

### Informing the Future: Critical Issues in Health, Fourth Edition

Institute of Medicine

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# Informing the Future

CRITICAL ISSUES IN HEALTH FOURTH EDITION

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

**INSTITUTE OF MEDICINE** 

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

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For more information about the Institute of Medicine, visit the IOM home page at: www.iom.edu.

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

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

—Goethe



Advising the Nation. Improving Health.

OF THE NATIONAL ACADEMIES

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## The Institute of Medicine: Advising the Nation, Improving Health

The story of human civilization is the story of knowledge: its pursuit and application. Nowhere is this more evident than in efforts to improve people's health and well-being.

The detailed observations of the ancient Egyptians led to cultural practices of hygiene and diet that would place them ahead of many developing nations today.

The Grefi medical schools of the fifth century B.C. began paving the way for the modern scientific pursuit of medicine and put the fundamentals of human biology on paper.

Louis Pasteur's work on germ theory in the 1800s ushered in the era of antiseptics, antibiotics, vaccination, and pasteurization—innovations that have saved untold millions of lives and improved the quality of life for nearly every person on the planet.

The efforts of James Watson and Francis Crick, who deciphered the structure of DNA in the 1950s, laid the groundwork for a deeper understanding of how the human body works, fails, and fights.

In each age of medicine, an increase in knowledge has led to improved public health. The work of great scientific minds has been bolstered, supported, and amplified by public policy, public opinion, and national action. Without massive infrastructure investments during World War II, for example, penicillin would have remained an interesting lab experiment.

The decisions that guide and shape these advances are profoundly important and often politically charged. Today, health care sits at the top of the nation's agenda. Issues such as the rising cost of health care and emerging threats such as avian flu and bioterrorism have created new challenges to the health care system. Meanwhile, advances in stem cells, nanotechnology, and genomics have brought the ethics of medicine further into the arena of politics, creating increasingly complex challenges for policy makers and scientists alike.

Against this backdrop, the need for independent, evidence-based information and analysis has become even more important. The Institute of Medicine (IOM), the health arm of the National Academies, meets this need.

Standing outside government, the IOM serves as adviser to the nation to improve health. As an independent, scientific authority, the IOM strives to provide advice that is unbiased, based on evidence, and grounded in science. The mission of the IOM embraces the health of people everywhere.

The IOM commitment to public service is locked into the words of its charter, where the IOM is described as

[A] national institution, composed of individuals of distinction and achievement, committed to the advancement of the health sciences and education and to the improvement of health care.

In addition to IOM members, more than 2,000 other experts—scientists, health professionals, legal experts, organizational executives, engineers, humanists, civic leaders, patient advocates, and others—volunteer to help the IOM answer the world's most challenging health questions: from AIDS to vaccine safety, from breast cancer to childhood obesity, and from the quality of medical care to public health preparedness.

Members and other experts all serve without compensation by conducting studies, participating in workshops and roundtable discussions, serving as reviewers, and supporting the IOM's many activities designed to improve health. The IOM adheres to strict standards to avoid conflicts of interest for the tasks assigned to its committees, and it benefits from the breadth of perspective brought by the diversity of backgrounds and expertise of its volunteers.

The IOM regularly undertakes studies to provide authoritative and scientifically balanced recommendations to Congress, to government agencies at all levels, to health professionals and institutions, to community organizations, and to the public. The IOM convenes roundtables, workshops, and symposia that provide an opportunity for public- and private-sector experts to discuss contentious issues in a neutral, open environment, which facilitates an evidence-based dialogue. Although many of its studies and other activities are requested and supported by the federal government, the IOM itself, private industry, foundations, and state and local governments may also advance and support ideas for studies or other activities that promote the public's health.

#### The Institute of Medicine

In addition, the IOM is home to several fellowship programs. For more than 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.

Another hallmark of the IOM process is its rigorous peer review. Every report that the IOM produces must first undergo extensive review and evaluation by a group of experts who are anonymous to the authoring committee, and whose names are revealed only when the study is published. The results of these peer-reviewed deliberations have been relied upon for nearly 40 years to provide policy makers and the American people with objective advice that is grounded in evidence.

The ultimate goal of all of these activities is to inform decision making and to improve health. By identifying scientifically sound evidence and presenting it in a well-reasoned and rational context, the IOM has become recognized as a trustworthy and apolitical national resource on topics related to biomedical science, medical care, and human health. IOM studies can be quite focused, as evidenced by the *Review of NASA's Space Flight Health Standards-Setting Process: Letter Report* (2007). They can also be sweeping in both scope and impact, spanning multiple academic disciplines, industries, and even international borders. For example, Congress asked the IOM to evaluate the implementation of the President's Emergency Plan for AIDS Relief, resulting in *PEPFAR Implementation: Progress and Promise* (2007), which offered evidence-based recommendations for improving the program.

Leveraging knowledge to improve health can have a lasting impact on the lives of everyday people:

—Since 1998, the IOM's ongoing work on nutrition has been represented in its Dietary Reference Intakes (DRI) series, a complete and thorough analysis of human nutrition that examines every nutrient in thousands of applications and variations. The DRIs form the basis for nearly all state and federal nutrition policy and serve as the scientific foundation for industry efforts to improve health through the removal of trans fats from foods and the education of consumers about nutritional issues.

—The IOM's *Crossing the Quality Chasm* series (2000–2007) has identified the unacceptable costs of medical errors and the challenges faced by the health care community in raising the overall standard of care for all Americans. The series

has been instrumental in guiding state-level patient safety centers to track and analyze medical error data. Reports and summits in the series have put forth actionable, real-world advice for practitioners and administrators at both the local and the national levels.

—The IOM's work on childhood obesity has been groundbreaking and influential. The 2005 report *Preventing Childhood Obesity: Health in the Balance* outlined the nature and scope of the childhood obesity crisis and offered a blueprint for action. The Robert Wood Johnson Foundation requested that the IOM continue this work, which resulted in *Progress in Preventing Childhood Obesity: How Do We Measure Up?* (2006). This renewed call for accountability again galvanized the debate and has kept the pressure on government and industry alike. It also provided meaningful measurements of the concrete work that has been done since 2005 and highlighted the tremendous efforts that are still necessary to improve the health of America's children.

These are just a few examples of the IOM's impact. This booklet opens a window into the broader work of the IOM and highlights some of the policy areas that will be critical to the nation's well-being in the years to come.

The main section of this booklet illustrates the work that IOM committees have done in several topic areas. There follows a description of IOM's convening and collaborative activities—those cases in which the IOM's unique position has brought people together in a common place and time to share ideas and discuss possible solutions. The last section provides a comprensive bibliography of IOM reports published since 2005.

## Quality of Care: A Health Professional Duty

Health care is a vast enterprise that now accounts for more than one in every seven dollars spent in the U.S. economy. Despite spending that dwarfs that of every other country in the world, more than 15 percent of Americans had no health care insurance in 2005, and the United States lags bind dozens of other nations on health measures such as infant mortality and life expectancy. Despite striking scientific advances and new therapies, too often the quality of care that every citizen deserves is not delivered.

Is it possible to attain a high-quality health system that functions well for every American and that is efficient and affordable in its operation? How will the nation cope as new technologies and an aging population add to the pressures on the system?

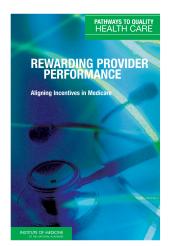
To help answer these questions, the Institute of Medicine (IOM) has focused on a fundamental triad of interdependent goals for improving the U.S. health system: access, quality, and cost of care. The IOM's recent work in this area includes proposals to reform the system of payment so as to improve both the efficiency and quality of care in America, to face up to the problem of the stressed emergency care system, and to improve tools for decisions in the Social Security disability process.

#### **REFORMING PAYMENT**

In 2006, Medicare provided more than \$300 billion in health care benefits to more than 42 million Americans. Yet this massive expenditure provided health security for only a fraction of U.S. citizens and optimal care for fewer still.

Medicare—and most private insurance—reimburses providers for the individual services delivered to treat injury and illness, but it does not provide comprensive coverage. By focusing on individual treatments, Medicare does not pay for coordination of care for patients whose health care involves multiple providers, nor does it offer incentives to improve patients' overall health over time. Each of these deficiencies is a roadblock on the path to quality health care. To address these problems, Congress turned to the IOM for strategies for change, which resulted in a series of studies *Pathways to Quality Health Care* (2006).

The first report in the series, *Performance Measurement: Accelerating Improve- ment* (2006), reviewed the available measures of health care performance that could be used for public reporting and recommended principles for a national measurement and reporting system. The second report, *Medicare's Quality Improve- ment Organization Program: Maximizing Potential* (2006), offered ways to strengthen the technical assistance function of Medicare's Quality Improvement Organizations so that all providers are ready to provide the highest quality of care. The



third and final report, *Rewarding Provider Performance: Aligning Incentives in Medicare* (2007), took an important step further by analyzing the risks and benefits of instituting a pay-for-performance program within Medicare to encourage a more value-driven health care system.

If implemented, pay for performance would fundamentally change the way Medicare works. Currently, the reimbursement system encourages quantity of care (performing more procedures) rather than quality (keeping patients healthy).

The third report acknowledged that changing the practice patterns of America's physicians is a huge challenge. Most physicians practice in small groups of two or three and lack the economies of scale necessary for optimal quality and

**TABLE 1-1** Estimated Medicare and National Health Expenditures, 1975–2004

Expenditures	1975 (billions of dollars)	1985 (billions of dollars)	1995 (billions of dollars)	2004 (billions of dollars)	Increase 1975–2004 (percent)
Medicare National health	16.3	71.4	182.4	309.0	1,796
expenditures Medicare expenditures as percentage of national health	133.6	441.9	1,020.4	1,877.6	1,305
expenditures	12.2	16.2	17.9	16.5	35

SOURCE: CMS, 2006.

Estimated Medicare and National Health Expenditures, 1975–2004. SOURCE: Rewarding Provider Performance, p. 24.

#### Quality of Care: A Health Professional Duty

efficiency improvements. The options and recommendations presented in the report discussed the implementation of such a program in stages to improve the return on health care investments. Although focused on Medicare, the report has many applications for payers and consumers in the private sector. Since the final report's release, the *New England Journal of Medicine* has published a number of articles that explore the implications of its recommendations.

In 2006, Medicare provided more than \$300 billion in health care benefits to more than 42 million Americans. Yet this massive expenditure provided health security for only a fraction of U.S. citizens and optimal care for fewer still.

Medicare needs incentives to promote better health outcomes as well as better quality and efficiency in services. Pay for performance creates these incentives, encouraging improved quality and value. To promote the participation of as many health care providers as possible, the program should reward those who improve their performance significantly, as well as those who meet or exceed designated thresholds of excellence.

#### FIXING EMERGENCY MEDICAL SERVICES

The United States is facing a national crisis in emergency care. The nation's emergency and trauma care system has made tremendous strides over the past few decades, but insufficient funding and uncompensated care have sapped its capacity. Despite the heroic, lifesaving feats performed every day by individuals in emergency departments (EDs) and ambulance services, the nation's emergency medical system as a whole is overburdened, underfunded, and highly fragmented.

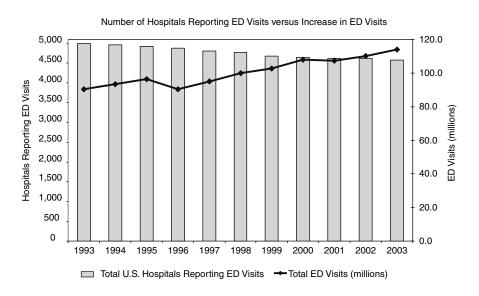
The precarious state of emergency care is documented in the IOM's three-report series *Future of Emergency Care* (2007). The facts are startling: ambulances are turned away from emergency departments once every minute, and ED patients admitted to the hospital often wait hours or even days for an in-patient bed. Already strained by routine care, the system is ill-prepared to handle surges from disasters. A hurricane, terrorist attack, or disease outbreak—even a fire in an office building—can quickly overwhelm a local ED.

The IOM Committee on Emergency Care was convened in 2003 to examine the state of emergency care in the United States, to create a vision for the future of emergency and trauma care, and to make recommendations to help the nation achieve that vision. It recommended that Congress allocate significant funds to ensure that America's emergency departments, trauma centers, and medical first

responders are fully equipped and ready to provide prompt and appropriate care. The committee also called for action to reduce crowding in emergency rooms, boost the number of specialists involved in emergency care, and create collaboration between all emergency medical services in a geographical area to ensure

... ambulances are turned away from emergency departments once every minute, and ED patients admitted to the hospital often wait hours or even days for an in-patient bed. that patients are sent to the most appropriate facilities. Immediately, professional societies and news groups responded to the alarm sounded by these reports, convening symposia and providing thorough media coverage. Recently, legislation based on the committee's recommendations has been introduced in Congress by Senator Barack Obama.

Hospital-Based Emergency Care: At the Breaking Point (2007) explored the changing role of the hospital emergency department and the national epidemic of overcrowded EDs and trauma centers. In 2003, emergency departments received nearly 114 million patients—a 26 percent increase over the past decade, but during the same period, the United States suffered a net loss of 703 hospitals and 425 emergency departments.



Hospital EDs versus ED visits. SOURCE: Hospital-Based Emergency Care: At the Breaking Point, p. 38.

#### **Quality of Care: A Health Professional Duty**

The wide range of issues covered in this report included

- the role and impact of the emergency department within the larger hospital and health care system;
- patient flow and information technology;
- workforce issues across multiple disciplines;
- patient safety and the quality and efficiency of emergency care services;
- basic, clinical, and health services research relevant to emergency care;
   and
- the special challenges of emergency care in rural settings.

Emergency Medical Services at the Crossroads (2007) described the development of emergency medical services (EMS) systems over the past 40 years—the roots of the fragmented structure that exists today. Ambulances were diverted 501,000 times in 2003 because of overcrowded EDs. EMS agencies do not effectively coordinate services with EDs and trauma centers, which results in poor management of the regional flow of patients.

To address the strengths, limitations, and future challenges of EMS, this report examined

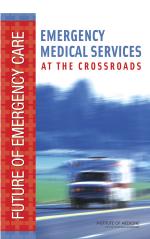
- the evolving role of EMS as an integral component of the overall health care system;
- EMS system planning, preparedness, and coordination at the federal, state, and local levels;
- EMS funding and infrastructure investments;
- EMS workforce trends and professional education; and
- EMS research priorities and funding.

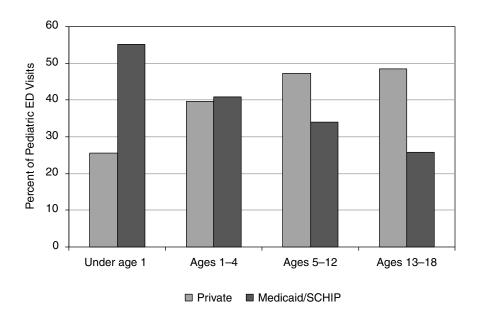
Emergency Care for Children: Growing Pains (2007) detailed the unique challenges of providing critical care for injured and seriously ill children. The nation's emergency care system is not well prepared to handle seriously ill or injured pediatric patients. Although children make

and seriously ill children. The nation's emergency care system is not well prepared to handle seriously ill or injured pediatric patients. Although children make up more than a quarter of all ED and trauma patients, only 6 percent of hospital EDs have all the supplies deemed essential for managing pediatric emergencies.

The report analyzed the U.S. emergency care system with specific regard to

• the role of pediatric emergency services as an integrated component of the overall health system;





Percentage of pediatric ED visits covered by private insurance or Medicaid/State Children's Health Insurance Program (SCHIP). SOURCE: Emergency Care for Children: Growing Pains, p. 68.

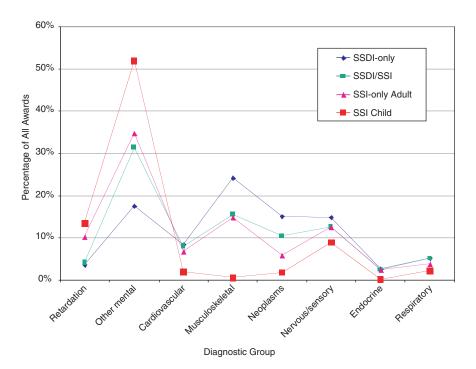
- system-wide pediatric emergency care planning, preparedness, coordination, and funding;
- pediatric training in professional education; and
- research in pediatric emergency care.

#### MAKING BETTER DECISIONS

The challenge of funding Social Security retirement benefits for "Baby Boomers" is well known. Less understood is the more immediate and severe challenge facing the Social Security disability benefits system. Approximately 2.5 million people apply for disability benefits each year. The Social Security Administration (SSA) expects the number of Social Security Disability Insurance (SSDI) beneficiaries to increase by 26 percent between 2005 and 2015. While this sharp increase in SSDI applications has many root causes, the insurance crisis is a significant and little-examined driver: SSDI status brings with it eligibility for Medicare.

In order to receive benefits, adult applicants for SSDI must be evaluated for their ability to work. The SSA uses a time-saving medical screening tool called the Listing of Impairments (the Listings) to identify individuals who meet the Social

#### Quality of Care: A Health Professional Duty



Distribution of initial awards of Social Security disability benefits among program and selected diagnostic groups, 2004 (percentage of all awards). SOURCE: Improving the Social Security Disability Decision Process, p. 40.

Security definition of disability. If the Listings work effectively, a high percentage of individuals who meet the SSA definition of disability are identified in the initial evaluation. If the Listings are out of date, a high proportion of those who will eventually be found eligible are deemed ineligible in initial screenings. This launches a lengthy and expensive appeals and reconsideration process. The SSA is concerned that because of the inaccuracies in the existing system, too many applicants are initially rejected, and costs are increased while quality and timeliness of care decrease.

At the request of the SSA, the IOM formed a committee to study the issue. Its report, *Improving the Social Security Disability Decision Process* (2007), addressed the medical aspects of disability determination and recommended improvements.

Specifically, the report recommended that the SSA investigate the reliability and validity of the Listings as a tool for identifying the truly disabled and incorporate condition-specific functional assessment tools that demonstrate a strong correlation with work disability. It also recommended that the SSA strengthen

the process for revising and updating the Listings, including expanding medical and functional expertise at the staff level as well as establishing an external advi-

... a streamlined assignment of SSDI benefits to those in need will provide timelier access to care. Earlier care is, almost always, both better and more cost-effective.

sory committee system. The committee advised partnering with other concerned agencies to conduct surveys and research on the population of persons with disabilities. The committee concluded that no better mechanism than the Listings exists at this time, but it recommended that SSA monitor and support promising alternative approaches to disability assessment. Improve-

ments to, and continuous updates of, the Listings will provide applicants with faster, more accurate determinations, thereby reducing administrative costs for SSA. More importantly, a streamlined assignment of SSDI benefits to those in need will provide timelier access to care. Earlier care is, almost always, both better and more cost-effective.

## Pharmaceuticals: The Good and the Bad

Every drug is a triangle with three faces, representing the healing it can bring, the hazards it can inflict and the economic impact of each. All of us—doctors, patients, regulators, taxpayers, insurers and policy makers—must learn how to balance these three dimensions better if we are to get the maximum benefit from this most common and powerful of all health care interventions.

—Jerry Avorn, Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs

The pharmaceutical industry highlights the complexity of the health care system and its interactions. Academics, manufacturers, research scientists, patient advocates, and customers all play a role, and the issues surrounding the development, regulation, marketing, and use of pharmaceuticals are often contentious.

Pharmaceuticals are the most common medical intervention, and their potential for both help and harm is enormous. Ensuring that the American people get the most benefit from advances in pharmacology is a critical component of improving the national health care system.

#### **BAD DRUGS OR A BAD SYSTEM?**

Pharmaceuticals are so prevalent in modern medicine that they are colloquially called just that: medicine. In any given wefi, four out of five U.S. adults will use prescription medicines, over-the-counter drugs, or dietary supplements. Nearly one-third of adults will take five or more different medications. Most of the time, medications are beneficial—or at least benign—but this isn't always the case. Injuries to the human body due to medication—or adverse drug events (ADEs)—are inevitable. Not surprisingly, the most powerful medications, such as chemotherapy treatments, are also the most likely to have significant harmful side effects. Equally troubling is the harm that results from human errors in prescribing or taking a broad range of medications. These mistakes can, and should, be minimized.

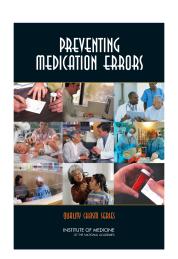
In hospitals, medication errors are more common than they should be at every step: they occur when procuring the drug, prescribing it, dispensing it, administering it, and monitoring its impact. Estimates of preventable hospital-based ADEs run from 380,000 to 450,000 a year, and they skyrocket to 800,000 a year

In any given week, four out of five U.S. adults will use prescription medicines, over-the-counter drugs, or dietary supplements. Nearly one-third of adults will take five or more different medications.

in long-term care facilities. Medicare outpatients experience an estimated 530,000 ADEs each year. Not only are these mistakes expensive, but they also have a serious impact on the health of patients and the health care system as a whole.

#### UNDERSTANDING THE PROBLEM

Recognizing this problem of medical errors, Congress urged the Centers for Medicare and Medicaid Services (CMS) to contract with the Institute of Medicane (IOM) to explore its extent and analyze possible solutions. *Preventing Medication Errors: Quality Chasm Series* (2007) documented the surprising frequency of

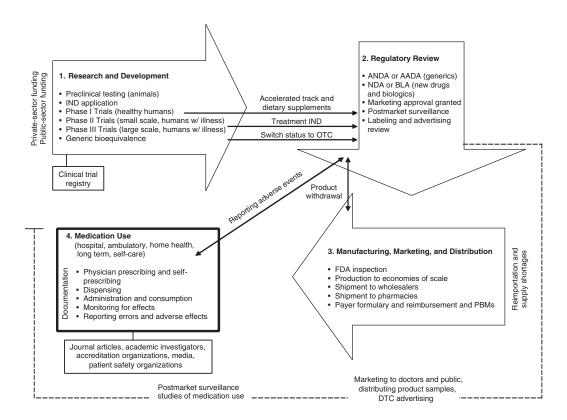


such errors and their cost to the nation. The report estimated that at least 1.5 million preventable ADEs occur in the United States each year. When all types of errors are taken into account, the average hospital patient can expect to be subjected to at least one medication error per day. While only a fraction of these errors are significantly harmful to the patient, the report estimated that the costs of treating drug-related injuries in hospitals alone were \$3.5 billion a year, not including lost wages, lost productivity, or additional health care costs. These dramatic facts resulted in media attention from National Public Radio to Rush Limbaugh and government attention from the halls of Congress to those of the Food and Drug Administration (FDA). The report also led to the IOM's recognition by national pharmacist groups with their "Safe-Rx Evangelist Award."

The report outlined a comproensive strategy to minimize this problem. Because medication errors are the result of multiple points of system failures, effective prevention will require changes on the part of the pharmaceutical industry, doctors, nurses, and pharmacists, as well as the organizations that support them, including hospitals, nursing homes, the FDA, and other government agencies. These stak-olders must become partners with the patients themselves to develop a solution. Reducing errors will come from fundamental changes in patients' at-

... the average hospital patient can expect to be subjected to at least one medication error per day.

titudes and expectations. Clear, complete, and continuing communication between patients and their health care providers is central to drug safety.



Four stages of the drug system. SOURCE: Preventing Medication Errors, p. 52.

#### MOVING TOWARD A SOLUTION

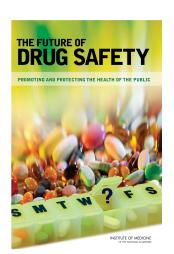
The path to widespread use of a drug starts with FDA approval. As recent drug safety issues have made evident, the nation's system for deciding what drugs are approved for marketing—and under what conditions—needs a major overhaul. *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007) powerfully analyzed the current state of drug regulation and created a blueprint for change.

The current problems stem partly from steps taken 15 years ago that were intended to speed up the FDA's drug approval process. The Prescription Drug User Fee Act (PDUFA) imposed fees on drugs submitted to the FDA for review and approval; sponsoring companies have to pay the FDA to review their drugs. These increased funds from PDUFA fees were used to expand FDA staff, and they have succeeded in speeding up the process of drug approval. Unfortunately, the

The IOM committee recommended that the FDA's authority to successfully monitor postmarket safety be clarified and their resources and expertise strengthened to enable effective surveillance and rapid action when problems are identified.

PDUFA legislation was written so that very little of this new funding could be used for postmarket drug safety surveillance. So while new drugs have been entering the market more quickly, the FDA's capacity to provide adequate safety monitoring and surveillance after the drugs become available for general prescription has been under-resourced and overwhelmed.

Because initial safety testing is limited to small groups of volunteers in order to minimize the risks of a new drug with unknown side effects, post-marketing surveillance is critical. Initial test groups are far too limited, and the study periods far too brief, to understand the effects that a drug may have on a diverse



population of users when taken over an extended period. Not surprisingly, safety problems have been discovered with some drugs long after marketing approval. These safety issues have had tremendous costs, both in dollars and, far more importantly, in lives lost or persons harmed by the drugs.

The IOM committee recommended that the FDA's authority to successfully monitor postmarket safety be clarified and their resources and expertise strengthened to enable effective surveillance and rapid action when problems are identified. It noted that Congress should grant the FDA the ability to require postmarket risk assessment and risk management programs, so that the FDA can do more than just ask drug companies for help. The committee also rec-

ommended the creation of regulations to limit direct-to-consumer advertising of new drugs until population-specific risks are understood as well as increased enforcement authority for the FDA, including better tools to ensure that inappropriate promotions and advertising can be quickly stopped.

Specifically, the committee recommended an array of actions, including

- symbols to alert consumers to new products and denote heightened regulatory attention;
- efforts to restore balance in the FDA between the resources necessary to approve new drugs and the resources necessary to monitor their safety once on the market:

#### Pharmaceuticals: The Good and the Bad

- tools to hold industry and researchers accountable for making results of a drug safety study public, including mandatory registration of clinical trial results:
- new rules to stabilize the leadership of the FDA by appointing commissioners for six-year terms;
- an increased role and formal responsibilities for the FDA's post-marketing drug safety staff; and
- an increase in funding and staffing for the agency.

The report provided the template for major reforms enacted by Congress. It continues today to inform the debate over post-approval drug surveillance in both the House and the Senate.

In addition to these studies, the IOM has organized roundtables, forums, and public workshops that provide opportunities for government, academic, industry, and consumer experts to meet and share knowledge on critical issues (see Chapter 9). Although these activities do not yield reports, each does provide an invaluable opportunity to focus on important questions, explore new alternatives, and consider options that may be available to the government or private sector. For example, the Forum on Drug Development, which looks at ways to improve the pharmaceutical system, has convened workshops on

- Emerging Safety Science (April 23, 2007);
- The Future of Drug Safety: Challenges for the FDA (March 12, 2007);
- Addressing the Barriers to Development in Pediatrics (June 13, 2006);
- Understanding the Benefits and Risks of Pharmaceuticals (May 30, 2006);
   and
- Adverse Drug Event Reporting (November 3, 2005).

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## Children and Youth: A Healthy Start

Few topics in health care are more emotionally charged than the health of America's youth. The patterns that children establish early in life—diet, exercise, good habits, and an appreciation for their own well-being—give them the best chance for a lifetime of good health.

The Institute of Medicine (IOM) approaches the issue of keeping the nation's children healthy by looking at the health conditions of children and young adults as well as the world in which they live. The IOM's work covers topics as broad as basic health and nutrition, as timely as childhood obesity, and as specific as teen driving.

The good news is that, in general, the health of children and youth has improved considerably over the past several decades. Still, the challenges that remain involve biological, bavioral, social, and physical environments alike. Effectively tackling these issues is a complex and multifaceted task and includes analyzing prevention and intervention strategies in addition to treatment.

The IOM has helped to foster the idea that childhood health is about context and not just conditions. This concept requires a significant change in the way that the health care community thinks about disease.

#### **FOOD FOR THOUGHT**

The foremost challenge to the long-term health of our children is clear: Children in the United States today are more overweight and obese than at any time in history, putting them at risk for serious health problems such as diabetes,

cardiovascular disease, elevated cholesterol, and high blood pressure—diseases that most people still consider "adult" conditions. In addition to obesity-related health concerns, poor food choices can also lead to long-term health issues such as osteoporosis from inadequate calcium intake or chronic iron deficiency.

Any competitive foods that are available should consist of fruits, vegetables, whole grains, and nonfat or low-fat milk and dairy products, consistent with the 2005 Dietary Guidelines for Americans.

In response to growing concerns over obesity and other nutritional concerns, national attention has focused on the need to establish school nutrition

standards. Children today spend the majority of their day at school and often stay for after-school activities. All together, the foods and beverages available both during and after school can contribute a significant number of calories to total daily consumption. Some improvements have been made in the food choices available in schools: General school nutrition policies have been put in place at the federal, state, and local levels, including a federally mandated wellness policy initiative. Furthermore, there has been increased recognition of the need to limit access to unhealthy foods such as those currently sold in vending machines in a school environment that otherwise offers federally reimbursable school nutrition programs.

Despite some progress, however, the response of school districts to meeting wellness policy requirements has been inconsistent. To augment local wellness policies, Congress directed the Centers for Disease Control and Prevention (CDC) to undertake a study with the IOM to make recommendations about appropriate nutritional standards for the availability, sale, content, and consumption of foods at school, with particular attention to competitive foods that are offered outside the school meal program. The resulting report, *Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth* (2007), concluded that

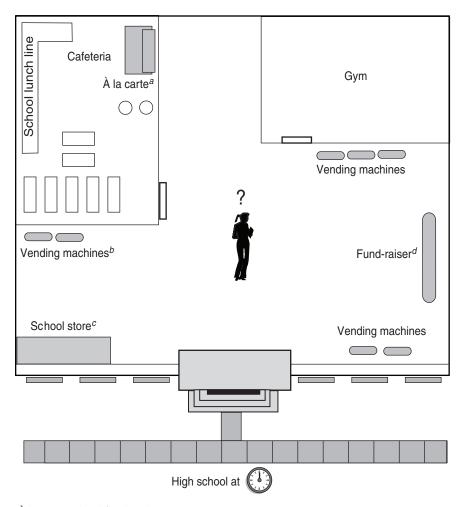
- federally-reimbursable school nutrition programs should be the main source of nutrition at school;
- opportunities for competitive foods should be limited; and
- any competitive foods that are available should consist of fruits, vegetables, whole grains, and nonfat or low-fat milk and dairy products, consistent with the 2005 Dietary Guidelines for Americans.

These standards should apply to à la carte cafeteria items, products sold in vending machines and at school stores, and other foods and drinks that are available outside of the school meals that are required to conform to federal nutrition guidelines. The committee proposed two grade-level-based tiers of competitive foods and beverages that could be made available in schools.

#### MARKETING WEIGHS IN

Creating an environment in which U.S. children and youth can grow up healthy should be a high priority for the nation. Yet the prevailing pattern of food and beverage marketing to children and youth in America represents, at best, a missed opportunity. At worst, the status quo is a direct threat to the health prospects of the next generation.

#### Children and Youth: A Healthy Start



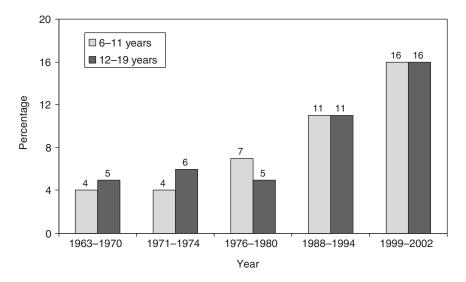
<sup>&</sup>lt;sup>a</sup>À la carte: school food authority.

Groups most frequently involved in various competitive food venues commonly available in high schools. SOURCE: Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth, p. 70.

<sup>&</sup>lt;sup>b</sup>Vending machines: school food authority, vending operator, school official or administrator, physical education department, student association or club.

<sup>&</sup>lt;sup>c</sup>School store: school official or administrator, student association or club.

<sup>&</sup>lt;sup>d</sup>Fund-raisers: physical education department, music or art department, business teacher, student association or club, booster groups.



Prevalence of obesity among U.S. children and adolescents by age group and selected period, 1963–2002. SOURCE: Food Marketing to Children and Youth: Threat or Opportunity?, p. 42.

Current food and beverage marketing targeted at children ages 12 years and under leads them to request and consume high-calorie, low-nutrient products. A broad effort, not just in schools, is needed to restore the knowledge balance and promote healthier habits.

Current food and beverage marketing targeted at children ages 12 years and under leads them to request and consume high-calorie, low-nutrient products. A broad effort, not just in schools, is needed to restore the knowledge balance and promote healthier habits.

The IOM report *Food Marketing to Children and Youth: Threat or Opportunity?* (2006) looked at how marketing influences children and youth. The report provided the most comprensive review to date of the scientific evidence on the influence of food marketing on diets and the diet-related health of U.S. children and youth.

The report found, quite simply and perhaps unsurprisingly, that current food and beverage marketing practices put children's long-term health at risk. If America's children and youth are to develop eating habits that will help them avoid early onset of diet-related chronic diseases, they must reduce their intake of high-calorie, low-nutrient snacks, fast foods, and sweetened drinks. Yet these very products make up the majority of those marketed to them. Companies spent an estimated \$10 billion to market foods,

#### Children and Youth: A Healthy Start

beverages, and meals to U.S. children and youth in 2004, most of which were products high in calories and low in nutrients. Unfortunately for children, the marketing works.

The report provided a set of policy and program recommendations to develop common standards and labeling policies for defining healthy foods, beverages, and meal options—a dramatic shift toward marketing and advertising strategies that promote these healthier foods. This would include both prohibiting the use of licensed cartoon characters on foods that are high in calories and low in nutrients and promoting a sustained social marketing program. Specific recommendations were offered for

- food, beverage, and restaurant industries;
- food retailers and trade associations:
- entertainment and media industries;
- parents and caregivers;
- schools; and
- government.

The report also offered guidance on additional research that is necessary to chart the path of future improvements and improve the ability to monitor and track changes in marketing practices that have an influence on children's diets and diet-related health. Collectively, these recommendations reflect the spectrum of current knowledge and understanding in a rapidly changing environment, and they need to be implemented as a package in order to support and complement one another.

The IOM report sparked several actions, including announcements by the soft drink industry of changes in their school marketing policies, by several large food companies of their plans to alter their products and marketing to children, and by Disney to prohibit the use of their characters for marketing products of concern. Reviews were also triggered by the board responsible for industry marketing guidelines, which is leading to a tightening of the standards, and by the Kaiser Family Foundation, who examined the even broader exposure of children to televised ads. Furthermore, policy makers in Congress and the Federal Trade Commission called for changes in corporate marketing strategies to make them consistent with IOM recommendations.

**TABLE 2-4** Fatal Crash Characteristics, 16-Year-Old Driver Alone or with Teen Passengers (percentage)

	Driver Alone	1 Teen Passenger	2 Teen Passengers	3+ Teen Passengers
Driver error	72ª	82	83	90
Speeding	30	45	50	59
Single vehicle	36	51	59	72
0.08+ blood alcohol level	9	8	10	12

<sup>&</sup>lt;sup>d</sup>Totals may exceed 100% because crashes may involve more than one characteristic. SOURCE: Insurance Institute for Highway Safety. Unpublished analysis of 2004 data from the Fatality Analysis Reporting System, National Highway Traffic Safety Administration.

Fatal Crash Characteristics, 16-Year-Old Driver Alone or with Teen Passengers (percentage). SOURCE: Preventing Teen Motor Crashes: Contributions from the Behavioral and Social Sciences, p. 12.

#### **BAD DRIVING = BAD HEALTH**

Unlike the long-term effects of poor nutrition, motor vicle crashes present an immediate and violent risk to far too many youth. Over the past decade, there have been significant decreases in the rate of motor vicle crashes involving teens, but teen drivers and passengers remain at substantial risk: motor vicle crashes remain the leading cause of death for young people in the United States, and they constitute a critical public health problem.

The IOM conducted a workshop and subsequently published *Preventing Teen Motor Crashes: Contributions from the Behavioral and Social Sciences* (2007). This project was a collaboration of the Transportation Research Board and the National Research Council/IOM Board on Children, Youth, and Families.

The workshop explored how knowledge from the bavioral and social sciences could contribute to the development of new prevention strategies to reduce the incidence of and injury from teen motor voicle accidents. Workshop speakers identified opportunities to apply new research and knowledge to driving practices, especially in areas such as coaching, novice driving practices, parental supervision, error detection, peer interactions, adolescent decision making, and the development of incentives to foster safe driving skills. Workshop participants also examined the social context of teen driving that influences cognitive development.

#### Children and Youth: A Healthy Start

opment and the acquisition of driving expertise—two areas that have received scarce attention in prior attempts to craft prevention strategies.

A collection of papers presented at the May 2006 workshop is now being prepared for publication in a supplemental issue of the *American Journal of Preventive Medicine*. The papers sefi to provide useful, actionable educational and research materials to support the next phase of prevention strategies.

Injuries and fatalities from teen motor crashes are preventable. Road accidents are not diseases or disorders that require scientific breakthroughs and massive research grants. Baviors must be changed, training must be provided, and concrete actions must be taken by administrators, parents, teachers, and policy makers.

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## Public Health: The Big Picture

The banner of public health unfurls to encompass a wide spectrum of subjects, and it is perhaps the most diverse area that the Institute of Medicine (IOM) investigates.

Public health addresses widespread, population-level issues. These important and often contentious problems affect Americans from every walk of life, in every part of the country. Included in this category are widely publicized issues such as tobacco use, the challenges that disabled citizens face, food safety concerns, preparedness for pandemic disease, and approaches to health care policy in government.

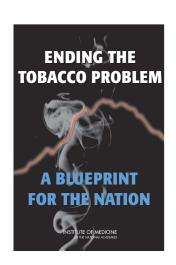
In these areas, the IOM's role as an impartial intermediary is critical. Because the IOM is highly respected as an independent resource that can objectively evaluate the science and evidence rather than being involved in politics or marketing, it is able to bring parties with widely differing viewpoints to the table and to craft well-researched, meaningful recommendations based on a firm understanding of the facts—and the risks and benefits of potential actions.

#### KICKING THE TOBACCO HABIT

Since 1964, when the first Surgeon General's report on smoking and health was released, a series of increasingly strong antismoking measures have cut the

rate of smoking among U.S. adults by 58 percent. That campaign, which has saved millions of men and women from lung cancer, heart disease, and other smoking-related maladies, has been one of the most important public health success stories of the past several decades.

Yet despite these achievements, more than one in five adults continue to smoke. In the United States, one-half of these 44.5 million people will die prematurely from a tobaccorelated disease unless they stop smoking. This year, tobacco use will cause 440,000 deaths in the United States, including 50,000 deaths from secondhand smoke. These smoking-related deaths take a greater toll than AIDS, alcohol, cocaine, heroin, homicide, suicide, motor voicle crashes, and fires combined. Their cost to the nation and the health care system is enormous.



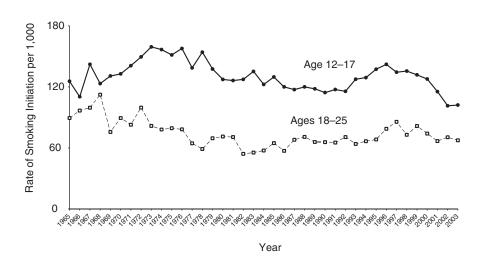
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To address this, the American Legacy Foundation asked the IOM to conduct a major study of tobacco use in the United States. The resulting report, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007), outlined the strategies needed to build on past antismoking efforts and expand that success in the coming decades.

While fewer people are smoking, the rate of decline might be leveling off. Teenagers are tak-

ing up and continuing to smoke at an alarming rate, which is one of the largest obstacles to achieving a permanent long-term reduction in tobacco use. The report proposed a two-pronged strategy for tobacco control.

First, traditional measures that have proven to be effective should be strengthened. These include supporting comprensive state tobacco control programs, increasing excise taxes, strengthening smoking restrictions, limiting youth access to tobacco products, intensifying prevention interventions, and increasing access to smoking cessation programs.



Smoking initiation rites among adolescents and young adults, 1965 to 2003. SOURCE: Ending the Tobacco Problem: A Blueprint for the Nation, p. 48.

#### **Public Health: The Big Picture**

The second prong involves significantly boosting federal involvement in antismoking efforts. To ensure that any success in curtailing tobacco use endures over time, Congress and other policy makers need to change the legal structure of tobacco policy. Congress should give the FDA (or another regulatory agency) broad authority to regulate the manufacture, distribution, marketing, and use of tobacco products.

The public and private sectors must work together to strengthen and implement tobacco control measures that have proven to be effective. Congress should empower state and federal governments to employ new weapons in the fight against tobacco use. Taking these steps will put the United States on a necessary and permanent course toward ending the tobacco problem.

#### THE NEW FACE OF DISABILITY

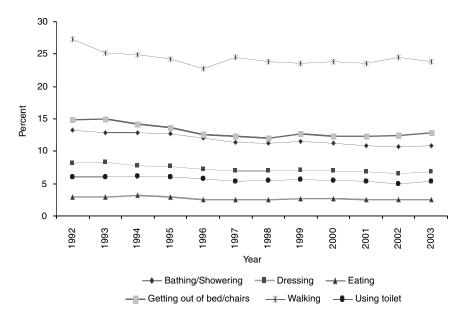
eration ages.

More than 40 million Americans live with a disability. In fact, most Americans will be affected by disabilities at some point in their lives, either their own or those of family members or friends. Although members of the "Baby Boom" generation will surely benefit from medical advances and interventions that did not exist in previous decades, the sheer number of older adults will strain both retirement and health care programs as this gen-

... outdated public policies and practices all too often create obstacles to independence and community involvement for people with disabilities.

In 1991 and again in 1997, the IOM released reports that highlighted disability as a pressing public health issue. Since that time, the country has made progress. Policy makers, clinicians, researchers, and others have increasingly recognized that environmental obstacles often contribute to disability. For example, the Americans with Disabilities Act has helped increase public awareness of the physical and social barriers faced by people with disabilities and, in many cases, has helped to eradicate them. Advances in science and engineering have led to better assistive technologies, which make it easier for individuals with disabilities to lead productive, independent lives. Still, outdated public policies and practices all too often create obstacles to independence and community involvement for people with disabilities.

To better understand disability in the United States, the Centers for Disease Control and Prevention, the Department of Education, and the National Institutes of Health asked the IOM to assess the current situation and provide recommendations for improvement. Among other recommendations in the resulting report,



Percentage of community-dwelling Medicare beneficiaries, age 65 and over, who have difficulty in performing selected personal care activities without help or special equipment, 1992 to 2003. SOURCE: The Future of Disability in America, p. 74.

The Future of Disability in America (2007), the IOM called on Congress and appropriate federal agencies to improve coverage of assistive technologies and services and to eliminate the requirement that individuals who qualify for Social Security disability benefits must wait 24 months before becoming eligible for Medicare.

Disability, in the form of limited activities and restricted participation in social life, is not an unavoidable result of injury or chronic disease. It results, in part, from the choices that society makes about working conditions, health care, transportation, housing, and other aspects of the environment. The United States faces important decisions that could reduce, or increase, the extent to which people with disabilities can live independently and be involved in their communities. Inaction will lead to diminished quality of life, increased stress on individuals and families, lost productivity, and higher costs of care.

#### **SAFE SEAFOOD**

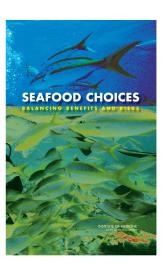
Seafood is a tremendously important part of the American menu. It is nutrient-rich and widely available to most Americans. High in protein and micro-

#### **Public Health: The Big Picture**

nutrients and low in saturated fat, it can be an excellent contribution to a well-balanced diet. However, seafood is also the major source of human exposure to contaminants, such as methylmercury, that may be harmful to pregnant women and young children. Eating seafood can also expose consumers to contaminants such as dioxin and polychlorinated biphenyls (PCBs), as well as microbial infections from the consumption of raw or undercooked fish and shellfish. The challenge for consumers is to sort through information on the benefits and risks of seafood and, ultimately, make informed decisions about what they eat.

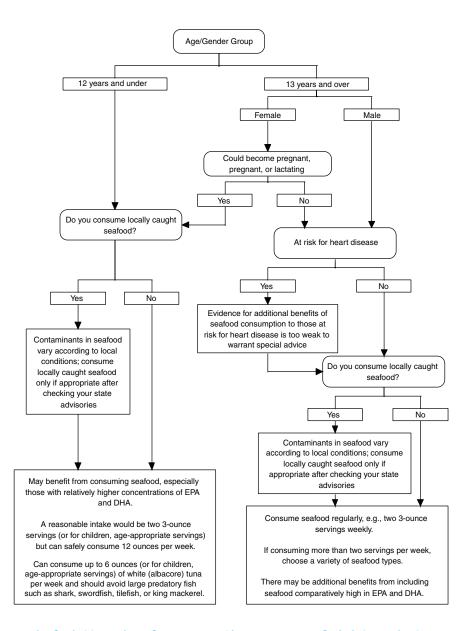
In response to a request from the National Oceanic and Atmospheric Administration, the IOM formed a committee to review evidence on the benefits and risks associated with seafood consumption. The committee's report, *Seafood Choices: Balancing Benefits and Risks* (2007), provided comprensive guidance about how to safely include seafood in diets.

The report affirmed current government recommendations that women who are pregnant, or wish to become pregnant, should avoid consumption of lean, predatory fish that are sources of methylmercury, such as swordfish, shark, king mackerel, and tilefish. They should also limit their consumption of albacore, or "white," tuna.



However, the report also suggested that most people can gain nutritional benefits from seafood, if they minimize their risk of exposure to contaminants by selecting a variety of fish and shellfish in amounts that fall within current dietary guidelines. Because seafood supplies and cultivation practices change constantly, it would be difficult for federal agencies to develop a list of "good fish" and "bad fish" that would not quickly become obsolete. However, the benefits and risks for broad categories of seafood are relatively consistent:

- Lean fish are good sources of protein, are low in saturated fat and cholesterol, and provide moderate amounts of omega-3 fatty acids. Predatory fish with long life spans—such as swordfish, shark, and tilefish—contain levels of methylmercury that are too high for pregnant and breast-feeding women and young children.
- Fatty fish, such as salmon, are good sources of protein and provide the highest amounts of omega-3 fatty acids. They can also contain higher levels of saturated fat and can accumulate greater amounts of contaminants such as dioxin and PCBs, depending on the source. However, their methylmercury burden is lower than that of many lean fish.



Example of a decision pathway for consumer guidance. SOURCE: Seafood Choices: Balancing Benefits and Risks, p. 254.

#### **Public Health: The Big Picture**

- Shellfish and crustaceans are good sources of protein and low in saturated fat, although some contain moderate amounts of cholesterol. They present the greatest risk of microbial infection if eaten raw.
- For all seafood categories, levels of contaminants such as dioxin and PCBs in commercially obtained fish generally do not pose health risks when consumed in amounts recommended by federal agencies. These contaminants tend to be geographically specific. State advisories are intended to alert the public about contaminated fish and shellfish from regional and local sources.

One of the biggest obstacles to these recommendations lies in disseminating them. Consumers need information to weigh the nutritional benefits against risks of contaminant exposure from various types of fish and shellfish. Consumers also need to be informed of the trade-offs of substituting seafood for other protein

sources. For example, healthy young women who are, or wish to become, pregnant should avoid certain types of fish that are higher in methylmercury, but this does not need to be a concern for men. Choosing a serving of salmon instead of a serving of fatty beef will lower a woman's intake of saturated fat and cholesterol and boost her intake of omega-3 fatty acids, but it also will reduce her iron intake and may increase her exposure to

... the report also suggested that most people can gain nutritional benefits from seafood, if they minimize their risk of exposure to contaminants by selecting a variety of fish and shellfish in amounts that fall within current dietary guidelines.

methylmercury slightly. Selecting canned albacore tuna instead of salmon will decrease her exposure to dioxin, but it may increase her exposure to methylmercury. Knowing the trade-offs will enable consumers to attain a smart and healthy balance.

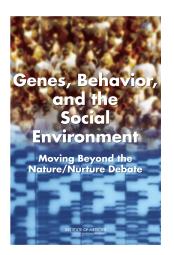
#### **NEXT-GENERATION RESEARCH**

Most U.S. citizens enjoy a level of health and well-being today that was unimaginable a century ago. Simple public health measures such as sanitation, improved hygiene, and workplace safety have led to huge reductions in the spread of disease and serious injuries. Scientific and medical advances have led to the development of new vaccines, drugs, and clinical procedures. Huge gains have been made, and most recently, a growing understanding of the human genome is playing a vital role in extending the duration and improving the quality of human life.

Today's detailed study of human genetics is forcing scientists to look at disease as a complex problem. Instead of focusing on one factor—a virus or toxin,

for example—scientists are now focusing on interacting factors involving social, bavioral, and genetic conditions, which may work in concert to influence health. Many researchers are convinced that this more holistic approach may yield scores of medical breakthroughs in the future. The potential benefit to health—and the well-being of the health care system—is enormous.

The IOM report *Genes, Behavior, and the Social Environment: Moving Beyond the Nature/Nurture Debate* (2006) examined a number of well-described gene–environment interactions, reviewed the state of the science in researching such interactions, and recommended priorities for both future research and the needs of the research workforce, its resources, and its infrastructure.



The report found that a number of far-reaching changes, specifically in the development of interdisciplinary research, are required if significant strides are to be made. The National Institutes of Health should encourage research that incorporates the study of key environmental, social, and bavioral factors over a lifetime. For example, certain social factors such as educational attainment, income, and workplace conditions have been consistently linked with health outcomes. Bavioral and psychological factors include smoking, drinking, and eating habits as well as physical activity and temperament. DNA sequence variation, structural chromosomal changes, and gene expression also affect health outcomes. A research approach that truly transcends disciplines in order to deal with these, as well as other factors, has the potential to generate a

far deeper understanding of how human beings remain healthy or become ill in the real world.

#### THE THREAT OF PANDEMIC FLU

The infamous 1918 influenza pandemic killed at least 20 million people, more than any other disease outbreak in history. It was by no means the first lethal flu pandemic, and most experts believe it will not be the last. There is no question that the United States is in a better position to deal with another outbreak than it was a century ago: scientists have a better understanding of the viruses themselves, and there are effective vaccines and antiviral drugs to forestall infection. Yet the world remains vulnerable to pandemic diseases, especially in this age of frequent global travel.

#### **Public Health: The Big Picture**

However, there are tools to help mitigate the effects of a pandemic. In *Modeling Community Containment for Pandemic Influenza: A Letter Report (2006)*, the IOM committee suggested that, based on computer models and analyses of past flu outbreaks, community-wide intervention such as isolating infected people or implementing a voluntary quarantine could be effective in decreasing the rate of illnesses and deaths during the next pandemic flu. The committee cautioned, however, that government and community leaders should not overstate the evidence base for these strategies and that a good

evidence base for these strategies and that a good spokesperson or leader on the subject should be appointed. After the report's release, the CDC released guidance on community containment during pandemic influenza based on IOM's advice.

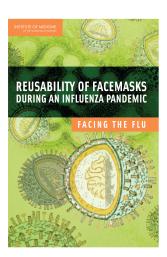
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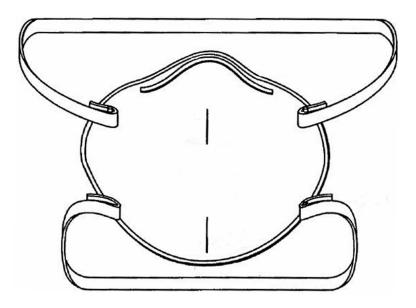
Barring complete containment if an influenza pandemic does strike, public health officials will need to employ multiple measures to reduce its

impact. Given that vaccines and antiviral medications will be in short supply in the early days of a pandemic, the public might turn to using facemasks to help prevent or slow the transmission of influenza.

Based on the assumption that efforts to produce and stockpile sufficient supplies of disposable masks and/or respirators may fall short in the event of a pandemic, the U.S. Department of Health and Human Services requested that an IOM committee examine the potential reuse of medical masks and N95 respirators.

The committee's report, Reusability of Facemasks During an Influenza Pandemic: Facing the Flu (2006), highlighted the fact that very little is known about the practicality or effectiveness of disinfecting and reusing either medical masks or respirators. There is no known simple and reliable way to decontaminate these devices that would enable people to safely use them more than once. This uncomfortable statement of fact resulted in media coverage ranging from WebMD to the New York Times, highlighting the potentially dire state of the nation's ability to respond to an influenza pandemic. Fundamental research both in the epidemiology of influenza and in the material properties of medical masks and respirators is needed before methods of disinfection and reuse can be developed.





Filtering facepiece respirator. SOURCE: Reusability of Facemasks During an Influenza Pandemic: Facing the Flu, p. 29.

#### **ENCOURAGING ORGAN DONATION**

Every year, thousands of people in the United States die while waiting for an organ transplant. These deaths have become more common even as the number of organ donations has increased. In 1996, more than 4,000 people died waiting for an organ transplant; in 2005, the number was 7,000.

Although the rate of organ donation in the United States has increased steadily since the late 1980s, organ donations continue to lag far bind the ever-increasing need. In 2005, 7,593 deceased donors provided 23,249 organs for transplantation, with an additional 6,896 living donors. Yet at the start of 2006, more than 90,000 people were waiting to receive organs, and approximately 40,000 people are added to the organ transplant waiting lists each year.

These shortages occur despite the fact that approximately 30,000 to 40,000 people who could be organ donors die each year. Most organs come from deceased donors whose deaths have been determined by neurologic criteria based on the irreversible loss of activity in the brain, including the brain stem. There are about 16,000 eligible donors whose deaths are declared in this way each year in the United States. Many more deaths are determined based on circulatory

#### **Public Health: The Big Picture**

criteria, meaning an irreversible loss of heart function that leads to permanent cessation of blood circulation. It is estimated that at least 22,000 people who die of heart attacks outside of hospitals could be potential donors, if certain ethical and practical issues are resolved.

Estimates indicate that each donor is worth more than \$1 million to society in reduced health care costs for dialysis and other medical interventions and in increased quality of life for donor recipients. With such enormous, life-saving po-

In 1996, more than 4,000 people died waiting for an organ transplant; in 2005, the number was 7,000.

tential and societal gains at stake, how can people be encouraged to grant this valuable gift?

In *Organ Donation: Opportunities for Action* (2006), an IOM committee urged federal agencies, nonprofit groups, and others to boost opportunities for people to record their decisions to donate, strengthen efforts to educate the public about the benefits of organ donation, and continue to improve donation systems.

**TABLE 2-4** Organ Donation, Transplantation, and Waiting List by Ethnicity

Ethnicity	Population Distribution (%) <sup>a</sup>	Percentage of Total Donations, 2005 <sup>b</sup>	Percentage of Transplant Recipients, 2005 <sup>c</sup>	Waiting List Distribution (%) as of March 24, 2006
White	75.1	68.9	63	49.3
African American	12.3	14	18.5	27.4
Hispanic	12.5	13.2	12	15.8
Asian	3.6	2.6	4.0	5.5
American Indian/				
Native Alaskan	0.9	0.5	0.7	0.9
Pacific Islander	0.1	0.1	0.4	0.5
Multiracial	2.4	0.7	0.7	0.6

<sup>&</sup>lt;sup>a</sup>U.S. Census Bureau data, 2001. The population distribution adds up to more than 100 percent because of the option in the 2000 census to select multiple categories to accurately describe one's ethnicity.

SOURCE: OPTN (2006); U.S. Census Bureau (2001).

Organ Donation, Transplantation, and Waiting List by Ethnicity. SOURCE: Organ Donation: Opportunities for Action, p. 50.

bIncludes deceased and living donors.

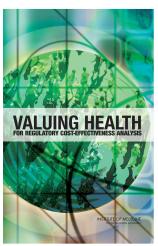
c0.7 percent of transplant recipients are of unknown ethnicity.

Although the committee supported initiatives to increase donations from people whose deaths are the result of irreversible cardiac failure, it concluded that the nation is not yet ready for an opt-out system, where donation consent is presumed. Further, it argued that financial incentives—including direct payments, coverage of funeral expenses, and charitable contributions—should not be used to increase donation rates.

The organ donation imbalance is an issue that will remain in the spotlight for the foreseeable future. Everyone has a stake in fixing the problem—after all, nearly everyone is a candidate to be either a donor or a recipient at some point.

### THE VALUE OF HEALTH: WEIGHING THE COSTS AND BENEFITS OF REGULATION

Government regulations are intended to ensure such things as the safety of the air Americans breathe, the food they eat, the water they drink, and many of the products they use. But in addition to the protections they afford, health and safety regulations also have costs associated with their implementation and enforcement. In promulgating regulations, federal agencies must weigh these costs against the potential health benefits to be realized. Anticipating the impacts of regulations is challenging and includes a great many variables; information is incomplete and a number of analytic decisions must be made in the course of evaluating proposed regulations.



In 2003, the U.S. Office of Management and Budget (OMB) instituted a new requirement: for health or safety regulations projected to have costs or benefits greater than \$100 million, agencies must also estimate that regulation's cost-effectiveness. Whereas cost–benefit analysis compares costs and benefits that are both expressed in monetary terms, cost-effectiveness compares monetary costs to benefits expressed as, for instance, cases of a particular illness or injury avoided, years of life extended, or improvements in health-related quality of life. At the request of OMB and several other federal agencies, the IOM developed guidance on how best to conduct cost-effectiveness analyses in the regulatory context.

The resulting report, Valuing Health for Regulatory Cost-Effectiveness Analysis (2006), reviewed and made recommendations for using integrated measures of morbidity and mortality (quality-adjusted life years) to

#### **Public Health: The Big Picture**

represent a regulation's health impacts and for standardizing the calculation and reporting of information about cost-effectiveness. It also highlighted the data and research needed to improve regulatory cost-effectiveness analysis. Finally, the report considered the ethical implications of using cost-effectiveness analysis and integrated measures of health impact in regulatory policy development.

Informing the Future: Critical Issues in Health, Fourth Edition http://www.nap.edu/catalog/12014.html

## Active-Duty Military and Veterans: America's Heroes

The men and women who serve the United States in the armed services face challenges that most Americans can hardly imagine. Besides the dedication, effort, and sacrifice required to do their jobs, those in the military have difficult and unique challenges in staying healthy during and after their service.

Some of these risks are obvious, but the others are no less noteworthy. An active-duty military deployed near an armed conflict faces risks of injury and death directly from combat. Those away from the front lines may be subject to lengthy exposures to hazardous environments, either natural or man made. Chemical exposures often far exceed those that would be considered safe in a normal working environment. Also, beyond the immediate physical threats, the U.S. military must deal with the effects of being in a high-intensity, stressful, and dangerous environment—sometimes for months or even years at a time.

The Department of Defense (DoD) and the Department of Veterans Affairs (VA) are charged with the weighty task of keeping active troops fit for service, protecting them from preventable risks, providing high-quality health care, and ensuring adequate care when their military service ends.

Because the challenge is so exceptional, scientific knowledge must be relied on as a powerful ally. The Institute of Medicine (IOM) regularly conducts research and analysis in support of the DoD and the VA in their mission to protect the health of active-duty military personnel, their families, and veterans.

## THE IMPACT OF WAR: VETERAN HEALTH AND THE GULF WAR

In 1991, nearly 700,000 U.S. troops, including many members of reserve units in the National Guard, took part in the Persian Gulf War. On returning home, a substantial 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 that examine the scientific and medical evidence on the potential health effects 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 the scientific literature on the health effects of exposure to depleted uranium, chemical warfare agents (including sarin), and pyridostigmine bromide. It also reviewed data on the anthrax and botulinum toxoid vaccines. The second volume, published in 2003, examined the health effects associated with exposure to pesticides and solvents. The third volume, published in 2005, analyzed the long-term human health effects associated with exposure to selected environmental agents, pollutants, and synthetic chemical compounds, such as fuels and propellants, believed to have been present during the Gulf War.

The report endorsed a policy of appropriate pre- and postdeployment medical screening of military personnel.

Following the publication of the first volume in the *Gulf War and Health* series, persistent concern was expressed by affected veterans and outside observers that there were unknown adverse neurological effects from exposure to sa-

rin and related chemical warfare compounds. In response, the VA asked the IOM to review the scientific and medical literature published since its initial report, which resulted in the report *Gulf War and Health: Updated Literature Review of Sarin* (2004).

Rather than focusing on specific causes, the fourth volume, *Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War* (2006), focused on the actual state of veterans' health in the years since the conflict. It concluded that service in the Persian Gulf during the 1990–1991 conflict places veterans at increased risk for developing psychiatric illnesses, particularly posttraumatic stress disorder, anxiety, depression, and substance abuse problems. In addition, the evidence suggests that there may be an elevated rate of the rare disorder amyotrophic lateral sclerosis among Gulf War veterans.

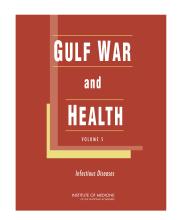
Ultimately, however, the report found that researchers lack the data needed to determine whether many long-term health problems are associated with service in the Persian Gulf, due to inadequate screenings and medical exams before deployment and only limited examinations of returning personnel. Predeployment screenings would have established a baseline for comparing health status after deployment. The report endorsed a policy of appropriate pre- and postdeployment medical screening of military personnel.

The report also called for improved monitoring of exposure to contaminants by the military in the future. With little direct monitoring of Gulf War soldiers' exposures to contaminants, it may never be possible to pinpoint whether exposures during service are associated with a specific illness. Conclusions often lie in

#### Active-Duty Military and Veterans: America's Heroes

the realm of uncertainty: personnel were potentially exposed to sarin gas, pesticides, air pollutants, vaccines, solvents, and pharmaceuticals.

The fourth report also looked at studies based on self-reports by Gulf War veterans, which have found a higher prevalence of symptoms such as fatigue, memory loss, muscle and joint pain, and sleeping difficulties—symptoms that are among those associated with chronic, multisymptom conditions such as fibromyalgia, chronic fatigue syndrome, and multiple chemical sensitivity. Not surprisingly, these studies find higher rates of chronic, multisymptom illnesses among Gulf War veterans as well, but there are no existing, objective diagnostic tests available to validate these self-reported disorders.

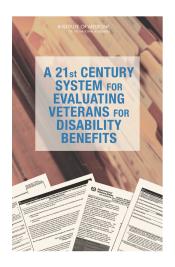


The fifth report in the series, *Gulf War and Health: Infectious Diseases* (2007), examined the long-term health effects associated with infectious diseases pertinent to Gulf War veterans, as well as veterans of the Afghanistan and Iraq wars that began in 2001 and 2003, respectively. The report detailed nine infectious diseases and found evidence, for example, of a connection between West Nile virus infection and long-term cognitive disabilities.

#### **EVALUATING DISABILITIES**

The Department of Veterans Affairs uses the "VA Schedule for Rating Disabilities," better known as "the Rating Schedule," to determine compensation for veterans who acquire or aggravate injuries and diseases during their military service. The Rating Schedule is based primarily on degree of impairment, such as the loss of a limb or an impairment of organ function. The VA's benefit policies are designed to reflect a grateful nation: the VA decides in favor of the veteran in cases of reasonable doubt, assists the veteran in gathering evidence, and identifies conditions that might make veterans eligible for compensation even if they don't initially make a claim.

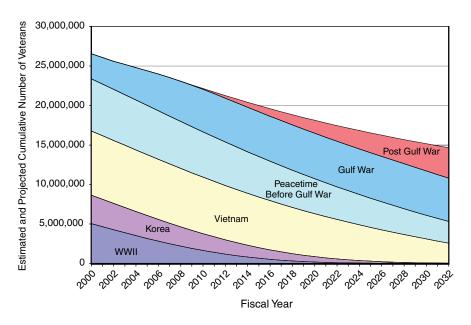
Clinical professionals medically evaluate each claimant and provide their assessment to a separate group of nonclinical professionals who manage the claims process. They use this information to determine the applicant's degree of disability according to the Rating Schedule, which is comprised of a list of about 700 diagnostic codes, each with criteria for determining the percentage of disability. Veterans who have a service-connected disability are eligible to receive monthly payments tied to their disability ratings, which currently range from \$115 a month



for a rating of 10 percent to \$2,471 per month for a rating of 100 percent. By federal statute, the veterans' disability benefits program is only required to compensate based on an average loss of earning capacity, although Congress and the VA also have recognized and compensated veterans for other, non-economic losses since the disability program was put in place in the 1920s.

The Veterans' Disability Benefits Commission requested that the IOM analyze the current state of, and recommend improvements to, this evaluation and rating system. The IOM published its findings in *A 21st Century System for Evaluating Veterans for Disability Benefits* (2007). The committee advised that the VA expand the current statutory purpose of its

disability compensation program to formally include compensation not just for work disability but also for disability related to non-work activity and a loss of quality of life. Furthermore, the report recommended that the Rating Schedule be revised more broadly to include factors that are more directly related to disability, such as limitations in activities of daily living, rather than the current focus



Estimated and projected cumulative number of veterans by period of service, 2000–2032. SOURCE: A 21st Century System for Evaluating Veterans for Disability Benefits, p. 31.

#### Active-Duty Military and Veterans: America's Heroes

on specific body structures and functions (which may, in fact, be poor measures of long-term disability).

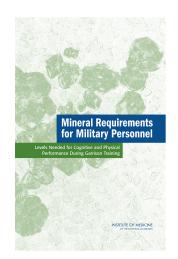
In addition, the report recommended that the VA update the entire Rating Schedule and establish a regular process for keeping it up to date. Staff should be dedicated to maintaining the Rating Schedule, and an external advisory committee of medical and other disability experts should assist in the updating process.

#### **MILITARY NUTRITION: MINERAL REQUIREMENTS**

As part of its mandate to promote the health and well-being of its soldiers, the U.S. military has focused much effort on improving the nutrient intake levels

of active-duty service members. Because of the unique physical and mental demands of many military situations, dietary recommendations for civilians can be insufficient. For example, a soldier on active duty loses many minerals through sweating in physically demanding training situations or in high temperatures. Recommended mineral intake for the average civilian might be insufficient.

The DoD requested that the IOM look at this issue in detail. In *Mineral Requirements for Military Personnel: Levels Needed for Cognitive and Physical Performance During Garrison Training* (2006), the IOM committee suggested that data to support new requirements for minerals for military personnel are scarce and that further research is needed in the unique scenarios of garrison training. However, the report did find that



higher intakes of certain minerals, specifically iron, magnesium, and zinc, are warranted. The report examined multiple factors that potentially affect mineral levels in military personnel, including physical activity, weight loss, stress, and the mineral content of military rations.

The report prioritized critical research needs and outlined a program for evaluating and implementing changes in military nutrition requirements. The report's research recommendations have since been incorporated in the U.S. Army Research Institute of Environmental Medicine nutrition research agenda.

Informing the Future: Critical Issues in Health, Fourth Edition http://www.nap.edu/catalog/12014.html

# Global Health: The Strength of Nations

Americans are fortunate to live in one of the most prosperous and scientifically advanced countries in the world. Organizations such as the Institute of Medicine (IOM) are able to be effective in large part due to the prevalence of scientific research and academic excellence in the United States.

However, neither the United States nor the IOM exists in a vacuum. Thanks to huge innovations in technology, the interactions between nations at a human level are greater than at any time in history. The development of this world community is one of the success stories of the last century. Yet globalization brings a shared responsibility to support countries with limited resources to tackle health problems within their own borders. In doing so, the United States has the opportunity to have a substantial, positive impact on the well-being of people around the globe. In this age of globalization, the actions of each nation globally will ultimately have an impact on its own welfare domestically.

The IOM is committed to act as an adviser not just to the nation but to the world. It sefis to advance the role of the United States as a force for improving global health and to explore international health issues that have implications for U.S. health policy.

#### **BETTER SCIENCE = BETTER HEALTH**

The American scientific community has a strong commitment to activities that will strengthen and support science in developing countries. The IOM's African Science Academy Development Initiative directly supports eight African academies of science in building their capacity to provide independent, evidence-based advice to their governments and countries on health-related matters, much as the IOM does for the United States.

Supported by the Bill and Melinda Gates Foundation, this 10-year effort aims to strengthen each African academy's capacity through better infrastructure, shared experience, and well-trained personnel. Each African academy is developing and sustaining a relationship with its government and nation to ensure, much like the IOM, that it will be recognized as a trusted source of excellent, actionable scientific advice.

Each African academy is developing and sustaining a relationship with its government and nation to ensure, much like the IOM, that it will be recognized as a trusted source of excellent, actionable scientific advice. The activities of the African Science Academy Development Initiative are diverse and take place both nationally and on a regional basis. The science academies of Nigeria, South Africa, and Uganda—competitively chosen to participate in the program at the most intensive level—are receiving support and collabora-

tive counsel in their advisory activities. Additional funds have been set aside for the science academies of Cameroon, Ghana, Kenya, and Senegal, as well as the broader African Academy of Sciences, with the purpose of crafting specific academy development strategies.

More donors and scientific partners are needed for these programs to reach their full potential and be maximally successful. African nations face critical problems and complex decisions, including HIV/AIDS; the acceptance of genetically modified crops; and the design of national systems for health, agriculture, and education.

The IOM sets an example of how a respected, impartial, independent, and unified voice from the scientific and medical communities can force political and public attention to address objective evidence. This drives public policy debate and increases the probability that decisions will be made in the public interest. By creating similar scientific bodies, Africa can secure a healthy population that is critical to its future as well as the world's.

#### **HIV/AIDS: TOWARD A SUSTAINABLE RESPONSE**

In 2003, Congress passed the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, establishing a five-year, \$15 billion initiative to help countries around the world respond to their AIDS epidemics. The initiative is generally referred to by the title of the five-year strategy required by the act—PEPFAR, or the President's Emergency Plan for AIDS Relief.

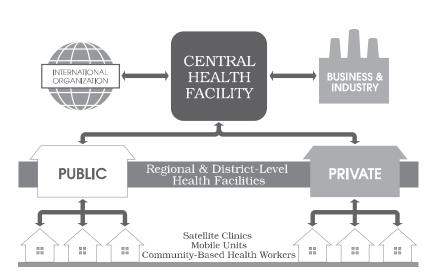
Congress asked the IOM to evaluate PEPFAR's progress in the three years after the act was passed. The resulting IOM report, *PEPFAR Implementation: Progress and Promise* (2007), concluded that PEPFAR had made a promising start. However, continuing U.S. leadership is needed in the effort to respond to the HIV/AIDS pandemic. Since its release, legislators in Congress and journalists in the media have echoed this call. To that end, the report recommended that the U.S. Global AIDS Initiative shift from a focus on emergency relief to an emphasis on the long-term strategic planning and capacity building necessary to develop a sustainable

#### **Global Health: The Strength of Nations**

response to the AIDS pandemic. Long-term factors that underlie the epidemics in each country should be addressed, including

- emphasizing and enhancing prevention by accumulating better data to determine the most appropriate interventions needed in each country;
- empowering women and girls by putting more focus on the factors that place them at greater risk of HIV/ AIDS and supporting improvements in their legal, economic, educational, and social status:
- building workforce capacity both by increasing direct support and by focusing on the education of new health care workers in addition to training for existing health care workers; and
- expanding the knowledge base by emphasizing evidence-based approaches, learning from experience, and adapting to new developments, as well as conducting operations research and robust program monitoring and evaluation.

These strategies will help enable PEPFAR to have lasting impact on the focus countries' AIDS epidemics. Making the transition to sustainability will require continuity with the established program but also improvement and greater flex-



PEPFAR's network model. SOURCE: PEPFAR Implementation: Progress and Promise, p. 57.

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ibility in implementation. In addition to addressing the long-term factors above, harmonization of efforts should occur through better coordination, the support of WHO prequalification, and the removal of budget allocations. Similarly, patient services should expand, improve, and integrate through data-driven prevention efforts, adequate provision of treatment medications, community- and family-centered care, performance targets for orphans and other vulnerable children, and greater attention to marginalized populations.

#### **EASING THE BURDEN OF CANCER**

Cancer is low on the health agenda of the world's low- and middle-income countries (LMCs), even as it becomes an ever-increasing proportion of their overall disease burden. Fully two-thirds of those dying from cancer globally live in

Fully two-thirds of those dying from cancer globally live in LMCs—many times more than those dying from AIDS, tuberculosis, or malaria. Yet for an LMC battling problems on many fronts, cancer does not command international headlines.

LMCs—many times more than those dying from AIDS, tuberculosis, or malaria. Yet for an LMC battling problems on many fronts, cancer does not command international headlines. In part, the lack of focus on cancer is due to an impression of intractability—people die and not much can be done.

In response to a request from the National Cancer Institute and the American Cancer Society, an IOM committee studied what efforts might be successful in easing the burden of cancer in LMCs. In *Cancer Control Opportunities in Low- and Middle-Income Countries* (2007), the committee described a series of appropriate, realistic actions that would help LMCs diminish the toll that cancer takes on their citizens. These opportunities include

- signing and ratifying the Framework Convention on Tobacco Control to tackle the most significant cause of cancer and other noncommunicable diseases;
- supporting measures to reduce the cancer burden related to infectious agents, responsible for one-quarter of all cancer deaths in LMCs;
- developing resource-level-appropriate guidelines for the overall management of cancers whose treatment can make a substantial difference to a large proportion of patients;
- creating cancer centers of excellence in these regions, which can leverage international partnerships;
- treating highly curable childhood cancers;

#### **Global Health: The Strength of Nations**

TABLE 3-3 Deaths, Years of Life Lost (YLL), and Disability-Adjusted Life Years (DALYs), All Causes and Cancers by Country Income Level, 2002 (all figures in millions)

	All Causes of Death		Cancer				
	Deaths	YLLa	$\mathrm{DALYs}^b$	Deaths	YLLa	$\mathrm{DALYs}^b$	Population
Country Income Level							
Low	28.5	606.4	877.7	1.8	20.8	21.4	2,560,762
Lower middle	17.2	221.0	402.6	2.7	29.4	30.3	2,214,697
Upper middle	3.4	42.2	90.4	0.6	5.9	6.3	513,406
High	7.9	52.4	118.7	2.1	15.4	17.4	933,917
All LMCs	49.1	869.6	1,370.7	5.1	56.1	58.0	5,288,865
World	57	922.5	1,490.1	7.1	71.6	75.5	6,224,985
LMC share of global burden	86%	94%	92%	72%	78%	77%	85%

<sup>&</sup>lt;sup>a</sup>The component of the DALY that measures years of life lost by a population due to premature mortality.

SOURCE: Data from World Health Organization (2006).

Deaths, Years of Life Lost (YLL), and Disability-Adjusted Life Years (DALYs), All Causes and Cancers by Country Income Level, 2002 (all figures in millions). SOURCE: Cancer Control Opportunities in Low- and Middle-Income Countries, p. 74.

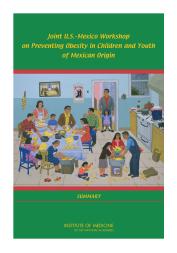
- removing barriers to inexpensive and effective pain control medications and providing other types of palliative care for those suffering from cancer; and
- gathering better data on the burden of cancer and the results of control efforts.

Progress on all of these fronts can be made with appropriate financial support from the global community and the sharing of technical expertise around the world.

#### **CHILDHOOD OBESITY: NOT JUST A U.S. PROBLEM**

The United States shares a great deal with its neighbors, and the global community is joined more tightly every day. As neighbors, Mexico and the United States are particularly united as they share residents, trade, and culture while at the same time maintaining their own cultural, social, and political uniqueness. Unfortunately, health issues are not immune to this relationship, and concerns

<sup>&</sup>lt;sup>b</sup> A measure of the gap in healthy years of life lived by a population as compared with a normative standard.



about public health often are common on both sides of the border. Among these problems is childhood obesity.

The Joint U.S.-Mexico Workshop on Preventing Obesity in Children and Youth of Mexican Origin (2007) developed from a desire to share experiences regarding the problem of obesity in children and youth of Mexican origin on both sides of the border, with a particular focus on actionable solutions. U.S. and Mexican researchers, public health officials, industry leaders, and policy makers engaged in a valuable dialogue, sharing perspectives, challenges, and ideas for success. Commonalities and differences in the United States and Mexico regarding risk factors, potential interventions and programs, and the need for all sectors to collaborate and make progress toward

reversing this serious public health problem were highlighted and characterized. This conversation served as the basis for a bilateral agenda dedicated to addressing this epidemic.

The situation is urgent. Despite the scarcity of data available to indisputably link risk factors to childhood obesity, all key players have a responsibility to develop and implement strategies to prevent childhood obesity based on the best available evidence.

Participants suggested the creation of a Mexican National Obesity Task Force in order to

- increase awareness of the problem;
- conduct assessment of human resources:
- develop and implement a national policy for obesity prevention;
- increase community participation;
- build trust among various sectors;
- provide decision makers with recommendations based on science; and
- develop prevention strategies.

The workshop also identified areas in which the United States and Mexico could collaborate, including advocacy, funding, a trained labor force, collection of scientific evidence, program evaluation, and consistency in programs and messages.

The workshop summary is being used in Mexico to support the formation of an interdisciplinary working group that would outline specific prevention initia-

#### **Global Health: The Strength of Nations**

tives for Mexican children. It is being translated into Spanish with the expectation that the translation will have an even greater impact among Mexican (and other Latin American) policy makers and government officials, school and industry leaders, and health providers.

#### **HIV/AIDS: PREVENTING INFECTIONS**

An estimated 13 million people worldwide inject drugs. Of those, 78 percent live in developing or transitional countries. The sharing of contaminated injecting equipment has become one of the driving forces bind the global AIDS epidemic and is the primary transmission vector in many countries, particularly throughout Eastern Europe, the Commonwealth of Independent States, and significant parts of Asia. In Asia, HIV infection rates have increased by as much as 20 times over the last two decades as a result of injection drug use. In some cases, HIV is spreading rapidly from drug users to their partners through sexual transmission and from drug users and their partners to newborns. Reversing the rise of HIV infection among injecting drug users is an urgent global problem—one that remains largely unaddressed.

In response to this crisis, the IOM was asked to evaluate strategies for stopping HIV transmission among this vulnerable population.

#### BOX 1-3 Hierarchy of Steps IDUs Can Take to Reduce HIV Risk

- 1. Stop using drugs.
- 2. Stop injecting drugs.
- 3. Always use a new, sterile syringe to inject drugs, and use sterile equipment to prepare drugs.
- 4. Never reuse or share syringes, water, or drug-preparation equipment.
- 5. Use bleach to properly disinfect injecting equipment.
- 6. Share supplies with as few other people as possible ("partner restriction").
- 7. Know your HIV status, and—if you are seropositive—do not pass on needles and syringes and use condoms during sex ("informed altruism") and seek antiretroviral therapy.
- 8. If you are an HIV-infected female who becomes pregnant, seek antiretroviral therapy to prevent perinatal transmission.

SOURCE: Adapted (with modifications by the Committee) from NIDA (2002) and Des Jarlais (2005).

Hierarchy of Steps IDUs Can Take to Reduce HIV Risk. SOURCE: Preventing HIV Infection Among Injecting Drug Users in High-Risk Countries: An Assessment of the Evidence, p. 50.

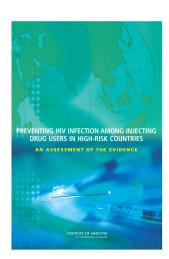
An estimated 13 million people worldwide inject drugs. Of those, 78 percent live in developing or traditional countries.

The resulting report, *Preventing HIV Infection Among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence* (2007), found that several key approaches can reduce the use and injection of illegal drugs and additionally curb

other drug- and sex-related baviors that increase the risk of HIV infection. There is strong evidence, for example, that two opioid agonist medications—methadone and buprenorphine—are effective in treating dependence on opioids such as heroin.

This IOM report provided evidence-based recommendations regarding drug dependence treatment, sterile needle and syringe access, and outreach and education. Multicomponent HIV prevention programs that include better sterile needle

and syringe access are effective in reducing drug-related HIV risks. High-risk countries are urged to take immediate steps to make these HIV prevention strategies widely available.



## Health Research: The Path to Knowledge

Over the course of human history, advances through research have had unparalleled impact on human health. The great improvements in our collective well-being have all come from revolutionary discoveries—the application of the scientific method to medicine, germ theory, and the structure of the human genome.

For this path of knowledge to continue, the scientific community must constantly reevaluate its methods, results, policies, and organizational structures, as well as the ethical implications of its work. Scientists from disparate fields need the opportunity to come together with professional counterparts in other disciplines on a regular basis. Only through this kind of sharing of focused and independent knowledge can the best possible research be done and the smartest minds be brought to bear on problems of public health.

Much of the Institute of Medicine's (IOM's) ethics-related work takes place in this arena. The issues of science policy, public support, research priorities, and collaboration are both sweeping in scope and critically important to our national well-being.

#### THE PROMISE OF STEM CELLS

Stem cell treatments have the potential to revolutionize medicine. Stem cell–based treatments may be able to address diseases (including chronic heart disease, type I diabetes, and Parkinson's disease) and tissue damage (including

spinal cord damage, brain damage caused by stroke, and damage to heart muscles caused by heart attacks).

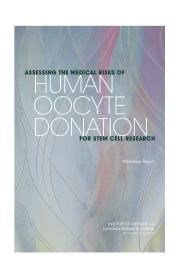
For several years, research on human embryonic stem cells has been mired in controversy. Restrictions on the use of federal funds for stem cell research have led this research to be privately funded and often carried out under a patchThe workshop and its report focused on the scientific and medical data about the potential risks of ovarian hyperstimulation syndrome, compromised future fertility, and psychological consequences, as well as the increased possibility of ovarian cancer.

work of existing regulations that were not developed with stem cells in mind. As a result, states and private entities have developed stem cell research policies in a vacuum, without federal guidance.

To enhance the integrity of human embryonic stem cell research by encouraging responsible practices, a joint project of the IOM and the National Research Council (NRC) issued *Guidelines for Human Embryonic Stem Cell Research* (2005). The guidelines addressed the many ethical, legal, scientific, and policy issues that are of concern to the public and the scientific community.

The report called for the establishment of a national body to periodically assess the adequacy of the guidelines in this rapidly changing field and to provide a forum for continuing discussion of human embryonic stem cell research.

Toward this end, in response to requests from the scientific community, the IOM and NRC convened a Human Embryonic Stem Cell Research Advisory Committee. The committee monitors and reviews scientific developments and the changing ethical, legal, and policy issues related to human embryonic stem cell research; discusses the need for revisions to the *Guidelines for Human Embryonic Stem Cell Research*; and updates the guidelines as needed. In the spring of 2007, the committee released its 2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research. The new report made several amendments to the 2005 version based upon feedback from the community. It addressed issues that were both in need of amendment and amenable to prompt solution. The advisory committee continues to gather information from public symposia and



written comments from members of the scientific community on developments in stem cell science and new or changing issues in ethics and policy. The committee uses these and other sources of information to continue monitoring and revising guidelines on the conduct of human embryonic stem cell research.

While this effort will go far to distill evidence-based information and make recommendations for the research community's practices, the IOM and NRC have done additional work as well. Recognizing the potential of stem cell treatments, California's Proposition 71 set up a 10-year, \$3 billion program to build facilities for stem cell studies and to fund research with the ultimate goal of helping to develop therapies based on stem cells. This research, however, will require a

steady supply of stem cells, particularly human embryonic stem cells. These cells are collected from developing human embryos that are created from eggs—or oocytes—harvested from the ovaries of female donors.

#### Health Research: The Path to Knowledge

This oocyte donation process is not without risk to donors. The California Institute for Regenerative Medicine asked the IOM and NRC to assemble a workshop that would bring together experts from various disciplines to analyze these risks in terms of the known science, the research necessary, and the actions needed to minimize any lingering issues. In response, the IOM and NRC established the Committee on Assessing the Medical Risks of Oocyte Donation for Stem Cell Research, which held a workshop in September 2006.

The resulting report, Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report (2007), synthesized the current state of knowledge in the field. The workshop and its report focused on the scientific and medical data about the potential risks of ovarian hyperstimulation syndrome, compromised future fertility, and psychological consequences, as well as the increased possibility of ovarian cancer. The workshop report did not review ethical and policy issues.

#### **RESEARCH WITH PRISONERS**

Medical research involving prisoners raises a host of ethical concerns, especially because such research has a tainted history. In the past, some scientific investigators used prisoners to study a variety of illnesses and toxins when human experimentation in free society was not allowed. Many prisoners who participated did not give voluntary, informed consent or fully understand the risks or possible benefits of research protocols. In the late 1970s, the U.S. government implemented federal legislation to protect human subjects in scientific research, which included specific guidance on prisoners.

In the past three decades, the U.S. prison population has expanded more than fourfold, and its makeup has changed dramatically. Correctional facilities are increasingly overcrowded and contain a diverse population, including some of the country's most disadvantaged populations. Racial minorities, women, people with mental illness, and people with communicable disease such as HIV/AIDS, hepatitis C, and tuberculosis are increasingly under correctional supervision. Prisoners' access to adequate health care has not always kept pace with this growth and diversity. These factors can be barriers to the prerequisites of ethical research, such as informed consent, privacy, and access to quality care. In fact, the situation is sometimes so stark that the choice to participate in research could be a desperate attempt to receive medical care.

Most research using prisoners currently takes place outside the scope of federal regulations and often without the scrutiny of institutional review boards

TABLE 2-13 Likelihood of Injury Based on Time in Prison, 1999

Time Since Admission	Injured (%)	Medical Problem (Excluding Injury) (%)
Less than 12 months	13.2	15.8
12-23 months	19.8	19.1
24-47 months	26.7	20.4
48-71 months	36.8	20.3
72 months or more	45.9	30.4

SOURCE: BJS, 2001b.

Likelihood of Injury Based on Time in Prison, 1999. SOURCE: Ethical Considerations for Research Involving Prisoners, p. 48.

(IRBs). Given these issues, the Department of Health and Human Services' Office for Human Research Protections commissioned the IOM to review the ethical considerations regarding research involving prisoners.

The goal, as stated in *Ethical Considerations for Research Involving Prisoners* (2007), is to "ensure rigorous responsible research that improves the well-being

of prisoners, while taking great care to protect their health, well-being, and human rights."

Prisoners' access to adequate health care has not always kept pace with this growth and diversity. These factors can be barriers to the prerequisites of ethical research, such as informed consent, privacy, and access to quality care. In fact, the situation is sometimes so stark that the choice to participate in research could be a desperate attempt to receive medical care.

The report recommended several steps that should be taken to provide prisoners involved in research with critically important protections. The definition of "prisoner" should be expanded to extend ethical protections to more people. Of the nearly 7 million people under correctional custody in 2004, only 2.1 million were in prisons or jails. The rest were on parole or probation. These groups need to be considered

"prisoners" under the law and thus covered by the same rigorous ethical rules. Protections should be applied uniformly to all subjects of prisoner research.

Under today's laws, research proposals involving prisoners are subject to reviews based on narrow categories that do not adequately consider the benefits and risks involved in the study. In addition, current reviews do not address the conditions of confinement or restrictions on the liberty of the subject. The IOM calls for a risk–benefit approach in evaluating research conducted on prisoners similar to that used for research involving children—a population with similar issues in terms of free will and capacity to make informed decisions without

#### Health Research: The Path to Knowledge

external influence. Therefore, ethically permissible research must offer prisoners potential benefits that outweigh the risks.

As with any field of medical inquiry, all aspects of prisoner-based research, including design, planning, and implementation, should include the input of relevant stak-olders, such as prisoners, correctional officers, medical staff, and administrators. Systematic oversight of research involving prisoners should also be enhanced.

#### PUBLIC INPUT ON CLINICAL TRIALS

The clinical trials process is perhaps the most critical step in determining the safety and effectiveness of a new drug or treatment. These trials, however, are often reported selectively and with a bias toward publishing positive results. The pharmaceutical industry is not motivated to publish the results of trials that do not support the introduction of a new product, and medical journals are more likely to publish positive results than negative results. As a result, the full range of results from clinical trials often is not part of the public record.

To improve public confidence in clinical research and ensure that results from all clinical trials are made available, a number of groups have called for a publicly accessible, comprensive, and transparent registry of relevant information on clinical trials for drugs and biologics. However, with their different interests, the public, consumer advocates, health care providers, researchers, editors of medical journals, pharmaceutical companies, health insurers, and regulators may all have different expectations and perceived needs regarding such a program.

The IOM Committee on Clinical Trial Registries hosted a workshop to obtain much-needed input from members of these constituencies, to examine the hard data elements that have been

... the full range of results from clinical trials often is not part of the public record.

examine the hard data elements that have been at the core of the debate, and to comment on the issues involved in enforcing compliance and implementing a national clinical trial registry. The results were published in *Developing a National Registry of Pharmacologic and Biologic Clinical Trials: Workshop Report* (2006). The discussion centered on

- the purposes of a registry;
- the inclusion or exclusion of exploratory trials;
- the need for a delayed disclosure mechanism for certain fields in the registry at the time of trial initiation (for information such as the hypothesis

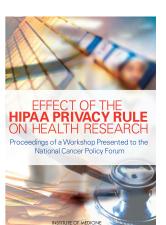
statement, primary and secondary outcomes measures, and projected year of trial completion);

- the timing and format for reporting results of completed trials; and
- the appropriate roles of IRBs, the FDA, and others in ensuring compliance.

#### HIPAA AND HEALTH RESEARCH

When the Health Insurance Portability and Accountability Act (HIPAA) was enacted a decade ago, one of the law's provisions was to simplify the exchange of electronic information for financial and administrative functions related to patient care. However, concerns have been raised about the transmission of sensitive personal information, and a Privacy Rule was adopted in 2003 to protect individual health information. This restriction has had the unintended consequence of posing serious challenges to medical researchers who depend on patient data for their studies.

Effect of the HIPAA Privacy Rule on Health Research: Proceedings of a Workshop Presented to the National Cancer Policy Forum (2006) summarized a series of presentations from officials of the Department of Health and Human Services Office



for Civil Rights, the National Institutes of Health, and other federal agencies, as well as from the pharmaceutical industry, experts in health law, privacy advocates, and academic leaders and researchers.

The presentations described the 2003 regulations governing the privacy of individually identifiable health information received by health plans, health care providers, and clearing-houses that engage in electronic transactions and the effects of those regulations on health research.

The workshop was instrumental in defining the issues and enabling the IOM to design a study to investigate the impact of the HIPAA privacy rule on health research. The IOM, with support from federal agencies, private-sector associations,

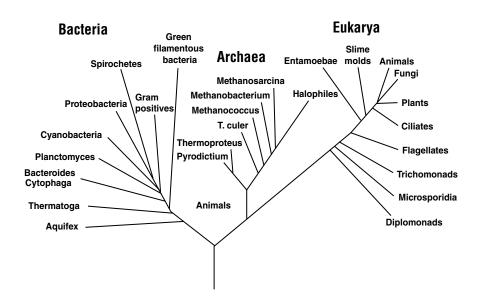
and foundations, has embarked on a major committee study *Health Research* and the *Privacy of Health Information: The HIPAA Privacy Rule*. The IOM committee is developing recommendations to facilitate important medical research while maintaining individual privacy. In conjunction with the study, the IOM has also commissioned several major surveys of U.S. epidemiologists, the HMO Research Network, and the public to strengthen the evidence base for examining the effects of the Privacy Rule on health research. Several organizations are also initiat-

#### Health Research: The Path to Knowledge

ing surveys on their own and plan to provide input to the committee, including American Society of Clinical Oncology, the American Heart Association, Academy Health, the International Pharmacy Privacy Consortium, and the North American Association of Central Cancer Registries. The committee's report, including findings and recommendations, is due at the end of 2008.

#### THE FUTURE OF THE LIFE SCIENCES

The field of life sciences is advancing with tremendous speed, enabling scientists to identify and manipulate features of living systems in ways never before possible. On a daily basis and in laboratories around the world, biomedical researchers use sophisticated technologies to manipulate microorganisms in an effort to understand how microbes cause disease and to develop better measures for fighting them. Plant biologists are applying similar tools in their studies of crops and other vegetation—both to improve agricultural yield and to explore the potential for the use of plants as inexpensive platforms for vaccine, antibody, and other product manufacturing. Similar efforts are underway with animal husbandry. Moreover, fields not traditionally viewed as having applications to the life sciences enterprise—materials science, information technology, and nanotechnology—are being integrated into traditional experimental and applied



Archaea represents one of the three domains of life, the other two being Bacteria and Eukarya. SOURCE: Globalization, Biosecurity, and the Future of the Life Sciences, p. 43.

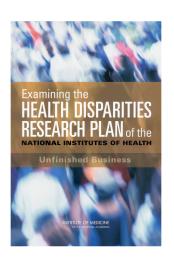
research approaches in extraordinary ways, enabling the development of previously unimaginable technological applications.

With this crucible of scientific exploration and insights into the way living systems "work," the continuing threat of the offensive applications of these tools and technologies is an ever present reality. The global spread of expertise and information in biotechnology and biological manufacturing processes has raised concerns about how advancing technological prowess could enable the creation and production of new threats of biological origin that possess dangerous and largely unpredictable characteristics. Among the recommendations contained in the NRC/IOM report *Globalization*, *Biosecurity*, and the Future of the Life Sciences (2006) were proposals to encourage

- the free and open exchange of scientific and technical information;
- the adoption of a broader perspective of the "threat spectrum;" and
- the enhancement of scientific and technical expertise within and across the national security communities.

#### THE NIH HEALTH DISPARITIES RESEARCH PLAN

"With the diversity of our population, it's in our interests as a nation to make sure that all of our people are as healthy as they can be," said former U.S. Surgeon General David Satcher.



Unfortunately, Dr. Satcher's comments remain an ideal and not a reality in today's society. Evidence shows that African Americans are disproportionately likely to struggle with diabetes, Hispanics are more likely to die of AIDS, and Native Americans have a higher risk of dying in infancy. Poor and rural populations are also disproportionately unhealthy. Eliminating these health disparities among U.S. populations requires an aggressive research agenda. National concerns about these health disparities have been noted as a high priority in national health status reviews, including Healthy People 2000 and 2010. As the nation's foremost research agency, the National Institutes of Health (NIH) naturally has a leading role in this effort, and the NIH ranks this issue among its top five priorities.

The "NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities" is intended to provide an overarching structure and coordination plan for research into these discrepancies by various NIH institutes

#### Health Research: The Path to Knowledge

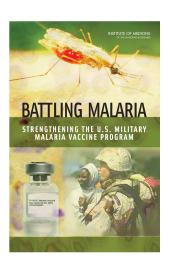
and centers. Examining the Health Disparities Research Plan of the National Institutes of Health: Unfinished Business (2006) assessed how well the plan provides the necessary guidance and recommended ways to improve oversight and coordination of these research efforts.

#### **BATTLING MALARIA**

Between 300 million and 500 million people worldwide will be treated for malaria infections this year. More than 1 million people will die from the disease. For more than 50 years, health care workers have effectively fought malaria with low-cost antimalarial drugs that have saved millions of lives. Unfortunately, these

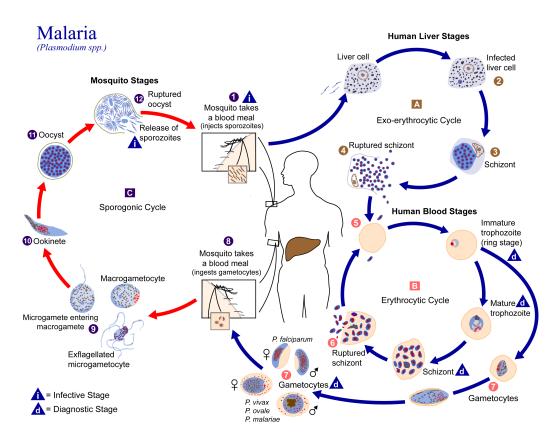
drugs are no longer effective against the deadliest forms of malaria. The U.S. military's concern that malaria is a major threat to overseas troops, and its recognition of the need for a vaccine to ward off the disease, has led it and philanthropic foundations, such as the Bill and Melinda Gates Foundation, to invest in vaccine research and development efforts.

During the past two decades, there have been two highly productive malaria vaccine research programs located at the Walter Reed Army Institute of Research (WRAIR) and the Naval Medical Research Center (NMRC). Although considerable collaboration and cooperation has occurred between the highly committed and productive staffs of both programs, there has also been divergence of strategies and some duplication of resources.



Recognizing the great complexity and expense of researching and developing a vaccine in an era of scant resources, the Department of Defense (DoD) asked the IOM to conduct a programmatic review of the military *Plasmodium falciparum* malaria vaccine research and development program. The IOM report *Battling Malaria: Strengthening the U.S. Military Malaria Vaccine Program* (2006) concluded that malaria remains a severe and ongoing threat to many military deployments. The DoD Malaria Vaccine Program represents a large proportion of the global malaria vaccine effort and has unique capabilities not readily available elsewhere, such as a well-defined sporozoite challenge model and a pilot production facility that ensures good manufacturing practices.

The program is pursuing three distinct approaches, each of which should continue, according to the report. However, the committee found a need to aggressively pursue fewer vaccine candidates within these approaches and to focus



The malaria life cycle. SOURCE: Battling Malaria: Strengthening the U.S. Military Malaria Vaccine Program, p. 22-23.

on human immune responses and correlates of protection. Clinical trials in nonimmune adults visiting malaria-endemic sites were suggested as a possible additional approach for moving candidates forward.

The report recommended that the program adopt a generational approach to vaccine development because even a partially protective first-generation vaccine would be a useful adjunct to preventive drugs while research continues to develop a vaccine sufficiently effective to be used alone.

It also recommended that the WRAIR and NMRC malaria vaccine programs be fully integrated into a unified organizational and legal entity—the Joint Task Force for Malaria Vaccines—with a single scientific director. The task force should

#### Health Research: The Path to Knowledge

be supported by an external scientific advisory board that would provide ongoing advice and assist in the selection of vaccine candidates.

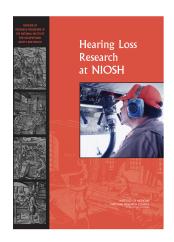
To use existing resources more efficiently, the report recommended an overhaul of the management structure of, and a significant increase in core support for, the DoD malaria vaccine enterprise. It is a worthwhile program that can be made more effective with these straightforward and easily implemented modifications.

#### **WORKPLACE SAFETY**

Every day, thousands of U.S. workers sustain disabling injuries on the job, more than a dozen die from injuries suffered at work, and at least a hundred

workers die from work-related illnesses. Charged with promoting safe and healthy workplaces, the National Institute for Occupational Safety and Health (NIOSH) supports and sponsors research to prevent work-related illnesses and injuries.

In 2004, the agency asked the National Academies to convene committees to review up to 15 of its research programs. The NRC and IOM committees in charge of conducting these reviews are tasked with assessing the relevance and impact of NIOSH research programs in improving occupational safety and health. The committees' reports are also intended to identify emerging issues and make recommendations for additional research to improve worker protection.



Hearing Loss Research at NIOSH (2006) was the first report in the series Reviews of Research Programs of the National Institute for Occupational Safety and Health. The report examined the problem of occupational hearing loss, a serious concern for many workers even though the number of people affected or at risk is uncertain. The report found that over the past decade, the Hearing Loss Research Program has made meaningful contributions to improving worker health and safety. Yet although some of its work is in high-priority subject areas and highly relevant to improvements in workplace protection, other efforts appear to be too narrowly targeted or directed to activities that are secondary to protecting the hearing of workers.

To enhance the relevance and impact of the program's work and fulfill its mission, the report recommended that the NIOSH Hearing Loss Research Program foster more effective leadership in program planning, implementation, and

Every day, thousands of U.S. workers sustain disabling injuries on the job, more than a dozen die from injuries suffered at work, and at least a hundred workers die from work-related illnesses.

evaluation. It must gain access to additional internal and external expertise, especially in epidemiology and noise control engineering, and initiate and sustain efforts to obtain surveillance data for occupational hearing loss and workplace noise exposure.

The IOM considers these kinds of evaluations critical to ensuring the effectiveness of federal agency efforts in human health and safety. Future reports in the series will be a valuable contribution to the work of NIOSH.

# Clinical Medicine: Best Practices for Better Health

At its core, the Institute of Medicine (IOM) is dedicated to bringing the best minds together to analyze all of the possible knowledge on a given topic and present evidence-based, actionable recommendations to better the health of the nation. Thus it is easy to imagine that the way medical research is applied in clinical settings—how it impacts actual human lives—is a critical focal point for the IOM's efforts.

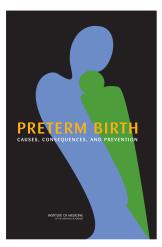
Science has led to many great advances in the practice of medicine. However, all too often there is a disconnect between the best practices identified by research and the care that patients actually receive. The IOM informs clinical decision making by evaluating research in many different arenas and providing the best possible advice and knowledge directly to health care practitioners and consumers. The subjects of the IOM's work include evidence-based medicine that is based on clinical practice, as well as evidence-based health care that responds to public health needs. