

Informing the Future: Critical Issues in Health, Third Edition

Institute of Medicine

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Informing The Future

CRITICAL ISSUES IN HEALTH
THIRD EDITION

Informing the Future: Critical Issues in Health, Third Edition http://www.nap.edu/catalog/11469.html

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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

Advising the Nation. Improving Health.

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Contents

Institute of Medicine: Advising the Nation, Improving Health	1
Making America's Health Care As Good As It Should Be	3
Health Risks and Public Policy: Perception and Reality	11
Guiding Biomedical and Clinical Research	19
The Nation's Future: Children and Youth	29
Global Health	41
Protecting the Health of Those Who Protect the Nation	49
The Power of Convening	59
Fellowship Programs at the Institute of Medicine	73
Recent and Upcoming Reports	77
Contact Us	121

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The Institute of Medicine: Advising the Nation, Improving Health

Childhood obesity, vaccination safety, pandemic flu, the problem of the uninsured, the quality of the U.S. health-care system—these are all health concerns that appear regularly in the national news. These topics are also some of the many subjects of recent reports by the Institute of Medicine.

The nation turns to the Institute of Medicine (IOM) of the National Academies¹ for science-based advice on matters of biomedical science, medicine, and health. A private, nonprofit organization specifically created for this purpose as well as an honorific membership organization, the IOM was chartered in 1970 as a component of the National Academy of Sciences. The Institute provides a vital public service by working outside the framework of government to ensure scientifically informed analysis and independent guidance.

As a vibrant and distinguished membership organization, the IOM celebrates outstanding achievement and sets standards for excellence. The Institute's members are elected on the basis of their professional achievement and capacity for service. They, along with many other experts, serve without compensation in the conduct of IOM studies, workshops, 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, law, administration, engineering, and the humanities. The number of regular members plus foreign associates currently exceeds 1500.

Unlike many honorific societies, the IOM is committed to public service. The Institute regularly undertakes studies to provide authoritative and scientifically balanced answers to difficult questions of national importance ranging

^{&#}x27;The National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council comprise the National Academies. The first three are professional elective bodies, and the latter is an operating arm of the National Academies. In carrying out its program, the IOM adheres to all procedures used by the National Research Council.

from quality of medical care to the national smallpox vaccination program; from centers of excellence at the National Institutes of Health to protecting the nation's food supply. The IOM also convenes roundtables, workshops, and symposia that provide an opportunity for public- and private-sector experts to discuss contentious issues in an open environment that facilitates evidence-based dialogue. The majority of our studies and other activities are requested and funded by the federal government. The IOM itself, private industry, foundations, and state and local governments may also initiate ideas for studies and programs.

Additionally, for three decades, the IOM has managed the Robert Wood Johnson Health Policy Fellowships Program, which is designed to develop the capacity of outstanding mid-career health professionals in academic and community-based settings to assume leadership roles in health policy and management.

The Institute and the National Academies use a unique process to obtain the most authoritative, objective, and scientifically balanced answers to difficult questions of national importance. Our work is conducted by committees of volunteer scientists—the country's leading 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 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 the past 35 years to provide policymakers with objective advice.

The aim in all of IOM's activities is to improve decision-making by identifying scientifically sound 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 topics related to biomedical science, medical care, and human health. Depending on the request, studies may be narrow in scope, designed to answer very specific and technical questions, or they may be broadbased examinations that span many academic disciplines, industries, and even international borders.

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 two sections. The first section illustrates the work that we have done in several topic areas and the last section provides a comprehensive bibliography of IOM reports published since 2001.

Making America's Health Care As Good As It Should Be

The United States has the distinction of spending more of its wealth on health care than any other nation—at last report, 15 percent of gross national product, compared with 11 percent for Switzerland, the second ranking country, and 9.6 percent for our neighbor Canada. With this level of investment, America should provide all of its residents with quality health care and access to health insurance. Overcoming barriers to achieving that vision and making the nation's health care as good as it should be is the objective of multiple Institute of Medicine (IOM) studies. These studies include comprehensively assessing the problem of uninsurance and its impact on individual, community, and national health; continuing to articulate next steps in the drive to improve the quality of health care; and calling attention to the importance of health literacy and health workforce diversity as key determinants of the quality and successful outcome of health care.

HEALTH INSURANCE FOR ALL

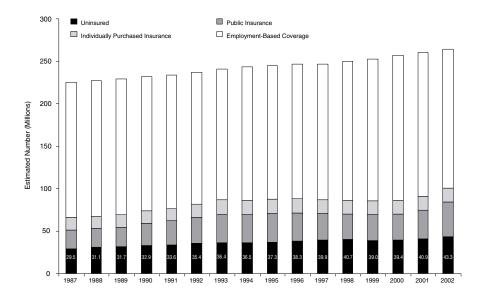
Insuring America's Health: Principles and Recommendations (2004) is the culminating and summary report of a series of six studies that collectively comprise the most comprehensive examination to date of the consequences that stem from the widespread lack of health insurance. When the report was issued, more than 43 million U.S. residents under the age of 65 lacked health insurance—roughly one Americans—and the numbers are higher today.

The report makes the compelling case that by 2010, everyone in the United States should

case that by 2010, everyone in the United States should have health insurance; calls on the president, Congress, and the nation to act immediately by establishing a firm and explicit plan to meet this goal; and provides a set of five principles that can be used to assess the merits of current proposals to expand health insurance coverage and design future strategies to improve coverage.

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have health insurance; calls on the president, Congress, and the nation to act immediately by establishing a firm and explicit plan to meet this goal; and provides a set of five principles that can be used to assess the merits of current proposals to expand health insurance coverage and design future strategies to improve coverage. These principles are:



Sources of health insurance coverage and number of uninsured persons for population under age 65 years, 1987-2002. SOURCE: *Insuring America's Health: Principles and Recommendations*, p. 79.

- Health-care coverage should be universal. This is the foundation for all other considerations—everyone living in the United States should be covered.
- Health-care coverage should be continuous. Continuous coverage, starting from birth, is more likely to lead to improved health outcomes. Conversely, gaps in coverage can interfere with therapeutic relationships and result in diminished health.
- Health coverage should be affordable to individuals and families. The main reason people give for being uninsured is the high cost of coverage. Lower-income families have little leeway in their budgets for health expenditures, so financial assistance will be necessary for them to obtain coverage.
- Health insurance should be affordable and sustainable for society. Any major reform proposal will need mechanisms to control spending and encourage use of efficacious and cost-effective services. Everyone should contribute financially through taxes, premiums, and cost sharing—because all members of society will benefit from universal coverage. Reforms should strive for efficiency and simplicity by eliminating complex eligibility rules, underwriting, billing procedures, and regulatory requirements.

Making America's Health Care As Good As It Should Be

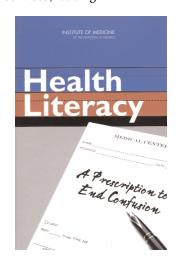
• Health insurance should enhance health and well-being by promoting access to high-quality care that is effective, efficient, safe, timely, patient-centered, and equitable. Basic benefit packages should include preventive and screening services, outpatient prescription drugs, and specialty mental health care, as well as outpatient and hospital services. Variations in patient cost sharing and provider payment levels could be used to encourage appropriate service use.

Other important barriers stand between patients and good health care: two that are not widely understood and appreciated are health literacy and the lack of diversity in the health care workforce.

HEALTH LITERACY

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand the basic information and services they need to make appropriate health decisions. People with limited health literacy experience higher rates of hospitalization and use more emergency services, leading

to billions of dollars in avoidable health care costs. It is more than a matter of education: people who have finished high school or college may still not be able to navigate the health system. While reading, writing, and mathematics skills make up part of the basis of health literacy, many other skills and abilities are important, such as speaking, listening, having adequate background information, and being able to advocate for oneself in the health system. Health literacy also goes beyond the individual: it depends on the skills, preferences, and expectations of the providers of health care and health information, including doctors, nurses, administrators, home health workers, the media, and many others. Health Literacy: A Prescription to End Confusion (2004) provides an action plan to help people of all races and ethnic groups, ages, and income levels become better able to manage their



health. Efforts will be needed by the public health and health-care systems, the education system, the media, and health-care consumers. In an unusual collaboration, the IOM worked with the Academy for Education Development and the Kellogg Foundation to train young people in Pinellas County, Florida, and Harlem, New York, to map health resources in their communities and help create a wider awareness of health literacy and its impact on the quality and accessibility of health care.

While reading, writing, and mathematics skills make up part of the basis of health literacy, many other skills and abilities are important, such as speaking, listening, having adequate background information, and being able to advocate for oneself in the health system.

DIVERSITY IN THE HEALTH-CARE WORKFORCE

Successful interactions between health-care professionals and patients depend on many factors. Important among them is the patient's sense of comfort with the individual or team providing care. Diversity in the health-care workforce is an important factor in assuring that all patients have confidence in the professionals who provide their care. The United

States is now a diverse nation and will become more so as this century progresses. The representation of minorities—African Americans, Hispanics, Islamic cultures—in the health professions is far below their representation in the general population.

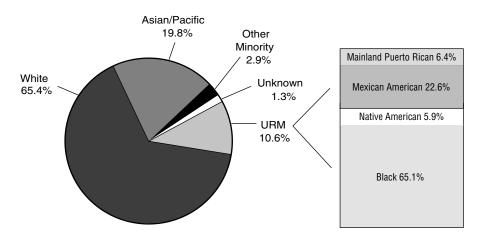
Increasing racial and ethnic diversity among health professionals is important because evidence indicates that such diversity is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better educational experiences for health professions students, among many other benefits. *In the Nation's Compelling Interest: Ensuring Diversity in the Health-Care Workforce* (2004) describes institutional and policy-level strategies to address this pressing need. Health professions educational institutions

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should begin by developing and implementing clear mission statements that recognize the value of diversity to their own environments as well as to the larger health-care professions. Admissions should be based on a comprehensive review of each applicant, including an assessment of both qualitative factors that may be relevant to enhancing diversity (race, ethnicity, background, foreign language abilities) and quantitative data that speak to academic skills (e.g., prior grades and test scores). Other recommendations include evaluating federal programs designed to support

minority and ethnic students and expanding those programs found to be successful in recruiting and graduating students.

Making America's Health Care As Good As It Should Be



U.S. medical school graduates, 2001. SOURCE: *In the Nation's Compelling Interest: Ensuring Diversity in the Health-Care Workforce*, p. 44.

THE QUALITY IN HEALTH-CARE INITIATIVE

The IOM continues its long-standing efforts to consolidate and articulate the knowledge base on which to build a quality health-care delivery system. *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) provided a framework and strategy to achieve this goal. Subsequent studies have focused on specific aspects of health-care delivery (such as the issue of workforce diversity) to "drill down" in a particular area and make concrete recommendations for action and research.

WORK ENVIRONMENT OF NURSES

Nurses are the largest profession in the nation's health-care workforce. *Keeping Patients Safe: Transforming the Work Environment of Nurses* (2003) docu-

ments the critical role that nurses play in hospitals, nursing homes, and other health-care settings. The report provides comprehensive guidance on how to redesign their jobs and the systems within which they work so that they can provide the highest quality of care. Threats to patient safety occur in four main areas—management practices that lead to failure to follow safety practices, unsafe workforce deployment, unsafe work and workspace design, and institu-

Threats to patient safety occur in four main areas—management practices that lead to failure to follow safety practices, unsafe workforce deployment, unsafe work and workspace design, and institutional cultures that discourage attention to safety. Improvements are recommended in all areas.

TABLE 1-1 Six Aims for Quality Improvement

Aim	Definition
Safety	Avoiding injuries to patients from the care that is intended to help them
Effectiveness	Providing services based on scientific knowledge (evidence-based) to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively)
Patient-centeredness	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions
Timeliness	Avoiding waits and sometimes harmful delays for both those who receive and those who give care
Efficiency	Avoiding waste, including waste of equipment, supplies, ideas, and energy
Equity	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

SOURCE: IOM, 2001.

Six Aims for Quality Improvements. SOURCE: *Quality Through Collaboration: The Future of Rural Health*, p. 24.

tional cultures that discourage attention to safety. Improvements are recommended in all areas.

RURAL AND SMALL-TOWN AMERICA

Rural America is home to 20 percent of the nation's population, but struggles to maintain physicians, hospitals, and other critical points of access to health-care services. The principles of *Crossing the Quality Chasm* have been difficult to calibrate to rural needs and resources. *Quality Through Collaboration: The Future of Rural Health Care* (2004) proposes a comprehensive strategy for meeting the health challenges that rural communities face. Many of the challenges stem from lack of access to core health-care services, such as primary care in the community, hospital and emergency services, long-term care, and mental health. Overcoming these barriers will require an integrated approach to meet personal and popula-

Making America's Health Care As Good As It Should Be

BOX 4-1 Core Competencies for Health Professionals

- · Provide patient-centered care
- · Work in interdisciplinary teams
- Employ evidence-based practice
- · Apply quality improvement
- · Utilize informatics

SOURCE: IOM, 2003c.

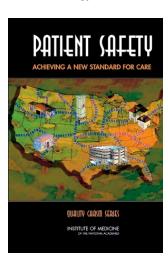
Core Competencies for Health Professionals. SOURCE: Quality Through Collaboration: The Future of Rural Health, p. 81.

tion needs at the community level; assist health systems professionals to acquire the knowledge and tools to improve quality; and enhance education and training to increase the supply of health professionals in rural areas.

PROTECTING PATIENTS

In rural areas and nationwide, the development of improved systems for reporting patient safety data is seen as a critical step in overall quality improvement. *Patient Safety: Achieving a New Standard for Care* (2004) offers a roadmap for developing and adopting key health-care data standards to support both the exchange of health information that is accessible by all health-care organizations and the reporting and analysis of patient safety data. New information technology

systems are needed that operate seamlessly as part of a national network of health information accessible by all health-care organizations. The systems must include electronic records of patients' care, secure platforms for the exchange of information among providers and patients, and data standards that will make health information easily understandable. Although most of this development must occur in the private sector, government should also provide financial incentives to spur private development of electronic health records (EHR). A related report, *Key Capabilities of an Electronic Health Record System* (2003), identifies a set of eight core functions that EHR systems should be capable of performing in order to promote greater safety, quality, and efficiency in health-care delivery. Having a common under-



Patient Safety: Achieving a New Standard for Care (2004) offers a roadmap for developing and adopting key health-care data standards to support both the exchange of health information that is accessible by all health-care organizations and the reporting and analysis of patient safety data.

standing about key functions will improve the capacity of health care organizations to compare the key features of EHR systems, guide vendors in building new systems with enhanced capabilities, help accreditation organizations in certifying systems that are ready for adoption, and guide the federal government as it considers ways to stimulate care providers to invest in electronic health records.

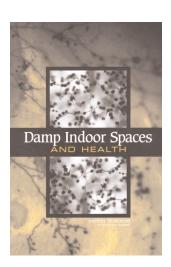
Health Risks and Public Policy: Perception and Reality

We live in a world filled with risks—and we always will. Going about our daily lives, we encounter risks ranging from illness due to *E. coli* 0157, to an adverse reaction to a medicine, to skin cancer caused by exposure to the sun, to death by a terrorist act. These and many other risks are real, but vary enormously in their probability of occurrence and the magnitude of their effects. Similarly, the public's perception of risks and their probabilities varies dramatically, and sometimes is not aligned with what the evidence tells us. The Institute of Medicine (IOM) has played critical roles over the years in going beyond perceptions of risks to evaluate the evidence on a wide range of risks and their likelihood, and then communicating these evidence-based findings to the public and to decision makers.

ASSESSING INDOOR HEALTH THREATS

Mold has been extensively reported in the media as the likely culprit in a wide array of routine and exotic illnesses. Since almost all homes, apartments, and commercial buildings will experience leaks, flooding, or other forms of

excessive indoor dampness at some point, the issue of health risks associated with damp spaces has emerged as a major public health and legal controversy, as concerns have grown that excessive dampness can cause or contribute to a host of adverse health effects. In light of such concerns, the Centers for Disease Control and Prevention (CDC) asked the IOM to examine what is known about potential links between dampness and health and to propose public health responses as needed. *Damp Indoor Spaces and Health* (2004) concludes that current scientific evidence is sufficient to link exposure to damp conditions and exposure to molds commonly found in damp environments to asthma symptoms in some people with the chronic disorder, as well as to coughing, wheezing, and upper respiratory tract symptoms in otherwise healthy people. However, available evidence



does not support an association between either indoor dampness or mold and the wide range of other health complaints that have been ascribed to them.

Given the frequent occurrence of moisture problems in buildings and their links to respiratory problems, this issue should be addressed through a broad

range of public health initiatives and changes in how buildings are designed, constructed, and maintained. Technical information already exists describing

Given the frequent occurrence of moisture problems in buildings and their links to respiratory problems, this issue should be addressed through a broad range of public health initiatives and changes in how buildings are designed, constructed, and maintained. how to control dampness, but architects, engineers, building contractors, facility managers, and maintenance staff do not always apply this knowledge. To help promote improvements, consensus guidelines for preventing indoor dampness should be developed at the national level, under the aegis of either a government agency or an independent nongovernmental organization. In addition, governments at appro-

priate levels should review building codes and modify them as necessary to reduce moisture problems.

The report's conclusions regarding health effects are rippling through the legal community. In a comprehensive review in the journal *Mold*, two leading environmental lawyers say the report will significantly affect toxic tort litigation nationwide, especially cases that involve exposure to household mold. Calling the report "by far the most comprehensive study presently available on the issue," the authors say it "significantly brings into question whether there is sufficient evidence to demonstrate the requisite causation necessary to meet the burden of proof in mold litigation." In most litigation of this type, plaintiffs rely on expert witnesses to testify that mold is causally responsible for their claimed health effects. Given the IOM report's exhaustive review of available scientific evidence, however, the authors suggest that plaintiffs' experts will have difficulty finding credible studies on which to base an opinion that mold and damp indoor environments can cause adverse health effects beyond those described in the report.

