Informing the Future: Critical Issues in Health, Second Edition

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INFORMING THE FUTURE

Critical Issues in Health

SECOND EDITION

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of th charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Bruce M. Alberts is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Wm. A. Wulf is president of the National Academy of Engineering.

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The National Research Council was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Bruce M. Alberts and Dr. Wm. A. Wulf are chair and vice chair, respectively, of the National Research Council.

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Shaping the Future for Health

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THE INSTITUTE OF MEDICINE: ADVISER TO THE NATION

Unprecedented opportunities and challenges face the nation and the world as we seek to improve human health through research, prevention, and clinical care. The federal government plays a pivotal role in shaping the opportunities and meeting the challenges through the policies it establishes, the programs it funds, and the leadership it provides. Both the public and private sectors are critical to the design and delivery of health care. Over the next decade, demographic trends, growth in chronic illness, and emerging disease threats will pose new challenges to health that must be confronted by our nation and the global health community.

The health sector now constitutes more than 14 percent of the nation's Gross Domestic Product (GDP)—a level projected to rise to 16 percent within the next few years. Approximately half this amount is spent through the public sector, a share also expected to rise in the coming decade. Purchasers of care in government and the private sector face difficult decisions about how to obtain the best value for these expenditures.

For advice about these issues, the nation often turns to an institution created specifically for this purpose: the Institute of Medicine (IOM) of The National Academies. The IOM was chartered in 1970 as a component of the National Academy of Sciences. The Institute provides a vital service by working outside the framework of government to ensure scientifically informed analysis and independent guidance. The IOM's mission is to serve

as adviser to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large.

The IOM and The National Academies use a unique process to obtain authoritative, objective, and scientifically balanced answers to difficult questions of national importance. Our work is conducted by committees of volunteer scientists—leading national and international experts—who serve without compensation. Committees are carefully composed to assure the requisite expertise and to avoid bias or conflict of interest. Every report produced by our committees undergoes extensive review and evaluation by a group of external experts who are anonymous to the committee, and whose names are revealed only once the study is published. The results of these committee deliberations have been relied upon for over 30 years to provide policy-makers with objective, scientifically sound advice.

The Institute's work centers principally on committee reports or studies on subjects ranging from quality of medical care to the national smallpox vaccination program; from centers of excellence at the National Institutes of Health (NIH) to protecting the nation's food supply. We also convene roundtables, workshops or symposia that provide an opportunity for public- and private-sector experts to discuss contentious issues in an open environment that facilitates evidence-based dialogue. Additionally, for 27 years, the IOM has managed The Robert Wood Johnson Health Policy Fellowships Program, designed to train outstanding mid-career health professionals in academic and community-based settings to assume leadership roles in health policy and management.

The majority of our studies and other activities are requested and funded by the federal government. Private industry, foundations, and state and local governments also initiate studies, as does the IOM itself.

The objective in all of our work is to improve decision-making by identifying and synthesizing relevant evidence to inform the deliberative process. Over its history, the IOM has become recognized through its projects as a national resource of judgment and veracity in the analysis of issues relating to human health. Depending on the request, studies may be narrow in scope, designed to answer very specific and technical questions, or they may be broad-based examinations that span myriad academic dis-

ciplines, industries, and even international borders. Many of today's health news stories concern topics on which we have reported; others, like childhood obesity, are currently under study.

IOM MEMBERS

The Institute of Medicine is both an honorific membership organization and a research organization. The Institute's members, elected on the basis of their professional achievement and commitment to service, serve without compensation in the conduct of studies and other activities on matters of significance to health. An unusual diversity of talent among Institute members is assured by the charter stipulation that at least one-quarter be selected from outside the health professions, from such fields as the natural, social, and behavioral sciences, as well as law, administration, engineering, and the humanities. Election to active membership is both an honor and a commitment to serve in Institute affairs.

The bylaws of IOM specify that no more than 65 new members shall be elected annually. The announcement of newly elected members occurs at the IOM Annual Meeting in October. The number of regular members plus foreign associates and emeritus members is currently about 1,400.

ADVISER TO THE NATION

This booklet provides a brief look at the work of the Institute and highlights some of the policy areas that we believe will be important in the next several years. It is organized into three sections. The first section illustrates ways the work of the IOM influences policy deliberations in a number of key areas; the second section samples work that we have recently completed or have under way; and the third section provides a comprehensive bibliography of IOM reports published over the past several years.

HIGHLIGHTED REPORTS

THE ANTHRAX VACCINE: IS IT SAFE? DOES IT WORK?

IOM released *The Anthrax Vaccine: Is It Safe? Does It Work?* in March 2002, in the wake of anthrax infections and deaths that resulted from bioterrorism in fall 2001. Congress requested the study because of concerns raised about the safety and efficacy of the anthrax vaccine when the Department of Defense (DoD) instituted a mandatory vaccination program in 1998. The IOM report reviewed the data available on the safety, efficacy, and manufacturing of the licensed anthrax vaccine, known as Anthrax Vaccine Adsorbed (AVA). Evidence from studies in both humans and animals led the committee to conclude that AVA, as licensed, is an effective vaccine to protect humans against anthrax, including inhalational anthrax. Moreover, AVA should be effective against not only all known strains of the organism, but also any new bioengineered strains. The committee also concluded, on the basis of epidemiologic studies and a review of numerous case reports, that AVA is reasonably safe. Reactions to the vaccine, and the rates at which they occur, are comparable to those observed with other vaccines regularly administered to adults. The committee found no evidence that AVA recipients face an increased risk of life-threatening or permanently disabling adverse events immediately after receiving the vaccine. Nor did it find any convincing evidence that vaccine recipients face higher, long-term risks, although data for assessing such effects are limited (as they are for all vaccines).

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The committee recommended that DoD continue and improve monitoring efforts to detect any adverse health effects caused by AVA and other vaccines, and that the production, testing, and licensure of a new anthrax vaccine requiring fewer doses and producing fewer local reactions is needed.

The Assistant Secretary of Defense for Health Affairs described the report as the most extensive review of the science underlying anthrax vaccine and good news for military personnel. Within months of the report's release, DoD reintroduced its Anthrax Vaccine Immunization Program, beginning with those service members considered to be at higher risk and essential to the accomplishment of military missions. As part of the civilian response to bioterrorism concerns, the Department of Health and Human Services (DHHS) has also made efforts to stockpile AVA. At the same time, both DoD and DHHS are pursuing the development of "next generation" anthrax vaccines as urged in the IOM report.

QUALITY OF CARE

In 1996, the Institute of Medicine launched a large-scale, ongoing effort focused on evaluating and improving the nation's quality of care, which is now in its third phase. The first phase of the IOM Quality Initiative documented the serious and far reaching nature of the nation's overall quality problem, including the pervasiveness of medical errors which account for thousands of patient deaths every year as described in *To Err is Human* (1999). In the initiative's second phase, the report *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) was released, offering a comprehensive vision for how the health system and larger policy environment might be transformed to meet six key aims, namely that care is safe, effective, patient-centered, timely, efficient and equitable. This report stimulated a national conversation about what needs to change on the environmental level, at the health care organization and small practice levels, as well as at the level where patients and clinicians interact. This dialogue has led to numerous public and private sector efforts to reform the health care system at each of these levels. These efforts include: national employers working to put safety practices into place in hospitals; health care providers acting to redesign care delivery and experiment with innovative financing; and federal and local agencies, including the Agency for Healthcare Research and

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Quality (AHRQ) and the Centers for Medicare/Medicaid Services (CMS), producing quality report cards and paying for quality demonstrations, among other activities.

Crossing the Quality Chasm also has provided a very important framework for the implementation or third phase of the IOM's Quality Initiative. This phase includes three different types of efforts all focused on reducing environmental barriers: developing reports that lay out a strategic direction for a particular area within the framework of the *Quality Chasm* report; designing demonstration ideas or tools and techniques, which aid in implementing that strategic direction; and fostering collaboration between the IOM and others who are working to redesign the health system.

The following upcoming and released reports and convening activities reflect the breadth and diversity of issues that must be faced to improve the quality of health care in the U.S.:

- At the request of the Secretary of the Department of Health and Human Services (DHHS), the IOM developed bold ideas that could be enacted at the state and community level to respond to system ills and guide future larger scale reform. The ensuing report, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations* (2002), focused on redesigning primary care and care for those with chronic conditions, creating an information and communications technology infrastructure, making health insurance coverage available and affordable at the state level, and reforming malpractice to make it patient-centered, safety focused and non-judicial.

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- In January 2003, the IOM issued the report *Priority Areas for National Action: Transforming Health Care Quality* (2003), also at the request of DHHS. The report recommends 20 priority areas that collectively span preventive, acute, chronic, and palliative care, and two interventions-—care coordination and self-management/health literacy—that cross each of these domains. As a follow up to this report, the IOM is hosting a summit in January 2004 that will involve both national and local leaders in developing work plans for redesigning care at the community level for seven of the 20 priority areas. The areas of focus include asthma, congestive heart failure, diabetes, major depression, and pain management for those with advanced cancer, as well as two crosscutting areas: care coordination and patient self-management. This summit will provide community leaders

with tools and techniques for overcoming barriers to improving care in these five areas, as well as ideas and support from other communities and national leaders respectively.

- *Key Capabilities of an Electronic Health Record* (2003) identifies a set of eight core functions that should be incorporated into electronic health records to guide standard setting bodies and software development organizations. These functionalities can also serve as a tool for health-care organizations as they compare different IT systems, and consider which to adopt. These functionalities may guide the federal government as they consider ways to encourage health-care organizations to implement electronic health records.

- The *Quality Chasm* report also recommended that an interdisciplinary summit of leaders be held to develop next steps for health professions education. This summit was hosted by the IOM and held in June 2002 and involved 150 leaders from education, oversight organizations, practice environments, purchasers, consumer groups and professional associations, among others. The summit participants' ideas and the resulting report, *Health Professions Education: A Bridge to Quality* (2003), include a mix of approaches, with a central message that efforts to reform health professions education should be interdisciplinary. The approaches include those related to oversight processes, the training environment, research, public reporting, and leadership. The goal is an outcome based education system that better prepares clinicians to meet both the needs of patients and the requirements of a changing health care system.

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- In *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality* (2003) the IOM recommends that the federal government use a multi-prong approach including rewarding high quality providers when they purchase health care services, leveraging their regulatory power to establish clinical data reporting requirements; using their own health care delivery systems, e.g., the VA (Department of Veterans Affairs) as laboratories to learn what does and does not work for a 21st century health system, and finally applying health services research as they seek to develop the knowledge base and tools that support quality enhancement.

FOOD CHEMICALS CODEX

The *Food Chemicals Codex (FCC)* project is an activity of the IOM's Food and Nutrition Board that has been supported by the U.S. Food and Drug Administration (FDA) for 40 years. The *Codex* is an important component of national food safety defenses. It was established following the passage of the Food Additives amendments to the federal Food, Drug, and Cosmetic Act in 1958. To date, four editions of the *Food Chemicals Codex* (1966, 1972, 1981, and 1996) have been published, as well as the *First (1997), Second (2000) and Third (2001) Supplement to the Fourth Edition.* The *Fifth Edition* is due for publication in late 2003. The FDA, by reference, incorporated into the *Code of Federal Regulations* many specifications published in the first three editions of the *Food Chemicals Codex*. Canada, Australia, and New Zealand have also adopted the Codex as part of their food regulatory systems.

The *FCC* establishes standards for the purity of food chemicals to ensure consumer safety and promote uniform quality in production of such chemicals. The *First Edition* was limited to chemicals that are added directly to foods to achieve a desired technological function. Succeeding editions upgraded the specifications for these substances and added specifications for processing aids, which come into contact with foods during processing but do not become part of them, as well as some that are regarded as foods rather than as additives. More recently, "functional" ingredients, which purportedly perform a function in the human body but not on the food itself, have been added to this list. The *FCC* has continued to expand and evolve as the FDA approves new food additives and as advances are made in scientific and manufacturing methods and technology. The *Fifth Edition* will contain more than 1000 monographs, many of them new, and will feature a thorough revision of *FCC* specifications.

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In the current era of global sourcing, which has promoted the entry of many suppliers of food chemicals and ingredients from other countries into the United States market, the *FCC* provides identity, strength, and purity specifications for food chemicals that are recognized nationally and internationally. "FCC-grade" is a term routinely used by many manufacturers in food chemicals and ingredients labels. Users of these substances, in turn, often require from suppliers that such substances be *FCC* compliant. In recognition of these standards, the *FCC* has been incorporated into the

food additive legislation of several countries and is used worldwide among manufacturers and users of food chemicals and ingredients.

FCC specifications are continuously updated, based on science, and in accordance with the rapidly increasing pace set by FDA approvals. Without frequent updating of the *FCC*, American consumers could be exposed to many new food additives for which there would be no agreed upon purity specifications. As concerns increase about the protection of the food supply from intentional contamination, the *FCC* also provides a scientific basis for screening food chemicals and ingredients. The primary goal remains: to define the quality of food-grade chemicals in terms of identity, strength, and purity, based on the elements of safety and good manufacturing practices.

MICROBIAL THREATS TO HEALTH

The IOM's interest and involvement in addressing the challenges of emerging microbial threats to health has spanned more than a decade and yielded several important contributions to public health and global security.

In its 1992 report *Emerging Infections: Microbial Threats to Health in the United States*, the Institute of Medicine pointed to major challenges for the public health, research, and medical care communities in detecting and managing infectious disease outbreaks and monitoring the prevalence of endemic diseases. The report's recommendations provided the basis for the Centers for Disease Control and Prevention's (CDC) National Center for Infectious Diseases' 1994 and 1998 strategic plans to address the threat of emerging infections nationally. The IOM report is credited also as the catalyst for the National Security Council's charge to the Committee on International Science, Engineering, and Technology (CISET) of the White House National Science and Technology Council to consider the global threat of infectious diseases.

***Emerging Infections: Microbial Threats to Health in the United States*... provided the basis for the CDC's National Center for Infectious Diseases' 1994 and 1998 strategic plans to address the threat of emerging infections nationally.**

To further illuminate these issues, the Centers for Disease Control and Prevention, along with the National Institutes of Health, asked the IOM to convene the Forum on Emerging Infections (1996), now known as the

Forum on Microbial Threats, to foster continuing and structured opportunities for dialogue around areas of shared concern among stakeholders within the public and private sectors. In recent years, such cross-sector dialogue has precipitated collaborative consideration and action around diseases on human health, microbial and disease vector resistance, biological threats and terrorism, the impact of globalization on infectious disease emergence, and the infectious causes of chronic diseases.

IOM's most recent report, *Microbial Threats to Health: Emergence, Detection, and Response* (2003), examines the complexities and challenges posed by infectious diseases and the corresponding trends that contribute to the emergence and reemergence of these threats. The report recognizes the vulnerability of populations in all nations as a threat not only to personal health, but also to public safety, economic stability and development, and national and international security.

Building on the factors of emergence identified in the 1992 report, this report explores an expanded number of human-microbe interactions that contribute to disease. Moreover, the report describes how the convergence of any number of factors (e.g., biological, ecological, and political) creates an environment in which infectious diseases can emerge and become rooted in society.

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The ever-worsening HIV/AIDS pandemic, the resurgence of once manageable diseases, such as tuberculosis, the emergence and spread of drug resistance and newly identified pathogens such as the SARS virus, and the first use of biological terrorism in the United States reflect the formidable problems that challenge individual agencies, governments, and markets. The report's recommendations propose a range of actions needed to keep pace with our microbial competitors and to define meaningful and sustainable solutions. Specific guidance is provided to improve and enhance domestic and global public health capacity, infectious disease reporting and surveillance systems, workforce education, and the availability and development of effective countermeasures to disease. The report's recommendations are currently under consideration by numerous federal and national and international decision -.

DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATES, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS

More than 60 years ago, the Food and Nutrition Board issued its first set of Recommended Dietary Allowances (RDAs) for vitamins, minerals, protein, and energy in response to the War Department's concern during World War II over the nutritional fitness of new recruits, malnutrition among existing troops, and the need to provide adequate nutrients to malnourished populations after they were liberated by Allied troops. Since 1941, RDAs have served as the basis of almost all federal and state food and nutrition programs and policies and have been revised nine times, with the list of RDAs growing from eight to 27 nutrients in 1989.

Since the publication of the 10th and last edition of the *Recommended Dietary Allowances in the United States* in 1989 and the *Recommended Nutrient Intakes in Canada* in 1990, new information has emerged about nutrient requirements that warranted the development of updated guidelines. Over the past eight years, the IOM has implemented an expanded system for determining the RDAs and other nutrient based reference values now called Dietary Reference Intakes (DRIs). The new DRIs are based on scientifically grounded relationships between nutrient intake and indicators of good health as well as the prevention of chronic diseases in apparently healthy populations.

In this recent report, *Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids,* the sixth in a series providing Dietary Reference Intakes (DRIs) developed jointly by American and Canadian scientists, the DRI recommendations are expanded to include carbohydrates, fiber, fat, fatty acids, cholesterol, protein, and amino acids, collectively known as the macronutrients, as well as energy and physical activity. The report recommends that to meet the body's daily nutritional needs while minimizing risk for chronic disease, adults should consume 45 to 65 percent of their total calories from carbohydrates, 20 to 35 percent from fat, and 10 to 35 percent from protein. These are of considerable importance to federal agencies in light of the growing concerns related to

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consumption of specific dietary components such as trans fatty acids or cholesterol and increased risk of chronic diseases, including cardiovascular disease and cancer. The acceptable ranges for children are similar to those for adults, except that infants and younger children need a somewhat higher proportion of fat in their diets. These ranges may be more useful and flexible for dietary planning than single maximum values recommended in the past.

Sponsors of the report, including the U.S. Departments of Agriculture and of Health and Human Services, as well as Health Canada, a division of the Canadian government, also asked the Academies to specifically provide guidance by defining "dietary fiber" for the purpose of regulating nutrition labels on foods, and on determining adverse health consequences of consuming sugar added to foods such as cakes and beverages compared to other sugars such as those naturally found in fruits and dairy products. New products that meet regulatory definitions of fiber have recently been marketed, yet isolation procedures and definitions of the term vary greatly, creating the need for a uniform concept. If adopted for use in food regulations, the new set of definitions will determine which fiber-like food additives are counted as fiber on the mandatory nutrition facts food labels.

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The report's recommendations provide the basis for the current review and update of Dietary Guidelines for Americans, to be completed by 2005 by an advisory committee to the U.S. Departments of Agriculture and of Health and Human Services, and similar evaluations in Canada. Additionally, a follow-on study by the Food and Nutrition Board is under way. Requested by Health Canada, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture, it is to provide specific guidance on how to adapt the DRIs for use as reference values on food labels. This will facilitate harmonizing food labels between the two countries, a move strongly supported by the food industry. In a related study, the U.S. Department of Agriculture has asked the Institute of Medicine to recommend foods to include in the food packages provided to participants in the agency's Supplemental Feeding Program for Women, Infants and Children (WIC), in line with the new DRI recommendations.

PROTECTING RESEARCH PARTICIPANTS

The explosion of knowledge emanating from basic science efforts, such as the Human Genome Project, will lead to previously unimagined therapies and an era of individualized medicine. The translation of discoveries in fundamental and applied science into useful clinical and public health interventions depends upon rigorous clinical trials involving large cohorts of patients with appropriate phenotypes for studies. Such trials, in turn, require a strong and effective system to protect the individuals who participate in them. Mounting concerns about the well-being of research participants and the capability of existing approaches to ensure participant protection, led the Department of Health and Human Services to commission a comprehensive assessment of the national system for providing participant protection. A fast-track first report, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs* (2001), focused on the potential value of accreditation. In that report and in the second phase report, *Responsible Research: A Systems Approach to Protecting Research Participants* (2002), the case was made that a set of complementary elements and activities are necessary to ensure adequate protection for research participants. Pilot testing accreditation was identified as one promising approach to improve the system. The reports also recommend that federal oversight be extended to all research, regardless of the sponsor; call for greater public participation in the ethical oversight of research; and make recommendations about education, coordination, monitoring, and other topics.

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The reports have resulted in a number of actions by the federal government. The Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), the National Institutes of Health, and the Department of Veterans Affairs coordinate the development and dissemination of ethics education practices. In addition, OHRP and FDA require that research organizations are notified of deficiency warnings and related communications by regulatory agencies and are harmonizing safety monitoring guidance, including standard practices to define and report adverse events. The Secretary's Advisory Committee for Human Research Protections will address a number of the committee's recommendations and advise the Secretary of DHHS how to proceed. Legislators also have cited the reports and intend to build on the committee's recommendations in legislation to extend federal oversight to all research.

A number of the report's recommendations can be implemented without direct government action. Their explicit incorporation into the accreditation standards of the Association for the Accreditation of Human Research Protection Programs and the Partnership for Human Research Protection is a notable early result. The committee's recommendations have been widely discussed in the research community and elsewhere, and members of the IOM's Clinical Research Roundtable have considered how to implement them. Other organizations also are evaluating the reports and determining their next steps in light of the recommendations.

PALLIATIVE AND END-OF-LIFE CARE FOR CHILDREN AND THEIR FAMILIES

In 1997, the Institute of Medicine published *Approaching Death: Improving Care at the End of Life,* the first comprehensive, evidence-based report on this subject. *Improving Palliative Care for Cancer* followed in 2001, building and extending on the earlier report, with a focus on the quality of palliative and end-of-life care for cancer patients.

In a new report, *When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families* (2002), the IOM examines care for children with fatal or potentially fatal medical conditions and their families. Although these children have some characteristics and problems in common with very ill adults, they also present special concerns and complexities. For example, whereas adults most often die of heart disease and other chronic conditions, the leading causes of death in childhood are problems related to prematurity and childbirth, congenital anomalies, and intentional and unintentional injuries. A child's death may be the most stressful and painful experience that a family can face.

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Unfortunately, children and families too often fail to receive palliative, end-of-life, and bereavement care that meets their special physical, psychological, and spiritual needs. To improve care, the report recommends changes in four broad areas:

- *Organizing and delivering services:* Develop care guidelines and protocols as a basis for assigning responsibility and evaluating and then improving performance;

- *Financing care:* Eliminate hospice coverage requirements for a 6-month prognosis and the foregoing of curative and life-prolonging care; reduce restrictions on palliative care benefits, including consultations and parent counseling;
- *Educating health professionals:* Provide undergraduate, graduate, post-graduate, and continuing education in palliative, end-of-life care, and bereavement care tailored to the responsibilities of every professional who cares for children; and
- *Strengthening the knowledge base:* Set priorities for research in palliative, end-of-life, and bereavement care.

Since the report was released in mid-2002, a group of clinicians, educators, researchers, and policy and financing experts have organized to promote the implementation of the report's recommendations. Legislation based on several of the committee's proposals has been introduced in Congress, and the National Institutes of Health has published priority areas for research in pediatric palliative and end-of-life care.

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IMMUNIZATION SAFETY

The Immunization Safety Review Committee was established at the request of the Centers for Disease Control and Prevention and the National Institutes of Health to provide independent, timely, and objective assistance to the Department of Health and Human Services in evaluating the available evidence on a series of immunization safety concerns. For each hypothesis to be examined, the IOM committee assesses both the scientific evidence and the significance of the issue for society. The scientific assessment has two components: an examination of the epidemiological and clinical evidence regarding a possible causal relationship between the immunization and the adverse event; and an examination of experimental evidence for any biological mechanism(s) relevant to the hypothesis. The significance assessment addresses such considerations as the burden of the health risks associated with the vaccine-preventable disease and with the adverse event in question, as well as the level of public concern about the safety issue.

Over a three year period, the Immunization Safety Review Committee has issued seven reports assessing putative adverse effects and immuniza-

tions. Thus far, the committee has considered the issues of multiple immunizations and immune dysfunction, hepatitis B and demyelinating disorders, SV40 contamination of Polio vaccine and cancer, vaccinations and sudden unexpected death in infancy, thimerosal-containing vaccines and-neurodevelopmental disorders, and measles-mumps-rubella vaccine and autism.

The project sponsors, CDC and the NIH, have responded quickly to many of the policy-analysis and research recommendations. For example, the NIH has pursued basic research on the pharmacokinetics of thimerosal exposure, and the CDC is developing a case-control study to study the putative relationship between vaccines and autism. CDC and other federal agencies prominently link from their websites to the committee reports. Decisions by Special Masters of the Vaccine Injury Compensation Program frequently cite IOM reports as evidence supporting or refuting a vaccine-causation allegation. At a recent conference of immunization program managers, several state and clinic-based providers reported that they use executive summaries and abstracts as communication tools for parents who desire more information about a specific vaccine safety concern. Committee reports and the material on the IOM Immunization Safety webpage, which includes audiofiles and PowerPoint presentations from public workshops of the committee, are used as teaching tools. Finally, the work of the committee is frequently cited as an authoritative voice to the general public in mass media stories about vaccine safety, including in *Parade* magazine, the BBC, the *Diane Rehm Show* on National Public Radio, and *American Baby*.

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SMALLPOX VACCINATION PROGRAM IMPLEMENTATION

In 2002, the Centers for Disease Control and Prevention requested targeted advice from the IOM on the implementation of a "pre-event" or precautionary smallpox vaccination program. CDC charged the IOM with providing guidance on how to best implement the President's policy regarding pre-event smallpox vaccination addressing the following eight areas: the informed consent process, contraindications screening, the system in place to assess the safety profile of the smallpox vaccine, guidance for the treatment of vaccine complications, professional training programs CDC is developing, the communications efforts, and guidance CDC offers to states in developing their implementation plans, and overall progress at achiev-

ing the goals of the program. In the process of providing rapid and timely advice to CDC, the IOM Committee on Smallpox Vaccination Program Implementation has held several meetings and issued four letter reports that have contributed significantly to improving CDC's implementation of the program.

Based on the committee's recommendations, CDC has put into operation an active surveillance system to supplement the data collected by the Pre-event Vaccination System and to help ensure that all adverse events following smallpox vaccination are reported and investigated. In their efforts to encourage Congress to pass a smallpox vaccine compensation program, professional groups representing some of the first smallpox vaccine recipients cited the committee's recognition that informed consent of the vaccinated individuals could be affected by their understanding of the compensation available (or lack thereof) for serious adverse reactions or subsequent medical costs. The committee's recommendations about critical education and communications issues prompted CDC to develop and implement informational sheets for household contacts of vaccine recipients and to prospective vaccine recipients with information about the status of compensation issues. Additionally, CDC has built in a great deal of flexibility for states to define priorities for preparedness, including pausing to evaluate and consider next steps. This is congruent with the committee's recommendations about balancing national goals with local needs and circumstances.

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The National Vaccine Advisory Committee (NVAC) and the Advisory Committee on Immunization Practices (ACIP) made note of IOM reports and recommendations at their meetings in February 2003 (NVAC) and June 2003 (ACIP). IOM's call for a pause to evaluate the program and ensure its continuing safety was part of the discussion at NVAC and ACIP meetings, and ultimately, helped with the development of those committees' recommendations for a delay in the vaccination program to ensure caution and allow for adequate evaluation. Additionally, the April 2003 General Accounting Office report assessing the progress of the smallpox vaccination program compared recommendations made in the IOM reports with CDC's implementation of the program, and identified areas of the program that needed improvement.

THE FUTURE OF PUBLIC HEALTH

In 1988, the IOM published *The Future of Public Health*. The report defined public health as what society does collectively to assure the conditions for people to be healthy and presented strong evidence to indicate that the public health system—the organizational mechanism for achieving the best population health—was in disarray. Although the report described the public health system as the governmental public health agencies and "the associated efforts of private and voluntary organizations and individuals," it focused specifically on ways to strengthen governmental public health infrastructure. In 2001, a new IOM committee was convened with the charge to create a framework for assuring population health in the United States that would be more inclusive than that of the 1988 report and that could be effectively communicated to and acted upon by diverse communities. In the new report, *The Future of the Public's Health in the 21st Century*, the committee examines both the governmental component of the public health system and the potential contributions of other sectors and entities. The report reviews the nation's public health capabilities and presents a comprehensive framework for how the government public health agencies, working with multiple partners from the public and private sectors as an intersectoral public health system, can better assure the health of communities by: adopting a population health approach that considers the multiple determinants of health; strengthening the governmental public health infrastructure, the backbone of the public health system; building a new generation of intersectoral partnerships; requiring accountability from and among all sectors of the public health system; making evidence the foundation of decision-making; and enhancing and facilitating communication within the public health system.

...a new IOM committee was convened with the charge to create a framework for assuring population health in the United States that would be more inclusive than that of the 1988 report and that could be effectively communicated to and acted upon by diverse communities.

The report was launched at the 130th Annual Meeting of the American Public Health Association (APHA) in November 2002. Audience reaction was brisk, including enthusiasm for the content, commitment to develop action agendas and, from the foundations, interest in a program of grants to implement several of the more far-reaching recommendations. Dissemination activities since launch have included presentations at meet-

ings of over twenty major national and state public health and professional leadership organizations, Congressional briefings and meetings with members of the press. At the federal level, CDC has adopted the report as the framework or starting point for its strategic planning process. Several programs within CDC have used the report to launch activities to strengthen the public health workforce and to improve public health system performance.

The report was also featured at the joint meetings of National Association of County and City Health Officials and Association of State and Territorial Health Officers in September 2003. In addition, the major public health organizations have developed committees to implement the report recommendations.

A related report, *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century,* was released on November 4, 2002, and has since become the focus of much planning and activity related to developing the public health workforce. The Public Health Workforce Development Collaborative has made the report the focus of strategic planning efforts—adopting the core recommended competencies, generating a set of curricula, and developing a research agenda. The Council on Linkages between Academia and Public Health Practice continues to develop the strategy to assure that the nation considers certification of public health professionals. The Association of Schools of Public Health has made several issues and recommendations in the report a priority for discussion and action at its upcoming meetings. The American Public Health Association is developing a "convener project" which will include an annual forum at the annual APHA meeting to report on the progress made to implement recommendations. An enthusiastic reception by the American College of Preventive Medicine led to adoption of a strongly worded resolution by the American Medical Association to advance the role of the physician in public health and re-constitute the medicine-public health initiative.

The Public Health Workforce Development Collaborative has made the report the focus of [its] strategic planning efforts...

Georgia State University recently developed a new undergraduate MPH program based on the proposed framework and recommendations of the *Who Will Keep the Public Healthy?* report. If approved, as expected, by the Board of Regents, Georgia will be the first state to adopt in full the recommended framework.

Selected Recommendations for Global Health and Infectious Disease

Microbial Threats to Health: The United States should seek to enhance the global capacity for response to infectious disease threats, focusing in particular on threats in the developing world. U.S. federal, state, and local governments should direct the appropriate resources to rebuild and sustain the public health capacity necessary to respond to microbial threats to health, both naturally occurring and intentional. CDC, DoD, and NIH should develop new and expand upon current intramural and extramural programs that train health professionals in applied epidemiology and field-based research and training in the United States and abroad.

The U.S. Secretary of Defense, the U.S. Secretary of Health and Human Services, and the U.S. Secretary of Homeland Security should work closely with industry and academia to ensure the rapid development and deployment of vaccines for naturally occurring or intentionally introduced microbial threats to national security. Further, CDC, FDA, professional health organizations, academia, health care delivery systems, and industry should expand efforts to decrease the inappropriate use of antimicrobials in human medicine. (*Microbial Threats to Health: Emergence, Detection, and Response,* 2003)

Global Emerging Infections Surveillance: Support for the Global Emerging Infections Surveillance and Response System of the Department of Defense and the facilities that sustain it should be increased to allow GEIS to completely fulfill its potential. Pursuit of collaborative, well-coordinated relationships with international organizations, U.S. Government agencies (including other DoD laboratory entities), and relevant agencies of foreign governments should be continued and expanded to the extent possible. (*Perspectives on the Department of Defense Global Emerging Infections Surveillance and Response System: A Program Review,* 2001)

Brain Disorders in Developing Countries: Extend and strengthen existing systems of primary care to deliver health services for brain disorders. Secondary and tertiary centers should train and oversee primary care staff, provide referral capacity, and provide ongoing supervision and support for primary care systems in developing countries. Make cost-effective interventions for brain disorders available to patients who will benefit. (*Neurological, Psychiatric, and Developmental Disorders: Meeting the Challenge in the Developing World,* 2001)

GLOBAL HEALTH AND INFECTIOUS DISEASE

Our national interests are inevitably linked to the health of people throughout the world. Health, like education, is an investment in human capital that can help break cycles of poverty and political instability—contributing to national and global economic development—and is of fundamental importance in shaping the stability and well-being of a nation or region. The tragedy of HIV/AIDS in Africa has deeply scarred large regions of the continent, and it threatens to undermine economic progress, institutional strength, and the survival of family units. Although less visible than the AIDS epid-emic, the human toll of economic hardship and social instability in Russia has resulted in a 10-year decrease in life expectancy for men, and an over 40 percent decrease in birth rate from the mid-80s to the mid-90s, far lower than the replacement rate needed to sustain population levels, the economy, and current standards of living. These are only two examples of global health events that could threaten peace, prosperity, and international relationships in the decades to come. The global reach of emerging infectious diseases can be more immediate. Within days of the issuance of *Microbial Threats to Health Emergence, Detection, and Response* (2003), the SARS epidemic burst into worldview, reminding us that a pandemic can emerge with astonishing speed and spread globally in a matter of weeks. Shortly thereafter, bovine spongiform encephalopathy (Mad Cow Disease) and monkeypox emerged for the first time in the Americas.

Health, like education, is an investment in human capital...

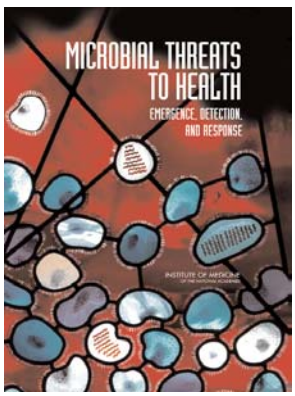
The IOM contributes to improved global health through studies that advise on how to reduce the burden of disease and disability in developing countries, that illuminate emerging threats to international and global health, and that emphasize infectious diseases—the most truly global threats to health.

INFECTIOUS DISEASE

Infectious diseases today ignore geographic and political boundaries, and thus constitute a global threat that places every nation and every person at risk. Food products, livestock, exotic pets, and material goods and the microbes they carry are exchanged as cultures from every region of the world are explored. –Microbial Threats to Health, 2003

Infectious diseases continue to burden populations around the world. Both naturally occurring and intentionally introduced biological threats hold increasing potential to cause disease, disability, and death. Through both committee studies and convening activities, the IOM assesses emerging threats, the capacity of national and international systems to respond to those threats, and the research and other investments necessary to mount an adequate response.

Microbial Threats to Health: Emergence, Detection, and Response (2003) concludes that the public health and medical communities in the United States are inadequately prepared to deal effectively with infectious diseases. The report extends and expands upon a 1992 IOM report, *Emerging Infections: Microbial Threats to Health* in the United States, which brought this issue to national attention and stimulated research efforts and policy actions. The new report describes scientific, social, and political trends that have influenced infection and disease emergence and control over the past decade. New or previously unrecognized diseases (such as SARS) have emerged, and known diseases that were thought to be virtually eradicated in the U.S. (such as measles and pertussis) have reappeared, occasionally in epidemic proportions. The report reviews the current state of knowledge on how infectious diseases emerge and identifies opportunities for public health actions, both domestic and worldwide, to strengthen capabilities for detecting and responding to microbial threats and preventing the



Leading Infectious Causes of Death Worldwide, 2001

Cause	Rank	Estimated Number of Deaths
Respiratory infections	1	3,871,000
HIV/AIDS	2	2,866,000
Diarrheal diseases	3	2,001,000
Tuberculosis	4	1,644,000
Malaria	5	1,124,000
Measles	6	745,000
Pertussis	7	285,000
Tetanus	8	282,000
Meningitis	9	173,000
Syphilis	10	167,000

SOURCE: WHO, 2002b.

spread of infectious diseases. It calls on the United States to make significant efforts to enhance the global capacity for responding to microbial threats, focusing in particular on threats in the developing world. This will require providing technical and financial assistance, expanding research and surveillance, and sharing knowledge and best public health practices across national boundaries. Among other recommendations, the report stresses the need for federal, state, and local governments to rebuild and sustain the infrastructure of the U.S. public health system, which has suffered from years of neglect.

An effective surveillance system is critical to detect and monitor infectious disease, both within the U.S. and globally. In 1996, the Executive Office of the President, acting on advice from its National Science and Technology Committee, issued a directive declaring that U.S. citizens were not being adequately protected from emerging infectious diseases. The directive (NSTC-7) stated that national and international capabilities for monitoring, responding to, and preventing infectious diseases were insufficient, and it called for a more robust national policy to improve these capabilities. Among actions taken in response, the Department of Defense in 1997 established the Global Emerging Infections Surveillance and Response System (GEIS). After several years of operation, managers of the GEIS asked IOM to conduct an independent evaluation of the system's structure and progress. *Perspectives on the Department of Defense Global Emerging Infections Surveillance and Response System* (2001) concludes that the GEIS is well organized, satisfies the requirements prescribed by the Presidential Directive, and comprises an appropriate response to the threat posed to national security by emerging infectious diseases. Although still in its early stages, the GEIS has made substantial progress

toward achieving its goals in protecting the health of U.S. military and civilian populations, as well as global health interests. The report recommended some refinements—such as increasing the number of personnel who have applied epidemiological expertise, expanding training programs, and broadening communications efforts to include public health partners—and called for the government to increase financial support for the system to help ensure its long-term success.

Unlike viruses and microorganisms—the agents of most known infectious diseases—prions are an abnormally shaped form of a normal mammalian protein. Identified in 1982, prions appear to be associated with a group of uniformly fatal neurodegenerative diseases called transmissible spongiform encephalopathies (TSEs), which include "Mad Cow Disease." Conventional methods useful to diagnose most infectious diseases fail to detect TSEs. There is no cure, prophylaxis, or fail-safe antemortem diagnostic test for TSEs. A decade's worth of attempts to develop effective prion-detection tests have largely failed. Consequently, the U.S. Department of Defense launched the National Prion Research Program in 2002 with $42.5 million and requested the assistance of the IOM to review scientific knowledge about TSEs and to recommend the highest-priority research for funding. *Advancing Prion Science: Guidance for the National Prion Research Program* (2003) concludes that progress in developing an antemortem diagnostic test to detect prions will be slow unless fundamental questions are answered about the molecular biology of prions and the normal prion protein from which it is derived. The committee stressed that the infrastructure capability for research on TSEs in the U.S. is limited due to constraints in funding, lab facilities, and number of investigators trained in this highly specialized area. International collaboration offers opportunities to expand that capacity.

...prions appear to be associated with a group of uniformly fatal neurodegenerative diseases called transmissible spongiform encephalopathies (TSEs), which include "Mad Cow Disease."

Antimalarials

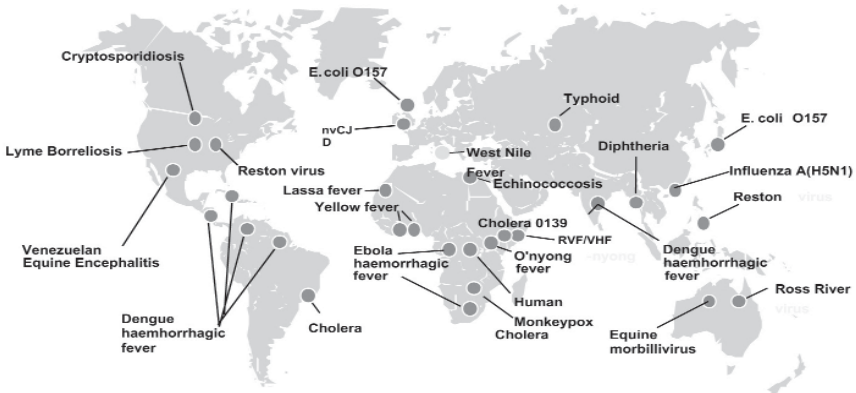
Malaria remains the leading killer of children in Africa and a significant cause of morbidity among adults and children in Africa, Asia, and focally, in other parts of the world. Resistance to inexpensive antimalarial drugs is widespread, and few effective drugs—even expensive ones—exist to fill the current need, which is growing. An upcoming IOM report will examine evolving patterns of malaria (including drug resistance) and the options for

controlling it, with the aim of developing policy strategies, particularly financing strategies, that could lead to the greatest good for those most affected, as well as for the larger population at risk. The potential for incremental improvement of existing, new antimalarials through pharmaceutical technology also will be explored.

FORUM ON MICROBIAL THREATS

The challenges posed by infectious diseases demand concerted and coordinated efforts along a number of fronts, from treating individual patients and preventing the spread of disease within communities to shaping public policies in the United States and worldwide. The IOM's Forum on Microbial Threats, created in 1996, fosters wide-ranging discussions among the various parties who share a stake in improving the prevention, detection, and management of these diseases. Forum workshops provide timely opportunities for representatives from academia, industry, professional and interest groups, and government to discuss, in a neutral setting, critical and sometimes contentious issues. Such cross-sector dialogue has helped in establishing priorities for research and public health policy, identifying areas in need of greater attention, and illuminating opportunities for more effective collaboration between the private and public sectors. Recent workshop reports include:

- *Emerging Infectious Diseases from the Global to the Local Perspective* (2001). Infectious diseases are the world's greatest killers, accounting for more than 13 million deaths annually among children and young adults alone. Most deaths from infectious diseases occur in developing countries,



Emerging and Re-emerging Infectious Diseases, 1996-1997. SOURCE: *Emerging Infectious Diseases from the Global to the Local Perspective: Workshop Summary,* 2001, page 3.

where they account for half of all deaths. But no region is free from concern, and every inhabited continent regularly experiences large outbreaks of some type of infectious disease. The IOM report concludes that fighting the global spread of infectious diseases will take political resolve and sufficient financial resources. The workshop brought together key representatives from the Americas, Africa, Asia and the Pacific, and Europe. They surveyed such issues as the factors that contribute to the emergence of infectious diseases, efforts to coordinate surveillance activities and responses within and across borders, and remaining needs for research and resources. In the report, participants stressed that the world community must work toward a set of common goals. Among these goals are strengthening disease surveillance of humans and domestic animals (which can pass diseases to humans), fostering good public health practices, expanding training programs, conducting collaborative research in a number of targeted areas, and accelerating vaccine development and distribution.

- *The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health* (2002). Diseases passed to humans from animals—zoonoses—are leading causes of illness and death in many nations, and they negatively affect commerce, travel, and economies worldwide. Many factors influence the emergence and spread of zoonoses, ranging from molecular interactions in microbes to forces that trigger the growth and movement of populations and changes in the environment. There also is concern about the potential use of zoonotic agents as "bioweapons" by terrorists. The IOM report explores the forces that drive zoonotic diseases and offers some broad-based strategies that will help the United States and the world in preventing and controlling them. Participants cited a need to expand research in a variety of areas, including the pathogenesis of zoonotic agents and the development of vaccines; to enhance national and international laboratory capabilities; to strengthen surveillance systems that can provide early warning for emerging zoonoses; and to mount education programs to increase public awareness of the problems and minimize undue fears. Perhaps the most fundamental need is for improved collaboration and cooperation among government agencies at all levels, as well as among members of the human health, veterinary, wildlife health communities.

There also is concern about the potential use of zoonotic agents as "bioweapons" by terrorists...

- *Considerations for Viral Disease Eradication: Lessons Learned and Future Strategies* (2002). The success in using vaccines to eradicate smallpox suggests the possibility of eradicating many other viral diseases that once

were considered beyond hope. Indeed, the eradication of several diseases, including polio and measles, is on the horizon. This prospect raises the importance of addressing early on a range of issues likely to surround the cessation of immunization and other prevention activities. The IOM report examines the biological challenges, medical interventions, and operational considerations to be faced and highlights efforts that may facilitate wise decision-making in the post-eradication era. Participants particularly emphasized that eradication must not beget complacency. Reemergence of a virus—or its intentional reintroduction—will remain a threat, especially as immunity wanes and the population at large grows more susceptible to infection. Enough vaccine should be stockpiled (or provision made for emergency replenishment) to cope with any outbreaks that might arise, and surveillance should continue to quickly identify local outbreaks before they can spread. Among other actions, it is vital to continue research on viral biology and vaccine technology, and to make sure that remaining viral stocks—if it is deemed necessary to maintain such stocks—be securely contained.

- In the wake of September 11 and recent anthrax events, our nation's bioterrorism response capability has become an imminent priority for policymakers, researchers, public health officials, academia and the private sector. In a three-day workshop that was captured in a workshop summary titled *Biological Threats to Terrorism: Assessing the Science and Response Capabilities* (2002), experts from each of these communities came together to identify, clarify, and prioritize the next steps that need to be taken in order to prepare and strengthen bioterrorism response capabilities. From the discussions, it became clear that of utmost urgency is the need to cast the issue of a response in an appropriate framework to attract the attention of Congress and the public in order to garner sufficient and sustainable support for such initiatives. No matter how the issue is framed, numerous workshop participants agreed that there are many gaps in the public health infrastructure and countermeasure capabilities that must be prioritized and addressed in order to assure a rapid and effective response to another bio-terrorist attack.

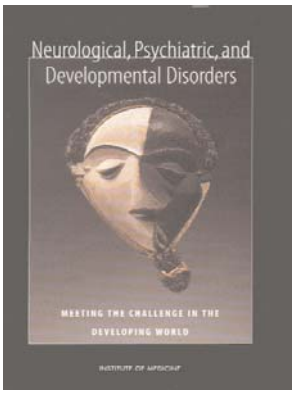
...our nation's bioterrorism response capability has become an imminent priority for policymakers, researchers, public health officials, academia and the private sector.

- *The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment* (2003). Resistance in bacteria, viruses, and protozoa to therapeutic agents is an increasing challenge. More microbes are becoming resistant to more

drugs, thereby reducing the power of drugs for combating infectious diseases. The IOM report discusses the causes and consequences of drug resistance in microbes and examines current and potential strategies for mitigating its impact on human health. Participants stressed that the emergence of resistance must be recognized as an integral part—not an aberrant part—of microbial life. Developing a fuller understanding of how microbes evolve when faced with drugs may lead to innovative ways to bring them under control. Additionally, the report examines the influence of pesticide and insecticide resistant infectious disease vectors on control measures for diseases such as malaria. Other suggestions for action include fully implementing national and international programs being developed to contain microbial resistance, expanding surveillance efforts to ensure early detection of problems, supporting scientific and epidemiological studies in targeted areas, strengthening professional education and training, and conducting economic studies to both inform policy making and suggest incentives for encouraging individuals and institutions to adopt practices that will help limit the spread of antimicrobial resistance.

IMPROVING CARE IN THE DEVELOPING WORLD

Brain disorders now affect at least 250 million people in the developing world, and this number is expected to increase as more people live to old age. Brain disorders encompass a wide range of disabling conditions, including epilepsy, stroke, schizophrenia, unipolar depression, bipolar disorder, mental retardation, cerebral palsy, and autism. Yet public and private health systems in developing countries have paid relatively little attention to brain disorders, concentrating instead on the major communicable diseases. *Neurological, Psychiatric, and Developmental Disorders: Meeting the Challenge in the Developing World* (2001) concludes that there are effective and affordable ways to treat or even prevent many brain disorders in developing countries, and it presents a comprehensive plan designed to help these countries help their citizens who have or are at risk of developing epilepsy, schizophrenia, depression, or other such disorders. The report outlines strategies that can be implemented immediately in developing countries, such as increasing public and professional awareness and understanding of brain disorders, extending and strengthening systems of primary care to deliver health services for brain disorders, and



making cost-effective interventions available to patients who will benefit. It also proposes strategies for creating better options for the future. Actions include assessing the cost-effectiveness of specific treatments and health services in local settings and monitoring the incidence, prevalence, and burden of brain disorders in developing countries; creating national centers in developing countries to carry out training and research on brain disorders, and linking these centers with institutions in high-income countries; and crafting and funding global programs devoted to improving understanding of brain disorders in the developing world.

The death of a mother, fetus, or newborn is tragic wherever it occurs. While relatively rare in the industrialized world, these deaths are considerably more common in developing countries, accounting for the vast majority of the 515,000 maternal deaths; 4 million late fetal deaths; and 4 million neonatal deaths conservatively estimated to occur each year. Most of these deaths occur between late pregnancy and the end of the first week of a child's life. Each year, more than 4 million children are born with birth defects, one of the major causes of death in newborns. A set of companion reports, *Improving Birth Outcomes: Meeting the Challenges in the Developing World* (2003) and *Reducing the Impact of Birth Defects: Meeting the Challenges in the Developing World* (2003), review the evidence on interventions that can improve birth outcomes and reduce birth defects. The *Outcomes* report recognizes the important role of women's education, social, and economic status on birth outcomes. It also reviews the available statistics on major causes of maternal and neonatal mortality and morbidity and of fetal loss, summarizes current knowledge and practice with regard to a healthy pregnancy, and identifies cost-effective opportunities for improving birth outcomes. Three adverse birth outcomes are addressed in more detail: low birthweight; birth defects; and perinatal transmission of HIV/AIDS. The report concludes that a skilled birth assistant should attend every birth.

Accessible essential obstetric and neonatal care facilities are also necessary. The *Defects* report highlights the unprecedented opportunity to improve the lives of children and families in developing countries by preventing some birth defects and reducing the consequences of some others. The report concludes that incidence and burden of certain birth defects can be reduced at very low costs and recommends increased collection of epidemiological data and increased genetic screening.

Selected Recommendations for Health Sciences Research

The Role of Large-Scale Science: NIH and other federal funding agencies that support large-scale biomedical science should develop a more open and systematic method for assessing important new research opportunities emerging from the scientific community in which a large-scale approach is likely to achieve the scientific goals more effectively or efficiently than traditional research efforts. (*Large-Scale Biomedical Science: Exploring Strategies for Future Research,* 2003)

Protecting Research Participants: Federal regulations should be extended to include every research project that involves human participants, regardless of the source of funding or the setting.

The Institutional Review Board (IRB), as the principal representative of the interests of potential research participants, should focus on the ethical aspects of protecting participants with other organizational units taking responsibility for risk management and regulatory compliance.

The informed consent process should be an ongoing, interactive dialogue between research staff and research participants that includes an assessment of participants' understanding of the discussion. (*Responsible Research: A Systems Approach to Protecting Research Participants,* 2002)

Focus on Integrity in Research: Funding agencies should establish research grant programs to identify, measure, and assess those factors that influence integrity in research. Also, each research institution should develop and implement a comprehensive program designed to promote integrity in research, using multiple approaches adapted to the specific environments within each institution.

Institutions should implement effective educational programs that enhance the responsible conduct of research. (*Integrity in Scientific Research,* 2002)

Expanding Research on the Role of Sex in Human Health: Promote research on sex at the cellular level; study sex differences over a lifetime; and examine genetic variability, disorders of sex differentiation, reproductive status, and environmental influences to better understand human health. Also, expand research on sex differences in brain organization and function. Monitor sex differences and similarities for all human diseases that affect both sexes. (*Exploring the Biological Contributions to Human Health: Does Sex Matter?,* 2001)

HEALTH SCIENCES AND THE RESEARCH ENTERPRISE

The pursuit and diffusion of knowledge enjoy a place of distinction in American culture, and the public expects to reap considerable benefit from the creative and innovative contributions of scientists.—Integrity in Scientific Research, 2002

HEALTH SCIENCES RESEARCH

Biomedical research is in a period of rapid change, as technological advances enable the study of complex biological systems. This ability has fueled the launch of projects that are large in scope, involve more cross-disciplinary research and promise faster improvements in human health. Supporting this new science will require major changes in planning, resources, and management. *Large-Scale Biomedical Science: Exploring Strategies for Future Research* (2003) describes how the National Institutes of Health (NIH) and other federal agencies should select, fund, implement, and evaluate large collaborative projects, and how their staffs should be trained and retained. Among the recommendations, agencies should develop a more open and systematic method for assessing research opportunities emerging from the scientific community in which a large-scale approach is likely to prove more effective than traditional research efforts. Projects must have clear but flexible plans that cover everything from how they are initially organized to how they will be phased out when goals are met. To ensure that

...agencies should develop a more open and systematic method for assessing research opportunities emerging from the scientific community...

high-caliber scientists and managers will want to participate, funding agencies and universities should develop new approaches for assessing teamwork and management, as well as novel ways of rewarding accomplishment in such positions. Universities, for example, could revise policies on tenure and promotion to recognize the value of contributions to collaborative research. Cooperation between academia and industry should be encouraged in order to speed research and development and reduce the overall cost of future large-scale projects.

The National Institutes of Health has a remarkable record of success. But concerns have arisen that the agency has grown too fragmented and unwieldy, and that its current organizational structure cannot accommodate the increasing pace of scientific discoveries. Acting on such concerns, Congress asked for advice on the organization and management of the NIH. *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (2003) concludes that important changes are needed and provides a blueprint for strengthening the agency's operations. In particular, it recommends modifications that will better enable NIH to pursue innovative interdisciplinary research that reflects strategic objectives and cuts across all of its institutes and centers. One fruitful area for such "trans-NIH" research is obesity, which is associated with health problems (such as heart disease, diabetes, and arthritis) that concern numerous of the agency's branches. NIH also should establish a special projects program, under the director's authority, to fund cutting-edge research that is risky but offers a high potential for payoff in terms of cures and new treatments. The report does not recommend major reorganization of NIH, noting the inevitable turmoil that creates within an organization. Rather, it calls for Congress to establish a formal process for reviewing specific proposals for changes in the NIH structure. This process should be used to study two mergers favored in the report: the combining of the National Institute on Drug Abuse with the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of General Medical Science with the National Human Genome Research Institute.

...important changes are needed [at NIH]...

Clinical trials are the primary means used to elucidate the most appropriate preventive, diagnostic, or treatment options for individuals with a given medical condition. Ample size is a crucial component of any clinical trial, and the number of participants should be large enough to provide a sufficiently precise answer to the research question posed. But the context

of clinical trials sometimes greatly limits the number of research subjects available. *Small Clinical Trials: Issues and Challenges* (2001) concludes that properly designed trials may provide substantial evidence of efficacy and be warranted under certain conditions. Situations in which small trials may be appropriate include evaluating treatments for rare disorders, studying unique patient populations (such as astronauts or members of isolated communities), assessing individually tailored therapies, and responding to urgent threats to public health. The report describes ways to design and analyze trials to obtain reliable and valid results when only limited numbers of participants are available. These include carefully defining the research question and tailoring the study design, clarifying sample characteristics and methods, performing corroborative analyses to evaluate the consistency and robustness of results, and exercising caution in interpreting the results before attempting to extrapolate or generalize the findings. The report also recommends that more research be conducted on the development and evaluation of alternative experimental designs and analysis methods for trials with small sample sizes.

Research on stem cells, primitive types of cells that transform in the body to become different kinds of tissue, may ultimately lead to improved

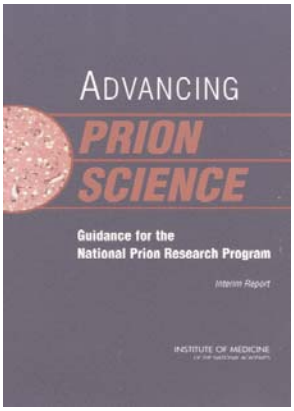
Important Concepts in Clinical Trial Design

- Does the trial measure efficacy or effectiveness?
- A method of reducing bias (randomization and masking [blinding])
- Inclusion of control groups
  - Placebo concurrent controls
  - Active treatment concurrent controls (superiority versus equivalence trial)
  - No-treatment concurrent controls
  - Dose-comparison concurrent controls
  - External controls (historical or retrospective controls)
- Use of masking (blinding) or an open-label trial
  - Double-blind trial
  - Single-blind trial
- Randomization
  - Use of randomized versus nonrandomized controls
- Outcomes (endpoints) to be measured: credible, validated, and responsive to change
- Sample size and statistical power
- Significance tests to be used

SOURCE: *Small Clinical Trials: Issues and Challenges,* 2001, page 21.

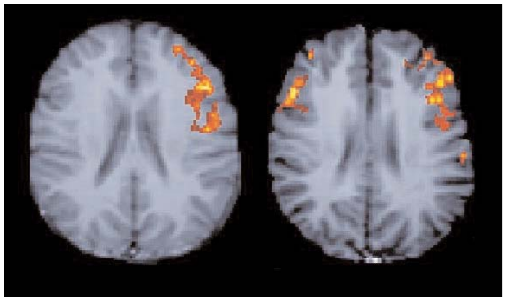
medical treatment, even cure, for millions of people who suffer from heart disease, cardiovascular disease, Alzheimer's disease, cancer, spinal-cord injuries, and numerous other disorders. But many people have moral and ethical concerns about such research, especially regarding the use of stem cells obtained from human embryos. *The Promise of Stem Cells: From Research to Medical Therapies* (2002) clarifies what is known about the scientific potential of stem cells, reviews concerns about their use in research and practice, and recommends ways to proceed responsibly from current understanding to useful treatments for people in need. Its primary message is that keeping as many avenues of research open as possible, including studies on both embryonic and adult stem cells from both animals and humans, will best pave the way to therapeutic advances. Moreover, it is vital to continue public funding of research on stem cells. Publicly funded research, conducted under established standards of open scientific exchange, peer review, and public oversight, offers the most efficient and responsible means to achieve medical breakthroughs. To address the ethical dilemmas and scientific uncertainties raised by research involving embryonic stem cells, the National Institutes of Health should create a national blue-ribbon advisory board to ensure that proposals for federal funding for such work are justified on scientific grounds and that they meet current and future federally mandated ethical guidelines.

The 1985 outbreak of mad cow disease in the United Kingdom generated global awareness of a new class of neurodegenerative diseases called transmissible spongiform encephalopathies (TSEs), which appear to be caused by infectious agents called prions. Identified in 1982, prions are an abnormally shaped form of a normal mammalian protein. There is no treatment for TSEs, which uniformly prove fatal. Nor is there a fail-safe method of diagnosing TSEs or detecting prions during the lengthy period in which they incubate in the body. Consequently, the Department of Defense launched the National Prion Research Program in 2002 and asked the IOM to provide a research agenda for the first round of grants. *Advancing Prion Science: Guidance for the National Prion Research Program* (2003) provides that agenda. It recommends a number of strategies for achieving a diagnostic test that is rapid, sensitive, and specific enough to detect minute amounts of prions without producing false-positives. One approach is to develop novel methods and reagents that detect or bind to prions, an advance that may lead not



only to better diagnostics but also to new methods of treating and even preventing TSEs. Another approach is to identify easier-to-spot surrogate markers that indicate the presence of prions or TSEs. The report stresses that funding should be expanded for basic research, as it will be virtually impossible to devise useful diagnostic tests without a better understanding of the structural and functional properties of prions and the pathogenesis and epidemiology of TSEs.

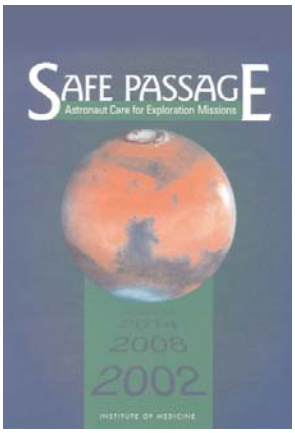
Being male or female is an important basic human variable that affects health and illness throughout life. But this realization has been slow in coming, as scientists until recent years largely ignored studies of the effects of sex at the basic cellular and molecular levels. *Exploring the Biological Contributions to Human Health: Does Sex Matter?* (2001) reviews the current understanding of sex differences and determinants at the biological level, identifies barriers to research in this area, and recommends ways to eliminate those barriers. It concludes that there is now sufficient knowledge to validate the study of sex differences and to enable the generation of hypotheses. The next step is to move from the descriptive to the experimental and establish the conditions that must be in place to facilitate and encourage study of the origins and mechanisms of sex differences. Sex differences should be studied across the entire lifespan. Interdisciplinary efforts will be needed, and studies to account for sex differences might require innovative designs, methods, and model systems. Meeting these needs will require additional resources. Among other recommendations, clinical researchers should attempt to identify the endocrine status of research subjects, and longitudinal studies should be designed to enable



Men and women differ in brain organization for language. Men (left image) rely on the left inferior frontal gyrus to carry out language tasks, such as determining if two nonsense words rhyme. Women (right image) use both the left and the right inferior gyri to carry out the same task. Shaywitz et al. (1995) *Nature* 373:607-609. SOURCE: *Exploring the Biological Contributions Human Health: Does Sex Matter?*, 2001.

analysis of data by sex. Once studies are conducted, data regarding sex differences, or the lack thereof, should be made readily available in the scientific literature. As research advances, care should be taken to reduce the potential for discrimination based on identified sex differences.

