Research and Service Programs in the PHS: Challenges in Organization

Committee on Co-Administration of Service and Research Programs of the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and Related Agencies; Institute of Medicine

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INSTITUTE OF MEDICINE

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatlichemuseen in Berlin.

Committee On Co-Administration of Service and Research Programs of the National of Health, the Alcohol Drug Abuse, and Mental Health Administration, and Related Agencies

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Preface

Over the past 25 years, questions have often been raised about the role of the Public Health Service (PHS) in funding, planning, and administering research and services development and demonstration programs, and about how the PHS is organized to carry out its research and services development functions. This study was motivated by a number of specific concerns raised in the past 5 years by constituency groups; by members of Congress; by the leadership of the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); by grantees of the two agencies; and by analysts of federal research and development activities. For example:

- Constituency groups (grantees, advocacy groups, professional associations, etc.) have raised questions about priorities and levels of funding for either research or service activities, and about how research and service development and demonstration programs fare under a single administration such as ADAMHA.
- The leadership of NIH and ADAMHA and professional groups have questioned whether a single director or administrator can effectively manage an agency responsible for both research and service activities.
- Members of Congress have expressed concern about reductions in the services components of ADAMHA (reductions that seem to reflect a change in ADAMHA's congressionally authorized mission) and about the need for increased attention by NIH to the transfer of the results of basic research into clinical practice.

The Committee on Co-Administration of Service and Research Programs was asked to evaluate and discuss the advantages and

disadvantages of administering service programs in conjunction with administering research and research-related activities in the PHS. The committee consisted of 14 individuals appointed by the president of the Institute of Medicine (IOM) with the concurrence of the president of the National Academy of Sciences. The committee met five times in the course of 15 months to develop a study plan, analyze the issues, and make recommendations. The project officer for the study from the Office of the Assistant Secretary for Health and the liaison committee of officials from NIH, ADAMHA, the Health Resources and Services Administration, the Centers for Disease Control, and the Office of the Assistant Secretary for Planning and Evaluation helped the committee gain access to the information necessary for the study.

This study, like previous studies of the organization and management of research and service programs in the PHS, attempted to respond to specific questions that involved issues of structure, leadership, and politics. The committee consulted the organizational and public administration literatures, as well as the literature on management of research and development programs, in establishing a framework for the study. This report is an attempt to pull together various ideas current in PHS agencies and to explore the apparent relationships (or lack thereof) between research and service programs in specific cases examined for this study.

In order to develop a study methodology and gather information, the committee established seven task forces. A member of the full committee either chaired or was a member of each task force. The task forces included, in total, 23 additional people (Appendix C); their reports have strongly influenced the deliberations of the full committee as well as many elements of this report.

The committee and task forces relied on a series of activities to gather information. Case studies and background papers were either commissioned or written by staff. The committee also reviewed many previous studies of ADAMHA, NIH, and other federal agencies, as well as numerous policy papers on organization and public management issues. In addition, after developing a classification scheme, research grants and services development and demonstration programs and projects were classified (within case study areas) for selected years between 1975 and 1989 to assess changes over time in the research and services portfolios of agencies and institutes.

During the course of the study, more than 150 interviews were conducted by staff and consultants. Interviews conducted with current federal officials included agency directors, policy analysts, directors of budget and planning offices, administrators of research and service development and demonstration programs, and scientists. In addition,

the directors, presidents, and staff of more than 25 constituency groups were interviewed. The interviews for the case studies and commissioned papers revealed a number of concerns about basic and clinical research training programs, health care financing and reimbursement policies, the long-term impact of dissemination of research findings on changing clinical practice patterns, and the size of allocations to both research and services programs in the PHS. These concerns deserve the full attention of the PHS but are beyond the committee's charge and thus are not dealt with in detail in this report.

Although the committee and task forces tried to be as thorough as possible in gathering objective information, much remains a matter of judgment. In the end, the findings and recommendations of this report are the product of a synthesis of objective analyses conducted by staff and consultants, the informed opinion of a wide range of respondents, committee members' extensive experience, and committee discussions.

Notwithstanding the many challenges presented by this study, committee discussions were at the same time both enthusiastic and deliberate. The resulting recommendations address a number of important issues. Throughout the course of this study, the committee benefited from the efforts of the task force participants, all of whom made significant contributions to the study. Important and necessary background materials were provided by John Burckhardt, the study's project officer, and by the members of the liaison committee. Data on grants, without which the study could not have proceeded, were provided by staff in the Division of Research Grants at NIH. The committee is grateful for the valuable contributions and insights of case study writers Kathleen Stratton, Lorraine Klerman, and Carol Blixen; the indispensable work of the writers of commissioned papers, Ruth Hanft, Beryl Radin, Jeffrey Fox, Phyllis Kaye, Sarah Williams, and Richard Schmidt; and the significant contributions of consultant Bob Walkington.

The committee could not have met its charge without the expertise and dedication of staff of the Institute of Medicine. The committee wishes to thank the director of the Division of Health Sciences Policy, Ruth Bulger, for her interest and useful suggestions throughout the study. The committee is especially indebted to study director Mady Chalk and her astute management of the entire effort. Her broad knowledge of issues and people, coupled with good judgment, fairness, enthusiasm, and patience moved the study forward efficiently. Kathleen Stratton, the associate study director and a case study writer, with her clarity of thinking, commitment, and good

humor, made invaluable contributions to the study. Catharine Chetney, research assistant, expressed interest in specific parts of the study that led to her assuming responsibility for one portion of it. Her willingness to help with the many tasks requested of her was especially helpful. All staff worked long and hard within extraordinary time constraints, given the scope of the study, to accomplish the committee's task. Beverly Proctor, Louise Gillis, and division secretary Rita Gibson made the meetings for the study in Washington and California comfortable for members and guests of the committee, as well as providing excellent secretarial support.

STEVEN BEERING, *CHAIR*

COMMITTEE ON CO-ADMINISTRATION OF SERVICE AND RESEARCH PROGRAMS OF THE NATIONAL INSTITUTIONS OF HEALTH, THE ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION, AND RELATED AGENCIES

Contents

Brief Summary of Recommendations

ACTIONS FOR CONGRESS:

- If reorganization of current agency structure is considered, it should be justified purely on policy grounds.
- When Congress initiates or authorizes new research or service program, it should consult with the Secretary of Health and Human Services to determine the appropriate locus of program administration within the Department. Priority should be given to providing sufficient staff and financial resources to carry out a new function.

ACTIONS FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES:

- The Secretary should further clarify the service mission of the PHS. Service programs should be given stability of organizational location, financing, personnel, and other resources.
- Below the agency level, research and service programs should be administered and conducted by separate institutes or offices.

ACTIONS FOR THE ASSISTANT SECRETARY FOR HEALTH:

- The Assistant Secretary for Health should assess and enhance the integration of program objectives related to the service mission across agencies in the PHS.
- All agencies within the PHS and each research institute should be mandated to develop five-year plans, the process for which shall be reviewed by the Assistant Secretary for Health.
- An interagency task force should be formed to develop a standard nomenclature for classifying basic and clinical research, demonstrations, dissemination, and service development activities across the PHS.

PROGRAMMATIC RECOMMENDATIONS:

- Validation through replication should be ensured in new and ongoing research demonstrations following single-site demonstrations and prior to national dissemination.
- A research program should be initiated to determine effective dissemination mechanisms for demonstrations and the results of health services research.
- A plan for incentives for translation of successful demonstration findings into the structure and delivery of services should be accompanied by opportunities for state review and comment on all types of federal demonstration applications.
- Potential sources of postdemonstration funding for successful demonstrations (i.e., federal, state. local, and private sources) also should be explored prior to initiating a demonstration project.
- Responsibility for technical assistance and clinical training programs for professionals and nonprofessionals should be a part of the explicit mission of agencies that fund and adininister operating programs.

Executive Summary

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) was created in 1973 as the result of many factors, including the notion of an inherent relatedness among the problems of alcoholism, drug abuse, and mental illness (the ADM disorders), and the presumption that research into mental illness would provide insights into the etiology of alcoholism and drug abuse. ADAMHA's status as a categorical agency also reflects the presumption that community-based treatment services could best be provided through affiliation and coordination among federal activities related to ADM disorders. Since the agency's inception, the expectations for it have included sharper research focus on the interrelated ADM disorders, rapid translation of research into service delivery, and increased efficiency and effectiveness of treatment and prevention services through program integration. Over the past 25 years, a number of attempts have been made to reform the organizational structure of the Public Health Service (PHS). The expressed goals of reorganizations include increasing efficiency and economy, promoting more effective planning and coordination, and reducing fragmentation or overlap. The reorganizations have also had political goals.

A number of underlying questions were raised during the last major reorganization of the PHS in 1973 and again in 1988, when a study was conducted to develop organizational options for ADAMHA:

- How, if at all, does organizational structure influence research, prevention, and services development or demonstration programs within the PHS?
- Does the administration of these different types of programs in a single agency (i.e., ADAMHA) produce results that are different from those obtained in organizational structures in which these

programs are separately administered, such as in the National Institutes of Health (NIH), the Centers for Disease Control (CDC) and the Health Resources and Services Administration (HRSA)?

- Are research results more easily transferred and applied to the structure and delivery of health care in an agency such as ADAMHA, which has statutory responsibility for research, prevention, and services development and demonstration programs?
- Under what organizational structure can the research and service missions of the PHS best be carried out?

This study responds to a congressional requirement in the Anti-Drug Abuse Act of 1988 (P.L. 100–690) that the Secretary of Health and Human Services request the National Academy of Sciences to conduct a review of the research activities of NIH, ADAMHA, and related agencies. Specifically, the committee was asked for:

- an evaluation of the appropriateness of administering health service programs in conjunction with the administration of biomedical and behavioral research; and
- a determination of the extent of duplication among selected research programs of NIH and ADAMHA.

To answer these questions, the committee was asked to develop and establish criteria and/or measures for determining the following:

- the effects of administering service programs in conjunction with research and research-related activities;
- the extent and effects of duplication, replication, and complementarity between the research activities of NIH and ADAMHA;
- the administrative, program, and policy relationships among service programs and research activities of ADAMHA and its institutes, and the extent to which patterns of communication and leadership activities are attributable to co-administration or to other factors; and
- the "appropriateness" of these effects, given both the statutory mission of the programs and the changing requirements of public policy, scientific opportunity, and economic conditions.

The questions posed by Congress do not lend themselves to a completely objective approach; by nature they include subjective evaluations. Consequently, data and information gathered for this study were supplemented by the expertise of diverse committee and task force members. Analyses conducted for this study include three

case studies of PHS research and service programs for categorical diseases (Alzheimer's disease, substance-abusing pregnant women, and dopamine research related to schizophrenia and Parkinson's disease). In addition, the committee commissioned or staff prepared ten background papers on PHS agency and institute activities that were thought to be most sensitive to organizational structure. In the course of the study, seven task forces met, well over 150 interviews were conducted, and five full committee meetings were held. The committee's recommendations fall into several categories:

- organizational goals and missions of PHS agencies;
- management of research and services programs including effectiveness of planning and priority-setting processes, demonstration programs, and information dissemination efforts;
- organizational capacity and program placement and replication and duplication of research projects and programs.

ORGANIZATIONAL GOALS AND MISSIONS

Lack of clarity about the services mission of the PHS seems to be a more important factor than organizational structure in problems relating to the administration of services development and demonstration (treatment or prevention) programs. **To facilitate accountability within the PHS regarding the objectives of services development and demonstration programs, the committee recommends that the Secretary further clarify the services mission of the PHS and of the agencies that administer programs related to development of the structure and delivery of services. Services program should be given stability, including stability of organizational location, financing, personnel, and other resources**. When responsibility for research and services development and demonstration programs for a single problem is divided among several agencies, however, the difficulties of communicating and collaborating across agency boundaries can inhibit success. **The committee recommends that the Assistant Secretary for Health take responsibility for assessing and enhancing the integration of program objectives related to the services mission across agencies in the PHS**.

It is the impression of many science administrators in federal agencies, as well as other scientists interviewed for this study, that in the past five or ten years the research programs of ADAMHA institutes have benefited from an increasingly singular research focus.

In case studies and interviews conducted for other background papers, the suggestion was made (almost uniformly by science administrators) that—at the level of institutes, bureaus, and offices—co-administration of research and service programs can retard the productivity of both programs through dilution of time, energy, and financial resources and increased difficulty in leadership recruitment.

Given the complexity of administering federal research and service programs, functional organization (i.e., the administration of research, services development, and prevention programs by three separate agencies, namely NIH, HRSA, and CDC) can be helpful in allowing for the development of specialized skills that lead to improved performance. Analyses conducted for this study and previous studies suggest that, while the administrative and political dictates of research and service programs differ (and, therefore, specialization may be useful), these differences often result in conflicting if not mutually exclusive priorities. These analyses point out the need to pay attention to jurisdictional disputes and overlapping responsibilities and, to avoid fragmentation in the implementation of policies and programs, the need for a focused effort to increase collaboration across research and service programs in the PHS.

The committee recommends that below the agency level, research and services programs be administered and conducted by separate institutes or offices that have substantial expertise in the specific substantive and functional area. In cases where ADAMHA institutes currently have responsibility for treatment services demonstrations, service development, or block grant compliance programs, for example, such programs might be placed more appropriately in an organizational unit that currently has responsibility for similar programs, along with staff of sufficient expertise in the substantive area to manage the programs effectively.

Analyses conducted for this study suggest that at the agency level, there are few significant differences in the functioning of similar kinds of research programs in NIH and ADAMHA that can be attributed to organizational structure. Research conducted through institute programs in ADAMHA appears to function in a fashion comparable to research programs administered in NIH. Research allocations are a more complicated question. On the one hand, NIH and ADAMHA have increased funding for biomedical research by similar amounts over the past 10 years; this does not support the perception that research has suffered within a categorical agency (responsible for both research and service programs) in comparison with a functional agency such as NIH. In fact, in the last 5 years it

appears that funding for research has fared somewhat better in ADAMHA than in NIH. On the other hand, over a longer period of time, perhaps 20 years, the data also suggest that research allocations to ADAMHA and its predecessors suffered during the 1970s and only began to recover following passage of the block grant legislation and internal reorganization of ADAMHA. A number of science administrators and science policy constituency groups interviewed for this study suggested that research allocations to ADAMHA in the 1970s may have been hurt by negative perceptions of early social research and that recent research allocations may have been helped by perceptions of drug abuse and AIDS as major social problems as well as by exciting research findings. The longer one's view, the more susceptible the data are to contradictory interpretation. **The committee encountered no persuasive evidence that overwhelmingly supports any specific agency structure, and it therefore recommends that agency-level organization not be used as the basis for deterring or encouraging reorganization. If reorganization of current agency structure is considered, it should be justified purely on policy grounds.**

PLANNING AND PRIORITY SETTING

An important question for this study was whether specific mechanisms existed for relating the program objectives of research, prevention, and services development and demonstration programs both within ADAMHA and among the relevant agencies of the PHS. There is no single, coherent system that can be labeled priority setting; rather, priorities are determined as a result of myriad discrete activities involving Congress, the administration, the research and service communities, and individual program managers. At the level of Congress and the administration, the annual budget is the only plan. The committee found that the budget planning and review process treats research separately from services but that the research programs of NIH and ADAMHA are treated similarly.

Strategic planning for scientific efforts has been important in the NIH institutes. Many institutes use selected portions of their strategic plans in order to contribute to broader agency and PHS plans and to guide preparation of budgets. Strategic planning has functioned more effectively in institutes that have an established knowledge base and stable mission than it has in institutes where the science is in a state of flux. Interviews in HRSA and ADAMHA revealed that the planning process in their offices and institutes is less ordered, and linkages

with agency and PHS plans less structured. Although institute planning processes within ADAMHA appear admirably flexible, that flexibility may also allow the planning process to be subject to frequent changes of direction and focus, thus failing to provide continuity to institute and bureau programs. **The committee recommends that all agencies within the PHS and each research institute be mandated to develop five-year plans, the process for which shall be reviewed by the Assistant Secretary for Health, and that plans be updated (with changes only) on a yearly basis. The committee notes that it is as important for five-year plans to specify program goals and objectives as it is that they be linked with and revised according to an annual budget.**

DEMONSTRATION AND INFORMATION DISSEMINATION PROGRAMS

Conflicting expectations on the part of Congress and federal agencies have created some difficulties in the administration of demonstration programs. The problems that arise for federal agencies from conflicts between the agendas and expectations of Congress and the administration can be formidable. The administration and Congress often fail to define their goals clearly, and when they do define their goals with some precision, the goals often conflict. Even when the administration, Congress, and agencies are in some agreement about their goals, they may disagree about how to accomplish what they want to accomplish. Although the administration and Congress are powerful in setting the agenda for federal agencies, they do not necessarily control the alternatives among which choices are made. These conflicts can result in insufficient resources being applied to a problem, inability to develop appropriate organizational structures for implementation, simple failure to initiate a program, or a deluge of demands for clarification of new legislation in the face of established, perhaps long-standing, policies that move in the opposite direction.

Examples of the effects of conflicts among the expectations of the administration, Congress, and agencies include failure to replicate successful demonstrations across multiple sites prior to implementation and failure to evaluate the effectiveness of implementation prior to national dissemination. Interviews indicate that the amount of funds available for replication and evaluation will affect whether new practices and system innovations will be disseminated appropriate

ly—that is, after having been shown to be cost-effective and efficacious. Replication and complementarity are essential as part of the research process. **The committee recommends that replication, which is vital to basic and clinical research but which has not been considered a central element of demonstrations, be ensured in new and ongoing research demonstrations following single-site experiments and prior to implementation and national dissemination.**

A related question is whether there might be fewer obstacles to the translation of research findings into service programs in a single agency than when translation requires collaboration across a number of agencies. According to program administrators in ADAMHA as well as CDC, there is no formal link between the demonstration and block grant programs they fund, even though they are often administered by the same state and local agencies. A number of models of the research-services continuum have been developed by PHS agencies and institutes, but the analyses for this study encountered little evidence of specific mechanisms for identifying the emerging results of clinical research or demonstrations that might serve as a basis for initiating intervention trials or for dissemination and introduction into state programs through the block grant program. **To ensure that the programmatic objectives of demonstrations are achieved, the committee recommends that a research program be initiated within the PHS to determine effective dissemination mechanisms for demonstrations and the results of health services research.**

Interviews with constituency groups noted that state agency officials often are unaware of the existence of federal demonstration projects in their states, particularly those funded by ADAMHA institutes and offices. In many instances, lack of consultation and collaboration has led state agencies to be reluctant to appropriate the funds to continue demonstrations, even successful ones, after federal funding has ended. **The committee recommends that a plan for incentives for translation of successful demonstration findings into the structure and delivery of services be accompanied by opportunities for state review and comment on all types of federal demonstration applications. Potential sources of postdemonstration funding for successful demonstrations (i.e., federal, state, local, and private sources) also should be explored prior to initiating a demonstration project.**

Articles in scientific journals targeted to researchers may not meet the needs of potential users of successful demonstrations. Previous studies, as well as the committee's own case studies, found that the

characteristics of individuals and organizations using new practices have an important influence on how the results of research are received and used. For instance, nonprofessional, community-based service providers may require access to training, technical manuals, or technical assistance in order to be able to adopt the results of successful demonstrations. **The committee recommends that the responsibility for technical assistance and clinical training programs for professionals and nonprofessionals, and the resources to carry them out, be part of the explicit mission of agencies that fund and administer operating programs (e.g., HRSA, the Indian Health Service, and ADAMHA).**

In the course of gathering information and deliberating on the central issues of this study, the committee reached other conclusions closely related to its primary charge. Serious questions were raised about how decisions are made about where to locate programs in the PHS and about the effects of frequent movement of programs. **The committee recommends that, when Congress authorizes new research or services programs, it consult with the Secretary of Health and Human Services to determine, within a brief period of time, the appropriate locus of program administration within the department. When a new or significantly expanded function is authorized, priority should be given to providing sufficient staff and financial resources to carry out the function.**

DUPLICATION, REPLICATION, AND COMPLEMENTARITY

Information gathered for this study suggests that wasteful duplication of basic and clinical biomedical research is not a problem in the PHS. Lack of coordination among demonstration projects being funded by institutes and offices within ADAMHA and across agencies in the PHS constitutes more of a problem than duplication.

The committee found it extremely difficult to address the question of duplication because of the lack of a standard nomenclature within PHS agencies and institutes for classifying research and service programs and projects. The lack of an agreed-upon nomenclature presents a barrier to planning, evaluation, public access to information, and accountability within the PHS. **The committee recommends that an interagency task force be formed to develop a standard nomenclature for classifying basic and clinical research, demonstrations, and service development activities**

across PHS agencies. The committee further recommends that the National Library of Medicine be mandated and given appropriate resources to carry out whatever research is necessary for the development of this standard nomenclature.

FINAL THOUGHTS

As this report was being readied for publication, both Congress and the Department of Health and Human Services (DHHS) announced plans to reorganize ADAMHA. The report itself and the background papers prepared for the committee provide significant information that can be used by Congress, the Secretary of Health and Human Services, the Assistant Secretary for Health, the agencies involved, and constituency groups to guide that reorganization.

The responsibilities of PHS agencies and officials have grown in substantive, technical, and administrative complexity over the past 20 years, often without regard for order or consistency. Interviews conducted for this study leave little doubt that the complexity of administering an agency such as ADAMHA, with two or more missions of equal importance, adds a magnitude of difficulty to the task of an agency administrator. Confusion and conflict over the interpretation of an agency's missions or the structures for carrying them out (which have occurred both in ADAMHA and HRSA) raise the level of difficulty even further.

Stability of organizational mission and program placement is important to a wide range of constituency groups. Analysis of constituency group relations with federal agencies suggests that instability undermines perceptions of the reliability of government operations, increases barriers to and frustration with development and maintenance of working relationships with agencies, and constrains group involvement with federal agencies. Changes in organizational arrangements are a particular problem when they are perceived as eliminating or reducing the standing of programs that have served as focal points for constituency group concerns. These arrangements are a particularly acute concern in the substance abuse and mental health fields, where organizational missions and arrangements have been less stable.

Finally, structural reorganization often has little or no impact on the actual delivery of services, as was pointed out in the analysis of linkage mechanisms within PHS agencies that was prepared for the committee:

Many of the reform efforts of the past have rested on the assumption that change can be devised and implemented at the administrative level, which will provoke change at the point of service delivery. The experience of these years, however, suggests that such a relationship may be an act of faith rather than demonstrated by evidence. While there may be strong and important reasons for making administrative changes (e.g., reorganization, joint planning efforts), the world of service delivery is rarely affected by forms or styles of organization. Rather, it is the nature of the policies to be administered and the resources available which impact the system at the point of service delivery.

1

Introduction

The purpose of this study was to respond to a congressional requirement in the Anti-Drug Abuse Act of 1988 (P.L. 100–690) that the Secretary of Health and Human Services request the National Academy of Sciences "to conduct a review with respect to the research activities of the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)" and related agencies, such as the Health Resources and Services Administration (HRSA) and the Centers for Disease Control (CDC). Specifically, the committee was asked for:

- an evaluation of the appropriateness of administering health service programs in conjunction with the administration of biomedical and behavioral research; and
- a determination of the extent of duplication among selected research programs of NIH and ADAMHA.

It is important to point out that the study was confined to the examination of agencies within the Public Health Service (PHS); it did not examine in depth the current organizational structure of the Department of Health and Human Services (DHHS).

To answer the above questions, the committee was asked in the contract for the study to develop and establish criteria and/or measures for determining the following:

- the effects of administering service programs in conjunction with research and research-related activities;
- the extent and effects of duplication, replication, or complementarity among the research activities of NIH and ADAMHA (to be determined through analysis of the scientific process and develop

ment of a classification scheme for research activities and health service programs that allows comparisons across agencies along a number of parameters);

- the administrative, program, and policy relationships among service programs and research/research-related activities of ADAMHA and its institutes, and the extent to which patterns of communication and leadership activities are attributable to co-administration or to other factors; and
- the "appropriateness" of these effects, given both the statutory mission of the programs and the changing requirements of public policy, scientific opportunity, and economic conditions.

In its early discussions, the committee arrived at a consensus that the outcome of the study ought not to be a "yes" or "no" decision about the value of co-administration but instead that the study should result in a series of pros and cons about co-administration as it exists at different levels of the PHS (the institute, bureau, or office level; the agency level; and the level of the Office of the Assistant Secretary). The committee interpreted the congressional request as a question about the efficiency of different organizational structures for administration of research and service programs in the PHS, given existing resources. Although many in the fields and disciplines related to basic and clinical research are convinced that there is a need to maximize resources for research, the committee agreed that the means of achieving maximal funding for biomedical research was not the question being asked by Congress.

The committee identified three important issues related to the organization of biomedical and behavioral research and services development and demonstration programs that the study would evaluate in a variety of ways:

- Do research and services development and demonstration programs benefit or suffer (as measured by funding levels, by analyses of planning and priority-setting activities, and by productivity) by being allied under a single administrative authority?
- What are the effects of dual missions on the effectiveness of senior agency and institute executives?
- Do particular organizational forms promote or hinder the transfer of basic research into clinical practice?

DEFINITION OF KEY TERMS USED IN THE STUDY

It is important to distinguish among three concepts that are often confused with each other—linkage, co-location, and co-administration. Also important to the understanding of this report is the distinction between categorical and functional organization:

- *Linkage* is a very general term that has emerged from the health services delivery programs. It relates to the processes necessary for the development of systems of care. When raised to the level of federal agencies, however, the concept of linkage seems to focus on choices made by two or more organizations or organizational units to engage (either directly or indirectly) in some sort of mutual activity.
- *Co-location* is a term that has been in use among state governments to describe situations in which two or more programs are located in a single organizational unit or in the same physical location. The concept of co-location does not imply a programmatic or budgetary relationship between programs.
- *Co-administration*, as defined in this study, includes administrative responsibility and authority for decision making that affects funding and priorities for federal research and service programs. Co-administration can exist at any level at which such responsibility is present, for example, the Office of the Secretary of Health and Human Services, the Office of the Assistant Secretary for Health, or in agencies, institutes, or programs.
- *Categorical organization* is defined as organization by field (for example, mental health, alcohol abuse, drug abuse) such as exists in ADAMHA, with subfields that include administration and coordination of research, services, and prevention programs.
- *Functional organization* is defined as organization by functional task areas (for example, research, services, or prevention), such as exists in the division of responsibilities among NIH, HRSA, and CDC, respectively; further differentiation may occur by subfields within research (e.g., biomedical research, health services research) and within services (e.g., preventive services, health care or treatment services).

ORGANIZATION OF THE REPORT

A discussion of the organization and mission of the Public Health Service and its agencies follows this introduction, including new

organizational developments that occurred in the spring of this year and resulted in the formation of the Administration for Children and Families. This new office reports directly to the Secretary of Health and Human Services and is composed of the previous Family Support Administration and Administration for Children, Youth, and Families, as well as parts of the Maternal and Child Health Program previously administered by HRSA.

Chapter 2 presents a brief history of the PHS and the agencies involved in the study, as well as a history of previous studies of the organization of ADAMHA. Chapter 3 discusses in detail the methodology the committee used to collect and evaluate data and information for the study. Chapter 3 also presents summaries of each of the background papers prepared for the committee's deliberations.

Chapter 4 presents in depth the findings and recommendations of the committee related to co-administration of research and service programs in the PHS. Chapter 5 presents the findings and recommendations of the committee concerning the issue of programmatic and project duplication, replication, and complementarity of research and service activities in the PHS.

The report also includes four appendixes: Appendix A lists all abbreviations used in the report; Appendix B describes the nomenclature used in analyses of research and services programs and projects; Appendix C lists the membership of the task forces established by the committee in the course of the study; and Appendix D lists the individuals interviewed in the course of the study.

ORGANIZATION AND MANAGEMENT OF THE FIVE PHS AGENCIES NOTES

This study has focused on two quite different organizational structures that exist side by side within the PHS: one that separates tasks (managing and funding research, service demonstrations and service system development, and prevention programs) by function into three distinct agencies, and another that incorporates all three tasks into a single agency with functionally organized units. The study also has looked at some important differences in the history and mission of the agencies and institutes being studied. It has then attempted to describe and analyze the relationship between these differences in history, mission, organizational structure, and leadership and the capacity to perform the tasks for which the PHS and, indeed, DHHS are authorized.

DHHS, a cabinet-level department of the federal government, is comprised of the Office of the Secretary and five operating divisions (Figure 1-1). This study focuses on agencies within one of these figure divisions, namely the PHS. The PHS was established by the Public Health Service Act of 1944 "to promote the coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."[1] The PHS is comprised of eight agencies and the Office of the Assistant Secretary for Health (OASH), which provides executive direction to the eight agencies (Figure 1-2). The Assistant Secretary for Health is responsible to Congress and to the Secretary of Health and Human Services

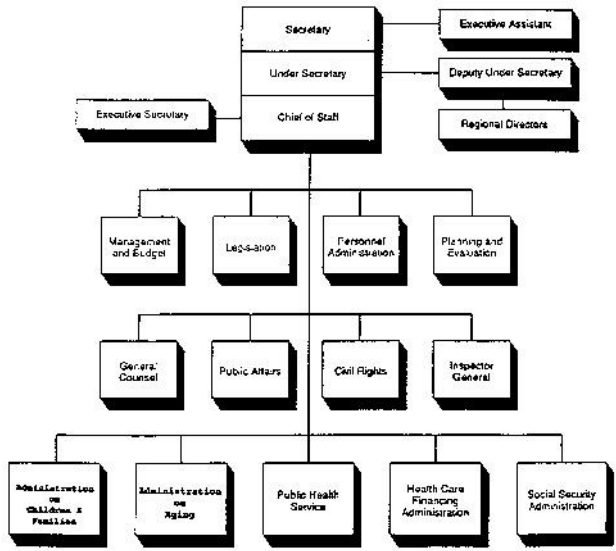

Figure 1-1 Organizational structure of the Office of the Secretary, Department of
Health and Human Services (DHHS). Also located administratively in DHHS, but
reporting to the President, is the Office of Consumer Affairs, which handles co nsumerrelated policy and programs in the federal government.
Source: General Accounting Office Report to Congress, February 1988 (GAO/ ARD90-54).

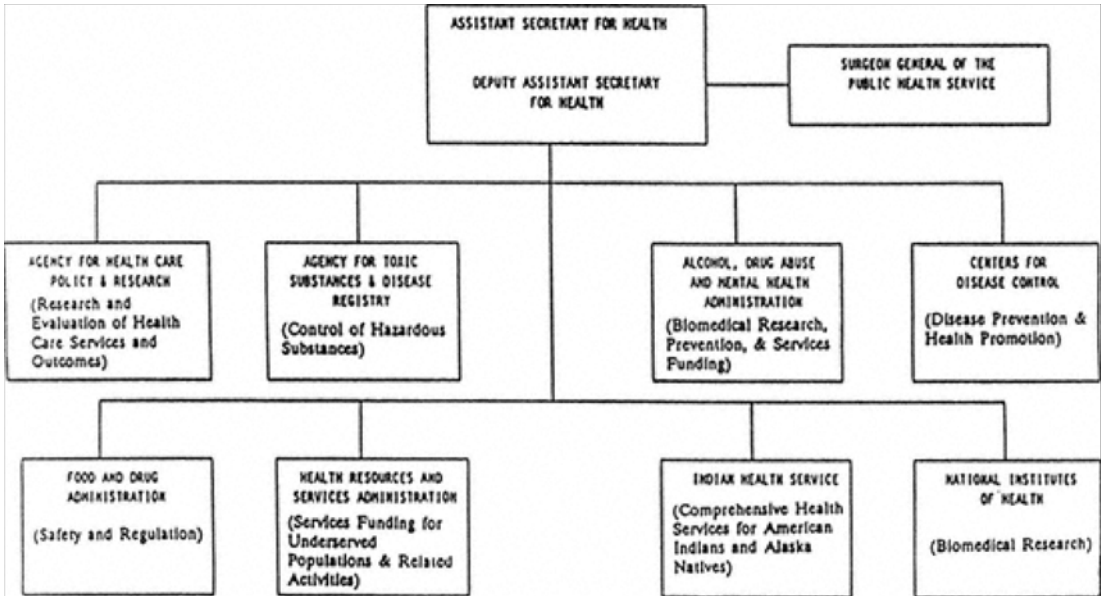

Figure 1-2 Organizational structure of the Public Health Service, Department of Health and Human Services.
Source: *Overview of the Major Components of the Public Health Service* , March 1990, Office of the Assistant Secretary for Health.

for the performance of the PHS, its agencies, and its programs in meeting national health objectives.

The five PHS agencies relevant to this study are those that administer and fund health research, prevention, or services programs for the nation. Four of these agencies are organized primarily by function:

1. the National Institutes of Health (NIH), which funds, administers, and conducts biomedical research;
2. the Health Resources and Services Administration (HRSA), which administers services programs for underserved populations;
3. the Centers for Disease Control (CDC), which is responsible for disease prevention and health promotion programs; and
4. the Agency for Health Care Policy and Research (AHCPR), which funds, administers, and conducts health services and outcomes research and evaluation.

The fifth relevant agency is the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), which administers a full range of programs including research, prevention, and services for the areas of mental health, alcohol abuse, and drug abuse. Figure 1-3 shows the relative shares of these agencies (as well as those of the Food and Drug Administration [FDA] and the Indian Health Service [IHS]) in the total DHHS budget.

NIH, ADAMHA, and AHCPR are established in law and granted specific authorities by Congress through amendments to the Public Health Service Act. HRSA and CDC are administratively created through authority vested in the Secretary of Health and Human Services. Whether legislatively or administratively created, every federal agency is required to publish a statement of its mission, functions, and organization in the *Federal Register*. Because each agency's activities are legally limited to what is contained in its functional statement, major agency-level policy changes generally require new legislation.[2] Similarly, some institutes and offices within agencies are established through acts of Congress, while others are administratively created. Those that are administratively created can be changed, merged, or dismantled at will by the Secretary of Health and Human Services, but legislation is required to alter the mission and authority of mandated offices or institutes. However, all offices and institutes are directly affected by Congress, which establishes funding levels for agencies through appropriations for all PHS programs. Thus, agencies could have authorization for activities, yet receive inadequate appropriations to carry them out. On the other

hand, the infusion of funds by Congress for new or expanded programs could alter the direction or focus of an agency or institute.

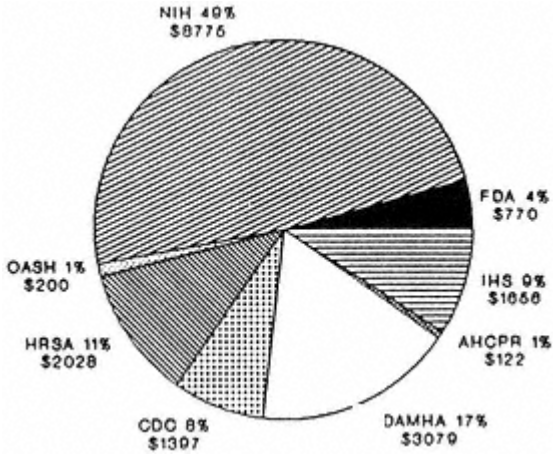

Figure 1-3 Relative size of Public Health Service agencies (in millions of dollars).
Public Health Service total—
$18,027 million. Based on fiscal year 1992 President's
Budget. The Agency for Toxic Substances and Disease Registry receives its funding
through a reimbursement agreement with the Environmental Protection Agency Superfund. Abbreviations: NIH, National Institutes of Health; FDA, Food and Drug Administration; IHS, Indian Health Service; AHCPR, Agency for Health Care Policy
Research; ADAMHA, Alcohol, Drug Abuse, and Mental Health Administration; CDC,
Centers for Disease Control; HRSA, Health Resources and Services Administration; OASH, Office of the Assistant Secretary for Health.
Source:
Overview of the Major Components of the Public Health Service , March 1990, Office of the Assistant Secretary for Health.

ORGANIZATION AND MISSION OF THE FIVE PHS AGENCIES

Office of the Assistant Secretary for Health

OASH is organized to support the Assistant Secretary's broad mandate to provide direction for a national health program.[3] OASH

activities include all aspects of planning and development of federal health policy. OASH coordinates and implements policies and programs that cut across agency lines (within and outside of the PHS) such as infant mortality, acquired immune deficiency syndrome (AIDS), minority health, and health promotion and disease prevention, including vaccination programs. OASH also administers some federal grant programs (Family Planning, Adolescent Family Life, and Population Research) and manages the Commissioned Corps (the Surgeon General's office is located in OASH).

National Institutes of Health

The primary responsibility of NIH is to provide federal support to research that stimulates the development of the science base for the generation of new knowledge to prevent, detect, diagnose, and treat disease and disability. The largest of the PHS agencies, NIH is organized into 13 research institutes, primarily by disease or population categories (cancer, heart disease, aging, etc.), plus the National Library of Medicine and seven research and support divisions (Figure 1-4). NIH institutes are considered to be semiautonomous: they are coordinated through the Office of the Director, but programmatic decisions and operations are carried out at the institute level.

NIH and its institutes pursue their mission through intramural and extramural research programs, through the support of research centers, and through training programs to enlarge the pool of skilled investigators. Some, but not all, NIH institutes are authorized to conduct research demonstrations. However, NIH does not provide health services other than therapeutic measures and care incidental to research. It has no regulatory responsibilities other than recommending standards for the use of animal and human subjects in federally supported health research and in recombinant DNA research.

Alcohol, Drug Abuse, and Mental Health Administration

ADAMHA holds lead responsibility for the federal government's efforts to seek scientific solutions to the causes, treatment, and prevention of alcohol, drug abuse, and mental health (ADM) disorders. While the research mandate is very similar to the mandate of NIH, ADAMHA's mission also includes authorization to conduct activities

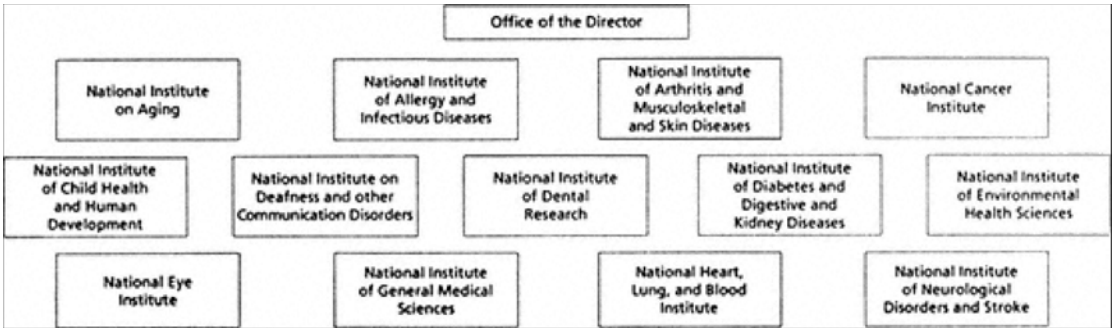

Figure 1-4 Organizational structure of the National Institutes of Health, Public Health Service, Department of Health and Human Services. Source: Adapted from the *NIH Data Book 1990*, Public Health Service, Department of Health and Human Services.

to help improve the nation's capacity to treat and prevent ADM disorders. In addition to basic and clinical biomedical research and research training programs, ADAMHA administers the following prevention and service activities:

- service demonstration programs related to the prevention and treatment of ADM disorders;
- administration of block and formula grants to states for ADM services;
- collection of data on incidence and prevalence of ADM disorders and the national response; and
- provision of assistance and information about ADM disorders to other federal agencies, states, health care providers, and public and private organizations.

Figure 1-5 shows the major organizational components of ADAMHA. The Office of the Administrator supervises and coordinates ADAMHA's institutes and offices, which include the National Institute of Mental Health (NIMH), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the Office for Substance Abuse Prevention (OSAP), and the Office for Treatment Improvement (OTI). Much like the NIH institutes, the three ADAMHA institutes support intramural and extramural basic and clinical research, research training, and research demonstration projects. In addition, NIMH continues to administer some services funding programs. In contrast, the activities of the newer ADAMHA offices, OSAP (established in 1986) and OTI (established in 1989), concentrate on the development and administration of programs for substance abuse prevention and treatment services, and information dissemination. Although the ADAMHA institutes and OSAP are separately authorized in legislation, OTI was administratively created and has yet to be ratified by Congress.

Health Resources and Services Administration

HRSA supports programs that provide health care services to a variety of medically underserved populations, with the goal of improving access, equity, and quality of care. HRSA's range of programs include both the direct and indirect funding of services and the training and placement of health care professionals in underserved

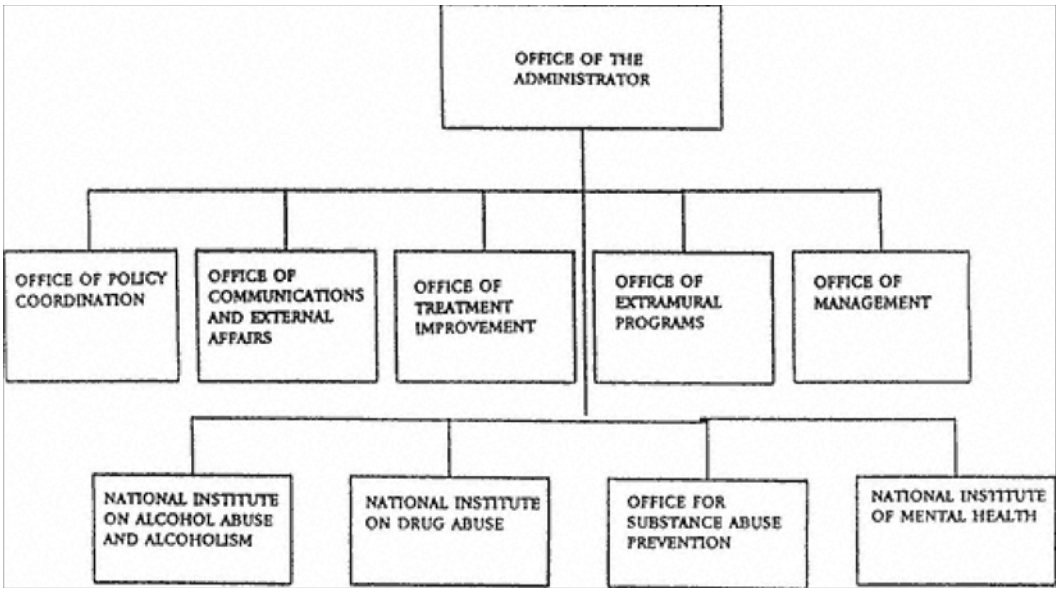

Figure 1-5 Organizational structure of the Alcohol, Drug Abuse, and Mental Health Administration.
Source: Adapted from *Overview of the Major Components of the Public Health Service* , March 1990, Office of the Assistant Secretary for Health.

areas. In addition, HRSA administers programs of national importance, such as AIDS service delivery and education, rural health services, and a national organ transplantation network to improve procurement and allocation of organs on a nationwide basis.

Centers for Disease Control

CDC is the federal agency responsible for protecting the public by preventing unnecessary diseases, disability, and premature death and by promoting healthy lifestyles. Included in CDC's mission are the study and prevention of chronic and infectious diseases, the reduction of injury, and the reduction of risk factors that are controllable. CDC also serves as the lead PHS agency in responding to public health emergencies, and it maintains national surveillance and statistics. Like the NIH institutes, which are organized to focus on disease categories or populations, the centers organizational pattern affords CDC the opportunity to organize its internal structure around specific disease prevention objectives or objectives targeting improved health status.

Agency for Health Care Policy Research

AHCPR, the newest PHS agency, was established by the Omnibus Budget Reconciliation Act of 1989. It builds on and succeeds the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) as the primary source of federal support for research on medical treatment effectiveness, general health services, and health care technology. Because provision of health care services includes both private and public providers, AHCPR's research focuses on both the private and the public sector. New knowledge generated through intramural and extramural research programs will be used to inform and assist health care decision makers.

NOTES

1. Public Health Service Act of 1944, P.L. 78–410.
2. Administrative Procedures Act, Title V, U.S.C.

3. This discussion is drawn primarily from *The Public Health Service. Overview of Major Components*, compiled by the Office of Management, Office of the Assistant Secretary for Health (1990). This document is also the source of the organizational charts included in this chapter.

2

A Brief History of ADAMHA and Previous Studies of Its Organization

OVERVIEW

The history of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), established in 1973, and its predecessor, the National Institute of Mental Health (NIMH), established in 1946, illustrates the continuing concern with the potential advantages and disadvantages of administering research programs in conjunction with health service programs. These concerns date back to the formation of NIMH, which adopted a model approach to mental disorders that stressed the interrelatedness of research, training, and services. The balance of the "three-legged stool" has shifted over time, leaving advocates for each side concerned that they may receive less funding and less support if the other is in favor.

This chapter traces that history, including a summary of the questions addressed and the findings of two previous major studies in 1973 and 1987. Leadership has had a strong impact on the history, first by successfully resisting attempts to break apart the agency, later by changing its focus to emphasize service delivery, and most recently by shifting its focus to biomedical research.

This history also reveals a pattern of responding to concerns raised by Congress and the administration. In recent years, Congress has reversed its policy focus: 1981 block grant legislation put the administration of service-funding programs into ADAMHA's central office; but since 1986, appropriations for service-related programs and demonstrations have shifted responsibility back to the institutes, as well as giving rise to two new offices within ADAMHA, the Office for Substance Abuse Prevention and the Office for Treatment Improvement.

EARLY HISTORY

Like the institutes established within the National Institutes of Health (NIH) during the postwar years, the creation of NIMH reflected a shift in federal policy that dramatically increased support for biomedical research programs that target specific diseases. From the beginning, however, the mission of NIMH was unique. The institute's authorizing legislation, the National Mental Health Act of 1946, incorporated three distinct missions:

1. to support research relating to the cause, diagnosis, and treatment of psychiatric disorders;
2. to train mental health personnel by providing individual fellowships and institutional grants; and
3. to award grants to states for the establishment of clinic and treatment centers and for demonstration studies dealing with the prevention, diagnosis, and treatment of neuropsychiatric disorders.[1]

In short, NIMH was founded on the premise that there is an inherent interrelatedness among the components of the "three-legged stool"—research, training, and services. This premise, reflected the views of Robert Felix, then director of the Division of Mental Hygiene, who drafted the proposal that led to the National Mental Health Act.[2] Felix regarded mental disorders as a public health problem, one that required not only the discovery of the causes of the disorders but also improved training of personnel and better methods of treatment and prevention.[3] Felix attempted to realize this vision as he helped to shape NIMH and later served as its first director, a position he held for 15 years (1949–1964).

From the inception of NIMH, there was controversy over its placement within the Public Health Service (PHS). Since it would incorporate the Division of Mental Hygiene, a services agency, some argued that NIMH should be placed in the Bureau of State Services. Others, including Felix and the National Advisory Mental Health Council (established under the act), argued that NIMH should become an institute of NIH, in order to focus its efforts on research and training and to clearly identify mental health and psychiatry with the field of biomedicine.[4] The latter view prevailed, and NIMH remained in NIH until 1967.

To some extent, however, the research portfolio of the NIMH differed from other NIH institutes. In addition to basic and clinical biomedical research, NIMH strongly supported behavioral research and some social science research. The enthusiasm for including

behavioral and social science in the NIMH research agenda was understandable: there was little knowledge at the time regarding the biological causes of mental disorders, whereas there were abundant data and explanatory theories of normal and abnormal behavior put forward by psychologists, psychiatrists, and sociologists.[5]

The placement of NIMH in NIH did not settle the controversy over the institute's threefold mission, however. As the service mission of NIMH continued to grow during the 1950s, spurted on by new congressional legislation, the director of NIH began to oppose including service programs within the agency. A 1960 proposal to reorganize PHS would have dismembered NIMH, retaining its research programs within NIH but moving its training and service programs to other PHS bureaus. Felix strongly opposed this move, ultimately successfully. Defending the threefold mission of NIMH, he wrote to the Surgeon General:

> An analysis on a point by point basis shows the disastrous results of this dismemberment of a presently integrated approach to a major health problem that appears to require, even more than other areas, integration of effort in all areas of approach: research, training, service, control.[6]

THE 1960S

During the 1960s, congressional interest in mental health shifted toward an even greater emphasis on service development. Congress enacted grant programs to improve state hospitals, to establish community-based psychiatric treatment, and to develop separate community-based treatment centers for alcoholism and drug abuse. In particular, the Community Mental Health Centers Act of 1963 led to a profound shift in NIMH budgetary priorities. Opponents of the Community Mental Health Centers (CMHC) program objected to the creation of a separate system of care that isolated the treatment of mental illness from the mainstream health care system and from existing state systems of care. However, the CMHC program received strong congressional support.

The Johnson administration's War on Poverty resulted in the expansion of NIMH activities in the areas of drug abuse and alcoholism. The National Center for Prevention and Control of Alcoholism, established within NIMH in 1966, included programs in research, training, and services. In the same year, a Center for Studies of Narcotic Addiction and Drug Abuse was created within

the NIMH Division of Special Mental Health Programs. Attempts to link alcohol and mental health treatment facilities date from this period, when amendments to the Comprehensive Mental Health Centers Act in 1968 provided for construction of alcoholic treatment facilities, to be operated in conjunction with CMHCs.

By 1967, the budget for the CMHC program exceeded the entire NIMH research budget. This led to concern in the research community that research funds were being channeled into service programs and that research had been downgraded as a programmatic priority. This concern was heightened by external pressure for a shift in focus in the NIMH research program. While the Johnson administration launched the Great Society programs to address social ills, including alcoholism and drug abuse, it questioned the relevance of research and particularly the balance between basic and applied research.[7] NIMH responded to administration and congressional pressure by targeting more of its research budget toward research into social problems, a shift in emphasis that was not welcomed by the director of NIH.

In addition, NIMH was by 1967 the largest institute in NIH, accounting for 22 percent of the total NIH budget.[8] NIMH's leadership and its various constituencies believed that its budget and its combination of research, training, and service activities gave NIMH enough size and stature to be an independent agency. Under a major reorganization of the PHS in 1967, NIMH became the only institute ever to leave the NIH. NIMH was elevated to bureau status, equal to the NIH. This reorganization occurred despite the opposition of the director of NIH and others in the research community who expressed concern that the NIMH research agenda would suffer as the agency sought to satisfy other priorities and fulfill other responsibilities.[9] In 1968 there was yet another reorganization of the PHS: NIMH was moved into the Health Services and Mental Health Administration (HSMHA), a new agency created to coordinate all PHS service delivery programs.

Over the next several years, the controversy over the relative status of the components of the NIMH mission was joined by a second controversy concerning the placement within NIMH of the rapidly growing alcohol and drug programs. In response to demands to expand efforts to address the needs of persons with alcohol problems, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 mandated the establishment of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) as a separate institute within NIMH. From the beginning, NIAAA chafed under its status as an institute within an

institute.[10] In addition, heightened interest in combatting drug abuse resulted in the extensive growth of NIMH's drug abuse programs. This led to the passage of the Drug Abuse and Treatment Act of 1972, which mandated the establishment of a National Institute on Drug Abuse (NIDA).

In the view of Bertram S. Brown, then director of NIMH, the problems of alcoholism, drug abuse, and mental illness (the ADM disorders) were inextricably related, and ongoing research into the sources of mental disorders should provide insights into the etiology of alcoholism and drug abuse. The presumption of inherent interrelationships among the three areas led the Assistant Secretary for Health to believe that community-based treatment services in the three areas could best be provided through affiliation and coordination among these activities. An internal management study in 1972 concluded that the NIH model—separate institutes working under an administrative umbrella—could be applied to the NIAAA-NIMH relationship. However, NIMH was not reorganized into this structure, pending a further reorganization of the PHS.

While NIMH was experiencing this internal pressure, external controversy over the research and service mission of NIMH and the PHS surfaced again. The Nixon administration was not enthusiastic about federal support for service and health manpower programs, nor did it support the behavioral and social research thrust of the 1960s. Seeking to limit the federal role in the direct provision of services, the administration moved to break apart HSMHA and to allow the authorities for "unnecessary categorical" programs (including those for drug abuse, alcoholism, and community mental health centers) to expire, despite strong opposition from Congress and constituency groups. Although services at that time represented 50 percent of the NIMH budget, the 1973 reorganization (the last major reorganization of the PHS), moved NIMH back to NIH with all of its programs intact, "because of its anticipated role as primarily a research institute."[11] This transfer proved to be very short-lived. Instead of allowing the authorization for support of services to expire, Congress appropriated increased amounts to community agencies and states for ADM treatment programs.

