HDP) was established by ECRI in 1971.

Purpose: To conduct assessments that provide independent, objective judgment for selection, purchase, and use of medical instruments, equipment, and systems; to func

tion as a clearinghouse for investigating and resolving hazards and deficiencies in medical devices; and to encourage the improvement of medical devices through an informed marketplace.

Primary intended users: Providers, generally; physicians; acute facility administrators; biomedical researchers.

Technologies: *Device*, support system, organizational or administrative system.

All types of diagnostic and therapeutic medical devices, equipment, and support systems, as well as some preventive and rehabilitative technologies are assessed. Examples range from disposables, such as incontinent pads and suction canisters, to electric beds, patient monitoring systems, anesthesia machines, infusion and imaging technologies, and clinical laboratory instruments. Comparative evaluations are usually conducted within a product category.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *Established or widespread practice*, new.

Properties: *Effectiveness*, safety, efficacy, cost, cost-effectiveness, service requirements, acceptance/adoption level, performance, ease of use, reliability, and appropriateness of use.

Selection process: Hospital members of the Health Devices Program may request that an assessment be conducted. ECRI/HDP may also determine the need for an evaluation based on inquiries received from member hospitals. Requests for assessments are made either informally by telephone conversation with staff members, by written correspondence, or by responding to periodic HDP member surveys. Topic selection is based on the volume of inquiries received from ECRI/HDP member hospitals; the ECRI's senior staff's experience regarding a product's importance to hospitals and to safe, efficacious, and cost-effective patient care; and the results of membership questionnaires.

Device categories are reassessed when member hospitals request more current information than is available from previous evaluations. This normally occurs when a significant number of new product models appear on the market in a given category.

Methods: *Bench testing*, information syntheses, expert opinion, group judgment, cost analyses, clinical trials.

The ECRI/HDP comparative evaluations are based on ECRI laboratory and clinical evaluations. Laboratory evaluations are conducted in ECRI's facility, and clinical studies (in vivo evaluations of device performance) are conducted in selected member hospitals. Evaluations follow appropriately reviewed medical/scientific protocols developed by ECRI. There is an extensive review process that involves both in-house and independent reviewers, typically including clinicians with special expertise in the subject area.

The approximate turnaround time from selection of assessment topic to reporting of findings is 6 to 9 months.

Assessors: Evaluations are conducted primarily by engineers, physicians, and chemists. As needed, ECRI's interdisciplinary staff collaborate on evaluations. ECRI employs more than 120 full-time staff with expertise in medical, engineering, and analytical sciences.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; procurement/deployment information; product recall history, liability actions.

Dissemination: *Journal articles*; advisories to members/constituents; clearinghouses, data/citation bases, on-line services. Specifically, abstracts are published in *Health Devices Alerts* and are available in an online database.

For each evaluation, a comprehensive report is published containing tables that show the product's characteristics and performance on each evaluation criterion. Modelspecific listings of advantages and disadvantages and ratings (e.g., recommended, not recommended) are also included. All reports are published in ECRI's monthly journal, *Health Devices* which began publication in 1971. *Health Devices* also contains reports of hazards with medical devices, as reported by ECRI/HDP member hospitals and investigated by ECRI engineers.

Copies of individual issues *of Health Devices* may be purchased from ECRI's Circulation Department. Hospitals and others may become members of the Health Devices Program and receive subscriptions to the weekly *Health Devices Alerts*, the bimonthly journal, *Health Technology: Critical Issues for Decision Makers*, and telephone consultation privileges. Individual subscriptions to *Health Devices* alone are not available. Summaries of relevant evaluations are also published in the *Technology for Health Care* family of seven specialized monthly newsletters. *Health Devices* is not indexed by the National Library of Medicine for the MEDLARS system. However, indexes and database searches are available directly from ECRI.

Budget: $2,000,000. Based on the type of device being evaluated, the cost per assessment ranges from $40,000 to $100,000. Funding source: 100 percent sponsors/members dues, contributions.

Use: Assessments reports are used by ECRI to serve the health care community and patients in the nation's hospitals. These reports are also used by members of the Health Devices Program (which includes hospitals representing about 70 percent of all acute care beds in the U.S.) in a variety of ways involving selection, acquisition, and use of medical devices.

Regular surveys of ECRI/HDP members and an annual membership renewal rate exceeding 95 percent provide indications of the value of these evaluations to member hospitals. Numerous specific product improvements have been directly attributed to ECRI/HDP evaluations. For instance, following an extensive 1973 study of electrosurgical machines, most manufacturers undertook major redesign to improve safety. Over the past decade 90 percent of the nation's inventory of these devices has been replaced. The impact has been significant; fewer electrosurgical burns are reported to ECRI.

ECRI estimates that cost savings in the hundreds of millions of dollars can be attributed to ECRI evaluations and other technology-related efforts on behalf of member hospitals.

One example is the National Electrical Code controversy over isolated power in anesthetizing locations.

ECRI assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Related activities: The Health Devices Program is closely related to other ECRI activities including: the Technology Assessment Program; a technology risk management program that produces the four-volume *Hospital Risk Control* information service; accident investigation, forensic engineering, engineering and management consultation; and field technical services for hospitals.

Completed Reports

EH1 ECRI Health Devices Program. Carbon dioxide monitors. Health Devices 1986; 15:255-85.
EH2 _____. Continuous passive motion (CPM) leg exercisers. Health Devices 1986;15:3-22.
EH3 _____. EEG monitors. Health Devices 1986;15:71-95.
EH4 _____. Electric beds. Health Devices 1986;15-299-316.
EH5 _____. Electrosurgical active electrode pencils, hand controlled. Health Devices 1986; 15:151-77.
EH6 _____. Neonatal ventilators. Health Devices 1986; 15:219-46.
EH7 _____. Patient care management system, Space-Labs. Health Devices 1986; 15:286-94.
EH8 _____. Peritoneal dialysis cyclers. Health Devices 1986;15:31-61.
EH9 _____. Sphygmomanometers, automatic. Health Devices 1986; 15:187-208.
EH10 _____. Surgical drapes. Health Devices 1986; 15:111-40.
EH11 _____. Arrhythmia monitoring systems, computerized. Health Devices 1985;14:287-319.
EH12 _____. Batteries, zinc air. Health Devices 1985;14:209-211.
EH13 _____. Electrode monitoring systems, electrosurgical. Health Devices 1985;14:115-31.
EH14 _____. Infusion controllers. Health Devices 1985;14:219-256.
EH15 _____. Oxygen-air proportioners. Health Devices 1985; 14:263-76.
EH16 _____. Physiologic monitoring systems. Health Devices 1985;14:143-182.
EH17 _____. Positive end expiratory pressure (PEEP) valves. Health Devices 1985; 14:379-99.
EH18 _____. Suction canisters (aspirator collection bottles). Health Devices 1985; 14:411-34.
EH19 _____. Suction regulators. Health Devices 1985;14:191-209.
EH20 _____. Blood warmers. Health Devices 1984;13:191-219.
EH21 _____. Disposable pressure transducers. Health Devices 1984;13:268-90.
EH22 _____. Electrocardiographs, three-channel. Health Devices 1984;13:235-59.
EH23 _____. Enteral feeding pumps. Health Devices 1984;14:9-30.
EH24 _____. Infant radiant warmers. Health Devices 1984;13:119-45.
EH25 _____. Infusion pumps. Health Devices 1983-84;13:31-62.
EH26 _____. Patient bed scales. Health Devices 1984;13:75-91.
EH27 _____. Pneumatic tourniquets. Health Devices 1984;13:299-316.
EH28 _____. Anesthesia unit gas scavengers. Health Devices 1983;12:267-286.
EH29 _____. Blood gas/pH analyzers. Health Devices 1983;12:59-78.
EH30 _____. Defibrillators, line-powered. Health Devices 1983; 12:291-314.
EH31 _____. External transcutanaeous pacemakers, Pace*Aid Model 50C. Health Devices 1983;13:3-13.
EH32 _____. Heat and moisture exchange humidifiers. Health Devices 1983;12:155-67.
EH33 _____. Incontinent pads. Health Devices 1983;12:108-18.
EH34 _____. Oxygen analyzers. Health Devices 1983;12:183-97.

EH35 _____. Oxygen monitors, transcutaneous. Health Devices 1983;12:213-51.
EH36 _____. Suction canisters (aspirator collection bottles). Health Devices 1983;12:127-49.
EH37 _____. Surgical gloves, latex. Health Devices 1983;12:83-98.
EH38 _____. Arrhythmia monitoring systems, computerized. Health Devices 1982;11:211-247.
EH39 _____. Electronic intermittent thermometers. Health Devices 1982;12:3-20.
EH40 _____. Ethylene oxide sterilizers. Health Devices 1982;11:287-301.
EH41 _____. Fetal monitors. Health Devices 1982;11:123-44.
EH42 _____. Infant incubators. Health Devices 1982;11:191-9.
EH43 _____. Infant transport incubators. Health Devices 1982; 11:179-91.
EH44 _____. Infusion controllers. Health Devices 1982;11:75-96.
EH45 _____. Operating room ECG monitors. Health Devices 1982;11:155-74.
EH46 _____. Physiologic monitoring systems. Health Devices 1982;11:211-47.
EH47 _____. Surgical case carts. Health Devices 1982;11:311-24.
EH48 _____. Surgical case carts. Health Devices 1982;12:33-9.
EH49 _____. Volume ventilators. Health Devices 1982;11:264-83.
EH50 _____. X-ray film processors. Health Devices 1982;11:99-115.

ECRI TECHNOLOGY ASSESSMENT PROGRAM

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Plymouth Meeting, PA 19462
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Contact: Malin Van Antwerp, Director of Policy Analysis. Telex 510-660-8023. Telefax 215-834-1275.

Overview: ECRI, formerly the Emergency Care Research Institute, is an independent, not-for-profit corporation that works to improve the quality of patient care. It provides a wide range of services dealing with health care technology including research, evaluation, assessment, consulting, environmental testing, and publications development. The Technology Assessment Program (ECRI/TAP) was established by ECRI in 1981.

Purpose: To provide to interested parties assessments of emerging and regularly used health care technologies.

Primary intended users: Providers, generally; physicians; acute facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; third party payers; government regulators; voluntary associations, organizations; financial analysts, consultants; reporters, writers, news media; information/computer industry; labs, blood banks; public policy-makers, legislators; policy research organizations; lawyers; liability, malpractice insurers.

Technologies: *Device*, medical or surgical procedure, support system.

Primarily diagnostic and therapeutic equipment are assessed. Occasionally, surgical procedures and clinical laboratory diagnostics are assessed.

Intervention: *Treatment*, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice, obsolete.

Technologies are generally assessed when it is appropriate for a "typical" hospital (i.e., smaller than a tertiary care/ medical center hospital but at least a 200-bed facility) to consider acquiring the technology, and sometimes when a technology may be unsafe or obsolete.

Properties: *Effectiveness*; safety; efficacy; cost; cost-effectiveness; service requirements; acceptance/adoption level; system impact; economic implications; ethical, legal, social implications.

Selection process: Assessment topics and priorities are set by ECRI/TAP staff. Decisions are based on their review of clinical journals, manufacturing/industry trade literature, and input from other ECRI staff (clinical/biomedical engineers, hospital consultants, etc.) who have contact with hospitals. A technology is reassessed when the previously published material becomes significantly outdated by more recent developments.

Methods: *Information syntheses*, expert opinion, group judgment, cost analyses.

A comprehensive review, evaluation, and synthesis of the published literature is at the core of the assessment process. ECRI in-house experts, nationally prominent clinicians, and others familiar with the technology conduct a thorough three-step review of draft assessment reports.

The average turnaround time from selection of assessment topic to reporting of findings is 2 to 3 months.

Assessors: The primary assessors are members of ECRI's interdisciplinary policy analysis staff which includes attorneys and experts in health care administration and planning. As needed, additional assessors are selected from ECRI's 120-member, full-time staff, or from among outside clinicians. The staff have expertise in medicine, engineering, and other relevant disciplines.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/ information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; procurement/deployment information; where technology is in use; regulatory agency approval status; coverage/ reimbursement status of the technology.

Dissemination: Journal articles.

The assessment products are comprehensive assessment reports and *New Technology Briefs*. Both comprehensive technology assessment reports and *New Technology Briefs* are published, beginning with the January/February 1987 issue, in ECRI's new *Health Technology: Critical Issues for Decision Makers*. This journal combines two previous ECRI publications, *the Journal of Health Care Technology* and *Issues in Health Care Technology* , which had been published since 1984 and 1981, respectively. Copies of the assessments

can be acquired by subscribing to *Health Technology* (either independently or by membership in the Health Devices Program) or purchasing single copies; reports are not available separately. Individual copies of back issues of the *Journal of Health Care Technology* may also be purchased from ECRI's Circulation Department.

Budget: $300,000. The approximate cost of an assessment ranges from $3,000 to $15,000 depending on the report's length and comprehensiveness. Funding sources: 67 percent sponsors/members dues, contributions; 33 percent subscriptions to *Health Technology*.

Use: Reports are used to support consulting and technical advice provided by ECRI personnel to hospitals. Based on responses from reader surveys, reports receive wide circulation in hospitals and are used for a variety of purposes, such as equipment acquisition and replacement decisions. Perhaps the most-cited of any assessment report is "Deaths during General Anesthesia," published in *the Journal of Health Care Technology* 1985;1:55-75, which was reprinted in full in the *Newsletter of the American Society of Anesthesiologists*.

ECRI assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Program evaluation: The only evaluations of the program have been reader surveys conducted on 3 occasions by the two ECRI predecessor publications.

Related activities: The Technology Assessment Program is closely related to ECRI's Health Devices Program (HDP); all HDP members receive *Health Technology* as one of their membership benefits. The ECRI/TAP staff also work closely with other ECRI activities. These include a technology risk management program that produces the four-volume *Hospital Risk Control* information service; accident investigation, forensic engineering, engineering, and management consultation; and field technical services for hospitals.

Completed Reports

ET1 ECRI Technology Assessment Program. Artificial urinary sphincters. Issues Health Care Technol 1986;sec.5.U.1. [Information syntheses]

ET2 _____. Automatic implantable cardioverter/defibrillator. Issues Health Care Technol 1986;sec.5.D.3. [Information syntheses]

ET3 _____. Bone mineral assessment, noninvasive (dual photon absorptiometry and quantitative computed tomography). J Health Care Technol 1986;2:183-200. [Information syntheses]

ET4 _____. Cardiokymography. Issues Health Care Technol 1986;sec.5.C.8. [Information syntheses]

ET5 _____. Chorionic villus sampling (CVS). Issues Health Care Technol 1986;sec.5.C.6. [Information syntheses]

ET6 _____. Clinical use of mass spectrometers. Issues Health Care Technol 1986;sec.5.M.2. [Information syntheses]

ET7 _____. Computer-processed EEG monitoring during surgery. Issues Health Care Technol 1986;sec.5.E.4. [Information syntheses]

ET8 _____. Extracorporeal membrane oxygenation (ECMO) for newborn respiratory failure. Issues Health Care Technol 1986;5.E.6. [Information syntheses]

ET9 _____. Gastric bubble. Issues Health Care Technol 1986;sec.5.G. 1. [Information syntheses]

ET10 _____. Image transmission and data compression. J Health Care Technol 1986;3:83-93. [Information syntheses]

ET11 _____. Interpretive reporting of clinical laboratory test results. J Health Care Technol 1986;2:269-82. [Information syntheses]

ET12 _____. Legal system, insurance, and health care: the liability problem. J Health Care Technol 1986;2:247-68. [Information syntheses]

ET13 _____. Low-osmolality radiographic contrast agents. Issues Health Care Technol 1986;sec.5.L.4. [Information syntheses]

ET14 _____. Medicare payment for new technologies. J Health Care Technol 1986;3:13-32. [Information syntheses]

ET15 _____. Multichannel cochlear implants for profound deafness. Issues Health Care Technol 1986;sec.5.C.7. [Information syntheses]

ET16 _____. Percutaneous balloon valvuloplasty. Issues Health Care Technol 1986;sec.5.P.9. [Information syntheses]

ET17 _____. Percutaneous transluminal coronary angioplasty (PTCA). Issues Health Care Technol 1986;sec.5.P.2. [Information syntheses]

ET18 _____. Personal emergency response system (PERS). Issues Health Care Technol 1986;sec.5.P.10. [Information syntheses]

ET19 _____. Physician office laboratories. J Health Care Technol 1986;3:95-115. [Information syntheses]

ET20 _____. Pulse oximeters. Issues Health Care Technol 1986;sec.5.O.1. [Information syntheses]

ET21 _____. SPECT imaging, J Health Care Technol 1986;3:33-62. [Information syntheses]

ET22 _____. Temporary external noninvasive pacemakers. Issues Health Care Technol 1986;sec.5.P.11. [Information syntheses]

ET23 _____. Three-dimensional computed tomography. Issues Health Care Technol 1986;sec.5.T.6. [Information syntheses]

ET24 _____. Two-dimensional Doppler echocardiography. Issues Health Care Technol 1986;sec.5.E.5. [Information syntheses]

ET25 _____ Urinalysis, automated. J Health Care Technol 1986;2:201-10. [Information syntheses]

ET26 _____. Angelchik gastroesophageal antireflux prosthesis. Issues Health Care Technol 1985;sec.5.A.4. [Information syntheses]

ET27 _____. Automated microbiology systems. Issues Health Care Technol 1985;sec.5.M.5. [Information syntheses]

ET28 _____. Automated microbiology systems. J Health Care Technol 1985;1:213-30. [Information syntheses]

ET29 _____. Bone marrow transplantation. Issues Health Care Technol 1985;sec.5.B.5. [Information syntheses]

ET30 _____. CT-assisted stereotactic neurosurgery. Issues Health Care Technol 1985;sec.5.S.3. [Information syntheses]

ET31 _____. Continuous passive motion (CPM) devices. Issues Health Care Technol 1985;sec.5.C.4. [Information syntheses]

ET32 _____. Deaths during general anesthesia. J Health Care Technol 1985;1:155-75. [Information syntheses]

ET33 _____. Digital subtraction angiography (DSA). J Health Care Technol 1985;1:177-212. [Information syntheses]

ET34 _____. Freestanding imaging centers. J Health Care Technol 1985;1:257-278. [Information syntheses]

ET35 _____. Hyperthermia treatment of tumors. Issues Health Care Technol 1985;sec.5.H.2. [Information syntheses]

ET36 _____. Imatron high-speed CT scanner. Issues Health Care Technol 1985;sec.5.C.5. [Information synthesis]

ET37 _____. Implantable vascular access ports. Issues Health Care Technology 1985;sec.5.V.2. [Information syntheses]

ET38 _____. Laser angioplasty for atherosclerosis. Issues Health Care Technol 1985;sec.5.L.3. [Information syntheses]

ET39 _____. Leukocyte differential counters, automated. J Health Care Technol 1985;2:51-72. [Information syntheses]

ET40 _____. Magnetic resonance imaging (MRI). J Health Care Technol 1985;2:23-50. [Information syntheses]

ET41 _____. Monitoring of exhaled CO2 levels during anesthesia. Issues Health Care Technol 1985;sec.5.M.4. [In formation syntheses]

ET42 _____. Patient-controlled analgesia. Issues Health Care Technol 1985;sec.5.P.8. [Information syntheses]

ET43 _____. Streptokinase thrombolysis of coronary arteries. Issues Health Care Technol 1985;sec.5.T.1. [Information syntheses]

ET44 _____. Therapeutic apheresis. J Health Care Technol 1985;1:279-98. [Information syntheses]

ET45 _____. Thermography for breast cancer prescreening. Issues Health Care Technol 1985;sec.5.T.5. [Information syntheses]

ET46 _____. Tumor markers. J Health Care Technol 1985;2:105-28. [Information syntheses]

ET47 _____. Two-dimensional Doppler echocardiography. J Health Care Technol 1985;2:129-50. [Information syntheses]

ET48 _____. Cementless hip prosthesis. Issues Health Care Technol 1984;sec.5.H.3. [Information syntheses]

ET49 _____. Digital imaging storage and retrieval. J Health Care Technol 1984;1:13-38. [Information syntheses]

ET50 _____. Dual-photon absorptiometry for bone mineral content. Issues Health Care Technol 1984;sec.5.A.3. [Information syntheses]

ET51 _____. Extracorporeal shock-wave lithotripsy (ESWL). Issues Health Care Technol 1984;sec.5.L.2. [Information syntheses]

ET52 _____. Percutaneous nephrostomy. Issues Health Care Technol 1984;sec.5.N.1. [Information syntheses]

ET53 _____. Photoradiation therapy (PRT) of tumors. Issues Health Care Technol 1984;sec.5.P.6. [Information syntheses]

ET54 _____. Plasminogen activator thrombolysis of coronary arteries. Issues Health Care Technol 1984;sec.5.T.4. [Information syntheses]

ET55 _____. Plethysmography for diagnosing deep vein thrombosis. Issues Health Care Technol 1984;sec.5.P.7. [Information syntheses]

ET56 _____. Prenatal alpha-fetoprotein (AFP) testing. Issues Health Care Technol 1984;sec.5.A.2. [Information syntheses]

ET57 _____. Surgery for morbid obesity. Issues Health Care Technol 1984;sec.5.S.2. [Information syntheses]

ET58 _____. Therapeutic drug monitoring (TDM). J Health Care Technol 1984;1:39-61. [Information syntheses]

ET59 _____. Transcatheter therapeutic embolization. Issues Health Care Technol 1984;sec.5.E.3. [Information syntheses]

ET60 _____. X-ray image digitizing systems. Issues Health Care Technol 1984;sec.5.D.4. [Information syntheses]

ET61 _____. Chemonucleolysis of herniated lumbar disks. Issues Health Care Technol 1983;sec.5.C.3. [Information syntheses]

ET62 _____. Collagen implants for smoothing skin. Issues Health Care Technol 1983;sec.5.C.2. [Information syntheses]

ET63 _____. Digital radiography and fluoroscopy. Issues Health Care Technol 1983;sec.5.D.2. [Information syntheses]

ET64 _____. Mobile computerized ECG interpretive systems. Issues Health Care Technol 1983;sec.5.E.2. [Information syntheses]

ET65 _____. Noninvasive bilirubinometers. Issues Health Care Technol 1983;sec.5.B.4. [Information syntheses]

ET66 _____. Penile prostheses. Issues Health Care Technol 1983;sec.5.P.5. [Information syntheses]

ET67 _____. Percutaneous lithotripsy of kidney stones. Issues Health Care Technol 1983;sec.5.L.1. [Information syntheses]

ET68 _____. Percutaneous transluminal angioplasty (PTA) of peripheral arteries. Issues Health Care Technol 1983;sec.5.P.4. [Information syntheses]

ET69 _____. Single-channel cochlear implants for profound deafness. Issues Health Care Technol 1983;sec.5.C.1. [Information syntheses]

ET70 _____. Transcutaneous CO2 monitors. Issues Health Care Technol 1983;sec.5.M.3. [Information syntheses]

ET71 _____. Transdermal delivery of nitroglycerin. Issues Health Care Technol 1983;sec.5.T.2. [Information syntheses]

ET72 _____. Transrectal ultrasound of the prostate. Issues Health Care Technol 1983;sec.5.T.3. [Information syntheses]

ET73 _____. Automatic indirect blood pressure monitors. Issues Health Care Technol 1982;sec.5.B.2. [Information syntheses]

ET74 _____. Blood substitute. Issues Health Care Technol 1982;sec.5.B.3. [Information syntheses]

ET75 _____. Diagnostic and operative arthroscopy. Issues Health Care Technol 1982;sec.5.A.1. [Information syntheses]

ET76 _____. Dual-energy scanned projection radiography. Issues Health Care Technol 1982;sec.5.D.1. [Information syntheses]

ET77 _____. Hyperbaric oxygen (HBO) therapy. Issues Health Care Technol 1982;sec.5.H.1. [Information syntheses]

ET78 _____. Implantable drug infusion pumps. Issues Health Care Technol 1982;sec.5.I.4. [Information syntheses]

ET79 _____. Intra-aortic balloon pumps. Issues Health Care Technol 1982;sec.5.I.3. [Information syntheses]

ET80 _____. Multiprogrammable pacemakers. Issues Health Care Technol 1982;sec.5.P.3. [Information syntheses]

ET81 _____. Multiprogrammable pacemakers. Issues Health Care Technol 1982;sec.5.P.3. [Information syntheses]

ET82 _____. Radial keratotomy. Issues Health Care Technol 1982;sec.5.R.1. [Information syntheses]

ET83 _____. Bone growth stimulators. Issues Health Care Technol 1981;sec.5.B.1. [Information syntheses]

ET84 _____. Evoked potential (EP) response measurement. Issues Health Care Technol 1981;sec.5.E.1. [Information syntheses]

ET85 _____. High-frequency ventilators. Issues Health Care Technol 1981;sec.5.V.1. [Information syntheses]

ET86 _____. Insulin delivery devices. Issues Health Care Technol 1981;sec.5.I.2. [Information syntheses]

ET87 _____. Insulin infusion systems (controlled). Issues Health Care Technol 1981;sec.5.I.1. [Information syntheses]

ET88 _____. Noninvasive blood gas oxygen monitors. Issues Health Care Technol 1981;sec.5.M.1. [Information syntheses]

ET89 _____. Remote control fluoroscopy units. Issues Health Care Technol 1981;sec.5.F.1. [Information syntheses]

ET90 _____. Therapeutic plasmapheresis. Issues Health Care Technol 1981;sec.5.P.1. [Information syntheses]

FOOD AND DRUG ADMINISTRATION

5600 Fishers Lane
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301-443-5470

Individual profiles on the Food and Drug Administration's Center for Devices and Radiological Health, Center for Drugs and Biologics, and the Center for Food Safety and Applied Nutrition follow this overview of the agency.

The Food and Drug Administration (FDA) is a component of the Public Health Service (PHS) within the U.S. Department of Health and Human Services (DHHS). Its purpose is to ensure that: (1) food is safe and wholesome; (2) drugs (both human and veterinary), biological products, such as vaccines and blood for transfusion, and medical devices are safe and effective; (3) cosmetics are safe; (4) the use of radiological products does not result in unnecessary exposure to radiation; and (5) all of these products are honestly and informatively labeled.

The FDA accomplishes its mission through premarket clearance; monitoring, using inspections, investigations, and surveillance; compliance activities involving corrections and penalties; promulgation of regulations; and bioresearch monitoring and good laboratory practices.

The body of law defining FDA's authority is comprehensive, providing a variety of controls required by the nature of the market, the products, and potential risks.

Statutes include: the Food, Drug, and Cosmetic Act (FD&C Act); the Public Health Service Act (PHS Act of 1944); the Fair Packaging and Labeling Act of 1966; and the Orphan Drug Act of 1983.

Federal laws define the requirements applicable to firms dealing in interstate commerce, as well as the authority of the agency that will administer and enforce each law. The FDA must make regulations telling how the law is to be applied. Regulations also describe the approval processes for many individual products and set forth required standards of product composition or performance. All FDA regulations, amendments, and other notices are published in the *Federal Register* , issued daily by the Federal Government.

The FDA's principal components include: the Commissioner, Deputy Commissioner, and the staff and line organizations. The line organizations concerned with technology assessment are the four product-oriented centers: Center for Devices and Radiological Health, Center for Drugs and Biologics, Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine. The first three are described separately in this directory. The National Center for Toxicological Research is a part of FDA's science foundation.

The Center for Devices and Radiological Health is responsible for ensuring the safety and effectiveness (efficacy) of medical devices, as provided for by the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act; and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products, as provided for by the Radiation Control for Health and Safety Act of 1968.

The Center for Drugs and Biologics (CDB) is responsible for ensuring that all humanuse drugs and biologics manufactured for interstate sale are safe and effective (efficacious) and that product labeling is truthful and informative.

The Center for Food Safety and Applied Nutrition (CFSAN) regulates foods and cosmetics to ensure that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that cosmetics are safe and made from appropriate ingredients; and that the labeling of foods and cosmetics is truthful and informative.

General information on the FDA's other functions may be obtained from the Associate Commissioner for Consumer Affairs at the above address. News of FDA activities is also available through the *FDA Consumer*, a magazine issued 10 times a year by the U.S. Government Printing Office, Washington, DC 20402; stock no. 717-009-00000-2; $17 per year.

FOOD AND DRUG ADMINISTRATION CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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301-443-5807
Contact: Bobbi Dresser, Program Analyst, (for general information).

Overview: The FDA Center for Devices and Radiological Health (CDRH) is responsible for ensuring the safety and effectiveness (efficacy) of medical devices, as provided for by the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act; and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products, as provided for by the Radiation Control for Health and Safety (RCHS) Act of 1968.

CDRH classifies each type of device into the appropriate regulatory control category (Class I, devices requiring only general controls; Class II, devices requiring standards; and Class III, devices requiring premarket approval). CDRH applies general controls, such as labeling, registration, listing, Good Manufacturing Practices, and repair/replace/refund requirements. It develops performance standards for Class II devices; conducts premarket review of new devices through the premarket notification, premarket approval, and product development protocol provisions of the Amendments; and encourages the discovery and development of useful new devices, while protecting the rights and safety of human subjects in testing of devices.

In the area of radiological health, CDRH conducts epidemiological and experimental research to assess the risk from various forms and sources of radiation; develops radiation measurement instruments and methods useful in evaluating radiation-emitting devices and products; develops performance standards for radiation-emitting devices and products; develops guidelines for the use of radiation-emitting devices and products to prevent unnecessary radiation exposure; and implements survey programs to determine trends in, and the current state of the use of radiation-emitting devices and products.

The CDRH review and approval process generates Premarket Approval Applications (PMAs), Summaries of Safety and Effectiveness Data (SSED), and other reports.

Purpose: To ensure the safety and effectiveness of medical devices; to eliminate unnecessary human exposure to man-made radiation from medical, occupational, and consumer products; and to educate consumers, industry, and health professionals to enable them to make more informed judgments.

(Note: CDRH assessment activities primarily address *efficacy* as the term is used in this Directory, especially with regard to premarket approval of new devices. The agency uses the term *effectiveness* in characterizing its activities because this term is used in the agency's legislative language.)

Primary intended users: General public; people concerned about their health; patients; providers, generally; health product manufacturers.

Technologies: *Devices*, medical or surgical procedure, support system.

Intervention: *Diagnosis, treatment*, prevention.

Stage: *Emerging, new*, established or widespread practice, obsolete.

Emerging and new technologies are assessed to prevent problems; mature technologies are assessed to solve problems.

Properties: *Safety; efficacy*; effectiveness.

Medical devices are assessed for safety and effectiveness (efficacy) in their broadest sense; certain radiological screening procedures are also assessed for medical productivity.

Selection process: Manufacturers submit an application to initiate PMAs. Other topics are selected internally and assessment of topic priorities are established as part of the program planning process. New information, particularly awareness of an unforeseen problem, can lead to reassessment.

Methods: *Information syntheses, group judgment*, expert opinion for device premarketing approval; also, epidemiological and other observational methods for postmarketing surveillance of devices and for radiological health.

The assessment process is usually conducted by panels who base their assessments on information synthesized by CDRH staff. Some assessments are prepared internally by the scientific staff.

PMAs have a statutory turnaround time of 180 days; other projects may average 2 to 3 years, with a range from 1 to 5 years.

Assessors: The panel members are usually clinicians who are experts in the field and may be experienced in the use of similar technologies.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; development of the technology; regulatory agency approval status; summary of pre-clinical and clinical data.

Dissemination: Printed reports, journal articles.

Reports are available from either the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 or the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Assessment results may also be published in the *Federal Register*.

Budget: Not provided. The approximate cost for a PMA is $24,000 and for x-ray criteria, $270,000. Funding source: 100 percent parent organization.

Use: SSEDs, by statute, are required for the information of parties outside the organization. Other types of assessments are used to develop educational or regulatory strategies. Based on requests for copies and references in other documents, the assessments are used by manufacturers, other government agencies, and foreign governments. Modifications of medical practice indicate that physicians also use the assessments.

Related activities: CDRH coordinates several postmarketing surveillance activities for medical devices and in vitro diagnostic (laboratory) products. The Device Experience Network (DEN) is a computer database system that collects, stores, and retrieves problem reports for these products submitted voluntarily by health professionals. The Medical Device and Laboratory Product Problem Reporting Program (PRP) provides DEN with its primary source of device experience information. PRP is funded by FDA, and is conducted by the United States Pharmacopeia. The Medical Device Reporting (MDR) database, established following enactment of the 1984 MDR regulations, contains mandatory reports from manufacturers and importers pertaining to device performance failures and malfunctions that have resulted in injury, death, or any hazard to safety.

Completed Reports

FA1 Alcon Laboratories, Inc. [Food and Drug Administration, Center for Devices and Radiological Health] Scanlens (Scafilcon A contact lens): summary of safety and effectiveness. 1987 Jan 16. (PMA no. P850033-000).

FA2 Paragon Optical Inc. [_____] Paraperm E.W. blue rigid gas permeable contact len: summary of safety and effectiveness. 1987 Feb 18. (PMA no. P850038-000).

FA3 Precision-Cosmet., Inc. [_____] Kelman (TM) omnifit II model 2100: summary of safety and effectiveness. 1987 Feb 2. (PMA no. P850059-000).

FA4 Scimed Life Systems, Inc. [_____] Scimed PTCA dilatation catheter: summary of safety and effectiveness. 1987 Jan 16. (PMA no. P860019-000).

FA5 Stericon Laboratories. [_____] Stericon saline solution: summary of safety and effectiveness. 1987 Jan 16. (PMA no. P850070-000).

FA6 Abbott Laboratories. [_____] Abbott anti-delta diagnostic kit (RIA): summary of safety and effectiveness. 1986 Aug 7. (PMA no. P850062-000).

FA7 Advanced Biosearch Assn. [_____] Orthopak (R) bone growth stimulator: summary of safety and effectiveness. 1986 Apr 9. (PMA no. P850022-000).

FA8 Akorn, Inc. [_____] Sodium chloride tablets, USP: summary of safety and effectiveness. 1986 Mar 14. (PMA no. 850037-000).

FA9 Allergan Pharmaceuticals, Inc. [_____] Oxysept system: summary of safety and effectiveness. 1986 Nov 20. (PMA no. P850088-000).

FA10 American Edwards Division of American Supply Corporation. [_____] Duromedics bileaflet heart valve: summary of safety and effectiveness. 1986 Sep 26. (PMA no. P850006-000).

FA11 American Edwards Laboratories. [_____] Amer. Ed. Labs. PTCA: summary of safety and effectiveness. 1986 Jul 9. (PMA no. P850021-000).

FA12 American Medical Electronics, Inc. [_____] Physio-stim (TM) I & II Model 6000 & 7000: summary of safety and effectiveness. 1986 Apr 18. (PMA no. P850007-000).

FA13 Barnes-Hind Inc. [_____] Softmate (R) hydrogen peroxide disinfection system: summary of safety and effectiveness. 1986 Oct 6. (PMA no. P840066-000).

FA14 Bausch & Lomb (R). [_____] B & L (R) (Amefocon A) oxygen permeable lens: summary of safety and effectiveness. 1986 Aug 7. (PMA no. P830050-000).

FA15 Bausch & Lomb (R). [_____] B & L sterile all purpose solution & contact cleaner: summary of safety and effectiveness. 1986 Dec 16. (PMA no. P830002-000).

FA16 Bausch & Lomb. [_____] B & L Sensitive Eyes (TM) saline/cleaning solution: summary of safety and effectiveness. 1986 Jul 7. (PMA no. 850036-000).

FA17 Bausch & Lomb. [_____] B & L Therma-zyne, Fizziclean: summary of safety and effectiveness. 1986 Nov 5. (PMA no. P850093-000).

FA18 Bausch & Lomb. [_____] Sensitive eyes chemical disinfectant: summary of safety and effectiveness. 1986 Jan 2. (PMA no. P840020-000).

FA19 Bausch & Lomb. [_____] Silsoft (Elastofilcon A) contact lenses: summary of safety and effectiveness. 1986 Feb 2. (PMA no. P850068-000).

FA20 Blairex Laboratories, Inc. [_____] Blairex sterile saline solution: summary of safety and effectiveness. 1986 Mar 6. (PMA no. P850045-000).

FA21 Briggs Ophthalmics Corp. [_____] Sunsoft (Methafilcon A) hydrophilic contact lens: summary of safety and effectiveness. 1986 Aug 7. (PMA no. P850077-001).

FA22 Briggs Ophthalmics Corporation. [_____] Sunsoft (Methafilcon A) hydrophilic contact lens: summary of safety and effectiveness. 1986 Mar 28. (PMA no. P850077-000).

FA23 CTL, Inc. [_____] Customeyes (TM) 45L & 55L (Bufilcon A): summary of safety and effectiveness. 1986 Jul I. (PMA no. P850057-000).

FA24 CTL, Inc. [_____] Customeyes 70L & 79L (Lidofilcon A & B): summary of safety and effectiveness. 1986 Jul 1. (PMA no. P850058-000).

FA25 Cardiac Pacemakers, Inc. [_____] Models 925, 2040, 2041, 6564: summary of safety and effectiveness. 1986 Jan 24. (PMA no. P840068-000).

FA26 Carl Zeiss, Inc. [_____] Visulas Nd: Yag laser: summary of safety and effectiveness. 1986 Aug 7. (PMA no. P850083-000).

FA27 Cilco, Inc. [_____] Sodium chrondroitin sulfate: summary of safety and effectiveness. 1986 Nov 5. (PMA no. P820079-000).

FA28 Cilco. [_____] Viscoat (TM): summary of safety and effectiveness. 1986 Jun 6. (PMA no. P840064-000).

FA29 Coast Contact Lens, Inc. [_____] Hydra (Methafilcon A) contact lens: summary of safety and effectiveness. 1986 Aug 7. (PMA no. P850079-001).

FA30 Coast Contact Lens, Inc. [_____] Hydrasoft (Methafilcon A) contact lens: summary of safety and effectiveness. 1986 Mar 28. (PMA no. P850079-000).

FA31 Coburn Optical Industries. [_____] Intraocular lens: summary of safety and effectiveness. 1986 Dec 16. (PMA no. P860002-000).

FA32 Coburn Optical. [_____] J loop posterior chamber type II 0 & 10: summary of safety and effectiveness. 1986 Jul 1. (PMA no. P840039-000).

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FA219 Allergan Medical Optics. [_____] Model AC 10 & AC20 10LS: summary of safety and effectiveness. 1983 Aug 16. (PMA no. P810056-000).

FA220 Allergan Medical Optics. [_____] Models PC 10 & PC21: summary of safety and effectiveness. 1983 Jun 17. (PMA no. P820049-000).

FA221 Allergan Pharmaceuticals, Inc. [_____] Lens Plus (TM): summary of safety and effectiveness. 1983 Jul 19. (PMA no. P820050-000).

FA222 Amcon Inc. [_____] The Amcon Way Plus: summary of safety and effectiveness. 1983 Feb 22. (PMA no. P800069-002).

FA223 Apothecary Products, Inc. [_____] The normaline kit: summary of safety and effectiveness. 1983 Jun 17. (PMA no. P800055-002).

FA224 Asahi Chemical Industry America, Inc. [_____] Plasmaflo AP-O5H Asahi plasma separator: summary of safety and effectiveness. 1983 Aug 12. (PMA no. P820033-000).

FA225 Avicon, Inc. [_____] Microfibrillar collagen hemostat non-woven web: summary of safety and effectiveness. 1983 Feb 15. (PMA no. P800002-000).

FA226 Barnes-Hind/Hydrocurve, Inc. [_____] Soft lens salt tablets: summary of safety and effectiveness. 1983 Jul 29. (PMA no. P800067-000).

FA227 Bausch & Lomb Optics Center. [_____] Sensitive Eyes (TM) saline & cleaning solution: summary of safety and effectiveness. 1983 Sep 16. (PMA no. P820031-000).

FA228 Bausch and Lomb. [_____Devics and Radiological Health] 03/04 (TM) lens series: summary of safety and effectiveness. 1983 Aug 16. (PMA no. N16895-025).

FA229 Blairex Laboratories, Inc. [_____] The Blairex system: summary of safety and effectiveness. 1983 Feb 18. (PMA no. PB00028-003).

FA230 Boehringer Mannheim Diagnostics Inc. [_____] Micur-mic systems: summary of safety and effectiveness. 1983 Jul 19. (PMA no. P820073-000).

FA231 C.C. Kelly Enterprises. [_____] Eyerisol (R): summary of safety and effectiveness. 1983 May 31. (PMA no. P810034-000).

FA232 CIBA Vision Care [_____] Salt tablets: summary of safety and effectiveness. 1983 Feb 18. (PMA no. P810015-001).

FA233 CIBA Vision Care Corporation. [_____] Septicon (TM) disinfection regimen for use with...: summary of safety and effectiveness. 1983 Apr 8. (PMA no. P820040-000).

FA234 CIBA Vision Care Corporation. [_____] Soft-con (Vifilcon A) soft contact extended wear lens: summary of safety and effectiveness. 1983 Apr 29. (PMA no. P820021-000).

FA235 Cabot Medical Corp. [_____] Lamicel (TM): summary of safety and effectiveness. 1983 Jul 19. (PMA no. P820075-000).

FA236 Cilco, Inc. [_____] Models IS & IP: summary of safety and effectiveness. 1983 Apr 26. (PMA no. P800049-000).

FA237 Cilco, Inc. [_____] Posterior chamber intraocular lenses: summary of safety and effectiveness. 1983 Apr 1. (PMA no. P810018-001).

FA238 Con-cise. [_____] Paraperm 02 contact lens clear & blue: summary of safety and effectiveness. 1983 Dec 8. (PMA no. P820061-000).

FA239 Contact Lens Corporation of America. [_____] Softact II (polymacon): summary of safety and effectiveness. 1983 Aug 5. (PMA no. P830006-000).

FA240 Coopervision Cilco. [_____] Model AC (ACI-AC5): summary of safety and effectiveness. 1983 Apr 12. (PMA no. P810001-000).

FA241 Coopervision, Inc. [_____] Heatcase (TM): summary of safety and effectiveness. 1983 Jul 19. (PMA no. P830001-000).

FA242 Cordis Corp. [_____] Gemini (R) theta model 415A cardiac pacer: summary of safety and effectiveness. 1983 Dec 7. (PMA no. P830007-000).

FA243 Custom Tint Lab., Inc. [_____] Permatint (R): summary of safety and effectiveness. 1983 Nov 9. (PMA no. P820059-000).

FA244 Depuy (R). [_____] Prosthesis, hip, hemi-femoral, metal: summary of safety and effectiveness. 1983 Sep 16. (PMA no. P820024-000).

FA245 Dow Corning Corporation. [_____] Silicon(R) (silafilcon A) contact lens daily wear: summary of safety and effectiveness. 1983 Dec 12. (PMA no. P800054-004).

FA246 Eaton Medical Corporation. [_____] Easy Eyes (TM): summary of safety and effectiveness. 1983 Jul 19. (PMA no. P830009-000).

FA247 Electro-Biology, Inc. [_____] Scolitron (TM) stimulator: summary of safety and effectiveness. 1983 Feb 25. (PMA no. P820008-000).

FA248 Food and Drug Administration, Center for Devices and Radiological Health. Investigation of the risks & hazards with devices associated with peritoneal dialysis (including intermittent dialysis & continuous ambulatory peritoneal dialysis) & sorbent regenerated dialysate delivery systems. 1983. (NTIS order no. PB83-175984).

FA249 _____. Vascular catheter devices: a study of safety and performance—volume 1. 1983. (NTIS order no. PB83-144659).

FA250 _____. Vascular catheter devices: a study of safety and performance—volume 2. 1983. (NTIS order no. 83-144667).

FA251 Frigitronics, Inc. [_____] Opus-III contact lenses: summary of safety and effectiveness. 1983 Sep 2. (PMA no. P820074-000).

FA252 Frigitronics, Inc. [_____] Softmark: summary of safety and effectiveness. 1983 Jul 19. (PMA no. P820027-000).

FA253 Horizon Pharmacal, Inc. [_____] The Horizon system: summary of safety and effectiveness. 1983 Feb 18. (PMA no. P810009-002).

FA254 Hydracon. [_____] Hydracon (R) contact lenses: summary of safety and effectiveness. 1983 Mar 25. (PMA no. P820017-000).

FA255 Intermedics Intraocular Inc. [_____] Models 011 & 011B iridocapsular IOLS: summary of safety and effectiveness. 1983 Jan 25. (PMA no. P810042-000).

FA256 Intermedics Intraocular Inc. [_____] Models 019B, 019C, 019E, 019F, 019J, 019K: summary of safety and effectiveness. 1983 Feb 25. (PMA no. P810055-000).

FA257 Kestrel. [_____] Kestrel no. 695 heater: summary of safety and effectiveness. 1983 Jun 10. (PMA no. P820087-000).

FA258 Marlin Industries. [_____] Marlin squeeze bottle & Marlin salt tablets: summary of safety and effectiveness. 1983 Feb 18. (PMA no. P800038-001).

FA259 Medtronic, Inc. [_____] Versatrax model 7000 universal A-V pulse generator: summary of safety and effectiveness. 1983 Jan 7. (PMA no. P820003-000).

FA260 Narco Scientific. [_____] Monitoring system TCPC02: summary of safety and effectiveness. 1983 Feb 15. (PMA no. P820025-000).

FA261 National Patent Development Corporation. [_____] Hydron (TM) saline system (135 & 250 mg): summary of safety and effectiveness. 1983 Feb 25. (PMA no. P810047-002).

FA262 New England Nuclear. [_____] Rianen (TM) (3H) progestin receptor assay kit: summary of safety and effectiveness. 1983 Oct 12. (PMA no. P820052-000).

FA263 Optacryl Inc. [_____] Optacryl 60-clear: summary of safety and effectiveness. 1983 Dec 8. (PMA no. P820056-000).

FA264 Optech, Inc, [_____] Optech fre-flex soft contact lens: summary of safety and effectiveness. 1983 Feb 15. (PMA no. P810050-000).

FA265 Osmed, Inc. [_____] Drilac cubes (TM): summary of safety and effectiveness. 1983 Feb 25. (PMA no. P800012-000).

FA266 Pacesetter Systems, Inc. [_____] Programalith (TM) model 223 pulse generator 398 P: summary of safety and effectiveness. 1983 Feb 25. (PMA no. P820023-000).

FA267 Paragon Optical Inc. [_____] Paraperm 02 contact lens: summary of safety and effectiveness. 1983 Dec 8. (PMA no. P820063-000).

FA268 Parker Hannifin Corporation. [_____] Cryo-max (TM): summary of safety and effectiveness. 1983 Feb 18. (PMA no. P820002-000).

FA269 Pharmacia Diagnostics. [_____] Healon: summary of safety and effectiveness. 1983 Feb 8. (PMA no. P810031-000).

FA270 Precision-Cosmet Co., Inc. [_____] Circular open loop posterior IOLS & Kratz elliptic: summary of safety and effectiveness. 1983 Aug 9 (PMA no. P820072-000).

FA271 Precision-Cosmet, Co. [_____] AMVISC (R): summary of safety and effectiveness. 1983 Nov 28. (PMA no. P810025-000).

FA272 Professional Supplies. [_____] The soft rinse system: summary of safety and effectiveness. 1983 Feb 18. (PMA no. P800060-003).

FA273 Sensormedics. [_____] Cutaneous gas monitor: summary of safety and effectiveness. 1983 Sep 16. (PMA no. P830008-000).

FA274 St. Jude Medical Inc. [_____] Bileaflet-center opening cardiac valve: summary of safety and effectiveness. 1983 Mar 1. (PMA no. P810002-000).

FA275 Storz Instrument Co. [_____] Lincoff-design scleral buckling balloon catheter: summary of safety and effectiveness. 1983 Nov 21. (PMA no. P820009-000).

FA276 Telectronics, Inc. [_____] Autima (TM) model 2251 & model 2600: summary of safety and effectiveness. 1983 Mar 11. (PMA no. P820018-000).

FA277 Travenol Laboratories. [_____] Plasma separation system: summary of safety and effectiveness. 1983 Nov 3. (PMA no. P820032-000).

FA278 Upjohn. [_____] Gelfoam: summary of safety and effectiveness. 1983 Aug 29. (PMA no. N18286-000).

FA279 Wesley Jesson Inc. [_____] Durasoft (R) Trufo-cal (TM): summary of safety and effectiveness. 1983 Jun 3. (PMA no. N 17852-008).

FA280 Advanced Catheter Systems. [_____] Simpson-Robert coronary balloon dilatation catheter: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P810046-000).

FA281 Allergan Pharmaceuticals. [_____] Lens-wet (TM): summary of safety and effectiveness. 1982 May 14. (PMA no. P800065-000).

FA282 Amcon Inc. [_____] Nor-Sa-Tab: summary of safety and effectiveness. 1982 Feb 19. (PMA no. P800069-000).

FA283 American Medical Products Corporation. [_____] Collastat: summary of safety and effectiveness. 1982 Jan 5. (PMA no. P810006-000).

FA284 Apothecary Products, Inc. [_____] The normaline kit: summary of safety and effectiveness. 1982 Jan 12. (PMA no. P800055-000).

FA285 Avery Labs, Inc. [_____] Spinal epidural electrode for P.E.N.S. models E-355: summary of safety and effectiveness. 1982 Mar 2. (PMA no. P810033-000).

FA286 Barnes-Hind Pharmaceuticals, Inc. [_____] Softmate weekly cleaning solution: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P810017-000).

FA287 Bausch & Lomb. [_____] Sensitive eyes (TM) saline solution: summary of safety and effectiveness. 1982 Nov 11. (PMA no. P810039-000).

FA288 Bausch and Lomb. [_____] Softens (r) polymacon P.A. 1 series: summary of safety and effectiveness. 1982 Dec 17. (PMA no. N 16895 019).

FA289 Biochem International Inc. [_____] Lifespan (TM) 100 TCPC02 monitor: summary of safety and effectiveness. 1982 Oct 1. (PMA no. P820019-000).

FA290 CIBA Vision Care. [_____] Weicon (R) (Tefilicon) hydrophilic contact lens: summary of safety and effectiveness. 1982 Jul 27. (PMA no. P810005-002).

FA291 Central Pharmaceuticals, Inc. [_____] Central's pharm. salt tablets for disinfection: summary of safety and effectiveness. 1982 Jan 15. (PMA no. P810030-000).

FA292 Cobe Laboratories, Inc. [_____] Cobe century (R) TPE system: summary of safety and effectiveness. 1982 Mar 9. (PMA no. P810023-000).

FA293 Coburn Optical Industries, Inc. [_____] Binkhorst & Fedorov I iris clip IOLS: summary of safety and effectiveness. 1982 Aug 31. (PMA no. P800027-000).

FA294 Cooper Labs, Inc. [_____] Clerz lubricating & rewetting eye drops: summary of safety and effectiveness. 1982 Jul 13. (PMA no. PB00034-000).

FA295 Coopervision Cilco. [_____] Posterior chamber intraocular lenses: summary of safety and effectiveness. 1982 Aug 31. (PMA no. P810018-000).

FA296 Coopervision, Inc. [_____] Cooper (TM) 38 (polymacon) hydrophilic contact lens: summary of safety and effectiveness. 1982 May 21. (PMA no. P810057-000).

FA297 Coopervision, Inc. [_____] Mirasol (TM): summary of safety and effectiveness. 1982 Jan 12. (PMA no. P810008-000).

FA298 Coopervision, Inc. [_____] Models B-13F (P-10) & B-1H (P-11): summary of safety and effectiveness. 1982 May 25. (PMA no. P810032-000).

FA299 Cordis Corp. [_____] Cordis sequicor theta models 233D & 233E: summary of safety and effectiveness. 1982 Dec 10. (PMA no. P820014-000).

FA300 Danker and Wohlk, Inc. [_____] Danker silicone lens (Dimefocon-A): summary of safety and effectiveness. 1982 Jun 13. (PMA no. P790010-000).

FA301 _____. Quality assurance in nuclear medicine—proceedings of an international symposium and workshop, held in Washington, D.C., April 27-29. 1981. 1982. (GPO Stock No. 017-015-00221-7, NTIS Order No. PB84-199306).

FA302 Genetics Lab. [_____] Bioflow (TM): summary of safety and effectiveness. 1982 Jul 20. (PMA no. P800064-000).

FA303 Hewlett-Packard Co. [_____] H-P capnometer model 47210A, option A10 cutaneous: summary of safety and effectiveness. 1982 Apr 13. (PMA no. P810043-000).

FA304 Horizon Pharmacal, Inc. [_____] The Horizon system: summary of safety and effectiveness. 1982 Jan 12. (PMA no. P810009-000).

FA305 Howmedica, Inc. [_____] Deklene (TM): summary of safety and effectiveness. 1982 Jun 4. (PMA no. P810028-000).

FA306 Interface Biomedical Labs., Inc. [_____] Superstat: summary of safety and effectiveness. 1982 Jun 25. (PMA no. P810040-000).

FA307 Intermedics Infusaid, Inc. [_____] Infusaid implantable infusion pump model 100, 200, 4: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P800036-000).

FA308 International Hydron Corporation. [_____ Hydron (TM) saline system (135 & 250 mg): summary of safety and effectiveness. 1982 Apr 9. (PMA no. P810047-000).

FA309 International Hydron Corporation. [_____] Hydron (R) lens care unit: summary of safety and effectiveness. 1982 Oct 9. (PMA no. P820007-000).

FA310 Johnson and Johnson Co. [_____] Chamber lens models 101, 101B, 101T: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P790027-000).

FA311 Kontron Cardiovascular Inc. [_____] Kontron cutaneous PC02 monitor: summary of safety and effectiveness. 1982 Jun 18. (PMA no. P810037-000).

FA312 Medtronic, Inc. [_____] Medtronic (r) Hall prosthetic heart valve: summary of safety and effectiveness. 1982 Jan 29. (PMA no. P790018-000).

FA313 Metrosoft, Inc. [_____] Metrosoft (TM) II (polymacon) hydrophilic contact: summary of safety and effectiveness. 1982 Sep 24. (PMA no. P820026-000).

FA314 Orange Medical Instruments. [_____] Transconjunctival oxygen monitor: summary of safety and effectiveness. 1982 Nov 19. (PMA no. P820011-000).

FA315 Pharmacia, Inc. [_____] Medallion (R): summary of safety and effectiveness. 1982 Jan 1. (PMA no. P810060-000).

FA316 Precision-Cosmet. [_____] Tennant (TM) & Kelman (TM) type II: summary of safety and effectiveness. 1982 Apr 20. (PMA no. PB00016-000).

FA317 Professional Pharmaceal Co. [_____] Salt tablets: summary of safety and effectiveness. 1982 Jan 5. (PMA no. P810003-000).

FA318 Professional Supplies. [_____] The soft rinse system: summary of safety and effectiveness. 1982 Jan 1. (PMA no. P800060-000).

FA319 Radionics, Inc. [_____] Cosman ICP Tele-sensor (R): summary of safety and effectiveness. 1982 Oct 1. (PMA no. P820012-000).

FA320 Richards Medical Co. [_____] Osteo ceramic hip: summary of safety and effectiveness. 1982 Dec 10. (PMA no. P810048-000).

FA321 Salvatori Ophthalmics, Inc. [_____] (Polymacon) contact lenses: summary of safety and effectiveness. 1982 Sep 17. (PMA no. P820005-000).

FA322 Sherman Labs, Inc. [_____] Soft Pro-clean contact lens cleaner: summary of safety and effectivness. 1982 Jul 23. (PMA no. P810041-000).

FA323 Siemens-Elema Pacemaker Div. [_____] Endocardial pacemaker lead w/carbon tip: summary of safety and effectiveness. 1982 Sep 24. (PMA no. P800041-000).

FA324 Standard Pharmacal Corp. [_____] Lens-sol: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P810012-000).

FA325 Syntex Ophthalmics Inc. [_____] Polycon contact lens: summary of safety and effectiveness. 1982 Sep 21 (PMA no. N 18120-008).

FA326 Teledyne, Inc. [_____] Sleep sentry (TM): summary of safety and effectiveness. 1982 Sep 17. (PMA no. P81004-000).

FA327 Unilab, Inc. [_____] Kiel Surgibone: summary of safety and effectiveness. 1982 Jun 18. (PMA no. P800044-000).

FA328 Warner Lambert. [_____] Autobac MTS plus test system: summary of safety and effectiveness. 1982 Mar 26. (PMA no. P810024-000).

FA329 Soft Lense Inc. [_____] Hydrocurve: summary of safety and effectiveness. 1980 Jan 11. (PMA no. N 17752-000).

FA330 Soft Lense Inc. [_____] Hydrocurve: summary of safety and effectiveness. 1980 Mar 14. (PMA no. N17752-001).

FOOD AND DRUG ADMINISTRATION CENTER FOR DRUGS AND BIOLOGICS

5600 Fishers Lane
Rockville, MD 20857
301-443-2894

Contact: Don McLearn (for general information); Linda Carter (for information on new SBAs) 301-443-4330; or FOI staff (Freedom of Information inquiries) 301-443-6310.

Overview: The FDA Center for Drugs and Biologics (CDB) is responsible for ensuring that all human drugs and biologics manufactured for interstate sale are safe and effective and that product labeling is truthful and informative. Drugs and biologics are evaluated to prevent potentially dangerous or ineffective drugs, vaccines, toxoids, immune sera, antigens and allergenic products, and blood and blood products from entering the nation's health care system. For many newly approved drugs, CDB prepares a Summary Basis of Approval (SBA).

Purpose: To evaluate and approve new drugs for marketing on the basis of safety and effectiveness (efficacy), to assure that these drugs are properly labeled, and to share with the public the key facts on which approval is based.

Primary intended users: General public; people concerned about their health; patients; providers, generally; health product manufacturers.

Technologies: *Drug*.

Human-use drugs for therapeutic use are assessed.

Intervention: *Treatment*, prevention, diagnosis.

Stage: *New*.

SBAs are prepared when the drug is released for use in the practice of medicine.

Properties: *Safety, efficacy*, effectiveness.

Selection process: The CDB has criteria that determine which drugs justify an SBA. No one can request that an assessment be done beyond the intended target group of a given drug.

Methods: *Information syntheses, expert opinion*, for premarketing approval; epidemiological and other observational methods for postmarketing surveillance.

Preparations of the SBA is based on information generated by the New Drug Application process, through which manufacturers submit information for new drug approval. The approval process actually involves two stages, called the Investigational New Drug (IND) and the New Drug Application (NDA). Before CDB will permit a new drug to be tested on humans, the drug's sponsor must file an IND. The IND contains the drug's structural formula, the results of animal testing, the proposed protocol for clinical testing on humans, and other data. The CDB reviews the IND to determine whether the data are complete and sufficient to initiate clinical trials.

After the trials, but before marketing, the manufacturer files an NDA, which must contain full information about the proposed product, including the results of the clinical testing. When the claims for safety, efficacy, and labeling have been approved, the drug may go on the market, but the manufacturer must continue to send periodic reports on adverse reactions and other aspects of drug experience. The CDB may require changes of labeling or take other actions because of dangers that are revealed in this way. If a manufacturer wants to change a drug with an approved NDA—for example, to claim a new use for it—a supplemental NDA may have to be filed and approved.

The average total approval time for an NDA, i.e., from receipt by the CDB of the application to the approval date, is approximately 2 years. This includes time required by the manufacturer to provide information in response to agency actions, which average 6 months.

Assessors: Each IND and NDA is reviewed by a team of FDA scientists—a physician, pharmacologist, a chemist, a pharmacokineticist, and a biometrician (usually, a biologist, and a microbiologist. The Center may also present important NDAs to advisory committees, whose recommendations are valued but are not binding.

The Summary Basis of Approval is generally developed collaboratively by the CDB and the NDA sponsor, with experts on medicine, biostatistics, chemistry, pharmacology, and toxicology. On occasion, the sponsor may develop a draft and submit it to the CDB.

Assessment reports include: Results, findings or conclusions, regulatory agency approval status.

Dissemination: *Printed reports*; clearinghouses, data/citation bases, on-line services.

SBAs are available through the FDA's Freedom of Information Office, 301-443-6310, and from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161.

Budget: $250,000. The approximate cost per assessment is under $5,000. Funding source: 100 percent parent organization.

Use: Pharmaceutical firms use the SBAs as a source of information on the industry. They are also reviewed by consumer advocates, health professionals in universities, and others.

Related activities: The CDB issues an annual list of *Approved Drug Products* with monthly updates. Subscriptions are available for $103 per year through the U.S. Government Printing Office, Washington, DC 20204; stock no. 917-001-00000-6.

CDB coordinates a number of postmarketing surveillance programs, including spontaneous reaction reporting programs, adverse reaction registries, and research programs. Manufacturers are required to send problem reports to CDB; many health professionals and hospitals send them voluntarily. The Drug Product Problem Reporting Program (DPPR), maintained by the United States Pharmacopeia, is a computer database containing voluntary reports from providers on problems experienced when pharmaceutical products are received, used, or dispensed. These might include unsatisfactory packaging, labeling, or insert information; poor pharmaceutical quality, stability; therapeutic effectiveness, or related characteristics.

Completed Reports

FD1 Food and Drug Administration, Center for Drugs and Biologics. Acetohydroxamic acid. 1987. (Summary basis of approval, NDA # 18-749). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD2 _____. Allopurinol 100 rag. 1987. (Summary basis of approval, NDA # 18-832). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD3 _____. Allopurinol 300 rag. 1987. (Summary basis of approval, NDA # 18-832). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD4 _____. Betamethasone dipropionate. 1987. (Summary basis of approval, NDA # 19-136). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD5 _____. Betamethasone dipropionate. 1987. (Summary basis of approval, NDA # 19-137). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD6 _____. Betamethasone dipropionate. 1987. (Summary basis of approval, NDA # 19-138). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD7 _____. Bronalide inhaler system. 1987. (Summary basis of approval, NDA #18-340). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD8 _____. Bumetanide injectable. 1987. (Summary basis of approval, NDA #18-226). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD9 _____. Bumetanide tablets. 1987. (Summary basis of approval, NDA # 18-225). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD10 _____. Clonidine. 1987. (Summary basis of approval, NDA # 18-891). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clincial trials, Bench testing]

FD11 _____. Clotrimazole. 1987. (Summary basis of approval, NDA #18-827). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD12 _____. Dopamine HCl. 1987. (Summary basis of approval substitute, NDA # 19-099) [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD13 _____. Dopamine HCl. 1987. (Summary basis of approval substitute, NDA # 19-099). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD14 _____. Enalapril maleate/hydrochlorothiazide. 1987. (Summary basis of approval substitute, NDA # 19-221). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD15 _____. Hydromorphone HCl. 1987. (Summary basis of approval, NDA # 19-034). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD16 _____. Ibuprofen. 1987. (Summary basis of approval, NDA #18-989). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD17 _____. Ibuprofen. 1987. (Summary basis of approval, NDA #19-012). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD18 _____. Potassium chloride. 1987. (Summary basis of approval substitute, NDA # 19-123). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD19 _____. Potassium chloride. 1987. (Summary basis of approval, NDA # 19-439). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD20 _____. Potassium chloride. 1987. (Summary basis of approval, NDA# 19-123). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD21 _____. Potassium citrate. 1987. (Summary basis of approval, NDA # 19-071). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD22 _____. Propranolol HCl liquid. 1987. (Summary basis of approval substitute, NDA# 19-536). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD23 _____. Propranolol SR/hydrochlorothiazide. 1987. (Summary basis of approval, NDA # 19-059). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD24 _____. Propranolol hydrochloride. 1987. (Summary basis of approval, NDA #18-553). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD25 _____. Ranitidine HCl. 1987. (Summary basis of approval NDA # 18-703). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD26 _____. Ranitidine HCl. 1987. (Summary basis of approval substitute, NDA # 19-593). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD27 _____. Sodium cellulose phosphate. 1987. (Summary basis of approval, NDA # 18-757). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD28 _____. Triamterene and hydrochlorothiazide. 1987. (Summary basis of approval, NDA # 19-129). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD29 _____. Verapamil HCl. 1987. (Summary basis of approval substitute, NDA # 19-152). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD30 _____. Verapamil. 1987. (Summary basis of approval substitute, NDA # 18-817/S-003). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD31 _____. Alclometasone dipropionate. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD32 _____. Aminocaproic acid injection. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD33 _____. Betamethasone valerate. 1983. (NTIS order no. PB83-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD34 _____. Chymopapain. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD35 _____. Ciclopirox olamine. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD36 _____. Dextromethorphan resin complex. 1983. (NTIS order no. PB83-915901. [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD37 _____. Diethylpropion hydrochloride. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD38 _____. Diltiazem hydrochloride. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD39 _____. Econazole nitrate. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testin]

FD40 _____. Etomidate. 1983. (NTIS order no. PB83-91590). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD41 _____. Guanabenz acetate. 1983. (NTIS order no. PB83-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD42 _____. Guanadrel sulfate. 1983. (NTIS order no. PB 83-915901). [Information syntehese, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD43 _____. Human insulin (recombinant DNA or-gin) isophane suspension. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD44 _____. Hydrocortisone butyrate. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD45 _____. Nadolol-bendroflumethiazide. 1983. (NTIS order no. PB 83-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD46 _____. Pentazocine HCl and naloxone HCl. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD47 _____. Praziquantel, 1983. (NTIS order No. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD48 _____. Regular human insulin (recombinant DNA origin) injection. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trails, Bench testing]

FD49 _____. Selenium sulfide. 1983. (NTIS order no. PB83-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD50 _____. Technetium Tc 99m albumin colloid kit. 1983. (NTIS order no. PB83-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD51 _____. Tioconazole. 1983. (NTIS order no. PB83-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD52 _____. Triazolam. 1983. (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD53 _____. Vidarabine. 1983. (NTIS order no. PB83-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD54 _____. Xenon Xe 127 gas. 1983 (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD55 _____. 8% amino acid injection. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD56 _____. Acyclovir. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD57 _____. Albuterol sulfate. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD58 _____. Alprazolam. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD59 _____. Alprostadil (PGE1). 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD60 _____. Amcinonide. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD61 _____. Amiloride HCl. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD62 _____. Amiloride HCl/hydrochlorothiazide. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD63 _____. Aminophylline, USP. 1982/(NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD64 _____. Azatadine maleate & pseud. sulfate. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD65 _____. Azlocillin sodium. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD66 _____. Bacampicillin hydrochloride. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD67 _____. Benoxaprofen. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD68 _____. Bupivacaine hydrochloride. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD69 _____. Buprenorphine HCl. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD70 _____. CaCl2, MgCl, Kcl, & NaCl. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD71 _____. Carbamazepine. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD72 _____. Cephradine. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD73 _____. Ceruletide diethylamine. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD74 _____. Cromolyn sodium. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD75 _____. Desoximetasone. 1982. (NTIS order no. Pb82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD76 _____. Diflunisal. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD77 _____. Digoxin. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD78 _____. Disopyramide phosphate. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD79 _____. Estramustine phosphate sodium. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD80 _____. Ethynodiol diacetate with ethinyl estradiol. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological, and other observational methods, Clinical trials, Bench testing]

FD82 _____. Gemfibrozil. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD82 _____. Gemfibrozil. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD83 _____. Gonadorelin HCl. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD84 _____. Hydrocortisone butyrate. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD85 _____. Ibuprofen. 1982. (NTIS order no. PB82-915902). [Information syntheses, expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD86 _____. Indomethacin. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD87 _____. Indomethacin. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD88 _____. Intravenous fat emulsion. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD89 _____. Isotretinoin. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD90 _____. Malathion. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD91 _____. Methoxsalen. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD92 _____. Metoclopramide HCl. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD93 _____. Metronidazole injection, 0.5%. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD94 _____. Miconazole nitrate. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD95 _____. Miconazole nitrate. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD96 _____. Moxalactam disodium. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, clinical trials, Bench testing]

FD97 _____. NaCl, KCl, MgSO4, NaPO4, & KPO4. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD98 _____. Niclosamide. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD99 _____. Nifedipine. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD100 _____. Norethindrone & ethinyl estradiol. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD101 _____. Pentazocine hydrochloride and acetaminophen. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, epidemiological and other observational methods, Clinical trials, Bench testing]

FD102 _____. Pentetate indium disodium In 111. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD103 _____. Peritoneal dialysis solutions in plastic containers. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epiderniological and other observational methods, Clinical trials, Bench testing]

FD104 _____. Pindolol, 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD105 _____. Piroxicam. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD106 _____. Salts solution plus dextrose and glutathione disulfides. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD107 _____. Silver sulfadiazine. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD108 _____. Sterile piperacillin sodium. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD109 _____. Streptozocin. 1982. (NTIS order no. PB82-915903).

FD110 _____. Sucralfate. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD111 _____. Sulfadoxine and pyrimethamine. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD112 _____. Technetium Tc 99M succimer kit. 1982. (NTIS order no. PB82-915903). [Information syntheses, Expert opinion, epidemiological and other observational methods, Clinical trials, Bench testing]

FD113 _____. Technetium Tc 99m disofenin kit. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD114 _____. Theophylline in 5% dextrose injection in plastic container. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD115 _____ Timolol maleate & hydrochlorothiazide. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD116 _____. Tobramycin. 1982. (NTIS order no. 82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD117 _____. Trazodone HCl. 1982. (NTIS order no. PB82-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD118 _____. Trimethoprim tablets. 1982. (NTIS order no. PB82-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD119 _____. Verapamil HCL. 1982. (NTIS order no. PB82-915902). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD120 _____. 0.45% sodium chloride injection, USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD121 _____. 0.9% sodium chloride injection, USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD122 _____. 10% Dextrose injection, USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD123 _____. 5% Dextrose & 0.3% NaCl Inj., USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD124 _____. 5% Dextrose & 0.9% NaCl Inj., USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD125 _____. 5% Dextrose in lactated Ringer's injection in polyolefin bottle. 1981. [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD126 _____. Aminoglutethimide. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD127 _____. Amoxicillin. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD128 _____. Atenolol. 1981. (NTIS order no. PB81-915911). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD129 _____. Azathioprine. 1981. (NTIS order no. PB81-915907). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD130 _____. Beclomethasone dipropionate. 1981. (NTIS order no. PB81-915912). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD131 _____. Bethanidine sulfate. 1981. (NTIS order no. PB81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD132 _____. Bromocriptine mesylate. 1981. (NTIS order no. PB81-915912). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD133 _____. Captopril. 1981. (NTIS order no. PB81-915907). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD134 _____. Chlorhexidine gluconate. 1981. (NTIS order no. PB81-915911). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD135 _____. Chlorpheniramine maleate pseudoephedrine sulfate. 1981. (NTIS order no. PB81-915906). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD136 _____. Clorazepate dipotassium. 1981. (NTIS order no. PB81-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD137 _____. Cyclothiazide. 1981. (NTIS order no. PB81-915905). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD138 _____. DTIC (Dome). 1981. (NTIS order no. PB81-15907). [Information syntheses, Expert opinion, epidemiological and other observational methods, Clinical trials, Bench testing]

FD139 _____. Diazepam. 1981. (NTIS order no. PB81-915906). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD140 _____. Dopamine hydrochloride injection. 1981. (NTIS order no. PB81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD141 _____. Ergoloid mesylates. 1981. (NTIS order no. PB81-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD142 _____. Erythromycin base (enteric-coated pellets). 1981. (NTIS order no. PB81-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD143 _____. Extended purified beef insulin zinc suspension. 1981. (NTIS Order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD144 _____. Furosemide injection. 1981. (NTIS order no. PB81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD145 _____. Furosemide tablets. 1981. (NTIS order no. PB81-915911). [Information syntheses, expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD146 _____. Halazepam. 1981. (NTIS order no. PB81-915912). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD147 _____. Hexachlorophene. 1981. (NTIS order no. PB81-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD148 _____. Hexachlorophene. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD149 _____. Ibuprofen. 1981. (NTIS order no. PB81-915908). [Information syntheses, expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD150 _____. Intravenous fat emulsion. 1981. (NTIS order no. 81-915904). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD151 _____. Iodoxamate meglumine. 1981. (NTIS order no. PB81-915911). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing.

FD152 _____. Iron dextran Inj. USP. 1981. (NTIS order no. PB81-915906). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD153 _____. Isophane purified beef insulin suspension. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD154 _____. Isophane purified pork insulin suspension. 1981. (NTIS order no. PB81-915910). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD155 _____. Isosulfan blue. 1981. (NTIS order no. PB81-915910). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD156 _____. Ketoconazole. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD157 _____. Lidocaine HCl in 5% dextrose in plastic container (PL-146). 1981. (NTIS order no. PB81-915907). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD158 _____. Lidocaine hydrochloride, USP sterile powder. 1981. (NTIS order no. PB81-915905. [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD159 _____. Methyldopa. 1981. (NTIS order no. PB81-915911. [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD160 _____. Metolazone. 1981. (NTIS order no. PB81-915905). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD161 _____. Mezlocillin sodium. 1981. (NTIS order no. PB81-915912). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD162 _____. Multiple electrolyte injection. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD163 _____. Nitroglycerin for injection. 1981. (NTIS order no. PB81-915912). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD164 _____. Phenylpropanolamine hydrochloride chlorpheniramine maleate. 1981. (NTIS order no. PB81-915910). [Information syntheses, expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD165 _____. Potassium chloride 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD166 _____. Prompt purified beef insulin zinc suspension. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD167 _____. Purified beef insulin zinc suspension. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD168 _____. Purified pork insulin injection. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD169 _____. Ringer's irrigation, USP in flex containers. 1981. (NTIS order no. PB81-915906). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD170 _____. Saralasin acetate. 1981. (NTIS order no. PB81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD171 _____. Secretin. 1981. (NTIS order no. PB81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD172 _____. Sisomicin sulfate. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD173 _____. Sodium nitroprusside. 1981. (NTIS order no. PB81-915912) [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD174 _____. Sterile cefotaxime sodium. 1981. (NTIS order no. PB81-915906). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD175 _____. Sterile water for injection, USP. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD176 _____. Sulfamethoxazole and trimethoprim. 1981. (NTIS order no. PB81-915909). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD177 _____. Technetium 99m oxidronate kit. 1981. (NTIS order no. PB81-915905). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD178 _____. Technetium Tc 99m medronate kit. 1981. (NTIS order no. PB81-915905). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD179 _____. Temazepam. 1981. (NTIS order no. PB81-915905). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD180 _____. Trimethoprim/sulfamethoxazole. 1981. (NTIS order no. 81-915908). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD181 _____. Verapamil. 1981. (NTIS order no. PB81-915911). [Information syntheses, expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FD182 _____. Zomepirac sodium. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Color For Drugs and Devices
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Special Purpose Infant Formulas
200 C Street SW, HFF-204
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Contact: Alan Rulis, Chief, Regulatory Chemistry Branch, (Colors for Drugs and Devices program) or Nicholas Duy, Chemist (Special Infant Formula program).

Overview: The FDA Center for Food Safety and Applied Nutrition (CFSAN) is primarily responsible for regulating foods and cosmetics. CFSAN is also responsible for assessment activities including: 1) the regulation of color additives in drugs and medical devices (as well as foods), and 2) the regulation of infant formulas that are prescribed as special diets. Both activities are federally mandated. The Special Infant Formulas program was implemented in 1986, pursuant to the Infant Formula Act of 1980, concerning special infant diets for inborn errors of metabolism and other special medical needs arising from such conditions as extreme low birthweight.

Purpose: To ensure the safety and suitability of colors added to foods, drugs, and devices and to ensure the safety and effectiveness of special purpose infant formulas.

Primary intended users: Health product manufacturers; health industry associations; government regulators.

Technologies: *Drug, device*, for color additives; *medical or surgical procedure* (i.e., special diet for medical reasons) for special infant formulas.

Intervention: *Treatment*, diagnosis, rehabilitation for color additives; *treatment* for special infant formulas.

Stage: *Emerging, new*, established or widespread practice for color additives and for special infant formulas.

Properties: *Safety* for color additives; *safety*, efficacy, effectiveness for special infant formulas.

Selection process: Manufacturers of both color additives and special infant formulas must request FDA assessment of their products. Exempted from this requirement are additives known as GRAS (generally recognized as safe) and "prior sanctioned." The latter are substances the FDA determined to be safe before the 1958 Food Additives amendment.

For color additives, the FDA is developing a program to reassess the safety of each previously approved additive in light of new scientific evidence and to remove unsafe ones from the market.

Reassessments of infant formulas are conducted if the agency receives information that infants are being harmed by a product or by a similar product.

Methods: *Information syntheses*, expert opinion, group judgment, bench testing.

For color additives, manufacturers submit test data that show the substance is safe and functional. The FDA then announces in the *Federal Register* that an additive petition has been filed. After experts have reviewed the data, CFSAN announces approval of the additive through a regulation, also published in the *Federal Register*. Under a provision that has become known as the "Delaney Clause," the agency is prohibited by law from approving any additive found to cause cancer in test animals. The agency conducts laboratory toxicology studies only in cases when already marketed products experience problems. Laboratory testing is also conducted for certification of purity of color additives that have potential for toxic contaminants.

For special infant formulas, the manufacturers submit the formulas for assessment. The formulas are assessed within the agency. The agency does conduct some laboratory analysis of special infant formula samples.

The approximate turnaround time from selection of assessment topic to reporting of findings varies widely.

Assessors: Experts in chemistry, toxicology, and environmental assessment review color additives.

Infant formulas are assessed within the CFSAN by experts in nutrition, diet, chemistry, medicine, and food technology.

Assessment reports include: The assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; results; findings or conclusions; limitations of findings; implications of findings for practice; regulatory agency approval status; product recall history, environmental impact.

Dissemination: Advisories; press conferences/news releases, TV/radio broadcasts, video products.

Assessments of color additives are announced in the *Federal Register*.

Assessments of special infant formulas will be disseminated primarily through advisories to manufacturers and to foreign health agencies. Copies may be obtained by contacting the FDA's Freedom of Information Office or the CFSAN contact person given above.

Budget: Not provided. The approximate cost of an assessment is $40,000 for color additives and $10,000 for special infant formulas. Funding source for color additives: 97 percent parent organization, 3 percent manufacturers; funding source for special purpose infant formulas: 100 percent parent organization.

Use: The FDA uses the CFSAN's assessments to permit or deny use of the product or to require modifications. The assessments are also used by the manufacturers.

Program evaluation: The Colors for Drugs and Devices program is reviewed periodically by Congress.

Related activities: The CFSAN also certifies the purity of colors for drugs and devices that have a potential for problems with toxic contaminants.

Completed reports: The first assessment reports for special infant formulas should be available in 1988 or 1989.

GEORGETOWN UNIVERSITY MEDICAL CENTER INSTITUTE FOR HEALTH POLICY ANALYSIS

2121 Wisconsin Avenue NW, Suite 220
Washington, DC 20007
202-625-2115

Contact: Seymour Perry, M.D., Deputy Director.

Overview: The Institute for Health Policy Analysis, a not-for-profit research institute, conducts research on and analyzes important national health policy issues. The Institute established its Technology and Health Care Program in 1983.

Purpose: To improve the public's understanding of national health policy issues and to aid the process by which policy is set within the government.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; health/medical professional associations; health industry associations; consumer associations; unions and other employee organizations; third party payers; reporters, writers, news media; policy-makers.

Technologies: Device, medical or surgical procedure.

Intervention: Diagnosis, treatment.

Properties: *Safety; effectiveness*; efficacy; cost; cost-benefit; cost-effectiveness; ethical, legal, social implications.

Selection process: Assessments may be requested by staff or by an outside organization. However, as a matter of policy, the Institute will not conduct an assessment for an outside group unless funding is obtained from multiple sources, so as to avoid any perception of bias. Requests are made either in writing or at a meeting, and Institute staff determine which assessment topics have priority.

Methods: *Group judgment*, information syntheses, expert opinion.

Workshops and conferences are the program's chief assessment method. The first step after selecting a topic is to establish a small planning committee of people outside the organization to develop the questions to be addressed, identify speakers, and plan other aspects of the workshop or conference. A neutral panel also is chosen. The approximate turnaround time from selection of assessment topic to reporting of findings is 4 to 6 months for a workshop and 12 to 18 months for a conference.

Assessors: Committee and panel members are experts in medical and technical areas or in other areas such as health economics, ethics, or law.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: Printed reports, journal articles.

The Institute publishes a newsletter and maintains a mailing list. Results may also be reported in the lay press. The reports may be obtained, upon request, from the Institute.

Budget: $250,000. The approximate cost for a workshop is $25,000 to $30,000 and for a conference, $75,000 to $100,000. Funding sources: 50 percent parent organization; 10 percent government grants, contracts; 10 percent foundations, other private grants; 30 percent sponsors/members dues, contributions.

Use: The Institute's reports have been used in a variety of ways. The proceedings of two of its conferences on the reuse of disposable medical devices, for example, were used by several groups, including the Association for the Advancement of Medical Instrumentation, the American Society for Testing and Materials, and Congressional committees.

Related activities: The Institute also sponsors the following programs: Financial Compensation for Disease and Disability, a Unit of Advanced Studies, and the Program on Science and the Media.

Completed Reports

GU1 Georgetown University Medical Center, Institute for Health Policy Analysis. Reuse of disposable medical devices: legal liability and public policy issues. (In press) [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU2 Chu F, Novak N, Radany MH, Perry S. [Georgetown University Medical Center, Institute for Health Policy Analysis] Reuse and reprocessing of disposable medical devices. J Health Care Technol 1986;3:5-12. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU3 Chu F. [Georgetown University Medical Center, Institute for Health Policy Analysis] Changing attitudes toward reusing medical devices. Health Span-Report of Health Bus Law 1986;3:14-8. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU4 Georgetown University Medical Center, Institute for Health Policy Analysis. New medical technologies in a cost containment environment: implantable anti-tachyarrhythmia devices. Washington, DC: Institute for Health Policy Analysis, 1986. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU5 Georgetown University Medical Center, Institute for Health Policy Analysis. National Health Services and Practice Patterns Survey. Report on fully automated blood pressure monitoring: current and future applications. Washington, DC: Institute for Health Policy Analysis, 1986. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU6 Perry S. [Georgetown University Medical Center, Institute for Health Policy Analysis] Reuse of medical devices intended for single use only. Health Care Instrum 1985;1:4-8. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU7 Perry S. [Georgetown University Medical Center, Institute for Health Policy Analysis] Reusing disposable medical devices raises ethical, legal and cost questions. Bus Health 1985;2:53-4. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

GU8 Georgetown University Medical Center, Institute for Health Policy Analysis. Conference proceedings: International Conference on the Reuse of Disposable Medical Devices in the 1980s. Washington, DC: Institute for Health Policy Analysis, 1984. [Information syntheses, Expert opinion, Group judgment, Cost analyses]

Ongoing Assessments

GU9 _____. Therapeutic drug substitution: legal liability. Ongoing.

Planned Assessments

GU10 _____. Extended wear contact lenses. Planned.
GU11 _____. Home health technologies. Planned.
GU12 _____. Orphan devices in health care. Planned.
GU13 _____. Regionalization of medical technologies. Planned.

HARVARD SCHOOL OF PUBLIC HEALTH INSTITUTE FOR HEALTH RESEARCH

677 Huntington Avenue
Boston, MA 02115
617-729-5657

Contact: Howard S. Frazier, M.D.

Overview: The Institute for Health Research is a medical technology assessment program sponsored by Harvard University and the Harvard Community Health Plan. The technology assessment activities were initiated in 1965 by the Center for the Analysis of Health Practices of Harvard University, the precursor to the current Institute.

Purpose: To enhance the understanding of innovation and its consequences in the health sector.

Primary intended users: Providers, generally; physicians; acute facility administrators; other care givers; health/medical professional associations; third party payers; government regulators; public policy-makers, legislators.

Technologies: *Device*, medical or surgical procedure, support system, organizational or administrative system.

Intervention: *Treatment*, diagnosis.

Stage: *New*, established or widespread practice, obsolete.

Properties: *Efficacy*; safety; cost; cost-effectiveness; service requirements; system impact; economic implications; ethical, legal, social implications.

Selection process: An Institute investigator or nonmember (e.g., government agency) can request that assessments be conducted. The Institute Executive Committee sets assessment topic priorities based on research interest, opportunities for methodologic advances, or the potential impact of the technology or assessment. The Committee also examines the comparative advantage of the Institute over other organizations when setting priorities.

Methods: *Information syntheses*, expert opinion, group judgment, cost analyses, epidemiological and other observational methods, clinical trials, meta-analysis.

The turnaround time from selection of assessment topic to reporting of findings is 1 to 2 years.

Assessors: The assessors have expertise in the areas of medicine, surgery, dermatology, pediatrics, economics, statistics, policy analysis, psychology, law, and social psychology.

Assessment reports include: The purpose of the assessment; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stages of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/

information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles.

Dissemination: *Journal articles*, printed reports.

Budget: $300,000. The cost per assessment is highly variable ranging from $5,000 to $250,000. Funding sources: 30 percent parent organization; 40 percent government grants/contracts; 30 percent foundations, other private grants.

Related activities: The Institute offers short postgraduate courses for medical educators and others. The courses include materials on aspects of technology assessment and cost effectiveness analysis.

Completed Reports

HA1 Hussain S, Belidegrun A, Seltzer SE, Feldstein ML, et al. [Harvard School of Public Health, Institute for Health Research] CT differentiation of malignant from benign adrenal masses. Am J Roentgenol, in press. [Epidemiological methods]

HA2 Stern RS and members of the 16-center PUVA Follow-up Study. [Harvard School of Public Health, Institute for Health Research] Long-term utilization of PUVA therapy for psoriasis—evidence for efficacy and cost savings. J Am Acad Dermatol, in press. [Clinical trials]

HA3 Stern RS, Pass TM, Komaroff AL. [Harvard School of Public Health, Institute for Health Research] Topical versus systemic agent treatment for papulopustular acne: A cost-effectiveness analysis. Arch Dermatol, in press. [Information syntheses]

HA4 Thompson M, Cohen A, Palmer H. [Harvard School of Public Health, Institute for Health Research] Decision making on clinical use of electronic fetal monitors. Semin Faro Med, in press. [Epidemiological methods]

HA5 Weinstein MC. [Harvard School of Public Health, Institute for Health Research] Economic techniques for technology assessment. In: Rutten F, Reiser S, eds. Economics of medical technology. Springer-Vering, in press. [Cost analyses]

HA6 Sandberg SI, Barnes BA, Weinstein MC, Braun P. [Harvard School of Public Health, Institute for Health Research] Elective hysterectomy: benefits, risks and costs. Med Care 1985;23:1067-1085. [Information syntheses]

HA7 Stason WB, Barnes BA. [Harvard School of Public Health, Institute for Health Research] Effectiveness and costs of continuous ambulatory peritoneal dialysis (CAPD). Washington, D.C.: U.S. Congress, Office of Technology Assessment, July 1985. (Health Technology Case Study 35, OTA-HCS-35) [Information syntheses]

HA8 Stason WB, Localio AR. [Harvard School of Public Health, Institute for Health Research] Magnetic resonance imaging: clinical efficacy, costs and policy considerations. Blue Cross and Blue Shield Association, 1985. [Information syntheses]

HA9 Li Tem, Sherman H, Cook EF, et al. [Harvard School of Public Health, Institute for Health Research] The selective impact of a cardiology data bank on physician's therapeutic recommendations. Medical Decision Making 1984;4(2): 165-177. [Epidemiological methods]

HA10 Shepard DS, Karon SL. [Harvard School of Public Health, Institute for Health Research] The market for wheelchairs: innovations and federal policy. Washington, D.C.: U.S. Congress, Office of Technology Assessment, 1984. Health Technology Case Study 30, OTA-HCS-30) [Information syntheses]

HA11 Fineberg HV, Wittenberg J., Ferrucci J, Meuller P, Simeone J, Goldman J. [Harvard School of Public Health, Institute for Health Research] The clinical value of body computed tomography over time and technologic change. Am J Roentgenol 1983; 141:1067-1072. [Epidemiological methods]

HA12 Berwick DM, Komaroff AL. [Harvard School of Public Health, Institute for Health Research] Cost effectiveness of lead screening. N Eng J Med 1982;306:1392-1398. [Information syntheses]

HA13 Fineberg HV, Stason WB. [Harvard School of Public Health, Institute for Health Research] Cost-effectiveness of alternative diagnostic strategies for coronary artery disease. Circulation 1982;66(III):80-86. [Information syntheses]

HA14 Kaufman SL, Shepard DS. [Harvard School of Public Health, Institute for Health Research] Costs of neonatal intensive care by day of stay. Inquiry 1982; 19:167-178. [Epidemiological methods]

HA15 Liang M, Komaroff A. [Harvard School of Public Health, Institute for Health Research] Roentgenograms in primary care patients with acute low back pain. Arch Intern Med 1982; 142:1108-1112. [Epidemiological methods]

HA16 Stason WB, Fortess E. [Harvard School of Public Health, Institute for Health Research] Case study # 13: Cardiac radionuclide imaging and cost effectiveness. In: Implications of cost-effectiveness analysis of medical technology. Office of Technology Assessment, U.S. Congress, 1982. [Information syntheses]

HA17 Weinstein MC, Stason WB. [Harvard School of Public Health, Institute for Health Research] Cost-effectiveness of coronary artery bypass surgery. Circulation 1982;66(Suppl III):III56-III66. [Information syntheses]

HA18 Fineberg HV, Pearlman LA. [Harvard School of Public Health, Institute for Health Research] Benefit-and-cost analysis of medical interventions: the case of cimetidine and peptic ulcer disease. In: The implications of cost-effectiveness analysis of medical technology/background paper #2: case studies of medical technologies. Office of Technology Assessment, U.S. Congress. Washington, D.C.: U.S. Government Printing Office, 1981. [Information syntheses]

HA19 Thompson MS, Cohen AB. [Harvard School of Public Health, Institute of Health Research] Decision analysis: electronic fetal monitoring. In: Wortman PM, ed. Methods for evaluating health services. Beverly Hills: Sage, 1981. [Epidemiological methods]

HA20 Weinstein MC, Pearlman LA. [Harvard School of Public Health, Institute for Health Research] Case study on cost-effectiveness of automated multichannel chemistry analyzers. The implications of cost-effectiveness analysis of medical technology background paper #2: case studies of medical technologies. Office of Technology Assessment, U.S. Congress. Washington, D.C.: U.S. Government Printing Office, 1981. [Epidemiological methods]

HA21 Fineberg HV, Wittenberg J. [Harvard School of Public Health, Institute for Health Research] Evaluation of computed tomography in pancreatic cancer. Bull Cancer (Paris) 1980;67:390-394. [Epidemiological methods]

HA22 Wittenberg J, Fineberg HV, Ferrucci JT Jr, Simeone JF, Mueller PR, van Sonnenberg E, Kirkpatrick RH. [Harvard School of Public Health, Institute for Health Research] The clinical efficacy of computed body tomography. II. Am J Roentgenol 1980;134:1111-1120. [Epidemiological methods]

HA23 Fineberg HV, Wittenberg J, Ferrucci JT, Jr. [Harvard School of Public Health, Institute for Health Research] The clinical value of diagnostic tests: CT as a prototype. IN: Margulis A, Burhenne HJ, eds. Alimentary tract radiology: abdominal imaging, v. 3. St. Louis, Missouri: C.V. Mosby, 1979. [Epidemiological methods]

HA24 Fineberg HV. [Harvard School of Public Health, Institute for Health Research] Assessing the diagnostic contribution of imaging tests: computed tomography and ultrasound of the pancreas. In: Alperovitch A, de Dombal FT, Gremy F, eds. Evaluation of efficacy of medical action. New York: Elsevier-North Holland, 1979. [Epidemiological methods]

HA25 Fineberg HV. [Harvard School of Public Health, Institute for Health Research] Gastric freezing: a study of diffusion of a medical innovation. In: Medical techonology and the health care system: a study of the diffusion of equipment-embodied technology. Washington, D.C.: National Academy of Sciences, 1979. [Epidemiological methods]

HA26 Fineberg HV. [Harvard School of Public Health, Institute for Health Research] Medical technology policies and computed tomography. Ann Intern Med 1979;90:114-115. [Information syntheses]

HA27 Koplan JP, Schoenbaum SC, Weinstein MC, Fraser DW. [Harvard School of Public Health, Institute for Health Research] Pertussis vaccine—an analysis of benefits, risks and costs. N Eng J Med 1979;301:906-911. [Information syntheses]

HA28 Thompson M. [Harvard School of Public Health, Institute for Health Research] Prenatal diagnosis and public policy. In: Milunsky A, ed. Genetic disorders and the fetus: diagnosis, prevention and treatment. New York: Plenum Press, 1979. [Information syntheses]

HA29 Weinstein MC. [Harvard School of Public Health, Institute for Health Research] Economic evaluation of medical procedures and technologies: progress, problems, and prospects. In: Medical technology. Washington, D.C.: National Center for Health Services Research, 1979. (NCHSR Research Proceedings Series, DHEW pub. no. (PHS) 79-3254) [Cost analyses]

HA30 Neuhauser D. [Harvard School of Public Health, Institute for Health Research] Cost effective clinical decision making: are routine pediatric preoperative chest X-rays worth it? Ann Radiol (Paris) 1978;21:80-83. [Information syntheses]

HA31 Neutra RR, Fienberg SE, Greenland S, Friedman EA. [Harvard School of Public Health, Institute for Health Research] Effect of fetal monitoring on neonatal death rates. N Eng J Med 1978;299:324-326. [Epidemiological methods]

HA32 Wittenberg J, Fineberg HV, Black EB, Kirkpatrick RH, Schaffer DL, Ikeda MK, Ferrucci JT Jr. [Harvard Medical School, Institute for Health Research] The clinical efficacy of computerized body tomography. Am J Roentgenol 1978;131:5-14. [Epidemiological methods]

HA33 Barnes BA, Barnes AB. [Harvard School of Public Health, Institute for Health Research] Evaluation of surgical therapy by cost-benefit analysis. Surgery 1977;82:21-33. [Information syntheses]

HA34 Bunker J, Barnes B, Mosteller F, eds. Costs, risks, and benefits of surgery. New York: Oxford University Press, 1977. [Information syntheses]

HA35 Fineberg HV, Bauman K, Sossman M. [Harvard School of Public Health, Institute for Health Research] Computerized cranial tomography: effect on diagnostic and therapeutic plans. JAMA 1977;238:224-227. [Epidemiological methods]

HA36 Fineberg HV, Parker GS, Pearlman LA. [Harvard School of Public Health, Institute for Health Research] CT scanners: distribution and planning status in the United States. N Eng J Med 1977;297:216-218. [Epidemiological methods]

HA37 Neuhauser D, Jonsson E. [Harvard School of Public Health, Institute for Health Research] Managerial response to new health care technology: coronary artery bypass surgery. In: Abernathy WJ, Sheldon A, Prahalad CK, eds. The management of health care. Cambridge: Ballinger Press, 1975. [Information syntheses]

HA38 Neuhauser D, Lewicki A. [Harvard School of Public Health, Institute for Health Research] What do we gain from the sixth stool guaiac? N Eng J Med 1975;293:226-228. [Epidemiological methods]

HASTINGS CENTER

255 Elm Road
Briarcliff Manor, NY 10510
914-762-8500

Contact: Paul Homer, Assistant to the Director.