Space travel is inherently risky, and plans for humans to venture into deep space for prolonged periods hold special health risks. *Safe Passage: Astronaut Care for Exploration Missions* (2001) presents a vision for protecting the health of voyagers on long-duration missions (a year or more) beyond Earth orbit. Requested by the National Aeronautics and Space Administration (NASA), the report concludes that not enough is yet known about the risks of prolonged missions, or about ways to mitigate those risks, to enable humans to travel and work safely in deep space, and that everything reasonable should be done to gain the necessary information before humans are sent on such missions. NASA should develop a comprehensive system that will provide current astronauts, those in training, and former astronauts with the full continuum of health care, while simultaneously collecting and analyzing all medical data relevant to space travel. The agency also should develop a long-term strategic research plan designed to obtain missing information about the health risks of space travel, including both biological and behavioral problems, and about methods to ameliorate the risks. To ensure that activities proceed in the most timely and coordinated fashion, NASA should develop a single organizational unit, either within or outside the agency, that has authority over and accountability for all aspects of astronaut health.

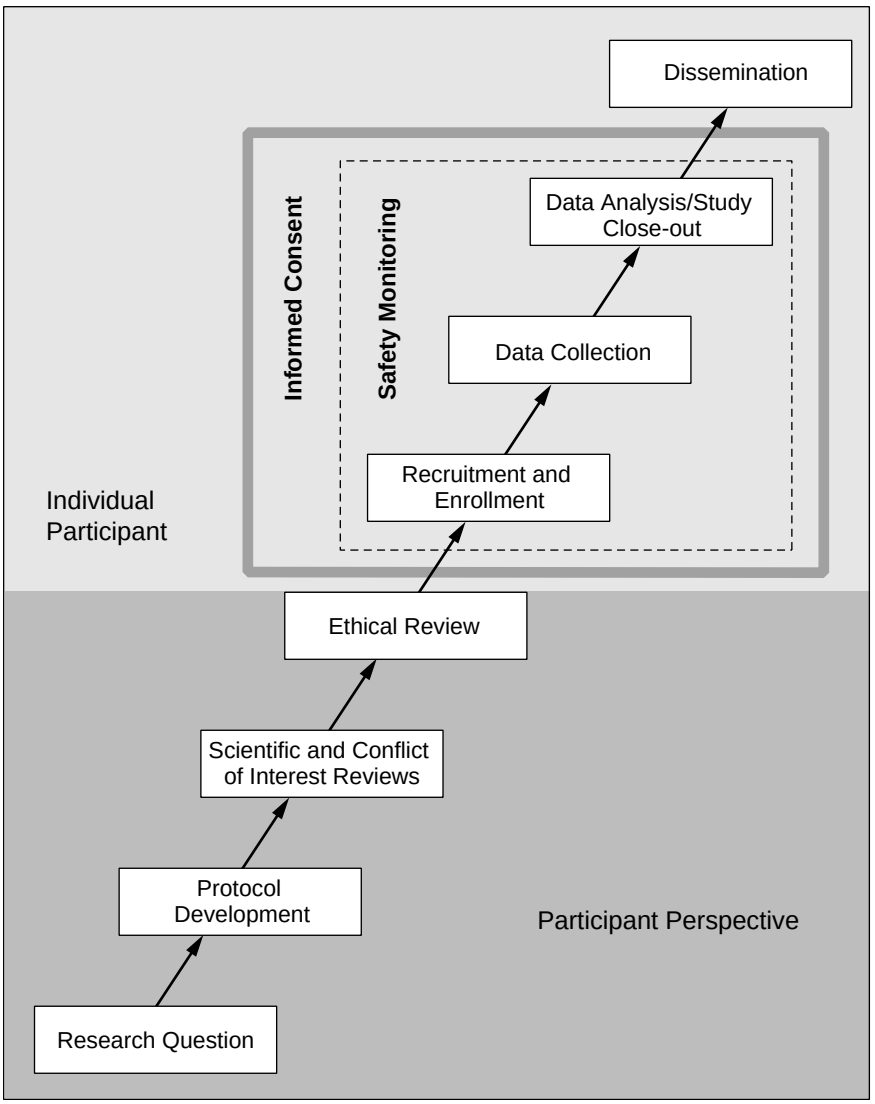


ENHANCING THE RESEARCH ENVIRONMENT

Protecting the safety and privacy of individuals who volunteer to participate in medical research is essential. But recent years have seen growing concern that protection systems have failed to keep up with the realities of contemporary research. In response to a request from the Department of Health and Human Services, the IOM has issued two reports addressing how to improve the structure and function of protection programs. The first, *Preserving Public Trust: Accreditation and Human Research Participant Programs* (2001), examines the role that accreditation, that is, the process by which organizations that conduct research achieve independent certification of their operations by meeting explicit performance

standards, can play in enhancing protection. It reviews a number of draft performance standards that have been proposed and recommends ways to improve the strongest of the standards, pilot test them, and ultimately move them into practice. Accreditation efforts should be evaluated after several years to determine their impact on protecting the rights and interests of participants in medical research, and the accreditation process should be revised as needed. The second report, *Responsible Research: A*

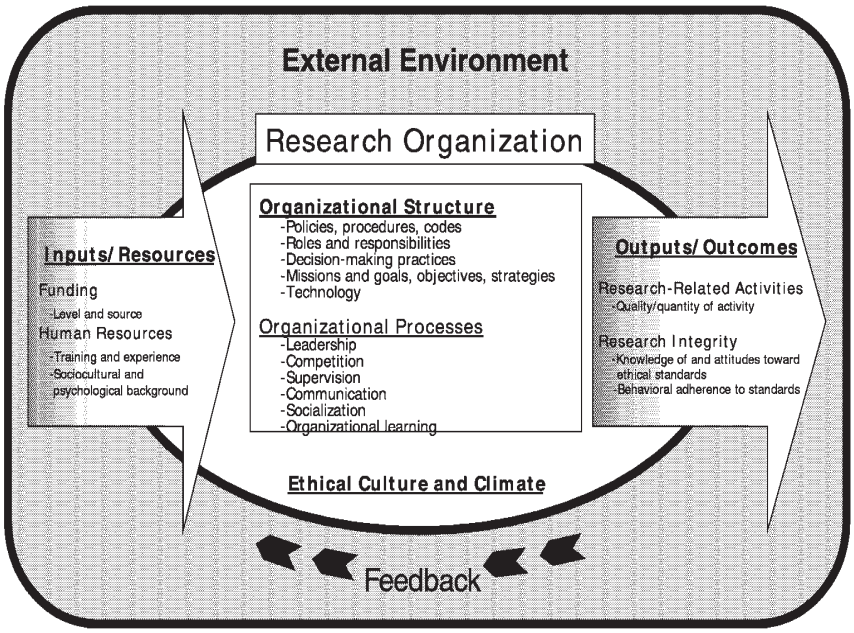
The Phases of Human Research. *Responsible Research: A Systems Approach to Protecting Research Participants,* 2002, page 41.



Systems Approach to Protecting Research Participants (2002), reviews in greater breadth and depth how the current system operates and how it goes awry, offers several broad recommendations for reform, and makes numerous practical suggestions for building more robust protection programs. Because no single cause explains failures in protecting participants, changes will be needed on many fronts. At the national level, for example, Congress should require that every organization conducting research with human subjects, regardless of the funding source, do so under the authority of a comprehensive research participant protection program, which would be subject to federal oversight. Within institutions, ultimate responsibility for an effective program of protections must rest with the highest levels of a research organization's leadership.

Most Americans willingly support public investments in research. They will continue their support only if they can trust the scientific community. This crucial link makes it imperative that both individual scientists and institutions conduct their research responsibly. *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct* (2002) reviews what is known about factors that enable and encourage individu-

Open-systems Model of the Research Organization. SOURCE: *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*, 2002, page 7.



als, regardless of their role in the research organization or their backgrounds, to carry out their jobs in the best possible manner. Since each participant brings unique qualities to the research environment, the constraints must come from the environment itself. The report calls on research institutions to develop policies and procedures that promote research integrity, to provide members of research teams with the tools and support systems they need to conduct research responsibly, and to conduct education and training efforts to help everyone involved (from students and trainees to senior scientists and top-level administrators) increase their understanding of the whys and hows of responsible research. Leaders should set the tone by their own actions, explicitly endorsing and participating in activities designed to promote research integrity. It also is vital that institutions continually evaluate their efforts, using a process of self-assessment and external peer review, in order to identify potential organizational or operational improvements. Indeed, much remains to be learned in this area, and public agencies and private foundations should increase their support for research on factors that can promote integrity in research across different disciplines and institutions.

Leaders should set the tone by their own actions, explicitly endorsing and participating in activities designed to promote research integrity.

PROMOTING TIMELY DISCUSSIONS

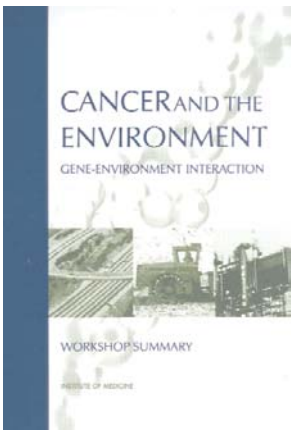
Environmental Health

IOM's Roundtable on Environmental Health Sciences, Research, and Medicine, was organized in 1998 to provide a structured opportunity and neutral setting for people from different scientific disciplines and organizational perspectives to discuss sensitive and difficult issues of mutual interest. By bringing together participants from the academic community, the federal government, industry, and other areas who are actively engaged in activities related to environmental health, research, and medicine, the Roundtable helps in identifying problems current, ongoing, or likely to arise within the next several years and in discussing ways to solve these problems. The Roundtable does not provide formal advice or recommendations, but shares knowledge and ideas. The nature of the deliberations and the neutrality of the setting facilitate fresh thinking.

The first Roundtable workshop explored the connection between human health and the natural environment that surrounds people, the

"built" environment that they have designed and constructed, and the social environment in which they interact with one another. In *Rebuilding the Unity of Health and the Environment: A New Vision of Environmental Health for the 21st Century* (2001), participants suggest that the infrastructure for linking environmental health and public health is not working as well as it should. Discussions of environmental health have become too narrowly focused around regulations, and particularly the effects of regulations on economic growth. Instead, the focus should be on creating and maintaining an environment that is healthy and livable for humans and other species, while absorbing population growth, and enabling manufacturing and agriculture to thrive.

The Roundtable has used the overarching discussions of the first workshop as a guideline for sponsoring additional workshops, regional workshops, and minisymposiums. These additional activities explore in more specific detail, the environmental issues that impact human health. For example, the second workshop focused on cancer, because of the observation that not everyone exposed to a particular cancer-causing chemical will develop the disease. Genetic variations, differences in the basic genetic blueprint from person to person, affect an individual's susceptibility. In a workshop summary, *Cancer and the Environment: Gene-Environment Interactions* (2002), participants review what is known about this complex interplay and suggest some fruitful areas for research. One emerging issue of concern is that cancer rates are accelerating among some racial and ethnic groups, possibly because of their social or economic status. New approaches will be needed to assess how genes and environmental factors act together to compound cancer risks. Further efforts also are needed to promote cancer prevention. It is well known that many behaviors are linked to cancer, such as smoking and eating too much of the wrong foods, but much more remains to be learned about other environmental and lifestyle-related causes of cancer and the role played by genetic variations among individuals.

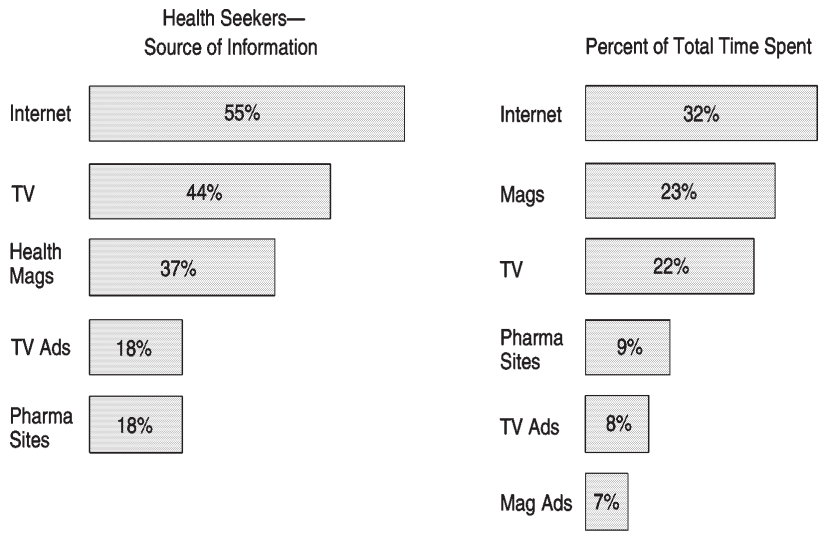


The Roundtable also has sponsored a number of minisymposiums and regional workshops. A symposium titled *Science and Risk Communication* (2001) addressed the challenges of how scientists can most effectively present information on current or emerging environmental health threats to the public. The discussion focused on how various segments of the popu-

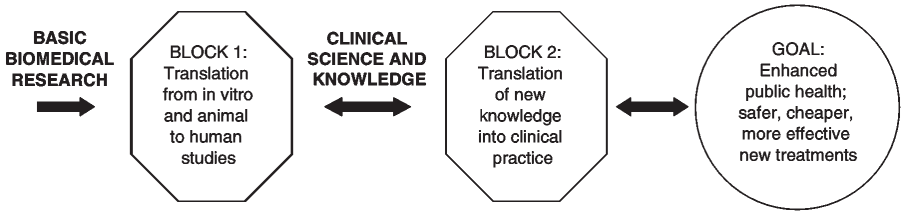
lation obtain and disseminate information and how this information and other factors influence behavior change. Recent events, such as the spread of West Nile virus and the deliberate distribution of potent forms of anthrax bacteria through the mail, underscore the need for the scientific community to improve its risk communication. In a workshop titled *Environmental Health Indicators: Bridging the Chasm of Public Health and the Environment,* (2002) workshop participants examined the issues of implementing a national environmental health monitoring system that would expand current human exposure monitoring and health surveillance efforts.

Clinical Research

IOM's Clinical Research Roundtable explores the challenges facing the field and discusses approaches that might be taken to improve the environment for the conduct of a broad agenda of high-quality clinical research. Participants come from the academic health community, federal agencies sponsoring and regulating clinical research, private-sector sponsors of clinical research, foundations, public and private insurance programs and health plans, corporate purchasers of health care, and groups representing the interests of patients. Workshops convened by the Roundtable cover a broad range of workforce and infrastructure-related issues that span the full spectrum of clinical research, and in all cases participants are attentive



Sources of Health Information. SOURCE: *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary,* 2003, page 38.



The Translational Blocks. SOURCE: *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Clinical Research Roundtable Workshop Summary,* 2003, page 10.

to the ethical underpinnings of clinical research. The Roundtable also conducts activities to enhance mutual understanding between the scientific community and the general public, while improving the public's understanding of and participation in clinical studies.

Organizations that purchase health care, such as employers, and organizations that pay for health care, such as insurance companies and health plans, often lack the information they need to make sound decisions. *The Role of Purchasers and Payers in the Clinical Research Enterprise* (2002) summarizes discussions during a Roundtable workshop devoted to this issue. Both purchasers and payers call for additional research to determine what does and does not work in treatment, diagnosis, and prevention. This "evaluative" research compares existing therapies to new treatments. They also cite a need to translate clinical research more effectively so that consumers and health care providers can make decisions based on the best available evidence, and to transform the health care culture into a team effort. Employers and insurers recognize the national trend toward a consumer-driven health care system and affirm the important contributions that they can make in promoting health by educating the people they serve and encouraging healthy lifestyle behaviors. Of particular note, both employers and insurers express a commitment to searching for solutions to national health care problems and then working together to apply them.

Although laypeople once played only a limited role in the clinical research enterprise as volunteers in clinical trials, recent years have brought a sea of change to public participation. Consumers now demand a role in the formulation of the research agenda and in the design, review, and pursuit of research. *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise* (2003) summarizes ideas explored during a workshop on this issue. Engaging the public, although posing certain difficulties, is deemed a strategic imperative. The public can help in translating research findings into practice, in speed-

ing up the clinical research process, and in making the research enterprise more efficient. For example, public support for and participation in AIDS trials and research on coronary heart disease has led to declines in the numbers of deaths from those diseases. Thus, the national movement toward "participant-centered research" is widely applauded. To foster increased public participation, several strategies should be employed. These approaches include striving to gain and maintain the public's trust in medical research, establishing two-way methods of communication between scientists and consumers, and mounting educational programs to provide consumers with factual information about clinical research that does not raise unrealistic expectations.

CURRENT STUDIES AND UPCOMING REPORTS

The National Institutes of Health supports a number of "centers of excellence" at leading academic institutions to focus research on particular diseases. In recent years, centers often have begun with a mandate from Congress in response to lobbying by patient or professional groups. But some government officials and other observers have expressed concern about whether establishing new centers is the best way to advance research. At the request of Congress, the IOM is reviewing how the NIH currently uses centers of excellence as a mechanism for conducting research. The study committee is examining, among other things, the criteria and procedures used in deciding to establish centers, how they are designed and administered, how much they cost, how they are evaluated, and how they compare with other mechanisms of research support. In its report, the committee will offer recommendations for improving the use of centers of excellence, given the many factors that must be taken into account in a specific area of research, including the burden of disease, the state of the science, the adequacy of the research infrastructure, the presence of promising research opportunities, and the need for interdisciplinary approaches to the problem.

The IOM is also continuing its work on the protection of human participants in research. A study now under way is examining the special issues and challenges in protecting individual children in clinical research while encouraging responsible research to promote the health and well-being of all children. Another study involving children will look at the nation's system for tracking the safety of pediatric medical devices.

There is a pressing need for safer, more effective, more acceptable methods of contraception, especially in the developing world. With sup-

port from the Bill and Melinda Gates Foundation, the IOM is studying novel approaches to contraceptive research. Recent advances in the biomedical sciences have provided exciting new opportunities to gain a better understanding of the basic biology of reproduction, and these advances may lead to the discovery of new targets for contraception. In particular, the tools and technologies of genomics and proteomics, new fields focused on how human genes and proteins function, could be brought to bear on the development of radically new approaches to contraception. Novel models for the development of drugs and other products also may provide insight for creating innovative contraceptives, once potential targets have been identified. The study committee will summarize the current state of contraceptive research, identify problems that impede advances in contraception, and make recommendations for priority areas for future research and development.

In older men, testosterone replacement therapy (TRT) may offer a means of preventing or treating osteoporosis and other age-associated conditions. Given this promise, the government is considering a large-scale clinical trial of TRT. But such therapy holds some risks, particularly regarding prostate and cancer outcomes. At the request of the National Institute on Aging, the IOM is reviewing current knowledge about the potential beneficial and adverse health effects of TRT in older men. If conducting a large-scale clinical trial is found to be warranted, the study committee will offer recommendations on how such a study should be designed, conducted, and evaluated.

Every year in the United States, an estimated 10,000 individuals suffer a spinal cord injury. There are 500 to 800 cases annually in New York alone. Recently, some states have allocated funds to support research to improve treatment and ultimately find a cure for such injuries. New York has launched a research program directed specifically at finding a cure for the paralysis caused by spinal cord injury, and its legislature has turned to the IOM for guidance. A study committee is reviewing current knowledge regarding spinal cord injury. It will identify gaps in knowledge, describe the technological barriers that hinder research, and highlight areas that are ripe for future investigation. The committee also will identify special strengths and resources that New York can bring to bear in searching for ways to cure spinal cord injury paralysis.

Recent decades have seen a significant decline in the number of physician-scientists in the United States. As physician-scientists are considered

critical for the translation of basic discoveries from the bench to the bedside, this trend is troubling. Psychiatry has been hit especially hard. The IOM is reviewing the forces that discourage psychiatry residents from pursuing research training, and examining the experiences of residency programs that successfully incorporate such training. A serious obstacle is the growing shortage in the availability of training programs. Moreover, the extensive core requirements for psychiatry residents (especially in child psychiatry) make it difficult for them to find time to incorporate training in research. The study committee's analysis will suggest strategies to make it easier for psychiatry residents to participate in research training programs and pursue careers as physician-scientists.

A person's behavior and social circumstances have a remarkably strong effect on his or her health. Taken together, behavioral patterns and social circumstances are estimated to account for more than half of the premature deaths in the United States each year. Yet medical schools often do not cover these topics, or do so only superficially. IOM is conducting a study to identify ways to make the behavioral and social sciences an integral part of medical education. Among its efforts, the study committee is reviewing approaches used by medical schools that have incorporated behavioral sciences and social sciences into their curricula. Based on its analysis, the committee will propose a list of topic areas that should be considered in designing curricula and suggest ways to encourage medical schools to adopt the new curricula in order to improve the education they provide their students.

The National Aeronautics and Space Administration (NASA) conducts a wide-ranging program in aerospace medicine and the medicine of extreme environments (such as the environment that astronauts would experience during lengthy missions to deep space). At NASA's request, the Institute of Medicine is reviewing this program. Among the study committee's tasks will be providing advice concerning the development of optimal health care programs to serve astronauts and allied aerospace personnel, reviewing or updating clinical research requirements and clinical strategies, and serving as a focal point for all work relating to the practice of medicine during space travel. Historically, NASA's research and development efforts have provided outstanding innovative techniques and products resulting in significant advancement of the general public health and quality of life. This promise continues, and it is therefore of critical importance that NASA receive the best advice available as it formulates strategic plans for developing the practice of medicine in space.

Selected Recommendations for Food and Nutrition

The Role of Nutrition in Improving Human Health: Research agencies should give high priority to the role of nutrients in human health and the relationship of intake to chronic diseases. For macronutrients, give priority to long-term, dose-response studies to identify the requirements for individual macronutrients such as omega-3 fatty acids, that are essential in the diet for all life-stage and gender groups, especially children and the elderly, and to enhance understanding of the beneficial roles of dietary fiber in human health; as well as provide definitive information on the form, frequency, intensity, and duration of physical activity to successfully manage body weight in both children and adults. (*Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids,* 2002)

The Function of Micronutrients: Research priority should be given to studies to identify and further understand the functional (e.g., cognitive function, regulation of insulin, bone health, and immune function) and biochemical endpoints that reflect sufficient versus insufficient body stores of vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc for various age and gender groups; and studies to further identify and quantify the effects of interactions between individual micronutrients in the diet as well as interactions between micronutrients and other food components, the food matrix, and food processing techniques. (*Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc,* 2002)

Reducing Nutrition Risk: Evidence shows that nearly all low-income women in the childbearing years and their children five-years-old and younger are at dietary risk and may thus benefit from USDA's Women, Infants, and Children's (WIC's) services. Screening to determine WIC eligibility based on dietary risk as a criterion is thus largely unnecessary for this group. Further, because of the complex nature of dietary, physical activity, and behavioral patterns, it is unlikely that a tool can be developed to classify individuals accurately with respect to their true dietary risks; if any tools were adopted for this purpose, they would result in misclassification of some, and potentially many, individuals. Therefore the committee recommends that all women and two- to five-year-old children who meet the above status requirements should automatically be considered to have also met the criterion for dietary risk—that is, routine failure to consume the recommended number of daily servings specified by the Food Guide Pyramid, in accordance with the Dietary Guidelines. (*Dietary Risk Assessment in the WIC Program,* 2002)

Focus on Food Safety: Congress should require the development of a comprehensive national plan to harmonize and integrate the data from foodborne disease surveillance conducted by public health agencies with data obtained through the monitoring of pathogens across the food production, processing, and distribution continuum conducted by food safety regulatory agencies. Such integration would reveal the links between specific food groups and foodborne diseases and allow the success of criteria such as performance standards or other interventions to be measured. Further, Congress should grant the regulatory agencies clear authority to establish, implement, and enforce food safety criteria, including performance standards, and the flexibility needed within the administrative process to update these criteria. Clear, science-based procedures and methodologies should be adopted by regulatory agencies to develop food safety criteria and monitor compliance with such criteria. (*Scientific Criteria to Ensure Safe Food,* 2003)

Ensuring Food Safety and Proper Nutrition

Although consumers, scientists, entrepreneurs, and policymakers want evidence on potential new relationships between nutrients and chronic diseases as soon as possible, conclusive evidence is typically elusive. Gathering sufficient knowledge to draw conclusions about causal relationships, especially between a given nutrient and a chronic disease, remains a challenge.—Evolution of Evidence for Selected Nutrient and Disease Relationships, 2002

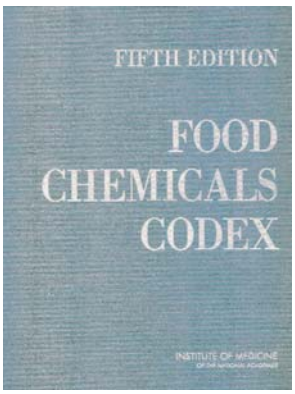
Food Regulation and Safety

A number of recent court cases have challenged the validity of criteria that underlie U.S. food safety regulations, potentially undermining the authority of regulatory agencies to enforce those standards. Concerned about the growing controversy, Congress requested that the Institute of Medicine and the National Research Council's Division of Earth and Life Studies (DELS) study the scientific basis for food safety criteria and the extent to which they actually protect the health of consumers. *Scientific Criteria to Ensure Food Safety* (2003), issued by the IOM's Food and Nutrition Board, provides a blueprint for development of scientifically based food safety regulatory criteria to protect human health. The report calls for Congress to require the development of a comprehensive nation-

Scientific Criteria to Ensure Food Safety (2003)...provides a blueprint for development of scientifically based food safety regulatory criteria to protect human health.

al plan to harmonize and integrate the foodborne disease surveillance conducted by public health agencies with the efforts of food safety regulatory agencies to monitor pathogens across the food production and distribution continuum. This integration would make it possible to define links between foodborne disease and specific foods or food groups and to measure the effectiveness of interventions. Congress also should give regulatory agencies clear authority to develop, implement, and enforce food safety criteria, as well as the administrative flexibility to update these criteria as needed. The criteria should be clearly linked to specific public health goals. In developing the criteria, regulatory agencies should adopt strategies based on sound science and that are clear in their intent. In this effort, the agencies can draw on a variety of scientific methods, such as risk assessments and statistical process control.

Many everyday foods contain chemicals that were added during production to achieve a desired result, such as enhancing flavor or extending shelf life. The *Food Chemicals Codex* (FCC), produced by the IOM's Food and Nutrition Board, is the accepted compendium of specifications for defining the quality and purity of direct and some indirect food additives, ingredients, and substances that are used in food. FCC specifications, which limit potential toxic contaminants, protect the health of consumers and provide a level playing field for industry. The U.S. Food and Drug Administration (FDA) and various national and international food regulatory authorities, recognizing the scientific basis of FCC specifications, frequently reference or have officially incorporated the FCC into their guides in an effort to ensure the safety of the food supply. The National Academies published the first edition of the *Food Chemicals Codex* in 1966, and has since issued three more editions, the latest in 1996, as well as a series of supplements. The *Food Chemicals Codex: Third Supplement to the Fourth Edition* (2001) is the latest of the updates. It describes several new testing methods and reviews changes in government policies, including revisions in policies pertaining to the contamination of food chemicals with heavy metals. Presented in an easy-to-use format, the report is of interest to producers and users of food chemicals, to researchers, and to other individuals and groups involved in the technical aspects of food safety. The fifth edition of the *Food Chemicals Codex* is slated for publication in autumn of 2003.



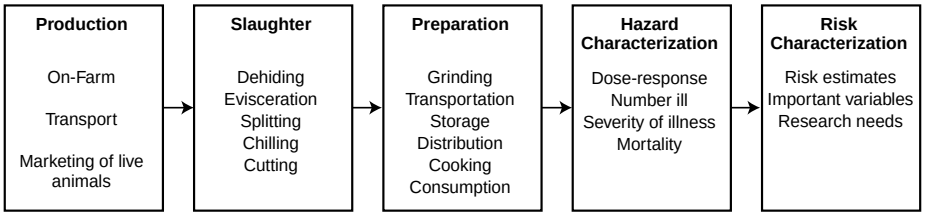
Ingredient Name	Human Data	Animal Data	Biological Activity of Structurally Related or Taxonomically Related Substances	In Vitro Data
Yellow plant extract	3	1	2	2
Vitamin X	2	NAD	2	NAD[a]
Animal tissue	2	1	1	1

[a] NAD = no appropriate data.

Matrix of Scores Used in Establishing Relative Priority Among Dietary Supplements. SOURCE: *Proposed Framework for Evaluating the Safety of Dietary Supplements,* 2002, page 9.

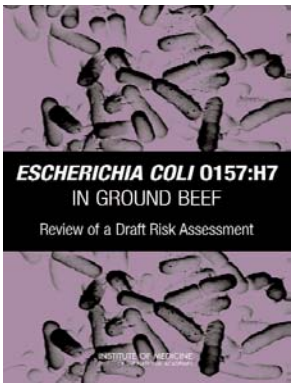
Consumer use of dietary supplements has increased significantly over the past decade since Congress passed the Dietary Supplement Health and Education Act in 1994. Based on this statute, these supplements are presumed safe, similar to conventional foods. The U.S. Food and Drug Administration has no authority to require safety studies prior to a product's commercial introduction and must prove that a supplement presents an unreasonable risk to health in order to remove it from the market. In contrast, drugs must be proven safe and effective before they are marketed. The FDA wants to improve its ability to assess the safety of both traditional and new supplements, and the agency turned to the IOM for help. In a report titled *Proposed Framework for Evaluating the Safety of Dietary Supplements* (2002), IOM's Food and Nutrition Board proposed a scientifically based approach that would enable the FDA to assess safety by analyzing information that already is available. The proposed process consists of three steps: reviewing readily available information to screen for potentially hazardous substances; identifying and prioritizing those substances that require the most immediate attention; and then conducting individual in-depth safety evaluations, which would be based on collecting and reviewing additional data regarding a substance's safety (including data obtained from industry). Comments received about the proposed framework have been undergoing review. Phase two of the study is to review six supplements to demonstrate how the proposed assessment process would work in practice. A final report will present the completed framework along with the prototype safety reviews.

Although the U.S. food supply is among the safest in the world, foodborne diseases still exact a considerable toll, causing some 76 million illnesses and 5,000 deaths in the country each year. In the face of such public health problems, the U.S. Department of Agriculture (USDA) is formulat-



Risk-assessment Structure for *E. coli* O157:H7 in Ground Beef. SOURCE: *Escherichia coli O157:H7 in Ground Beef: Review of a Draft Risk Assessment,* 2002, page 14.

ing risk assessments to identify important foodborne hazards and evaluate potential strategies to prevent, reduce, or eliminate those hazards. One of the initial projects is a risk assessment of the health impact of a particular variety of the bacterium Escherichia coli, called E. coli O157:H7, that is frequently found in ground beef. The USDA asked the IOM to review the project's first draft of this risk assessment. Its report, titled *Escherichia coli O157:H7 in Ground Beef: Review of a Draft Assessment* (2002), commends the USDA on the magnitude of its effort and the principles underlying the assessment. In its recommendations, the report notes that the assessment as with all risk assessments will be improved by making the inner workings of the analysis more explicit. This will require, making public details about assumptions, data sources, and equations used, and limitations and uncertainties of the conclusions. The report also calls on the developers of the risk assessment model to identify any gaps in the available data. Charting such deficiencies will help in setting priorities for future research, which, in turn, may lead to more informed policy decisions.