THE GARDNER REPORT AND THE BIRTH OF ADAMHA

The research community continued to express concern about the perceived negative effects (on research funding) of combining the

administration of services and research programs in the same organization. This led Assistant Secretary for Health Charles Edwards to establish a task force in 1973 to examine the relationships among the ADM disorders and to determine how to administer the needs for research, services, and training. The Mental Health Task Force, chaired by Elmer Gardner, analyzed professional issues relating to the three fields and how these concerns were coordinated within the structure of NIMH. Interviews were conducted with mental health professionals and health professionals, both inside and outside the government.

The task force report, delivered in August 1973, presented a number of organizational options for structuring ADM activities within the PHS (Figure 2-1). Ideally, the task force favored the integration of ADM research, training, and services with the larger health care system (option 5). Yet despite the fact that PHS, except for NIMH, was organized functionally (i.e., research at NIH, prevention at the Centers for Disease Control, clinical training at the Health Resources Administration, and service delivery at the Health Services Administration), the task force concluded that the continuing social stigma attached to the ADM disorders precluded their integration into the general health agencies of that time. The task force perceived a need for continued visibility and leadership, especially in the areas of drug abuse and alcohol abuse, which were important national priorities. The task force recommended either of two temporary options and estimated that it would take about five years to make the transition from either option to the goal of a fully integrated PHS (research in NIH; prevention in CDC; services in HSA; training in HRA).

The Secretary of Health, Education, and Welfare chose the option that created the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) as an umbrella organization, with a presidentially appointed administrator providing general supervision and policy direction for three institutes: the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). This option placed NIDA and NIAAA on an equal footing with NIMH.

The task force concluded that the drug abuse and alcohol abuse fields should gradually be combined, in part because basic research and training for these fields were thought to be similar but also because there were an increasing number of people who abused both. On the other hand, the task force noted some important differences between the substance abuse and mental health fields, despite their close historical association.[12]

FIGURE 2-1 Organizational Options: The Gardner Report

OPTION 1: A sixth agency, the Substance Abuse Administration (SAA) would be created, including NIAAA and NIDA. Research activities, both intramural and extramural, would comprise the totality of NIMH's functions in NIH; basic drug and alcohol research also would be transferred gradually to NIH. Mental health service activities would be transferred to the Health Services Administration (HSA). Mental health training and data collection activities would be moved to the Health Resources Administration.

OPTION 2: A sixth agency, the Substance Abuse and Mental Health Administration (SAMHA), would be created. The substance abuse institutes, NIDA and NIAAA, would be taken out of NIMH and instead would be placed as institutes coequal to NIMH.

OPTION 3: A sixth and seventh agency would be placed directly under the Assistant Secretary for Health: NIMH and a Substance Abuse Administration (SAA), which would include NIDA and NIAAA. This option was rejected by the task force because of the lack of separate high-level visibility of drug and alcohol programs and because of the training and service functions, which would remain in the research-oriented NIH.

OPTION 4: The organizational structure would remain as it existed under the 1973 PHS reorganization. This option also was not seriously considered by the task force because of the lack of separate high-level visibility of drug and alcohol programs and because of the training and service functions which would remain in the research-oriented NIH.

OPTION 5: The mental health, drug abuse, and alcohol activities would be immediately integrated with the health system, A research institute for mental health and substance abuse would be created in the NIH. This option was unanimously

considered to be the most desirable eventual organizational structure because it represented a unified health system and ideal integration of the mental health, substance abuse, and health fields. However, this option was felt to be politically infeasible, because the leadership and visibility needed by mental health, drugs, and alcohol would be severely compromised.

ADAMHA

Each of the component institutes of the new ADAMHA agency continued to combine research, training, and services in its mission, but controversy about this mission had not ended. From 1973 to 1982, the largest proportion of ADAMHA funds were used for services programs. By contrast, allocations for research fell, in part as a reflection of the Nixon administration's dislike of behavioral and social science research. This fueled the belief among the research community that research is shortchanged when it is administered by an agency that also administers services programs.

Changes in program funding mechanisms during the Reagan administration brought about further profound changes in the structure and functions of NIMH, NIAAA, and NIDA. In 1981, the categorical and formula grant programs at all three institutes, including most ADM services activities, were combined into a single Alcohol, Drug Abuse, and Mental Health (ADMS) block grant to the states. Since then, the focus of the three institutes has been on improving the quality of their biomedical and behavioral research efforts. This concentrated focus has been welcomed by many in the research community, particularly in light of promising recent breakthroughs in biological and psychosocial approaches.

On the other hand, some service advocates see the emphasis on basic research as an abandonment of the original leadership mission assigned to the ADAMHA institutes for the enhancement of effective services. Under the previous system of categorical grants, the three institutes were able to exercise national leadership through their authority to develop, select, and monitor services and service-related programs, including demonstrations. Under the ADMS block grant,

however, these responsibilities devolve to the states; the ADAMHA institutes have no authority to guide, shape, or assess federally supported state programs.

Despite the shift to the block grant program, service-related constituency groups have continued to look to ADAMHA for national leadership on policy issues such as reimbursement for mental health and substance abuse services. Such groups have expressed an interest in having ADAMHA take a more active role in working with other federal agencies on these issues. Particular concern has been expressed that, as the institutes within ADAMHA redefined their mission, previous leadership roles in services policy diminished or disappeared and were not taken up structurally at other levels of the organization.

Although the ADMS block grant program is a substantial part of the total ADAMHA budget, the program has not been a top priority. The 1980s saw decreasing interest in programs for services development, and the organizational placement of the ADMS block grant program within ADAMHA has changed on an almost yearly basis since its inception. The actual administration of the block grant program has moved from the Office for Policy Evaluation and Legislation, to the Office of the Associate Administrator for Prevention, to the Office of Financing and Data Policy, to the Office of Policy and Legislation, to the Office of Communications and External Affairs, and, finally, in 1990, to the Office for Treatment Improvement. In each case, the block grant program was a stepchild to another primary function and the block grant office continued to have only two or three full-time staff members. The change to the block grant program also coincided with the implementation of the 1981 Office of Management and Budget Paperwork Reduction Act, which severely limited the authority of federal agencies to collect data and standardize report formats on state-administered federal programs.

Many in the research community supported the removal of services responsibilities from the ADAMHA institutes, the renewed focus on biomedical research, and the appointment of scientists to top-level agency positions. It was only a short time, however, before Congress, under pressure from advocacy groups, began to authorize additional demonstration and service programs for special populations, to be administered by ADAMHA. The Office for Substance Abuse Prevention (OSAP), established within ADAMHA by the Anti-Drug Abuse Act of 1986 (P.L. 99–570), began awarding demonstration grants to community agencies to provide prevention services to youth at high risk of substance abuse. NIDA also received a large infusion of funds for demonstrations to target drug abusers at risk for AIDS.

The Homeless Assistance Act of 1987 authorized more demonstration programs and a services block grant targeting homeless mentally ill and homeless with substance abuse problems. Other legislation mandated the establishment of a services program for Protection and Advocacy for the Mentally Ill, to be administered by NIMH. The ADAMHA institutes have been reluctant to incorporate some of these demonstration and service programs, which they considered to be organizationally out of line with their research focus.

The Lewin Report

The organizational placement of the research and services development and demonstration components of the ADAMHA institutes became an issue again in 1987. Some scientists and an advocacy group, the National Alliance for the Mentally Ill (NAMI), expressed the view that funding for research programs was lagging because of NIMH's location within ADAMHA. These advocates supported the introduction by Senator Daniel Inouye of legislation (S.164) to transfer NIMH to NIH again. NAMI also favored the transfer of NIDA and NIAAA to NIH, although it was not part of the proposed legislation. The goals of the proposed reorganization were to enhance the perceived quality of NIMH research, to place NIMH on an equal footing with other NIH institutes in competing for research funds, and to reduce stigmatization, which some believed decreased the agency's ability to command priority in obtaining the needed level of research funds. Others in the field opposed the move, citing the gains to be achieved when the same agency administered both services and intramural and extramural research programs.

The Senate requested a position statement from the Department of Health and Human Services (DHHS), which in turn commissioned Lewin and Associates to investigate the organizational options for ADAMHA and the organizational preferences of interested parties. Lewin conducted 62 interviews with key PHS officials, state health administrators, advocacy groups, service providers, and scientific researchers. The "Lewin Report," submitted in January 1988, identified five organizational options (Figure 2-2).[13] The interview results showed no strong preference for or against changing the organizational structure of ADAMHA, although choices of respondents split along interest areas (i.e., biomedical researchers, state officials, and service providers chose options consistent with others in their interest area).

FIGURE 2-2 Organizational Options. The Lewin Report

OPTION 1: Retain ADAMHA in Current Form (January 1988). ADAMHA remains intact with three institutes. OA retains some limited operating functions (notably the Office of Substance Abuse Prevention or OSAP) but decentralizes others, primarily retaining policy support functions and a Science Advisor.

OPTION 2: Transfer all of NIMH to NIH. NIDA and NIAAA remain as separate institutes in a renamed agency, perhaps a National Center for Addictive Disorders. NIMH becomes an institute within NIH.

OPTION 3: Transfer only NIMH Research to NIH. Differs from option 2 in that service-related and perhaps some service demonstrations and statistical functions would not transfer to NIH. They would instead be retained in the new National Center (but not within NIAAA or NIDA) or transferred to the Health Resources and Services Administration (HRSA).

OPTION 4: Disband ADAMHA; Move NIMH, NIDA, and NIAAA Research to NIH and Services-Related Programs to HRSA, CDC, NCHSR, and/or OASH. Service-related programs would be carefully studied and reorganized into a new bureau-level agency within HRSA or, alternatively, integrated into existing service, clinical training, health services research, statistical, and advocacy prevention programs through the PHS. NIMH, NIAAA and NIDA research functions would be organized either as:

a three independent institutes within NIH;

b two independent institutes: NIMH and a new National Institute for Addictive Disorders (NIDA and NIAAA); or

c. a single National Institute for Alcohol, Drug, and Mental Disorders much like the National Cancer Institute and National Heart, Lung, and Blood Institute, with major divisions that would retain the identity and autonomy of the three fields.

As analysis of the study findings proceeded, it became clear that one of the possible variations—a bureau-level organization of ADM service-related programs—was important enough to identify as a separate option, although it represents a variation of option 1. This option was not a direct product of the working group process, nor was it raised with the majority of discussants because it was generated subsequent to most of these discussions.

OPTION 5: Retain ADAMHA and Its Institutes but Create a New Bureau of ADM Service-Related Programs. Operating programs such as OSAP and service demonstration grants, block grants administration, clinical training, some statistical functions, service research, program evaluation, financing, education, and state liaison, for example, would become part of this new bureau. It would be headed by someone comparable in stature to the institute directors. ADAMHA/OA would retain certain science policy, budget, administrative, legislative liaison, and other cross-cutting functions along the lines of the NIH directorate. The institutes would concentrate primarily on research.

Of particular interest to the current study, respondents were also asked whether, in their opinion, organizationally separating ADM scientific research programs from ADM service-related programs would harm either or both. Although a majority of respondents favored keeping research and services in the same organization, it was felt that connections between research and services "range[d] from weak to non-existent," at the state and local levels as well as at the federal level. Respondents identified the consolidation of ADM services programs under the 1981 block grant legislation as a contributing factor. In addition, some respondents reported that

federal demonstration programs have inadequate scientific rigor, and therefore fail to act as useful bridges between research and services. Other respondents pointed to the inadequacy of traditional dissemination techniques, particularly in the area of substance abuse, which may require greater federal intervention (i.e., clinical training and demonstrations). A majority of respondents favored efforts to ensure greater continuity of leadership at ADAMHA, such as "depoliticizing" the appointments of key institute personnel in order to attract eminent scientists. This could also serve to improve program stability and insulate research from changing political priorities.

The DHHS working group report, submitted in February 1988, presented the five organizational options as part of the larger organizational question: the relative merits of change versus no change.[14] The working group identified three overarching policy issues that needed to be addressed before this organizational question could be answered:

1. *Clarify the nature and scope of the federal leadership role in services and prevention activities in the ADM fields*. In addition, the relationship of research to ADM services and prevention needs to be better defined. Consolidation of ADM services under the block grant program eliminated federally directed services programs, yet the states and service providers continue to look to ADAMHA and expect the agency to play a strong role in mental health services research, policy direction, and advocacy in the ADM fields. It remains unclear, however, if the institutes should be expected to take an advocacy role on policy issues or if this role should be assumed elsewhere in the federal government. The lack of consensus on the role of ADAMHA in all of the above issues was evident.
2. *Determine how best to foster connections between research and services at the federal level, and whether such connections are desirable* . Although research, training, and services are co-located in ADAMHA, there was little evidence to suggest that there were significant connections among these areas in any ADM field. Thus, the issue becomes not whether these connections should be continued, but whether there could or should be attempts to nurture them. A second part of this question is whether these connections could be developed if ADM programs were organized functionally like the rest of the activities of the PHS.
3. *Decide what, if anything, should be done by DHHS to promote ADM mainstreaming*. This means the integration of ADM research, medical education, and services delivery activities with the broader health system. Some argue that ADM programs, particularly sub

stance abuse, are not yet well enough developed for mainstreaming and continue to require the added visibility and special focus of a separate ADM agency. Others argue that separating ADM disorders encourages stigmatization, which reinforces attitudes leading to discrimination both in the provision of care and in health insurance coverage.

Thus, the working group concluded that, although destigmatization and integration of ADM activities are appropriate goals for DHHS, organizational change alone would not achieve these objectives. Clarification of administrative policy and continuity of leadership are prerequisites to effective organizational change. No organizational change in ADAMHA resulted from the Lewin Report.

The Anti-Drug Abuse Act of 1988

The Anti-Drug Abuse Art of 1988 raised the Office for Substance Abuse Prevention (OSAP) to a status equal to the ADAMHA institutes. The act authorized further expanded research demonstrations on drug abuse and a major prevention services demonstration program for substance-abusing pregnant women, as well as demonstration programs to target improvement of treatment for substance abusers. It also authorized for the first time a federal set-aside from the ADMS block grant program, to be used by ADAMHA to conduct services demonstrations and health services research, to collect data, and to provide technical assistance to the states. The 1988 legislation resulted in the administrative creation of the Office for Treatment Improvement (OTI) to administer many of these new programs as well as the ADMS block grant program. The current study was also authorized under this legislation.

NOTES

1. G. N. Grob, "The National Institute of Mental Health," Washington, D.C., 1991, unpublished.

2. S. D. Nelson, "A Case Study of the National Institute of Mental Health," paper prepared for the IOM Committee for a Study of the Organizational Structure of the National Institutes of Health, Washington, D.C., 1984.

3. Grob, "The National Institute of Mental Health."

4. C. C. White and R. S. Hanft, "The Changing Relationship of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Services, Springfield, Va.;* Grob, "The National Institute of Mental Health."

5. Grob, "The National Institute of Mental Health."

6. E. Carper, *The Reorganization of the Public Health Service, Inter-University Case Program No. 89* (Bobbs-Merrill Company: 1965).

7. Nelson, "A Case Study of the National Institute of Mental Health."

8. R. A. Walkington, "The Health Resources and Services Administration: Evolution and Current Programs," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Services, Springfield, Va.; R. E. Miles, *The Department of H.E.W*. (New York: Praeger Publishers, 1974); Nelson, "A Case Study of the National Institute of Mental Health."

9. White and Hanft, "The Changing Relationship of the NIH and ADAMHA."

10. White and Hanft, "The Changing Relationship of the NIH and ADAMHA."

11. E. A. Gardner, *Final Report of the Mental Health Task Force* (Washington D.C.: Department of Health and Human Services, 1973).

12. Gardner, *Final Report of the Mental Health Task Force*.

13. Lewin and Associates, *Examination of the Advisability and Feasibility of Restructuring Federal Alcohol, Drug Abuse, and Mental Health Activities* (Washington, D.C.: Lewin and Associates, 1988).

14. DHHS Task Force, *Options for the Organization of the Alcohol, Drug Abuse, and Mental Health Administration* (Washington, D.C.: DHHS, 1988).

* For readers interested in obtaining copies of these papers, the full address of the National Technical Information Service is 5285 Port Royal Road, Springfield, VA 22161; telephone 703-487-4650.

3

Methodology

OVERVIEW

The questions posed by Congress do not lend themselves to a completely objective approach; by nature they include subjective evaluations. Nonetheless, the committee gathered as much data as possible within the constraints offered by time and funds and supplemented that information with the expertise of diverse committee members. The committee also developed the following criteria by which to evaluate the questions posed by the study:

Organizational goals and funding—Does co-administration enhance or detract from:

- clarity of organizational mission;
- level and growth in funding at the institute (bureau or office) level and at the agency level;
- relationships with significant constituency groups.

Effectiveness of organization—Does co-administration enhance or detract from:

- effectiveness of services programs;
- effectiveness of research programs;
- efficiency of research and service programs;
- coordinating overlapping programmatic research and service priorities and eliminating unwarranted duplication of research and service projects;
- avoiding gaps in research and service programs.

Management—Does co-administration enhance or detract from:

- capacity to recruit and retain talented leadership;
- organizational management functions, for example, planning, priority setting, budgeting, and program evaluation;
- effectiveness of dissemination of research findings into clinical practice, as well as the translation of clinical issues into research priorities.

The committee used two approaches to obtain and analyze the information pertinent to the questions being addressed:

1. *categorical analyses* (i.e., case studies of disease-specific research and service development and demonstration programs conducted by different agencies, which are used to analyze the effects of differences in organizational arrangements; and
2. *functional analyses* of operational activities that are thought to be most sensitive to differences in organizational structure.

Thirteen background papers (3 case studies and 10 functional analyses) were commissioned to help the committee grapple with the criteria listed above. These 13 papers provide the basis for the analysis, conclusions, and recommendations in the chapters that follow.

CATEGORICAL ANALYSES (CASE STUDIES)

The committee commissioned three case studies on the following topics: (1) Alzheimer's disease, (2) substance-abusing pregnant women, and (3) dopamine research related to schizophrenia and Parkinson's disease. Several criteria were used for choosing the three studies. As a whole they were to represent:

- significant areas of research for both the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA);
- an aspect of service development in the Public Health Service (PHS), either in ADAMHA or the Health Resources and Services Administration (HRSA), and of prevention programs in NIH, ADAMHA, or the Centers for Disease Control (CDC);
- research in different stages of maturity in terms of providing a basis for treatment options;

- different types of research (e.g., social and behavioral, biomedical, clinical, epidemiological, health services research, and demonstrations);
- different funding patterns and trends; and
- differences among the external forces that shape federal programs (e.g., constituency groups, congressional interest, and social forces).

The case study approach permitted discrete, detailed, yet cross-cutting analysis of the many issues facing the committee. Analysis of the details of research grants within discrete categories also provided a manageable means for assessing duplication in research programs. Each case study was supervised by a task force composed of experts in the field, and each was written by an individual knowledgeable in the field.

Underlying Principles for the Case Study Method

The case study method, with its ability to collect, integrate, and interpret large amounts of information from a variety of sources, seemed to provide the most promising means for developing an analytic framework to understand the complexities of policy development for health-related research and service programs. The case study method has its limitations, however: time and resources preclude more than a few intensive case studies, and no case study, by itself, can be representative of the full spectrum of research and service programs, or the full spectrum of institutes, within NIH and ADAMHA. It is therefore necessary that the case studies *as a group* represent different types of research and services programs and projects, a variety of organizational approaches, special populations, involvement of different levels of government, varied kinds of financing, and different political climates in which research and service programs have developed over time.

Each of the three case studies chosen by the committee represents a number of issues with regard to stages of research and services and the linkage between federal research and service programs:

1. *Alzheimer's Disease*. This case exemplifies early stages of research and the difficulty of linking research to service development programs when the underlying disease process is not sufficiently well understood to be treated. It focuses on how approaches to research and services differ from cases in which service provision is more

directly related to research findings. Because research is funded by a number of PHS institutes, coordination of research priorities was a focus in this case.

2. *Substance-Abusing Pregnant Women*. This case exemplifies a combination of several stages of research: one mature area of research (smoking), one area of research approaching maturity (fetal alcohol syndrome), and one new research problem (cocaine-addicted mothers) with overlapping issues. Collaborative efforts by agencies (HRSA and the former Office of Human Development Services, each of which has responsibility for the development of policy and programs related to the impact of maternal addictive behaviors on children) were explored in this case. Issues of replication and duplication of demonstrations (administered by the Maternal and Child Health Bureau in HRSA, and by the Office of Substance Abuse Prevention [OSAP] in ADAMHA) can be assessed in this case as well.
3. *Dopamine Research (Parkinson's Disease and Schizophrenia)*. These are two diseases for which the etiology is unknown and for which pharmacological treatment for symptomatic relief is widely used but rarely completely effective. Research focuses on pharmacological interventions, and services focus on chronic, long-term care. This case study explored communication among basic scientists addressing the same area of research across institutes and agencies; it also examined the translation of clinical findings into the service delivery sector (i.e., drug development) and the translation of clinical observations from the service delivery sector into new research priorities.

A standard outline was used to guide the case study writers (Figure 3-1). The findings of the case studies are presented below, following a brief description of the nomenclature and the process used to classify research grants within the case studies. The nomenclature is described in detail in Appendix B. This classification activity served two purposes: (1) to help paint a broad picture of the research portfolios of the agencies in selected categorical areas (i.e., the case studies), and (2) to serve as the basis of the analyses of replication and duplication (see Chapter 5).

NOMENCLATURE AND CLASSIFICATION

A significant problem arose with regard to classification of research projects. As described in Appendix B, the committee found no acceptable, universal nomenclature for describing research and services programs. It therefore developed its own for use in this study,

FIGURE 3.1 Outline for Case Studies

A standard outline was used by each of the case study writers for collecting and analyzing information. It is described below:

I. What are the current research, service, and prevention programs?

A. Allocations

B. Loci—agencies, institutes, bureaus, etc.

C. Foci—basic research, clinical applications demonstrations, services development

What are the separate objectives of current programs? If objectives were aggregated, do they amount to a national policy, or are there conflicting objectives generated from different constituencies?

II. How did programs develop historically? What groups or factors were involved in the historical development of the programs and in establishing their objectives?

A. Particular leaders

B. Constituencies

C. Scientific discoveries

III. How do we evaluate research, service, and prevention programs in terms of the two objectives of the study? Possible outcomes include, but are not limited to, the following:

A. Research and research-supported programs are effective, or the obverse

B. Service development and demonstration programs are effective, or the obverse

C. Research is having a transfer impact that helps promote service effectiveness or efficiency, or the obverse

D. Service feedback is informing the development of the research agenda (e.g., services per se, service demonstrations, clinical applications, etc.), or the obverse

E. Is there evidence of public/private exchange of knowledge from basic biomedical research through health services research and service delivery?

F. Is there favorable or unfavorable duplication, or complementarity of research (e.g., research reaching different populations, healthy competition, etc.) versus waste and turf battles?

V. Summary

To what extent can outcomes be attributed to co-administration or the lack of it? To what extent can outcomes be attributed to ad hoc phenomena such as leadership, important events including scientific events, politics of researchers, or politics of health status constituency groups (health care providers, patients, families, etc.)?

based on an extensive search of the literature related to classification systems for health research.

Information for classifying research grants within the case study areas was obtained from the NIH Division of Research Grants (DRG), which manages the Computerized Retrieval of Information on Scientific Projects (CRISP), a database of all PHS-funded grants. CRISP includes extramural grants, research contracts, and cooperative agreements, as well as intramural projects. Each grant is described by key words, which allow the grants to be identified by topic, rather than by institute or funding mechanism.

Grant information for selected years (1975, 1978, 1982, 1985, 1987, and 1989) was classified according to the committee's nomenclature (see Chapter 5). Grant titles were sufficient for classification in many instances; abstracts and lists of the key terms provided additional information. CRISP lists subprojects falling under program

project grants, research centers, and general clinical research centers separately; the committee classified these individually.

In some years, the grants for a particular case study were so numerous as to warrant sampling. In Alzheimer's disease, for example, one of every three grants in 1982 and one of every seven in 1985–1989 were used for classification purposes. For fetal alcohol syndrome related to the maternal addictive behavior case study, one of every two grants for the years 1982–1989 were classified. With these exceptions, all other years and areas of research were assessed in their entirety.

Difficulties in Grant Classification

Classification of grants within case study areas presented several difficulties. Grant listings were not available in a tape format, which precluded electronic transfer and extensive manipulation of the data. This computerization problem emerged only after the study had been under way for close to a year, and there was insufficient time to make other arrangements. The records were therefore entered by hand, which limited the amount of information available and the depth of the committee's analyses.

A second problem was lack of information about the dollar amounts of some awards. For example, CRISP contains no information on dollar amounts for intramural research projects. In addition, the CRISP listing of awards for subprojects of a multiproject grant (e.g., a clinical research center or a program project grant) shows the *average* of all subproject awards on the grant—not the actual amount for a particular subproject. This problem weighs heavily in any analysis, since centers and program project grants constitute a sizable portion of research funds. Furthermore, the costs of different kinds of research vary greatly, making comparisons difficult. (For example, epidemiological or health services research based on existing data sources is considerably less costly than research requiring many animals, particularly subhuman primates, or expensive equipment.)

Given these difficulties with ascertaining the actual *funding* appropriated for research projects, the committee moved to an investigation of the number of grants funded in a particular category of activity. Data on this parameter were considerably easier to assemble because NIH uses the *number of grants* in an area as part of its overall planning and budgeting process. Nevertheless, even this seemingly straightforward information was not always available.

For example, it was difficult to retrieve data from the CRISP system on projects in certain categories. The committee requested special searches for health services research, demonstrations, [1] information dissemination, epidemiology, and social and behavioral research. Yet many of the grants identified by CRISP within these categories bore no relationship to the topics the categories appeared to cover. For example, a search of the health services research area identified grants on epidemiological assessments of Alzheimer's disease, patient education programs, effects of the endocrine system on aggression in rats, training programs, assorted surveys, and general core support components of clinical research centers. The search on information dissemination programs in schizophrenia retrieved health status research grants on information processing and sensory system integration in schizophrenia.