Overview: The Hastings Center is a nonprofit corporation formerly known as the Institute of Society, Ethics and Life Sciences. Since its founding in 1969, the Center has addressed ethical issues arising from advances in health and medicine, the natural sciences, and the social and behavioral sciences. The Center has about 11,000 individual members, including 2,200 libraries. Membership fees range from $38 for students to $48 for institutions and libraries.

Purpose: To carry out nonpartisan research on pressing ethical issues; to develop educational programs and literature; and to assist universities, legislators, and professional organizations in coping with moral problems.

Primary intended users: General public; providers, generally; health/medical professional associations; third party payers; government regulators; public policy-makers, legislators; policy research organizations.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system.

Most Hastings Center work is conducted by research groups that address certain technological areas. Among those currently active are groups on health policy research, chronic illness, neonatology, genetic screening, and organ transplantation.

Intervention: Prevention, diagnosis, treatment.

Stage: Emerging, new, established or widespread practice.

By examining technologies already in use—such as dialysis and heart transplants—and those currently under development, the members of the health policy research group aim to arrive at some consensus that may prove useful to researchers and policy-makers who face difficult decisions about the appropriate direction for financing and distributing new medical technologies.

Properties: Ethical, legal, social implications.

The Center is especially interested in highlighting the role played by regulatory agencies and committees in monitoring new technologies. Research groups have addressed the ethical, social, and legal issues in genetic counselling and genetic engineering; occupational health; death and dying; and alternative forms of care for the terminally ill.

The death and dying research group, established in 1970, has examined the moral, social, and legal issues of the care of the dying engendered by advanced medical technology. Subjects included organ transplantation and the definition of death, the termination of treatment of dying patients, and the allocation of scarce resources to the dying. A successor group examined the goals of medicine and their relationship to death, suffering, and well-being. It examined changing social attitudes and practices toward childbirth; the difficulties of treating pain that appears to be psychological in origin; and the nature of suffering in a life-threatening illness, including the role of hospices. The current group examines decisions to forgo various life-sustaining technologies.

Selection process: Subjects for assessments may originate from many sources, including Center staff, fellows of the Center, medical societies and professional organizations, government agencies, foundations, and subscribing members of the Center. The selection of project topics is generally made by Center staff, as approved by the board of directors. In some cases, final selection is made by foundation approval of project grant proposals made by the Center.

Methods: Information syntheses, expert opinion, group judgment.

The Center works primarily through small, multidisciplinary study groups of about 10 to 12 outside specialists. Each group is set up to address a particular set of problems, and may meet 4 or 5 times over 12 months or more. Groups usually meet first for informal planning in response to staff suggestions. Work plans are finalized and

approved by groups, then approved by the Center director or associate director. Groups often discuss relevant case studies or case histories, and may use a consensus development format. Reports and guidelines go through numerous drafts by Center staff and subgroups.

Turnaround time from selection of assessment topic to reporting of findings varies among types of projects. Most studies range from 6 to 12 months, although some have taken 2 to 3 years. The Center must also respond quickly to certain types of requests, such as requests to present testimony at Congressional hearings and requests from State and local government agencies.

Dissemination: Printed reports, journal articles.

The bimonthly *Hastings Center Report* is devoted to case studies, court decisions, other news, and articles regarding ethical problems of the biomedical, behavioral, and social sciences and issues in professional and applied ethics. Published since 1971, this is the Center's primary means of communication with its members and the general public. Other publications include monographs, reports, and books resulting from project work. Also, Center staff publish papers on ethical issues in medical technology, speak at medical conferences, and respond to inquiries from attorneys and journalists.

Budget: The annual budget of the Center is about $1.5 million, including about $250,000 devoted to studies in health and medicine. Funding sources: 56 percent foundations, other private grants; 44 percent sponsors/members dues, contributions, publications, workshops, other sources.

Technology assessment activities are supported directly by foundations such as the General Electric Foundation, the Charles A. Dana Foundation, and the Pettus-Crowe Foundation and by general funds from the Hastings Center's budget.

Use: Use of studies varies. For example, the program on ethical problems of research on human subjects monitors government regulations regarding human subjects research, develops educational and training programs and related activities, and serves as a resource for institutional review boards. A 1981 Hastings report, *The Hastings Center: Ethics in the 80s*. listed a variety of activities in which it had participated to indicate both the scope of its work and range of possible impact. The Center is described in: Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies* . Washington, DC: National Academy Press, 1985.

Related activities: The Hastings Center conducts an educational workshop program for teachers and other professionals throughout the country, and sponsors study programs for graduate and undergraduate students and visiting scholars. The Center holds workshops on problems in the ethical and legal assessment of new technologies and week-long seminars on medical ethics.

Completed Reports

HC1 Caplan A. [The Hastings Center] Should fetuses or infants be used as organ donors? Bioethics, forthcoming.

HC2 Bermel J. [The Hastings Center] Mothers vs. their babies in fetal therapy. Dialog Pediat Urol 1986 Jan.

HC3 Callahan D. [The Hastings Center] How technology is reframing the abortion debate. Hastings Cent Rep 1986 Feb.

HC4 Callahan D. [The Hastings Center] Public policy and the cessation of nutrition. In: Lynn J, ed. By no extraordinary means: the choice to forgo life-sustaining food and water. University of Indiana Press, 1986.

HC5 Caplan A. [The Hastings Center] A new dilemma: quality, ethics and expensive medical technologies. NY Med Q 1986;6(1).

HC6 Caplan A. [The Hastings Center] Ethics of in vitro fertilization. Primary Care 1986 Jun.

HC7 Caplan A. [The Hastings Center] The morality and immorality of reuse. Renal Life. 1986 Oct.

HC8 Cohen C. [The Hastings Center] Autonomy and equity in the ICU. Hastings Cent Rep 1986.

HC9 Cohen C. [The Hastings Center] Ethical and legal considerations in the care of the infant with end stage renal disease whose parents elect conservative therapy. Pediatr Nephrol 1986.

HC10 Cohen C. [The Hastings Center] Ethical problems in the clinical practice of anesthesia. In: Dekornfeld T, ed. Textbook of anesthesia. 1986.

HC11 Wolf S. [The Hastings Center] Ethics committees in the courts. Hastings Cent Rep 1986 Jun.

HC12 The Hastings Center. Ethical, legal and policy issues pertaining to solid organ procurement: a report of the Project on Organ Transplantation. 1985 Oct.

HEALTH CARE FINANCING ADMINISTRATION BUREAU OF ELIGIBILITY, REIMBURSEMENT, AND COVERAGE

East Building, Room 401
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Baltimore, MD 21207
301-594-9690

Contact: Robert E. Wren, Director, Office of Coverage Policy; or Barton McCann, M.D., 301-594-9370.

Overview: The Health Care Financing Administration (HCFA) is responsible for administering the Medicare program, provided for in title XVIII of the Social Security Act, and Federal participation in the Medicaid program. HCFA will spend approximately $84 billion for Medicare and $27 billion for Medicaid in 1988. Almost 400 million individual Medicare claims were processed in 1987.

The Medicare law provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility care, home health care, and physicians' services. It places general and categorical limitations on the coverage of the services furnished by certain health care practitioners. Medicare payment is prohibited for any expenses incurred for items and services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." HCFA regulations do not define "reasonable and necessary," and the regulations do not denote a process for how this term is to be applied.

The process used for making Medicare coverage determinations is largely a decentralized one. Most decisions are made by the 35 carriers, 54 fiscal intermediaries, and 54 professional review organizations (PROs) that contract with DHHS to review and adjudicate Medicare claims. (In general, carriers administer hospital services and related aspects of Part A of Medicare, intermediaries administer physician claims and other aspects of Part B, and PROs review appropriateness of services, utilization, and related aspects of delivery of services under Medicare.)

Although most "reasonable and necessary" coverage issues can be decided by contractors based on the Medicare statute, regulations, and policy precedents, some cannot be resolved without seeking additional expertise. Some 20 to 30 procedures per year are subject to a centralized technology assessment process coordinated by the HCFA Central Office. These issues are referred within HCFA to the Bureau of Eligibility, Reimbursement and Coverage (BERC), which assists in development of national policy on coverage, payment, and eligibility of services under Medicare and Medicaid.

HCFA's Medicaid responsibilities deal primarily with guidelines for appropriate institutional settings for services, eligibility for services, payment limitation rates, and other administrative matters. HCFA does not set technology policy for Medicaid programs, which are administered by the States, although the States often look to Medicare coverage rules for guidance. State Medicaid programs do follow HCFA policy regarding discontinuation of coverage for certain drugs—generally old ones—found by the FDA to be less than effective and that are no longer to be marketed for certain indications.

Purpose: To determine whether items and services are, or continue to be, reasonable and necessary for Medicare coverage purposes.

Primary intended users: Patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; third party payers; government regulators; public policy-makers, legislators.

Technologies: *Device, medical or surgical procedure*, drug, support system, organizational or administrative system.

Medicare coverage of drugs is treated differently from procedures. Current Medicare manual instructions provide for coverage of drugs that have been approved for marketing by FDA, except when a particular use has been expressly disapproved or withdrawn from the market by the FDA, or designated as not covered in a national HCFA instruction.

Intervention: *Diagnosis, treatment*, rehabilitation.

Stage: *New*, established or widespread practice, obsolete.

Coverage questions may concern either new or unusual technologies, or those that are believed to be outmoded and no longer reasonable and necessary.

Properties: *Safety; effectiveness*; efficacy; cost; cost-effectiveness; service requirements; acceptance/adoption level; system impact; economic implications; ethical, legal, social implications.

Selection process: Coverage inquiries normally come through the HCFA regional offices from a number of sources, usually Medicare contractors. Inquiries are also raised by individual beneficiaries, physicians and other health care providers, health product manufacturers, public officials, professional associations, and government agencies. Other coverage issues are raised during HCFA's ongoing review of medical practice, and in the course of hearings on disputed claims.

Medicare contractors have the discretion—within HCFA national coverage determinations, rulings, or manual instructions—to decide coverage issues identified in the claims review process. When a claim for a new or otherwise questionable technology is received for which national HCFA policy does not exist, contractors are authorized to make "reasonable or necessary" decisions with respect to the technology, taking into account the frequency, duration, and the setting in which it was furnished. Such decisions are usually made in consultation with the contractor's own medical staff and local medical specialty groups. Thus, coverage of any particular technology may vary among contractors.

If contractors cannot resolve a question locally, or believe a national coverage determination may be necessary, the issue is referred to the HCFA Central Office through a HCFA regional office. Assessment priorities are set by the HCFA Central Office, based on Medicare significance, potential expenses, diffusion, and level of controversy regarding the technology.

Technologies may be reassessed when new or forthcoming published information indicates the need for reconsideration of an assessment. HCFA may choose to reassess an item or service that is already excluded or covered under the Medicare program. This might occur if, in a previous assessment, PHS suggests a reevaluation of a technology at a later date.

Methods: *Information syntheses, group judgment*, expert opinion, cost analyses.

The assessment process involves the HCFA Central Office staff and Physicians Panel, the PHS, and the national medical community. Upon receiving a coverage issue, the BERC staff prepares a background paper based on a medical literature search, the status of any FDA action, administrative aspects of the issue, current applicable Medicare coverage guidelines, and any available assessments from other organizations.

The background paper is presented to the HCFA Physicians Panel for review. The Panel meets once every 6 to 8 weeks in closed session. Based on the background paper, other evidence, and discussion, the Panel may recommend that the technology be: (1) covered or not covered, (2) referred to PHS on either an informal inquiry basis or with a request for a full assessment, (3) covered or not at the discretion of the particular Medicare contractor pending receipt of more information, or (4) subject to a special study or action (e.g., as in the case of the special study on heart transplantation commissioned by HCFA.)

When a referral is made to PHS, it is made to the NCHSR Office of Health Technology Assessment (OHTA). In the case of an informal request (known as an inquiry) OHTA conducts a review of the medical literature, discusses the issue with other government agencies and medical groups, and responds to the specific questions raised by HCFA. Handling of requests for full assessments varies according to the topic, though usually involves an announcement in the *Federal Register* soliciting comments from interested parties, seeking information from other agencies and medical groups, an extensive literature search, and synthesis of this information. (This process is described in the profile on OHTA in this Directory.) HCFA coverage decisions are based on recommendations from the PHS and other available sources of public comment and expert opinion. For those issues referred to OHTA, HCFA coverage decisions have nearly always been consistent with OHTA's recommendations.

The time to complete an assessment generally ranges from 6 months to 2 years, depending upon the quality of available information, potential impact on the Medicare population, and availability of alternative technologies.

Reassessments are conducted as are those for new technologies, except that decisions to withdraw coverage call for publication of a notice in the *Federal Register* announcing that intent.

Assessors: The HCFA Physicians Panel includes about eight HCFA staff physicians, as well as other HCFA staff members with health financing expertise. Ex officio members of the Panel include representatives from OHTA, NIH, and FDA. Depending upon the assessment topic, other experts may be consulted as well. HCFA is establishing referral lists of experts in particular technological areas from other Federal agencies to be called upon for consultation on coverage decisions.

Assessment reports include: Description of the technology; findings or conclusions; coverage/reimbursement status of the technology.

National Medicare coverage decisions made by HCFA usually appear as guidelines in the *Medicare Coverage Issues Manual* provided to Medicare contractors. (Some coverage decisions require no revision of the manual.) Rather than being assessment reports as such, the guidelines in the *Manual* usually consist of at most several sentences describing a technology, whether it is covered or not, and if so, under what conditions it is covered. A few guidelines, such as those on cardiac pacemaker evaluation services (section 50-1 in the *Manual*) and magnetic resonance imaging (50-13), are 3 to 4 pages long. The background papers prepared by HCFA staff for the Physicians Panel and the OHTA assessments on which many HCFA coverage decisions are based are more detailed reports. See the Completed Reports section at the end of this profile for an example of a *Manual* coverage guideline.

Although most coverage guidelines derive from the assessment process described in this profile, the *Manual* includes some coverage guidelines set by statutory changes and other rulings. Examples are the guidelines on laser procedures (section 35-52 in the *Manual*), artificial hearts and related devices (65-15), and enteral and parenteral nutritional therapy (65-10); these guidelines are not associated with assessment reports. A coverage decision that was not subject to normal OHTA or HCFA assessment procedures was the 1986 ruling on heart transplantation, based in part on the findings of the special DHHS-sponsored study completed in 1984 by the Battelle Human Affairs Research Centers.

Dissemination: *Printed reports*; press conferences/news releases, TV/radio broadcasts, video products.

After a final HCFA coverage decision is made, the guidelines are disseminated via the *Medicare Coverage Issues Manual* and through public notice of rules, regulations, and informally through correspondence and public presentations. Background papers prepared for the Physicians Panel are for internal use only.

The *Medicare Coverage Issues Manual (HCFA Publication 6)* is available from the U.S. Government Printing Office, Washington, DC 20402. The *Manual* is updated about 15 to 20 times a year by transmittal sheets sent to its users. Individual guidelines are available from HCFA.

Budget: The budget for the HCFA Office of Coverage Policy was approximately $2,000,000 in 1986. This figure does not include the cost of OHTA assessments, the value of consultation from outside experts, and related assessment costs; and does include the cost of a variety of Medicare and Medicaid coverage activities not directly pertinent to technology assessment. Funding source: 100 percent parent organization.

Use: HCFA coverage decisions are used as a basis for Medicare coverage policy. Coverage decisions made by other government entities and private third party payers are also influenced by the guidelines.

The Medicare coverage process is described by HCFA in: Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, *Federal Register*; 52(82), April 29, 1987, 15560-62.

The HCFA assessment activity has been evaluated in the following two reports sponsored by DHHS:

Lewin and Associates. *A forward plan for Medicare coverage and technology assessment*. Prepared for the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 1986.

Macro Systems, Inc. *Technology assessment and coverage decision-making in the Department of Health and Human Services*. Prepared for the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 1984.

Related activities: BERC staff members participate in meetings and conferences sponsored by other organizations conducting technology assessment. BERC also convenes regular meetings with medical directors of HCFA contractors to discuss coverage, payment, and medical review issues.

Completed Reports:

As discussed above under Assessment Reports, HCFA coverage decisions appear as guidelines in the *Medicare Coverage Issues Manual* and normally do not generate assessment reports other than those provided by OHTA. Therefore, no listing of HCFA assessment reports is shown here; the reader may consult the profile on OHTA in this *Directory* for a listing of assessments conducted for HCFA.

For purposes of illustration, the following HCFA national coverage guideline appearing in the *Medicare Coverage Issues Manual* is reproduced here. This HCFA coverage decision followed a 1985 OHTA assessment report, *Implantable Automatic Cardioverter-Defibrillators*.

35-85 IMPLANTATION OF AUTOMATIC DEFIBRILLATORS (Effective for services performed on and after 1-24-86.)

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. The implantation of an automatic defibrillator is a covered service only when used as a treatment of last resort for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. Patients must also be found, by electro-physiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy).

It must be emphasized that unless all of the above described conditions and stipulations are met in a particular case, including the inducibility of tachyarrhythmia, etc., implan-implantation of an automatic defibrillator cannot be covered.

HEALTH CARE FINANCING ADMINISTRATION OFFICE OF RESEARCH AND DEMONSTRATIONS

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Baltimore, MD 21207
301-597-1435

Contact: Joel Broida, Research Analyst.

Overview: The Office of Research and Demonstrations (ORD), Health Care Financing Administration (HCFA) is a Federal agency that directs more than 300 research, evaluation, and demonstration projects. ORD's activities are carried out by three major components—the Office of Research, the Office of Demonstrations and Evaluations, and the Office of Operations Support. The Office of Research conducts and supports data collection efforts and research on health care providers, reimbursement, beneficiary behavior, and health care utilization. The Office of Demonstrations and Evaluations funds, manages, and evaluates pilot programs that test new ways of delivering and financing Medicare and Medicaid services. The Office of Operations Support provides ORD-wide administrative direction for its research, demonstration, and evaluation projects, which includes the budget and accounting operations; grants, cooperative agreements, and contracts-award process; and publications and information resources program.

Purpose: To carry out research, evaluation, and demonstration projects related to the administration and operation of the Medicare and Medicaid programs. A major focus is on expenditures as they relate to reimbursement, coverage, eligibility, and management alternatives. Study activity also examines program impact on beneficiary health status, access to services, utilization, and out-of-pocket expenditures. The behavior and economics of health care providers and the overall health care industry are also topics of investigation.

Primary intended users: Providers, generally; acute facility administrators; long-term care facility administrators; health industry associations; employers; unions and other employee organizations; third party payers; government regulators; biomedical researchers; public policy-makers, legislators; policy research organizations.

Technologies: *Organizational or administrative system*, drug, device, medical or surgical procedure, support system.

Intervention: Prevention, diagnosis, treatment, rehabilitation.

Stage: New, established or widespread practice.

Generally, devices and procedures are assessed after they have been introduced in the clinical setting.

Properties: *Effectiveness, cost, cost-effectiveness*, safety, efficacy, cost-benefit, service requirements, acceptance/ adoption level, system impact, economic implications.

Selection process: Requests for assessments may originate either within the agency or from outside it, through Medicare insurance contractors, other third party payers,

physicians, intermediaries, and other persons. Some requests come in the form of unsolicited grant applications. Questions about reassessments are usually decided in HCFA's Bureau of Eligibility, Reimbursement, and Coverage.

Methods: Information syntheses, expert opinion, group judgment, modeling, cost analyses, epidemiological and other observational methods.

Assessments are conducted in-house or extramurally through contracts, grants, and cooperative agreements.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who-conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/ synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how much the assessment cost; how the technology works, including theory, principles; development of the technology; procurement/deployment information; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology; product recall history, liability actions.

Dissemination: *Printed reports*; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products; clearinghouses, data/citation bases, online services, specifically, the NTIS database.

As extramural projects are completed, the final reports are placed with the National Technical Information Service (NTIS). For those projects with final reports at NTIS, the accession number is necessary when ordering. Further information may be obtained from: NTIS, Document Sales, 5285 Port Royal Rd., Springfield, VA 22151, 703-487-4650.

A select number of final reports is published by HCFA under its *Grants and Contracts Reports Series*. These reports are available for sale from the U.S. Government Printing Office (GPO). Reports must be ordered by title and stock number directly from GPO: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

In addition, results from intramural and extramural research projects and demonstrations are often featured in the *Health Care Financing Review*, the agency's quarterly journal. The journal also offers synopses on newly awarded research and demonstration projects being funded by HCFA. The *Review* is available on a subscription basis from the GPO for $18.00 ($22.50 foreign).

Budget: Not provided. Funding source: 100 percent parent organization.

Use: HCFA uses the assessment reports to assess new methods and approaches for providing quality health care while containing costs and to help make policy decisions on coverage and reimbursement of services for Medicare beneficiaries. The reports are also used by the research community, other Government agencies, universities, and other interested parties in the private sector such as private health insurers.

Completed Reports

HF1 A demonstration and evaluation of a preventive services package to provide early detection of illness and monitoring high-risk Medicare beneficiaries. In: Office of Research and Demonstrations, Health Care Financing Administration. Health care financing status report: research and demonstrations in health care financing. Jan 1986. (HCFA Pub. No. 03219).

HF2 A demonstration of cost control and patient satisfaction resulting from the relaxation of the maximum public enrollment rule for HMO's. In: _____.

HF3 A longitudinal study of case-mix outcomes and resource use in nursing homes. In: _____.

HF4 A national study of resource-based relative value scales for Physician Services. In: _____.

HF5 AFDC/Medicaid eligibility—impact on prenatal care use. In: _____.

HF6 Acquisition and analysis of state Medicaid data. In: _____.

HF7 Alcoholism services under Medicare and Medicaid: Illinois demonstration. In: _____.

HF8 Alcoholism services under Medicare and Medicaid: Michigan demonstration. In: _____.

HF9 Alcoholism services under Medicare and Medicaid: New Jersey demonstration. In: _____.

HF10 Alcoholism services under Medicare and Medicaid: New York demonstration. In: _____.

HF11 Alcoholism services under Medicare: Connecticut demonstration. In: _____.

HF12 Alcoholism services under Medicare: Oklahoma demonstration. In: _____.

HF13 Alternate models for prepaid capitation of health care services for Medicare beneficiaries—Oregon. In: _____.

HF14 American Association of Retired Persons' Informed Buyer Program. In: _____.

HF15 An analysis of long-run rate setting strategies for risk-based contracting under Medicare. In: _____.

HF16 An evaluation of "Life-Continuum of Care" residential centers in the United States. In: _____.

HF17 An independent evaluation of the reliability of the standardized Medreview Instrument. In: _____.

HF18 Analysis of Medicare routine costs under alternative assumptions. In: _____.

HF19 Analysis of NMCUES data. In: _____.

HF20 Analysis of long-term care payment systems. In: _____.

HF21 Analysis of physician fee information from several sources. In: _____.

HF22 Analysis of physician pricing behavior, third-party administrative practices. In: _____.

HF23 Analysis of the 1982 Long-Term Care Survey. In:

HF24 Analysis of the 1982 survey of informal care-givers. In: _____.

HF25 Annual reports to Congress on the impact of the Medicare Hospital prospective payment system. In: _____.

HF26 Appropriateness of hospitalization: a comparative analysis of reliability and validity of the Appropriateness Evaluation Protocol and the Standardized Medreview Instrument. In: _____.

HF27 Aspects of physician behavior in Medicare and Medicaid. In: _____.

HF28 Assess (State) tax incentives as a means of strengthening the informal support system for the elderly. In: _____.

HF29 Assessment of emerging technologies for the treatment of end-stage renal disease. In: _____.

HF30 Assignment rates revisited. In: _____.

HF31 California State Copayment Project In: _____.

HF32 Can geriatric nurse practitioners improve nursing home care? In: _____.

HF33 Capitation payment system for all end-stage renal disease services. In: _____.

HF34 Case mix and resource use in hospital emergency room settings. In: _____.

HF35 Case-managed medical care for nursing home patients. In: _____.

HF36 Case-mix measure for long-term care Medicare patients. In: _____.

HF37 Changes in the distribution of Medicare expenditures. In: _____.

HF38 Children's Hospital Case-Mix Classification System Project. In: _____.

HF39 Comparative analysis of the costs and outcomes of kidney transplants. In: _____.

HF40 Comparison by state of SNF/ICF types: beds, staffing, utilization, and ownership. In: _____.

HF41 Comparison of quality of life of end-stage renal disease patients. In: _____.

HF42 Comparison of the cost and quality of home health and nursing home care. In:

HF43 Competitive managed health plans for AFDC/Medicaid recipients. In: _____.

HF44 Consumer as a partner in medical cost containment. In: _____.

HF45 Cost of care information to consumers. In: _____.

HF46 Costs, outcomes, and competition in the End-Stage Renal Disease Program. In: _____.

HF47 Creating diagnosis-related-group-based physician reimbursement schemes: a conceptual and empirical analysis. In: _____.

HE48 Demonstration and evaluation of competitive bidding as a method of purchasing durable medical equipment. In: _____.

HF49 Demonstration and evaluation of competitive bidding as a method to purchase clinical laboratory services. In: _____.

HF50 Demonstration of community-wide, alternative long-term care model. In: _____.

HF51 Determination of health maintenance organization capitation rates for Medicare beneficiaries. In: _____.

HF52 Develop the technology of aide sharing into a transferable form for use by home health agencies to reduce home health costs. In: _____.

HF53 Developing incentive systems to increase the supply of cadaveric kidneys for transplants. In: _____.

HF54 Development of a case-mix based reimbursement method for hospital outpatient departments and freestanding clinics. In: _____.

HF55 Development of staging for six rehabilitation conditions and a cross-reference system with their respective diagnosis-related groups. In: _____.

HF56 Development, pilot testing, and refinement of valid outcome measures for the home care setting. In: _____.

HF57 Diagnosis-related groups and nursing resources. In: _____.

HF58 Diagnosis-related groups refinement for nursing care. In: _____.

HF59 Diagnosis-related groups refinement using measures of disease severity. In: _____.

HF60 Diagnostic mix, illness severity, and costs in teaching and nonteaching hospitals. In: _____.

HF61 Disease-specific severity adjustments to diagnosis-related groups. In: _____.

HF62 Disproportionate share hospitals: costs and case mix. In: _____.

HF63 Economic and clinical outcomes of three drug cost-containment strategies in Medicaid. In: _____.

HF64 Economics of diagnosis-related-group-based physician reimbursement. In: _____.

HF65 Effects of alternative family support strategies. In: _____.

HF66 Encouraging appropriate care for the chronically ill elderly: a controlled experiment to evaluate the impacts of incentive payments on nursing home admissions, discharges, case mix, care, outcomes, and costs. In: _____.

HF67 End-Stage Renal Disease Nutritional Therapy Study. In: _____.

HF68 End-stage renal disease annual report to Congress. In: _____.

HF69 End-stage renal disease competitive bidding demonstration. In: _____.

HF70 Enrollment of Medicare beneficiaries under a unique intra-health maintenance organization competition model. In: _____.

HF71 Evaluability assessment of the Medicare prospective payment system on long-term care. In: _____.

HF72 Evaluation of Massachusetts case-managed medical care for nursing home patients. In: _____.

HF73 Evaluation of Medicaid competition demonstrations. In: _____.

HF74 Evaluation of Medicare health maintenance organization demonstration projects. In: _____.

HF75 Evaluation of Municipal Health Services Program. In: _____.

HF76 Evaluation of National Rural Swing-Bed Program. In: _____.

HF77 Evaluation of Obstetrical Access Pilot Project. In: _____.

HF78 Evaluation of coordinated community-oriented, long-term care demonstration. In: _____.

HF79 Evaluation of health maintenance organization (HMO) capitation demonstrations. In: _____.

HF80 Evaluation of prepaid managed health care demonstration. In: _____.

HF81 Evaluation of prepaid risk-bearing care organization. In: _____.

HF82 Evaluation of social health maintenance organization demonstrations. In: _____.

HF83 Evaluation of the Arizona health care cost-containment system. In: _____.

HF84 Evaluation of the Medicare competition demonstrations. In: _____.

HF85 Evaluation of the Medicare mental health demonstration. In: _____.

HF86 Evaluation of the alcoholism services demonstration. In: _____.

HF87 Evaluation of the impact of second opinions for elective surgery. In: _____.

HF88 Evaluation of the urban health clinics demonstration. In: _____.

HF89 Evaluation of three-state demonstration in nursing home quality assurance. In: _____.

HF90 Feasibility of incorporating CPT-4 codes for physician billing into the diagnosis-related groups system for in-hospital Medicare surgical patients. In: _____.

HF91 Foot care coverage study. In: _____.

HF92 Further analysis of the medical doctor diagnosis-related groups algorithms. In: _____.

HF93 Geriatric Continence Research Project. In: _____.

HF94 Health Care Plus: the Lutheran Medical Center program for prepaid managed health care. In: _____.

HF95 Health Status at Discharge Research Project. In: _____.

HF96 Health care alternatives within Title XIX: evaluation of alternative reimbursement methods to providers of primary care medical services. In: _____.

HF97 Health care services for children under Medicaid. In: _____.

HF98 Health services utilization study. In: _____.

HF99 Home health agency prospective payment demonstration. In: _____.

HF100 Home respiratory therapy services. In: _____.

HF101 Home services for functionally disabled adults. In: _____.

HF102 Hospice patient outcomes and quality of care. In: _____.

HF103 Impact of DRG-based prospective payment system on quality of care for hospitalized Medicare patients. In: _____.

HF104 Impact of Medicare fee freeze and participation agreements on physicians. In: _____.

HF105 Impact of Medicare's prospective payment system and private sector initiatives: the Blue Cross and Blue Shield Organization's experiences. In: _____.

HF106 Impact of physician supply and regulation on physician fees and utilization of services. In: _____.

HF107 Impact of psychological intervention on health care utilization and costs: a prospective study. In: _____.

HF108 Impact of the prospective payment system on the quality of inpatient care. In: _____.

HF109 Implications of the National Hospice Study for hospice prospective reimbursement. In: _____.

HF110 Improving New York State's Nursing Home Quality Assurance Program. In: _____.

HF111 Incentive prospective payment system for hospitals through fiscal intermediaries (Massachusetts). In: _____.

HF112 Incentive reimbursement plan for Medicaid home health services. In: _____.

HF113 Incorporating the cost of ambulatory care into case-mix based hospital reimbursement. In: _____.

HF114 Independent broker: coordinating open enrollment for Medicare health maintenance organizations and competitive medical plans. In: _____.

HF115 Information for prudent insurance choices. In: _____.

HF116 Learning from and improving diagnosis-related groups for end-stage renal disease patients. In:

HF117 Long-term care of aged individuals with hip fractures: public versus private costs. In:

HF118 Long-term care residential services for developmentally disabled people. In: _____.

HF119 Longitudinal studies of local area hospital use. In: _____.

HF120 Longitudinal study of the impact of prospective reimbursement under Medicaid on nursing home care in Maine. In: _____.

HF121 Malpractice component of the Medicare economic index. In: _____.

HF122 Massachusetts Health Care Panel Study of Elderly-Wave IV. In: _____.
HF123 Measuring the cost of case mix using patient management categories. In: _____.
HF124 Medicaid child health care evaluation. In: _____.
HF125 Medicaid program evaluation. In: _____.
HF126 Medicaid program evaluation: cluster I. In: _____.
HF127 Medicaid program evaluation: cluster II. In: _____.
HF128 Medicaid program evaluation: cluster III. In: _____.
HF129 Medicaid tape-to-tape ambulatory services project. In: _____.
HF130 Medicaid tape-to-tape: data and analysis. In: _____.
HF131 Medicaid voucher demonstration. In: _____.
HF132 Medical doctor diagnosis-related groups algorithms. In: _____.
HF133 Medicare Prospective Capitation Demonstration Project. In: _____.
HF134 Medicare and Medicaid data book. In: _____.
HF135 Medicare automated data retrieval system. In: _____.
HF136 Medicare clinical social worker demonstration. In: _____.
HF137 Medicare competition demonstrations. In: _____.
HF138 Medicare health maintenance organization additional benefits. In: _____.
HF139 Medicare reimbursement regression to the mean. In: _____.
HF140 Medicare-Medicaid payment policies and capital formation. In: _____.
HF141 Medigap study of comparative effectiveness of state regulations. In: _____.
HF142 Methods of improving case mix and severity of illness classification for use in the Medicare prospective payment system. In: _____.
HF143 Metropolitan Comprehensive Care Program: a health systems organization demonstration. In: _____.
HF144 Missouri Medicaid Prepaid Health Demonstration Project. In: _____.
HF145 National Hospice Study. In: _____.
HF146 National Hospital Rate-Setting Study. In: _____.
HF147 National Kidney Dialysis and Kidney Transplantation Study. In: _____.
HF148 National and cross-national study of long-term care populations. In: _____.
HF149 New Jersey mobile intensive care system. In: _____.
HF150 New York Ambulatory Care Reimbursement Project. In: _____.
HF151 New York State case-mix, prospective reimbursement system for long-term care. In: _____.
HF152 Noncertified hospice cost analysis. In: _____.
HF153 Nonintrusive outcome measures: identification and validation. In: _____.
HF154 Organ Donor Education Project. In: _____.
HF155 Payment options for nonphysician anesthetists under the prospective payment system. In: _____.
HF156 Physician reimbursement and continuing care under Medicaid in Suffolk County, New York. In: _____.
HF157 Planning study: phase I of a major study of national long-term care policies. In: _____.
HF158 Population-based study of hospice. In: _____.
HF159 Post-surgical mortality among the aged for common operations. In: _____.
HF160 Prenatal care and its relationship to Medicaid costs. In: _____.
HF161 Prevention of falls in the elderly. In: _____.
HF162 Prevention of future utilization of health and long-term care services. In: _____.
HF163 Program for prepaid managed health care. In: _____.
HF164 Prospective payment beneficiary impact study. In: _____.
HF165 Prospective payment in rehabilitation hospitals and programs. In: _____.
HF166 Prospective payment of physicians. In: _____.
HF167 Prospective payment system and post-hospital care: use, cost, and market changes. In: _____.

HF168 Prospective payment system for acute and chronic care hospitals in Maryland. In: _____.
HF169 Prospective reimbursement system based on patient case mix for New Jersey hospitals. In: _____.
HF170 Quality and effectivness of preventive medical care. In: _____.
HF171 Quality assurance sampling: a statistical quality-control approach to inspection of care. In: _____.
HF172 Quality of life among life-care facility and community residents: A comparison. In: _____.
HF173 Reducing inappropriate use of inpatient medical, surgical, and pediatric services—extension of the Appropriateness Evaluation Protocol. In: _____.
HF174 Registered dietitians in home care. In: _____.
HF175 Rehospitalization after surgery among Medicare enrollees. In: _____.
HF176 Relative effectiveness and cost of transplantation and dialysis in end-stage renal disease. In: _____.
HF177 Research on competitive forces driving Medicare utilization. In: _____.
HF178 Resource utilization groups: validation and refinement of a case-mix system for long-term care reimbursement. In: _____.
HF179 Respite care co-op for impaired elderly. In: _____.
HF180 Response of Massachusetts acute-care hospitals to the Massachusetts Cost-Containment Act. In: _____.
HF181 Responsibility of children for financing institutional care: potential response and possible adjustments. In: _____.
HF182 Section 1619 study on the working disabled. In: _____.
HF183 Selected analyses of the prospective payment system's impact on hospital's behavior In: _____.
HF184 Self-care home computer program to reduce health care costs. In: _____.
HF185 Senior Group Health Plan Waiver-Only Medicare Competition Demonstration Program. In: _____.
HF186 Severity of illness and diagnosis-related groups in selected cancers. In: _____.
HF187 Severity of illness in end-stage renal disease population in northern Florida. In: _____.
HF188 Social Health Maintenance Organization Project for long-term care. In: _____.
HF189 South Carolina Community Long-Term Care Project. In: _____.
HF190 State Medicaid nursing home policies, utilization, and expenditures. In: _____.
HF191 Statewide Medicaid competition demonstration. In: _____.
HF192 Studies evaluating Medicaid home- and community-based services: a report to Congress. In: _____.
HF193 Studies of Medicare use before death. In: _____.
HF194 Study of Medicare-funded heart transplants. In: _____.
HF195 Study of high-cost infants under Medicaid. In: _____.
HF196 Study of long-term care quality and reimbursement in teaching and nonteaching nursing homes. In: _____.
HF197 Study of the quality and effectiveness of experimental fixed-price Medicare Part A intermediary contracting. In: _____.
HF198 Systematic examination of factors that promote home care by the family. In: _____.
HF199 Test of the out-of-pocket cost savings as an incentive for changing beneficiary choice behavior. In: _____.
HF200 Texas Long-Term Care Case-Mix Reimbursement Project. In: _____.
HF201 The economy and efficacy of Medicare reimbursement for preventive services. In: _____.
HF202 The impact of Medicaid home and community-based waiver services for the mentally retarded in Maine. In: _____.
HF203 The nature, process, and modes of hospice care delivery. In: _____.
HF204 The relation of surgical volume and other factors to mortality after surgery. In: _____.
HF205 Title XVIII Hospice Benefit Program evaluation (Medicare). In: _____.
HF206 Urban health clinics demonstration. In: _____.
HF207 Use of Medicare services by disabled enrollees under 65 years of age. In: _____.
HF208 Use of services by the dually entitled (cross-overs). In: _____.
HF209 Waiver-Only Competition Project for Southern California, Illinois, Indiana, and Texas. In: _____.

HEALTH COUNCIL OF THE NETHERLANDS

PO Box 90.517
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The Netherlands
(31-70) 47-14-41

Contact: Dr. Henk Rigter, Executive Director.

Overview: The Health Council of The Netherlands is a not-for-profit, independent advisory council funded by the Government of The Netherlands. The Council was established in 1903 and its position was reconfirmed in the Health Act of 1956.

Purpose: To advise the government about the "state of science" with respect to health care and environmental protection.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; financial analysts, consultants; reporters, writers, news media; information/computer industry; labs, blood banks; public policy-makers, legislators; policy research organizations; lawyers.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system, environmental protection technologies.

Intervention: *Prevention, treatment*, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice, obsolete.

Properties: Safety; efficacy; effectiveness; cost; cost-benefit; cost effectiveness; service requirements; acceptance/ adoption level; system impact; economic implications, ethical, legal, social implications; psychological issues.

Selection process: Although financed by the government, the Council operates as an independent agency. The Council selects assessment topics, sets priorities, and decides how an assessment should be conducted. The government may also formally request advice on specific topics. The Council is free to issue reports at its own initiative. Reports are updated regularly. Staff members, Council members, or committee members may suggest reassessments to the President of the Council.

Methods: *Group judgment*, information syntheses, expert opinion, modeling, cost analyses, epidemiological and other observational methods.

The Council's assessment activities emphasize state-of-the-art syntheses. For each subject, the President or Vice-President of the Council appoints a multidisciplinary committee of experts. At any given time, about 65 committees are at work, involving a total of approximately 600 persons (members and non-members of the Council). The approximate turnaround time from selection of assessment topic to reporting of findings is 18 months.

Assessors: Committee members have expertise in medical specialties, economics, psychology, sociology, law, ethics, management, physics, chemistry, and biology.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; procurement/deployment information; where technology is in use; coverage/reimbursement status of the technology.

Dissemination: *Printed reports*; journal articles; advisories to profession, hospitals; press conferences/news releases, TV/radio broadcasts, video products.

In general, the reports of the Council are public. They are printed and distributed by the Council and sent to the press and interested organizations and individuals. Most reports have an English summary; this is only the first step in making the publications accessible to an international audience. The Council plans to produce an English newsletter, to be published 3 times a year. The first issue is scheduled to appear in 1987.

Budget: $1.7 million. The approximate cost per assessment is $70,000. Funding sources: 90 percent government grants/contracts; 5 percent foundations, other private grants; 5 percent sales of assessments, consultant services.

Use: Although formally addressed to the government, some reports of the Council are directly relevant to health care professionals. For example, most hospitals in The Netherlands use reports issued by the Council as a reference source for radiation protection and prevention of hospital infections.

Program evaluations: In 1983, the government established a national commission to evaluate the Council. The evaluation consisted of interviews and the results were very positive.

Related activities: The Council publishes a newsletter, sponsors symposia, and serves a clearinghouse function for medical technology assessment in The Netherlands.

Completed Reports

HN1 Health Council of The Netherlands. CO2. 1987
HN2 _____. Transplantation issues. 1987.
HN3 _____. Ultrasound. 1987.
HN4 _____. Artificial procreation. 1986. (English summary only).
HN5 _____. Dialysis and kidney transplantation. 1986. [English summary only].
HN6 _____. Inhalation sedation in dentistry. 1986. [English summary only].
HN7 _____. Inhalation sedation in dentistry. 1986. [English summary only].
HN8 _____. Magnetic resonance spectroscopy. 1986. [English summary only].
HN9 _____. Mental health care. 1986. [English summary only].

HN10 _____. Monoclonal antibodies. 1986.
HN11 _____. Monoclonal antibodies. 1986. [English summary only].
HN12 _____. Otitis media. 1986. [English summary only].
HN13 _____. Pain treatment. 1986. [English summary only].
HN14 _____. Positron emission tomography. 1986. [English summary only].
HN15 _____. Sexually transmitted diseases. 1986.
[English summary only].
HN16 _____. Suicide. 1986. [English summary only].
HN17 _____. Therapeutic hemapheresis. 1986. [English summary only].
HN18 _____. Very low energy diets. 1986. [English summary only].
HN19 _____. Allogenic bone marrow transplantation. 1985. (English summary only).
HN20 _____. Classification of and standards for radionuclide laboratories. 1985. (English summary only).
HN21 _____. Guidelines for radiation protection in hospitals and out-patient departments. 1985. (English summary only).
HN22 _____. Minimal brain dysfunction. 1985. (English summary only).
HN23 _____. Second report on AIDS: clinical, psychosocial and ethical aspects. 1985. (English summary only).
HN24 _____. Cardiac surgery. 1984.
HN25 _____. Brain death criteria. 1983.
HN26 _____. Hepatitis B. 1983.
HN27 _____. Neonatal intensive care. 1982.
HN28 _____. Hypertension. 1978.
HN29 _____. Recent developments in anesthesiology. 1978.
HN30 _____. Transsexualism. 1977.
HN31 _____. Use of antibiotics. 1977.
HN32 _____. Coronary heart surgery. 1976.
HN33 _____. Preventing hospital infections. 1976.

Ongoing Assessments

HN34 _____. AIDS (acquired immune deficiency syndrome). Ongoing.
HN35 _____. Admission of new sera and vaccines. Ongoing.
HN36 _____. Alternative medicine. Ongoing.
HN37 _____. Anorexia nervosa and boulimia. Ongoing.
HN38 _____. Biotechnology: new avenues of research. Ongoing.
HN39 _____. Bone marrow transplantation. Ongoing.
HN40 _____. Breast feeding (contamination of milk). Ongoing.
HN41 _____. Chymopapain. Ongoing.
HN42 _____. Diagnosis and treatment of the fetus. Ongoing.
HN43 _____. Dialysis. Ongoing.
HN44 _____. Endoscopy. Ongoing.
HN45 _____. Fetal surgery. Ongoing.
HN46 _____. Food irradiation. Ongoing.
HN47 _____. Hair analysis. Ongoing.
HN48 _____. In vitro fertilization. Ongoing.
HN49 _____. Innovations in medical technology. Ongoing.
HN50 _____. Lasers. Ongoing.
HN51 _____. Lithotryptor. Ongoing.
HN52 _____. Liver transplantation. Ongoing.
HN53 _____. Medical equipment: priorities in research and development. Ongoing.
HN54 _____. Minimal brain dysfunction. Ongoing.
HN55 _____. Monoclonal antibodies, advice on regulatory issues. Ongoing.
HN57 _____. NMR/MRI. Ongoing.
HN58 _____. National vaccination program. Ongoing.
HN59 _____. Osteoporosis. Ongoing.
HN60 _____. Otitis media. Ongoing.
HN61 _____. PET-scan. Ongoing.
HN62 _____. Pain treatment and clinics. Ongoing..
HN63 _____. Pediatric surgery. Ongoing.
HN64 _____. Prevention of hospital infections. Ongoing.
HN65 _____. Psychogeriatrics. Ongoing.

HN66 _____. Psychosurgery. Ongoing.
HN67 _____. Screening for breast cancer. Ongoing.
HN68 _____. Screening for neural tube defects. Ongoing.
HN69 _____. Stress and health. Ongoing.
HN70 _____. Suicide. Ongoing.
HN71 _____. Transplantation: ethical and legal; kidney; heart; liver; pancreas; bone marrow. Ongoing.
HN72 _____. Treatment of kidney stone disease. Ongoing.
HN73 _____. Ultrasound. Ongoing.
HN74 _____. Vaccination against haemophilus influenzae B. Ongoing.
HN75 _____. Vaccination against influenza. Ongoing.

Planned Assessments

HN76 _____. Home care. Planned.
HN77 _____. Lasers. Planned.
HN78 _____. Medical, ethical, and legal implications of advances in genetics. Planned.
HN79 _____. Post marketing surveillance of drugs. Planned.
HN80 _____. Radiation risks. Planned.
HN81 _____. Synthetic growth hormone. Planned.

HEALTH AND WELFARE CANADA HEALTH SERVICES AND PROMOTION BRANCH

Institutional and Professional Services Division
Guidelines for Institutional Programs
Ottawa, Ontario K1A 1B4
Canada
613-954-8623

Contact: David L. Martin, Consultant in Health Technology or Donald F. Moffatt, Director, Institutional and Professional Services Division.

Overview: The Institutional and Professional Services Division is a government agency that provides leadership in the development of Canada's health services system. The Guidelines for Institutional Programs is a technology assessment program that issues guidelines on specific health services.

Purpose: To provide guidelines for the planning, organization, staffing, and operation of institutional health programs.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; health/medical professional associations; government regulators; labs, blood banks; public policy-makers; legislators; lawyers; provincial and regional health planners.

Technologies: Device, medical or surgical procedure, support system, organizational or administrative system.

Technologies with a major impact on institutional resources, provincial fiscal resources, or patient well-being are assessed.

Intervention: *Treatment*, diagnosis, rehabilitation.

Stage: *New*, established or widespread practice.

Assessments are generally conducted after the initial introduction of a technology; many assessments address how technologies should be implemented in established systems.

Properties: *Service requirements*, effectiveness.

A technology's requirements for medical and allied health staff preparation and maintenance of skills, support services, and other resources are assessed.

Selection process: Provincial ministries of health usually request that an assessment be conducted. Occasionally health professional associations, other institutions, or individuals initiate a request. Requests are submitted to the appropriate federal/provincial review committee for approval. The committee also sets assessment topic priorities. Anyone can suggest the periodic review of a guideline.

Methods: Group judgment, information syntheses.

Departmental staff prepares information syntheses on a specific technology. An expert panel meets on several occasions and then drafts a report. It requires 8 months to prepare the report and obtain the review committee's approval. An additional 6 months is needed to edit, translate, and publish the final report.

Assessors: The assessors' areas of expertise cover a broad range of disciplines.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; minimum requirements in terms of workload support services.

Dissemination: Printed reports, journal articles.

Assessment results are disseminated using a mailing list and are publicized in professional journals. Copies of the reports may be requested from the provincial or federal health ministry.

Budget: $400,000. The approximate cost per assessment is $30,000 plus department staff time (1 man-year each). Funding source: 100 percent parent organization.

Use: The government uses the guidelines to promote uniform health care standards for all Canadians. Provincial ministries, hospital administrators, and others use the guidelines for planning purposes.

Program evaluation: The Division requested an evaluation of the program to determine relevance and to identify potential improvements. Funded by the government, a private consulting firm (RMS Consultants) conducted the evaluation from November

1985 to March 1986. Based on interviews with provincial and hospital administrators, it was learned that the program is well received but marketing of products needed improvement. Within current budget constraints, efforts are being made to increase awareness of the program. The evaluation's findings were distributed to the provincial ministries.

Related activities: The Division is involved in several related activities including consensus development conferences; surveys of hospital practices; and consultant services, particularly to interpret report recommendations.

Completed Reports

HW1 Subcommittee on Institutional Program Guidelines. [Health and Welfare Canada, Health Services and Promotion Branch, Institutional and Professional Services Division] Rehabilitation medicine program guidelines. 1986. [Information syntheses, Expert opinion, Group judgment]

HW2 _____. Spinal cord injury program guidelines. 1986. [Information syntheses, Expert opinion, Group judgment]

HW3 _____. Stroke program guidelines. 1986. [Information syntheses, Expert opinion, Group judgment]

HW4 _____. Burn unit guidelines. Revised 1985. [Information syntheses, Expert opinion, Group judgment]

HW5 _____. Child and youth long term services guidelines. 1985. [Information syntheses, Expert opinion, Group judgment]

HW6 _____. Nuclear medicine units in hospitals. 1985. [Information syntheses, Expert opinion, Group judgment]

HW7 _____. Prehospital emergency care services. 1985. [Information syntheses, Expert opinon, Group judgment]

HW8 Subcommittee on Special Services in Hospitals. [Health and Welfare Canada, Health Services and Promotion Branch, Institutional and Professional Services Division] The reuse of disposables: an information report. 1985. [Information syntheses, Expert opinion, Group judgment]

HW9 _____. Diagnostic ultrasound facilities in hospital guidelines. 1985. [Information syntheses, Expert opinion, Group judgment]

HW10 _____. Hospital day medicine unit guidelines. 1984. [Information syntheses, Expert opinion, Group judgment]

HW11 _____. Addiction services in hospitals guidelines. 1984. [Information syntheses, Expert opinion, Group judgment]

HW12 _____. Adult long-term institutional care. 1984. [Information syntheses, Expert opinion, Group judgment]

HW13 _____. Child and adolescent services in general hospitals. 1982. [Information syntheses, Expert opinion, Group judgment]

HW14 _____. Day surgery unit guidelines. 1982. [Information syntheses, Expert opinion, Group judgment]

HW15 _____. Pulmonary function laboratories guidelines. 1982. [Information syntheses, Expert opinion, Group judgment]

HW16 _____. Child adolescent psychiatric services provided by general hospitals. 1981. [Information syntheses, Expert opinion, Group judgment]

HW17 Subcommittee on Institutional Program Guidelines. [Health and Welfare Canada, Health Services and Promotion Branch, Institutional and Professional Services Division] Computed tomography guidelines. 1980. [Information syntheses, Expert opinion, Group judgment]

HW18 Subcommittee on Special Services in Hospitals. [Health and Welfare Canada, Health Services and Promotion Branch, Institutional and Professional Services Division] Regional Renal Failure Program. 1980. [Information syntheses, Expert opinion, Group judgment]

HW19 _____. Adult psychiatric services provided by general hospitals guidelines. 1979. [Information syntheses, Expert opinion, Group judgment]

HW20 _____. Geriatric units in hospitals, geriatric day hospital guidelines. 1979. [Information syntheses, Expert opinion, Group judgment]

HW21 _____. Intensive care unit guidelines. 1979. [Information syntheses, Expert opinion, Group judgment]

HW22 _____. Perinatal intensive care unit guidelines. 1979. [Information syntheses, Expert opinion, Group judgment]

HW23 _____. Diabetic day care unit guidelines. 1978. [Information syntheses, Expert opinion, Group judgment]

HW24 _____. Patient hostel unit guidelines. 1978. [Information syntheses, Expert opinion, group judgment]

HW25 _____. Respiratory technology service unit guidelines. 1978. [Information syntheses, Expert opinion, Group judgment]

JOHNS HOPKINS PROGRAM FOR MEDICAL TECHNOLOGY AND PRACTICE ASSESSMENT

Center for Hospital Finance and Management
624 North Broadway, Room 305
Baltimore, MD 21205
301-955-2300

Contact: Earl P. Steinberg, M.D., Director, Johns Hopkins Hospital, 624 North Broadway, Baltimore, MD, 21205.

Overview: The Johns Hopkins Program for Medical Technology and Practice Assessment was established in July 1986 to merge the functions of the Johns Hopkins Center for Hospital Finance and Management and the Johns Hopkins Office of Medical Practice Evaluation. As a collaborative effort of the Johns Hopkins School of Medicine, the Johns Hopkins School of Hygiene and Public Health, the Johns Hopkins Hospital, and the Johns Hopkins Health System, it draws together a multidisciplinary faculty to address both broad medical technology matters and issues of institutional concern.

Purpose: (1) To assess the clinical efficacy and financial implications of new and established medical technologies in order to assist hospitals and other providers in making informed decisions concerning the acquisition and use of certain technologies; (2) to evaluate the short- and long-term cost and quality implications of alternative technologies and practice patterns; (3) to assess the relative costs and benefits of alternative medical practices; (4) to examine the clinical and economic impacts of health care payment innovations; (5) to provide information to ensure that appropriate reimbursement is available for medical technologies, procedures and services; and (6) to influence State and Federal policy-makers concerning the financing and regulation of health care delivery with particular attention to technology use and medical practice patterns.

Primary intended users: Providers, generally; physicians; acute facility administrators; health product manufacturers; health/medical professional associations; health industry associations; employers; third party payers; government regulators; reporters, writers, news media; public policy-makers, legislators; policy research organizations.

Technologies: *Device*, drug, medical or surgical procedure, support system, organizational or administrative system.

Intervention: *Diagnosis*, prevention, treatment, rehabilitation.

Stage: *New*, emerging, established or widespread practice, obsolete.

Properties: *Cost-effectiveness*; safety; efficacy; effectiveness; cost; cost-benefit; service requirements; acceptance/ adoption level; system impact; economic implications; ethical, legal, social implications.

Technologies are assessed for their clinical impacts, including their efficacy and effectiveness, effect on patient outcome and on physicians' use of other technologies and resources. Assessments also include evaluations of technologies' actual and potential economic effects from the perspective of providers, payers, patients, and society as a whole.

Selection process: Assessments are initiated by Program faculty after consultation with members of the medical staff and administration of the Johns Hopkins Medical Institutions. Outside parties, including hospitals, hospital systems or other providers, government agencies, insurers, employers, private industry, or foundations may suggest assessments that would be of particular interest to them. Requests for assessments are made by telephone call, memorandum, letter, or request for proposal. The Program faculty set assessment topic priorities based on several criteria: resources required, feasibility in terms of available data and funding timeliness, and relevancy. Decisions to initiate an assessment are also based on the recommendations of the Program's Advisory Board. Priority is given to issues that have important clinical, economic, and policy implications; capitalize on the multidisciplinary strengths of Program faculty; and have particular interest and concern to the Johns Hopkins Hospital and Health System. Final decisions regarding the performance of assessments are made by the Program's Director and Co-Director.

Methods: *Cost-analyses*, Information syntheses, expert opinion, group judgment, modeling, epidemiological and other observational methods, clinical trials.

The Program conducts original research and synthesizes existing knowledge from the health services and medical literature. Generally, assessments are conducted by teams of researchers under the direction of a project manager. Teams first develop a set of medically important and policy-relevant issues to be addressed in the assessment and then develop methods of addressing those issues. Frequently government or medical experts are consulted in developing the project's issues, approach, scope, and purpose.

Some assessments will be completed in 3 or 4 months, others in 12 to 15 months. The average turnaround time is expected to be 8 months.

Assessors: The assessors have expertise in medicine, health economics, health care financing, business, health policy, and public health, computer science, artificial intelligence, decision analysis, cost effectiveness analysis, clinical epidemiology and education. Each of the physicians involved in technology assessment also has clinical responsibilities at the Johns Hopkins Hospital and continues to be involved in the practice of medicine. Several of the analysts have previous experience in government policymaking. The Program's Advisory Board consists of a representative from each of the schools, from the Johns Hopkins Hospital, and from the Johns Hopkins Health System, so there is a direct link between the Program, the hospital, and the health system.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who

sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; development of the technology; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: *Journal articles*; printed reports; press conferences/news releases, TV/ radio broadcasts, video products.

Assessment results are disseminated through publication of articles and reports; seminars sponsored by the Johns Hopkins School of Hygiene and Public Health; presentations at professional society conferences; meetings with public and private officials; and press releases and press conferences. In some instances, project sponsors, such as manufacturers, are likely to publish or disseminate their own reports based on Program findings.

Budget: $165,000. The cost per assessment will depend on the type of assessment undertaken. Costs are expected to vary considerably, ranging from small ($15,000) contracts to $800,000 clinical trials. Most assessments are expected to cost $20,000 to $100,000. Funding source: 90 percent parent organization, 10 percent government grants/contracts. The School of Medicine, School of Hygiene and Public Health, and the Johns Hopkins Hospital each contributed $50,000 per year for the first 2 years of the Program. This funding is being used to initiate Program activities. it is expected that in the future the Program will be supported both by grants and contracts to perform specific assessments and contributions to support the Program more generally.

Use: The Program provides a means to assist the Johns Hopkins Hospital and the Johns Hopkins Health System administrators and medical staff in decisions regarding the acquisition of new technologies and optimal use of existing resources. Assessment results will be shared with administrators and medical staff.

Ongoing Assessments

JH1 Johns Hopkins Program for Medical Technology and Practice Assessment. A synthesis of the published literature regarding the comparative toxicity of high osmolar and low osmolar radiographic contrast dyes. Ongoing.

JH2 _____. An analysis of economic and policy issues related to the introduction of low osmolar radiographic contrast dyes. Ongoing.

JH3 _____. An assessment of the potential effects of changes in supply purchasing behavior and arrangements in hospitals on quality of care. Ongoing.

JH4 _____. Analysis of the comparative cost-effectiveness of alternative strategies for managing acute heart attacks, including use of thrombolytic drugs, such as tissue plasminogen activator and steptokinase, and emergency coronary angioplasty. Ongoing.

Planned Assessments

JH5 _____. A clinical trial at determining the comparative nephrotoxicity and comparative cost-effectiveness of low osmolar versus high osmolar radiographic contrast dyes. Planned.

JH6 _____. An analysis of automatic implantable cardiac defibrillators (AICDs). Planned.

JH7 _____. An analysis of the comparative costs of inpatient versus outpatient surgery for several types of surgery. Planned.

JH8 _____. An analysis of the potential cost implications of Medicare of unbundling of services (particularly diagnostic services provided by hospitals). Planned.

JH9 _____. An assessment of automatic blood pressure monitoring. Planned.

JH10 _____. An evaluation of patterns of utilization of CT scanners, with particular attention to variations in practice patterns. Planned.

KINGS FUND CENTRE FOR SERVICE DEVELOPMENT KINGS FUND FORUM CONSENSUS AND CONTROVERSIES IN MEDICINE

126 Albert Street
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(44-1) 267-6111

Contact: Dr. J. Spiby.

Overview: The Kings Fund Centre for Service Development is a not-for-profit foundation that promotes good practice in health care organizations. The first Kings Fund Forum Consensus and Controversies in Medicine conference was held in 1984.

Purpose: To produce consensus statements.

Primary intended users: General public; patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health/medical professional associations; consumer associations; government regulators; voluntary associations, organizations; biomedical researchers; financial analysts, consultants; reporters, writers, news media; public policy-makers, legislators; policy research organizations; lawyers.

Technologies: *Medical or surgical procedure*, support system, organizational or administrative system.

Intervention: Prevention, diagnosis, treatment, rehabilitation.

Stage: *Established or widespread practice*, new.

Properties: Efficacy; effectiveness; cost; cost-benefit; cost-effectiveness; service requirements; system impact; economic implications; ethical, legal, social implications.

Selection process: Suggestions for assessment topics are accepted from anyone, although the Steering Group provides major input to the selection process. The Steering Group sets assessment topic priorities.

Methods: *Group judgment*.

The assessment process is conducted as a consensus conference. The average turnaround time from selection of assessment topic to reporting of findings is 1 year.

Assessors: Consensus panels consist of medical professionals and laymen who represent mixed areas of expertise.

Assessment reports include: Consensus statement; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/ commissioned/supported the assessment; who conducted the assessment; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/ information; results; findings or conclusions; recommendations for practice, future assessments, technology development, research.

Dissemination: Printed reports; journal articles; press conferences/news releases, TV/ radio broadcasts, video products.

Budget: $30,000. The approximate cost per assessment is $15,000. Funding sources: 50 percent foundations, other private grants; 50 percent sponsors/members due, contributions.

Program evaluation: To review the usefulness of the Kings Fund Forum, the Project Coordinator is conducting a survey which was initiated in May 1986.

Completed Reports

KF1 King's Fund. [King's Fund Centre for Service Development. King's Fund Forum Consensus and Controversies in Medicine] Treatment of primary breast cancer: the Second King's Fund Forum. 1986.

KF2 King's Fund. [King's Fund Centre for Service Development. King's Fund Forum Consensus and Controversies in Medicine] Coronary artery bypass surgery: the First UK Consensus Development Conference. 1984.

LEWIN AND ASSOCIATES, INC. MEDICAL TECHNOLOGY GROUP

1090 Vermont Avenue NW, Suite 700
Washington, DC 20005
202-842-2800

Contact: Wayne Roe, Vice President.

Overview: Lewin and Associates is a for-profit consulting firm specializing in the health care field. It offers a range of services including hospital strategic planning; HMO, PPO, and insurance industry consulting; strategic market analysis for medical technology product firms; and health policy consulting for federal, state, and local governments and private sector organizations. The Medical Technology Group program was initiated in 1985; since then numerous retrospective and prospective studies have been conducted.

Purpose: To assist technology developers, providers, purchasers, and payers to develop objective, sophisticated, empirical analyses on the impacts of new and existing technologies.

Primary intended users: Providers, generally; physicians; health product manufacturers; health/medical associations; third party payers; government regulators; public policy-makers, legislators.

Technologies: Drug, device, medical or surgical procedure, support system, organizational or administrative system.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *New*, established or widespread practice.

Properties: *Cost*, safety, effectiveness, cost-effectiveness, service requirements, economic implications.

Properties assessed depend on the client's information need and audience.

Selection process: Anyone can request that an assessment be conducted. Requests are made through client inquiries and occasionally the program receives formal RFPs. Staff and clients set assessment topic priorities.

Methods: *Information syntheses, cost analyses, expert opinion, group judgment, modeling*.

As part of the assessment process, staff conduct statistical studies, prepare quantitative simulation models, collect primary data from prospective trials, and analyze Lewin databases and private insurance claims.

The approximate turnaround time from selection of assessment topic to reporting of findings depends on the study and ranges from 4 months to 2 years.

Assessors: The assessors have expertise in clinical medicine, economics, statistics, health policy, and modeling. Frequently, outside academic/research consultants are used.

Assessment report include: The assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: Printed reports; journal articles; advisories to members/constituents; public presentations; private meetings with policy-makers.

If an assessment report is not proprietary, copies may be obtained through the Lewin and Associates library.

Budget: Not available.

Use: Public and private third party payers use the assessment reports in formulating reimbursement policy. For example, Lewin and Associates recently conducted a reimbursement analysis of a new cardiovascular device. The results of the study have been used by public and private insurers to develop reimbursement policy. Other studies have been submitted to the Health Care Financing Administration and the Prospective Payment Assessment Commission.

Completed Reports

LE1 [Lewin and Associates, Inc.] The safety, efficacy, and cost effectiveness of home intravenous antibiotics. 1986 Feb. [Information syntheses, Modeling, Cost analyses]

LE2 Roe W, Anderson M, Strauss M, Arnold J, Gong J, Eresian K. [Lewin and Associates, Inc.] Technology assessment and coverage decision making. 1986 Oct. [Information syntheses, Modeling, Cost analyses]

LINKÖPING UNIVERSITY CENTER FOR MEDICAL TECHNOLOGY ASSESSMENT

S-581 83 LinköPing, Sweden
(46-13) 28-10-00, Ext. 2310

Contact: Bengt Jonsson, Ph.D., Director; or Ann Bonair, Research Assistant.

Overview: The Center for Medical Technology Assessment (CMT) is an independent research unit at Linköping University. The Center was established in fall 1084 after an agreement between Linköping University and the Ostergotland County Council, the local government's health unit. Inauguration took place in April 1985.

Purpose: To develop a long-term knowledge base and methodology pertinent to medical technology assessment; to initiate, support and undertake medical technology assessment in a joint medical, economic, and social perspective; to identify areas of medical technology in need of evaluation in terms of cost, benefits, diffusion potential, and relevant social and ethical consequences; and to organize and support courses, seminars, conferences, and information exchange and dissemination in the field.

Primary intended audience: Providers, generally; physicians; health product manufacturers; health/medical professional associations; health industry associations; third party payers; government regulators; reporters, writers, news media; public policymakers, legislators.

Technologies: *Medical or surgical procedure*, drug, device, support system, organizational or administrative system.

Intervention: *Treatment*, prevention.

Stage: Emerging, new, established or widespread practice.

Properties: Safety; efficacy; effectiveness; cost; cost-benefit; cost-effectiveness; service requirements; acceptance/ adoption level; system impact; economic implications; ethical, legal, social implications.

Selection process: Executive Committee members, health care providers, government agencies, and health product manufacturers can request, through formal and informal contacts with the CMT Director, that an assessment be conducted. Assessment topic priorities are guided by CMT's internal framework and objectives. The Director decides if the CMT will undertake a requested assessment after screening the proposed study. The screening process includes determination of resource and time requirements.

Methods: Information syntheses, expert opinion, modeling, cost analyses, epidemiological and other observational methods, clinical trials.

Drafts of assessments are presented at staff seminars before the final report is written. The turnaround time from selection of assessment topic to reporting of findings varies from 6 months to 2 years.

Assessors: CMT has a multidisciplinary staff representing economics, business administration, medicine, biomedical engineering, philosophy, and nursing. Depending on the assessment topic, experts from different areas may be added to the staff team on a temporary basis.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implication of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; procurement/deployment information; where technology is in use; coverage/reimbursement status of the technology.

Dissemination: *Printed reports*; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

Abstracts and lists of assessment reports are published in the *CMT Newsletter*. The *Newsletter* is distributed free of charge to approximately 1000 subscribers primarily in the health care sector. Five issues of the *CMT Newsletter* have been published; the first issue in English was published in January 1987. Assessment results are also disseminated at conferences and seminars. The CMT accepts telephone and written requests for copies of assessment reports.

Budget: $270,000. The approximate cost per assessment is $7,500. Funding sources: 60 percent parent organization; 10 percent government grants, contracts; 30 percent foundations, other private grants.

Use: Linköping University uses the CMT's assessment reports in courses and as background papers for conferences. Based on personal communications, CMT staff are aware that other researchers in the field, physicians, and health care administrators use the assessment reports for various purposes.

Related activities: An international conference on quality of life was held in September 1986; the proceedings will be published in English. Educational activities include undergraduate courses and a postgraduate course in medical technology assessment.

The CMT Director is the Associate Editor for *the Journal of Health Economics* and is also a member of the following committees: Nordic Planning Group for Health Services Research, the Government Committee for Research about the Public Sector, the Executive Committee of the European Association of Programmes in Health Service Studies, and the Scientific Advisory Board, National Board of Health and Welfare, Sweden.

In collaboration with the World Health Organization's European Program for Health Technology Assessment, the University Library, and the Health University in Linköping, the CMT is establishing a clearinghouse on the evaluation of medical technology literature. It is anticipated that the clearinghouse will be operational in late 1987.

COMPLETED REPORTS

LU1 Bjork S, Bonair A. [Linköping University, Center for Medical Technology Assessment] Quality of life measurements. 1986. (Discussion series paper #7) (Swedish language only) [Information syntheses]

LU2 Carlsson P, Jonsson. [Linköping University, Center for Medical Technology Assessment] Medical technology assessment in a macroeconomic perspective—a study of the introduction of cimetidine for treatment of ulcers. 1986. (Discussion series paper # 1) [Swedish language only] [Cost analyses, Epidemiological methods]

LU3 Carlsson P, Tiselius HG. [Linköping University, Center for Medical Technology Assessment] Evaluation of extracorporeal shock-wave lithotripsy treatment for upper urinary tract calculi—the first year experiences. 1086. (Discussion series paper # 10) [Swedish language only] [Cost analyses, Clinical trials, Epidemiological methods]

LU4 Jonsson B. [Linköping University, Center for Medical Technology Assessment] Cost benefit analysis of hepatitis-B vaccination. 1986. (Discussion series paper # 12) [Information syntheses]

LU5 Jonsson B. [Linköping University, Center for Medical Technology Assessment] Economic aspects of prevention as a health technology. 1086. (Discussion series paper #3) [Swedish language only] [Information syntheses]

LU6 Jonsson, B. [Linköping University, Center for Medical Technology Assessment] Economic aspects of health care provision—is there a current crisis? 1986. (Discussion series paper #4)

LU7 Jonsson, B. [Linköping University, Center for Medical Technology Assessment] The economics of drug regulation. 1986. (Discussion series paper #5) [Information syntheses]

LU8 Karlsson CT. [Linköping University, Center for Medical Technology Assessment] Economics of osseointegrated implants—a prestudy. 1986. (Discussion series paper #8) [Swedish language only] [Cost analyses, Epidemiological methods]

LU9 Levin, LA. [Linköping University, Center for Medical Technology Assessment] Economic consequences of postinfarction prophylaxis with beta-blockers: a cost effect study of metoprolol treatment. 1982. (Discussion series paper #2) [Swedish language only] [Cost analyses, Epidemiological methods]

Ongoing Assessments

LU10 Linköping University, Center for Medical Technology Assessment. Alternative treatments in stroke—assessment of cost and social implications. Ongoing.

LU11 _____. Assessment of quality of life and medical resource requirements in patients with rheumatoid arthritis—evaluation of cooperation between primary health care and specialized care. Ongoing.

LU12 _____. Economics of ossointegrated implants. Ongoing.

LU13 _____. Ethical issues in medical technology assessment. Ongoing.

LU14 _____. Health care information systems and cost-effectiveness: a review of methodological issues and assessment methods. Ongoing.

LU15 _____. Medical technology in primary health care—an explorative study. Ongoing.

LU16 _____. Quality of life and pharmacotherapy in angina pectoris. Ongoing.

LU17 _____. The cost of prostate cancer in a defined population. Ongoing.

Planned Assessments

LU18 _____. Development of simulation models for use in cost-effectiveness studies. Planned.
LU19 _____. Diffusion of innovations—methodological issues. Planned.
LU20 _____. Economic aspects of prevention as a health care technology. Planned.
LU21 _____. Methodological issues in quality of life measurements, health indicators, and utility index. Planned.

MCGILL UNIVERSITY DEPARTMENT OF EPIDEMIOLOGY AND BIOSTATISTICS

1020 Pine Avenue West
Montreal, Canada H3A 1A2
514-392-4740

Contact: Dr. Walter O. Spitzer, Chairman, Department of Epidemiology and Biostatistics 514-392-4741.

Overview: McGill University, a public institution, established its Department of Epidemiology and Biostatistics in 1964. Technology assessment is an integral part of the Department's research function.

Purpose: To provide teaching, research, and consultation in epidemiology, statistics, and community medicine.

Primary intended users: General public, people concerned about their health, patients, government regulators.

Technologies: Drug, medical or surgical procedure, organizational or administrative system.

Intervention: Prevention, diagnosis, treatment.

Stage: Emerging, new, established or widespread practice.

Properties: Safety, efficacy, effectiveness, cost, cost-effectiveness.

Selection process: Assessments are an integral part of the Department's research function. They are initiated as a result of interaction between the investigators and the person or organizations interested in the results. Assessment topic priorities also emerge from this interaction.

Methods: Information syntheses, expert opinion, group judgment, cost analyses, epidemiological and other observational methods, clinical trials.

The approximate turnaround time from selection of assessment topic to reporting of findings is 2 years.

Assessors: Assessors are experts in epidemiology, biostatistics, community medicine, and various substantive areas such as cancer, nephrology, and adverse drug reactions.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles, where technology is in use.

Dissemination: Printed reports; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

Copies of assessments can be acquired through the publishers, the authors, or the Chairman of the Department.

Budget: Variable. The cost of individual assessments varies. Funding sources: 75 percent government grants/contracts; 25 percent foundations, other private grants.

Completed Reports

MG1 Clark DC, Hanley JA, Geoghegan S, Vinet D. [McGill University, Department of Epidemiology and Biostatistics] The effectiveness of a desensitizing toothpaste in treating dentinal hypersensitivity. J Periodontol Res 1985;20:212-219.

MG2 Clark DC, Hanley JA, Stamm JW, Weinstein PL. [McGill University, Department of Epidemiology and Biostatistics] An empirically based system to estimate the effectiveness of caries-preventive agents: a comparison of the effectiveness estimates of APF gels and solutions and fluoride varnishes. Caries Res 1985;19:83-95.

MG3 Hutchinson TA, Harvey CE. [McGill University, Department of Epidemiology and Biostatistics] Survival with different forms of dialysis treatment—a prognostically controlled comparison. J Am Soc Artif Inter Organs 1985;8:13-17.

MG4 Hutchinson TA, Michaud L, Thomas DC. [McGill University, Department of Epidemiology and Biostatistics] Comparison of survival with dialysis and renal transplanation - the effect of the method of statistical analysis on results. J Am Soc Artif Intern Organs 1985;8:18-21.

MG5 Ostrowsky JT, Lippman A, Scriver CR. [McGill University, Department of Epidemiology and Biostatistics] Cost-benefit analysis of thalassemia disease prevention program. Am J Public Health 1985;75:732-736.

MG6 Parfrey PS, Hutchinson TA, Harvey C, Guttman RD. [McGill University, Department of Epidemiology and Biostatistics] Transplantation versus dialysis in diabetic patients with renal failure. Am J Kidney Dis 1985;5:112-116.

MG7 Parfrey PS, et al. [McGill University, Department of Epidemiology and Biostatistics] The impact of renal transplantation on the course of hepatitis B liver disease. Transplantation 1985 ;39:610-615.

MG8 Robitaille Y, Kramaer MS. [McGill University, Department of Epidemiology and Biostatistics] Does participation in prenatal courses lead to heavier babies? Am J Public Health 1985;75:1186-1189.

MG9 Strom BL, Melmon KL, Miettinen OS. [McGill University, Department of Epidemiology and Biostatistics] Post marketing studies of drug efficacy: why? Am J Med 1985;78:475-480.

MG10 Strom BL, Melmon KL, Miettinen OS. [McGill University, Department of Epidemiology and Biostatistics] Post-marketing studies of drug efficacy: a perspective. Arch Intern Med 1985; 145:1791-1793.

MG11 Tousignant P, Hollomby D, Guttman RD. [McGill University, Department of Epidemiology and Biostatistics] Transplantation and home hemodialysis: their cost-effectiveness in the treatment of end stage renal disease. J Chronic Dis 1985;38.

MG12 [McGill University, Department of Epidemiology and Biostatistics] The nurse practitioner revisted: slow death of a good idea. (Editorial retrospective) N Engl J Med 1984; 130:1049-1051.

MG13 Boivin JF, Hutchinson GB, Lyden M, Godbold J, Chorosh J, Schottenfeld D. [McGill University, Department of Epidemiology and Biostatistics] Second primary cancers following treatment of Hodgkin's disease. J Natl Cancer Inst 1984;72:233-241.

MG14 Fox ZR, Dupont C, Kramer MS, Stewart JH. [McGill University, Department of Epidemiology and Biostatistics] A double-blind crossover comparison between Phyllocontin and Theo-Dur in asthmatic children. In: Turner-Warwick M, Levy J, eds. New perspectives in theophylline therapy. London: Royal Society of Medicine, 1984:29-37.

MG15 Hutchinson TA, Thomas DC, Lemieux JC, Harvey CF. [McGill University, Department of Epidemiology and Biostatistics] A prognostically controlled comparison of dialysis and renal transplantation. Kidney Int 1984;26:44-51.

MG16 Kramaer MS, Naimark LE, Leduc DG. [McGill University, Department of Epidemiology and Biostatistics] Is antipyresis harmful? Proceedings of the Ambulatory Pediatric Association 1984 annual meeting, San Francisco. 1984:88.

MG17 Parfrey PS, Hutchinson TA, Lowry RP, Knaack J, Guttman RD. [McGill University, Department of Epidemiology and Biostatistics] Causes of late allograft failure and the role of azathioprine reduction. Transplant Proc 1984; 16:1100-1102.

MG18 Parfrey PS, et al. [McGill University, Department of Epidemiology and Biostatistics] The diagnostic and prognostic value of renal allograft biopsy. Transplantation 1984;38(6):586-590.

MG19 Shamian J, Clarfield AM, Maclean J. [McGill University, Department of Epidemiology and Biostatistics] A randomized trial of intra-hospital relocation of geriatric patients in a tertiary-care teaching hospital. J Am Geriatr Soc 1984;32:794-800.

MG20 Spitzer WO. [McGill University, Department of Epidemiology' and Biostatistics] The periodic health examination: 1. Introduction. Can Med Assoc J 1984; 130:1376-1278

MG21 The Task Force on the Periodic Health Examination. W.O. Spitzer, Chairman. [McGill University, Department of Epidemiology, and Biostatistics] The periodic health examination: 2. 1984 update. Can Med Assoc J 1984; 130:1278-1285.

MG22 Williams JI, Hanley JA. [McGill University, Department of Epidemiology and Biostatistics] Assessing and diffusing today's medical technologies. Dimens Health Serv 1984;61(7):10-14.

MG23 Wood-Dauphinee SS, et al. [McGill University, Department of Epidemiology and Biostatistics] A randomized trial of team care following stroke. Stroke 1984; 15:864-872.

MG24 Battista RN, Spitzer WO. [McGill University, Department of Epidemiology and Biostatistics] Adult cancer prevention in primary care: contrasts among primary care settings in Quebec. Am J Public Health 1983;73(9): 1040-1041.

MG25 Battista RN. [McGill University, Department of Epidemiology and Biostatistics] Adult cancer prevention in primary care: patterns of practice in Quebec. Am J Public Health 1983;73(9): 1036-1039.

MG26 Grover S, Gagnon G, Flegel K, Hoey JR. [McGill University, Department of Epidemiology and Biostatistics] Improving appointment-keeping by patients new to a hospital medical clinic with telelphone or mailed reminders. Can Med Assoc J 1983; 129:1101-1103.

MG27 Loeser J, Zvagulis I, Hercz L, Pless IB. [McGill University, Department of Epidemiology' and Biostatistics] The organization and evaluation of a computer-assisted centralized immunization registry. Am J Public Health 1983;73(11): 1298-1301.

MG28 McNeil B J, Hanley JA. [McGill University, Department of Epidemiology and Biostatistics] Critical questions regarding a new diagnostic technology: a case study using computed tomography (CT) of the head. In: Culyer AJ, Horisberger, eds. Economic and medical evaluation of health care technologies, proceedings of Wolfsberg Conference. 1983.

MG29 Thomson ME, Kramer MS. [McGill University, Department of Epidemiology and Biostatistics] Methodological standards for controlled clinical trials of perinatal contact: studies of early contact and maternal-infant behavior. Pediatrics 1983;73:294-300.

MG30 Hutchinson TA, Cole CH, Kaye M. [McGill University, Department of Epidemiology and Biostatistics] Chronic ambulatory peritoneal dialysis versus other dialysis therapy—a matched cohort study. Clin Res 1982;30:431A.

MCMASTER UNIVERSITY DEPARTMENT OF CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS

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Contact: Dr. Peter Tugwell, Chairman, Department of Clinical Epidemiology and Biostatistics. Telex 061-8347.

Overview: The Department of Clinical Epidemiology and Biostatistics was founded as part of the medical school at McMaster University in 1967. The University provides health care services, research, and education.

Purpose: To provide rigorous evidence on the effectiveness and efficiency of health care interventions and to improve medical practice.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; financial analysts, consultants; reporters, writers, news media; information/computer industry; public policy-makers, legislators; policy research organizations.

Technologies: *Medical or surgical procedure*, drug, device, support system, organizational or administrative system.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice.

Although technologies have been assessed at a variety of points in their life-cycles, the focus is usually upon emerging technologies or major established ones for which there is not rigorous evidence.

Properties: *Effectiveness*, safety, efficacy, cost, cost-benefit, cost-effectiveness, service requirements, acceptance/ adoption level, system impact, economic implications.

The evaluative focus is on efficiency, effectiveness, community effectiveness and efficiency in both pecuniary and quality of life terms.

Selection process: An assessment may be requested by clinical colleagues, funding agencies, public policy authorities. Assessments are made by clinical colleagues approaching members of the Department for methodological assistance; or external agencies may invite grant and contractual arrangements. Assessment topic priorities are based on external interest and support, internal expertise, and availability of appropriate investigators.

Methods: *Clinical trials*, information syntheses, expert opinion, group judgment, modeling, cost analyses, epidemiological and other observational methods.

Randomized controlled clinical trials and the utilization of other prospective designs are the primary methods used. Most assessments are done in the context of "management" trials with randomization. The approximate turnaround time from selection of assessment topic to reporting of findings is 3 years.

Assessors: The assessors have expertise in the areas of study and trial design; data collection, management, analysis, interpretation; economic evaluation; and quality of life assessment.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: *Journal articles*; printed reports; press conferences/news releases, TV/ radio broadcasts, video products; clearinghouses, data/citation bases, on-line services.

Assessment results are disseminated primarily through published journal articles, supplemented by reports, testimony, media interviews, and continuing medical education. Copies of assessments are available in the open scientific literature.

Budget: $4,000,000. The approximate cost of each assessment is $90,000. Funding sources: 25 percent parent organization; 25 percent government grants/contracts; 25 percent foundations, other private grants; 25 percent sponsors/members, contributions.

Use: Reports and publications are made available to clinicians, hospital administrators, and other interested parties. These assessment reports have had an impact in several areas. For example, the results of hypertension screening studies have influenced public health policy in Canada; related studies on compliance and treatment have contributed to the increasing effectiveness of hypertension control; and rigorous studies on the detection and treatment of deep vein thrombosis have also influenced clinical practice but have had a less pervasive impact.

Related activities: The Department of Clinical Epidemiology and Biostatistics offers, within the Faculty of Health Sciences, a Master's of Health Science in Design, Measurement, and Evaluation. Through the Rockefeller Foundation it participates as a training center for the International Clinical Epidemiology Network for medical school faculty members in less developed countries.

Completed Reports

MM1 Birkett NJ, Evans CE, Haynes RB, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Hypertension control in two Canadian communities: evidence for better treatment and overlabelling. J Hypertension 1986;4:369-374.

MM2 Haynes RB. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Physician interventions to improve compliance. Geriatr Consultant 1986 Jul/Aug:20.

MM3 Haynes RB. [McMaster, Department of Clinical Epidemiology and Biostatistics] Is weight loss an effective treatment for hypertension? The evidence against. Can J Physiol Pharmacol 1986;64:825-830.

MM4 EC/IC Bypass Study Group. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke. New Eng J Med 1985;313:1191-1200.

MM5 Gent M, Blakely JA, Hachinski V, et al. [McMaster University. Department of Clinical Epidemiology and Biostatistics] A secondary prevention, randomized trial of suloctidil in patients with a recent history of thromboembolic stroke. Stroke 1985; 16(3).

MM6 Haynes RB. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Office management of patient compliance in the treatment of hypertension. Pract Cardiol 1985; 11:63.

MM7 Haynes RB. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Initial therapy for patients with uncomplicated hypertension. Can Fam Physician 1985;31:321.

MM8 Hull RD, Hirsch J, Carter CJ, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Diagnostic value of ventilation-perfusion lung scanning in patients with suspected pulmonary embolism. Chest 1985;88:819.

MM9 Evans CE, Haynes RB, Gilbert JR, Taylor DW, Sackett DL, Johnston M. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Educational package on hypertension for primary care physicians. Can Med Assoc J 1984;130:719.

MM10 Johnston ME, Gibson ES, Terry CW, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Effects of labelling on income, work and social function among hypertensive employees. J Chron Dis 1984;37 (6):417-423.

MM11 McDonald LA, Sackett DL, Haynes RB, Taylor DW. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Labelling in hypertension: a review of the behavioral and psychological consequences. J Chron Dis 1984;37(12):933-942.

MM12 Gafni A, Gibson ES, Johnston M, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Is there a trade-off between income and health? the case of hypertensive steelworkers in Canada. Inquiry 1983;20:343-349.

MM13 Hull R, Delmore T, Carter C, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Adjusted subcutaneous heparin versus warfarin sodium in the long-term treatment of venous thrombosis. New Eng J Med 1982;306:189-194.

MM14 Hull R, Hirsch J, Sackett DL, et al. [McMaster University, Department of Clinical Epidemiology] Replacement of venography in suspected venous thrombosis by impedance plethysmography and I-fibrinogen leg scanning. Ann Intern Med 1981;94:12-15.

MM15 Hull R, Hirsh J, Sackett DL, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Clinical validity of a negative venogram in patients with clinically suspected venous thrombosis. Circulation 1981 ;64:622.

MM16 Logan AG, Milne BJ, Achber C, Campbell WP, Haynes, RB. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Cost-effectiveness of a worksite hypertension treatment program. Hypertension 1981;3 (2):211-218.

MM17 Gent M, Barnett HJM, Sackett DL, Taylor DW. [McMaster University, Department of Clinical Epidemiology and Biostatistics] A randomized trial of aspirin and sulfinpyrazone in patients with threatened stroke: results and methodologic issues. Circulation 1980;62(Suppl v):V-97.

MM18 Haynes RB, Sackett DL, Gibson ES, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Improvement of medication compliance in uncontrolled hypertension. Lancet 1976;(June 12): 1265.

MEDICAL RESEARCH COUNCIL NATIONAL HEALTH AND WELFARE CANADA

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Contact: Lewis Slotin, Ph.D., Director, Programs Branch.

Overview: The Medical Research Council of Canada (MRC) is one of three Federal granting agencies responsible for supporting research conducted primarily in universities and their affiliated institutions. The other agencies, the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), are responsible for the areas indicated by their names. Both the MRC and the NSERC operated originally within the framework of the National Research Council of Canada; the first became fully autonomous in 1969, the second in 1978. The SSHRC, also established in 1978, encompasses programs administered originally by the National Research Council of Canada. The MRC does not conduct research programs of its own; it is dedicated entirely to the provision of grants and awards for the support of extramural research.

Purpose: According to the Medical Research Act (R.S., c.M-9), the Council's function is to: "(a) promote, assist, and undertake basic, applied, and clinical research in Canada in the health sciences; and (b) advise the Minister of National Health and Welfare Canada in respect of such matters relating to such research as the Minister may refer to Council for its consideration."

Primary intended users: Biomedical researchers.

Technologies: Drug; device; medical or surgical procedure.

Generally, MRC supports basic primary research rather than evaluations of technologies or interventions. (The National Health Research and Development Program is the major source of funds within the Department of National Health and Welfare for the support of extramural research and related scientific activities in public health, health care organization, and health care delivery.)

Intervention: Diagnosis, treatment.

Stage: *Emerging*, new, established or widespread practice.

Properties: Efficacy; effectiveness; ethical, legal, social implications.

Ethical considerations are addressed in an agreement between MRC and the applicant regarding investigations involving human subjects, care and use of experimental animals, and research involving biohazards.

Selection process: The Council accepts applications designed to achieve the objectives set out in the Federal Main Estimates, which are: "to help attain the quality and scale of research in the health sciences essential to the maintenance and improvement of health services." Application forms are available from the Council or from the dean's office at

any Canadian school of medicine, dentistry, pharmacy, or veterinary medicine. Further information on specific types of grants, application requirements, and deadlines is found in the MRC's *Grants and Awards Guide*, issued annually. The guide is available by contacting the MRC.

Methods: *Group judgment*, expert opinion, clinical trials.

The Council is comprised of 22 members representing the scientific and lay community, and its programs are administered by a staff of 53. In carrying out its grant-making functions, it is assisted by 37 peer review committees drawn chiefly from universities in Canada. The Council also makes wide use of external referees from Canada and other countries. For some applications, the Council may arrange for a site visit and ask reviewers to prepare a report following such a visit.

Dissemination: Grants awarded by the MRC are listed in *Reference List of Health Science Research in Canada 1984-1985*. Single copies are available upon request from the Council. The Council does not disseminate research results or final reports. Findings or results of MRC-sponsored research should be obtained directly from the individual or organization conducting the research.

Budget: $164,236,000. Funding source: 100 percent parent organization.

Completed reports: Cited below are a selection of the grants that the Council awarded in 1984-1985. Grants were selected from the *Reference List* based on their relevance to technology assessment as used in this Directory.

Completed Reports

MR1 Albisser AM. [Hospital for Sick Children, Toronto] [Medical Research Council—Canada] Clinical applications of an artificial pancreas. (Grant period 1975-1985).

MR2 Allen PS. [Department Medicine, University Alberta] [Medical Research Council—Canada] In-vivo medical applications of nuclear magnetic resonance. (Grant period 1984-1985).

MR3 Barbeau A. [Clinical Research Institute of Montreal] [Medical Research Council—Canada] Etiology and treatment of Parkinson's disease (with a study of efficacy and side effects of levodopa therapy). (Grant period 1973-1985).

MR4 Bergeron C. [Department Pathology, University Toronto] [Medical Research Council—Canada] Canadian brain tissue bank. (Grant period 1983-1985).

MR5 Bitter-Suermann H. [Department Surgery, Dalhousie University] [Medical Research Council—Canada] Liver preservation. (Grant Period 1984-1985).

MR6 Bronskill MJ. [Princess Margaret Hospital, Toronto] [Medical Research Council—Canada] Physical studies of NMR imaging. (Grant period 1983-1985).

MR7 Chang EJH. [Department Computer Science, University Victoria] [Medical Research Council— Canada] Computer assisted medical reasoning. (Grant period 1984-1985).

MR8 Chernick V. [Department Pediatrics, University Manitoba] [Medical Research Council—Canada] Clinical trial of naloxone in birth asphyxia. (Grant period 1983-1985).

MR9 Chouinard G. [Department Psychiatry, McGill University] [Medical Research Council-Canada] A clinical trial of L-dopa in the prevention of tardive dyskinesia and in the long-term treatment of Parkinsonian side effects induced by neuroleptics. (Grant period 1982-1985).

MR10 Chouinard G. [Department Psychiatry, McGill University] [Medical Research Council—Canada] Controlled clinical trials of lithium and tryptophan in the treatment of patients with bipolar affective disorders. (Grant period 1982-1985).

MR11 Chouinard G. [Louis-H. La Fontaine Hospital, Montreal] [Medical Research Council—Canada] A controlled clinical trial of rubidium in chronic schizophrenia. (Grant period 1983-1985).

MR12 Clark DC. [Department Dentistry, McGill University] [Medical Research Council—Canada] The preventive effect of fluoride varnishes on dental caries: three year community trial. (Grant period 1981-1985).

MR13 Daniel RK. [Department Plastic Surgery, McGill University] [Medical Research Council—Canada] Surgical reconstruction utilizing microsurgical tissue transplants. (Grant period 1984-1985).

MR14 Fenster A. [Princess Margaret Hospital, Toronto] [Medical Research Council—Canada] Investigations of new imaging system and dose reduction. (Grant period 1979-1985).

MR15 Garfinkel PE. [Department Psychiatry, University Toronto] [Medical Research Council—Canada] Bulimia: Neuroendocrine evaluation, relationship to effective disorder and treatment with carbamazepine. (Grant period 1983-1985).

MR16 Guttman FM. [Montreal Children's Hospital] [Medical Research Council—Canada] Long term organ preservation. (Grant period 1979-1985).

MR17 Inch WR. [Department Radiation Oncology, University Western Ontario] [Medical Research Council—Canada] Nuclear magnetic resonance to monitor lung injury. (Grant period 1983-1985).

MR18 Jugdutt, BI. [Department Medicine, University Alberta] [Medical Research Council—Canada] Preservation of ischemic myocardium. (Grant period 1983-1985).

MR19 Man GCW. [Department Medicine, University Alberta] [Medical Research Council—Canada] The effect of high frequency oscillatory ventillation. (Grant period 1983-1985).

MR20 Mclachlan KR. [Department Dentistry, University Manitoba] [Medical Research Council—Canada] The effectiveness of loops and auxiliary appliances in continuous arch orthodontic therapy.

MR21 Miller JE. [Montreal General Hospital Research Institute] [Medical Research Council—Canada] Optimization of fixation of artificial joint components to bone—the prevention of loosening in total joint arthroplasty.

MR22 Milner M. [Department Biomedical Engineering, University Toronto] [Medical Research Council—Canada] Therapeutic and orthotic aspects of electrostimulation in paediatric cerebral palsy. (Grant period 1981-1985).

MR23 Morales A. [Department Urology, Queens University] [Medical Research Council—Canada] The validation of nocturnal and sexual erections in the etiological diagnosis of impotence. (Grant period 1984-1985).

MR24 Morales A. [Department Urology, Queens University] [Medical Research Council—Canada] A controlled clinical trial of yohimbine in the treatment of impotence. (Grant period 1981-1985).

MR25 Nattel S. [Department Pharmacology and Therapeutics, McGill University] [Medical Research Council—Canada] Effects of antiarrhythmic drugs on arrhythmias related myocardial infarction. (Grant period 1981-1985).

MR26 Pape KE. [Hospital for Sick Children, Toronto] [Medical Research Council—Canada] A prospective study of the evolution and outcome of cystic brain damage in the preterm infant utilizing diagnostic ultrasound brain scans.

MR27 Paty DW. [Department Medicine, University British Columbia] [Medical Research Council—Canada] A therapeutic trial of interferon in multiple sclerosis (MS). (Grant period 1983-1985).

MR28 Paty DW. [Department Medicine, University British Columbia] [Medical Research Council—Canada] Interferon therapeutic trial in MS—supplemental application. (Grant Period 1984-1985).

MR29 Paty DW. [Department Medicine, University British Columbia] [Medical Research Council—Canada] NMR imaging in MS, I: The nature of the lesion. (Grant period 1984-1985).