Dioxin and dioxin-like compounds, or DLCs, are found throughout the environment; they are transported through air and deposit on plants, soil, and sediment in waterways. People are exposed to these unintentional environmental contaminants primarily through the food supply, although at low levels, particularly by eating animal fat in meat, dairy products, and fish. While the amount of DLCs in the environment has declined since the late 1970s, the public continues to be concerned about the safety of the food supply and the potential adverse health effects of DLC exposure, especially in groups such as developing fetuses and infants, who may be more

sensitive to the toxic effects of these compounds. Numerous health effects have been linked to exposure to DLCs, including skin damage, cancer, non-insulin dependent diabetes in adults, neurological and immune system impairments in infants, and endocrine system disruption. Many of these effects were identified in individuals who had high levels of exposure. However, information is limited on how low-level DLC exposure through foods, defined as occurring in everyday life, influences the development of cancer and other diseases. To devise strategies for reducing human exposure to DLCs from the food supply, the National Science and Technology Council's Interagency Working Group on Dioxin with support from the U.S. Department of Agriculture, the U.S. Department of Health and Human Services, and other agencies and sponsors, requested the help of the IOM. The resulting study, *Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure* (2003), recommends policy options to reduce exposure to these contaminants while considering how implementing these options could both reduce health risks and affect nutrition, particularly in sensitive and highly exposed groups. The report recommends that a federally-sponsored interagency task group develop and implement an integrated risk-management strategy and action plan to reduce human exposure to dioxins in foods and that government officials collaborate with the private sector to identify and pursue voluntary interventions to further minimize levels of these toxic compounds in human foods and animal feeds. However, the health risks posed by the levels of dioxins in foods have yet to be ascertained, so the report does not recommend regulatory limits on DLCs in food or feed.

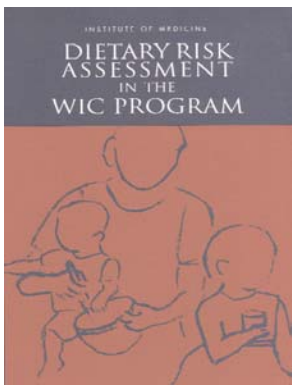
Numerous health effects have been linked to exposure to DLCs, including skin damage, cancer, non-insulin dependent diabetes in adults, neurological and immune system impairments in infants, and endocrine system disruption.

Currently, the IOM and DELS are conducting a study to outline science-based approaches to identify and assess (or predict) unintended effects of genetically engineered foods on human health. This study will identify appropriate scientific questions and methods for determining unintended changes in the levels of nutrients, toxicants, allergens, or other compounds in food from genetically engineered plants and animals and outline methods to assess the potential short and long-term human health consequences of such changes. The study will compare genetically engineered foods to foods derived from other genetic modification methods (e.g. cross breeding) with respect to the expected frequency of compositional

changes resulting from the modification process and the potential frequency and severity of the effects of these changes on consumer health. As part of this comparison, the likelihood that elevated toxin or allergen levels would occur in domesticated animals or plants that are modified by different methods will be considered. Based on this analysis, the committee will discuss whether certain safety issues are specific to genetically engineered foods, and, if so, recommend approaches for addressing these issues. The committee also will separately evaluate potential unintended compositional changes and health effects of foods derived from cloned animals. This evaluation will be presented in a short report separate from, but designed to accompany, the full-length report on foods derived from genetic modification methods.

ENSURING ADEQUATE NUTRITION FOR THOSE AT RISK

The Special Supplemental Nutrition Program for Women, Infants, and Children commonly called the WIC program provides food and nutrition education to low-income pregnant or postpartum women, infants, and children to age 5 years. Applicants must face "nutrition risk" in order to receive services. The most common category of risk is "dietary risk" that is, routine failure to consume the number of daily servings of various types of foods specified by the U.S. Department of Agriculture's Food Guide Pyramid. But in practice, assessing dietary risk is difficult. The USDA asked the IOM to evaluate various tools for assessing dietary risk and to make recommendations on how risk assessment can be used in determining eligibility for the WIC program. *Dietary Risk Assessment in the WIC Program* (2002) concludes that none of the assessment tools currently available can accurately measure an individual's true dietary risk and, further, that developing a useful tool is unlikely. The report recommends instead that all women and children ages 2 to 5 years who meet the program's general eligibility requirements (based on income and other social factors) should be presumed to also meet the requirement of dietary risk, since abundant evidence shows that nearly all of these individuals routinely fail to meet national nutrition guidelines. By presuming dietary risk, the WIC program retains its potential for preventing and correcting nutrition-related problems while avoiding misclassification errors that could lead to denial of services.



Dietary Guidelines for Americans

AIM FOR FITNESS
- Aim for a healthy weight.
- Be physically active each day.

BUILD A HEALTHY BASE
- Let the Pyramid guide your food choices.
- Choose a variety of grains daily, especially whole grains.
- Choose a variety of fruits and vegetables daily.
- Keep foods safe to eat.

CHOOSE SENSIBLY
- Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.
- Choose beverages and foods to moderate your intake of sugars.
- Choose and prepare foods with less salt.
- If you drink alcoholic beverages, do so in moderation.

SOURCE: *Dietary Risk Assessment in the WIC Program,* 2002, page 2.

A vast majority of infants in the United States and other industrialized countries receive infant formula at some time during the first year of life. For many of these infants, formula is often the sole source of nutrition for the first four to six months of life. Proper nutrition, while important throughout life, is particularly important during infancy when growth and development are most rapid and when the consequences of inadequate nutrition are most severe. Because of the paucity of consistent guidelines for assessing the safety of ingredients added to infant formula, the U.S. Food and Drug Administration (FDA) and Health Canada asked the IOM to review methods currently used to assess safety of ingredients new to infant formula and identify tools to evaluate the safety of ingredients new to infant formula under intended conditions of use in term infants.

In the face of natural disasters or other emergency situations, such as the displacement of large numbers of people by political or military conflicts, providing the victims with rapid, short-term food relief at an early stage is often of paramount importance. The U.S. Agency for International Development (USAID) and the Department of Defense, which distribute most of the emergency food aid provided by the federal government, asked

the IOM for advice on developing a product specifically tailored to this use. An IOM report, titled *High-Energy, Nutrient-Dense Emergency Relief Food Product* (2002), describes the technical specifications for a product that would satisfy the nutritional requirements of all people older than 6 months and serve as their sole source of subsistence for up to 15 days. To achieve this, the committee first determined the nutritional profile of a single product that would meet the nutritional needs of young children as well as older adults. The product also needed to be able to be delivered by either land or air; to be able to be eaten on the move without preparation, and; to be acceptable to people from diverse cultural, ethnic, and religious

Assumptions Used in Developing the Nutrition Composition of the EFP

- Potable water is provided as a top priority and is available with the EFP.
- Individuals will eat to meet their energy requirements.
- The product is to be consumed by all age groups, except infants less than 6 months of age; thus the product is not to be used in lieu of breast feeding, which is encouraged to at least 1 year of age with complementary use of the EFP after 6 months of age.
- It is not to be used as a therapeutic product and is not appropriate for severely malnourished individuals.
- It may constitute the sole source of food for target recipients for up to 15 days.
- Recipients are likely to be at least mildly malnourished and/or suffer from mild to moderate diarrhea and other debilitating diseases brought about by unsanitary conditions and exacerbated by stress.
- The recipient population may have nutrient needs comparable to well-nourished individuals in spite of smaller body weights due to maintaining muscle and visceral mass at the expense of body fat.
- The product should provide a nutrient density that will meet or exceed the nutrient recommendations as specified by the recommended intakes (IOM, 1997, 1998, 2000, 2001; NRC, 1989) which are designed to meet the needs of almost all individuals in each life stage and gender group (with the exception of infants) without exceeding Tolerable Upper Intake Levels (IOM, 1997, 1998, 2000, 2001).
- Nutrient needs of pregnant and lactating women are not included in the calculations, but it is assumed they will consume more than the daily ration based on individual needs for additional energy beyond the average of 2,100 kcal/day.

SOURCE: *High-Energy, Nutrient-Dense Emergency Relief Food Product,* 2002, page 4.

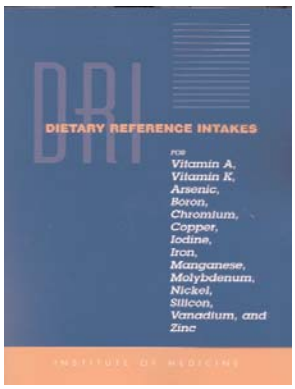
backgrounds. In addition, the product needed to be stable during prolonged storage under adverse conditions. When the study was requested, no U.S. company produced such a product, though some foreign firms did so. The specifications detailed in the report are to be used by both agencies in their call for bids from U.S. companies to supply such products. Since federal regulations require that most of the food to be distributed as aid be purchased from U.S. companies, providing specification for use by domestic manufacturers would greatly assist the agencies in responding quickly and effectively to emergencies.

DIETARY REFERENCE INTAKES

Consumers armed with sound information about food and nutrition are more likely to make good choices about what they eat. In 1941, the Food and Nutrition Board (FNB) issued its first set of Recommended Dietary Allowances (RDAs) for vitamins, minerals, proteins, and energy. Since then, RDAs revised numerous times and expanded to include 27 nutrients have served as the basis of almost all federal and state food and nutrition programs and policies. As scientific knowledge regarding the roles of nutrients has multiplied, the FNB has now adopted an expanded system for describing nutritional needs. This system is collectively called Dietary Reference Intakes (DRIs). Developed jointly by U.S. and Canadian scientists, the new DRIs provide quantitative estimates as reference values for specific uses. These include the amounts of nutrients that individuals need to optimize their health and prevent disease and deficiencies, as well as amounts that are upper intake levels or limits to help people avoid potential adverse effects from consuming too much of a nutrient. To date, seven reports have been published by IOM; the three most recent reports provide DRIs for energy yielding nutrients such as dietary fats and carbohydrates and for trace elements and important vitamins, as well as a report on how DRIs should be used in dietary planning. The IOM is currently working on two additional DRI reports: one will focus on the intakes of sodium, potassium, chloride, sulfate, and water; and another will identify general guiding principles for use of DRIs in nutrition labeling.

DRIs...include the amounts of nutrients that individuals need to optimize their health and prevent disease and deficiencies, as well as amounts that are upper intake levels or limits to help people avoid potential adverse effects from consuming too much of a nutrient.

• *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc* (2001). This report concludes, based on national nutrition surveys in the United States, that most people can obtain the recommended intakes for these nutrients from their diets, without taking supplements. One exception is that pregnant women usually need iron supplements to meet their increased daily requirements. Among other findings, the report notes that fruits and vegetables yield significantly less vitamin A than previously thought. This means people must make sure they eat enough of the foods that are richest in vitamin A (such as carrots, sweet potatoes, and broccoli) in order to meet their daily requirement, especially if they do not eat animal-derived foods, which serve as additional good sources of the nutrient for most people. The report also identifies several important gaps in what is known about these micronutrients. Some of the priority areas for research include identifying factors that impair or enhance their absorption and metabolism in the body, and exploring more fully the role of arsenic, boron, nickel, silicon, and vanadium in human health.



• *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002). This report describes acceptable intake ranges for each of these energy sources, based on evidence that consumption above these ranges can lead to developing chronic diseases, including coronary heart disease, obesity, diabetes, and cancer, while consumption below these ranges can lead to problems caused by nutrient imbalances or inadequacies. Adults should get 45 percent to 65 percent of their calories from carbohydrates, 20 percent to 35 percent from fat, and 10 percent to 35 percent from protein. Acceptable ranges for children are similar to those for adults, except that infants and younger children need a slightly higher proportion of fat (from 25 percent to 40 percent of their caloric intake). The report recommended ranges for polyunsaturated fats and recommends that saturated fatty acids, trans fatty acids, and cholesterol be as low as possible in the diet while consuming a nutritionally adequate diet. Among other findings, the report suggests that added sugars that is, sugars incorporated into foods and beverages during production should not exceed a maximal level of 25 percent of total calories consumed, since more people whose diets are high in added sugars in the United States have been found to consume inadequate amounts of essential nutrients. The report also stresses the importance of balancing diet

with exercise. To maintain cardiovascular health at a maximal level, adults and children alike should spend at least one hour each day in moderately intense physical activity, a total that is double the daily minimum goals set by previous federal recommendations.

• *Dietary Reference Intakes: Applications in Dietary Planning* (2003). This report is the second in a series providing guidance on the use and interpretation of DRIs in planning and assessing diets. Some of the activities that can benefit by taking DRIs into account include individual dietary planning, institutional and military food planning, planning for food assistance programs, food labeling, food fortification, developing new or modified food products, and assuring food safety. Whether for an individual or a group, dietary planning involves developing a diet that is nutritionally adequate without being excessive. Food-based education tools, such as the USDA's Food Guide Pyramid, are frequently used to help an individual plan a healthful diet. For group planning, the report presents a new approach based on determining the distribution of the long-term average intakes of individuals in the group. This method can serve to maximize the number of group members whose daily nutritional intakes are likely to be adequate but not excessive. The report stresses that dietary planning must be a cyclical activity that involves planning, implementation, assessment, and reassessment.

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PROMOTING TIMELY DISCUSSIONS

The Department of Health and Human Services estimates that 64 percent of adults are overweight and obese, more than 15 percent of children and teens carry excess pounds, and a total cost estimated to be $117 billion is spent annually on obesity and obesity-related health problems. Research shows that overweight children are at risk for serious health problems, including diabetes and cardiovascular disease. According to one report, about 60 percent of children ages 5 to 10 who are overweight or obese already have at least one cardiovascular disease risk factor, such as elevated total cholesterol levels or higher blood pressure, and 25 percent have two or more. The IOM is currently conducting a study on the Prevention of Obesity in Children and Youth to assess the factors responsible for the epidemic of obesity in children and to develop an action plan (focusing on prevention) to decrease its prevalence. The study will assess the social, environmental, medical, dietary, and other factors responsible

for the increasing prevalence of childhood obesity and identify the most promising methods for prevention, including interventions and policies for immediate action and for the longer term. Research opportunities will be identified. Although consideration will be given to how heredity and other biologic factors contribute to the development of obesity, primary emphasis will be directed to environmental and cultural factors, social constructs that encourage appropriate eating patterns, and other broader environmental factors.

In 1993, the IOM's FNB created the Food Forum to periodically bring together leading scientists, administrators, and policy-makers from academia, government, industry, and the public sector to discuss issues related to food, food safety, and the array of regulations that affect how food is produced and consumed. Forum meetings provide a relatively rapid way to identify important issues of common interest and to develop new approaches to solving problems. Recent meetings have produced workshop summaries on such topics as *Food Safety Science, Policy, and Risk Assessment: Strengthening the Connection* (2001) and *Enhancing the Regulatory Decision-Making Process for Direct Food Ingredient Technologies* (1999). The Forum does not produce policy recommendations or offer advice regarding specific issues. Rather, it brings together interested parties, compiles authoritative information, develops possible options for consideration, and brings together outside experts to present information on the topic under discussion. The unofficial nature of the deliberations, the neutrality of the setting, and the continuity presented by regular meetings has proved effective in stimulating fresh thinking and promoting frank exchanges of views.

With similar motives and means in mind, the FNB also has created the International Food and Nutrition Forum. It provides an ongoing mechanism for scientists, administrators, and policy-makers from the U.S. government, nongovernmental organizations, and academia to discuss global issues related to food and nutrition. Such issues include food security and nutritional deficiencies that can cause morbidity and mortality. Where problems exist, the discussions may lead to identification of possible solutions, such as promoting efforts in research and training. As with the Food Forum, the goal is not to develop specific policy recommendations, but to catalyze frank and open discussions that will help improve understanding among the participants of the topics under consideration.

In 1982, following a request by the Assistant Surgeon General of the

Army, the National Academies set up a committee to advise the U.S. Department of Defense on the need for and conduct of nutrition research and related issues. This became the IOM's Committee on Military Nutrition Research (CMNR). The committee's tasks continue to be (1) to identify nutritional factors that may critically influence the physical and mental performance of military personnel under all environmental extremes; (2) to identify gaps in the existing data base concerning the relationship of diet to performance of military personnel; (3) to recommend research thrusts to fill significant gaps in the data base; (4) to recommend appropriate research strategies and methodologies to study the relationship of diet to physical and mental performance; and (5) to review and advise on current nutritional guidelines for military feeding systems. Although the membership of the committee changes periodically, the disciplines represented have consistently included human nutrition, nutritional biochemistry, performance physiology, food science, and psychology. In 2003, the CMNR released *Weight Management: State of the Science and Opportunities for Military Programs* to aid in developing strategies for the prevention and remediation of overweight in military personnel. The report reviews existing data on optimal components of a weight-management program; the role of age, gender, and ethnicity in weight management; and assesses current DoD activities in weight management. Specifically, the report provides guidance on the appropriate degree of standardization of programs across the services, whether specific aids for weight loss (e.g., drugs) should be considered, how dietary changes would impact successful weight loss, and whether resistiveness to weight loss and maintenance are genetically controlled to the extent that individuals with genetic predispositions for obesity should be identified and automatically excluded. The CMNR will soon be releasing a study on metabolic monitoring technologies for military field applications, which focuses on ways to monitor metabolic status in the field in order to predict individual health and performance outcomes. This will include an analysis of metabolic regulation during prolonged, exhaustive efforts (such as combat training or field operations), where nutrition/hydration and repair mechanisms may be mismatched to intakes and rest, or where specific metabolic derangements are present (e.g., following toxic chemical exposures or psychological threats). Other workshops or symposia conducted by CMNR have dealt with topics such as food components to enhance performance; nutritional needs in hot, cold, and high-altitude environments; body composition and physical performance; nutrition and physical performance; cognitive testing methodology; fluid replacement and heat stress; and antioxidants and oxidative stress.

Selected Recommendations for Public Health Policy

Focus on Public Health Infrastructure: The Department of Health and Human Services should develop a comprehensive investment plan for a strong national governmental public health infrastructure with a timetable, clear performance measures, and regular progress reports to the public. State and local governments should also provide adequate, consistent, and sustainable funding for the governmental public health infrastructure. DHHS should review the regulatory authorities of its health agencies to reduce overlap and inconsistencies and to simplify relationships with state and local public health agencies. A national commission is needed to develop a framework and recommendations for state public health law reform.

Schools of public health should emphasize the importance and centrality of the ecological approach. Further, schools have a primary role in influencing the incorporation of this ecological view of public health, as well as a population focus, into all health professional education and practice. (*The Future of the Public's Health in the 21st Century,* 2002)

The Role of Public Health Education: Schools of public health should enhance faculty involvement in policy development and implementation for relevant issues; provide increased academic recognition and reward for policy-related activities; play a leadership role in public policy discussion about the future of the U.S. health care system, including its relation to population health; enhance dissemination of scientific findings and knowledge to broad audiences; and actively engage with other parts of the academic enterprise that participate in policy activities.

The Federal government should provide funding to develop competencies and curriculum in emerging areas of practice; fund degree-oriented public health fellowship programs; provide incentives for developing academic/practice partnerships; and support increased participation of public health professionals in the education and training activities of schools and programs of public health. (*Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century,* 2002)

Reducing Tobacco's Harm: A national comprehensive surveillance system is urgently needed to collect information necessary to understand the population impact of tobacco products and potential reduced-exposure products, including attitudes, beliefs, product characteristics, product distribution and usage patterns, marketing messages such as harm reduction claims and advertising, the incidence of initiation and quitting, and non-tobacco risk factors for tobacco-related conditions.

Federal regulation of all modified tobacco products with risk reduction or exposure reduction claims, explicit or implicit, and any other products offered to the public to promote reduction in or cessation of tobacco use should be strengthened. (*Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction,* 2001)

ASSURING THE PUBLIC'S HEALTH

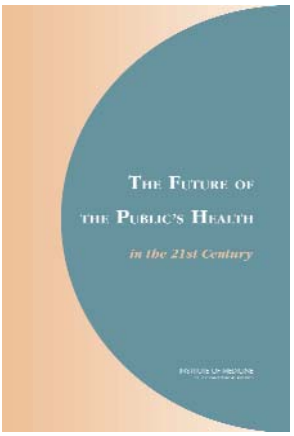
The community as a whole has a stake in environmental protection, hygiene and sanitation, clean air and surface water, uncontaminated food and drinking water, safe roads and products and the control of infectious disease. These collective goods, and many more, are essential conditions for health, but these "public" goods can be secured only through organized action on behalf of the population.—The Future of the Public's Health in the 21st Century, 2003

In 1988, an IOM report on *The Future of Public Health* pronounced the nation's public health system to be in disarray. The report outlined a strategy to improve the governmental public health system, and, indeed, significant progress has since been made in strengthening federal, state, and local health departments. But at a time when public health threats are so numerous and diverse—obesity, AIDS, and bioterrorism are but a few pressing problems—the need for an effective public health system remains as urgent as ever. Concurrently, our understanding of the determinants for health—what makes individuals or populations healthy—has expanded enormously. One important insight is that the health of any individual is appreciably influenced by the health of others living in the same local or even national community. Thus, actions needed to protect and improve individual and population health require the engagement of multiple actors inside and outside the public

...public health threats are so numerous and diverse—obesity, AIDS, and bioterrorism are but a few pressing problems—the need for an effective public health system remains as urgent as ever.

health and health care systems. Several recent IOM reports provide both over-arching and specific guidance into how well the current public health system is meeting national needs and how it can be further strengthened.

The Future of the Public's Health in the 21st Century (2003) concludes that the governmental public health system still suffers from under-appreciation and under-investment while facing dramatically more complex and menacing challenges. The report elaborates on the conceptual model of what society must do to protect and improve the health of its population. It also recommends ways to maximize the contributions that voluntary agencies, governments, employers, individuals, the research and health care delivery systems, and even the media can make in improving public health. One of the requirements of an effective public health system is well-educated public health professionals. A companion report, *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century* (2003) provides a framework for how schools of public health can improve their education, training, and research over the next five years in order to prepare the public health workforce to play its role. At their core, schools should build their curricula and training programs on an ecological model of public health which assumes that health and well-being are affected by interaction among multiple factors, including not only personal and behavioral characteristics but also environmental, social, economic, and political determinants.

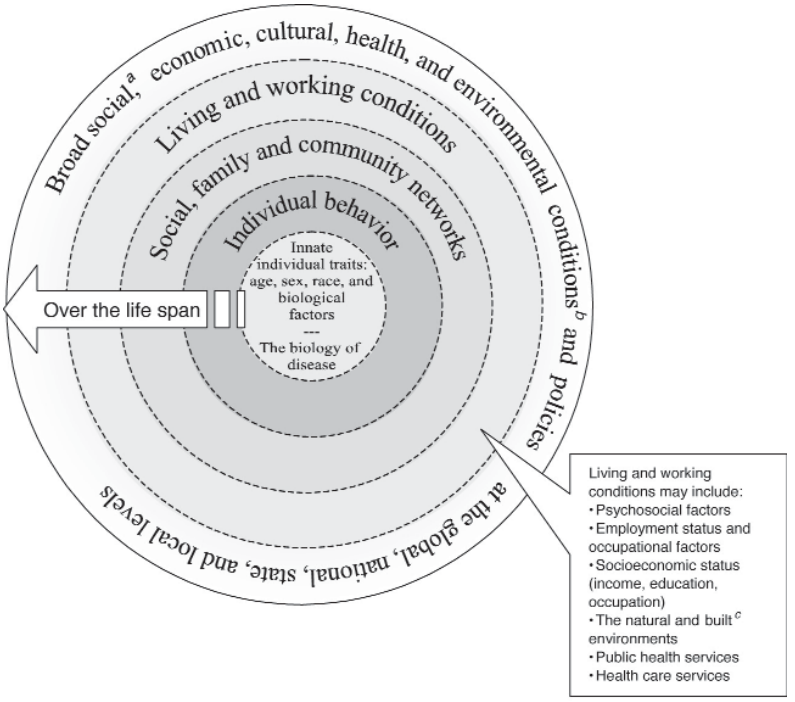


CONFRONTING HEALTH DISPARITIES

Not all Americans, when looked at by population groups, are equally healthy, nor do they share all of the same health behaviors. What is now becoming much clearer is how closely related an individual's lifetime health is to the health of the larger community in which that person lives. In the United States, significant health disparities exist and across diverse populations, despite efforts to reduce or eliminate those disparities. The problem will grow unless effective steps are taken to address the causes of inequality: these include income disparities; lack of access to health insurance and health services; as well as language and culture barriers.

In *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (2002), an IOM committee reviewed well over 100 studies that

A Guide to Thinking About the Determinants of Population Health



NOTES: Adapted from Dahlgren and Whitehead, 1991. The dotted lines between levels of the model denote interaction effects between and among the various levels of health determinants (Worthman, 1999).

[a]Social conditions include, but are not limited to: economic inequality; urbanization; mobility; cultural values; attitudes and policies related to discrimination and intolerance on the basis of race, gender, and other differences.

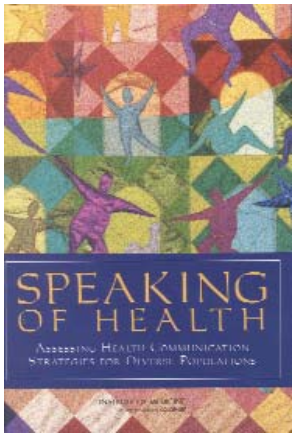
[b]Other conditions at the national level might include major sociopolitical shifts, such as recession, war, and governmental collapse.

[c]The built environment includes transportation, water and sanitation, housing, and other dimensions of urban planning.

SOURCE: *The Future of the Public's Health in the 21st Century,* 2003, page 53.

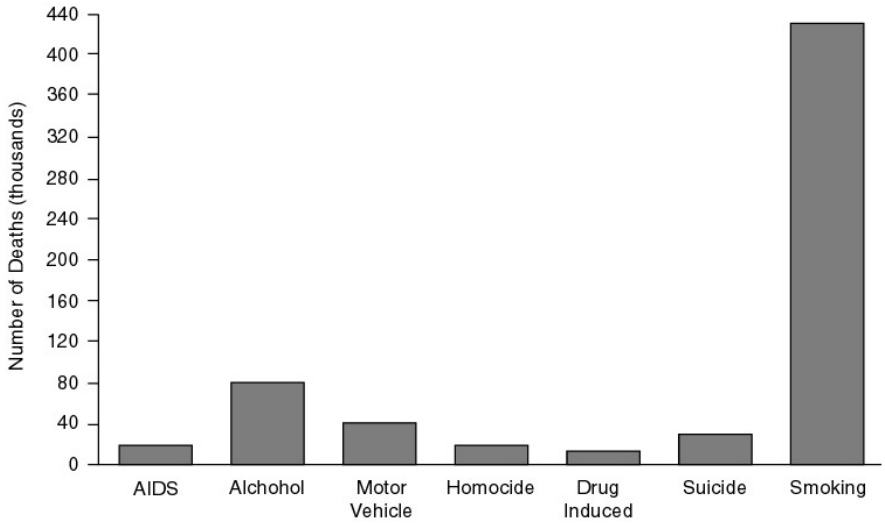
assessed the quality of health care for various racial and ethnic minority groups, while holding constant variations in insurance status, patient income, and other access-related factors. The research revealed that minorities tend to receive a lower quality of care than non-minorities, even when they have similar insurance or the ability to pay for care. Many potential sources for these health care disparities were identified, including the need to make medical decisions under time pressure with limited information, patient attitudes and behaviors, and health care providers' biases,

prejudices and uncertainty when treating minorities. The report recommends increasing awareness about the problem, improving provider training, and empowering patients through education. *Speaking of Health: Assessing Health Communication Strategies for Diverse Populations* (2002) explores the best ways to reach all segments of society with messages that effectively promote healthy behaviors. The report reviews existing theory and research applications in health communication and health behavior change, especially as they relate to culturally diverse populations, and defines areas that would benefit from expanded or new research. Among the questions ripe for exploration is how the boom in new communication technologies, such as the Internet, can be harnessed for reaching diverse audiences. The report also recommends how health communication strategies may be designed and implemented to achieve gains in public health across population groups. National communication campaigns—well funded and carried out with the coordination of multiple government agencies—will often be needed if many different groups of people are to be reached and effects are to be sustained over time.



HEALTH AND BEHAVIOR

Two of the most important threats to the health of the American people are obesity and tobacco. Both exemplify the necessity to consider interventions at multiple levels and through many types of mechanisms. Do unhealthy behaviors flow from a simple lack of willpower or knowledge of risk? What actions work in helping to modify unhealthy behaviors? In countless ways, our behavior influences our health—and thus health professionals, patients, families, and leaders at the community and national level struggle to understand the complex interactions between health and behavior and to use that knowledge to improve health status of individuals or populations. *Health and Behavior: The Interplay of Biological, Behavioral and Societal Influences* (2001) presents current knowledge about links between health and behavior, and about interventions to improve health through modifying behavior or personal relationships. The report outlines what must still be learned in order to better understand the complex relationship between health and behavior and to design and implement cost-effective methods for promoting behavioral changes that will foster good health.



Comparative Causes of Annual Deaths in the United States. SOURCE: CDC.

National attention has focused on the dangers of tobacco use, particularly cigarette smoking, for several decades, and the knowledge and lessons learned in that campaign are instructive for addressing other public health risks. Tobacco use is the single largest environmental cause of death and disease in the United States, claiming more than 400,000 lives annually. Although the dangers have been known for decades, roughly 48 million adults—nearly one-quarter of the adult population—continue to smoke cigarettes. Several IOM reports have been important in shaping public opinion and national policy regarding the use of tobacco. The most recent is *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* (2001), which focuses on the array of products that claim to be less risky: low-tar and low-nicotine cigarettes, cigarette-like devices that change the composition of smoke inhaled, and gums that reduce tobacco craving. This report found that there is not enough scientific evidence to conclude that any of these products actually confers any degree of health protection. It outlines how classic public health tools—research, surveillance, communication, and regulation—should be used to prevent misleading claims of lower risk of these products to individuals or populations.