Indeed, the report already has entered the courtroom. In Arizona, the owners of an apartment building successfully defended themselves against a tenant's claims that exposure to mold in her apartment caused brain injury, seizures, and several other neurological and immune disorders. In its ruling, the U.S. District Court hearing the case cited the report's conclusions in rejecting expert testimony that sought to establish causation between the presence of mold and the plaintiff's symptoms.

Damp Indoor Spaces and Health also is contributing to scientific and medical discussions. Participants highlighted the report at the Surgeon General's Workshop on Healthy Indoor Environments, held in January 2005. In addition,

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Health Risks and Public Policy: Perception and Reality

TABLE ES-1 Summary of Findings Regarding the Association Between Health Outcomes and Exposure to Damp Indoor Environments^a

Sufficient Evidence of a Causal Relationship

(no outcomes met this definition)

Sufficient Evidence of an Association

Upper respiratory (nasal and throat) tract symptoms

Cough

Wheeze

Asthma symptoms in sensitized

asthmatic persons

Limited or Suggestive Evidence of an Association

Dyspnea (shortness of breath)

Lower respiratory illness in otherwise-healthy children

Asthma development

Inadequate or Insufficient Evidence to Determine Whether an Association Exists Airflow obstruction (in otherwise-healthy persons)

Skin symptoms

Mucous membrane irritation syndrome Chronic obstructive pulmonary disease Inhalation fevers (nonoccupational exposures)

Lower respiratory illness in otherwise-healthy adults Acute idiopathic pulmonary hemorrhage in infants Skin symptoms Gastrointestinal tract problems Fatigue Neuropsychiatric symptoms

Cancer

Cancer

Reproductive effects Rheumatologic and other immune diseases

Summary of Findings Regarding the Association Between Health Outcomes and Exposure to Damp Indoor Environments. SOURCE: *Damp Indoor Spaces and Health*, p. 9.

the American College of Physicians summarized the report's health conclusions in *CHEST*, the group's online journal, and several environmental publications, including Environmental Health Perspectives, have covered the report in news articles.

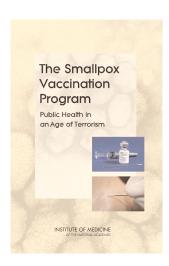
VACCINATING AGAINST THE THREAT OF SMALLPOX

Smallpox, historically one of the most dreaded and deadly infectious diseases, was eradicated in 1980 with the help of universal vaccination of children and strategic vaccination campaigns in the developing world. With the disease no longer a threat and smallpox virus remaining in only two laboratories (in the United States and Soviet Union, now Russia), routine vaccination ended. However, the fall of the Soviet Union occasioned concern that smallpox virus stocks could have fallen into the wrong hands. The events of September 11, 2001, and subsequent anthrax attacks created an environment in which fears of bioterrorism led to calls to prepare the country against potential threats,

^aThese conclusions are not applicable to immunocompromised persons, who are at increased risk for fungal colonization or opportunistic infections.

including the possibility of smallpox, a disease against which most Americans are not immune.

In December 2002, the federal government announced that smallpox vaccination would be administered to certain high-risk military personnel and would



be offered on a voluntary basis to select civilian public health and medical professionals, emergency response personnel, and others who would be "first responders" in a smallpox emergency. This was an unusual policy decision: to vaccinate people against a microbe that no longer exists (outside of two laboratories) with a vaccine that poses some well-known risks. The smallpox vaccination program presented a case study at the intersection of public health and national security—two fields brought together by the threat of bioterrorism. Bioterrorism attacks epitomize "low-likelihood, high-consequence" events, and preparing for them is challenging. Efforts to prepare for an event that may never occur are likely to come under criticism if the threat never materializes. Also, such events are accompanied by a high level of uncertainty,

including an unclear ratio of risk to benefit. For this reason, implementing a program of preparedness for bioterrorism and similar types of events requires careful consideration of information and communication needs.

As the federal agency charged with administering the public vaccination program, the CDC turned to the IOM for guidance on selected aspects of implementation and evaluation. In a timely manner, the IOM issued six letter reports to help guide the program and its integration into the broader public health preparedness efforts. The seventh and final report in the series, The Smallpox Vaccination Program: Public Health in an Age of Terrorism (2005), discusses lessons learned that can inform not only the operation of the smallpox vaccination program but also other public health efforts to prepare for terrorism. The report concludes that it is not possible to determine the level of smallpox preparedness in local jurisdictions and nationally, because the CDC did not systematically assess program outcomes. In order to gain such understanding, the CDC, in collaboration with state and local partners, should set specific goals for preparedness that reflect the best available scientific and public health reasoning; conduct regular, comprehensive assessments of preparedness at the national level and by state; and communicate to the public about the status of preparedness efforts. The CDC also did not communicate vital information to key constituencies

Health Risks and Public Policy: Perception and Reality

expected to play vital roles in the program, such as public health and health care administrators, and this gap limited the program's success. The numbers of individuals vaccinated fell far short of the CDC's goals, and the program had very little support among the key constituencies essential to its success. Based on these lessons, the report concludes that in future efforts to prepare for bioterrorism, public health officials and policymakers should develop strategies to balance national security imperatives—such as protecting classified information—with the need to provide key constituencies and the broader public with appropriate explanations and guidance about a program's rationale,

... the report concludes that in future efforts to prepare for bioterrorism, public health officials and policymakers should develop strategies to balance national security imperatives—such as protecting classified information—with the need to provide key constituencies and the broader public with appropriate explanations and guidance about a program's rationale, implementation, and objectives.

implementation, and objectives. In the absence of complete and credible information, the public's perception of risks and benefits will be driven by rumor and media rather than good science.

GENETICALLY ENGINEERED FOODS

Genetic engineering is one of the newest technologies available for producing desired traits in plants, animals, and microorganisms used for food. Put simply, genetic engineering uses molecular biology techniques to delete unwanted genes or to transfer desirable genes from one species to another. Today, genetically engineered foods (GE foods), including some cereals, snack foods, and soft drinks, have become more common. GE foods have not been found to pose adverse health effects in humans. But current evidence suggests that any technique for genetically altering plants and animals—whether by genetic engineering or more conventional breeding methods—carries the

potential to result in unintended changes in the composition of the food, such as the addition of new toxins or allergens. Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Issues (2004) proposes a new framework for examining, identifying, and evaluating systematically the compositional changes

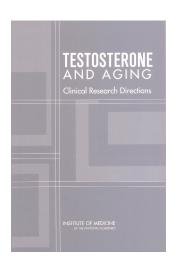
The report . . . calls for federal agencies to assess the safety of all genetically altered foods on a case-by-case basis, regardless of the method used to create them.

and potential health effects of all genetically altered foods, including GE foods, before they are sold to the public. The report, issued jointly by the IOM and the National Research Council, calls for federal agencies to assess the safety of all

genetically altered foods on a case-by-case basis, regardless of the method used to create them. The evaluations should place the greatest scrutiny on determining whether an altered food product contains new compounds or unusual amounts of naturally occurring substances that exceed the range of recommended or tolerable intake. Foods warranting further evaluation should undergo more detailed safety assessment prior to their commercialization, and post commercialization monitoring should be conducted to spot any problems that may arise over the longer term. Failure to exercise diligence in review and regulation of genetically altered foods could risk loss of public confidence and a rejection of GE foods, as has been experienced in Europe and Africa.

TESTOSTERONE REPLACEMENT THERAPY

The rapidly growing use of the hormone testosterone among men in the United States has outpaced the scientific evidence about the therapy's benefits and risks, especially the risk of developing prostate cancer. The Food and Drug Administration (FDA) has approved testosterone products for treating a limited number of conditions, particularly hypogonadism, and researchers have care-



fully evaluated this form of therapy, used primarily by younger men. Far fewer clinical studies, however, have been conducted in middle-aged and older men who are turning in increasing numbers to testosterone therapy in an effort to counter the effects of aging. Now, the National Institutes of Health and other research organizations are considering clinical trials to assess the use of testosterone in these populations, and the National Institute on Aging and the National Cancer Institute turned to the IOM for guidance.

Testosterone and Aging: Clinical Research Directions (2003) presents a road map for how clinical trials should proceed. Initial studies should focus on determining the efficacy of testosterone therapy in older men and the

nature and extent of the risks and benefits. In a coordinated set of trials, several hundred men 65 years and older should be monitored for 1 to 2 years to determine whether testosterone is effective in treating specific conditions. Limited preliminary evidence suggests that testosterone may help improve strength, sexual function, cognitive function, and general well-being. If testosterone proves effective, then a large-scale trial involving several thousand men followed over a longer time frame is warranted. All studies should involve only

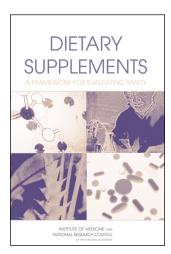
Health Risks and Public Policy: Perception and Reality

men who have been diagnosed with low testosterone levels and at least one symptom that might be remedied by the therapy, and who are not a high risk for developing prostate cancer or other prostate problems.

DIETARY SUPPLEMENTS

Consumer use of dietary supplements has increased significantly in recent years. Estimates are that more than 29,000 different supplements are on the

market and an average of 1,000 new products are introduced annually. Supplements are widely promoted for virtually every health concern, and the public has little scientifically grounded information about their safety or effectiveness. The Dietary Supplement Health and Education Act of 1994 requires that supplements be regulated as if they were foods, not drugs; that is, they are to be presumed safe and are not required to be clinically tested before being marketed. The Food and Drug Administration must prove that a particular supplement presents an unreasonable health risk in order to remove it from the market. In order to improve its ability to assess the safety of both traditional and new supplements, the FDA turned to the IOM for assistance.



Dietary Supplements: A Framework for Evaluating Safety (2003) proposes a science-based process for assessing safety, even when data are scarce. The proposed process consists of three steps: reviewing readily available information to screen for potentially hazardous substances; 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 (including from industry). The report also calls on Congress to require manufacturers and distributors to notify the FDA in a timely manner of any supplement-related health problems that they discover once products are on the market. To further boost reporting, labels on supplements should include a toll-free number that consumers and health professionals can use to report problems. To meet the growing challenge of ensuring the safety of supplements, the FDA

The report . . . calls on Congress to require manufacturers and distributors to notify the FDA in a timely manner of any supplement-related health problems that they discover once products are on the market. To further boost reporting, labels on supplements should include a toll-free number that consumers and health professionals can use to report problems.

will need sufficient funding to collect and analyze data and to carry out its various protection and education activities.

RANKING THE MOST SERIOUS RISKS TO HEALTH

Lifestyle choices—including smoking, alcohol consumption, poor diet, and physical inactivity, among others—are known to affect health and well-being. But to what extent? The answer will influence priorities for investing public funds, public policies, and individual lifestyle decisions. In recent years, the CDC and other organizations have attempted to quantify and interpret the contributions of lifestyle-related factors to preventable death. In 2004, the CDC published a study in the *Journal of the American Medical Association* that estimated the numbers of preventable deaths linked to a range of lifestyle choices—and controversy emerged, about both the study's conclusions and its methodology.

At the request of the CDC, the IOM convened a workshop to bring together experts in a variety of disciplines to review methodologies and explore broader scientific challenges involved in assessing the health effects of lifestyle choices. *Estimating the Contributions of Lifestyle-Related Factors to Preventable Death* (2005) summarizes the deliberations. No "perfect" solution emerges, but participants identify four areas where advances would be valuable. These areas include reframing the debate (although ideas differ on parameters); improving methodology (including identifying critical gaps in data, methods, and estimates); developing an action plan (including steps to improve research methods, communicate findings, and develop interventions that would exert an impact on public health); and guiding public policy and creating public health messages that provide understandable information that neither understates nor overstates the risks related to particular lifestyle choices.

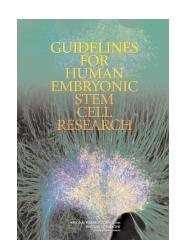
Guiding Biomedical and Clinical Research

Questions of science policy, the organization of the scientific enterprise at the federal and state levels, the most promising paths to follow in pursuing specific areas of research inquiry, and research ethics are all subjects that have been studied by Institute of Medicine (IOM) committees.

EMBRYONIC STEM CELL RESEARCH

One of the most controversial issues facing the life sciences today centers on research involving the use of human embryonic stem cells (hES cells). These cells offer enormous promise for new medical interventions to prevent and treat disease, disability, and injuries. At the same time, the use of hES cells is one of the most polarizing issues to face medical research in decades. The limitation

placed on federal funding of hES cell research has resulted in an anomalous situation where the majority of such research is being conducted using private or state-generated funds. A patchwork of federal regulations apply, most of which were not developed with such research in mind. Further, there are gaps in how well current regulations cover hES cell research. It is vital that a comprehensive and consistent approach be adopted and followed by all research institutions to ensure the integrity of this research and to avoid misadventures that further delay the acceptance and regularization of this important science.



In order to fill this void, the National Academies, with additional support from the Greenwall Foundation and the Ellison Medical Foundation, funded a study to define an

approach and set of guidelines for the regulation of stem cell research. The study was conducted jointly by the IOM and the National Research Council's (NRC) Board on Life Sciences. *Guidelines for Human Embryonic Stem Cell Research* (2005) recommends an oversight process which should assure that hES cell research is conducted in a responsible and ethically sensitive manner, and in compliance with all regulatory requirements pertaining to biomedical research in general. The guidelines cover how hES cells are obtained, stored, distributed, and used. All institutions conducting research with hES cells are urged to estab-

Guidelines for Human Embryonic Stem Cell Research (2005) recommends an oversight process which should assure that hES cell research is conducted in a responsible and ethically sensitive manner, and in compliance with all regulatory requirements pertaining to biomedical research in general.

lish oversight committees to ensure that the new guidelines will be followed. As more private entities and individual states move into hES cell research, and in light of the special concerns that such research presents, a national body should be established to assess periodically the adequacy of the guidelines and to provide a forum for a continuing discussion of hES cell research.

RESEARCH INVOLVING CHILDREN

Biomedical research has saved or improved the lives of countless children in the United States and worldwide. Still, many pediatricians and other observers have argued that infants, children, and adolescents have not shared equally with adults in advances in biomedicine. Congress and various government agencies have acted in recent years to expand research involving children. At the same time, concerns remain about the adequacy of current systems for protecting children who participate in research projects.

The Best Pharmaceuticals for Children Act of 2002 charged the IOM with reviewing current regulations and research efforts and recommending desirable

Developing an effective and adequately funded system for protecting all human research participants is a must, but safeguarding children requires extra attention and resources because they lack the maturity, and usually the legal right, to consent to experiments on their own behalf.

practices for clinical research involving children. Ethical Conduct of Clinical Research Involving Children (2004) concludes that it is possible to strike an appropriate balance in protecting children and adolescents who take part in clinical research while helping all children reap more benefits from biomedical science. Developing an effective and adequately funded system for protecting all human research participants is a must, but safeguarding children requires extra

attention and resources because they lack the maturity, and usually the legal right, to consent to experiments on their own behalf.

Existing federal rules to protect children from risky or unethical clinical research should be extended to cover all pediatric research in both the public and private sectors. Currently, the rules apply primarily to studies that are supported by the Department of Health and Human Services (DHHS) or regulated by the Food and Drug Administration (FDA), although many research institu-

Guiding Biomedical and Clinical Research

BOX 5.2 Questions Parents May Want to Ask When Considering Their Child's Participation in Clinical Research

- What is the purpose of the research? Who is paying for it?
- · Where will the research be done? How long will it last?
- What kinds of procedures and/or tests will be involved? How will they differ from what would happen if my child doesn't participate?
- What are the possible short-term and long-term harms and benefits (if any) of the study? How do they compare with treatments that my child is receiving or might receive without being in the research?
- Will the research procedure(s) hurt? If so, for how long? What can be done to prevent or limit pain? Are there other side effects?
 - · What will I have to do? What will my child have to do?
- Will I have to pay anything if my child is part of the study? Will my child or I be paid anything for participating?
- Who do I call with questions or in an emergency? What will happen if something goes wrong?
 - What will I be told during the study and after it is finished?
 - How can I withdraw my child from the study? Will that affect my child's care?
 - · Who will know that my child is in the study? What information will they get?

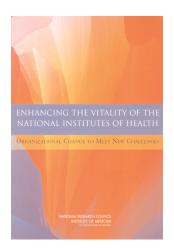
SOURCES: Adapted from Children's Hospital of Philadelphia, 2002; Children's Hospital Boston, no date; and ECRI, 2002.

Questions Parents May Want to Ask When Considering Their Child's Participation in Clinical Research. SOURCE: Ethical Conduct of Clinical Research Involving Children, p. 178.

tions voluntarily apply them to all of their studies. The government also should offer better guidance—and in more accessible formats—to clinical researchers and institutional review boards (IRBs) to help them interpret federal rules, which are more restrictive for children than adults. IRBs are responsible for approving human research, and they should be more thorough and explicit in judging whether research involving children meets the highest ethical and scientific standards. Parents and, when appropriate, children should be allowed sufficient time for questions and explanations of the research. In order to help fill gaps in information about how well current federal regulations are working in protecting children, the DHHS should develop and carry out a plan for collecting and reporting data on pediatric research and its oversight. In addition, national and local professional organizations and research institutions should voluntarily promote quality-improvement efforts in the design, review, and conduct of clinical research involving children.

THE FUTURE OF THE NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is the primary driver of biomedical research in the United States, and globally. Because the structure and quality of



scientific decision-making at the NIH has such a large impact on the productivity of the research enterprise, it is a recurring subject of debate in the research community and in Congress. Two recent IOM studies requested by Congress have addressed these issues and made recommendations to improve the administrative efficiency and scientific focus of the NIH.

Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges (2003), issued jointly by the IOM and the NRC's Board on Life Sciences, agrees that significant changes are needed and provides a blueprint for strengthening the agency's operations. In particular, it recommends modifications to improve fund-

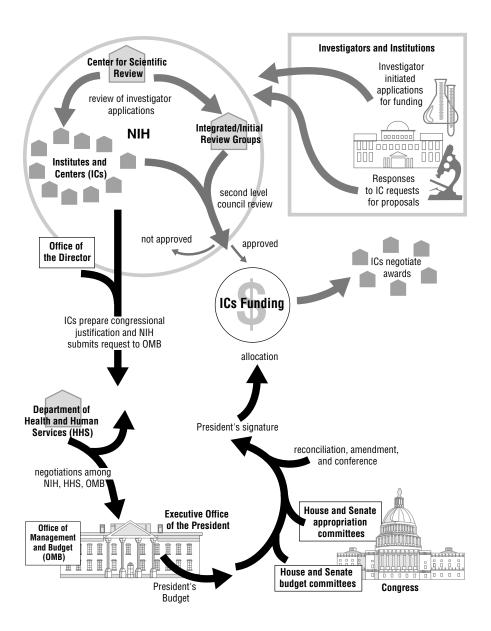
ing procedures for innovative interdisciplinary research that reflects strategic objectives and cuts across all of the institutes and centers. One fruitful area for such "trans-NIH" research is obesity, which is associated with health problems (such as heart disease, diabetes, and arthritis) that concern multiple institutes. The 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 the NIH, noting the inevitable turmoil that radical

[The report] recommends modifications to improve funding procedures for innovative interdisciplinary research that reflects strategic objectives and cuts across all of the institutes and centers. restructuring creates within an organization. Instead, it calls for a congressional process for reviewing specific proposals for change in the NIH structure.

The second study addresses the contentious question of how to apportion funding within the NIH between investigator-initiated

grants (RO1s) and support for specialized extramural centers located in universities, medical centers, and other nonprofit research institutions. Currently, approximately 9 percent of the NIH budget goes for the support of extramural centers. The centers also receive a substantial number of NIH awards to support individual investigators, group projects, research training, and other research-related efforts. The NIH supports such centers as a means of encouraging basic,

Guiding Biomedical and Clinical Research



This figure illustrates the complex processes involved in NIH's budget. SOURCE: *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, p. 40.

clinical, and population-based research or scientific problems not adequately addressed solely by RO1 grants. The centers are popular with Congress, patient advocacy groups, and the public because they can bring focus, visibility, and more funding to research on specific diseases and conditions. In order to bring greater order to the process by which funds are allocated, Congress asked the IOM to provide guidance in deciding which diseases and research areas warrant additional financial support by the establishment of new centers and which are adequately supported by present arrangements. NIH Extramural Center Programs: Criteria for Initiation and Evaluation (2004) offers recommendations for improving the classification and tracking of center programs, improving the decision processes, setting criteria for establishing new centers, resolving disagreements, and evaluating the performance of center programs more regularly and systematically. The report concludes by noting that recent changes in the nature of biomedical research have opened the possibilities for understanding complex biological systems through collaborations among multiple investigators in different fields and at different institutions and through the assembly of largescale research infrastructures and databases. These changes will support the broader moves toward expanded use of centers and other mechanisms that support collaborative research by multidisciplinary teams.

In addition to advising on the general structure and method of conducting research at the NIH, the IOM also is involved in reviewing specific fields of research for the NIH, the Department of Defense (DoD), and state governments.

One such review considered the question of how the NIH should design its research strategy to study complementary and alternative medicine (CAM). U.S. consumers are increasingly using complementary and alternative medicine, including such products and practices as herbal remedies, acupuncture, and naturopathy, instead of or in addition to conventional medicine. Yet much remains unknown about CAM therapies, and there have been few scientific studies to determine how well they actually work. Facing such knowledge gaps, the NIH and the Agency for Healthcare Research and Quality turned to the IOM for help.

Complementary and Alternative Medicine in the United States (2005) reviews what is known about these therapies and offers a comprehensive set of strategies that the NIH can use to evaluate them. The core message is that health care should strive to be both comprehensive and evidence based, and that conventional medical treatments and complementary and alternative medical treatments should be held to the same standards for demonstrating

Guiding Biomedical and Clinical Research

clinical effectiveness. The same general research principles should be followed in evaluating both types of treatments, although innovative methods to test some CAM therapies may have to be devised. Given that funding for research is

limited, the report outlines criteria to help in determining which CAM therapies to prioritize for study. The report notes, in particular, the escalating popularity of dietary supplements as well as the lack of consistency and quality in these products, which are important components of several CAM approaches. Product inconsistency hinders health professionals' abilities to guide patients on the use of supple-

... health care should strive to be both comprehensive and evidence based, and that conventional medical treatments and complementary and alternative medical treatments should be held to the same standards for demonstrating clinical effectiveness.

ments and hinders researchers' abilities to study them. Thus, Congress should work with stakeholders to amend the current system for regulating supplements in order to improve quality control and consumer protections and to create incentives for research on the efficacy of these products. As a foundation for improving the performance of both CAM and conventional practitioners, the report calls for expanded education. CAM practitioners should receive more training in research principles and methods, while all doctors, nurses, and other health care providers should learn about CAM therapies as a regular part of their professional training.

The DoD turned to the IOM for guidance about the design of a research strategy to study prion disease. 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. Because of the large numbers of service men and women stationed in countries where TSEs have emerged, the DoD 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 (2004) 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

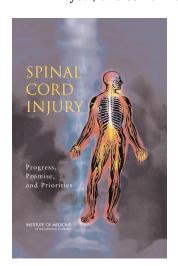
that could lead not only to better diagnostics but also to new methods of treating and even preventing TSEs. Another approach is to identify easier-to-spot surrogate markers that indicate the presence of prions or TSEs. The report

... 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 of transmissible spongiform encephalopathies.

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 of TSEs.

The state of New York asked for the IOM's help in structuring its efforts aimed at improving the understanding and treatment of spinal

cord injuries. The nation is aware of the heroic efforts of the late Christopher Reeve to encourage research that would find a cure for spinal cord injuries. It is less well known that New York and several other states have set aside funds to support research to that end. New York approached the IOM for assistance in defining a research strategy and setting priorities for its investments in this area. An estimated 11,000 people nationwide suffer spinal cord injuries each year, and some 247,000 people are living with a spinal cord injury. In recent



decades, advances in neuroscience have widely expanded the horizons of potential therapies for spinal cord injuries. What once was dogma—that the central nervous system cannot regenerate—has been dismissed, and this newly discovered potential for regeneration and repair has opened up numerous therapeutic targets and opportunities.

Spinal Cord Injury: Progress, Promise, and Priorities (2005) surveys the current status of spinal cord injury research, examines research and infrastructure needs, and provides recommendations for advancing and accelerating progress in the treatment of spinal cord injuries. Particular attention is given to translational research, which focuses on transferring basic discoveries in the lab-

oratory into clinical trials and ultimately into practice. Efforts should focus on three areas: increasing knowledge of basic neurobiology and therapeutic approaches, emphasizing and coordinating translational multidisciplinary research and clinical trials, and strengthening the research infrastructure and enhancing the training of scientists and physicians working in this field. As keys

Guiding Biomedical and Clinical Research

to accelerating progress, the NIH should establish a National Spinal Cord Injury Research Network, which would support the work of an expanded cadre of researchers and connect individual researchers and research programs, and it should establish 5 to 7 Centers of Excellence that receive adequate resources to sustain multidisciplinary basic, clinical, and translational research on spinal cord injuries. The report also offers specific recommendations for the New York Spinal Cord Injury Research Board, which requested the study.

Efforts should focus on three areas: increasing knowledge of basic neurobiology and therapeutic approaches, emphasizing and coordinating translational multidisciplinary research and clinical trials, and strengthening the research infrastructure and enhancing the training of scientists and physicians working in this field.

Informing the Future: Critical Issues in Health, Third Edition http://www.nap.edu/catalog/11469.html

The Nation's Future: Children and Youth

The Institute of Medicine's (IOM) work concerning children and youth is wide ranging. It encompasses such issues as finding better methods to assess and monitor health status; improving the nutrition for all, with special attention to vulnerable populations; developing strategies to reduce underage drinking; examining concerns about childhood vaccines; and improving children's access to better drugs and safe medical devices.

Children's health has improved considerably over the past several decades. Scientific and public health advances have reduced infant mortality and morbidity from infectious diseases and accidental causes, improved access to health care, and reduced the effects of lead and other environmental contaminants. Today's health challenges result from the interactions of influences in children's biological, behavioral, social, and physical environments. The interventions needed are therefore complex and multifaceted. Protecting and promoting health now requires considering the overall context in which children live, in addition to identifying and treating specific diseases or injuries.

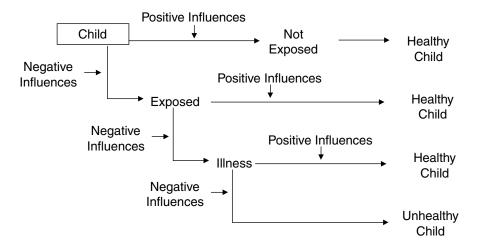
First-order questions concern how to define children's health, how to monitor influences that affect health outcomes, and how to apply appropriate

measurement tools. *Children's Health, the Nation's Wealth: Assessing and Improving Child Health* (2004) offers a new framework for measuring the health of children from birth through age 18 and provides a foundation on which to build a comprehensive children's health measurement system. One practical value of this type of measurement

Protecting and promoting health now requires considering the overall context in which children live, in addition to identifying and treating specific diseases or injuries.

system will be improved ability to target scarce resources to assure that investments make the maximum contribution to improving child health.

The new approach assesses dynamic interactions over time, and portrays their effects on health throughout different stages of childhood. The report's recommendations call on the federal government to set monitoring children's health as a national priority, and to designate a specific unit within the Department of Health and Human Services (DHHS) to take the lead in coordinating agency efforts to standardize, coordinate, and develop new data on



Where services can effect change in healthy development. SOURCE: Children's Health, the Nation's Wealth: Assessing and Improving Child Health, p. 85.

children's health. States and communities also should strengthen their efforts, with expanded federal support, to monitor children's health and coordinate

Children's Health, the Nation's Wealth: Assessing and Improving Child Health (2004) offers a new framework for measuring the health of children from birth through age 18 and provides a foundation on which to build a comprehensive children's health measurement system.

their findings with federal programs. In addition, the report identifies wide-ranging opportunities for research. Advances are needed, for example, in deciphering the unique susceptibilities of children to a variety of toxins and other environmental health hazards, and in understanding how health promotion interventions in early childhood or adolescence can modify trajectories and health outcomes in adult years. This report is from the Board on Children,

Youth, and Families, a shared activity of the IOM and the National Research Council's (NRC) Division of Behavioral and Social Sciences and Education.

ENSURING ADEQUATE NUTRITION FOR HEALTH AND DEVELOPMENT

Improving the health of America's children requires special attention to the needs of mothers and children who are at high risk of malnutrition. The Special Supplemental Nutrition Program for Women, Infants, and Children—commonly called the WIC program—provides supplemental food, nutrition education, and

The Nation's Future: Children and Youth

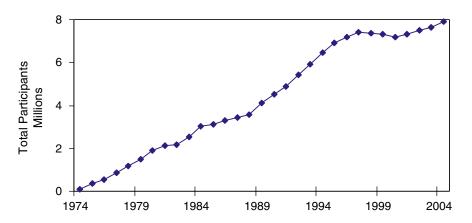
other valuable services to low-income pregnant or postpartum women, infants, and children to age 5 years. Administered by the U.S. Department of Agriculture (USDA), it is one of the nation's largest nutrition programs, reaching millions of families each year. Although WIC has demonstrated great success, a number of factors at work in today's society are creating new challenges. In response, the USDA asked the IOM to evaluate one of the program's main components, the food packages that are supplied to participants, and to determine if revisions are needed. The food packages, which WIC participants typically obtain by redeeming vouchers or checks for specific foods at local grocery outlets, have

remained largely unchanged since the program's inception in 1974.

The first report, *Proposed Criteria for Selecting the WIC Food Package* (2004), evaluated the dietary needs and intakes of the WIC-eligible population and identified which food groups and nutrients needed priority attention. *WIC Food Packages: Time for a Change* (2006)

In a key revision, the packages are restructured to encourage participants to consume more fruits and vegetables (especially fresh produce) and to switch to more whole-grain varieties of cereals and bread, shifts that are in line with new federal dietary guidelines.

builds on this foundation, proposing a number of changes to ensure that the packages promote a healthy diet and encourage breast-feeding, among other goals. Proposed packages give participants more options in their food choices and are individually tailored to the needs of specific groups, including infants, children, individuals with special dietary needs, and women (based on whether



Annual number of participants in the WIC Program constructed from monthly averages of participants, fiscal years 1974-2004. SOURCE: WIC Food Packages: Time for a Change, pp. 1-8.

they are fully breast-feeding, partially breast-feeding, or not breast-feeding). In a key revision, the packages are restructured to encourage participants to consume more fruits and vegetables (especially fresh produce) and to switch to more whole-grain varieties of cereals and bread, shifts that are in line with new federal dietary guidelines. The new packages also are attractive for breast-feeding mothers, and they would provide incentives for breast-feeding, especially full breast-feeding. Foods in the packages are commonly consumed and take into account cultural food preferences, and they are widely available in forms suitable for low-income persons who may have limited transportation, storage, and cooking facilities. Importantly, the packages overall do not cost more than current versions. Given that the proposed changes are likely to entail significant adjustments among WIC participants and could result in some unanticipated effects, the report suggests that the USDA introduce the new food packages in a number of pilot tests before they are implemented nationwide.

THE EPIDEMIC OF CHILDHOOD OBESITY

A walk down the street of any American town or city, or a visit to any school or sports event, exposes the epidemic of obesity that has overtaken the nation's children and adolescents. Because the consequences of this epidemic are less

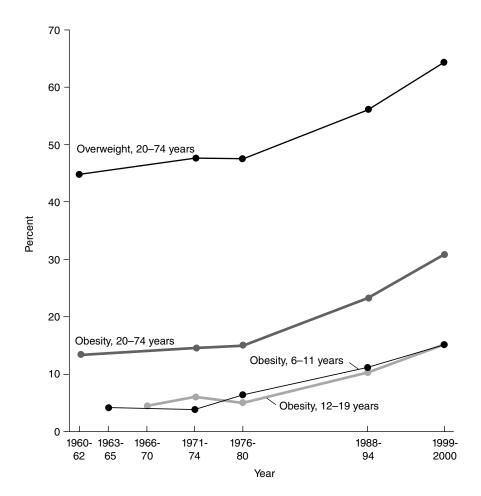
The report finds that preventing childhood obesity on a national scale will require a comprehensive approach that begins with the family and involves government at all levels, industry and media, communities, schools, and health-care professionals. A total effort will be needed to increase and improve opportunities for children to eat healthful diets and to engage regularly in physical activity—the essential keys to preventing obesity.

immediate and dramatic than the major child-hood epidemics of prior generations, such as polio, the nation has been slow to grasp the immediate and long-term consequences.

Preventing Childhood Obesity: Health in the Balance (2004) examines the various factors that promote childhood obesity, identifies promising methods for prevention, describes continuing research needs, and assigns responsibilities for action across a broad sweep of society. Requested by Congress, the report finds that preventing childhood obesity on a national scale will require a comprehensive

approach that begins with the family and involves government at all levels, industry and media, communities, schools, and health-care professionals. A total effort will be needed to increase and improve opportunities for children to eat healthful diets and to engage regularly in physical activity—the essential keys to preventing obesity. Importantly, the nation cannot wait to design a "perfect" prevention program in which every intervention has been scientifically

The Nation's Future: Children and Youth

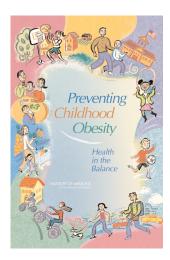


Overweight and obesity by age in the United States, 1960-2000. SOURCE: *Preventing Childhood Obesity: Health in the Balance*, p. 63.

tested ahead of time to guarantee success. Wide-ranging interventions are needed now, based on the best available evidence, while research continues to refine ongoing efforts. Some of the recommendations challenge entrenched aspects of American life and business—but the report concludes that if the nation is not willing to make some fundamental shifts in attitudes and actions, obesity's toll on the health and well-being of children and youth will only worsen.

Encouragingly, the report's recommendations are being put into practice. The report called on the DHHS to convene a national conference drawing

together representatives from industry, public heath, and consumer advocacy groups to develop guidelines for the advertising and marketing of foods, beverages, and sedentary entertainment directed at children and youth. Industry would then be responsible, on a voluntary basis, to implement the



guidelines, and the Federal Trade Commission (FTC) would monitor compliance and propose more stringent regulations if industry fails in its actions. In response, the FTC and DHHS organized a public workshop—held in July 2005—on *Marketing, Self-Regulation, and Childhood Obesity.* Stakeholders shared their perspectives on the food and beverage marketing practices to children, industry self-regulatory efforts, and current or planned initiatives taken by individual companies to respond to childhood obesity through changes in their products, packaging, and marketing guidelines and practices.

Several leading food companies have taken constructive steps to expand healthier options. Kraft Foods, PepsiCo, and General Mills all announced new initiatives in

January 2005 to increase the availability and visibility of their more nutritious products. One program involves using a prominent company logo to label branded products that meet specific nutrition criteria based on IOM report recommendations and the Food and Drug Administration's (FDA's) guidelines. Other initiatives involve shifting the mix of products available to children in schools to more nutritious options, and setting guidelines on advertising healthier options in media viewed primarily by children toward more nutritious items. All three companies have expressed support for the IOM report's proposal to strengthen industry self-regulation of food and entertainment advertising to children.