In these two instances, the committee sought other sources of information on which to base its deliberations. In the first case, it arranged a meeting of federal health services research administrators to discuss various aspects of health services research, including the effects of different organizational arrangements on programs. The meeting included representatives from the National Institute of Mental Health (NIMH), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), the Office for Treatment Improvement (OTI), the Office of the ADAMHA Administrator (OA), the Agency for International Development (AID), the Department of Veterans Affairs (VA), the Agency for Health Care Policy and Research (AHCPR), and NIH. In the second case, the committee based its discussion of information dissemination activities on an evaluation of five information dissemination programs in the PHS and on information from interviews for the case studies.

In defense of the CRISP system and the Division of Research Grants (DRG), which is charged with its operation and maintenance, the committee notes that the system was not designed specifically to provide the information being sought. On the other hand, as the only systematic source of information for both NIH and ADAMHA, the committee used it for classification, supplementing where possible with data gathered through other means. The system was most problematic for those research and research-related categories to which the PHS devotes the smallest amount of resources. It was most valuable for its information on basic and clinical biomedical research.

In sum, the information assembled by the committee through its classification effort paints a broad picture of the PHS and is not an exact accounting of agency research portfolios. The five main categories used in the following discussions are (1) health status

research, (2) health interventions research, (3) systems development, (4) services, and (5) information dissemination (see Appendix B for details). The areas the committee found most amenable to classification were health status research and health interventions research (with the exception of health services research and research demonstrations).

CASE STUDY OF ALZHEIMER'S DISEASE

A large proportion of Alzheimer's disease (AD) research is health status research (due to a lack of discoveries immediately applicable to interventions) and research in humans (due to the lack of satisfactory animal models for AD).[2] The large influx of funds for AD research (Figure 3-2) has greatly increased the knowledge base regarding the

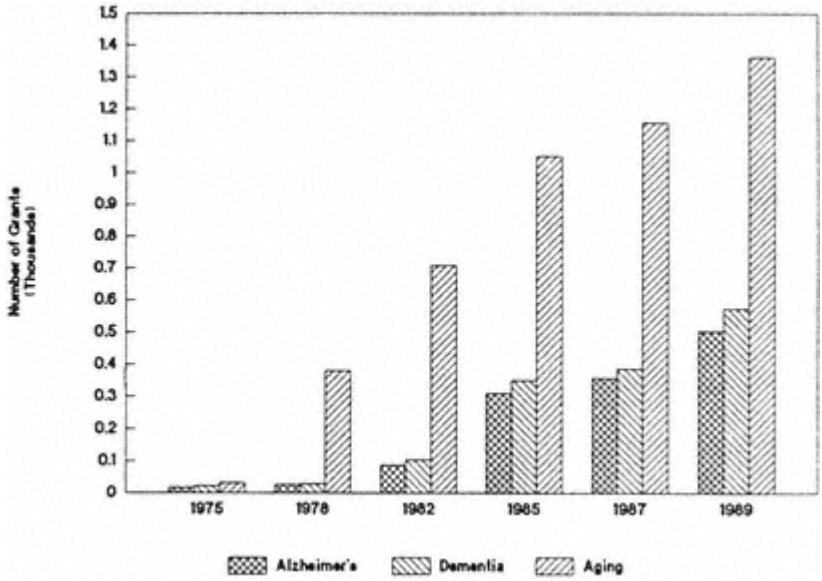

Figure 3-2 Grants for Alzheimer's disease research. The number of research gra nts
on aging has grown dramatically since 1975, as have the grants in dementia and Alzheimer's disease. The data suggest that the vast majority of dementia researc h is
on Alzheimer's disease and that Alzheimer's disease is a large component but n ot the only focus of aging research.
Source: National Institutes of Health CRISP system.

molecular and chemical nature of the disease. Health interventions research has not progressed as rapidly (although there currently are many promising leads) because the health status research is not at an appropriate stage for translation into medical interventions. The major intervention for people suffering from AD is long-term custodial care. Due to the stress of chronic care, which is provided in most cases by the family, research programs on caregiver stress are also being developed.

The National Institute of Mental Health (NIMH), the National Institute of Neurological Diseases and Stroke (NINDS), and the National Institute on Aging (NIA) all sponsor significant research programs in AD. Many other NIH institutes also fund research germane to AD. Coordinating mechanisms, such as the DHHS Alzheimer's Disease Council and the congressionally appointed Advisory Panel on Alzheimer's Disease, serve to limit (but probably not totally eliminate) duplication in AD research between institutes and agencies. Current institute personnel and grantees interviewed for the case study firmly believe in the usefulness of these mechanisms for increasing communication and coordination and in decreasing duplication. As discussed at length in Chapter 5, the relatively young knowledge base about the cause and manifestations of AD means that most seemingly duplicative research projects or programs are in fact replicative and/or complementary.

Organizational arrangements were not considered a significant factor in the development or success of either AD research or service programs. Factors that have contributed to the success of research in AD include the foresight and devotion of particular institute personnel, an infusion of research funds, attention by key members of Congress, and biomedical and technological breakthroughs. The main factor in the inadequate service programs for AD patients is the lack of a national long-term care policy in the face of a widespread disease for which the only treatment is long-term care.

Co-administration of AD research and service programs does not exist at the agency level; rather, it is the Secretary of Health and Human Services who oversees agencies that support AD research and that provide social services and reimbursement for services. As a prominent AD researcher and clinician points out, there is little co-administration and integration of research and service programs at the federal level, as well as little integrated knowledge. Barriers to interdisciplinary research efforts exist within federal agencies as well as among professional groups and clinical sites. In fact, lack of coordination at the national level offers disincentives to organizations

such as teaching hospitals that attempt to bridge fields and integrate disciplines at the local level.

CASE STUDY OF SUBSTANCE-ABUSING PREGNANT WOMEN

Health status research on the effects of substances of abuse on the fetus has been fairly well developed and includes studies in animals and humans.[3] Health interventions research has received much less attention. Research in this field is a small subset of research in the fields of pregnancy and addiction (Figure 3-3). However, treatment and prevention programs supported by the Office of Substance Abuse Prevention (OSAP) are not related to or seemingly supported by a substantive research base.

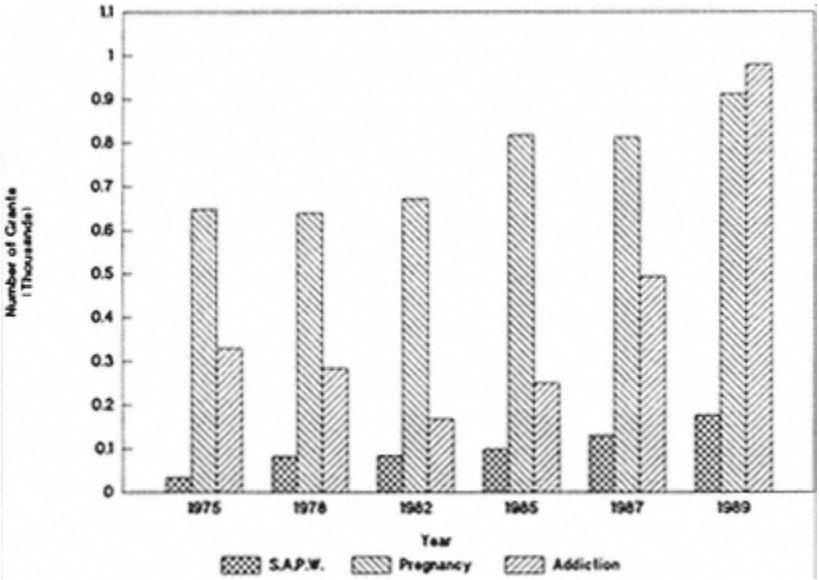

Figure 3-3 Grants for research on substance-abusing pregnant women. The data show that research into pregnancy has increased slightly since 1975. Research into addiction decreases drastically between 1978 and 1982 but has increased even more dramatically since then. Research into substance-abusing pregnant women is a small portion of pregnancy research and of addiction research.
Source: National Institutes of Health CRISP system.

In contrast to the AD case study, the concern about replication, duplication, and complementarity in programs for substance-abusing pregnant women centers on demonstration programs, not health status research. Interviews for this case study revealed two main concerns in this regard. First, there is little attention to the need to replicate research demonstrations before widespread dissemination and implementation. Second, little or no coordination occurs within the three ADAMHA units working in this area (the National Institute on Drug Abuse [NIDA], OTI, and OSAP). Demonstration programs within OTI and OSAP that are applicable to substance-abusing pregnant women are frequently administered by the same state agency or in the same city with little or no communication between the ADAMHA personnel overseeing these projects. Likewise, HRSA programs for primary care are not integrated effectively with addiction treatment programs administered through ADAMHA.

Co-administration for substance-abusing pregnant women can be found at two levels: the administrator of ADAMHA, and (when considering HRSA, primary care activities and NIH, and research on child development) the Assistant Secretary for Health, as well as the Secretary of Health and Human Services, in light of the recent creation of the Administration on Children and Families. The potential for programmatic overlap and duplication in demonstration programs and service system development activities requires attention and coordination of objectives by an official who sees all the players—namely, the Assistant Secretary for Health.

Co-administration or any specific organizational arrangement of research and service programs at the agency level was not considered to be a factor in the problems identified in this case study. Rather, the decision to give ADAMHA responsibility for programs for these women was believed to be insufficiently considered. When responsibility for programs for substance-abusing pregnant women was placed in ADAMHA, it focused the concern on substance abuse exclusively and seemed to ignore consideration of the population of pregnant and substance-abusing women using primary care programs (administered by HRSA). Other relevant concerns identified in the case study include stigma attached to alcohol and drug use, particularly in pregnancy; the general lack of attention to women's issues in federal research and service programs; congressional ambivalence about the mission of ADAMHA and the relative importance of federal and state program planning; insularity in federal agencies; and the decision to deal with ADM problems largely outside the primary health care arena.

The case study also faulted NIDA for not pursuing treatment interventions research sooner and more aggressively. Its response was slow even after the public health problem of addicted and affected babies was documented. Considerable responsibility for this failure could be attributed to neglect and to conflicting priorities between biomedical research and the development of interventions.

CASE STUDY OF DOPAMINE RESEARCH: SCHIZOPHRENIA AND PARKINSON'S DISEASE

The role of dopamine in the etiology and treatment of both schizophrenia and Parkinson's disease has been studied for over 20 years (Figures 3-4 and 3-5).[4] Health status research and health interventions research for both these diseases are well developed. The research includes a great deal of both animal and human research. There is no discernible difference in the quality or technological sophistication of the research currently sponsored by NIMH for schizophrenia and by NINDS for Parkinson's disease. This is in contrast to the 1970a and even early 1980, when many constituency groups felt that the NIMH research was inferior to the biomedical research conducted in NIH, despite substantial evidence to the contrary. Many observers attribute the recent success of the NIMH research programs to its declining responsibility for administering service programs, although a number of such activities still remain in NIMH.

There is also no evidence that these research programs and projects duplicate each other. Rather, the health status and interventions research programs focused on dopamine in the two institutes are competitive and complementary. Both institutes have high regard for the value of fundamental research and, when appropriate, this research contributes to new interventions research and new interventions. Many years of health status research have contributed to the development and evaluation in the past few years of very promising pharmacological interventions for both schizophrenia and Parkinson's disease (clozapine and deprenyl, respectively).

Health services research, demonstration projects, and service system development are supported by NIMH for the severely mentally ill. NINDS does not support any of these activities, limiting its activities to biomedical research. NIMH provides a nurturing environment for health services research and research demonstrations. Services demonstrations and service system development activities receive less support.

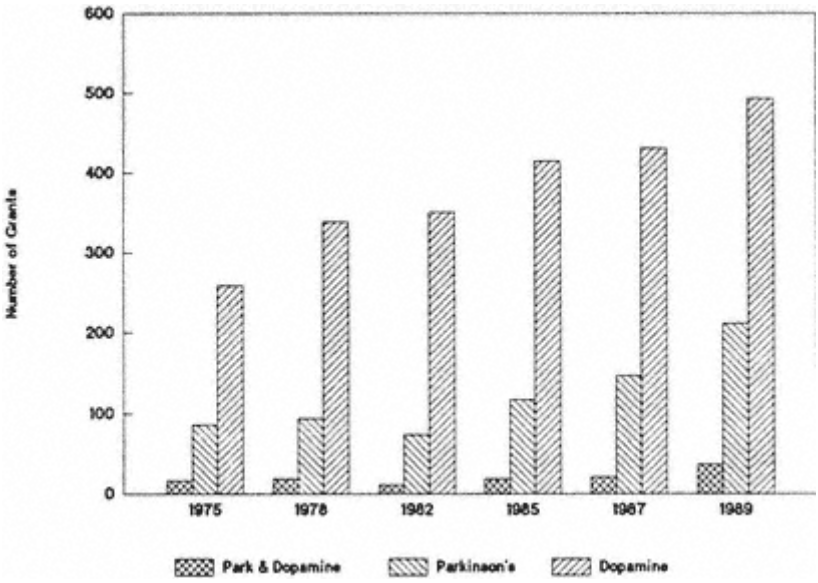

Figure 3-4 Grants for Parkinson's disease and for dopamine research. This comparison of the growth in research grants for all dopamine research, all Parkinson's disease research, and research on the role of dopamine in Parkinson's disease shows that research on dopamine has increased steadily since 1975. Research into Parkinson's disease increased particularly after 1985. The biggest factors in this growth are the discovery of the MPTP model of parkinsonism and research fundamental to neurotransplantation. Research specific to the role of dopamine in Parkinson's disease is only a fraction of the research in either Parkinson's disease or in dopamine and has increased far less than either of them. The role of dopamine in parkinsonism was already a priority in 1975, and rapid growth in this particular field would have occurred prior to 1975.
Source: National Institutes of Health CRISP system.

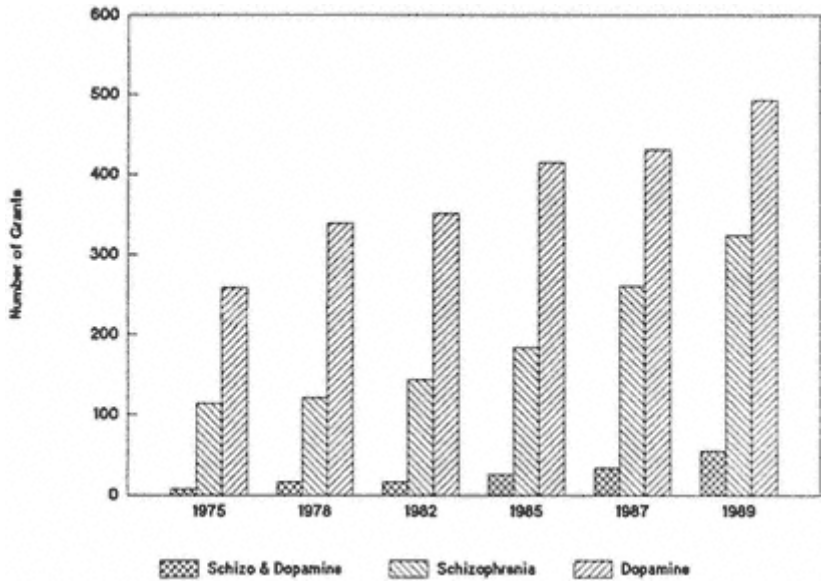

Figure 3-5 Grants for schizophrenia and for dopamine research. The number of research grants in schizophrenia has increased almost threefold since 1975, reflecting the increased attention in NIMH to severe mental illness. Schizophrenia was designated the foremost research priority at NIMH in 1986, which undoubtedly accounts for the big increase in grants between 1986 and 1989. Research grants in the role of dopamine in schizophrenia have also increased greatly between 1975 and 1989, although they are only a fraction of the total research in schizophrenia. Source: National Institutes of Health CRISP system.

Co-administration is seen, to a minor degree, at the level of the director of NIMH for schizophrenia and at the level of the DHHS Secretary for Parkinson's disease. Co-administration was not thought to be a major factor in the success of the research programs or in the relative lack of attention to service programs. (The success of the health services research program in NIMH was an exception to this opinion; it was suggested that the history of service development and demonstration programs in NIMH provided fertile and nurturing ground for health services research.) Rather, the leadership of the research institutes, the missions of the institutes and agencies, and the desires of constituency groups played the major roles in federal programs for schizophrenia and Parkinson's disease.

FUNCTIONAL ANALYSES

In addition to the case studies, 10 analyses were conducted in functional areas that were considered most sensitive to differences in organizational structure. Study staff prepared some of the analyses; other papers were commissioned. Brief summaries of their findings follow.

Planning, Priority Setting, and Budgeting

The policymaking system is complex, changing, convoluted, and (since public financing is involved) inherently political.5 In fact, there are multiple systems operating simultaneously, frequently with only minimal coordination. The major dichotomy that seems to arise is between what might be termed program planning (i.e., the content of the programs) and the budget planning and review process (which determines how much money will be available for a particular activity). This dichotomy is particularly evident in the research programs of ADAMHA and NIH, where the budget review process does not become involved with the actual content of the research programs (which is left to the individual institutes, divisions, and disciplinary study sections).

Priority setting involves the entire complex process by which decisions are made concerning the direction and level of support for federal programs. There is no single coherent system that can be labeled priority setting; rather, it is the result of myriad discrete activities (involving congressional committees, the administration, the research and service communities, and individual program managers).

At the level of Congress and the administration, the annual budget is the only "plan." Budget decisions are largely incremental, and the most important single factor in determining the current year's budget is the past year's budget. Exceptions are relatively rare and reflect either major policy issues (such as concern about drug abuse and AIDS) or the specific concerns of key individuals in Congress or the administration. In the budgeting process, there are relatively few discussions of trade-offs between programs, especially between programs of different types. At no level of budget review, above the programs themselves, is there evidence of an analytic or fact-driven approach to determining resource allocations.

With regard to budget increases, there is a de facto PHS policy to treat the research programs of ADAMHA and NIH similarly. Breakthroughs or advances in the state of science generally command more

attention and give rise to budget increments greater than those adopted for the overall research budget. However, any differences in the final appropriations for the various institutes tend to reflect congressional interests and the effectiveness of various constituency groups. The content of research program is rarely considered in the budget process except at the level of individual programs. Discussions in Congress focus instead on such issues as the number of new and continuing grants, types of awards, indirect cost rates, and pay lines.

Organizational Arrangements for Health Services Research in Federal Agencies

A number of federal agencies devote significant resources to health services research programs: (1) the Office of Veterans Affairs (VA), (2) AHCPR, (3) ADAMHA, and (4) the Agency for International Development (AID).[6] Health services research programs are located in very different parts of the organizational structures of each of these agencies. Important considerations include the interaction of health services researchers and service providers, collaboration within and across agencies, flexibility in allocating resources, broadening the constituency for health services research, equality of health services research and other research, stable leadership, and the policy orientation of research.

Integral to this analysis was the identification of three types of demonstration projects: (1) research demonstrations, (2) service demonstrations, and (3) technology introduction demonstrations. Health services research methodology has much to offer all three types of demonstration projects and therefore needs ties to agencies, institutes, and offices administering either research or services programs. Likewise, demonstration projects of all three types benefit from ties to health service research, which serve to strengthen the evaluation of costs and effectiveness. To some degree, demonstrations and services development programs administered by HRSA have suffered from a lack of capacity in that agency to conduct health services research.

No single organizational arrangement was identified as superior to all others; health services research is such a broad category that the specifies of the research topic need to be considered. However, certain general pros and cons can be identified. The advantages of placing responsibility for health services research and demonstration programs at the *division level within an institute or office* include the ability to work more closely with service providers in setting a

research agenda, equality with other divisions (which increases the ability to collaborate across divisions), and the depoliticalization of demonstrations. The disadvantages are loss of visibility for service demonstrations, difficulties in reaching across agencies from the division level for collaboration, and isolation from policymaking.

The advantages of placing the responsibility at the *institute or agency level* are a broader constituency for health services research, less difficulty in reaching across agencies to collaborate, and greater visibility for demonstrations. The disadvantages are that a broader constituency for health services research can lead to more difficulty in reaching down into the division to promote collaboration, and that increased policy sensitivity of demonstrations leads to difficulties in objectively administering the programs.

Research and Service Demonstrations and Block Grants

Demonstrations are used in DHHS for a wide variety of purposes.[7] Broadly, a demonstration may be defined as "a project involving the use of an innovation and operating at or near full scale in a realistic environment for the purpose of: (1) formulating national policy, (2) improving national programs, or (3) promoting the use of the innovation."[8]

Demonstrations can be either research oriented or service oriented. Research demonstrations serve to develop, test, and evaluate health service activities, as well as to foster the application of existing knowledge through experimental studies in services settings. Service demonstrations develop and provide new services for rehabilitation, treatment, and prevention of illness. In research demonstrations, services must be designed around a set of hypotheses; in services demonstrations, evaluating specific interventions is secondary to demonstrating the ability to develop and provide a set of new services to a specific population. In addition, two other types of demonstration activities are administered in ADAMHA and HRSA (see the definitions in Chapter 4). This paper discusses several paradigms for the research-services continuum in which demonstrations play an important role. The large recent increases in appropriations for demonstration programs in ADAMHA have been attributed to congressional displeasure with the declining federal role in service development that followed enactment of the block grant program.

The passage of the Omnibus Budget Reconciliation Act of 1981 substantially altered the administration of many of the major service

programs in the PHS, consolidating individual categorical services programs under broad-based block grant programs. PHS agencies that administer block grant programs are ADAMHA, HRSA, and CDC. Although mandated by the same legislation, historical and administrative differences between the block grant programs within PHS agencies have had a direct bearing on the relationship of research and services in the respective programs. The office and personnel responsible for administering the block grants changed repeatedly in all three PHS agencies, beginning in 1982. Currently, OTI is responsible for administering the drug abuse portion of the block grant, while NIMH administers the mental health portion of the same program.

Changing the funding mechanism from categorical grants to block grants significantly altered the federal role in health services delivery. The message sent to the agencies was to work under a "hands off" policy. In addition, the subsequent dismantling of national data collection efforts meant that there is no information about how the block grant funds are being used, who is being served and how, and what needs remain.

Information Dissemination

This paper reviewed the literature on information dissemination activities and described several information dissemination activities sponsored by PHS agencies and institutes including the following:

- Depression/Awareness, Recognition, and Treatment Program;
- National High Blood Pressure Education Program;
- Diabetes Control Activities in High-Risk Populations;
- Treatment of Early-Stage Breast Cancer; and
- Alcohol Warning Labels.[9]

Information dissemination efforts vary greatly, depending on the stage of the knowledge being disseminated, the audience to whom the effort is targeted, the resources dedicated to it, and the measures used to evaluate it. The single most important determinant of the success of any information dissemination activity is the charisma, dedication, and leadership qualities of the person spearheading the effort. Current organizational arrangements did not affect dissemination efforts. This lack of effect was seen when the dissemination efforts required collaboration between agencies or within agencies, or when agency

and institute dissemination efforts were directed specifically at practitioners in the field.

The problem most frequently identified was the difficulty in evaluating the success of dissemination programs. Much of the evaluation is inferential; efforts at increasing professional knowledge are easiest to evaluate, whereas activities aimed at the general public are extremely difficult to evaluate. For example, evaluation is reportedly a missing element in the information dissemination process related to diabetes. CDC is attempting to find funding to do a longitudinal study of the impact of its training materials; federal funding for such an effort is unlikely, however, and the agency is seeking foundation support.

There is little or no support in the federal system for "classical" evaluation, in which the plan for data collection and monitoring is developed and implemented at the beginning of the program. Rather, evaluation is usually attempted at a later stage, retrospectively, as an effort to "look back and figure out what the program did." In the absence of a clear commitment to evaluation, and with few resources available for the collection of data and for other activities on which effective evaluation depends, it is not surprising that little is known about the relative effectiveness of the various methods of information dissemination and their impact on targeted populations.

Constituency Group Relations with Federal Agencies

This paper discusses constituency groups and their relationships with research and service agencies in the PHS, focusing on the effects on constituency groups of federal organizational arrangements for the administration of research and services programs and the related issues of mission and leadership.[10] Perceptions varied, but the interviews suggest that a consensus exists on the importance of (1) clarity of agency missions, as well as stability of program placement and leadership, and (2) the need for coordination of programs across agencies.

Both the interviews and the history of different federal programs suggest that organizational arrangements are of particular importance when a constituency group perceives a need for a focal point for its concerns, an increase in the priority given to an area, and/or increased linkage between research and service activities. A focal point is more important to constituency groups interested in services

development than it is to groups interested in science policy because science policy is represented in all NIH and ADAMHA research institutes, as well as in the NIH Office of the Director and the ADAMHA Office of the Administrator. Arrangements may also be of concern when they are perceived to affect program funding. Organizational arrangements per se, although important, were not found to influence the style of a constituency group's involvement with an agency—that is, how it goes about the business of building relationships with programs and the repertoire of advocacy techniques that it uses.

Linkage Mechanisms Between Research and Service Programs

This paper describes and analyzes linkage between six research and service programs in federal agencies.[11] The six examples provide evidence that the classic research and development continuum does not apply to all situations in which research and services programs are supported or administered by federal agencies. No single model can be used to describe the complex relationships among different types of research, evaluation, and the operational environment in which services are delivered. Each situation contains volatile policy controversies; in each the relationship between services and research is variable, and the specific formulation depends on the nature of the policy area, differences in federal policy roles, the nature of the target population, and the type of research required.

The paper also presents evidence that organizational location may be an artifact of history and, as such, is difficult to relate to measures of technical program effectiveness. There is evidence that research units can establish linkages and boundary-spanning activities with the world of operations and services if and when the work of the organization is perceived to be important enough to demand new modes of operation.

The Research Process: Replication and Duplication

Concern over potential duplication of research between two large research agencies spurred the second charge to the committee.[12] This paper uses examples to explain the need for replication as part of the scientific process. It describes situations in which duplication

knowingly occurs and is not to be discouraged. It also explains the importance of sponsoring complementary research, which sometimes may appear to be duplicative.

Duplication of research projects probably occurs, but it is not felt to be a major problem. Mechanisms exist to decrease, but certainly not eliminate, wasteful duplication. These mechanisms include pressures brought to bear by the scientific community, the peer review process for grants and journal articles, computerized databases for the published literature, administrative mechanisms in the Division of Research Grants, and inter-and intra-agency coordinating mechanisms for areas of research that are particularly cross-cutting and extensively investigated.

History of the Public Health Service

Several important and relevant historical trends can be observed in the evolution of the agencies within the PHS.13 Although it has been 17 years since the last major reorganization, the "new federalism" has had a decided impact on the organization of PHS agencies. Although the larger structure of the PHS has remained relatively unchanged, this impact is revealed through changes in the internal structure of the agencies, particularly those responsible for the administration of block grant programs.

The change from categorical grants to the block grant system resulted in a significant decrease in federal leadership in implementing domestic policies. Although service activities have been deemphasized since 1981, ADAMHA continues to have funding mandates for services and demonstration programs. Within the past 5 years, congressional authorization for demonstration and services programs that target specific diseases or populations has increased significantly.

Authorizations, Missions, and Appropriations

Congressional authorization and mission statements influence the culture and activities of government organizations.[14] An agency's mission drives both its culture and its structures. The PHS mission with regard to administration and funding for health care services programs, historically and in the present, remains less clear than its biomedical research mission.

Interviews and case studies revealed significant confusion on the agency level about federal expectations for services funded through

block grants administered by states and localities. In addition, continuous changes in the organizational placement of services demonstrations and block grant programs administration have had some negative effects on constituency group relationships with federal agencies and have raised questions about program effectiveness.

Allocations to Health Research and Service Programs

Analyses of research and service allocations were conducted (1) to establish trends over a 17-year period within NIH, HRSA, CDC, ADAMHA, and the PHS as a whole and (2) to assess perceptions that changes in allocations had differed over time for agencies and institutes.[15] In the past 8 years, research budgets have increased by similar rates for NIH and ADAMHA. Although research budgets increased in ADAMHA institutes subsequent to the initiation of the block grant program, there is no evidence of causality or direct correlation between the two events.

In the past 5 years, block grant and service demonstration allocations have increased massively across the PHS. The interpretation of those interviewed is that the increase in appropriations for demonstrations reflects congressional discomfort with a declining federal role in service development. Some suggested that research has benefited from recent social perceptions of drug abuse as a major societal problem, others that discontinuation of institute responsibility for administration of services and services development programs has allowed institute leadership to focus on the quality of research and on increasing research allocations.

HRSA has suffered the most in its allocations over the last 17 years. Its decreasing allocations have been attributed both to congressional and PHS ambivalence about the services mission of the PHS and to its limited ability to evaluate the costs, effectiveness, and efficiency of the programs it funds.

NOTES

1. Institute of Medicine staff report, "Demonstrations and Block Grants in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service,

Springfield, Va.* Demonstrations presented yet another set of problems in that it was difficult to categorize demonstration projects as either research or service demonstrations on the basis of the information in the system.

2. C. E. Blixen, "Case Study on Alzheimer's Disease," prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

3. L. V. Klerman and M. A. Johnson, "Case Studies of Substance-Abusing Pregnant Women, Their Infants and Children," prepared for the IOM Committee on Co-Administration of Service and Research Program of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

4. K. Stratton, "Parkinson's Disease and Schizophrenia: Dopamine and Beyond," prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

5. R. Schmidt, "Research Planning and Priority Setting in the Alcohol, Drug Abuse, and Mental Health Administration," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.; R. A. Walkington, "Planning, Priority Setting, and Budgeting in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

6. S. Williams, "Health Services Research in Federal Agencies," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

7. Institute of Medicine staff report, "Demonstration and Block Grants in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

8. T. K. Glennan, Jr., *The Management of Demonstration Programs in the Department of Health and Human Services* (Santa Monica, Calif.: RAND, 1985).

9. Institute of Medicine staff report, "Information Dissemination in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

10. P. Kaye, "An Analysis of the Effects of Organizational Arrangements for the Conduct of Research and Services on Constituency Group Relations with Federal Agencies," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NTH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

11. B. A. Radin, "Linkage Mechanisms in Services and Research," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

12. J. Fox, "Report on Scientific Methodology," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

13. C. C. White and R. S. Hanft, "The Changing Relationship of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.; R. A. Walkington, "The Health Resources and Services Administration: Evolution and Current Programs," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

14. Institute of Medicine staff report, "Authorizations, Appropriations, and Missions," prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

15. R. A. Walkington, "Allocations in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

* For readers interested in obtaining copies of these papers, the full address of the National Technical Information Service is 5285 Port Royal Road, Springfield, VA 22161; telephone 703-487-4650.

4

Co-Administration of Research and Services

OVERVIEW

This study was conducted against a background of shifting opinion within Congress and among constituency groups about the roles, responsibilities, and organization of federal agencies that administer health-related research and service programs. Congressional legislation over the past five years has increased federal oversight of block grant and demonstration programs. Increased funding and authorization of new demonstration programs, as well as large increases in block grant funding for drug abuse treatment programs, brought with them increasing interest by Congress to ensure that funds were reaching their target populations. New offices and programs were created within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to administer a complex of treatment and prevention programs for drug abuse. In another example, a new agency was created in the Department of Health and Human Services (DHHS) as recently as the spring of 1991 to provide a focus for federal demonstration and block grant activities related to children and families.

As noted in the introduction to this report, the committee agreed at its inception to conduct a study that would explore the pros and cons of co-administration of research and services programs at different levels of the Public Health Service (PHS): the institute, bureau, or office level; the agency level; and the level of the Office of the Assistant Secretary for Health. The committee sought to determine the effects of co-administration of research and service programs in three areas: (1) organizational goals and level of funding at the institute and agency level, (2) clarity of the missions of the PHS as a whole and of individual agencies, and (3) relationships with constituency groups.

However, the effectiveness of the organization of research and service activities is also expressed (4) in management functions such as planning, priority setting, and budgeting; (5) in the creation of mechanisms to allow for timely response to new information and policies such as research information and service problems; (6) in the development of mechanisms for effective dissemination of research findings into clinical practice, as well as for identification and translation of clinical issues into research priorities; and (7) in mechanisms for recruitment and retention of talented leadership. The committee evaluated each of these functions for ADAMHA and, as appropriate, for the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA), as well as for the Public Health Service (PHS) as a whole.

This chapter begins with a discussion of the goals and missions (including funding) of the PHS and its agencies and then moves to a discussion of the research-services continuum—the relationship between research and services programs in the PHS. It continues with a discussion of management issues, including planning, priority setting, and budgeting; timeliness of response to new information and policies; and dissemination. It then discusses organizational effectiveness as seen in research, demonstration, and services development programs and concludes with a discussion of organizational capacity and program placement.

RESEARCH AND SERVICES MISSIONS OF THE PHS

Congressional authorizations and statements of mission strongly influence the "culture" and activities of government organizations. Within DHHS, in some instances, the management of programs is assigned to a specific agency. In other instances, management is assigned to the Secretary, who may delegate primary program responsibility to one or more specific DHHS components. A department or an agency's mission is the purpose for which it was established. However, missions are more than statements of task. Goals and missions "describe what it is hoped the organization's activities will do and produce; they say something about what and who is important...."[1]

While goals and missions, in and of themselves, do not define the organizational structures that are required to carry them out, they do define the arena within which government organizations can operate and the activities for which they will be held accountable. As

statements of purpose, missions heavily influence both the culture of federal organizations and their structures. Controversy over the goals that a government organization should pursue, however, can create significant obstacles for the performance of a government organization.

To many current federal administrators and constituency groups interviewed for this study, the missions of NIH and ADAMHA are the same. To others, the greater apparent broadness of ADAMHA's mission (which includes dealing with "health problems and issues associated with the use and abuse of alcohol and drugs, and with mental illness and mental health"2) suggests significant differences from NIH in its responsibilities related to clinical applications and funding of services. Interviews with current agency and institute directors, as well as with constituency groups, point out that the basic biomedical and clinical research mission of NIH and ADAMHA is in little doubt. A review of the history of the PHS and its agencies suggests that clarity about the research mission of the PHS has been a critical factor in the growth and development of research programs and structures within NIH institutes and, increasingly, within ADAMHA institutes.

Interviews conducted with current agency and institute directors suggest that the ability to achieve a coherent federal mission at the agency, institute, or bureau level is important for a number of reasons. Primary among them is that a coherent mission allows for the consistent recruitment of institute and agency executives with similar backgrounds. Achieving such a mission can be impeded, however, by external factors that have an impact on how the organization perceives its mission. Differences of opinion among multiple and often fragmented health constituencies as well as the political autonomy of state and local governments (combined with grants-in-aid, e.g., formula grants over which secretaries and directors have little direct control) can affect the way an agency defines its purpose. During the 1980s, for example, the priorities of ADAMHA, in the view of most constituency groups, shifted from services to research. Interviews with constituency groups indicate that the shift has been viewed positively by the constituent community with research interests. It has been viewed negatively, however, by a number of services-related groups that have continued to look to ADAMHA for national leadership on such policy issues as reimbursement for mental health and substance abuse services. These groups expressed particular concern that, as the institutes within ADAMHA redefined their missions, previously assumed leadership roles in services policy have diminished or disappeared and have not been

taken up structurally at other levels of the organization. As ADAMHA institutes have become more focused on biomedical research, therefore, services-related constituency groups have shifted their efforts either to other organizational units within ADAMHA that are more directly related to their concerns (e.g., the Office of Treatment Improvement [OTI], the Office of Substance Abuse Prevention [OSAP]) or to agencies outside of the PHS.

Interviews conducted for the committee's analyses of demonstration and block grant programs confirm the finding of the Lewin Report of 1988: the shift to block grant funding of most health-related services in the early 1980s resulted in a decrease, if not total elimination, of the federal role in transforming the way basic services are provided at the local level and in ensuring that monies directed toward populations with special needs indeed reach them. There remains significant confusion about the PHS mission with regard to services development, especially regarding expectations for services funded through block grants that are administered by the states. Although it is well known among the states that federal oversight of block grant programs (particularly with regard to drug abuse) has increased in the past several years, officials in OTI and the National Institute of Mental Health (NIMH) have noted, for instance, that many state program directors seem bewildered by and resistant to planning and needs assessments related to block grant programs.

The problems that arise for federal agencies from conflicts between the agendas and expectations of Congress and the administration can be formidable. The administration and Congress often fail to define their goals clearly, and when they do define their goals with some precision, they often conflict. Even when the administration, Congress, and the agencies are in some agreement about their goals, they may disagree about how to accomplish what they want to accomplish. Although the administration and Congress are powerful in setting the agenda for federal agencies, "they do not necessarily control the alternatives among which authoritative choices might be made.[3] " These conflicts can result in insufficient resources being applied to a problem, inability to develop appropriate organizational structures for implementation, simple failure to initiate a program, or a deluge of demands for clarification of new legislation in the face of established, perhaps long-standing, policies that move in the opposite direction.

Interviews for the study also revealed that confusion exists among both constituency groups and federal administrators about the direction and importance of block grant programs in relation to other parts of ADAMHA's mission. On the one hand, the block grant pro

gram is viewed in OTI and in ADAMHA as part of a research-services continuum and as an important step in the process of implementation of demonstrations. On the other hand, agency officials point out that the purpose of block grants is to reduce federal oversight and provide autonomy in planning and priority setting to states and localities.

One outcome of the discrepant views of the administration and Congress about the importance of block grant programs to the missions of ADAMHA and HRSA seems to be unstable organizational placement of services demonstrations and block grant administration. In a number of instances, the agencies and organizational units that administer services development and block grant programs are not congressionally authorized (e.g., the Centers for Disease Control [CDC], HRSA, and OTI). Since the enactment of block grant legislation for funding of services programs in 1982, the organizational unit within ADAMHA responsible for administration of block grants has shifted eight times. Within HRSA, an apparent lack of political agreement on the services mission of the PHS has led to great difficulty in integrating diverse service delivery programs as well as confusion and disagreement among the administration, Congress, constituency groups, and agency staff about the appropriate balancing of priorities. During the eight years of HRSA's existence, programs have been added and deleted, changes in direction have been proposed by the administration and Congress (only occasionally in the same direction), and bureaus have been added and deleted, split and combined. "In part ... organizations such as HRSA are more bureaucratic in nature and need competent bureaucratic/administrative leadership because their mission comes largely from the political process. Their job is to execute political programs efficiently."[4]

These constant programmatic changes appear to indicate ambivalence about the services mission of the PHS. Whether this ambivalence emanates from Congress, the administration, or agency leadership and personnel themselves, the result has been a failure to develop adequate, appropriate organizational capacity and mechanisms for enacting services development and demonstration programs. Allocations for HRSA, for example, have declined steadily beginning in 1977 and at an increasing rate since the passage of block grant legislation in 1982 (Figures 4-1 and 4-2). No clear evidence could be found to support a cause-and-effect relationship, but some relationship is suggested between the decline in allocations and ambivalence about the services development and demonstration mission of the PHS. Also seemingly related to this trend is the lack of health services research capacity within HRSA that has made it difficult for that agency to

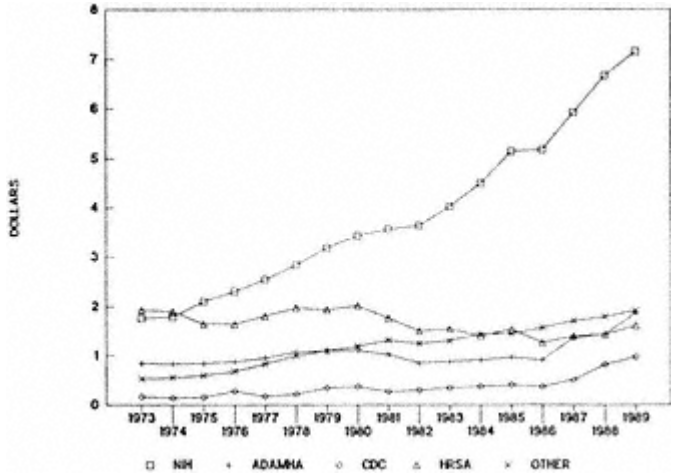

Figure 4-1 Public Health Service budget obligations in constant dollars, 1973–1989.
Abbreviations: NIH, National Institutes of Health; ADAMHA, Alcohol, Drug Abuse, and
Mental Health Administration; CDC, Centers for Disease Control; HRSA, Heal th Resources and Services Administration.
Source. Public Health Service Budget Office.

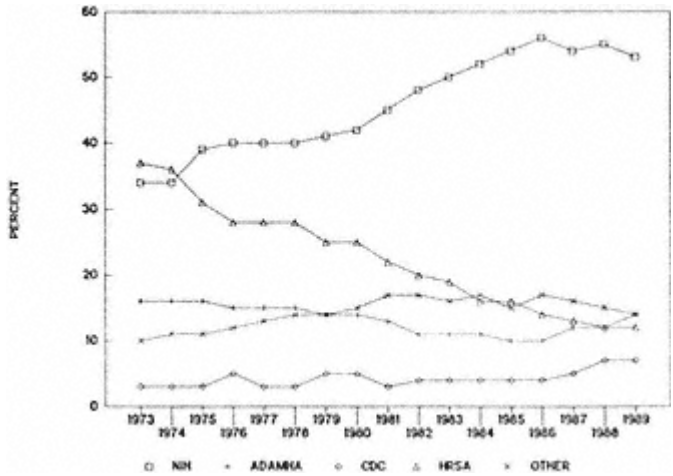

Figure 4-2 Public Health Service budget obligations as percentage, 1973–1989.
Abbreviations. NIH, National Institutes of Health; ADAMHA, Alcohol, Drug Abuse, and
Mental Health Administration; CDC, Centers for Disease Control; HRSA, Heal th Resources and Services Administration.
Source: Public Health Service Budget Office.

evaluate and defend the effectiveness, efficiency, and outcomes of its programs.

Interviews conducted with constituency groups suggest that shifts in the organizational placement of programs have made it difficult for services-related constituency groups to maintain contact with federal agencies on specific issues related to their areas of interest or to build working relationships and trust with agency and institute programs. In many instances, constituency groups have expressed dismay about changes in organizational arrangements that are perceived as eliminating or reducing the standing of programs that had served as focal points for their concerns.

The committee believes that clarity of mission is critical to accountability and to the exercise of programmatic responsibility. **To facilitate accountability within the PHS regarding the objectives of services development and demonstration programs, the committee recommends that the Secretary of Health and Human Services further clarify the services mission of the PHS (and of the agencies that administer programs related to development of the structure and delivery of services). Services programs should be given stability, including stability of organizational location, financing, personnel, and other resources.**

When responsibility for research and services development and demonstration programs for a single problem (such as substance abuse among pregnant women) is divided among several agencies, the difficulties of communicating and collaborating across agency boundaries can also inhibit success in addressing the problem. The case study of substance-abusing pregnant women pointed out that federal agencies tend to work alone unless forced to do otherwise, or unless a well-defined need presents itself. The case study notes, as a case in point, the lack of relatedness, until quite recently, between ADAMHA institutes and offices and HRSA's maternal and child health programs.

Federal legislation requires maternal and child health agencies to work collaboratively with Medicaid and other federal programs. Until very recently, however, neither Congress, nor the Maternal and Child Health Bureau in HRSA, nor ADAMHA had considered the need for collaboration between the two agencies in relation to substance abuse and pregnant women. Further, although HRSA has direct responsibility for funding primary care programs in states and localities, where a significant majority of substance-abusing pregnant women are likely to be seen (if they are seen at all), little effort was made within

the PHS until this past year to incorporate substance abuse programs into primary care settings.

Agencies may develop effective programs in isolation from each other, but implementation will probably be fragmented unless due attention is paid to settling jurisdictional disputes and creating mechanisms (at the level of DHHS) to increase collaboration across agencies. For example, a recent General Accounting Office report on drug-exposed infants made a number of recommendations that cut across agency lines: at least two related to block grant services administered by ADAMHA; two others related to support services administered by HRSA; and another related to reimbursement of services by the Health Care Financing Administration (HCFA).

There is no guarantee that several agencies working on a common problem, such as drug-exposed infants, will develop an integrated approach to the problem. The committee believes that integration of the programmatic objectives of services development and demonstration programs within the PHS is vital to the success of these programs. Attempts to integrate programmatic objectives related to science and research within the PHS (e.g., the Council on Alzheimer's Disease) seem more impressive than efforts to integrate the objectives of services development and demonstration programs. **The committee recommends that the Assistant Secretary for Health take responsibility for assessing and enhancing the integration of program objectives related to the services mission across agencies in the PHS.**

THE RESEARCH-SERVICES CONTINUUM

The ultimate goal of biomedical research is improved health of the population. One presumption that seems to lie behind questions about the effectiveness of co-administration is that biomedical research and services development and demonstration programs exist along a continuum, the end result of which is nationwide diffusion of clinical practices, technologies, and system innovations (Figure 4-3).

Figure 4-3 The classic research and development continuum.

In theory, a continuum does exist between research and services provision, but in practice, it is difficult to find mechanisms within any of the PHS agencies for carrying it out. Some models of this continuum move from basic research to clinical trials; other models include movement from basic research to changes in the structure and delivery of health care services. The utility of both kinds of models is that once the notion of stages is established, one can address the question of how to transfer knowledge from the beginning of the process through to the end. However, there are no fixed criteria to distinguish between basic research, applied research, and development, nor does the naming of these stages assist in understanding the actual processes involved in moving from one stage to another.

Some PHS agencies and institutes operate on only a portion of the research-services continuum, while others span most or all of the spectrum. Six NIH institutes (the National Cancer Institute [NCI], the National Heart, Lung, and Blood Institute [NHLBI], the National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], the National Institute of General Medical Sciences [NIGMS], the National Institute of Dental Research [NIDR], and the National Institute on Aging [NIA]) have statutory authority to support basic and applied research, clinical investigations and trials, and demonstrations. This authority sets them apart from the more limited missions of other NIH institutes.

Although NIH has often been under pressure to expand its activities to include greater emphasis on applications, it has successfully resisted numerous attempts to alter its basic mission as a biomedical research agency. Most NIH institutes, for example, provide very limited funding for health services research. This was attributed, in many interviews and discussions, to the functional organization of much of the PHS, in which the mission of health services research is primary to another unit, the Agency for Health Care Policy and Research (AHCPR).

One of the expectations in the creation of ADAMHA in 1973 was that the administration of research and services development or demonstration programs in a single agency would result in easier information transfer to the health delivery system. ADAMHA has a statutory mission to administer both (1) basic and clinical biomedical and behavioral research and (2) demonstration and services development programs. All of the ADAMHA institutes (NIMH, the National Institute on Alcohol Abuse and Alcoholism [NIAAA], and the National Institute on Drug Abuse [NIDA]) are authorized to support and conduct basic and clinical research, research training, and demonstrations. In addition, NIMH is authorized to support and administer

service development programs such as the Community Support Program (CSP) for adults with severe, long-term mental illnesses, and the Child and Adolescent Service Support Program (CASSP).

Critics object that this linear model of the continuum is not a useful concept. As a previous study of research and development programs in NIH noted:

> Trying to capture important technical and social complexities in a one-dimensional continuum oversimplifies and obscures some critical organizational processes such as transferring knowledge produced in one part of the organization to other parts, or the organization's response to the concerns of groups in the environment.[5]

Exclusive reliance on the classic, linear model has also been responsible, at least in part, for the lack of explicit attention to coordinating the various objectives of federal research and services programs.

Most of the scientific community believes that, to protect the creativity of investigators and the vigor of research, planning of research should be done by scientists using scientific criteria. For others, however, the best way to ensure progress is through targeted research efforts, maximizing immediate returns on invested tax dollars. Previous studies of medical science have been critical of this narrow, short-term approach on the basis that scientific breakthroughs often come where least expected:

> Planning for future clinical advances must include generous support for [basic, fundamental, undirected, nontargeted research] that bears no discernible relation to a clinical problem at the time ... [of its inception] ... because it pays off in terms of key discoveries almost twice as handsomely as other types of research and development combined.[6]

Or, as former NIH director James Shannon argued, an overemphasis on the immediately practical tends "to limit the likelihood of an ultimate solution of the more important problems of medicine within any reasonable time frame."[7]

These differing views have led to tension between "those who advocate increased funds for basic research, those who feel more work is needed in applying more fully the knowledge and technologies that exist, and those who believe that it is important to examine what is already in place to determine how it is working and how to make it work better."[8] While the importance of applied research has not been

at issue, a good deal of debate has occurred about the appropriate amount of resources to devote to applied research relative to basic research. The need for applied research, at a particular time and in a specific area of research, is often dependent on the basic knowledge that is available to be applied.

The relationships among applied research, applications, and implementation are less clear than the relationship between basic and applied research. As Beryl Radin notes in her background paper on linkage mechanisms, "The specific formulation depends on the nature of the policy area, the difference in federal policy roles related to the area of concern, the nature of the population with the problem, and the type of research required."[9]

In the last decade, as pressure has mounted for tangible results of biomedical research, Congress has expressed its clear intent that demonstrations, information dissemination, and technology transfer be an important part of the activities of all federal agencies engaged in research. For example, the Stevenson-Wydler Act of 1980 mandated that all federal agencies with significant research and development budgets set aside 0.5 percent of those budgets for technology transfer activities. The Technology Transfer Act of 1986 created additional incentives for the transfer and application of technologies developed from federally funded research to scientists and health professionals as well as to industry.

Models of this process (basic research leading to applications, demonstrations, information dissemination, and implementation) have been developed by a number of NIH institutes (among them NHLBI [Figure 4-4] and NCI) as well as by ADAMHA (Figure 4-5) and one of its offices, the Office for Treatment Improvement (OTI) (Figure 4-6). Each of the models represents the desirable sequence of component stages, but the process is far less linear or systematic than the models imply. Demonstrations and control programs occupy a critical position in the models for testing the feasibility of widespread use of new practices and systems innovations prior to dissemination. The effectiveness of these models in providing a framework for the development of administrative mechanisms within agencies and institutes is discussed in more detail later in the chapter.

CO-ADMINISTRATION OF RESEARCH AND SERVICE PROGRAMS

As noted in Chapter 1, the recent reorganization of ADAMHA (with the formation of OSAP and OTI and the increased focus of

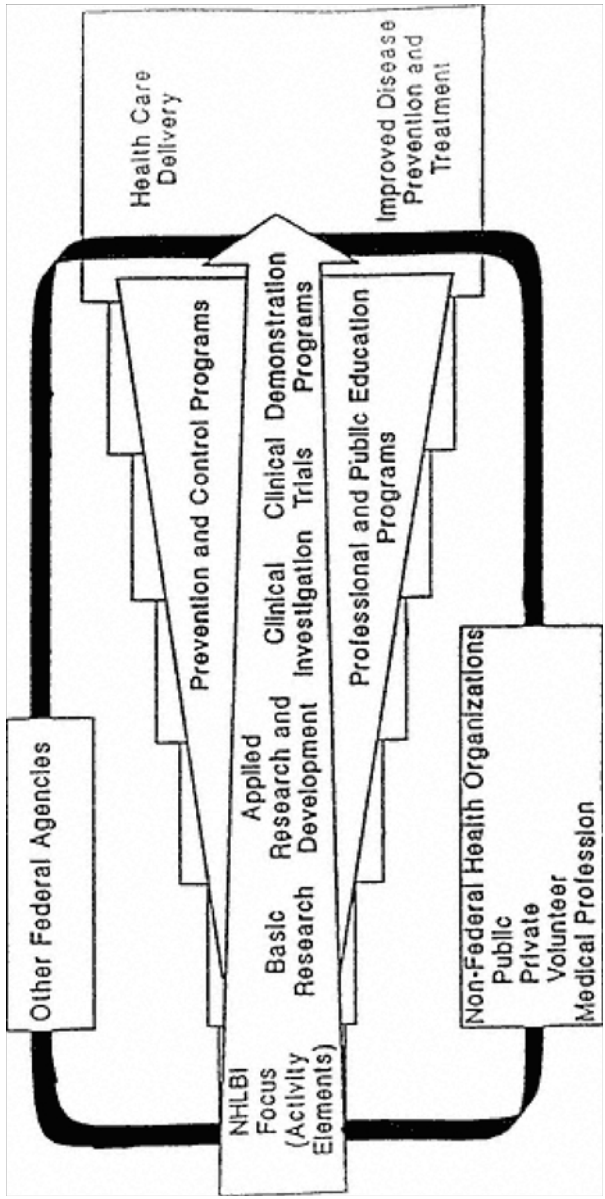

Figure 4-4 The biomedical research spectrum (also applicable to behavioral research).
Source: "Seventh Report of the Director, National Heart, Lung, and Blood Institute" (NHLBI). Prepared by CDP Associates, Inc., under contract for NHLBI.

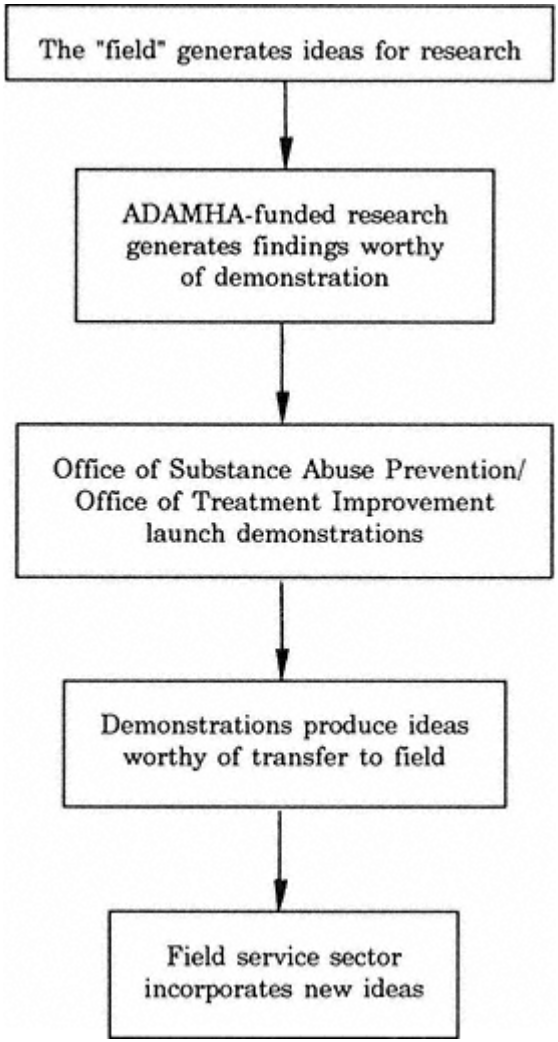

Figure 4-5 Alcohol, Drug Abuse, and Mental Health Administration research services "paradigm."
Source: R. Schmidt, "Research Planning and Priority Setting in the Alcohol, Drug Abuse, and Mental Health Administration," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991.

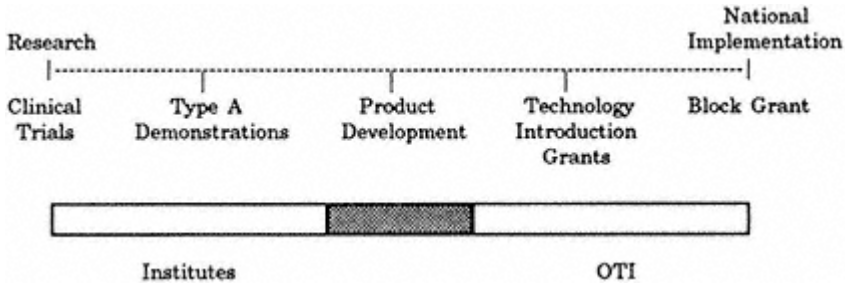

Figure 4-6 OTI treatment improvement model.
Source: L. V. Klerman and M. A. Johnson, "Case Studies of Substance-Abusing Pregnant Women," prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991.

ADAMHA institutes on research) has created, de facto, organizational units within the agency that do not differ significantly in their goals and objectives from the research, prevention, and services goals of NIH, CDC, and HRSA, respectively. Interviews conducted for the case study of substance-abusing pregnant women and for analyses of planning and priority-setting processes indicated that this functional reorganization (which removed responsibility for administration of many demonstrations and much of the block grant program from ADAMHA institutes) has allowed programs housed in NIMH, NIAAA, and NIDA to focus almost exclusively on research and thereby to grow and develop.

The basic biomedical and clinical research missions of NIH and ADAMHA are very clear. The stated mission of NIH is more exclusively focused on research and research-related activities, including a few demonstration and control programs and some dissemination activities. Some view the "narrowness" of NIH's mission as supportive of more effective research programs; of enhanced communication among NIH institutes, constituency groups, and Congress; and of consistent recruitment of talented agency and institute executives. Others view the NIH mission as restrictive: the case studies of Alzheimer's and Parkinson's disease pointed out that NIH institutes restrict their mission to exclude much-needed health services research related to costs and effectiveness, for example, because it is viewed as falling within someone else's jurisdiction.

Clarity about the research mission of the PHS, according to science administrators and others interviewed for each of the case studies, has protected and supported the development of research programs and structures within NIH institutes and, in the past 10 years, in ADAMHA institutes. These structures, in turn, have permitted the research enterprise to develop. The effectiveness of biomedical research programs within NIH has often been attributed to the ability of the research institutes to defend their boundaries and limit their mission to research. Not surprisingly, therefore, interviews conducted with current institute division directors in ADAMHA for the case studies of schizophrenia and substance-abusing pregnant women, as well as for analyses of demonstrations and block grant programs, indicated that programs administered by research institutes, if they are not directly related to their basic and clinical research missions, are viewed as stepchildren and may not be appropriately incorporated into planning and priority setting. It is the impression of many current science administrators in federal agencies as well as other scientists interviewed for this study that in the last 5 or 10 years the research programs of ADAMHA institutes have benefited from an increasingly singular research focus. In case studies and interviews conducted for other background papers, the suggestion was made (almost uniformly by science administrators as well as policy analysts) that—at the level of institutes, bureaus, and offices—co-administration of research and service programs can retard the productivity of both programs through dilution of time, energy, and financial resources and increased difficulty in leadership recruitment.

Following the 1982 shift to the block grant for funding service development and demonstration programs, a number of other changes occurred in ADAMHA. Those changes include (1) the reduction of responsibility for administering prevention programs and service development programs in NIMH, NIAAA, and NIDA (with the exception of a few remaining programs in NIMH); (2) increases in research allocations to ADAMHA institutes; and (3) greater differentiation in the organizational structure within institutes. It is tempting to see a direct relationship between the change in funding mechanism and the increases in research funding in ADAMHA (Figure 4-7). No firm evidence could be found supporting such a relationship, although a number of current agency and institute staff suggested that decreasing responsibility for services development and demonstration programs and increasing focus on research were positively related to increased allocations to research.

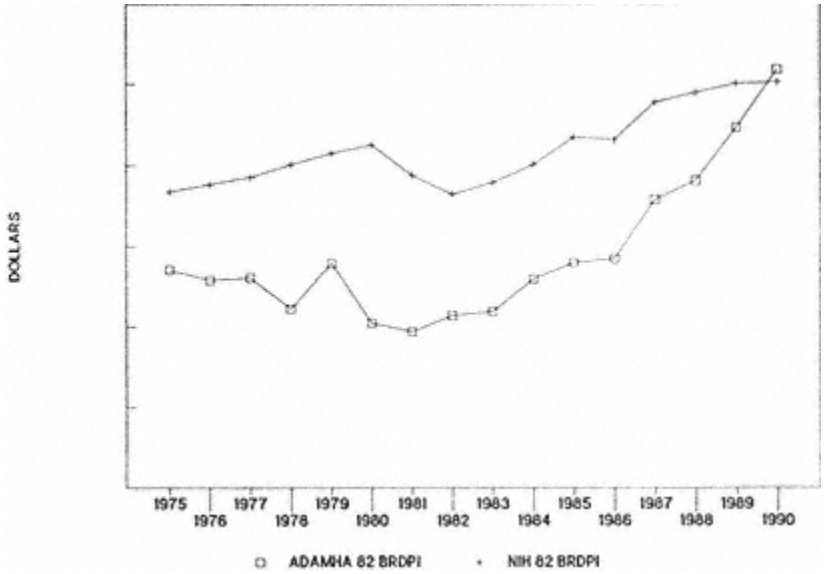

Figure 4-7 Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and
National Institutes of Health (NIH) research appropriations in 1982 constant dollars (1982 Biomedical Research and Development Price Index [BRDPI]).
Source: R. Walkington, "Allocations in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; adapted from information provided by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration budget offices.

The committee recommends that, below the agency level, research and services programs be administered and conducted by separate institutes or offices that have substantial expertise in the specific substantive and functional area. In cases where ADAMHA institutes currently have responsibility for treatment services demonstrations, service development, or block grant compliance programs, for example, such programs might be placed more appropriately in an organizational unit that currently has responsibility for similar programs, along with staff of sufficient expertise in the substantive area to manage the programs effectively.

The organizational shifts that occurred with the enactment of the block grant program seemed to lead ADAMHA away from co-admin

istration during the early 1980s. Block grant funding was viewed as a federal "pass through" to the states; little if any decision-making authority for services development and demonstration programs remained with federal administrators. In the years immediately following the block grant legislation, therefore, ADAMHA construed its mission more narrowly as focused on research. Recently, however, with increases in federal oversight of the block grant program and in funding for demonstrations, the effectiveness of co-administration in ADAMHA has again surfaced as a concern. Questions were raised in the case studies of schizophrenia and substance-abusing pregnant women about whether the increasing service component of ADAMHA might make it difficult in future to ensure stable scientific leadership at the agency level. It was pointed out in the analyses of planning, priority setting, and budgeting that within ADAMHA, block grant and demonstration programs have become increasingly significant responsibilities of the administrator. Allocations data show that funding for demonstration programs in ADAMHA has been increasing since the passage of the Anti-Drug Abuse Act of 1986 (Figures 4-8 and 4-9). Interviews with current agency administrators and staff attribute this increase to greater congressional concern (beginning in the mid-1980s) about a lack of federal leadership in services development at the state and local levels.

Divergent views exist about how to interpret longitudinal data on research allocations to NIH and ADAMHA. On the one hand, the similarity of increases in funding for biomedical research in NIH and ADAMHA does not support the perception that allocations to biomedical research have suffered in the last 10 years within a categorical agency responsible for both research and services development and demonstration programs, in contrast to a functional agency such as NIH. In fact, in the past 5 years it appears that funding for research has fared somewhat better in ADAMHA than in NIH. On the other hand, over a longer period of time, perhaps 20 years, one might interpret the data as suggesting that during the 1970s research allocations to ADAMHA and its predecessors suffered and only began to recover following passage of the block grant legislation and some internal reorganization of ADAMHA. A number of current science administrators and science policy constituency groups interviewed for this study suggested that research allocations to ADAMHA in the 1970s may have been hurt by negative perceptions of early social research; recent research allocations to ADAMHA may have been helped, on the other hand, by perceptions of drug abuse and AIDS as major social problems. The longer the time span one considers, the more the allocations data are susceptible to contradictory interpretations.

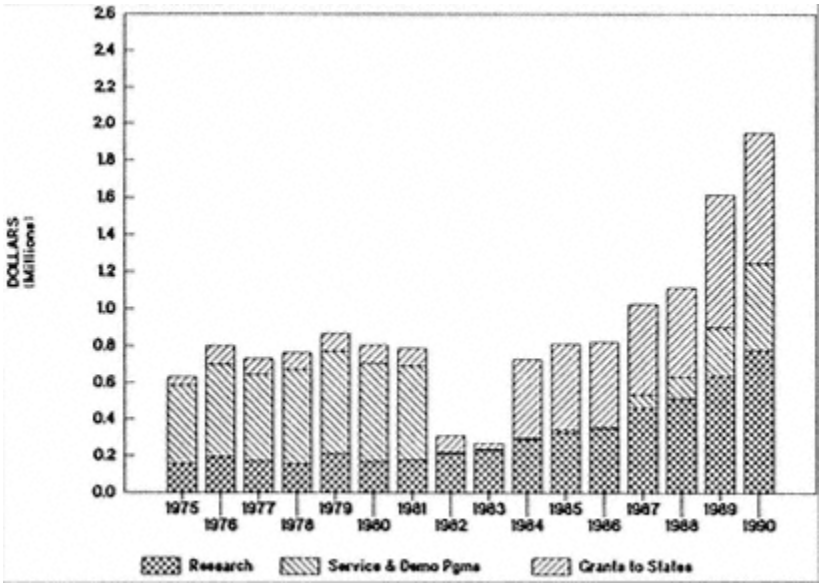

Figure 4-8 Alcohol, Drug Abuse, and Mental Health Administration expenditures by major purpose (in constant dollars): 1982—passage of block grants to states; 1986—passage of Anti-Drug Abuse Act. Source: R. Walkington, "Allocations in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; adapted from information provided by NIH and ADAMHA budget offices.

Given the complexity of administering federal research and service programs, functional organization (i.e., the administration of research, services development, and prevention programs by three separate agencies, namely, NIH, HRSA, and CDC) can be helpful in allowing for the development of specialized skills that lead to improved performance. Analyses conducted for this study and previous studies suggested that, while the administrative and political dictates of research and service programs differ (and, therefore, specialization may be useful), these differences often result in conflicting if not mutually exclusive priorities. These analyses pointed out the need to pay attention to jurisdictional disputes and overlapping responsibilities and, to avoid fragmentation in the implementation of policies and

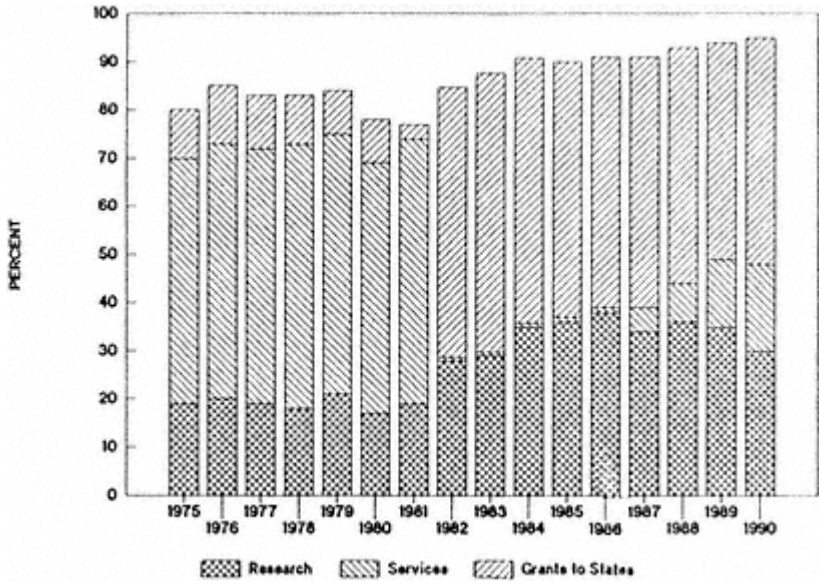

Figure 4-9 Alcohol, Drug Abuse, and Mental Health Administration expenditures by major purpose (as percentage). Expenditures do not sum to 100 percent because training is omitted: 1982—passage of block grants to states; 1986—passage of Anti-Drug Abuse Act.
Source: R. Walkington, "Allocations in the Public Health Service," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; adapted from information provided by the NIH and ADAMHA budget offices.

programs, the need for a focused effort to increase collaboration across research and service programs in the PHS.

Other evidence presented in the case studies and in the analysis of planning and priority setting did not suggest that co-administration of research, prevention, and service development programs was a guarantee of any specific relationships among the programs. Nor did it suggest that research findings were translated more effectively or benefited patients more quickly under the organizational structure of either ADAMHA or NIH. At the agency level, no evidence could be found that organizational structure bears any necessary relation to allocations for research or services development and demonstration programs. **Because it found no persuasive evidence that overwhelmingly supports any specific agency structure, the**

committee recommends that agency-level organization not be used as the basis for deterring or encouraging reorganization. If reorganization of current agency structure is considered, it should be justified purely on policy grounds.

PLANNING, PRIORITY SETTING, AND BUDGETING

The effectiveness of ADAMHA, NIH, and other PHS agencies is dependent on their ability to carry out such management functions as planning, priority setting and budgeting; responding to new information and policies; disseminating research findings; coordinating programmatic objectives; and recruiting and retaining leadership. To balance the needs of research, applications, and services development and demonstration programs, an organization must possess criteria for setting priorities, evaluating work in progress, assessing relationships with other organizations, and guiding action.

Commissioned analyses of institute-, agency-, and PHS-level processes conducted for this study show that planning, priority setting, and budgeting differ according to the culture and organizational structure of each of the PHS agencies. Assertions have been made throughout the history of the PHS that co-administration makes planning significantly more difficult and that priority setting and budgeting exact trade-offs between research and service programs. These discussions have centered on agencies such as ADAMHA and, before its creation, institutes such as NIMH that had responsibility for administering both research and services programs.

An important question for this study of co-administration was whether specific mechanisms existed for relating the program objectives of research, prevention, and service development and demonstration programs within ADAMHA and among the relevant agencies of the PHS. In addition, the committee wanted to clarify the similarities and differences in the programmatic objectives and priorities across research and service programs in the PHS and in ADAMHA.

At the Department and PHS Level

The policymaking system is complex, changing, convoluted, and (since public financing is involved) inherently political. In fact, there are at least two systems operating simultaneously, frequently with only minimal coordination: program planning (i.e., the content of the programs) and the budget planning and review process (which deter

mines how much money will be available for a particular activity). This dichotomy is particularly evident with regard to the research programs of ADAMHA and NIH, where the budget review process rarely becomes involved with the actual content of the research programs, which is left to the individual institutes, divisions, and disciplinary study sections. The result is constant tension between long-range, science-based planning at the programmatic level within institutes and the yearly, policy-based priority setting conducted by Congress and the administration. This latter process, by its very nature, is political.

There is no single, coherent system that can be labeled priority setting; rather, it is the result of myriad discrete activities involving Congress through its committees, the administration, the research and service communities, and individual program managers. At the level of Congress and the administration, the annual budget is the only plan. Budget decisions are largely incremental, and the most important single factor in determining a current budget is the last year's budget. Exceptions are relatively rare and reflect either major policy issues (such as drug abuse or AIDS) or the specific concerns of key individuals in Congress or the administration.

The budgeting process involves relatively few discussions of trade-offs between programs, especially between programs of different types. The only cross-agency comparison mentioned by any of the individuals interviewed for the planning and priority-setting analyses in this study was a general statement that every effort is made to balance the research increases of NIH and ADAMHA. At no level of budget review, above the programs themselves, was there evidence of an analytic or fact-driven approach to determining resource allocations.

The functional analysis of this subject found that "the budget planning and review process treats research separately from services (block grants, for example) and, in that process, NIH and ADAMHA research programs are treated similarly by the Assistant Secretary's Office and the Department. With regard to budget increases, it is a de facto PHS policy to treat the research programs of ADAMHA and NIH similarly"[10] (see Figure 4-10). Most differences in the final appropriations for the various institutes reflect congressional interests and the effectiveness of various constituency groups.

There is no separate health policy or plan at the DHHS or PHS level to guide the preparation of the budget or to set mutually agreed-upon directions. Planning and budgeting operates on a program-by-program basis. Budget requests are considered in the light of a program's past history and accomplishments and the effects of infla

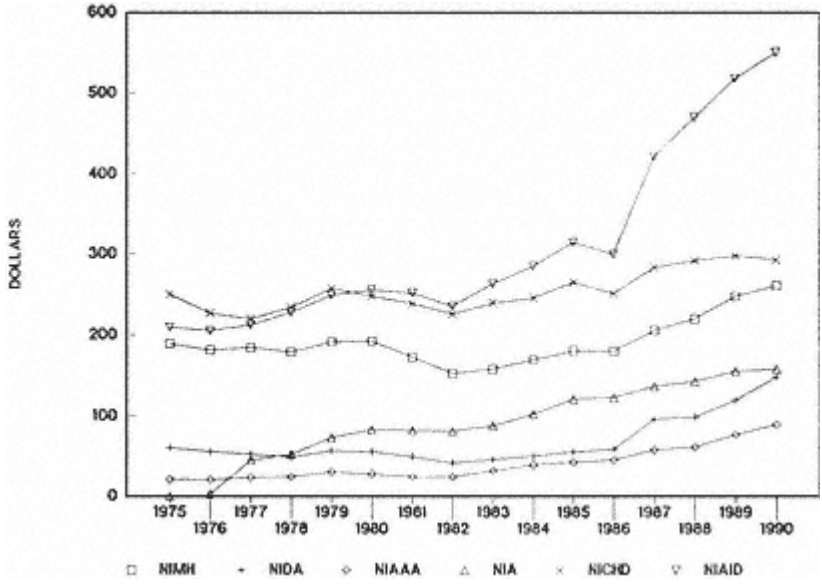

Figure 4-10 National Institutes of Health and Alcohol, Drug Abuse, and Mental Health Administration obligations for research, selected institutes, in constant d ollars.
Abbreviations: NIMH, National Institute of Mental Health; NIDA, National Ins titute
on Drug Abuse; NIAAA, National Institute on Alcoholism and Alcohol Abuse; NIA,
National Institute on Aging, NICHD, National Institute of Child Health and Hu man
Development; NIAID, National Institute of Allergy and Infectious Diseases.
Source: R. Walkington, "Allocations in the Public Health Service," paper prepa red for the IOM Committee on Co-Administration of Service and Research Programs of the
NIH, ADAMHA, and Related Agencies, 1991; adapted from information provi ded by the NIH and ADAMHA budget offices.

tion. Little consideration is likely to be given to the relationship between programs, and comparisons among programs rarely occur. Programs of different types are normally not considered as alternate answers to multifaceted problems; alternative allocation of resources based on a greater ability to solve a problem is seldom considered.

No evidence could be found of trade-offs between the NIH and ADAMHA research budgets or between the research and service budgets within the PHS. For example, discussions at the level of the Assistant Secretary's and Secretary's offices will tend to focus on one program, such as the maternal and child health block grant program

in HRSA, and then turn to another HRSA program, community and migrant health centers. It is unlikely that the discussions will include careful consideration of whether increasing the maternal and child health block grant in HRSA or increasing the research funds at the National Institute of Child Health and Human Development (NICHD) would have a greater impact on infant mortality. Nor is consideration likely to be given to relationships among child development programs such as the research programs of NICHD in NIH, the mental health service development programs of NIMH, and the financing programs of HCFA.

The following statement, while referring to the establishment of a congressional budget, is a realistic description of the entire process:

> The final budget resolution is a patchwork compromise of the views of all who participate in the budget process—the different parts of government, the press, the public policy community (think tanks, commentators, former officials), the lobbyists representing a multitude of interests. The final budget's form reflects the deals cut within the executive branch, among the congressional representatives of diverse constituencies, and between the Congress and the administration. Rarely do the January budget and the final resolution match. To understand the budget process is therefore to understand that the budget economies and politics of any federal effort are inextricably entwined, for the budget is fundamentally a political statement.[11]

Within PHS Agencies

The various PHS agencies that are addressed in this study (NIH, ADAMHA, and HRSA) differ significantly in their approaches to planning and budgeting. While there are many reasons for these differences, such as history, mission, and leadership, the appropriation structure appears to have a significant effect on the relationships between the agencies and their organizational components. To a much greater degree than in ADAMHA or HRSA, planning and budgeting in NIH is initiated at the institute level and then consolidated at the agency level. Because its mission is research oriented, congressional decisions to increase or decrease health care financing or services-related budgets are largely irrelevant to NIH concerns.

Strategic planning for science has been important in many NIH institutes. Many of the institutes use selected portions of their

strategic plans to contribute to agency and PHS plans and to guide preparation of budgets. Strategic planning has functioned more effectively in institutes with an established knowledge base and stable mission (e.g., the National Eye Institute [NEI], NIDR) than in institutes where the science is in a state of flux (e.g., the National Institute for Allergy and Infectious Diseases [NIAID]) or in an agency such as HRSA where both the science base and agency mission are subject to dispute.[12] NEI's strategic plan is an example of a structured, ordered planning and priority-setting process:

> This five-year plan will be the latest in a series of national vision research plans that began in 1974 and have been updated at roughly three-to five-year intervals as a joint effort of the [Advisory] Council, the NEI staff, and leading representatives of the vision research community. Among their many uses, the Plans have served the Council in its oversight of the NEI program and provided the NEI staff a guide for day-today management as well as long-range forecasting of the appropriate level of federal support for vision research.[13]

NIAID, by contrast, is in a state of evolution and conducts only short-term tactical planning. This appears to reflect a realistic response to a rapidly changing and developing field of research. ADAMHA's budgeting and planning process recognizes that the agency is unique in its mix of research and services development and demonstration programs. ADAMHA's budget attempts to implement the concept of an integrated mission, in which progress depends on linking (1) research, (2) treatment, (3) prevention, and (4) national leadership and advocacy and which relies on the notion of program balance rather than trade-offs among alternatives. This balancing act is made somewhat easier by the recent unwritten but widely understood PHS policy that ADAMHA and NIH research budgets will be treated similarly. In a sense, ADAMHA research is protected by this policy.[14]

The FY 1992 preliminary budget presentation of ADAMHA to DHHS, for example, makes the following points:

> Striking what we believe to be the appropriate balance between expansion of research activities and the need to expand and improve treatment capability . . . [l]inking treatment improvement programs and Office for Substance Abuse Prevention (OSAP) prevention programs to studies of the research institutes, using categorical grants to test hypotheses through field trials.[15]

Historically, however, ADAMHA's budget has been driven by the political perception of the importance of the social problems underlying its programs. The early growth of its mental health program was the result of dismantling the archaic state hospital structure. Its more recent growth is driven by perceptions of problems arising from substance abuse and AIDS. In both cases, budget growth was triggered by presidential and congressional needs for visible action.