The growing rate of obesity is another public health challenge that has reached epidemic proportions in the United States, with the Department

of Health and Human Services estimating that 64 percent of adults are overweight and obese, more than 15 percent of children and teens carry excess pounds, and a total cost estimated to be $117 billion annually. Research shows that overweight children are at risk for serious health problems, including diabetes and cardiovascular disease. According to one report, about 60 percent of children ages 5 to 10, who are overweight or obese, already have at least one cardiovascular disease risk factor, such as elevated total cholesterol levels or higher blood pressure, and 25 percent have two or more. Data suggest that 70 percent of overweight children will remain so as adults, with all the attendant risks for greater health problems and earlier mortality. In 2001, the U.S. Surgeon General issued a call to action to prevent and decrease overweight and obesity in the United States. Recognizing the need for greater attention directed to children and youth, Congress requested that the Institute of Medicine develop an action plan targeted specifically at the prevention of obesity among youngsters. The study committee will assess social, environmental, medical, dietary and other factors responsible for the increasing prevalence of childhood obesity and identify the most promising methods for prevention, including interventions and policies for immediate action and for the longer term. In tandem with this study, the IOM is also focusing on a study on the effects of transportation and land use on physical activity levels. This study will address the role of transportation and land use on recent increases in sedentary behavior. It is designed as a framing effort to help sort out the complex factors affecting development and travel; assess the potential for policies that promote more walking, cycling, and transit trips through changes in land use and transport systems; and identify areas for further research.

...70 percent of overweight children will remain so as adults, with all the attendant risks for greater health problems and earlier mortality.

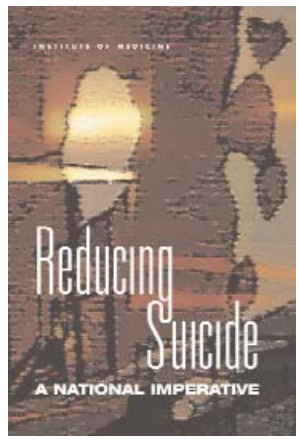
COMMUNITY HEALTH

Two other recent reports exemplify the coordinating role that public health plays in linking the actions of community services such as law-enforcement, schools, and social services with clinical services to address complex threats to health: family violence and suicide.

Family violence—child abuse and neglect, intimate partner violence, and elder abuse—is a deeply troubling problem in American society. Studies consistently report that such violence affects as many as 25 percent of children and adults during their lifetimes, as victims, as perpetrators or

as witnesses. Health professionals are often the first to encounter the victims of family violence and thus can play an important role in ensuring that those individuals—as well as the perpetrators—get the help they need. Getting that help requires engagement with a range of actors outside of the health care delivery system. But health professionals now receive little education in how to deal with family violence. *Confronting Chronic Neglect: The Education and Training of Health Professionals on Family Violence* (2002) recommends a variety of steps for improving the ability of health professionals to screen, diagnose, treat, and refer victims of abuse and neglect. The report also makes clear that health professionals alone cannot solve this problem—and that society as a whole must pay greater attention to the tragedy of family violence.

Approximately 30,000 people die each year as a result of suicide in the United States, making it the third leading cause of death among adolescents and the eleventh leading cause of death for people of all ages. Suicide is an international problem as well, claiming around a million lives annually. *Reducing Suicide: A National Imperative* (2002) summarizes current knowledge about the various factors—biological, genetic, psychological and cultural that make people more or less likely to kill themselves, and about methods and programs that have proven effective for treating and preventing suicide. Prevention programs built on the public health model—those that address risk and protective factors from the individual to the community level—are most likely to succeed. The report also identifies areas where more research is needed and provides a blueprint for filling those gaps. This includes a national network of laboratories devoted to interdisciplinary research on suicide and suicide prevention across the life cycle and a national system for monitoring attempted and completed suicides. Efforts are needed to better train primary care providers (who are often the first and only contacts that suicidal individuals have with the medical system) in how to recognize and address both chronic and acute risk factors.



PREVENTION

Prevention is the core of public health. Indeed the roots of public health are often traced to the case of John Snow, an English physician of the 19th century. During the 1854 cholera epidemic in London, Snow

observed that the disease mainly afflicted people who had used water from the Broad Street Pump. Snow, who had spent years researching the causes and transmission of cholera, convinced the government to remove the pump handle, thus averting future outbreaks of cholera. Immunization might be called the contemporary equivalent of the removal of the Broad Street Pump handle: it is widely regarded as one of the world's most effective tools for protecting public health.

Immunization

Immunization programs have resulted in the elimination of wild smallpox globally, and the elimination of polio in the developed world and much of the developing world. A number of life-threatening diseases that were once common, including diptheria, measles, mumps and pertussis have been nearly eliminated in the United States. However, as these terrible diseases have largely disappeared, concern has focused on both established rare side-effects and those that have been hypothesized to result from immunization. Because vaccines are so widely used—and because state laws require that children be vaccinated to enter daycare and school, in part to protect others—immunization safety concerns are a serious matter.

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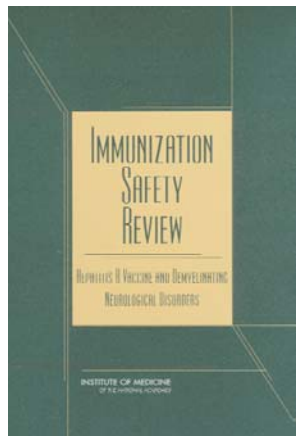
Toward this goal, the IOM was asked by the Centers for Disease Control and Prevention and the National Institutes of Health to review some of the emerging concerns about the safety of vaccination. The IOM has a long history in assessing vaccine safety, having issued its first major report on this subject in 1977. For the current reviews, the IOM committee includes independent health professionals with wide-ranging expertise. The members have no ties to vaccine manufacturers, have not conducted research on vaccine safety, and have not served on any vaccine advisory committees. The committee to date has issued six safety reviews:

- *Measles-Mumps-Rubella Vaccine and Autism* (2001). This report concludes that the total body of scientific evidence favors rejection of a causal relationship between measles-mumps-rubella (MMR) vaccination and autism at the population level. But the report could not exclude the possibility that MMR vaccine might contribute to autism in a small number of children—in part because existing epidemiological tools may not have enough precision to detect the occurrence of such rare effects—and recommends that the issue receive continued attention.

• *Thimerosal-Containing Vaccines and Neurodevelopmental Disorders* (2001). Thimerosal has been used for decades as a preservative in vaccines to prevent bacterial and fungal contamination. It contains mercury, which at high doses is known to cause serious neurodevelopmental problems in humans. This has prompted concerns that infants and children might accumulate hazardous levels of mercury through vaccines. As a result, thimerosal is no longer used for children's vaccines in the U.S., but is contained in a relatively small number of vaccines, including influenza vaccine. The report concluded that evidence is inadequate to accept or reject a causal relationship from vaccine exposure to neurodevelopmental disorders. But the connection is at least biologically plausible, and additional research should be conducted.

• *Multiple Immunizations and Immune Dysfunction* (2002). By age two, healthy infants in the U.S. can receive up to 20 vaccinations to protect against 11 diseases. Many parents are concerned that this level of immunization can overwhelm an infant's immune system and increase the risk for immune dysfunction, resulting in vulnerability to diseases such as pneumonia ad meningitis, type 1 diabetes, and asthma. The report concluded that scientific evidence favors a rejection of a causal relationship between multiple immunizations and increased risk of infections or type 1 diabetes, while being inadequate to either reject or accept a causal relationship with allergic disorders.

• *Hepatitis B Vaccine and Demyelinating Neurological Disorders* (2002). Immunization advisory groups recommend that all infants and adolescents, and all adults at high risk of exposure to the hepatitis B virus, such as health care workers, receive the hepatitis B vaccine for protection from serious liver disease. However, there is some degree of concern that the vaccine can cause demyelinating neurological disorders, such as multiple sclerosis. (In these disorders, the protective coating of myelin that surrounds nerve fibers is somehow damaged or destroyed, thus disrupting the transmission of nerve impulses that control bodily functions and mobility.) The IOM report concludes that scientific evidence—though scant and indirect—favors rejection of a causal relationship between administration of the hepatitis B vaccine to adults and an increased risk of developing multiple sclerosis. The evidence was inadequate to either reject or accept a causal relationship between the vaccine and all other demyelinating conditions.



• *SV40 Contamination of Polio Vaccine and Cancer* (2002). It is known that some of the polio vaccine administered to adults and children in the United States from 1955 through 1963 was contaminated with simian virus 40 (SV40), which came from monkey kidney cells used to produce the vaccine. SV40 has biological properties that are similar to other viruses known to cause cancer in humans, although it has not been conclusively established that SV40 actually has this ability. Prior to its elimination from the vaccine, it is estimated that between 10 million and 30 million people received contaminated vaccine, and researchers have long wondered about the health effects, if any, of their exposure. The IOM report concludes that scientific evidence is insufficient to prove or disprove the theory that exposure to contaminated polio vaccine has triggered cancer in humans. The vast majority of population studies, which carry the most weight in establishing causal relationships, have found no increased rates of cancer in people who received the vaccine during the period when it was contaminated. However, a possible link cannot be completely ruled out, because of limitations in the available data and in the way the studies were conducted.

SV40 has biological properties that are similar to other viruses known to cause cancer in humans...

• *Vaccinations and Sudden Unexpected Death in Infancy* (2003). Most infants receive multiple doses of vaccines during their first year. Most infants who die during their first year do so suddenly and unexpectedly. This overlap has raised concern that vaccinations might play a role in sudden unexpected death in infants. The IOM report examines possible connections between vaccinations and three outcomes: all cases of sudden unexpected infant deaths; cases of sudden infant death syndrome (SIDS), which is the most common cause of death during the neonatal period; and cases in which infants die, whether unexpectedly or not, during their first four weeks. The report concludes that scientific evidence favors rejection of a causal relationship between one type of vaccine (the combination diphtheria, tetanus, whole-cell pertussis vaccine) and SIDS, but favors acceptance of a causal relationship between this vaccine and death due to anaphylaxis, which is an extremely rare event caused by an allergic reaction. It says the evidence is inadequate to either reject or accept a causal relationship between the other vaccines studied and all forms of sudden unexpected infant death.

Smallpox Vaccination

One of public health's greatest triumphs was the World Health Organization declaration in 1980 that the world was free from the ancient scourge of smallpox. Tragically, however, the emergence of global terrorist organizations preparing to use biological weapons against the United States and other targets has created a credible threat of possible outbreaks of smallpox in the general population as a result of its use as a biological weapon. The smallpox vaccine (vaccinia virus) is a highly effective immunizing agent against the disease. But its use is not without risk, and reintroduction of wide-scale vaccination must be done judiciously. The IOM has issued several reports related to developing and implementing smallpox vaccination programs:

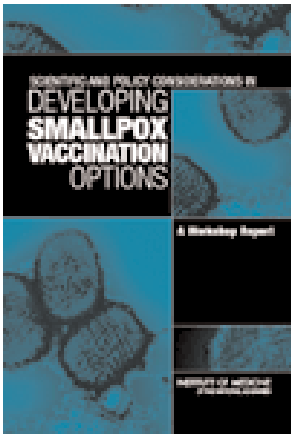
...the emergence of global terrorist organizations preparing to use biological weapons against the United States and other targets has created a credible threat of possible outbreaks of smallpox...

- *Scientific and Policy Considerations in Developing Smallpox Vaccination Options* (2002) summarizes the results of a public workshop organized by the IOM at the request of the Centers for Disease Control and Prevention (CDC). Participants discussed the scientific, clinical, social, procedural, and administrative aspects of various immunization strategies being considered by the federal government for smallpox immunization. The report was presented to the Advisory Committee on Immunization Practices (ACIP), an independent body that provides guidance to the government regarding the most appropriate use of vaccines and related agents for effective disease control in the civilian population, which used the workshop results in crafting updated recommendations for smallpox vaccination of the general population and for vaccination of individuals at risk.

- Review of the Centers for Disease Control and Prevention's *Smallpox Vaccination Program Implementation: Letter Report #1* (2003) is the first of several reports requested by the CDC to provide timely advice on how best to implement the national smallpox immunization program announced in late 2002 and begun in early 2003. The initial plan, broken into phases, first involved vaccinating 500,000 public health and health care workers who volunteered to be part of smallpox response teams that would take action during a bioterrorist attack. The second phase would include vaccination of 10 million health workers and other traditional "first responders," such as police and firefighters. Vaccination eventually would be available to members of the general public who want it, but it is not suggested. Among its recommendations, the report urges the CDC to proceed with the immu-

nization program as cautiously as possible, allowing continuous opportunity for deliberation and analysis.

- Review of the Centers for Disease Control and Prevention's *Smallpox Vaccination Program Implementation: Letter Report #2* (2003) offers recommendations that reflect changes made by the government to the original program based on phased-in vaccination. Under the new plan, states would be allowed to expand voluntary vaccination to all health care workers and first-responders before completing the first phase involving a much smaller group of key personnel. The report urges the CDC to make every effort to plan, implement, and evaluate the program, even without an official break between its phases, in order to improve its implementation and protect both the people who are vaccinated and the public. The main focus should be on maximizing preparedness to deal with a bioterrorist attack. In addition to increasing the number vaccinated, preparedness means that states and communities must have coordinated their public health workers, medical personnel, and other emergency responders to ensure that they can react quickly and effectively when needed. *Letter Report #3* (2003) reaffirms the need for a pause in the smallpox vaccination program and provides commentary about the Centers for Disease Control and Prevention's smallpox program activities to date, including next steps in the pre-event vaccination program.



Vaccine Finance

Concerns about vaccines include not only issues of safety, but also of cost. Vaccine manufacture is not profitable for pharmaceutical companies when compared to drugs with broad markets, such as the class of statins that prevent heart disease. At the same time, the new vaccines are expensive, and much of the purchase burden falls on governments at the federal and state level. The IOM has issued several reports on approaches to vaccine finance, the most recent being *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003), which recommends bold, fundamental changes to the current system of vaccine purchasing and distribution. The principal recommendation of the report is that the current government vaccine purchasing programs be replaced with a new government-funded insurance mandate and voucher plan for Advisory Committee on Immunization Practices (ACIP)-approved vaccines. The mandate would

require all public and private health plans to include vaccine benefits, coupled with vouchers for uninsured children and adults. The role of the federal government would be to reimburse plans and health care providers for the costs of their vaccine purchases. The report includes an analysis of alternative strategies that were considered in formulating this approach. In addition, the committee recommends changes in the composition and decision-making procedures of the ACIP, the entity that currently recommends vaccines.

CHILDREN, YOUTH, AND FAMILIES

There are 85 million families in the United States today and a new birth cohort of 11,000 infants arrives each day. Today's children, adolescents, and youth confront a world in which rapidly evolving technology, changing social and health environments, and growing multicultural diversity pose new opportunities and complex challenges. An explosion of research in the neurobiological, behavioral, and social sciences has led to major advances in understanding the conditions that influence children. Although we have long known how to identify problems and risk behaviors among children and adolescents, only recently has the science of positive child and youth development emerged. Such research has profound implications for employment trends and child care practices, family and neighborhood processes and relationships, educational programs and health care services, and community initiatives within local jurisdictions, states, and the nation as a whole. Research on children, youth, and families is thus watched carefully by millions of families, policy-makers, employers, and service providers who seek authoritative guidance as they address the challenges of promoting the health and well-being of today's children, adolescents, and families.

...recent decades have altered the landscape for early childhood policy, service delivery and child-rearing in the United States.

To address these concerns, the Board on Children, Youth, and Families (BCYF) was established in 1993 under the joint aegis of the Institute of Medicine and the National Research Council. The Board has sponsored over 40 activities since that time, including broad consensus-based studies (such as the landmark report *From Neurons to Neighborhoods*, published in 2000) and smaller workshop reports (examples include projects on the quality of after-school programs, the education of language minority children, the impact of welfare assistance on child development, and efforts to

reduce child pornography). Current projects and recent reports include evaluating risk and protective factors for assessing child health in the community; promoting child and family well-being through family work policies; training health professionals on family violence; achieving positive outcomes for children in child care; and drawing policy implications from research on early childhood development and learning.

Recognizing the persistent concerns about adolescence and youth development, the Board was supplemented in 2000 by the Committee on Adolescent Health and Development (CAHD), a new standing committee that also generates consensus and workshop reports. The CAHD assumed responsibility for taking stock of what is known about adolescent health and development, applying this knowledge to pressing issues facing adolescents and their families, and stimulating new directions for inquiry and innovation. Current and recent projects include a study on transitions to adulthood in developing countries and administration of the W.T. Grant Youth Development Prize.

Low levels of health literacy can lead to higher levels of mortality, morbidity, inequity, and cost...

Recent examples of IOM studies on children, youth, and families include the following:

- Contemporary American high schools are expected to meet the needs of a diverse and growing population of youth, providing them with knowledge, skills, and credentials for successful transition into adulthood, higher education, and the workforce. For many adolescents, schools do not meet these expectations, despite years of public debate. *Engaging Schools: Fostering High School Students' Motivation to Learn* (2002) provides a detailed analysis of how application of the psychological theories of motivation and engagement can be applied to urban school reform.

- Two changes in recent decades have altered the landscape for early childhood policy, service delivery, and childrearing in the United States. The first is the set of major advances in understanding interactions among the many factors that influence child health and development. The second is the expansion of time that young children spend in child care settings, frequently starting in infancy, as a result of changed social and economic circumstances of working families. *Working Families and Growing Kids: Caring for Children and Adolescents* (2003) examines these changes and

offers recommendations for employers, government agencies, child care providers, and parents to assure quality of care and family friendly practices.

UPCOMING REPORTS

Damp Indoor Spaces and Health. Recent attention has been given to the relationship between damp or moldy indoor environments and the manifestation of adverse health effects, particularly respiratory and allergic symptoms. In response to a request by the Centers for Disease Control and Prevention, a comprehensive review will focus on fungi and mycotoxins, including Stachybotrys chartarum—thought by some to be associated with a cluster of pediatric pulmonary hemosiderosis in Cleveland during the early 1990s. In addition, it will make recommendations or suggest guidelines for public health interventions and for future basic science, clinical, and public health research in these areas.

The Future of Poison Prevention and Control Services. Over 4 million poison exposures occur annually in the United States. Approximately half of these exposures are reported to the Poison Control Centers (PCCs), which provide free support to callers through a telephone hotline staffed by toxicology professionals. Ready access to PCCs reduces the cost and improves the quality of emergency care of poisoning exposures. Yet the funding for the PCCs over the last 20 years has been limited and unstable. In response to a request from the Maternal and Child Health Bureau of the Health Resources and Services Administration, an IOM committee is considering the future of poison prevention and control services in the United States. To address this charge, the committee is evaluating the role, funding organizational structure, and scope of services of the PCCs, and providing recommendations for assuring the optimal provision of poison prevention and control services in the future. The committee is also considering future demographic and population trends, and how these might have an impact on population needs for poison prevention and control services, and other relevant factors.

Ready access to PCCs reduces the cost and improves the quality of emergency care of poisoning exposures.

Health Literacy. The health care system increases in complexity every week. As a result, emphasis is being put on the consumer to play a key role in making health decisions and in ensuring that their own health care and that of their families is of high quality, appropriate, and error free. Health literacy, the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions, is therefore an increasingly important aspect of public health.

It has been estimated that 46 percent of American adults, 60 million people, are functionally illiterate in dealing with health. This problem is as profound as any new infectious or chronic disease, but is not spoken of by patients and is not appreciated by policy makers and the general public. Without significant improvements in health literacy, the promise of all the scientific advances to improve health outcomes will be significantly diminished.

Low levels of health literacy can lead to higher levels of mortality, morbidity, inequity, and cost. One study in 1997 found that poor literacy resulted in five times the number of mistakes in interpreting prescriptions and twice the number of visits to the doctor compared to those with adequate literacy skills. These costs fall not only on patients, but also on employers, insurers, Medicaid/Medicare, and health care providers. Conversely, high levels of health literacy can lead to lower levels of mortality, morbidity, inequity, cost as well as greater improvement in health and well being.

One study...found that poor literacy resulted in five times the number of mistakes in interpreting prescriptions and twice the number of visits to the doctor compared to those with adequate literacy skills.

To date, policy efforts to address quality of care are focusing principally on the health care system but do not consider the impact of health literacy. An IOM study is currently assessing the problem of health literacy and is considering the next steps within a public health/public education framework. The study will evaluate approaches that have been attempted to increase health literacy and identify the gaps in research and programs that need to be addressed.

Underage Drinking. Multiple strategies are currently in operation to reduce underage drinking, but little is known about the effects of differing approaches. In response to a request from the U.S. Congress, the IOM established a committee to review governmental and nongovernmental programs, including media-based programs, designed to change youth attitudes and drinking behaviors. The final study, *A Strategy for Reducing and Preventing Underage Drinking,* assesses programs that focus directly on behavior changes as well as those that seek to reduce adolescent access to alcohol (through higher taxes, aggressive enforcement of age and identification checks, and restriction of alcohol on college campuses, for example). The study is expected to be released in fall 2004.

Selected Recommendations for Health Care Delivery

Improving the Quality of Health Care: All health care organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable. DHHS should be given the responsibility and necessary resources to establish and maintain a comprehensive program aimed at making scientific evidence more useful and accessible to clinicians and patients. Congress, the executive branch, leaders of health care organizations, public and private purchasers, and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education. Private and public purchasers should examine their current payment methods to remove barriers that currently impede quality improvement, and to build in stronger incentives for quality enhancement. (*Crossing the Quality Chasm: A New Health System for the 21st Century,* 2001)

The Role of Leadership in Health Quality: The federal government should assume a strong leadership position in driving the health care sector to improve the safety and quality of health care services provided to the approximately 100 million beneficiaries of the six major government health care programs. Further, the federal government should take maximal advantage of its unique position as regulator, health care purchaser, health care provider, and sponsor of applied health services research to set quality standards for the health care sector. (*Leadership by Example: Coordinating Government Roles in Improving Health Care Quality,* 2003)

Focus on Health Professions Education: All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice, quality improvement approaches, and informatics. (*Health Professions Education: A Bridge to Quality,* 2003)

Reducing Racial and Ethnic Disparities in Health Care: It is critical that all relevant policy makers increase awareness of racial and ethnic disparities in health care among the general public and key stakeholders, especially including health care providers. The proportion of underrepresented U.S. racial and ethnic minorities among health professionals should be increased. Governments should strengthen the stability of patient-provider relationships in publicly-funded health plans, and apply the same managed care protections to publicly funded HMO enrollees that apply to private HMO enrollees. Payment systems should be structured to ensure an adequate supply of services to minority patients and limit provider incentives that may promote disparities. (*Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,* 2002)

Addressing Cancer Risk Factors: A national strategy should be developed and coordinated by DHHS to address the epidemic of obesity, unhealthy diet, and physical inactivity in America. The U.S. Congress and state legislatures should enact and provide funding for enforcement of laws to substantially reduce and ultimately eliminate the adverse public health consequences of tobacco use and exposure. (*Fulfilling the Potential of Cancer Prevention and Early Detection,* 2003)

HEALTH CARE DELIVERY SYSTEM AND PERFORMANCE CAPABILITIES

Quality problems are everywhere, affecting many patients. Between the health care we have and the care we could have lies not just a gap, but a chasm.—Crossing the Quality Chasm: A New Health System for the 21st Century, 2001

THE QUALITY CHASM

Recent years have brought to national attention a troubling fact: the U.S. health care delivery system does not provide consistent, high-quality medical care to all people all of the time. *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) calls for a sweeping redesign of the entire delivery system. Modifying the current system cannot do the job, because its inherently poor design sets up health care workers to fail, regardless of how hard they try. The report presents a strategy and action plan for developing a system that ensures the delivery of care that is safe, effective, patient-centered, timely, efficient, and equitable over the next decade. It provides a set of ten general principles for improving how health professionals and their institutions care for patients. Among these rules, care should be customized according to patient needs and values, decisions should be made based on the best

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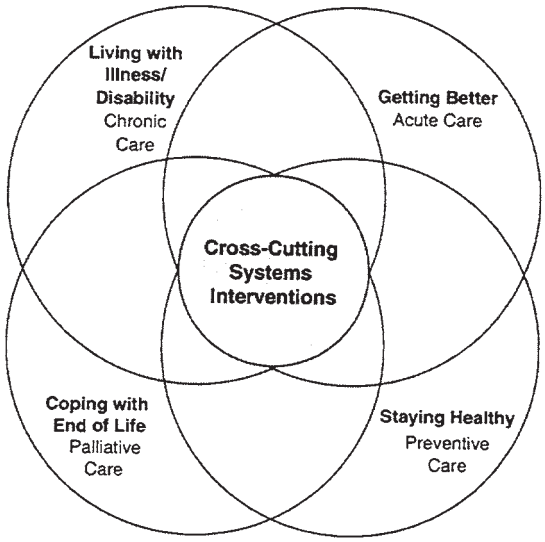


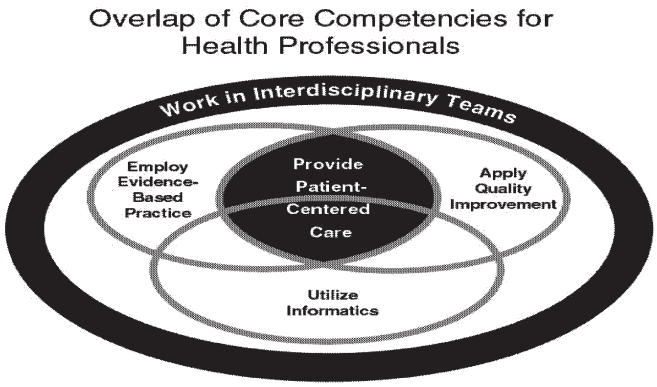
The Committee's Initial Framework for Determining Priority Areas. SOURCE: *Priority Areas for National Attention: Transforming Health Care Quality,* 2003, page 3.

scientific evidence, patients should be kept safe from injury caused by the care system, and cooperation among clinicians and institutions should be made a priority. Broader-based actions also are needed, such as setting national priorities for improving care delivery, creating better methods for disseminating and applying knowledge to practice, fostering the use of information technology in clinical care, creating payment policies that encourage innovation and reward improvement in performance, and enhancing educational programs to strengthen the health care workforce.

As a crucial first step in making the health care system more responsive to the needs of patients and more capable of delivering science-based care, the *Quality Chasm* report recommends the systematic identification of priority areas for quality improvement. In response, the Department of Health and Human Services turned to the Institute of Medicine for assistance. *Priority Areas for National Attention: Transforming Health Care Quality* (2003) identifies 20 focus areas covering the entire spectrum of health care, from preventive and acute care through palliative care at the end of life. Taken together, the priority areas touch all age groups, health care settings, and care providers. Most of the areas focus on chronic conditions heart disease, cancer, stroke, chronic obstructive pulmonary disease, and diabetes, among others given that such conditions account for the major-

ity of the nation's health care burden and resource use. Several of the areas, such as the need for coordination among clinicians and institutions in patient care, cut across specific conditions and health care settings. Collective action in these priority areas could help transform the entire heath care system. As steps are taken to improve care, it will be vital to measure their impact regularly, using standardized methods that permit comparisons. Over time, new priority areas may need to be identified, using the criteria and selection process spelled out in the report.

The Quality Chasm report also stresses that transforming the health care delivery system will require transforming how physicians, nurses, pharmacists, and other health professionals are educated. *Health Professions Education: A Bridge to Quality* (2003) provides a blueprint for change. Educators should develop curricula and programs for undergraduate, graduate, and continuing education to ensure that clinicians achieve proficiency in five core areas: providing patient-oriented care; working in interdisciplinary teams; practicing evidence-based medicine; applying quality improvement approaches; and using information technologies. Organizations with oversight responsibilities including accreditation, licensure, and certification groups also should adopt mechanisms to ensure that students and working professionals develop and maintain proficiency in these areas. Among other recommendations, the report calls for changes to training programs, for research to improve educational practices and identify what clinicians should be taught to improve patient care, for public reporting related to health professions education to better



Relationship Among Core Competencies for Health Professionals. SOURCE: *Health Professions Education: A Bridge to Quality,* 2003, page 46.

coordinate and integrate across their multiple roles, and for active leadership across disciplines to improve health professions education.

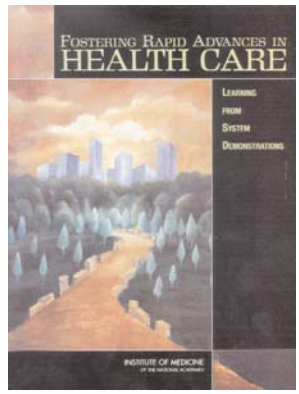
REFORMING THE SYSTEM

Given their key role in training health professionals, conducting research that advances health, and treating the neediest of patients, academic health centers can lead efforts to improve health care. *Academic Health Centers: Leading Change in the 21st Century* (2003) offers a comprehensive plan for how academic health centers (AHCs) should reform their own operations, proposes public policy actions needed to ensure that AHCs carry out reforms, and describes how AHCs can serve as models to guide change for health care delivery, education, and research. Among priority needs, AHCs should take the lead in redesigning the content and methods of health professions education (and Congress should create a dedicated fund to support such innovation), and they should design and assess new organizational structures and team approaches for patient care (and government agencies, organizations that pay for health care, and foundations should support demonstration projects to evaluate these approaches). AHCs also should increase their emphasis on clinical, health services, and prevention research in order to answer questions about the clinical effectiveness and cost effectiveness of both current practices and emerging technologies and funders of health-related research, especially at the federal level, should enhance and foster collaboration across departments, professional schools and institutions. AHCs must set clear goals so that progress in these diverse areas can be steadily monitored, and leaders of the centers must step forward to guide the nation toward improved health.

Academic health centers must set clear goals so that progress in these diverse areas can be steadily monitored, and leaders of the centers must step forward to guide the nation toward improved health...

In many fields, conducting demonstration projects often proves of great benefit in determining the best ways to reach desired goals. For this reason, the Department of Health and Human Services asked the IOM to identify possible demonstration projects focused on improving health care that could be conducted in the near term and that might yield models for broad reforms of the overall delivery system within a few years. *Fostering Rapid Advances in Health Care: Learning from System Demonstrations* (2003) describes a carefully crafted set of projects that hold promise of breaking new ground and potentially could improve health, save dollars, or both.