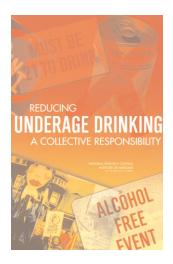
CONSEQUENCES OF UNDERAGE DRINKING

Underage drinking is a major problem in the United States. Youth drinking is associated with a variety of health risks, as well as with traffic injuries and fatalities, violence, unsafe sex, suicide, educational failure, and other behaviors that diminish the prospects of future success. And the earlier teens start drinking, the greater the danger. Numerous programs are under way to reduce or prevent underage drinking, but little is known about the comparative success of differing approaches. Congress asked the IOM and the NRC to review the evidence on various existing programs, including media-based programs, and to

The Nation's Future: Children and Youth

recommend a strategy for addressing the problem. *Reducing Underage Drinking: A Collective Responsibility* (2003) offers a comprehensive plan with 10 core components. These components include creating a national partnership dedicated to reducing underage drinking, developing a national adult-oriented media

campaign to sustain a broad national commitment and address misperceptions about youth drinking, reducing underage exposure to unsuitable messages in alcohol advertising and marketing, reducing youth exposure to unsuitable messages in the entertainment media, limiting youth access to alcohol, implementing evidence-based youth oriented interventions, mobilizing communities, increasing federal and state excise taxes to both decrease consumption and raise revenue for the plan, improving government coordination and monitoring, and implementing expanded and ongoing research and evaluation. These strategies will require shared commitment and efforts by national, state, and local governments; the alcohol and entertainment industries; retailers, restaurants, and bars; schools, colleges, and universities; law enforcement agencies; community



organizations; and parents and other adults. Without such coordinated measures, the nation—and its youth—will continue to pay the tragic costs of underage drinking.

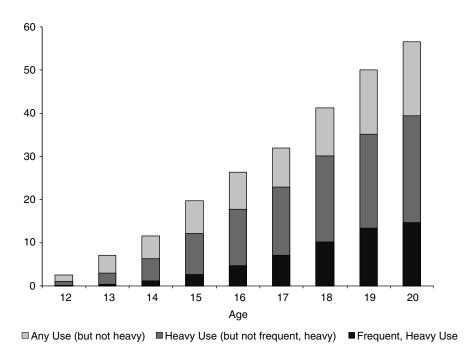
The report generated major media attention, boosted by a NRC and IOM webcast news conference and related press activities. *The New York Times, The Washington Post, The Wall Street Journal,* and *The Los Angeles Times* ran lengthy

articles (some on the front page) and supporting editorials. Television and radio gave the report ample play, and wire services circulated stories nationally. Countless local media outlets followed the breaking story.

A host of organizations enthusiastically offered their support. The American Medical Association "applauded" the report in a news release and circulated a fact sheet summarizing its findings and recommendations. The

These strategies will require shared commitment and efforts by national, state, and local governments; the alcohol and entertainment industries; retailers, restaurants, and bars; schools, colleges, and universities; law enforcement agencies; community organizations; and parents and other adults.

Governors Highway Safety Association declared itself "heartened by the recommendations" and "looking forward to working with the federal government and other partners to see that its recommendations are implemented." Mothers



Prevalence of any use, heavy use, and frequent, heavy use of alcohol in the past 30 days, for youths aged 12 to 20, 2000. SOURCE: *Reducing Underage Drinking: A Collective Responsibility*, p. 42.

Against Drunk Driving praised the findings as "an important step in finally putting underage drinking on the nation's policy and public health agenda." The Center for Science in the Public Interest announced that the report "signals a historic first step toward ending decades of complacency about one of the most damaging and widespread public health and safety threats facing society." In later recognition, Students Against Destructive Decisions gave its 2005 Outstanding Contribution Award for Academic Excellence to the study committee that produced *Reducing Underage Drinking: A Collective Responsibility*.

Government officials took notice as well. Numerous senators and representatives issued statements calling the report a national wake-up call. Importantly, governmental gears also started turning. Congress required the DHHS to form an interagency group focused on underage drinking, as the report recommends. Funds also have been appropriated for the National Ad Council to conduct a parent-oriented campaign against underage drinking. Both the Senate and the

The Nation's Future: Children and Youth

House have introduced legislation proposing the Sober Truth on Preventing Underage Drinking Act—appropriately shortened to the STOP Underage Drinking Act. The legislative proposal prominently cites the NRC/IOM report and incorporates many of its recommendations, including establishing an interagency coordinating committee, conducting a national media campaign, and providing grants to community-based coalitions to support prevention intervention efforts. "It is the sense of the Congress," the proposal states, that "a multifaceted effort is needed to more successfully address the problem of underage drinking in the United States."

CHILDHOOD IMMUNIZATION

Childhood vaccines are the single most important contribution that medicine and public health have made to protect children from disease, lifelong disability, or premature death. Yet in recent years, the very absence of the diseases that population-wide immunization have prevented has caused complacency among many parents about the need to immunize their children. Further, the hypothetical but widely publicized assertions that childhood vaccines are responsible for an increase in diagnosed cases of autism have alarmed many parents. 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.

In an effort to help ensure safety, the Centers for Disease Control and Prevention and the National Institutes of Health (NIH) asked the IOM to review some of the concerns that have emerged in recent years 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. The Immunization Safety Review Committee established to conduct the reviews included independent health professionals with wide-ranging expertise. Members had no ties to vaccine manufacturers, had not conducted research on vaccine safety, and had not served on any vaccine advisory committees. The committee

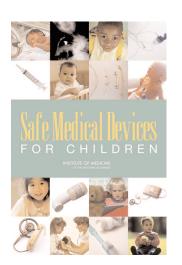
Based on a thorough review of clinical and epidemiological studies, the report concludes that neither the MMR vaccine nor the preservative thimerosal are associated with autism.

published a series of eight reports under the general title *Immunization Safety Review. Immunization Safety Review: Vaccines and Autism* (2004) addresses one of the most contentious recent issues regarding vaccine safety: the hypothesized link, proposed in 1998, between certain types of vaccines and autism. At question are the measles-mumps-rubella (MMR) vaccine administered to

children in the series of early childhood immunizations, and vaccines that contain thimerosal, a mercury-based preservative once used in some vaccines and still used in tiny amounts in some types of influenza vaccines. Based on a thorough review of clinical and epidemiological studies, the report concludes that neither the MMR vaccine nor the preservative thimerosal are associated with autism. Moreover, the hypotheses regarding how the MMR vaccine and thimerosal could trigger autism lack supporting evidence and are theoretical only. Further research to find the cause of autism should be directed toward other lines of inquiry that are supported by current knowledge and evidence and offer more promise for providing an answer.

IMPROVING THE SAFETY AND QUALITY OF TREATMENTS

Advances in biomedical science and engineering have yielded a range of medical devices that have reduced the burden of illness and injury and improved the quality of live for countless children. For example, children who once would have died from congenital heart conditions now survive with the aid of such



implanted devices as pacemakers and mechanical heart valves. The FDA is charged with the responsibility of ensuring that medical devices are safe—for children and adults alike. In 2002, Congress passed the Medical Device User Fee and Modernization Act, which, among other actions, called on the IOM to evaluate one particular component of the FDA's regulatory efforts—the postmarketing surveillance of pediatric medical devices. Children's rapid growth and development, as well as their smaller size and typically active lifestyles, can affect the longevity, effectiveness, and safety of devices that are used long term. Postmarketing surveillance is intended to detect early on any safety problems that may arise as the devices are used with larger and more varied populations and in circumstances different from those examined during pre-

market evaluations. *Safe Medical Devices for Children* (2006) details a number of shortfalls in the FDA's performance and recommends steps toward improvement. Among major problems, the agency lacks effective procedures for monitoring the status of postmarket studies that manufacturers are sometimes required to undertake, and it lacks programs for communicating information about the studies to the public. Congress should take steps to ensure that the FDA establishes a reliable system for monitoring and publicly reporting the status of postmarket studies involving medical devices used in all populations.

The Nation's Future: Children and Youth

This public database should, among other features, enable parents, health-care providers, researchers, and others to easily determine the status of studies that involve questions about the use of devices in children. In addition, Congress

should expand the FDA's authority, as part of its regulatory clearance process, to order manufacturers to conduct postmarket studies of certain types of devices that currently are exempt. Congress also should remove the current 3-year limit on studies ordered after a device is cleared or approved in cases where devices are intended for use in pediatric patients and where such issues as children's growth and development cannot be adequately addressed in shorter periods.

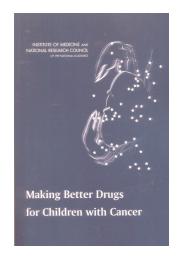
that the FDA establishes a reliable system for monitoring and publicly reporting the status of postmarket studies involving medical devices used in all populations. This public database should . . . enable parents, health care providers, researchers, and others to easily determine the status of studies that involve questions about the use of devices in children.

Congress should take steps to ensure

Cancer during childhood and adolescence has been transformed since the 1950s from a death sentence into long-term survival for most

individuals who get state-of-the-art treatment. Success has come mainly through more intense use of decades-old drugs developed originally for adult cancers. In recent years, however, the death rate from childhood cancers has remained virtually unchanged. This means simply using today's drugs is not enough—and the scientific community must find new drugs that once again will help to drive down the mortality rate from childhood cancers. *Making Better*

Drugs for Children with Cancer (2005), issued jointly by the IOM and the NRC, provides an innovative route for progress. Childhood cancers differ at the molecular level from adult cancers, and these molecular differences represent promising places to start in searching for new drug "targets." However, market forces are not sufficient to drive the search for drugs specifically tailored for children—the potential market is simply too small for industry to mount major research and development efforts that are unlikely to recoup their costs. As an alternative pathway, the report calls for establishing a new public-private partnership that joins the capabilities of the NIH, academic laboratories, and the pharmaceutical industry in a virtual research and development network to pursue drugs for childhood cancers. Such networks are relatively new, but are working well for



cystic fibrosis, tuberculosis, malaria, and other neglected diseases. Related recommendations call for the government to assume responsibility as the

The report calls for establishing a new public-private partnership that joins the capabilities of the NIH, academic laboratories, and the pharmaceutical industry in a virtual research and development network to pursue drugs for childhood cancers.

developer of last resort when an agent shows promise only in children but companies decide not to proceed with full-scale development, and for the government's scientific and regulatory bodies to work with industry to reduce the delays that currently plague pediatric clinical testing of new cancer drugs developed for adults.

Global Health

A 1997 Institute of Medicine (IOM) report, *America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests*, described the globalization of health and the interdependency of the health of peoples worldwide. It noted that the health of all people is profoundly affected by economic, social, behavioral, political, scientific, and technological factors, many of which are changing at an unprecedented pace domestically and globally. Subsequent events have affirmed the report's foresight and underscored the importance of American attention to global as well as local health. The IOM is active on multiple fronts to address global health challenges and to strengthen the capacity of scientific organizations in developing countries so that they can act locally in the same manner as the IOM in bringing good science to inform public- and private-sector actions.

ACTIVATING SCIENCE GLOBALLY TO IMPROVE HEALTH

A major investment in this regard is the IOM's leadership in forming and helping to operationalize the InterAcademy Medical Panel (IAMP), an organization of medical academies in the developed and developing world. In its form-

ative phase, the IAMP has been cochaired by the IOM's Foreign Secretary and his counterpart at the French Medical Academy. Today, more than 40 academies are members of the IAMP, and collectively they have undertaken a project to provide scientific review of the new edition of *Disease Control Priorities in Developing Countries (DCPP)*. When completed, the *DCPP* will provide a blueprint for investments in health improvement by country governments and international

The IOM is active on multiple fronts to address global health challenges and to strengthen the capacity of scientific organizations in developing countries so that they can act locally in the same manner as the IOM in bringing good science to inform public- and private-sector actions.

donor agencies. Over time, the activities of the IAMP will improve the visibility of country academies as a resource for science-based advice to their own governments.

In a parallel but more intensely engaged effort, the IOM and the National Research Council have undertaken a project to develop the capacity of academies of science and medicine in Africa to provide advice to their governments in the same manner that the National Academies advise the U.S. government. Supported by a 10-year grant from the Bill & Melinda Gates Foundation, this

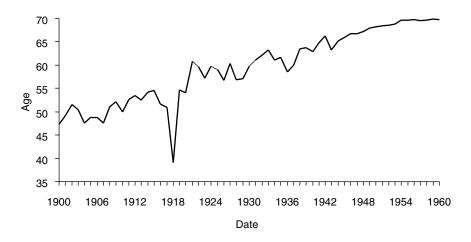
ambitious effort will work intensively with three African academies: in Uganda, South Africa, and Nigeria. In addition, four additional academies in Africa will be involved in annual symposia and other developmental efforts to enhance their role and visibility as science advisers to their countries and governments.

The need for global communication and cooperation could not be more urgent. Most infectious disease experts believe that a future influenza pandemic is inevitable—and may be on the near horizon. News coverage has highlighted this concern, especially with the recent appearance of the H5N1 "bird flu" in Asia, which also has resulted in some human cases.

Despite the clear precedent of the 1918 "Spanish flu" pandemic that killed an estimated 50 million to 100 million people, and of the more recent 1957 and 1968 pandemics that claimed millions more lives, the public appears relatively unaware of the gravity of the threat and the preparations that should be under way to mitigate loss of life and economic disruption when the virus breaks loose.

COMBATTING INFECTIOUS DISEASE

The IOM has addressed pandemic influenza in several of its activities. In June 2004, the Forum on Microbial Threats held a workshop to examine the



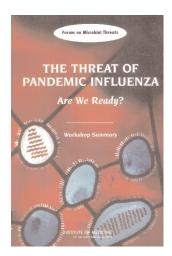
Life expectancy in the United States, 1900-1960 showing the impact of the 1918 influenza pandemic. SOURCE: *The Threat of Pandemic Influenza: Are We Ready? A Workshop Summary*, pp. 1-23.

Global Health

nation's level of preparedness. The workshop report, *The Threat of Pandemic Influenza: Are We Ready?* (2005), explores a broad range of medical, technical, social, economic, and political opportunities for enhancing pandemic preparedness and details the many obstacles that stand in the way of achieving this goal. Subsequently, the John R. La Montagne Memorial Symposium on Pandemic

Influenza Research was held in April 2005 to discuss the current state of research on pandemic influenza and to identify research gaps. The symposium marked an important step toward a combined and coordinated research effort among Department of Health and Human Services (DHHS) agencies, other governmental agencies, international partners, and the private sector. The IOM also has been asked to assist the Secretary of DHHS in additional activities to support readiness planning for the expected epidemic.

Africa lives with a permanent epidemic of malaria that is especially lethal for its children. More African children die of malaria than any other disease, and Africans of all ages suffer hundreds of millions of episodes of malarial illness each year. Malaria is considered a major health threat in



Asia, South America, and other regions of the world. Over the past several decades, chloroquine, a low-cost malaria drug, has saved millions of lives and cured billions of debilitating infections. But chloroquine is losing its effectiveness as parasites that transmit the disease to humans develop resistance to the drug. As a result, death rates from malaria now are increasing in sub-Saharan Africa, for the first time in decades.

Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance (2004) provides a detailed plan for getting new classes of antimalarial agents to all people in need. International organizations and world leaders should collectively contribute \$300 million to \$500 million annually over five years to create a global subsidy that would make new malaria treatments—called artemisinin-based combination therapies, or ACTs—widely available and at the cost of the older drug. ACTs have proved highly effective in treating malaria, and parasites have not yet developed resistance to them, but their current high cost has limited affordability for individuals and governments. The report proposes that a centralized procurement agency would use subsidy funds to buy ACTs from drug manufactures at competitive prices and then resell them at substantially lower prices to public and private distribution organizations. This strategy would take advantage of the largely private drug-distribution network that

MARA Mauritania Mali Niger <u>ARM</u>A Sudan Chad ibouti Ethiopia Central African Repu Somali Equatorial Gui Climate unsuitable ____ Malaria absent 📕 Malaria marginal / epidemic prone Malaria endemic Climate suitable nbique Namibia Botswana Lesotho, South Africa

Distribution of Endemic Malaria

Distribution of endemic malaria in Africa. SOURCE: Saving Lives, Buying Time: Economics of Malarial Drugs in an Age of Resistance, p. 25.

already successfully delivers chloroquine even into remote rural areas where malaria is endemic but where the public sector has little presence.

Shortly after the report's release, *The Lancet*, a leading medical journal, published an editorial calling the recommendations "strong and convincing" and highlighting the various advantages of an internationally subsidized system for distributing ACTs. "The IOM plan could offer a way to improve the lives of people living in the most malarious regions of the world," the journal concludes. "It deserves serious consideration." Indeed, leading organizations are getting involved. The World Bank, a major supporter of malaria control efforts, has recognized the value of the report's proposed strategy. The organization commissioned its own internal economic analysis, which reaffirmed the basic premise of an internationally subsidized system for distributing ACTs, and is con-

Global Health

sidering feasibility studies to determine whether and how to proceed with implementation.

Throughout the developing world, there has been an urgent need for practical and affordable methods for preventing human immunodeficiency virus (HIV) transmission from mother to child. The problem is especially pressing in sub-Saharan Africa, where 10 percent to 30 percent

The report proposes that a centralized procurement agency would use subsidy funds to buy ACTs from drug manufactures at competitive prices and then resell them at substantially lower prices to public and private distribution organizations.

of pregnant women carry the virus. This need has prompted a number of studies to identify antiretroviral regimens that are inexpensive, simple, and easy to implement in resource-poor locations. HIVNET 012 was one such study. Conducted in Uganda beginning in 1997, the study found that a single dose of the drug nevirapine, given to the mother at the onset of labor and to the infant within 72 hours of birth, appeared to be highly effective and safe in preventing HIV transmission. The results encouraged the manufacturer to submit a supplemental new drug application to the U.S. Food and Drug Administration to allow nevirapine to be used for this purpose. However, some observers had concerns about the scientific validity of the trial's conclusions. In response, the National Institutes of Health, which funded the study in Uganda, asked the IOM to independently analyze its design, execution, and conclusions. *Review of the HIVNET 012 Perinatal HIV Prevention Study* (2005) concludes that the trial was generally well conducted (despite some flaws in record keeping and procedural matters)

and that its findings are sound and reliable. Policymakers and other scientists therefore can rely on the study's data and conclusions.

In high-income countries, many people infected with HIV now enjoy significantly longer, good-quality lives as a result of receiving antiretroviral therapy (ART). However, most HIV-infected individuals live in low-income countries, where ART has been largely inaccessible.

In recognition of this gap, governments and international organizations have recently launched or are planning large-scale programs that will bring ART to millions of people in developing countries. *Scaling Up Treatment for the Global AIDS*

Review of the
HIVNET 012 Perinatal
HIV Prevention Study

Pandemic: Challenges and Opportunities (2004) reviews these initiatives and identifies a rational framework and key principles that will help ensure their success. One core message that the report delivers: it is critical to act now and act well

TABLE 1-1 Coverage of ART in Developing Countries, 2003 (adults by WHO region)

Region	Number of People on ART	Estimated Need	Coverage
Africa	100,000	4,400,000	2%
Americas	210,000	250,000	84%
Europe (Eastern Europe,	,	Ź	
Central Asia)	15,000	80,000	19%
Eastern Mediterranean	5,000	100,000	5%
Southeast Asia	60,000	900,000	7%
Western Pacific	10,000	170,000	6%
All WHO Regions	400,000	5,900,000	7%

SOURCE: WHO, 2003.

Coverage of ART in developing countries, 2003 (adults by WHO region). SOURCE: *Scaling Up Treatment for the Global AIDS Pandemic: Challenges and Opportunities*, p. 21.

with respect to the rollout of major new ART programs in resource-poor settings. Moreover, donors must be prepared to support effective programs over the long term, as HIV infection will persist for decades and the number of people needing treatment will increase. Programs should incorporate strategies that promote the highest levels of patient adherence to drug regimens, in order to minimize the chances of treatment failure or the development of drug-resistant strains of the virus, and they should take a "learning by doing"

It is critical to act now and act well with respect to the rollout of major new ART programs in resource-poor settings. Moreover, donors must be prepared to support effective programs over the long term, as HIV infection will persist for decades and the number of people needing treatment will increase.

approach in which monitoring and evaluation play integral roles in identifying program successes and failures. At the very heart of matters, the ART programs collectively will require tens of thousands of well-trained health care and management personnel. To help in developing this workforce, all stakeholders should support robust efforts to educate and train people in these highly affected areas. In the short term, the United States and other

developed nations can mobilize cadres of professionals and technicians to provide needed health services and assist with training efforts.

Responding to the humanitarian and health crisis of HIV/AIDS in the developing world, the president proposed, and Congress enacted, an ambitious program to provide care to 2 million HIV-infected people in 15 countries—

Global Health

primarily in Africa. Recognizing the scale and complexity of this initiative, Congress requested that the IOM conduct an evaluation of the program in both its start-up and full operational stages. The evaluation will cover all aspects of the program—prevention, treatment, and care. The first phase of the evaluation is under way; it will develop and test metrics to measure the early stages of implementation. Teams of staff and committee members will visit the countries receiving funds to assess their progress in creating the infrastructure needed to deliver care and services.

IMPROVING BIRTH OUTCOMES

The death of a mother, fetus, or newborn child is tragic whenever it occurs. Although relatively rare in the developed world, such 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. Many of these deaths are preventable, yet this important period between late pregnancy and the end of the first month of the child's life receives inadequate attention in the health care programs of most countries. *Improving Birth Outcomes: Meeting the Challenges in the Developing World* (2003) outlines a series of cost-effective inter-

ventions that can greatly reduce maternal, fetal, and neonatal mortality. Among recommendations to be adopted immediately, a skilled birth attendant (a physician, nurse, or midwife) should help with every delivery, including those that take place in the home, and adequate care should be provided to mother and child during the postpartum period (particularly the first 48 hours). In order to sustain improvement of birth outcomes over the longer term, developing

A skilled birth attendant (a physician, nurse, or midwife) should help with every delivery, including those that take place in the home, and adequate care should be provided to mother and child during the postpartum period (particularly the first 48 hours).

countries will need to increase investments in their health-care systems, often with assistance from wealthier countries and private funders. This will require devising strong health care policies supported by adequate resources and expanding public health capacity to recognize priority interventions and implement them effectively.

OUARANTINE IN THE 21ST CENTURY

The threat of global dispersal of infectious diseases and heightened concern about bioterrorism have stimulated calls for greater vigilance for microbial threats of public health significance at U.S. gateways. For years, the first line of

defense has rested with the eight quarantine stations located at major ports of entry and run by the Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine. But with 120 million people—along with countless animals and huge amounts of cargo—moving in and out of the United States annually, the quarantine stations face a daunting task in adequately protecting the nation's health. In 2003, Congress began to allocate funds to establish new quarantine stations at 17 additional major airports, seaports, and land-border crossings. In a significant departure from the recent past, both the current and new stations will be expected not only to continue their customary activities but also to play an active, anticipatory role in nationwide biosurveil-lance. In this light, the CDC asked the IOM to assess the present quarantine stations and recommend how they should evolve to meet the challenges posed by microbial threats at the nation's gateways.

Quarantine Stations at Ports of Entry: Protecting the Public's Health (2006) concludes that the stations, as they currently operate, can no longer sufficiently protect the population from the growing list of possible microbial threats. The report calls for a major restructuring of the entire quarantine system, which spans many sectors and jurisdictions and comprises an array of diverse groups and organizations, including the quarantine stations. In addition to continuing

In addition to continuing their usual functions, the quarantine stations should expand their vision and take on a new role in providing national public health leadership for all of the quarantine system's activities. their usual functions, the quarantine stations should expand their vision and take on a new role in providing national public health leadership for all of the quarantine system's activities. In exercising such leadership, the stations should work in collaboration with the Division of Global Migration and Quarantine and draw extensively on the CDC's scientific and organi-

zational capacity. One goal should be to develop a national strategic plan with uniform principles and outcomes designed to mitigate identified risks. If followed, this plan would help the disparate members of the quarantine system to prioritize their activities and focus their resources on the people, animals, and goods arriving from abroad that pose the greatest risks to the health of the U.S. population. Additionally, the quarantine stations should work closely with state and local partners in order to assure the capacity of local health departments to take on newly designated responsibilities while continuing to provide essential public health services.

Protecting the Health of Those Who Protect the Nation

The Department of Defense (DoD) and the Department of Veterans Affairs (VA) share the responsibility of assuring that the men and women of the armed services receive the best possible support to be fit while on active duty, to be protected from preventable risks, to receive the highest quality health care, and to be appropriately cared for when their service ends. This is a complex challenge. Today's warfare involves extended deployment in hazardous environments and the risks associated with combat. Exposure to high levels of various compounds—including chemicals, combustion products, and chemical warfare agents—creates potential long-term health risks. So, too, does the stress of living and working in extremely dangerous environments. The DoD faces the task of maintaining deployed forces at optimal readiness, taking all possible steps to protect their health, and delivering the highest standard of care for the injured. The DoD and VA also must assure military personnel a smooth transition from active duty to veteran status. The VA faces the long-term responsibility to provide health care and financial compensation for service-related injuries.

The Institute of Medicine (IOM) conducts studies and data analyses to assist the DoD and the VA and to protect the interests of active duty personnel, military families, and veterans.

PROTECTING THE HEALTH OF DEPLOYED FORCES

Congressional concern about the limited availability of medical countermeasures against biological warfare agents resulted in a request that the IOM review the Department of Defense's efforts in developing such vaccines and pharmaceutical products. *Giving Full Measure to Countermeasures: Addressing Problems in the DoD Program to Develop Medical Countermeasures Against Biological Warfare Agents* (2004) points to problems that include fragmentation of responsibility and authority, changing strategies that resulted in lost time and expertise, and a lack of financial commitment adequate to meet the requirements of the program's goals. The report's recommendations include making the program to develop medical countermeasures a truly high priority, creating a Medical Biodefense Agency within the Office of the Secretary of Defense to lead the program, and establishing external oversight and accountability for program performance.

PROMOTING HEALTH AND IMPROVING PERFORMANCE

The success of military operations depends greatly on the physical and mental status of the soldiers and other personnel involved. During combat operations, military commanders would like to be able to monitor the physiological and cognitive status of their troops. This ability would enable the leaders to determine when individual soldiers need to rest, eat, or consume fluids, and

The report identifies a number of promising biomarkers for predicting health deterioration . . . ; describes technologies for monitoring metabolic status under field conditions; and reviews analytical techniques, or algorithms, for interpreting the data.

to determine whether their condition has deteriorated to the point that they need to be replaced rather than risk combat injury. Monitoring Metabolic Status: Predicting Decrements in Physiological and Cognitive Performance During Military Operations (2004) examines current and needed technologies and information that can inform command decisions concerning the "readiness" of individual service members dur-

ing combat operations or training. The report identifies a number of promising biomarkers for predicting health deterioration (for example, muscle fatigue, dehydration, and impairments of renal function, cognitive function, and stress and immune responses); describes technologies for monitoring metabolic status under field conditions; and reviews analytical techniques, or algorithms, for interpreting the data. It also makes a "blue sky" forecast of research areas that may lead to revolutionary advances, such as developing techniques for using odors and tears as markers of metabolic status, developing new algorithms for integrating complex biological information, and developing genetic techniques that can help in predicting how individual soldiers will perform under the dietary and environmental conditions of combat.

Soldiers involved in short-term, high-intensity assault missions need to perform at optimal efficiency. Ensuring that they maintain proper nutrition during such missions is a continuous challenge, mainly because individuals under stress typically have diminished appetites. In fact, soldiers in combat usually

... soldiers in combat usually consume about half of the calories needed for optimal performance, leaving them prone to fatigue and mental impairments.

consume about half of the calories needed for optimal performance, leaving them prone to fatigue and mental impairments. In addition, weight and size ration constraints as well as food technology issues impose further limitations to ration design. With the number of such

missions increasing, the military is placing high priority on developing new types of light-weight rations. *Nutrient Composition of Rations for Short-Term, High*-

Protecting the Health of Those Who Protect the Nation

Box ES-1 Assumptions Regarding Assault Missions

Population

 Soldiers deployed to assault missions are male with an average body weight of 80 kg, approximately 16 percent body fat who are relatively fit and within an age range of 18– 45 years (average < 25 years).

Prior to Assault Mission

- Soldiers may be using dietary supplements and caffeine.
- Immediately prior to a mission soldiers are well hydrated, not abusing alcohol, but may be using tobacco products.

During Assault Mission

- Soldiers may be on a mission for as many as 24 out of 30 days, with each mission lasting three to seven days.
- There may be as much as 20 hr/day of physical activity, with an average of 4 hr/day of sleep. Total daily energy expenditure will be approximately 4,500 kcal.
- Soldiers are likely to have an average energy intake of 2,400–2,800 kcal/day.
- Soldiers are likely to have access to 4-5 L of chlorinated water per day.
- Some soldiers may experience diarrhea, constipation, or kidney stones during the assault mission.
- Soldiers have different electrolyte intakes before a mission than during a mission; thus, during a mission a period of biological adjustment may occur.

Ration

- The daily ration must fit within 0.12 cubic feet and weigh 3 lb or less. It will be approximately 12–17 percent water but varying greatly from one item to the other; most items will be energy dense and intermediate in moisture.
- There will be no liquid foods in the rations, although gels and powders may be provided.
- The food available during recovery periods will provide, at a minimum, the nutritional standards for operational rations.

Assumptions Regarding Assault Missions. SOURCE: *Nutrient Composition of Rations for Short-Term*, *High-Intensity Combat Operations*, p. ES-3.

Intensity Combat Operations (2005) reviews the unique circumstances of soldiers deployed in such operations and provides recommendations for designing rations that contain all of the essential nutrients and food components needed

to sustain physical and mental performance while minimizing adverse health consequences. In particular, the rations should contain set amounts of high-quality protein to preserve body lean mass, carbohydrates to provide fuel for optimal physical performance, and enough fat to enhance palatability. In addition to aiding military operations, the rations also may be of

... the rations should contain set amounts of high-quality protein to preserve body lean mass, carbohydrates to provide fuel for optimal physical performance, and enough fat to enhance palatability.

benefit to civilian workers, including firefighters and other emergency workers, who encounter similar conditions of high-stress, intense physical activity.

In the military, as in civilian life, proper body weight supports good health. Soldiers who maintain proper body weight and composition also are best suited to the physical demands of military service, including combat. *Weight Management: State of the Science and Opportunities for Military Programs* (2003) reviews the scientific evidence on factors that influence body weight and the role of gender, age, and ethnicity in weight management, and it recommends optimal components for weight loss and weight management programs that can be used across the services.

Among its recommendations, each service should provide training on diet and health (including the fundamentals of energy balance, the caloric content of

... each service should provide training on diet and health ...; education programs should include components directed at military spouses and families; and base dining facilities should incorporate "heart healthy" menus as standard fare.

foods, portion size, and the importance of maintaining high levels of daily activity); education programs should include components directed at military spouses and families; and base dining facilities should incorporate "heart healthy" menus as standard fare. Evaluation should be made an integral part of weight management programs in order to determine

their effectiveness; this will require following personnel for at least 2 to 5 years after they have participated in the programs, and preferably for their entire military careers.

TABLE 1-3 Percent Body Mass Index (BMI) of Military Branches^a by Gender Compared with the General U.S. Population

	Army		Navy	
BMI	Men	Women	Men	Women
< 18.5	0.3	0.6	0.5	1.8
18.5-24.9	39.6	58.8	30.4	52.2
25.0–29.9	46.0	34.4	52.9	38.6
30.0-34.9	13.2	5.6	14.3	6.5
35.0-39.9	0.9	0.5	1.7	0.8
≥ 40	< 0.1	< 0.1	0.2	0.1

^a No data available for U.S. Marine Corps.

Adapted from Flegal et al. (2002); Freedman et al. (2002). BMI categories for U.S. population data are $< 25, 25.0-29.9, 30.0-39.9, \ge 40$.

SOURCE: Army data: Personal communication, G. Bathalon, U.S. Army Medical

Percent Body Mass Index (BMI) of Military Branches by Gender Compared with the General U.S. Population. SOURCE: *Weight Management: State of the Science and Opportunities for Military Programs*, p. 24.

Protecting the Health of Those Who Protect the Nation

THE HEALTH OF VETERANS

Just as the IOM conducts a range of studies to advise the DoD on how to maintain optimum health status of active-duty personnel and their families, it

also advises the VA on a variety of issues relating to the health of veterans. During military service and especially in warfare, troops may be exposed to toxic agents and other conditions that may have long-term health effects. However, it can be difficult to discern whether health problems experienced by veterans are causally related to their military experiences. The Congress and many veterans groups rely on the IOM to provide

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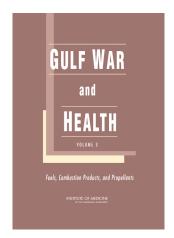
objective analyses of health effects associated with military deployments as recent as the 1991 Persian Gulf War and the conflicts in Iraq and as long ago as World War II.

HEALTH PROBLEMS FOLLOWING THE GULF WAR

Almost 700,000 U.S. troops, including many members of reserve units in the National Guard, took part in the 1991 war in the Persian Gulf. After returning home, a number of military personnel reported health problems that they believed to be service-connected. At the request of Congress, the IOM has conducted a series of studies examining the scientific and medical literature on the potential health effects of a variety of biological and chemical agents to which military personnel may have been exposed during the war. The first volume in the *Gulf War and Health* series, published in 2000, reviewed health effects related to exposure to depleted uranium, the chemical-warfare agent sarin, pyridostigmine bromide, and anthrax and botulinum toxoid vaccines. The second volume, published in 2003, examined health effects associated with exposure to pesticides and solvents.

Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants (2005) is the latest in the series. The report concludes that current scientific evidence is inadequate to determine whether there is—or is not—a causal link between exposure to the compounds in question and the majority of types of health problems experienced by Gulf War veterans. However, there is sufficient evidence of an association (if not a causal relationship) between combustion products and an increased risk of lung cancer. Military personnel may have encountered combustion products from diesel-fueled heaters in poorly venti-

lated tents, cooking stoves, vehicle exhaust systems, and oil-well fires. There also is limited or suggestive evidence that exposure to combustion products is



linked to asthma and to cancers of the nose, mouth, throat, and bladder, as well as to premature births and low birth-weight babies among women exposed during pregnancy. Similarly, there is limited or suggestive evidence that exposure to hydrazines, chemical components of the propellants used in Scud missiles, is associated with lung cancer. As with the previous reports in the series, the VA will consider these results in developing compensation programs for veterans who have developed health problems as a result of their wartime service.

Following publication of the first volume in the *Gulf War and Health* series, some veterans and other observers continued to express concerns about possible adverse

neurologic or cardiovascular effects of exposure to sarin and related chemical-warfare compounds. In response, the VA asked the IOM to review the scientific and medical literature published since the initial report. *Gulf War and Health: Updated Literature Review of Sarin* (2004) concludes that the evidence remains insufficient or inadequate to determine whether an association exists between

Gulf War and Health: Updated Literature Review of Sarin (2004) concludes that the evidence remains insufficient or inadequate to determine whether an association exists between low-dose exposures and any subsequent cardiovascular or neurological effects over the long term. low-dose exposures and any subsequent cardiovascular or neurological effects over the long term.