ADAMHA yearly budgets, unlike those of NIH, are prepared and sent forward as a package, grouped according to goals determined by the ADAMHA administrator, senior staff, and institute leadership. However, no evidence could be found that long-term strategic planning is used in ADAMHA or HRSA as a major planning tool. Instead, as was noted in planning, priority-setting, and budgeting analyses conducted for the committee, planning proceeds differently:

> Planning in the Office of the ADAMHA Administrator and within institutes or their equivalents has been integrated in recent years with the budget process. The integration has the advantage of making planning more relevant since it is directly tied to the resources needed for implementation. It also has the advantage of making budget documents more cohesive. The negative side of this integration is that planning may acquire some of the characteristics of the budget process: fragmentation, short-range orientation, and the need to mirror current administration policy including shifts in focus. While the integration is too new to assess, an early impression is that the benefits accrue to the budget process more than to the planning process.[16]

HRSA, the newest of the major PHS agencies, was created in 1982 and has had a difficult time in articulating its mission, which includes a wide range of disparate activities and discrete programs. The planning process in HRSA is centralized, in that regard more like ADAMHA's planning process than NIH's. Budgeting, however, tends to be program specific rather than thematic and goal oriented as in ADAMHA. The focus of HRSA's current planning activities, as its budgeting process, is to develop a comprehensive agency mission and increase linkages with other PHS agencies.

Based on interviews in HRSA and ADAMHA, the planning processes in these agencies appear less ordered, and linkages with agency and PHS plans less structured, than in NIH. Although institute planning processes within ADAMHA appear admirably flexible, "with continuing review and revision as circumstances

dictate,"[17] a number of current science administrators and policy analysts pointed out that flexibility also allows the planning process to be subject to frequent changes of direction and focus. Plans that have been developed at the institute or bureau level often appear to have been prepared in an ad hoc manner and are frequently disregarded. As a result, they fail to provide continuity of direction and focus to institute and bureau programs, as they have in NIH.[18] **The committee recommends that all agencies within the PHS and each research institute be mandated to develop five-year plans, the process for which shall be reviewed by the Assistant Secretary for Health, and that plans be updated (with changes only) on a yearly basis. The committee notes that it is as important that five-year plans specify program goals and objectives as that they be linked with and revised according to an annual budget.**

In summary, each of the three agencies discussed above has a very different management style and organizational ethos:

1. NIH is scientific, collegial, and consensual, with the role of individual institutes highlighted.
2. ADAMHA is centralized and thematic with the roles of individual institutes deemphasized.
3. HRSA, which has been administratively centralized but programmatically disparate, is attempting to integrate its programs thematically.

EFFECTIVENESS OF DEMONSTRATION AND INFORMATION DISSEMINATION PROGRAMS

The committee understands information dissemination and knowledge transfer to be the process by which the results of biomedical and behavioral research are moved from their creation to their application in clinical practice (i.e., new knowledge into new practices) through applied research, clinical education and training, and demonstrations. The committee wanted to know whether, within a single agency such as ADAMHA, there were fewer obstacles to the translation of research findings into service programs.

As described earlier, within the ADAMHA model of the so-called research-services continuum, more than in other models, demonstrations provide a theoretical link between the findings of clinical research and the introduction of innovations into the structure and delivery of services.[19] However, few of the models include replication

of demonstrations in multiple sites (a critical component of any evaluation of the effectiveness of the new technology or knowledge being "demonstrated"). The case studies revealed that very little funding was available specifically for replication of demonstrations, and very little if any replication was being carried out. In addition, epidemiologic research and education and training (which has been noted in previous studies to be indirectly related to technology transfer) are completely omitted from the models. For several years in the 1980s, after the majority of demonstration programs were consolidated under the block grant program, ADAMHA administered no demonstrations at all. Most of the other demonstration programs in the PHS are administered by HRSA. Demonstration programs are also administered in other parts of DHHS (for example, the Office of Human Development Services [OHDS], the Family Support Administration [FSA], and the Health Care Financing Administration [HCFA]).

Within ADAMHA and elsewhere in the PHS, research and service demonstrations serve different functions; in most instances within ADAMHA they are administered by different organizational units. Four types of demonstrations were identified:

1. *Research demonstrations* are hypothesis-driven demonstrations based on previous basic and applied research. They employ experimental or quasi-experimental designs (including either control groups or comparison groups) to develop, test, and foster the application of existing knowledge gained from basic and clinical research for the control of categorical diseases or behavioral dysfunctions. Research demonstrations may also evaluate the feasibility, productivity, or outcomes of treatment approaches in community-based settings. Use of research demonstrations as a method for testing treatment models is consistent with the scientific research focus of the other major activities of research institutes.
2. *Service demonstrations*, on the other hand, focus on demonstrating the ability to develop and provide a set of new services targeting a specific population or disease. In contrast to research demonstrations, service demonstrations are not typically hypothesis driven, nor do they employ comparison or control groups. However, service demonstrations most often include (or should include) either process or outcome evaluations or both. Service demonstrations, if properly evaluated, can be a first step in development of community-based models that later can be rigorously tested as research demonstrations.

3. *Technology introduction or treatment diffusion demonstrations* at present have been defined as part of the research-services continuum only by OTI. Such demonstrations are designed to replicate successful demonstrations across multiple sites to establish the feasibility of broad implementation of models and to evaluate costs and benefits in a variety of settings.
4. *Services systems development demonstrations* are often used to build services capacity in states and localities. The funds provided through these demonstrations can act as a catalyst or provide an incentive for making programmatic changes at state and local levels that would not be possible without this funding.

The relationship between health services research and these types of demonstrations differs. For the demonstrations to achieve the goals described above, however, some form of collaboration among clinical research, health services research, and the structure and delivery of services is critical. For example, if costs, effectiveness, and efficiency of demonstrations or the feasibility of broad dissemination is to be analyzed prior to implementation and national dissemination, decisions about research design need to be made at the outset of demonstrations. With regard to evaluation of effectiveness and outcomes of services demonstrations, a different level of collaboration may be critical to the outcome. As noted in the background paper prepared for the committee's analyses of health services research programs:

> There is general recognition that the research component within demonstrations differs as one moves from research demonstrations to treatment diffusion demonstrations and services delivery. This view has led some to suggest that health services research and research demonstrations should be co-administered and that treatment diffusion and services demonstrations that include a health services research component should be co-administered with programs related to the structure and delivery of health care services.[20]

The committee's analyses also pointed out that both within and outside government, health services research needs strong links to research settings and to the services community.

Conflicting expectations on the part of Congress and federal agencies have created a number of difficulties in administration of demonstration programs. Congress has not fully appreciated the differences in the functions of demonstrations, "routinely viewing

demonstrations simply as a disguised form of service."[21] Interviews conducted for an evaluation of demonstration activities in ADAMHA, NIH, and HRSA suggest that one result of this view is a failure to replicate successful demonstrations across multiple sites prior to implementation; another result is the subsequent failure to evaluate the effectiveness of implementation prior to national dissemination. The case study of substance-abusing pregnant women, for example, raised important questions about the transfer of demonstration results into community settings without due attention to evaluations of costs and staffing arrangements. Another illustration of this same point is that until early in 1991, no evaluation component was considered for service demonstration projects funded by OSAP. A number of federal officials have suggested that there is a need for better articulation of the different types of demonstrations and of the appropriateness of translating a demonstration into an operating program. Analyses of many demonstration programs conducted for this study found evidence that the management of demonstration programs has been hampered by differences in agency and congressional objectives. For example, a second cycle of research demonstration grants for an ADAMHA institute was funded by Congress before the first was complete, thus preventing the results of the first cycle from being used to inform the second. In addition, instability in funding for demonstrations seems to have made long-range planning for demonstration programs almost impossible. Interviews conducted for this study indicated that the amount of funds available for replication of demonstrations and evaluation of their implementation affect whether new practices and systems innovations will be disseminated appropriately—that is, after having been shown to be cost-effective and efficacious. **The committee recommends that replication, which is vital to basic and clinical research but which has not been considered a central element of most demonstrations, be ensured in new and ongoing research demonstrations following single-site experiments and prior to implementation and national dissemination.**

In the ADAMHA and OTI models of the research-services continuum, as well as in the health care system in general, the block grant program serves as an important focal point for the transfer of demonstration results into the structure and delivery of services. Since 1981, virtually all funding for service development programs has been provided through the ADMS block grant program (small exceptions are the CSP and CASSP programs in NIMH). As discussed in Chapter 2, the change to block grants statutorily limited agency involvement in health services and demonstrations, which devolved to

the states. Although Congress seemed to have wanted a larger federal role in the block grant program in the 1980s, it did not appropriate funds to agencies for the purposes of guiding, shaping, or assessing federally supported state programs. According to ADAMHA administrations, it seemed pointless, at the time, to establish structures without resources. The focus of ADAMHA institutes shifted away from services development programs toward biomedical research, as did the focus of the entire agency. In addition, data collection requirements (previously mandated for states to receive federal funds) were eliminated, as was the availability of discretionary funds for services evaluation. "As a result, researchers did not have data, policy planners did not have data, and perhaps most importantly, program administrators ... did not have data to describe program performance to their political masters."[22]

Discontent with this lack of federal direction and oversight began to surface in Congress by the mid-1980s. Under continued pressure from advocacy groups, Congress has increasingly limited state discretion under block grant programs by mandating setaside requirements for expenditures of funds to target specific populations and health problems (e.g., intravenous drug users, substance-abusing pregnant women, health services for mothers and children, and children with special health care needs). In addition, since 1986, there has been a continuing and massive infusion of funds for service and research demonstrations in ADAMHA and HRSA, targeted at a variety of populations and problems. For some within ADAMHA, the recent infusion of funds for demonstration programs has been viewed as a diversion from the predominant research orientation of the agency. In the last few years, tensions have developed between those who would restrict the mission of the agency to research and those who would create a more integrated agency structure that encompasses research, prevention, and services development and demonstration programs.

A number of officials in ADAMHA, HRSA, and CDC feel that state allocations of block grant funds not only could but should be used to continue the service portion of successful demonstrations and to serve as the means for introducing innovations. However, until 1988, the structure of the block grant system inhibited this process by minimizing the federal role in promoting services innovations. According to program administrators in ADAMHA and CDC, there is no formal link between demonstration and block grant programs funded by those agencies, although many demonstration programs are administered by the same state agencies that administer the block grant program. **To ensure that the programmatic objectives of**

demonstrations are achieved, the committee recommends that a research program be initiated within the PHS to determine effective dissemination mechanisms for demonstrations and the results of health services research.

Interviews with constituency groups noted that state agency officials often are unaware of the existence of federal demonstration projects in their states, particularly those funded by ADAMHA institutes and offices. The Bureau of Maternal and Child Health in HRSA has a long history of collaborating with and consulting states with regard to demonstration projects. Interviews conducted for the committee revealed that this collaboration has increased the potential of demonstrations being focused on high-priority health problems in each state and has ensured that states are knowledgeable about proposed maternal and child health projects. In ADAMHA demonstration projects, however, such consultation and collaboration with states are less likely to be uniformly incorporated into the application process. In many instances state agencies have been reluctant to appropriate the funds to continue demonstrations, even successful ones, after federal funding is ended. **A plan that includes incentives for translating successful demonstration findings into the structure and delivery of services should be accompanied by opportunities for state review and comment on all types of federal demonstration applications. Potential sources of postdemonstration funding for successful demonstrations (i.e., federal, state, local, and private sources) should be explored prior to initiating a demonstration project.**

One of the important questions raised in the case studies conducted for this study was how to shorten the time between the "production" of research findings from basic research and their applications in applied research. In fact, the case study of substance-abusing pregnant women raised serious questions about the lag between findings in basic research (about the effects on pregnant women of alcohol and cocaine) and federal funding of studies on clinical interventions. None of the case study analyses found specific mechanisms in place for identifying the emerging results of clinical research or demonstrations that might serve as a basis for initiating intervention trials. The case studies of substance-abusing pregnant women and schizophrenia found no evidence of established mechanisms for identifying demonstration or other research results appropriate for dissemination and introduction into state programs through the block grant program. In the absence of established policies or mechanisms, program administrators at one ADAMHA institute initiated a campaign to encourage state agency directors receiving block

grant funds to support the service delivery costs associated with demonstrations.

With only one exception (the model developed by OTI), none of the models of the research-services continuum from the NIH institutes or ADAMHA refers to the specific mechanisms required to move research findings through demonstrations to evaluation, introduction, and implementation. Although the theoretical models developed in NIH, ADAMHA, and OTI are useful, they are difficult to implement. As Beryl Radin points out in her background paper on linkages between research and service programs in federal agencies, "even when an agency is convinced that it has developed an understanding of an issue through demonstration programs and/or evaluations, there is significant evidence that the diversity of decision settings and populations within the United States makes it difficult to think of simple dissemination of findings."[23] The organizational structure that exists in ADAMHA does not seem, by itself, to foster more rapid or improved dissemination.

In 1988, ADAMHA was authorized to set aside between 5 and 15 percent of the total ADMS block grant allocation to be used for data collection, health services research, and technical assistance to states and localities. This marked a significant shift in federal participation in the block grant program, allowing ADAMHA to begin rebuilding some national analytical capacities. Throughout the 1980s, states were free to evolve their own systems for data collection, systems that are not necessarily compatible with the goal of producing accurate or meaningful national statistics. As noted in a background paper on PHS block grants, congressional legislation in the early 1980s in effect dismantled the data collection systems that had existed under categorical programs, and members of Congress seemed unaware that the effect was to leave federal agencies without information about how federal allocations were being used by states and localities.

Setaside funds are currently available from the ADMS block grant for data collection, health services research, and technical assistance. However, analyses conducted for this study pointed out that the activities supported by the setaside did not seem to be directly tied to the objectives or the administration of the block grant program. A number of federal officials interviewed for this study felt that setaside funds could and should be used (1) to evaluate the feasibility of implementing interventions that have been proved successful in single-site demonstrations in other sites and conditions, (2) to facilitate data collection by the states related to the objectives of the block grant program, and (3) to provide technical assistance to states

and localities necessary for introducing innovations into the structure and delivery of health care services.

With the creation of OTI and a shift toward planning in block grant administration, increased attention is being paid to the technical assistance needs of states in the development of adequate data collection systems. If OTI is to carry out its tasks effectively, however, new and unfamiliar administrative mechanisms may need to be put in place to allow for negotiation across unit boundaries. For example, ensuring that data collection is not duplicative or inappropriate is likely to require central planning and coordinative strategies. Yet none of the case studies or interviews conducted for this study could establish the existence of specific mechanisms or leadership strategies for moving successful services demonstrations from one unit into research demonstrations carried out in the institutes and, subsequently, into a unit responsible for applications and implementation. The case study of substance-abusing pregnant women, for example, noted that in the absence of such mechanisms the "potential for duplication of efforts among the many different services demonstrations is present."[24] Although ADAMHA is also responsible for block grant services and for prevention programs for substance-abusing pregnant women, the Office of the Administrator did not appear to have provided policy direction to such efforts.

It was suggested in many interviews with current administrators and grantees that the skills necessary for the effective management of research and service programs are quite different. The research process requires time and autonomy, for which one set of management skills is appropriate. But social and political pressure for immediate results (for problems such as substance abuse) may require targeted efforts to facilitate movement from clinical research to demonstrations and, ultimately, to national dissemination, for which quite another set of skills are needed. Technical assistance and program development require not only another set of management skills but also an understanding of needs assessment, the organization and staffing of clinical programs, financing and reimbursement, and staff development. And because of differences in the level of training of those responsible for providing care at the local level, federally funded service development or demonstration programs are likely to require yet another set of specialized skills and knowledge.

Information dissemination activities commonly cited in interviews for this study include publication in scientific journals, creation of national clearinghouses and telephone information lines, and conferences for health care professionals and constituency groups. In most institutes these activities are well administered. It was suggested in

a number of the interviews with constituency groups, however, that the clearinghouse approach (cataloging information about innovative demonstrations) may make it difficult for users to distinguish between successful and less successful demonstration results. In addition, the case study of substance-abusing pregnant women, as well as analyses of information dissemination activities, suggests that current dissemination activities may be insufficient to promote the use of many new clinical practices or systems innovations.

Articles in scientific journals targeted to researchers may not meet the needs of all those who use research findings. Previous analyses, as well as the committee's case studies, found that the characteristics of individuals and organizations using new practices heavily affect how the results of research are received and used. For instance, nontraditional service providers may require access to training, technical manuals, or technical assistance in order to be able to adopt the results of successful demonstrations. The committee also believes that there are areas in which technical assistance and clinical training are needed if demonstration results are to be effectively disseminated to state and local programs. **The committee therefore recommends that the responsibility for technical assistance and clinical training programs of professionals and non-professionals (and the resources to carry them out) be part of the explicit mission of agencies that fund and administer operating programs (e.g., HRSA, the Indian Health Service, and ADAMHA).**

ORGANIZATIONAL CAPACITY AND PROGRAM PLACEMENT

In the course of gathering information and deliberating on the central issue of this study, the committee reached other conclusions closely related to its primary charge. Analyses of these issues and recommendations are included here as an adjunct to the report. For example, the case study of substance-abusing pregnant women raised serious questions about how decisions are made regarding where to locate programs within the PHS. As noted earlier, analyses of block grant and demonstration programs and of planning and budgeting processes also raised a number of concerns about the effects of frequent movement of programs.

The extraordinary growth in demonstration and block grant funds (particularly for drug treatment) in the past several years has resulted in some increase in organizational differentiation—that is,

separate offices and institutes handling prevention, block grant activities, and research within ADAMHA. On the other hand, the case study of substance-abusing pregnant women suggests that these differentiated organizational units (e.g., OSAP) have had problems in developing the infrastructure necessary to keep pace with the rapid growth of funds. The implementation of some federal programs may be unsuccessful because political agreement about their objectives has never been obtained, funding is not obtained, or political strategies are ill conceived. Other programs may founder because federal organizations fail to develop the necessary organizational capacity to produce results, or because they give insufficient attention to the consequences to the organization as a whole of creating new capacity. The complexity and shifting nature of tasks and programs may call for specialized units with the capacity for discretionary functioning within an agency or institute. It was difficult to determine with assurance the extent to which these difficulties are related to a lack of political consensus about the programs, to inadequate attention to organizational development, or to leadership problems at the office or agency level. It is most likely to be some combination of all three.

The successful implementation of new or greatly expanded programs may entail significant change in standard operating procedures or in the very "culture" of the existing organization and its units. For example, the creation of a new organizational unit within the Office of the Administrator (OTI, and before it, OSAP) gave ADAMHA a new organizational capacity to administer treatment improvement and preventive services and services demonstrations. As noted in the case study of substance-abusing pregnant women and in the analyses of planning, priority setting, and budgeting, the creation of OTI has usefully increased functional specialization within ADAMHA.

Interviews with constituency groups also suggested that specialized organizational arrangements are important because they provide a focal point for group efforts by bringing visibility, expertise, and a concentration of resources to a specific disease or problem. In several interviews, constituency groups questioned the rationale for placement of programs within specific PHS agencies. There was some indication, however, that these arrangements had more of an effect on constituency groups with interests in a substantive area than on those with interests in cross-cutting issues such as science policy.

Specialization comes with a price. Interviews conducted with constituency groups suggest that the creation of new organizational capacity, such as the Center for Medical Effectiveness Research (CMER) in the Agency for Health Care Policy and Research and OTI, has resulted in the need for coordination of programmatic objectives.

As pointed out in the case studies, in the report of the task force on health services research, and in interviews with current administrators of block grant and demonstration programs, the different administrative requirements of research and service program often result in conflicting priorities that require negotiation and mediation at the most senior agency levels.

Co-location does not guarantee, by itself, any specific relationship between research and service development or delivery programs. Each of the case studies underscores the need for federal executives to understand not only the shared characteristics but also the lines of division, suspicion, and rivalry among organizational units involved in a common effort. Interviews for analyses of block grant and demonstration programs and the case study of schizophrenia reveal a variety of differences, jealousies, and lack of clarity about overlapping responsibilities across organizational units within ADAMHA as it has grown and expanded its scope. In another area, the case study of schizophrenia also points out that a shift in leadership within an institute brought with it a change in the focus of research efforts, resulting in significant rivalry among divisions. Interviews conducted for the case study of Alzheimer's disease point out similar rivalries when a significant number of institutes are responsible for research programs related to the same disease.

Inadequate attention to program placement seems to have had more important effects than organizational structure on attempts to integrate the objectives of research, prevention, and services development programs, both within ADAMHA and across the PHS. The appropriate locations for the various activities are a question that appears to be asked infrequently, and there appear to be no routine procedures, other than history, to determine where programs should be located. When a question is raised, such as the potential movement of the management of the ADMS block grant to HRSA or the appropriate location for management of the National Research Service Awards for primary care, the decision process is informal and ad hoc, with the final decision being made by the Assistant Secretary for Health.

An example of this process is the creation of research and services programs for pregnant women with substance abuse problems. The case study suggested that stigma, congressional ambivalence, and insularity in federal agencies were important factors in delaying a response of any kind to the problem. However, the apparent lack of consideration of program placement was a significant determinant of the inadequate speed and scope of the response, particularly with regard to interventions research and development of services.[25] No

evidence could be found that the question of program location—whether it should be based on the problem (substance abuse) or the population (pregnant women)—was ever specifically considered or decided. Pregnant women, as a population, are a small subset of those at whom substance abuse programs are directed, and an even smaller subset within the population of substance abusers in the United States. However, substance abuse looms large among the problems of pregnant women who use public health clinics and primary care facilities funded by HRSA. **The committee recommends that when Congress initiates or authorizes new research or services programs, it consult with the Secretary of Health and Human Services to determine, within a brief period of time, the appropriate locus of program administration within the department. When a new or significantly expanded function is authorized, priority should be given to providing sufficient staff and financial resources to carry out the function.**

FINAL THOUGHTS

The responsibilities of PHS agencies and officials have grown in substantive, technical, and administrative complexity over the past 20 years, often without regard for order or consistency. Interviews conducted for this study leave little doubt that the complexity of administering an agency such as ADAMHA, with two or more missions of equal importance, adds a magnitude of difficulty to the task of an agency administrator. Confusion and conflict over the interpretation of an agency's missions or about the structures for carrying them out (which has occurred both in ADAMHA and HRSA) raise the level of difficulty even further.

Stability of organizational mission and program placement are important to a wide range of constituency groups. Analysis of constituency group relations with federal agencies suggests that instability undermines perceptions of the reliability of government operations, increases barriers to and frustration with development and maintenance of working relationships with agencies, and constrains group involvement with federal agencies. Changes in organizational arrangements are a special problem when they are perceived as eliminating or reducing the standing of programs that have served as focal points for constituency group concerns. These arrangements are a particularly acute concern in the substance abuse

and mental health fields, where organizational missions and arrangements have been less stable.

Regardless of how research, services, and prevention activities are organized in the PHS, clarity of mission, coordination of programmatic objectives within or across agencies, and stability of program placement remain significant issues for the PHS. Finally, structural reorganization often has little or no impact on the actual delivery of services, as was pointed out in the analysis of linkage mechanisms within PHS agencies:

> Many of the reform efforts of the past have rested on the assumption that change can be devised and implemented at the administrative level, which will provoke change at the point of service delivery. The experience of these years, however, suggests that such a relationship may be an act of faith rather than demonstrated by evidence. While there may be strong and important reasons for making administrative changes (e.g., reorganization, joint planning efforts) the world of service delivery is rarely affected by forms or styles of organization. Rather, it is the nature of the policies to be administered and the resources available which impact the system at the point of service delivery.

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* For readers interested in obtaining copies of these papers, the full address of the National Technical Information Service is 5285 Port Royal Road, Springfield, VA 22161; telephone 703-487-4650.

5

Duplication, Replication, and Complementarity

INTRODUCTION

The second charge to the committee was to determine any areas of duplication in the research programs of the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).[1] The impetus for such concern is that, with two agencies comprising 16 research institutes, federal dollars might be wasted funding duplicative research. The committee used the research in the three case studies as examples for its examination of replication, duplication, and complementarity.

DEFINITIONS

In discussing these terms, it is important to distinguish between research projects and research programs. *Projects* refers to singular research efforts, such as individual experiments or a set of experiments, that are designed to answer a specific hypothesis and that are funded by a research grant or reported in a journal article. *Programs*, on the other hand, refers to a much larger constellation of research funded by an institute or performed by an investigator over a period of time. *Replication* is an integral part of research projects; *duplication* and *complementarity* are related to both projects and programs. The committee employed the following definitions for replication, duplication, and complementarity:[2]

- *Replication* represents the deliberate or conscious repetition of research efforts, intended to confirm or extend previously or simultaneously obtained, but still uncertain, findings.

- *Duplication* represents inadvertent, unconscious, or, more rarely, deliberate repetition of research efforts, thus not serving a need to confirm or otherwise verify conclusions from previous research undertakings.
- *Complementarity* represents efforts involving independent approaches or overall strategies to confirm, overturn, or extend particular research findings.

Replication is important at the project level, because single experiments must be repeated and hypotheses constantly reevaluated. The scientific process depends in no small part on the ability of independent observers to repeat and confirm one another's findings. In this context, replication is not only legitimate but essential, providing "proof positive" of otherwise uncertain research findings and lending confidence to conclusions drawn from them. Replication also serves to overthrow false hypotheses: if an experiment is repeated and does not confirm the original results, the alternative hypothesis must be seriously considered. Once a research finding or hypothesis is well accepted, however, repeating experiments no longer adds to the knowledge base and becomes duplicative.