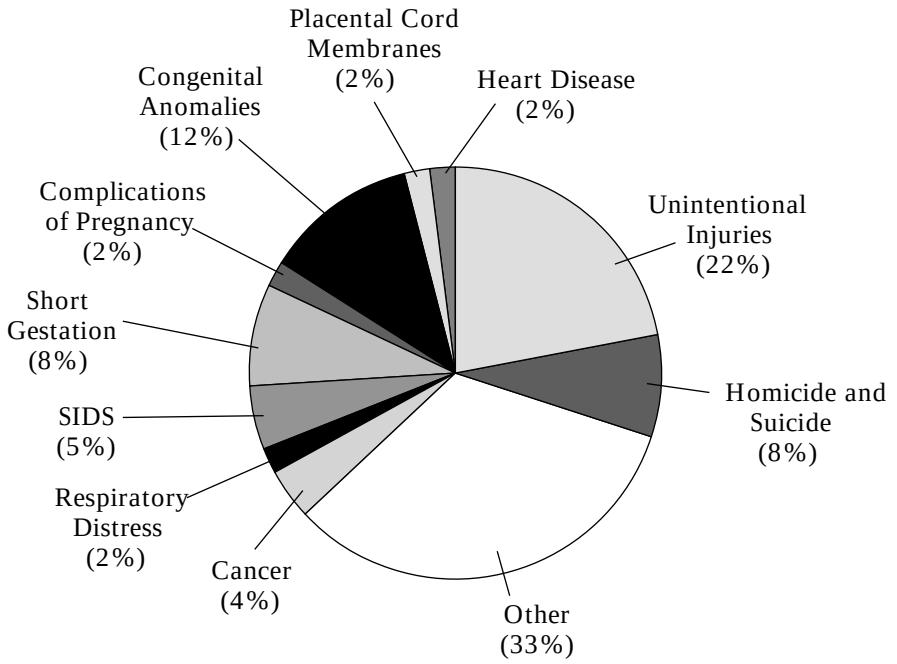
The projects fall into five basic categories: chronic care; primary care; the information and communications technology infrastructure; state health insurance, and medical liability. Taken together, the projects address critical elements of proposed strategies for system-wide health care reform. All or nearly all of the projects will involve public and private partnerships and collaborative efforts, and with the exception of the uninsured demonstration, they are expected to require modest increases in health care expenditures beyond initial upfront investment. As with all demonstrations, these projects should be viewed as experiments and should be carefully evaluated to determine whether and to what extent they achieve intended outcomes.



Proposals for improving the quality, safety, and efficacy of the health care system typically place considerable emphasis on developing and implementing electronic health record (EHR) systems. Although an increasing number of health care organizations already use such systems, most providers continue to write orders for services and maintain patient records on paper, and most also practice without computer-assisted decision supports, such as prompts to check a diabetic patient's blood glucose or alerts that indicate drug interactions. As part of a national effort to encourage the adoption of computer-based health records, the Department of Health and Human Services asked the IOM for help in establishing what characteristics EHR systems should possess to be most useful. *Key Capabilities of an Electronic Health Record System* (2003) identifies a set of eight core functions that EHRs should be capable of performing. The functions were selected on the basis of their ability to improve patient safety, support effective care, assist in the management of chronic diseases, and improve efficiency. They all protect patient privacy and confidentiality, and they comply with established standards for security, storage, and exchange of data. Having a common understanding about key functions will enable health care organizations to more easily compare the EHR systems that are currently available, guide vendors in building new systems with enhanced capabilities, help accreditation organizations in certifying systems that are ready for adoption, and may guide the federal government as it considers ways to stimulate care providers to invest in EHR.

To help in determining whether the nation is making progress in improving the delivery of health care, Congress has mandated the Agency for Healthcare Research and Quality to prepare an annual report on quality trends, with the first report slated for 2003. The agency asked the IOM to develop a vision of the design and contents of this report. *Envisioning the National Health Care Quality Report* (2001) offers a broad framework for assessing quality of health care; describes specific examples of the types of measures that should be included and suggests how to obtain such data most efficiently; and provides advice on how to reach intended audiences with this information. Although its primary audience is intended to be policy makers and health care leaders at the national and state levels, the report also should be of interest to the public, clinicians, researchers, purchasers of health care, and other individuals and groups concerned with health quality.

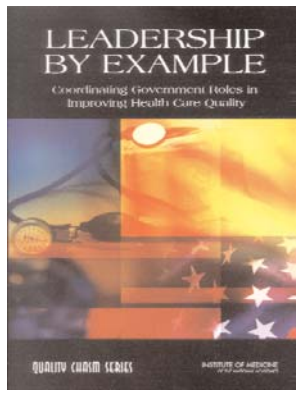
Children with life-threatening conditions and their families too often fail to receive competent, compassionate, and consistent health care that meets their physical, emotional, and spiritual needs. *When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families* (2003)



Percentage of Total Childhood Deaths by Age Group (1999). SOURCE: *When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families,* 2002, page 4.

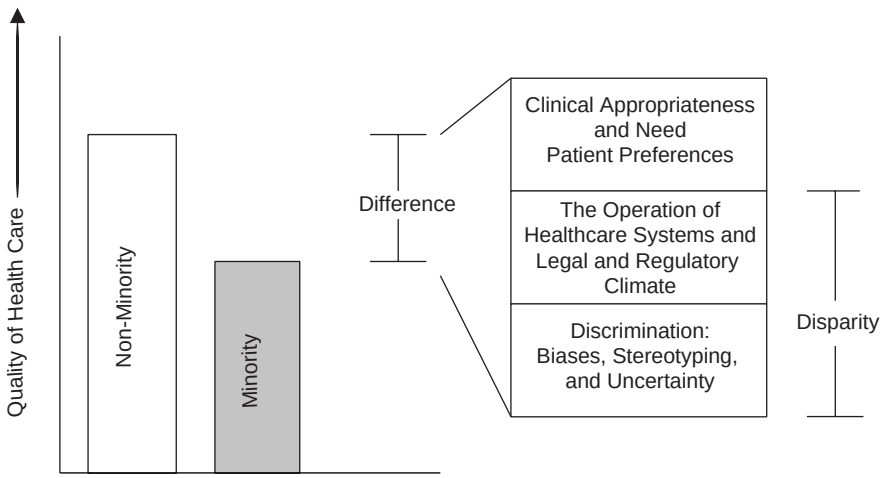
concludes that the nation must do more to deliver effective and appropriate care in these tragic situations. It provides a set of working principles that characterize high-quality palliative, end-of-life, and bereavement care, and suggests a broad-based strategy for making such care widely available. Indeed, good care already is possible but current methods of organizing and financing complicate the provision and coordination of services, and sometimes even require families to choose between curative or life-prolonging care and palliative services, particularly hospice care. Inadequate scientific knowledge also impedes efforts to deliver effective care and design supportive public policies, and the report calls for expanded research to fill current data gaps. Expanded educational efforts are needed as well to provide all physicians, nurses, and other health professionals with basic competence in palliative, end-of-life, and bereavement care, and to provide specialists and others who routinely treat children with life-threatening conditions with advanced competence in these types of care.

ASSESSING GOVERNMENT HEALTH PROGRAMS



The government's six major health care programs serve some 100 million people directly and significantly influence how the private sector provides care to millions more. In response to a request from Congress, the IOM analyzed how well these programs: Medicare; Medicaid; the State Children's Health Insurance Program; the Veterans Health Administration program; the Department of Defense TRICARE programs; and the Indian Health Service program are meeting their responsibility to improve the quality of the care they provide. *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality* (2003) calls for stronger federal actions and proposes a rigorous implementation strategy. Specifically, the government should take full advantage of its unique position as purchaser, regulator, and provider of health care, as well as its role as the leading sponsor of research, to improve care both in its own programs and in the private sector. Among recommended actions, public care providers should serve as laboratories for developing fundamentally new delivery systems, regulatory processes should be used to establish clinical data reporting requirements, purchasing strategies should provide rewards to providers who achieve higher levels of quality, and applied health research programs should be expanded to accelerate development of knowledge and tools in support of quality enhancement.

The government's main programs for providing cash benefits and eligibility for medical benefits to people with disabilities—the Social Security Disability Insurance program and the Supplemental Security Income program—have experienced unexpectedly rapid growth during the past two decades. For guidance on managing these programs, the Social Security Administration (SSA) turned to the Institute of Medicine. *The Dynamics of Disability: Measuring and Monitoring Disability for Social Security Programs* (2002) offers a comprehensive set of recommendations. Since disability is a dynamic process that can fluctuate in breadth and severity across the life course, the SSA should develop a monitoring system to continually gather information in a variety of areas. This system would provide the agency with data needed to respond to a variety of policy and planning issues, such as changes in the size, distribution, and characteristics of the working population with disabilities; demographic trends, fluctuations in labor markets, and changes in economic conditions; needs of minority and special populations with disabilities; and the impacts of legislative, regulatory, and judicial actions on disability programs. The SSA also desperately needs to develop a systematic long-term research program to address growing demands on its disability programs and to provide the basis for improving how it makes decisions about program eligibility. Strengthening research efforts, within the agency and through extramural programs, will require a major infusion of new resources, in terms of both dollars and recruitment of qualified researchers.

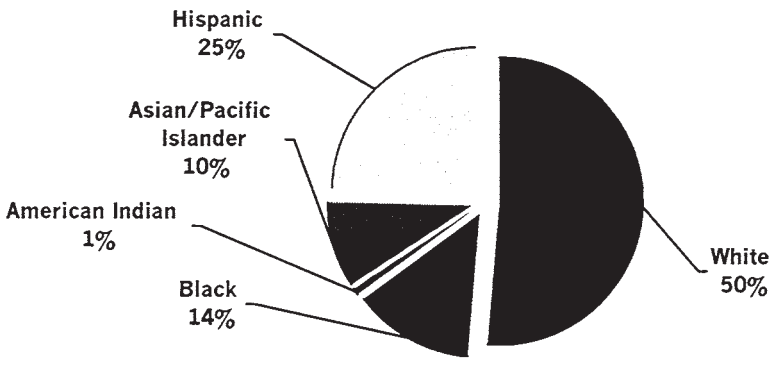


Difference, Disparities, and Discrimination: Populations with Equal Access to Health Care. SOURCE: *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* 2002, page 33.

CONFRONTING DISPARITIES IN HEALTH CARE

It is well established that members of racial and ethnic minority groups in the United States experience a lower quality of health services, including even routine medical procedures, than do white people. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (2002) reviews the extent of such disparities, explores factors that cause them, and suggests policies and practices to ensure that all people receive the same level of care. Among its recommendations, efforts are needed to make health care providers, insurance companies, policy-makers, and members of the public more aware of these disparities; to encourage health care providers and health plans to adopt evidence-based guidelines for making decisions about which procedures to order or pay for; to integrate cross-cultural education into the training of all health professionals; and to recruit and train more minority health professionals. In addition, public education programs should be stepped up to ensure that minority patients know how to access care and participate in treatment decisions.

Guidance for increasing the representation of racial and ethnic minority groups in the health professions is offered in an earlier IOM report. *The Right Thing to Do, The Smart Thing to Do: Enhancing Diversity in the Health Professions* (2001) summarizes the proceedings of a major symposium organized in conjunction with the American Association of Medical Colleges and the Association of Academic Health Centers. The report discusses barriers to recruiting and training underrepresented minority students and proposes steps for overcoming these obstacles. Efforts will be

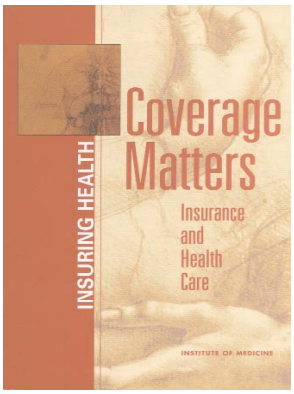


U.S. Population Aged 16–64, Year 2050 (percentages). SOURCE: *The Right Thing to Do, The Smart Thing to Do: Enhancing Diversity in Health Profession: Summary of the Symposium on Diversity in Health Professions in Honor of Herbert W. Nickens, M.D.*, 2001, page 2.

needed at all stages of the academic pipeline, beginning with programs to help minority students perform better in science and mathematics in grade school and high school. Promising students must be encouraged to pursue these fields during undergraduate and professional training, and they must be provided with a variety of tools and support to ensure their success. Educational institutions and health professional organizations can help smooth the academic pathway, especially at the undergraduate level, by training career advisers in the particular needs of minority students and by rewarding faculty for serving as student mentors. Both undergraduate and professional schools also face the challenge of developing admissions policies that address the need for racial and ethnic diversity while keeping in mind recent shifts in legislative and judicial positions regarding affirmative action. New strategies and mechanisms are needed as well for overcoming the financial constraints that too often have prevented underrepresented minority students from pursuing careers in the health professions.

HELPING THE UNINSURED

Over the years, the IOM has issued numerous reports focused on the nation's approach to health insurance coverage. One problem that remains particularly challenging is the large number of people who do not have health insurance. In 2000, the IOM established the Committee on the Consequences of Uninsurance, with support from the Robert Wood Johnson Foundation, to consider what lack of coverage means not only for the more than 40 million people who go without, but also for their families and communities, for health care organizations, and for the larger society. The committee's charge is to critically review and synthesize the extensive but diffuse policy and clinical research literature and to communicate its findings and recommendations to policy-makers and the general public.



The committee has issued five of its six scheduled reports, each rigorously examining different aspects of the problem. The breadth and analytic depth of these reports has helped to expand policy discussions beyond a moral imperative for insurance coverage. Key findings from the reports include the following:

- *Coverage Matters: Insurance and Health Care* (2001) concludes that many more people are regularly or periodically uninsured than widely believed. An estimated one out of seven people goes without coverage for

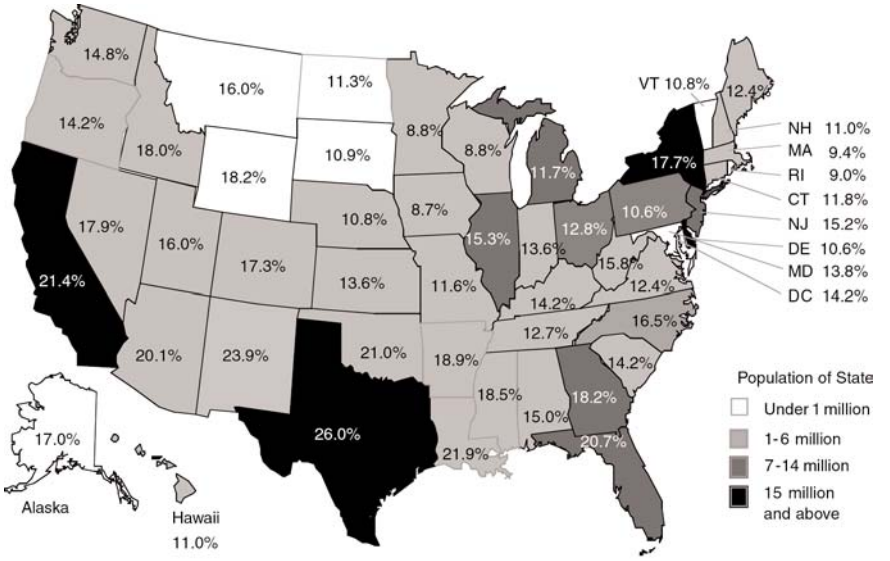
a year or more at some point in life, and many more go without coverage for shorter periods, sometimes on a recurring basis. More than 80 percent of the uninsured live in families in which at least one person works, and roughly 80 percent of the uninsured are U.S. citizens. More than the state of the economy, the rising cost of health care services and insurance premiums, combined with a hodgepodge of government policies, undermines the affordability of health insurance.

- *Care Without Coverage: Too Little, Too Late* (2002) finds that working-age adults who are uninsured tend to be sicker and die earlier than insured adults. The uninsured are significantly less likely to receive needed health care, including preventative services and care for chronic conditions. The health benefits of insurance are strongest when coverage is continuous rather than sporadic, and broad-based strategies to foster coverage across the entire uninsured population are more likely to improve health outcomes than are "rescue" programs aimed primarily at people who already are seriously ill.

- *Health Insurance Is a Family Matter* (2002) concludes that families without health insurance risk not only their health but also their economic viability. Indeed, the physical, emotional, and financial well-being of all members of a family may be adversely affected if any member lacks coverage. In families where someone is uninsured, both parents and children are less likely to get timely health services. Uninsured children receive fewer services, including important preventative services (such as routine checkups) that can have beneficial long-term effects. Most uninsured families do not have sufficient funds to purchase health insurance independently, as the cost of premiums is too high.

An estimated one out of seven people goes without coverage for a year or more at some point in life...

- *A Shared Destiny: Community Effects of Uninsurance* (2003) describes spillover effects that go far beyond any given uninsured person or family. In communities where many people lack coverage or their numbers are rising rapidly, health often suffers among insured people as well as among the uninsured. A variety of factors play a role. Communities that must devote increased public funds to caring for the uninsured often resort to cutting back on other medical services aimed at the general population, including clinic-based primary care, specialty health services, and hospital-based care, particularly emergency medical services and trauma care. Also, since uninsured people generally are more likely to develop communicable diseases (and less likely to be fully vaccinated against such diseases), they may hasten the spread of infections throughout the community.



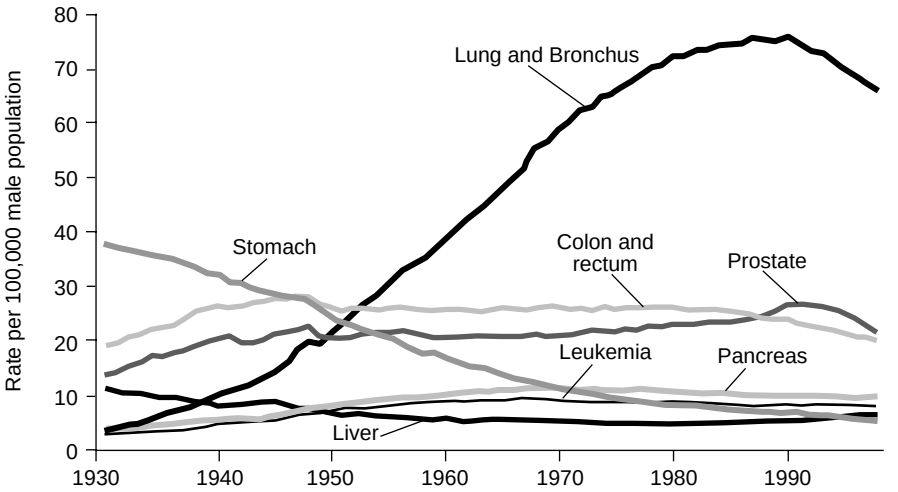
Probability of Being Uninsured for Population Under Age 65, by State, 2001. SOURCE: *A Shared Destiny,* 2003, page 182.

• *Hidden Costs, Value Lost: Uninsurance in America* (2003) describes the economic and social benefits that could be realized if everyone had medical insurance on a continuous basis. The potential value of the improved health outcomes expected to be gained from expanded coverage is estimated to range from $65 billion to $130 billion annually. (The range results from different assumptions about the extent to which disparities in health status would be eliminated by full coverage.) These benefits in "health capital" capture in monetary terms the value of an individual's health over future years of life, including such factors as the subjective value of being alive and healthy, earning potential, and improved physical and mental development. The estimated economic returns are likely to outstrip the cost of providing health insurance to all people who now lack coverage.

The sixth and last report in the series, to be published in January 2004, will help policy-makers and consumers review and assess proposals to expand health care insurance. National discussion of such proposals is expected to gain steam as the 2004 presidential election cycle gets under way. Specifically, the IOM report will offer a set of general principles, supported by research, against which specific proposals can be evaluated.

FOSTERING CANCER PREVENTION

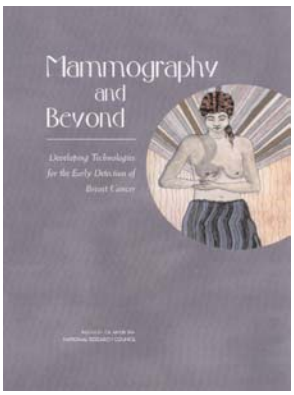
Cancer ranks second only to heart disease as the nation's leading cause of death. Yet many types of cancers can be prevented or at least detected early enough to make effective treatment possible by changing how people behave. *Fulfilling the Potential of Cancer Prevention and Early Detection (2003)* examines the extent to which the burden of cancer can be reduced by promoting behavioral changes and outlines a national strategy to achieve such gains. In order to save the most lives, health care providers, health plans, insurers, employers, policy-makers, and researchers should be concentrating their resources on helping people to stop smoking, maintain a healthy weight and diet, exercise regularly, keep alcohol consumption at low to moderate levels, and get screened for breast, cervical, and colorectal cancer. A 19 percent decline in the rate at which new cancer cases occur and a 29 percent decline in the rate of cancer deaths could be achieved by the year 2015, if efforts to help people change behaviors that put them at risk are stepped up and if those people maintain their new lifestyles. This would equate to the prevention of approximately 100,000 cancer cases and 60,000 cancer deaths each year. These behavioral changes



Age-adjusted Cancer Death Rates,* for Males by Site, U.S. 1930–1997.*Per 100,000, age-adjusted to the 1970 standard population. NOTE: Due to changes in ICD coding, numerator information has changed over time. Rates for cancers of the liver, lung and bronchus, and colon and rectum are affected by these coding changes. Data obtained from U.S. Mortality Public Use Data Tapes 1960–1968, U.S. Mortality Volumes 1930–1959, National Center for Health Statistics, Centers for Disease Control and Prevention, 2000. SOURCE: *Fulfilling the Potential of Cancer Prevention and Early Detection*, 2003, page 19.

may help to alleviate, in particular, the disproportionate burden of cancer borne by members of certain racial and ethnic minority groups. The benefits of promoting such behaviors also may extend beyond cancer to cardiovascular disease and diabetes as well.

Breast cancer strikes more than 180,000 women, and kills more than 40,000 women, in the United States each year. Early detection of invasive tumors currently is the best hope for reducing this disease burden—and X-ray mammography screening is the mainstay for early detection. But this method has its limits, and researchers are pursuing a range of new approaches. *Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer* (2001) identifies promising technologies and explores their merits and drawbacks. Among the technologies are modified versions of conventional mammography that use computer programs to spot suspicious areas, and alternative methods of detection such as magnetic resonance imaging and biochemical testing of breast fluids. The report also details ways to improve the development process. Actions include increasing government support for research on "cancer markers," or biological characteristics associated with breast cancer; ensuring that federal regulations regarding approval of detection devices are consistent and as uncomplicated as possible; and developing more comprehensive and coordinated insurance mechanisms to cover screening tests. To help reduce the toll from breast cancer as improved technologies make their way into general use, there remains a need to reach many more women with screening efforts. The report recommends several steps to optimize the use of proven technologies currently available, such as expanding federal screening programs to include women without insurance, and determining whether there is (or soon will be) a shortage of radiologists trained in breast imaging.



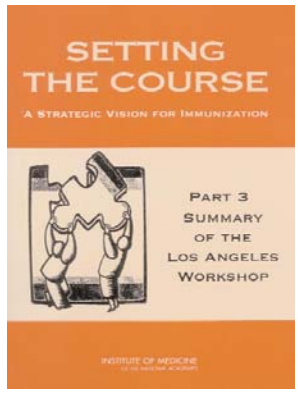
ASSESSING IMMUNIZATION FINANCE

Immunization offers a highly effective means of preventing serious illnesses and deaths in children and adults. But the nation's system for financing immunization services has developed gaps. In 2000, the IOM issued a report that focused attention on the uncertainties and instability of the public health infrastructure that supports immunization programs. *Calling the Shots: Immunization Finance Policies and Practices* proposed sever-

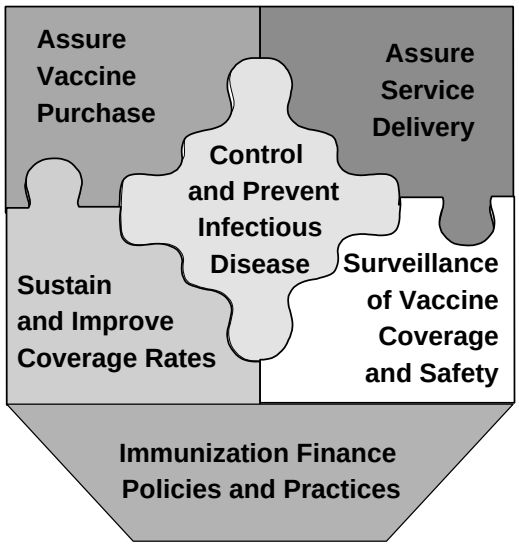
al strategies to address these concerns and to provide an adequate funding level for immunization infrastructure. To help catalyze reforms, the Centers for Disease Control and Prevention asked the IOM to undertake a special effort to foster discussions among the various public and private groups who participate directly or indirectly in the immunization system.

In response, the IOM held a series of four workshops designed to increase awareness of the conclusions and recommendations of *Calling the Shots*; build consensus for initiatives to redesign the infrastructure of the immunization system, measure its performance, and finance its operations; and identify unresolved public health and health finance issues and concerns at the regional, state, and local levels that require further attention from public and private policy-makers. Reports have now been published on each of the workshops. Highlights of the reports, which carry the general title *Setting the Course: A Strategic Vision for Immunization*, include the following:

- *Part 1: Summary of the Chicago Workshop* (2002) emphasizes the need for collaborative strategies to engage the health care, business, and government sectors in identifying opportunities to achieve public health immunization goals. Efforts are needed to encourage private health plans and care providers to assume responsibility for ensuring that large numbers of children and adults receive needed immunizations within the communities they serve. New approaches that use information resources efficiently and reduce reliance on public funding will be required to meet persistent and routine immunization needs.



- *Part 2: Summary of the Austin Workshop* (2002) reinforces the importance of collaboration, consultation, and partnership efforts across levels of government and between the public and private sector. For Texas, in particular, efforts to improve vaccination rates, which are among the lowest in the nation, are hampered by many obstacles, including the state's increasing birth rate and national shortages of some vaccines. Legislative action presents one strategy for moving ahead. For example, the state might change its guidelines to automatically place children on the immunization registry (unless they opt out of participating). Health agencies and professional groups also can establish incentives to encourage more care providers to participate in immunization programs.



Six Roles of the National Immunization System. SOURCE: *Setting the Course: A Strategic Vision for Immunization--Part 3: Summary of the Los Angeles Workshop,* 2003, page 14.

• *Part 3: Summary of the Los Angeles Workshop* (2003) finds that although state and local efforts to aid clinics and care providers have boosted immunization coverage levels to the national average, problems loom on the horizon. California's economic downturn is expected to mean reductions in state and local funding for immunization services, and this dilemma is compounded by the high cost of new vaccines and the increasing cost of older vaccines. The high cost of vaccines also results in serious financial risk for many private providers who depend on reimbursements to cover their vaccine purchases. To address such concerns, it will be necessary to explore public policy tools that can aid in creating incentives for the production and distribution of vaccines. Leadership also is needed within the public health community to ensure that immunization issues remain visible and receive adequate attention.

• *Part 4: Summary of the Washington, D.C., Workshop* (2003) describes strategies to preserve and support traditional public health efforts (such as outreach, education, and monitoring and surveillance) while also meeting new demands associated with delivering a higher proportion of vaccines in the private health sector. The shift in immunization service settings has created new stresses and tensions over the appropriate roles of public health departments and the manner in which those roles should be financed. One particular difficulty facing the public health system is maintaining vigilance even when visible signs of infectious disease outbreaks

are not apparent. Developing a plan to determine how the costs of immunizations efforts should be allocated across the federal, state, and private health agencies also remains a significant challenge.

The IOM also has examined problems in how vaccines are purchased and distributed in the health care system. Vaccine manufacture is not profitable for pharmaceutical companies when compared to drugs with broad markets, such as the class of statins that prevent heart disease. At the same time, new vaccines are expensive, and much of the burden for their purchase falls on governments at the federal and state level. *Financing Vaccines in the 21st Century: Assuring Access and Availability* (2003) calls for fundamental changes to the system used by the government to buy and distribute vaccines. The principle recommendation is that current government programs for purchasing vaccines be replaced with a new government-funded insurance mandate and voucher plan for vaccines that are approved by the Advisory Committee on Immunization Practices (ACIP), which is the body that recommends vaccines. The mandate would require all public and private health plans to include vaccine benefits, coupled with vouchers for uninsured children and adults. The role of the federal government would be to reimburse plans and health care providers for the costs of their vaccine purchases. The report also recommends changes in the composition of the ACIP and in the procedures it uses for making decisions about vaccines, in order to better define its mission.

UPCOMING REPORTS

Improving Quality of Care. *To Err Is Human: Building a Safer Health System,* an IOM study issued in 2000, established that protecting patients from accidental injury during medical treatment is a critical first step in improving quality of care. Among its recommendations, the report called for developing improved systems for reporting patient safety data. At the request of the Department of Health and Human Services, the IOM is conducting a study to develop a detailed plan to facilitate the generation of standards for the collection, coding, and classification of data on patient safety. It is expected that the standards will maximize the usefulness of information derived from the data collected, and in particular will enable comparisons to be made across reporting systems and over time.

Another study is under way to identify key aspects of the work environment for nurses (in both acute and long-term care delivery settings) that are likely to have an impact on patient safety. Efforts in recent years to

reduce costs and streamline the delivery of health care have led to significant changes in the workplace. In other industries, such significant changes often have been accompanied by increased safety problems, but few studies have addressed this issue in health care settings. Topics to be covered in the study include the nature of the work performed by nurses and nursing assistants, including such factors as workload and working hours; the effects of pressures to work quickly with numerous interruptions; the effects of having to work with poorly designed processes or processes that are not standardized; and the impact of social, physical, and other barriers to effective communications among the care team. The study report will propose changes in nurses' working conditions that potentially can enhance patient safety.

U.S. consumers are increasingly using complementary and alternative medicines (CAMs), rather than relying solely on conventional therapies. With this increased use comes the need for scientific investigation to determine how widely CAMs are being used and whether they are effective and safe. The IOM is conducting such a study. The objectives are to determine which CAMs are in widespread use and what populations are using them; to critically assess the risks and benefits of CAMs; and to describe policy implications arising from CAM use that may affect the continuing evolution of the practice of medicine and the education of physicians, allied health professionals, and practitioners of CAM therapies. The findings are expected to be useful to a variety or audiences, including government regulatory agencies and policy-makers, heath care organizations and care providers, researchers, pharmaceutical companies, and members of the general public.

Cancer Detection and Treatment. There are approximately 9 million people in the United States who are cancer survivors but relatively little is known about their medical care experiences following their initial treatment or about the psychological and social adjustments that they must make. While the spectrum of care for survivors may span primary care, psychosocial assessment and care, rehabilitative services, and palliative care, there is no clear consensus on who should provide services, what services are clinically appropriate, and whether the cancer "system" is functioning to provide coordinated services. The IOM is conducting a study to provide answers. It will result in separate reports focused on survivors of childhood cancers and on adult survivors, and each report will offer recommendations for improving the quality of care and the quality of life for their target groups. A third report will focus on policies to improve psychosocial interventions for women with breast cancer.

A variety of new technologies including devices, software programs, and drugs hold promise for detecting breast cancer at an early stage when it is most treatable. But the pathway for taking a promising technology to the clinic, where it can be used to help patients, is fraught with hurdles. The IOM is conducting a study to determine which of the existing and evolving approaches hold the greatest promise for improving the early detection and diagnosis of breast cancer, and to identify technological, financial, and regulatory obstacles that are limiting their further development. Strategies will be identified to accelerate the flow of targeted new approaches into clinical practice.