The IOM continues to examine a variety of health issues related to military service during the 1991 Persian Gulf War. The Committee on the Review of the Medical Literature Relative to Gulf War Veterans' Health is reviewing and evaluating the medical and scientific literature to determine what that

information, taken together, can reveal about the general health status of Gulf War veterans. The Committee on Gulf War and Health: Infectious Diseases is reviewing the literature regarding possible associations between deployment and infectious diseases, including shigellosis, leishmaniasis, sandfly fever, and diseases caused by pathogenic *Escherichia coli* bacteria. In addition, the Committee on Gulf War and Health: Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress is examining the possible long-term health effects associated with the physiological, psychological, and psychosocial

Protecting the Health of Those Who Protect the Nation

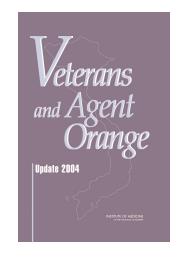
stresses of service during the 1991 Persian Gulf War as well as the current conflict in Iraq and Afghanistan.

Recently, the VA has asked the IOM to conduct a study on amyotrophic lateral sclerosis (ALS) not only in Gulf War veterans, but in all deployed military personnel since World War II. Concern has been raised recently about an increase in the incidence in ALS in all veteran populations.

VETERANS, AGENT ORANGE, AND VIETNAM

From 1962 to 1971, U.S. forces sprayed significant amounts of herbicides over Vietnam. 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 Agent Orange or to dioxin (a contaminant found in the mixture), and in 1991 Congress directed the IOM to study the issue. *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (1994) provided the first comprehensive, unbiased review of the scientific evidence regarding links between such exposure and various adverse health effects, including cancer, reproductive and developmental problems, and neurobiological disorders. The IOM has since published a series a biennial updates to this pioneering report.

Veterans and Agent Orange: Update 2004 is the latest in the series. The report builds on information gathered for previous reports, but also focuses on more recent scientific studies and other information developed since their release. Overall, the report reaffirms the conclusions of Veterans and Agent Orange: Update 2002 about specific health effects associated with herbicide exposure. There is sufficient evidence of a positive association between exposure and chronic lymphocytic leukemia, soft-tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease, and chloracne. There is limited or suggestive evidence of an association with respiratory cancers, prostate cancer, multiple myeloma, early-onset transient peripheral neuropathy, porphyria cutanea tarda, type 2 diabetes, and spina bifida in offspring of exposed



individuals. The evidence is considered limited because the influences of chance, bias, and confounding—three factors that affect the confidence that can be placed in the results of epidemiologic studies—cannot be ruled out. There is limited or suggestive evidence that there is no association with

gastrointestinal tumors and brain tumors. For other health concerns, however, the evidence remains inadequate or insufficient to determine either a positive or negative association. The report recommends that several lines of research should be continued to help answer remaining questions.

EPIDEMIOLOGICAL STUDIES OF THE HEALTH OF VETERANS

During warfare and overseas deployments, troops can be exposed to combat trauma, infectious agents, toxic chemicals, and other conditions that can cause disease or other adverse health effects, both immediately and over the longer term. The IOM's Medical Follow-Up Agency, established shortly after World War II, conducts epidemiological studies involving original research on the health and well-being of military personnel following their terms of service. For these studies, the agency obtains and analyzes military records and other health outcome data and often collaborates with researchers from academic centers and federal agencies. Since the Medical Follow-Up Agency's inception, its research has resulted in publication of more than 500 scientific papers in the peer-reviewed literature. Recent research articles from the Medical Follow-Up Agency are found in peer-reviewed journals.

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Page, W.F., Hoaglund, F.T., Steinbach, L.S., Heath, A.C., Primary osteoarthritis of the hip in monzygotic and dizygotic male twins, *Twin Research*, Vol. 6, 2003, pp. 147-151.

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Groves, F.D., Page, W.F., Gridley, G., Lisimaque, L., Stewart, P.A., Tarone, R.E., Gail, M.H., Boice, J.D., Beebe, G.W. Cancer in Korean War Navy technicians: Mortality survey after 40 years (abstract), *Annals of Epidemiology*, Vol. 12, 2002, p. 510.

Informing the Future: Critical Issues in Health, Third Edition http://www.nap.edu/catalog/11469.html

The Power of Convening

The Institute of Medicine's (IOM) convening activities—forums, round-tables, workshops, summits, and symposia—provide a different approach to exploration of issues in science and public policy. As the term suggests, convening activities draw together diverse parties who have shared interests in the health sciences. Workshops, summits, and symposia are designed to explore tightly defined topics, such as the contribution of lifestyle factors to premature death. Symposia may also be held as part of dissemination activities for a report. A series of symposia on the subject of childhood obesity has served to bring the subject, and the IOM's report, to the attention of regional media markets. Forums and roundtables, in contrast, are held to bring together a community of stakeholders interested in a broad area of health science policy for a long-term, evidence-based dialogue. Members of forums or roundtables include individuals

from the relevant scientific and practice communities; leaders from government, academia, and industry; and representatives from consumer and public interest groups. The purpose is not to directly resolve pressing issues, but rather to illuminate them through dialogue and discussion across sectors and institutions. This bringing together of individuals who reflect key institu-

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FORUMS AND ROUNDTABLES

Examples from some of the IOM's convening activities illustrate the range of topics they cover.

FORUM ON MICROBIAL THREATS

In its 1992 report *Emerging Infections: Microbial Threats to Health in the United States*, the IOM pointed to some major challenges for the public health and medical care communities in detecting and managing infectious disease outbreaks and monitoring the prevalence of endemic diseases. In response, the

Centers for Disease Control and Prevention (CDC) developed a national strategy for doing so and, with the National Institutes of Health's National Institute for Allergy and Infectious Diseases, asked the IOM to convene a Forum on Microbial

The Forum [on Microbial Threats] provides a structured opportunity, in a neutral setting, for stakeholder discussion and scrutiny of critical—and sometimes contentious—scientific and policy issues related to research on and the prevention, detection, and management of infectious diseases and dangerous pathogens.

Threats that would serve as a follow-up activity for these initiatives. The Forum provides a structured opportunity, in a neutral setting, for stakeholder discussion and scrutiny of critical—and sometimes contentious—scientific and policy issues related to research on and the prevention, detection, and management of infectious diseases and dangerous pathogens. The Forum's membership includes individuals from a wide range of disciplines and organiza-

tions in the public and private sectors, including the public health, medical, pharmaceutical, veterinarian, academic science, agricultural, and environmental communities.

In 2005, the complexities and challenges posed by infectious diseases and the corresponding trends that contribute to the emergence and reemergence of these threats continue to confound the world's public health, scientific, medical, pharmaceutical, and policymaking leaders. The vulnerability of populations in all nations has been increasingly recognized as a threat not only to personal health but also to public safety, economic stability and development, and national and international security. The Forum continues to play an important role in the identification and exploration of emerging and newly recognized threats. By fostering cross-cutting dialogues, Forum workshops help 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 workshops from the Forum on Microbial Threats illustrate the scope of its interests and activities.

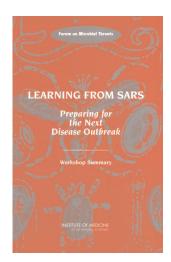
SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

The emergence of severe acute respiratory syndrome (SARS) in southern China in late 2002 and its spread in 2003 alarmed populations around the globe elicited a massive public health campaign. By the time the causative virus apparently receded from human hosts, nearly 10 percent of more than 8,000 individuals thought to be infected had died of the disease. The Forum on Microbial Threats convened a workshop to consider the lessons that might be drawn from the experience. *Learning from SARS: Preparing for the Next Disease*

The Power of Convening

Outbreak (2004) provides insight into the origin, spread, and eventual control of the virus and the epidemic it triggered. Although there have been fundamental improvements in the world's ability to respond to outbreaks of infectious disease, there remains a continuing need for expanded investments to produce robust

response systems that are better able to handle future emerging disease threats. The report discusses current activities and remaining gaps in a variety of areas, including the early detection of future outbreaks of SARS or other "novel" infectious diseases, effective communications to the public in the event of an outbreak, the promotion of research and development, strategies for containment, and the importance of multinational cooperation and collaboration in implementing such strategies.



PANDEMIC INFLUENZA

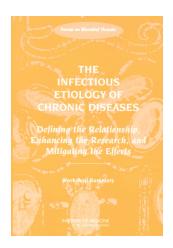
Infectious disease experts believe that a future influenza pandemic is inevitable. Yet despite the legacies of the 1918 "Spanish flu" pandemic that killed an estimated 50 million to

100 million people and of the more recent 1957 and 1968 pandemics that claimed millions more, the general public appears relatively unaware about the next "killer flu" and the devastation it could create worldwide. Meanwhile, the danger of an influenza pandemic mounts due to the emergence in Asia of a highly pathogenic strain of avian influenza (H5N1) that shows some capacity to infect humans now, and a strong probability of mutating into a human virus. The world has no capacity to produce adequate amounts of influenza vaccine against this virus. In the face of this threat, the Forum held a workshop to examine the nation's level of preparedness. *The Threat of Pandemic Influenza: Are We Ready?* (2005) describes a nation and world community that are woefully unprepared to meet the challenges that lie ahead. To help in moving forward, the report explores a broad range of medical, technical, social, economic, and political opportunities for enhancing pandemic preparedness, and details the many obstacles that stand in the way of achieving this goal.

THE RELATIONSHIP BETWEEN INFECTIOUS AND CHRONIC DISEASES

Chronic diseases cause 70 percent of all deaths in the United States, yet the factors that cause many of these conditions are poorly understood. In recent years, however, the picture has begun to change. A number of chronic diseases have been discovered to be caused by infectious agents. For example, the

human papillomavirus causes more than 90 percent of cervical cancers, and the bacterium *Helicobacter pylori* has been linked to a number of disorders, including peptic ulcers, gastric cancer, and certain types of lymphomas. Nor do connections stop with physical ailments; infections are increasingly being examined as



associated causes of or contributors to a variety of serious chronic neuropsychiatric disorders and to developmental problems, especially in children. *The Infectious Etiology of Chronic Diseases: Defining the Relationship, Enhancing the Research, and Mitigating the Effects* (2004) summarizes a Forum workshop that explored the rapid scientific advances taking place in this field. The report reviews research linking diverse infections to chronic diseases, suggests chronic diseases and syndromes that warrant further investigation, identifies difficulties in linking infectious agents with chronic outcomes, and describes broad-based strategies and research programs that can contribute to improved understanding of the complex and intriguing connections between microbes and chronic ailments.

ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES, RESEARCH, AND MEDICINE

The Roundtable on Environmental Health Sciences, Research, and Medicine (EHS Roundtable) was established in 1997. It brings together participants from the academic community, federal government agencies, industry, public interest groups, and other organizations that are engaged in activities related to envi-

Environmental health issues are often particularly polarizing, and the opportunities for evidence-based dialogue that involves government scientific and regulatory agencies, public health professionals, consumer advocates, and public officials from the state and local level are rare. The EHS Roundtable identifies problems current, ongoing, or likely to arise within the next several years and orchestrates discussions to examine strategies to address them.

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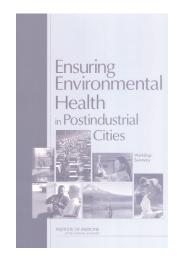
ESTABLISHING A UNIFYING VISION FOR ENVIRONMENTAL HEALTH

The first EHS 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), workshop 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 EHS Roundtable has used the overarching themes from this workshop as the framework for its convening activities.

CONSIDERING ONE CITY'S EXPERIENCE

Taking the concept "on the road," the EHS Roundtable met in Pittsburgh, a quintessential postindustrial city whose past featured the dirtiest of workplaces. Today, the city boasts cleaner air and water, new businesses and residences

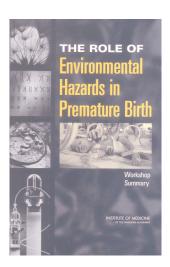
where major industrial facilities once stood, and a strong focus on developing knowledge-intensive activities in its government, industrial, and academic institutions. In *Ensuring Environmental Health in Postindustrial Cities* (2003), workshop participants use Pittsburgh as a model for examining the variety of complex issues facing many urban areas in the United States and worldwide. Several cross-cutting themes are central to strategies for achieving environmental health. Among them, cities can take advantage of the genuine concern that policymakers and the general public have for the environment, involve the public and all stakeholders early and often, form partnerships among public and private institutions and groups, integrate environmental goals with goals for economic growth, determine the true costs and benefits of possible actions, and understand the



consequences of inaction. Participants also identify a number of promising areas for research—from basic studies to better understand the effects of pollutants at the cellular level to applied studies on how to design communities that are livable and promote good health.

EFFECT OF THE ENVIRONMENT ON PREMATURE BIRTHS

Each year in the United States, more than 440,000 babies are born prematurely. Compared with full-term babies, premature infants have a much greater chance of dying, having breathing problems, or suffering such lifelong medical problems as cerebral palsy, visual and hearing disabilities, and mental retardation. Although vast improvements have been made in treating premature



infants, there has been less success in understanding and preventing prematurity. Cigarette smoking, disorders that raise blood pressure, and certain complications of pregnancy make well-recognized contributions to the risk of prematurity, but they account for only a small amount of the problem. Recent research suggests that some environmental factors, including exposure to chemical agents and toxins, also may play important, though as yet unspecified, roles in determining a woman's risk of delivering a preterm baby. An EHS Roundtable workshop to explore possible connections is summarized in *The Role of* Environmental Hazards in Premature Birth: Workshop Summary (2003). Among their observations, participants stress the importance of improved interactions across disciplines—particularly among epidemiologists, reproductive biologists, and toxicologists—to elucidate the role of

social and environmental factors, genetic factors, and gene-environment interactions in influencing preterm births. Having this information in hand will be invaluable in developing and implementing public health strategies to reduce the number of women delivering premature babies.

CLINICAL RESEARCH ROUNDTABLE

Clinical research is the essential intermediary or translation between basic science and medical treatment—yet for many years it has been a neglected part of the research enterprise. From 2000 to 2005, the Clinical Research Roundtable (CRR) played an important role in forming a shared vision to improve understanding of and support for this critical area of medical science. The CRR provided a venue where all of the primary players—including stakeholders in the clinical research enterprise who are not always represented in other venues—could discuss the challenges facing clinical research and possible approaches to resolving them. The discussions enabled a meeting of the minds among diverse parties who, absent the experience, would not have gained an appreciation for the risks, opportunities, limitations, and resources of one another.

The Power of Convening

The CRR conceptualized the relationship between medical research and clinical practice as a continuum involving two translational blocks—the first from laboratory to clinic, and the second from clinical research to improved clinical

practice. A corollary of the framing accomplishment was that the CRR created an understandable vocabulary to clearly distinguish between different elements of the translational blocks. The CRR published six workshop summaries and its members published ten independently authored articles concerning CRR discussions. In addition, 38 articles concerning CRR discussions were published in various media outlets.

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Several stakeholders referenced these works in support of their activities. For example, an article describing some of the CRR's findings—"Central Challenges Facing the Nation's Clinical Research Enterprise," published by Sung et al. in the March 2, 2003, issue of the *Journal of the American Medical Association*—was cited in the 2005 Senate Appropriation Committee Bill for the Departments of Labor, Health and Human Services, and Education and Related Agencies; in the American Association for the Advancement of Science 2003 Presidential Address; and in the National Institutes of Health's *Request for Application for Small Research Grants for Primary Care Practice-Based Research Networks*.

Discussions at the CRR also influenced the Government Accountability Office's report *Implementation of the Clinical Research Enhancement Act* and the United Kingdom's Academy of Medical Sciences' report *Strengthening Clinical Research*. In addition, the CRR provided input and influenced several National Academies reports.

Among other impacts, CRR discussions were instrumental in the Office of Human Research Protection's decision to emphasize the importance of training clinical investigators relative to the protection of human subjects in research. Discussions concerning the clinical research workforce influenced changes in training grants at the American Diabetes Association. The CRR helped shape the National Institutes of Health Roadmap, particularly regarding activities related to reengineering the clinical research enterprise. The recent Centers for Medicare & Medicaid Services' (CMS) *Coverage with Evidence Development Policy Guidance* publication, which proposes criteria under which the CMS can request formal data gathering as a condition of coverage under its existing National Coverage Determination process, was developed from CRR discussions.

The CRR also conducted several workshops on such important issues as the role of laypeople in clinical research. Recent years have brought a sea 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 speeding up the clinical research process, and in making the research enterprise more efficient. For example, public support for research on coronary heart disease and support for and participation in AIDS trials have led to declines in the numbers of deaths from those diseases. Several strategies are available to support this movement. They include striving to gain and maintain the public's trust in medical research, establishing two-way communication between scientists

and patients, and mounting educational programs to provide patients with information about clinical research that is factual and does not raise unrealistic expectations.

FOOD FORUM

Few subjects excite more interest than food—its safety, availability, health-fulness, and cost. The food and agriculture sector is large, dispersed, and fragmented. Since 1993, the Food Forum has brought together leading scientists,

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administrators, and policymakers from government, industry, academia, and the public sector to discuss issues related to food, food safety, and the array of regulations that affect how food in produced and consumed. Importantly, the Forum includes participation from the primary agencies that have regulatory authority in this area: the Food and Drug Administration and the Department of Agriculture. The Forum provides a rapid way to identify areas of

concordance among diverse interest groups and to highlight emerging crosssectoral issues. It does not produce policy recommendations or offer advice about specific issues. Recent discussions have focused on food allergies, food

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traceability, risk communication, consumer research about qualified health claims, and the food industry's role in addressing the obesity epidemic.

NATIONAL CANCER POLICY FORUM

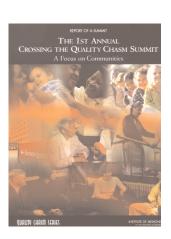
The newly formed National Cancer Policy Forum is designed to enable government, industry, academic, and other representatives to meet and confer on subject areas of mutual interest. Likely discussions may cover issues in science, clinical medicine, public health, and public policy relevant to the goals of preventing, palliating, and curing cancer. The Forum will not produce policy recommendations or offer advice regarding specific issues. Rather, it will convene interested parties, compile authoritative information, and develop possible scientific and policy options for consideration. As other forums have demonstrated, the unofficial nature of the deliberations, the neutrality of the setting, and continuity presented by regular meetings should stimulate fresh thinking and promote frank exchanges of views. One topic of early interest to the Forum is how to design a national quality of cancer care system.

WORKSHOPS AND SUMMITS

Workshops and summits differ from forums and roundtables in that they are one time events, not a continuing engagement of the same members. Workshops and summits may issue a summary of discussions or a proceedings report.

QUALITY CHASM SUMMIT

In January 2004, the IOM convened the First Annual Crossing the Quality Chasm Summit, a high-energy endeavor designed to help move the nation closer to realizing the vision of the 2001 IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century.* The summit focused particularly on issues and activities at the community level, as successful community innovations can provide a lens for viewing how to redesign care delivery systems, and involving community stakeholders can help mobilize the next round of quality improvement efforts. Communities also can serve as "laboratories of innovation" to assess what does and does not work prior to the adoption of a national policy. Additionally, working at the community level can strengthen



the interface between the personal and the population-based health systems. At the summit, representatives of innovative communities from across the country joined forces with national leaders and organizations to identify strategies for improving the quality of care for individuals with five common chronic conditions: asthma, depression, diabetes, heart failure, and advanced cancer requiring intensive pain control. Participants described strategies for advances—and opportunities for overcoming barriers to such advances—in six key areas: measurement, information and communications technology, care coordination, patient self-management support, finance, and community coalition building.

The spirit, knowledge, and commitment of the participants are reflected in the resulting IOM report, *The 1st Annual Crossing the Quality Chasm Summit: A Focus on Communities* (2004), which synthesizes the strategies and action plans proposed to improve health care. The plans will need to be further refined and modified for different settings, but the message is clear—change is possible. With future support, the IOM hopes to convene future summits that build on the vision of *Crossing the Quality Chasm* and looks forward to hearing about the continued progress that communities make in delivering high-quality care.

SCREENING FOR COLORECTAL CANCER

Colorectal cancer is the second leading cause of death from cancer in the United States. Screening adults for early cancers or their precursor lesions, followed by appropriate therapy and continued surveillance, can reduce the incidence and mortality of colorectal cancer. There is general consensus that periodic screening of adults over age 50 is a valuable preventive intervention, and today most health plans cover such screening. Yet, there is uncertainty about the specific screening strategies that should be offered to at-risk individuals. Cost-effectiveness analysis models offer a means of comparing screening strategies, but current models disagree about how alternative strategies stack up against one another. Understanding the reasons for such differences is therefore an important first step in building confidence among policymakers and the public that the models can, in fact, provide objective and informative insights into the consequences of health policy choices. Economic Models of Colorectal Cancer Screening in Average-Risk Adults: Workshop Summary (2005) explores the reasons for differences among the leading models. After running their models using a variety of standardized inputs, workshop participants discussed the five models, examining differences among their structures and assumptions and possible explanations for their varied results. Participants also examined the current state

The Power of Convening

of knowledge on key inputs to the models, with a view toward identifying areas where further research may be warranted. An obvious next step would be for modelers and clinicians to continue working together to identify and explore critical sources of variations and thereby reduce conflicting findings.

LIFESTYLE CHOICES AND HEALTH: ESTIMATING RISKS

Lifestyle choices—including smoking, alcohol consumption, poor diet, and physical inactivity, among others—are known to affect health and well-being. But to what extent? In recent years, the Centers for Disease Control and Prevention (CDC) and other organizations have attempted to quantify and interpret the contributions of lifestyle-related factors to preventable death. In 2004, the CDC published a study in the *Journal of the American Medical Association* that estimated the numbers of preventable deaths linked to a range of lifestyle choices—and controversy emerged, about both the study's conclusions and its methodology. At the request of the CDC, the IOM convened a workshop to bring together experts in a variety of disciplines to review methodologies and explore broader scientific challenges involved in assessing the health effects of lifestyle choices. *Estimating the Contributions of Lifestyle-Related Factors to Preventable Death* (2005) summarizes the deliberations. No "perfect" solution emerges, but participants identified areas where advances would be valuable.

COMMUNICATING THE RESULTS OF IOM REPORTS

Workshops also serve as important opportunities for stimulating action on completed IOM studies, and they provide an effective means of communicating the results of studies to key audiences. One example centers on an influential

IOM report—Calling the Shots: Immunization Finance Policies and Practices (2000)—on child-hood immunization. The report focused national attention on the uncertainties and instabilities of the public health infrastructure that supports immunization programs, and proposed several strategies to address these

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concerns and to provide an adequate funding level for the immunization infrastructure. To help catalyze reforms, the CDC 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 across the country designed to increase awareness of the report's conclusions and recommendations; 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 policymakers.

COMPLETE LIST OF CURRENT IOM FORUMS AND ROUNDTABLES

- Roundtable on Biomedical Engineering Materials and Applications (joint with National Research Council)
- Forum on Drug Discovery, Development, and Translation
- Roundtable on Environmental Health Sciences, Research, and Medicine
- Roundtable on Evidence-Based Medicine
- Food Forum
- Forum on Microbial Threats
- National Cancer Policy Forum

WORKSHOP SUMMARIES

CLINICAL RESEARCH ROUNDTABLE

- Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise: Workshop Summary
- The Role of Purchasers and Payers in the Clinical Research Enterprise: Workshop Summary
- Public Confidence and Involvement in Clinical Research: Symposium Summary, Clinical Roundtable, September 2000
- Exploring the Map of Clinical Research for the Coming Decade: Symposium Summary, Clinical Roundtable, December 2000
- Summary of the June 2000 Meeting of the Clinical Research Roundtable

ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES, RESEARCH, AND MEDICINE

- Rebuilding the Unity of Health and the Environment: A New Vision of Environmental Health for the 21st Century: Workshop Summary
- Cancer and the Environment: Gene-Environment Interactions: Workshop Summary
- Health and the Environment in the Southeastern United States: Rebuilding the Unity: Workshop Summary

The Power of Convening

- The Role of Environmental Hazards in Premature Birth: Workshop Summary
- Ensuring Environmental Health in Postindustrial Cities: Workshop Summary
- Environmental Health Indicators: Bridging the Chasm of Public Health and the Environment: Workshop Summary
- From Source Water to Drinking Water: Workshop Summary
- Public Health Risks of Disasters: Communication, Infrastructure, and Preparedness: Workshop Summary
- Rebuilding the Unity of Health and the Environment, The Greater Houston Metropolitan Area: Workshop Summary
- Implications of Nanotechnology for Environmental Health Research: Workshop Summary

FORUM ON MICROBIAL THREATS

- The Threat of Pandemic Influenza: Are We Ready?: Workshop Summary
- The Infectious Etiology of Chronic Diseases: Defining the Relationship, Enhancing the Research, and Mitigating the Effects: Workshop Summary
- Learning from SARS: Preparing for the Next Disease Outbreak: Workshop Summary
- The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment: Workshop Summary
- Biological Threats and Terrorism: Assessing the Science and Response Capabilities: Workshop Summary
- The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health: Workshop Summary
- Considerations for Viral Disease Eradication: Lessons Learned and Future Strategies: Workshop Summary
- Emerging Infectious Diseases from the Global to the Local Perspective: Workshop Summary
- Managed Care Systems and Emerging Infections: Opportunities for Strengthening Surveillance, Research, and Prevention: Workshop Summary
- Public Health Systems and Emerging Infections: Assessing the Capabilities of the Public and Private Sectors: Workshop Summary
- Antimicrobial Resistance: Issues and Options: Workshop Summary
- Orphans and Incentives: Developing Technologies to Address Emerging Infections: Workshop Summary

Informing the Future: Critical Issues in Health, Third Edition http://www.nap.edu/catalog/11469.html

Fellowship Programs at the Institute of Medicine

In addition to providing guidance on a range of health and policy issues, the Institute of Medicine (IOM) offers a number of fellowship opportunities for health professionals. The fellowships are designed to provide exposure to the health policy processes of government—in Congress, the Executive Branch, and through IOM committee service.

ROBERT WOOD JOHNSON HEALTH POLICY FELLOWSHIPS

For three decades, the Robert Wood Johnson Foundation® 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 IOM, followed by high-level work assignments in Congress or the Administration, almost 200 fellows have participated in shaping federal health policy. Strategically positioned at the nexus of health care, policy, and politics, fellows have frontline responsibilities in shaping the nation's legislation and regulations governing health and health care.

Fellows frequently have been cited by members of Congress, the Administration, and the health policy community as significantly improving the outcomes of the health policymaking process. For example, Mario Pacheco (2000-2001) came to his congressional assignment with a concern about obesity in the Hispanic population, and he energetically supported the successful passage of legislation that created a study of school-based vending machines and their effect on childhood nutrition.

The scientific and clinical expertise that fellows possess make valuable contributions to the deliberations that face federal policymakers. Consequently, fellows are in high demand during their year in Washington, D.C., and beyond. They are recruited aggressively for congressional committee and personal staff positions on both sides of the aisle and in both the House and Senate, and they are sought for assignments in the Administration, including in the Office of the Secretary of Health and Human Services, the Department of Defense, and the White House Office of Domestic Policy. Federal and state agencies, as well as professional organizations and associations, also aggressively pursue alumni for

their insights and newly found abilities to serve in leadership roles. As examples, Lisa Kaplowitz (1996-1997) is now deputy commissioner of emergency preparedness and response for the Commonwealth of Virginia, and Larry Kerr (1998-1999) serves in the Executive Office.

Outside of government, alumni serve as university presidents, vice chancellors, and department chairs, and as deans of schools of medicine, nursing, and public health. Many of them continue to enthusiastically maintain their connections to the workings of government, and some alumni have become official liaisons in government relations for their universities and professional societies.

SENIOR NURSE SCHOLARS-IN-RESIDENCE

In collaboration with the American Academy of Nursing and the American Nurses Foundation, the IOM manages a Senior Nurse Scholar-in-Residence Program to encourage and assist prominent nurse leaders in the articulation and assessment of health policy issues of national concern. Each scholar selects a specific health policy issue consistent with priority activities of the IOM and the nursing profession. Based at the IOM, the scholar attends orientation meetings with key officials in federal agencies and, along with other IOM fellows, meetings with congressional committees. The scholar also attends forums and meetings of the IOM and other branches of the National Academies, as well as meetings of the American Academy of Nursing, the American Nurses Foundation, and the American Nurses Association. Mentors work with each scholar to help in refining the selected policy issue and in bridging the gap between academia and the service and health policy sectors. Before the end of the residency program, the scholar is required to submit a paper for peerreviewed publication that frames academic or experiential knowledge into policy-relevant recommendations.

IOM ANNIVERSARY FELLOWSHIPS

To celebrate its 35th anniversary in 2005, the IOM is developing a new fellowship program to enable talented health science scholars early in their careers to participate in the work of the IOM and to further their careers as future leaders in the field. IOM boards, committees, and roundtables offer exceptional—and in many ways unique—learning environments that can offer early-career scholars extensive opportunities to interact with eminent

Fellowship Programs at the Institute of Medicine

researchers, policy experts, and clinicians from across the country on a range of important health issues.

The 2-year program, which is expected to begin accepting applications in 2006, will be open to individuals who hold nontenured faculty positions in any university. It will especially welcome applications from underrepresented minority candidates. Fellows will continue with their main academic responsibilities while engaging part-time in various IOM activities. A 1-week immersion in the health policy arena in Washington, D.C., a mentoring relationship with a senior IOM member, and a flexible research stipend enhance the value of the program. The IOM anticipates that the benefits of gaining new knowledge, professional connections, and broad exposure to policy leaders will attract an outstanding pool of applicants from a range of health-related disciplines.

Informing the Future: Critical Issues in Health, Third Edition http://www.nap.edu/catalog/11469.html

This chapter lists reports released by the Institute of Medicine from 2001 through 2005 as well as select older reports, grouped by subject area. Following the reports are upcoming reports expected to be released through 2006. A "...." denotes a congressionally mandated study.

RECENT REPORTS

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, IOM/NRC, 2003.
- The Dynamics of Disability: Measuring and Monitoring Disability for Social Security Programs, Health Care Services, 2002.
- **Health Insurance Is a Family Matter**, Health Care Services, 2002.
- Improving the Quality of Long-Term Care, Health Care Services, 2000.
- 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.
 - Testosterone and Aging: Clinical Research Directions, Health Sciences Policy, 2003.

CHILD/YOUTH HEALTH

- Adolescent Risk and Vulnerability: Concepts and Measurement, Board on Children, Youth, and Families, IOM/NRC, 2001.
- America's Children: Health Insurance and Access to Care, Health Care Services and Board on Children, Youth, and Families, IOM/NRC, 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, IOM/NRC, 2003.

NOTE: The Board on Global Health was previously known as the Board on International Health; the Board on Population Health and Public Health Practice was previously known as the Board on Health Promotion and Disease Prevention.

- Children's Health, the Nation's Wealth: Assessing and Improving Child Health, Board on Children, Youth, and Families, IOM/NRC, 2004.
- **Community Programs to Promote Youth Development**, Board on Children, Youth, and Families, IOM/NRC, 2001.
- Confronting Chronic Neglect: The Education and Training of Health Professionals on Family Violence, Board on Children, Youth, and Families, IOM/NRC, 2001.
- The Ethical Conduct of Clinical Research Involving Children, Health Sciences Policy, 2004.
 - From Generation to Generation: The Health and Well-Being of Children in Immigrant Families, Board on Children, Youth, and Families, IOM/NRC, 1998.
 - From Neurons to Neighborhoods: The Science of Early Childhood Development, Board on Children, Youth, and Families, IOM/NRC, 2000.
 - Getting to Positive Outcomes for Children in Child Care—A Summary of Two Workshops, Board on Children, Youth, and Families, IOM/NRC, 2001.
 - Health Insurance Is a Family Matter, Health Care Services, 2002.
 - Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders, Health Promotion and Disease Prevention, 2002.
 - Immunization Safety Review: Influenza Vaccines and Neurological Complications, Health Promotion and Disease Prevention, 2003.
 - Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism, Health Promotion and Disease Prevention, 2001.
 - Immunization Safety Review: Multiple Immunizations and Immune 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.
 - Immunization Safety Review: Vaccinations and Sudden Unexpected Death in Infancy, Health Promotion and Disease Prevention, 2003.
 - **Immunization Safety Review: Vaccines and Autism**, Health Promotion and Disease Prevention, 2004.
 - Improving Birth Outcomes: Meeting the Challenge in the Developing World, Global Health, 2003.

- Is Soccer Bad for Children's Heads?: Summary of the IOM Workshop on Neuropsychological Consequences of Head Impact in Youth Soccer, Neuroscience and Behavioral Health, 2002.
- **Juvenile Crime**, **Juvenile Justice**, Board on Children, Youth, and Families, IOM/NRC, 2001.
- **Making Better Drugs for Children with Cancer**, National Cancer Policy Board, IOM/NRC, 2005.
- Non-technical Strategies to Reduce Children's Exposure to Inappropriate Material on the Internet: Summary of a Workshop, Board on Children, Youth, and Families, IOM/NRC, 2001.
- Preventing Childhood Obesity: Health in the Balance, Food and Nutrition Board, 2005.
 - **Proposed Criteria for Selecting the WIC Food Packages**, Food and Nutrition Board, 2004.
 - Reducing Birth Defects: Meeting the Challenge in the Developing World, Global Health, 2003.
 - Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States, Health Promotion and Disease Prevention and Board on Children, Youth, and Families, IOM/NRC, 1998.
- Reducing Underage Drinking: A Collective Responsibility, Board on Children, Youth, and Families, IOM/NRC, 2003.
- Safe Medical Devices for Children, Health Sciences Policy, 2006.
 - Veterans and Agent Orange: Herbicide/Dioxin Exposure and Acute Myelogenous Leukemia in the Children of Vietnam Veterans, Health Promotion and Disease Prevention, 2002.
 - When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families, Health Sciences Policy, 2002.
 - WIC Food Packages: Time for a Change, Food and Nutrition Board, 2005.

DISEASES AND CONDITIONS (FOR HIV/AIDS, SEE PUBLIC HEALTH)

- Advancing Prion Science: Guidance for the National Prion Research Program, Medical Follow-Up Agency, 2003.
- Advancing Prion Science: Guidance for the National Prion Research Program, Interim Report, Medical Follow-Up Agency, 2003.
- 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
 - Antimicrobial Resistance: Issues and Options, Health Sciences Policy, 1998.

- **Assessment of Future Scientific Needs for Live Variola Virus,** Global Health, 1999.
- Biological Threats and Terrorism: Assessing the Science and Response Capabilities, Global Health, 2002.
- Cancer and the Environment: Gene-Environment Interactions, Workshop Summary, Health Sciences Policy, 2002.
- Case Control Study of Cancer Among US Army Veterans Exposed to Simian Virus 40-contaminated Adenovirus Vaccine, Medical Follow-Up Agency, 2004.
- Childhood Cancer Survivorship: Improving Care and Quality of Life, National Cancer Policy Board, IOM/NRC, 2003.
- **Clearing the Air: Asthma and Indoor Air Exposures**, Health Promotion and Disease Prevention, 2000.
- Como Mejorar el Cuidado Paliativo: Podemos mejorar el cuidado de personas con cancer, National Cancer Policy Board, IOM/NRC, 2003.
- Considerations for Viral Disease Eradication: Lessons Learned and Future Strategies: Workshop Summary, Global Health, 2002.
- Diet and Health: Implications for Reducing Chronic Disease Risk, Food and Nutrition Board, 1989.
- Eat for Life: The Food and Nutrition Board's Guide to Reducing Your Risk of Chronic Disease, Food and Nutrition Board, 1992.
- Economic Models of Colorectal Cancer Screening in Average-Risk Adults: Workshop Summary, National Cancer Policy Board, IOM/NRC, 2005.
- The Emergence of Zoonotic Diseases: Understanding the Impact on Animal and Human Health: Workshop Summary, Global Health, 2002.
- Emerging Infections: Microbial Threats to Health in the United States, Health Sciences Policy, 1992.
- Emerging Infectious Diseases from the Global to Local Perspective: Workshop Summary, Global Health, 2001.
- Ending Neglect: The Elimination of Tuberculosis in the United States, Health Promotion and Disease Prevention, 2000.
- Evolution of Evidence for Selected Nutrient and Disease Relationships, Food and Nutrition Board, 2002.
- Fulfilling the Potential of Cancer Prevention and Early Detection, National Cancer Policy Board, IOM/NRC, 2003.
- Fulfilling the Potential of Cancer Prevention and Early Detection: An American Cancer Society and Institute of Medicine Symposium, National Cancer Policy Board, IOM/NRC, 2003.

- Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders, Health Promotion and Disease Prevention, 2002.
- 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 Birth Outcomes: Meeting the Challenge in the Developing World, Global Health, 2003.
- Improving Palliative Care for Cancer—Summary and Recommendations, National Cancer Policy Board, IOM/NRC, 2001.
- **Improving Palliative Care for Cancer**, National Cancer Policy Board, IOM/NRC, 2001.
- Improving Palliative Care: We Can Take Better Care of People With Cancer, National Cancer Policy Board, IOM/NRC, 2003.
- The Infectious Etiology of Chronic Diseases: Defining the Relationship, Enhancing the Research, and Mitigating the Effects: Workshop Summary, Global Health, 2005.
- Interpreting the Volume-Outcome Relationship in the Context of Cancer Care, National Cancer Policy Board, IOM/NRC, 2001.
- Learning from SARS: Preparing for the Next Disease Outbreak: Workshop Summary, Global Health, 2004.
- Mammography and Beyond: Developing Technologies for Early Detection of Breast Cancer—A Non-Technical Summary, National Cancer Policy Board, IOM/NRC, 2001.
- Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer, National Cancer Policy Board, IOM/NRC, 2001.
- Marijuana and Medicine: Assessing the Science Base, Neuroscience and Behavioral Health, 1999.
- The Medicare Coverage of Routine Screening for Thyroid Dysfunction, Health Care Services, 2003.
 - Meeting the Psychosocial Needs of Women with Breast Cancer, National Cancer Policy Board, IOM/NRC, 2004.

- Microbial Threats to Health: Emergence, Detection, and Response, Global Health, 2003.
- Multiple Sclerosis: Current Status and Strategies for the Future, Neuroscience and Behavioral Health, 2001.
- Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities, Commission on Behavioral and Social Sciences and Education, National Research Council, 2001.
 - Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White, Health Promotion and Disease Prevention, 2004.
 - Reducing Birth Defects: Meeting the Challenge in the Developing World, Global Health, 2003.
 - **Reducing Suicide: A National Imperative**, Neuroscience and Behavioral Health, 2002.
 - The Resistance Phenomenon in Microbes and Infectious Disease Vectors: Implications for Human Health and Strategies for Containment: Workshop Summary, Global Health, 2003.
 - 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.
 - Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #5, Health Promotion and Disease Prevention, 2003.
 - Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #6, Health Promotion and Disease Prevention, 2004.
 - **Risk Factors for Suicide: Summary of a Workshop,** Neuroscience and Behavioral Health, 2001.
 - Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance, Global Health, 2004.

- Saving Women's Lives: Strategies for Improving Breast Cancer Detection and Diagnosis—A Breast Cancer Research Foundation and Institute of Medicine Symposium, National Cancer Policy Board, IOM/NRC, 2005.
- Saving Women's Lives: Strategies for Improving Breast Cancer Detection and Diagnosis, National Cancer Policy Board, IOM/NRC, 2005.
- Scaling Up Treatment for the Global AIDS Pandemic: Challenges and Opportunities, Global Health, 2004.
- Scientific and Policy Considerations in Developing Smallpox Vaccination Options: A Workshop Report, Health Sciences Policy, 2002.
- The Smallpox Vaccination Program: Public Health in an Age of Terrorism, Health Promotion and Disease Prevention, 2005.
- Suicide Prevention and Intervention: Summary of a Workshop, Neuroscience and Behavioral Health, 2001.
- The Threat of Pandemic Influenza: Are We Ready? Workshop Summary, Global Health, 2005.
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- **Veterans and Agent Orange: Update 2000**, 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: Herbicide/Dioxin Exposure and Acute

 Myelogenous Leukemia in the Children of Vietnam Veteran, Health

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- Veterans and Agent Orange: Length of Presumptive Period for Association Between Exposure and Respiratory Cancer, Health Promotion and Disease Prevention, 2004.

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- The Anthrax Vaccine: Is It Safe? Does It Work? Medical Follow-Up Agency, 2002.
 - Assessing the Quality of Cancer Care: An Approach to Measurement in Georgia, National Cancer Policy Board, IOM/NRC, 2005.
- An Assessment of the Safety of the Anthrax Vaccine: Letter Report,
 Health Promotion and Disease Prevention and Medical Follow-Up
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 - **Assessment of Future Scientific Needs for Live Variola Virus**, Global Health, 1999.

- **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.
 - Complementary and Alternative Medicine in the United States, Health Promotion and Disease Prevention, 2005.
- Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program, Health Sciences Policy, 2006.
 - **Dietary Supplements: A Framework for Evaluating Safety**, Food and Nutrition Board, IOM/NRC, 2005.
 - Enabling America: Assessing the Role of Rehabilitation Science and Engineering, Health Sciences Policy, 1997.
 - Federal Agency Roles in Cancer Drug Development from Preclinical Research to New Drug Approval: The National Cancer Institute And The Food and Drug Administration, National Cancer Policy Board, IOM/NRC, 2005.
- Gulf War and Health, Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines, Health Promotion and Disease Prevention, 2000.
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- Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants, Health Promotion and Disease Prevention, 2005.
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 - Interactions of Drugs, Biologics, and Chemicals in U.S. Military Forces, Medical Follow-Up Agency, 1996.
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 - Marijuana As Medicine?: The Science Beyond the Controversy, Neuroscience and Behavioral Health, 2000.
 - Medical Innovation in the Changing Healthcare Marketplace: Conference Summary, Health Care Services, IOM/NRC, 2002.
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 - Neurological, Psychiatric, and Developmental Disorders: Meeting the Challenges in the Developing World, Global Health, 2001.
 - Rational Therapeutics for Infants and Children: A Workshop Summary, Health Sciences Policy, 2000.
 - Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #6, Health Promotion and Disease Prevention, 2004.
 - Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #5, Health Promotion and Disease Prevention, 2003.
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- Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #1, Health Promotion and Disease Prevention, 2003.
- The Richard and Hinda Rosenthal Lectures 2001: Exploring Complementary and Alternative Medicine, 2003.
- **Safe Medical Devices for Children**, Health Sciences Policy, 2006.
 - Scaling Up Treatment for the Global AIDS Pandemic: Challenges and Opportunities, Global Health, 2004.
 - Statement from the IOM Council on Vaccine Development, 2001.
 - **Stem Cells and the Future of Regenerative Medicine**, Board on Neuroscience and Behavioral Health, IOM/NRC, 2001.
 - **Testosterone and Aging: Clinical Research Directions**, Health Sciences Policy, 2003.
 - Vaccines for the 21st Century: A Tool for Decisionmaking, Health Promotion and Disease Prevention, 2000.
 - When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families, Health Sciences Policy, 2002.

ENVIRONMENTAL AND OCCUPATIONAL HEALTH

- Cancer and the Environment: Gene-Environment Interactions, Workshop Summary, Health Sciences Policy, 2002.
- **Clearing the Air: Asthma and Indoor Air Exposures**, Health Promotion and Disease Prevention, 2000.
- **Damp Indoor Spaces and Health**, Health Promotion and Disease Prevention, 2004.
- Does the Built Environment Influence Physical Activity? Examining the Evidence—Special Report 282, Health Promotion and Disease Prevention and Transportation Research Board, 2005.
- Ensuring Environmental Health in Postindustrial Cities: Workshop Summary, Health Sciences Policy, 2003.
- **Ensuring Safe Food From Production to Consumption,** Food and Nutrition Board, 1998.

- Environmental Health Indicators: Bridging the Chasm of Public Health and the Environment, Health Sciences Policy, 2004.
- From Source Water to Drinking Water: Workshop Summary, Health Sciences Policy, 2004.
- **Gulf War and Health: Updated Literature Review of Sarin**, Health Promotion and Disease Prevention, 2004.
- Gulf War and Health, Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines, Health Promotion and Disease Prevention, 2000.
- Gulf War and Health, Volume 2: Insecticides and Solvents, Health Promotion and Disease Prevention, 2003.
- Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants, Health Promotion and Disease Prevention, 2005.
 - Health and the Environment in the Southeastern United States: Rebuilding the Unity: A Workshop Summary, Health Sciences Policy, 2002.
 - Keeping Patients Safe: Transforming the Work Environment of Nurses, Health Care Services, 2003.
- Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities, Commission on Behavioral and Social Sciences and Education, National Research Council, 2001.
 - Public Health Risks of Disasters: Communication, Infrastructure, and Preparedness, Health Sciences Policy, IOM/NRC, 2005.
 - Rebuilding the Unity of Health and the Environment: A New Vision of Environmental Health for the 21st Century: Workshop Summary, Health Sciences Policy, 2001.
 - Rebuilding the Unity of Health and the Environment: The Greater Houston Metropolitan Area: Workshop Summary, Health Sciences Policy, 2005.
 - Reducing the Burden of Injury: Advancing Protection and Treatment, Health Promotion and Disease Prevention, 1998.
 - The Role of Environmental Hazards in Premature Birth: Workshop Summary, Health Sciences Policy, 2003.
 - **Safe Passage: Astronaut Care for Exploration Missions**, Health Sciences Policy, 2001.
 - 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, 2001.

- Scientific Criteria to Ensure Safe Food, Food and Nutrition Board, IOM/NRC, 2003.
- Tuberculosis in the Workplace, Health Promotion and Disease Prevention, 2001.

FOOD, NUTRITION, AND DIET

- 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, 2005.
- 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 for Water, Potassium, Sodium, Chloride, and Sulfate, Food and Nutrition Board, 2004.
- 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.
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UPCOMING REPORTS

CHILD/YOUTH HEALTH

Adolescent Health and Development, Board on Children, Youth, and Families, IOM/NRC

Disability in America, Health Sciences Policy

- Ethical Issues in Housing-Related Health Hazard Research Involving Children, Youth, and Families, Board on Children, Youth, and Families, IOM/NRC
- Workshop on the Synthesis of Research on Adolescent Health and Development, Board on Children, Youth, and Families, IOM/NRC Understanding Premature Birth and Assuring Healthy Outcomes, Health Sciences Policy

DISEASES AND CONDITIONS

Cancer Control in Low- and Middle-Income Countries, Global Health Cancer Survivorship: Improving Care and Quality of Life, Institute of Medicine

Shortening the Time Line for New Cancer Treatments, Institute of Medicine

DRUGS, DEVICES, AND BIOLOGICS

- Assessment of the U.S. Drug Safety System, Population Health and Public Health Practice
- Identifying and Preventing Medication Errors, Health Care Services Shortening the Time Line for New Cancer Treatments, Institute of Medicine

ENVIRONMENTAL AND OCCUPATIONAL HEALTH

Asbestos: Selected Health Effects, Population Health and Public Health Practice

Ethical Issues in Housing-Related Health Hazard Research Involving Children, Youth, and Families, Board on Children, Youth, and Families, IOM/NRC

Evaluating Measures of Health Benefits for Environmental, Health, and Safety Regulation, Health Care Services

Review of NIOSH Research Programs (joint with NRC), Health Sciences Policy

FOOD, NUTRITION, AND DIET

Food Chemicals Codex, Food and Nutrition Board

Food Marketing and the Diets of Children and Youth, Food and Nutrition Board and Board on Children, Youth, and Families, IOM/NRC

- Mineral Requirements for Cognitive and Physical Performance of Military Personnel, Food and Nutrition Board
- Nutrient Relationships In Seafood: Selections To Balance Benefits And Risks, Food and Nutrition Board
- **Progress In Preventing Childhood Obesity**, Food and Nutrition Board and Population Health and Public Health Practice

GLOBAL AND INTERNATIONAL HEALTH

Cancer Control in Low- and Middle-Income Countries, Global Health

President's Emergency Plan for AIDS Relief [PEPFAR] Implementation Evaluation, Board on Global Health and Board on Children, Youth, and Families, IOM/NRC

HEALTH CARE PROFESSIONAL TRAINING, EDUCATION, AND WORKFORCE

Sleep Medicine and Research, Health Sciences Policy

President's Emergency Plan for AIDS Relief [PEPFAR] Implementation
Evaluation, Board on Global Health and Board on Children, Youth, and
Families, IOM/NRC

HEALTH CARE SERVICES, QUALITY OF CARE

- Cancer Survivorship: Improving Care and Quality of Life, Institute of Medicine
- Crossing the Quality Chasm: Adaptation to Mental Health and Addictive Disorders, Health Care Services
- Evaluating Measures of Health Benefits for Environmental, Health, and Safety Regulation, Health Care Services
- The Future of Emergency Care in the United States Health System,
 Health Care Services
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- Redesigning Health Insurance Benefits, Payment and Performance Improvement Programs: Pay for Performance, Health Care Services
- Redesigning Health Insurance Benefits, Payment and Performance
 Improvement Programs: Performance Measures, Health Care Services
- Redesigning Health Insurance Benefits, Payment and Performance Improvement Programs: Quality Improvement Organizations' Evaluation, Health Care Services

HEALTH SCIENCES AND BIOMEDICAL RESEARCH

Assessing Interactions Among Social, Behavioral, and Genetic Factors in Health, Health Sciences Policy

Ethical Considerations for Revisions to the DHHS Regulations for Protection of Prisoners Involved in Research, Health Sciences Policy Increasing Rates of Organ Donation, Health Sciences Policy

Review and Assessment of the National Institutes of Health's Strategic Research Plan to Reduce and Ultimately Eliminate Health Disparities, Health Sciences Policy

Review of NASA's Bioastronautics Critical Path Roadmap (BCPR), Health Sciences Policy

Review of NIOSH Research Programs (joint with NRC), Health Sciences Policy Shortening the Time Line for New Cancer Treatments, Institute of Medicine Sleep Medicine and Research, Health Sciences Policy

Traumatic Brain Injury, Health Sciences Policy

Understanding Premature Birth and Assuring Healthy Outcomes, Health Sciences Policy

MENTAL AND BEHAVIORAL HEALTH, NEUROSCIENCE

Assessing Interactions Among Social, Behavioral, and Genetic Factors in Health, Health Sciences Policy

Crossing the Quality Chasm: Adaptation to Mental Health and Addictive Disorders, Health Care Services

Sleep Medicine and Research, Health Sciences Policy

Traumatic Brain Injury, Health Sciences Policy

MILITARY AND VETERANS

- Advances in Technology and the Prevention of their Application to Next Generation Biowarfare Agents, Global Health
- Disposition of the Air Force Health Study, Population Health and Public Health Practice
- Gulf War and Health: Infectious Diseases, Population Health and Public Health Practice
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- Gulf War and Health: Review of the Medical Literature Relative to Gulf War Veterans' Health, Population Health and Public Health Practice

- Health Effects in Vietnam Veterans of Exposure to Herbicides (Agent Orange), Population Health and Public Health Practice **Injection Drug Users Natural History**, Medical Follow-Up Agency Long-term Health Effects of Participation in Project SHAD, Medical Follow-Up Agency
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MINORITY HEALTH

Ethical Considerations for Revisions to the DHHS Regulations for Protection of Prisoners Involved in Research, Health Sciences Policy Review and Assessment of the National Institutes of Health's Strategic Research Plan to Reduce and Ultimately Eliminate Health **Disparities**, Health Sciences Policy

PUBLIC HEALTH AND PREVENTION

- Advances in Technology and the Prevention of their Application to Next Generation Biowarfare Agents, Global Health
- **Asbestos: Selected Health Effects, Population Health and Public Health Practice**
- Assessment of the U.S. Drug Safety System, Population Health and Public Health Practice
- Food Marketing and the Diets of Children and Youth, Food and Nutrition Board and Board on Children, Youth, and Families, IOM/NRC
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PUBLIC POLICY

Assessment of the U.S. Drug Safety System, Population Health and Public **Health Practice**

Disability in America, Health Sciences Policy

Ethical Considerations for Revisions to the DHHS Regulations for Protection of Prisoners Involved in Research, Health Sciences Policy Improving the Disability Decision Process: SSA's Listing of Impairments and Agency Access to Medical Expertise, Medical Follow-Up Agency **Increasing Rates of Organ Donation**, Health Sciences Policy Review and Assessment of the National Institutes of Health's Strategic Research Plan to Reduce and Ultimately Eliminate Health **Disparities**, Health Sciences Policy

WOMEN'S HEALTH

Understanding Premature Birth and Assuring Healthy Outcomes, Health Sciences Policy

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