MR30 Paty DW. [Department Medicine, University British Columbia] [Medical Research Council—Canada] NMR imaging in MS, II, diagnosis of the disease and quantitation. (Grant period 1984-1985).

MR31 Podgorsak EB. [Department Radiation Oncology, McGill University] [Medical Research Council— Canada] Noninvasive thermometry and hyperthermia in cancer treatment. (Grant period 1982-1985).

MR32 Podgorsak FB. [Department Radiation Oncology, McGill University] [Medical Research Council— Canada] Radiographic imaging by solid state electrostatic techniques. (Grant period 1981-1985).

MR33 Pomier-Layrargues G. [Department Medicine, University Montreal] [Medical Research Council— Canada] Treatment of portal hypertension—a randomized clinical trial. (Grant period 1984-1985).

MR34: Poznansky MJ. [Department Physiology, University Alberta] [Medical Research Council—Canada] Soluble enzyme-albumin polymers: new approaches to enzyme therapy. (Grant period 1976-1985).

MR35 Price M. [Department Ophthalmology, University British Columbia] [Medical Research Council— Canada] The development of electrodiagnostic tests to detect early chronic open angle glaucoma. (Grant period 1983-1985).

MR36 Pritchard KI. [Department Medicine, University of Toronto] [Medical Research Council—Canada] A trial of adjuvant therapy in post menopausal women with axillary node positive breast cancer. (Grant period 1984-1985).

MR37 Racz WJ. [Department Pharmacology, Queens University] [Medical Research Council—Canada] Acetaminophen induced hepatotoxicity. (Grant period 1983-1985).

MR38 Roder JC. [Department Microbiology and Immunology, Queens University] [Medical Research Council—Canada] The application of human hybridoma technology to cancer and autoimmune disease. (Grant period 1983-1985).

MR39 Schachar NS. [Department Surgery, University Calgary] Investigation of optimal methods of cryopreservation of osteoarticular allografts for transplantation. (Grant period 1984-1985).

MR40 Sherwin BB [Sir Mortimer B. Davis-Jewish General Hospital, Montreal] [Medical Research Council-Canada] Long-term effects of androgen and/or estrogen on psychosexual functioning, hormone levels, and lipid metabolism in surgically menopausal women. (Grant period 1984-1985)

MR41 Szarek W. [Department Chemistry, Queens University] Radiopharmaceutical development for positron imaging. (Grant period 1981-1985).

MR42 Trachtenberg J. [Department Surgery, University Toronto] [Medical Research Council—Canada] Hormonal control of human prostatic cancer. (Grant period 1980-1985).

MR43 Trevithick JR,. [Department Biochemistry, University Western Ontario] [Medical Research Council—Canada] Microwave and heat-induced cataracts: prevention by vitamin E and chronic studies of low level pulsed irradiation. (Grant period 1983-1985).

MR44 Tugwell P. [Department Medicine, McMaster University] [Medical Research Council—Canada] Clinical trials computer network. (Grant period 1984-1985).

MR45 Viviani GR. [Department Surgery, McMaster University] [Medical Research Council—Canada] Biomechanical studies of surgical systems to correct spinal deformities. (Grant period 1982-1985).

MR46 Ward RH. [Medical Genetics, University British Columbia] [Medical Research Council—Canada] Identifying pregnancies at high risk for neural tube defects. (Grant period 1984-1985).

MEDICAL TECHNOLOGY AND PRACTICE PATTERNS INSTITUTE

National Health Services and Practice Patterns Survey
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Contact: Dennis J. Cotter, Director.

Overview: The Medical Technology and Practice Patterns Institute (MTPPI) was initiated at the Institute for Health Policy Analysis, Georgetown University Medical Center. In July 1986, MTPPI was established as an independent entity, separate from Georgetown, to allow broad participation by the health care industry. MTPPI is in the process of affiliating with organizations representing the health care industry. The National Health Services and Practice Patterns Survey (NHSPPS) was the first MTPPI program.

Purpose: To provide current information regarding adoption and use of new medical technologies to health care providers, hospital administrators, and policy makers to

assist them in making appropriate payments for new and emerging technologies. The objective is to avoid financial barriers to these technologies for all categories of patients. NHSPPS seeks to accomplish this through collection and analysis of primary data, education, and the exchange of information on resource requirements and changes in practice patterns resulting from use of new medical technologies.

Primary intended users: Providers, generally; acute facility administrators; health product manufacturers; health/ medical professional associations; health industry associations; third party payers; government regulators.

Technologies: Drug, device, medical or surgical procedure.

Intervention: Diagnosis, treatment.

Stage: Emerging, new, established or widespread practice.

Properties: Cost, cost-effectiveness, service requirements, economic implications.

In order to encourage the optimal use of a technology, the NHSPPS is primarily concerned with assessing a technology's costs, charges, practice pattern variation, and utilization.

Selection process: Requests for assessments come from hospitals, third party payers, clinicians, medical specialty societies, and industry. NHSPPS reports include mail-in forms that recipients may use to suggest assessment topics. Assessment topics are approved by the MTPPI Governing Boards.

Methods: Information syntheses, cost analyses.

Approximately 50 medical centers/hospitals participate in the NHSPPS Program. The process includes four activities: 1) collection and analysis of hospital cost and utilization information; 2) solicitation of judgment by participating hospitals reporting appropriate applications and costs of new technologies; 3) development and distribution to participating hospitals of reports on study findings; and 4) submission of NHSPPS results to appropriate government agencies for their consideration of diagnosis-related group (DRG) assignment and reimbursement. Anonymity of individual hospital data is maintained in all NHSPPS studies.

Each NHSPPS project monitors a specific new or emerging technology over a 3 to 4 year period during the early phase of diffusion. Individual projects end when there is general agreement among providers regarding third party payment or other policy concerns for a specific technology. Reports for each technology involved in the survey are updated and generated annually. NHSPPS reports are comprised of hospital data collected during the previous year.

MTPPI reports are conducted by a core staff and associates from other institutions with expertise relevant to particular assessments.

Assessors: Staff and associates have expertise in bioengineering, medicine, law, public health, and economics. Once the new MTPPI governing board is appointed, it will have approximately 18 members representing medical professionals, insurers, hospitals, manufacturers, others from the health care industry, and community representatives.

Assessment reports include: Abstract; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; results; findings or conclusions; recommendations for practice, future assessments, technology development, research; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: Printed reports; journal articles; advisories to member/constituents; press conference/news releases.

MTPPI publishes two types of reports. *NHSPPS Public Policy Reports* are available to the public. Approximately 20 to 50 pages in length, they include aggregate and average cost, payment, and utilization data on technologies used by the national sample of participating hospitals and related narrative discussion. *NHSPPS National Average Amounts Reports* are available only to participating hospitals; they provide the hospitals with information comparing their respective experiences with national averages. Public policy report prices range from $19 to $40; rates are discounted for member hospitals that participate in the surveys. NHSPPS reports can be ordered from MTPPI. MTPPI mails notices about report availability and related information to over 4,000 health care related organizations and professionals. Reports are also distributed to congressional and executive branches of government and insurance companies.

Budget: The annual budget for all MTPPI activities is $425,000, including $250,000 for NHSPPS. Funding sources: 10 percent foundations, other private grants; 75 percent sponsors/members dues, contributions; 15 percent sales of assessments, consultant services.

Use: The first NHSPPS public policy report on extracorporeal shockwave lithotripsy was used in reassigning DRG levels by the Prospective Payment Assessment Commission. Findings have appeared in such publications as: *Technology Reimbursement Reports—Beige Sheet, COTH Report, Hospitals, Washington Actions on Health, Trends in Health Business*, and reports of the Prospective Payment Assessment Commission.

Related Activities: The Medical Technology Forum is a new program that sponsors conferences on selected medical technology topics. It serves as a catalyst to focus the expertise of public and private organizations on issues such as costs and quality of care, third party payer coverage and reimbursement policy, equitable access to care, and regulating the distribution and use of major medical technologies. The first forum was held on fully automated ambulatory blood pressure monitoring. Forum reports are made public.

The Hospital Stay Charge Profile (HSCP) is a new service that provides MTPPI client hospitals with computer analysis of: (1) current demand for acute-care services, (2) resources consumed during the hospital stay, and (3) practice pattern information related to the care given Medicare beneficiaries. This includes analyses of public and private health care costs and utilization databases (e.g., Medicare's MEDPAR and PATBILL data) and data collected from client hospital discharge records. HSCP reports that address public policy issues may be made public subject to agreement by the client and MTPPI.

Completed Reports

MT1 Medical Technology and Practice Patterns Institute. Ambulatory blood pressure monitoring. 1987.
MT2 _____. Bone marrow transplantation. 1987.
MT3 _____. Cochlear implantation. 1987.
MT4 _____. Cochlear implants outpatient training. 1987.
MT5 _____. Dialysis treatment for end stage renal disease (inpatient). 1987.
MT6 _____. Dialysis treatment for end stage renal disease (outpatient). 1987.
MT7 _____. End tidal carbon dioxide monitoring. 1987.
MT8 _____. Endocardial electrical stimulation. 1987.
MT9 _____. Extracorporeal shockwave lithotripsy (inpatient). 1987.
MT10 _____. Extracorporeal shockwave lithotripsy (outpatient). 1987.
MT11 _____. Fetal heart monitoring. 1987.
MT12 _____. Gastric bubble for treatment of morbid obesity. 1987.
MT13 _____. Heart transplantation. 1987.
MT14 _____. Left ventricular assist device. 1987.
MT15 _____. Liver transplantation. 1987.
MT16 _____. Magnetic resonance imaging (inpatient). 1987.
MT17 _____. Magnetic resonance imaging (outpatient). 1987.
MT18 _____. Percutaneous lithotripsy. 1987.
MT19 _____. Percutaneous transluminal coronary angioplasty. 1987.
MT20 _____. Pulse oximetry. 1987.
MT21 _____. Total parenteral nutrition (inpatient). 1987.
MT22 _____. Total parenteral nutrition (outpatient). 1987.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT

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Individual profiles on two assessment-related programs of the National Center for Health Services Research and Health Care Technology Assessment, the Division of Extramural Research and the Office of Health Technology Assessment, follow this overview of the agency. In addition, the agency's National Advisory Council on Health Care Technology Assessment is described in the organizational resources section of this Directory.

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) is part of the Office of the Assistant Secretary for Health, Public Health Service (PHS), U.S. Department of Health and Human Services (DHHS). NCHSR/HCTA is the primary source of federal support for research on problems related to the quality and delivery of health services. NCHSR/HCTA programs evaluate health services, assess technologies, and improve access to new scientific and technical information for research users. NCHSR/HCTA's research is targeted to the needs of health care policy-makers, those who operate hospitals and other health care institutions, and those who are responsible for health care expenditures.

NCHSR/HCTA's extramural research program is directed toward health promotion and disease prevention, technology assessment, the role of market forces in the delivery of health care, primary care, and state and local health problems. It provides support for investigator-initiated projects in these areas conducted at universities, nonprofit organizations and institutions, and by industry.

The NCHSR/HCTA intramural research program conducts studies that have immediate as well as long-term policy relevance. It addresses four major health care issues in the following programs: the Hospital Studies Program, the Health Services for the Aged Studies Program, the National Health Care Expenditures Study, and the Health Status and Health Promotion Studies Program.

The Office of Health Technology Assessment (OHTA) conducts evaluation of the safety and clinical effectiveness of medical technologies in order to provide federally funded agencies such as the Health Care Financing Administration (HCFA) with medical and scientific information to assist in policy formulation involving issues related to Medicare or other coverage.

The NCHSR/HCTA has a National Advisory Council on Health Care Technology Assessment to advise the Secretary of DHHS and the Director of NCHSR/HCTA with respect to the performance of NCHSR/HCTA technology assessment activities. The National Advisory Council is described in another section of this Directory.

Inquiries about NCHSR/HCTA and its programs may be directed to the NCHSR/ HCTA Publications and Information Branch, 301-443-4100. NCHSR/HCTA research reports are available for sale through the U.S. Department of Commerce, National Technical Information Service (NTIS), 703-487-4650. Reports are announced in the NTIS *Government Reports Announcements and Index* and *NTIS Abstract Series 44*. Abstracts may be accessed directly through two online databases: the NTIS database, and the National Library of Medicine's MEDLARS Health Planning and Administration file.

Research reports of particular interest are published by NCHSR/HCTA in its own publication series. Information materials are available on various topics, including *NCHSR/HCTA Research Activities*, which announces the availability of NCHSR/HCTA research results in journals, books, reports, and papers. A publications list will be sent on request.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT DIVISION OF EXTRAMURAL RESEARCH

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Contact: James R. Ullom; or Maria Friedman, Publications and Information Branch 301-443-4100.

Overview: The National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) is the primary source of federal support for research on problems related to the quality and delivery of health services. NCHSR/

HCTA programs evaluate health services, assess technologies, and improve access to new scientific and technical information for research users.

This profile addresses the NCHSR/HCTA Division of Extramural Research. An overview of the NCHSR/HCTA is provided immediately preceding this profile. Another profile in this section describes the NCHSR/HCTA Office of Health Technology Assessment. The NCHSR/HCTA National Advisory Council of Health Technology Assessment is described in the organizational resources section of this Directory.

NCHSR/HCTA's extramural research program is directed toward health promotion and disease prevention, technology assessment, the role of market forces in the delivery of health care, primary care, and state and local health problems. It provides support for investigator-initiated projects in these areas conducted at universities, nonprofit organizations and institutions, and by industry.

Purpose: To provide support for health services research, including investigations on specific health care technologies, methods to improve technology assessment, and ways to monitor and affect the introduction and use of health care technologies.

Primary intended users: General public; patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; reporters, writers, news media; information/computer industry; public policy-makers, legislators; policy research organizations.

Technologies: *Device*, drug, medical or surgical procedure, support system, organizational or administrative system.

Intervention: *Treatment*, prevention, diagnosis.

Stage: *Established or widespread practice*, new, obsolete.

Properties: *Effectiveness; cost-effectiveness: system impact*; safety; efficacy; cost; cost-benefit; service requirements; acceptance/adoption level; economic implications; ethical, legal, social implications.

Selection process: Most projects are initiated by outside investigators through the formal grant application process established by NCHSR/HCTA. Applications are reviewed by nonfederal peer panels and by the National Advisory Council on Health Care Technology, and are selected for funding based on their scientific merit and their potential for improving the cost-effectiveness and quality of health services. Dissertation research grants are available. Assessment topic priorities are developed by the Director of NCHSR/HCTA with the input and advice of the Director of Extramural Research, senior NCHSR/HCTA staff, advisory councils, study sections, and health services researchers.

Methods: *Epidemiological and other observational methods*, information syntheses, expert opinion, group judgment, modeling, cost analyses, clinical trials, bench testing.

Grant project periods can be as long as 5 years, but most projects are completed within 3 years.

Assessors: Assessors are experts in the areas of medicine, health, nursing, economics, epidemiology, biostatistics, computer sciences, informatics, and sociology.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/ supported the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/ information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; where technology is in use.

Dissemination: *Journal articles*; printed reports; clearinghouses, data/citation bases, online services, specifically, the National Library of Medicine MEDLARS and National Technical Information Service (NTIS) databases.

Results are also disseminated through NCHSR/HCTA publications and presentations at professional meetings. Reports are disseminated to State and local users. Copies of reports may be obtained by contacting the NCHSR/HCTA Publications and Information Branch.

Budget: $4,000,000. Grant awards vary greatly, with the average being approximately $500,000 for a 3-year study. Funding source: 100 percent parent organization.

Use: NCHSR/HCTA uses assessment reports as the basis for policy recommendations and testimony before Congress. Based on references in the literature, the reports are also used outside the agency.

The general programs of the Division of Extramural Research are described in the *Catalog of Federal Domestic Assistance* and in the *NCHSR/HCTA Progam Note*, September 1986.

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NA125 Hallstrom A, Eisenberg MS, Bergner L. [_____] Modeling the effectiveness and cost-effectiveness of an emergency service system. Soc Sci Med 1981 Mar;15c(1):13-17.

NA126 Keller MD, et al. [_____] The impact of mobile coronary care units. 1981. (NTIS order no. PB81-13381)

NA127 Pittman JT. [_____] Health information system transferability evaluation. 1981. (NTIS order no. PB81-206500)

NA128 Ruchlin HS, Morris JN. [_____] Cost-benefit analysis of an emergency alarm and response system: a case study of a long term care program. Health Serv Res 1981 Spring; 16(1):65-80.

NA129 Sherwood S. [_____] Effects of an emergency alarm and response for the aged. 1981. (NTIS order no. PB81-137259)

NA130 Strauss j, et al. [_____] Evaluation of emergency room referral system. 1981. (NTIS order no. PB81-231755)

NA131 Wiederhold GC, Blum RL. [_____] Integrating medical knowledge and clinical data banks. 1981. (NTIS order no. PB81-227233)

NA132 Eisenberg MS, Bergner L, Hallstrom A. [_____] Out-of-hospital cardiac arrest: improved survival with paramedic services. Lancet 1980 Apr 12:812-814.

NA133 Harris PJ, et al. [_____] The prognostic significance of 50% coronary stenosis in medically treated patients with coronary artery disease. Circulation 1980 Aug:62(2):240-248.

NA134 Harris PJ, et al. [_____] Outcome in medically treated coronary artery disease. Ischemic events: nonfatal infarction and death. Circulation 1980 Oct;62(4): 718-726.

NA135 Stiles GL, Rosati RA, Wallace AG. [_____] Clinical relevance of exercise-induced ST segment elevation. Am J Cardiol 1980 Dec;46:936.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT OFFICE OF HEALTH TECHNOLOGY ASSESSMENT

5600 Fishers Lane, Room 18A-27
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301-443-4990

Contact: Enrique D. Carter, M.D., Director; or Morgan N. Jackson, M.D., Deputy Director. Telex 301-443-6463, 301-443-1719, or 301-443-1726. Telefax 301-443-2706.

Overview: The National Center for Health Services Research and Health Care Technology Assessment (NCHSR/ HCTA) is the primary source of federal support for research on problems related to the quality and delivery of health services. NCHSR/ HCTA programs evaluate health services, assess technologies, and improve access to new scientific and technical information for research users.

This profile addresses the NCHSR/HCTA Office of Health Technology Assessment. An overview of the NCHSR/ HCTA is provided immediately preceding the profile on the NCHSR/HCTA Division of Extramural Research. The NCHSR/ HCTA National Advisory Council on Health Technology Assessment is described in the organizational resources section of this Directory.

The NCHSR/HCTA Office of Health Technology Assessment (OHTA) has direct responsibility for assessing technologies and making Public Health Service (PHS) recommendations in response to requests from federally funded programs such as the Health Care Financing Administration (HCFA) and the Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS). OHTA (originally as the Office of Health Research, Statistics, and Technology) assumed these responsibilities following the dissolution of the National Center for Health Care Technology in 1981. OHTA also collects and maintains data on organ transplants in the U.S.

Purpose: To provide the clinical and scientific basis on which federally reimbursed health programs may develop coverage policies.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health/medical professional associations; consumer associations; employers; unions and other employee organizations;

third party payers; government regulators; biomedical researchers; public policy-makers, legislators; policy research organizations; Federal health programs.

Technologies: *Device, medical or surgical procedure*, drug.

Intervention: *Diagnosis, treatment*, prevention, rehabilitation.

Stage: *Established or widespread practice*, emerging, new, obsolete.

Properties: *Safety, effectiveness*, efficacy, cost, cost-effectiveness, acceptance/adoption level.

Selection process: Assessments are requested by federally reimbursed programs, such as HCFA and OCHAMPUS. In the case of HCFA, the first step in the selection process is a joint discussion of the issues by the Physicians Panel, a formal HCFA review board. The second step is a written interagency memorandum to the OHTA, by the requester. HCFA and the OHTA Program Director determine priorities for assessment topics.

Reassessments are also requested through HCFA and reviewed by the Physicians Panel, which decides whether there is enough new information to warrant reassessment. In other cases, OHTA itself makes plans to reopen an issue after a specified time period, with HCFA concurrence.

Methods: *Information syntheses*, expert opinion, cost analyses.

When the HCFA Physicians Panel decides that a technology warrants an assessment, a formal written request is submitted to the OHTA. The OHTA announces impending assessments in the *Federal Register*, inviting comments from appropriate federal agencies. It seeks advice from medical associations, manufacturers' groups, and experts in the medical and life sciences. A literature search is also performed. The OHTA staff then synthesizes the available information and develops the PHS recommendation. Once HCFA has made its coverage decision, the OHTA disseminates its findings in an assessment report. The average turnaround time from selection of topic to reporting of findings is 10 months.

Assessors: Assessments are conducted by OHTA staff in cooperation with outside experts and other federal agencies. OHTA is staffed by approximately 7 physicians and 2 non-physician professionals, as well as support staff.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; sources of data/information; methods for collecting data/information; results; findings or conclusions; how the technology works, including theory, principles; regulatory agency approval status.

Dissemination: Printed reports, advisories to members/constituents, memoranda of recommendation.

Reports are disseminated through direct mailings. They may be requested by contacting NCHSR/HCTA Publications and Information Branch, 5600 Fishers Lane, Room 18-12, Rockville, MD 20857, 301-443-4100. Reports are also available through the

National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, 703-487-4650. Reports are published occasionally in the professional literature.

Budget: $789,000. The approximate cost per assessment is $15,000 to $20,000. Funding source: 100 percent parent organization.

Use: Assessment reports are used by the OHTA to make policy recommendations to HCFA and OCHAMPUS. Third party reimbursers, providers, hospital administrators, health policy-makers and analysts, and government officials have reported using the assessments as well. The impact of the OHTA's assessments is exemplified by *Liver Transplants*, which constitutes the formal basis for federal policy on this procedure. The program has been described in:

Marshall JE, Carter ED. The role of the OHTA in medicine coverage decisions. J *Health Care Technol* 1986;3(2):75-78.

Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Program evaluation: The OHTA program has been evaluated by several groups and individuals including a 1984 study conducted by Macro Systems, Inc., and a 1986 study conducted by Lewin and Associates, both for the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. The program is also described in SN Finkelstein et al., J *Health Care Technol* 1984;1(2):89-102.

Completed Reports

NC1 National Center for Health Services Research and Health Care Technology Assessment, Office of Health Technology Assessment. Angelchik anti-reflux prosthesis. 1986.

NC2 _____. Apheresis in the treatment of systemic lupus erythematosus (SLE). 1986.

NC3 _____. Cochlear implants. 1986.

NC4 _____. Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea. 1986.

NC5 _____. Dual photon absorptiometry for measuring bone mineral density. 1986.

NC6 _____. Endoscopic electrocoagulation of upper gastrointestinal bleeding. 1986.

NC7 _____. Fully automated blood pressure monitoring of hypertension. 1986.

NC8 _____. Hemodialyzer reuse. 1986.

NC9 _____. Hemofiltration as a substitute for hemodialysis. 1986.

NC10 _____. Hemoperfusion in conjunction with deferoxamine for the treatment of aluminum toxicity or iron overload in ESRD patients. 1986.

NC11 _____. Laboratory tests for the management of ESRD dialysis patients. 1986.

NC12 _____. Single photon absorptiometry for measuring bone mineral density. 1986.

NC13 _____. 24-hour ambulatory esophageal pH monitoring. 1985.

NC14 _____. Allogenic bone marrow transplantation for indications other than aplastic anemia and leukemia. 1985.

NC15 _____. Apheresis in the treatment of Guillain-Barré syndrome. 1985.

NC16 _____. Autologous bone marrow transplantation (ABMT). 1985.

NC17 _____. Bilateral carotid body resection. 1985.

NC18 _____. Debridement and other treatment of mycotic toenails. 1985.

NC19 _____. Extracorporeal shock wave lithotripsy (ESWL) procedures for the treatment of kidney stones. 1985.

NC20 _____. Implantable automatic cardioverter-defibrillators. 1985.

NC21 _____. Magnetic resonance imaging (MRI). 1985.

NC22 _____. Patient selection criteria for percutaneous coronary angioplasty of a stenotic lesion in a single coronary artery. 1985.

NC23 _____. Percutaneous ultrasound procedures for the treatment of kidney stones. 1985.

NC24 _____. Portable hand-held x-ray instrument (lixiscope). 1985.

NC25 _____. Reassessment of cardiokymography. 1985.

NC26 _____. Stereotactic cingulatomy as a means of psychosurgery. 1985.

NC27 _____. Transurethral ureteroscopic lithotripsy procedures for the treatment of kidney stones. 1985.

NC28 _____. 13CO2 breath test for diagnosing bile acid malabsorption. 1984.

NC29 _____. 13CO2 breath test for diagnosing fat malabsorption. 1984.

NC30 _____. Ambulatory electroencephalographic (EEG) monitoring. 1984.

NC31 _____. Apheresis in the treatment of chronic relapsing polyneuropathy. 1984.

NC32 _____. Apheresis used in preparation for kidney transplant. 1984.

NC33 _____. Carbon dioxide lasers in head and neck surgery. 1984.

NC34 _____. Diagnostic endocardial electrical stimulation. 1984.

NC35 _____. Electrotherapy for treatment of facial nerve paralysis. 1984.

NC36 _____. External counterpulsation. 1984.

NC37 _____. External open-loop pump for the subcutaneous infusion of insulin in diabetics. 1984.

NC38 _____. Hyperbaric oxygen for treatment of chronic peripheral vascular insufficiency. 1984.

NC39 _____. Hyperbaric oxygen in treatment of severed limbs. 1984.

NC40 _____. Hyperbaric oxygen therapy for acute cerebral edema. 1984.

NC41 _____. Implantable pump for chronic heparin therapy. 1984.

NC42 _____. Intraoperative ventricular mapping. 1984.

NC43 _____. Laser trabeculoplasty (LTP) for open angle glaucoma. 1984.

NC44 _____. Local hyperthermia for treatment of superficial and subcutaneous malignancies. 1984.

NC45 _____. Nd:YAG laser for posterior capsulotomies. 1984.

NC46 _____. Neuromuscular electrical stimulation in the treatment of disuse atrophy in the absence of nervous system involvement. 1984.

NC47 _____. Noninvasive method of monitoring cardiac output by doppler ultrasound. 1984.

NC48 _____. Percutaneous transluminal angioplasty for obstructive lesions of arteriovenous dialysis fistulas. 1984.

NC49 _____. Percutaneous transluminal angioplasty for obstructive lesions of the aortic arch vessels. 1984.

NC50 _____. Streptokinase infusion for acute myocardial infarction. 1984.

NC51 _____. Transcutaneous electrical nerve stimulation for acute pain treatment for ambulatory patients. 1984.

NC52 _____. Transillumination light scanning for the diagnosis of breast cancer. 1984.

NC53 _____. Transplantation of the pancreas. 1984.

NC54 _____. Anti-gastroesophageal reflux implantation. 1983.

NC55 _____. Apheresis for the treatment of Goodpasture's syndrome and membranous proliferative glomerulonephritides. 1983.

NC56 _____. Cardiokymography. 1983.

NC57 _____. Closed-loop blood glucose control device. 1983.

NC58 _____. Computer enhanced perimetry. 1983.

NC59 _____. Diathermy as a physical therapy modality. 1983.

NC60 _____. EEG monitoring during open heart surgery. 1983.

NC61 _____. Electroversion therapy for the treatment of alcoholism. 1983.

NC62 _____. External infusion pump for heparin. 1983.

NC63 _____. Fully automated ambulatory blood pressure monitoring of hypertension. 1983.

NC64 _____. Hyperbaric oxygen for treatment of actinomycosis. 1983.

NC65 _____. Hyperbaric oxygen therapy for treatment of crush injury and acute traumatic peripheral ischemia. 1983.
NC66 _____. Implantable chemotherapy infusion pump for the treatment of liver cancer. 1983.
NC67 _____. Lactose breath hydrogen test for the diagnosis of lactose malabsorption.
NC68 _____. Lactulose breath hydrogen test for small bowel bacterial overgrowth and small bowel transit time. 1983.
NC69 _____. Liver transplantation. 1983.
NC70 _____. Negative pressure respirators. 1983.
NC71 _____. Photokymography. 1983.
NC72 _____. Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease. 1983.
NC73 _____. Thermography for breast cancer detection. 1983.
NC74 _____. Topical oxygen therapy in the treatment of decubitus ulcers and persistent skin lesions. 1983.
NC75 _____. Ambulatory blood pressure monitoring in hypertensives using semiautomatic, patient-activated portable devices. 1982.
NC76 _____. Apheresis for multiple sclerosis. 1982.
NC77 _____. Bendien's test for cancer and tuberculosis. 1982.
NC78 _____. Bolen's test for cancer. 1982.
NC79 _____. Bone mineral studies. 1982.
NC80 _____. Carbon dioxide laser surgery for selected conditions. 1982.
NC81 _____. Electrotherapy for treatment of facial nerve paralysis (Bell's Palsy). 1982.
NC82 _____. Endothelial cell photography. 1982.
NC83 _____. Gastric freezing for peptic ulcer disease. 1982.
NC84 _____. Home blood glucose monitors. 1982.
NC85 _____. Hyperbaric oxygen therapy for treatment of arthritic diseases. 1982.
NC86 _____. Hyperbaric oxygen therapy for treatment of chronic refractory osteomyelitis. 1982.
NC87 _____. Hyperbaric oxygen therapy for treatment of multiple sclerosis. 1982.
NC88 _____. Hyperbaric oxygen therapy for treatment of organic brain syndrome (senility).
NC89 _____. Hyperbaric oxygen therapy for treatment of soft tissue radionecrosis and osteoradionecrosis. 1982.
NC90 _____. Melodic intonation therapy. 1982.
NC91 _____. Obesity and protein supplemented fasting. 1982.
NC92 _____. Percutaneous transluminal angioplasty for treatment of stenotic lesions of a single coronary artery. 1982.
NC93 _____. Percutaneous transluminal angioplasty in treatment of stenotic lesions of the renal arteries. 1982.
NC94 _____. Photoplethysmography. 1982.
NC95 _____. Plasmapheresis and plasma exchange for thrombotic thrombocytopenic purpura. 1982.
NC96 _____. Rehfuss test for gastric acidity. 1982.
NC97 _____. Rheumatoid vasculitis therapeutic apheresis. 1982.
NC98 _____. Serum seromucoid assay. 1982.
NC99 _____. Alcohol aversion therapy. 1981.
NC100 _____. B-mode scan in peripheral arterial disease. 1981.
NC101 _____. Cytotoxic leukocyte test for the diagnosis of food allergy. 1981.
NC102 _____. Desoxyribonucleic acid-bentonite flocculation for the diagnosis of rheumatoid arthritis. 1981.
NC103 _____. Ethylenediamine-tetra-acetic acid (EDTA) chelation therapy for atherosclerosis. 1981.
NC104 _____. Hydrotherapy (whirlpool) baths for treatment of decubitus ulcers. 1981.
NC105 _____. Intracranial pressure measurement. 1981.
NC106 _____. Intracutaneous (intradermal) and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies. 1981.
NC107 _____. Percutaneous transluminal angioplasty in treatment of the lower extremities. 1981.
NC108 _____. Shortwave diathermy. 1981.
NC109 _____. Stereotaxic depth electrode implantation prior to surgical treatment of focal epilepsy. 1981.
NC110 _____. Sublingual provocative testing and neutralization therapy for food allergies. 1981

NC111 _____. The Kunkel test for estimating total serum gamma globulin levels in patients with rheumatoid arthritis. 1981.

NC112 _____. The of use anti-inhibitor coagulant complex (activated prothrombin-complex concentrate) in the treatment of patients with hemophilia A and antibodies to factor VIII. 1981.

NC113 _____. The role of joint scans using technetium-99m pertechnetate in diagnosing and assessing therapeutic gain in arthritis. 1981.

NC114 _____. The use of human tumor stem cell drug sensitivity assays for predicting anticancer drug effects. 1981.

NC115 _____. The use of the bentonite flocculation test in the diagnosis of rheumatoid arthritis. 1981.

NC116 _____. The use of the mycoplasma complement fixation test in the diagnosis of rheumatoid arthritis. 1981.

NC117 _____. Therapeutic apheresis for rheumatoid arthritis. 1981.

NC118 _____. Tinnitus maskers. 1981.

NC119 _____. Transcutaneous electrical nerve stimulation for acute postoperative incision pain. 1981.

NC120 _____. Transsexual surgery. 1981.

NC121 _____. Ultraviolet absorbing or reflecting spectacle lenses for aphakic and pseudophakic patients. 1981.

NC122 _____. Ultraviolet light for treatment of decubitus ulcers. 1981.

NC123 _____. Urine autoinjection (autogenous urine immunization). 1981.

Ongoing Assessments

NC124 _____. Adult liver transplantation. Ongoing.

NC125 _____. Bone mineral density studies: computed tomography. Ongoing.

NC126 _____. Bone mineral density studies: radio-graphic absorptiometry. Ongoing.

NC127 _____. Cardiac catheterization in a freestanding setting. Ongoing.

NC128 _____. Cardiac rehabilitation program services. Ongoing.

NC129 _____. Cardiointegram as an alternative to stress test or thallium stress test. Ongoing.

NC130 _____. Cardiokymography. Ongoing.

NC131 _____. Carotid endarterectomy. Ongoing.

NC132 _____. Chemical aversion therapy for treatment of alcoholism. Ongoing.

NC133 _____. Coverage of gating devices and the use of surface radio frequency coils in conjunction with magnetic resonance imaging (MRI) procedures. Ongoing.

NC134 _____. Development of criteria for speech pathologist's services for dysphagia. Ongoing.

NC135 _____. Diagnostic tests for impotency: devices (Snap-gauge, Rigi-scan). Ongoing.

NC136 _____. Diagnostic tests for impotency: papaverine injections. Ongoing.

NC137 _____. Diagnostic tests for impotency: plethysmography. Ongoing.

NC138 _____. Drug delivery systems: external infusion pumps for IV antibody therapy. Ongoing.

NC139 _____. Drug delivery systems: external infusion pumps for rehydration therapy. Ongoing.

NC140 _____. Drug delivery systems: external pump for chemotherapy for other than liver cancer. Ongoing.

NC141 _____. Drug delivery systems: external pumps for morphine for pain of nonmalignant origin. Ongoing.

NC142 _____. Drug delivery systems: implantable pumps for chemotherapy for other than liver cancer. Ongoing.

NC143 _____. Drug delivery systems: implantable pumps for infusion of drugs for congestive heart failure. Ongoing.

NC144 _____. Drug delivery systems: implantable pumps for morphine (analgesia) intractable cancer pain. Ongoing.

NC145 _____. Drug delivery systems: implanted pumps for morphine for pain of nonmalignant origin. Ongoing.

NC146 _____. Endoscopic photocoagulation for upper gastrointestinal hemorrhage. Ongoing.

NC147 _____. Extra-intracranial artery bypass surgery in the treatment of strokes. Ongoing.

NC148 _____. Intermittent positive pressure breathing (IPPB therapy). Ongoing.

NC149 _____. Percutaneous transluminal coronary angioplasty when multi-vessel disease is involved (reassessment). Ongoing.

NC150 _____. Real time cardiac monitors. Ongoing.

NC151 _____. Reassessment of autologous bone marrow transplantation (ABMT). Ongoing.
NC152 _____. Thermography for indications for other than breast lesions. Ongoing.
NC153 _____. Transillumination light scanning for use in detection of diseases of the breast. Ongoing.
NC154 _____. Treatment of kidney stones—transurethral ureteroscopic lithotripsy. Ongoing.
NC155 _____. Treatments for impotency: surgical treatments. Ongoing.
NC156 _____. Treatments for impotency: Erect-aid system. Ongoing.
NC157 _____. Treatments for impotency: drug injections. Ongoing.
NC158 _____. Treatments for impotency: other significant therapeutic modalities. Ongoing.
NC159 _____. Treatments for impotency: papaverine. Ongoing.
NC160 _____. Treatments for impotency: penile artery bypass. Ongoing.

NATIONAL HEALTH RESEARCH AND DEVELOPMENT PROGRAM

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613-954-8543

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Overview: The National Health Research and Development Program (NHRDP) is a government agency that supports scientific activities to provide the Department of National Health and Welfare with the information needed to fulfill its statutory functions and responsibilities. The NHRDP funds extramural research focusing on public health and health services delivery issues. The technology assessment activities are an integral part of the extramural research program.

Purpose: To fund public health and health services management research through the competitive grant process.

Primary intended users: General public; health/medical professional associations, government regulators; voluntary associations, organizations; biomedical researchers; public policy-makers, legislators; policy research organizations.

Technologies: *Organizational or administrative system*, drug, device, medical or surgical procedure, support system.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *Established or widespread practice*, new.

Drugs and specific treatments are assessed usually after clinical efficacy has been established and biomedical studies have been completed. Rehabilitation devices are assessed after the basic engineering phases have been completed.

Properties: *Effectiveness*, safety, cost, cost-benefit, cost-effectiveness, service requirements, system impact, economic implications.

Selection process: Any Canadian researcher can submit a research protocol to the NHRDP. The protocol must be submitted as part of a formal research application. Peer review competition is used to evaluate the protocol's methodological acceptability. Department officials assess the relevance to Department programs.

Methods: *Epidemiological and other observational methods*, modeling, cost analyses.

A variety of assessment methods may be selected at the discretion of the investigators. The approximate turnaround time from selection of assessment topic to reporting of findings is 3 to 4 years.

Assessors: The assessors are usually university or hospital faculty.

Dissemination: The NHRDP does not use a standard format for reporting assessment results. All research projects are required to submit five copies of a final report. The final reports are available through interlibrary loan. Further dissemination is primarily the researchers responsibility. Most results are published in academic journals.

Budget: $19,000,000. The approximate cost for a 3-year project is $60,000 to $80,000. Funding source: 100 percent parent organization.

Use: The NHRDP uses the reports to assist in the planning and delivery of health care services in Canada. Based on interlibrary loan requests, the library has some potential data on outside use of the reports. After 10 years of supporting research in this area, the number of published reports and references to NHRDP-funded research are too numerous to mention.

Related activities: The NHRDP directly supports the research community through other activities including training and career grant awards and funding for conferences and workshops. The conferences and workshops must be sponsored by Canadian organizations, held in Canada, and address health care research issues.

Completed Reports

ND1 Aierre YN, Waters BGH. [National Health Research and Development Program—Canada] Erythrocyte membrane enzyme and lithium in manic-depressive disorder. 1986. (Grant No. 6606-2149-52).

ND2 Broder I. [_____] A study of the health status of residents in homes insulated with urea formaldehyde foam, before and after remedial measures are undertaken. 1986. (Grant No. 6606-2286-03).

ND3 Brown RE, Schipper, H. [_____] Electronic diaphanography (E/DPG) as an adjunct to the early diagnosis of breast cancer. 1986. (Grant No. 6607-1304-07).

ND4 Buchanan WW, Kragg G, Tugwell R. [_____] A trial to assess the efficacy of peer group rehabilitative counselling in patients with rheumatoid arthritis. 1986. (Grant No. 6606-1941-43).

ND5 Burrunham RC, Binns B. [_____] Etiology and therapy of acute salpingitis. 1986. (Grant No. 6607-1323-54).

ND6 Burton HJ. [_____] Factors influencing outcome of home and satellite care dialysis. 1986. (Grant No. 6606-2304-05).

ND7 Byles JA. [_____] An assessment of a survey instrument designed to diagnose children's behavioural disorders. 1986. (Grant No. 6606-2245-04).

ND8 Cadman D. [_____] Mental health problems associated with chronic physical disability in children: prerequisites for a family-focused preventive mental health strategy. 1986. (Grant No. 6606-2899-43).

ND9 Cameron R, Horlick L, Shepel L. [_____] Toward an economical, broadly accessible weight control program: the refinement and evaluation of a correspondence approach. 1986. (Grant No. 6606-2588-42).

ND10 Chamberg LW, Mohide AE, Tugwell P, Bayne R, Pill ML, Nightingale H. [_____] Randomized trial of resident care quality assurance by criteria mapping in nursing homes. 1986. (Grant No. 6606-2450-44).

ND11 Chandra RK. [_____] Influence of nutritional counselling and support on immunocompetence, nutritional status and illness in the elderly. 1986. (Grant No. 6601-1063-56).

ND12 Chapman JS, Pike R, Segalowitz S. [_____] Incidence and degree of laterality preference and cerebral dominance for speech as related to prematurely born 5 1/2 year olds' degree of perinatal stress and cognitive functioning. Effects of hospital and home intervention programmes in preventing deficits of language comprehension skills in prematurely born 5 1/2 year olds. 1986. (Grant No. 6606-1956-43).

ND13 Chipman ML. [_____] Population-based studies of corneal graft outcome. 1986. (Grant No. 6606-2671-46).

ND14 Chretien M, M'Bikay M. [_____] Screening of bronchogenie adenocarcinoma: development of a model to use turnout markers. 1986. (Grant No. 6605-2299-52).

ND15 Cohen MM. [_____] A population-based study of cervical screening in Manitoba. 1986. (Grant No. 6607-1401-53).

ND16 Cole EH, Cattran DC. [_____] A controlled trial of plasmapheresis in idiopathic rapidly progressive glomerulonephritis. 1986. (Grant No. 6606-2372-52).

ND17 Colle E. [_____] Study of siblings of patients with type I insulin dependent diabetes mellitus: tests which predict the development of disease. 1986. (Grant No. 6605-2390-54).

ND18 Collins J. [_____] An evaluation of infertility therapy in Canadian infertility clinics. 1986. (Grant No. 6606-2628-44).

ND19 Conine TA. [_____] A controlled randomized trial of two seat cushions in the prevention of decubitus ulcers in institutionalized elderly persons. 1986. (Grant No. 6610-1493-55).

ND20 Conrath DW. [_____] The effect of health care practice and environmental factors on the health of, and the use of health care services by, Native Canadians. 1986. (Grant No. 6606-2309-05).

ND21 Cott A. [_____] Intervention in disability and chest pain associated with (a) mitral valve prolapse and (b) no known cardiac disease: a cognitive-behavioral approach. (Grant No. 6606-2250-05).

ND22 Crawhall, J. [_____] Effect of D-penicillamine on circulating immune complexes and rheumatoid factor. What is the mechanism of its therapeutic action? 1986. (Grant No. 6605-1758-52).

ND23 Cunningham AJ. [_____] A randomized control trial of a brief behavioural training group programme for alleviating psychological distress in cancer patients. 1986. (Grant No. 6606-2884-44).

ND24 Curry L. [_____] Improving physician manpower distribution and cost effectiveness of training: an application of individual difference theory. 1986. (Grant No. 6606-2982-55).

ND25 D'Arcy C. [_____] Phobia, anxiety and alcoholism: evaluating a behavioural treatment program. 1986. (Grant No. 6608-1182-43).

ND26 Detsky A, Baker JP, Jeejeebhoy KN. [_____] Predicting nutrition-associated complications in hospitalized patients. 1986. (Grant No. 6606-2362-42).

ND27 Doehring DG [_____] Reading in heating-impaired children: word recognition skills of children educated by auditory-oral methods. 1986. (Grant No. 6605-2452-45).

ND28 Dubois S. [_____] Validity of food records and dietary recalls in elderly subjects. 1986. (Grant No. 6605-2284-42).

ND29 Duncan PG. [_____] The influence of anesthesia and surgery on the outcome of pregnancy—pilot analysis. 1986. (Grant No. 6607-1289-53).

ND30 Durance JP. [_____] Modular sockets in the prosthetic fitting of below-knee amputees (evaluation). 1986 (Grant No. 6606-2315-01).

ND31 Edgar LJ. [_____] Implementation and evaluation of a rehabilitative approach as a part of normal nursing care of cancer patients. 1986. (Grant No. 6605-2223-46).

ND32 Eyssen GE. [_____] Methods of assessing neurological abnormality for use in remote areas. 1986. (Grant No. 6606-2216-55).

ND33 Fancott T. [_____] A prototype ambulatory ECG tape analysis system. 1986. (Grant No. 6605-2052-51).

ND34 Ferguson HB. [_____] Assessment of cognitive functioning in learning disabled children. 1986. (Grant No. 6606-2096-46).

ND35 Fernie GR. [_____] An evaluation of computer-aided design of trans-tibial prosthetic sockets. 1986. (Grant No. 6606-3024-51).

ND36 Fernie GR. [_____] Balance training device for stroke rehabilitation. 1986. (Grant No. 6606-3023-45).

ND37 Fernie GR. [_____] High speed dimensional shape sensor for clinical application. 1986. (Grant No. 6606-2404-51).

ND38 Fernie GR. [_____] Use of trunk shape measurements to quantify scoliotic deformity. 1986. (Grant No. 6606-2995-51).

ND39 Foort J. [_____] A modular exoskeletal system for supporting heavy disabled people in the sitting position. 1986. (Grant No. 6610-1291-51).

ND40 Foort J. [_____] Amputee fitting—standard shape processing. 1986. (Grant No. 6610-1289-51).

ND41 Foort J. [_____] Tabular orthoses for stabilizing body joints. 1986. (Grant No. 6610-1290-51).

ND42 Frasure-Smith N. [_____] The long-term out-comes of the ischemic heart disease life stress monitoring program. 1986. (Grant No. 6605-2388-44).

ND43 Frasure-Smith N. [_____] The psychosocial outcomes of coronary bypass surgery: a study of patient and spouse adjustment during the first post-surgical year. 1986. (Grant No. 6605-2021-44).

ND44 Fried PA. [_____] Long-term effects of maternal soft drug use on the development of pre-school children. 1986. (Grant No. 6606-1887-46).

ND45 Friel JK. [_____] Trace element supplementation of pre-term infants. 1986. (Grant No. 6602-1087-56).

ND46 Frost BL, Mason JL. [_____] The development and evaluation of a portable vibrotactile auditory prosthetic device for the profoundly deaf. 1986. (Grant No. 6606-1959-51).

ND47 Garner DM. [_____] Cognitive therapy for anorexia nervosa and bulimia. 1986. (Grant No. 6606-2666-46).

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

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Overview: The National Institutes of Health (NIH) is the principal biomedical research agency of the Federal government. NIH is composed of 12 bureaus and institutes and six research and support divisions. The National Heart, Lung, and Blood Institute (NHLBI) is the second largest in terms of funding. It was established in 1948 as the National Heart Institute. With a growing awareness of national health problems, it was redesignated the National Heart and Lung Institute in 1969 and in 1976 was redesignated the National Heart, Lung, and Blood Institute.

Purpose: To serve the overriding strategy of the Institute's national program. This strategy is represented by the biomedical research and clinical applications spectrum in which the products of research flow from basic research and clinical research to applied research and development and practical health care.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; employers; unions and other employee organizations; voluntary associations, organizations; biomedical researchers; reporters, writers, news media; labs, blood banks.

Technologies: *Medical or surgical procedure*, drug, device, support system.

NHLBI also devotes considerable attention to the roles of smoking, diet, and other aspects of lifestyle and the environment in heart and vascular diseases, lung diseases, and blood diseases.

Intervention: *Treatment*, prevention, diagnosis.

Stage: *New*, emerging, established or widespread practice, obsolete.

According to the Institute, emerging technologies are those under development that appear likely to be used in the practice of medicine within 4 years. New technologies are those that may have passed the stage of clinical trials but are not yet widely disseminated, or those that are moving into general use without benefit of clinical trials. The last group are those established technologies that are currently undergoing or likely to undergo major changes in use or costs as a result of new research findings, or for which serious concerns have been raised concerning safety and effectiveness.

Properties: *Effectiveness*; safety; efficacy; ethical, legal, social implications.

The principal concerns of NHLBI assessment activities are safety and efficacy. The planning and conduct of research reported by NHLBI, particularly clinical trials, are

subject to detailed review of ethical considerations. The Institute does conduct some cost studies, such as in-house studies to demonstrate the cost-effectiveness of its clinical trials. It must also evaluate the cost-effectiveness of the Federal investment in the National Heart, Blood Vessel, Lung, and Blood Program, and make recommendations regarding future resource allocations.

Selection process: Large-scale clinical trials are usually initiated by Institute staff, advisory groups, and other biomedical scientists and health care researchers. The smaller, grant-supported clinical trials are usually initiated by investigators who apply for grants. Consensus development conferences are initiated by the Institute, Office of Medical Applications of Research (OMAR), other government agencies, or the public.

If the concept of a large-scale clinical trial is approved by the Institute, a request for proposal (RFP) or request for application (RFA) is prepared and advertised. The RFP or RFA defines the program requirements and describes the criteria by which the proposals will be evaluated. Consensus development conferences may be requested by the Institute, OMAR, other government agencies, and the public.

Institute Advisory Groups, Institute staff, and the National Heart, Lung, and Blood Advisory Council all set assessment topic priorities throughout the processes of concept development and initiation of assessments.

The NHLBI reassesses technologies in light of new scientific evidence of efficacy or of long-term adverse effects not apparent in short-term studies, and gives suggested new uses for established technologies.

Methods: *Clinical trials*, information syntheses, expert opinion, group judgment, epidemiological and other observational methods, bench testing.

If NHLBI makes a commitment to conduct a trial, subject recruitment and clinical intervention begin. Generally subjects are not recruited simultaneously, and thus the recruitment and intervention activities proceed together.

Once the trial is under way, it is managed by a complex of committees composed of the investigators, advisors, and Institute staff. Often, the central organizational element of the trial is a steering committee that provides overall scientific direction for the study at the operational level. Various subcommittees appointed by the steering committee are responsible for reviewing such matters as patient adherence, quality control, nonfatal events, natural history, mortality classification, bibliography, and editorial review. An assembly of investigators representing all of the clinical and logistical coordinating centers reports to the steering committee. A policy data-monitoring board which does not include any of the trial investigators acts in a senior advisory capacity to the NHLBI on policy matters throughout the trial's duration. It periodically reviews study results and evaluates the study treatments for beneficial and adverse effects, and consults on such major policy decisions as trial safety and termination, changes in protocol, measurement procedures, and publication.

Analysis continues during the trial. By the time the trial is ended, much of the analysis concerning the major question may already have been completed. However, only in rare cases such as those in which a trial is not double-blind and the trends are extraordinary, might the findings of a trial be published during its course.

The duration of clinical trials supported by NHLBI has ranged from 2 to 18 years (including patient follow-up), averaging about 6.6 years, although interim assessments

and other reports are made during the longer trials. Consensus conferences, state-of-the-art conferences, and workshops generally take about 1 year to plan.

Assessors: NHLBI technology assessment activities entail the participation of the full complement of biomedical research and health care delivery personnel. Various advisory groups also include representatives of other professions. As noted above, members of the National Heart, Lung, and Blood Advisory Council include scientists and others who are lay community members with a demonstrated interest in health areas relevant to the program area of the Institute. The study sections that review proposals are composed of nonfederal scientists selected for their competence in the particular scientific areas for which a study section has review responsibilities.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/ supported the assessment; who conducted the assessment; description of the technology; stage of lifecycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: *Journal articles*; printed reports; press conferences/news releases, TV/ radio broadcasts, video products.

NHLBI promotes and disseminates assessment findings through workshops; information centers; and prevention, education, and control programs. The Institute also disseminates information through professional societies, educational programs such as the National High Blood Pressure Education Program, clearinghouses such as the High Blood Pressure Information Center, interactions with industry representatives, and activities of the Institute's Office of Prevention, Education, and Control.

Copies of assessments are available in the open scientific literature. Many special reports can be obtained from the Communications and Public Information Branch, NHLBI, NIH, Building 31 Room 4A-31, 9000 Rockville Pike, Bethesda, MD 20892.

Budget: $29,000,000. The cost of large scale clinical trials ranges between $1.6 million and $142.3 million. Funding source: 100 percent parent organization.

Use: The NHLBI uses the assessment reports for planning and evaluation. The NIH and NHLBI conducted an evaluation of the impact of clinical trials on medical practice. The study evaluated the relationship between the dissemination of the clinical trial results and subsequent physician knowledge and medical practice. The two trials, both supported by NHLBI, were the Coronary Drug Project (CDP) reported in 1976 and the Aspirin Myocardial Infarction Study (AMIS) which was completed in 1979 with results disseminated in 1980. Following AMIS, there was a small increase in the number of physicians who said aspirin was of unproven benefit for post-myocardial infarction use, but most physicians still heavily prescribed aspirin.

NHLBI assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies. *Assessing medical technologies* . Washington, DC: National Academy Press, 1985.

Program evaluations: NHLBI has sponsored several evaluations of its assessment program and clinical trials. Listed below are the evaluation project names followed by citations to published documents about the evaluation or its findings.

1. Evaluation of Clinical Trial Coordinating Center Model Project. The University of Maryland conducted this study from June 1976 to June 1979.

The following reports were submitted to the NHLBI.

I. *Study design and methods*

II. *RFPs for coordination centers: a content evaluation*

III. *The contract process for selecting coordination centers*

V. *Terminology*

VI. *Phases of a multicenter clinical trial*

X. *Management of coordinating centers*

XIV. *Enhancement of methodological research in the field of clinical trials*

XVI. *CCMP manuscripts presented at the Annual Symposia on Coordinating Clinical Trials*

2. Evaluation of the Impact of Clinical Trials on Medical Practice. Market Facts, Inc. conducted this study from September 1978 to January 1982.

Markets Facts, Inc. *The impact of clinical trials on physician knowledge and practice*. 1982 Mar.

3. Evaluation of the Impact of Adenine on Blood Banking. JRB Associates conducted this study from June 1979 to June 1983.

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4. Evaluation of Regimen Compliance in Long-term Clinical Trials. The University of Maryland conducted this study from June 1979 to September 1984.

Howard J, Whittemore AS, Hoover J J, Panos M, and the Aspirin Myocardial Infarction Study Research Group. How blind was the patient blind in AMIS? *Clin Pharmacol Ther* 1982;32:543-553.

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7. Evaluation of the Impact of the Coronary Primary Prevention Trial (CPPT) on Clinical Practice: Measurement of Practice after Release of Clinical Trial Results. National Capitol Systems conducted this study from October 1985 to October 1986. The findings have not yet been published.

8. Evaluation of the Impact of the Coronary Primary Prevention Trial (CPPT) on Public Attitudes, Knowledge, and Behavior Regarding Serum Cholesterol and Other Risk Factors for Coronary Heart Disease. This study was conducted by the Food and Drug Administration and NHLBI staff from January 1984 to September 1985. The findings have not yet been published.

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NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

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Contact: James G. Hill, Chief Office of Planning and Evaluation. Telex 494-8446.

Overview: The National Institute of Child Health and Human Development (NICHD) supports and conducts research to help families have healthy children at the time they are wanted, to prevent disease and disability among children, to foster normal development, and to insure that each child will have a healthy and productive life. The NICHD Technology Assessment/Transfer program was initiated in 1978.

Purpose: To maintain an awareness of technologies used in fields related to NICHD's mission and to conduct assessments of technologies with high public interest and importance.

Primary intended users: General public; people concerned about their health; patients; providers, generally; physicians; other care givers; health product manufacturers; health/medical professional associations; health industry associations; consumer associations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; reporters, writers, news media; public policy-makers, legislators; policy research organizations; lawyers; liability, malpractice insurers.

Technologies: *Medical or surgical procedure*, drug, device, support system.

Intervention: *Prevention*, diagnosis, treatment, rehabilitation.

Stage: *New*, emerging, established or widespread practice.

Properties: *Effectiveness*; safety; efficacy; cost; cost-benefit; ethical, legal, social implications.

Selection Process: Requests for assessment can come from any source, but most suggestions come from Institute staff, advisory groups, and professional associations within the scope of the Institute's mission. In addition, an annual request for assessment topics is sent to the NICHD research programs and the primary professional organizations within the Institute's mission.

Topics submitted are reviewed and analyzed by the Office of Planning and Evaluation (OPE) according to the criteria for selection of consensus topics developed by the Office of Medical Applications of Research (OMAR), NIH. In addition, relevance to the NICHD mission and research priorities are considered. The OPE Analysis of the suggested topics is reviewed by the Director, NICHD and a list of topics (usually two or three) are selected for formal assessment during the year. The selected topics are reviewed with OMAR to determine which will be consensus development conferences. Remaining topics are subjected to full scale assessment (e.g. prenatal and perinatal factors in brain injury, contents of prenatal care) or a workshop (e.g. malpractice issues in childbirth).

Technologies are reassessed when, in the judgment of Institute staff, sufficient new information is available. For example, when the clinical trial on chorion villi sampling is complete, antenatal diagnosis will be reassessed.

Methods: *Group judgment*, information synthesis, expert opinion, cost analyses, epidemiological and other observational methods, clinical trials.

Task Force, expert panels and workshops are used for conducting assessments. Once a topic is selected, a planning meeting is held. Three tasks are completed: l) selection of a chairperson; 2) specification of the types of individuals to serve on the panel; and 3) identification of the questions to be answered by the panel. With the assistance of the National Library of Medicine, a major literature search is undertaken. The panel meets for the first time. Armed with their questions, the results of the literature search, and other information (e.g. hearings or new data sets), the panel drafts a report containing the draft consensus statement. The draft report is circulated among interested organizations and individuals who are encouraged to submit written comments and/or give oral testimony at the consensus meeting. The next step is a consensus conference that is open to the public. It consists of a summary presentation of the draft report by the members of the panel, invited comments, presentation of additional data not considered by the panel, testimony from individuals and organizations, and a closed executive

session in which the panel resolves and includes additional information and prepares the final statement. The panel chairperson concludes the conference by delivering the final consensus statement in an open session.

The approximate turnaround time from selection of assessment topic to reporting of findings ranges from 1 to 2 years.

Assessors: The expertise of the panel members varies with the technology. At a minimum the group is composed of basic scientists, academic physicians, epidemiologists, practicing physicians, and consumer representatives.

Assessment reports include: The assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology.

Dissemination: Printed reports, journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

Results are disseminated using mailing lists, working with professional organizations such as the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, and at professional and lay meetings. Copies of assessment reports can be obtained from the Office of Research Reporting, NICHD, Bldg. 31, Room 2A32, 9000 Rockville Pike, Bethsda, MD 20892, (301)496-5133.

Budget: $200,000. The approximate cost per assessment is $200,000. Funding source: 100 percent parent organization.

Use: Based on an analysis of requests, practicing physicians, health consumers, researchers, and physician residency training programs use the assessment reports.

The following articles reference the NICHD program:

Hill, JG. Technology assessment at the National Institute of Child Health and Human Development: an alternative model. In: Wisniewski HM, Snider DA, eds. *Mental retardation: research, education, and technology transfer*. New York: Annals of the New York Academy of Sciences 1986;477:351-355.

Shino, et al. Recent trends in C/B and trial of labor rates in the *U.S. JAMA* 1987;257(4).

Completed Reports

NK1 National Institute of Child Health and Human Development. Infantile apnea and home monitoring. Bethesda, MD: National Institute of Child Health and Human Development, 1987 (in press). [Group judgment, Expert opinion]

NK2 International Childbirth Education Association, National Institute of Child Health and Human Development, Division of Maternal and Child Health. Malpractice issues in childbirth. Minneapolis, MN: International Childbirth Education Association, 1985. [Group judgment, Expert opinion]

NK3 National Institute of Child Health and Human Development, National Institute of Neurological and Communicative Disorders and Stroke. Prenatal and perinatal factors associated with brain disorders. Bethesda, MD: National Institutes of Health, 1985. (NIH publication no. 85-1149) [Group judgment, Expert opinion]

NK4 National Institute of Child Health and Human Development. Diagnostic ultrasound imaging in pregnancy. Bethesda, MD: National Institute of Child Health and Human Development, 1984. (NIH publication no. 84-667) [Group judgment, Expert opinion]

NK5 _____. Cesarean childbirth. Bethesda, MD: National Institute of Child Health and Human Development, 1981. (NIH publication no. 82-2067) [Group judgment, Expert opinion]

NK6 _____. Antenatal diagnosis. Bethesda MD: National Institute of Child Health and Human Development, 1979. (NIH publication no. 80-1973) [Group judgment, Expert opinion]

Ongoing Assessments

NK7 _____. Division of Maternal and Child Health. Content of prenatal care. Ongoing. [Group judgment, Expert opinion]

Planned Assessments

NK8 _____. Antenatal diagnosis of hereditary disease (an update of the 1979 Conference on Antenatal Diagnosis). Planned. [Group judgment, Expert opinion]

NK9 _____. Modification of inappropriate behavior in the mentally retarded. Planned. [Group judgment, Expert opinion]

NK10 _____. Safety and efficacy of oral contraceptives. Planned. [Group judgment, Expert opinion]

NATIONAL INSTITUTES OF HEALTH CONSENSUS DEVELOPMENT PROGRAM

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301-496-1143

Contact: Michael J. Bernstein, Director of Communications, Office of Medical Applications of Research.

Overview: The National Institutes of Health (NIH) is the principal biomedical research agency of the Federal Government. The NIH Office of Medical Applications of Research (OMAR) operates the NIH Consensus Development Program which conducts consensus conferences. The conferences are jointly sponsored by OMAR and one or more of the NIH Institutes; other Public Health Service (PHS) agencies occasionally join in the sponsorship.

Purpose: To evaluate in a public forum the use of biomedical technologies, to publish a consensus statement relevant to the public at large that provides guidelines for practitioners on the use of the technology, and to disseminate this information to the intended audience.

Primary intended users: General public; providers, generally; physicians; biomedical researchers.

Technologies: Drug, device, medical or surgical procedure, support system.

Intervention: Prevention, diagnosis, treatment, rehabilitation.

Stage: *New*, established or widespread practice.

Most often the program focuses on new information. This information can pertain to existing technologies, making them obsolete, or to emerging technologies.

Properties: Safety, efficacy, effectiveness, service requirements.

Selection process: Most often topics are selected by the NIH leadership as part of the NIH-wide planning process. At times topics are requested for consideration by other PHS agencies or organizations outside the government. Requests are submitted to OMAR. Assessment topic priorities are set by the OMAR Director in consultation with the NIH Coordinating Committee on Assessment and Transfer of Technology. Meetings can be held to reassess topics; for example adjuvant chemotherapy for breast cancer was recently reexamined.

Methods: *Group judgment*, information syntheses, modeling.

OMAR uses consensus conferences as its assessment method. A consensus panel, after listening to expert presentations, develops a consensus statement. This statement is a response to a set of questions presented to the panel.

The average turnaround time from selection of assessment topic to reporting of findings is 1 year.

Assessors: The assessors' areas of expertise include biomedical research, clinical practice, biostatistics, epidemiology, and public policy.

Assessment reports include: The assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: *Printed reports*; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

The consensus statements are widely disseminated through targeted mailing lists, dedicated TV networks such as the Hospital Satellite Network, and professional journals such as the *Journal of the American Medical Association* Copies of consensus statements are available from OMAR.

Budget: $900,000. The approximate, all-inclusive cost per conference is $95,000. Funding source: 100 percent parent organization.

Use: Summary statements are widely used by practitioners as well as the public in considering care and patient management. Impact has been shown recently by the significant sales increases of certain drugs following the consensus conferences on

osteoporosis and blood cholesterol. The use of these drugs was recommended in the summary statements.

The following articles describe the Consensus Development Program:

Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Jacoby I, Mullan F. The town meeting for technology: the maturation of consensus conferences. *JAMA* 1985 Aug;254(8).

Jacoby, I. The Consensus Development Program of the National Institutes of Health: current practices and historical perspectives. *Internal J Technol Assessment Health Care* 1985 Jun; 1(2).

A Rand note: "Treatment of eight NIH Consensus Development Conferences in the biomedical literature." 1986 Sep.

Program evaluation: During 1982 to 1986, the Rand Corporation conducted an evaluation of the Consensus Development Program's impact. Funded by OMAR, the study included lengthy questionnaires responded to by physicians, a detailed hospital chart-audit, and analyses based upon literature searches. The findings suggested that while the program has a positive impact, some elements of the process can be improved. Evaluation results are continuously introduced to improve topic selection, synthesis of data, the conduct of the group process, and dissemination methods.

The Rand Corporation report will be available shortly upon request from the Rand Corporation, Santa Monica, California. See also: Wortman P, Vinokura A, and Sechrest L. *Evaluation of NIH consensus development process: phase I: final report*. Center for Research on Utilization of Scientific Knowledge, Institute for Social Research, University of Michigan, Ann Arbor. 1982;Sep.

Completed Reports

NL1 National Institutes of Health, Consensus Development Program. Assessment methods for decisions about long-term care. (Consensus Development Conference Statement, Oct 19-21, 1987). [Group judgment]

NL2 _____. Differential diagnosis of dementing diseases. (Consensus Development Conference Statement, Jul 6-8, 1987). [Group judgment]

NL3 _____. Magnetic resonance imaging. (Consensus Development Conference Statement, Oct 26-28, 1987). [Group judgment]

NL4 _____. Management of clinically localized prostate cancer. (Consensus Development Conference Statement, Jun 15-17 1987). [Group judgment]

NL5 _____. Newborn screening for sickle cell disease and other hemoglobinopathies. (Consensus Development Conference Statement, Apr 6-8 1987). [Group judgment]

NL6 _____. Diet and exercise in noninsulin-dependent diabetes mellitus. (Consensus Development Conference Statement, Dec 8-10 1986). [Group judgment]

NL7 _____. Impact of routine HTLV-III antibody testing of blood and plasma donors on the health of the public. (Consensus Development Conference Statement, Jul 7-9 1986). [Group judgment]

NL8 _____. Infantile apnea and home monitoring. (Consensus Development Conference Statement, Sep 29-Oct 1 1986). [Group judgment]

NL9 _____. Integrated approach to the management of pain. (Consensus Development Conference Statement, May 19-21 1986). [Group judgment]

NL10 _____. Platelet transfusion therapy. (Consensus Development Conference Statement, Oct 6-8 1986). [Group judgment]

NL11 _____. Prevention of venous thrombosis and pulmonary embolism. (Consensus Development Conference Statement, Mar 24-26 1986). [Group judgment]

NL12 _____. The utility of therapeutic plasmapheresis for neurological disorders. (Consensus Development Conference Statement, Jun 2-4 1986). [Group judgment]

NL13 _____. Adjuvant chemotherapy for breast cancer. (Consensus Development Conference Statement, Sep 9-11 1985). [Group judgment]

NL14 _____. Anesthesia and sedation in the dental office. (Consensus Development Conference Statement, Apr 22-24 1985). [Group judgment]

NL15 _____. Electroconvulsive therapy. (Consensus Development Conference Statement, Jun 10-12 1985). [Group judgment]

NL16 _____. Health implications of obesity. (Consensus Development Conference Statement, Feb 11-13 1985). [Group judgment]

NL17 _____. Travelers' diarrhea. (Consensus Development Conference Statement, Jan 28-30 1985). [Group judgment]

NL18 _____ Analgesic-associated kidney disease. (Consensus Development Conference Statement, Feb 27-29 1984). [Group judgment]

NL19 _____. Diagnostic ultrasound imaging in pregnancy. (Consensus Development Conference Statement, Feb 6-8 1984). [Group judgment]

NL20 _____. Fresh frozen plasma: indications and risks. (Consensus Development Conference Statement, Sep 24-26 1984). [Group judgment]

NL21 _____ Limb-sparing treatment of adult soft-tissue sarcomas and osteosarcomas. (Consensus Development Conference Statement, Dec 3-5 1984). [Group judgment]

NL22 _____. Lowering blood cholesterol to prevent heart disease. (Consensus Development Conference Statement, Dec 10-12 1984). [Group judgment]

NL23 _____. Mood disorders: pharmacologic prevention of recurrences. (Consensus Development Conference Statement, Apr 24-26 1984). [Group judgment]

NL24 _____. Osteoporosis. (Consensus Development Conference Statement, Apr 2-4 1984). [Group judgment]

NL25 _____. Critical care medicine. (Consensus Development Conference Statement, Mar 7-9 1983). [Group judgment]

NL26 _____. Dental sealants in the prevention of tooth decay. (Consensus Development Conference Statement, Dec 5-7 1983). [Group judgment]

NL27 _____. Drugs and insomnia: the use of medications to promote sleep. (Consensus Development Conference Statement, Nov 15-17 1983). [Group judgment]

NL28 _____. Liver transplantation. (Consensus Development Conference Statement, Jun 20-23 1983). [Group judgment]

NL29 _____. Precusors to malignant melanoma. (Consensus Development Conference Statement, Oct 24-26 1983). [Group judgment]

NL30 _____. Treatment of hypertriglyceridemia. (Consensus Development Conference Statement, Sep 27-29 1983). [Group judgment]

NL31 _____. Clinical applications of biomaterials. (Consensus Development Conference Statement, Nov 1-3 1982). [Group judgment]

NL32 _____. Defined diets and childhood hyperactivity. (Consensus Development Conference Statement, Jan 13-15 1982). [Group judgment]

NL33 _____. Total hip joint replacement. (Consensus Development Conference Statement, Mar 1-3 1982). [Group judgment]

NL34 _____. Computed tomographic scanning of the brain. (Consensus Development Conference Statement, Nov 4-6 1981). [Group judgment]

NL35 _____. Diagnosis and treatment of Reye's syndrome. (Consensus Development Conference Statement, Mar 2-4 1981). [Group judgment]

NL36 _____. Adjuvant chemotherapy of breast cancer. (Consensus Development Conference Statement, Jul 14-16 1980). [Group judgment]

NL37 _____. CEA as a cancer marker. (Consensus Development Conference Statement, Sep 29-Oct 1 1980). [Group judgment]

NL38 _____. Cervical cancer screening: the pap smear. (Consensus Development Conference Statement, Jul 23-25 1980). [Group judgment]

NL39 _____. Cesarean childbirth. (Consensus Development Conference Statement, Sep 22-24 1980). [Group judgment]

NL40 _____. Coronary artery bypass surgery: scientific and clinical aspects. (Consensus Development Conference Statement, Dec 3-5 1980). [Group judgment]

NL41 _____. Endoscopy in upper GI bleeding. (Consensus Development Conference Statement, Aug 20-22 1980). [Group judgment]

NL42 _____. Febrile seizures. (Consensus Development Conference Statement, May 19-21 1980). [Group judgment]

NL43 _____. Thrombolytic therapy in thrombosis. (Consensus Development Conference Statement, Apr 10-12 1980). [Group judgment]

NL44 _____. Amantadine: does it have a role in the prevention and treatment of influenza? (Consensus Development Conference Statement, Oct 15-16 1979). [Group judgment]

NL45 _____. Antenatal diagnosis. (Consensus Development Conference Statement, Mar 5-7 1979). [Group judgment]

NL46 _____. Estrogen use and postmenopausal women. (Consensus Development Conference Statement, Sep 13-14 1979). [Group judgment]

NL47 _____. Improving clinical and consumer use of blood pressure measuring devices. (Consensus Development Conference Statement, Apr 26-27 1979). [Group judgment]

NL48 _____. Intraocular lens implantation. (Consensus Development Conference Statement, Sep 10-11 1979). [Group judgment]

NL49 _____ Pain, discomfort, and humanitarian care. (Consensus Development Conference Statement, Feb 16 1979). [Group judgment]

NL50 _____. Removal of third molars. (Consensus Development Conference Statement, Nov 28-30 1979). [Group judgment]

NL51 _____. Steroid receptors in breast cancer. (Consensus Development Conference Statement, Jun 27-29 1979). [Group judgment]

NL52 _____. The treatment of primary breast cancer: management of local disease. (Consensus Development Conference Statement, Jun 5 1979). [Group judgment]

NL53 _____. The use of microprocessor-based "intelligent" machines in patient care. (Consensus Development Conference Statement, Oct 17-19 1979). [Group judgment]

NL54 _____. Transfusion therapy in pregnant sickle cell disease patients. (Consensus Development Conference Statement, Apr 23-24 1979). [Group judgment]

NL55 _____. Availability of insect sting kits to non physicians. (Consensus Development Conference Statement, Sep 14 1978). [Group judgment]

NL56 _____. Dental implants: benefit and risk. (Consensus Development Conference Statement, Jun 13-14 1978). [Group judgment]

NL57 _____. Indications for tonsillectomy and adenoidectomy: phase I. (Consensus Development Conference Statement, Jul 20 1978). [Group judgment]

NL58 _____. Mass screening for colorectal cancer. (Consensus Development Conference Statement, June 26-28 1978). [Group judgment]

NL59 _____. Mass screening for lung cancer. (Consensus Development Conference Statement, Sep 18-20 1978). [Group judgment]

NL60 _____. Supportive therapy in burn care. (Consensus Development Conference Statement, Nov 10-11 1978). [Group judgment]

NL61 _____. Surgical treatment of morbid obesity. (Consensus Development Conference Statement, Dec 4-5 1978). [Group judgment]

NL62 _____. Treatable brain diseases in the elderly. (Consensus Development Conference Statement, Jul 10-11 1978). [Group judgment]

NL63 _____. Breast cancer screening. (Consensus Development Conference Statement, Sep 14-16 1977). [Group judgment]

NATIONAL LIBRARY OF MEDICINE

Building 38, Room 2s-18
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301-496-8834

Contact: Elliot R. Siegel, Ph.D., Special Assistant for Operations Research; or Robert Mehnert, Chief, Office of Public Inquiries and Publications Management 301-496-6308.

Overview: The National Library of Medicine (NLM) was established in 1836 as the Library of the Army Surgeon General's Office. Transferred in 1956 to the National Institutes of Health in the U.S. Public Health Service, the Library today collects materials exhaustively in all major areas of the health sciences. To aid in the dissemination and exchange of information, the Library produces specialized medical bibliographies such as *Index Medicus*, and the computer-based Medical Literature Analysis and Retrieval System (MEDLARS).

One component of the Library, the Lister Hill National Center for Biomedical Communications, conducts and supports research in techniques for recording, storing, retrieving, and communicating health information. Another, the Division of Extramural Programs, supports research on the generation, organization, and utilization of health information. Both are concerned with technology assessment.

Purpose: To evaluate new and existing biomedical information technologies that help disseminate information and facilitate its use by health professionals and others.

Primary intended users: Patients; providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; third party payers; government regulators; voluntary associations, organizations; biomedical researchers; reporters, writers, news media; information/computer industry; labs, blood banks; public policy-makers, legislators; policy research organizations.

Technologies: Support system.

Assessments include, but are not limited to, systems for information storage, retrieval, and dissemination; teaching/learning systems; artificial intelligence or expert systems; and the management of health information.

Stage: *New*, emerging, established or widespread practice, obsolete.

Properties: *Effectiveness*, cost, cost-benefit, cost-effectiveness, service requirements, acceptance/adoption level, system impact, economic implications.

Selection process: Assessments may be requested by intramural research and development staff; NLM management; and officials of the National Institutes of Health, the Department of Health and Human Services, and Congress. Selection is influenced by the source of the request, the information needs of the biomedical community, potential impact on the performance of the Library's statutory mission, and availability of funds. Technologies involved in NLM's own internal operations, such as MEDLARS, are evaluated and improved periodically.

Methods: *Epidemiological and other observational methods*, information syntheses, expert opinion, group judgment, cost analyses, bench testing.

Assessments are performed in-house by research and development and operations staff and extramurally through grants. Whenever feasible, evaluations are designed to allow for the participation of those who will be affected by the product or service, including health professionals and researchers. Assessments are generally carried out within a period of 6 to 8 months. Evaluations lasting up to 3 years may be appropriate in certain instances, when the study design incorporates both formative and summative features.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; recommendations for practice, future assessments, technology development, research; how much the assessment cost; how the technology works, including theory, principles; development of the technology; procurement/deployment information; where technology is in use.

Dissemination: Printed reports; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products; clearinghouses, data/citation bases, on-line services.

Reports are routinely sent to the original requestor. Study reports may be filed with the National Technical Information Service (NTIS), the Educational Resources Information Center (ERIC), and similar document distribution centers. NLM staff report study findings at meetings and in the professional literature, as well.

Budget: $500,000. The approximate cost of an assessment ranges from $25,000 to $125,000, depending on the nature and amount of external support services required. Funding source: 100 percent parent organization.

Use: Evaluation studies have affected NLM's research and development activities as well as its products and services. For instance, 1) a field test and evaluation of the Hepatitis Knowledge Base System resulted in the adoption of computer conferencing technology as an important feature of the NLM information systems; 2) a survey of the users of the Library's Videocassette Loan Program led to an expansion of the program; and 3) a comparative study of the coverage of the medical behavioral services by MEDLARS and other databases resulted in the NLM's reconsidering its indexing and coverage policies.

Colleagues in the information and computer science communities keep abreast of the latest research and development activities at NLM. In addition, the Nation's biomedical library network uses NLM as a leader and role model for technological advancements affecting information transfer.

Research scientists at the OCLC adapted the NLM's methodology and evaluation strategy in the design of an evaluation of alternative searching strategies for online catalogs. For a discussion see: Markey K. The Dewey decimal classification as a library

user's tool in an online catalog. In: Flood B, Witiak J, Hogan TH, comps. *Proceedings of the American Society for Information Science 47th annual meeting, 1984*. White Plains, NY: Knowledge Industry Publications, 1984:121-5.

Frequent reference is made in the literature to NLM's development and assessment of the Hepatitis Knowledge Base System and to other assessment activities at the Library.

NLM assessment activities are described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

Completed Reports

NM1 [National Library of Medicine] Health professionals use of MEDLINE. Bethesda, MD: National Library of Medicine, 1087. [Epidemiological and other observational methods]

NM2 La Croix EM. [National Library of Medicine] A comparison of interlibrary loan requests received by the National Library of Medicine: 1959 and 1984. Bull Med Libr Assoc 1987 Jan (in press). [Epidemiological and other observational methods]

NM3 [National Library of Medicine] Medical education in the information age. Proceedings of the Symposium on Medical Informatics. Washington, DC: Association of American Medical Colleges, 1986. [Epidemiological and other observational methods]

NM4 [National Library of Medicine] Evaluation of medical information science in medical education. Adopted by the Executive Council of the Association of American Medical Colleges, Washington, DC, January 23, 1986. J Med Educ 1986;61:487-543. [Epidemiological and other observational methods]

NM5 Griffith BC, White HD, Drott MC, Saye JD. [National Library of Medicine] Tests of methods for evaluating bibliographic databases—an analysis of the National Library of Medicine's handling of literatures in the medical behavioral sciences. J Am Soc Info Sci 1986 ;37:261-70. [Epidemiological and other observational methods]

NM6 Bratton B, Brooks CM, Holland GJ, Weinholtz D, Jackson J. [National Library of Medicine] Study of the audiovisual selection and acquisition process in health professions education. Ames, IA: Iowa State University, 1985. (NTIS order no. PB86-10813/XAB) [Epidemiological and other observational methods]

NM7 Kopp JJ. [National Library of Medicine] Research and writing in the history of health sciences, 1970-1982: a quantitative analysis of NLM's HISTLINE database. Bull Med Libr Assoc 1985;73:146-152. [Epidemiological and other observational methods]

NM8 Siegel ER, Spann M, Collins KA, Hazard G, Woodsmall RM. [National Library of Medicine] Report on the CHEMLINE evaluation study. Bethesda, MD: National Library of Medicine, 1985. [Epidemiological and other observational methods]

NM9 Woelfel JC, Tesorero J. [National Library of Medicine] An evaluation of CHEMLINE: the results of a survey of users by the National Library of Medicine. Vienna, VA: Market Dynamics, Inc, 1985. [Epidemiological and other observational methods]

NM10 [National Library of Medicine] An analysis of the National Library of Medicine's (NLM) handling of the medical behavioral sciences' (MBS) literatures. Final report. (Five volumes plus executive summary). Bethesda, MD: National Library of Medicine, 1984. [Epidemiological and other observational methods]

NM11 Siegel ER, Kameen K, Sinn SK, Weise FO. [National Library of Medicine] A comparative evaluation of the technical performance and user acceptance of two prototype online catalog systems. Info Technol Libr 1984;3:35-46. [Epidemiological and other observational methods]

NM12 Ullmer E, Kuenz M, Seibert W. [National Library of Medicine] Audiovisual evaluation survey final report. Bethesda, MD: Lister Hill Center, National Library of Medicine, 1983. [Epidemiological and other observational methods]

NM13 Watson L. [National Library of Medicine] NLM videocassette interlibrary loan program report. Bethesda, MD: Audiovisual Resources Section, National Library of Medicine, 1983. [Epidemiological and other observational methods]

NM14 Roderer NK, King DW, McDonald DD, Bush CG. [National Library of Medicine] Evaluation of the Hepatitis Knowledge Base System. Rockville, MD: King Research, Inc., 1981. [Epidemiological and other observational methods]

NM15 [National Library of Medicine] Performance evaluation of a satellite-linked experimental network. IEEE Trans Aerosp Electron Syst 1980;16:771-82. [Epidemiological and other observational methods]

NM16 [National Library of Medicine] Biomedical communications experiments using the communications technology satellite: technical evaluation. Bethesda, MD: Lister Hill Center, National Library of Medicine, 1979. (NTIS order no. PB-80-111-016/GBB). [Epidemiological and other observational methods]

Ongoing Assessments

NM17 [National Library of Medicine] Development of evaluation methodologies to assess NLM's coverage of new biomedical literatures. Bethesda, MD: National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NM18 [National Library of Medicine] Evaluation of PC-oriented training packages for the NLM chemical and toxicological online files. Bethesda, MD: National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NM19 [National Library of Medicine] Evaluation of the Technological Innovations in Medical Education (TIME) Project. Bethesda, MD: Lister Hill Center, National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NM20 [National Library of Medicine] Evaluation of the scope and coverage of NLM's TOXLINE. Bethesda, MD: National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NM21 [National Library of Medicine] Field test and evaluation of MEDLINE on optical disk. Bethesda, MD: National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NM22 [National Library of Medicine] Testing of a general methodology for the evaluation of expert systems in medicine. Bethesda, MD: Lister Hill Center, National Library of Medicine. Ongoing. [Epidemiological and other observational methods]

NETHERLANDS ORGANIZATION FOR APPLIED SCIENTIFIC RESEARCH MEDICAL TECHNOLOGY UNIT (TNO)

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Contact: G.J. van Keulen.

Overview: The Netherlands Organization for Applied Scientific Research is an independent, not-for-profit organization created by law. It conducts research in the health, nutrition, industrial, and defense areas. The Medical Technology Unit (TNO) is a medical technology assessment program that evaluates medical devices.

Purpose: To establish the safety, efficiency, and effectiveness of medical devices; to examine the technical and ergonomic properties of medical devices; and to give information and advice to health care institutions.

Primary intended users: Acute facility administrators; long-term care facility administrators; health product manufacturers; government regulators; liability, malpractice insurers; clinical engineers.

Technologies: *Device*.

Intervention: *Diagnosis, treatment*.

Stage: *New, established or widespread practice.*

Properties: *Safety, efficacy, effectiveness.*

Selection process: There are no strict procedures established for requesting an assessment. Any party who can pay for an assessment can request that one be conducted. The Medical Technology Unit (TNO) sets assessment topic priorities in consultation with the National Hospital Institute or the party funding the assessment.

Methods: *Expert opinion, group judgement, bench testing.*

The approximate turnaround time from selection of assessment topic to reporting of findings is 1 year.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; how the technology works, including theory, principles; procurement/deployment information; regulatory agency approval status; product recall history, liability actions.

Dissemination: *Printed reports.*

An online network to Dutch hospitals is planned. Copies of assessment reports may be ordered from the Advisory Center of the Medical Technology Unit (TNO).

Budget: $1.5 million. The approximate cost per assessment varies between $50,000 to $100,000. The cost depends on the complexity of the device and the number of different types of devices to be evaluated. Funding sources: 70 percent parent organization; 30 percent sales of assessments, consultant services.

The annual budget amount includes the following activities: evaluating a single device for the manufacturer; testing devices for manufacturers to prove compliance with regulations; developing functional specifications for devices with respect to safety, efficacy, and effectiveness; advising hospital technicians and administrators in the safe and effective use of devices; and offering courses for hospital technicians in quality control.

Completed Reports

NS1 Netherlands Organization for Applied Scientific Research, Medical Technology Unit (TNO). Syringe pumps for non-ambulatory use. 1986.

NS2 _____. Drip-rate controlled and volumetric infusion pumps. 1984.

NS3 _____. Defibrillators. 1983.

NS4 _____. Portable defibrillators. 1983.

NS5 _____. Blood-warmers for use during transfusion. 1981.

NS6 _____. Electroencephalographs. 1981.

NS7 _____. Heart monitors. 1981.

NS8 _____. Intensive care convection incubators. 1981.

NS9 _____. External pacemakers. 1978.

NS10 _____. Sphygmomanometers. 1978.

NS11 _____. Three channel (phono) electrocardiographs. 1977.

NS12 _____. One channel electrocardiographs. 1975.

Ongoing Assessments

NS13 _____. Ambulatory insulin pumps. Ongoing. [Expert opinion, Group judgment, Bench testing]
NS14 _____. Ultra-sound physiotherapy equipment. Ongoing. [Expert opinion, Group judgment, Bench testing]

POLICY ANALYSIS, INC.

Medical Technology Cost-Effectiveness Program
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617-232-4400

Contact: Gerry Oster, Vice President.

Overview: Policy Analysis, Inc. is a business, founded in 1973, that conducts cost-benefit and cost-effectiveness analyses for organizations in both the public and private sectors. Its Medical Technology Cost-Effectiveness Program was started in 1982.

Purpose: To provide state-of-the-art analyses of the cost-effectiveness of new and existing medical technologies, including drugs, devices, and diagnostic products.

Primary intended users: Patients; providers, generally; physicians; acute facility administrators; health product manufacturers; health/medical professional associations; health industry associations; third party payers; government regulators; reporters, writers, news media; public policy-makers, legislators; policy research organizations.

Technologies: *Drug*, device, medical or surgical procedure, organizational or administrative system.

Intervention: Prevention, diagnosis, treatment.

Stage: New, established or widespread practice.

Properties: *Cost-effectiveness*, safety, efficacy, effectiveness, cost, cost-benefit, economic implications.

Selection process: Any funding organization, private or public, may request an evaluation, beginning usually with informal discussions that lead to a formal written request. Assessment topic priorities are generally set by the funding organization.

Methods: Information syntheses, modeling, cost analyses, epidemiological and other observational methods, clinical trials.

The approximate turnaround time from selection of assessment topic to reporting of findings is 6 months to 2 years.

Assessors: Assessors typically are experts in medicine, economics, and epidemiology.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; coverage/reimbursement status of the technology.

Dissemination: Journal articles.

Reprints are available upon request.

Budget: $750,000. Costs of assessments start at $50,000. Funding sources: 10 percent government grants/contracts; 90 percent sales of assessments, consultant services.

Use: Funding organizations use the reports to address issues of concern regarding the cost-effectiveness of particular drugs, devices, or diagnostic products among patients, providers, and third-party payers.

Completed Reports

PA1 Oster G, Epstein AM. [Policy Analysis, Inc.] The cost-effectiveness of cholestyramine in the prevention of coronary heart disease: whom should we treat? JAMA, submitted for publication.

PA2 Oster G, Huse DM, Delea TE, Savage DD, Colditz GA. [Policy Analysis, Inc.] Cost effectiveness of labetalol and propranolol in the treatment of hypertension among blacks. 1987 Mar.

PA3 Oster G, Tuden RL, Colditz GA. [Policy Analysis, Inc.] A cost-effectiveness analysis of prophylaxis against deep-vein thrombosis in major or orthopedic surgery. JAMA 1987;257:203-208.

PA4 Oster G, Tuden RL, Colditz GA. [Policy Analysis, Inc.] Prevention of venous thromboembolism after general surgery: a cost effectiveness analysis of alternative approaches to prophylaxis. Am J Med 1987 (in press)

PA5 Oster G, Epstein AM. [Policy Analysis, Inc.] Primary prevention and coronary heart disease: the economic benefits of lowering serum cholesterol. Am J Public Health 1986;76:647-656.

PA6 Oster G, Huse DM, Delea TE, Colditz GA. [Policy Analysis, Inc.] Cost-effectiveness of nicotine gum as an adjunct to physician's advice against cigarette smoking. JAMA 1986;256:1315-1318.

PROJECT HOPE CENTER FOR HEALTH AFFAIRS

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301-656-7401

Contact: Gail Wilensky, Ph.D., Vice President; or Louis P. Garrison, Jr., Ph.D., Deputy Director.

Overview: Project HOPE (Health Opportunity for People Everywhere) is the principal activity of the People-to-People Health Foundation, Inc., an independent, nonprofit corporation headquartered in Millwood, Virginia. Founded in 1958, Project HOPE is currently conducting health sciences education and training programs in 18 countries.

This profile addresses a division of Project HOPE, the Center for Health Affairs (CHA), which conducts research and policy analysis primarily related to issues of the U.S. health care system, as well as those of other countries.

Purpose: To conduct health policy research and analysis for private and public sector needs. With regard to assessment, CHA examines the interaction of technologies and their financing, and presents options regarding technologies to policy makers. In particular, CHA provides technical assistance to the Prospective Payment Assessment Commission (ProPAC) for updating and improving the Medicare Prospective Payment System (PPS), such as modifying diagnosis-related groups (DRGs) and studying the impact of the PPS on utilization of technologies.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; third party payers; government regulators; public policy-makers, legislators; policy research organizations.

Technologies: *Organizational or administrative system*, medical or surgical procedure, device.

Intervention: *Treatment*, prevention, diagnosis.

Stage: New, established, widespread.

Properties: *Cost, cost-effectiveness*, service requirements, system impact, economic implications.

Selection process: Under its task order agreement with ProPAC, CHA responds to assessment requests that originate with ProPAC commissioners or staff.

Methods: *Cost analyses*, information syntheses, expert opinion, group judgment, modeling.

CHA reports are written primarily by staff members who draw upon a variety of experts and information sources in industry and the medical community. In addition, CHA is studying the use of physician panels, in face-to-face settings and using Delphi-style mail surveys, as a means for making adjustments in the PPS. These panels have been used in such exercises as developing lists of complications and comorbidities for DRGs in order to improve the ability of the system to capture variations in cost among patients, modifying surgical classes and hierarchies in selected diagnostic categories, and determining the scientific and technological component of the discretionary adjustment factor used in the PPS to account for changes in the cost of hospital services. Turnaround time for assessments ranges from 2 to 8 months, averaging about 6 months.

Assessors: CHA staff members have backgrounds in such fields as economics, health policy administration and management, political science, public policy, sociology, and computer science. Physicians and other experts are used for panels and as consultants as needed.

Assessment reports include: Abstract; assessment's intended audience; purpose of the assessment; who sponsored/ commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when

assessed; properties assessed; procedure used for the assessment; sources of data/ information; methods for collecting data/ information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: Reports are presented in monographs to ProPAC and other organizations, in journal articles, and in oral presentations. Reports are available from CHA.

Budget: The CHA budget is approximately $1.5 million, about one-third of which is devoted to assessment activities described here. Funding sources: 67 percent government grants/contracts; 33 percent foundations, other private grants.

Use: A number of CHA report recommendations have been adopted by ProPAC and used by the Department of Health and Human Services (DHHS) in making adjustments in the PPS. For example, as a result of the CHA analysis of PPS payments for expensive prosthetic and implantable devices, ProPAC recommended to DHHS that adjustments be made to the labor portion of the standardized amount for some DRGs involving these devices. The CHA analysis of heterogeneity of DRGs involving lymphomas and leukemias prompted ProPAC to recommend to DHHS that a separate DRG be created for acute leukemia patients and that other modifications to the assignment of the remaining patients be made. DHHS adopted one part of the recommendation that acute leukemias be assigned to a newly created DRG. Based on CHA recommendations regarding cardiac pacemakers, ProPAC recommended reclassification of cases based on pacemaker type and reassignment of some cases involving pacemaker replacement.

Related activities: Among its related activities, CHA is evaluating the impact of work-site health promotion programs at several major corporations. CHA is also studying the impact of corporate intervention in health benefits redesign and utilization review on the use of health services by employees. CHA has assisted DHHS in outlining recommendations for coverage of catastrophic illness. Staff members are examining the potential impact of HMOs and other competitive medical plans on quality of care and access to technology.

Completed Reports

PH1 Project HOPE, Center for Health Affairs. A pilot study in the use of physician panels to develop-specific lists of complications and comorbidities for Medicare diagnosis-related groups (for Prospective Payment Assessment Commission). 1987 Jan. [Group judgment]

PH2 _____. A technology-specific approach to estimating the scientific and technological component of the discretionary adjustment factor for excluded hospitals: options and issues. (for Prospective Payment Assessment Commission). 1987 Feb. [Cost analyses]

PH3 _____. A technology-specific approach to estimating the scientific and technological component of the discretionary adjustment factor: options and issues. (for the Prospective Payment Assessment Commission). 1987 Feb. [Cost analyses]

PH4 Garrison LP, Wilensky GR. [Project Hope Center for Health Affairs] Cost containment and technology. Health Affairs 1986;Summer:46-58. [Information syntheses]

PH5 Project Hope, Center for Health Affairs. A pilot study in the use of physician panels; to modify surgical classes and hierarchies in selected major diagnostic categories. (for Prospective Payment Assessment Commission). 1986 Dec. [Group judgment]

PH6 _____. Developing alternative DRG classifications for Medicare cases involving cardiac pacemakers. (for Prospective Payment Assessment Commission). 1986 Aug. [Information syntheses, Cost analyses]

PH7 _____. Evaluating the heterogeneity of DRGs involving lymphomas, leukemias, and chemotherapy and developing alternative classifications of discharges. (for Prospective Payment Assessment Commission). 1986 Aug. [Information syntheses, Cost analyses]

PH8 _____. PPS payments for expensive devices: issues and evidence. (for Prospective Payment Assessment Commission). 1986 Aug. [Cost analyses]

PH9 _____. Paying for heart transplantation under Medicare. (for Prospective Payment Assessment Commission). 1986 Feb. [Information syntheses, Cost analyses]

PH10 _____. Review of evidence in literature relevant to the measurement of hospital case mix index. (for Prospective Payment Assessment Commission). 1986 Jul. [Information syntheses]

PH11 _____. Background paper on cataract surgery and physician payment under the Medicare program. (for U.S. Congress, Office of Technology Assessment). 1985 Oct. [Information syntheses, Cost analyses]

Ongoing Assessments

PH12 _____. A review of the cost-effectiveness of home health care services. Ongoing, expected 1987. [Information syntheses, Cost analyses]

PH13 _____. Access to technology and quality of care in capitated plans. Ongoing. expected completion 1987. [Information syntheses]

PH14 _____. Evaluating the clinical and resource heterogeneity in DRG 468. (for Prospective Payment Assessment Commission). Ongoing; expected 1987. [Information syntheses]

PH15 _____. The effect of PPS on the diffusion and use of medical technologies. (for Prospective Payment Assessment Commission). Ongoing, expected 1987. [Information syntheses]

PH16 _____. Work site health promotion program evaluation. Ongoing, expected 1987. [Information syntheses]

PROSPECTIVE PAYMENT ASSESSMENT COMMISSION

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Contact: Donald A. Young, Executive Director; or Judith D. Moore 202-453-3871.

Overview: The Prospective Payment Assessment Commission (ProPAC) is an independent agency that was established by Congress under the Social Security Act Amendments of 1983 (PL 98-21). The Commission is an advisory body and does not exercise regulatory or appeals functions.

Purpose: To recommend to the Congress and the Secretary of Health and Human Services (HHS) an appropriate percentage change in the payments made under the Medicare prospective payment system (PPS) for in-patient hospital services, and to recommend adjustments to the diagnosis-related groups (DRG) classification and weighting factors. These recommendations may concern specific technologies or practice patterns.

Primary intended users: Third party payers; public policy-makers, legislators.

Technologies: *Organizational or administrative system*, drug, device, medical or surgical procedure, support system.

ProPAC is primarily interested in those technologies having the greatest impact on the Medicare population.

Intervention: *Treatment*, diagnosis, rehabilitation.

Stage: New, emerging, established or widespread, obsolete.

The Commission withholds making recommendations until the technology is FDA-approved and is covered or about to be covered by Medicare.

Properties: *System impact*; safety; efficacy; effectiveness; cost; cost-benefit; cost-effectiveness; service requirements; acceptance/adoption level; economic implications; ethical, legal, social implications.

Other attributes that are assessed include number and distribution of Medicare patients affected, number and distribution of hospitals affected; financial impact on hospitals; financial impact on Medicare beneficiaries; estimate of impact on quality of care, access to care, or innovation and technology changes; complexity of the analysis that would be required; availability of data; and the likelihood improvements could be made in DRG classification and weights.

Selection process: Requests for assessments are made through telephone contact, correspondence, meetings, and public comment at Commission meetings. Commissioners on the Diagnostic and Therapeutic Practices Subcommittee prioritize topics brought to their attention by ProPAC staff and then send them to the full Commission for final approval. ProPAC monitors ongoing activities and performs reassessments as necessary. Permanent DRG assignment should be reconsidered within a period not to exceed 3 years.

Methods: *Cost analyses*, information syntheses, expert opinion, group judgment, modeling.

The assessment process consists of 3 stages: 1) identification of topics for consideration, 2) initial staff review, and 3) indepth analysis. There are two types of indepth analyses: 1) a comprehensive analysis of a specific technology or a practice pattern, and 2) a comprehensive analysis of generic issues related to case-mix measurement or payment. The approximate turnaround time from selection of assessment topic to reporting of findings varies from a few weeks to over a year.

Assessors: The assessors have expertise in medical/clinical specialties, economics, computer programming, medical record coding, and statistics.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; where technology is in use; regulatory

agency approval status; coverage/reimbursement status of the technology; technology's impact on the Medicare population.

Dissemination: *Printed reports*; advisories to members/constituents; press conferences/ news releases; open public meetings.

ProPAC accepts telephone and written requests for copies of assessment reports. A mailing list is maintained for those interested in receiving meeting announcements, agendas, and reports.

Budget: $1.5 million. The approximate cost per assessment is $50,000 to $100,000. Funding source: 100 percent Congressional appropriations.

Use: ProPAC is mandated to report annually to the Congress and the Secretary of HHS its recommendations on the prospective payment system. The technology assessments are incorporated into the recommendations. The recommendations made in ProPAC's annual reports are reviewed by the Secretary of HHS as potential areas for PPS modification. These modifications, based upon selected ProPAC recommendations, can be found in the final Medicare PPS regulations for fiscal year 1986 and fiscal year 1987 published in the September 3, 1985 and September 3, 1986 *Federal Register*, respectively. Congressional committees also use ProPAC's assessments.

ProPAC is described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies* . Washington, DC: National Academy Press, 1985.

Program evaluation: The U.S. Congress Office of Technology Assessment (OTA) is required to report annually on all phases of ProPAC's operations, including technology assessment. The first OTA report covered ProPAC's first year in operation and was issued in March 1985. The second OTA report was issued in March 1986. The OTA Health Program Advisory Committee provided advice and comment to the OTA on its oversight activities related to ProPAC; however, the content is the responsibility of the OTA and does not constitute consensus or endorsement by the advisors. General conclusions from both the first and second OTA reports find ProPAC's overall performance to be exceptionally high. OTA concluded that "the process by which ProPAC conducts its analyses and delivers them to the Congress is an effective one." ProPAC has continued its assessment program without major modifications. The following documents present OTA's findings: Office of Technology Assessment, *First report on the Prospective Payment Assessment Commission (ProPAC)*. Washington, DC: Office of Technology Assessment, 1985. Office of Technology Assessment. *Second report on the Prospective Payment Assessment Commission (ProPAC)*. Washington, DC: Office of Technology Assessment, 1986.

Related Activities: The Commission is required to collect and assess information on regional variations in medical practice; the length of hospitalization; and the safety, efficacy, and cost-effectiveness of new and existing medical and surgical procedures, practices, services, and technologies. In meeting this requirement, ProPAC has, among other things, convened panels of experts and organized conferences.

Completed Reports

PP1 Burn DRGs. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:124-126. [Information syntheses, Cost analyses]

PP2 Cardiac pacemakers. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:09-101. [Information syntheses, Cost analyses]

PP3 Extracorporeal shockwave lithotripsy. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986 Washington, DC: Government Printing Office, 1986:112-114. [Information syntheses, Cost analyses]

PP4 Implantable defibrillator. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1086. Washington, DC: Government Printing Office, 1986:103. [Information syntheses, Cost analyses]

PP5 Lymphomas, leukemia, and chemotherapy. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:121-123. [Information syntheses, Cost analyses]

PP6 Magnetic resonance imaging. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:107-111.

PP7 PPS payments for expensive prosthetic and implantable devices and other medical supplies. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:87-96 [Information syntheses, Cost analyses]

PP8 Penile prostheses. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:104-106. [Information syntheses, Cost analyses]

PP9 Upper extremity procedures. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986:115-117. [Information syntheses, Cost analyses]

PP10 Prospective Payment Assessment Commission. Medicare prospective payment and the American health care system: report to the Congress, February 1986. Washington, DC: Government Printing Office, 1986. [Information systheses, Cost analyses]

PP11 _____. Report and recommendataions to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986. [Information syntheses, Cost analyses]

PP12 _____. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1986. Washington, DC: Government Printing Office, 1986. [Information syntheses, Cost analyses]

PP13 Intraocular lens implants. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1985. Washington, DC: Government Printing Office, 1985:101-105. [Information syntheses, Cost analyses]

PP14 Percutaneous transluminal coronary angioplasty. In: Prospective Payment Assessment Commission. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1985. Washington, DC: Government Printing Office, 1985:105-111. [Information syntheses, Cost analyses]

PP15 Prospective Payment Assessment Commission. Report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1985. Washington, DC: Government Printing Office, 1985. [Information syntheses, Cost analyses]

PP16 _____. Technical appendixes to the report and recommendations to the Secretary, U.S. Department of Health and Human Services, April 1, 1985. Washington, DC: Government Printing Office, 1985. [Information syntheses, Cost analyses]

STEERING COMMITTEE ON FUTURE HEALTH SCENARIOS COMMISSION ON FUTURE HEALTH CARE TECHNOLOGY

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Contact: R.F. Schreuder, LL.M, Secretary Ministry of Welfare, Health and Cultural Affairs; or David Banta, (31-70) 47-14-41.

Overview: The Steering Committee on Future Health Scenarios (STG) was set up in 1983 by the State Secretary of Welfare, Health and Cultural Affairs. The Committee's chief task is to create "scenarios" of possible and desirable futures in the field of public health and health care. A scenario may be defined as a description of the current situation in a society (or part of it), or potential and desirable future situations and a description of a series of events which could lead from the former to the latter. The health scenarios are used to increase the anticipatory and priority-setting ability of policy-making in the field of health and health care. The findings are incorporated in strategic policy documents and also serve as a basis for future planning.

The Steering Committee decides on topics to be studied, setting priorities on the basis of social relevance and the opportunities for research into future developments. For each topic an independent scenario committee is established; the STG appoints the chairman and its members. Attached to each committee is a research team comprised of experts in the relevant field as well as experts in scenario research.

The activities of each scenario committee are divided into five stages: preliminary research, formulation of draft report, organization of symposia to discuss results, draft of final report, and the development of a monitoring system to update the information collected.

The STG has established scenario committees on the following topics: aging (1983), cardiovascular diseases (1983), life styles (1983), oncology (1983), accidents and traumas (1985), care of the elderly, and Amsterdam in the year 2010 (1985). Currently, the STG is considering the feasibility of scenario committees on the following topics: health and environment, health and labor, mental health, chronic diseases, primary health care, and dental care.

The scenario project on medical technology is known as the Commission on Future Health Care Technology and was established in 1983. Renewal of Commission activities following the end of the scenario project in September 1987 is under consideration. This profile describes the Commission's activities.

Purpose: To identify future health care technologies and to conduct prospective assessments of health care technologies of the future.

Primary intended users: General public; providers, generally; consumer associations; third party payers; government regulators; reporters, writers, news media; public policy-makers, legislators; policy research organizations.

Technologies: Drug, device, medical or surgical procedure.

Intervention: Prevention, diagnosis, treatment.

Stage: Emerging, future.

Properties: Cost; service requirements; system impact; economic implications; ethical, legal, social implications.

Methods: Information syntheses, expert opinion, group judgment, modeling, cost analyses.

The staff prepare a draft paper on the assessment topic using the scientific literature, consultation with experts, and modeling, if appropriate. Outside reviewers discuss the paper and it is revised as necessary. The revised paper undergoes a second external review by a broad-based group of experts. Any revisions are incorporated and the final paper is then submitted to the Commission for approval.

The approximate turnaround time from selection of assessment topic to reporting of findings is 1 year.

Assessors: The assessors' areas of expertise include technology assessment, medicine, law, and pharmacology.

Assessment reports include: The purpose of the assessment; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; how the technology works, including theory, principles; where technology is in use; regulatory agency approval status; coverage/reimbursement status of the technology.

Dissemination: *Printed reports*; journal articles; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

Copies of assessment reports are available, on request, from the Steering Committee on Future Health Scenarios. Copies may also be purchased directly from the publisher: Kluwers Publishers, Bohn Scheltema, PO Box 13079, 3507 LB Utrecht, The Netherlands.

Budget: $300,000. The approximate cost per assessment is $25,000. Funding source: 90 percent parent organization, 10 percent World Health Organization.

Use: The Steering Committee relies on the assessment reports when formulating policy recommendations. The World Health Organization, the Health Council of the Netherlands, students, and faculty have also used the reports.

Completed Reports

SC1 Steering Committee on Future Health Scenarios, Commission on Future Health Care Technology (Netherlands). Prospective assessment of future health care technology: applications of the neurosciences. 1987.

SC2 _____. Prospective assessment of future health care technology: biotechnology and new vaccines. 1987.

SC3 _____. Prospective assessment of future health care technology: digital imagery. 1987.
SC4 _____. Prospective assessment of future health care technology: genetic screening. 1987.
SC5 _____. Prospective assessment of future health care technology: home care technology. 1987.
SC6 _____. Prospective assessment of future health care technology: lasers in cardiovascular surgery. 1987.
SC7 _____. Prospective assessment of future health care technology: monoclonal antibodies and diagnostic kits. 1987.

SWEDISH PLANNING AND RATIONALIZATION INSTITUTE OF THE HEALTH SERVICES

Technology Assessment and Health Economics
Box 27310
102 54 Stockholm, Sweden
(46-8) 663-05-60

Contact: Stefan Hakansson Ph.D. Director; Pia Maria Jonsson, M.D.; or Eric Paulson, M.D. Telefax 46-8-60 35 10.

Overview: The Technology Assessment and Health Economics program is sponsored by the Swedish Planning and Rationalization Institute of the Health Services (SPRI). SPRI is a government agency that provides health authorities in the Swedish county councils with recommendations for health care.

Purpose: To provide the county councils with recommendations on new and established medical technologies.

Primary intended users: General public, physicians, acute facility administrators, health product manufacturers, health/medical professional associations, government regulators, public policy-makers, legislators.

Technologies: *Medical or surgical procedure*.

Preventive, diagnostic, and therapeutic technologies are assessed.

Intervention: *Diagnosis*.

Stage: *New*.

Properties: *Cost-effectiveness*.

Selection process: Program staff, board members, and clinicians can request that an assessment be conducted. The requests are usually generated by the staff. In collaboration with clinicians, the staff set the assessment topic priorities. This process is based on actual or perceived problems in the health services.

Methods: *Cost analyses*; surveys; interviews, before and after investigations; randomized controlled trials.

Working with clinicians, program staff conduct assessments. There is a 2-year turnaround time from selection of assessment topic to reporting of findings.

Assessors: The assessors have expertise in economics, medicine, and statistics.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/ synthesizing data/information; results; findings or conclusions; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how technology works, including theory principles; development of the technology; where technology is in use; coverage/reimbursement status of the technology.

Dissemination: *Printed reports*.

Using internal files reports are mailed to predetermined target groups in the health services. Copies of assessment reports may be obtained by writing to SPRI.

Budget: $500,000. The approximate cost per assessment is $100,000. Funding source: 100 percent parent organization.

Use: The assessment reports are frequently used in health planning within Sweden. For an example see: Lindgren E, Jonsson E, Neuhauser D. Controlling medical technology in Sweden. In: *Implications of cost-effectiveness analysis of medical technology*. Washington DC: Office of Technology Assessment, U.S. Congress, 1980.

Related activities: SPRI and its equivalent institutes in other Scandinavian countries, i.e. Finish Hospital League, Norwegian Institute of Hospital Research, and the Danish Hospital Institute, have jointly set up a body for collaboration on technology assessment activities. This body is called NEMT: Nordic Evaluation of Medical Technology. NEMT is presently finishing a study on nuclear magnetic resonance in the Nordic countries. SPRI, in collaboration with the Swedish Medical Research Council, is also responsible for the Consensus Development Conferences Program in Sweden. Conference topics have included: the artificial hip, treatment of myocardial infarction, treatment of depressive disorders, sight improving surgery, diagnostic imaging of liver cancer, diagnosis and treatment of stroke, and urinary incontinence among adults.

The technology assessment program at SPRI is related to a small program of technology assessment at the Karolinska Institute (The Stockholm School of Medicine). The Karolinska Institute program includes one ongoing project on treatment methods for obesity—costs, risks, and benefits. A randomized controlled trial for the treatment of leukemia is also planned. This project will examine bone marrow transplantation versus chemotherapy.

Completed Reports

SP1 Swedish Planning and Rationalization Institute of the Health Services. Spri technology report 8: treatment with insulin infusion pump: cost and effects. 1987. [Cost analyses, Epidemiological and other observational methods]

SP2 Swedish Planning and Rationalization Institute of the Health Services and the Swedish Medical Research Council. Diagnosing and treatment of stroke. 1986. [Cost analyses, Epidemiological and other observational methods]

SP3 _____. Urinary incontinence in adults. 1986. [Cost analyses, Epidemiological and other observational methods]

SP4 Swedish Planning and Rationalization Institute of the Health Services. Spri technology report 7: MRT—magnetic resonance tomography: experience in Sweden. 1986. [Cost analyses, Epidemiological and other observational methods]

SP5 Swedish Planning and Rationalization Institute of the Health Services and the Swedish Medical Research Council. Diagnostic imaging of liver cancer. 1985. [Cost analyses, Epidemiological and other observational methods]

SP6 Swedish Planning and Rationalization Institute of the Health Services. Spri technology report 6: digital subtraction angiography—economical, medical, technical and planning aspects. 1985. [Swedish language only] [Cost analyses, Epidemiological and other observational methods]

SP7 _____. Spri technology report 5: how can we assess medical technology? 1984. [Cost analyses, Epidemiological and other observational methods]

SP8 Swedish Planning and Rationalization Institute of the Health Services and the Swedish Medical Research Council. Sight improving surgery. 1984. [Cost analyses, Epidemiological and other observational methods]

SP9 _____. Treatment of depressive diseases. 1984. [Cost analyses, Epidemiological and other observational methods]

SP10 _____. Treatment of myocardial infarction. 1983. [Cost analyses, Epidemiological and other observational methods]

SP11 _____. The artificial hip. 1982. [Cost analyses, Epidemiological and other observational methods]

SP12 Swedish Planning and Rationalization Institute of the Health Services. Spri technology report 4: must we assess medical technology? 1982. [Cost analyses, Epidemiological and other observational methods]

SP13 _____. Spri technology report 2: CT scanning in Sweden—costs and effectiveness. 1981. (Spri report 73) [Cost analyses, Epidemiological and other observational methods]

SP14 _____. Spri technology report 3: cost effectiveness analysis in health care. 1981. [Cost analyses, Epidemiological and other observational methods]

Ongoing Assessments

SP15 _____. Artificial lens implantation: a cost-effectiveness analysis. Ongoing. [Cost analyses, Epidemiological and other observational methods]

SP16 _____. Mammography screening for breast cancer: a randomized controlled cost-effectiveness analysis. Ongoing. [Cost analyses, Epidemiological and other observational methods]

UNITED KINGDOM DEPARTMENT OF HEALTH AND SOCIAL SECURITY SUPPLIES TECHNOLOGY DIVISION

Medical Devices Evaluation Programme
14 Russell Square
London WC1B SEP
England
(44-1) 636-6811, Ext. 3248

Contact: Derek E. Weston. Telex 88 3669. Telefax 01 637 8990.

Overview: The United Kingdom Department of Health and Social Security (DHSS) operates the Medical Services Evaluation Programme. The DHSS started the evaluation

Programme in the 1960s to satisfy the growing need within the National Health Service. (NHS) for guidance in selecting suitable medical devices. The DHHS promotes the production and supply of safe and effective medical equipment; supports the research,

development, and evaluation of equipment; and provides technical advice to equipment suppliers and users in the NHS.

Purpose: To assist prospective purchasers of medical devices in making an informed choice from the products available.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; other care givers; health product manufacturers; health/medical professional associations; health industry associations; labs, blood banks.

Technologies: *Device*.

Devices related to a wide range of technologies are assessed. They are frequently, although not exclusively, electrically powered.

Intervention: *Treatment*, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice.

Devices are usually evaluated when they become established in the marketplace, but sometimes when a production model is first available.

Properties: *Safety*, efficacy, effectiveness, costs.

The following attributes of a device are assessed: safety in use for both operators and patients, performance (against specifications), standard of construction, ease of repair, availability and cost of spare parts, standard of user information, and user reactions.

Selection process: The DHSS accepts written and verbal requests for assessments from all segments of the National Health Service. The Supplies Technology Division, DHSS in consultation with the NHS set assessment topic priorities using the following criteria: the equipment is 1) widely used, 2) relatively expensive, 3) complex (making technical judgment difficult), and 4) available in a variety of models (making selection difficult).

Methods: *Bench testing*, expert opinion, epidemiological and other observational methods.

Assessment methods vary according to the type of device being evaluated. Physical tests for safety and performance are conducted and are supplemented by user questionnaires. In the last 10 years, Centers of Continuous Evaluation have been established within the NHS to continually examine a single equipment category. A list of the current Centers and the equipment category evaluated is provided at the end of this profile. Each Center familiarizes itself with the category of equipment; develops test methods; and produces relevant, well-informed, and up-to-date information. Generally, reports from the Centers discuss several models of competing equipment, identify the advantages/disadvantages of each model, and give recommendations on models preferred in different circumstances. The equipment is not evaluated in clinical use, which limits the value of the information somewhat. The evaluation activity is based on these continuous assessments and is supplemented by individual examinations of single items of equipment. Approximately 50 evaluations are conducted annually.

In most cases, each item of equipment is subjected to each of the following assessment procedures: 1) a technical assessment against current safety and performance standards,

using draft versions if final standards do not yet exist; a subjective assessment of the construction quality, the serviceability and the likely reliability; and 3) a period of user experience to establish its clinical acceptability, in operational and ergonomic terms. All findings and results relating to a particular model are discussed with the manufacturer or suppliers, who are given an opportunity to comment in writing.

Assessors: The assessors are scientists, engineers, technicians, nurses, and clinicians in the National Health Service units and specialized evaluation centers. The approximate turnaround time from selection of assessment topic to reporting of findings is 18 months for a full evaluation including user experience and 9 to 12 months for technical evaluation.

Assessment reports include: The assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; results; findings or conclusions; limitations of findings; implications of findings for practice; procurement/deployment information; where technology is in use.

Dissemination: *Printed reports*, journal articles.

Assessment results are published in *Health Equipment Information*. Each issue is intended to be a "buyer's guide," covering all models which have been evaluated and are still on the market in the United Kingdom. Full reports on any recent models are also included. Summaries are presented for all models, together with a photograph, current price, country of origin, and a reference to where the reader can find the full report.

Reports are available to anyone at their cover price. For details on individual report prices or for subscription information, contact: DHSS Leaflets Unit, PO Box 21, Stanmore, Middlesex, HA7 IAY, United Kingdom.

Budget: $3.2 million. Funding source: 100 percent parent organization.

Use: Based on feedback from the NHS, equipment manufacturers, and suppliers the assessment reports are widely used by the NHS when selecting equipment for purchase.

Program evaluation: To ensure that the Programme meets the NHS needs for information, the DHHS evaluates the Programme on a continuous basis.

Centers of Continuous Evaluation
Bath
Institute of Medical Engineering
Equipment category: infusion pumps and controllers, breathing system connectors.
Birmingham
Dudley Road Hospital
Equipment category: humidifiers, CO2 expired gas analysers
Cardiff
Medical Physics Department, South Glamorgan Health Authority
Equipment category: surgical diathermy units, baby incubators, infant warmers.

University of Wales
College of Medicine
Equipment category: lung ventilators, ventilator alarms, resuscitators.
London
St. Mary's Hospital, Paddington
Equipment category: fetal monitors.
Newcastle
Regional Engineer's Department, Northern Regional Health Authority
Equipment category: ECG monitors, automatic non-invasive blood pressure monitors.
Oxford
Regional Engineer's Department, Oxford Regional Health Authority
Equipment category: ECG recorders, ambulatory ECG (Holter) systems.
Sheffield
University and Health Authority, Department of Medical Physics and Clinical Engineering
Equipment category: dialysis and associated equipment (not dialysers).

Completed Reports

UA1 United Kingdom Department of Health and Social Security, Medical Devices Evaluation Programme. Assessment of Elscint Mam LS3 mammographic unit. 1986 Jan. (Report no. STB6E/86/3) [Epidemiological and other observational methods, Bench testing]

UA2 _____. Assessment of IGE L/U arm angiograph unit. 1986 Feb. (Report no. STB/86/7) [Epidemiological and other observational methods, Bench testing]

UA3 _____. Assessment of Siemens Optilux 57 intensifier associated with the Sircam 100mm camera and Polyphos 300E generator. 1986 Jan. (Report no. STB6E/86/4) [Epidemiological and other observational methods, Bench testing]

UA4 _____. Assessment of Wolverson X-ray (Acoma) MXR 102 mammography unit. 1986 Jan. (Report no. STB6E/86/1) [Epidemiological and other observational methods, Bench testing]

UA5 _____. Assessment of medical X-ray supplies (Soredex) Mammex DC mammographic unit. 1986 Jan. (Report no. STB6E/86/2) [Epidemiological and other observational methods, Bench testing]

UA6 _____. Comparison of imaging performance of CT scanners (Issue four). 1986 Mar. (Report no. STB/86/10) [Epidemiological and other observational methods, Bench testing]

UA7 _____. Evaluation of Don Whitley Mark II anaerobic cabinet/work station. 1986 Mar. (Report no. STB/86/11) [Epidemiological and other observational methods, Bench testing]

UA8 _____. Performance assessment of gamma cameras, part four. 1986 Mar. (Report no. STB/86/9) [Epidemiological and other observational methods, Bench testing]

UA9 _____. An evaluation of eight non-invasive electronic KV measuring instruments which are commercially available in the UK. 1985 Jun. (Report no. STB6E/85/19) [Epidemiological and other observational methods, Bench testing]

UA10 _____. An evaluation of the Beckman Astra 8 with enzymes. 1985 Jul. (Report no. STB3A/85/32) [Epidemiological and other observational methods, Bench testing]

UA11 _____. An evaluation of the Hamilton Microlab 2100. 1985 Apr. (Report no. STB3A/85/18) [Epidemiological and other observational methods, Bench testing]

UA12 _____. An evaluation of the Kone Process selective chemistry analyser. 1985 Jul. (Report no. STB3A/ 85/31) [Epidemiological and other observational methods, Bench testing]

UA13 _____. Assessment of Kodak M8 radiographic film processor. 1985 Jun. (Report no. STB6E/85/24) [Epidemiological and other observational methods, Bench testing]

UA14 _____. Assessment of Lixiscope hand held imager with radioactive source. 1985 Sep. (Report no. STB6E/85/33) [Epidemiological and other observational methods, Bench testing]

UA15 _____. Assessment of Phillips Medical Systems Saturn 500 and Saturn 850 generators. 1985 Aug. (Report no. STB6E/85/28) [Epidemiological and other observational methods, Bench testing]

UA16 _____. Assessment of Picker Clinix C servo chest unit. 1985 Jun. (Report no. STB6E/85/14) [Epidemiological and other observational methods, Bench testing]

UA17 _____. Assessment of Picker Modulex T for radiography, tomography and occasional peripheral angiography. 1985 Dec. (Report no. STB6E/85/45) [Epidemiological and other observational methods, Bench testing]

UA18 _____. Assessment of Siemens basic radiological system (BRS) to WHO modified specification. 1985 Sep. (Report no. STB6E/85/34) [Epidemiological and other observational methods, Bench testing]

UA19 _____. Assessment of Sine Mobil 3N and 3H mobile imaging intensifiers. 1985 Sep. (Report no. STB6E/85/30) [Epidemiological and other observational methods, Bench testing]

UA20 _____. Assessment of Todd Research BRS to WHO modified specification. 1985 Sep. (Report no. STB6A/85/36) [Epidemiological and other observational methods, Bench testing]

UA21 _____. Assessment of Wolverson Mylo X radio-graphic unit, Royal Preston Hospital, North Manchester. 1985 Apr. (Report no. STB6E/85/8) [Epidemiological and other observational methods, Bench testing]

UA22 _____. Assessment of a Siemens Polydoros 80 X-ray generator. 1985 Aug. (Report no. STB6E/85/ 27) [Epidemiological and other observational methods, Bench testing]

UA23 _____. Comparative evaluation of free thyroxine assay kits. 1985 Nov. (Report no. STB3A/85/44) [Epidemiological and other observational methods, Bench testing]

UA24 _____. Comparative evaluation of prostatic acid phosphatase kits. 1985 May. (Report no. STB3A/85/ 21) [Epidemiological and other observational methods, Bench testing]

UA25 _____. Evaluation of Analogue LM3 analyser. 1985 May. (Report no. STB3/85/25) [Epidemiological and other observational methods, Bench testing]

UA26 _____. Evaluation of sickle cell haemoglobin (HBS) screening methods. 1985 Sep. (Report no. STB3A/85/41) [Epidemiological and other observational methods, Bench testing]

UA27 _____. Evaluation of the Autobac IDX. 1985 Dec. (Report no. STB3A/85/46) [Epidemiological and other observational methods, Bench testing]

UA28 _____. Evaluation of the IQ Bio Microlite Floteskan system. 1985 Oct. (Report No. STB3A/85/43) [Epidemiological and other observational methods, Bench testing]

UA29 _____. Evaluation of the Matascan. 1985 May. (Report no. STB3A/85/23) [Epidemiological and other observational methods, Bench testing]

UA30 _____. Evaluation of the Syra Advance (summary report). 1985 May. (Report no. STB3A/85/22) [Epidemiological and other observational methods, Bench testing]

UA31 _____. Evaluation of the Syva advance automated fluorescence immunoassay system. Final report. 1985 Dec. (Report no. STB3A/85/47) [Epidemiological and other observational methods, Bench testing]

UA32 _____. Introduction to imaging cameras with assessment of Matric HPC 1010/4. 1985 Nov. (Report no. STB6E/85/42) [Epidemiological and other observational methods, Bench testing]

UA33 _____. PHLS & DHSS evaluation of five anti-HTLV3/LAV assay kits. 1985 Sep. (Report no. STB3A/85/40) [Epidemiological and other observational methods, Bench testing]

UA34 _____. Physical evaluation of the imaging performance of the Agfa Gevaert range of screen film systems. 1985 Aug. (Report no. STB6E/85/26) [Epidemiological and other observational methods, Bench testing]

UA35 _____. Survey of bench top centrifuges. 1985 May. (Report no. STB3A/85/20) [Epidemiological and other observational methods, Bench testing]

U.S. ADMINISTRATORS INC.

Professional Policy Committee
5016 North Parkway Calabasas
Calabasas, CA 91302
800-872-7526, Ext. 173

Contact: Marvin J. Shapiro, M.D., Medical Director.

Overview: The U.S. Administrators Inc. is a for-profit corporation that manages self-funded medical care programs of corporations, unions, and government entities. It is sponsered by the Crownx Corporation of Canada and Samuel X. Kaplan and family. The Professional Policy Committee was organized in spring 1983 to obtain timely information on which daily reimbursement decisions could be based.

Purpose: To guide reimbursement policies.

Primary intended users: Physicians; acute facility administrators; long-term care facility administrators; other care givers; employers; unions and other employee organizations; third party payers; financial analysts, consultants; lawyers.

Technologies: *Medical or surgical procedure*, drug, device, support system, organizational or administrative system.

Any technology is assessed that requires a decision as to whether or not it should be reimbursed and/or under what circumstances it should be reimbursed.

Intervention: *Treatment*, prevention, diagnosis, rehabilitation.

Stage: *Established or widespread practice*, emerging, new, obsolete.

As soon as the Committee has knowledge of a new technology not yet released for general use it seeks to develop a policy. Technologies are also evaluated if evidence from claims indicates that there may be misuse of a technology, or a technology may become obsolete.

Properties: *Effectiveness*; safety; efficacy; cost; cost-benefit; cost-effectiveness; system impact; economic implications; ethical, legal, social implications.

Technologies are assessed from the perspective of their contribution to patient care. Does a technology contribute significantly to diagnosis or treatment? Does it do a better job than other technologies in that it is more convenient, causing less patient distress, and/or is less expensive?

Selection process: Account executives, clients, health benefit coordinators, claims personnel, committee members, the Medical Director, or physician consultants may request that an assessment be conducted. Requests may be either written or oral. Assessment topic priorities are set by the Medical Director. An assessment is performed if a problem with a procedure or a technology is identified. The staff presents the problem and a proposed resolution to the Policy Committee for discussion, evaluation, and final resolution.

Methods: *Group judgment*, information syntheses, expert opinion.

The Medical Director and his staff prepare a literature review and an agenda. This material is sent to the Committee members 4 to 6 weeks prior to the meeting. The Committee meets to consider and recommend actions. The Medical Director prepares the minutes, which are reviewed and approved by all Committee members. The results are presented in language suitable for clients and internal personnel and are then circulated in written form. The approximate turnaround time from selection of assessment topic to reporting of findings is 6 to 9 months.

Assessors: The assessors are physicians with various associations in the medical and academic communities.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/ information; resuits; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; where technology is in use; regulatory agency approval status; coverage/ reimbursement status of the technology.

Dissemination: Advisories to members/constituents.

The assessment policies are called "Professional Policy Committee Recommendations." The recommendations are sent to all clients and concerned personnel within the organization. Copies of the assessments may be obtained by contacting Marvin J. Shapiro at U.S. Administrators.

Budget: $150,000. The approximate cost per assessment is $5,000. Funding source: 100 percent parent organization.

Use: The information is used by the parent organization to adjudicate the payment of claims for services. Claims personnel, professional review departments, and physician advisors all make use of the recommendations.

Program evaluation: There have been no formal evaluations, but the program is under constant review by the internal personnel who use the recommendations, and by clients. The ongoing review seems to be very positive, since the recommendations have, almost without exception, been accepted, and found helpful in adjudicating claims, dealing with providers, and educating claims personnel of clients as well as employees.

Completed Reports

UB1 U.S. Administrators, Professional Policy Committee. A.I.D.S. [7/86] [Group judgment]
UB2 _____. Adjuvant chemotherapy for breast cancer. [7/86] [Group judgment]
UB3 _____. Admission screening—hospital. [7/86] [Group judgment]
UB4 _____. Allergy—new tests for treatment. [7/86] [Group judgment]
UB5 _____. Alopecia areata. [7/86] [Group judgment]
UB6 _____. Arthritis—diagnostic procedures. [7/86] [Group judgment]

UB7 _____. Arthritis—medical therapy. [7/86] [Group judgment]
UB8 _____. Arthritis—surgical intervention. [7/86] [Group judgment]
UB9 _____. Arthritis, low-dose methotrexate therapy. [7/86] [Group judgment]
UB10 _____. Arthroscopy of joints other than the knee. [7/86] [Group judgment]
UB11 _____. Arthroscopy of knee. [7/86] [Group judgment]
UB12 _____. B.E.A.M. [7/86] [Group judgment]
UB13 _____. Biofeedback. [7/86] [Group judgment]
UB14 _____. Bone marrow transplantation. [7/86] [Group judgment]
UB15 _____. Breast imaging. [7/86] [Group judgment]
UB16 _____. CT scans—head. [7/86] [Group judgment]
UB17 _____. CT scans cervical and lumbar spine. [7/ 86] [Group judgment]
UB18 _____. Cardiac rehabilitation programs. [7/86] [Group judgment]
UB19 _____. Cardioverter defibrillator, implantable. [7/86] [Group judgment]
UB20 _____. Carotid artery disease. [7/86] [Group judgment]
UB21 _____. Cerebral artery anastomosis, superficial temporal-middle. [Group judgment]
UB22 _____. Cerebral artery anastomosis, superficial temporal-middle. [7/86] [Group judgment]
UB23 _____. Chemotherapy. [7/86] [Group judgment]
UB24 _____. Chest pain—chronic. [7/86] [Group judgment]
UB25 _____. Chiropractic services. [7/86] [Group judgment]
UB26 _____. Cholangiography, routine operative. [7/ 86] [Group judgment]
UB27 _____. Cholecystectomy. [7/86] [Group judgment]
UB28 _____. Cochlear implants. [7/86] [Group judgment]
UB29 _____. Coronary arteriography. [7/86] [Group judgment]
UB30 _____. Coronary artery angioplasty. [7/86] [Group judgment]
UB31 _____. Coronary care units, admission to. [7/86] [Group judgment]
UB32 _____. Decubitus surgery. [7/86] [Group judgment]
UB33 _____. Diabetes mellitus—diagnosis and management. [7/86] [Group judgment]
UB34 _____. Digital subtraction angiography—intravenous. [7/86] [Group judgment]
UB35 _____. Dilatation and curettage. [7/86] [Group judgment]
UB36 _____. E.S.W.L. [7/86] [Group judgment]
UB37 _____. Echocardiography in atherosclerotic coronary artery disease. [7/86] [Group judgment]
UB38 _____. Emergency rooms. [7/86] [Group judgment]
UB39 _____. Epikeratophakia grafts. [7/86] [Group judgment]
UB40 _____. Exercise training for chronic obstructive lung disease. [7/86] [Group judgment]
UB41 _____. Eye surgery. [7/86] [Group judgment]
UB42 _____. Fertilization, in vitro. [7/86] [Group judgment]
UB43 _____. Fetal monitoring—non-stress training. [7/86] [Group judgment]
UB44 _____. Gastric bubble, Garren-Edwards. [7/86] [Group judgment]
UB45 _____. Genetic counselling and screening. [7/ 86] [Group judgment]
UB46 _____. Growth hormone—human. [7/86] [Group judgment]
UB47 _____. Hodgkin's disease, routine lymphangiography. [7/86] [Group judgment]
UB48 _____. Hodgkin's disease, routine staging laparotomy. [7/86] [Group judgment]
UB49 _____. Holter monitoring. [7/86] [Group judgment]
UB50 _____. Hypertension, evaluation and management. [7/86] [Group judgment]
UB51 _____. Hyperthermia. [7/86] [Group judgment]
UB52 _____. Immuno-augmentative therapy. [7/86] [Group judgment]

UB53 _____. Incentive spirometry. [7/86] [Group judgment]
UB54 _____. Intermittent positive pressure breathing. [7/86] [Group judgment]
UB55 _____. Investigations (clinical). [7/86] [Group judgment]
UB56 _____. Kyphoscoliosis surgery. [7/86] [Group judgment]
UB57 _____. Laser therapy. [7/86] [Group judgment]
UB58 _____. Linear Pump, Wright. [7/86] [Group judgment]
UB59 _____. Maternity benefits. [7/86] [Group judgment]
UB60 _____. Metastatic neoplasms. [7/86] [Group judgment]
UB61 _____. Morbid obesity. [7/86] [Group judgment]
UB62 _____. Multiple views—diagnostic radiology. [7/ 86] [Group judgment]
UB63 _____. Nail bed transplants. [7/86] [Group judgment]
UB64 _____. Non-invasive testing—lower extremities. [7/86] [Group judgment]
UB65 _____. Non-invasive testing—peripheral artery disease. [7/86] [Group judgment]
UB66 _____. Nuclear magnetic resonance imaging. [7/ 86] [Group judgment]
UB67 _____. Organ transplantation. [7/86] [Group judgment]
UB68 _____. Orthoptic training. [7/86] [Group judgment]
UB69 _____. Pain rehabilitation programs. [7/86] [Group judgment]
UB70 _____. Periodic health screening. [7/86] [Group judgment]
UB71 _____. Peripheral pulmonary lesions. [7/86] [Group judgment]
UB72 _____. Physical therapy. [7/86] [Group judgment]
UB73 _____. Preadmission/presurgical screening. [7/ 86] [Group judgment]
UB74 _____. Psychiatric disorders—testing. [7/86] [Group judgment]
UB75 _____. Radionuclide scans (post-operative). [7/ 86] [Group judgment]
UB76 _____. Radionuclide scans (pre-operative). [7/ 86] [Group judgment]
UB77 _____. Research grants—investigational. [7/86] [Group judgment]
UB78 _____. Somatization disorder. [7/86] [Group judgment]
UB79 _____. Spinal stenosis. [7/86] [Group judgment]
UB80 _____. Streptokinase. [7/86] [Group judgment]
UB81 _____. Stress tests. [7/86] [Group judgment]
UB82 _____. Subcutaneous (subareolar) mastectomy (bilateral). [7/86] [Group judgment]
UB83 _____. Swan Ganz. [7/86] [Group judgment]
UB84 _____. Thallium and/or equilibrium-gated myocardial imaging. [7/86] [Group judgment]
UB85 _____. Therapeutic apheresis (plasmapheresis). [7/86] [Group judgment]
UB86 _____. Transfusion—preparation of blood. [7/ 86] [Group judgment]
UB87 _____. Unbundling. [7/86] [Group judgment]
UB88 _____. Upper G-I endoscopy. [7/86] [Group judgment]
UB89 _____. Urography (excretory). [7/86] [Group judgment]

Ongoing Assessments

UB90 _____. Autologous blood transfusions. Ongoing. [Group judgement]
UB91 _____. Bone healing/electromagnetic stimulation. Ongoing. [Group judgment]
UB92 _____. Bone marrow transplant—reconsideration. Ongoing. [Group judgment]
UB93 _____. CEA testing. Ongoing. [Group judgment]
UB94 _____. Carotid endarterectomy. Ongoing. [Group judgment]
UB95 _____. Chronic backache—diagnosis and therapy. Ongoing. [Group judgment]
UB96 _____. Echocardiography/re-evaluation. Ongoing. [Group judgment]
UB97 _____. Environmental illness and testing. Ongoing. [Group judgment]
UB98 _____. Evoked potential monitoring. Ongoing. [Group judgment]

UB99 _____. Guidelines for reimbursement policies for inpatient and outpatient therapy for alcoholism and psychiatric disorders. Ongoing. [Group judgment]
UB100 _____. Guidelines of appropriate indications for "oscopies". Ongoing. [Group judgment]
UB101 _____. Hospice care/Alzheimer's. Ongoing. [Group judgment]
UB102 _____. Hyperbaric oxygen therapy. Ongoing. [Group judgment]
UB103 _____. Intrapartum fetal monitoring. Ongoing. [Group judgment]
UB104 _____. Intrauterine fetal shunts. Ongoing. [Group judgment]
UB105 _____. Lithotripsy—reconsideration re expanded indications. Ongoing. [Group judgment]
UB106 _____. Liver/spleen scans. Ongoing. [Group judgment]
UB107 _____. Pain clinics. Ongoing. [Group judgment]
UB108 _____. Penile implants. Ongoing. [Group judgment]
UB109 _____. Programmed electronic stimulation—post-myocardial infarct. Ongoing. [Group judgment]
UB110 _____. Protocol for use of multiple EKG's and chest X-rays in CCUs and ICUs. Ongoing. [Group judgment]
UB111 _____. Radiation therapy for lung carcinoma. Ongoing. [Group judgment]
UB112 _____. Relaxation therapy for hypertension. Ongoing. [Group judgment]
UB113 _____. Sclerosing therapy for esophageal varices. Ongoing. [Group judgment]
UB114 _____. Screening tests for osteoporosis. Ongoing. [Group judgment]
UB115 _____. Sleep testing and therapy of sleep apnea. Ongoing. [Group judgment]

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO INSTITUTE FOR HEALTH POLICY STUDIES

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415-476-4921
Contact: Jonathan Showstack, Associate Professor of Health Policy; or Phyllis Fetto, Program Administrator.

Overview: The Institute for Health Policy Studies (IHPS) is an academic and research unit of the University of California, San Francisco (UCSF). It was established in 1972 as the Health Policy Program. In 1982, the name officially changed to the IHPS when it was formally designated an Organized Research Unit within the School of Medicine, UCSF.

Purpose: The IHPS has a threefold purpose. First, IHPS provides education and training programs for students and practitioners in the health professions; for students and faculty in other disciplines; and for policy-makers, program managers, and others in the health field. Second, the IHPS faculty conduct health services research and policy analysis projects. Third, the IHPS gives advice on effective and efficient health care delivery systems to federal and state governments and other policy-making bodies.

Primary intended users: Physicians, third party payers, government regulators, public policy-makers, legislators, policy research organizations.

Technologies: *Medical or surgical procedure*, device, support system, organizational or administrative system.

In recent years, IHPS's priorities in research and policy analysis have been health maintenance organizations and other organized health care delivery systems, cost containment, impact of medical technology on health care, ethical issues in health care, reproductive health, the aged, child health, prescription drugs, health manpower, health planning, health promotion and disease prevention, and health care for disadvantaged persons.

Intervention: *Treatment*, diagnosis.

Stage: *Established or widespread practice*, new.

Properties: *Cost-effectiveness*; efficacy; effectiveness; cost; cost-benefit; service requirements; acceptance/adoption level; system impact; economic implications; ethical, legal, social implications.

Selection process: Faculty and staff members generally select assessment topics. Projects must be within a faculty/staff member's area of interest; consistent with the purposes of IHPS; and subject to university policies regarding grants, contracts, and other arrangements with outside parties.

Methods: *Cost analyses*, information syntheses, expert opinion, group judgment, modeling, epidemiological and other observational methods.

Through its formal relationships with other university institutions, IHPS has access to clinical data. The turnaround time from selection of assessment topic to reporting of findings varies according to the type of study conducted or other assistance provided. For instance, the case studies on various technologies conducted for the Congressional Office of Technology Assessment took approximately 6 months to complete. Responses to requests for technical assistance may take 1 day to several weeks and formal health services research projects are often 2 to 3 years long.

Assessors: The IHPS has approximately 30 faculty members and 28 affiliated faculty, over 20 full-time research staff, 40 predoctoral and postdoctoral fellows and visiting scholars, and approximately 20 full-time support staff. This multidisciplinary staff represents the fields of law, pharmacology, philosophy and ethics, medicine, economics, public policy and administration, planning, statistics, sociology, epidemiology, political science, medical anthropology, and medical information sciences.

Assessment reports include: Abstract; the purpose of the assessment; who sponsored/ commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; source of data/information; methods for collecting data/in formation; methods for analyzing/synthesizing data/in formation; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles; development of the technology; regulatory agency approval status; coverage/ reimbursement status of the technology.

Dissemination: Printed reports; journal articles; press conferences/news releases, TV/ radio broadcasts, video products.

A comprehensive dissemination program exists to communicate information on health policy issues and research findings to four major audiences: federal, state and local policy-makers; the health services research and health policy research communities; representatives of not-for-profit and for-profit organizations that provide health services; and the general public.

Faculty and research staff place a high priority on the development of publications including books, monographs, discussion papers, book chapters, and journal articles. There are three internal publication series: a discussion paper series; a monograph series; and a reprint series.

The Institute's semiannual newsletter *IHPS Report*, is designed to communicate Institute research findings. The Institute's Center for Population and Reproductive Health Policy produces the semiannual newsletter *Research Highlights*.

Institute faculty and research staff organize conferences on national, state, and local health policy issues. The conferences bring selected groups together to share research findings and to analyze the implications of these findings for key policy questions.

Budget: Research, $1,500,000, technology assessment, $750,000. Funding sources: 50 percent government grants/ contracts, 50 percent foundations, other private grants.

Use: It is difficult to measure directly the impact of IHPS activities, because IHPS acts as an analytic and advisory body, not a policy-making body. Results of health services research and policy analyses projects have had wide circulation through publication in peer-reviewed journals and are often cited by other investigators. Technical assistance and policy analyses provided by IHPS have been used in augmenting and guiding legislative efforts and various policy changes.

From 1977 through 1983, IHPS faculty and research staff responded to approximately 800 requests for technical assistance. Over 50 percent of the requests were from federal policy-makers and staff.

The primary users have been Congress and Congressional offices, the Executive Office of the President, the Department of Health and Human Services, and the Federal Trade Commission. For these and other federal agencies, IHPS analyses have contributed to research agendas and policy options in such areas as prescription drugs, health manpower, health promotion and disease prevention, and health planning and regulation.

For the state of California, IHPS provided analyses of MediCal reform options, the impact of prepaid medical care plans, health and social service policy options in long-term care, the cost-effectiveness of prenatal care, and other areas. The health provider community—individual providers, institutions, and service programs—have benefited from IHPS technical assistance, information, and educational programs.

The expansion of IHPS research and analyses activities has augmented its role in education and training. IHPS faculty have developed some 20 courses in health policy and related areas for students on the UCSF and University of California, Berkeley campuses.

IHPS has been instrumental in several major developments in academic programs at UCSF, including the establishment of the Division of General Internal Medicine; the Division of Medical Ethics; the Aging Health Policy Center; and postgraduate programs in health policy research, health policy management, and clinical epidemiology.

The IHPS is described in Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies.* Washington, DC: National Academy Press, 1985.

Completed Reports

UF1 Showstack JA, Hughes Stone M, Schroeder SA. [University of California, San Francisco, Institute for Health Policy Studies] The role of changing clinical practices in the rising costs of hospital care. N Engl J Med 1985;313:1201-1207.

UF2 Korenbrot CC, Aalto LH, Laros RK. [University of California, San Francisco, Institute for Health Policy Studies] The cost effectiveness of stopping preterm labor with beta-adrenergic treatment. N Engl J Med 1984;310:691-696.

UF3 Nevitt MD, Epstein WV, Masem M, Murray WR. [University of California, San Francisco, Institute for Health Policy Studies] Work disability before and after total hip arthroplasty: assessment of effectiveness in reducing disability. Arthritis Rheum 1984;27:410-421.

UF4 Schroeder SA, Myers LP, McPhee SJ, et el. [University of California, San Francisco, Institute for Health Policy Studies] The failure of physician education as a cost containment strategy: report of a prospective controlled trial at a university hospital. JAMA 1984;252:225-230.

UF5 Budetti P, McManus P. [University of California, San Francisco, Institute for Health Policy Studies] Assessing the effectiveness of neonatal intensive care. Med Care 1982;20:1027-1039.

UF6 McPhee SJ, Myers LP, Schroeder SA. [University of California, San Francisco, Institute for Health Policy Studies] The costs and risks of medical care. An annotated bibliography for clinicians and educators. West J Med 1982; 137(2): 145-161.

UF7 Showstack JA, Schroeder SA, Matsumoto MF. [University of California, San Francisco, Institute for Health Policy Studies] Changes in the use of medical technologies, 1972-1977. A study of 10 in-patient diagnoses. N Engl J Med 1982;306:706-712.

UF8 Simborg DW, Whiting-O'Keefe QE. [University of California, San Francisco, Institute for Health Policy Studies] Evaluation methodology for ambulatory care information systems. Med Care 1982;20:255-265.

UF9 Myers LP, Schroeder SA. [University of California, San Francisco, Institute for Health Policy Studies] Physician use of services for the hospitalized patient: a review, with implications for cost containment. Milbank Mem Fund Q 1981;59 (4):481-507.

UF10 Showstack JA, Schroeder SA, Steinberg HR. [University of California, San Francisco, Institute for Health Policy Studies] Evaluating the costs and benefits of a diagnostic technology: the case of upper gastrointestinal endoscopy. Med Care 1981;19:498-508.

UNIVERSITY OF LAUSANNE INSTITUTE OF SOCIAL AND PREVENTIVE MEDICINE

Evaluation of the Efficacy and Safety of Chorionic Villi Sampling
17 r. Bugnon
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(41-21) 41-28-66

Contact: R. Chrzanowski, M.D., M.PH; or G. Pesia, Professor, Department of Human Genetics, University Hospital (CHUV) 1011 Lausanne, Switzerland.

Overview: The Evaluation of the Efficacy and Safety of Chorionic Villi Sampling (CVS) is a randomized clinical trial sponsored by the Institute of Social and Preventive Medicine, University of Lausanne. The CVS registry and trial began January 20, 1986. By October 1, 1986, the pilot stage of the study had ended and a 3-year grant was awarded.

Purpose: To evaluate the efficacy and safety of prenatal diagnostic tests for genetic disease.

Primary intended users: Patients, physicians, health/medical professional associations, consumer associations, third party payers, government regulators.

Technologies: Medical or surgical procedure.

Specifically, chorionic villi sampling (CVS) and amniotic liquid sampling (ALS) are assessed.

Intervention: *Diagnosis*.

Stage: *New*, established or widespread practice.

Properties: *Efficacy*; safety; effectiveness; cost-benefit; cost-effectiveness; acceptance/ adoption level; system impact; ethical, legal, social implications.

Selection process: Physicians, health/medical associations, third party payers, and government regulators can request that an assessment be conducted. An interdisciplinary research group at the direction of the Institute sets assessment topic priorities.

Methods: *Clinical trials*, expert opinion, modeling, cost analyses, epidemiological and other observational methods.

The assessment project consists of a questionnaire, registry (computerized database), followup, intermediary analysis and report, and a final statistical analysis and report. Project presentations are made to the Directory Committee, the Ethical Committee, and the Expert Committee. The CVS assessment will be completed in 1989.

Assessors: Assessors have expertise in the areas of community medicine, epidemiology, human genetics, gynecology, and biostatistics.

Assessment reports include: The purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how the technology works, including theory, principles.

Dissemination: *Printed reports*, journal articles, advisories to members/constituents.

Copies of publications and the final report are available from the Institute.

Budget: $60,000. Funding source: 100 percent parent organization.

Use: Third party payers and the federal insurance agency have asked to be informed about the project results.

Related activities: Project staff participate in international conference on CVS.

Completed Reports

UL1 Gutzwiller F, Grob PJ, Boppart I, Marguerat PH, eds. [University of Lausanne, Institute of Social and Preventive Medicine] Swiss alpha-foetoprotein screening working group: results of the collaborative study of early detection of neural tube defects. 1985. [Epidemiological and other observational methods]

Ongoing Assessments

UL2 [University of Lausanne, Institute of Social and Preventive Medicine] Evaluation of efficacy and safety of chorionic villi sampling (CVS). Ongoing. [Clinical trials]

UNIVERSITY OF PENNSYLVANIA LEONARD DAVIS INSTITUTE OF HEALTH ECONOMICS

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Contact: Joanne Levy, Assistant Director.

Overview: The Leonard Davis Institute of Health Economics is a not-for-profit research institute that emphasizes an interdisciplinary approach to health services research. Allied principally with the Wharton School and the University of Pennsylvania's medical school, the Institute is perhaps the earliest effort to build formal partnerships within the same university among the clinical, management, and social sciences.

The Institute assesses impact and cost-effectiveness of various health policy practices. Projects in the area of medical technology examine patterns of technology adoption, diffusion, and use, particularly as they relate to management decision-making.

Purpose: To promote an interdisciplinary approach to health services research and education in the organization, financing, and delivery of health care.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term care facility administrators; health product manufacturers; health industry associations; government regulators; public policy-makers, legislators.

Technologies: *Organizational or administrative system*, device, medical or surgical procedure, support system.

Intervention: Prevention, diagnosis, rehabilitation.

Stage: *New*, emerging, established or widespread practice.

The Institute focuses on health policies that are just coming into practice.

Properties: *Cost-effectiveness, economic implications*, efficacy, effectiveness, cost, cost-benefit, acceptance/adoption level, system impact.

Selection process: Assessments are initiated by senior fellows of the Institute, individually or jointly, based on their interests, the availability of data, and availability of funding. Investigators respond to requests for proposals or submit unsolicited grant

proposals to government agencies, foundations, corporations, university funding sources, and providers.

Assessment topic priorities are set by the Institute's national advisory council, its governing board, and its executive committee. Followup studies are undertaken when interest persists and funding is available.

Methods: *Cost analyses, modeling*, information syntheses, expert opinion, group judgment, epidemiological and other observational methods.

Specifically, methods include interviews, on-site observations, and computer modeling and simulation. Medical management models are developed to improve the screening, diagnostic, and treatment decisions of clinicians and to understand resource allocation decisions at a societal level. Descriptive studies examine the actual decision processes used by clinicians when recommending the use of alternative technologies, procedures, and pharmaceuticals.

The average project is completed in 18 months although the range is from 4 months to 5 years.

Assessors: The Institute draws upon health services researchers in the university community and faculty from a variety of disciplines, including management, insurance, medicine, economics, decision sciences, dentistry, law, psychology, nursing, and sociology.

Assessment reports include: Abstract; the assessment's intended audience; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/supported the assessment; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research; how much the assessment cost; how the technology works, including theory, principles; coverage/reimbursement status of the technology.

Dissemination: *Journal articles*; printed reports; advisories to members/constituents; press conferences/news releases, TV/radio broadcasts, video products.

Research results are disseminated through published articles in the academic, professional, and popular press; press releases; books; and book chapters. In addition, senior fellows are frequent lecturers at universities, professional conferences, and association meetings. The Institute also has its own publication series. To obtain publications, contact Jennifer Conway, Editor and Manager of Information Services, Leonard Davis Institute of Health Economics, 215-898-4750.

Budget: $1,723,300. Funding for current and recent projects has ranged from $3,000 to $612,000 with scope and length of the project being the determining factors. Funding sources: 2 percent parent organization; 42 percent government grants/contracts; 56 percent foundations, other private grants.

Use: The Institute's studies are used primarily by policy-makers, researchers, and practitioners judging from citations in the literature, speaking invitations, and followup work.

Related activities: The Institute conducted a two-part conference on Medicare research and policy in 1986 and 1987. Two books will contain the conference papers and presentations. In addition, the Institute sponsors advanced education programs and a seminar series on health services research topics.

Completed Reports

UP1 University of Pennsylvania, Leonard Davis Institute of Health Economics. A study of voluntary hospital governance. 1986 Sep. (Study for the Robert Wood Johnson Foundation)

UP2 _____. Antecedents and consequences of contract management. 1986 Feb. (Final report to National Center for Health Services Research, DHHS)

UP3 _____. Cost of generic vs. branded ethical drugs. 1986 Jun. (Final report to Ayerst Laboratories)

UP4 _____. Financing options for health care for uninsured poor. 1986 Dec. (Study for North Carolina Hospital Foundation, Inc)

UP5 _____. Hospital contract management: structure, process, and outcome. 1986 Apr. (Final report to the Hospital Corporation of America)

UP6 _____. Magnetic resonance imaging. 1986 Dec. (Pilot study for University of Pennsylvania)

UP7 _____. Designing and evaluating incentives for ambulatory surgery: a nationwide study. 1986 Dec. (Study for Robert Wood Johnson Foundation)

UP8 _____. Adjustment artifacts in DRG-based Medicare reimbursement. 1985 Aug. (Final report to the National Center for Health Services Research, DHHS)

UP9 _____. DRG's disease staging, and variance reduction. 1985 Jul. (Final Report to the National Center for Health Services Research, DHHS)

UP10 _____. The effect of telemetry on advanced life support care. 1984 Apr. (Final Report to the National Center for Health Services Research, DHHS)

UP11 _____. Vertically-integrated systems: a preliminary study. 1984 Jul. (Final report to the Center for the Study of Aging, University of Pennsylvania)

UP12 _____. Cost benefit, cost effectiveness, and other decision making techniques in health care resource allocation. 1983. (Proceedings of a Regional Symposium, November 4-6, 1982, funded by Smith Kline and French Laboratories)

UP13 _____. Cost of medical education in West Virginia: policy research and analysis. 1983 Dec. (Final report to the Claude Worthington Benedum Foundation)

UP14 _____. The spatial distribution of hospital utilization. 1983 May. (Final report submitted to the National Center for Health Services Research, DHHS)

UP15 _____. A review of the economic benefits of selected health education and promotion activities. 1982 May. (Interim report submitted to Johnson and Johnson Live for Life Program)

UP16 _____. Cost-benefit and cost-effectiveness analysis in policymaking: cimetidine as an example. 1982. (Proceedings of an International Symposium, November 22-24, 1981, funded by Smith Kline and French Laboratories)

UP17 _____. Hospital services coordination: a comparative case study of triad and care program management systems. 1982 May. (A final report to the National Center for Health Services Research, DHHS)

UP18 _____. Methodological limitations of hospital case-mix measures (Task III). 1982 Aug. (Final report to the Hospital Research and Educational Trust of New Jersey)

UP19 _____. Indentifying hospital variables that might improve the incentives in New Jersey's prospective hospital reimbursement program (Task II). 1981 Oct. (Final report to the Hospital Research and Educational Trust of New Jersey)

UP20 _____. National conference monograph: evaluating the performance of multi institutional systems. 1981 Sep. (Final report to the National Center for Health Services Research, DHHS)

UP21 _____. The causes and significance of clinically inappropriate patient assignments. 1981 Oct. (Final report to the Hospital Research and Educational Trust of New Jersey)

UP22 _____. Vertical integration of care for cancer patients: a Markovian approach. 1981 May. (Final report to the Cancer Center, Hospitals of the University of Pennsylvania)

Ongoing Assessments

UP23 _____. Adoption and diffusion of magnetic resonance imaging under DRGs. Ongoing. (Study for the National Center for Health Services Research, DHHS)

UP24 _____. Adverse selection in multiple-option group insurance. Ongoing. (Study for National Center for Health Services Research, DHHS)

UP25 _____. Evaluation of the DEW National Dental Education Program. Ongoing. (Study for the Glenmede Trust Co)

UP26 _____. Heuristics and biases in diagnostic decisions. Ongoing. (Study for the National Science Foundation and the National Library of Medicine)

UP27 _____. Policy implications of hospital contract management. Ongoing. (Project for the Commonwealth Fund)

Planned Assessments

UP28 _____. Evaluation of magnetic resonance imaging. Planned. (Submitted to Riverside Methodist Hospital, Columbus, OH).

UP29 _____. Full Medicare capitation for ESRD beneficiaries: design, implementation, and evaluation of a controlled nationwide demonstration. Planned. (Submitted to the Health Care Financing Administration).

UP30 _____. The cost-quality tradeoff for trauma patients treated in a non-designated trauma hospital. Planned. (Submitted to University of Pennsylvania)

VETERANS ADMINISTRATION COOPERATIVE STUDIES PROGRAM (151 I)

Veterans Administration Medical Center
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617-739-3479

Contact: Daniel Deykin, M.D., Chief; or Ping C. Huang, Ph.D., Staff Assistant, Cooperative Studies Program, Veterans Administration, 810 Vermont Ave. NW, Washington, DC 20420, 202-872-1151.

Overview: The Veterans Administration (VA) extends to eligible veterans free or highly subsidized health care services, including hospital, ambulatory, and nursing home care. Most of these services are provided at its 172 hospital centers. The VA annually assists about 3 million veteran patients, including about 1.4 million inpatients.

The VA also has three major research and development services: the Medical Research Service, the Rehabilitation Research and Development Service, and the Health Services Research and Development Service. The Cooperative Studies Program is in the Medical Research Service. The Program in its present form was instituted in 1972 in recognition of the growing number of multi-hospital studies in the VA medical system. The VA is an especially useful environment for multicenter study because it has a relatively uniform and large patient base under one management.

Purpose: To provide coordination and support for multiple medical centers to study collectively a selected medical problem in a uniform manner, using a common protocol.

Primary intended users: Providers, generally; physicians; acute facility administrators; long-term facility administrators; other care givers; regulators; biomedical researchers; public policy-makers.

Technologies: Drug, device, medical or surgical procedure, support system.

If drugs or devices used in a study require approval from the Food and Drug Administration, an investigational new drug application or investigational device exemption must be filed with the FDA before the study can begin.

Intervention: Diagnosis, treatment, rehabilitation.

Stage: Emerging, new, established or widespread practice.

Properties: *Safety, efficacy*, effectiveness, cost-benefit, cost-effectiveness.

Selection process: Any eligible (more than 5/8 time) researcher-physician or medical investigator in the VA system can request the support to undertake a cooperative study, by sending a proposal to the Chief of the Program. The Chief may encourage studies in certain areas of special interest to the VA. Proposals are reviewed by experts in the area of the study and then either assigned to a coordinating center for planning, returned to the requester for revision, or rejected. This process culminates in the development of a final protocol that is reviewed by the Cooperative Studies Evaluation Committee, a group of medical and biostatistical experts who serve 3-year terms. The Committee's recommendations are reviewed by the Director of the Medical Research Service. Reassessments are initiated in the same way.

Methods: *Clinical trials*, cost analyses, epidemiological and other observational methods.

The majority of VA cooperative studies are randomized clinical trials. A few have been nonrandomized trials and observational studies. Cost analyses are included when appropriate.

Five groups share the responsibility for conducting or monitoring a cooperative study: a study group, an executive committee, an operations committee, the cooperative studies coordinating center human rights committee, and the cooperative studies evaluation committee. In general, the study group, executive committee, and operations committee meet prior to patient intake for organizational, information, and training purposes; again 9 months after patient intake; and annually for the duration of the study. The human rights committee meets with the operations committee at least once a year for the course of the study. All cooperative studies undergo an in-depth review by the cooperative studies evaluation committee at 3-year intervals during their active phase.

The approximate turnaround time from selection of assessment topic to reporting of findings may range from 1 to 7 years.

Assessors: Assessors include physicians and other health care providers, biostatisticians, clinical pharmacists, and other experts in the subject matter of the study.

Assessment reports include: Abstract; the purpose of the assessment; relationship of the assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who sponsored/commissioned/ supported the assessment; who conducted the assessment; description of the technology; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/information; methods for analyzing/synthesizing data/information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Dissemination: Journal articles; press conferences/news releases, TV/radio broadcasts, video products.

All VA medical centers conducting medical research report regularly to the VA Medical Research Service which maintains an R&D Information System database. An annual report to Congress on medical research in the VA includes summaries of cooperative studies. Results are also presented at scientific meetings and published in refereed journals. Reprints of articles may be requested from the author or through the Program office.

Budget: $14,000,000. The average cost for a clinical trial is $2-2.5 million. Funding sources: 86 percent parent organization; 7 percent government grants/contracts (interagency agreements); 7 percent foundations, other private grants.

Use: Citations in the published literature to the Program include the following:

Institute of Medicine, Committee on Evaluating Medical Technologies in Clinical Use. *Assessing medical technologies*. Washington, DC: National Academy Press, 1985.

James KE. A model for the development, conduct, and monitoring of multicenter clinical trials in the Veterans Administration. *Controlled Clin Trials* 1980; 1:193-207.

Henderson WG. Some operational aspects of the Veterans Administration Cooperative Studies Program from 1972 to 1979. *Controlled Clin Trials* 1980; 1:209-226.

Kathe BA, et al. Patients rights and welfare in the VA Cooperative Studies Program. *Controlled Clin Trials* 1981;4:267-274.

Program evaluation: To review the progress and future direction of certain aspects of the Program, evaluations have been made from time to time, as requested by the Director of the Medical Research Service and the Chief of the Program. Congress also has asked the Government Accounting Office to evaluate VA medical research, including the Cooperative Studies Program.

In 1983, evaluations were performed for the Program as a whole and for its cost-effectiveness analysis activities. An ad hoc advisory committee of experts was appointed to conduct site visits, interviews, and group discussions. The committee's recommendations were adopted whenever feasible.

Completed Reports

VC1 Veterans Administration, Cooperative Studies Program. A randomized clinical trial of total parenteral nutrition in malnourished surgical patients. Pending. [Clinical trials]

VC2 _____. Anticoagulants in the Rx of CA (RA-233). Pending. [Clinical trials]

VC3 _____. Bactrim in leukopenia with non-lymphocytic leukemia. Pending. [Clinical trials]

VC4 _____. Effects of reduction in drugs or dosage after long term control of hypertension. Pending. [Clinical trials]

VC5 _____. Evaluations of corticosteroid therapy in gram negative sepsis. Pending. [Clinical trials]

VC6 _____. Surgical shunt vs. medical treatment in alcoholic cirrhosis ascites. Pending. [Clinical trials]

VC7 _____. Treatment of mild hypertension in the aged. Antihypertensive effectiveness and patients' toleration of different regimens. Pending. [Clinical trials]

VC8 _____. A comparison of hospital and home treatment programs for aphasic patients. [1980] [Clinical trials]

VC9 _____. Alcoholic hepatitis (steroid therapy). [1980] [Clinical trials]

VC10 _____. Antabuse in the treatment of alcoholics on methadone maintenance. [1980] [Clinical trials]

VC11 _____. Anticoagulants in RX of CA (warfarin). [1980] [Clinical trials]

VC12 _____. Clinical studies on captopril: evaluation of low doses, twice daily doses and addition of hydrochlorothiazide. [1980] [Clinical trials]

VC13 _____. Community vs. VA nursing home care vs. hospitalization in psychiatric patients. [1980] [Clinical trials]

VC14 _____. Comparison of propranolol with hydrochlorothiazide for the "step 1" treatment of hypertension. [1980] [Clinical trials]

VC15 _____. Disulfiram (antabuse) in the treatment of alcoholism. [1980] [Clinical trials]

VC16 _____. Efficacy of low doses of reserpine plus chlorthalidone in comparison with standard dosage of reserpine plus chlorthalidone in hypertension. [1980] [Clinical trials]

VC17 _____. Evaluation of anti-epileptic drugs (phenobarb vs. phenytoin vs. primidone vs. carbamazepine). [1980] [Clinical trials]

VC18 _____. Evaluation of nadolol in treatment of hypertension. [1980]. [Clinical trials]

VC19 _____. Hepatitis and dentistry. [1980]. [Clinical trials]

VC20 _____. Nafcillin therapy of staphylococcal bacteremia. [1980]. [Clinical trials]

VC21 _____. Oxprenolol vs. propranolol in hypertension. [1980]. [Clinical trials]

VC22 _____. Platelet aggregation in diabetes (use of ASA & persantine). [1980]. [Clinical trials]

VC23 _____. Pneumococcal capsular vaccine immunity in high risk patients. [1980]. [Clinical trials]

VC24 _____. Prazosin vs. hydralazine in hypertension. [1980] [Clinical trials]

VC25 _____. Renal failure self-care dialysis (hemo vs. peritoneal dialysis). [1980]. [Clinical trials]

VC26 _____. Treatment and prevention of infection-induced urinary stones in spinal cord injuries. [1980]. [Clinical trials]

VC27 _____. Vasodilators used in chronic heart failure (CSP 153). [1980]. [Clinical trials]

VC28 _____. Vasodilators used in chronic heart failure (CSP 19). [1980]. [Clinical trials]

Ongoing Assessments

VC29 _____. A five year clinical evaluation of alternative crown and bridge systems (NIDR). Ongoing. [Clinical trials]

VC30 _____. A new strategy to preserve the larynx in treatment of advanced laryngeal cancer. Ongoing. [Clinical trials]

VC31 _____. A prospective randomized cooperative study of cochlear implants. Ongoing. [Clinical trials]

VC32 _____. A prospective randomized trial of medical and surgical therapies for gastroesophageal reflux disease. Ongoing. [Clinical trials]

VC33 _____. A randomized study of prostatic surgery for moderately symptomatic benign prostatic hyperplasia in elderly men. Ongoing. [Clinical trials]

VC34 _____. Antiplatelet therapy after coronary artery by-pass graft (CABG) surgery-I. Ongoing. [Clinical trials]

VC35 _____. Antiplatelet therapy after coronary artery bypass graft (CABG) surgery-II. Ongoing. [Clinical trials]

VC36 _____. Asymptomatic carotoid stenosis etiological importance in development of stroke. Ongoing. [Clinical trials]

VC37 _____. Clinical comparison of base metal alloys vs. a gold alloy used in the fabrication of fixed (crown and bridge) restorations. Ongoing. [Clinical trials]

VC38 _____. Clinical studies of biphasic calcium phosphate ceramic in peridontal osseous defects. [Clinical trials]

VC39 _____. Comparative efficacy of vascular by-pass graft materials in lower extremity revascularization. Ongoing. [Clinical trials]

VC40 _____. Cooperative clinical trial of sclerotherapy for esophageal varices in alcoholic liver disease. Ongoing. [Clinical trials]

VC41 _____. Coronary artery surgery I: stable angina (vein by-pass). Ongoing. [Clinical trials]

VC42 _____. Coronary artery surgery II: unstable angina (vein by-pass). Ongoing. [Clinical trials]

VC43 _____. Dental implants (removable vs. permanent dentures). Ongoing. [Clinical trials]

VC44 _____. Detection and treatment of influenza A infections in high risk ambulatory care patients. Ongoing. [Clinical trials]

VC45 _____. Efficacy and toxicity of carbamazepine vs. valproic acid for partial seizures. Ongoing. [Clinical trials]

VC46 _____. Evaluations of corticosteroid therapy in severe sepsis. Ongoing. [Clinical trials]

VC47 _____. Lithium treatment in alcohol dependence. [Clinical trials]

VC48 _____. Monotherapy of hypertension. Ongoing. [Clinical trials]

VC49 _____. Percutaneous transluminal angioplasty in the lower extremity. Ongoing. [Clinical trials]

VC50 _____. Percutaneous transluminal coronary angioplasty (PTCA). Ongoing. [Clinical trials]

VC51 _____. Prognosis and outcome following heart valve replacement (non-biological vs. tissue). Ongoing. [Clinical trials]

VC52 _____. Prospective evaluation of the efficacy & tolerance of oral trimethoprim sulfamethoxazole prophylaxis in granulocytopenic patients with acute non-lymphocytic leukemia. Ongoing. [Clinical trials]

VC53 _____. Protein-calorie therapy in combination with anabolic steroids in alcoholic hepatitis. Ongoing. [Clinical trials]

VC54 _____. Randomized clinical trial of total parenteral nutrition in malnourished surgical patients. Ongoing. [Clinical trials]

VC55 _____. Spontaneous pneumothorax. Ongoing. [Clinical trials]

VC56 _____. Stroke prevention in non-valvular atrial fibrillation. Ongoing. [Clinical trials]

VC57 _____. Treatment of AIDS and AIDS related complex. Ongoing. [Clinical trials]

VC58 _____. Treatment of multiple myeloma directed by in vitro chemosensitivity testing. Ongoing. [Clinical trials]

VC59 _____. Vasodilators used in chronic heart failure-II. Ongoing. [Clinical trials]

VETERANS ADMINISTRATION HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (152)

810 Vermont Avenue NW
Washington, DC 20420
In collaboration with:
Special Projects Office
VA Medical Center (152)
Perry Point, MD 21902
301-642-2411
Contact: Prakash L. Grover, Ph.D., Chief, Special Projects Office.

Overview: The Veterans Administration Health Services Research and Development Service (VA-HSR&D) works to improve the health care of veterans by supporting research on the planning, organization, management, delivery, utilization, and evaluation of health care. The overall purpose is to generate information and to improve

understanding of how health services may be provided more effectively, efficiently, and at lower cost without compromising quality of care.

The Special Projects Office (SPO) was created in August 1984 to provide scientific, educational, and administrative support to the VA-HSR & D system through the VA Central Office, Washington, DC. The SPO was fully staffed in March 1985, plans for a technology assessment system were developed during the spring 1985, and activities began in June 1985.

Purpose: To monitor and evaluate emerging and new health care technologies and to provide information needed by policy-makers and managers regarding adoption and acquisition of such technologies in the VA health care system; and to identify emerging or new technologies that may be useful for improving the health care of veterans.

Primary intended users: Physicians, acute facility administrators, long-term care facility administrators, government regulators, public policy-makers, legislators.

Technologies: *Device*, medical or surgical procedure, support system, organizational or administrative system.

The SPO assesses any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient health and quality of life, or facilitate the provision of health care services. It examines processes of health care delivery aimed at achieving outcomes such as improved health, improved quality of life, optimal use of resources, lower costs, and rational use of health services.

Intervention: *Diagnosis*, prevention, treatment, rehabilitation.

Stage: *New*, emerging.

Properties: *Cost-effectiveness*, safety, efficacy, effectiveness, cost, service requirements, economic implications.

Assessments primarily focus on the technical characteristics, established and potential clinical applications, cost-effectiveness, and capital costs of a medical technology. There is some attention to the safety, efficacy, service requirements, and system impact (i.e., on the VA health care system). When appropriate, modeling is conducted to determine levels of potential utilization and application in veteran populations.

Selection process: System level managers in the VA Central Office request that an assessment be conducted. Requests are made to the SPO through the HSR&D in the Office of the Assistant Chief Medical Director, Research and Development.

Senior managers in the VA Central Office set assessment topic priorities depending on the projected needs of the VA health care system and financial considerations. Highest priority is given to the assessment of tangible technologies (e.g., diagnostic imaging equipment) that have costs expected to (1) exceed $100,000 per unit, (2) in the aggregate exceed $1,000,000 per year, or (3) result in annual use costs that in the aggregate exceed $10,000,000.

Methods: *Information syntheses*, expert opinion, modeling, cost analyses, epidemiological and other observational methods.

The SPO normally synthesizes existing knowledge from the medical, health services, and health policy literature with the assistance of expert consultants. The staff identifies and works with an expert panel of consultants, identifies and reviews published and unpublished literature, solicits expert opinion, analyzes and synthesizes this information, and develops a draft final report. The draft report is reviewed by VA Central Office managers and expert VA and non-VA consultants. No consensus of expert opinion is developed for the content or findings of the report. The final report generally concerns the technical attributes of the technology, clinical effectiveness, capital acquisition, operational costs, cost-effectiveness, and a summary of findings.

The average turnaround time from selection of assessment topic to reporting of findings is 9 months with a range from 6 to 15 months. The amount of time and the resources needed to conduct an assessment vary, depending on the amount of available information and whether it is necessary to collect and analyze primary data.

Assessors: The SPO has a staff of three permanent health science specialists that spend some portion of their time in technology assessment activity. Areas of expertise include health care, social science, statistics, public health, and evaluation. Outside consultants are contracted to conduct review and draft reports. Consultants are recruited from universities, private research organizations, and the government.

Assessment reports include: Abstract; the purpose of the assessment; relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes; who conducted the assessment; description of the technology; stage of life-cycle of technology when assessed; properties assessed; procedure used for the assessment; sources of data/information; methods for collecting data/ information; methods for analyzing/synthesizing data/ information; results; findings or conclusions; limitations of findings; implications of findings for practice; recommendations for practice, future assessments, technology development, research.

Two types of reports have been developed: a technology assessment information synthesis and a technology assessment. The information synthesis reports are more narrowly focused on new and emerging medical technologies or specific issues in technology assessment. A technology assessment involves a more comprehensive evaluation of the performance standards; safety; efficacy; clinical effectiveness; cost-effectiveness; the immediate and long-term social, economic, and organizational consequences of the new medical technology; and guidance on policy questions regarding its acquisition and use. The information synthesis report usually covers one or more of the issues within a technology assessment.

Dissemination: Printed reports, journal articles.

Following approval by the VA Central Office, the SPO disseminates reports to the VA Central Office managers and VA medical center clinicians and administrators. On request, the reports are transmitted to other government agencies, universities, professional associations, and private organizations. Copies of the reports may be obtained by contacting the SPO at 301-642-2411 Ext. 5442 or the Director, HSR & D, VA Central Office (152), 810 Vermont Ave. NW, Washington, DC 20420, 202-233-2666.

Budget: $100,000. The approximate cost per assessment is $30,000 to $50,000. Funding source: 100 percent parent organization.

Use: The Chief Medical Director of the VA recently commissioned a task force to develop policy options on technology assessment, including those focusing on formalizing ways to use the products of assessment in planning the acquisition and location of new medical technology for the VA.

Completed Reports

VH1 Health Systems Research and Development Division. [Veterans Administration] Management of technology assessment. Perry Point, MD: Special Projects Office, Health Systems Research and Development Division, Veterans Administration, in preparation, expected 1987.

VH2 Health Systems Research and Development Division. [Veterans Administration] Technology assessment of magnetoencephalography (MEG). Perry Point, MD: Special Projects Office, Health Systems Research and Development Division, Veterans Administration, in preparation, expected August 1987.

VH3 Goldschmidt PG. [Veterans Administration] Health services research and development: the Veterans Administration program. Health Serv Res 1986;20(6):Part II 789-824.

VH4 Health Services Research and Development Service. [Veterans Administration] Nuclear magnetic resonance imaging: information synthesis on clinical applications and cost considerations. Perry Point, MD: Special Projects Office, Health Services Research and Development, Veterans Administration, April 1986.

VH5 Health Services Research and Development Service. [Veterans Administration] Technology assessment of extracorporeal shock wave lithotripsy (ESWL). Perry Point, MD: Special Projects Office, Health Services Research and Development, Veterans Administration, 1986.

VH6 Health Services Research and Development Service. [Veterans Administration] The cost-effectiveness of lithotripsy: an information synthesis. Perry Point, MD: Special Projects Office, Health Services Research and Development, Veterans Administration, 1986.

ASSESSMENT REPORT CODE PREFIXES

The assessment report citations listed in Part 1 are grouped by sponsoring assessment program. Each citation has been assigned a unique code consisting of a prefix designating the sponsoring program and a sequential report number. This list contains all the report code prefixes and the corresponding program. The prefixes are arranged alphabetically; the first letter of the prefix is the first initial of a program's name. The Index to Assessment Report Citations guides the user to a specific report code.

Prefix Program Name

AA -American Academy of Neurology, Practice Committee
AB -American Academy of Ophthalmology, Ophthalmic Procedures Assessment Program
AC -American Academy of Pediatrics
AD -American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures
AE -American College of Obstetricians and Gynecologists, Committee Opinions
AF -American College of Obstetricians and Gynecologists, Committee on Technical Bulletins
AG -American College of Physicians, Clinical Efficacy Assessment Project
AH -American College of Radiology, Task Force on Breast Cancer
AJ -American Dental Association, Council on Dental Materials, Instruments, and Equipment
AK -American Dental Association, Council on Dental Therapeutics
AL -American Diabetes Association
AM -American Gastroenterological Association, Patient Care Committee
AN -American Hospital Association, Hospital Technology Series Program
AO -American Medical Association, Council on Scientific Affairs
AP -American Medical Association, Diagnostic and Therapeutic Technology Assessment
AQ -American Medical Association, Drug Evaluations
AS -American Society for Gastrointestinal Endoscopy
BA -Battelle Memorial Institute
BC -Blue Cross and Blue Shield Association, Medical Necessity Program
BS -Blue Cross and Blue Shield Association, Technology Evaluation and Coverage Program
BU -Brandeis University Health Policy Center
CA -California Medical Association
CB -Centraal Begeleidingsorgaan voor de Intercollegiale Toetsing, National Organization for Quality Assurance in Hospitals
CP -College of American Pathologists
CU -Congress of the United States, Office of Technology Assessment
DC -Duke University, Center for Health Policy Research and Educating
EH -ECRI Health Devices Program
ET -ECRI Technology Assessment Program
FA -Food and Drug Administration, Center for Devices and Radiological Health
FD -Food and Drug Administration, Center for Drugs and Biologics

Prefix	Program Name
GU	-Georgetown University Medical Center, Institute for Health Policy Analysis
HA	-Harvard School of Public Health, Institute for Health Research
HC	-Hastings Center
HF	-Health Care Financing Administration, Office of Research and Demonstrations
HN	-Health Council of The Netherlands
HW	-Health and Welfare Canada
JH	-Johns Hopkins Program for Medical Technology and Practice Assessment
KF	-Kings Fund Centre for Service Development
LE	-Lewin and Associates, Inc.
LU	-Linköping University, Center for Medical Technology Assessment
MG	-McGill University, Department of Epidemiology and Biostatistics
MM	-McMaster University, Department of Clinical Epidemiology and Biostatistics
MR	-Medical Research Council, Canada
MT	-Medical Technology and Practice Patterns Institute
NA	-National Center for Health Services Research and Health Care Technology Assessment, Division of Extramural Research
NC	-National Center for Health Services Research and Health Care Technology, Office of Health Technology Assessment
ND	-National Health Research and Development Program (Canada)
NH	-National Heart, Lung, and Blood Institute
NK	-National Institute of Child Health and Human Development
NL	-National Institutes of Health, Consensus Development Program
NM	-National Library of Medicine
NS	-Netherlands Organization for Applied Scientific Research
PA	-Policy Analysis, Inc.
PH	-Project HOPE
PP	-Prospective Payment Assessment Commission
SC	-Steering Committee on Future Health Scenarios
SP	-Swedish Planning and Rationalization Institute of the Health Services
UA	-United Kingdom Department of Health and Social Security
UB	-U.S. Administrators, Inc.
UF	-University of California, San Francisco, Institute for Health Policy Studies
UL	-University of Lausanne, Institute of Social and Preventive Medicine
UP	-University of Pennsylvania, Leonard Davis Institute of Health Economics
VC	-Veterans Administration, Cooperative Studies Program
VH	-Veterans Administration, Health Services Research and Development Service

Index to Report Citations

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PART 2 TECHNOLOGY THESAURUS AND ASSESSMENT REPORT CITATIONS

PART 2

TECHNOLOGY THESAURUS AND ASSESSMENT REPORT CITATIONS

This part has two major sections: a 1,200-term technology thesaurus beginning on page 313, and a listing of assessment report citations by technology beginning on page 361. The listing of assessment report citations is arranged according to the terminology set forth in the technology thesaurus. Referring to the technology thesaurus first is the best way to search for assessment report citations by technology.

To enhance searching, the thesaurus includes many synonyms, acronyms, and cross-references, and indicates broader and narrower terms to lead users to desired citations. The thesaurus uses the following reference terms:

BT	indicates to the user a broader term under which additional citations may be listed. Most, but not all, **BTs** have additional citations. Some terms have more than one **BT.** This is the complementary reference to **NT.**
NT	indicates to the user a narrower term under which additional citations are listed. This is the complementary reference to **BT**.
SEE	refers the user to a searchable term, i.e. a synonym or closely related term under which citations are listed, from a non-searchable term. This is the complementary reference to **x.**
x	indicates a non-searchable term, i.e. a synonym or closely related term, from which the user may have been referred to the present searchable term. This is the complementary reference to **SEE.**
SEE ALSO	refers the user to a related, though not necessarily synonymous, searchable term.

TECHNOLOGY THESAURUS

Absorptiometry	
x	Radiographic absorptiometry
BT	Bone mineral studies
—Dual photon	
—ingle photon	
Acetaminophen	
BT	Analgesics
	Antipyretics
Acetohydroxamic acid	
BT	Antiurolithics
Acidulated phosphate fluoride	
x	APF
BT	Dental materials
Acoustic impedance tests	
x	Tympanometry
BT	Audiometry tests
Activated prothrombin-complex concentrate	
SEE	Anti-inhibitor coagulant complex
Acupuncture	
BT	Alternative medicine
	Pain therapy
Acute Physiology and Chronic Health Evaluation	
SEE	APACHE
Acyclovir	
BT	Antivirals
Adenoidectomy	
BT	Surgery
Adhesives	
NT	Bone cements
	Cyanoacrylates
Adjuvant chemotherapy, Breast cancer	
SEE	Chemotherapy—Cancer
Admission testing, Routine	
SEE ALSO	specific diagnostic tests, procedures, e.g. Radiography
Adrenal cortex hormones	
x	Adrenocorticoids
	Corticosteroids
BT	Hormones
	Steroids
NT	Androgens
	Estrogens
	Glucocorticoids
	Progestins
Adrenergic beta receptor blockaders	
SEE	Beta blockers
Adrenocorticoids	
SEE	Adrenal cortex hormones
Aerosol therapy	
BT	Respiratory therapy
SEE ALSO	Nebulizers
AFP monitoring	
SEE	Alpha fetoprotein assays
	Maternal serum alpha fetoprotein monitoring
AIDS tests	
SEE	HIV detection assays

Albuterol	
BT	Bronchodilators
Alclometasone diproprionate	
BT	Anti-inflammatory agents
	Glucocorticoids
Alcohol-abuse deterrents	
NT	Disulfiram
Alcoholism screening	
Allergy-immunology tests	
BT	Diagnostic tests
NT	Challenge food testing
	Cytotoxic food testing
	ELISA
	Immunoradiometric assays
	Intracutaneous titration
	Migration inhibition test
	Patch tests
SEE ALSO	Immunoassay systems, Fluorescence
Allogenic bone marrow transplantation	
SEE	Transplantation—Bone marrow, Allogenic
Allopurinol	
BT	Antigout agents
	Antihyperuricemics
	Antiurolithics
Alpha fetoprotein assays	
x	AFP monitoring
	Alpha fetoprotein monitoring
BT	Maternal serum alpha fetoprotein monitoring
	Oncology tests
SEE ALSO	Tumor markers
Alpha fetoprotein monitoring	
SEE	Alpha fetoprotein assays
	Maternal serum alpha fetoprotein monitoring
Alpha receptor blocking agents	
NT	Dihydroergotamine
	Yohimbine
Alprazolam	
BT	Antianxiety agents
Alprostadil	
BT	Ductus arteriosus patency adjuncts
	Prostaglandins
Alternative medicine	
NT	Acupuncture
Amantadine	
BT	Antivirals
Ambulances	
SEE ALSO	Intensive care systems, Mobile
Ambulatory surgery	
SEE	Surgery—Ambulatory
Amcinonide	
BT	Glucocorticoids
Amiloride	
BT	Diuretics
Amino acids	
BT	Metabolic and nutrient agents
Aminocaproic acids	
BT	Antihemorrhagics
Aminoglutethimide	
BT	Antiadrenals
Aminophylline	
BT	Bronchodilators
	Diuretics
SEE ALSO	Theophylline
Amoxicillin	
BT	Antibiotics
Anabolic steroids	
SEE	Protein-calorie therapy with anabolic steroids
Analgesia	
SEE	Pain therapy
Analgesics	
NT	Acetaminophen
	Aspirin
	Benoxaprofen
	Buprenophine
	Narcotic analgesics

Nonsteroidal anti-inflammatory analgesics
Zomepirac sodium
SEE ALSO Pain therapy

Androgens
BT Adrenal cortex hormones
Sex hormones
SEE ALSO Protein-calorie therapy with anabolic steroids

Anesthesia
NT Dental anesthesia
Gas scavengers
SEE ALSO Anesthetics

—Epidural
—Inhalation

Anesthetics
NT Bupivacaine
Etomidate
Lidocaine
SEE ALSO Anesthesia

Angiographic injectors
SEE ALSO Angiography

Angiography
NT Arteriography
Digital subtraction angiography
Lymphangiography
Radionuclide angiography
SEE ALSO Angiographic injectors
Cardiac catheterization
Coronary artery disease diagnosis

Angioplasty
BT Surgery
NT Laser angioplasty
Percutaneous transluminal angioplasty
SEE ALSO Balloon dilatation catheters

Antabuse
SEE Disulfiram

Anthelmintics
BT Antiparasitics
NT Niclosamide
Praziquantel

Antiacne agents
NT Isotretinoin

Antiadrenals
NT Aminoglutethimide

Antiallergic agents
NT Disodium cromoglycate

Antianxiety agents
x Tranquilizers
BT Psychoactive drugs
NT Alprazolam
Clorazepate
Diazepam
Halazepam
Lactates
Lithium
Temazepam
Triazolam

Anti-arrhythmics
NT Digitalis
Digoxin
Disopyramide

Antiarthritics
NT Benoxaprofen
Esterine
Methotrexate
Metronidazole
Penicillamine

Antibacterials
BT Antibiotics
NT Cephalosporins
Chlorhexidine
Hexachlorophene
Sulfamethoxazole
Trimethoprim

Antibiotics
NT Amoxicillin
Antibacterials
Antifungal agents
Antiparasitics
Antiprotozoals
Antivirals
Azlocillin
Bacampicillin
Erythromycin
Mezlocillin

Metronidazole
Nafcillin
Piperacillin
Silver sulfadiazine
Sisomicin
Tobramycin
Trimethoprim

—Intravenous
—Prophylactic

Antibodies
SEE
Monoclonal antibodies

Antibody tests
SEE
DNA antibody test
HIV detection assays
Rubella tests

Anticholinergics
Anticoagulants
NT
Heparin
Warfarin

Anticonvulsants
NT
Carbamazepine
Magnesium sulfate
Phenobarbital
Phenytoin
Primadone
Valproate

Antidepressants
BT
Psychoactive drugs
NT
Trazodone
Tryptophan

Antidyskinetics
NT
Levodopa

Antifungal agents
BT
Antibiotics
NT
Ciclopirox
Clotrimazole
Econazole
Ketoconazole
Miconazole nitrate
Selenium sulfide
Sporicidin
Tioconazole

Antiglaucoma agents
NT
Timolol

Antigout agents
NT
Allopurinol
Sulfinpyrazone

Antihemorrhagics
x
Hemostatic drugs
NT
Aminocaproic acids
SEE ALSO
Hemostatic materials

Antihistamines
NT
Azatadine
Chlorpheniramine

Antihyperlipidemics
NT
Cholestryamine
Gemfibrozil

Antihyperprolactinemics
NT
Bromocriptine

Antihypertensives
NT
Bethanidine sulfate
Captopril
Captopril with hydrochlorothiazide
Clonidine
Enalapril
Guanabenz
Guanadrel sulfate
Hydralazine
Methyldopa
Metolazone
Nitroprusside
Prazosin
Reserpine
Reserpine with chlorthalidone
Saralasin

Antihyperuricemics
NT
Allopurinol
Sulfinpyrazone

Anti-inflammatory agents
NT
Alclometasone dipropionate
Aspirin
Benoxaprofen
Dimethyl sulfoxide

Anti-inhibitor coagulant complex	
x	Activated prothrombin-complex concentrate
	Prothrombin-complex concentrate
Antilymphocyte serum	
BT	Immunosuppressants
Antimanics	
NT	Lithium
Antineoplastics	
NT	Carmustine
	Cyclophosphamide
	Dacarbazine
	Estramustine
	Interferons
	Methotrexate
	Streptozocin
	Tamoxiphen
SEE ALSO	Antineoplastics handling
	Chemotherapy—Cancer
Antineoplastics handling	
SEE ALSO	Antineoplastics
Antiparasitics	
BT	Antibiotics
NT	Anthelmintics
	Insecticides
Antiplatelet therapy	
Antiprotozoal agents	
BT	Antibiotics
NT	Pyrimethamine
	Sulfadoxine
Antipruritics	
NT	Camphor
Antipsoriatics	
NT	Methotrexate
	Methoxsalen
SEE ALSO	PUVA therapy
Antipsychotics	
BT	Psychoactive drugs
NT	Rubidium
Antipyresis	
SEE ALSO	Antipyretics
Antipyretics	
NT	Acetaminophen
	Aspirin
	Benoxaprofen
	Ibuprofen
SEE ALSO	Antipyresis
Antiseborrheic agents	
NT	Selenium sulfide
Antispasmodics	
NT	Oxybutynin chloride with metoclopramide
Antithymocyte serum	
BT	Immunosuppressants
Antitussives	
NT	Dextromethorphan
Antiulcer agents	
NT	Gastric acid secretion inhibitors
	Sucralfate
Antiurolithics	
NT	Acetohydroxamic acid
	Allopurinol
	Penicillamine
Antivirals	
BT	Antibiotics
NT	Acyclovir
	Amantadine
	Interferons
	Vidarabine
Aortocoronary bypass	
SEE	Coronary artery bypass grafting
APACHE	
x	Acute Physiology and Chronic Health Evaluation
APF	
SEE	Acidulated phosphate fluoride

Apheresis	
NT	Plasma exchange
	Plasma perfusion
	Plasmapheresis
SEE ALSO	Plasma separation systems
Apnea monitoring	
SEE ALSO	Apnea monitors
Apnea monitors	
SEE ALSO	Apnea monitoring
	Physiologic monitoring systems
Appetite suppressants	
NT	Diethylpropion
	Phenylpropranolamine
Appointment reminders	
SEE	Reminder systems
Appropriateness Evaluation Protocol	
Arrhythmia monitoring	
BT	Electrocardiography
SEE ALSO	Arrhythmia monitors
Arrhythmia monitors	
SEE ALSO	Arrhythmia monitoring
Arteriography	
BT	Angiography
NT	Ultrasound—Arteries
Arthritis tests	
SEE	Rheumatology tests
Arthroscopy	
BT	Endoscopy
Artificial heart	
BT	Circulatory assistance
Artificial hip	
SEE	Hip joint replacement
	Hip prothesis
Artificial intelligence	
SEE	Expert systems
Artificial pancreas	
Artificial procreation	
NT	In vitro fertilization
Artificial sweeteners	
BT	Metabolic and nutrient agents
NT	Aspartame
	Saccharin
	Sorbitol
	Xylitol
Aspartame	
BT	Artificial sweeteners
Aspirin	
BT	Analgesics
	Antipyretics
	Anti-inflammatory agents
Assertiveness training	
Assessment methods	
NT	Clinical trials
	Cost benefit/effectiveness analysis
	Double blinding
	Postmarketing surveillance
Asthma prophylactics	
NT	Disodium cromoglycate
Atenolol	
BT	Beta blockers
Attention deficit disorder therapy	
SEE	Methylphenidate
Audiometry tests	
BT	Diagnostic tests
NT	Acoustic impedance test
Autologous blood transfusion	
SEE	Blood transfusion—Autologous
Autologous bone marrow transplantation	
SEE	Transplantation—Bone marrow, Autologous
Automated microbiology systems	
Automobile passenger restraints	
x	Car seats
	Seat belts (Automobile)

Autopsy	
Autotransfusion units	
BT	Blood transfusion systems
Aversion therapy	
Azatadine	
BT	Antihistamines
Azathioprine	
BT	Immunosuppressants
Azlocillin	
BT	Antibiotics
B-mode scanning	
SEE	Ultrasonography
Bacampicillin	
BT	Antibiotics
Bacterial antigens	
Balance training devices	
Balloon angioplasty	
SEE	Percutaneous transluminal angioplasty
Balloon dilatation catheters	
x	Dilatation catheters
SEE ALSO	Angioplasty
	Percutaneous balloon valvuloplasty
Bar codes	
Barbiturates	
BT	Sedatives
Barium enema with sigmoidoscopy	
SEE ALSO	Cancer screening, Colorectal Sigmoidoscopy
Batteries, Electric	
BCG immunotherapy	
BT	Immunotherapy—Cancer
BCG vaccine	
BT	Vaccines
BCNU	
SEE	Carmustine
BEAM	
SEE	Brain electrical activity mapping
Beclomethasone	
BT	Glucocorticoids
Beds, Electric	
Behavioral disorders screening	
Behavioral therapy	
Bendien's test	
BT	Oncology tests
Benoxaprofen	
BT	Analgesics
	Antiarthritics
	Anti-inflammatory agents
	Antipyretics
Bentonite flocculation test	
x	DNA-bentonite flocculation test
BT	Rheumatology tests
Benzyl alcohol	
Beta blockers	
x	Adrenergic beta receptor blockaders
NT	Atenolol
	Labetalol
	Metoprolol
	Nadolol
	Oxprenolol
	Pindolol
	Propranolol
Beta-carotene	
SEE ALSO	Vitamin A
Betamethasone	
BT	Glucocorticoids
Bethanidine sulfate	
BT	Antihypertensives

Bibliographic information bases	
x	Computer databases
	Databases
BT	Information systems
NT	CHEMLINE
	HISTLINE
	MEDLINE
	TOXLINE
SEE ALSO	Computer-assisted instruction
	Computer-assisted patient care
	Data banks
—Training	
Bicap probe treatment	
SEE	Endoscopy and electrocoagulation
Bilio-pancreatic bypass	
BT	Surgery—Morbid obesity
Bilirubinometers	
Biochemical analyzers	
SEE ALSO	Biochemical profiles
Biochemical profiles	
BT	Diagnostic tests
SEE ALSO	Biochemical analyzers
Biofeedback	
x	Electromyographic biofeedback
Biopsy	
BT	Diagnostic tests
	Surgery
—Endometrial	
—Fetal blood	
—Renal	
Blood banks	
SEE ALSO	Blood transfusion
Blood cell count	
BT	Cell counts
	Hematology tests
Blood chemistry analyzers	
SEE ALSO	Blood gas monitors
	Blood glucose monitors
Blood cultures	
BT	Infectious disease tests
Blood gas monitoring	
BT	Cardiopulmonary tests
SEE ALSO	Blood gas monitors
Blood gas monitors	
x	Carbon dioxide monitors
NT	Oximeters
SEE ALSO	Blood chemistry analyzers
	Blood gas monitoring
	Oxygen analyzers
Blood glucose control devices	
SEE ALSO	Blood glucose monitors
Blood glucose monitoring	
BT	Endocrinology-metabolism tests
SEE ALSO	Blood glucose monitors
Blood glucose monitors	
SEE ALSO	Blood chemistry analyzers
	Blood glucose control devices
	Blood glucose monitoring
Blood pressure monitoring	
x	Sphygmomanometry
SEE ALSO	Blood pressure monitors
Blood pressure monitors	
x	Sphygmomanometers
SEE ALSO	Blood pressure monitoring
	Physiologic monitoring systems
Blood substitutes	
Blood transfusion	
BT	Transfusion
SEE ALSO	Blood banks
	Blood transfusion systems
	Infectious disease tests
—Autologous	
Blood transfusion systems	
NT	Autotransfusion units
SEE ALSO	Blood transfusion
	Granulocyte transfusion

Blood urea concentration	
BT	Kidney function tests
Blood warmers	
Bolen's test	
BT	Oncology tests
Bone cements	
BT	Adhesives
SEE ALSO	Bone prosthesis
	Joint prosthesis
Bone densitometry	
SEE	Bone mineral studies
Bone growth stimulation	
x	Electrical stimulation—Bone growth
SEE ALSO	Bone growth stimulators
Bone growth stimulators	
SEE ALSO	Bone growth stimulation
Bone marrow transplantation	
SEE	Transplantation—Bone marrow
Bone mineral studies	
x	Bone densitometry
	Densitometry
	Photodensitometry
	Radiogrammetry
BT	Endocrinology-metabolism tests
NT	Absorptiometry
	Computed tomography—Bone mineral
Bone prosthesis	
SEE ALSO	Bone cements
	Joint prosthesis
Boston elbow	
SEE	Elbow prosthesis
Botulinum toxin	
BT	Neurotoxins
Brain electrical activity mapping	
x	BEAM
SEE ALSO	Electroencephalography
	Evoked potentials
Breast cancer screening	
SEE	Cancer screening—Breast
Breast feeding	
Breast imaging	
NT	Mammography
	Thermography—Breast
	Transillumination—Breast
	Ultrasonography—Breast
SEE ALSO	Breast physical examination
	Cancer screening—Breast
Breast physical examination	
SEE ALSO	Breast imaging
	Cancer screening—Breast
Breath tests	
BT	Gastroenterology tests
Bromocriptine	
BT	Antihyperprolactinemics
Bronchodilators	
NT	Albuterol
	Aminophylline
	Ephedrine
	Iodide therapy
	Theophylline
Bumetanide	
BT	Diuretics
Bupivacaine	
BT	Anesthetics
Buprenorphine	
BT	Analgesics
Burn units	
SEE ALSO	Supportive care
Bypass graft materials	
CABG	
SEE	Coronary artery bypass grafting
CAD	
SEE	Computer-aided design

Caerulein	
x	Ceruletide
BT	Diagnostic agents
CAI	
SEE	Computer-assisted instruction
Calcium channel blockers	
NT	Diltiazem
	Nifedipine
	Verapamil
Calcium chloride	
BT	Metabolic and nutrient agents
Camphor	
BT	Antipruritics
Cancer screening	
SEE ALSO	Oncology tests
—Breast	
SEE ALSO	Breast imaging
	Breast physical examination
—Cervical	
SEE ALSO	Pap smear
—Colorectal	
SEE ALSO	Barium enema with sigmoidoscopy
	Colonoscopy
	Sigmoidoscopy
	Stool guaiac
—Lung	
Cannabis	
x	Marijuana
CAPD	
SEE	Continuous ambulatory peritoneal dialysis
Capitation payment	
x	Prepayment
SEE ALSO	Competition
	Health maintenance organizations
	Incentive payment
	Prospective payment systems
Capsule method	
Captopril	
BT	Antihypertensives
Captopril with hydrochlorthiazide	
BT	Antihypertensives
SEE ALSO	Hydrochlorthiazide
Car seats	
SEE	Automobile passenger restraints
Carbamazepine	
BT	Anticonvulsants
Carbon dioxide laser surgery	
SEE	Laser surgery—Carbon dioxide
Carbon dioxide lasers	
SEE	Lasers—Carbon dioxide
Carbon dioxide monitors	
SEE	Blood gas monitors
Carcinoembryonic antigen assays	
x	CEA
BT	Oncology tests
SEE ALSO	Tumor markers
Cardiac catheterization	
x	Heart catheterization
BT	Surgery—Heart
SEE ALSO	Angiography
	Catheters
Cardiac enzyme assays	
BT	Cardiopulmonary tests
Cardiac monitors	
x	Heart monitors
NT	Electrocardiographs
Cardiac pacemakers	
SEE ALSO	Circulatory assistance
Cardiac rehabilitation	
BT	Rehabilitation
Cardiointegram	
BT	Coronary artery disease diagnosis
SEE ALSO	Electrocardiography

Cardiokymography	
x	Electrokymography
SEE ALSO	Coronary artery disease diagnosis
Cardiopulmonary tests	
BT	Diagnostic tests
NT	Blood gas monitoring
	Cardiac enzyme assays
	Ergonovine provocative testing
	Lipoprotein evaluation
Carmustine	
x	BCNU
BT	Antineoplastics
Carotid body resection	
BT	Surgery
Carotid endarterectomy	
BT	Surgery
Case management	
CAT scanners	
SEE	Computed tomography scanners
CAT scans	
SEE	Computed tomography
Cataract extraction	
BT	Surgery—Eye
SEE ALSO	Corneal endothelial cell microscopy
Catheters	
NT	Dilatation catheters
SEE ALSO	Cardiac catheterization
CEA	
SEE	Carcinoembryonic antigen assays
Cefotaxime	
BT	Cephalasporins
Cell counters	
NT	Leukocyte differential counters
SEE ALSO	Cell counts
Cell counts	
BT	Diagnostic tests
NT	Blood cell count
SEE ALSO	Cell counters
Centrifuges	
Cephalosporins	
BT	Antibacterials
NT	Cefotaxime
	Cephradine
	Moxalactam
Cephradine	
BT	Cephalasporins
Cerebral artery anastomosis	
BT	Surgery
SEE ALSO	Extracranial-intracranial arterial bypass
Cerebrospinal fluid shunt valves	
Ceruletide	
SEE	Caerulein
Cervical cancer screening	
SEE	Cancer screening—Cervical
Cervical cap	
BT	Contraception
Cervical dilators	
Cesarean section	
BT	Surgery
Challenge food testing	
x	Provocation tests
BT	Allergy-immunology tests
SEE ALSO	Cytotoxic food testing
Chelation therapy	
—Deferoxamine	
x	Hemoperfusion with deferoxamine
—EDTA	
—Penicillamine	
SEE ALSO	Penicillamine
Chemical Dictionary Online	
SEE	CHEMLINE

CHEMLINE	
x	Chemical Dictionary Online
BT	Bibliographic information bases
	MEDLARS
Chemonucleolysis	
x	Enzyme therapy
SEE ALSO	Chymopapain
Chemonucleolytics	
NT	Chymopapain
Chemotherapy—Cancer	
x	Adjuvant chemotherapy, Breast cancer
SEE ALSO	Antineoplastics
	In vitro chemosensitivity testing
Chlorhexidine	
BT	Antibacterials
Chlorpheniramine	
BT	Antihistamines
Chlorthalidone	
BT	Diuretics
SEE ALSO	Reserpine with chlorthalidone
Cholangiography	
SEE ALSO	Cholangiopancreatography
	Cholecystography
Cholangiopancreatography	
x	Endoscopic retrograde cholangiopancreatography
	ERCP
BT	Gastroenterology tests
SEE ALSO	Cholangiography
	Cholecystography
Cholecystectomy	
BT	Surgery
Cholecystography	
SEE ALSO	Cholangiography
	Cholangiopancreatography
Cholestryamine	
BT	Antihyperlipidemics
Chorionic villi sampling	
BT	Genetic screening
Chromatogenesis assist devices	
Chymopapain	
BT	Chemonucleolytics
SEE ALSO	Chemonucleolysis
Ciclopirox	
BT	Antifungal agents
Cimetidine	
BT	Histamine H2-receptor antagonists
Cine-CT	
BT	Computed tomography
Cingulotomy	
BT	Surgery
Circulatory assistance	
NT	Artificial heart
	External counterpulsation
	Intra-aortic balloon pumps
	Ventricular assist devices
SEE ALSO	Cardiac pacemakers
Circumcision	
BT	Surgery
Citrates	
SEE	Potassium citrate
Clinical ecology	
Clinical trials	
BT	Assessment methods
—Randomized	
Clonidine	
BT	Antihypertensives
Clorazepate	
BT	Antianxiety agent
Clotrimazole	
BT	Antifungal agents
Coagulation assays	
BT	Hematology tests
NT	Partial thromboplastin time
	Prothrombin time

Cochlear implantation
BT Surgery
SEE ALSO Cochlear implants
Cochlear implants
SEE ALSO Cochlear implantation
Hearing aids
Cochleostomy
BT Surgery
Codeine
NT Narcotic analgesics
Cognitive therapy
Collagen implants
BT Surgery
Colonoscopy
BT Gastrointestinal endoscopy
SEE ALSO Cancer screening—Colorectal
Colorectal cancer screening
SEE Cancer screening—Colorectal
Communication aids for the handicapped
Communication systems
NT Emergency communications systems
Satellite communication
Telemetry
SEE ALSO Information systems
Community health centers
Competition
NT Competitive bidding
SEE ALSO Capitation payment
Prospective payment systems
Competitive bidding
BT Competition
Computed tomography
x CAT scans
CT scans
Tomography, X-ray computed
BT Radiography
NT Cine-CT
Dual-energy scanned projection radiography
SEE ALSO Computed tomography scanners
SPECT imaging
Stereotactic neurosurgery, Computed tomography-assisted
—Bone mineral assessments
BT Bone mineral studies
—Head
—Liver and spleen
—Pancreas
—Spine
Computed tomography scanners
x CAT scanners
CT scanners
Tomographic scanners
BT Radiographic equipment
SEE ALSO Computed tomography
Computer-aided design
x CAD
Computer-assisted instruction
x CAI
BT Information systems
SEE ALSO Bibliographic information bases
Computer-assisted patient care
Computer equipment
Computer software
Computer-assisted patient care
NT Decision support systems
Expert systems
SEE ALSO Bibliographic information bases
Computer-assisted education
Computer equipment
Data banks
Medical record systems
Computer databases
SEE Bibliographic information bases
Data banks

Computer equipment	
x	Decision support systems
SEE ALSO	Computer-assisted education
	Computer-assisted patient care
	Computer software
	Expert systems
	MEDLINE—Optical disks
Computer software	
SEE ALSO	Computer equipment
Contact lens cleaners	
SEE ALSO	Contact lenses
Contact lens lubricants	
SEE ALSO	Contact lenses
Contact lens markers	
SEE ALSO	Contact lenses
Contact lenses	
NT	Contact lenses, Hydrophilic
SEE ALSO	Contact lens cleaners
	Contact lens lubricants
	Contact lens markers
Contact lenses, Hydrophilic	
BT	Contact lenses
Continuing medical education	
SEE	Physician education
Continuous ambulatory peritoneal dialysis	
x	CAPD
BT	Peritoneal dialysis
Continuous arteriovenous hemofiltration	
SEE	Hemofiltration
Continuous passive motion devices	
SEE ALSO	Continuous passive motion therapy
Continuous passive motion therapy	
BT	Exercise therapy
SEE ALSO	Continuous passive motion devices
Continuous positive airway pressure	
x	CPAP
BT	Respiratory therapy
Contraception	
NT	Cervical cap
	Oral contraceptives
	Tubal ligation
SEE ALSO	Estrogens
Contralateral breast surgery	
BT	Surgery—Breast
Contrast media	
SEE	Radiographic contrast dyes
Cornea transplantation	
SEE	Transplantation—Cornea
Corneal endothelial cell microscopy	
SEE ALSO	Cataract extraction
Corneal grafts	
BT	Surgery—Eye
Coronary artery bypass grafting	
x	Aortocoronary bypass
	CABG
	Coronary artery surgery
BT	Surgery—Heart
Coronary artery disease diagnosis	
SEE ALSO	Angiography
	Cardiointegram
	Cardiokymography
	Echocardiography
	Electrocardiography
	Exercise tests
	Photokymography
	Ultrasound—Cardiac output
Coronary artery jeopardy score	
Coronary artery surgery	
SEE	Coronary artery bypass grafting
	Percutaneous transluminal coronary angioplasty
Coronary care units	
Coronary care units, Mobile	
SEE	Intensive care systems, Mobile
Corticosteroids	
SEE	Adrenal cortex hormones

Cost benefit/effectiveness analysis	
BT	Assessment methods
Counseling	
NT	Genetic counseling
	Nutritional counseling
	Peer group counseling
CPAP	
SEE	Continuous positive airway pressure
CPT-4 codes	
x	Current Procedural Terminology
Creatinine concentration, Serum	
x	Serum creatinine concentration
BT	Kidney function tests
Cromolyn sodium	
SEE	Disodium cromoglycate
Cryometers	
SEE ALSO	Cryopreservation
Cryopreservation	
SEE ALSO	Cryometers
Cryosurgery	
BT	Surgery
—Arrhythmias	
CT scanners	
SEE	Computed tomography scanners
CT scans	
SEE	Computed tomography
Current Procedural Terminology	
SEE	CPT-4 codes
Cushions	
Cyanoacrylates	
BT	Adhesives
Cyclophosphamide	
x	Cytoxan
BT	Antineoplastics
Cyclothiazide	
BT	Diuretics
Cytotoxic food testing	
BT	Allergy-immunology tests
Cytotoxic tests	
SEE ALSO	Challenge food testing
Cytotoxic tests	
BT	Diagnostic tests
NT	Cytotoxic food testing
	Hair analysis
	Micronucleus test
Cytoxan	
SEE	Cyclophosphamide
Dacarbazine	
x	DTIC
BT	Antineoplastics
DAF	
SEE	Discretionary adjustment factor
Darkrooms	
SEE	Radiographic darkrooms
Data banks	
x	Computer databases
	Databases
SEE ALSO	Bibliographic information bases
	Computer-assisted patient care
	Information systems
	Registries
Databases	
SEE	Bibliographic information bases
	Data banks
Day care	
Debridement	
BT	Surgery
Decision support systems	
SEE	Computer-assisted patient care
	Computer equipment
	Information systems
Decubitus surgery	
BT	Surgery

Deferoxamine	
SEE	Chelation therapy—Deferoxamine
Defibrillation	
SEE ALSO	Defibrillators
Defibrillators	
SEE ALSO	Defibrillation
Densitometry	
SEE	Bone mineral studies
Dental alloys	
BT	Dental materials
Dental amalgam	
BT	Dental materials
SEE ALSO	Dental amalgamators
Dental amalgamators	
x	Dental equipment
SEE ALSO	Dental amalgam
Dental anesthesia	
BT	Anesthesia
Dental bonding	
SEE ALSO	Dental resins
Dental bridges	
Dental caries removal systems	
Dental ceramics	
BT	Dental materials
Dental crowns	
Dental equipment	
SEE	Dental amalgamators
	Dental scaling and stain-removal devices
	Dental sterilization devices
	Dental visible light-curing units
Dental implants	
x	Osseointegrated implants
Dental materials	
NT	Acidulated phosphate fluoride
	Dental alloys
	Dental amalgam
	Dental ceramics
	Dental resins
	Dental sealants
	Fluoride varnishes
	Toothpaste
Dental radiography	
x	Radiography, Dental X-rays, Dental
NT	Radiopaque plastics
Dental resins	
BT	Dental materials
SEE ALSO	Dental bonding
Dental scaling and stain-removal devices	
x	Dental equipment
Dental sealants	
BT	Dental materials
Dental sterilization devices	
x	Dental equipment
Dental visible light-curing units	
x	Dental equipment
Denture cleansers	
Dentures	
Depo-Provera	
SEE	Medroxyprogesterone
Desoximetasone	
BT	Glucocorticoids
Detoxification	
NT	Hubbard method
Developmental disabilities screening	
Dexamethasone	
BT	Glucocorticoids
SEE ALSO	Dexamethasone suppression test
Dexamethasone suppression test	
BT	Endocrinology-metabolism tests
SEE ALSO	Dexamethasone
Dextromethorphan	
BT	Antitussives

Dextrose	
BT	Metabolic and nutrient agents
Dextrose with saline solution	
BT	Metabolic and nutrient agents
Diagnosis related groups	
SEE	DRGs
Diagnostic agents	
NT	Caerulein
	Isosulfan blue
	Secretin
SEE ALSO	Radiographic contrast dyes
	Radiopharmaceuticals
Diagnostic imaging	
NT	Magnetic resonance imaging
	Positron emission tomography
	Radionuclide imaging
	Radiography
	Thermography
	Transillumination
	Ultrasonography
SEE ALSO	specific anatomical sites, e.g. Angiography; Breast imaging
Diagnostic tests	
NT	Allergy-immunology tests
	Audiometry tests
	Biochemical profiles
	Biopsy
	Cardiopulmonary tests
	Cell counts
	Cytotoxic tests
	Endocrinology-metabolism tests
	Fertility tests
	Gastroenterology tests
	Genetic tests
	Hematology tests
	Infectious disease tests
	Kidney function tests
	Microbiological testing systems
	Oncology tests
	Rheumatology tests
	Seromucoid assays
Dialysis	
NT	Hemodialysis
	Peritoneal dialysis
Diaphanography	
SEE	Transillumination
Diathermy	
Diazepam	
BT	Antianxiety agents
Diet therapy	
NT	Sodium restriction
	Protein-calorie therapy with anabolic steroids
SEE ALSO	Food diaries
	Ileal bypass with diet therapy
	Infant foods
	Nutritional counseling
Diethylpropion	
BT	Appetite suppressants
Diflunisal	
BT	Nonsteroidal anti-inflammatory analgesics
Digital imaging	
x	Digital radiography
NT	Digital subtraction angiography
	Dual-energy scanned projection radiography
SEE ALSO	Picture archiving and communication systems
	Radiography
Digital radiography	
SEE	Digital imaging
Digital subtraction angiography	
x	DSA
BT	Angiography
	Digital imaging
Digitalis	
BT	Anti-arrhythmics
Digoxin	
BT	Anti-arrhythmics
Dihydroergotamine	
BT	Alpha receptor blocking agents
	Vascular headache suppressants

Dilatation and curettage	
BT	Surgery
Dilatation catheters	
SEE	Balloon dilatation catheters
Diltiazem	
BT	Calcium channel blockers
Dimethyl sulfoxide	
x	DMSO
BT	Anti-inflammatory agents
Dipyridamole	
x	Persantine
BT	Vasodilators
Discography	
BT	Radiography
Discretionary adjustment factor	
x	DAF
BT	Prospective payment systems SEE ALSO DRGs
Disodium cromoglycate	
x	Cromolyn sodium
BT	Antiallergic agents
	Asthma prophylactics
Disopyramide	
BT	Anti-arrhythmics
Disposables reuse	
SEE	Reuse of disposables
Disulfiram	
x	Antabuse
BT	Alcohol-abuse deterrents
Diuretics	
NT	Amiloride
	Aminophylline
	Bumetanide
	Chlorthalidone
	Cyclothiazide
	Furosemide
	Hydrochlorthiazide
	Metolazone
	Triamterene
DMSO	
SEE	Dimethyl sulfoxide
DNA antibody test	
x	Antibody tests
BT	Rheumatology tests
DNA-bentonite flocculation test	
SEE	Bentonite flocculation test
Doman-Delacato treatment	
BT	Physical therapy
Dopamine	
BT	Vasopressors
Doppler ultrasound	
SEE	Ultrasound
Dosimetry	
SEE	Radiation measurement
Double blinding	
BT	Assessment methods
DRGs	
x	Diagnosis related groups
SEE ALSO	Discretionary adjustment factor
	Prospective payment systems
Drug costs	
Drug labeling	
Drug monitoring	
SEE	Therapeutic drug monitoring
Drug ordering	
x	Drug prescribing
	Prescribing
Drug preparation	
NT	Ethanol
Drug prescribing	
SEE	Drug ordering
Drug regulation	
DSA	
SEE	Digital subtraction angiography

DTIC	
SEE	Dacarbazine
Dual-energy scanned projection radiography	
BT	Computed tomography
	Digital imaging
Ductus arteriosus patency adjuncts	
NT	Alprostadil
ECG	
SEE	Electrocardiography
Echocardiography	
BT	Ultrasonography
SEE ALSO	Coronary artery disease diagnosis
Echocine	
SEE	Ultrasonography
ECMO	
SEE	Extracorporeal membrane oxygenation
Econazole	
BT	Antifungal agents
ECT	
SEE	Electroconvulsive therapy
Edinburgh masker	
EDTA	
SEE	Chelation therapy—EDTA
EEG	
SEE	Electroencephalography
EKG	
SEE	Electrocardiography
Elbow prosthesis	
x	Boston elbow
BT	Joint prosthesis
Electrical stimulation	
NT	Transcutaneous electrical nerve stimulation
SEE ALSO	Electrical stimulators
—Bone growth	
SEE	Bone growth stimulation
—Cardiac	
—Cerebellar	
—Cerebral palsy	
—Cranial	
—Facial nerve palsy	
—Muscular	
—Neural	
—Neuromuscular	
—Scoliosis	
—Spinal	
Electrical stimulators	
SEE ALSO	Bone growth stimulators
	Electrical stimulation
Electrocardiographs	
NT	Cardiac monitors
SEE ALSO	Electrocardiography
	Physiologic monitoring systems
Electrocardiography	
x	ECG
	EKG
NT	Arrhythmia monitoring
	Holter monitoring
	Minnesota Q-Q codes
	Ventricular mapping, Intraoperative
SEE ALSO	Coronary artery disease diagnosis
	Cardiointegram
	Electrocardiographs
Electrocoagulation	
BT	Surgery
SEE ALSO	Laser photocoagulation
Electroconvulsive therapy	
x	ECT

Electroencephalographs
SEE ALSO Electroencephalography
Electroencephalography
x EEG
SEE ALSO Brain electrical activity mapping
Electroencephalographs
Evoked potentials
Stereotaxic depth electrode implantation
Topographic brain mapping
Electrokymography
SEE Cardiokymography
Electrolyte injection
BT Metabolic and nutrient agents
Electromyographic biofeedback
SEE Biofeedback
Electronystagmography
Electrosurgery
BT Surgery
SEE ALSO Electrosurgical devices
Electrosurgical devices
SEE ALSO Electrosurgery
Electroversion therapy
ELISA
x Enzyme-linked immunosorbent assay
BT Allergy-immunolgy tests
Embolotherapy
SEE Therapeutic embolization
Emergency communication systems
BT Communication systems
Emergency kits
SEE ALSO Emergency services
First aid
Emergency services
SEE ALSO Emergency kits
Enalapril
BT Antihypertensives
Endocrinology-metabolism tests
BT Diagnostic tests
NT Blood glucose monitoring
Bone mineral studies
Dexamethasone suppression test
Hydroxycholecalciferol level
Thyroxine assays
Vitamin B 12 assay
Endoscopes
SEE ALSO Endoscopy
Endoscopic retrograde cholangiopancreatography
SEE Cholangiopancreatography
Endoscopic retrograde sphincterotomy
SEE Sphincterotomy
Endoscopy
BT Surgery
NT Arthroscopy
Esophagoscopy
Fetoscopy
Gastrointestinal endoscopy
Hysteroscopy
Ureteroscopy
Endoscopy and electrocoagulation
x Bicap probe treatment
Endothelial cell photography
x Specular microscopy
Enteral nutrition
SEE ALSO Enteral nutrition pumps
Enteral nutrition pumps
SEE ALSO Enteral nutrition
Metabolic and nutrient agents
Enzyme-albumin polymers
x Enzyme therapy
Enzyme-linked immunosorbent assay
SEE ELISA
Enzyme therapy
SEE Chemonucleolysis
Enzyme-albumin polymers
Hyaluronidase

Ephedrine	
BT	Bronchodilators
Epikeratophakia	
BT	Keratoplasty
ERCP	
SEE	Cholangiopancreatography
Ergonovine provocative testing	
BT	Cardiopulmonary tests
Ericsson sex selection method	
x	Sex selection
ERS	
SEE	Sphincterotomy
Erythrocyte sedimentation rate	
BT	Hematology tests
Erythromycin	
BT	Antibiotics
Esophageal pH monitoring	
BT	Gastroenterology tests
Esophageal reflux surgery	
SEE	Surgery—Esophageal reflux
Esophagoscopy	
BT	Endoscopy
Esterine	
x	Antiarthritics
Estramustine	
BT	Antineoplastics
Estrogen replacement therapy	
BT	Hormone therapy
SEE ALSO	Estrogens
Estrogens	
BT	Adrenal cortex hormones
	Sex hormones
SEE ALSO	Estrogen replacement therapy
	Oral contraceptives
ESWL	
SEE	Lithotripsy—Extracorporeal shock wave
Ethanol	
BT	Drug preparation
Ethynodiol diacetate with ethinyl estradiol	
BT	Oral contraceptives
Etomidate	
BT	Anesthetics
Evoked potentials	
x	Visual evoked potentials
SEE ALSO	Brain electrical activity mapping
	Electroencephalography
Exercise tests	
x	Stress tests
SEE ALSO	Coronary artery disease diagnosis
Exercise therapy	
BT	Physical therapy
NT	Continuous passive motion
SEE ALSO	Physical therapy with home exercise
Expert system evaluation	
SEE ALSO	Expert systems
Expert systems	
x	Artificial intelligence
BT	Computer-assisted patient care
SEE ALSO	Computer equipment
	Expert system evaluation
	Information systems
	Medical record systems
External counterpulsation	
BT	Circulatory assistance
Extracorporeal membrane oxygenation	
x	ECMO
Extracorporeal shock wave lithotripsy	
SEE	Lithotripsy—Extracorporeal shock wave
Extracranial-intracranial arterial bypass	
BT	Surgery
SEE ALSO	Cerebral artery anastomosis

Eye surgery	
SEE	Surgery—Eye
Eyeglasses	
BT	Vision aids
Fat emulsions	
SEE	Intravenous fat emulsions
Fertility tests	
BT	Diagnostic tests
NT	Sperm penetration assay
Fertilization in vitro	
SEE	In vitro fertilization
Fetal monitoring	
SEE ALSO	Fetal monitors
Fetal monitors	
SEE ALSO	Fetal monitoring
Fetal shunts	
SEE ALSO	Surgery—Fetal
Fetal surgery	
SEE	Surgery—Fetal
Fetoscopy	
BT	Endoscopy
SEE ALSO	Genetic screening
Fibrinogen scanning	
First aid	
SEE ALSO	Emergency kits
	Heimlich maneuver
Fish oils	
x	Omega-3 fatty acids
Flagyl	
SEE	Metronidazole
Flexible sigmoidoscopy	
SEE	Sigmoidoscopy
Fluid therapy	
SEE	Oral rehydration therapy
Fluoride varnishes	
BT	Dental materials
Fluoroscopy	
BT	Radiography
SEE ALSO	Fluoroscopy units
Fluoroscopy units	
BT	Radiographic equipment
SEE ALSO	Fluoroscopy
Food diaries	
SEE ALSO	Diet therapy
Food irradiation	
Fructose	
BT	Metabolic and nutrient agents
Functional tests	
Furosemide	
BT	Diuretics
Gait assessment	
Gamma cameras	
BT	Radionuclide imaging
Gammaglobulin, Total serum	
SEE	Kunkel test
Garren gastric bubble	
SEE	Gastric bubble
Gas scavengers	
BT	Anesthesia
Gastric acid secretion inhibitors	
BT	Antiulcer agents
NT	Histamine H2-receptor antagonists
	Secretin
Gastric balloon dilatation	
Gastric bubble	
x	Garren gastric bubble
Gastric freezing	
Gastric restrictive surgery	
BT	Surgery—Morbid obesity

Gastroenterology tests	
BT	Diagnostic tests
NT	Breath tests
	Cholangiopancreatography
	Esophageal pH monitoring
	Rehfuss test
Gastroesophageal antireflux prosthesis	
BT	Prostheses
Gastro-ileal bypass	
BT	Surgery—Morbid obesity
Gastrointestinal endoscopy	
BT	Endoscopy
NT	Colonoscopy
	Sigmoidoscopy
Gemfibrozil	
BT	Antihyperlipidemics
Generators, Electric	
Genetic complementation test	
BT	Genetic tests
Genetic counseling	
BT	Counseling
SEE ALSO	Genetic screening
Genetic engineering	
SEE ALSO	Interferons
	Monoclonal antibodies
Genetic screening	
BT	Genetic tests
NT	Chorionic villi sampling
	Hemoglobinopathies screening
	Maternal serum alpha fetoprotein monitoring
	Hypothyroidism screening, Neonatal Phenylketonuria screening
SEE ALSO	Fetoscopy
	Genetic counseling
Genetic tests	
BT	Diagnostic tests
NT	Genetic complementation tests
	Genetic screening
	Genetic toxicology tests
	Somatic cell mutation tests
Genetic toxicology tests	
BT	Genetic tests
Glaucoma screening	
BT	Vision screening
SEE ALSO	Perimetry
	Tonometry
Glucocorticoids	
BT	Adrenal cortex hormones
NT	Alclometasone dipropionate
	Amcinonide
	Beclomethasone
	Betamethasone
	Desoximetasone
	Dexamethasone
	Hydrocortisone
Glutathione disulfides	
BT	Metabolic and nutrient agents
Glyceryl trinitrate	
x	Nitroglycerin
BT	Vasodilators
Gonadorelin hydrochloride	
BT	Pituitary and hypothalmic hormones
Granulocyte transfusion	
BT	Transfusion
Growth hormone	
SEE	Human growth hormone
Guanabenz	
BT	Antihypertensives
Guanadrel sulfate	
BT	Antihypertensives
Hair analysis	
BT	Cytotoxic tests
Halazepam	
BT	Antianxiety agents
Health examination	
x	Medical evaluation
	Physical examination
Health insurance	
NT	Unbundling

Health maintenance organizations
x HMOs
SEE ALSO Capitation payment
Health promotion
x Disease prevention
Hearing aids
SEE ALSO Cochlear implants
—Use
Heart catheterization
SEE Cardiac ctheterization
Heart-lung transplantation
SEE Transplantation—Heart-lung
Heart monitors
SEE Cardiac monitors
Heart surgery
SEE Surgery—Heart
Heart transplantation
SEE Transplantation—Heart
Heart valve implantation
SEE ALSO Heart valve prosthesis
Heart valve prosthesis
SEE ALSO Heart valve implantation
Heavy-ion irradiation
SEE Radiation therapy
Heimlich maneuver
SEE ALSO First aid
Hematology tests
BT Diagnostic tests
NT Blood cell count
Coagulation assays
Erythrocyte sedimentation rate
Hemoglobin A 1 C measurements
Hemoglobinopathies screening
Hemodialysis
BT Dialysis
SEE ALSO Chelation therapy—Deferoxamine
Hemofiltration
Hemofiltration
x Continuous arteriovenous hemofiltration
SEE ALSO Hemodialysis
Hemoglobin A1C measurements
BT Hematology tests
Hemoglobinopathies screening
x Sickle cell screening
BT Genetic screening
Hematology tests
Hemoperfusion with deferoxamine
SEE Chelation therapy—Deferoxamine
Hemophilus influenza type B vaccine
x HiB vaccine
BT Vaccines
Hemostatic drugs
SEE Antihemorrhagics
Hemostatic materials
SEE ALSO Antihemorrhagics
Heparin
BT Anticoagulant s
Hepatitis B tests
BT Infectious disease tests
Hepatitis B vaccine
SEE Vital hepatitis vaccine
Herpes simplex infection screening, Neonatal
Hexachlorophene
BT Antibacterials
HGH
SEE Human growth hormone
HiB vaccine
SEE Hemophilus influenza type B vaccine
Hip joint replacement
x Artificial hip
Total hip joint replacement
BT Surgery
SEE ALSO Hip prosthesis

Hip prosthesis	
x	Artificial hip
BT	Joint prosthesis
SEE ALSO	Hip joint replacement
Histamine H2-receptor antagonists	
BT	Gastric acid secretion inhibitors
NT	Cimetidine
	Ranitidine
Histamine therapy	
HISTLINE	
x	History of Medicine Online
BT	Bibliographic information bases
	MEDLARS
History of Medicine Online	
SEE	HISTLINE
HIV detection assays	
x	AIDS tests
	Antibody tests
	HTLV III antigen detection assays
BT	Infectious disease tests
HMOs	
SEE	Health maintenance organizations
Holter monitoring	
BT	Electrocardiography
Home care	
Hormone therapy	
NT	Estrogen replacement therapy
SEE ALSO	Hormones
Hormones	
NT	Adrenal cortex hormones
	Pituitary and hypothalmic hormones
	Secretin
	Sex hormones
SEE ALSO	Hormone therapy
Hospice	
Hostel	
HTLV III antigen detection assays	
SEE	HIV detection assays
Hubbard method	
BT	Detoxification
Human growth hormone	
x	Growth hormone
	HGH
	Somatotropin
BT	Pituitary and hypothalmic hormones
Human milk banking	
Humidifiers	
Hyaluronidase	
BT	Enzyme therapy
Hybridomas	
SEE ALSO	Monoclonal antibodies
Hydralazine	
BT	Antihypertensives
Hydrochlorothiazide	
BT	Diuretics
SEE ALSO	Captopril with hydrochlorothiazide
Hydrocortisone	
BT	Glucocorticoids
Hydromorphone	
BT	Narcotic analgesics
Hydrotherapy	
x	Whirlpool baths
Hydroxycholecalciferol level	
x	25 hydroxyvitamin D level
BT	Endocrinology-metabolism tests
Hyperbaric oxygen therapy	
BT	Oxygen therapy
Hyperthermia systems	
SEE ALSO	Hyperthermia therapy
Hyperthermia therapy	
SEE ALSO	Hyperthermia systems
Hypnosis	
SEE ALSO	Hypnotic drugs

Hypnotic drugs	
BT	Psychoactive drugs
NT	Methaqualone
	Phenobarbital
SEE ALSO	Hypnosis
Hypothyroidism screening, Neonatal	
Hysterectomy	
BT	Surgery
Hysteroscopy	
BT	Endoscopy
Ibuprofen	
BT	Antipyretics
	Nonsteroidal anti-inflammatory analgesics
Ileal bypass	
BT	Surgery—Morbid obesity
SEE ALSO	Ileal bypass and diet therapy
Ileal bypass and diet therapy	
SEE ALSO	Diet therapy
	Ileal bypass
Imaging centers	
SEE ALSO	Radiography
Immunoassay systems, Fluorescence	
SEE ALSO	Allergy-immunology tests
Immunologic diagnostic tests	
SEE	Allergy-immunology tests
Immunoradiometric assay with monoclonal antibodies	
BT	Immunoradiometric assays
SEE ALSO	Monoclonal antibodies
Immunoradiometric assays	
x	Radioimmunoassays
BT	Allergy-immunology tests
NT	Immunoradiometric assay with monoclonal antibodies
	Radioallergosorbent test
Immunosuppressants	
NT	Antilymphocyte serum
	Antithymocyte serum
	Azathioprine
Immunotherapy —Cancer	
NT	BCG immunotherapy
Impedance plethysmography	
SEE	Plethysmography
Impotence diagnosis	
NT	Papaverine
SEE ALSO	Plethysmography
Impotence surgery	
SEE	Surgery—Impotence
Impotence treatment	
NT	Papaverine
	Yohimbine
In vitro chemosensitivity testing	
SEE ALSO	Chemotherapy
	Oneology testing
In vitro fertilization	
x	Fertilization in vitro
BT	Artificial procreation
Incentive payment	
SEE ALSO	Capitation payment
Incentive spirometry	
BT	Respiratory therapy
Incontinent pads	
Incubator therapy	
SEE ALSO	Incubators
Incubators	
SEE ALSO	Incubator therapy
	Radiant warmers
Indomethacin	
BT	Nonsteroidal anti-inflammatory analgesics
Induction of labor	
Infant foods	
BT	Metabolic and nutrient agents
SEE ALSO	Diet therapy
Infectious disease tests	
BT	Diagnostic tests
NT	Blood cultures Hepatitis B tests

	HIV detection assays
	Rubella tests
	Syphilis tests
	Throat cultures
	Urinalysis
Influenza vaccine	
BT	Vaccines
Information systems	
x	Decision support systems
	Online information systems
NT	Bibliographic information bases
	Computer-assisted instruction
	Medical record systems
	MEDLARS
	Reminder systems
SEE ALSO	Communication systems
	Data banks
	Expert systems
Infusion controllers	
SEE	Infusion pumps
Infusion pumps	
x	Infusion controllers
	Insulin deliver), devices
	Insulin pumps
—External	
—Implantable	
Injury severity scales	
Insecticides	
BT	Antiparasitics
NT	Malathion
Insulin	
Insulin delivery devices	
SEE	Infusion pumps
Insulin injection	
Insulin pumps	
SEE	Infusion pumps
Intensive care	
NT	Neonatal intensive care
SEE ALSO	Intensive care systems, Mobile
	Physiologic monitoring systems
Intensive care systems, Mobile	
x	Coronary care units, Mobile
	Mobile intensive care systems
SEE ALSO	Ambulances
	Intensive care
Interferons	
BT	Antineoplastics
	Antivirals
SEE ALSO	Genetic engineering
Intermittent positive pressure breathing	
x	IPPB
BT	Respiratory therapy
Intra-aortic balloon pumps	
BT	Circulatory assistance
Intracranial pressure monitoring	
SEE ALSO	Intracranial pressure monitors
Intracranial pressure monitors	
SEE ALSO	Intracranial pressure monitoring
Intracutaneous titration	
x	Rinkel serial intracutaneous titration
BT	Allergy-immunology tests
Intraocular lens implantation	
BT	Surgery—Eye
SEE ALSO	Intraocular lenses
Intraocular lenses	
SEE ALSO	Intraocular lens implantation
Intraosseous pressure measurement	
Intravenous fat emulsions	
x	Fat emulsions
Iodide therapy	
BT	Bronchodilators
Iodoxamate meglumine	
BT	Radiographic contrast dyes

Iontophoresis	
IPPB	
SEE	Intermittent positive pressure breathing
Iridology	
Iron-dextran complex	
BT	Metabolic and nutrient agents
Isosulfan blue	
BT	Diagnostic agents
Isotretinoin	
BT	Antiacne agents
Joint prosthesis	
x	Orthopedic joint implants
BT	Prostheses
NT	Elbow prosthesis
	Hip prosthesis
	Knee prosthesis
SEE ALSO	Bone cements
	Bone prosthesis
Joint scanning using Technetium Tc-99m	
SEE	Scintiphotography—Joint
Keratomileusis	
BT	Keratoplasty
Keratophakia	
BT	Keratoplasty
Keratoplasty	
NT	Epikeratophakia
	Keratomileusis
	Keratophakia
	Radial keratotomy
Ketoconazole	
BT	Antifungal agents
Keyes technique	
Kidney function tests	
BT	Diagnostic tests
NT	Blood urea concentration
	Creatinine concentration, Serum
Kidney transplantation	
SEE	Transplantation—Kidney
Kinetic therapy	
BT	Physical therapy
Knee prosthesis	
x	New Jersey integrated knee replacement system
BT	Joint prosthesis
Kunkel test	
x	Gammaglobulin, Total serum
BT	Rheumatology tests
Kyphoscoliosis surgery	
SEE	Surgery—Scoliosis
L-Dopa	
SEE	Levodopa
Labetalol	
BT	Beta blockers
Lactates	
BT	Anti-anxiety agents
Laparotomy	
BT	Surgery
Laser angioplasty	
BT	Angioplasty
	Laser surgery
Laser iridotomy	
BT	Laser surgery
	Surgery—Eye
Laser photocoagulation	
x	Photocoagulation
BT	Laser surgery
SEE ALSO	Electrocoagulation
Laser radiation therapy	
x	Photoradiation therapy
Laser surgery	
BT	Surgery
NT	Laser angioplasty
	Laser iridotomy
	Laser photocoagulation
	Laser trabeculoplasty
SEE ALSO	Lasers

—Carbon dioxide	
—Nd:YAG	
Laser trabeculoplasty	
x	Trabeculoplasty
BT	Laser surgery
Lasers	
SEE ALSO	Laser surgery
—Carbon dioxide	
—Nd:YAG	
x	Neodymium: Yttrium-aluminum garnet lasers
Laxatives	
NT	Sodium cellulose phosphate
	Sodium phosphate
Lead screening	
Leisure skills training	
Leukocyte differential counters	
BT	Cell counters
Levodopa	
x	L-Dope
BT	Antidyskinetics
Lidocaine	
BT	Anesthetics
Ligament prosthesis	
BT	Prostheses
Limb perfusion	
Linear pumps	
Lipectomy	
SEE	Suction lipectomy
Lipoprotein evaluation	
BT	Cardiopulmonary tests
Lithium	
BT	Anti-anxiety agents
	Antimanics
Lithotripsy	
—Extracorporeal shock wave	
x	ESWL
	Extracorporeal shock wave lithotripsy
SEE ALSO	Lithotripters, Extracorporeal shock wave
—Percutaneous	
—Transurethral	
SEE ALSO	Nephrolithotomy
Lithotripters, Extracorporeal shock wave	
BT	Ultrasound equipment—Therapeutic
SEE ALSO	Lithotripsy—Extracorporeal shock wave
Liver transplantation	
SEE	Transplantation—Liver
Lixiscope	
BT	Radiographic equipment
Long term care	
x	Nursing homes
Lung cancer screening	
SEE	Cancer screening—Lung
Lymphangiography	
BT	Angiography
Magnesium chloride	
BT	Metabolic and nutrient agents
Magnesium sulfate	
BT	Anticonvulsants
Magnetic resonance imaging	
x	MRI
	NMR
	Nuclear magnetic resonance
BT	Diagnostic imaging
SEE ALSO	Magnetic resonance imaging systems

—Brain and spine
—Lung injury
—Multiple sclerosis
—Neoplasms
Magnetic resonance imaging systems
SEE ALSO Magnetic resonance imaging
Magnetic resonance spectroscopy
Magnetoencephalography
x MEG
Malathion
BT Insecticides
Mammographic devices
SEE ALSO Mammography
Mammography
BT Breast imaging
SEE ALSO Mammographic devices
Maple syrup urine disease screening
Marijuana
SEE Cannabis
Mass spectroscopy
Mastectomy
BT Surgery—Breast
Maternal serum alpha fetoprotein monitoring
x AFP monitoring
Alpha fetoprotein monitoring
BT Genetic screening
NT Alpha fetoprotein assays
Measles-mumps-rubella vaccine
x MMR vaccine
BT Vaccines
Medical evaluation
SEE Health examination
Medical Literature Analysis and Retrieval System
SEE MEDLARS
Medical record systems
BT Information systems
NT Registries
SEE ALSO Computer-assisted patient care
Expert systems
Reminder systems
Medicare Prospective Payment System
SEE Prospective payment systems
MEDLARS
x Medical Literature Analysis and Retrieval System
BT Information systems
NT CHEMLINE
HISTLINE
MEDLINE
TOXLINE
MEDLARS Online
SEE MEDLINE
MEDLINE
x MEDLARS Online
BT Bibliographic information bases
MEDLARS
—Optical disks
SEE ALSO Computer equipment
Medroxyprogesterone
x Depo-Provera BT Progestins
MEG
SEE Magnetoencephalography
Melodic intonation therapy
Metabolic and nutrient agents
x Minerals
NT Amino acids
Artificial sweeteners
Calcium chloride
Dextrose
Dextrose with saline solution
Electrolyte injection
Fructose
Glutathione disulfides
Infant foods
Magnesium chloride

	Polydextrose
	Potassium chloride
	Potassium citrate
	Potassium phosphate
	Vitamins
SEE ALSO	Enteral nutrition
	Oral rehydration therapy
	Parenteral nutrition
	Protein-calorie therapy with anabolic steroids
Methaqualone	
BT	Hypnotic drugs
	Sedatives
Methotrexate	
BT	Antiarthritics
	Antineoplastics
	Antipsoriatics
Methoxsalen	
BT	Antipsoriatics
	Repigmenting agents
Methyldopa	
BT	Antihypertensives
Methylethylketone	
BT	Solvents
Methylphenidate	
x	Attention deficit disorder therapy
Metoclopramide	
SEE	Oxybutynin chloride with metoclopramide
Metolazone	
BT	Antihypertensives
	Diuretics
Metoprolol	
BT	Beta-blockers
Metronidazole	
BT	Antiarthritics
	Antibiotics
Mezlocillin	
BT	Antibiotics
Miconazole	
BT	Antifungal agents
Microbiological testing systems	
BT	Diagnostic tests
NT	Automated microbiology systems
Microbiology equipment	
Micronucleus test	
BT	Cytotoxic tests
Microsurgery	
BT	Surgery
Migration inhibition test	
BT	Allergy-immunology tests
Minerals	
BT	Metabolic and nutrient agents
Minnesota Q-Qs codes	
BT	Electrocardiography
MMR vaccine	
SEE	Measles-mumps-rubella vaccine
Mobile intensive care systems	
SEE	Intensive care systems, Mobile
Mobility aids	
Moire topography	
x	Photogrammetry
	Shadow moire contourography
Monoclonal antibodies	
x	Antibodies
SEE ALSO	Genetic engineering
	Hybridomas
	Immunoradiometric assay with monoclonal antibodies
Mouth protectors	
Moxalactam	
BT	Cephalosporins
MRI	
SEE	Magnetic resonance imaging

Mycoplasma complement fixation test
BT Rheumatology tests
Myoelectric prostheses
BT Prostheses
Nadolol
BT Beta blockers
Nafcillin
BT Antibiotics
Nail bed transplantation
SEE Transplantation—Nail bed
Naloxone
BT Narcotic antagonists
Narcotic analgesics
BT Analgesics
NT Codeine
Hydromorphone
Pentazocine
Narcotic antagonists
NT Naloxone
Nd: YAG laser surgery
SEE Laser surgery—Nd:YAG
Nd: YAG lasers
SEE Lasers—Nd:YAG
Nebulizers
SEE ALSO Aerosol therapy
Needle aspiration cytology
Negative pressure respirators
BT Respirators
Neodymium: Yttrium-aluminum garnet lasers
SEE Nd:YAG lasers
Neonatal intensive care
BT Intensive care
SEE ALSO Neonatal monitors
Neonatal monitors
SEE ALSO Neonatal intensive care
Nephrolithotomy
BT Surgery
SEE ALSO Lithotripsy—Transurethral
Nephrostomy
BT Surgery
Neurosonology
SEE Ultrasound
Neurotoxins
NT Botulinum toxin
Neutralization therapy
—Food allergies
SEE ALSO Challenge food testing
New Jersey integrated knee replacement system
SEE Knee prosthesis
Niclosamide
BT Anthelmintics
Nicotine gum
Nifedipine
BT Calcium channel blockers
Nissen fundoplication
BT Surgery—Morbid obesity
Nitroglycerin
SEE Glyceryl trinitrate
Nitroprusside
BT Antihypertensives
NMR
SEE Magnetic resonance imaging
Noncardiac pain diagnosis
Nonionizing radiation measurement devices
BT Radiation measurement devices
Nonsteroidal anti-inflammatory analgesics
NT Diflunisal
Ibuprofen
Indomethacin
Piroxicam

Norethindrone with ethinyl estradiol	
BT	Oral contraceptives
Normaline kit	
Nuclear magnetic resonance imaging	
SEE	Magnetic resonance imaging
Nursing homes	
SEE	Long term care
Nutritional counseling	
BT	Counseling
SEE ALSO	Diet therapy
Obesity surgery	
SEE	Surgery—Morbid obesity
Omega-3 fatty acids	
SEE	Fish oils
Oncology tests	
BT	Diagnostic tests
NT	Alpha fetoprotein assays
	Benallen's test
	Bolen's test
	Carcinoembryonic antigen assays
	In vitro chemosensitivity testing
	Pap smear
	Prostatic acid phosphatase kits
	Stool guaiac
	Tumor stem cell assays
SEE ALSO	Cancer screening
Online information bases	
SEE	Information systems
Optical disk	
SEE	MEDLINE—Optical disks
Oral contraceptives	
BT	Contraception
NT	Ethynodiol diacetate with ethinyl estradiol
	Norethindrone with ethinyl estradiol
SEE ALSO	Estrogens
	Progestins
Oral rehydration therapy	
x	Fluid therapy
	ORT
	Rehydration therapy
SEE ALSO	Metabolic and nutrient agents
Organ preservation	
SEE ALSO	Organ procurement
	Transplantation
Organ procurement	
SEE ALSO	Organ preservation
	Transplantation
Organ transplantation	
SEE	Transplantation
Orphan devices	
ORT	
SEE	Oral rehydration therapy
Orthodontic appliances	
x	Orthodontic wires
Orthodontic wires	
SEE	Orthodontic appliances
Orthopedic joint implants	
SEE	Joint prosthesis
Orthotic devices	
NT	Posture control devices
	Shoe insoles
Osseointegrated implants	
SEE	Dental implants
Osteoporosis screening	
Osteotomy	
SEE	Tibial osteotomy
Outpatient surgery	
SEE	Surgery, Ambulatory
Oximeters	
BT	Blood gas monitors
SEE ALSO	Oximetry
Oximetry	
SEE ALSO	Oximeters
Oxprenolol	
BT	Beta blockers
Oxybutynin chloride with metoclopramide	
x	Antispasmodics
	Metoclopramide

Oxygen-air proportioners
Oxygen analyzers
SEE ALSO Blood gas monitors
Oxygen therapy
NT Hyperbaric oxygen therapy
—Inhalation
—Topical
PACS
SEE Picture archiving and communication systems
Pain assessment
Pain therapy
x Analgesia
NT Acupuncture
Transcutaneous electrical nerve stimulation
SEE ALSO Analgesics
Palatopharyngoplasty
BT Surgery
Pancreas transplantation
SEE Transplantation—Pancreas
Pap smear
BT Oncology tests
SEE ALSO Cancer screening—Cervical
Papaverine
BT Impotence diagnosis
Impotence treatment
Vasodilators
Parenteral nutrition
x Total parenteral nutrition
TPN
SEE ALSO Metabolic and nutrient agents
Partial thromboplastin time
BT Coagulation assays
Patch tests
BT Allergy-immunology tests
PEEP valves
x Positive end expiratory pressures valves
Peer group counseling
BT Counseling
Penicillamine
BT Antiarthritics
Antiurolithics
SEE ALSO Chelation therapy—Pencillamine
Penile artery bypass
BT Surgery—Impotence
Penile prosthesis
BT Prostheses
Pentazocine
BT Narcotic analgesics
Pentetate indium disodium
BT Radiopharmaceuticals
Percutaneous balloon valvuloplasty
BT Surgery
SEE ALSO Balloon dilatation catheters
Percutaneous transluminal angioplasty
x Balloon angioplasty
PTA
BT Angioplasty
NT Percutaneous transluminal coronary angioplasty
Percutaneous transluminal coronary angioplasty
x Coronary artery surgery
PTCA
BT Percutaneous transluminal angioplasty
Surgery—Heart
Perimetry
BT Vision screening
Periodontal ligament injection
Peritoneal dialysis
BT Dialysis
NT Continuous ambulatory peritoneal dialysis
SEE ALSO Peritoneal dialysis cyclers
Peritoneal dialysis solutions

Peritoneal dialysis cyclers	
SEE ALSO	Peritoneal dialysis
	Peritoneal dialysis solutions
Peritoneal dialysis solutions	
SEE ALSO	Peritoneal dialysis
	Peritoneal dialysis cyclers
Permanent eyeliner	
BT	Surgery
Persantine	
SEE	Dipyridamole
Pertussis vaccine	
BT	Vaccines
PET scan	
SEE	Positron emission tomography
Phenobarbital	
BT	Anticonvulsants
	Hypnotic drugs
	Sedatives
Phenylketonuria screening	
BT	Genetic screening
Phenylpropanolamine	
BT	Appetite suppressants
Phenytoin	
BT	Anticonvulsants
Phlebography	
x	Venography
Phonocardiography	
Photocoagulation	
SEE	Laser photocoagulation
Photodensitometry	
SEE	Bone mineral studies
Photogrammetry	
SEE	Moire topography
Photokymography	
SEE ALSO	Coronary artery disease diagnosis
Photoplethysmography	
SEE	Plethysmography
Photoradiation therapy	
SEE	Laser radiation therapy
Phototherapy	
NT	Ultraviolet therapy
SEE ALSO	Laser radiation therapy
Phyllocontin	
SEE	Aminophylline
Physical examination	
SEE	Health examination
Physical therapy	
x	Physiotherapy
NT	Doman-Delacato treatment
	Exercise therapy
	Kinetic therapy
Physical therapy with home exercise	
SEE ALSO	Exercise therapy
Physician education	
x	Continuing medical education
SEE ALSO	Computer-assisted instruction
Physiologic monitoring systems	
SEE ALSO	Apnea monitors
	Blood pressure monitors
	Electrocardiographs
	Intensive care
Physiotherapy	
SEE	Physical therapy
Picture archiving and communication systems	
x	PACS
SEE ALSO	Digital imaging
Pindolol	
BT	Beta blockers
Piperacillin	
BT	Antibiotics
Piroxicam	
BT	Nonsteroidal anti-inflammatory analgesics

Pituitary and hypothalmic hormones	
BT	Hormones
NT	Gonadorelin hydrochloride
	Human growth hormone
Plasma exchange	
x	Therapeutic plasma exchange
	TPE
BT	Apheresis
SEE ALSO	Plasma exchange devices
	Plasma, Frozen
	Plasma infusion
	Plasmapheresis
Plasma exchange devices	
SEE ALSO	Plasma exchange
Plasma filters	
SEE ALSO	Plasma perfusion
	Plasma separation systems
Plasma, Frozen	
SEE ALSO	Plasma exchange
	Plasma infusion
Plasma infusion	
SEE ALSO	Plasma exchange
	Plasma, Frozen
Plasma perfusion	
BT	Apheresis
SEE ALSO	Plasma filters
Plasma separation systems	
SEE ALSO	Apheresis
	Plasma filters
Plasmapheresis	
BT	Apheresis
SEE ALSO	Plasma exchange
Plasminogen activators	
SEE	Tissue plasminogen activators
Plasticizers	
Platelet transfusion	
x	Thrombocyte transfusion
BT	Transfusion
Plethysmography	
x	Impedance plethysmography
	Photoplethysmography
SEE ALSO	Impotence diagnosis
Pneumococcal vaccine	
BT	Vaccines
Polydextrose	
BT	Metabolic and nutrient agents
Polypectomy	
BT	Surgery
Polyurethane tubing	
Positive end expiratory pressure valves	
SEE	PEEP valves
Positron emission tomography	
x	PET scan
	Tomography, Emission computed
	Tomography, Positron emission
SEE ALSO	SPECT imaging
Postmarketing surveillance	
BT	Assessment methods
Postural drainage	
BT	Respiratory therapy
Posture control devices	
BT	Orthotics
Potassium chloride	
BT	Metabolic and nutrient agents
Potassium citrate	
x	Citrates
BT	Metabolic and nutrient agents
Potassium phosphate	
BT	Metabolic and nutrient agents
PPS	
SEE	Prospective payment systems
Praziquantel	
BT	Anthelmintics
Prazosin	
BT	Antihypertensives

Prenatal care	
Prenatal education	
Prepayment	
SEE	Capitation payment
Prescribing	
SEE	Drug ordering
Pressure transducers	
Primadone	
BT	Anticonvulsants
Progestin receptor assays	
Progestins	
BT	Adrenal cortex hormones
	Sex hormones
NT	Medroxyprogesterone
SEE ALSO	Oral contraceptives
	Progestin receptor assays
Prolotherapy	
SEE ALSO	Sclerotherapy
Propranolol	
BT	Beta blockers
Prospective payment systems	
x	Medicare Prospective Payment System
	PPS
NT	Discretionary adjustment factor
SEE ALSO	Capitation payment
	Competition
	DRGs
Prostaglandins	
NT	Alprostadil
Prostate surgery	
SEE	Surgery—Prostate
Prostatic acid phosphatase kits	
BT	Oncology tests
SEE ALSO	Tumor markers
Prostheses	
NT	Gastroesophageal antireflux prosthesis
	Joint prosthesis
	Ligament prosthesis
	Myoelectric prostheses
	Penile prosthesis
	Socket prosthesis
Protein-calorie therapy with anabolic steroids	
x	Anabolic steroids
BT	Diet therapy
SEE ALSO	Metabolic and nutrient agents
Prothrombin-complex concentrate	
SEE	Anti-inhibitor coagulant complex
Prothrombin time	
BT	Coagulation assays
Provocation tests—Food allergies	
SEE	Challenge food testing
Psoralens and ultraviolet A therapy	
SEE	PUVA therapy
Psychoactive drugs	
BT	Psychotherapy
NT	Antianxiety agents
	Antidepressants
	Antipsychotics
	Hypnotic drugs
	Sedatives
Psychosurgery	
BT	Psychotherapy
	Surgery
Psychotherapy	
NT	Psychoactive drugs
	Psychosurgery
PTA	
SEE	Percutaneous transluminal angioplasty
PTCA	
SEE	Percutaneous transluminal coronary angioplasty
Pulmonary function tests	
SEE ALSO	Respiratory therapy
Punctal occlusion	
BT	Surgery—Eye

PUVA therapy
x Psoralens and ultraviolet A therapy
BT Ultraviolet therapy
Pyelography
BT Radiography
Pyrimethamine
BT Antiprotozoal agents
Quality assurance programs
Radial keratotomy
BT Keratoplasty
Radiant warmers
SEE ALSO Incubators
Radiation measurement
x Dosimetry
NT Nonionizing radiation measurement devices
SEE ALSO Radiation protection
Radiation protection
SEE ALSO Radiation measurement
Radiation therapy
x Heavy-ion irradiation
Radioactive materials
NT Radiopharmaceuticals
Radioallergosorbent test
x RAST
BT Immunoradiometric assays
Radiogrammetry
SEE Bone mineral studies
Radiographic absorptiometry
SEE Absorptiometry
Radiographic contrast dyes
x Contrast media
BT Radiographic materials
NT Iodoxamate meglumine
SEE ALSO Radiopharmaceuticals
Radiographic darkrooms
x Darkrooms
Radiographic equipment
x X-ray equipment
NT Computed tomography scanners
Fluoroscopy units
Lixiscope
Radiographic film processors
SEE ALSO Radiography
Radiographic film
x X-ray film
BT Radiographic materials
Radiographic film processors
x X-ray film processors
BT Radiographic equipment
Radiographic materials
NT Radiographic contrast dyes
Radiographic film
Radiography
x Roentgenography
X-rays
BT Diagnostic imaging
NT Cholangiography
Cholangiopancreatography
Cholecystography
Computed tomography
Discography
Fluoroscopy
Pyelography
Urography
SEE ALSO Digital imaging
Imaging centers
Radiation protection
Radiographic equipment
Radiographic materials
Radiography, Dental
SEE Dental radiography
Radioimmunoassays
SEE Immunoradiometric assays
Radionuclide angiography
BT Angiography
Radionuclide imaging
Radionuclide imaging
BT Diagnostic imaging
NT Gamma cameras
Radionuclide angiography

	Scintiphotography
	SPECT
	Thallium imaging
	Ventilation-perfusion lung scans
SEE ALSO	Radionuclide laboratories
	Radiopharmaceuticals
Radionuclide laboratories	
SEE ALSO	Radionuclide imaging
Radiopaque plastics	
BT	Dental radiography
Radiopharmaceuticals	
BT	Radioactive materials
NT	Pentetate indium sodium
	Technetium Tc-99m kits
	Xenon
SEE ALSO	Radiographic contrast dyes
	Radionuclide imaging
Randomized clinical trials	
SEE	Clinical trials—Randomized
Ranitidine	
BT	Histamine H2-receptor antagonists
RAST	
SEE	Radioallergosorbent test
Rectal mucosal replacement	
Registries	
BT	Medical record systems
SEE ALSO	Data banks
Rehabilitation	
NT	Cardiac rehabilitation
	Pain rehabilitation
SEE ALSO	Rehabilitation programs
Rehabilitation programs	
SEE ALSO	Rehabilitation
—Spinal cord injury	
—Stroke	
Rehfuss test	
BT	Gastroenterology tests
Rehydration therapy	
SEE	Oral rehydration therapy
Relative value scales	
Relaxation therapy	
Reminder systems	
x	Appointment reminders
BT	Information systems
SEE ALSO	Medical record systems
Repigmenting agents	
NT	Methoxsalen
Reserpine	
BT	Antihypertensives
Reserpine with chlorthalidone	
BT	Antihypertensives
SEE ALSO	Chlorthalidone
Respirators	
NT	Negative pressure respirators
SEE ALSO	Respiratory therapy
	Ventilators
Respiratory therapy	
NT	Aerosol therapy
	Continuous positive airway pressure
	Incentive spirometry
	Intermittent positive pressure breathing
	Postural drainage
SEE ALSO	Pulmonary function tests
	Respirators
Resuscitation	
SEE ALSO	Resuscitators
—Mouth-to-mouth	
Resuscitators	
SEE ALSO	Resuscitation
Reuse of disposables	
x	Disposables reuse
Rheumatology tests	
x	Arthritis tests
BT	Diagnostic tests
NT	Bentonite flocculation test
	DNA-antibody test
	Kunkel test
	Mycoplasma complement fixation test

Rhinoplasty
BT Surgery
Ringer's irrigation
Rinkel serial intracutaneous titration
SEE Intracutaneous titration
Roentgenography
SEE Radiography
Routine admission testing
SEE Admission testing, Routine
Rubella tests
x Antibody tests
BT Infectious disease tests
Rubidium
BT Antipsychotics
Saccharin
BT Artificial sweeteners
Saralasin
BT Antihypertensives
Satellite communication
BT Communication systems
Scales, Patient
Schizophrenia screening
Scintiphotography
BT Radionuclide imaging
SEE ALSO Technetium Tc-99m kits
—Heart
—Joint
Sclerotherapy
SEE ALSO Prolotherapy
Scoliosometry
Screening
SEE specific diseases or disorders, e.g. Cancer screening
Seat belts (Automobile)
SEE Automobile passenger restraints
Second opinions
Secretin
BT Diagnostic agents
Gastric acid secretion inhibitors
Hormones
Sedatives
BT Psychoactive drugs
NT Barbiturates
Methaqualone
Phcnobarbital
Selenium sulfide
BT Antifungal agents
Antiseborrheic agents
Sensory integrative therapy
Seromucoid assay
BT Diagnostic tests
Serum creatinine concentration
SEE Creatinine concentration, Serum
Sex hormones
BT Hormones
Steroids
NT Androgens
Estrogens
Progestins
Sex selection
SEE Ericsson sex selection method
Shadow moire contourography
SEE Moire topography
Shape sensor
Shoe insoles
BT Orthotic devices
SI units
SEE Systeme International units
Sickle cell screening
SEE Hemoglobinopathies screening
Sigmoidoscopy
x Flexible sigmoidoscopy
BT Gastrointestinal endoscopy

SEE ALSO	Barium enema with sigmoidoscopy
	Cancer screening—Colorectal
Silver sulfadiazine	
BT	Antibiotics
Singer-Blom valve operation	
BT	Surgery
Single photon emission computed tomography	
SEE	SPECT imaging
Sisomicin	
BT	Antibiotics
Smoke detectors	
Socket prosthesis	
BT	Prostheses
Sodium cellulose phosphate	
BT	Laxatives
Sodium chloride	
BT	Metabolic and nutrient agents
Sodium phosphate	
BT	Laxatives
Sodium restriction	
BT	Diet therapy
Solvents	
NT	Methylethylketone
Somatic cell mutation tests	
BT	Genetic tests
Somatotropin	
SEE	Human growth hormone
Sorbitol	
BT	Artificial sweeteners
SPECT imaging	
x	Single photon emission computed tomography
	Tomography, Single photon emission computed
BT	Radionuclide imaging
SEE ALSO	Computed tomography
	Positron emission tomography
Specular microscopy	
SEE	Endothelial cell photography
Sperm penetration assay	
BT	Fertility tests
Sphincterotomy	
x	Endoscopic retrograde sphincterotomy
	ERS
BT	Surgery
Sphygmomanometers	
SEE	Blood pressure monitors
Sphygmomanometry	
SEE	Blood pressure monitoring
Spinal injury programs	
SEE	Rehabilitation programs—Spinal cord injury
Spinal puncture	
BT	Surgery
Sporicidin	
BT	Antifungal agents
Sprinklers	
Standardized Medreview Instrument	
Stapedectomy	
BT	Surgery
Stapling	
SEE	Surgical stapling
Stereotaxic depth electrode implantation	
BT	Surgery
SEE ALSO	Electroencephalography
Stereotaxic neurosurgery, Computed tomography-assisted	
BT	Surgery
Sterile water for injection	
Sterilization equipment	
SEE ALSO	Sterilizers
Sterilizers	
SEE ALSO	Sterilization equipment

Steroids	
NT	Adrenal cortex hormones
	Sex hormones
SEE ALSO	Hydroxycholecalciferol level
	Protein-calorie therapy with anabolic steroids
Stool guaiac	
BT	Oncology tests
SEE ALSO	Cancer screening—Colorectal
Streptokinase	
x	Thrombolytic therapy
Streptozocin	
BT	Antineoplastics
Stress tests	
SEE	Exercise tests
Stroke programs	
SEE	Rehabilitation programs—Stroke
Sucralfate	
BT	Antiulcer agents
Suction equipment	
Suction lipectomy	
x	Lipectomy
BT	Surgery—Morbid obesity
Sulfadoxine	
BT	Antiprotozoal agents
Sulfamethoxazole	
x	Sulfonamides
BT	Antibacterials
Sulfinpyrazone	
BT	Antigout agents
	Antihyperuricemics
Sulfonamides	
SEE	Sulfamethoxazole
Suloctidil	
BT	Vasodilators
Sunlamps	
SEE ALSO	Phototherapy
Supportive care	
SEE ALSO	Burn units
Surgery	
NT	Adenoidectomy
	Angioplasty
	Biopsy
	Carotid body resection
	Carotid endarterectomy
	Cerebral artery anastomosis
	Cesarean section
	Cholecystectomy
	Cingulotomy
	Circumcision
	Cochlear implantation
	Cochleostomy
	Collagen implants
	Cryosurgery
	Debridement
	Decubitus surgery
	Dilatation and curettage
	Electrocoagulation
	Electrosurgery
	Endoscopy
	Extracranial-intracranial arterial bypass
	Hip joint replacement
	Hysterectomy
	Laparotomy
	Laser surgery
	Mastectomy
	Microsurgery
	Nephrolithotomy
	Nephrostomy
	Palatopharyngoplasty
	Percutaneous balloon valvuloplasty
	Permanent eyeliner
	Polypectomy
	Psychosurgery
	Rhinoplasty
	Singer-Blom valve operation
	Sphincterotomy
	Spinal puncture
	Stapedectomy
	Stereotaxic depth electrode implantation
	Stereotaxic neurosurgery, Computed tomography-assisted
	Surgical stapling
	Temporomandibularjoint procedure
	Thoracentesis

	Tibial osteotomy
	Tibial tubercle elevation
	Tonsillectomy
	Tooth extraction
	Transplantation
	Transsexual surgery
	Tubal ligation
	Vertebral artery surgery
—Ambulatory	
x	Outpatient surgery
—Breast	
NT	Contralateral breast surgery
	Mastectomy
—Esophageal reflux	
—Eye	
NT	Cataract extraction
	Corneel grafts
	Intraocular lens implantation
	Keratoplasty
	Laser iridotomy
	Punctal occlusion
SEE ALSO	Surgical aids—Ophthalmic
—Fetal	
SEE ALSO	Fetal shunts
—Heart	
NT	Cardiac catheterization
	Coronary artery bypass grafting
	Percutaneous transluminal coronary angioplasty
SEE ALSO	Cryosurgery—Arrhythmias
	Percutaneous transluminal valvuloplasty
—Impotence	
NT	Penile artery bypass
—Morbid obesity	
NT	Bilio-pancreatic bypass
	Gastric restrictive surgery
	Gastro-ileal bypass
	Ileal bypass
	Nissen fundoplication
	Suction lipectomy
—Prostate	
—Scoliosis	
Surgical aids	
—Ophthalmic	
Surgical case carts	
Surgical drapes	
Surgical gloves	
Surgical shunt	
Surgical stapling	
x	Stapling
BT	Surgery
Sutures	
Syphylis tests	
BT	Infectious disease tests
Syringe pumps	
Systeme International units	
x	SI units
Tamoxifen	
BT	Antineoplastics
Team care	
Technetium Tc 99m kits	
BT	Radiopharmaceuticals
SEE ALSO	Scintiphotography
Telemetry	
BT	Communication systems
Temazepam	
BT	Antianxiety agents
Temporomandibular joint procedure	
x	TMJ procedure
BT	Surgery
TENS	
SEE	Transcutaneous electrical nerve stimulation

Thallium imaging	
BT	Radionuclide imaging
Theo-Dur	
SEE	Theophylline
Theophylline	
x	Theo-Dur
BT	Bronchodilators
SEE ALSO	Aminophylline
Therapeutic drug monitoring	
x	Drug monitoring
Therapeutic embolization	
x	Embolotherapy
Therapeutic plasma exchange	
SEE	Plasma exchange
Thermography	
BT	Diagnostic imaging
—Breast	
BT	Breast imaging
Thermometers	
Thiamine	
SEE	Vitamin B1
Thoracentesis	
BT	Surgery
Throat cultures	
BT	Infectious disease tests
Thrombocyte transfusion	
SEE	Platelet transfusion
Thrombolytic therapy	
NT	Streptokinase
	Tissue plasminogen activators
Thymoxamine	
BT	Vasodilators
Thyroxine assays	
BT	Endocrinology-metabolism tests
Tibial osteotomy	
x	Osteotomy
BT	Surgery
Tibial tubercle elevation	
BT	Surgery
Timolol	
BT	Antiglaucoma agents
Tinnitus maskers	
Tioconazole	
BT	Antifungal agents
Tissue banks	
SEE ALSO	Tissue preservation technics
Tissue plasminogen activators	
x	Plasminogen activators
	TPA
BT	Thrombolytic therapy
Tissue preservation technics	
SEE ALSO	Tissue banks
TMJ procedure	
SEE	Temporomandibular joint procedure
Tobramycin	
BT	Antibiotics
Tocodynamometry	
x	Uterine monitoring
Tomographic scanners	
SEE	Computed tomographic scanners
Tomography, Emission computed	
SEE	Positron emission tomography
Tomography, Positron emission	
SEE	Positron emission tomography
Tomography, Single photon emission computed	
SEE	SPECT imaging
Tomography, Standard	
Tomography, X-ray computed	
SEE	Computed tomography
Tonometry	
BT	Vision screening
Tonsillectomy	
BT	Surgery

Tooth extraction	
BT	Surgery
Toothpaste	
BT	Dental materials
Topical oxygen therapy	
SEE	Oxygen therapy—Topical
Topographic brain mapping	
SEE ALSO	Electroencephalography
Total hip joint replacement	
SEE	Hip joint replacement
Total parenteral nutrition	
SEE	Parenteral nutrition
Tourniquets	
Toxicology Information Online	
SEE	TOXLINE
TOXLINE	
x	Toxicology Information Online
BT	Bibliographic information bases
	MEDLARS
TPA	
SEE	Tissue plasminogen activators
TPE	
SEE	Plasma exchange
TPN	
SEE	Parenteral nutrition
Trabeculoplasty	
SEE	Laser trabeculoplasty
Tranquilizers	
SEE	Antianxiety agents
Transcutaneous electrical nerve stimulation	
x	TENS
BT	Electrical stimulation
	Pain therapy
Transfer factor therapy	
Transfusion	
NT	Blood transfusion
	Granulocyte transfusion
	Platelet transfusion
Transillumination	
—Breast	
x	Diaphanography
BT	Breast imaging
	Diagnostic imaging
Transplantation	
BT	Surgery
SEE ALSO	Organ preservation
	Organ procurement
—Bone marrow	
—Bone marrow, Allogenic	
—Bone marrow, Autologous	
—Cornea	
—Heart	
—Heart-lung	
—Kidney	
—Liver	
—Nail bed	
—Pancreas	
Transsexual surgery	
BT	Surgery
Trazodone	
BT	Antidepressants
Triamterene	
BT	Diuretics
Triazolam	
BT	Antianxiety agents
Trimethoprim	
BT	Antibiotics

Tryptophan	
BT	Antidepressants
Tubal ligation	
BT	Contraception
	Surgery
Tuberculosis screening	
Tumor markers	
SEE ALSO	Alpha fetoprotein assays
	Carcinoembryonic antigen assays
	Prostatic acid phosphatase kits
Tumor stem cell assay	
BT	Oncology tests
Tympanometry	
SEE	Acoustic impedance test
Type A score	
Ultrasonography	
x	B-mode scanning
	Echocine
BT	Diagnostic imaging
	Ultrasound
NT	Echocardiography
—Arteries	
BT	Arteriography
SEE ALSO	Echocardiography
—Breast	
—Follicular growth	
SEE ALSO	Ultrasound—Obstetrics and gynecology
—Head	
—Pancreas	
—Pregnancy	
SEE ALSO	Ultrasound—Obstetrics and gynecology
—Prostate	
—Sinuses	
Ultrasound	
x	Doppler ultrasound
	Neurosonology
NT	Ultrasonography
SEE ALSO	Lithotripsy, Extracorporeal shock wave
	Lithotripsy, Percutaneous
	Ultrasound equipment—Therapeutic
—Cardiac output	
SEE ALSO	Coronary artery disease diagnosis
—Intraoperative	
—Obstetrics and gynecology	
SEE ALSO	Ultrasonography—Follicular growth
—Pelvimetry	
Ultrasound equipment	
SEE ALSO	Ultrasound
—Diagnostic	
—Therapeutic	
NT	Lithotripters, Extracorporeal shockwave
Ultraviolet therapy	
BT	Phototherapy
NT	PUVA therapy
Unbundling	
BT	Health insurance
Ureteroscopy	
BT	Endoscopy
Urinalysis	
x	Urine culture
BT	Infectious disease tests
SEE ALSO	Urologic disease screening
Urinary sphincter, Artificial	
Urine autoinjection	
Urine culture	
SEE	Urinalysis

Urography	
BT	Radiography
Urologic disease screening	
SEE ALSO	Urinalysis
Uterine monitoring	
SEE	Tocodynamometry
Vaccination policy	
Vaccines	
NT	BCG vaccine
	Hemophilus influenza type B vaccine
	Influenza vaccine
	Measles-mumps-rubella vaccine
	Pertussis vaccine
	Pneumococcal vaccine
	Viral hepatitis vaccine
Valproate	
x	Valproic acid
BT	Anticonvulsants
Valproic acid	
SEE	Valproate
Vascular access ports	
Vascular headache suppressants	
NT	Dihydroergotamine
Vasodilators	
NT	Dipyridamole
	Glyceryl trinitrate
	Papaverine
	Suloctidil
	Thymoxamine
Vasopressors	
NT	Dopamine
Venography	
SEE	Phlebography
Ventilation-perfusion lung scans	
BT	Radionuclide imaging
Ventilators	
SEE ALSO	Respirators
Ventricular assist devices	
BT	Circulatory assistance
Ventricular mapping, Intraoperative	
BT	Electrocardiography
Verapamil	
BT	Calcium channel blockers
Vertebral artery surgery	
BT	Surgery
Vidarabine	
BT	Antivirals
Viral hepatitis vaccine	
x	Hepatitis B vaccine
	BT Vaccines
Vision aids	
NT	Eyeglasses
Vision screening	
NT	Glaucoma screening
	Perimerry
	Tonometry
Visual evoked potentials	
SEE	Evoked potentials
Vitamin A	
SEE ALSO	Beta-carotene
Vitamin B1	
x	Thiamine
Vitamin B 12 assay	
BT	Endocrinology-metabolism tests
	Vitamins
Vitamin E	
BT	Vitamins
Vitamins	
BT	Metabolic and nutrient agents
NT	Vitamin A
	Vitamin B 1
	Vitamin B 12 assay
	Vitamin E
SEE ALSO	Hydroxycholecalciferol level
Warfarin	
BT	Anticoagulants
Wheelchair tray systems	

Wheelchairs
Whirlpool baths
SEE Hydrotherapy
X-ray equipment
SEE Radiographic equipment
X-ray film
SEE Radiographic film
X-ray film processors
SEE Radiographic film processors
X-rays
SEE Radiography
X-rays, Dental
SEE Radiography, Dental
Xenon
BT Radiopharmaceuticals
Xylitol
BT Artificial sweeteners
Yohimbine
BT Alpha receptor blocking agents
Impotency treatment
Zomepirac sodium
BT Analgesics
25 hydroxyvitamin D level
SEE Hydroxycholecalciferol level

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California Medical Association, Medical Practice Opinion Program. Assistant surgeon at elective abdominal tubal ligation. 1985 Nov. (Medical Practice Opinion #333) [Group judgment]

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California Medical Association, Medical Practice Opinion Program. Human tumor stem cell assay. 1982 Jul. (Medical Practice Opinion #273) [Group judgment]

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California Medical Association, Medical Practice Opinion Program. Echocine for diagnosis of sinusitis. 1985 Jun. (Medical Practice Opinion #318) [Group judgment]

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ECRI Technology Assessment Program. Urinalysis, automated. J Health Care Technol 1986;2:201-10. [Information syntheses]

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Medical Technology and Practice Patterns Institute. Left ventricular assist device. 1987.

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National Center for Health Services Research and Health Care Technology Assessment, Office of Health Technology Assessment. Intraoperative ventricular mapping. 1984.

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Vitamin B1

American Medical Association, Council on Scientific Affairs. Addition of thiamine to alcoholic beverages (Resolution 140, A-81). 1989. [Group judgment]

Vitamin B 12 assay

Cooper BA. [National Health Research and Development Program - Canada] Evaluation and development of assays for B12 and folate. 1985. (Grant No. 6605-1784-52).

Vitamin E

Robertson JMD. [National Health Research and Development Program - Canada] Does supplementary vitamin E prevent cataracts? 1986. (Grant No. 6606-2445-43).

American Academy of Pediatrics, Committee on Fetus and Newborn. Vitamin E and the prevention of retinopathy of prematurity. Pediatrics 1985 Aug.

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American Medical Association, Council on Scientific Affairs. Vitamin preparations as dietary supplements and as therapeutic agents. 1985. [Group judgment]

American Academy of Pediatrics, Committee on Nutrition. Vitamins and mineral supplement needs. 1980.

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Hull R, Delmore T, Carter C, et al. [McMaster University, Department of Clinical Epidemiology and Biostatistics] Adjusted subcutaneous heparin versus warfarin sodium in the long-term treatment of venous thrombosis. New Eng J Med 1989;306:189-194.

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Food and Drug Administration, Center for Drugs and Biologics. Xenon Xe 127 gas. 1983 (NTIS order no. PB83-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

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Yohimbine

Morales A. [Department Urology, Queens University] [Medical Research Council - Canada] A controlled clinical trial of yohimbine in the treatment of impotence. (Grant period 1981-1985).

Z

Zomepirac sodium

Food and Drug Administration, Center for Drugs and Biologics. Zomepirac sodium. 1981. (NTIS order no. PB81-915901). [Information syntheses, Expert opinion, Epidemiological and other observational methods, Clinical trials, Bench testing]

PART 3 INFORMATION AND DATA RESOURCES

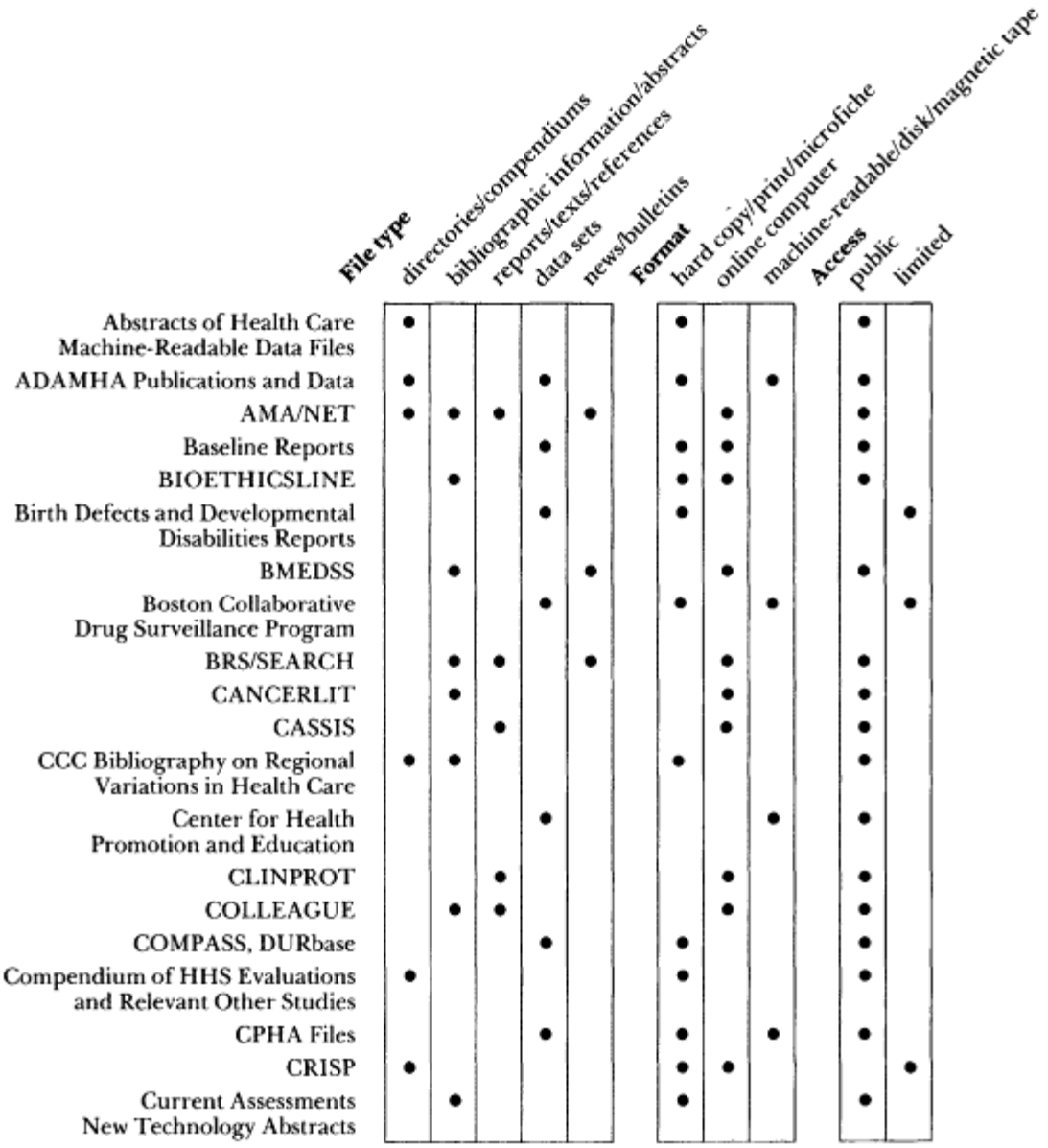
PART 3

INFORMATION AND DATA RESOURCES

This part has three sections: a categorical chart of information and data resources beginning on page 501, the 73 resource descriptions beginning on page 504, and a subject index to the resource descriptions beginning on page 551.

The categorical chart indicates which of three broad types of descriptors, i.e. file type, format, and access, characterizes each resource. The descriptions of each of the 73 information and data resources are arranged alphabetically by name of resource; each is described in terms of source, subject, content, compilation, and access. The subject index is for identifying information and data resources relevant to particular topics.

CATEGORIES OF INFORMATION AND DATA RESOURCES



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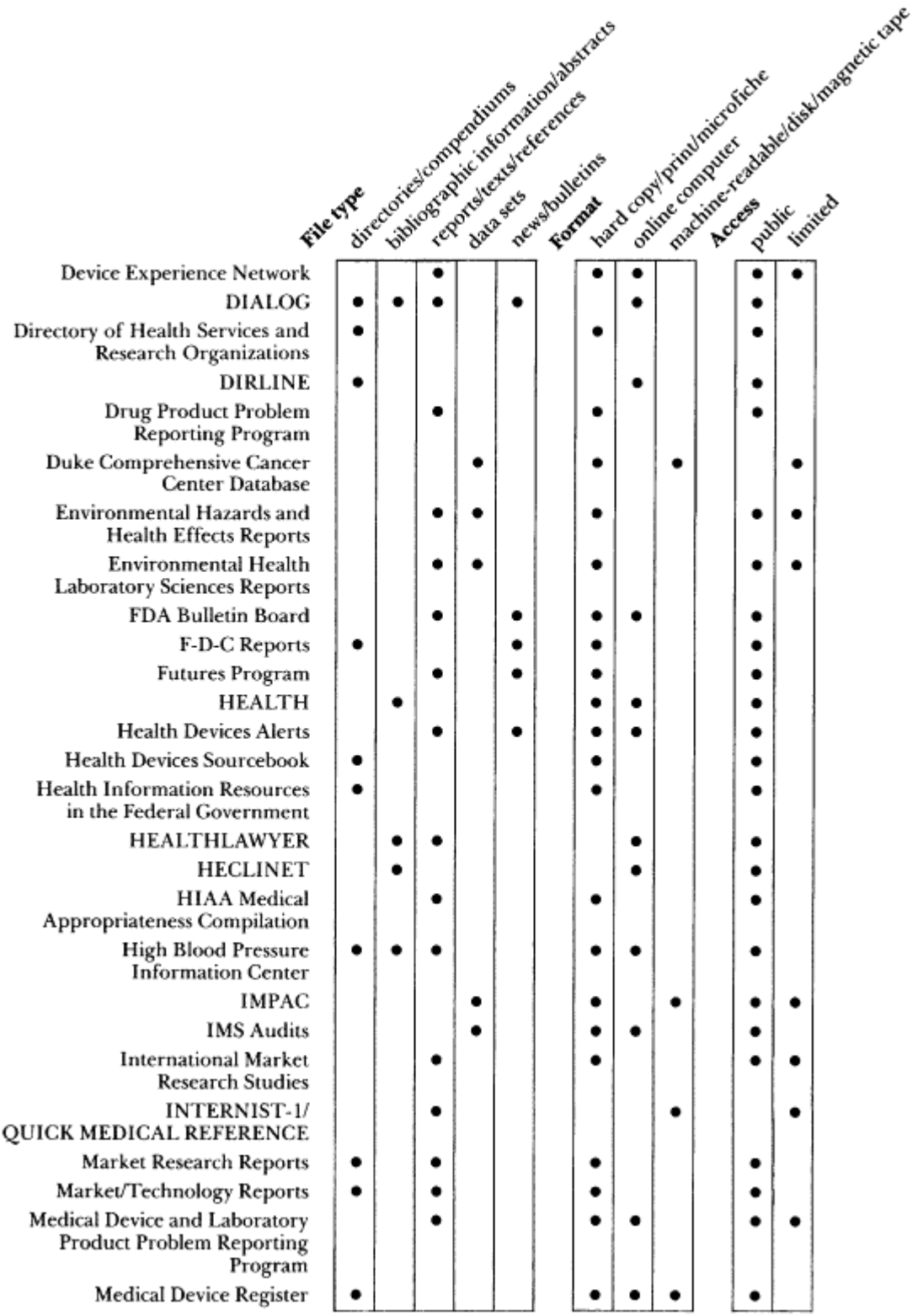
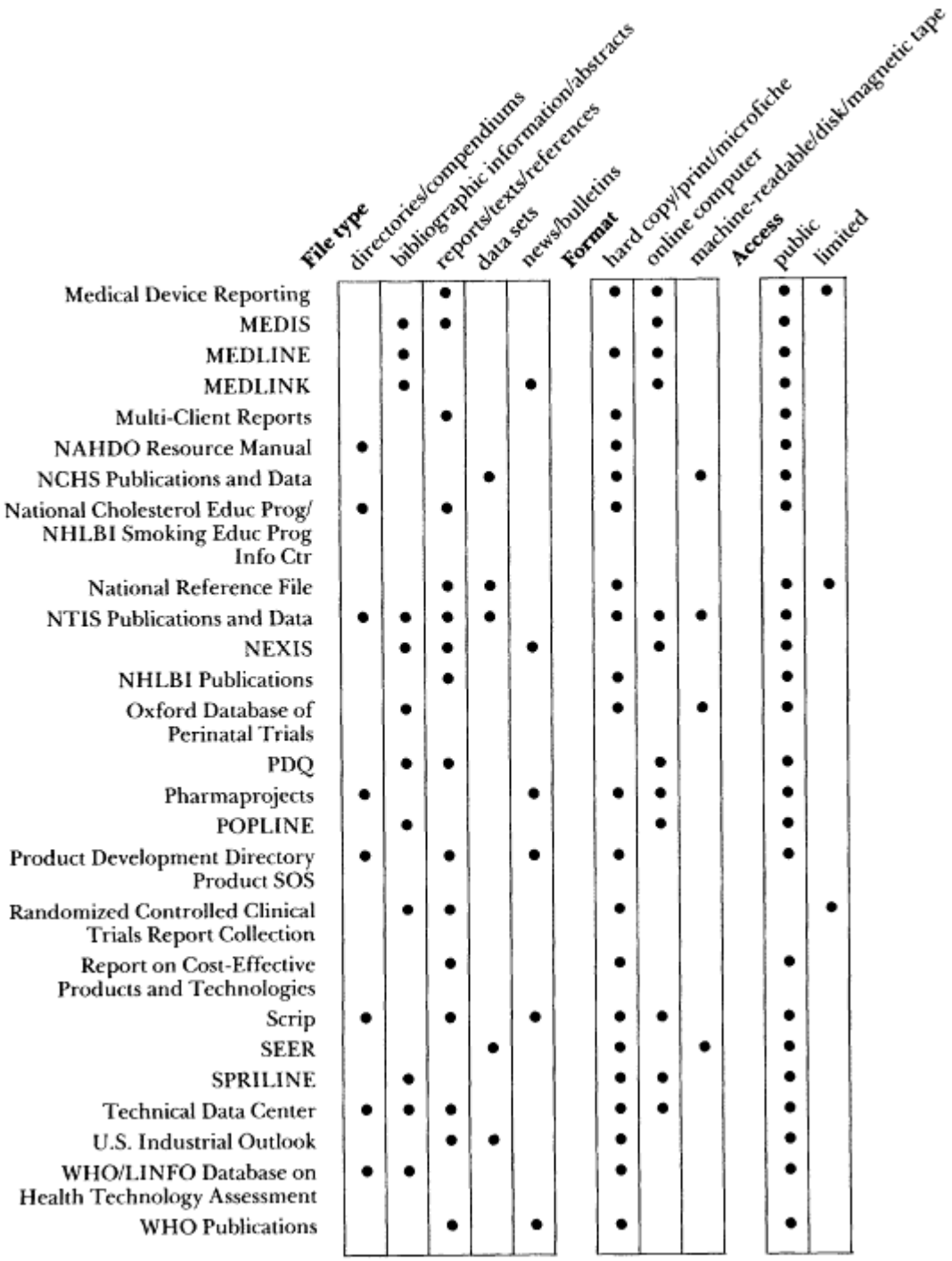


File type	directories/compendiums	bibliographic information/abstracts	reports/texts/references	data sets	news/bulletins	Format	hard copy/print/microfiche	online computer	machine-readable/disk/magnetic tape	Access	public	limited
Device Experience Network			•				•	•			•	•
DIALOG	•	•	•		•			•			•	
Directory of Health Services and Research Organizations	•						•				•	
DIRLINE	•							•			•	
Drug Product Problem Reporting Program			•				•				•	
Duke Comprehensive Cancer Center Database				•			•		•			•
Environmental Hazards and Health Effects Reports			•	•			•				•	•
Environmental Health Laboratory Sciences Reports			•	•			•				•	•
FDA Bulletin Board			•		•		•	•			•	
F-D-C Reports	•				•		•				•	
Futures Program			•		•		•				•	
HEALTH		•					•	•			•	
Health Devices Alerts			•		•		•	•			•	
Health Devices Sourcebook	•						•				•	
Health Information Resources in the Federal Government	•						•				•	
HEALTHLAWYER		•	•					•			•	
HECLINET		•						•			•	
HIAA Medical Appropriateness Compilation			•				•				•	
High Blood Pressure Information Center	•	•	•				•	•			•	
IMPAC				•			•		•		•	•
IMS Audits				•			•	•			•	
International Market Research Studies			•				•				•	•
INTERNIST-1/ QUICK MEDICAL REFERENCE			•						•			•
Market Research Reports	•		•				•				•	
Market/Technology Reports	•		•				•				•	
Medical Device and Laboratory Product Problem Reporting Program			•				•	•			•	•
Medical Device Register	•						•	•	•		•	



ABSTRACTS OF HEALTH CARE MACHINE-READABLE DATA FILES

Source: Hospital Data Center, Department of Special Studies, American Hospital Association (AHA), 840 North Lake Shore Drive, Chicago, IL 60611, 312-280-6520

Subject: Machine-readable databases related to health care that are national in scope and are available to users outside the source organizations, with or without restrictions on use or conditions of release.

Content: The 1986 version contains 137 abstracts of non-bibliographic machine-read-able files. Each abstract includes the file citation, brief narrative description, descriptors based on NLM controlled vocabulary MESH, geographic coverage, time coverage, technical notes, information about related files, availability, and contact person. The abstracts are arranged alphabetically by title and are indexed by source and by MESH. The 1986 version is an expansion and updating of shorter descriptions of 257 databases contained in the 1984 version. The forthcoming version will be an expansion and update of the two earlier documents.

Compilation: All versions were compiled by the AHA from survey forms sent to source organizations. Databases listed include data pertaining to periods later than January 1, 1970.

Access: The 1986 volume *Abstracts of Health Care Machine-Readable Data Files* (157 pages) is available from the AHA Hospital Data Center; price to be set by AHA. Its predecessor, the 1984 *Inventory of U.S. Health Care Data Bases 1976-1983*, was originally published by HRSA, and is available from NTIS (order HRP0906300LP) for $18.95 plus $3 handling. An updated version, *Inventory of Machine-Readable Healthcare Data Bases* will be available in 1988; price to be set by AHA.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION PUBLICATIONS AND DATA

Source: Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), Park-lawn Building, Room 13C-05, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3820

Subject: Alcohol, drug abuse, and mental health (ADM) disorders.

Content: Publications and data cover statistical, epidemiological and services research information pertaining to substance abuse and mental health disorders and their public health implications. Includes ADM client/patient data, research findings on ADM disorders, facility service and resources information, and financial data. Also available: directory of organizations involved in ADM research, treatment, and related issues.

Compilation: Most ADAMHA activities initiated in 1972. Information gathered from clients in treatment; facilities providing alcohol, drug abuse, and mental health treatment and prevention services in U.S., Puerto Rico, and six territories. Publications issued periodically.

Access: Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) publications are available free of charge by contacting individual institutes within ADAMHA, i.e., National Institute on Drug Abuse (NIDA) 301-443-4577, National Institute on Mental Health (NIMH) 301-443-4515, National Institute on Alcohol Abuse and Alcoholism (NIAAA) 301-443-2954. Studies independently conducted for use by NIAAA, NIDA, NIMH; IBM-compatible data tapes available from sponsoring Institute, price to be determined. Sample formats of particular data collections or surveys are available from sponsoring Institutes.

AMA/NET

Source: SoftSearch, Inc., 1560 Broadway, Suite 900, Denver, CO 80202, 303-832-7111, 800-426-2873. Sponsored by the American Medical Association (AMA).

Subject: Medicine and health care delivery; designed for health care professionals.

Content: AMA/NET provides the following databases. AP MEDICAL NEWS SERVICE is a compendium of health care-related articles selected from Associated Press news wires and U.S. newspapers. EMPIRES CURRENT AWARENESS provides access to specialty specific citations; contains references to articles from over 300 international medical and scientific journals covering some 65 medical specialties and subspecialties. DISEASE INFORMATION is a reference summary of more than 3,500 distinct diseases, disorders, and conditions; provides synopsis of classic signs and symptoms, as well as laboratory and radiologic findings of the entities. MEDICAL PROCEDURE CODING & NOMENCLATURE, based on AMA publication *Physicians' Current Procedural Terminology* includes descriptive terms and billing codes for more than 6,000 medical procedures and services performed by physicians. SOCIO/ ECONOMIC BIBLIOGRAPHIC INFORMATION contains over 5,500 citations to documents pertaining to health care delivery and economic issues in medicine.

Also available are electronic communications services, including electronic mail and bulletin boards; public information services providing direct access to such government organizations as the Centers for Disease Control, the Surgeon General's Office, and the National Library of Medicine/National Institutes of Health; AMA; literature ordering service providing reprints of articles referenced in either the SOCIO/ECONOMIC BIBLIOGRAPHIC INFORMATION or EMPIRES databases; interactive, computer-based continuing medical education courses developed at the Massachusetts General Hospital Laboratory of Computer Science.

Compilation: Databases compiled from journal articles, legislative reports, books, wire services, and newspapers. AP MEDICAL NEWS SERVICE updated daily; EMPIRES updated weekly.

Access: Online databases and other services available at any time; accessible via modem from remote terminal. Subscription required. One-time subscription fee ($30 for AMA members, $50 for non-members) includes one user name and introductory materials. Registration fee for each additional user $15. Basic service charge $14/hour peak time; $10/hour off-peak. Information service charge varies with service used.

BASELINE REPORTS

Source: Massachusetts Health Data Consortium, Inc., 400-1 Totten Pond Road, Waltham, MA 02154, 617-890-6040

Subject: Diagnosis, treatment, costs, and outcomes of all patients discharged from acute care hospitals in Massachusetts.

Content: Database covers information on hospital utilization, hospital charges, patient sociodemographic characteristics, clinical status including principle diagnoses and procedures, and discharge status. The following types of reports and data sets are available. Patient origin report sets identify hospital service areas and community dependency for pediatrics, medical/surgical, obstetrics/gynecology, and psychiatry. Market position reports analyze market penetration by town, age, and payer. Market position trend analyses chart market share changes over time by hospital for 24 clinical specialties. Statewide summary charge data reports rank top 100 diagnosis-related groups (DRGs) by payers, hospital bed size, patient discharge status, sex, and age. Hospital-specific charge data reports highlight charges and length of stay by DRGs. Case mix profiles display a case mix adjustment factor and length-of-stay performance measures. Per diem charge profiles provide case mix adjusted per diem charges for Blue Cross and commercially insured patients. Payer mix trend analyses display changes in payer mix for 24 clinical specialties. Community use rate reports contain population-based discharge and use rates. DRG outlier and mortality reports include hospital-specific length of stay, deaths, and outliers by DRG. Data express service provides custom reports in response to special requests for data or analyses.

Compilation: Information gathered from data tapes supplied by 109 acute care hospitals and two Veterans Administration hospitals in Massachusetts and surrounding communities. Coverage from 1978 to present; updated annually.

Access: Free catalog of publications available upon request. Report prices range from $75 to $1,850. Database available online; accessible via modem from remote terminal.

BIOETHICSLINE

Source: Bioethics Information Retrieval Project, Kennedy Institute of Ethics, Georgetown University, Washington, DC 20057, 202-687-3885

Subject: Multidisciplinary coverage of the ethical, legal, and public policy aspects of medicine, health care, and biomedical and behavioral research.

Content: Database includes bibliographic citations to documents relating to euthanasia, organ donation and transplantation, allocation of health care resources, patients' rights, codes of professional ethics, in vitro fertilization and other reproductive technologies, genetic intervention, abortion, behavior control and mental health therapies, and human experimentation. About 20 percent of citations include abstracts. Approximately 80 percent of database keywords are mapped to terms in NLM controlled vocabulary MeSH, making it possible to search BIOETHICSLINE using MESH. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Compiled from journal articles, monographs, newspaper articles, court decisions, bills, laws, audiovisual materials, and unpublished documents. Coverage from 1973 to present. Updated bimonthly with approximately 2,000 citations added annually.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. To contact MEDLARS Management Division call 800-638-8480 or 301-496-6193 in Maryland. Call source for search strategies and further information about *Bibliography of Bioethics* and related services. Connect cost averages $22/hour peak time, $15/hour off-peak.

Individual searches available free of charge from the affiliated National Reference Center for Bioethics Literature 800-633-3849; citations are printed offline and arrive in about one week. Printed bibliographies on selected topics are available bimonthly ($10/topic, $60/complete package). BIOETHICSLINE citations appear in print form in the annual *Bibliography of Bioethics* ($25).

BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES REPORTS

Source: Division of Birth Defects and Developmental Disabilities (BDDD), Center for Environmental Health, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333, 404-454-4706

Subject: Adverse reproductive outcomes, congenital malformations, genetic diseases, and other diseases or conditions that originate before birth or that develop during childhood.

Content: BDDD surveillance activities include the following programs. Metropolitan Atlanta Congenital Defects Program (MACDP) monitors occurrence of congenital malformations (e.g., structural, chromosomal, or biochemical abnormalities) in Atlanta-area hospitals and maintains a case registry for epidemiologic and genetic studies. Birth Defects Monitoring Program (BDMP) monitors U.S. incidence of birth defects; functions primarily as an early warning system for correlating incidence patterns with temporal and geographic distribution of drugs, chemicals, other possible human teratogens. Developmental Disabilities Surveillance Program collects and analyzes data on developmental disabilities in 10 year-olds in Atlanta area. Data include statistical information for trend analysis and selected regional comparisons.

Compilation: MACDP initiated in 1967; BDMP initiated in 1975; Developmental Disabilities Surveillance initiated in 1985. BDMP data gathered from hospital discharge data on newborns. MACDP drawn from Atlanta-area hospital records. Disabilities Surveillance Program drawn from educational and health care providers records. MACDP updated monthly; BDMP updated quarterly. Surveillance reports published intermittently.

Access: Copies of *Congenital Malformations Surveillance* reports available upon request. All data maintained in computer files is for access by CDC staff; no public use data tapes available. Staff may prepare documents or data sets in response to justified individual requests made directly to BDDD for specific data or information.

BMEDSS (BIOMEDICAL ENGINEERING DECISION SUPPORT SERVICES)

Source: Medical Engineering Department, Akron City Hospital, 525 East Market Street, Akron, OH 44309-2090, 216-375-3501

Subject: Pharmaceuticals, medical devices and equipment. Designed primarily for biomedical engineers, device/equipment manufacturers, purchasing agents, materiel managers, biomedical research and teaching professionals.

Content: BMEDSS databases include FDA ENFORCEMENT REPORTS on medical devices and lab reagents, FDA RECALL REPORTS on pharmaceuticals, FDA TALK PAPERS, FDA MEDICAL DEVICE BULLETIN, FDA DEN (Device Experience Network) and MDR (Medical Device Reporting) as formatted and coded by ECRI, abstracts from *Journal of Clinical Engineering* from 1976 to present, abstracts of AAMI (Association for the Advancement of Medical Instrumentation) publications including *National Standards and Recommended Practices, Technology Assessment Reports, Updates and Information Reports*, and *Medical Instrumentation*; ECRI databases including HDA (Health Devices Alerts), abstracts and indexes of ECRI publications. Other services include User Report Forum that allows device experiences to be entered onto FDA DEN; Inventory Comparison Program permits in-house medical device inventories to be compared to current FDA recall file and ECRI's HDA and DEN files, and automatically flags recalled equipment; electronic mail and bulletin board.

Compilation: Information gathered from FDA sources, ECRI publications and databases, professional journals, and other relevant publications. Databases updated monthly. BMEDSS initiated in 1984.

Access: Databases available online through COMPUSERVE 800-848-8990; accessible via modem from remote terminal. Charges are $50 subscription fee plus approximately $35/month and $35/connect hour, adjusted for usage. Special group rates available. Connect cost varies with service used. Reprints of abstracts are available; contact BMEDSS for further information.

BOSTON COLLABORATIVE DRUG SURVEILLANCE PROGRAM

Source: Boston University Medical Center, 400 Totten Pond Road, Waltham, MA 02154, 617-890-1300. Supported by the FDA and the pharmaceutical industry.

Subject: Postmarketing drug surveillance.

Content: Program monitors clinical effects of drugs routinely prescribed to hospitalized and ambulatory-care patients. Database includes information on frequency and importance of adverse drug reactions, adverse reaction rates, adverse reaction causation, assessment of adverse drug interactions, unsuspected drug side effects, drug efficacy, and evaluation of the role of certain patient characteristics in influencing clinical drug effects. Information is also available regarding drug utilization and prevailing practices in drug therapy such as magnitude of drug use, frequencies of various indications, utilization of specific drugs, and variability of utilization patterns by hospital and geographic area.

Compilation: Program implemented in 1966. Studies use data from two primary sources: drug use experience of 50,000 people hospitalized in one of eight hospitals in the U.S., Canada, and Israel; and members of Group Health Cooperative of Puget Sound (GHC) in Seattle, Washington. Hospital data include records of all drug exposures and all adverse events at the selected hospitals. Automated data files received from GHC on annual basis include all prescriptions and refills filled by GHC members at one GHC pharmacy, hospitalizations of GHC members, and routine information on GHC members.

Access: Boston Collaborative Drug Surveillance Program (BCDSP) computer tapes are not in the public domain. Contact BCDSP regarding access to data resources in collaboration with BCDSP. Over 200 articles describing past BCDSP studies have been published in various medical and professional journals. Reprints are available upon request. Listing of publications is available in: Cohen, M.R. A Compilation of Abstracts and Index Published by the Boston Collaborative Drug Surveillance Program 1966-1985. *Hospital Pharmacy* 21:497-559, 1986.

BRS/SEARCH

Source: BRS Information Technologies, 1200 Route 7, Latham, NY 12110, 800-345-4277

Subject: Health, medicine, pharmacology, biosciences, science and technology, education, business and finance, social sciences, politics, humanities.

Content: BRS/SEARCH Service includes over 90 multidisciplinary databases. Among those relevant to medical technology are MEDLINE, HEALTH, PDQ, HEALTHLAWYER, DRUG INFORMATION FULL TEXT (full-text information on current and investigational drugs, including research, treatment, and pharmacological practice), INTERNATIONAL PHARMACEUTICAL ABSTRACTS (indexes and abstracts from international pharmaceutical and health-related journals, covering drug development, use, and professional pharmaceutical practice), DIOGENES (FDA Medical Device Reporting, other regulatory information), EMBASE (from Excerpta Medica; references and summaries of international medical literature covering biomedicine, health, and health care management), IRCS MEDICAL SCIENCE DATABASE (full-text articles on biomedical research). Many databases provide bibliographic citations, many include abstracts; others provide complete document texts; most are indexed by title, subject, author, publication date. Monthly *BRS Bulletin* provides information on new databases, developments, and features.

Compilation: Databases are compiled from journal articles, books, periodicals, dissertations, monographs, government reports, corporate reports, newspaper articles. Most references are updated monthly; newspaper files are updated daily.

Access: Databases available online; accessible via modem from remote terminal through TELENET, TYMNET, OCLC GATEWAY, IN-WATS, direct dial. Outside U.S. and Canada, accessed through BRSNET. Online or offline document printing. Subscription required. Two basic subscription plans offered: (1) basic plan allows access to BRS on an as-needed basis; annual password fee ($75); connect cost ($25/hour plus database royalties), telecommunications, and document charges; (2) advance purchase plan provides volume discounts; a variety of subscription levels available. User manual ($45), database guides ($5 each), database summaries, and catalog available to subscribers. Training seminars offered in BRS/SEARCH features and search procedures.

CANCERLIT

Source: International Cancer Information Center, Office of International Affairs, National Cancer Institute (NCI), Building 82 Room 103, Bethesda, MD 20892, 301-496-7403

Subject: Major cancer topics.

Content: Database includes more than 600,000 citations and abstracts of published cancer literature and other sources. All records from non-MEDLINE sources contain abstracts; more than 60 percent of MEDLINE-derived records include abstracts. Records added since January 1980 have been indexed using NLM controlled vocabulary MESH. All records are retrievable by free-text searching. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Compiled from articles appearing in approximately 2,000 biomedical journals, government reports, meeting abstracts, papers presented at conferences, books, monographs, theses and dissertations. Most journal literature is derived from MEDLINE. Approximately 200 additional foreign journals and published literature references are also screened. 5,000 new references are added monthly.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. To contact MEDLARS Management Division call 800-638-8480 or 301-496-6193 in Maryland. Connect cost averages $22/hour peak time, $15/hour off-peak. Also available through BRS 800-345-4277, COLLEAGUE (BRS/Saunders) 800-468-0908, and DIALOG 800-334-2564.

CASSIS (CLASSIFICATION AND SEARCH SUPPORT INFORMATION SYSTEM)

Source: Patent Depository Library Program Office, Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231, 703-557-9686

Subject: Patent information of the U.S. Patent and Trademark Office.

Content: Encompasses information on the 4.9 million U.S. patents. Generally used to search classes and subclasses of patents in order to identify patent numbers that may be used to locate patent documents in microfilm holdings of Patent Depository Libraries. CASSIS searches or displays classifications of patents, patents in classifications, structured classification titles, keywords in classification titles, keywords in patent abstracts, and terms in the patent classification index.

Within the patent classification system, the following are examples of classes of patents that pertain to medical technologies: surgery (classes 128 and 604); drugs, bio-affecting, and body treating compositions (424,514); dentistry (433); prosthesis, i.e., artificial body members, parts thereof, or aids and accessories therefore (623); genetic engineering technology (935); multicellular living organisms and unmodified parts thereof (800); chemistry: molecular biology and microbiology (435); chemistry: analytical and immunological testing (436); eye examination, vision testing, and correcting (351). Each class has many subclasses.

Compilation: Operational since the late 1970s. Updated continuously; information about a new patent appears in the system approximately two months after it is issued. Although all patent numbers and classification information remain on the system, patent abstracts are rotated off after one to three years.

Access: Available online at no charge through any of the 60 Patent Depository Libraries located in 38 states in the U.S. No direct access from other remote terminals.

CCC (COPENHAGEN COLLABORATING CENTER) BIBLIOGRAPHY ON REGIONAL VARIATIONS IN HEALTH CARE

Source: Copenhagen Collaborating Center for the Study of Regional Variations in Health Care, Institute of Social Medicine, University of Copenhagen, Panum Institute, Blegdamsvej 3, 2200 Copenhagen N., Denmark, (45-1) 35-79-00 Ext. 3011. CCC is a World Health Organization (WHO) Collaborating Center established by four Danish research institutes.

Subject: Regional variation in the provision, utilization, and outcomes of health care.

Content: Studies covered in bibliography focus on small area variations, employ epidemiological methods, and include interpretation and discussion of variations. 1986 bibliography contains 153 entries, abstracts/extracts, author and subject index. Quarterly *International Newsletter on Regional Variations in Health Care* reports regional variations in medical practice, practice outcomes, clinical decision-making processes. Other articles include meeting announcements, summaries of proceedings, international activities in technology assessment, e.g., WHO Global Programme for Appropriate Health Care Technology. Also available is a directory of persons and institutions interested in regional variations in health care. Other CCC activities include research, organization of international meetings, and international research training.

Compilation: Bibliography compiled through unpublished literature reviews and information from researchers in the field. Data for other organizational and information activities are acquired through questionnaires sent to individuals and research institutes. CCC activities initiated in 1985. First bibliography was published in 1986; to be updated periodically. Directory is updated continuously.

Access: Online text retrieval and literature searches available from Danish Hospital Institute. Printed copy of bibliography and copies of newsletter available upon request. Contact CCC about receiving newsletter on regular basis.

CENTER FOR HEALTH PROMOTION AND EDUCATION

Source: Centers for Disease Control (CDC), 1600 Clifton Road, Atlanta, GA 30333, 404-321-2263

Subject: Nutritional status of select U.S. populations, behavioral risk factors, women's reproductive health.

Content: Reports and data tapes from Center for Health Promotion and Education's (CHPE) national surveillance activities cover nutritional status of high-risk pediatric populations and low-income, high-risk pregnant women, adolescent pregnancy, infant mortality, abortion, and behavioral risk factors such as smoking, hypertension, obesity, and alcohol use. Areas of applied research include female reproductive cancer and endogenous hormones, and the safety and efficacy of tubal ligation/female sterilization procedures. Data include statistical and demographic information which permit trend analysis and select regional comparisons.

Compilation: CHPE established in 1981. Information gathered primarily from state health departments, clinics, and select health and nutrition programs, e.g., Supplemental Food Program for Women, Infants, and Children (WIC), Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. Information on behavioral risk factors gathered through telephone surveys by states. Reports usually issued annually.

Access: Reports available upon request, free of charge. Contact CHPE) for further information regarding access and availability of public use data tapes.

CLINPROT

Source: International Cancer Information Center, Office of International Affairs, National Cancer Institute (NCI), Building 82 Room 103, Bethesda, MD 20892, 301-496-7403

Subject: Clinical investigations of new anti-cancer agents and treatment modalities.

Content: Database contains comprehensive information on approximately 6,000 experimental cancer therapy protocols from the U.S. and other countries; approximately 1,500 are active protocols and over 4,000 are completed studies. Protocol summaries provide descriptions of clinical trials, including protocol objectives, study outline, patient entry criteria, treatment regimen, special study parameters, and status of the protocol. Active protocols indexed according to type and stage of cancer treated, phase of clinical investigation, specific agents or combination of agents, treatment modalities. Records retrieved by free-text searching or by using the 300 clinical protocol terms used for indexing. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Coverage from 1960 to present. Currency and accuracy of information are maintained through monthly updates.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. To contact MEDLARS Management Division call 800-638-8480 or 301-496-6193 in Maryland. Connect cost averages $22/hour peak time, $15/hour off-peak.

COLLEAGUE

Source: BRS/Saunders, 1290 Avenue of the America's, New York, NY 10104, 800-468-0908

Subject: Health care, medicine, pharmaceuticals; designed for health care professionals.

Content: Medical Search Service offers bibliographic sources including MEDLINE, HEALTH, EMBASE (from Excerpta Medica), BIOSIS PREVIEWS, INTERNATIONAL PHARMACEUTICAL ABSTRACTS, COMPREHENSIVE CORE MEDICAL LIBRARY, and PDQ. Medical and Psychological Previews Service permits access to citations from over 200 journals indexed by title and author prior to their inclusion in MEDLINE; also includes editorials, letters, and clinical notes. Complete Text Library incorporates full text of more than 20 medical books and textbooks in critical care medicine, and more than 50 medical and health-related journals. General Searching Service allows access to 70 other nonmedical databases offered by BRS. Electronic mail and bulletin boards are available through COLLEAGUE Mail service.

Compilation: Databases compiled from journal articles, periodicals, textbooks, monographs, medical manuals. Most references updated monthly; Medical and Psychological Previews updated weekly.

Access: Databases available online; accessible via modem from remote terminal through TELENET, TYMNET, direct dial. Online or offline document printing are available. Connect cost $32 to $79/hour peak time, $20 to $69/hour off-peak. Connect time volume discounts available. Subscription required. One-time registration fee ($95/ individual, $175/group), includes password, user manual, and support services. Tutorial diskettes explaining COLLEAGUE and search strategies available upon request.

COMPASS (COMPUTERIZED ON-LINE MEDICAID PHARMACEUTICAL ANALYSIS AND SURVEILLANCE SYSTEM), DURBASE (DRUG UTILIZATION REVIEW BASE)

Source: Health Information Designs, Inc. (HID), 1616 North Fort Meyer Drive, Suite 1420, Arlington, VA 22209, 703-528-2032

Subject: Postmarketing drug surveillance.

Content: COMPASS database is composed of patient-specific billing data, including age, sex, state, inpatient and outpatient diagnoses recorded by ICD-9-CM codes, and outpatient drugs dispensed. Drug data are retrievable by strength, generic name, therapeutic class, or manufacturer. Database is supplemented by data on mortality, maternal-child linkages, and nursing home status. Reports available on individual patient diagnosis and prescription profiles, rankings of drugs and diagnoses, demographic characteristics, drug use patterns, average daily doses for specific drugs, comparisons of clinical outcomes between patients receiving specific drugs and control groups, and temporal relationships between specific drugs and subsequent diagnoses.

DURbase is a computerized drug utilization review system for identifying patients at high risk for drug-induced illness. Reports include chronological listings of all pharmaceuticals for patients identified as being at risk for drug-induced illness, summaries of individual patient prescription patterns, and other services.

Compilation: COMPASS and DURbase are drawn from HID database consisting primarily of billing data covering hospital, dental, and pharmaceutical services provided to 9 million patients, including 7 million Medicaid patients from 11 states and 2 million patients from HMOs, major employers, and other private sector sources. Medicaid data come from state Medicaid Management Information Systems. More than 20 million encounter records are added to the database monthly, including 7 million prescription drug claims. System includes data collected since 1980.

Access: COMPASS is used primarily by the FDA and pharmaceutical companies for postmarketing surveillance. DURbase is used primarily by government and private sector providers and payers for drug utilization monitoring and related quality review activities for their patient groups. Most HDI products are in the form of reports generated from COMPASS and DURbase data and analysis. Report prices depend upon the amount of data, level of analysis, and computer time required; charges for COMPASS products may range from $2,000 to $250,000. Online access to COMPASS is available only to the FDA. DURbase charges generally are based upon the size of the patient group studied and a per patient record charge. Patient group sizes range from 10,000 to 1.5 million people for certain Medicaid data sets. Charge per patient record ranges from $0.60 to $1.25 depending upon the extent to which HDI is asked to undertake clinical review of the data.

COMPENDIUM OF HHS EVALUATIONS AND RELEVANT OTHER STUDIES

Source: HHS Evaluation Documentation Center (EDC), Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services (HHS), Room 438F Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, 202-245-6445

Subject: Examples from 300-term subject index are ambulatory and outpatient health care, biomedical research, drugs therapeutic and devices, economic analysis, health care delivery systems, health insurance and financing, information systems, medical practice, medical technology, quality assurance, and utilization review.

Content: Project descriptions of in-process and completed evaluations from the Office of the Secretary of HHS, HCFA, PHS (e.g., ADAMHA, CDC, FDA, HRSA, NIH, OASH), Social Security Administration, and other agencies. *Compendium* is organized by HHS operating divisions and agencies; it includes project descriptions (1,800 in 1985 edition), a subject index, agency sponsor index, and program name index. Project descriptions include agency sponsor, project title, report title, performer, agency contact, programs evaluated, abstract, access descriptors, and other information. The 1985 edition is 926 pages long; the 1987 edition is approximately 1,100 pages long.

Compilation: Compiled from one-page descriptions of all ongoing and completed HHS evaluation studies carried out since the early 1970s. EDC first published project descriptions of HHS evaluation activities in 1976. System was computerized in 1979. Database was expanded in later years to include more agencies.

Access: Copies *of Compendium*, a bound volume, may be obtained from NTIS 703-487-4650. 1985 (fifth) edition (order PB86112281) price is $66.95 plus $3 handling. Sixth edition due summer 1987. For electronic access to the EDC database, users must register with EDC and have an account with the Parklawn Computer Center. EDC makes available *Users Guide to the Evaluation Documentation Center* and *Sponsors Guide to the Evaluation Documentation Center*. The quarterly *Memorandum* provides information on EDC acquisitions as they occur.

CPHA (COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES) FILES

Source: CPHA, 1968 Green Road, PO Box 1809, Ann Arbor, MI 48106. 800-521-6210, 800-828-6762 in Michigan

Subject: Computerized patient discharge data.

Content: *National Inpatient Profile* is a diagnosis and procedure utilization data set drawn from the CPHA *National Patient Sample File*. Two-volume annual set is sequenced by ICD-9-CM diagnoses and procedures. The summary profile section provides overview of projected number of principal and secondary diagnoses or procedures treated in U.S. hospitals. The detail profile displays demographic, clinical, and facility characteristics of these diagnoses and procedures. For each ICD-9-CM code, data are provided on patient demographics, patient clinical information, number and percent of patients having the code as a principal procedure, number and percent of occurrences of the code as a secondary procedure, and hospital facility information.

Other standard CPHA data sets include *Cost Containment Series: Length of Stay and Medicare Ancillary Charge Norms, Quality of Care Series: Case Fatalities by DRG*, and *National Outpatient Profile. National Patient Sample File* is also used to generate other data files and customized data sets on, e.g., newborns, inpatient charges, and trends in occurrences of diseases and procedures.

Compilation: CPHA files are compiled from patient discharge data from more than 1,400 hospitals, covering 10 million patients and 25 percent of North America's acute care hospitalizations. *National Patient Sample File* is based on 2 million patient sample drawn every year. CPHA archive maintains a total of 300 million patient records. For some files, CPHA merges its patient data with institutional data from the American Hospital Association and other sources.

Access: CPHA files are available as hard copy reports, on floppy disk, or magnetic tape. Charge for *National Inpatient Profile* is $5,000 to commercial and $750 to non-commercial buyers. Charge for *National Outpatient Profile* is $3,000 to commercial and $500 to non-commercial buyers. Charge for *Length of Stay* information sets (one each on diagnoses and procedures) is $85 for books and $4,500 for tapes. Prices for customized statistical reports vary; typical charge may be $500, or less if client is a regular subscriber to CPHA information services.

CRISP (COMPUTER RETRIEVAL OF INFORMATION ON SCIENTIFIC PROJECTS)

Source: Statistics and Analysis Branch, Division of Research Grants (DRG), National Institutes of Health, Bethesda, MD 20892, 301-496-7543

Subject: Scientific information on extramural research projects supported through grants and contracts programs of NIH, ADAMHA, and other PHS agencies, as well as intramural research projects conducted by NIH and ADAMHA.

Content: In general, information from CRISP can take the form of topical scientific information or institution-based scientific profiles. The five files of CRISP computer information system use disk storage for random and sequential access. CRISP is capable of subdividing program projects, center, and other multifaceted projects into smaller research components. File 1 is a master dictionary of scientific subject headings corresponding to those appearing in MHRST (Medical and Health Related Sciences Thesaurus used for describing research projects). File 2 stores the indexed subject heading numbers with their associated project numbers. File 4 serves to combine the data elements contained in the Files 1 and 2. File 3 is a project identification master file, consisting of information transferred from IMPAC (a related system dealing with administrative aspects of NIH extramural programs; see description), including project and subproject numbers and titles, investigators names and addresses, initial review group designations, institution codes, and amounts awarded. File 5 contains the investigator-prepared narrative for each project. The two-volume Research Awards Index, compiled from CRISP, contains project and contract information listed by subject, project or contract number, and principal investigator.

Compilation: Projects are indexed based on applications or progress reports for extramural research, and on annual reports or project narratives for intramural research. CRISP is updated twice weekly; intramural projects are reported and entered into CRISP annually. The project identification master file (File 3) is updated through weekly links with IMPAC. MHRST is updated semiannually. The Research Awards Index is published annually.

Access: Direct access to CRISP files is available to all N I H staff with registered accounts by contacting DRG. Online access to selected data from the latest fiscal year files is available to outside individuals or organizations through subscription from NTIS 703-487-4808.

CURRENT ASSESSMENTS, NEW TECHNOLOGY ABSTRACTS

Source: New York State Center for Assessing Health Services, Health Services Center 4L 215, State University of New York at Stony Brook, Stony Brook, NY 14794, 516-444-2101

Subject: *Current Assessments* covers public health, clinical and health services research; *New Technology Abstracts* covers innovations in health care technology and biomedical research.

Content: *Current Assessments* provides annotated summaries of journal articles that report findings from public health, clinical, and health services research; and address the impact of technology on health policy. Summaries include reference citation, research findings, description of data source, study population, research methodology, study limitations, and implications of research for health care industry and subsequent policy decisions.

New Technology Abstracts lists citations to journal articles and reports that cover new technologies in health care and biomedical research, or innovative applications of existing technologies. Also includes listings of FDA notices and notices from U.S. Patent Office. Center also conducts studies of the impact of changes in health services for health policy. Studies conducted during 1987 address innovations in intensive home health care, regulation of risk in ambulatory surgery, organization of organ replacement services by states, and cost of inpatient treatment for patients with AIDS in four hospitals in metropolitan New York.

Compilation: Journal articles were selected through monthly computer search *of Index Medicus, Index to Dental Literature, International Nursing Index, Hospital Literature Index*, and staff review of recent publications. Center also conducted monthly search of U.S. government technical and research reports listed in NTIS Bibliographic Data Base, FDA notices listed in *Federal Register*, and patents for medical devices reported in the *Official Gazette of the U.S. Patent and Trademark Office*. Publications were first issued in 1985. *Current Assessments* and *New Technology Abstracts* published every few months.

Access: In 1987, the New York State Department of Health ended its cosponsorship of the Center, hence, publication of *Current Assessments* and *New Technology Abstracts* has been suspended. Back publications, reports, and copies of articles listed in *New Technology Abstracts* ' are available upon request.

DEVICE EXPERIENCE NETWORK (DEN)

Source: Division of Product Surveillance, Office of Compliance, Center for Devices and Radiological Health, HFZ-343, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-8100

Subject: Postmarketing surveillance of FDA-approved medical devices and in vitro diagnostic and laboratory products.

Content: Computerized database contains voluntary reports from health care providers and provider organizations concerning device-related hazards, defects, and deficiencies; these include performance failures, improper labeling, incomplete, inadequate, or erroneous instructions, unsatisfactory packaging, or defective components. DEN identifies industry-wide problems and significant trends, e.g., product recalls and regulatory actions related to a particular product.

Compilation: DEN consists primarily of information from the Medical Device and Laboratory Product Problem Reporting Program (PRP) administered by the United States Pharmacopeial Convention and the Medical Device Reporting (MDR) program of the FDA. Information is gathered from health care professionals, hospitals, state and local government, public health officials, FDA field offices, contracting groups, consumer organizations, and consumers. Established in 1973. Updated continuously.

Access: DEN reports accessible through BMEDSS 216-375-3501, National Technical Information Service 703-487-4630, Medical Device Register's *Product SOS* 203-348-6319, and ECRI 215-825-6000. Confidential trade, commercial, financial, personnel, medical, and patient information are deleted from publicly available reports. DEN reports in microfiche and additional information about specific reports available from FDA, Freedom of Information Office, Room 12A16, HFI-31, 5600 Fishers Lane,

Rockville, MD 20857, 301-443-6310. Monthly publication *Device Experience Network Reports*, which includes PRP but not MDR information, is available from FOI Services 301-881-0410 for $190. To report a device problem call U.S. Pharmacopeial Convention 800-638-6725 or contact FDA.

DIALOG

Source: DIALOG Information Services, Inc., 3460 Hillview Avenue, Palo Alto, CA 94304, 800-334-2564, 415-858-3785

Subject: Databases cover biosciences, health care, medicine, science and technology, business and finance, law, government, social sciences, current affairs/news, humanities, education.

Content: Includes over 250 multidisciplinary databases. Those relevant to medical technology include BIOSIS PREVIEWS, CANCERLIT, CLINICAL ABSTRACTS (abstracts from journals covering clinical medicine, clinical practice, and research), DRUG INFORMATION FULL TEXT (full-text information on current and investigational drugs, including research, treatment, and pharmacological practice), EMBASE (from Excerpta Medica, with references and summaries of international medical literature, covering biomedicine, health, and health care management), HEALTH, and MEDLINE. Many databases offer bibliographic citations, summaries of articles and reports, detailed financial data on companies, directory listings of companies and associations, or full-text articles and newswires; most indexed by title, subject, author, publication date. Monthly newsletter provides information on DIALOG system and databases. Electronic mail and bulletin boards available through DIALMAIL service.

Compilation: Databases are compiled from journal articles, books, periodicals, patent indexes, business/company directories, newspaper articles, government documents, dissertations and theses, wire services, corporate reports. Most references are updated monthly; newspaper files are updated daily.

Access: Databases are available online; accessible via modem from remote terminal through DIALNET, TYMNET, TELENET, MEADNET, IN-WATS, INFONET, DUNSNET, direct dial. Online or offline document printing available. Subscription required. Standard service plan requires no initiation fee or monthly charge; first password free for new users. Optional starter package ($150) includes training seminar and user guide. Connect cost includes all database royalties; varies with database searched. Several other service plan/advance purchase options available, e.g., connect cost discounts of up to $15/hour.

DIRECTORY OF HEALTH SERVICES RESEARCH ORGANIZATIONS

Subject: Health services and policy research centers.

Content: Describes more than 100 university-based health services and policy research centers, Veterans Administration health services research and demonstration field programs, and AHSR institutional members. Notes each organization's budget, primary area of emphasis and expertise, staffing, training capabilities, organizational location, address, telephone number, and name of director. Highlights major research projects, funding source, and principle investigator. Indexed by subject, funding source, and principle investigators.

Compilation: Information collected through mail survey and follow-up telephone interviews. Current edition of directory available early 1988.

Access: Directory available upon request. Cost for AHSR members $10; non-members $15.

DIRLINE (DIRECTORY OF INFORMATION RESOURCES ONLINE)

Source: MEDLARS Management Section, National Library of Medicine (NLM), Building 38, Room 4N421, 8600 Rockville Pike, Bethesda, MD 20894, 800-638-8480, 301-496-6193 in Maryland

Subject: Public and private sector health and biomedical organizations.

Content: Database contains information on over 14,000 resource centers, with specialized information in a variety of disciplines. Also includes over 1,500 records for organizations providing information in various areas of health and disease. Contains two subfiles on specialty topics: poison control and substance abuse. Information provided for each organization includes its full name, address, contact person, and telephone number, as well as a summary of its services, activities, publications and interests. Can be searched by organization name using text words or subject-related keywords. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Information gathered from Library of Congress National Referral Center database and the ODPHP National Health Information Center database (a product of the Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services). Specialty subfiles derived from Poison Control Centers and Drug Abuse Communications Network. All records updated at least once every two years. File updated quarterly.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. Connect cost averages $22/hour peak time, $15/hour off-peak.

DRUG PRODUCT PROBLEM REPORTING PROGRAM (DPPR)

Source: Practitioner Reporting System, United States Pharmacopeial Convention, Inc. (USP), 12601 Twinbrook Parkway, Rockville, MD 20852, 301-881-0666. DPPR supported by FDA.

Subject: Postmarketing surveillance of FDA-approved prescription, over-the-counter, and radiopharmaceutical drug products.

Content: Database contains voluntary reports from health care practitioners on problems experienced when pharmaceutical products are received, used, or dispensed; these include unsatisfactory packaging, erroneous or deficient labeling, inadequate package insert information, poor pharmaceutical quality, questionable bioavailability, stability, and therapeutic effectiveness. Reports retrievable by date report submitted, product name, manufacturer and/or type of problem. DPPR identifies trend by specific product, across product lines by drug entity, and by manufacturer.

Compilation: Information gathered via toll-free telephone line or prepared reporting forms from health care professionals including physicians, nurses, pharmacists, biomedical engineers, medical laboratory personnel, risk managers, purchasing and quality assurance personnel, and consumers. Reports are entered as unverified information into FDA databases; FDA is responsible for follow up, i.e., determining manufacturer's evaluation of problem and establishing final assessment of problem. Program initiated in 1971. Updated continuously.

Access: For copies of DPPR reports and product experience data, contact FDA, Freedom of Information Office, 5600 Fishers Lane, Room 12A16, HFI-31, Rockville, MD 20857, 301-443-6310. To report a drug product problem call 800-638-6725 or contact USP for reporting form.

DUKE COMPREHENSIVE CANCER CENTER DATABASE

Source: Duke Comprehensive Cancer Center (DCCC), Duke University Medical Center, Box 3153, Durham, NC 27710, 919-684-2057

Subject: Cancer cases diagnosed or treated at DCCC; designed for clinical and research oncologists.

Content: Database includes epidemiological, histological, and patient demographic information such as patient medical history and history of prior cancers, state of birth, state of residency, zip code, type and stage of cancer/tumor, and treatment regimen. In addition to this comprehensive tumor registry, special registries are often established to investigate specific research questions, to examine sequelae of particular cancers, or to facilitate statistical analyses. *Annual Data Management Unit Report* provides statistical summaries of registry data, e.g., cancer-specific frequencies, county-specific frequencies, tumor-specific trends, survival rates, as well as an in-depth analysis of one or more types of cancer. Research findings also reported in medical journals and at medical conferences.

Compilation: Tumor registry initiated in 1970. All living cancer patients in registry are routinely monitored; individual follow-up every 13 months. Information gathered from daily oncology clinic visits, as well as surveys designed for specific research purposes. Registry data obtained primarily from medical charts; special registries may also obtain data from laboratory and pathology reports.

Access: DCCC computer tapes are not in public domain due to patient confidentiality constraints. Contact DCCC Director regarding access to data resources; written requests indicating purpose of data acquisition and specific data required are preferred. Database search costs, if any, vary according to information requested. Searches available include frequencies and survival graphs.

ENVIRONMENTAL HAZARDS AND HEALTH EFFECTS REPORTS

Source: Division of Environmental Hazards and Health Effects (DEHHE), Center for Environmental Health, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333, 404-454-4772

Subject: Health hazards resulting from environmental contaminants, e.g., toxic chemicals and radiation.

Content: DEHHE databases cover disasters, environmental hazards, toxic chemicals, and other miscellaneous events. National data are collected on deaths, populations exposed to environmental toxicants, persons injured by man-made or natural disasters (e.g., nuclear or chemical disasters, hurricanes, earthquakes, tornados, etc.), variety of public health hazards, and resultant health outcomes. Reports and other publications are based on these databases.

Compilation: Division activities initiated in 1984. Information gathered from individual studies, surveillance systems, laboratory data of subjects in special studies, and National Medical Examiner/Coroner Survey. Reports and other publications issued on an ad hoc basis. Databases updated as necessary.

Access: Reports of studies are usually available from the requesting agency within or outside CDC for which studies are done, rather than from DEHHE. Reports from DEHHE often appear in CDC *Morbidity and Mortality Weekly Report* and scientific journals; reprints available upon request by writing to source. Justified requests for use of databases must usually be made in writing to individual investigator, study collaborators, or CDC Freedom of Information Office.

ENVIRONMENTAL HEALTH LABORATORY SCIENCES REPORTS

Source: Division of Environmental Health Laboratory Sciences (EHLS), Center for Environmental Health, Centers for Disease Control, Chamblee 17/1103, 1600 Clifton Road, Atlanta, GA 30333, 4044524152

Subject: Application of laboratory technology for the diagnosis, treatment, and prevention of chronic diseases and toxic chemical exposures.

Content: EHLS activities include international surveillance of lipid and apolipoprotein measurements for determination of risk to coronary heart disease; international surveillance of toxic chemical exposure incidents (on request); and laboratory support for the National Health and Nutrition Examination Survey (HANES). Data collected on levels of dioxin and related compounds in population; cholesterol and apolipoprotein levels; exposure to and levels of polychlorinated biphenyls; cytology of cervical cancer; levels of lead, cadmium, and arsenic in the population; nutritional markers; exposure to pesticides; phenylketonuria and hypothyroidism; and biomarkers. Reports and other publications are based on these databases; also covered are descriptions of the development, validation, and evaluation of analytical methods used in surveillance activities, e.g., methods for monitoring human exposure to toxicants; responses to acute and chronic occurrences, e.g., exposures; and general epidemiological information.

Compilation: Division activities initiated in 1970. Information gathered from research and clinical laboratories; public health community studies; and national, stratified, probability sample of U.S. households (HANES data). Reports and other publications issued upon study/survey completion.

Access: Reports of studies are usually available from the requesting agency within or outside CDC for which studies are done, rather than from EHLS. Reprints of journal articles written by EHLS staff and other publications available upon request by writing to source. Justified requests for use of databases must usually be made in writing to individual investigator, study collaborators, or CDC Freedom of Information Office.

FDA BULLETIN BOARD

Source: Food and Drug Administration, Press Office, 5600 Fishers Lane, Parklawn Building, Room 1505, HFI-20, Rockville, MD 20857, 301-443-3285

Subject: FDA communications and meetings.

Content: NEWS file contains FDA news releases covering public health and product safety issues, and some product recalls. ENFORCE file contains the weekly *FDA Enforcement Report*, a list of FDA-regulated products under recall; also includes seizure items, prosecution actions, injunction actions, and health fraud notices. CONSUMER file provides table of contents and selected articles from FDA's monthly magazine *FDA Consumer*; also covers topical updates, regulatory matters, and reports on actions by FDA investigators. APPROVALS file contains complete text of the monthly *Drug and Device Products Approvals List* ; includes human drug approvals, medical device approvals, biological licenses issued, and veterinary drug approvals. DATE-REG file provides summaries of all FDA announcements made in the *Federal Register* arranged by publication date; includes short summary of article, name of contact person, and time and place of public meetings. SUBJ-REG provides summaries of all FDA *Federal Register* announcements arranged by subject. BULLETIN contains the current *Drug Bulletin, a* newsletter useful for physicians and other health professionals. CDRH file includes the *Centers for Devices and Radiological Health Bulletins* that are issued monthly and contain information on recent CDRH developments and meetings. MEETINGS file covers upcoming FDA meetings announced in the *Federal Register*; describes time and place of meetings, topics to be discussed, and contact person. CONGRESS file contains full text of prepared statements delivered by FDA officials at congressional oversight hearings. SPEECH file provides full text of prepared speeches delivered by FDA Commissioner and Deputy Commissioner at various meetings. Keyword searching available; document can be scanned or read in its entirety.

Compilation: Most items are added to bulletin board as soon as they are issued and are held for one month.

Access: Available through DAILCOM 202-488-0550. Charges are $25/hour peak time and $22.30/hour off-peak, plus $0.05/kilocharacter; $25 monthly minimum. Contact Press Office for information on obtaining bulletin board documents in print form.

F-D-C REPORTS

Source: F-D-C Reports, Inc., Suite One, 5550 Friendship Boulevard, Chevy Chase, MD 20815, 301-657-9830

Subject: Pharmaceutical product development information.

Content: *NDA Pipeline* is a 600-page annual reference volume covering drug developments during the previous calendar year. Contents include listing by company and generic name of new drug approvals (NDAs) and biological product licenses; original NDAs listed according to FDA classification system for NDAs and investigational new drug applications (INDs); index of products reviewed by FDA advisory committees; descriptions of 1,200 drug and biological products under development; articles from *Prescription and OTC Pharmaceuticals*; FDA drug advisory committee members and meetings; list of orphan products; and index and contact information for companies mentioned in volume.

Additional F-D-C Reports include the following weekly newsletters. *Prescription and OTC Pharmaceuticals* covers regulatory activities, industry developments, new product introductions, and financial changes. *Medical Devices, Diagnostics & Instrumentation Reports* covers similar topics for the medical devices, diagnostics, and instrumentation industries. *Health Policy & Biomedical Research* covers Medicare and Medicaid, public health, health professions education and supply, federal health policy, developments concerning NIH and ADAMHA, university and industrial biomedical research, and FDA regulatory activity affecting these. *Technology Reimbursement Reports* covers health care reimbursement and the medical technology industry. *Weekly Pharmacy Reports* covers news on introduction and pricing of new pharmaceuticals, regulatory activity, lawsuits, and related developments of interest to pharmacists. *Quality Control Reports*, published monthly, addresses quality assurance and quality control procedures in prescription, over-the-counter pharmaceutical, cosmetics, and medical device industries.

Compilation: F-D-C Reports are compiled from FDA public documents, meetings, and press releases; other federal agencies such as Federal Trade Commission and Justice Department; congressional publications, hearings and other sources; health product company reports and announcements, industry and professional society conferences, news services, and investment sources.

Access: F-D-C Reports may be ordered from source. Annual *NDA Pipeline* costs $175. Cost of *Weekly Pharmacy Reports* is $25/year; other weekly newsletters range from $260 to $470/year. Cost of *Quality Control Reports* is $85/year. Discounts for multiple copies.

FUTURES PROGRAM

Source: Center for Health Management Research, 1423 South Grand Avenue, Los Angeles, CA 90015, 213-742-6335. Member of American Healthcare Systems.

Subject: Market trends in health care industry; intended primarily for health care management personnel.

Content: Futures Program includes series of publications covering the social, technological, environmental, economic, and political events and trends affecting health care.

Forecast is an annual report on market trends and projections; recent subjects include cost-containment, intrauterine devices, laser surgery, lithotripter, long-term care, product liability, transplants. *Forecast* slides and scripts or videotapes also available. *Health Scan* assesses the impact of emerging technology and business innovations on the health care industry in terms of strategic implications for management; topics include AIDS, Alzheimer's disease, fiber optics, HMOs, marketing, technological change. *Market Scan* informs health care managers of new product and service opportunities; recent topics include bioethics, cardiac imaging, cardiac monitoring, cryosurgery, echocardiography, gamma camera, gene therapy, home care, diagnostic imaging, interferon, interleukin-2, mammography, non-invasive technology, PPOs, perinatal services, prostheses, recombinant DNA, tomography, ultrasound. *Mini Trends* covers market trends and intelligence information derived from sources not generally scanned by health care managers; recent issues include AZT, artificial kidney, bioengineering, cataracts, dialysis, genetic engineering, steroids. *Book Digest* provides synopses of management literature and other select publications pertinent to health care.

Compilation: Information gathered from trade journals, periodicals, books, and other relevant literature. Active since 1980.

Access: Annual subscription fee of $2,500 includes five copies of each publication mailed bimonthly. Additional subscriptions may be purchased on sliding-fee basis.

HEALTH (HEALTH PLANNING AND ADMINISTRATION)

Source: American Hospital Association (AHA) Resource Center, 840 North Lake Shore Drive, Chicago, IL 60611,312-280-6263

Subject: Non-clinical aspects of health care delivery, including administration and planning of health care facilities, services and manpower; health insurance; health policy; financial management; law and regulation; personnel administration; quality assurance; licensure and accreditation; and patient education and health promotion.

Content: Database includes approximately 330,000 bibliographic citations, 90 percent of which are to English language publications. Indexed using NLM's controlled vocabulary MeSH (Medical Subject Headings). *Hospital Literature Index* produced from HEALTH file. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Citations derived from MEDLINE, AHA, and National Health Planning Information Center (1975-1981). Source documents include journal articles, technical reports, government documents, theses, monographs, and monographic chapters. Approximately 3,000 citations added monthly.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. To contact MEDLARS Management Division call 800-638-8480 or 301-496-6193 in Maryland. Call source for information about *Hospital Literature Index* and related information. Connect cost averages $22/ hour peak time, $15/hour off-peak. Also available through BRS 800-345-4277, COLLEAGUE (BRS/Saunders) 800-468-0908, and DIALOG 800-334-2564.

HEALTH DEVICES ALERTS

Source: ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, 215-825-6000

Subject: Problems, hazards, and recalls involving medical devices or equipment.

Content: The publication reflects recalls, hazards, and problems with medical devices where these have been verified by ECRI. A typical issue of *Health Devices Alerts Abstracts* consists of 80 to 100 abstracts, organized by device type. Also included are presentations of the problem and of the action needed, as well as a list of hospital departments that might be affected.

Compilation: Information is compiled from review of more than 500 English-language medical, engineering, legal, and government publications. *Health Devices Alerts* was initiated in 1976.

Access: *Health Devices Alerts* is published in two forms: *Health Devices Alerts Abstracts* is published twice monthly; *Health Devices Alerts Action Items* is published weekly. Subscriptions are $235/year. The database is currently on ECRI computer systems; searches are available. The database is to be available online through BMEDSS in 1988.

HEALTH DEVICES SOURCEBOOK

Source: ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462, 215-825-6000

Subject: Medical device nomenclature and manufacturers.

Content: Cross-referenced list of more than 5,000 categories of medical devices and related products, based on ECRI numerical coding system. Each product is listed along with its U.S. and Canadian manufacturers, importers, and distributors, with contact information; a trade name section is included. Directory has references to brand-name product ratings and comparisons, and database searches made available by ECRI.

Compilation: Any firm that is the manufacturer, exclusive distributor, or importer of a medical device that is sold to hospitals, either directly or through distributors or dealers qualifies for inclusion in the directory.

Access: *Health Devices Sourcebook* published annually; 1987 edition price $140.

HEALTH INFORMATION RESOURCES IN THE FEDERAL GOVERNMENT

Source: ODPHP National Health Information Center (ONHIC), Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, PO Box 1133, Washington, DC 20013-1133, 800-336-4797, 202429-9091

Subject: Selected federal agencies and federally sponsored organizations with information in various areas of health and disease.

Content: Information provided for each organization/resource in the directory includes contact information, summary of services, activities, databases, publication topics and access information. Entries arranged alphabetically by principal keyword.

Compilation: Entries selected based on resource's ability to provide health information to health professionals and general public, and resource's existence as an office within, or a project of, the federal government.

Access: 1987 directory is available from source for $2 handling fee. ONHIC database of referral organizations available online through NLM MEDLARS computer system as a component of DIRLINE. Directory provides DIRLINE record accession number for each organization to facilitate online searching.

HEALTHLAWYER

Source: American Hospital Association (AHA), Office of Legal Communications, 840 North Lake Shore Drive, Chicago, IL 60611,312-280-6679

Subject: Legal and regulatory issues of health care.

Content: Search capability by subject headings from thesaurus, keywords. Contains case digests, including those from *Hospital Law* and *Health Law Digest*; abstracts of articles selected from over 100 journals, including *American Journal of Law and Medicine, Law Medicine and Health Care*, and *Hospitals*; full text of selected articles from newsletters such as *Health Law Vigil, Hospital Ethics*, and *Medical Staff News*, abstracts of educational conference materials.

Compilation: Compiled from government reports/documents, papers presented at conferences, wire services, corporate reports, and periodicals. Database established in January 1984, updated monthly; 6,000 new records added per year.

Access: Available online from BRS 800-345-4277. Connect costs $16 to $35/hour, plus $33 to $40 royalty. Printing costs $0.37/record online, $0.40/record offline; plus $3 to $9 telecommunication fee. Accessed through TELENET, direct dial. Subscription required. Thesaurus/search aid available to subscribers for $10.

HECLINET (HEALTH CARE LITERATURE INFORMATION NETWORK)

Source: Deutsches Institute für Medizinische Dokumentation und Information (DIMDI), Welbhausstrasse 27, Postfach 42 05 80, D-50000 Cologne 41, Federal Republic of Germany, (49-221) 47-24-1

Subject: Hospital administration, design and construction, maintenance, financing, hygiene, and economics; and non-clinical aspects of health services, including policy, economics, education, insurance, organization, planning, law, jurisdiction, and regional planning.

Content: HECLINET indexes articles from approximately 400 journals on hospital affairs and public health services; 200 journals on architecture, city planning and engineering; 20 journals on operations research; and 700 journals on economics; as well as 400 books, monographs, conference proceedings, and company publications

annually. Approximately 50 percent of the articles indexed are in German; approximately 30 percent are in English. 60 percent of the literature indexed in HECLINET appears in the printed version of the database, *Informationsdienst Krankenhauswesen/Health Care Information Service*. HECLINET's Thesaurus Krankhauswesen uses 1,100 indexing terms, available in German and English. Under new indexing system, all records will be indexed in both languages.

DIMDI also provides access to U.S. National Library of Medicine databases MEDLINE, CANCERLIT, CLINPROT, HEALTH, and TOXLINE, as well as databases from other sources such as BIOSIS PREVIEWS, EMBASE (Excerpta Medica), IRCS (Elsevier International Research Communications System), MEDITEC (Medizinische Technik), and SCISEARCH (Science Citation Index).

Compilation: HECLINET has been compiled cooperatively since 1969 by the hospital institutes of the Federal Republic of Germany, Denmark, Sweden, Austria, and Switzerland. The system has a total of approximately 70,000 document records; 4,500 new records are added to HECLINET each year. The system is updated bimonthly.

Access: Accessible via modem from remote terminal from DIMDI. Connection to DIMDI is possible via COMPUSERVE, DATAPAK, ITT-UDTS, TELENET, TYMNET, WUI-DBS, RCA-LSDS, TRT and UNINET. User number codes and English language user handbook available from DIMDI. Charges for HECLINET from DIMDI include $25/year for user number code, $15/connect hour for royalties, $0.2/ printed citation, and other charges for systems time, think time, number of characters, and downloading. Some charges are reduced for non-profit users; rebates apply after 60 hours of connect time. About 65 percent of HECLINET users as German.

HIAA (HEALTH INSURANCE ASSOCIATION OF AMERICA) MEDICAL APPROPRIATENESS COMPILATION

Source: Health Insurance Association of America, 1025 Connecticut Avenue, NW, Washington, DC 20036-3998, 202-223-7837

Subject: Appropriateness of diagnostic and therapeutic medical procedures.

Content: Each procedure transmittal in the *Compilation* includes name of procedure, definition of procedure, name of assessment program—usually the Council of Medical Specialty Societies (CMSS), date submitted by HIAA to CMSS, date of opinion provided by CMSS to HIAA, source of opinion (e.g., CMSS and one or more specialty societies), and opinion (most are from one sentence to one paragraph in length). In addition, the *Compilation* has sections on how to participate, assessment organizations, technology news, procedure listings, sources of definitions, and a topical index of procedures.

Compilation: Medical appropriateness opinions in the *Compilation* have been generated through an arrangement initiated in 1977 between HIAA and the CMSS. HIAA has accepted requests for opinions from its member companies and forwarded these to CMSS (specifically, its Program for Clinical Procedure Review), which distributed them to one or more of its 24 respective specialty societies, as appropriate. When the specialty societies rendered opinions to CMSS, these have been forwarded to HIAA for distribution. A few opinions have been used from other assessment sources. Since 1985, these

opinions, referred to as procedure transmittals, have been organized in the loose-leaf *Compilation*, which is updated approximately annually. Since 1978, CMSS has returned opinions on 115 of approximately 200 HIAA requests. The CMSS is reviewing and considering revisions to its clinical procedures review process and related technology assessment activities.

Access: The *Compilation* is available from HIAA for $25.

HIGH BLOOD PRESSURE INFORMATION CENTER

Source: Office of Prevention, Education, and Control, National Heart, Lung, and Blood Institute (NHLBI), 120/80 National Institutes of Health, Bethesda, MD 20892, 301-496-1809

Subject: High blood pressure and prevention of hypertension-related death and disability.

Content: Bibliographic database provides citations to over 6,000 journal articles pertaining to hypertension, cardiovascular disease risk factors, and related topics. Information resources cover consumer and professional health education interventions for control and detection of high blood pressure (HBP), materials and guides on planning, implementing, and evaluating HBP control programs, guidelines for detection, diagnosis, and treatment of HBP, recommendations on the roles of health care providers in HBP control, catalogs of audiovisual and printed educational materials, and ongoing community and state activities in HBP control. Center maintains information on research, funding, and principal investigators in hypertension and assists in referrals to appropriate sources of research information. Other services: preparation of customized information packets containing journal reprints, resource materials on current topics of interest and relevant publications, literature searches, and technical assistance for program planning or workshop development. Publishes quarterly newsletter featuring ongoing projects and activities.

Compilation: Information gathered from medical and professional journals, National Health and Nutrition Examination Survey, Health Interview Survey, National Center for Health Statistics reports, NHLBI demonstration and education projects, NHLBI research grants, state and local health departments, voluntary health agencies, pharmaceutical company publications, and member organizations on National High Blood Pressure Education Program Coordinating Council. Database updated monthly. Active since 1972.

Access: Publications list available upon request. All services and materials are free of charge; however, materials available in limited quantities. Database is available online through BRS 800-345-4277, and is also part of the Combined Health Information Database (CHID). Database indexed by keywords; thesaurus available to users.

IMPAC (INFORMATION FOR MANAGEMENT PLANNING ANALYSIS AND COORDINATION)

Source: Statistics and Analysis Branch, Division of Research Grants (DRG), National Institutes of Health, Bethesda, MD 20892, 301-496-7543

Subject: Administrative information on reviews and awards for extramural research programs of NIH, ADAMHA, and other PHS programs.

Content: The IMPAC Pending and Open Master Files include master records of basic data on NIH extramural programs. The Institutional Profile File is used to retrieve institution-specific information. The Project Address File is used to retrieve address and related information for Notices of Grant Award. The Trainee Appointment File contains information on NIH, ADAMHA, and CDC training grant programs. The Committee Management Information System includes information on NIH public advisory committees. The National Research Service Award (NRSA) Payback File contains information on fellows and trainees who have incurred a payback obligation under a National Research Service Award.

Compilation: Much of IMPAC data is compiled from the approximately 50,000 competing and noncompeting applications for PHS extramural support processed through the system annually; data are updated continuously during the review and award process and with feedback from recipients of IMPAC output. Each week, administrative data from IMPAC are transferred to CRISP (a related system dealing with scientific aspects of extramural and intramural research supported by PHS; see CRISP description).

Access: IMPAC is designed primarily for access by DHHS staff. DRG offers a variety of IMPAC services to DHHS users, including an extensive query software system. Specified data sets on magnetic tape are provided to most PHS awarding agencies. A variety of reports on active grants and training awards are provided in hard copy, magnetic tapes, and microfiche. DRG provides publications generated from IMPAC on trends in extramural research, characteristics of NIH public advisory committees and peer review of grant applications, and related information.

IMS AUDITS

Source: IMS America Ltd., 660 West Germantown Pike, PO Box 905, Plymouth Meeting, PA 19462-0905, 215-834-5000

Subject: Sales and market research on health care products.

Content: Data provided on prescription, distribution, promotion, and sale of pharmaceuticals; purchase of hospital supplies; patterns of diagnosis and treatment of disease. Among the audits provided by IMS are the following. *U.S. Pharmaceutical Market—Hospitals* reports hospital purchases of pharmaceuticals and diagnostics, including a monthly report of new drugs on clinical trial. *Hospital Supply Index* reports on hospital purchases of medical/surgical supplies. *New Product Digest* covers new products and their progress in the market. *LabList* audits census information on laboratory instrumentation and equipment in clinical laboratories. *Grou Practice Market: Instrumentation and Testing* audits census data on instrumentation in physician group practices. *Clinical Laboratory Audit*, based on survey data from the College of American Pathologists, covers test volume and brand share for clinical laboratory tests. *National Disease and Therapeutic Index* covers data on patterns and treatment of disease encountered in medical practice. Other audits cover circulation and cost of pharmaceutical advertising, sales of pharmaceuticals and diagnostic reagents, and prescribing activities of individual physicians. Data from these audits may be customized in a variety of formats.

IMSPACT is an online system for access to the complete IMS pharmaceutical database, including data on drugstore, hospital, physician, and promotional activities in the U.S.

Compilation: IMS collects census or sample data from 27,000 anonymous sources in U.S. and Canada, including drugstores, hospitals, physicians, and laboratories.

Access: Data are accessible on a contractual basis through remote online terminals, printed matter, and microfilm. Charges vary depending upon choice of audit and the amount of data required. For instance, charges for *LabList* may range from approximately $2,600 for smaller portions of the audit, to approximately $93,000 for the entire audit. The charge for the 12-14 volume annual *LabFile* from the *LabList* is approximately $25,000. Charges for *Clinical Laboratory Audit* may range from $1,000 for certain portions to $36,000 for the entire audit. IMSPACT is accessible online for subscribers to printed IMS audits. The charge for online access to the complete set of files in IMSPACT is approximately $94,000, plus computer charges. When approved by IMS, certain data sets may be accessible at reduced or no charges to university or other researchers for non-commercial purposes.

INTERNATIONAL MARKET RESEARCH STUDIES

Source: Division of Market Analysis, Office of Commercial Information Management, Room 2012, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, 202-377-4203

Subject: Export market information for many U.S. industries, including medical equipment and supplies and health care service industries.

Content: *International Market Research Studies* analyze market size, trends, competition, distribution channels, competition, distribution channels, business practices, barriers, and other market factors for an industry in a selected country. Studies on medical equipment and/or health care services were conducted for approximately 30 countries during the period 1982-1987.

Compilation: Majority of reports conducted using Commerce specifications under contracts issued by U.S. embassies to consultants in respective countries. *Special Situation Reports* generally conducted by U.S. and Foreign Commercial Service and/or embassies.

Access: Print copies formerly available from U.S. Department of Commerce. During 1987, information for all studies was loaded on new U.S. Department of Commerce computer system CIMS (Commercial Information Management System). Tailored reports of varying lengths may be printed for set-up fee (e.g., $15) and per-page fee (e.g., $2). Computer files not directly accessible to public. Some back reports are available from local district and regional Commerce offices for approximately $100. More than 80 new reports reviewed during 1987 to be placed directly onto CIMS. Related reports include *Export Statistics Profiles, Export Overviews*, and *Special Situation Reports. Country Market Surveys* and *Annual Worldwide Industry Reviews* no longer produced, though back issues may be available in district offices.

INTERNIST-1/QUICK MEDICAL REFERENCE (QMR)

Source: Section of Medical Informatics, Department of Medicine, 190 Lothrop Street #165A, University of Pittsburgh School of Medicine, Pittsburgh, PA 15261, 412-648-3190

Subject: Diseases in internal medicine; designed as diagnostic consultant system for health care professionals.

Content: Information organized in disease profiles, a list containing an average of 85 findings per disease. Findings include demographic data, predisposing factors, patient symptoms, signs, and laboratory abnormalities. Knowledge base describes 573 diagnoses, recognizes 4,100 patient findings, and includes more than 4,000 links detailing causal, temporal, and probable interrelationships among disorders. Approximately 250,000 medical facts and other items of information are included in the knowledge base. QMR augments INTERNIST-1 capabilities, allows direct access to information in knowledge base, provides users with multiple ways of reviewing and manipulating diagnostic information, and assists users with generating hypotheses in complex patient cases.

Compilation: INTERNIST-1 developed in 1973; successor program QMR developed in 1985. Data about a disease or clinical syndrome and its diagnosis derived primarily from two sources: review of medical literature, including general and subspecialty textbooks, monographs, and approximately 50-100 relevant primary journal articles; and debriefing medical experts, i.e., gathering information about their factual and heuristic knowledge of a given disease. Knowledge base updated weekly. Several publications appear annually describing progress in further refining program capabilities and related research activities.

Access: Computer programs run on IBM-PC-AT compatible microcomputers. Knowledge base is copyrighted and proprietary to the University of Pittsburgh; contact directly for further information. Several articles describing knowledge base and related research activities have appeared in medical and professional journals; reprints available upon request.

MARKET RESEARCH REPORTS

Source: Theta Corporation, Theta Building, Middlefield, CT 06455, 203-349-1054

Subject: Market analysis/research on health care, biotechnology, pharmaceuticals, analytical instruments; intended primarily for medical device manufacturers.

Content: Reports cover specific markets, including description and analysis of technology, review of other technologies in field, evaluation of competitors, current market assessment, market trends and projections. Reports generally include executive summary, technology, market factors, market size, market shares, and company profiles. Recent topics include electrophoresis, spectroscopy, DNA synthesizers, monoclonal antibodies, endoscopy, diagnostic imaging equipment, fetal monitoring, cardiac monitoring, medical ultrasound, arthroscopy surgical systems, lithotripsy, cryosurgery equipment, kidney dialysis supplies and equipment, contraceptive devices, and dental equipment. Monthly newsletter *Changing Medical Markets* covers business/finance, medical

products, premarket approvals, recalls and patents, new technology, sales and acquisitions, management changes, publications/journals, the courts, and meetings. *1986 Med Tech Director*, profiles 800 publicly owned health care companies. *MPA Healthcare Distributor Guide* describes product distributor selection.

Compilation: Information gathered from industry personnel, trade journals, government publications, annual reports, trade shows, conferences. Active since 1968.

Access: Free catalog, report table of contents, and sample newsletter available upon request. Report prices range from $300 to $900. Newsletter subscriptions $195/year or $325/two years. *1986 Med Tech Directory* price $150. *MPA Healthcare Distributor Guide* price $495.

MARKET/TECHNOLOGY REPORTS

Source: Biomedical Business International, 17722 Irvine Boulevard, Tustin, CA 92680, 714-838-8350

Subject: Market research on health care products and services.

Content: Three major types of reports are *Market/Technology Reports* (ranging from 40 to 500 pages in length) covering current markets, technologies, competition and environmental factors, and market forecasts; *Strategic Marketing Studies* (50-230 pages) covering marketing and sales approaches; and *Conference Proceedings* (86-183 pages). Major subject areas for reports are anesthesiology, biomaterials, cardiovascular products, catheters, clinical testing, critical care/monitoring, dentistry, disposables, drugs and drug delivery, extracorporeal therapy, HMOs/alternate site services, fertility control, hematology, home health/self care, imaging, information management, IV fluids/ nutrition, neurology, ob/gyn/perinatology, oncology, ophthalmology, orthopedics/ trauma, respiratory therapy, and surgery. Newsletters include: *Biomedical Business International* (20 issues/year) covers market segments, companies and business issues, new technologies; *Worldwide Medical Markets* (44/year) covers international product sales opportunities; *Healthcare Marketing* (12/year); *Medical Product Development (12/* year). Directories on genetic engineering and biotech firms, biotech firms medical products of Japan, West Germany Directory of Medical Devices, and U.K. Health Service Buyers Guide. *Healthcare Technology Transfer and Product Opportunities* directory covers descriptions and contact information for technologies available for purchase, license, or distribution. Other reports cover international regulations for health care products, and market research reports for specific countries. Arranges approximately 20 conferences annually, usually in conjunction with professional society meetings.

Compilation: Information gathered from interviews of health care providers and industry personnel, trade journals, government publications, annual and quarterly company reports, conferences, press contacts, literature searches.

Access: Free catalog, sample newsletters, tables of contents for *Market Technology Reports, Strategic Marketing Studies, Conference Proceedings*, and directories available upon request. Market/Technology Reports prices range from $450 to $2,900, newsletters $275-$695, conference report proceedings $100-$700, product and firm directories $80-$195, *Healthcare Technology Transfer and Product Opportunities* directory $775 plus monthly updates. Customized information services also available.

MEDICAL DEVICE AND LABORATORY PRODUCT PROBLEM REPORTING PROGRAM (PRP)

Source: Practitioner Reporting System, United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, 301-881-0666. PRP supported by FDA Center for Devices and Radiological Health.

Subject: Postmarketing surveillance of FDA-approved medical and radiological health devices and laboratory products.

Content: Computerized database contains voluntary reports from health care practitioners on problems experienced with medical or lab products such as improper labeling, design problems, defective components, performance failures, poor packaging, incomplete or confusing instructions, and erroneous information. Products covered include intravenous pumps, catheters, in vitro diagnostic reagents and kits, cardiac and respiratory monitors, ultrasound and X-ray equipment. Reports retrievable by date report submitted, product name, manufacturer and/or type of problem. PRP identifies industry-wide problems or trends and highlights specific product problems.

Compilation: Information gathered via toll-free telephone line or reporting forms from health care professionals including physicians, nurses, pharmacists, biomedical engineers, medical laboratory personnel, risk managers, purchasing and quality assurance personnel, and consumers. PRP reports are used to compile the Device Experience Network (DEN) files for FDA. Reports are submitted as unverified information to FDA, which is responsible for follow up, i.e., determining manufacturer's evaluation of problem and establishing final assessment of problem. Program initiated in 1973. Updated continuously.

Access: PRP reports are included in DEN reports accessible through BMEDSS 216-375-3501, National Technical Information Service 703-487-4630, Medical Device Register's *Product SOS* 203-348-6319, and ECRI 215-825-6000. Confidential trade, commercial, financial, personnel, medical, and patient information are deleted from publicly available reports. DEN reports in microfiche and additional information about specific reports available from FDA, Freedom of Information Office, Room 12A16, HFI-31, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6310. Monthly publication *Device Experience Network Reports*', which includes PRP but not Medical Device Reporting information, is available from FOI Services, Inc., 301-881-0410 for $190. To report a device problem call U.S. Pharmacopeial Convention 800-638-6725 or contact USP for reporting form.

MEDICAL DEVICE REGISTER

Source: Medical Device Register, Inc., 655 Washington Boulevard, Stamford, CT 06901,800-222-3045, 203-348-6319

Subject: Medical devices, equipment, and supplies; includes manufacturers and distributors.

Content: *Volume 1* covers over 8,000 manufacturers and 13,000 distributors in U.S. and Canada, with data on company size, ownership, key executives, financial status, distribution method, and product line. Products are organized into 6,000 FDA categories;

includes definitions and product descriptions, as well as comparison of prices and specifications for competing products. *Volume 1* contains keyword index, device information, and trade name index. *Volume 2* covers over 3,000 manufacturers and 3,300 distributors located outside the U.S. and Canada. Both volumes are divided into four sections: directory of products, supplier profiles, supplier geographical index, and directory of local dealers. Bimonthly newsletter *Supplier Hotlist* profiles new companies and their products added to MDR database during previous two-month period. *Catalog Library Service* consists of catalogs on microfiche of 2,000 medical product manufacturers. *Distributor Profiles* contains company descriptions and contact information. *Public Company Profiles* highlights the 500 publicly owned companies covered in *Medical Device Register*.

Compilation: Information is gathered primarily from product manufacturers and distributors, as well as news releases, reports from various other sources, including FDA. Database is updated daily; approximately 3,000 manufacturers and distributors added annually. Publications are issued annually. Active since 1981.

Access: Charge for *Medical Device Register Volume 1* (1987) is $150; charge for *Medical Device Register Volume* 2 (1987) is $120. Charge for computer tapes is $400 for set up plus $400/1,000 companies, or $6,800 for all companies; floppy disks also available. Medical Device Register information is to be available online through DIALOG in 1988. *Supplier Hotlist* subscription $125/year. Brochure and price list available upon request.

MEDICAL DEVICE REPORTING (MDR)

Source: Division of Product Surveillance, Office of Compliance, Center for Devices and Radiological Health, HFZ-343, Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-8100

Subject: Postmarketing surveillance of medical devices and in vitro diagnostic products.

Content: Medical Device Reporting regulation (1984) requires that manufacturers and importers of medical and diagnostic products report to FDA any information that suggests one of their devices may have caused or contributed to a death or serious injury, or has malfunctioned and, if such malfunction recurs, is likely to cause or contribute to death or serious injury. MDR database contains reports from manufacturers and importers pertaining to device performance failures and/or malfunctions that have resulted in injury, death, or any hazard to safety.

Compilation: Information reported to FDA is gathered from physicians nurses, patients, consumers, and hospitals; medical and scientific literature; and from independent research, testing, evaluation, servicing, or maintenance of devices by the manufacturer. Program established in 1984. Updated continuously.

Access: MDR reports are included in DEN reports accessible through BMEDSS 216-375-3501, National Technical Information Service 703-487-4630, Medical Device Register's *Product SOS* 203-348-6319, and ECRI 215-825-6000; and are available from the BRS/SEARCH database DIOGENES. Confidential trade, commercial, financial, personnel, medical, and patient information are deleted from publicly available reports.

DEN reports in microfiche and additional information about specific reports available from FDA, Freedom of Information Office, Room 12A 16, HFI-31, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6310.

MEDIS

Source: Mead Data Central, PO Box 933, Dayton, OH 45401,800-227-4908, 513-865-6800

Subject: Medicine, drugs, health care, pediatrics, psychology.

Content: MEDIS service is divided into the following files: GENMED, PHARM, CANCER, MEDLINE, and ADMIN. Provides full text of more than 60 clinical journals, newsletters, and textbooks covering a broad range of medical topics. Covers publications of American Medical Association, American Society of Hospital Pharmacists, American Health Consultants, and F-D-C Reports. Also includes PDQ and MEDLINE. Full-text searching capability by subject. Electronic clipping service ECLIPSE automatically repeats stored MEDIS searches.

Compilation: Compiled from journal articles, monographs, books, and newsletters. Updates vary with publication.

Access: Database available online from remote terminal. Connect cost is $30/hour including telecommunication cost. Search charge is $3 to $13/search during peak time; 30 percent discount for off-peak. Accessed through MEADNET, TELENET, direct dial. Subscription required, fee for physicians $50/month, includes access to NEXIS. Different price structure available for hospitals and medical groups.

MEDLINE

Source: MEDLARS Management Section, National Library of Medicine (NLM), Building 38, Room 4N421, 8600 Rockville Pike, Bethesda, MD 20894, 800-638-8480, 301-496-6193 in Maryland

Subject: Medicine, biomedicine, health care.

Content: Database includes bibliographic citations to over 5 million articles from approximately 3,200 biomedical journals published in the U.S. and abroad. Contains all citations published in *Index Medicus* , as well as citations found in *International Nursing Index* and *Index to Dental Literature*. Citations include English abstracts, if published with article. Indexed using NLM controlled vocabulary MESH. Published literature searches on selected topics available from NLM, including, e.g., percutaneous ultrasonic lithotripsy, adjuvant chemotherapy for breast cancer, therapeutic plasmapheresis in neurological disorders, surgical treatment of morbid obesity, peer review organizations, HMOs, and indigent care. Also available are brochure and fact sheets covering online services, specialized information sources, and extramural programs; and online services training courses.

Other databases provided by MEDLARS that are described in this section include BIOETHICSLINE, CANCERLIT, CLINPROT, DIRLINE (Directory of Information Resources Online), HEALTH (Health Planning and Administration), PDQ (Physician

Data Query), and POPLINE (Population Information Online). Additional databases provided by MEDLARS are AVLINE (Audiovisuals Online), CATLINE (book Catalog Online), CHEMLINE (Chemical Dictionary Online), HISTLINE (History of Medicine Online), MeSH VOCABULARY FILE, NAME AUTHORITY FILE, RTECS (Registry of Toxic Effects of Chemical Substances), SERLINE (Serials Online), and TOXLINE (Toxicology Information Online).

Compilation: Compiled primarily from journal articles and selected chapters and articles from monographs. Coverage from 1966 to present. Updated monthly with approximately 25,000 citations.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. Connect cost averages $22/hour peak time, $15/hour off-peak. Also available through BRS 800-345-4277, COLLEAGUE (BRS/Saunders) 800-468-0908, DIALOG 800-334-2564, MEDIS (Mead Data Central) 800-227-4908, and PAPERCHASE (Beth Israel Hospital) 617-735-2253 in Massachusetts, 800-722-2075 elsewhere. *NLM Publications* available upon request; provides current ordering information, titles, and prices for NLM publications. *Online Services Reference Manual, 1986* ($46) and *Basics of Searching MEDLINE: A Guide for the Health Professional* ($12) available from NTIS 703-487-4650.

GRATEFUL MED is a software package on two floppy disks for facilitating online searching and search downloading of MEDLINE, CATLINE, CHEMLINE, DIRLINE, HEALTH, TOXLINE, and other MEDLARS databases. Contact MEDLARS Management for additional information. GRATEFUL MED can be ordered for $29.95 plus $3 for shipping from NTIS 703-487-4650.

MEDLINK (MASSACHUSETTS MEDICAL INFORMATION LINK)

Source: PO Box 9080, Waltham, MA 02254-9080, 800-342-1338, 617-890-0385 in Massachusetts. Directed by the Publishing Operation of the Massachusetts Medical Society.

Subject: Electronic mail and interlibrary loan networking service.

Content: Information services such as document delivery, literature searching, topic bibliographies, newsletters. Information sources available on the network include newswires and EASYNET, a service linking many databases including MEDLINE and HEALTH. Network also offers general use electronic mail, bulletin boards, online directory of subscribers, access to American Library Association's ALANET electronic information service. Provides network services for groups seeking to establish their own subnetworks. Training classes available for searching MEDLINE, BRS/COLLEAGUE, and PAPERCHASE.

Compilation: Network links approximately 80 Massachusetts health science libraries and five out-of-state resource libraries, including the National Library of Medicine and its regional medical library at the New York Academy of Sciences. Began operations in 1985.

Access: Accessible via modem from remote terminal. One-time registration fee ($50) includes three user IDs, set-up, and introductory materials. Registration fee for each additional user $5. Annual service fee $100/year; statistics fee $85/year. Connect time $18/hour peak time; $14/hour off-peak. Surcharges for newswires, bulletin board, gateway to other databases, text storage, and training classes.

MULTI-CLIENT REPORTS

Source: International Resource Development, Inc., 6 Prowitt Street, Norwalk, CT 06855, 203-866-7800

Subject: Market analysis/research reports on biotechnology, medical devices and systems, telecommunications, consumer electronics, financial services, personal computers, robotics, electro-optics.

Content: Reports cover international high-technology industries and markets, including the development of selected industries and companies, critical trends and technologies, and 10-year growth projections. Reports normally include: executive summary, background description of the field, market segments, market analysis, market assessment, market forecasts, and company profiles. Recent report topics include biotechnology equipment and supplies, prostheses for sensory and internal organs, European medical imaging equipment markets, impact of biotechnology on specialty chemicals and pharmaceutical markets, high-tech drug delivery systems, laser market opportunities, emerging membrane separation technologies. Publishes several newsletters on software distribution technologies, electronic mail and micro systems, telecommunications equipment and services, and electronic home information.

Compilation: Information derived from interviews with industry personnel, industry data, current publications, reports, and other relevant literature. Approximately 50 studies conducted annually, five to ten of which are in the biotechnology and life sciences field. Active since 1971.

Access: Free catalog of publications available upon request. Report prices range from $900 to $2,500. Newsletter subscriptions $260 to $375/year.

NAHDO RESOURCE MANUAL

Source: National Association of Health Data Organizations (NAHDO), 316 Pennsylvania Avenue, SE, Suite 202, Washington, DC 20003, 202-546-5881

Subject: Compendium of information regarding statewide health data organizations. Intended audience includes state governments, health services researchers, health insurers, consulting firms.

Content: Contents arranged by state. Included are copies of legislation and regulations authorizing data collection, analysis and dissemination; data dictionaries for financial and discharge databases; documentation of sources of data used, e.g., providers or third parties; description of data system software and hardware; descriptions of coding systems; standard report formats; procedures for requesting data and reports; plan or procedure for report dissemination; and budget and staffing information.

Compilation: State health data organizations submit information and data annually to NAHDO for compilation of manual.

Access: First edition available early 1988; price to be determined.

NATIONAL CENTER FOR HEALTH STATISTICS PUBLICATIONS AND DATA

Source: Scientific Information Branch, Division of Data Services, National Center for Health Statistics (NCHS), 3700 East-West Highway, Hyattsville, MD 20782, 301-436-8500

Subject: Vital and health statistics for the U.S.

Content: Public use data tapes include: Vital Statistics (natality, mortality, marriage, divorce, other vital events); National Health and Nutrition Examination Survey (disease prevalence, normative ranges for physiological and body measurements, and nutritional status); National Health Interview Survey (extent of illness and disability in the population); National Survey of Family Growth (contraception, reproduction, family formation and dissolution); National Hospital Discharge Survey, National Ambulatory Medical Care Survey, National Nursing Home Survey (supply and utilization of health resources/services); National Master Facility Inventory (inpatient health facilities); National Inventory of Family Planning Services (facilities providing medical and nonmedical family planning services); National Medical Utilization and Expenditure Survey (costs of illness and health care expenditures).

Data from surveys and studies are presented in a variety of publications, including the *Vital and Health Statistics* series, *Advance Data from Vital and Health Statistics, Vital Statistics of the U.S., Monthly Vital Statistics Report, Statistical Notes for Health Planners*, and selected articles published in medical and scientific journals. Public use data tapes and unpublished tabulations are also available. NCHS provides technical assistance through conferences, seminars, workshops, and individual consultations to foster and improve health statistics analysis and use.

Compilation: Data obtained from several statistical data collection systems: national vital registration system, surveys based on samples of birth and death records, continuing nationwide interview survey of households, series of national surveys in which physical examinations are conducted on samples of populations, periodic surveys of institutions and their patients, continuous national sampling of short-stay hospital records, and surveys of various categories of health manpower. Reports cover monthly, annual, and periodic data collection activities. Active since 1960.

Access: Catalog of NCHS publications available upon request. Catalog provides list of free reports, order form, prices, and instructions for purchasing reports from U.S. Government Printing Office 202-783-3238; publications indexed by major health topics. Catalog providing availability and price information on NCHS public use data tapes available upon request. Public use data tapes sold through NTIS 703-487-4650. *Data Tape Update* provides current information on data tapes and prices.

NATIONAL CHOLESTEROL EDUCATION PROGRAM (NCEP)/NHLBI SMOKING EDUCATION PROGRAM (NSEP) INFORMATION CENTER

Source: Office of Prevention, Education, and Control, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 4A-21, National Institutes of Health, Bethesda, MD 20892, 301-230-1340

Subject: Health effects of cholesterol and smoking; prevention of coronary heart disease and chronic obstructive pulmonary disease.

Content: Publications cover arteriosclerosis, heart disease, management strategies for detection and treatment of persons with high blood cholesterol levels, consensus statements concerning high blood cholesterol, counseling techniques and consumer education sheets, cardiovascular disease risk factors, materials for work-site heart disease risk reduction programs, physician continuing medical education materials related to cholesterol and smoking, primary care physician's role in promoting smoking cessation, and suggestions for public, professional, and patient education. NCEP publications list is organized alphabetically by title and annotated; NSEP resource list is annotated and divided into professional and patient education resources. Center is developing a database on smoking and cholesterol programmatic materials, including curriculum guides and other educational materials, descriptions or evaluations of specific programs, directories and bibliographies, relevant laws and legislation.

Compilation: Information gathered from NHLBI-sponsored research and working groups, expert panels, results of biomedical, epidemiological and health behavior studies. Active since 1985.

Access: Current NCEP publications list and NSEP resource list available upon request. Single copies of publications available free of charge. NCEP/NSEP Information Center database not yet publicly available; however, planning is underway to make it available through BRS 800-345-4277, as part of the Combined Health Information Database (CHID).

NATIONAL REFERENCE FILE

Source: Health Data Institute (HDI) (subsidiary of Caremark, Inc.), 20 Maguire Road, Lexington, MA 02173, 617-863-2000

Subject: Compilation of national normative statistics on health care utilization and cost trends and patterns of care.

Content: Database contains information provided by client organizations' employee health insurance claims data. Clients include major corporations, unions, commercial insurance companies, and Blue Cross and Blue Shield plans, as well as state and federal health care providers. The file provides data by population subgroup, region of the country, industry, diagnosis or provider or other information relevant to the location of care (inpatient, outpatient, office), length of stay, appropriateness of care, average cost per service, and utilization rates.

Compilation: All clients of HDI Claims Data Analysis Division are asked to add their claims data to the national database. HDI edits and merges all relevant data into the National Reference File.

Access: HDI clients who provide data into National Reference File (NRF) can get comparative statistics included with other HDI analytic reports. Clients who have no data to provide are charged a fee based on data requested. HDI plans to publish normative descriptive statistics and trends in a subscription series format in late 1987.

NATIONAL TECHNICAL INFORMATION SERVICE PUBLICATIONS AND DATA

Source: National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161, 703-487-4650

Subject: Among the subject categories of the NTIS information classification system are biomedical technology and human factors engineering; computers, control, and information theory; government inventions for licensing; health planning and health services research; library and information sciences; and medicine and biology.

Content: NTIS BIBLIOGRAPHIC DATABASE has bibliographic summaries of NTIS reports. *1986 Published Search Catalog* provides bibliographic citations of NTIS reports in such areas as diagnostic agents, health care costs, health information systems, health insurance, HMOs, mechanical organs, medical computer applications, medical equipment, and medical imaging. Among weekly NTIS abstract newsletters covering new entries to NTIS collection are *Biomedical Technology & Human Factors Engineering, Health Planning & Health Services Research, Government Inventions for Licensing*, and *Medicine & Biology*. FEDRIP (Federal Research in Progress) database provides bibliography of ongoing federally funded research projects, including NIH, VA, other sources.

NTIS provides data files from such agencies as NCHS (health and vital statistics), NCHSR (hospital care, home care, national medical expenditures, HMOs, services to the elderly), and FDA (summary reports of newly approved medical products, national drug code directory). Monthly *Tech Notes* provides fact sheets on new applied technology and R&D results in medicine and biology and other fields; these are compiled by subject in *Federal Technology Catalogs*. Other products are *Directory of Federal Laboratory & Technology Resources* and *Government Reports Annual Index*.

Compilation: NTIS holdings are compiled from scientific, technical, engineering, and business studies sponsored by the U.S. government and international sources. Among the federal sources are CDC, DOD, EPA, FDA, NASA, NCHS, NCHSR, NIH, NLM, USDA, and VA. NTIS BIBLIOGRAPHIC DATABASE includes 1.2 million records, increased by 70,000/year. Collection contains 350,000 technical reports from other countries.

Access: NTIS information is available in technical reports, software, data files, databases, abstract newsletters, published searches, and other formats. *Guide to NTIS* brochure provides overview to resources and access information. Charges for printed reports generally cover the cost of duplication plus $3 handling fee. Annual subscription charges range from $79 to $205 for weekly abstract newsletters, $127 for monthly *Tech Notes*. NTIS BIBLIOGRAPHIC DATABASE is available through DIALOG 800-227-1960, SDC Search Services 800-421-7229, and Bibliographic Retrieval Services

800-833-4707. Database search help is available at no charge from NTIS 703-487-4640; call 703-487-4929 for international access information. NTIS sales desk 703-487-4650; for rush orders call 800-336-4700, 703-487-4700 in Virginia.

NEXIS

Source: Mead Data Central, PO Box 933, Dayton, OH 45401, 800-227-4908, 513-865-6800

Subject: General reference, business and industry, marketing, finance, science, technology.

Content: NEXIS service includes the following library files: NEXIS, ASAP II, ENCYLOPAEDIA BRITANNICA, GOVERNMENT DOCUMENTS, INFORMATION BANK, and U.S. PATENT AND TRADEMARK OFFICE. Files cover more than 160 newspapers, magazines, wire services, newsletters, trade and professional journals in full text. Files organized by publication type and subject. Full-text searching capability by subject.

Compilation: Compiled from journal articles, government reports/documents, published proceedings, theses and dissertations, news releases, broadcasts, security analysts' reports. Updates vary with publication; daily for newspapers.

Access: Database available online via modem from remote terminal. Connect cost: $30/ hour including telecommunication cost, plus $7 peak time search charge for individual files; 30 percent discount for off-peak. Accessed through MEADNET, TELENET, direct dial. Document delivery through NEXIS mail service, offline or online printers. Subscription fee is $50/month. Contact producer for one-time installation charge and monthly charges. Free user manual and database documentation available to subscribers.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE PUBLICATIONS

Source: Communications and Public Information Branch, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 4A-21, National Institutes of Health, Bethesda, MD 20892, 301-496-5343

Subject: Causes, detection, treatment, and prevention of heart, lung, and blood disease and management of blood resources.

Content: Publications cover summaries of NHLBI-sponsored working groups; state-of-the-art assessments; recommendations for future research; annual Institute Director's reports; NHLBI Advisory Council reports; and health education, community intervention, and medical intervention strategies for control of high blood pressure, high blood cholesterol, and smoking cessation. Publications organized by NHLBI programmatic area and subject.

Compilation: Publications prepared by NHLBI Office of Prevention, Education, and Control (OPEC). Information gathered from studies supported by NHLBI, working groups or conferences sponsored by NHLBI, programmatic materials developed by NHLBI or by NHLBI-supported researchers, and OPEC's three cardiovascular disease/chronic

obstructive pulmonary disease risk factor reduction programs: National High Blood Pressure Education Program, National Cholesterol Education Program, and NHLBI Smoking Education Program. Publications list updated annually. NHLBI activities initiated in 1948; Office of Prevention, Education, and Control created in 1972.

Access: Current listing of publications available upon request. Many publications are free, however, supplies are limited.

OXFORD DATABASE OF PERINATAL TRIALS

Source: National Perinatal Epidemiology Unit, Radcliffe Infirmary, Oxford OX2 6HE, England, (44-865) 81-68-76. Research sponsored by Department of Health and Social Services and Oxford University Press.

Subject: Perinatal medicine

Content: Database provides bibliographic citations to, evaluation of, and analyses based on more than 3,000 reports of randomized controlled trials in perinatal medicine conducted in approximately 57 countries. Includes data derived from meta-analyses of subject-specific subgroups of trials, as well as information on unpublished, ongoing, and planned trials. Reports are classified according to stage of perinatal period covered in trial, entry characteristics and total number of participants, intervention, outcome, methods of treatment allocation, number of treatment groups; also indexed by author, title, journal, year of publication, country, title keyword, and subject. Records may be accessed using any of above categories alone or in combination.

Compilation: Database has been compiled since 1978 from articles in obstetric, pediatric, and other medical journals, MEDLINE searches, lists of citations used in reviews and other reports of research, conference reports and abstracts, correspondence, and informal meetings. Coverage from 1940 to present; updated daily.

Access: Database on computer disk, including user manual and tutorial package, available in 1988; charge is approximately $750. For further information, contact Anne Yates, Oxford Electronic Publishing, Oxford University Press, Walton Street, Oxford OX2 6DP, England. Listing of reports published between 1940 and 1984 is available in: *National Perinatal Epidemiology Unit: A Classified Bibliography of Controlled Trial in Perinatal Medicine, 1940-1984*, Oxford University Press, 1985.

PDQ (PHYSICIAN DATA QUERY)

Source: International Cancer Information Center, Office of International Affairs, National Cancer Institute (NCI), Building 82 Room 103, Bethesda, MD 20892, 301-496-7403

Subject: Advances in cancer treatment and clinical trials; designed for use by physicians.

Content: Databank provides detailed summaries of all major tumor types, including prognosis, staging, cellular classification, and state-of-the-art treatment options. Contains comprehensive information on more than 1,000 active cancer-treatment protocois

approved by NCI. Protocol summaries include study objectives, patient entry criteria, and treatment regimen, as well as names, addresses, and telephone numbers of the principle investigators. Each protocol indexed according to disease, stage-specific eligibility criteria, and details of treatment. Physician directory contains information on more than 12,000 physicians who treat cancer patients. Organization directory has contact information for approximately 2,000 organizations associated with cancer treatment. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: An editorial board of 70 cancer specialists solicits opinions from experts in oncology concerning treatment options to list; statements of treatment are formulated and subsequently reviewed by consultants with expertise in cancer management. Editorial board maintains currency and accuracy of information on available cancer therapies, treatment research, physician, and organization directories through monthly updates.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. To contact MEDLARS Management Division call 800-638-8480 or 301-496-6193 in Maryland. Connect cost averages $22/hour peak time, $15/hour off-peak. Also available through BRS 800-345-4277, COLLEAGUE (BRS/Saunders) 800-468-0908, and MEDIS (Mead Data Central) 800-227-4908. Will be available in Europe on TELMED, a Swiss medical information system.

PHARMAPROJECTS

Source: U.S. office: PharmaBooks, Ltd., 1775 Broadway, Suite 511, New York, NY, 10019. 212-262-8230. Head office: Pharmaprojects, 18/20 Hill Rise, Richmond, Surrey, TW10 6UA, United Kingdom, (44-1) 94-83-26-2

Subject: Pharmaceutical product development information.

Content: *Manufacturers Volume* lists more than 4,000 products under development by more than 800 companies. Each product entry includes generic names, research codes, trade names, financial and other information about originating companies and licencees, standardized activity descriptors, stage of development, related text and literature references. *Therapeutic Categories Volume* lists product developments in particular therapeutic fields arranged by an anatomically-based classification system. Monthly updates identifying recent developments parallel both annual volumes. Cumulative indexes available on products, manufacturers, product activity, and licensing opportunities. PHARMAPROJECTS ONLINE includes manufacturers and therapeutic categories information corresponding to printed version (PHAR file); additional online files contain information on products whose development has been discontinued (PHAD), and products that have been placed in major markets (PHAL).

Compilation: Compiled from medical and scientific publications, brokers' reports, company annual reports, conference papers, and direct contacts with companies. Printed version updated monthly. Online version updated monthly (PHAR) and quarterly (PHAD and PHAL).

Access: Annual subscription for printed versions is $2,525 from U.S. office; subscriptions elsewhere available from Head office. PHARMAPROJECTS ONLINE available in U.S. on Data-Star via modem from remote terminal through TELENET, TYMNET, RS-NET; available on other networks in other countries. Online access cost approximately $110/hour plus $0.55/record for printed version subscribers and $30/ record for nonsubscribers; discounts available. Call 800-221-7754 for further information about access and use of Data-Star.

POPLINE (POPULATION INFORMATION ONLINE)

Source: MEDLARS Management Section, National Library of Medicine (NLM), Building 38, Room 4N421, 8600 Rockville Pike, Bethesda, MD 20894, 800-638-8480, 301-496-6193 in Maryland.

Subject: Population issues and family planning.

Content: Database includes bibliographic citations and abstracts to documents relevant to human fertility, contraceptive methods, community-based services, program evaluation, demography, censuses, vital statistics, and related health, law and policy issues. See MEDLINE description for listing of NLM MEDLARS databases.

Compilation: Compiled from journal articles, monographs, technical reports, and unpublished works. Coverage 1970 to present; selected citations date back to 1886. Updated monthly with approximately 10,000 citations added annually. POPLINE produced in cooperation with the Johns Hopkins University Population Information Program, Columbia University Center for Population and Family Health, Princeton University Population Index Library/Information Program, and the University of North Carolina at Chapel Hill Carolina Population Center; supported by U.S. Agency for International Development and National Institute of Child Health and Human Development.

Access: Available online at any time through NLM MEDLARS computer system to more than 6,000 online centers in hospitals, medical schools, universities, government agencies, commercial firms, and other organizations throughout U.S., as well as MEDLARS centers located in 13 other countries. Also accessible via modem from remote terminal through TELENET, TYMNET, direct dial. Connect cost averages $22/hour peak time, $15/hour off-peak.

PRODUCT DEVELOPMENT DIRECTORY, PRODUCT SOS

Source: Medical Device Register, Inc., 655 Washington Boulevard, Stamford, CT 06901, 800-222-3045, 203-348-6319 in Connecticut

Subject: Non-drug medical products and product safety problems.

Content: *Product Development Directory* indexes 40,000 510(k) filings on medical products approved by the FDA since 1976, organized by product category. Product approvals arranged historically within product category by FDA approval date; manufacturer and name of product approved are listed. *Product SOS* (Situation Occurrence Service) presents information on medical product problem reports. 1986 edition includes more than 3,000 user reports from DEN (Device Experience Network of FDA) for 1985 and

22,000 reports from MDR (Medical Device Reporting regulations of FDA) from beginning of MDR in December 1984 through first quarter of 1987. Included with 1986 edition are bimonthly alerts on new problems as they are reported.

Compilation: Information is gathered primarily from FDA sources, which delete certain confidential trade, commercial, financial, personnel, medical, and patient information. *Product Development Directory* was first issued in January 1987. *Product SOS* updated regularly.

Access: *Product Development Directory* price $87; *Product SOS* (1986 edition) price $360. Detailed documents, FDA 510(k) filings on each product may be obtained from Medical Device Register or FDA.

RANDOMIZED CONTROLLED CLINICAL TRIALS REPORT COLLECTION

Source: Thomas C. Chalmers, M.D., Harvard School of Public Health, 677 Huntington Avenue, Kresge 4th Floor, Boston, MA 02115, 617-732-1090

Subject: Randomized controlled clinical trials (RCTs) and meta-analyses of RCTs.

Content: Database contains approximately 8,000 articles describing RCTs, quality assessments and meta-analyses in various fields, and methodological books and articles. Contents partially indexed.

Compilation: Collection activities initiated in 1973. Information gathered through published and unpublished literature searches. Five to ten papers or abstracts based on the collection published yearly.

Access: Collection partially supported by NLM. Database currently not machine-readable. Contact source for further information about access to collection.

REPORT ON COST-EFFECTIVE PRODUCTS AND TECHNOLOGIES

Source: Friedman, Eisenstein, Raemer, and Schwartz (FER & S), Certified Public Accountants/Business and Personal Consultants, 401 North Michigan Avenue, Chicago, IL 60611, 312-644-6000

Subject: Cost-effectiveness of medical devices, pharmaceuticals, medical services, and other health care products. Designed for hospital administrators, medical directors, and other health care facility and industry managers.

Content: Each report provides synopses of cost-effectiveness analyses of up to five medical products. Each synopsis describes the product, how it is used, and applicable diagnosis-related group (DRG) where appropriate. Study results and analysis are presented. Features of analysis discussed are product orientation (beneficiary of product's cost-effectiveness), study objectives, study methodology, production relationships (impact of product application on other labor, supply, equipment, and overhead resources), cost identification, differential benefit identification (product's cost-effectiveness versus alternative product-type or technique), and factors affecting study's scope and validity. Independent organization conducting or reviewing study and contact person at medical product company are identified.

Compilation: Medical product and pharmaceutical companies submit cost-effective-ness analyses of their products to FER & S. Studies to be included in report are reviewed to determine whether they are methodologically valid, were conducted or reviewed by an independent third party, and involve an FDA-approved product. First report issued in October 1986; subsequent reports published quarterly.

Access: Reports routinely distributed to selected hospital administrators nationwide. Copies of reports available upon request.

SCRIP

Source: U.S. Office: Scrip World Pharmaceutical News, 1775 Broadway, Suite 511, New York, NY, 10019, 212-262-8230. Head office: Scrip 18/20 Hill Rise, Richmond, Surrey, TW10 6UA, United Kingdom, (44-1) 94-83-26-2

Subject: Pharmaceutical industry news, including international industry, regulatory environment, development of new products, and company affairs.

Content: 20-28 page newsletter on pharmaceutical products, finance, world news and markets, company news, advertising. Among other Scrip reports are *Scrip Yearbook; Scrip's Pharmaceutical Company League Tables; New Product Reviews*; monographs on such subjects as biotechnology companies, product liability, European drug registration, Japanese companies; and monographs on product types such as cardiovascular, chemotherapy, thrombolytics, and asthma. Scrip provides copies of selected FDA Summary Bases of Approval reports, and recent FDA guidelines for new drug applications.

The Scrip database PHIND (Pharmaceutical and Healthcare Industries News Database) is available online. It includes the text from Scrip and other publications in two files; PHID is updated daily, and PHIN contains Scrip archival material up to three weeks prior to the current date.

Compilation: Scrip is published twice a week; 100 issues/year. PHIND is updated daily. Compiled from medical and scientific publications, brokers' reports, company annual reports, conference papers, and direct contacts with companies.

Access: Annual Scrip subscription $523; $282 for additional copies sent in same envelope. PHIND is available in U.S. on Data-Star via modem from personal computer through TELENET, TYMNET, RS-NET; available on other networks in other countries. PHIND online access costs approximately $11 O/hour, $1.55/current article, $0.35/ back article. Call 800-221-7754 for further information about access and use of Data-Star.

SEER (SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS PROGRAM)

Source: Surveillance and Operations Research Branch, Blair Building, Room 532, National Cancer Institute (NCI), National Institutes of Health, Bethesda, MD 20892-4200, 301-427-8829

Subject: Cancer surveillance and epidemiology.

Content: Database provides statistical data on cancer incidence, mortality, and survival in about 10 percent of the U.S. population; based on several defined geographic areas: Connecticut, Iowa, Detroit, Atlanta and four rural counties in Georgia, Utah, Hawaii, New Mexico and Arizona Native Americans, San Francisco, Seattle, New Jersey, and Puerto Rico. Serves as basis for cancer research, cancer prevention and control research program evaluation. Data include cancer site, year of diagnosis, diagnostic procedures, histology, staging, treatment regimen and date initiated, follow up, i.e., date and cause of death or vital status, patient demographics. SEER issues *Annual Cancer Statistics Review* and reprints of monographs and numerous journal articles that detail research findings and examine other relevant topics.

Compilation: Program activities initiated in 1973; 1 million records are on file. Information gathered from hospital/ medical records and pathology reports of cancer cases.

Access: Published SEER reports are available from source upon request; some are also available from U.S. Government Printing Office 202-783-3238. Requests for public use data tapes and for special data runs must be justified in writing. Online access to database is available to NIH users only.

SPRILINE

Source: Library and Research Report Bank, Swedish Planning and Rationalization Institute for the Health Services (SPRI), Box 27310, S-102 54, Stockholm, Sweden, (46-8) 63-05-60

Subject: Health services administration and planning, health economics, health personnel, health statistics, hospital construction, hospital equipment, hospital supplies, medical ethics, medical technology, nursing, social services.

Content: Interactive online bibliographic database and library system includes references to literature, reports, organizations, and individuals; Swedish health services data; information on surveys and pilot projects. SPRILINE database includes 13,000 records of books, journal articles, and unpublished research reports on Swedish health care from Research Report Bank. About 15 percent of the records are from English language sources. All records for journal articles and research reports contain an abstract; searches can be made using free-text technique or controlled terms from thesaurus, which covers 1,200 Swedish indexing terms. Author, title, abstract, keywords, corporative author, publication year, serial title, and language fields may be searched. Printed products include indexes of books and journals, unpublished research reports, annual catalog of research report bank holdings, bibliography of primary care. Subject-coded references of recently acquired books and journal articles are mailed 10 times/year to public health agencies and medical libraries in Sweden and abroad, including the American Hospital Association and the National Library of Medicine. Information about new acquisitions is published in news bulletin *Spri Informerar.*

Compilation: More than 3,000 records are added each year, including 1,300 books, 1,000 journal articles, and 700 research reports. System is linked to other libraries in Sweden, and participates in the HECLINET (Health Care Literature Information Network) European documentation service. SPRILINE has been available for online searching since 1984.

Access: User ID and password are available from source. SPRILINE is available online via modem from remote terminals all hours except 2am-4am Wednesdays and Fridays. Telephone inquiries accepted 9am-3pm weekdays. Document delivery service supplies copies of journal articles and lends books and reports; document requests can be made online via electronic mailbox, mail, and telephone. Except for a nominal fee for multiple photocopies, SPRILINE has no access charges.

TECHNICAL DATA CENTER

Source: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor, 200 Constitution Avenue, NW, Room N2439, Washington, DC 20210, 202-523-9700

Subject: Occupational safety and health, including biochemistry, analytical chemistry, biology, physiology, industrial toxicology, sampling and analysis, ergonomics, engineering, health physics, radiology, industrial medicine and health, environmental health, industrial hygiene, sanitation, and safety.

Content: TDC collection contains books and monographs (approximately 5,000), encyclopedias, subject and language dictionaries, various specialized guides, and approximately 250 technical journals; complete list of journals and years covered is available. Available on microfiche: dissertations, abstracts, standards material, product catalogs, back issues of the *Federal Register*, technical papers, reports, publications, material safety data sheets, and numerous publications from government agencies, e.g., National Bureau of Standards, National Institute for Occupational Safety and Health. TDC docket office maintains collection of OSHA rulemaking files, as well as transcripts of advisory committee meetings and impact statements. In-house computerized database, Technical Information Retrieval System includes docket office files, TDC collection, and card catalog. TDC distributes monthly compendium of table of contents of recent journals and publishes quarterly *TDC Information and Insight Bulletin*. Subject bibliographies prepared through manual and online searches available upon written request.

Compilation: TDC established in 1972. Collection compiled of published and unpublished documents acquired from various federal agencies, private industry, research organizations, and private standards setting organizations. Technical Information Retrieval System created in 1983; updated continuously. Subject bibliographies updated quarterly.

Access: Information regarding the use of Technical Data Center (TDC) reference materials and services is available upon request. In-house database may be used free of charge. TDC resources committed primarily to meeting needs of OSHA program activities in national office and field offices; however, non-government personnel may use center during office hours for reference purposes.

U.S. INDUSTRIAL OUTLOOK

Source: Industry Publications Division, Office of Industrial Assessment, International Trade Administration, Trade Development, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, 202-377-4356

Subject: Economic data and analyses of specific U.S. industries, including drugs, medical and dental instruments and supplies, and health and medical services.

Content: Each of nearly 70 chapters in this annual volume covers one or more Standard Industrial Classifications (SICs) of industry types. Chapters generally address each SIC's current situation, outlook for that year, and long-term prospects. Historical trends are given for each industry and type of product, and for international trade. Chapters relevant to medical technology include drugs (covering SICs for biologicals, medicinals and botanicals, and pharmaceutical preparations), medical and dental instruments and supplies (x-ray and electromedical equipment, surgical and medical instruments, surgical appliances and supplies, and dental equipment and supplies), and health and medical services. Chapters address such topics as industry production levels, domestic and foreign-based R&D expenditures, levels of innovation, international competition, areas of new product development, and impact of government regulations and policies.

Compilation: Published annually. The edition for any given year is written during the third quarter of the previous year, based on data that are generally two years old. Data for the intervening years are estimated, and data for the current year are forecasts. Data are compiled from Bureau of the Census sources, as well as other government and private sector sources appropriate for each industry.

Access: Can be purchased for $24 from U.S. Government Printing Office 202-783-3238, (order 003-008-00200-5); U.S. Department of Commerce federal bookstore; or local Commerce district offices. Inquiries about the content of the volume may be directed to the industry specialist whose name and telephone number appears at the end of each chapter or section.

WHO/LINFO DATABASE ON HEALTH TECHNOLOGY ASSESSMENT

Source: Joint effort of Department of Computer and Information Science and Center for Medical Technology Assessment, Linköping University, S-581 83 Linköping, Sweden, (46-13) 28-19-69; and Regional Office for Europe, Hospital Programme, World Health Organization, 8 Scherfigsvej, DK-2100 Copenhagen, Denmark, (45-1) 29-06-19

Subject: Organizational based information about health technology assessment activities and reports.

Content: Information collected from more than 140 primarily European organizations. Records for descriptions of each assessment program include program name, contact person, address, telephone number, electronic mail address, type of institution (university, research institute, professional association, etc.), staff size, how assessments are initiated, types of technologies assessed (e.g., drugs, devices, procedures, etc.), list of assessments carried out, means of report dissemination, other services, organizational databases and means of accessing them, and availability of annual report. First product of information base is *WHO/LINFO Directory*, in which program descriptions are arranged by country and by type of technology usually assessed. Assessment reports records to include author, title, keywords or other indexing terms, abstract, and other bibliographic information.

Compilation: Database compiled by surveys of health related programs in Europe, Australia, Canada, and U.S. Planning and organizational based information collection initiated in late 1986; collection of bibliographic information for assessment reports initiated in 1987. Planning underway to initiate WHO/LINNET, a user network based on WHO/LINFO database.

Access: WHO/LINFO directory available from Linkping sources.

WORLD HEALTH ORGANIZATION PUBLICATIONS

Source: World Health Organization (WHO), 1211 Geneva 27, Switzerland, (41-21) 91-21-11

Subject: Public health, including epidemiological data and statistical indicators.

Content: Books, reports, monographs, periodicals covering such topics as biologicals, pharmaceuticals, radiation and health, laboratories, health systems development, hospitals and health care facilities, human rights and medical ethics, immunology and immunization, health economics and expenditures, health statistics, cancer, cardiovascular diseases, chronic diseases, environmental health, health of the elderly. *Public Health Papers* focuses on modern trends and changing concepts in public health, *Technical Report Series* covers consensus findings and recommendations on medical and public health issues, quarterly journal *World Health Forum* presents new concepts in public health and new approaches to health problems, bimonthly *Bulletin of the World Health Organization* reviews progress in medical and related scientific research, *World Health Statistics Quarterly* assesses health situation worldwide and projects future trends, *Weekly Epidemiological Record* contains notifications of diseases and epidemiological data on diseases of international importance. Others include numerous regional publications, publications of the International Agency for Research on Cancer, and publications of the Council for International Organizations of Medical Sciences. Catalog contains author and subject index.

Compilation: WHO activities initiated in 1948. Information gathered from WHO programs, activities, and consensus reports of international groups of experts. WHO reports published continuously; new books featured in catalog issued every six months.

Access: Catalog of publications available upon request.

Subject Index to Information and Data Resources

D

Database utilities
- BRS
- COLLEAGUE
- DIALOG
- MEDLINK

Developmental disabilities
- Birth Defects and Developmental Disabilities Reports

Diagnosis
- INTERNIST 1/Quick Medical Reference

Disasters
- Environmental Hazards and Health Effects Reports

DRGs
- Baseline Reports

Drug abuse
- Alcohol, Drug Abuse, and Mental Health Administration Publications and Data

Drug utilization review
- SEE Pharmaceuticals

E

Environmental health
- Environmental Hazards and Health Effects Reports
- Environmental Health Laboratory Sciences Reports
- Technical Data Center

Evaluation studies
- Compendium of HHS Evaluations and Relevant Other Studies

Expert systems
- INTERNIST 1/Quick Medical Reference

F

Family planning
- National Center for Health Statistics Publications and Data

POPLINE

G

Genetic diseases
- Birth Defects and Developmental Disabilities Report

H

Health administration
- HEALTH
- SPRILINE

Health care delivery
- AMA/NET
- HEALTH
- National Reference File

Health care data
- SEE ALSO Hospital data, Patient data
- Abstracts of Health Care Machine-Readable Data Files
- NAHDO Resource Manual
- National Reference File

Health care economics
- Baseline Reports
- National Center for Health Statistics Publications and Data

Health care product manufacturers
- Health Devices Sourcebook
- Medical Device Register
- National Reference File
- Pharmaprojects
- Scrip
- U.S. Industrial Outlook

Health planning
- HEALTH

Health policy
- BIOETHICSLINE
- Current Assessments, New Technology Abstracts
- Directory of University-Based Health Services and Policy Research Centers

Health promotion
- Center for Health Promotion and Education
- HEALTH
- High Blood Pressure Information Center
- National Cholesterol Education Program/ NHLBI Smoking Education Program Information Center

Health services research
- Current Assessments, New Technology Abstracts
- Directory of Health Services Research Organizations

PART 4 ORGANIZATIONAL RESOURCES

PART 4

ORGANIZATIONAL RESOURCES

This part provides brief descriptions and contact information for 72 organizations that are active in affairs related to medical technology. Although most of these organizations do not generate technology assessment reports on a regular basis, they have memberships concerned with medical technologies, conduct relevant meetings and symposiums, publish conference proceedings and other documents of note, establish standards for technologies, or are active in government, regulatory, or other policy affairs relevant to the field.

The organizational descriptions are arranged alphabetically by organization name. Each includes name, address, and telephone number of the organization; contact person(s), and a brief narrative description of the organization. Beginning on page 603 is a subject index for identifying organizations involved in particular areas.

ALLIANCE FOR ENGINEERING IN MEDICINE AND BIOLOGY

1101 Connecticut Avenue, NW, Suite 700
Washington, DC 20036
202-857-1199
Contact: Patricia I. Horner, Executive Director

The Alliance for Engineering in Medicine and Biology (AEMB) was established in 1969 in response to a recognition among engineers, physicians, and other scientists that the development of the field of biomedical engineering needed improved linkages among those in medicine, the life sciences, engineering, and the physical sciences.

The alliance consists of 17 professional associations whose members are concerned with the introduction and use of advanced technology in life sciences research and in clinical practice. These associations are the: American Association for Medical Systems and Informatics, American Association of Physicists in Medicine, American College of Radiology, American Institute of Chemical Engineers, American Society for Artificial Internal Organs, American Society for Engineering Education, American Society for Hospital Engineering of the American Hospital Association, American Society for Testing and Materials, American Society of Agricultural Engineers, American Society of Mechanical Engineers, American Society of Civil Engineers, Biomedical Engineering Society, Institute of Electrical and Electronics Engineers, Instrument Society of America, Neuroelectric Society, RESNA—Association for the Advancement of Rehabilitation Technology, and SPIE—International Society for Optical Engineering. AEMB is the U.S. affiliate to the International Federation for Medical and Biological Engineering.

The alliance has conducted and participated in a number of significant programs, including an International Biomedical Engineering Workshop Series that resulted in a six-volume publication; a five-year medical ultrasound research and development agendum; a systems design for a clinical ultrasound facility; technology procurement in health care institutions; and an international technology transfer project in Cairo, Egypt, now a Middle East center for ultrasonography training and expertise.

The Annual Conference on Engineering in Medicine and Biology is a major national, interdisciplinary meeting; its published proceedings are an important reference for the field. AEMB sponsors a national honor society for biomedical engineering students.

AMERICAN ACADEMY OF DERMATOLOGY

1567 Maple Avenue
PO Box 3116
Evanston, IL 60204-3116
312-869-3954

Contact: Raymond W. Cunningham, Jr., Director, Department of Dermatologic Practice

The 6,700-member American Academy of Dermatology (AAD) represents most practicing dermatologists in the U.S. The principle objective of the Association is the continuation of dermatologic education. AAD is committed to quality standards in continuing education and plays a role in formulating policies that can influence the quality of dermatologic care. The academy has developed programs that promote and advance the science and art of medicine and surgery related to the skin, hair and nails; promote standards in clinical practice, education and research in dermatology and related disciplines; support and enhance patient care; and promote public interest related to dermatology.

AAD is interested and aware of the many technological advances that have been made in the last few years. The AAD Council on Clinical and Laboratory Services is reviewing mechanisms to allow the academy to formally assess these technologies as they relate to dermatology. New technology requiring review and comment by the academy is now referred to the appropriate council, committee or task force germane to that particular issue.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

222 South Prospect Avenue
Park Ridge, IL 60068-4058
312-823-7186

Contact: Rebecca M. Maron, Director, Department of Professional Affairs & Policy Analysis

The American Academy of Orthopaedic Surgeons (AAOS) is a nonprofit corporation founded in Chicago in 1933. With 12,181 members, the AAOS is the largest medical organization for musculoskeletal specialists. Members of the academy have completed up to five years of specialty study in orthopaedics in an accredited residency program, passed a comprehensive oral and written exam, and been certified by the American Board of Orthopaedic Surgery.

Educating its members to help assure a high level of skill and competence is the major function of the AAOS. Its educational programs include an appraisal of the effectiveness of relevant technology. Each year the academy offers more than 30 continuing medical education courses across the country.

The academy's annual meeting is its primary education program. It features the presentation of scientific papers, instructional courses, technical exhibits, audiovisual presentations, and symposia on a variety of topics.

The 50 committees of the academy address a myriad of technical subjects, sponsor education programs, and inform the membership and the public about the latest developments within orthopaedics. The academy is currently involved in a pilot project to develop minimum standards for orthopaedic care; these standards may or may not ultimately include technology assessments.

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

1101 Vermont Avenue, NW, Suite 302
Washington, DC 20005-3521
202-289-4607
Contact: Jerome C. Goldstein, M.D., Executive Vice President

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) is a nonprofit medical association that provides governmental and socioeconomic support for otolaryngologists. It is intended to advance the science and art of medicine related to otolaryngology and provide educational services for the specialty. AAO-HNS conducts two scientific meetings per year and offers continuing education programs.

AAO-HNS relates to agencies of the federal government concerning matters relevant to otolaryngology such as ambulatory surgery, thyroid surgery, drug problems, hearing aids and other assistive devices, Medicare and Medicaid, noise, manpower, and technology assessment. It monitors legislative and regulatory activities and has activated a legislative network. Drawing from government publications and other sources, the academy keeps its members informed of advances in medical and surgical procedures, including new drug and device modalities.

The academy's 50 committees are involved with medical and surgical practices and procedures. These committees generate voluntary standards of care and develop policy statements. Several committees are working at developing guidelines for instruments, diagnostic tools and medical and surgical devices. One committee is concerned with safety standards for the use of lasers in surgery. The Hearing and Equilibrium Committee keeps abreast of standards for the manufacture and development of the cochlear implants and criteria for patient selection. Members of the Committee on National and International Standards work with the American National Standards Institute and the American Society of Testing and Materials in developing standards for medical equipment and devices and other standards for health care delivery. One committee has recently been developed to produce a manual for quality assurance.

AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

122 South Michigan Avenue, Suite 1300
Chicago, IL 60603-6107
312-922-9366
Contact: Ike A. Mayeda, Executive Director

Founded in 1938, the American Academy of Physical Medicine and Rehabilitation (AAPMR) is the national organization for physicians who have been certified through examination as specialists in physical medicine and rehabilitation by the American Board of Physical Medicine and Rehabilitation. This specialty focuses on patients who are disabled and whose functional abilities have been impaired to varying degrees.

These include disabilities and impairments from strokes, cerebral palsy or other birth defects; arthritis, cardiac disease, pulmonary disease, or from other paralyses; and injuries.

The academy is accredited by the Accreditation Council for Continuing Medical Education to sponsor CME programs, publishes study guides in nine areas related to physical medicine and rehabilitation, provides a self-assessment program for residents and practicing physicians to assess their knowledge, and works with other organizations in maintaining and improving educational standards for the profession.

The AAPMR Medical Practice Committee has various subcommittees for quality assurance and health care financing, facility standards, assessment of diagnostic and therapeutic modalities and devices. Other major activities include publication of the monthly journal *Archives of Physical Medicine and Rehabilitation*, annual meeting, and tracking legislative development and issues in physician medicine and rehabilitation practice, education and research.

AMERICAN ASSOCIATION OF BLOOD BANKS

1117 North 19th Street, Suite 600
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703-528-8200
Contact: Jackie Campbell, Director of Communications

The American Association of Blood Banks (AABB) is a nonprofit professional, scientific and administrative association for individuals and institutions engaged in blood banking and transfusion medicine. The 7,000 individual members are physicians, medical technologists, nurses, administrators, donor recruiters, and others involved in blood banking. Institutional members are 2,400 community and hospital blood banks and hospital transfusion services that are responsible for collecting nearly half, and transfusing 80 percent, of the nation's blood supply.

AABB supports making available for patients a safe, adequate, economical and voluntary supply of blood and components; to encourage the voluntary donation of blood and other tissues and organs; to foster scientific investigation, clinical application, education and exchange of ideas; to encourage, advance and certify high standards of administrative and technical performance; to function as a clearinghouse for the exchange of blood and blood credits nationwide; and to plan for cooperation in times of disaster.

The AABB Committee on Standards sets standards for practice used world-wide in blood banks and transfusion services. The inspection and accreditation program strives to improve the safety and quality of transfusions and assists in determining whether methods, procedures and personnel meet established standards. AABB reference laboratories provide exchange of information and consultation on rare blood group antibodies and other advanced technical and scientific problems. The parentage testing program provides for accreditation in parentage testing and monitors advancements in the field. The autologous transfusion information file assists in planning programs and monitoring new techniques. AABB's annual meeting highlights new research and technology in the fields of blood banking, transfusion medicine, hematology, immunohematology and tissue/organ transplantation. AABB publishes several new books yearly on issues of significance in blood banking.

AMERICAN ASSOCIATION FOR MEDICAL SYSTEMS AND INFORMATICS

1101 Connecticut Avenue, NW, Suite 700
Washington, DC 20036
202-857-1189
Contact: Patricia I. Horner, Executive Director

The American Association for Medical Systems and Informatics (AAMSI) is a national professional medical society incorporated in 1981 in a merger of the Society for Computer Medicine and the Society for Advanced Medical Systems. In AAMSI, expertise is shared to ensure continued flow of information, research and education in the health care field.

Members are entitled to join one of 14 professional specialty groups that provide the opportunity to contribute, obtain, and exchange information about their professional areas of health care. AAMSI conducts its annual congress on the west coast each spring and a conference on the east coast in the fall. These meetings provide forums for sharing and teaching current developments and implementation of systems for health care and medical informatics in support of patient care, research and health administration.

AAMSI's two bimonthly journals are *Computers and Biomedical Research* and *M.D. Computing*. AAMSI makes available proceedings of the annual congress, a *Mental Health Systems Software Directory*, and a *Directory of Publications in Health Systems and Informatics*.

AMERICAN ASSOCIATION OF TISSUE BANKS

1117 North 19th Street, Suite 402
Arlington, Virginia 22209
703-528-0663
Contact: Jeanne C. Mowe, Executive Director

The American Association of Tissue Banks (AATB) is a nonprofit organization founded in 1976 in response to increased need for transplantable tissues. AATB has two principal goals: to establish standards for the collection, preservation, and distribution of tissues leading to the development of inspection and accreditation mechanisms for tissue collecting organizations, and to improve the efficiency of tissue banking by encouraging the development of regional tissue banks that collect and distribute a variety of tissues of high quality with maximum economy.

AATB is structured into councils in five areas: musculoskeletal, ocular, reproductive, skin, and tissue bank. Each council is responsible for development of guidelines and standards, and for scientific programs. In September 1984, the association published standards for tissue banking. Each of the councils has formulated, for its respective type of tissue, procedures for donor selection, retrieval procedures, maintenance of asepsis, storage conditions, quality control and record keeping. Based on these standards and procedures, AATB has developed a program of inspection and accreditation for organizations that retrieve, bank, and distribute tissues.

AATB acts as an information center regarding tissue retrieval and processing activities in the U.S. AATB collects and disseminates information regarding tissue banking and undertakes promotional and educational programs for stimulating tissue donation and encouraging efficiency of tissue banking. A program for training and certification of tissue bank personnel is currently under development.

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

1125 Executive Circle
Irving, TX 75038-2522
214-550-0911
Contact: Colin C. Rorrie, Jr., Ph.D., Executive Director

The American College of Emergency Physicians (ACEP) is a nonprofit professional medical association founded in 1968 to facilitate the exchange of information among physicians practicing emergency medicine. The college has more than 11,000 members, and is dedicated to the education and professional growth of emergency physicians and to the improvement of patient care.

ACEP conducts continuing medical education programs on clinical and non-clinical subjects through meetings, workshops, seminars, publications, cassettes, and courses. It provides such member services as monitoring federal legislation and regulations, programs related to pre-hospital emergency care, assistance to its state chapters, and liaison programs with government, third-party carriers, other medical associations, and various scientific and research organizations.

Although the college does not conduct technology assessment, the annual ACEP scientific meeting features more than 200 scientific and commercial exhibits. Technical information is sometimes addressed in articles in *Annals of Emergency Medicine*, the college's monthly clinical and scientific journal. For example, the journal has published articles on the effectiveness of different types of cervical immobilization collars and scientific studies comparing different techniques of drug administration.

AMERICAN COLLEGE OF GASTROENTEROLOGY

13 Elm Street
Manchester, ME 01944
617-927-8330
Contact: Thomas F. Fise, Executive Director

The American College of Gastroenterology (ACG) is an international nonprofit organization of over 2,000 members dedicated to serving the clinically oriented gastroenterologist. It is composed of gastroenterologists, surgeons, radiologists, hepatologists, pediatricians, and other physicians sharing an interest in the care of patients with digestive disease. ACG's purposes include promoting and advancing gastroenterology and allied subjects in medical schools and hospitals, and maintaining and promoting standards in medical education, practice, and research in gastroenterology. ACG endeavors to provide public education regarding digestive disease and develop and implement health care standards at the national and local level.

ACG is committed to clinical research and provides conceptual and financial support for investigative studies. Efforts in the area of technology assessment fall within the purview of the Committee on Research, which numbers 10 physicians engaged in teaching and patient care programs at major academic institutions and hospitals. Through this committee, competitive grants are awarded annually. In addition, national clinical research projects are supported through awards granted by the ACG board. The results of these and other ACG sponsored projects are presented at the national and local meetings. The emphasis on clinical relevance provides is intended to keep the

practitioner abreast of trends in diagnosis and treatment modalities in gastroenterology, and serves to encourage clinical researcher-investigators by providing a forum for their work. Most recently ACG has provided grants in support of selected research programs on Barrett's esophagus and colon polyps.

ACG provides a broad spectrum of educational programs through meetings and courses with CME accreditation. Its annual meeting includes sessions, poster sessions, and symposia, and is held in conjunction with a postgraduate course and a large commercial exhibit covering the latest in gastrointestinal technology, therapy and literature. ACG also sponsors regional meetings.

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

1101 Connecticut Avenue, NW, Suite 700
Washington, DC 20036
202-857-1135
Contact: Carol A. Lively, Executive Director

The American College of Nuclear Physicians (ACNP) represents over 1,200 physicians and scientists engaged in the practice or development of nuclear medicine. In support of the development and implementation of new and improved medical technology in the field of nuclear medicine, the college promotes funding for research and development, and works with federal agencies in addressing regulatory issues inherent in bringing nuclear medicine materials and instrumentation safely and efficiently to market and to medical practice and research.

The college's standing committees on nuclear medicine science, radiopharmaceuticals, and standardization of nuclear medicine instrumentation provide forums in which members can monitor and have input into the development of nuclear medicine technology.

As the need arises, the college establishes ad hoc task forces to address specific issues relevant to certain nuclear medicine technologies. For example, college members have participated in a joint task force with the Society of Nuclear Medicine to develop a comprehensive paper on the clinical utility of positron emission tomography, for purposes of recommending reimbursement under Medicare. college members have also promoted reimbursement for the use of dual photon absorptiometry in the diagnosis and monitoring of treatment of osteoporosis.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

1015 Fifteenth Street, NW, Suite 403
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202-789-0003
Contact: William M. Kane, Ph.D., Executive Director

The American College of Preventive Medicine (ACPM), established in 1954, is a society of physician specialists whose mission is to foster the professional standards, provide for scholarly exchanges, promote prevention-oriented medical care and research, and give national leadership in enhancing public awareness of benefits of health promotion, risk reduction and disease prevention.

Although the college does not engage directly in technology assessment, it has participated in the technology assessment activities of the American Medical Association and those conducted by the Council of Medical Specialty Societies. The college has identified a number of members with expertise in specific areas to work with both the AMA and CMSS. When issues related to preventive medicine procedures and technologies arise, the AMA and the CMSS refer these questions to selected ACPM members. In addition, the college has cooperated with the congressional Office of Technology Assessment.

AMERICAN COUNCIL ON TRANSPLANTATION

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Alexandria, VA 22314-2040
703-836-4301
Contact: Nancy R. Holland, Executive Director

The American Council on Transplantation (ACT) was established in 1983 as a nonprofit, national federation to bring together organizations and individuals to improve the donation and delivery of organs and tissue transplantation. The council has over 800 organizational and individual members.

ACT provides a national public policy forum to address and seek consensus on social, psychological, ethical, and economic issues involved in organ and tissue recovery and transplantation. It provides the opportunity for individuals and organizations concerned with organ and tissue transplantation to have an active voice in the discussion and formulation of public policy regarding transplantation.

Among its activities, ACT encourages the availability of immunosuppressive drugs for patients on an outpatient basis; promotes the establishment of scientific registries for transplant recipients for ongoing scientific and clinical evaluations; promotes a national task force to evaluate the medical, ethical, legal, and economic and social issues of transplantation and to make recommendations for improvements; encourages the passage of require-request legislation; supports Medicare coverage of heart transplantation; and supports in principle the federal task force on organ transplantation.

Major avenues through which ACT's missions and objectives are carried out are its four forums on: organ retrieval and networking, patient and family issues, professional education, and public education.

The council publishes the bimonthly newsletter *Transplant Action*, which serves as the primary means of communicating with ACT membership. ACT holds annual meetings. The council responds to thousands of requests for information annually, which are made primarily through ACT's toll free number (1-800-ACT-GIVE).

AMERICAN GERIATRICS SOCIETY

770 Lexington Avenue, Suite 400
New York, NY 10021
212-308-1414
Contact: Carol S. Goodwin, Director of Executive Affairs

The American Geriatrics Society (AGS) is a nonprofit professional medical society founded in 1942 that attempts to provide optimal health care for the elderly through programs relating to graduate medical education, fellowship training, continuing medical education, and research and its practical applications. In addition, the society is active in issues related to long term care health policy and ethical problems in terminal care. The society's goals are defined by the health and social problems of the elderly.

The AGS is active in technology assessment through the following programs and activities.

- Publication of clinical investigations relating to technologies in the care of the elderly in the society's *peer-reviewed Journal of the American Geriatrics Society*.
- Preparation of an *amicus* brief relating to ethical problems in tube feeding of individuals in vegetative states.
- A project on clinical decision-making in catastrophic situations, including issues relating to ICU care.
- Preparation of material for the congressional Office of Technology Assessment concerning technologies in health care as related to the elderly.
- Preparation of policy statements on various issues in technologies in health care, such as drugs and devices.
- A summer research institute, sponsored jointly with the National Institute on Aging, intended to stimulate interest in careers in aging research.

The AGS conducts an annual scientific meeting on broad issues in the health care of the elderly, which includes presentations on new and established technologies and advances in all clinical fields concerned with geriatric care.

AMERICAN HEALTHCARE INSTITUTE

1919 Pennsylvania Avenue NW, Suite 703
Washington, DC 20006
202-293-2840
Contact: Merlin K. DuVal, M.D., President

The American Healthcare Institute (AHI) is a nonprofit organization that represents interests of its 31 members, each of which is a large, vertically integrated, nonprofit, multi-hospital system. Its constituent institutions number approximately 1,300 located in 44 states. The institute conducts an annual governance education conference for its members' trustees and corporate officers; sponsors research into the profiles and operation of multi-hospital systems; develops health policies supportive of development and growth of multi-hospital systems and the operation of not-for-profit hospitals generally; and promotes the implementation of those policies.

AMERICAN INSTITUTE OF ULTRASOUND IN MEDICINE

4405 East-West Highway, Suite 504
Bethesda, MD 20814
301-656-6117
Contact: James S. Packer, Ph.D., Executive Director

The American Institute of Ultrasound in Medicine (AIUM) is a nonprofit medical society founded over 30 years ago to advance the art and science of ultrasonics in medicine and research. AIUM's membership of over 7,000 consists of physicians, scientists, engineers and sonographers as well as technicians, manufacturers, manufacturers' representatives and medical students. In addition to its annual convention featuring scientific sessions, educational courses, and exhibits, the AlUM makes available a variety of publications and videotapes on relevant ultrasound topics.

The AIUM Standards Committee and Manufacturers Commendation Committee are directly involved in activities related to technology assessment. The Standards Committee is responsible for developing standardized approaches to instrument performance measurements as well as presentation and labeling, phantoms, and nomenclature. The committee reviews documents, manuals, and standards produced by other organizations, government bodies, and individuals, especially as these documents relate to the physics, engineering, performance testing and clinical use of ultrasound equipment.

The Manufacturers Commendation Committee encourages manufacturers to make data on ultrasonic intensities and other parameters of their systems readily available to users by awarding certificates of commendation to manufacturers meeting the appropriate requirements. The requirements for commendation are based upon the guidelines established by a joint task force on standards sponsored by the AlUM and the National Electrical Manufacturers Association (NEMA).

In addition to these activities, the AlUM maintains liaison with other organizations developing standards for ultrasound equipment, including NEMA, International Electrochemical Commission, Acoustical Society of America and the Food and Drug Administration.

AMERICAN MEDICAL CARE AND REVIEW ASSOCIATION

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301-493-9552
Contact: Charles Stellar, Director, Medical Issues

The American Medical Care and Review Association (AMCRA, formerly the American Association of Foundations for Medical Care) was founded in 1971. It is a national organization representing more than 600 individual practice associations (IPAs), IPA—type health maintenance organizations (HMOs), preferred provider organizations (PPOs), foundations for medical care (FMCs), peer review organizations (PROs), and other medical plans. AMCRA member plans work with industry, labor, insurance, and other organizations to develop and offer competitive health programs to emphasize quality of care and cost-effectiveness through utilization review programs.

AMCRA provides to its members a variety of educational programs, including those on data systems for claims processing, physician reimbursement, etc.; utilization review seminars; and medical issues meetings. Publications include an AMCRA newsletter and a PPO newsletter, and various bulletins, special surveys, and reports. Reports have covered such subjects as management information systems, drug and other ancillary coverages, marketing techniques, capital formation, premium comparisons, and reinsurance trends. AMCRA has a directory of PPOs and HMOs.

AMCRA cosponsors with the Group Health Association of America a National Committee for Quality Assurance, composed of HMO clinicians, that does quality assurance review under state and federal contracts. AMCRA is involved in monitoring, evaluating, and offering suggestions to federal and state policy makers and regulatory agencies.

AMCRA's nonprofit affiliate foundation, The AMCRA Foundation, is chartered to accept donations, initiate and manage research, and provide information to the HMO and PPO industry. It is sponsoring a patterns of treatment project involving peer review development of guidelines for 50 to 100 most common medical procedures to simplify claims management and to address outlier cases for peer review entities.

AMERICAN MEDICAL PEER REVIEW ASSOCIATION

440 First Street NW, Suite 510
Washington, DC 20001
202-628-1853
Contact: Andrew Webber, Executive Vice President

The American Medical Peer Review Association (AMPRA) is an educational, nonprofit organization of parties interested in quality assurance and utilization review. The purposes of AMPRA are to improve the ability of its members to assess the quality of medical care services through the exchange of ideas, techniques and information; and assist in the development of methods for the monitoring of the appropriateness of medical care.

The institutional members of AMPRA are physician-directed organizations performing medical review services in the public and private sectors. Included in the AMPRA membership are the federally designated peer review organizations (PROs). The number of these organizations is increasing with the demand for cost-effective review programs from major purchasers of medical care in government, business, labor, and the insurance industry. AMPRA functions as an advocate for physician directed medical review services, acts as a liaison for government, private industry, consumer, and health care organizations; and serves as an information clearinghouse for organizations and individuals with an interest in the field.

In response to the need for standards for review of quality care, AMPRA acts as a clearinghouse for collecting and disseminating review criteria that will provide review groups with the tools to analyze and measure health care delivery performance. This effort is fostered through the conduct of regional conferences and the work of the AMPRA Quality Assurance and Data Committees.

AMERICAN MEDICAL REVIEW RESEARCH CENTER

440 First Street, NW, Suite 510
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Contact: Carole J. Magoffin, M.S., Executive Director

The American Medical Review Research Center (AMRRC) is a nonprofit organization founded in 1985 by medical quality and utilization review physicians and professionals. AMRRC's central objective is to develop physician leadership and the tools to analyze medical practice patterns relative to their implications for quality medical care.

AMRRC seeks to provide a link between the research investigation of the development of quality evaluation methods and their application in quality-monitoring operational settings. AMRRC encourages provision of state-of-the-art information on current and developing quality review programs in all settings.

AMRRC's primary constituency includes peer review quality monitoring and educational organizations as well as quality assurance researchers and professionals in all settings. AMRRC facilitates physicians peer review involvement in academic research and development activities designed to improve the efficacy of physician quality monitoring programs.

AMRRC is interested in area-wide, regional and national comparisons that yield medical practice variation data on quality patient outcomes. AMRRC and four peer review organizations are collaborating with George Washington University Medical Center on a project to develop quality measures for intensive care unit services. AMRRC has initiated a peer review outcome data project to aid peer review organizations in analyzing and responding to hospital-specific outcome data released by the Health Care Financing Administration. AMRRC publishes the newsletter *Quality Review News*.

AMERICAN NATIONAL STANDARDS INSTITUTE

1430 Broadway
New York, NY 10018
212-354-3300

Contact: Joseph Tretler, Jr., Assistant Program Administrator, Medical Devices

The American National Standards Institute (ANSI) is the coordinating organization for the federated national standards system of the U.S. It is a private nonprofit organization founded in 1918 to coordinate standardization activities in the private sector. The federation consists of approximately 900 companies and 200 trade, technical, professional, labor, and consumer organizations.

In cooperation with its membership and through its councils, boards, and committees, ANSI coordinates the efforts of hundreds of U.S. organizations that develop consensus standards. ANSI does not develop the standards, but provides means for determining their need and ensures that appropriate organizations undertake standards development. Participating organizations submit standards to ANSI developed under their own procedures for recognition as national consensus standards, and often cooperate in the development of standards within committees that operate under ANSI procedures.

ANSI standards deal with dimensions, ratings, terminology and symbols, test methods, and performance and safety specifications. The standards are developed and used voluntarily; they become mandatory only when adopted or referenced by government.

There are some 10,000 sets of ANSI standards in many fields, among them electrical and electronics, information systems, and medical devices. Major categories of ANSI standards for medical and dental material, devices, and equipment include: anesthetic equipment, dental material, health care facilities, hearing aids, instrumentation, medi

cal and surgical material, nuclear medicine, ophthalmics, and radiographic film equipment.

ANSI acts as a clearinghouse on standardization and the source of standards documents, including those of the International Organization for Standardization, International Electrotechnical Commission, and national standards bodies in other countries. ANSI makes available its own standards and those of many international standards organizations. It provides an annual catalog of ANSI standards with supplements and specialized listings, and a biweekly periodical *Standards Action*.

AMERICAN PSYCHIATRIC ASSOCIATION

1400 K Street, NW
Washington, DC 20005
202-682-6138

Contact: Harold A. Pincus, M.D., Director, Office of Research

The American Psychiatric Association (APA) is a medical specialty society representing more than 33,000 psychiatrists nationwide. Its members share an interest in the continuing study of psychiatry and in the search for more effective ways to combat mental illnesses.

The association has a range of ongoing scientific assessment processes such as the development of the *Diagnostic and Statistical Manual of Mental Disorders*, as well as a task force on psychiatric treatments that is preparing a report on the utility of psychiatric treatments for specific disorders.

Issues pertaining to psychiatric research and technology assessment are addressed through the APA Office of Research and its Council on Research. In addition to the task force on treatments, the council is responsible for task forces on safety and performance standards for electroconvulsive therapy devices, use of laboratory tests, long-term effects of lithium on the kidney, sudden death, tardive dyskinesia, benzodiazepene dependency, and psychosocial treatment research.

The association also publishes the *American Journal of Psychiatry*, the *Journal of Hospital and Community Psychiatry*, and *Psychiatric News*. All of these report on new developments in diagnosis and treatment and on technological development within the field.

AMERICAN PUBLIC HEALTH ASSOCIATION

1015 15th Street, NW
Washington, DC 20005
202-789-5600

Contact: Seiko Baba Brodbeck, Associate Executive Director, Programs

The American Public Health Association (APHA), founded in 1872, is a membership organization representing 50,000 health workers. APHA is the oldest and largest organization of public health professionals in the world. APHA is organized by public health discipline. Its twenty-three sections and six special primary interest groups cover such areas as maternal and child health, occupational health and safety, radiological health, medical care, injury control and emergency health services, and health law.

APHA draws upon its members in accomplishing certain tasks, such as the development of books, monographs and technical reports. Among these diverse activities is the development of guidelines and technical standards. Examples include the following.

- The Committee on Laboratory Standards and Practices has developed publications on: methods for examination of water and wastewater, laboratory methods for sexually transmitted diseases, quality control for diagnostic microbiology, bacterial and viral diagnostic procedures, and quality assurance in health labs.
- The Task Force on Health Care in Prisons and Jails has published reports on standards for health services in correctional institutions.
- Program Development Board work groups have developed technical reports on the public health implications of the Bhopal disaster, and criteria for the development of health promotion and education programs.
- APHA was involved in the development and promotion of guidelines for abortion services in the U.S.
- APHA conducts various meetings and workshops throughout the year to address such issues as the role of nurses in meeting the health/mental health needs of the homeless.
- APHA public policy statements are used as the basis of its stand on legislative, legal and regulatory issues, and may stimulate scientific inquiry.

AMERICAN RHEUMATISM ASSOCIATION

17 Executive Park Drive, NE, Suite 480
Atlanta, GA 30329
404-633-3777
Contact: Lynn M. Forbes, Director of Communications

The American Rheumatism Association (ARA) is a 3,000-member nonprofit medical organization founded in 1934. ARA members are clinical and research professionals concerned with the prevention, treatment, and eventual cure of rheumatic diseases, and provision of optimal care. ARA seeks to provide leadership for scientific research, education, and professional care of people with rheumatic diseases.

Yearly, ARA conducts a national and four regional educational symposia that present the latest research findings and clinical advances in the areas of humoral immunology, cellular immunology, inflammation, biochemistry, cartilage, molecular biology and genetics, mineral metabolism and bone, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, osteoarthritis, spondylarthropathies, other rheumatic syndromes, pediatrics, orthopedics, health services, and rehabilitative rheumatology.

The Diagnostic and Therapeutic Criteria Committee of the ARA Research Council has been responsible for setting internationally accepted criteria for the classification of systemic lupus erythematosus, juvenile rheumatoid arthritis, osteoarthritis of the knee, rheumatoid arthritis, Reiter's Syndrome, gout, and scleroderma.

ARA publishes *Arthritis and Rheumatism*, a monthly journal of peer-reviewed articles covering all aspects of rheumatology. Other ARA publications include *Guidelines for Reviewers of Rheumatic Disease Care*, and the *Dictionary of the Rheumatic Diseases*.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS

515 Busse Highway
Park Ridge, IL 60068
312-825-5586

Contact: John Andes, Executive Secretary (Park Ridge office), or G.W.N. Eggers, M.D., Vice President for Scientific Affairs, University of Missouri Medical Center, Columbia, MO 65201, 314-882-2568

Founded in 1905, the American Society of Anesthesiologists (ASA) is an organization of 24,000 physician and scientists engaged in the field of anesthesiology. It encourages specialization in the field, seeks to raise the standards of the specialty through education, research, and scientific progress in anesthesiology, recommends standards of postgraduate education in the field, and disseminates information in regard to the field.

The ASA is concerned with the safety and effectiveness of anesthetic drugs and adjunct drugs, mechanical anesthesia and ventilatory equipment, electrical and monitoring devices, and the operating room system. The ASA Section on Clinical Care addresses the anesthesia care team, acute medicine, ambulatory surgical, care, blood and blood products, equipment and standards, obstetrical anesthesia, occupational health of operating room personnel, pain therapy, pediatric anesthesia, respiratory care, and surgical anesthesia. ASA also has a Committee on Peer Review.

The society has issued statements, positions, guidelines, or standards in such areas as invasive monitoring in anesthesiology, monitored anesthesia care, delineation of privileges, ambulatory surgical facilities, delegation of technical functions to non-physician personnel, basic intra-operative monitoring, peer review, ethical practice, critical care, regional anesthesia, organization of an anesthesia department, physician DRGs, and records to facilitate medical audit. ASA publishes the journal *Anesthesiology*. In addition, it makes available a monthly newsletter, manpower reports, refresher course materials, and manuals in peer review and quality assurance.

ASA works with such organizations as the Joint Commission on Accreditation of Hospitals, American Board of Anesthesiology, American Medical Association, and American Society for Testing and Materials to maintain quality of care and training.

AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

1101 Vermont Avenue, NW, Suite 604
Washington, DC 20005
202-371-0515

Contact: Robbi-Lynn Watnik, Legislative Assistant (Washington, DC office), or George F. Stevenson, M.D., Senior Vice President, 312-738-1336

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its membership numbers over 45,000 board-certified pathologists, other physicians, clinical scientists, and certified technologists and technicians. The society is intended to be a principal source of continuing education in pathology and a leading organization for the certification of laboratory personnel. ASCP's certifying board registers over 140,000 certified laboratory professionals annually.

The ASCP Commission on Continuing Education, composed of about 125 scientists representing all fields of laboratory medicine, annually conducts several hundred continuing education programs, many of which include extensive sections on new developments. It has formed a New Technology Committee that includes a section on communications technology and a section on laboratory technology. At least one content expert for each emerging technology is involved in the committee. The committee is considering subjects such as the CD-ROM interactive video disk, enhanced television for diagnosis of disease, flocytometry, DNA probes, and cutaneous sensor/ monitoring devices. The ASCP Research Development and Strategic Planning Committee may consider an enhanced technology assessment role as it reviews the goals of the ASCP.

AMERICAN SOCIETY OF INTERNAL MEDICINE

1101 Vermont Avenue, NW, Suite 500
Washington, DC 20005
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Contact: Robert Doherty, Vice President, Governmental Affairs and Public Policy

The American Society of Internal Medicine (ASIM) represents 20,000 physicians specializing in adult medical care. ASIM is concerned with social, political, and economic developments having an impact on the practice of internal medicine.

The society has a broad interest in issues relating to the use of technology in the delivery of medical care. ASIM has a strong interest in the pricing of new technologies. In 1983, the society adopted a policy calling for payments for new technology to be based on the resource costs associated with such technologies. ASIM is concerned about the disparity in payment between physicians' cognitive services and technologically-oriented services. ASIM has published several papers on the subject, including an issue of its journal *The Internist* and two white papers on reimbursement for physicians' cognitive and procedural services.

ASIM publishes *Guidelines on the Delineation of Hospital Medical Staff Privileges*, which includes recommendations on delineation of privileges to perform certain procedures. ASIM sponsors a proficiency testing program on medical laboratory evaluation to help improve the quality of physicians' office laboratory testing. The society also participates, along with the College of American Pathologists and the American Academy of Family Physicians, in the Commission on Office Lab Assessment, a voluntary initiative to develop quality standards for in-office labs. ASIM maintains liaison with government agencies and industry associations pertinent to its interests in medical technology.

AMERICAN SOCIETY OF MECHANICAL ENGINEERS

345 East 47th Street
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Contact: Julie Trunzo, Technical Administrator

The American Society of Mechanical Engineers (ASME) is an educational and technical society of mechanical engineers with a membership of 115,000. With 4,600 members, the ASME bioengineering division is a growing division of the society. It has technical

committees on biomechanics, fluid mechanics, heat mass transfer, instrumentation and control, medical devices, and rehabilitation engineering. Members apply engineering concepts and technology to the design and development of instrumentation, substitutes for biological materials, diagnostic and therapeutic devices, and artificial organs. The division is also concerned with the issues of health care delivery, standards for medical devices, and government regulation of health care.

The Bioengineering division sponsors a full technical program at each ASME winter annual meeting, and several other technical meetings each year. In the summers of odd-numbered years, it sponsors a biomechanics symposium. The division publishes the quarterly *Journal of Biomechanical Engineering*, which addresses biocompatible materials, bioinstrumentation, biomechanics, and design and control of biological systems; *Advances in Bioengineering*, compiled from the annual meeting; *Biomechanics Symposium Proceedings*, and other special publications.

Other activities relevant to medical technology are conducted by the ASME Technology and Society division, which sponsors such sessions as social responsibility in technological development and applications, technology transfer, and biotechnology and society.

AMERICAN SOCIETY FOR PARENTERAL AND ENTERAL NUTRITION

8605 Cameron Street, Suite 500
Silver Spring, MD 20910
301-587-6315
Contact: Sol Eskenazi, Research and Data Consultant

The American Society for Parenteral and Enteral Nutrition (ASPEN) was established in 1976 as a nonprofit, professional society to assist individuals in becoming more educated and knowledgeable about the field of parenteral and enteral nutrition. Through its membership of over 4,200 physicians, nurses, dietitians, pharmacists, and nutritionists, it promotes optimum nutrition for all patients, improved patient care by emphasizing the role of nutrition in rehabilitation and recovery, a multidisciplinary team approach to nutrition delivery, and professional education and scientific advancement in nutrition support.

ASPEN conducts continuing education programs, postgraduate courses, national and regional meetings, and scientific, clinical and educational workshops. Its two major publications are the *Journal of Parenteral and Enteral Nutrition* and *Nutrition in Clinical Practice*.

ASPEN has several activities related to technology assessment. The Research Workshop is conducted each year to examine important and controversial issues in the area of parenteral and enteral nutrition; the 1987 workshop dealt with nutrition in acute renal failure. The Research and Data Committee conducts programs and services to promote and support research and seeks to establish data resources for which analyses regarding the effectiveness of therapies can be assessed. ASPEN conducts an annual clinical congress in which events frequently focus on emerging devices, drugs, and techniques in providing nutritional care. In 1987 ASPEN convened a meeting to address how to assess the effectiveness of parenteral and enteral nutrition technology, and what further research is needed.

ASPEN is consulted by such organizations as the Office of Technology Assessment, the National Center for Health Services Research and Health Care Technology Assessment, and the Prospective Payment Assessment Commission regarding technological matters related to parenteral and enteral technologies.

AMERICAN SOCIETY FOR TESTING AND MATERIALS

1916 Race Street
Philadelphia, PA 19103
215-299-5400

Contact: Ray Sansone, Staff Manager for Medical and Surgical Materials and Devices

The American Society for Testing and Materials (ASTM) is a nonprofit organization in which producers, users, consumers, and representatives of government and academia develop voluntary consensus standards for materials, products, systems, and services. ASTM has 30,000 individual and organizational members worldwide.

ASTM has 140 technical committees and many subcommittees involved in standards writing for a wide variety of products from iron and steel to petroleum to textiles to medical devices. These address test methods, specifications, definitions, practices, and classifications.

The ASTM Committee on Medical and Surgical Materials and Devices is concerned with terminology and nomenclature, test methods, specifications, and performance standards. It includes 50 subcommittees on, e.g., orthopaedics, soft tissue replacement, electrodes, plastic and reconstructive surgery, mammary implants, urological materials and devices, surgical instruments, cardiovascular, neurosurgical, cranioplasty, device retrieval, and polymeric, metallurgical, and ceramic materials. ASTM also has committees on occupational health and safety; orthotics, external prosthetic, and mobility aids; anesthetic and respiratory equipment, emergency medical services; and health care services. Other ASTM committees have subcommittees in health-related areas, such as drug product packaging, medical thermometry, clinical laboratory systems, pharmacy automation, clinical data standards, and medical informatics.

The 66-volume *Annual Book of ASTM Standards* contains more than 8,000 sets of standards. The medical device standards volume addresses medical and surgical materials and devices, orthotics, external prosthetics, mobility aids, and forensic sciences. The quarterly *Journal of Forensic Sciences* covers instrumental analysis, measurement, and testing for forensic toxicology, pathology, psychiatry, immunology, odontology, and related topics. Other publications include standards adjuncts, special technical publications, data series, consumer publication series, and compilations of standards.

AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS

Contact: Lawrence G. Hunsicker, M.D., President, Director, Bldg. 3, VA Medical Center, Iowa City, IA 52240, 319-338-0581

The American Society of Transplant Physicians (ASTP) is a professional society of physicians and immunologists with a commitment to clinical transplantation. The society's objectives are to promote education and research in transplantation medicine and immunology, to provide a scientific forum on transplantation medicine and immunology, and to provide for transplant physicians and immunologists a voice in dealing with governmental, medical, professional and private organizations.

ASTP deals with issues related to technology assessment in several forums. All recommendations of committees to establish policy relating to technology assessment are forwarded to the ASTP council for review and action. The Patient Care Standards Committee is charged with reviewing and recommending standards for the care of candidates for and recipients of organ transplants. This committee is preparing a pamphlet listing the information that potential transplant recipients should be able to obtain from their physicians to help them evaluate their medical care options.

The Committee on the Training of Transplant Physicians is charged with defining the role of transplant physicians in clinical practice, with establishing qualification criteria for use by such organizations as the National Organ Procurement and Transplantation Network, and with establishing requirements of and criteria for approval of programs for training transplant physicians.

Representatives of the ASTP Council serve on intersociety committees established for other specific purposes related to technology assessment. For example, the ASTP, American Society of Transplant Surgeons, American Society for Histocompatibility and Immunogenetics, and International Society for Heart Transplantation, drafted a 1986 consensus statement on criteria for designation of organ transplant centers.

ASTP conducts an annual scientific session focusing on new findings in the fields of the basic immunology of transplantation and advances in the clinical management of transplant patients.

AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Contact: Robert J. Corry, M.D., Professor and Chairman, Office of the Chairman, Department of Surgery, The University of Iowa Hospitals and Clinics, Iowa City, IA 52242, 319-356-2545

The American Society of Transplant Surgeons (ASTS) is a nonprofit professional society founded in 1974 consisting of surgeons trained in organ transplantation. Members of the society are limited to surgical specialists actively engaged in organ transplantation. Further qualifications consist of certification by American Boards or their foreign equivalent.

The purpose of the society is to promote and encourage education and research with respect to transplantation surgery. ASTS collaborates with public and private organizations to promote and encourage education and research in transplantation surgery, and participates in coordinating efforts or formulation of programs by physicians, agencies, and health personnel to provide maximum efficiency and optimal benefit to recipients of organ transplants.

ASTS holds a two-day annual meeting at which original scientific papers are presented. Papers at the annual meeting are published annually in the journal *Transplantation*. The society, often through its Advisory Committee on Issues, takes positions on ethical and societal issues involving organ transplantation.

AMERICAN UROLOGICAL ASSOCIATION

1120 North Charles Street
Baltimore, MD 21201
301-727-1100
Contact: Richard J. Hannigan, Executive Secretary

The American Urological Association (AUA) is a nonprofit medical society founded in 1902 with the goal of advancing the practice of urology and providing optimal care for persons with urological diseases and disorders. Its 6,100 members are physicians and scientists concerned with the clinical and basic sciences related to urology.

AUA receives requests from private insurers, federal agencies, and health care provider organizations regarding standard guidelines and appropriateness of urological procedures. Prior to replying to requests for information and opinions, AUA consults with panels of experts in the various facets of urology. Three complete sets of urological standards have been promulgated by the AUA since 1974. The 1987 edition of *Guidelines for Urologic Patient Care* is available from AUA.

AUA's official journal is the *Journal of Urology*, a monthly publication containing articles on the latest advancements in medicine and surgery pertaining to urology. AUA conducts an annual symposium focusing on recent advancements to urological care. Included is a biomedical engineering forum that concerns itself primarily with emerging modalities in urology. AUA conducts continuing medical education programs for urologists that include assessments of recent technological advances related to urology.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

1901 N. Fort Meyer Drive, Suite 602
Arlington, VA 22209-1699
703-525-4890
Contact: Elizabeth A. Bridgman, Director of Technical Programs

The Association for the Advancement of Medical Instrumentation (AAMI) is an alliance of individuals and organizations sharing interests in medical devices and instrumentation. Its 5,000 individual members include clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, researchers, manufacturers, government representatives, and other health professionals. AAMI has 250 institutional members and 125 corporate members.

AAMI is a voluntary consensus standards organization accredited by the American National Standards Institute (ANSI). AAMI's technical committees and their sponsored programs produce several categories of documents. Standards and recommended practices are developed and voted on by technical committees. Medical device standards recommend to the manufacturer the labeling, safety, and performance requirements that the product should meet, and describe test methods for determining conformance with such requirements. Recommended practices for use, care, and processing devices and systems are directed primarily to users. Technical information reports disseminate new information on specific technologies. Monographs, technology assessment reports, technology updates, and technology analyses and reviews explore medical technology issues through articles written by experts, and are normally based on AAMI technical course or meeting proceedings.

AAMI's periodicals include the bimonthly peer-reviewed journal *Medical Instrumentation*, the newsletter *AAMI News*, and the magazine *Biomedical Technology Today*. ANSI standards on medical technology are available through AAMI. AAMI also provides biomedical engineering textbooks and reference materials, a membership directory, and annual meeting proceedings.

AAMI conducts an annual meeting, regional meetings, technology analysis and review conferences, and technical training seminars. It provides clinical engineering certification and biomedical equipment technician certification programs. AAMI provides to members free subscriptions to the BMEDSS (Biomedical Engineering Decision Support Services) electronic data base.

ASSOCIATION OF BIOTECHNOLOGY COMPANIES

1220 L Street, NW, Suite 615
Washington, DC 20005
202-842-2229
Contact: Bruce F. Mackler, Ph.D., J.D., General Counsel

The Association of Biotechnology Companies (ABC) is a nonprofit trade association in biotechnology. Formed in 1983, it has 180 member companies in eleven countries. Its purpose is to convene the companies on issues of common concern and to promote the growth of the biotechnology industry. Included among its major areas of interest are raising capital for the industry; trends in patenting biotechnology; regulatory policies of the Food and Drug Administration, U.S. Department of Agriculture, and Environmental Protection Agency; and public perceptions of biotechnology.

ABC has committees and working groups in insurance, import/export, and legislative and regulatory affairs. It acts as a liaison for the biotechnology industry to government, and has been active with regard to legislation relevant to the industry, such as regulations affecting export of biotechnology products, importation of cell lines and biological materials, environmental release of genetically engineered microorganisms, and patent protection of biotechnology products. ABC has developed a product and professional liability insurance program for its member companies. It publishes a bimonthly newsletter *Details*. It held its first international meeting in 1987, and holds regional regulatory workshops. In conjunction with the American Society of Testing and Materials, ABC will hold an October 1987 conference on worker and product safety related to biotechnology.

ASSOCIATION FOR HEALTH SERVICES RESEARCH

2100 M Street, NW, Suite 402
Washington, DC 20037
202-223-2477
Contact: Alice Hersh, Executive Director

The Association for Health Services Research (AHSR) is a national membership organization formed to represent the field of health services research. As such, AHSR promotes cooperative relationships between researchers and public and private decision makers, serves as a source of expertise and knowledge about health services research, and educates the public about the need for and contributions of the field.

As a national voice for health services research, AHSR monitors federal legislation and funding for health services research activities. It also serves to educate members of Congress and the Executive branch about the contributions of health services researchers.

The association's annual meeting provides a forum for researchers and health policy decision makers to discuss issues of common concern. This meeting also gives researchers the opportunity to discuss how health services research can be more effectively utilized in the decision making process.

The association publishes two *newsletters—HSR Update*, which keeps members current on federal policy initiatives and activities of major research centers, and *Focus on Mental Health Services Research*, which addresses developments in the mental health field. In 1985, the association published the *Directory of University-Based Health Services and Policy Research Centers*, and is updating this publication.

The Foundation for Health Services Research is the educational affiliate of the association. It conducts professional and educational activities such as the annual meeting, in addition to other conferences and workshops on topics important to the field.

CANADIAN ASSOCIATION OF MANUFACTURERS OF MEDICAL DEVICES

10 Four Seasons Place
Etobicoke (Tor.), Ontario M9B 6H7
Canada
416-620-1915
Contact: Margaret Guerrier, Director of Regulatory Affairs and Standards

Founded in 1972, the Canadian Association of Manufacturers of Medical Devices (CAMMD) is an organization of approximately 120 health product companies. The mission of the CAMMD is to encourage a business environment conducive to investment and growth of the Canadian health care industry by developing Canadian manufacturing and marketing capabilities, becoming involved in setting regulations governing medical devices, and writing of standards for these products.

CAMMD maintains contact with federal and provincial government agencies regarding regulations, trade development, occupational health and safety, and environmental issues. The association makes regulatory recommendations to the Canadian Health Protection Branch concerning such technologies as diagnostic pregnancy test kits, cardiac pacemakers, dental implants, AIDS test kits, intravenous therapy, and the reuse of disposable devices.

CAMMD has technical committees on diagnostic instrumentation and in-vitro products; general hospital equipment; implants, prosthetics, and sensory aids; orthopaedic equipment; radiation; and surgical supplies, sterile and disposable devices. Its members are active in committees of the Canadian Standards Association responsible for development of consensus standards, and certification standards. CAMMD holds an annual and semi-annual meeting.

CENTER FOR THE STUDY OF DRUG DEVELOPMENT

Tufts University
136 Harrison Avenue
Boston, MA 02111
617-956-0070
Contact: Kenneth I. Kaitin, Ph.D., Assistant Director

The Center for the Study of Drug Development (CSDD) is an independent nonprofit research organization affiliated with Tufts University. Its purpose is to explore scientific, economic, marketing, regulatory and other public policy issues that affect U.S. and international pharmaceutical research and development. It has an interdisciplinary perspective intended to involve government, industry, and the public.

Topics of current and recent projects include FDA use of outside advisors, new drug development by the U.S. pharmaceutical industry, new indications for already-approved drugs, post-approval research as a condition of approval, informed consent by patients for medication, and analysis of the 1984 generic drug and patent restoration legislation. Recent case studies have been conducted on such drugs as Bendectin, Depo-Provera, and AZT. International projects address such areas as development and introduction of new drugs in the U.S. and U.K., and the selection of drugs for the World Health Organization's model list of essential drugs.

CSDD has an in-house computerized library on drug development and regulation, including books, manuscripts, journal articles, government publications, articles from the news media, and trade publications. CSDD's New Chemical Entity (NCE) database includes information on drug development by the U.S. and European pharmaceutical industries. As some of the data are confidential, published analyses are in aggregate form only. Subjects of conferences recently sponsored by CSDD have included ibuprofen in its post-market stage, FDA use of foreign clinical trials data, maximizing the benefits of antibiotics, and therapeutic substitutions The center holds an annual five-day course on clinical pharmacology, drug development, and regulation.

The center responds to requests by industry, universities, and other outside parties for information from its library and NCE database. The center periodically sends out reprints and preprints of selected articles, as well as a newsletter with announcements of conferences and publications.

COUNCIL OF MEDICAL SPECIALTY SOCIETIES

PO Box 70
Lake Forest, IL 60045
312-295-3456
Contact: Rebecca S. Rhine, Associate Executive Vice President

The Council of Medical Specialty Societies (CMSS) is a nonprofit scientific and educational organization. Founded in 1965 as the Tri-College Council by the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Surgeons, CMSS was established to provide a forum for the discussion by medical specialists of issues of mutual concern and national interest. In 1967, as other specialty societies joined, the CMSS adopted its current name. Today, 24 major specialties with certifying boards sanctioned by the American Board of Medical Specialties are represented on CMSS. The total active voting membership of the 24 CMSS member societies is more than 280,000.

Since 1978, CMSS has collected and disseminated to the public and private sectors information concerning the clinical appropriateness of various diagnostic and therapeutic procedures. The CMSS Program for Clinical Procedure Review provides for the evaluation by physician specialists of medical and surgical procedures and makes the results of these assessments available to all interested parties. The CMSS program

draws upon its ability to bring together experts from major clinical disciplines to reach consensus on a procedures or modalities that apply to more than one specialty.

EMPLOYEE BENEFIT RESEARCH INSTITUTE

2121 K Street, NW, Suite 860
Washington, DC 20037-2121
202-659-0670
Contact: Dallas Salisbury, President

The Employee Benefit Research Institute (EBRI) is an independent, nonprofit, public policy research organization established in 1978 to provide educational and research materials on employee benefits. Its work is intended to serve employers, employees, retired workers, public officials, news media, and academicians as they address health, welfare, and retirement issues. EBRI has a separate Education and Research Fund that performs the charitable, educational, and scientific functions of the institute.

EBRI publishes three periodicals: the monthly *Employee Benefit Notes* analyzes and discusses newly released employee benefits data and reviews a wide range policy issues, research, and publications. *EBRI Issues Briefs* summarize and analyze evolving current issues and trends; recent topics include features of employer health plans: cost containment, plan funding, and coverage continuation, and private initiatives to contain health care expenditures. The *EBRI Quarterly Pension Investment Report* tracks the flow and investment of private and public pensions. It provides historical data on net contributions to pension plans and the investment allocation of the contributions by plan type, examines pension plan earnings and rates of return by plan type, and looks at the portfolio allocation of pension funds.

EBRI provides other reports, seminars, and press statements, and it holds several policy forums each year on economic and social issues having impacts on health, welfare, and retirement programs. Policy studies and forum proceedings have addressed such topics as financing the elderly's health care, Medicare reform, and employer-provided health benefits coverage issues.

FEDERATION OF AMERICAN HEALTH SYSTEMS

1111 19th Street, NW, Suite 402
Washington, DC 20036
202-833-3090
Contact: Albert C. Baker, Deputy Director for Government Relations

The Federation of American Health Systems (FAHS, formerly the Federation of American Hospitals) acts as trade representative of the nation's 1,400 investor-owned hospitals, hospital management companies, and health systems and allied companies involved in the delivery of long-term care, home health care, and health insurance.

Members of the federation include such major hospital companies as Hospital Corporation of America, Humana, American Medical International, and National Medical Enterprises, as well as several hundred independent, free-standing hospitals.

The federation's primary objective is to monitor and influence federal legislative developments, and to inform and educate members of Congress, the Executive Branch

and the national press about important issues in health care, particularly those issues relating to federal health programs.

In the medical technology arena, the federation's primary goal is to ensure that adequate federal funding is maintained for the research and development of new technologies. This is accomplished through the efforts of several FAHS committees, notably the Health Finance Committee and the Quality Care Task Force. Those committees work with leaders of government and industry to assess the impact of new technologies on the costs and quality of health care, as well as the impact of federal spending policies on the availability of important technologies.

FINNISH SOCIETY OF TECHNOLOGY ASSESSMENT IN HEALTH CARE

c/o National Public Health Institute
Department of Epidemiology
Mannerheimintie 166
SF-00280 Helsinki
Finland
(358-0) 75-70-32-9

Contact: Seppo Leisti, M.D., President, or Jari Kankaanpää, M.D., Secretary

The Finnish Society of Technology Assessment in Health Care was founded in 1986. Its purpose is to promote communication, training, and research in health care technology assessment.

The society will provide a means to consider assessment needs, resource needs, and the organizational structure of assessment in Finland. It is intended to organize courses and conferences, publish articles and reports, support research, make initiatives toward the health care community, industry, and government, and act as a means for gathering and disseminating information about assessment.

The governing board includes representatives from the Ministry of Health and Social Affairs, National Public Health Institute, National Board of Health, Finnish Hospital League, State Technical Research Center, and City of Helsinki Department of Health, as well as hospitals and universities.

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

200 Madison Avenue, Suite 2404
New York, NY 10016
212-683-1881

Contact: Dee Fensterer, President

The Generic Pharmaceutical Industry Association (GPIA) is a national association of independent manufacturers, distributors, and industry suppliers of generic prescription pharmaceuticals. The organization promotes increased acceptance and use of generic pharmaceuticals. It provides educational and technical information to physicians, pharmacists, consumers, legislators and government officials about the safety, efficacy, and therapeutic equivalence of generic pharmaceuticals.

GPIA monitors legislative developments in areas such as trade, intellectual property rights, and changes in regulatory technology requirements, and presents research

materials and assessment reports to legislative committees and government agencies. Passage of the 1984 Drug Price Competition and Patent Term Restoration Act codified FDA approval requirements for generic pharmaceuticals via testing methodologies that compare the serum bioequivalence of generic pharmaceuticals to reference drug products. Increased use of bioequivalency testing technologies by generic pharmaceutical producers to meet federal approval requirements has led to further development of these technologies. Member firms and the association's Technical Committee prepare reports on such developments for publication and for presentation to regulatory bodies.

GPIA and its member firms also assist in the development of orphan drugs for rare diseases through sponsorship of product research and support of the National Organization for Rare Disorders (NORD), as well as NORD's Rare Disease Data Base, a computer-accessible library of current information for practitioners, researchers and patients. GPIA's Institute for Orphan Drugs monitors developments in technologies related to the development and testing of orphan drugs.

GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER

Office of Research and Sponsored Programs
2300 Eye Street, NW
Washington, DC 20037
202-676-2995

Contact: Michael J. Jackson, Ph.D., Associate Dean for Research and Sponsored Programs

The George Washington University School of Medicine and Health Sciences is a private, nonprofit institution for education and research in fields related to health care. Technology assessment activities are concentrated mainly on a broadly based clinical research program. This program currently includes more than 400 projects directed to a wide range of new diagnostic or therapeutic modalities. Approximately 20 percent of the projects are institutionally sponsored, and the remainder are supported as collaborations between the institution and industrial, federal or private sponsors.

Oversight of the program is exercised by the Committee on Human Experimentation, consisting mainly of expert clinicians with specialist representation from the lay community as required by federal regulations. The committee reviews study protocols prior to initiation for subject safety and risk protection, study design and scientific value, and for provisions made for subject confidentiality and information.

Approved studies are reviewed at regular intervals for progress, incidence of adverse or unanticipated responses, and for compliance with required conditions. Protocols for proposed studies are submitted to the committee by members of the faculty of the school who assume responsibility for direction of approved studies. Reports on progress and final outcome of approved studies are provided to extramural sponsors by arrangement with the responsible faculty members.

Most projects in the program are directed to evaluation of safety and efficacy of new drugs and medical or surgical devices, but survey instruments, epidemiologic studies and expert opinions may be developed where appropriate. The program is fully supported by laboratory, inpatient, and ambulatory clinical care facilities.

GROUP HEALTH ASSOCIATION OF AMERICA

1129 20th Street, NW, Suite 600
Washington, DC 20036
202-778-3200
Contact: Margaret E. O'Kane, Director, Medical Directors Division

The Group Health Association of America (GHAA) is a national organization representing prepaid health care systems. GHAA currently represents more than 150 member health maintenance organizations (HMOs), including group. staff, network, individual practice association (IPA), and mixed models. GHAA represents the interests of the industry in Congress and with federal agencies, conducts conferences, seminars, and workshops, performs data collection and analysis, and maintains a comprehensive collection of published and unpublished work on prepaid managed care systems.

GHAA is involved in several activities relevant to technology assessment. Among its activities, the Medical Directors Division of GHAA responds to inquiries regarding coverage policies and disseminates information on NIH consensus development conferences, Office of Health Technology Assessment reviews, and other assessment findings.

GHAA research staff produce ad hoc studies of interest to the HMO industry. These have included issues in organ transplantation, alcoholism treatment, and supplemental benefits. The transplantation study assessed coverage for transplantation, volume of transplant procedures, HMO coverage compared to competition, role of formal HMO committees in decisions to cover and provide transplantation, and contractual arrangements for providing transplants. Also issued was an analysis of the integration of organ transplantation into HMO benefit structures. The research department generates an annual membership survey and, new in 1987, a national HMO industry survey. The latter uses a comparative data base of 410 HMOs to yield information describing benefits, coverage policies, and utilization. Included are data on coverage of such services as durable medical equipment, prosthetics, hospice care, in vitro fertilization, and organ transplantation, as well as enrollment profiles, premium structures, and other plan characteristics.

GHAA publishes *The Group Health Journal*, the monthly newsletter *Group Health News*, and an *HMO Managers Letter*.

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

1030 15th Street, NW, Suite 1100
Washington, DC 20005
202-452-8240
Contact: Paul Campbell, Director, Health Policy Research

The Health Industry Manufacturers Association (HIMA) includes over 300 companies that develop or manufacture more than 90 percent of the devices and diagnostic products used in the U.S. These products range from gauze bandages to artificial skin, from stethoscopes to computer assisted echocardiographs, and from surgical scalpels to CT scanners and magnetic resonance imaging scanners. HIMA's major policy initiative

is to focus attention on the resources committed by the medical products industry to gaining FDA approval for marketing its products.

HIMA has three sections that address a wide range of issues affecting the medical product industry, including issues related to medical technology assessment. The Science and Technology Section has several committees and task forces which address topics such as product manufacture, safety, domestic and international standards, in vitro diagnostics, and biotechnology. The Legal and Regulatory Section focuses on the regulation and payment of medical devices and diagnostic products; it has proposed ways to streamline the FDA device approval process and the HCFA coverage process while assuring public safety and the integrity of industry's products. The Government and Public Affairs Section addresses public and private sector initiatives relating to health care financing and controlling health care costs.

HIMA conducts research and educational programs addressing medical technology assessment. HIMA contracted with Battelle Institute to develop a manual which gives companies a blueprint for conducting cost-effectiveness analyses. HIMA cosponsored two conferences with the National Center for Health Services Research that focused on use of patient classification systems for measuring health outcomes. HIMA contracted with Duke University's Center for Health Policy and Education for an analysis of the key medical technology assessment trends affecting the device industry. HIMA has also conducted research that documents health insurance and managed care industry trends affecting medical technology. A recent report outlines the current status of coverage and payment policies of Medicare and private payers.

HEALTH INSURANCE ASSOCIATION OF AMERICA

1025 Connecticut Avenue, NW
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202-223-7836
Contact: Joel E. Miller, Deputy Director, Consumer and Professional Relations Division

The Health Insurance Association of America (HIAA) represents approximately 330 insurance companies responsible for over 85 percent of health care and disability benefit plans provided by insurance companies. HIAA conveys the industry's views to government, health care providers, news media, business, labor, and consumer groups. Member companies are kept apprised of government activities, trends and developments within the health care delivery system, and public opinion on health care issues. Technical assistance is provided to national, state, and local consumer and health care organizations.

Although HIAA does not have an internal mechanism to assess technologies, it serves as an information clearinghouse on assessments performed by public and private sector organizations. HIAA periodically publishes assessment findings from organizations such as the American Medical Association, American College of Physicians, and Office of Health Technology Assessment.

Through its Medical Relations Committee, HIAA serves as an intermediary between the Council of Medical Specialty Societies (CMSS) and HIAA member companies. HIAA forwards company inquiries to CMSS, evaluations or opinions on technologies are rendered, and this information is published in the HIAA's *Medical Appropriateness Compilation*, which is distributed to member companies. The Medical Relations Com

mittee also monitors developments in the area of medical technology and related ethical, legal and economic considerations; and maintains liaison between the insurance industry and relevant organizations.

The Task Force on Health Care Technology Assessment of the Medical Relations Committee was established in 1983 to monitor public policy developments in the area of organ transplantation and technology assessment.

INSTITUTE FOR ALTERNATIVE FUTURES

1405 King Street
Alexandria, VA 22314
703-684-5880

Contact: Clement Bezold, Ph.D., Executive Director

The Institute for Alternative Futures (IAF) is a nonprofit research and educational organization founded in 1977. It is primarily involved in futures research, using a variety of techniques related to environmental scanning and strategic planning. IAF attempts to assist organizations and communities in considering how they want the future to be shaped, and emphasizes community participation in evaluating technological impacts.

An emphasis of IAF's work has been in the health care field. With its for-profit consulting firm Alternative Futures Associates, IAF has prepared presentations and workshops on trends, alternative futures, and foresight for congressional staff and federal agencies, state governments, health professions organizations, hospitals, and health product manufacturers.

IAF has focused on the assessment of health care technology in a variety of ways. It has conducted forecasting projects on the development of new technologies such as the "hospital-on-the-wrist" and vaccines for cancer. IAF has conducted foresight seminars on biomedical issues intended to clarify the role of societal assumptions in technology assessment; these have addressed, for instance, the future of diagnostic testing, future of drugs and the elderly, future of organ transplantation, prospects for home health care, and pharmaceutical research and development for geriatric medicine and for vaccines and treatments for AIDS. Other futures projects have been conducted in nursing, mental health services, blood services, and artificial intelligence in health care. Examples of IAF publications are *Pharmacy in the 21st Century, Pharmaceuticals in the Year 2000*, and *The Future of Work and Health*.

INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS

1111 19th Street, NW, Suite 608
Washington, DC 20036
202-785-0017

Contact: Heidi Fauth James, Program Analyst (Washington, DC office), or Dr. Joseph D. Bronzino, Biomedical Engineering Program, Trinity College, Hartford, Connecticut 06106, 203-527-3151

The Institute of Electrical and Electronics Engineers, Inc. (IEEE) is the world's largest technical professional society with approximately 280,000 members, including 229,000 in the U.S. The organization's primary purpose is to serve as a forum for the dissemina

tion of technical and scientific information through publications, conferences and educational programs. IEEE also serves, through its U.S. Activities Board and Technical Activities Board, as a resource for technology policy concerns to government.

IEEE is involved in technology assessment through numerous routes. It has 35 specialty societies with technical interests that span the scope of electrotechnology, including engineering in medicine and biology, computers, imaging, and social implications of technology. It maintains standing committees to gather and analyze information relative to specific topics, both technical and professional. The IEEE Standards Board issues voluntary standards developed by the members of IEEE societies and working groups. In the health care area, standards for the utilization of biomedical instruments and devices are established. IEEE societies hold hundreds of conferences each year on state-of-the-art applications of emerging technologies.

There are several IEEE societies that focus on health care related technologies and maintain an active interest in medical technology assessments. The IEEE Engineering in Medicine and Biology Society has the broadest scope. The Health Care Engineering Policy Committee consists of representatives from these societies to assist in formulation of health care legislation, regulation, and policy in the U.S. through the provision of technical and professional counsel.

INSTITUTE FOR THE FUTURE

2740 Sand Hill Road
Menlo Park, CA 94025-7097
415-854-6322
Contact: Roy Amara, Ph.D., President

The Institute for the Future (IFTF) attempts to assist organizations to plan their long-term futures. Typical project areas include environmental scanning, strategic planning assistance, policy analyses, and market outlooks and social impacts of emerging products and technologies. IFTF takes a futures orientation, with emphasis on structured workshops and other forms of networking, and use of environmental scenarios to identify and study organizational issues and options. It has conducted projects for insurers, manufacturers, federal and state agencies, and foundations and other nonprofit organizations.

IFTF's Health Care Outlook project is an ongoing forecasting and strategic planning service conducted with the Louis Harris survey firm to study structural change in the U.S. health care system and its impact on business strategy, product development, and marketing. Industry outlooks studies of the pharmaceutical and medical equipment industries were conducted for the California state government. Other efforts include studies of cost-effectiveness of clinical laboratories in Canada, and health futures workshops for trade associations and government and health care provider organizations.

Recent reports include *The Impact of New Diagnostic Technologies on the Practice of Medicine, 1982-95* (1985), *Twelve Emerging Technologies for the 1990s* (1986), and *Looking Ahead at American Health Care, Final Report* (1987).

INTERNATIONAL FEDERATION FOR MEDICAL AND BIOLOGICAL ENGINEERING

Contact: Dr. Jan Persson, Chairman, Joint Working Group, Implications and Assessment of Biomedical Innovations, c/o Dept. of Biomedical Engineering, University Hospital, S-581 85 Linköping, Sweden, (46-13) 19-24-56

The International Federation for Medical and Biological Engineering (IFMBE), founded in 1959, is a nonprofit scientific organization of independent affiliates in 30 countries. (The U.S. affiliate is the Alliance for Engineering in Medicine and Biology.)

IFMBE members include biomedical engineers, technologists and technicians, clinical engineers, rehabilitation engineers, physicians, medical physicists, and biologists. The objectives of the IFMBE are to generate and disseminate information to the international biomedical engineering community, provide a forum, encourage research and application of biomedical engineering knowledge in support of life quality and cost-effective health care, stimulate international cooperation in the field, and encourage educational programs in biomedical engineering.

IFMBE publishes the *bimonthly Journal of Medical and Biological Engineering and Computing*, the bimonthly news report *The MBEC News*, and the annual *IFMBE Directory* of affiliates and committees. In collaboration with the International Organization for Medical Physics, IFMBE organizes a world conference every three years; the next are in San Antonio, Texas in 1988 and Kyoto, Japan in 1991.

The IFMBE Joint Working Group on the Implications and Assessment of Biomedical Innovations seeks to convene engineers and medical scientists to explore social and economic influences of biomedical innovations, develop and apply assessment methods, and analyze means by which social and economic factors should influence engineering decisions.

IFMBE consults with the International Electric Commission and the International Measurement Confederation in developing standards, e.g., for digital imaging. IFMBE affiliates participate on technology assessment councils, standards and safety boards, and other efforts related to international standards in medical device safety.

INTERNATIONAL FEDERATION OF VOLUNTARY HEALTH SERVICE FUNDS

15-17 Essex Street
London WC2R 3AD, England
United Kingdom
(44-1) 35-31-15-9

Contact: Kenneth N. Groom, Secretary General

The prime objective of the International Federation of Voluntary Health Service Funds (IFVHSF) is to promote the development and study of voluntary non-profit health services throughout the world in order to assist individuals in obtaining health services, and to strengthen the business capability of these services. The federation has 170 organizational members which together provide health care benefits for a total of 120 million people in twenty countries.

Voluntary health service funds exist to encourage the support and expansion of a private sector not-for-profit role in the financing and delivery of health care. The federation serves as a medium for the exchange of information on, and skills and experience in, voluntary non-profit health services; encourages research in voluntary non-profit health services; promotes and facilitates reciprocal arrangements among member funds for persons changing domicile between countries; organizes international conferences; and fosters relationships between organizations and persons carrying out, or interested in, voluntary non-profit health services in different countries.

The federation pursues its mission through a development program, meetings program, information program (conference and seminar proceedings, newsletters, and ad hoc publications), and a reciprocal services program among members.

The federation's role in health technology is to inform members in order to promote the assessment of new technology and to encourage the application of technologies that have proven cost-effectiveness. The federation provides international comparative information concerning voluntary health services. Other issues of the information program have included data processing, health education, health needs, and health economics. The federation has examined and made recommendations to the World Health Organization and the Pan American Health Organization regarding health care delivery systems of selected countries.

INTERNATIONAL SOCIETY OF TECHNOLOGY ASSESSMENT IN HEALTH CARE

Contact: Els Borst-Eilers, Secretary, and Vice Chairman, Health Council of the Netherlands, PO Box 90517, 2509 LM The Hague, Netherlands, (31-70) 47-14-41. Journal subscription and society membership: Cambridge University Press, 510 North Avenue, New Rochelle, New York 10501 (for U.S. and Canada), or Cambridge University Press, Edinburgh Building, Shaftesbury Road, Cambridge CB2 2RU, England (for U.K. and other countries)

The International Society of Technology Assessment in Health Care (ISTAHC) was organized in 1985 to encourage research, education, cooperation and the exchange of information concerning the clinical and social implications of technologies used in health care and to foster their optimal use.

The society has more than 400 members representing 30 countries. Members represent many disciplines, including physicians, nurses, biomedical engineers, economists, ethicists, policy analysts, sociologists, epidemiologists and hospital administrators. There are also representatives from health care insurers, the medical device industry, government, health policy institutes, universities and medical schools, and independent research organizations.

The society publishes the quarterly journal *International Journal of Technology Assessment in Health Care*. Themes of various issues have included technology and the elderly, advanced technology and home health care, magnetic resonance imaging, technology in prenatal care, organ transplantation, and the implantation of artificial organs.

The principal activity of the society is its annual meeting, held alternately on different sides of the Atlantic. The society plans to convene workshops and conferences to

provide forums for exchange of data and information on specific topics of international interest and to foster international collaboration.

Technological issues of interest to the society include determination of evidence for safety and efficacy, cost and cost-effectiveness, ethical aspects and access, quality of care, legal and regulatory considerations, and comparison with competing technologies. Accordingly, the society is concerned with assessment of all the implications of health care technology and the use of assessment findings to provide a rational basis for the acquisition, diffusion and application of technology so as to foster and enhance the delivery of quality health care.

MARYLAND HOSPITAL ASSOCIATION

1301 York Road, Suite 800
Lutherville, MD 21093
301-321-6200
Contact: Steven J. Summer, Vice President

The Maryland Hospital Association (MHA) is a nonprofit organization formed to encourage cooperation and communication among the state's 64 community acute care and special hospitals. MHA is governed by citizen volunteers who serve on hospital boards. MHA activities include advocacy, information, education, research, and programs to enhance the management efficiency and quality of care in Maryland hospitals. MHA also conducts educational programs through its affiliate, the Maryland Hospital Education Institute.

MHA's Maryland Council for Quality Health Care addresses the need for data collection and analysis to help member hospitals monitor and enhance the quality of care. Composed of hospital trustees, hospital medical staff representatives, and CEOs, the council's work is divided into four major areas:

- The Committee on Treatment and Technology is responsible for disseminating information to member hospitals on outcome studies, the efficacy of new treatment modalities, and emerging technology. It collects and distributes the results of clinical tests, assessments, and other materials concerning recently introduced technologies. It also considers related policy and payment implications for Maryland hospitals.
- The Committee on Practice Pattern Variations reviews geographic and medical practice variation data for surgical procedures and medical treatments. It promotes research through coordination with medical specialty groups and academic institutions.
- The Committee on Institutional Mortality Data initiates hospital review of mortality information generated by the association. It looks at trends and recommends in-house educational programs for hospital quality assurance.
- The Committee on Quality Indicators is responsible for overseeing the MHA Quality Indicator Project, currently testing nine quality indicators in seven Maryland hospitals.

NATIONAL ADVISORY COUNCIL ON HEALTH CARE TECHNOLOGY ASSESSMENT

National Center For Health Services Research and Health
Care Technology Assessment
Parklawn Building Room 18-05
5600 Fishers Lane
Rockville, MD 20857
301-443-5650

Contact: Nancy Blustein, Executive Secretary, and Special Assistant to the Director, National Center for Health Services Research and Health Care Technology Assessment

The Health Promotion and Disease Prevention Amendments of 1984 (P.L. 98-551) provided for the establishment of the National Advisory Council on Health Care Technology Assessment. The National Advisory Council is to advise the Secretary of the Department of Health and Human Services and the Director of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) with respect to the performance of NCHSR technology assessment activities. (P.L. 98-551 also provided for the establishment of the separate Council on Health Care Technology at the Institute of Medicine, National Academy of Sciences.)

The National Advisory Council's functions, as prescribed by law, include assisting the NCHSR Director in developing criteria and methods to be used in making coverage recommendations (particularly those of the NCHSR Office of Health Technology Assessment), and reviewing technology assessment research applications (particularly those administered by the NCHSR Division of Extramural Research) in excess of $50,000 in direct costs.

The National Advisory Council is composed of 12 voting members appointed by the Secretary. Six members are distinguished in medicine, engineering, and science, and four members represent individuals distinguished in law, ethics, economics, and management. Membership requirements provide for at least two physicians, two representatives of business engaged in the production or development of medical technology, one hospital administrator, one health insurance company or self-insured employer representative, and two individuals who represent the interests of health care consumers.

The National Advisory Council meets at least three times a year to review technology assessment research applications and to carry out its other advisory functions. Subcommittees are established by the National Advisory Council to conduct specific activities. For example, subcommittees have been utilized to prepare a preamble of overarching principles to guide the technology assessment process, to develop recommended criteria to be utilized in performing technology assessments, and to study and make recommendations regarding the technology assessment process and the coverage process.

NATIONAL ASSOCIATION OF HEALTH DATA ORGANIZATIONS

316 Pennsylvania Avenue SE, Suite 202
Washington, DC 20003
202-546-5881

Contact: Marlene Larks, Executive Director

The National Association of Health Data Organizations (NAHDO) was established in 1986 by the Washington Business Group on Health to promote appropriate and accurate collection and analysis of health care data. Members include health data organizations that have legislative authority to collect and analyze health care data on a statewide or other jurisdictional basis, such as state health departments, health data commissions, rate setting commissions, hospital commissions, federal agencies, national associations, corporations, and individuals.

Through exchange of information between member organizations and educational programs, NAHDO seeks to improve the quality of health care data and data management. NAHDO intends to support the work of existing state data collection authorities, and to provide assistance to new and emerging health data organizations. To enhance this effort, the Intergovernmental Health Policy Project at George Washington University provides certain information and dissemination services to NAHDO.

NAHDO activities and projects underway include an annual meeting, technical seminars and other special meetings, a resource manual, the newsletter *NAHDO News*, an electronic bulletin board, circulation of health data organization reports, and a health data organization directory. One 1987 technical seminar, "Micro to Mainframe," addressed the collection, electronic transfer, and use of hospital discharge data. The NAHDO Ambulatory Data Committee addresses ambulatory data issues, and provides technical assistance to member organizations wanting to establish or modify their ambulatory data bases. NAHDO is conducting a two-year project to develop recommendations for an acute care uniform data set intended to minimize the number of different definitions imposed by data gatherers such as purchasers and insurers.

NATIONAL ASSOCIATION OF MANUFACTURERS

1776 F Street, NW
Washington, DC 20006
202-637-3000
Contact: Sharon Canner, Director, Employee Benefits

The National Association of Manufacturers (NAM) is a nonprofit organization of over 13,500 corporations of many sizes and industrial classifications in every state. NAM represents members' interests to Congress and regulatory agencies. Members determine association policy through participation in 14 policy committees.

The Employee Benefits Committee is concerned with private sector retirement and health and welfare plans as well as federal health policy and legislation affecting individual company plans. Of special interest are Medicare's financing and benefit structure, the program's coverage decisions and their relationship to company medical plans for retirees. Other areas of focus are catastrophic insurance, the uninsured, health care data, and health care technology and its impact on corporate health care costs.

In 1984, NAM appointed a task force on technology. Concerns of this task force include issues related to technologies and health care costs, the role of the employer as purchaser and evaluator of efficacy and cost/benefits of the health services provided to workers under company plans, and the role of some employers in producing and marketing health care products. The committee is also concerned with the availability and utility of assessment information, appropriate utilization of technologies, and the impact of public and private sector policy on technological innovation and diffusion.

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

2101 L Street, NW, Suite 300
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202-457-8432
Contact: Robert G. Britain, Manager, Diagnostic Imaging and Therapy Systems Division

The National Electrical Manufacturers Association (NEMA) is the principal national trade association of the electrical manufacturing industry. NEMA has 570 member manufacturing companies that are affiliated with one or more of its product divisions representing distinct industries.

NEMA's Diagnostic Imaging and Therapy Systems Division represents more than 95 percent of the market for manufacturers providing medical devices to the health care field in the areas of conventional medical and dental x-ray imaging, computed tomography, diagnostic ultrasound, nuclear imaging, radiation therapy, magnetic resonance, lithotripsy, and picture archiving and communication systems.

NEMA is especially concerned with the electrical equipment standards to facilitate uniform repetitive manufacture, and with product performance and safety. NEMA standards-writing activities are continuous. Standards are derived from industry-wide cooperative efforts with input from user organizations such as the American College of Radiology and regulatory agencies such as the FDA. Standards are approved by the NEMA Council for compliance with association policies and federal law prior to their adoption. NEMA standards are not sustained for more than five years without being revised, reaffirmed or rescinded. Performance characteristics of imaging equipment can be confirmed by users with the use of referee test procedures associated with NEMA standards.

NATIONAL HEALTH COUNCIL

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202-785-3913
Contact: Joseph C. Isaacs, Director of Government Relations

The National Health Council (NHC) is a nonprofit association that has served for nearly 70 years as an umbrella organization for many U.S. health groups. The council brings together such diverse organizations as charitable voluntaries, health care providers, insurers, manufacturers, and federal health agencies. Its current membership includes 65 such organizations.

The council's mission is to enhance the ability of its members to work together effectively to promote the health of all Americans and ensure accessibility to quality health care. Among its activities, the council monitors developments pertaining to a broad array of health policy issues, including technology assessment, management and innovation. As a service to its members and as a contribution to the policymaking process, the NHC has written reports and conducted seminars on technology issues and other topics of national interest. Additionally, it hosts an annual National Health Forum which addresses comprehensively a current or emerging health care system theme.

One of the long-standing traditions of the council is hosting breakfast briefings with leading federal policymakers. Several of these are sponsored each year to help professionals in the field obtain first-hand information on health care issues and the broad policy environment from key decision makers in Congress, the White House, and the various executive agencies.

OLEY FOUNDATION FOR HOME PARENTERAL AND ENTERAL NUTRITION

214 Hun Memorial
Albany Medical Center
Albany, NY 12208
518-445-5079
Contact: Lenore Heaphey, Associate Director

Oley is a nonprofit research and education organization founded in 1983 for the purpose of promoting optimal care for those requiring long-term specialized nutritional therapy. The foundation has established a network of clinicians and patients throughout the U.S. and several other countries. This network is based on four major activities: an annual research registry of patients in the U.S. and Canada receiving home nutritional support, the publication of a bimonthly newsletter, an outreach system of patients, and coordination and oversight of multi-center research efforts related to long-term parenteral nutrition.

Oley has several mechanisms that relate to assessment of nutrition technology. It conducts research surveys to obtain patient product experience and evaluation. It disseminates information to clinicians and consumers through publications and conferences. Oley makes available consumer volunteers to provide feedback in the development of technology tailored for the ambulatory or home setting. Oley has affiliations with agencies developing and monitoring standards for specialized nutritional therapy in the home and nursing home. The foundation's Scientific Advisory Committee addresses a broad range of questions regarding the technology of home parenteral and enteral nutrition.

PAN AMERICAN HEALTH ORGANIZATION

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202-861-3219
Contact: Jorge Peña Mohr, Regional Advisor on Health Technology, Health Policies Program

The Pan American Health Organization (PAHO) is an international organization of the Pan American System and the Regional Office of the World Health Organization. PAHO is supporting:

- A comprehensive research project on health technology development in seven countries including sixteen lines of study in four main topics: policy, supply, utilization, and impacts.

- A development and evaluation project on maternal and child health technology supported by the W. K. Kellogg Foundation.
- A technology information support system including regulatory, purchasing, and industrial development policy and decision making needs for member countries.

PAHO publishes the *Latin American Medical Index*, a scientific series, and other publications covering a large range of public health topics. More than 50 reports have been published on health technology issues; most of these reports are written in Spanish.

PAHO's health technology clearinghouse activity consists primarily of annotated bibliographies on technology development in health, as well as in the national economies, agriculture, manufacturing, and industrial sectors that encompass health. One technology evaluation report written in English, *Effectiveness of Cervical Cancer Screening Programs* (1986), is an annotated bibliography of 100 articles drawn from National Library of Medicine online information bases. The 22nd Pan American Sanitary Conference of PAHO included health technology as one of the six major priorities for the American Region.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

1100 15th Street, NW
Washington, DC 20005
202-835-3420
Contact: Gerald J. Mossinghoff, President

The Pharmaceutical Manufacturers Association (PMA) is a nonprofit scientific and professional organization of more than 100 firms that discover, develop and produce prescription drugs and biological products in the United States. The association's members produce most of the prescription drugs used in the U.S., and about half of the western world's supply of prescription drugs. PMA has a staff of approximately 90 and is governed by a 35-member board.

PMA has 13 Sections (with many subsections and committees) composed of representatives of member firms. The Sections are Biological, Financial, International, Law, Marketing, Medical, Personnel, Production, Engineering and Materials Management; Public Affairs, Quality Control, Research and Development, State Government Affairs, and Washington representatives. The sections identify issues and develop options and recommendations for the Board of Directors as well as relating with government agencies on legislative, regulatory and technical matters. Section meetings, seminars, workshops, and training courses deal with a wide variety of issues important to maintaining high standards of safety, efficacy and quality of prescription pharmaceuticals and other issues relating to quality of health care in this country.

PMA's regular publications include *The Annual Report*, the *Annual Statistical Fact Book and Survey*, a weekly newsletter, a quarterly bulletin, the biweekly *Trademark Bulletin*, a weekly *State Capital Report*, the monthly *Science and Technology Notes*, and periodic *Research Reports*. Other publications on policy and technical issues are published from time to time. A list of PMA publications may be obtained from the Communications Division.

PHYSICIAN PAYMENT REVIEW COMMISSION

2120 L Street, NW, Suite 510
Washington, DC 20037
202-653-7220
Contact: Paul B. Ginsburg, Ph.D., Executive Director

The Physician Payment Review Commission (PPRC) was created by Congress in 1986 to provide advice on reforms in the methods used to pay physicians for services to Medicare beneficiaries. PPRC began its work in November 1986. It is comprised of 13 members who represent a broad range of experience and perspectives on issues concerning physician payment.

The commission plays four roles. First, it serves as a source of independent expert advice to Congress and to the Secretary of Health and Human Services. Second, it provides opportunities for beneficiaries, physicians, and other interested parties to have their views considered in policy deliberations on physician payment issues. Third, PPRC conducts analyses to provide a basis for policy decisions to alter Medicare's method of paying physicians. Fourth, it performs design work necessary to implement major changes in physician payment.

PPRC is mandated to make recommendations to Congress by March 1 of each year regarding payment for physicians' services under Part B of the Medicare program. PPRC is required to address specific issues related to physician payment, including the variation in payment rates among specialties and geographic areas, the inherent reasonableness of charges for specific services or procedures, methods for developing a relative value scale for physicians' services, and physician participation in the Medicare program. The commission intends to consider both short-term improvements in the current payment system and alternatives for more fundamental long-term reform.

The title of PPRC's 1987 report to Congress is *Medicare Physician Payment: An Agenda for Reform*. The report outlines goals for physician payment policy, the commission's findings, a range of alternatives for physician payment reform, and a time frame for reform. Analyses and recommendations are also given for fee schedules, geographic variation in charges, inherent reasonableness, assignment and the participating physician program, the Medicare Economic Index, improving program administration, coding, data issues, and assistant at surgery.

RENAL PHYSICIANS ASSOCIATION

1101 Vermont Avenue, NW, Suite 500
Washington, DC 20005-3457
202-898-1562
Contact: M. Eileen Widmer, Executive Director

The Renal Physicians Association (RPA) is a national organization of more than 1,200 physicians who care for patients with renal disease. Established in 1973 to represent the interests of physicians and their patients under the End Stage Renal Disease (ESRD) Program, RPA has since expanded its activities into various areas concerning treatment of renal disease.

RPA's goals are to ensure optimal care for patients with renal disease and related disorders, to act as a national representative for physicians in the field, and to serve as a resource for development of national health policy concerning renal disease. RPA monitors legislative and regulatory activity involving the ESRD program, and acts as an advocate for graduate medical education in nephrology. RPA supports various research activities and promotes funding for kidney disease research.

In cooperation with the Health Care Financing Administration and the Registry Committee of the European Dialysis and Transplant Association, RPA has undertaken a national random sample survey of ESRD patients in order to gauge the application and effectiveness of various modes of therapy for chronic renal failure. RPA also supports research efforts to improve and develop technologies for treatment of renal disease. The association has undertaken some informal and formal technology assessment activities including, most recently, a full-scale evaluation of the procedure of reprocessing dialyzers. RPA holds an annual three-day educational meeting on health policy and scientific issues. The association publishes the quarterly newsletter *RPA News.*

RESNA—ASSOCIATION FOR THE ADVANCEMENT OF REHABILITATION TECHNOLOGY

1101 Connecticut Avenue, NW, Suite 700
Washington, DC 20036
202-857-1199
Contact: Patricia I. Horner, Executive Director

RESNA—Association for the Advancement of Rehabilitation Technology, formerly the Rehabilitation Engineering Society of North America, was renamed to better reflect the broad array of interests and skills within the organization. The organization was established in 1979, and membership includes rehabilitation professionals, providers, and consumers who are dedicated to putting technology to work for disabled persons.

RESNA annual conferences are held at various locations in North America. Other symposia and workshops are held periodically to seek answers to questions critical to the welfare of disabled persons. The proceedings of the conference are published, as well as a variety of other pertinent publications that emanate from the work of RESNA committees or from rehabilitation professionals.

Sixteen RESNA special interest groups respond to the need for a communication network within the rehabilitation community to address the diverse needs of consumers, providers, and industry. Regional conferences are being developed to provide members with the opportunity to meet more frequently to discuss their mutual interests.

RESNA has developed strategies to ensure interactions among relevant professions, and to develop consensus on definition of rehabilitative needs; funding requirements for R&D, education and training; monitoring legislation; working with industry to ensure high standards and to promote the marketing of new devices; and identifying funding sources for consumers.

SOCIETY FOR MEDICAL DECISION MAKING

One Main Street
PO Box 447
West Lebanon, NH 03784
603-298-9929
Contact: John Tomeny, Administrator

The Society for Medical Decision Making (SMDM) is a nonprofit professional society founded in 1979 for the purpose of advancing the teaching and scholarship in medical decision making. The 700 members of SMDM include physicians, public health scientists, economists, computer scientists, health services researchers, and cognitive scientists. Their interests revolve around clinical decision analysis, cost-effectiveness analysis, technology assessment, medical databases, and artificial intelligence. The SMDM conducts continuing education courses in decision analysis and technology assessment.

Medical Decision Making, an international journal of record in the field, is published quarterly by the society. SMDM holds an annual conference on decision making in the health sciences. This meeting is principally devoted to the presentation of abstracts, but hour lectures in decision science and technology assessment are staples of the conference.

SOCIETY OF NON-INVASIVE VASCULAR TECHNOLOGY

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Contact: Patricia I. Horner, Executive Director

The Society of Non-Invasive Vascular Technology (SNIVT) is a nonprofit professional medical society founded in 1977 to provide education for the profession of noninvasive vascular technology and to represent the field among other health professions and to the public by providing information and education. Approximately 60 percent of the society's 2,700 members are practicing noninvasive vascular technologists or are technologists involved in supervision and/or education in a clinical setting. Physicians, other health care providers, researchers, and those involved in the sale and manufacture of equipment comprise the balance of the membership.

Through its publications, *the Journal of Vascular Technology* and newsletter *Spectrum*, and local and national meetings, the society attempts to meet the educational and professional needs of the technologists involved in vascular testing. In addition, SNIVT offers patient education pamphlets and training center directories.

SNIVT is a member of and maintains liaison with organizations whose goals are related to maintaining excellence in the field. These include the American Medical Association's Joint Review Committee on Education in Cardiovascular Technology, and the American Society of Allied Health Professions. SNIVT is represented on the AMA Panel of Consultants and the American Registry of Diagnostic Medical Sonographers (ARDMS).

In an effort to support the continuing education efforts of the registered vascular technologists, the society provides continuing education credits accepted by the ARDMS. SNIVT provides educational support for technologists preparing for the Vascular Technology Exam through its referenced study outlines.

SOCIETY OF NUCLEAR MEDICINE

136 Madison Avenue
New York, NY 10016-6784
212-889-0717
Contact: Henry L. Ernstthal, Executive Director

The Society of Nuclear Medicine (SNM) is a multidisciplinary organization of physicians, physicists, chemists, radiopharmacists, technologists, and others interested in the diagnostic, therapeutic, and investigational use of radioactive and stable nuclides. Founded in 1954, it is the largest scientific organization dedicated to nuclear medicine with over 10,500 members world-wide.

The society has established special interest councils that function autonomously within the society. The Cardiovascular Council addresses performance and application of cardiovascular nuclear medicine procedures. The Computer Council is concerned with computer applications in diagnostic, therapeutic, and investigative areas of nuclear medicine. The Correlative Imaging Council is interested in developing and disseminating information on medical and physiological applications of various imaging modalities. The Instrumentation Council promotes advancement and dissemination of knowledge of instrumentation used in nuclear medicine. The Radioassay Council is concerned with the scientific, economic, and historic elements of the radioassay discipline. The Radiopharmaceutical Science Council addresses dissemination of information relating to the radiopharmaceutical sciences and encourages basic radiopharmaceutical research and development. The Academic Council promotes education in the field.

SNM has participated in technology assessments conducted by other institutions by forming ad hoc committees to address specific issues referred to it by such organizations as the American Medical Association and the Council of Medical Speciality Societies. The society recently formed a committee on positron emission tomography (PET) to examine the literature on PET scanning and to inquire as to its applications that improve patient management. Scientific data pertaining to assessment is published in SNM's *Journal of Nuclear Medicine* and as part of other ongoing educational activities through its annual and other meetings and publications.

SWEDISH NATIONAL CENTER FOR TECHNOLOGY ASSESSMENT IN HEALTH CARE

Drottning Gatan 16
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(46-8) 24-05-65
Contact: Egon P. Jonsson, Ph.D., Director

The Swedish National Center for Medical Technology Assessment was established in 1987 and will begin operations in 1988. An independent government agency, it reports to the cabinet level of government, rather than being part of a particular ministry. The center's first-year budget is approximately $1.5 million.

The major purpose of the center is to enhance and coordinate health care technology assessment activities in Sweden. It was established in response to increased international interest in medical technology assessment and considerations of rising health care costs. Significant impetus to the center's formation arose from concern regarding the purportedly slow pace at which certain technologies have diffused in Sweden; an enhanced assessment capacity has been advanced as an appropriate means for enabling worthy technologies to diffuse more readily. Further, the center is intended to improve the transfer of information about medical technologies from the biomedical research community to health care providers and the public.

The governing board of the National center includes representation from the Ministry of Health, Medical Research Council, National Board of Health and Welfare, Federation of the County Councils, Swedish Planning and Rationalization Institute for the Health and Social Services (SPRI), Swedish Medical Association, and Swedish College of Physicians.

The center's program will address medical, economic, social, and ethical aspects of new and established technologies used for diagnosis and treatment. Assessments conducted by the center will largely involve syntheses of existing information, and it may purchase data from other organizations and encourage them to conduct assessments on certain topics. The center intends to coordinate its activities with similar organizations in other nations, such as the U.S. Office of Technology Assessment and the Council on Health Care Technology of the Institute of Medicine.

TECHNOLOGY ASSESSMENT AND FORECAST PROGRAM

U.S. Patent and Trademark Office
CM2-313
Washington, DC 20231
703-557-0433
Contact: Jane Myers, Office of Documentation

The U.S. Patent and Trademark Office (PTO) established the Technology Assessment and Forecast Program (TAF) to stimulate the use and enhance the usability of the patent file, and to assemble, analyze, and make available meaningful data about the file.

TAF uses the database in two principal ways. First, it periodically issues general distribution publications. One series of publications, the *Technology Assessment Forecast Reports*, have included reviews of highly active technological areas and areas experiencing high levels of patenting by foreign residents, profiles of the patenting patterns of the residents of selected foreign countries and U.S. states, reviews of the patent activity of the most active patent assignees, and comparisons of patent activity with economic activity in selected Standard Industrial Classification categories. Another series of publications, *Patent Profiles*, surveys the U.S. patenting activity in specific technologies.

One such profile is *Biotechnology: 1982 Update*; others address such topics as robots, telecommunications, and microelectronics. The second principal use of the TAF database is to prepare custom data reports tailored to individual needs. These reports, provided on a cost reimbursable basis, are used by government agencies and the private sector. One such custom report was a technology profile report on genetic engineering, an analysis of patent activity in this area from 1963 to 1986.

UNITED STATES PHARMACOPEIAL CONVENTION

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Contact: Diane M. McGinnis, Assistant Coordinator, Practitioner Reporting System

The U.S. Pharmacopeial Convention (USP) is an private, nonprofit body of 300 delegates representing state and national associations and colleges of medicine, nursing, and pharmacy; industry; and agencies of the federal government. Incorporated in 1900, the purposes of USP are to set standards for health care products in the U.S. and to collect and disseminate product use information to providers and consumers.

Every five years, USP publishes revised standards for drugs in *The United States Pharmacopeia* and *The National Formulary*. These standards are recognized as official by the federal government and are enforceable by the FDA. The standards include specifications pertaining to drug strength, quality, purity, packaging, and labeling.

USP provides official drug reference standards, which are highly characterized specimens of drugs, impurities, and degradation products. USP laboratories test and monitor these standards, and develop analytical procedures and tests of proposed revisions of tests and assays. USP publications include *USP DI Volume I: Drug Information for the Health Care Provider* and *USP DI Volume II: Advice for the Patient*. Other publications are the consumer edition of the reference volumes *About Your Medicines*, the bimonthly newsletter *About Your Medicines*, and various brochures and books.

The Drug Product Problem Reporting Program (DPPR) and the Medical Device and Laboratory Product Problem Reporting Program (PRP) are systems funded by the FDA for identifying and correcting problems associated with prescription and over-the-counter drugs and medical devices, laboratory products, radiopharmaceutical drugs, and radiological devices. Problem reports are usually submitted by practitioners to the USP via toll-free telephone or reporting forms, and are forwarded to the FDA and other appropriate government and industry agents for corrective action. Addressing product quality, DPPR is one of two FDA voluntary drug problem reporting programs (the other is the Drug Experience Reporting program for adverse drug reactions). PRP is the largest single source of device experience information for the FDA's Device Experience Reporting Network.

UNITED NETWORK FOR ORGAN SHARING

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The United Network for Organ Sharing (UNOS) was incorporated in 1984 as a private non-profit organization, having grown out of the South-Eastern Organ Procurement Foundation. Its purpose is to provide the best possible organs to patients best suited to receive them, to the end that transplants may be successful and quality of life is sustained and improved.

The UNOS computer system has transplant-related data on 10,000 potential recipients, involving approximately 250 transplant centers, organ procurement organizations, and laboratories in the U.S. The system matches data on newly available organs and tissues with potential recipients. UNOS uses its database to study factors affecting recipients after they have received transplants, to evaluate transplant procedures, and to improve the computer system.

Linked to the computer system, the UNOS Organ Center assists procurement teams by providing information concerning potential placement of organs prior to procurement. With ties to transportation services, the Organ Center is the central point for organ distribution outside the U.S., and maintains relationships with transplant programs worldwide.

In 1984, the National Transplant Act mandated the establishment of a national computer transplant system. In 1986, UNOS received the federal contract to establish the national Organ Procurement and Transplantation Network (OPTN). Among its tasks, OPTN is to develop and implement a transplant information systems plan, develop and maintain a potential transplant recipient registration system, match donors and recipients, develop a telephone system, provide a transportation assistance system, develop organ procurement standards, conduct a high percent reactive antibodies patient transplant feasibility study, and improve professional education.

UNOS is developing a population-based Scientific Registry for Organ Transplantation for reporting to the federal government about transplantation and to study risk factors affecting transplantation outcomes. Requests by outside parties for access to the registry data will be considered by the UNOS scientific advisory committee. UNOS publishes the monthly newsletter *UNOS Update*.

UNIVERSITY HOSPITAL CONSORTIUM

One Mid America Plaza, Suite 624
Oakbrook Terrace, IL 60181
312-954-6766
Contact: Robert Baker, President

The University Hospital Consortium (UHC) is a nonprofit organization formed in 1984 to aid university teaching hospitals in their efforts to maintain and strengthen their positions in the marketplace. UHC includes 43 university hospitals in 24 states with a total of 23,000 beds, 775,000 admissions per year, and 25,300 medical school enrollees. UHC seeks to promote group efforts among academic teaching hospitals concerning access to information, alternative delivery systems, capital formation, insurance, research, marketing, and volume-purchasing.

UHC is considering methods through which its member hospitals can participate in alternative delivery systems by monitoring the development of such systems on a nationwide basis and making recommendations to its members. UHC is working to promote enhanced capital formation and improved malpractice insurance for its members. It is committed to sponsoring management research programs, information exchange, and sharing of marketing information. UHC's subsidiary, the University Hospital Consortium Services Corporation, develops agreements with providers to reduce costs to UHC institutions. It sponsors pharmacy, capital equipment, and supplies purchasing programs, and provides a management consulting pool.

UHC is developing a program to assist health product makers and venture capitalists to conduct multi-center technology assessments at its member institutions. Such a program may enhance universities' role in developing and testing technologies, and could provide a means of generating and gathering data for various assessment needs of government and the private sector.

Subject Index to Organizational Resources

Genetic engineering
Association of Biotechnology Companies

Geriatric medicine
American Geriatrics Society

H

Health benefits
Employee Benefit Research Institute
National Association of Manufacturers

Health care data
National Association of Health Data Organizations

Health insurance
Health Insurance Association of America
International Federation of Voluntary Health Service Funds

Health maintenance organizations
American Medical Care and Review Association
Group Health Association of America

Health policy
National Health Council

Health promotion
American College of Preventive Medicine
American Public Health Association

Health services research
Association for Health Services Research

Home care
Oley Foundation for Home Parenteral and Enteral Nutrition

Hospital management
American Healthcare Institute
Federation of American Health Systems
Maryland Hospital Association
University Hospital Consortium

Hospitals—Nonproprietary
American Healthcare Institute

Hospitals—Proprietary
Federation of American Health Systems

Hospitals—University
University Hospital Consortium

I

Immunology
American Society of Transplant Physicians

Immunosuppressants
American Council on Transplantation

Individual practice associations
American Medical Care and Review Association
Group Health Association of America

Information systems
American Association for Medical Systems and Informatics
Society for Medical Decision Making

Internal medicine
American Society of Internal Medicine

L

Laboratories
American Society of Clinical Pathologists
American Society of Internal Medicine

Lithium
American Psychiatric Association

Long term care
American Geriatrics Society

M

Magnetic resonance imaging
American College of Nuclear Physicians
Society of Nuclear Medicine

Medical devices manufacturers
Canadian Association of Manufacturers of Medical Devices
Health Industry Manufacturers Association
National Electrical Manufacturers Association

Medical instrumentation
Association for the Advancement of Medical Instrumentation

Medical specialities
Council of Medical Specialty Societies

Medical systems
American Association for Medical Systems and Informatics

Medicare reimbursement
Physician Payment Review Commission

Mental health
Association for Health Services Research

Mental illnesses
American Psychiatric Association

Multi-hospital systems
American Healthcare Institute

N

Noninvasive vascular technology
Society of Non-Invasive Vascular Technology

Nuclear medicine
American College of Nuclear Physicians
Society of Nuclear Medicine

O

Organ procurement
SEE Tissue procurement

Otolaryngology
American Academy of Otolaryngology—Head and Neck Surgery

P

Parenteral nutrition
American Geriatrics Society
American Society for Parenteral and Enteral Nutrition
Oley Foundation for Home Parenteral and Enteral Nutrition

Patents
Office of Technology Assessment and Forecast

Pathology
American Society of Clinical Pathologists

Peer review organizations
American Medical Care and Review Association
American Medical Peer Review Association
American Medical Review Research Center

Pharmaceutical manufacturers
Generic Pharmaceutical Industry Association
Pharmaceutical Manufacturers Association

Pharmaceutical research
Center for the Study of Drug Development

Pharmaceuticals, Generic
Center for the Study of Drug Development
Generic Pharmaceutical Industry Association

Positron emission tomography
American College of Nuclear Physicians
Society of Nuclear Medicine

Physical medicine
American Academy of Physical Medicine

Postmarketing surveillance
Center for the Study of Drug Development
United States Pharmacopoeial Convention

Preferred provider organizations
American Medical Care and Review Association

Preventive medicine
American College of Preventive Medicine

Psychiatry
American Psychiatric Association

Psychosocial therapy
American Psychiatric Association

Public health
American Public Health Association
Pan American Health Association

Q

Quality assurance programs
American Medical Care and Review Association
American Medical Peer Review Association
American Medical Review Research Center
American Public Health Association
Maryland Hospital Association

R

Radiation therapy devices
National Electrical Manufacturers Association

Radiology
American College of Nuclear Physicians
Society of Nuclear Medicine

Radiopharmaceuticals
American College of Nuclear Physicians
Society of Nuclear Medicine

Rehabilitation
American Academy of Physical Medicine and Rehabilitation
RESNA—Association for the Advancement of Rehabilitation Technology

Rheumatic diseases
- American Rheumatism Association

S

Standards and specifications
- American National Standards Institute
- American Public Health Association
- American Society of Mechanical Engineers
- American Society for Testing and Materials
- Association for the Advancement of Medical Instrumentation
- National Electrical Manufacturers Association
- United States Pharmacopoeial Convention

Strategic planning
- Institute for the Future

Surgery—Head
- American Academy of Otolaryngology—Head and Neck Surgery

Surgery—Neck
- American Academy of Otolaryngology—Head and Neck Surgery

Surgery—Orthopedic
- American Academy of Orthopaedic Surgeons

T

Technology assessment (general)
- Finnish Society of Technology Assessment in Health Care
- International Society of Technology Assessment in Health Care
- National Advisory Council on Health Care Technology Assessment
- Swedish National Center for Technology Assessment in Health Care

Tissue banks
- American Association of Tissue Banks

Tissue procurement
- American Association of Blood Banks
- American Association of Tissue Banks
- American Council on Transplantation
- United Network for Organ Sharing

Transplantation
- American Council on Transplantation
- American Society of Transplant Physicians
- American Society of Transplant Surgeons
- United Network for Organ Sharing

U

Ultrasound
- American Institute of Ultrasound in Medicine

Urology
- American Urological Association
- Renal Physicians Association

Utilization review
American Medical Review Research Center

PART 5 INDEX TO ORGANIZATIONS

PART 5

INDEX TO ORGANIZATIONS

This part includes an alphabetical listing with addresses and telephone numbers for all organizations described in the *Directory*, as well as a page index to the organizations beginning on page 622.

ORGANIZATION ADDRESSES AND TELEPHONE NUMBERS

Alcohol, Drug Abuse, and Mental Health Administration
Parklawn Building, Room 13C-05
5600 Fishers Lane
Rockville, MD 20857
301-443-3820

Alliance for Engineering in Medicine and Biology
1101 Connecticut Avenue NW, Suite 700
Washington, DC 20036
202-857-1199

American Academy of Dermatology
1567 Maple Avenue
PO Box 3116
Evanston, IL 60204-3116
312-869-3954

American Academy of Neurology
Practice Committee
2221 University Avenue SE, Suite 335
Minneapolis, MN 55414
612-623-8115

American Academy of Ophthalmology
Ophthalmic Procedures Assessment Program
PO Box 7424
655 Beach Street
San Francisco, CA 94120-7424
415-561-8500

American Academy of Orthopaedic Surgeons
222 South Prospect Avenue
Park Ridge, IL 60068-4058
312-823-7186

American Academy of Otolaryngology-Head and Neck Surgery
1101 Vermont Avenue NW, Suite 302
Washington, DC 20005-3521
202-289-4607

American Academy of Pediatrics
141 Northwest Point Boulevard
PO Box 927
Elk Grove Village, IL 60009-0927
312-228-5005

American Academy of Physical Medicine and Rehabilitation
122 South Michigan Avenue, Suite 1300
Chicago, IL 60603-6107
312-922-9366

American Association of Blood Banks
1117 North 19th Street, Suite 600
Arlington, VA 22209
703-528-8200

American Association for Medical Systems and Informatics
1101 Connecticut Avenue NW, Suite 700
Washington, DC 20036
202-857-1189

American Association of Tissue Banks
1117 North 19th Street, Suite 402
Arlington, VA 22209
703-528-0663

American College of Cardiology
1111 Old Georgetown Road
Bethesda, MD 20814
301-897-5400

American College of Emergency Physicians
1125 Executive Circle
Irving, TX 75038-2522
214-550-0911

American College of Gastroenterology
13 Elm Street
Manchester, ME 01944
617-927-8330

American College of Nuclear Physicians
1101 Connecticut Avenue NW, Suite 700
Washington, DC 20036
202-857-1135

American College of Obstetricians
and Gynecologists Committee Opinions
600 Maryland Avenue SW
Washington, DC 20024
202-638-5577

American College of Obstetricians
and Gynecologists
Committee on Technical Bulletins
600 Maryland Avenue SW
Washington, DC 20024
202-638-5577

American College of Physicians
Clinical Efficacy Assessment Project
4200 Pine Street
Philadelphia, PA 19104
215-243-1200; 800-523-1546

American College of Preventive Medicine
1015 15th Street NW, Suite 403
Washington, DC 20005
202-789-0003

American College of Radiology
Task Force on Breast Cancer
1891 Preston White Drive
Reston, VA 22091
703-648-8925

American Council on Transplantation
700 North Fairfax Street, Suite 505
Alexandria, VA 22314-2040
703-836-4301

American Dental Association
Council on Dental Materials, Instruments,
and Equipment
211 East Chicago Avenue
Chicago, IL 60611
312-440-2507

American Dental Association
Council on Dental Therapeutics
211 East Chicago Avenue
Chicago, IL 60611
312-440-2523

American Diabetes Association
1660 Duke Street
Alexandria, VA 22314
703-549-1500

American Gastroenterological Association
Patient Care Committee
c/o John Balint, M.D.
Chairman, Department of Medicine
Albany Medical College
47 New Scotland Avenue
Albany, NY 12208
518-445-5376

American Geriatrics Society
770 Lexington Avenue, Suite 400
New York, NY 10021
212-308-1414

American Healthcare Institute
1919 Pennsylvania Avenue NW, Suite 703
Washington, DC 20006
202-293-2840

American Heart Association
National Center
7320 Greenville Avenue
Dallas, TX 75231
214-373-6300

American Hospital Association
Hospital Data Center
Department of Special Studies
840 North Lake Shore Drive
Chicago, IL 60611
312-280-6520

American Hospital Association
Hospital Technology Series Program
Division of Clinical Services and Technology
840 North Lake Shore Drive
Chicago, IL 60611
312-280-6084

American Hospital Association
Office of Legal Communications
840 North Lake Shore Drive
Chicago, IL 60611
312-280-6679

American Hospital Association
Resource Center
840 North Lake Shore Drive
Chicago, IL 60611
312-280-6263

American Institute of Ultrasound In Medicine
4405 East-West Highway, Suite 504
Bethesda, MD 20814
301-656-6117

American Medical Association
Council on Scientific Affairs
535 North Dearborn Street
Chicago, IL 60610
312-645-5335

American Medical Association
Diagnostic and Therapeutic Technology Assessment
535 North Dearborn Street
Chicago, IL 60610
312-645-4530

American Medical Association
Drug Evaluations
535 North Dearborn Street
Chicago, IL 60610
312-645-4560

American Medical Care and Review Association
5410 Grosvenor Lane, Suite 210
Bethesda, MD 20814
301-493-9552

American Medical Peer Review Association
440 First Street NW, Suite 510
Washington, DC 20001
202-628-1853

American Medical Review Research Center
440 First Street NW, Suite 510
Washington, DC 20001
202-639-8614

American National Standards Institute
1430 Broadway
New York, NY 10018
212-354-3300

American Psychiatric Association
1400 K Street, NW
Washington, DC 20005
202-682-6138

American Public Health Association
1015 15th Street, NW
Washington, DC 20005
202-789-5600

American Rheumatism Association
17 Executive Park Drive NE, Suite 480
Atlanta, GA 30329
404-633-3777

American Society for Gastrointestinal Endoscopy
Committee on Technology Assessment
13 Elm Street
Manchester, MA 01944
617-927-8330

American Society of Anesthesiologists
515 Busse Highway
Park Ridge, IL 60068
312-825-5586

American Society of Clinical Pathologists
1101 Vermont Avenue NW, Suite 604
Washington, DC 20005
202-371-0515

American Society of Internal Medicine
1101 Vermont Avenue NW, Suite 500
Washington, DC 20005
202-289-1700

American Society of Mechanical Engineers
345 East 47th Street
New York, NY 10017
212-705-7797

American Society for Parenteral and Enteral Nutrition
8605 Cameron Street, Suite 500
Silver Spring, MD 20910
301-587-6315

American Society for Testing and Materials
1916 Race Street
Philadelphia, PA 19103
215-299-5400

American Society of Transplant Physicians
c/o Lawrence G. Hunsicker, M.D.
President, Director
VA Medical Center, Bldg. 3
Iowa City, IA 52240
319-338-0581

American Society of Transplant Surgeons
c/o Robert J. Corry, M.D.
Professor and Chairman
Office of the Chairman
Department of Surgery
The University of Iowa Hospitals and Clinics
Iowa City, IA 52242
319-356-2545

American Urological Association
1120 North Charles Street
Baltimore, MD 21201
301-727-1100

Association for the Advancement of Medical Instrumentation
1901 North Fort Meyer Drive, Suite 602
Arlington, VA 22209-1699
703-525-4890

Association of Biotechnology Companies
1220 L Street NW, Suite 615
Washington, DC 20005
202-842-2229

Association for Health Services Research
2100 M Street NW, Suite 402
Washington, DC 20037
202-223-2477

Battelle Medical Technology Assessment Program
2030 M Street NW
Washington, DC 20036
202-785-8400

Battelle Memorial Institute
Battelle Human Affairs Research Centers
4000 NE 41st Street
Seattle, WA 98105
206-525-3130

Bioethics Information Retrieval Project
Kennedy Institute of Ethics
Georgetown University
Washington, DC 20057
202-687-3885

Biomedical Business International
17722 Irvine Boulevard
Tustin, CA 92680
714-838-8350

Blue Cross and Blue Shield Association
Medical Necessity Program
676 North St. Clair Street, 11th Floor
Chicago, IL 60611
312-440-5577

Blue Cross and Blue Shield Association
Technology Evaluation and Coverage Program
676 North St. Clair Street, 11th Floor
Chicago, IL 60611
312-440-5577

Boston University Medical Center
400 Totten Pond Road
Waltham, MA 02154
617-890-1300

Brandeis University Health Policy Center
Organ Procurement Project
415 South Street
Waltham, MA 02254
617-736-3900

BRS Information Technologies
1200 Route 7
Latham, NY 12110
800-345-4277

BRS/Saunders
1290 Avenue of the America's
New York, NY 10104
800-468-0908

California Medical Association
Medical Practice Opinion Program
PO Box 7690
San Francisco, CA 94120-7690
415-863-5522

Canadian Association of Manufacturers of Medical Devices
10 Four Seasons Place
Etobicoke (Tor.), Ontario M9B 6H7
Canada
416-620-1915

Center for Health Management Research
1423 South Grand Avenue
Los Angeles, CA 90015
213-742-6335

Center for the Study of Drug Development
Tufts University
136 Harrison Avenue
Boston, MA 02111
617-956-0070

Centers for Disease Control
Center for Environmental Health
Division of Birth Defects and Developmental Disabilities
1600 Clifton Road
Atlanta, GA 30333
404-454-4706

Centers for Disease Control
Center for Environmental Health
Division of Environmental Hazards and Health Effects
1600 Clifton Road
Atlanta, GA 30333
404-454-4772

Centers for Disease Control
Center for Environmental Health
Division of Environmental Health Laboratory Sciences
Chamblee 17/1103
1600 Clifton Road
Atlanta, GA 30333
404-452-4152

Centers for Disease Control
Center for Health Promotion and Education
1600 Clifton Road
Atlanta, GA 30333
404-321-2263

CBO (Centraal Begeleidingsorgaan voor de Intercollegiale Toetsing)
National Organization for Quality Assurance in Hospitals
Consensus Development Program
PO Box 20064, Churchilllaan 11
3502 LB Utrecht, The Netherlands
(31-30) 96-06-47

College of American Pathologists
Surveys Program
5202 Old Orchard Road
Skokie, IL 60077-1034
312-966-5700

Congress of the United States
Office of Technology Assessment Health Program
Washington, DC 20510
202-226-2070

Copenhagen Collaborating Center for the Study of Regional Variations in Health Care
Institute of Social Medicine
University of Copenhagen, Panum Institute
Blegdamsvej 3
2200 Copenhagen N., Denmark
(45-1) 35-79-00 Ext. 3011

Council of Medical Specialty Societies
PO Box 70
Lake Forest, IL 60045
312-295-3456

Commission on Professional and Hospital Activities
1968 Green Road
PO Box 1802
Ann Arbor, MI 48106
800-521-6210, 800-828-6762 in Michigan

Deutsches Institut für Medizinische
Dokumentation und Information
Welbhausstrasse 27
Postfach 42 05 80
D-5000 Cologne 41
Federal Republic of Germany
(49-221) 47-24-1

DIALOG Information Services, Inc.
3460 Hillview Avenue
Palo Alto, CA 94304
800-334-2564, 415-858-3785

Duke Comprehensive Cancer Center
Duke University Medical Center
PO Box 3153
Durham, NC 27710
919-684-2057

Duke University
Center for Health Policy Research and Education
Box GM, Duke Station
Durham, NC 27706
919-684-3023

ECRI Health Devices Program
5200 Butler Pike
Plymouth Meeting, PA 19462
215-825-6000

ECRI Technology Assessment Program
5200 Butler Pike
Plymouth Meeting, PA 19462
215-825-6000

Employee Benefit Research Institute
2121 K Street NW, Suite 860
Washington, DC 20037-2121
202-659-0670

F-D-C Reports, Inc.
5550 Friendship Boulevard, Suite One
Chevy Chase, MD 20815
301-657-9830

Federation of American Health Systems
1111 19th Street NW, Suite 402
Washington, DC 20036
202-833-3090

Finnish Society of Technology Assessment in
Health Care
c/o National Public Health Institute
Department of Epidemiology
Mannerheimintie 166
SF-00280 Helsinki
Finland
(358-0) 75-70-32-9

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-443-5470

Food and Drug Administration
Center for Devices and Radiological Health
12720 Twinbrook Parkway
Rockville, MD 20857
301-443-5807

Food and Drug Administration
Center for Devices and Radiological Health
HFZ-343
Division of Product Surveillance
Office of Compliance
8757 Georgia Avenue
Silver Spring, MD 20910
301-427-8100

Food and Drug Administration
Center for Drugs and Biologics
5600 Fishers Lane
Rockville, MD 20857
301-443-2894

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Color for Drugs and Devices
200 C Street SW, HFF-214
Washington, DC 20204
202-485-0099

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Special Purpose Infant Formulas
200 C Street SW, HFF-204
Washington, DC 20204
202-245-3117

Food and Drug Administration
Press Office
5600 Fishers Lane, HFI-20
Parklawn Building, Room 1505
Rockville, MD 20857
301-443-3285

Friedman, Eisenstein, Raemer, and Schwartz
Certified Public Accountants/Business and Personal Consultants
401 North Michigan Avenue
Chicago, IL 60611
312-644-6000

Generic Pharmaceutical Industry Association
200 Madison Avenue, Suite 2404
New York, NY 10016
212-683-1881

George Washington University Medical Center
Office of Research and Sponsored Programs
2300 Eye Street NW
Washington, DC 20037
202-676-2995

Georgetown University Medical Center
Institute for Health Policy Analysis
2121 Wisconsin Avenue NW, Suite 220
Washington, DC 20007
202-625-2115

Group Health Association of America
1129 20th Street NW, Suite 600
Washington, DC 20036
202-778-3200

Harvard School of Public Health
Institute for Health Research
677 Huntington Avenue
Boston, MA 02115
617-729-5657

Hastings Center
255 Elm Road
Briarcliff Manor, NY 10510
914-762-8500

Health Care Financing Administration
Bureau of Eligibility, Reimbursement, and Coverage
East Building, Room 401
6325 Security Boulevard
Baltimore, MD 21207
301-594-9690

Health Care Financing Administration
Office of Research and Demonstrations
Oak Meadows Building, Room 2-B-12
6325 Security Boulevard
Baltimore, MD 21207
301-597-1435

Health Council of The Netherlands
PO Box 90.517
2509 LM The Hague
The Netherlands
(31-70) 47-14-41

Health Data Institute
(subsidiary of Caremark, Inc.)
20 Maguire Road
Lexington, MA 02173
617-863-2000

Health Industry Manufacturers Association
1030 15th Street NW, Suite 1100
Washington, DC 20005
202-452-8240

Health Information Designs, Inc.
1616 North Fort Meyer Drive, Suite 1420
Arlington, VA 22209
703-528-2032

Health Insurance Association of America
1025 Connecticut Avenue, NW
Washington, DC 20036-3998
202-223-7836

Health and Welfare Canada
Health Services and Promotion Branch
Institutional and Professional Services Division
Guidelines for Institutional Programs
Ottawa, Ontario K1A 1B4
Canada
613-954-8623

HHS Evaluation Documentation Center
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Humphrey Building, Room 438F
200 Independence Avenue SW
Washington, DC 20201
202-245-6445

IMS America Ltd.
660 West Germantown Pike
PO Box 905
Plymouth Meeting, PA 19462-0905
215-834-5000

Institute for Alternative Futures
1405 King Street
Alexandria, VA 22314
703-684-5880

Institute of Electrical and Electronics Engineers
1111 19th Street NW, Suite 608
Washington, DC 20036
202-785-0017

Institute for the Future
2740 Sand Hill Road
Menlo Park, CA 94025-7097
415-854-6322

International Federation for Medical and Biological Engineering
c/o Dr. Jan Persson, Chairman
Joint Working Group
Implications and Assessment of Biomedical Innovations
c/o Dept. of Biomedical Engineering
University Hospital
S-581 85 Linköping, Sweden
(46-13) 19-24-56

International Federation of Voluntary Health Service Funds
15-17 Essex Street
London WC2R 3AD, England
United Kingdom
(44-1) 35-31-15-9

International Resource Development, Inc.
6 Prowitt Street
Norwalk, CT 06855
203-866-7800

International Society of Technology Assessment in Health Care
c/o Els Borst-Eilers, Secretary, and Vice Chairman
Health Council of the Netherlands
PO Box 90517
2509 IM The Hague
The Netherlands
(31-70) 47-14-41

Johns Hopkins Program for Medical Technology and Practice Assessment
Center for Hospital Finance and Management
624 North Broadway, Room 305
Baltimore, MD 21205
301-955-2300

Joint effort of Department of Computer and Information Science and Center for Medical Technology Assessment
Linköping University
S-581 83 Linköping, Sweden
(46-13) 28-19-69

Kings Fund Centre for Service Development
Kings Fund Forum Consensus and Controversies in Medicine
126 Albert Street
London NWI, England
(44-1) 267-6111

Lewin and Associates, Inc.
Strategic Technology Group
1090 Vermont Avenue NW, Suite 700
Washington, DC 20005
202-842-2800

Linköping University
Center for Medical Technology Assessment
S-581 83 Linköping, Sweden
(46-13) 28-10-00, Ext. 2310

Maryland Hospital Association
1301 York Road, Suite 800
Lutherville, MD 21093
301-321-6200

Massachusetts Health Data Consortium, Inc.
400-1 Totten Pond Road
Waltham, MA 02154
617-890-6040

McGill University
Department of Epidemiology and Biostatistics
1020 Pine Avenue West
Montreal, Canada H3A 1A2
514-392-4740

McMaster University
Department of Clinical Epidemiology and Biostatistics
1200 Main Street
Hamilton, Ontario L8N 325
Canada
416-525-9140, Ext. 2425

Mead Data Central
PO Box 933
Dayton, OH 45401
800-227-4908, 513-865-6800

Medical Device Register, Inc.
655 Washington Boulevard
Stamford, CT 06901
800-222-3045, 203-348-6319 in Connecticut

Medical Engineering Department
Akron City Hospital
525 East Market Street
Akron, OH 44309-2090
216-375-3501

Medical Research Council
National Health and Welfare Canada
Jeanne Mance Building, Tunney's Pasture
Ottawa, Ontario K1A OW9
Canada
613-954-1959

Medical Technology and Practice Patterns Institute
National Health Services and Practice Patterns Survey
2233 Wisconsin Avenue NW, Suite 302
Washington, DC 20007
202-333-8841

MEDLINK
PO Box 9080
Waltham, MA 02254-9080
800-342-1338, 617-890-0385 in Massachusetts

National Advisory Council on Health Care Technology Assessment
National Center for Health Services Research and Health Care Technology Assessment
Parklawn Building, Room 18-05
5600 Fishers Lane
Rockville, MD 20857
301-443-5650

National Association of Health Data Organizations
316 Pennsylvania Avenue SE, Suite 202
Washington, DC 20003
202-546-5881

National Association of Manufacturers
1776 F Street NW
Washington, DC 20006
202-637-3000

National Cancer Institute
International Cancer Information Center
Office of International Affairs
Building 82, Room 103
Bethesda, MD 20892
301-496-7403

National Cancer Institute
National Institutes of Health
Surveillance, Epidemiology, and End Results Program
Surveillance and Operations Research Branch
Blair Building, Room 532
Bethesda, MD 20892-4200
301-427-8829

National Center for Health Services Research and Health Care Technology Assessment
Parklawn Building Room 18-05
5600 Fishers Lane
Rockville, MD 20857

National Center for Health Services Research and Health Care Technology Assessment
Division of Extramural Research
5600 Fishers Lane, Room 18A-19
Rockville, MD 20857
301-443-2080

National Center for Health Services Research and Health Care Technology Assessment
Office of Health Technology Assessment
5600 Fishers Lane, Room 18A-27
Rockville, MD 20857
301-443-4990

National Center for Health Statistics
Scientific Information Branch
Division of Data Services
3700 East-West Highway
Hyattsville, MD 20782
301-436-8500

National Electrical Manufacturers Association
2101 L Street NW, Suite 300
Washington, DC 20037
202-457-8432

National Health Council
1700 K Street NW, Suite 1005
Washington, DC 20006
202-785-3913

National Health Research and Development Program
Jeanne Mance Building, Room 513
Tunney's Pasture
Ottawa, Ontario K1A 1B4
Canada
613-954-8543

National Heart, Lung, and Blood Institute
Communications and Public Information Branch
Building 31, Room 4A-21
Bethesda, MD 20892
301-496-5343

National Heart, Lung, and Blood Institute
National Cholesterol Education Program/NHLBI Smoking Education Program Information Center
Office of Prevention, Education, and Control
Building 31, Room 4A-21
Bethesda, MD 20892
301-230-1340

National Heart, Lung, and Blood Institute
National Heart, Blood Vessel, Lung, and Blood Program
Office of Program Planning and Evaluation
National Institutes of Health
Building 31, Room 5A-11
9000 Rockville Pike
Bethesda, MD 20892
301-496-3620

National Heart, Lung, and Blood Institute
Office of Prevention, Education, and Control
120/80 National Institutes of Health
Bethesda, MD 20892
301-496-1809

National Institute of Child Health and Human Development
Office of Planning and Evaluation
Building 31, Room 2A10
9000 Rockville Pike
Bethesda, MD 20892
301-496-1877

National Institutes of Health
Consensus Development Program
Building 1, Room 210
9000 Rockville Pike
Bethesda, MD 20892
301-496-1143

National Institutes of Health
Statistics and Analysis Branch
Division of Research Grants
Bethesda, MD 20892
301-496-7543

National Library of Medicine
Building 38, Room 2S-18
8600 Rockville Pike
Bethesda, MD 20894
301-496-8834

National Library of Medicine
MEDLARS Management Section
Building 38, Room 4N421
8600 Rockville Pike
Bethesda, MD 20894
800-638-8480, 301-496-6193 in Maryland

National Perinatal Epidemiology Unit
Radcliffe Infirmary
Oxford OX2 6HE
England
(44-865) 81-68-76

National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161
703-487-4650

Netherlands Organization for Applied Scientific Research
Medical Technology Unit
PO Box 188
2300 AD Leiden
The Netherlands
(31-71) 21-4441

New York State Center for Assessing Health Services
Health Services Center 4L 215
State University of New York at Stony Brook
Stony Brook, NY 11794
516-444-2101

Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue NW, Room N2439
Washington, DC 20210
202-523-9700

ODPHP National Health Information Center
Office of Disease Prevention and Health Promotion
U.S. Department of Health and Human Services
PO Box 1133
Washington, DC 20013-1133
800-336-4797, 202-429-9091

Oley Foundation for Home Parenteral and Enteral Nutrition
214 Hun Memorial
Albany Medical Center
Albany, NY 12208
518-445-5079

Pan American Health Organization
525 23rd Street NW
Washington, DC 20037
202-861-3219

Patent Depository Library Program Office
Patent and Trademark Office
U.S. Department of Commerce
Washington, DC 20231
703-557-9686

PharmaBooks, Ltd.
1775 Broadway, Suite 511
New York, NY 10019
212-262-8230

Pharmaceutical Manufacturers Association
1100 15th Street NW
Washington, DC 20005
202-835-3420

Pharmaprojects
18/20 Hill Rise
Richmond, Surrey, TW10 6UA
United Kingdom
(44-1) 94-83-26-2

Physician Payment Review Commission
2120 L Street NW, Suite 510
Washington, DC 20037
202-653-7220

Policy Analysis, Inc.
Medical Technology Cost-Effectiveness Program
1577 Beacon Street
Brookline, MA 02146
617-232-4400

Practitioner Reporting System
United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852
301-881-0666

Project HOPE
Center for Health Affairs
2 Wisconsin Circle, Suite 500
Chevy Chase, MD 20815
301-656-7401

Prospective Payment Assessment Commission
300 Seventh Street SW, Suite 301B
Washington, DC 20024
202-453-3986

Randomized Controlled Clinical Trials Report Collection
c/o Thomas C. Chalmers, M.D.
Harvard School of Public Health
677 Huntington Avenue
Kresge 4th Floor
Boston, MA 02115
617-732-1090

Renal Physicians Association
1101 Vermont Avenue NW, Suite 500
Washington, DC 20005-3457
202-898-1562

RESNA-Association for the Advancement of Rehabilitation Technology
1101 Connecticut Avenue NW, Suite 700
Washington, DC 20036
202-857-1199

Scrip
18/20 Hill Rise
Richmond, Surrey TW10 6UA
United Kingdom
(44-1) 94-83-26

Scrip World Pharmaceutical News
1775 Broadway, Suite 511
New York, NY 10019
212-262-8230

Society for Medical Decision Making
One Main Street
PO Box 447
West Lebanon, NH 03784
603-298-9929

Society of Non-Invasive Vascular Technology
1101 Connecticut Avenue NW, Suite 700
Washington, DC 20036
202-857-1149

Society of Nuclear Medicine
136 Madison Avenue
New York, NY 10016-6784
212-889-0717

SoftSearch, Inc.
1560 Broadway, Suite 900
Denver, CO 80202
303-832-7111, 800-426-2873

Steering Committee on Future Health Scenarios
Commission on Future Health Care Technology
Room BCB 203
PO Box 5406
2280 HK Rijwijk
The Netherlands
(31-70) 40-72-05

Swedish National Center for Technology Assessment in Health Care
Drottning Gatan 16
11151 Stockholm
Sweden
(46-8) 24-05-65

Swedish Planning and Rationalization Institute of the Health Services
Library and Research Report Bank
PO Box 27310
S-102
Stockholm, Sweden
(46-8) 63-05-60

Swedish Planning and Rationalization Institute of the Health Services
Technology Assessment and Health Economics
Box 27310
102 54 Stockholm, Sweden
(46-8) 663-05-60

Technology Assessment and Forecast Program
U.S. Patent and Trademark Office
CM2-313
Washington, DC 20231
703-557-0433

Theta Corporation
Theta Building
Middlefield, CT 06455
203-349-1054

United Kingdom Department of Health and Social Security
Supplies Technology Division
Medical Devices Evaluation Programme
14 Russell Square
London WC1B SEP
England
(44-1) 636-6811, Ext. 3248

United Network for Organ Sharing
3001 Hungary Spring Road
PO Box 28010
Richmond, VA 23228
804-289-0600

U.S. Administrators Inc.
Professional Policy Committee
5016 North Parkway Calabasas
Calabasas, CA 91302
800-872-7526, Ext. 173

U.S. Department of Commerce
Industry Publications Division
Office of Industrial Assessment
International Trade Administration
Trade Development
14th Street and Constitution Avenue NW
Washington, DC 20230
202-377-4356

U.S. Department of Commerce
Office of Commercial Information Management
Division of Market Analysis
14th Street and Constitution Avenue NW
Room 2012
Washington, DC 20230
202-377-4203

United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852
301-881-0666

University of California, San Francisco
Institute for Health Policy Studies
1326 Third Avenue
San Francisco, CA 94143
415-476-4921

University Hospital Consortium
One Mid America Plaza, Suite 624
Oakbrook Terrace, IL 60181
312-954-6766

University of Lausanne
Institute of Social and Preventive Medicine
Evaluation of the Efficacy and Safety of Chorionic Villi Sampling
17 r. Bugnon
1005 Lausanne, Switzerland
(41-21) 41-28-66

University of Pennsylvania
Leonard Davis Institute of Health Economics
3641 Locust Walk
Philadelphia, PA 19104
215-898-6011

University of Pittsburgh School of Medicine
Section of Medical Informatics
Department of Medicine
190 Lothrop Street #165A
Pittsburgh, PA 15261
412-648-3190

Veterans Administration
Cooperative Studies Program (151 I)
Veterans Administration Medical Center
150 South Huntington Avenue
Boston, MA 02130
617-739-3479

Veterans Administration
Health Services Research and Development Service (152)
810 Vermont Avenue NW
Washington, DC 20420
In collaboration with:
Special Projects Office
VA Medical Center (152)
Perry Point, MD 21902
301-642-2411

World Health Organization (WHO)
1211 Geneva 27
Switzerland
(41-21) 91-21-11

Index to Organizations

APPENDICES

Appendix A

About the Council on Health Care Technology Rosters of Council and Panels

About the Council on Health Care Technology

The National Academy of Sciences (NAS) is a private, non-profit organization established by federal charter in 1863 to provide advice to the government on matters of science. The Institute of Medicine (IOM) was established under the NAS charter in 1970 to conduct studies of policy issues related to health and medicine, acting both as an advisor to the federal government and on its own initiative. It is the responsibility of the IOM for establishing and operating the Council on Health Care Technology.

The Council on Health Care Technology (CHCT) was established within the IOM in 1986 to promote the development and application of technology assessment in health care and to review health care technologies for their appropriate use. The council was mandated by the U.S. Congress in the Health Promotion and Disease Prevention Amendments of 1984 (P.L. 08-551) and by technical amendments made in 1085 (P.L. 99-117).

The functions of the council are: to serve as a clearinghouse for data and information sources related to health care technologies and technology assessments; to improve the methodologies, techniques, and procedures of technology assessment; to identify needs in assessment of technologies and the criteria for setting priorities among assessment needs; to stimulate, coordinate, and commission the assessment of health care technologies; and to promote related education, training, and technical assistance.

The federal government provided the IOM with initial funding for the council in December 1985. The IOM appointed the council in March 1986, which met for the first time in April 1986. The council consists of 16 people who are experts on the safety, efficacy, effectiveness, appropriateness, and cost of health care technology, and who represent health professionals, hospitals and other health care providers, health care insurers, employers, consumers, and manufacturers of products for health care.

The council established four panels, each of which has as many as 18 members with appropriate ranges of expertise, to help fulfill the council's responsibilities. The Evaluation Panel was established to address the council functions to identify and set priorities among assessment needs and to stimulate, coordinate, and commission assessments. The Information Panel oversees the development and operation of the information clearinghouse for health care technologies and assessments. The Methods Panel was established to improve the methods, techniques, and procedures of technology assessment and to promote education and training in the use of these approaches. The Federal Liaison Panel was established to maintain a strong relationship between the council and federal agencies with assessment programs and interests. Federal Liaison Panel members participate in activities of the council and other panels. Except for the

Federal Liaison Panel, at least two members of the council serve on each of the panels. Council and panel members and their respective organizational affiliations are shown in the appendices.

In addition to the activities of the panels, the council sponsors other matters of interest to the assessment community. The council's forum series consists of two-day symposiums linked by a common concern for major health policy issues that cut across the public and private sectors. They are invitational conferences held two or three times annually, organized to promote interaction among speakers and audience to encourage the exchange of differing views without pressure to resolve differences. Themes for the first two forums in 1987 were *Quality of Care and Technology Assessment* and *Care of the Elderly Patient: Policy Issues and Research Opportunities*. Also in 1987, the IOM cosponsored with the National Academy of Engineering a symposium entitled *New Medical Devices: Factors Influencing Invention, Development, and Use*. It addressed key economic, technical, and political factors expected to influence development and appropriate use of innovative medical devices during the coming decade. Published proceedings of that symposium will be available in early 1988.

The council published its first issues of its *CHCT Newsletter* during 1986, and plans to continue publication quarterly. The newsletter reports current council activities, lists forthcoming conferences and events of interest to the assessment community, and describes recent report releases and other publications, and related developments of interest to the assessment community. Most issues include a profile of an assessment program similar to those in Part 1 of this *Directory* . The first annual report of the council, to cover activities through 1987, will be available in early 1988.

The council is supported by contributions and grants from the private sector and by federal matching grants. Public Law 98-551 set aside up to $500,000 for the first year, $750,000 for the second year, and $750,000 for the third year in federal grants for initial, partial support of the council. These amounts were earmarked for the council in annual appropriations made by Congress for the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), a component of the U.S. Public Health Service. According to the statute, granting of any portion or all of these funds was subject to matching requirements for financial support from the private sector. First year federal grant funds had to be matched by half their amount from other sources, i.e. two federal dollars for every non-federal dollar. Second and third year federal grants for operation of the council were to be matched by twice these amounts from private sector sources, i.e. one federal dollar for every two non-federal dollars. Thus, the activities of the council, including production of this *Directory*, have been supported in part by grant number HS 05526 from the NCHSR.

Private sector contributors to the council include health insurers, medical professions organizations, health product makers, hospitals, health maintenance organizations, business groups, and other organizations served by the council and that participate in its activities. Other non-federal grant support is to include some cost-recovery on council products and services, such as this *Directory*. Also, the National Research Council, a component of the NAS, has provided program initiation support for certain activities. A list of contributors to the council is shown in Appendix B.

In December 1987, the President signed the Public Health Service Amendments of 1987, (P.L. 100-177). These amendments to the Public Health Service Act pertain in part to the Council on Health Care Technology, and extend the authority of the NCHSR, the National Center for Health Statistics, and other Public Health Service programs for fiscal years 1988, 1989, and 1990.

The 1987 amendments affecting the council provide for the Secretary of Health and Human Services to make available up to $750,000 for the support and operation of the council in each of the three fiscal years. Awarding of these federal funds is contingent upon matching support from non-federal sources. The matching requirement for fiscal 1988 and 1989 is one federal dollar for one non-federal dollar; in fiscal 1990, the ratio is one federal dollar for every two non-federal dollars.

In support of the 1987 legislation, the report of the Senate Committee on Labor and Human Resources stated: "The Committee continues to support this program which it believes provides an important forum for joint government and private cooperation to promote the development of methods of health care technology assessment." The House Committee on Energy and Commerce stated: "The Committee wishes to reaffirm its support for the Council and its expectation that the Council will play a vital role in the development of health policy and improvements in the delivery of health care services. Federal health programs, and their beneficiaries, stand to benefit immensely from the activities of the Council, and the Federal government should continue to be an effective participant in the activities and funding of the Council."

Council on Health Care Technology

WILLIAM N. HUBBARD, JR.
former President, The Upjohn Company, Hickory Corners, Michigan *(Chairman)*

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Professor of Radiology, Stanford University School of Medicine, Stanford, California

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Dean, School of Medicine, Case Western Reserve University, Cleveland, Ohio

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Director, American College of Surgeons, Chicago, Illinois

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Director, Health Security Action Council, Washington, D.C.

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President, Pfizer Inc., New York, New York

WALTER B. MAHER
Director, Employee Benefits and Health Services, Chrysler Corporation, Detroit, Michigan

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GAIL L. WARDEN
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Evaluation Panel of the Council on Health Care Technology

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ROGER C. HERDMAN
Assistant Director, Health and Life Sciences Division, Office of Technology Assessment, U.S. Congress, Washington, D.C.

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President, Pfizer Inc., New York, New York

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HAROLD C. SOX
Associate Chief of Staff for Ambulatory Care, Veterans Administration Medical Center, Palo Alto, California

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Director, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland

DONALD A. YOUNG
Executive Director, Prospective Payment Assessment Commission, Washington, D.C.

Information Panel of the Council on Health Care Technology

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President, Meta Medical Inc., Beverly Hills, California

C. THOMAS SMITH
President, Yale-New Haven Hospital, New Haven, Connecticut

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Director, Professional Activities, Office of the Secretary of Defense, Health Affairs, Washington, D.C.

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Senior Research Scientist, Battelle Human Affairs Research Centers, Washington, D.C.

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Assistant Director for Science, Center for Environmental Health, Centers for Disease Control, Atlanta, Georgia

ELEANOR TRAVERS
Chairman, Task Force on Technology Assessment, Veterans Administration, Washington, D.C.

NORMAN W. WEISSMAN
Director, Division of Extramural Research, National Center for Health Services Research and Health Care Technology Assessment, Rockville, Maryland

Federal Liaison Panel of the Council on Health Care Technology

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Assistant Director, Health and Life Sciences Division, Office of Technology Assessment, U.S. Congress, Washington, D.C. *(Chairman)*

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Director, Division of Science and Public Health Policy, Office of Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Washington, D.C.

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JAY MOSKOWITZ
Associate Director for Program Planning and Evaluation, National Institutes of Health, Bethesda, Maryland

GEORGE E.T. STEBBING
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STEPHEN B. THACKER
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DONALD A. YOUNG
Executive Director, Prospective Payment Assessment Commission, Washington, D.C.

Appendix B

Funding Sources for the Council on Health Care Technology

Contributors to the Council on Health Care Technology

The Council on Health Care Technology is supported by contributions and grants from the private sector and by federal matching grants made as described in the preceding discussion about the council. These federal matching grants have been provided by grant number HS 05526 from the National Center for Health Services Research and Health Care Technology Assessment.

Private sector contributors to the council through 1987 include the following.

$10,000 and More

American Academy of Pediatrics
American College of Cardiology
American College of Physicians
American Hospital Association
American Medical Association
Baxter Travenol Foundation
Blue Cross and Blue Shield Association
CIGNA Corporation
Equicor, Inc.
Ford Motor Company Fund
The HCA Foundation
Health Industry Manufacturers Association
Hoffman-La Roche, Inc.
Kaiser Foundation Hospitals
Metropolitan Life Foundation
National Research Council Fund
The Prudential Foundation
Squibb Corporation
The Upjohn Company

$5,000 to $9,999

American Academy of Ophthalmology
General Mills Foundation
John Hancock Mutual Life Insurance Company
Pfizer Inc.
Provident Life and Accident Insurance Company

Under $5,000

Aid Association for Lutherans
American Chambers Life Insurance company
American College of Radiology
American Community Mutual Insurance Company
American General Corporation
American Hardware Mutual Insurance Company
Association Life Insurance Company
Benefit Trust Life Foundation
Boston Mutual Life Insurance Company
Business Men's Assurance Company of America
The Canada Life Assurance Company
Central Life Assurance Company
Central States Health and Life Co. of Omaha

Under $5,000 continued

CNA Insurance Companies
Cologne Life Reinsurance Company
Colonial Life and Accident Insurance Company
The Colonial Penn Life Insurance Company
Continental Casualty Company
Country Life Insurance Company
Educators Mutual Life Insurance Company
Family Health Plan, Inc.
Farm Bureau Insurance
Farm Family Life Insurance Company
Federal Home Companies
Federal Life Insurance Company (Mutual)
Federated Mutual Insurance Company
First Colony Life Insurance Company
General American Life Insurance Company
General Reassurance Corporation
Great American Reserve Insurance Company
Great-West Life Assurance Company
Group Health Association
Group Health Plan of Southeast Michigan
Guarantee Mutual Life Company
Guarantee Trust Life Insurance Company
The Guardian Life Trust
The Hartford Insurance Group
Health Care Plus of America, Inc.
HMO of Western Pennsylvania
IBA Health and Life Assurance Company
J.C. Penney Life Insurance Company
Jefferson Pilot Life Insurance Company
Lamar Life Insurance Company
Liberty Mutual Insurance Company
Life Insurance Company of Georgia
The Life Insurance Company of Virginia
Lincoln National Life Insurance Company
Lutheran Brotherhood
Massachusetts Mutual Life Insurance Company
Ministers Life
Monarch Capital Corporation
Munich American Reassurance Company
Mutual Benefit Life
The Mutual Life Insurance Company of New York
Mutual of Omaha
National Travelers Life Company
Nationwide Life Insurance Company
The New England
New York Life Insurance Company
North American Life and Casualty Company
Northwestern Mutual Life Insurance Company
Northwestern National Life Insurance Company
The Ohio National Life Insurance Company
Pacific Mutual Foundation
Pan-American Life Insurance Company
The Paul Revere Life Insurance Company
Peak Health Plan, Ohio Region
Phoenix Mutual Life Insurance Company
Prime Health
Principal Mutual Life Insurance Company
Protective Life Insurance Company
Reserve Life Insurance Company
Shelter Life Insurance Company
Shenandoah Life Insurance Company
State Farm Mutual Automobile Insurance Company
Teachers Insurance and Annuity Association/College Retirement Equities Fund
Time Insurance Company
Transamerica Occidental Life Insurance Company
The Union Central Life Insurance Company
Washington National Insurance Company
Wausau Insurance Companies
Western Life Insurance Company
Wisconsin National Life Insurance Company
Woodmen Accident and Life Company

Appendix C

Survey of Organizations with an Ongoing Medical Technology Assessment Program

Name of person completing survey _____
Telephone: _____

Survey of Organizations With an Ongoing Medical Technology Assessment Program

The purpose of this survey is to compile a directory of **organizations** with an **ongoing program** of **medical technology assessment**. For purposes of this survey:

an organization may be a professional, trade, or other association, university or other not-for-profit entity, government agency, or for-profit corporation

an ongoing program is a structure or process within the organization, if not the entire organization, that assesses medical technologies and generates assessment reports

a medical technology assessment is any study or inquiry the objective of which is to provide information regarding the effects of a technology designed to maintain or improve health or be used as part of an intervention for such purpose, whether or not the study evaluates the effects

an assessment may be made by any one or a combination of methods, e.g., panel of experts, information synthesis, empirical study

the report of results may be published by the organization/program, in a journal, or other vehicle. However, for the organization/program to be eligible for inclusion in this survey, the report must be available to others outside of the organization.

This survey is **not** for organizations that: may have conducted medical technology assessments but do not have any ongoing program; catalog, index, or evaluate assessments but do not produce them; conduct assessments but do not make results available to anyone outside of the organization. Information on these types of activities may be incorporated into the directory using other collection instruments.

If your organization contains two or more programs that qualify for inclusion, please complete a separate survey form for each one. Additional copies, and information, may be obtained from Pamela Simerly on 202/334-2319.

Please complete and return this survey by _____ using the envelopes provided or mail to **Pamela Simerly, IOM Council on Health Care Technology, 2101 Constitution Avenue, N.W., JH 751, Washington, DC 20418**.

Instructions for Completing the Survey

This survey consists of four parts.

- Part I asks you to describe your organization.
- Part II consists of categorized checklists that ask you to select one or more response categories to describe your program.
- Part III is a series of open-ended questions that ask you to describe your program in a brief narrative format.
- Part IV requests listings of completed, ongoing, and planned assessment reports.

If an item is not applicable, please note "NA" (rather than leaving the answer space blank).

In completing this survey, if more convenient, you may type answers on separate sheets and append them to the survey form. If you do append sheets, be sure that you have keyed them to the question, responded to all survey items, and completed structured items on the survey form.

Please provide a current example of a medical technology assessment report published by your program. **By providing the report you are consenting to its reproduction in**

the directory as a sample assessment, if the IOM chooses to include it. If you produce different types of assessment reports, please append a current example of each type; key the report to the type of assessment.

If your organization has two or more assessment programs, please complete a separate survey form for each one (Parts II, III, and IV).

If your program conducts two or more types of medical technology assessment, please complete a separate survey form for each one (Parts II, III, and IV).

Does your organization have two or more assessment **programs?**

_____ yes (**If yes**, please list the separate programs below, and complete a separate survey form for each one. You may copy survey formats or request additional copies from Pamela Simerly, 202/334-2319.)

_____ no

List of programs (only if your organization has two or more distinct programs that assess medical technology).

1. _____
2. _____
3. _____
4. _____

Does your program conduct two or more **types of assessment** that differ materially with respect to purpose, subject selection, method of assessment, or assessment process or methods? Check **one**:

_____ yes (If yes, please list the separate types of assessment below and complete a separate survey form for each one. You may copy survey formats or request additional copies from Pamela Simerly, 202/334-2319.)

_____ no (A "**no**" response implies that your program and its assessments are uniform with respect to purpose, subject selection, method of assessment, and assessment process, even though some slight variation may occur to suit individual assessments.)

List separate types of assessment (only if your program conducts two or more types).

1. _____
2. _____
3. _____
4. _____

To the extent possible, please provide publication titles and citations in *Index Medicus* style. Examples follow:

Journal

1. Standard Journal Article (List all authors when six or less; when seven or more, list only first three and add et al.)

Sorer NA, Wasserman SI, Austen KF Cold urticaria: release into the circulation of histamine and eosinophil chemotactic factor of anaphylaxis during cold challenge, N Engl J Med 1976;294 687-90.

2. Corporate Author

The Committee on Enzymes of the Scandinavian Society for Clinical Chemistry and Clinical Physiology. Recommended method for the determination of gammaglutamyltransferase in blood. Send J Clin Lab Invest 1976,36:119-25.

Anonymous. Epidemiology for primary health care. Int J Epidemiol 1976;5:224-5.

Books and Other Monographs

3. Personal Author(s)

Osier AG. Complement: mechanisms and functions. Englewood Cliffs: Prentice-Hall, 1976.

4. Corporate Author

American Medical Association Department of Drugs. AMA drug evaluations. 3rd ed. Littleton: Publishing Sciences Group. 1977.

5. Editor, Compiler, Chairman as Author

Rhodes A J, Van Rooyen CD, comps. Textbook of virology for students and practitioners of medicine and other health sciences. 5th ed. Baltimore: Williams & Wilkins, 1968.

6. Chapter in Book

Weinstein L, Swartz MN. Pathogemic properties of invading microorganisms. In: Sodeman WA Jr, Sodeman WA, eds Pathologic physiology: mechanisms of disease Philadelphia: WB Sauders, 1974:457-72.

7. Agency Publication

National Center for Health Statistics. Acute conditions: incidence and associated disability, United States July 1968-June 1969. Rockville, Md.: National Center for Health Statistics, 1972. (Vital and health statistics. Series 10: Data from the National Health Survey. no. 69) (DHEW publication no. (HSM) 72-1036).

Other Articles

8. Newspaper Article

Shaffer RA. Advances in chemistry are starting to unlock mysteries of the brain: discoveries could help cure alcoholism and insomnia, explain mental illness. How the messengers work Wall Street Journal 1977 Aug 12:1 (col. 1), 10 (col. 1).

9. Magazine Article

Roueche B Annals of medicine: the Santa Claus culture. The New Yorker 1971 Sep 4:66-81.

Part I. Description of Parent Organization

Please complete a separate survey form for each program/ type of assessment conducted. For each, please specify the program/type of assessment covered by this survey format.

Program:_____

Type of assessment:_____

A. For the parent organization to the assessment program, please describe the following.

1. **Name, address, telephone**

Name: _____

Address: _____

Telephone: _____

2. **What is the organization's purpose?**

3. **Who are its sponsors, owners, stockholders?**

4. **What products or services does the organization provide?**

B. Which of the following categories best describes your organization? Circle **one** number.

Government agency

1. federal
2. state/local
3. international

Not-for-profit

4. university
5. research institute
6. foundation

Association

7. professional
8. trade/industry
9. labor union

For-profit corporation

10. business

Other, specify: _____

Part II. Type of Assessment Program

Please complete a separate survey form for each program/type of assessment conducted. For each, please specify the program/type of assessment covered by this survey format.

Program:_____

Type of assessment:_____

A. Who are the primary intended users of your assessments? **Check** all that apply.

_____ General public
_____ People concerned about their health
_____ Patients
_____ Providers, generally
_____ Physicians
_____ Acute facility administrators
_____ Long-term care facility administrators
_____ Other care givers
_____ Health product (drugs, devices, equipment) manufacturers
_____ Health/medical professional associations
_____ Health industry associations
_____ Consumer associations
_____ Employers
_____ Unions and other employee organizations
_____ Third party payers
_____ Government regulators
_____ Voluntary associations, organizations
_____ Biomedical researchers
_____ Financial analysts, consultants
_____ Reporters, writers, news media
_____ Information/computer industry
_____ Labs, blood banks, etc.
_____ Public policy-makers, legislators
_____ Policy research organizations
_____ Lawyers
_____ Liability, malpractice insurers
_____ Other, specify:
_____

B. Which of the following technologies does your program assess? **Check** all that apply. **Circle** the **one** assessed most often.

_____ 1. **Drug**: any chemical or biological substance that may be applied to, ingested by, or injected in order to prevent, treat, or diagnose disease or other medical conditions. Included are biologicals such as vaccines and blood products, medicinals and botanicals, and pharmaceutical preparations.

_____ 2. **Device**: any physical item, excluding drugs, used in medical care. Included are diagnostic and therapeutic equipment, prostheses, surgical and medical instruments and supplies, dental equipment and supplies, ophthalmic goods, and *in vitro* diagnostic products-reagents, instruments, and systems used in the collection, preparation, and examination of specimens taken from the human body to determine the state of a patient's health.

_____ 3. **Medical or surgical procedure**: a practice of a health care provider that generally involves a combination, often quite complex, of special skills or abilities with drugs, devices, or both. In some cases, the drugs or devices involved are not predominant factors in a procedure. Instead, the technique of the provider performing the procedure is most important, such as in the performance of a surgical procedure facilitated by the use of scalpels, clamps, and drugs against infection. Psychotherapy or prescription of a special diet are examples of procedures which may not involve drugs or devices.

_____ 4. **Support system**: a system that provides the environment for and otherwise facilitates the provision of health care, but is not the focal technology in a medical regimen, surgical procedure, or other form of health care. Examples are laboratory and radiology services, medical information systems, blood banking services, hospital infection control programs, food services, laundry, hospital facilities, and physical plant. Many of these are often referred to as ancillary services.

_____ 5. **Organizational or administrative system**: used in management and administration to ensure that health care is delivered effectively. Included are alternative delivery modes or settings (e.g., health maintenance organizations (HMOs), area-wide emergency care systems, and home health delivery), and payment systems (e.g., prospective payment using diagnosis-related groups).

_____ 6. **Other,** specify:
_____

C. Which of the following phases of technological intervention does your program normally assess? **Check** all that apply. **Circle** the **one** assessed most often.

_____ 1. **Prevention**: designed to prevent a disease from occurring, reduce the risk of its occurrence, or promote health and welfare.
_____ 2. **Diagnosis**: designed to identify an individual at high-risk (of a disease) or who has the disease (whether or not clinical signs and symptoms are present).
_____ 3. **Treatment**: designed to restore, maintain or improve health status, encompassing cure (of an acute disease), care (of a chronic disease), or avoidance of further deterioration (of a degenerative process).
_____ 4. **Rehabilitation**: designed to restore, maintain, or improve a person's ability to function without necessarily affecting health status.
_____ 5. **Other**, specify:
_____

D. At what stages in the life-cycle of technologies do you carry out your assessments? **Check** all that apply. **Circle** the **one** assessed most often.

_____ 1. **Emerging**: in the applied research or development stage, at about the time of initial clinical testing; once the prototype has been built (device) or described (procedure) but prior to the point were the technology can be readily used by practitioners other than its developers.
_____ 2. **New**: initial use of the defined by practitioners other than its developers but not in widespread use; the beginnings of diffusion.
_____ 3. **Established or widespread practice**: when practitioners generally consider the technology to be accepted or standard practice.
_____ 4. **Obsolete**: when one or more other technologies (or using no technology) have superseded the technology as established practice, but it continues to be used by some practitioners.
_____ 5. **Other**, specify:
_____

E. What properties (or attributes) of a technology do you assess? **Check** all that apply. **Circle** the **one** usually emphasized.

_____ 1. **Safety**: a judgment of the acceptability of risk in a specified situation, e.g., for a given medical problem, by a provider with specified training, at a specified type of facility.
_____ 2. **Efficacy**: health benefit for a specified population with a given medical problem under ideal conditions of use (i.e., a special case of effectiveness).
_____ 3. **Effectiveness**: the health benefit for a specified population with a given medical problem under average conditions of use.
_____ 4. **Cost**: of using the technology for an individual application (e.g., direct and indirect/overhead costs) including charges or prices.
_____ 5. **Cost-benefit**: the costs of a technological application compared to the resultant benefits, with both costs and benefits expressed in the same (usually monetary) units.
_____ 6. **Cost-effectiveness**: the costs of a technological application compared to the resultant benefits, with cost and benefits/effectiveness not expressed by the same unit. Costs are usually expressed in monetary units, but benefits/effectiveness are ordinarily expressed in such terms as lives saved, disability avoided, quality-adjusted life years or other similar measures.
_____ 7. **Service requirements**: for using the technology in practice, such as its placement and distribution within a health care system, organizational arrangements within a facility, need for technologists or staff training.
_____ 8. **Acceptance/adoption level**: actual/projected level of a technology's acceptability among providers, extent of diffusion/use, stage in lifecycle, etc.
_____ 9. **System impact**: beyond clinical effectiveness, the actual/projected impact on medical practice patterns, health care delivery organization/systems.
_____ 10. **Economic implications**: the cost of the technology in the aggregate, and its impact on factor prices, medical costs, alternative uses of national or industrial resources, etc.
_____ 11. **Ethical, legal, social implications**: of using the technology, including, e.g., its impact on moral values, challenges to legal principals, and effects on society.

_____ 12. **Other**, specify: _____

F. Which of the following broad categories of assessment methods do you employ to conduct an assessment? **Check** all that apply. **Circle** the **one** relied on primarily.

_____ 1. **Information syntheses**: summarizing, integrating, and interpreting findings reported in the literature. May include unstructured literature reviews as well as various systematic and quantitative procedures such as meta-analysis.

_____ 2. **Expert opinion**: consultation with individual experts who may be involved in drafting, editing, reviewing assessments but who do not interact as a group.

_____ 3. **Group judgment**: a process in which a group of experts interact in assessing a technology and formulate findings by vote or other process of reaching general agreement. It is necessary that group members have the opportunity to interact in formulating and reviewing each other's and the group's observations and findings.

_____ 4. Modeling: use of simulations or models to test or evaluate proposed interventions, often undertaken when evaluation of the actual intervention would be impractical.

_____ 5. Cost analyses: analyses, including cost-benefit and cost-effectiveness analyses, that identify, measure, and compare both the benefits and costs of medical technologies. Analyses may vary in terms of perspective (i.e., the parties to whom the benefits and costs accrue) and the choice and valuation of the benefits and costs considered.

_____ 6. **Epidemiological and other observational methods** : excludes the more rigorous experimental design studies such as randomized clinical trials. Included are such studies known as quasi-experiments, including those with historical cohorts, series, case studies, cohort studies, natural experiments, descriptive surveys and certain cross-sectional, case control, and longitudinal methods.

_____ 7. **Clinical trials**: prospective clinical experiments designed to test the safety and efficacy of a technology in which people are assigned to experimental or control groups and outcomes are compared. Includes randomized controlled clinical trials, in which people are randomly assigned to experimental and control groups.

_____ 8. **Bench testing** in the laboratory; non-clinical, *in vitro* testing, experiments, or related observations.

G. Which of the following items/topics are included/ addressed in most or all of your assessment reports? **Check** all that apply.

_____ 1. Abstract
_____ 2. The assessment's intended audience
_____ 3. The purpose of the assessment (i.e., why it was conducted)
_____ 4. Relationship of this assessment to prior or concurrent assessments of the technology or other technologies intended for similar purposes
_____ 5. Who sponsored/commissioned/supported the assessment
_____ 6. Who conducted the assessment (including, e.g., identity of subcontractors or support agencies, assessors' types of expertise)
_____ 7. Description of the technology (including, e.g., intended purpose, target patients/populations, indications/ contraindications, competing technologies for the same type intervention)
_____ 8. Stage of life-cycle of technology when assessed
_____ 9. Properties assessed (e.g., safety, effectiveness, efficacy, service arrangements, economic, ethical, legal, social implications)
_____ 10. Procedure used for the assessment
_____ 11. Sources of data/information (e.g., patient groups studied, types of experts surveyed)
_____ 12. Methods for collecting data/information
_____ 13. Methods for analyzing/synthesizing data/information
_____ 14. Results (quantitative and/or qualitative)
_____ 15. Findings or conclusions
_____ 16. Limitations of findings
_____ 17. Implications of findings for practice
_____ 18. Recommendations for practice, future assessments, technology development, research

_____ 19. How much the assessment cost
_____ 20. How the technology works, including theory, principles
_____ 21. Development of the technology (including, e.g., its development, evolution, prospects for further development)
_____ 22. Procurement/deployment information (e.g., manufacturer name, how to order, cost, availability, delivery, installation, staffing/training requirements, quality control procedures, maintenance)
_____ 23. Where technology is in use
_____ 24. Regulatory agency approval status (e.g., status of premarketing approval or 510(k) application, supplemental approvals, regulatory agency product identification/docket numbers, certificate-of-need status)
_____ 25. Coverage/reimbursement status of the technology (e.g., which payers cover the technology and how much is paid for it, diagnosis-related group status)
_____ 26. Product recall history, liability actions
_____ 27. Other, specify: _____

H. How do you disseminate technology assessment results? Check **all** that apply. **Circle** the **one** relied on primarily.
_____ 1. Printed reports (excluding journal articles)
_____ 2. Journal articles
_____ 3. Advisories to members/constituents
_____ 4. Press conferences/news releases, TV/radio broadcasts, video products
_____ 5. Clearinghouses; data/citation bases; on-line services; specify which: _____
_____ 6. Other, specify: _____

I. What is your assessment program's approximate annual budget (excluding value of in-kind services)? What percentage of the budget is met by each of the following sources?
Approximate annual budget: U.S. $ _____

Sources (total = equal 100%; figures may be approximate)	**Percent**
Parent organization (for programs that are part of government agencies, this line would likely be 100%)	_____ %
Government grants/contracts	_____ %
Foundations, other private grants	_____ %
Sponsors/members dues, contributions	_____ %
Sales of assessments, consultant services, etc.	_____ %
Other (specify source, percentage)	
	_____ %
	_____ %
Total	100%

Part III. Description of Assessment Program

Please complete a separate survey form for each program/type of assessment conducted. For each, please specify the program/type of assessment covered by this survey format.

Program:_____

Type of assessment:_____

This section of the survey is for **brief narrative** descriptions of selected aspects of your assessment program. These descriptions will enable a better understanding of your program than can be conveyed alone by the categorical checklists in the previous section. Many of the selected aspects below are accompanied by questions and other items that may be used as guides to your descriptions. Some of these may not be applicable to your program; if so, simply indicate "NA."

The descriptions for this section need not be detailed. It descriptions of selected aspects of your assessment program. These descriptions will enable a better understanding of your program than can be conveyed alone by the categorical checklists in the previous section. Many of the selected aspects below are accompanied by questions and other items that may be used as guides to your descriptions. Some of these may not be applicable to your program; if so, simply indicate "NA."

The descriptions for this section need not be detailed. It is sufficient to complete the items in the space provided. You may use more words if appropriate, but please try not to exceed 250 words per item. Should you require extra space for your answers or the requested citations, please append extra sheets, keying your answers to the item in the survey.

A. Identification and access

Program name:

_____

Type of assessment:

_____

Director:

_____

Contact person and title:

_____

_____

Address:

_____

Telephone:_____

Telex:_____

Telefax:_____

Other access information (e.g., alternative contact persons, publications office, special inquiries)

_____

B. Program origin/chronology

C. What is the purpose of the assessment program?

D. What types of technologies are assessed?

E. During what stages of their life-cycles are technologies assessed?

F. What properties or attributes of technologies are assessed?

G. Selection process for assessment topic

1. Who can request that an assessment be conducted?

2. How are requests for assessment made?

3. How and by whom are assessment topic priorities set?

4. What, if any, provisions are made for reassessing technologies?

H. Assessment process

1. What methods are used to conduct assessments?

2. How is the assessment process conducted?

3. What are areas of expertise of the assessors?

4. What is the approximate (e.g., average or range of) turnaround time from selection of assessment topic to reporting of findings?

5. What is the approximate cost per assessment?

I. Assessment products and dissemination

1. What are the types of assessment products?

2. How are assessment results disseminated?

3. How does one acquire copies of your assessments?

J. Use of assessments

1. How does the parent organization use the program's assessment reports?
2. Who else uses the reports and for what purposes? How do you know?
3. Please describe briefly any documented instances of use of your assessment reports and their impact, citing any pertinent published documents.
4. Please list any citations in the published literature (journal articles and other publicly available documents) to the program.

5. Please list any citations in the published literature to individual assessment reports from your program.

K. Assessment program evaluations. Please briefly describe below any evaluations that have been made of your assessment program. If more than one evaluation has been conducted, please provide information separately for each one.

1. What was the purpose of the evaluation? Who requested that it be conducted? Who funded it?

2. How was it conducted?

3. Who conducted it?

4. During what period (starting and ending dates) was it conducted?

5. What were the findings?

6. How were the findings used to modify the assessment program?

7. Please list citations to published documents about the evaluation or its findings.

L. Related Activities. If appropriate, please describe (in 250 words or less) activities other than, but related to, technology assessment with which your program is involved. These activities could include conferences, symposia, newsletters, special panels or committees, etc.

Part IV. Listing of Assessment Reports

Please complete a separate survey form for each program/type of assessment conducted. For each, please specify the program/type of assessment covered by this survey format.

Program:_____

Type of assessment: format._____

This section asks you to append lists of citations for the assessment reports that your program has completed, has in progress, and is planning; and to note the primary assessment method(s) used for each. When appending these lists, please key them to the appropriate section.

To indicate the primary assessment method used to produce each report, please complete the following steps.

1. **Check below the method you usually rely on for conducting assessments** . you generally use two or more methods for conducting each assessment, you may check the corresponding methods listed (although we would prefer you check only one—the method primarily relied upon for producing the assessment). **Definitions of methods may be found in Part II of the survey (Question F).**
2. **For assessment reports produced using a method other than that indicated in step I above**, as your usual method for assessing a technology, indicate the method used in the particular case by writing (in parenthesis following the report title) the letter (from the following list) corresponding to the assessment method actually used. Thus, you have only to indicate exceptions to your usual method for conducting assessments.

If you have never deviated from your usual method for conducting an assessment, which you described in step 1 above, then you would have nothing to add after any of your assessment report titles.

General category of assessment method	
_____A.	Information syntheses
_____B.	Expert opinion
_____C.	Group judgment
_____D.	Modeling
_____E.	Cost analyses
_____F.	Epidemiological and other observation methods
_____G.	Clinical trials
_____H.	Bench testing

A. **Completed reports. Please append a list of all medical technology assessment reports that your program has published from its inception to the present**.

If your reports are only published elsewhere, e.g., in a journal, please provide the citation. If you publish the report **and** permit collateral journal publication, listing your publication is sufficient, although you may list both together if you choose.

If you already have a list of publications or journal citations, please check that it is current, and that it specifies clearly the technologies assessed.

To the extent possible, provide publication titles and citations in *Index Medicus* style. (See page 2 of the instructions for examples.) Please provide at minimum the report title, date of publication, other citation information such as volume, number, and publisher where appropriate; and primary assessment method(s) as described above.

We would appreciate receiving an **abstract** of each assessment, **if available**. We are not asking that you create abstracts if none are available presently, unless you want to do so.

B. List of ongoing assessments. Please append a list of all medical technology assessments that your program is conducting presently or are in the process of being published and their expected publication dates.

To the extent possible, provide (anticipated) publication titles and citations in *Index Medicus* style. Please provide where possible the (anticipated) report title, date of publication, other citation information such as volume, number, and publisher where appropriate; and primary assessment method(s) as described above.

If you already have a list of anticipated reports, please check that it is current, and that it specifies clearly the technologies being assessed.

C. List of planned assessments. Please append a list of any medical technology assessments that your program is planning to conduct within the next three years. A planned study is one that is not being conducted presently, but that you have identified as needed and have or will set aside resources to conduct it, whether or not a starting date has been set.

To the extent possible, provide (planned) publication titles and citations in *Index Medicus* style. Please provide where possible the (planned) report title, date of publication, other citation information such as volume, number, and publisher where appropriate; and primary assessment method(s) as described above.

If you already have a list of planned reports, please check that it is current, and that it specifies clearly the technologies to be assessed.

Other information, comments. Please provide below any other information you think is relevant to the purpose of this survey or any comments you may have about the survey. Thank you very much for completing it.