Financing and Delivery of HIV Care. The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act provides medical treatment and support services for uninsured or underinsured people living with HIV disease. When the act was reauthorized in 2000, Congress directed the IOM to study various aspects of its operation, particularly in the areas of data gathering and evaluation. Among issues being addressed, the study will determine whether the HIV surveillance system of each state reports HIV cases in a manner that provides adequate information on the number of such cases and their demographic characteristics. Also being examined is the availability and utility of health outcomes measures for HIV primary care and support services, and the extent to which that information can be used to measure the quality of funded services. This information, along with other study findings, will be useful in planning programs and allocating resources at local and national levels.

In reauthorizing the Ryan White Care Act, Congress also directed the IOM to study more broadly the public financing and delivery of HIV services. As the HIV/AIDS epidemic has grown, there has been a substantial increase in the number and size of public programs that provide care for people living with HIV, but the current system of public funding still results in inequities in access to care. The study will address such issues as the financing and health delivery challenges posed to HIV health centers at the local, state, and national levels; methods for reducing the barriers that people sometimes face in obtaining quality HIV health services; and the role of the private insurance industry is assuring appropriate access to HIV care and treatment throughout the entire course of HIV disease. The study report will propose a policy framework and recommendations that will improve the continuity, equity, and efficiency of the systems that provide HIV care.

Selected Recommendations for Human Security and Bioterrorism

The Role of Technology in Countering Terrorism: Ensure production and distribution of known treatments and preventatives for pathogens. Develop effective treatments and preventive measures for known pathogens for which current responses are unavailable and for potential emerging pathogens. Deploy known technologies and standards for allowing emergency responders to reliably communicate with each other. Develop new and better technologies (e.g., protective gear, sensors, and communications) for emergency responders. Ensure that trusted spokespersons will be able to inform the public promptly and with technical authority whenever the technical aspects of an emergency are dominant in the public's concerns. (*Making the Nation Safer: The Role of Science and Technology in Countering Terrorism,* 2002)

Focus on Vaccines: IOM recommends that better ways to administer vaccines should be developed. Also, the Department of Defense should strengthen systems for detecting health problems that might occur months or years after the receipt of any vaccine, including the anthrax vaccine. Future monitoring of adverse health effects should continue to include separate analyses of data for men and women. And finally, the Department of Defense should speed up its research to develop an improved vaccine. (*The Anthrax Vaccine: Is It Safe? Does It Work?,* 2002)

Reducing the Psychological Consequences of Terrorism: The Department of Health and Human Services should develop evidence-based techniques, training, and education in psychological first aid to address all hazards and all members of society before, during, and after a terrorism event in order to limit the psychological consequences of terrorism. DHHS should also develop public health surveillance for pre- and post-event factors relevant to addressing the psychological consequences of terrorism and develop methods of applying the findings through appropriate interventions for groups of special interest. Academic health centers, professional associations and societies for mental health professionals, and state boards of education should ensure the education and training of mental health care providers, including community- and school-based mental health care providers to respond to the psychological aftermath of terrorism, and should ensure the education and training of relevant health professionals. DHHS and the Department of Homeland Security should analyze federal, state, and local preparedness for terrorism to ensure that the nation's public health infrastructure is prepared to adequately respond to psychological consequences. (*Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy,* 2003)

HUMAN SECURITY AND BIOTERRORISM

Our society is too complex and interconnected to defend against all possible threats. As some threats are diminished, others may arise; terrorists may change their goals and tactics.... For that reason, strengthening the national effort in long-term research that can create new solutions should be a cornerstone of the strategy for countering terrorism.—Making the Nation Safer: The Role of Science and Technology in Countering Terrorism, 2002

The September 11, 2001 terrorist attacks on the United States, along with the subsequent deliberate spread of potent forms of anthrax bacteria through the U.S. mail, have mobilized diverse local and national responses to prevent, detect, and defend against acts of terrorism. Since the founding of the National Academy of Sciences in 1863, the importance of mobilizing science, medicine, and engineering in defense of the nation has been a central purpose of the component scientific elements now collectively known as the National Academies. Indeed, the National Academies' ability to create, maintain, and draw from a reservoir of scientific, medical, and technological knowledge has underpinned many of the nation's security strategies.

...mobilizing science, medicine, and engineering in defense of the nation has been a central purpose of the component scientific elements now collectively known as The National Academies.

COUNTERING TERRORISM

The Institute of Medicine has conducted or participated in a number of studies focused on better understanding the threats of terrorism and identifying ways to prevent terrorist attacks or reduce their consequences.

In 1998, the IOM released *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, a report that assessed the state of the art for detecting potential chemical and biological agents and for protecting both the targets of attack and the health care providers who will be vital in responding to such attacks. The report identified 61 specific Research & Development (R&D) needs in the following areas: pre-incident intelligence; detection and identification of chemical and biological agents in the environment and in clinical samples from victims; personal protective equipment; recognizing covert exposures of a population; mass-casualty decontamination and triage procedures; availability, safety, and efficacy of drugs, vaccines, and other therapeutics; prevention and treatment of psychological effects, and computer related tools for training and operations.

Following the events of September 11, the National Academies initiated a project drawing on the experience of more than 100 distinguished experts from a variety of fields to help the federal government meet the complex new challenges posed by terrorism. *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* (2002) outlines a national strategy by which the strengths of U.S. science, medicine, and engineering can be enlisted on a continuing basis to assist the nation in anticipating, preventing, and responding to terrorism. Issued by the National Research Council, the report identifies numerous key actions that can be taken now, based on knowledge and technologies in hand, and describes opportunities for reducing current and future risks through longer-term research and development activities. Its recommendations cover such areas as nuclear and radiological threats, toxic chemicals and explosive materials, human and agricultural health systems, energy and transportation systems, information technology, and helping people respond appropriately to threats or occurrences of terrorism. Priorities in medicine include

***Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* (2002)...describes opportunities for reducing current and future risks through longer-term research and development activities.**

Groups That Can Help Respond to a Terrorist Attack Using a Chemical Agent

Many (if not most) cities and many industries have HAZMAT teams trained and equipped to deal with accidental spills and releases of toxic industrial chemicals. They have not been trained or equipped to deal with terrorist incidents, but chemical weapons of the types that would most plausibly be used by terrorists are not fundamentally different from the chemicals that these teams already address.

Among the first responders to chemical terrorism, fire departments can be a major resource. All fire departments have personnel who are trained and equipped to work with respirators and protective gear (as hazardous vapors are always a part of fires), and they are of course trained to deal with emergencies. The police are not routinely equipped to respond to chemical incidents *per se* (although they play an essential role in maintaining order). Equipping police units with protective gear is, however, a practical way of expanding the number of individuals who can actively participate in the response to a chemical incident.

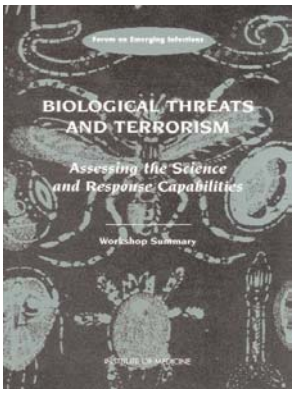
Weapons of Mass Destruction Civil Support Teams from the Department of Defense are deployed around the country. These groups have a limited but possibly useful capability to coordinate communications among responders and to carry out chemical and biological analyses.

Another substantial capability in place is the military, including active-duty, reserve, and National Guard personnel. The military has trained and equipped for chemical warfare during the past 50 years. It maintains large supplies of relevant equipment-protective suits, prophylactics, and medical countermeasures against nerve and blister agents. These assets are geared, however, to wars on foreign battlefields. An important issue is to understand how to use this capability in time of need inside the continental United States. As of April 2002, 27 teams had been deployed, with five more authorized and in the planning stage.

SOURCE: *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism,* 2002, page 128.

expanded research efforts to produce new vaccines and other therapeutics that target bioterrorist agents, and new tools for surveillance of infectious agents in the environment for identification of pathogens and for rapid and accurate diagnoses of diseases linked to bioterrorist agents. The nation's public health system, weakened by years of underinvestment, must be revitalized and given "surge capacity" to manage the masses of people who may be exposed to pathogens or other hazardous substances during a terrorist attack.

The anthrax attacks of 2001 moved bioterrorism from hypothetical to real. Bioterrorism is now a priority for policy-makers, researchers, public health officials, and members of private industry, although these communities continue to struggle with finding affordable and effective protective measures. *Biological Threats and Terrorism: Assessing the Science and Response Capabilities: A Workshop Summary* (2002) reviews current knowledge about potential bioterrorist agents, including anthrax and smallpox, and presents a discussion of the steps needed to strengthen response capacity. Issued for the IOM's Forum on Emerging Infections, the workshop summary presents participants' arguments that bioterrorism is an urgent national security issue for which policy-makers and the public must develop and maintain a coordinated set of response initiatives. Specific priorities fall into three areas: developing vaccines and therapeutics that act against bioterrorist agents; implementing a research agenda that reflects current and emerging understanding of bioterrorism threats; and strengthening the public-health infrastructure in order to ensure effective response to an attack. Changes in the public health system should include improving communication and information programs; expanding laboratory capacity at local, state, and federal levels; enhancing surveillance systems for detecting suspicious outbreaks of disease; and strengtheing local agencies that likely will serve as the first line of defense against bioterrorist attack. To strengthen response capabilities most efficiently, many workshop participants called for expanding partnerships within and among government, industry, academia, the health care system, and the intelligence community. The United States also should enlist the aid of other countries and international organizations in improving bioterrorism response preparedness globally.



Since 1997, as part of the federal government's efforts to combat terrorism, the Office of Emergency Preparedness (OEP) has provided funds to the nation's most heavily populated cities to help them develop plans for coping with the health and medical consequences of a catastrophic terrorist attack with chemical, biological, or radiological agents. More than 120 cities have now received funding through the Metropolitan Medical Response System (MMRS) program. For assistance in judging the program's effectiveness, the OEP turned to the Institute of Medicine. *Preparing for Terrorism: Tools for Evaluating the Metropolitan Medical Response System Program* (2002) provides a detailed guide for assessing both the level of preparedness of cities that have participated in the program and how well its officials have managed the program. Among its proposed tools, the report lists 23 essential capabilities that any community must have in order to be able to respond effectively to the wide variety of terrorism attacks that it may suffer. How well each city has developed those capabilities can be measured through a three-part process that includes a site visit by a team of expert peers, observation of exercises and drills within the community, and periodic review of documents and records. Since the threats of terrorism are continually changing, the evaluation of preparedness also must be a continual process rather than a one-time event or even a series of events spaced at long time intervals.

Timeline for Production of AVA

Activity	Week
Initiate sublot production	1
Formulate bulk lot	7
Fill into vials	9
Complete testing	15
Submit release protocol to FDA	17
Release for distribution by FDA	22

SOURCE: *The Anthrax Vaccine: Is It Safe? Does It Work?* 2002, page 189.

PREPARING FOR BIOLOGICAL AND CHEMICAL TERRORISM

Anthrax Vaccine

Anthrax is an attractive biological weapon, and its deadly capability has prompted the U.S. Department of Defense to launch a mandatory vaccination program for military personnel. But concerns have been raised about the vaccine's efficacy and safety. *The Anthrax Vaccine: Is It Safe? Does It Work?* (2002) concludes that AVA is indeed both effective and safe. It, however, does have certain drawbacks, including a six-dose vaccination schedule over 18 months that underscores the need for a better vaccine. Although the current vaccine can still be used, the government should vigorously support research to improve administration of the current vaccine and to develop a better alternative. The Centers for Disease Control and Prevention requested an IOM review of its anthrax vaccine research program. *An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program* (2002) found that CDC had provided a generally complete and appropriate response to the charge from Congress, but noted that additional research needs had become evident following the bioterrorist events of 2001 and made recommendations about the leadership of the overall program.

Smallpox Vaccine

Public and scientific concern about smallpox as a bioweapon also emerged after September 11. How best to respond continues to be a matter of national debate. Following the President's decision to immunize 500,000 first responders, the CDC was charged with implementation of the program. The smallpox vaccine (vaccinia virus) is highly effective in preventing the disease, but its use is not without risk. Recognizing the usefulness of independent scientific advice, CDC requested IOM assistance in evaluating issues that might arise as the vaccination program unfolded. A standing committee was established to provide continuing assessment and advice. Three letter reports, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation: Letter Report #1* (2003), *Letter Report #2* (2003) and *Letter Report #3* (2003), have been issued. The second report offers updated recommendations that reflect changes made by the government to the program and the third report reaffirms the need for a pause in the smallpox vaccination program. The program originally called for phased-in vaccina-

The smallpox vaccine (vaccinia virus) is highly effective in preventing the disease, but its use is not without risk.

tion, beginning with health workers who would form volunteer teams during a bioterrorist attack. A second wave of vaccinations was to include other health workers and traditional "first responders," such as police and firefighters. Under the revised plan, states could begin vaccinating all health workers and first responders before completing the first phase. The report urges the CDC to make every effort to evaluate the program continuously, in order to improve its implementation and protect both the people who are vaccinated and the public.

Chemical Warfare Agents

The possible exposures that U.S. troops may have suffered to the chemical warfare agent sarin during the 1991 Gulf War, as well as the experience of civilian exposures to the nerve gas in Japan during the mid-1990s, has generated considerable interest in the possible long-term health effects of exposure to this compound or similar compounds. To address this issue, the IOM's Medical Follow-up Agency conducted a study of more than 4,000 military volunteers who had been exposed to sarin and other anticholinesterse chemical warfare agents during experiments run by the U.S. Army from 1955 to 1975 at Edgewood Arsenal, Maryland. A report on the study, *Long-Term Health Effects of Exposure to Sarin and Other Anticholinesterase Chemical Warfare Agents* (published in the March 2003 issue of the journal *Military Medicine*), concluded that there were few differences in health between the volunteers and men in control groups who had not participated in the military tests. These findings are similar to the results of a 1985 study, in which the same group of volunteers reported few health problems related to their test experience. Immediately after the end of the 1991 Gulf War, demolitions carried out at the Khamisiyah ammunition depot resulted in possible exposure of troops to sarin and cyclosarin. Discovery of this potential exposure led the Department of Defense to undertake efforts to notify military personnel of potential exposure. An upcoming report will look at the health effects of this potential exposure among deployed Army personnel. Separate analyses will examine the health effects of potential exposure to sarin on morbidity and on mortality, as well as the effects of the DoD's notification program on morbidity. Publication of these findings is expected in late 2003.

...Congress directed the Secretary of Defense to contract with the Institute of Medicine...for a study of the review and approval process for new medical countermeasures in order to identify new approaches to accelerate that process and to identify methods for assuring that new countermeasures will be safe and effective.

Strategies for Preparing for and Responding to the Psychological Consequences of Terrorism Summary of Recommendations

Preventive Measures

- *Recommendation 2-1:* HHS, including NIH, SAMHSA, and CDC, should develop evidence-based techniques, training, and education in psychological first aid.
- *Recommendation 2-2:* HHS, including NIH, SAMHSA, and CDC, should develop public health surveillance for pre-event, event, and post-event factors related to the psychological consequences of terrorism.

Education and Training for Providers

- *Recommendation 3-1:* Academic healthcare centers, professional associations and societies for mental health professionals, and state boards of education, in collaboration with HHS, including SAMHSA, NIH, and CDC, should ensure the education and training of mental health care providers on responding to the psychological consequences of terrorism.
- *Recommendation 3-2:* Academic centers and professional associations and societies, in collaboration with HHS, including SAMHSA, NIH, and CDC, should ensure the education and training of relevant professionals in health fields in the psychological consequences of terrorism.
- *Recommendation 3-3:* SAMHSA, in collaboration with academic centers and state and local health care agencies, should ensure the provision of education and training in the psychological consequences of terrorism for a range of relevant community leaders and ancillary providers.

Workplace Preparedness

- *Recommendation 3-4:* NIOSH, the Department of Labor, and the Department of Education should ensure appropriate guidelines to protect people in a variety of work environments including response sectors, food production and distribution, and schools.

Research Needs

- *Recommendation 3-5:* Federal agencies should coordinate research agendas, cooperate in funding, and award timely and sufficient funding.

Ensuring Preparedness Through a Comprehensive Public Health Strategy

- *Recommendation 4-1:* DHHS and the Department of Homeland Security should analyze terrorism preparedness to ensure that the public health infrastructure is prepared to respond to the psychological consequences of terrorism.
- *Recommendation 4-2:* Federal, state, and local disaster planners should address psychological consequences in their planning and preparedness for terrorist attacks.

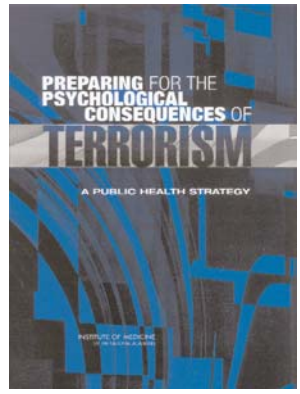
SOURCE: *Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy,* 2003, page 18.

Biological Warfare Agents

Currently, the United States has a limited repertoire of licensed medical countermeasures that the Department of Defense can use to protect members of the armed forces against more than a dozen bacteria, viruses, and toxins identified as possible biological warfare agents. As part of its Chemical and Biological Defense Program, DoD is engaged in research and development efforts aimed at making available a broader range of medical countermeasures. In the National Defense Authorization Act for Fiscal Year 2002, Congress directed the Secretary of Defense to contract with the Institute of Medicine and the National Research Council for a study of the review and approval process for new medical countermeasures in order to identify new approaches to accelerate that process and to identify methods for assuring that new countermeasures will be safe and effective. The Institute of Medicine/National Research Council Committee on Accelerating the Research, Development, and Acquisition of Medical Countermeasures against Biological Warfare Agents has released an interim report that provides information on study progress, but does not contain findings and recommendations. The committee will issue a final report by the end of 2003.

PSYCHOLOGICAL CONSEQUENCES OF TERRORISM

The Oklahoma City bombing, intentional crashing of airliners on September 11, 2001, anthrax attacks in the fall of 2001, and continued threats of terrorism have raised questions about the psychological impact of these terrorism events on the nation and how prepared the public health infrastructure is to mitigate effects of this type. In the report *Preparing for the Psychological Consequences of Terrorism: A Public Health Strategy* (2003), an IOM committee highlights some of the critical issues and possible interventions for responding to the psychological needs that result from terrorism and provides possible options for intervention. Psychological consequences include an array of emotional, behavioral, and cognitive reactions ranging from insomnia, fear, anxiety, or vulnerability to increased alcohol consumption or smoking. A minority of people will develop psychiatric illnesses such as posttraumatic stress disorder. The nation's mental health, public health, medical, and emergency response systems currently are not able to meet the psychological needs that result from terrorism. Gaps exist in the coor-



dination of agencies and services, training and supervision of professionals, public communication and dissemination of information, financing, and knowledge- and evidence-based services. The committee offers an example for a public health strategy from which plans to prevent and respond to the psychological consequences of terrorism events can be formulated. The report includes recommendations for preventive measures, training and education of service providers, workplace preparedness, research needs, and ensuring preparedness through a comprehensive public health strategy.

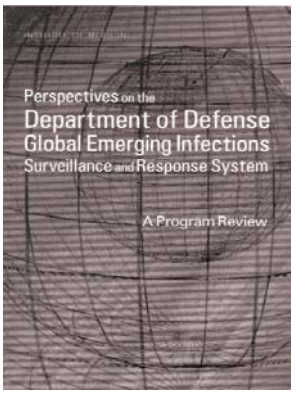
AN INTEGRATED APPROACH: REDUCING THE SPECTRUM OF INFECTIOUS DISEASE THREATS

Potential bioterrorism events must be seen in the context of an ever-increasing frequency of naturally occurring infectious disease events. The global dimensions of the Severe Acute Respiratory Syndrome or SARS outbreak in 2002-2003 are just one illustration of how even naturally occurring outbreaks can have major local, regional, and global impacts. These consequences include not only effects on physical health, but also commerce, travel, civil liberties, education, security, and mental health. Whether arising as a criminal act or as a result of ever more complex and dynamic inter-relationships between environmental factors, human behaviors and vulnerabilities, and biologic agents, the key defense to natural and intentional outbreaks is an integrated, broadly capable global public health network. The 2003 IOM report, *Microbial Threats to Health: Emergence, Detection, and Response*, highlighted the value of such an integrated public health network which, if implemented more widely, should help recognize and contain disease emergences before they produce global consequences.

Whether arising as a criminal act or as a result of ever more complex and dynamic inter-relationships between environmental factors, human behaviors and vulnerabilities, and biologic agents, the key defense to natural and intentional outbreaks is an integrated, broadly capable global public health network.

Concerned that U.S. citizens were not being adequately protected from emerging infectious diseases, the President called on the Department of

Defense in 1997 to contribute to the integrated international surveillance and response effort through the establishment of the Global Emerging Infections Surveillance and Response System. At the request of the system's managers, the IOM has evaluated the system's structure and progress. *Perspectives on the Department of Defense Global Emerging Infections Surveillance and Response System* (2001) concludes that it is well organized and comprises an appropriate response to the threat posed to national security by emerging infectious diseases. The report recommended some refinements to the system and called for the government to increase financial support to help ensure its long-term success.



Selected Recommendations for Military and Veterans

The Role of Vaccine Acquisition and Availability in the Military: The Department of Defense (DoD) should combine all vaccine acquisition responsibilities under a single DoD authority and consolidate infrastructure, funding, and personnel for acquisition programs for biodefense and naturally occurring infectious disease vaccines. DoD should also work toward arrangements with manufacturers that ensure consistent vaccine availability by addressing long term commitment, predictable volumes and prices, indemnification, and intellectual property issues; and should also seek a new approach to the regulation of certain special-use vaccines that remain in Investigational New Drug status at FDA. (*Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military,* 2002)

Focus on Gulf War Veterans: The Department of Veterans Affairs (VA) should provide specific training to health care providers caring for Gulf War veterans to ensure that they are skilled in patient-centered care, and the VA should further ensure that such providers are allowed sufficient time with each patient in order to provide patient-centered care.

In conducting treatment research, the VA should use a hierarchy of evidence structure that includes effectiveness studies as well as efficacy studies for any future treatment guidelines it develops for symptoms or illnesses of Gulf War veterans. Current VA and Department of Defense Gulf War registries should be used as one way to identify patient samples and serve as a sampling frame for future treatment effectiveness studies. (*Gulf War Veterans: Treating Symptoms and Syndromes,* 2001)

MILITARY PERSONNEL AND VETERANS

Information gained from the numerous studies of veterans of specific conflicts has given rise to broader questions regarding the consequences of service in any major military engagement. Concern now is being focused on questions of war-related illnesses and postdeployment health issues...

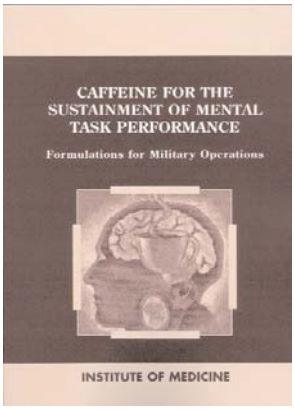
PROMOTING HEALTH AND IMPROVING PERFORMANCE

Infectious diseases pose a substantial threat to the nation's military forces. Troops both at home and abroad face risk from exposure to natural pathogens or, as recent events have graphically demonstrated, from the intentional use of weaponized infectious agents. Vaccines often are the best way to provide protection against such infections. The U.S. Army Medical Research and Materiel Command asked the IOM to review the process by which the Department of Defense acquires vaccines and maintains their availability. *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military* (2002) concludes that the DoD's acquisition process is overly complex, fragmented, and thwarts effective coordination with the vaccine industry. Problems exist at all stages, from identifying disease risks through laboratory research, product development, clinical trials, vaccine licensure, and ensuring that manufacturers comply with regulatory requirements. Indeed, poorly aligned acquisition processes and an inade-

Troops both at home and abroad face risk from exposure to natural pathogens or...from the intentional use of weaponized infectious agents.

quate commitment of financial resources rather than uncleared scientific or technological hurdles contribute to the unavailability of some vaccines. The report outlines a number of ways by which the DoD can strengthen the process, beginning with combining all vaccine acquisition responsibilities under a single authority and providing funding commensurate with the task. Other recommendations include adopting program goals that ensure greater strength and continuity in the science and technology base across the full spectrum of infectious disease threats, and developing manufacturing arrangements that ensure consistent vaccine availability by addressing such issues as long-term commitment, predictable volumes and prices, indemnification, and intellectual property rights.

Military personnel must often be alert for extended periods. Providing the opportunity for adequate sleep would be ideal, but is often impractical. Both scientific research and everyday experience have demonstrated that caffeine can increase alertness measurably. The U.S. Army asked the IOM to assess whether and how caffeine can be used to help alleviate the various impairments that sleep deprivation can produce in military situations. *Caffeine for the Sustainment of Mental Task Performance: Formulations for Military Operations* (2001) concludes that caffeine in amounts of 100 to 600 milligrams per day can effectively maintain cognitive performance in such areas as reaction speed and visual and auditory vigilance. (For comparison, a five-ounce cup of coffee contains roughly 100 mg of caffeine.) A similar amount, 200 to 600 mg per day, can enhance physical endurance in a variety of activities and may be especially useful in restoring decreases in performance that occur at high altitudes. Moreover, sustained use of caffeine at these levels does not appear to pose any serious acute or chronic health risks. The best way to give caffeine to military personnel would be via a delivery system such as caffeinated chewing gum or caffeine-supplemented food bars that provides it in 100-milligram increments. Total dosage should not exceed 600 mg per day. The report also recommends that the military conduct further research on the drug modafinil, which may be even more effective than caffeine while lacking some of its less desirable traits, such as appetite suppression.



During warfare, troops can be exposed to a variety of infectious agents, toxic chemicals, and other conditions that can cause disease, both

immediately and over the longer term. The IOM's Medical Follow-up Agency, established shortly after World War II, monitors the health and well-being of military personnel following their terms of service. In its early years, the program consisted predominantly of clinical follow-up studies in which veterans were examined for after-effects of injuries and diseases. The program now conducts a variety of epidemiological research studies, collaborates with researchers from diverse backgrounds to obtain and analyze records data, and manages traditional deliberative studies using panels of expert volunteers. One ongoing project is the *Medical Follow-up Agency Cohort Catalog*. The catalog describes a collection of study populations of former military personnel, with the cohorts being assembled as part of completed or proposed research projects dating to the 1940s. A dynamic work in progress, the catalog currently contains summary information on 48 different populations. These cohorts, as compiled, do not exist anywhere else. The cohorts range in size from small, such as a group of 1,500 soldiers who fought in the Korean War and developed hemorrhagic fever, to large, such as a group with all individuals admitted to military hospitals during World War II. The catalog was developed to make outside researchers and organizations aware of the wealth of data resources available and ultimately to stimulate them to conduct collaborative research with the agency.

[T]he *Medical Follow-up Agency Cohort Catalog* ...describes a collection of study populations of former military personnel, with the cohorts being assembled as part of completed or proposed research projects dating to the 1940s.

IOM's Medical Follow-up Agency also conducts a program that addresses health-related questions ranging far beyond the specific effects of participating in warfare. For more than a century, studies of human twins have provided a unique way to gauge the relative effects of genetics and environment on health. With this in mind, the agency in 1958 began developing what has come to be called the National Academy of Sciences-National Research Council WWII Veteran Twin Registry. The registry includes detailed information on nearly 16,000 sets of twins who had jointly entered military service during World War II. The fact that members of the registry are veterans is not, *per se*, a material factor in their health, but their status does provide a number of practical advantages for researchers. Indeed, the registry represents one of the most valuable longitudinal cohorts of aging men available. Over the years, researchers have published more than 200 journal articles that drew on data from the registry. The variety of these studies illustrates the registry's wide-ranging usefulness,

with the topics addressed including heart disease, Alzheimer's disease, schizophrenia, alcoholism and tobacco-related diseases, suicide, and declines in cognitive functioning. The registry operates under a set of principles designed to maintain its value as a resource for research as well as to protect the twins' privacy against unwarranted intrusion.

The U.S. military currently has only a limited number of licensed medical countermeasures to use in protecting service personnel against more than a dozen different bacteria, viruses, and toxins that have been identified as possible biological warfare agents. The Department of Defense, as part of its Chemical and Biological Defense Program, is conducting a broad research and development program aimed at adding new drugs, vaccines, antitoxins, and other protective agents to this repertoire. At the request of Congress, the IOM currently is reviewing these efforts. *Accelerating the Research, Development, and Acquisition of Medical Countermeasures Against Biological Warfare Agents: Interim Report* (2003) provides a description of the study's approach. The final report, slated for publication in late 2003, will identify obstacles to the development and licensure of new products and make recommendations for how the acquisition processes can be accelerated while ensuring that new countermeasures will be effective and safe.

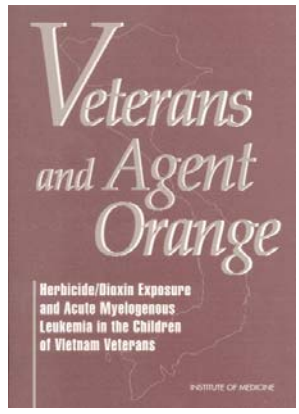
The U.S. military currently has only a limited number of licensed medical countermeasures to use in protecting service personnel against more than a dozen different bacteria, viruses, and toxins...

VETERANS AND AGENT ORANGE

From 1962 to 1971, U.S. forces sprayed several types of herbicides over Vietnam in order to achieve several military goals. One of the main chemical mixtures sprayed was called Agent Orange. Following the war, many veterans and their families began to attribute varied chronic and life-threatening diseases to exposure to the chemicals in Agent Orange (including dioxin, a toxic contaminant found in the mixture), and in 1991 Congress directed the IOM to study the issue. The IOM's report, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (1994) provided the first comprehensive, unbiased review of the scientific evidence regarding a link between such exposure and various adverse health effects, including cancer, reproductive and developmental problems, and neurobehavioral disorders. Since then, the IOM has published a series of biennial updates to the 1994 report, as well as several focused reports examining specific issues related to herbicide exposure:

• *Veterans and Agent Orange: Update 2000*. This report reaffirms most of the findings of the initial report and the first two updates. In one exception, it concludes that there is "limited or suggestive" evidence of an association between exposure and an increased risk of acute myelogenous leukemia (AML) in the children of veterans. AML is a cancer of the bone marrow cells that produce several forms of blood cells. Previous reports had found that the evidence was "inadequate or insufficient" to determine whether a link existed between herbicide exposure and AML or other cancers in veterans' children. The update also concludes that there is limited or suggestive evidence of an association with type 2 (adult onset) diabetes. This link was not found in previous updates, although an IOM report focused on diabetes and issued in 2000 had suggested such a connection.

• *Veterans and Agent Orange: Herbicide/Dioxin Exposure and Acute Myelogenous Leukemia in the Children of Vietnam Veterans (2002)* Upon examining all available evidence regarding a potential link between exposure and AML, this report downgrades the level of risk that was expressed in the 2000 update on Agent Orange. The update founded its conclusion, in part, on the suggestive results of a study by the Australian Institute of Health and Welfare but that study was later found to contain a miscalculation that led to an incorrect assessment of risk. There also is new evidence from German and Norwegian studies of AML in the offspring of parents who had been exposed on their jobs to pesticides that are chemically similar to the herbicides used in Vietnam, with neither study finding a significantly increased level of risk. The report concludes that current evidence is inadequate or insufficient to determine whether there is an association between veterans' herbicide exposure and AML in their children.



• *Veterans and Agent Orange: Update 2002*. Beyond affirming previous reports, this update finds sufficient evidence to conclude that there is an association between exposure and an increased risk of developing chronic lymphocytic leukemia. This is a specific form of leukemia that shares many traits with Hodgkin's disease and non-Hodgkin's lymphoma, both of which are known to be positively associated with herbicide exposure. Previous updates had considered all forms of leukemia collectively, and had found the combined evidence to be inadequate or insufficient to support a generalized association with herbicide exposure. For this update, however, the Department of Veterans Affairs (VA) asked the IOM to consider chronic lymphocytic leukemia on its

own. Regarding other forms of leukemia, the available evidence remains inadequate or insufficient to establish whether there is an association with herbicide exposure. The report makes recommendations for research to resolve this and other continuing scientific uncertainties about the health effects of the herbicides used in Vietnam.

• *Characterizing Exposure of Veterans to Agent Orange and Other Herbicides Used in Vietnam: Interim Findings and Recommendations (2003)*. In studying the effects of herbicides on the health of veterans, a major problem has always been the lack of detailed information on the actual exposures of individual veterans. The IOM's initial report on Agent Orange offered a number of recommendations for how to obtain better data, and the Department of Veterans Affairs asked the IOM to oversee the development and evaluation of improved exposure models. In 1998, an independent group of researchers was commissioned to develop and test models of herbicide exposure. This report reviews the progress to date, concluding that the draft model is a valid means of assessing the wartime exposure of veterans to herbicides. When completed, this modeling system and the expanded database that it should produce, increases the potential values of research into the health effects of the herbicides sprayed in Vietnam. Toward this end, the report recommends that the VA and other government agencies facilitate additional epidemiological studies of veterans by nongovernmental organizations and independent researchers.

Regarding other forms of leukemia, the available evidence remains inadequate or insufficient to establish whether there is an association with herbicide exposure.

The next update in the *Veterans and Agent Orange* series is in progress. This review will build on information gathered for previous reports, but will focus to a large degree on more recent scientific studies and other information developed since their release. In addition, the IOM is conducting a review and evaluation of the evidence regarding the time period between exposure to dioxin, the toxic contaminant often present in Agent Orange, and the occurrence of respiratory cancer.

HEALTH EFFECTS OF THE GULF WAR

Almost 700,000 U.S. troops, including many members of reserve units, participated in the 1991 war in the Persian Gulf. Within a relatively short time of returning home, a number of reservists and active-duty personnel reported health problems that they believed to be service connected.

As mandated by Congress, the IOM has conducted several studies to assess the potential health effects of a variety of biological and chemical agents to which military personnel may have been exposed during the war. *Gulf War and Health, Volume II: Insecticides and Solvents* (2003) confirms known associations and concludes that there is sufficient evidence to support a causal relationship between the solvent benzene and two kinds of disorders, acute leukemia and aplastic anemia, based on the current body of peer-reviewed literature. There also is sufficient evidence of an association between benzene and adult leukemia, between solvents and acute leukemia, and between propylene glycol and allergic contact dermatitis. For a variety of other chemicals there is limited or suggestive evidence of an association with a range of cancers, neurobehavioral problems, and other health effects. For the majority of agents, however, the evidence is inadequate or insufficient to determine whether there is a link between

Demographic Characteristics of U.S. Gulf War Troops

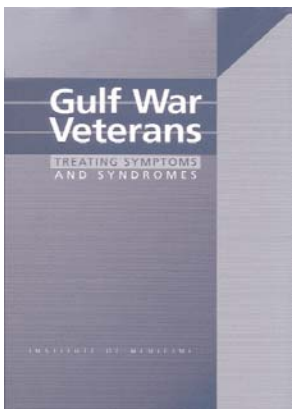
Characteristics	Percentage of Troops
Sex	
Male	93
Female	7
Age (mean) in 1991 (years)	27
Race or Ethnicity	
Non-Hispanic/White	70
Black	23
Hispanic	5
Other	2
Rank	
Enlisted	90
Officer	10
Military Branch	
Army	50
Navy	23
Marines	15
Air Force	12
Military Status	
Active Duty	
Reserves or National Guard	17

SOURCE: *Gulf War and Health, Vol. II: Insecticides and Solvents,* 2003, page 575.

exposure and adverse health effects. The evidence is insufficient to rule out any health effects associated with chemicals.

The third volume in the IOM series on health effects stemming from the Gulf War is in progress. It is focused on a variety of environmental particulates, pollutants, and synthetic chemical compounds believed to have been present in the region. Among the agents under review are hydrogen sulfide, fumes from diesel heaters, gasoline, jet fuels, by-products from oil fires, hydrazine, and nitric acid. As with the previous reports, the Department of Veterans Affairs will consider the results in developing compensation programs for veterans who have developed health problems as a result of their wartime service.

More than a decade after the end of the Gulf War, concerns remain about whether military personnel who were deployed to the region are now receiving effective treatment for any health problems brought about by their service. *Gulf War Veterans: Treating Symptoms and Syndromes* (2001) identifies a variety of problems known to occur, evaluates the efficacy of methods available for treating these disorders, and recommends treatments that will provide the greatest degree of benefit to given groups of patients. Where effective treatments are not available, the report recommends new directions for research. Among the disorders for which specific treatments are suggested are chronic fatigue syndrome, depression, fibromyalgia, headache, irritable bowel syndrome, panic disorder, and post-traumatic stress disorder. The report also notes that the general principles of the patient-centered approach to medicine should form part of the evaluation and treatment of all patients. This approach, intended to foster excellent communication between the care provider and the patient, involves the investigation of all complaints, respect for the patient's perspective, avoidance of excessive testing, and the greatest possible degree of joint decision-making regarding treatment.



PROTECTING AGAINST ANTHRAX

In autumn of 2001, anthrax erupted into the national spotlight with the deliberate distribution through the U.S. mail of potent forms of the

bacteria that cause the disease. These events lent urgency to an IOM study already under way on the vaccine currently being used to protect against anthrax. The Department of Defense in 1997 had announced a plan for the mandatory vaccination of all military personnel against the disease. To be phased in gradually, the program began in 1998 with personnel scheduled for deployment to high-risk areas. However, some service members and scientists expressed concern about the vaccine's efficacy and safety, and the DoD, at the request of Congress, asked the IOM to study these issues. *The Anthrax Vaccine: Is It Safe? Does It Work?* (2002) answers both questions in the affirmative. But the vaccine does have certain drawbacks, including reliance on a six-dose vaccination schedule over 18 months, and improvements are needed. The report calls for efforts in several main areas: improving the way the vaccine is used, expanding surveillance efforts to detect side effects from its use, and developing a better vaccine. A new vaccine should not cause any severe local reactions, should require only two or three injections that provide protection for at least a year, and should remain potent for a long period so that it can be stockpiled to ensure that ample supplies are available when needed.

...the [anthrax] vaccine does have certain drawbacks, including reliance on a six-dose vaccination schedule over 18 months, and improvements are needed.

After the Department of Defense launched its plan for the mandatory vaccination of all military personnel against anthrax, Congress directed the Centers for Disease Control and Prevention (CDC) to develop a research program to address concerns about the vaccine's safety and efficacy. The CDC, in turn, asked the Institute of Medicine to review the resulting program. *An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program* (2002) concludes that the program provides a generally complete and appropriate response to the Congressional mandate. Among the planned activities, for example, a clinical trial with civilian volunteers will help in optimizing the way that the vaccine is administered and will enable researchers to explore risk factors for adverse events caused by vaccination. The report also outlines additional research needs that became evident following the bioterrorist events of 2001, including studies of the vaccine's efficacy (when used in conjunction with antibiotics) in preventing people who have been exposed to anthrax bacteria from developing the disease. In addition, the report makes recommendations about the leadership of the overall research program. It calls for the appointment of a single senior CDC biomedical scientist to oversee all phases of its operation,

Studies Proposed by CDC for the Anthrax Vaccine Safety and Efficacy Research Program

Efficacy

- Anthrax Vaccine Absorbed: Human Teactogenicity and Immunogenicity Trial to address change in route of administration and dose reduction
- Nonhuman primate vaccine dose ranging, immunogenicity, and challenge trial
- Immune Correlates of Protection (ICP) against inhalational anthrax

Safety

- Anthrax Vaccine Adsorbed: Human Reactogenicity and Immunogenicity Trial to address change in route of administration and dose reduction
- Follow-up study of textile mill workers vaccinated against anthrax
- Studies based in the vaccine health care center network
- Effects of change of route of administration on local adverse events following AVA vaccination
- Effect of AVA vaccination on health-related quality of life
- Effect of hormonal phase in the female population on the occurrence of adverse events following immunization with AVA
- Enhanced signal detection and hypothesis testing for adverse events following anthrax vaccination
- Possible role of aluminum hydroxide adjuvant in AVA-associated adverse events

Acceptability

- Survey of knowledge, attitudes, and beliefs regarding the anthrax vaccine among military personnel
- Survey of civilian and military health care providers regarding the anthrax vaccine and the reporting of possible vaccine-associated adverse events

SOURCE: *An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program,* 2002, page 3.

and for the establishment of a committee of external scientific experts to assist in planning and setting priorities for individual studies and for the program as a whole.

HEALTH EFFECTS OF CHEMICAL AND BIOLOGICAL WARFARE AGENTS

In the wake of potential exposures of U.S. troops to the chemical warfare agent sarin during the 1991 Gulf War, as well as civilian exposures to

the nerve gas in Japan during the mid-1990s, there is considerable current interest in the possible long-term health effects of exposure to this compound or similar compounds. To address this issue, the IOM's Medical Follow-up Agency conducted a study of more than 4,000 military volunteers who had been exposed to sarin and other anticholinesterase chemical warfare agents during experiments run by the U.S. Army from 1955 to 1975 at Edgewood Arsenal, Maryland. The study, *Long-Term Health Effects of Exposure to Sarin and Other Anticholinesterase Chemical Warfare Agents* (reported in the March 2003 issue of the journal *Military Medicine*), found few differences in health between the volunteers and men in control groups who had not participated in the military tests. One difference was that test volunteers reported greater sleep disturbance than did men who were not exposed to anticholinesterase agents. The report's findings are similar to the results of a 1985 study, in which the same group of volunteers said that they had developed few health problems related to their test experience. In another study, the IOM is examining data on a group of Gulf war soldiers who were putatively exposed to low levels of the chemical warfare agents sarin and cyclosarin while destroying stockpiles of rockets captured in Khamisiyah, Iraq. Performed at the request of the U.S. Army, the epidemiological study will compare over a five-year follow-up period the health outcomes of the participants with a similar group of unexposed military personnel.

Several current studies also focus on assessing the health effects of exposure to various warfare agents. One study examines the health of military personnel who participated in Project SHAD (Shipboard Hazard and Defense), a series of tests conducted by the Department of Defense in the 1960s to investigate the effectiveness of procedures used on warships to detect chemical and biological attacks and protect crew members from harm. Although the tests were originally classified, public and media interest has led the DoD to declassify their results and make them available in a series of fact sheets. The study will determine the current health of participants in each of the 29 SHAD tests and compare their health status with a similar group of veterans who did not participate. It is expected to provide the Department of Veterans Affairs with medically sound information that it needs to settle benefits claims as quickly as possible and to evaluate and treat veterans who developed health problems as a result of their participation in Project SHAD. The results of this study will be submitted to a peer-reviewed scientific journal for publication.

Robert Wood Johnson Health Policy Fellowships Program

For three decades, the Robert Wood Johnson Health Policy Fellowships Program has enhanced the careers of outstanding mid-career academic health professionals, community health leaders, and behavioral scientists. Through a unique and comprehensive orientation program designed and administered by the Institute of Medicine, followed by high level work assignments in the U.S. Congress or the Administration, almost 200 Fellows have participated in shaping federal health policy. Fellows, strategically positioned at the nexus of health care, policy, and politics in Washington D.C., accept front line responsibilities in shaping the nation's legislation and regulations governing health and health care in the United States.

Formal evaluations of the program have demonstrated that the fellowship promotes and accelerates professional career development. The commissioned studies, corroborated by recent surveys and focus groups of alumni, have repeatedly documented the transforming nature of the experience including:

- Attainment of subsequent leadership roles in major professional societies and voluntary health organizations;

- A track record of prestigious promotions in academia and health care organizations; and
- A lasting connection to both the program and fellow alumni, creating an influential and powerful health policy network.

Fellows have been frequently cited by members of Congress, the Administration, and the health policy community at large as significantly improving the outcomes of health policymaking process. For example, Mario Pacheco (2000-2001) arrived in Washington with a concern about obesity in the Hispanic population. During his Congressional assignment, Mario energetically and effectively supported the successful passage of anti-obesity legislation that created a study of school-based vending machines and their effect on childhood nutrition. The scientific and clinical expertise Fellows possess make valuable contributions to the deliberations that face federal policymakers. Consequently, the demand for Robert Wood Johnson Foundation Health Policy Fellows is high, both during the year in Washington D.C. and during the years that follow. Fellows are aggressively recruited for Congressional committees and personal staff positions on both sides of the aisle. They are also sought for assignments in the Administration, including the Office of the Secretary of Health and Human Services, the Department of Defense, and the White House Office of Domestic Policy.

After completion of the DC experience, federal and state agencies and professional organizations and associations aggressively pursue alumni for their insights and newly found abilities to serve in leadership roles. For example, Lisa Kaplowitz (1996-1997) is the current Deputy Commissioner of Emergency Preparedness and Response for the Commonwealth of Virginia; while Larry Kerr (1998-1999) serves in the Executive Office of the President of the United States.

Alumni also serve as University Presidents, Vice Chancellors, and Deans of Schools of Medicine, Nursing and Public Health. They are Directors of State Medicaid Programs, Department Chairs, and Health Policy Directors. Alumni also continue to enthusiastically maintain their connections to Washington D.C. and some have even become official liaisons in government relations for their universities and professional societies.

While many changes have come about since the Program's inception in 1973, a recent notable addition is the availability of additional financial

support to enable fellows to extend the length of their assignments in D.C. so they can complete the legislative session in Congress. Alternatively, fellows may elect to use the additional funds to continue a planned program of health policy leadership development for up to two years after the D.C. assignment. At the end of the residential time in Washington, Fellows select two or three mentors who will serve as coaches or advocates. The mentoring component is intended to expand health policy leadership skills and abilities in order to sustain engagement in health policy and politics at the local, state, and/or federal levels.

The Fellowship experience fosters valuable and effective communication between academia, health care delivery, public policy, and politics. Not only do Robert Wood Johnson Foundation Health Policy Fellows serve as a vital resource to Congress, providing much needed clinical and scientific expertise, they also become members of an expanding and experienced network of leaders who share a remarkable commitment to the improvement of health policy in the United States.

Senior Nurse Scholar Program

The Institute of Medicine (IOM), in collaboration with the American Academy of Nursing (AAN) and the American Nurses Foundation (ANF), manages a Senior Nurse Scholar-in-Residence Program. The purpose of the program is to encourage and assist a prominent nurse leader in the articulation and assessment of health policy issues of national concern. The Senior Nurse Scholar selects a specific health policy issue consistent with the priority activities of the IOM and the nursing profession. The Scholar is located at the IOM, attends selected orientation meetings with key officials in federal agencies as well as Congressional committees with other IOM Fellows, and attends forums and meetings of the Institute, the National Academy of Sciences, the AAN, the ANF, and the American Nurses Association. The Scholar works with mentors who assist the individual in refining the selected topic and bridging the gap between academia and the service and health policy sectors. As part of the residency program, the Scholar is required to submit a peer-reviewed paper before the end of the program that should be published and disseminated to a broad audience. The paper is expected to translate and frame academic or experiential knowledge into policy-relevant recommendations on a specific topic.

RECENT AND UPCOMING REPORTS

This chapter first lists reports released by the Institute of Medicine from 1999 through 2003 and older reports mentioned in the text, grouped by subject area, then reports expected to be released through 2004. A "⌘" denotes a congressionally mandated study.

RECENT REPORTS (1999-2003)

Aging and the Elderly

Approaching Death: Improving Care at the End of Life, Health Care Services, 1997.

Describing Death in America: What We Need to Know, National Cancer Policy Board, Institute of Medicine/National Research Council, 2003.

Pharmacokinetics and Drug Interactions in the Elderly and Special Issues in Elderly African-American Populations: A Workshop Summary, Neuroscience and Behavioral Health and Health Sciences Policy, 1997.

⌘*The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population,* Food and Nutrition Board, 2000.

The Second Fifty Years: Promoting Health and Preventing Disability, Health Promotion and Disease Prevention, 1992.

Working Together: We Can Help People Get Good Care When They Are Dying, Health Care Services, 2000.

Child/Youth Health

Adolescent Decision Making: Implications for Prevention Programs. Summary of a Workshop, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Adolescent Development and the Biology of Puberty: Summary of a Workshop on New Research, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Adolescent Risk and Vulnerability: Concepts and Measurement, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2001.

America's Children: Health Insurance and Access to Care, Health Care Services and Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families, Health Promotion and Disease Prevention, 1995.

Childhood Cancer Survivorship: Improving Care and Quality of Life, National Cancer Policy Board, Institute of Medicine/National Research Council, 2003.

Children of Immigrants: Health, Adjustment, and Public Assistance, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Community Programs to Promote Youth Development, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2001.

⌘*Confronting Chronic Neglect: The Education and Training of Health Professionals on Family Violence,* Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2001.

Early Childhood Intervention: Views from the Field. Report of a Workshop, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2000.

From Generation to Generation: The Health and Well-Being of Children in Immigrant Families, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

From Neurons to Neighborhoods: The Science of Early Childhood Development, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2000.

Getting to Positive Outcomes for Children in Child Care — A Summary of Two Workshops, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2001.

Immunization Safety Review: Vaccinations and Sudden Unexpected Death in Infancy, Health Promotion and Disease Prevention, 2003.

Juvenile Crime, Juvenile Justice, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2001.

Nontechnical Strategies to Reduce Children's Exposure to Inappropriate Material on the Internet: Summary of a Workshop, Board on Children, Youth, and Families, Computer Science and Telecommunications Board, Institute of Medicine/National Research Council, 2001.

Protecting Youth at Work: Health, Safety, and Development of Working Children and Adolescents in the United States, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

Rational Therapeutics for Infants and Children: A Workshop Summary, Health Sciences Policy, 2000.

Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States, Health Promotion and Disease Prevention and Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

Research to Improve Intergroup Relations Among Youth, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Revisiting Home Visiting: Summary of a Workshop, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Risks and Opportunities: Synthesis of Studies on Adolescence, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1999.

Sleep Needs, Patterns, and Difficulties of Adolescents: Summary of a Workshop, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 2000.

Systems of Accountability: Implementing Children's Health Insurance Programs, Health Care Services and Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families, Health Sciences Policy, 2002.

Diseases and Conditions (for HIV/AIDS, see Public Health)

An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program, Medical Follow-Up Agency, 2002.

⌘*The Anthrax Vaccine: Is It Safe? Does It Work?,* Medical Follow-Up Agency, 2002.

Bridging the Gap Between Practice and Research: Forging Partnerships with Community-Based Drug and Alcohol Treatment, Neuroscience and Behavioral Health, 1998.

Clearing the Air: Asthma and Indoor Air Exposures, Health Promotion and Disease Prevention, 2000.

Considerations for Viral Disease Eradication: Lessons Learned and Future Strategies, A Workshop Summary, Global Health, 2002.

Control of Cardiovascular Diseases in Developing Countries: Research, Development, and Institutional Strengthening, International Health, 1998.

Developing Technologies for Early Detection of Breast Cancer: A Public Workshop Summary, National Cancer Policy Board, Institute of Medicine/National Research Council, 2000.

Diet and Health: Implications for Reducing Chronic Disease Risk, Food and Nutrition Board, 1989.

Disability in America: Toward a National Agenda for Prevention, Health Sciences Policy, 1991.

Dispelling the Myths About Addiction: Strategies to Increase Understanding and Strengthen Research, Neuroscience and Behavioral Health, 1997.

Eat for Life: The Food and Nutrition Board's Guide to Reducing Your Risk of Chronic Disease, Food and Nutrition Board, 1992.

The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health, Global Health, 2002.

Ending Neglect: The Elimination of Tuberculosis in the United States, Health Promotion and Disease Prevention, 2000.

Enhancing Data Systems to Improve the Quality of Cancer Care, National Cancer Policy Board, Institute of Medicine/National Research Council, 2000.

Fulfilling the Potential of Cancer Prevention and Early Detection, National Cancer Policy Board, Institute of Medicine/National Research Council, 2003.

Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism, Health Promotion and Disease Prevention, 2001.

Immunization Safety Review: Multiple Immunizations and Immune System Dysfunction, Health Promotion and Disease Prevention, 2002.

Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer, Health Promotion and Disease Prevention, 2002.

Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders, Health Promotion and Disease Prevention, 2001.

Improving Palliative Care for Cancer—Summary and Recommendations, National Cancer Policy Board, Institute of Medicine/National Research Council, 2001.

Improving Palliative Care for Cancer, National Cancer Policy Board, Institute of Medicine/National Research Council, 2001.

Interpreting the Volume-Outcome Relationship in the Context of Cancer Care, Division on Earth and Life Studies, 2001.

Mammography and Beyond: Developing Technologies for Early Detection of Breast Cancer—A Non-Technical Summary, National Cancer Policy Board, Commission on Life Sciences, Institute of Medicine/National Research Council, 2001.

Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer, National Cancer Policy Board, Commission on Life Sciences, Institute of Medicine/National Research Council, 2001.

Marijuana and Medicine: Assessing the Science Base, Neuroscience and Behavioral Health, 1999.

Marijuana as Medicine?: The Science Beyond the Controversy, Neuroscience and Behavioral Health, 2000.

⌘*The Medicare Coverage of Routine Screening for Thyroid Dysfunction,* Health Care Services, 2003.

New Partnerships for a Changing Environment: Why Drug and Alcohol Treatment Providers and Researchers Need to Collaborate, Neuroscience and Behavioral Health, 1999.

Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #1, Health Promotion and Disease Prevention, 2003.

Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #2, Health Promotion and Disease Prevention, 2003.

Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #3, Health Promotion and Disease Prevention, 2003.

Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #4, Health Promotion and Disease Prevention, 2003.

The Role of Co-occurring Substance Abuse and Mental Illness in Violence: A Workshop Summary, Neuroscience and Behavioral Health, 1999.

Scientific and Policy Considerations in Developing Smallpox Vaccination Options: A Workshop Report, Health Sciences Policy, 2002.

⌘*Tuberculosis in the Workplace,* Health Promotion and Disease Prevention, 2001.

⌘*Veterans and Agent Orange: Herbicide/Dioxin Exposure and Type 2 Diabetes,* Health Promotion and Disease Prevention, 2000.

Veterans and Agent Orange: Update 2000, Health Promotion and Disease Prevention, 2001.

Veterans and Agent Orange: Herbicide/Dioxin Exposure and Acute Myelogenous Leukemia in the Children of Vietnam Veterans, Health Promotion and Disease Prevention, 2002.

Drugs, Devices, and Biologics

Assessment of Future Scientific Needs for Live Variola Virus, Global Health, 1999.

⌘*An Assessment of the Safety of the Anthrax Vaccine: Letter Report,* Health Promotion and Disease Prevention and Medical Follow-Up Agency, 2000.

Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making: A Workshop Report, Health Sciences Policy, 1999.

Blood and Blood Products: Safety and Risk, Health Sciences Policy, 1996.

Blood Banking and Regulation: Procedures, Problems, and Alternatives, Health Sciences Policy, 1996.

⌘*Calling the Shots: Immunization Finance Policies and Practices,* Health Care Services, 2000.

Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response, Health Sciences Policy, 1998.

Improving Civilian Medical Response to Chemical or Biological Terrorist Incidents: Interim Report on Current Capabilities, Health Sciences Policy, 1998.

⌘*Innovation and Invention in Medical Devices: A Workshop Summary,* Health Sciences Policy, 2001.

Interactions of Drugs, Biologics, and Chemicals in U.S. Military Forces, Medical Follow-Up Agency, 1996.

Marijuana and Medicine: Assessing the Science Base, Neuroscience and Behavioral Health, 1999.

Marijuana as Medicine?: The Science Beyond the Controversy, Neuroscience and Behavioral Health, 2000.

Microbial Threats to Health: Emergency, Detection, and Response, Global Health, 2003.

Rational Therapeutics for Infants and Children: A Workshop Summary, Health Sciences Policy, 2000.

Urgent Attention Needed to Restore Lapsed Adenovirus Vaccine Availability: A Letter Report, Medical Follow-Up Agency, 2000.

Vaccines for the 21st Century: A Tool for Decisionmaking, Health Promotion and Disease Prevention, 2000.

Environmental and Occupational Health

Clearing the Air: Asthma and Indoor Air Exposures, Health Promotion and Disease Prevention, 2000.

Environmental Medicine: Integrating a Missing Element into Medical Education, Health Promotion and Disease Prevention, 1995.

⌘*Exposure of the American People to Iodine-131 from Nevada Atomic Bomb Tests: Review of the National Cancer Institute Report and Public Health Implications,* Health Care Services, joint with the Board on Radiation Effects Research, 1998.

Health and the Environment in the Southeastern United States: Rebuilding the Unity, Health Sciences Policy, 2002.

⌘*Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities, Commission on Behavioral and Social Sciences and Education,* National Research Council, 2001.

Protecting Youth at Work: Health, Safety, and Development of Working Children and Adolescents in the United States, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, 1998.

Rebuilding the Unity of Health and the Environment: A New Vision of Environmental Health for the 21st Century, Health Sciences Policy, 2000.

Rebuilding the Unity of Health and the Environment: A New Vision of Environmental Health for the 21st Century, Health Sciences Policy, 2001.

Reducing the Burden of Injury: Advancing Protection and Treatment, Health Promotion and Disease Prevention, 1998.

Review of the Disability Evaluation Study Design: Third Interim Report, Health Care Services, 1999.

Safe Work in the 21st Century: Education and Training Needs for the Next Decade's Occupational Safety and Health Personnel, Health Sciences Policy, 2000.

Science and Risk Communication: A Mini-Symposium Sponsored by the Roundtable on Environmental Health Sciences, Research, and Medicine, Health Sciences Policy, Institute of Medicine, 2001.

Toward Environmental Justice: Research, Education, and Health Policy Needs, Health Sciences Policy, 1999.

⌘*Tuberculosis in the Workplace,* Health Promotion and Disease Prevention, 2001.

Food, Nutrition, and Diet

Assessing Readiness in Military Women: The Relationship of Body Composition, Nutrition, and Health, Food and Nutrition Board, 1998.

Caffeine for the Sustainment of Mental Task Performance: Formulations for Military Operations, Food and Nutrition Board, 2001.

Diet and Health: Implications for Reducing Chronic Disease Risk, Food and Nutrition Board, 1989.

Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride, Food and Nutrition Board, 1997.

Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, Food and Nutrition Board, 2002.

Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Food and Nutrition Board, 1998.

Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Food and Nutrition Board, 2001.

Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Food and Nutrition Board, 2000.

Dietary Reference Intakes: A Risk-Assessment Model for Establishing Upper Intake Levels for Nutrients, Food and Nutrition Board, 1998.

Dietary Reference Intakes: Applications in Dietary Assessment, Food and Nutrition Board, 2000.

Dietary Reference Intakes: Applications in Dietary Planning, Food and Nutrition Board, 2003.

Dietary Reference Intakes: Proposed Definition of Dietary Fiber, Food and Nutrition Board, 2001.

Dietary Risk Assessment in the WIC Program, Food and Nutrition Board, 2002.

Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure, Food and Nutrition Board, 2003.

Eat for Life: The Food and Nutrition Board's Guide to Reducing Your Risk of Chronic Disease, Food and Nutrition Board, 1992.

Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies: A Workshop Summary, Food and Nutrition Board, 1999.

⌘*Ensuring Safe Food: From Production to Consumption,* Food and Nutrition Board, joint with the Board on Agriculture, 1998.

Evaluating Food Assistance Programs in an Era of Welfare Reform: Summary of a Workshop, Board on Children, Youth, and Families, Institute of Medicine/National Research Council, joint with the Committee on National Statistics, 1999.

Evolution of Evidence for Selected Nutrient and Disease Relationships, Food and Nutrition Board, 2002.

Food Chemicals Codex: First Supplement to the Fourth Edition, Food and Nutrition Board, 1997.

Food Chemicals Codex: Second Supplement to the Fourth Edition, Food and Nutrition Board, 2000.

Food Chemicals Codex: Third Supplement to the Fourth Edition, Food and Nutrition Board, 2001.

Food Safety Policy, Science, and Risk Assessment: Strengthening the Connection: Workshop Proceedings, Food and Nutrition Board, 2001.

High-Energy, Nutrient-Dense, Emergency Relief Food Product, Food and Nutrition Board, 2002.

Letter Report on the Dietary Reference Intakes for Trans Fatty Acids, Drawn from the Report on Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids, Food and Nutrition Board, 2001.

Military Strategies for Sustainment of Nutrition and Immune Function in the Field, Food and Nutrition Board, 1999.

Nutrition During Lactation, Food and Nutrition Board, 1991.

Nutrition During Pregnancy: Part 1: Weight Gain, Part 2: Nutrient Supplements, Food and Nutrition Board, 1990.

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Work Environment for Nurses and Patient Safety, Health Care Services.

Health Care Services, Quality of Care

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Aerospace Medicine and the Medicine of Extreme Environments, Health Sciences Policy.

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⌘*Ryan White CARE Act: Data for Resource Allocation, Planning, and Evaluation*, Health Promotion and Disease Prevention.

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⌘*Smallpox Vaccination Program Implementation,* Health Promotion and Disease Prevention.

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Women's Health

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