Duplication, on the other hand, is inherently wasteful and is normally guarded against, although it can also be excused or even encouraged under special circumstances. For example, an investigator can diligently search existing sources to verify that proposed research has not been done before, but the enormity of the scientific literature precludes complete assurance that a project is novel. This inadvertent duplication of research projects is not optimal but excusable. It is not thought to be particularly rampant. Eliminating duplicative research programs is a means of saving public money, but duplication of research projects and programs is acceptable under special circumstances, such as a period of great scientific opportunity or a period of great crisis. For example, the AIDS crisis demanded changes in the normal scientific process:

> As part of the federal response to the AIDS crisis, certain usually stringent practices for evaluating research proposals were eased somewhat as efforts began rapidly accelerating to formulate and then pursue as many promising leads as possible.... When a deadly disease with a high social cost dictated an extraordinarily rapid research program build-up, it made sense to start many similar, potentially duplicative research efforts in parallel. Although some fraction of those parallel efforts inevitably led down blind alleys, others served

> to confirm new and unexpected findings or to provide insights that gave renewed momentum to projects that may have temporarily stalled. In the aggregate, such a broad-based effort has expedited the development of novel therapies for individuals with AIDS or improved the quality of medical care available to them.[3]

Complementarity, by contrast, is an important attribute of research and is to be encouraged. In essence, complementarity depends on reaching the same or very similar conclusions by taking different approaches. Addiction, for example, is a complex problem with far-reaching social consequences, and it is being studied at many levels simultaneously—neurochemical and neurophysiological as well as behavioral and sociological—in an appropriately complementary strategy for identifying and understanding fundamental components of this complex phenomenon. Examples of complementarity within research *projects* would be to include both in vivo and in vitro effects of a drug, or to compare both rat and mouse responses to a particular manipulation. If the results of comparisons between species or techniques agree, the experiments confirm the findings; if the results differ, they provide new information that spurs new research. Examples of complementary research programs, for example, are the pain research programs in the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), the National Institute of Neurological Diseases and Stroke (NINDS), and the National Institute of Dental Research (NIDR). As indicated in Public Health Service (PHS) agreements on funding and referral guidelines,[4] each institute is interested in unique aspects of pain—anatomy, physiology, pharmacology, etiology, organ systems, behavior, and so forth—and, therefore, the overlapping research programs are, for the most part, complementary.

REPLICATION, DUPLICATION, AND COMPLEMENTARITY IN THE CASE STUDIES

Information on research grants funded by NIH and ADAMHA in the case study areas was obtained and classified as described in Chapter 3. Table 5-1 shows the number of grants in each case study area in health status research and health interventions research. (*Health status research* is defined as that which provides new knowledge regarding health, disease, biological, and behavioral processes. *Health interventions research*, by contrast, is defined as

TABLE 5-1 Results of Classification of Case Study Research Grants

Year	Alzheimer's Disease	Schizophrenia and Parkinson's Disease: Dopamine[a]	Substance-Abusing Pregnant Women
Health Status Research			
1975	17	14	30
1978	24	26	73
1982	72[b]	20	79[b]
1985	266[b]	34	88[b]
1987	308[b]	46	119[b]
1989	469[b]	70	153[b]
Health Interventions Research [c]			
1975	0	11	1
1978	3	10	1
1982	18[b]	7	5[b]
1985	49[b]	10	6[b]
1987	42[b]	9	6[b]
1989	7[b]	21	19[b]

[a] The search was on "schizophrenia and dopamine" or "Parkinson's disease and dopamine"; therefore, many grants on schizophrenia research and Parkinson's disease research are not represented in this search. See Figures 3-3 and 3-4 for comparison.
[b] Represents estimates based on sampling as described in Chapter 3.
[c] Health services research and research demonstrations are not well represented as discussed in Chapter 3.

that which provides new knowledge concerning the modulation of or intervention in health status. These are discussed in more detail in Appendix B.)

The assessment of the extent of duplication is based on several approaches and several premises. A major premise in this analysis is that, by definition, grants in separate categories cannot be duplicative. A second premise is that duplication is most likely in situations where there are many grants funded in a particular area, particularly in several institutes.

Alzheimer's disease research, for example, was thought most likely to include duplication because of the large number of grants in health status research and the many institutes that support research in this

area. As discussed below, however, there did not seem to be much duplication in Alzheimer's disease research. As with AIDS research, duplication can be deliberate and excusable when an overwhelming social and medical problem, such as Alzheimer's disease, demands attention. Although the substance-abusing pregnant women category seems to include quite a large number of grants, it includes research on at least four abused substances. It was only in the fetal alcohol syndrome that the number of health status research grants was large enough to cause concern about duplication. Information gathered for the study suggests that duplication of basic and clinical biomedical research is not a problem in the PHS.

The approach to assessing duplication entailed looking at grants within categories, reading titles and abstracts of the grants within a category, and deciding, given the definitions and discussion of replication, duplication, and complementarity, whether grants were duplicative. Additional information used in the following discussion of the case study areas comes from the Division of Research Grants Referral Guidelines and from interviews conducted for the case studies.

As described in Chapter 3, the committee found it extremely difficult to address the question of duplication because of the lack of a standard nomenclature within PHS agencies for classifying research and service programs and projects. The lack of an agreed-upon nomenclature presents a barrier to planning, evaluation, public access to information, and accountability within the PHS. If the Congress and executive agencies have a continued interest in periodic assessments of research, demonstration, service, and dissemination programs and of the relationships among programs, it will be necessary to develop a standard nomenclature that allows for consistent use of terms across PHS agencies. **The committee recommends that an interagency task force be formed to develop a standard nomenclature for classifying basic and clinical research, demonstrations, and service development activities across PHS agencies. The committee further recommends that the National Library of Medicine be mandated and given appropriate resources to carry out whatever research is necessary for the development of this standard nomenclature.**

Alzheimer's Disease Case Study

The Alzheimer's disease (AD) research programs in the National Institute on Aging (NIA), NINDS, and NIMH are more complemen

tary than duplicative.[5] For example, as a disease primarily of the aged, with neurological and psychiatric symptoms, AD is clearly of interest to NIMH, NIA, and MINDS, as well as many other federal research organizations.[6] However, each institute's AD program differs in primary emphasis: NIA has primary responsibility for AD and investigates it with an eye to the aging process; NINDS emphasizes the neurological aspects of the disease; and NIMH emphasizes the neuropsychiatric aspects, as well as the problems of caregiving stress.[7] This is not to say that there are no overlaps, or (for example) that some grantees funded by NIA could not have applied for funding for the same project from NINDS. In fact, these margins of overlap are thought to generate healthy competition both between institutes for the best researchers and between researchers for the most generous and stable funding.[8]

The particular aspect of AD research that crosses institute boundaries most obviously is the cellular and molecular biology of cells that degenerate in AD or produce the abnormal protein associated with AD symptoms. However, current thinking is that the research opportunities for AD are so promising that there are more questions to be asked than there are dollars to pay: with so little understanding and so many leads, the chances of individual projects being duplicative are small. These projects are replicative or complementary. Not nearly enough is known about the cellular and molecular biology of AD for projects to be duplicative. (Coordinating mechanisms within the PHS and the Department of Health and Human Services [DHHS] to deal with potential duplication and coordination of priorities within AD are discussed later in the chapter.) If in the course of this all-out attack on many fronts of a very difficult scientific problem, some potentially duplicative research projects or programs are funded, it is probably not worth ferreting out or worth the risk of missing a potentially important discovery.[9, 10]

Schizophrenia and Parkinson's Disease: Dopamine Research

In the case study of schizophrenia and Parkinson's disease, the area of most likely overlap is the aberrant chemical system common to both diseases—the dopamine system.[11] However, the dopamine systems relevant to schizophrenia differ in anatomy, biochemistry, genetics, pharmacology, and physiology from those relevant to Parkinson's disease. Parkinson's is primarily a disease of degenerating dopamine neurons that result in motor system dysfunction. Schizo

phrenia is primarily a disease of aberrant, but not degenerating, dopamine system functioning that results primarily in cognitive, emotional, and sensory dysfunction.

Although both NIMH and NINDS sponsor very fundamental research on, for example, the molecular genetics of the dopamine receptor, recent research has demonstrated separate genes that encode for distinct dopamine receptors. If there are many projects on dopamine receptor genetics and physiology, it is because there are many dopamine receptors to study. These projects in NINDS and NIMH are not duplicative. Neither research projects nor research programs regarding dopamine in NIMH or NINDS are significantly duplicative according to the committee's analysis. In fact, they are replicative in some cases, but more often they are complementary.

Substance-Abusing Pregnant Women

The case study of substance-abusing pregnant women revealed the least potential for duplication of health status and health interventions research.[12] So little is known in this area that research could hardly be duplicative. Only in the field of fetal alcohol syndrome did there seem to be a risk of duplication, but inspection of the research grants did not reveal significant duplication even in this area. The research grants were replicative and complementary.

This case study illustrates that the concepts of replication, duplication, and complementarity apply to demonstration research as well. Research demonstrations need to be replicated at several sites before being accepted as effective treatment interventions, and demonstrations can also involve complementary approaches to the same problem or population. Demonstration programs and service system development activities for substance-abusing pregnant women are sponsored by NIDA, the Office of Treatment Improvement (OTI), and the Office of Substance Abuse Prevention (OSAP), frequently in the same state and city with no coordination within ADAMHA. Other efforts aimed at pregnant women (sponsored by the Health Resources and Services Administration [HRSA]) and at substance abusers (sponsored by ADAMHA) run the risk of being neither duplicative nor complementary, but simply uncoordinated. Therefore, the case study identified at least one specific example where coordination across agencies at the Assistant Secretary level would be helpful: between programs for primary care for pregnant women (through HRSA) and programs for substance abuse treatment for female addicts (through ADAMHA). In addition, within ADAMHA, there was no evidence of

coordination between the block grant programs for substance abuse treatment administered by OTI and treatment demonstrations for pregnant women administered by OSAP.

GUARDING AGAINST DUPLICATION

In light of the finding that duplication is not a serious problem in the case study research areas, it is important to discuss what mechanisms, characteristics, or procedures serve to decrease duplication. Mechanisms in place to limit unnecessary duplication of research include self-regulation by the scientific community, the peer review process for journal publication and grant applications, and guidelines developed by the PHS for funding and referral. Perhaps the most effective of these measures is the intense competitive pressure that scientists apply to one another and to themselves:

> The federal biomedical research system works like a marketplace, with imaginative ideas and specialized materials being the principally traded commodities, and information exchange as well as peer recognition for one's accomplishments acting as the currency of trade. In such a system, quite naturally, there are penalties for doing purely duplicative work, and a premium is put on being creative and making breakthrough discoveries.... Reporting a supposedly new finding that turns out to be previously acknowledged work inevitably carries a severe penalty to one's reputation within the scientific community. Part of the penalty can be an investigator's subsequent difficulty in obtaining federal (or private) support for further research. Thus, although this crucial safeguard against duplication may not work in the initial instance, it can prove devastatingly effective in the long term.[13]

A significant means by which federal research administrators guard against duplication occurs through coordinating councils, described in Chapter 3 in the discussion of Alzheimer's disease. The DHHS Alzheimer's Disease Council and the congressionally appointed Advisory Panel on Alzheimer's Disease are a means for the many federal agencies and institutes involved in AD programs to communicate on a regular basis. Interviews conducted for the AD case study suggest that these mechanisms contribute significantly to a comprehensive approach to AD and a decrease in duplicative efforts.[14]

The process of peer review of scientific journal articles and grant applications also functions to detect and reduce duplicative research. When a researcher submits a grant proposal requesting funds for a set of experiments, or submits an article for publication describing the results of research, the group of scientists who review the proposal (or manuscript) and make recommendations regarding funding (or publication) consider the originality of the work. These scientists, as a group, are well acquainted with a vast proportion of the relevant scientific literature; proposals (or manuscripts) that include a great deal of unoriginal work would not be approved for funding (or publication). Although this monitoring system is generally considered effective, it has not been subject to a rigorous analysis. It is not designed to recognize or stop all duplicative efforts—such a system would be cumbersome to establish and costly to maintain.

Another important protective mechanism against duplication occurs through the NIH Division of Research Grants (DRG), whose responsibility it is to receive, review, and assign research grants to the appropriate review committee and funding institute, center, or division (ICD). DRG makes every effort to resolve areas of overlapping scientific interest among ICDs, and to assign research applications to the appropriate ICD, but it also makes liberal dual assignments to ICDs in cases of genuine overlap.[15] ICDs also protect themselves against duplication through coordinating councils such as exist for Alzheimer's disease.[16] Institute and agency administrators meet on a regular basis to discuss their contribution to the cross-cutting effort; such communication helps to decrease the chances that institute research programs seriously duplicate each other; instead, these coordinating mechanisms encourage the development of complementary programs. The scientist-administrators would gain nothing by approving, encouraging, or funding duplicative research; the key to increasing next year's appropriation is to show results from this year's investment. Duplicative research would do little to advance the goals of the researcher, the administrator, or the agency, much less the goals of science.

NOTES

1. Anti-Drug Abuse Act of 1988 (P.L. 100–690), section 2073.

2. A task force was convened to discuss the concepts. A document based on the day's discussion was prepared by science writer Jeffrey Fox.

3. J. Fox, "Report on Scientific Methodology," paper prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.*

4. Division of Research Grants, NIH, PHS, DHHS, "Referral Guidelines for Funding Components of PHS," 1990.

5. C. E. Blixen, "Case Study on Alzheimer's Disease," prepared for the IOM Committee on Co-Administration of Service and Programs of the NIH, ADAMHA, and Related Agencies, available from the National Technical Information Springfield, Va.

6. Justification of Appropriation Estimates for Committee on Appropriations, Public Health Service Supplementary Budget Data (Moyer Material), Part 1, Volume IX, Fiscal Year 1991.

7. Division of Research Grants, NIH, PHS, DHHS, "Referral Guidelines for Funding Components of PHS," 1990.

8. Blixen, "Case Study on Alzheimer's Disease."

9. Fox, "Report on Scientific Methodology."

10. Based on discussions in the task force meeting.

11. K. Stratton, "Parkinson's Disease and Schizophrenia: Dopamine and Beyond," a case study prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

12. L. V. Klerman and M. A. Johnson, "Case Studies of Substance Abusing Pregnant Women, Their Infants and Children," prepared for the IOM Committee on Co-Administration of Service and Research Programs of the NIH, ADAMHA, and Related Agencies, 1991; available from the National Technical Information Service, Springfield, Va.

13. Fox, "Report on Scientific Methodology."

14. Blixen, "Case Study on Alzheimer's Disease."

15. Division of Research Grants, NIH, PHS, DHHS. "Referral Guidelines for Funding Components of PHS," 1990.

16. Blixen, "Case Study on Alzheimer's Disease."

* For readers interested in obtaining copies of these papers, the full address of the National Technical Information Service is 5285 Port Royal Road, Springfield, VA 22161; telephone 703-487-4650.

Appendix A

List of Abbreviations

AD	Alzheimer's disease
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
ADM	Alcohol, Drug Abuse, and Mental Health
ADMS	Alcohol, Drug Abuse and Mental Health Services
AHCPR	Agency for Health Care Policy Research
AID	Agency for International Development
ASPE	Assistant Secretary for Planning and Evaluation
CASSP	Child and Adolescent Service System Program
CDC	Centers for Disease Control
CMER	Center for Medical Effectiveness Research
CMHC	Community mental health center
CRISP	Computer Retrieval of Information on Scientific Projects
CSP	Community support program
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic acid
DRG	Division of Research Grants
FDA	Food and Drug Administration
FSA	Family Support Administration
HRA	Health Resources Administration
HRSA	Health Resources and Services Administration
HSA	Health Services Administration
HCFA	Health Care Financing Agency
HEW	Department of Health, Education, and Welfare
HIV	Human immunodeficiency virus
ICD	Institutes, centers, and divisions
IHS	Indian Health Service
IOM	Institute of Medicine

NAMI	National Alliance of the Mentally Ill
NCHSR/HCTA	National Center for Health Services Research and Health Care Technology Assessment
NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NICHD	National Institute of Child Health and Human Development
NIAID	National Institute of Allergy and Infectious Diseases
NIDA	National Institute on Drug Abuse
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDR	National Institute of Dental Research
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Diseases and Stroke
OASH	Office of the Assistant Secretary for Health
OA	Office of the Administrator
OHDS	Office of Human Development Services
OSAP	Office of Substance Abuse Prevention
OTI	Office of Treatment Improvement
PHS	Public Health Service
SAA	Substance Abuse Administration
SAMHA	Substance Abuse and Mental Health Administration
SATT	Science, applications, transfer and training
VA	Office of Veterans Affairs

Appendix B

Nomenclature for Research and Service Activities

The committee did not find it useful to categorize grants by funding mechanisms because the number of grants in some funding categories is too large to be manageable (e.g., R01s), the use of other funding mechanisms is inconsistent across time (e.g., R18s), some funding mechanisms are not used uniformly (e.g., P60s), and other funding mechanisms are interchangeable in the eyes of some funding institutes (e.g., R01s, P50s, P01s). Similarly, it was not useful to categorize grants strictly by the terms used by the institutes because most have in-house classifications that are not intended to be used by others. Nor was it helpful to categorize grants by the thesaurus developed by the Division of Research Grants (DRG), which changes from year to year based not on scientific principles but on the level of use of terms. Thus, it was necessary to develop a classification that could be used across time, across agencies, and across disciplines.

The most common language used to describe research and research-related activities includes *basic research, clinical research, applied research, development, and technology transfer*. These categories represent a continuum of activities, the boundaries between which are not well defined. (In addition, there is considerable question as to whether there truly is a meaningful research-services continuum.) The utility of such a simple nomenclature is limited by the different and often conflicting definitions used for these terms. The distinctions between these standard typologies do not necessarily reflect the research process, and the mystique surrounding the use of the term *basic research* , in particular, limits its utility.[1] Because there is no standardized terminology within DHHS for describing research and service programs, the committee developed its own nomenclature for research, research-related, and service programs after a review of the pertinent literature.

In 1979, the then Department of Health, Education, and Welfare (HEW) proposed a classification system that was intended to describe the substance of research programs and to be a universal mechanism by which HEW would assign resources and plan allocations.[2] The so-called SATT system was composed of four parts: science base, applications, transfer, and training. Most PHS components experienced difficulty classifying their activities within the SATT system, however, and it was not formally adopted by HEW.

A recently published alternative nomenclature for health research emphasizes the content of functional areas rather than providing a dictionary of descriptive terms. This framework has three levels of criteria:

1. the focus of research (health state or health intervention);
2. the level of research (molecule-cell, tissue-organ, individual, and community-population for health states and technique, practice, program, and policy for health interventions); and
3. its purpose (development, description, explanation, and evaluation).

The framework's authors describe it as follows:

> a straightforward, comprehensive classification scheme that demonstrates the continuity of health-related research across the whole range of disciplines now engaged and is capable of including any that might become involved in the future. It directs attention to the content of areas rather than to the development of a lexicon of standard terms to replace discipline specific jargon ... [It does] attempt, nonetheless, to fit the more commonly used terms into the framework.3

The nomenclature used in this study was based to a large extent on the two systems described above. Several criteria were used in the development of this system. First, the system had to include research, research-related, and service activities. By definition, the research classification schemes described above did not include health service development and delivery systems; the services classifications were therefore developed based on background information, but still stressing functional areas. Second, the activities within each category should make scientific and programmatic sense. Although standard terms such as *basic, applied*, and *development* are not used, activities generally described by such terms fall within the classification scheme. A third criteria was that activities within each category could

not be identified only by the funding mechanism used by the funding institute or agency, as these have shifted over time. Lastly, the nomenclature should facilitate communication rather than hinder it.

The five main components of the nomenclature are (1) health status research, (2) health interventions research, (3) systems development, (4) services, and (5) information dissemination. Specific categories within this nomenclature are descriptive of functional activities that, it was thought, best represent and communicate the breadth of research, research-related, and service activities undertaken by the PHS:

1. *Health status research* provides new knowledge regarding health, disease, biological, and behavioral processes. Health status research is distinguished from health interventions research in that health status research does not study ways to change or influence health status.

a. *Nonhuman research* includes both in vivo and in vitro research, ranging from molecules to cells to organs to organism.
b. *Human research* includes behavioral, biobehavioral, or biomedical research in individual humans (frequently referred to as clinical research) or research on populations, such as epidemiological or demographic studies.

2. *Health interventions* research provides new knowledge concerning the modulation of health status (i.e., those research endeavors addressing not just disease but attempts to intervene in disease). This topic is quite broad:

a. *Product development* includes research applicable to the development of a new product or procedure that will then be tested to intervene in health and disease. This would include animal or human in vivo or in vitro research or even nonbiological research, such as medicinal chemistry research on pharmaceuticals or engineering research applicable to new devices.
b. *Program assessment* includes research that tests the efficacy or effectiveness of an intervention in diseased humans (frequently referred to as clinical research or clinical trials) or in animal models of human disease. The intervention can address prevention, diagnosis, or treatment of disease with any number of strategies (e.g., behavioral, pharmacological, surgical, mechanical, or any combination of the above).
c. *Health services research* includes research examining the relationships among health care consumers, providers, services, and facilities in order to increase effectiveness and efficiency, improve clinical care and outcomes, and evaluate health care policies. It

includes research into the access, utilization, organization, costs, financing, and outcomes of service delivery systems.

d. *Research demonstrations* include those demonstration projects that are hypothesis-driven and include control groups, and whose purpose is the generation of new knowledge.

3. *Systems development* refers to activities intended to provide incentives for the development of service systems.

a. *Services demonstrations* includes demonstration projects that gather information about populations or services about which there is little information, as well as demonstration projects intended to illustrate that a given service system works in real-world settings. These demonstrations are not hypothesis driven and do not have a strong research component, although evaluation is frequently included in the design.

b. *Technical assistance (including technology introduction)* includes activities aimed at helping state and local governments or service providers develop and implement prevention or treatment service delivery systems.

4. *Services* includes activities that directly or indirectly provide services.

a. *Direct services* includes activities in which direct treatment of patients occurs, such as those of the Veterans Administration hospitals, other military hospitals, and the Indian Health Service.

b. *Indirect services* includes funding to state or local groups to provide care; this can include categorical or formula grants as well as block grants to states. PHS block grant programs provide money to states for preventive health care programs (via CDC) and for health care programs relevant to select populations: substance abusers, the mentally ill, and women and their children (via ADAMHA and HRSA). An important federal contribution to patient care (reimbursement for health care services by Medicare and Medicaid through the Health Care Financing Administration) was not assessed directly in the study because HCFA is outside of the PHS.

5. *Information dissemination* includes activities that transmit information about research results or services to any population, such as professional, patient, or public education programs. (Training of research and service personnel is an important means of disseminating information, but neither the case studies nor the report included training programs in analyses.) Information dissemination programs differ greatly, depending upon the knowledge base from which information is drawn and the population for whom the information is intended. Information dissemination includes but is not limited to

conferences, publications, workshops, pamphlets, hotlines, and clearinghouses.

NOTES

1. H. W. Lane, R. G. Beddows, and P. R. Lawrence, *Managing Large Research and Development Programs* (Albany: State University of New York Press, 1981).
2. Department of Health Education and Welfare, "Appendix B SATT-A New Viewpoint On Health Research," *Health Research Activities of the Department of Health, Education, and Welfare Current Efforts and Proposed Initiatives. A Report of the HEW Steering Committee for the Development of a Health Research Strategy* (Rockville, Md.: DHEW, 1979).
3. R. N. Battista, A. P. Contandriopoulos, F. Champagne, J. I. Williams, R. Pineault and P. Boyle, "An Integrative Framework for Health-Related Research" *(Journal of Clinical Epidemiology* 42, 1989: 1155–1160).

Appendix C

Task Forces and Liaison Committee

TASK FORCE ON ALZHEIMER'S DISEASE CASE STUDY

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Appendix D

Interview List

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Steven Berkowitz, Chief, Financial Management and Information System Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland

Karste Besteman, Alcohol and Drug Problems Association of America, Washington, D.C.

Katherine Bick, Scientific Liaison, Studio Multicentrico Italiano Sulla Demenzia, Washington, D.C.

Christopher Bladen, Director for Health Financing Policy, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Washington, D.C.

Evelyn Bonder, Administrative Assistant to Senator Howard Metzen-baum, United States Senate, Washington, D.C.

Elvira Brands, Chief, ADMS Block Grant Program, Division of Applied and Services Research, National Institute of Mental Health, Alcohol, Drug Abuse, and Mental Health Administration, Rockville, Maryland

Norman Braveman, Division of Planning and Evaluation, National Institutes of Health, Bethesda, Maryland

Stuart Broad, Division Administrator, Representatives of State Mental Health Programs for the Aged and Council, National Association of State Mental Health Program Directors, Arlington, Virginia

Barry Brown, Chief, Community Research Branch, National Institute on Drug Abuse, Alcohol, Drug Abuse, and Mental Health Administration, Rockville, Maryland

Neal B. Brown, Chief, Community Support Section, Division of Applied and Services Research, National Institute of Mental

Health, Alcohol, Drug Abuse, and Mental Health Administration, Rockville, Maryland

Jay Burke, Director, Division of Applied Science and Services Research, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland

William Butynski, Executive Director, National Association of State Alcohol and Drug Abuse Directors, Arlington, Virginia

Diane Canova, Director of Public Policy, National Association of State Alcohol and Drug Abuse Directors, Washington, D.C.

Barbara J. Calkins, Director, Legislative and Federal Affairs, Science Directorate, American Psychological Association, Washington, D.C.

Ronald Carlson, Associate Administrator for Planning, Evaluation and Legislation, Health Resources and Services Administration, Rockville, Maryland

William T. Carpenter, Director, Maryland Psychiatric Research Center, Baltimore, Maryland

David Cavenaugh, Research Specialist, National Association of Community Health Centers, Washington, D.C.

Thomas Chase, Chief, Experimental Therapeutics Branch, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland

Richard Chinick, Budget Analyst, Office of the Assistant Secretary for Health, Department of Health and Human Services, Washington, D.C.

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Timothy Condon, Deputy Associate Administrator, Office of Policy Coordination, Alcohol, Drug Abuse, and Mental Health Administration, Rockville, Maryland

Maureen Corry, Director, Community Services, March of Dimes Birth Defects Foundation, New-York, New York

Michael Davis, Chief, Policy, Legislation & Planning Section, National Eye Institute, National Institutes of Health, Bethesda, Maryland

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Miles J. Doherty, Deputy Director, Division of Demonstrations and Evaluations, Office of Substance Abuse Prevention, Alcohol, Drug Abuse, and Mental Health Administration, Rockville, Maryland

Morgan Downey, Associate Director, National Foundation for Brain Research, National Coalition for Research in Neurological Disorders, Arlington, Virginia

Alfred Duncker, Director, Division of Research and Demonstrations Administration on Aging, Department of Health and Human Services, Washington, D.C.

Kenneth Eaton, Chairman, Ad Hoc Coalition on Alcohol and Drug Abuse, Washington, D.C.

Florence Fiori, Associate Administrator for Extramural Affairs, Health Resources and Services Administration, Rockville, Maryland

Gretchen Fleming, Director of Research Department, American Academy of Pediatrics, Washington, D.C.

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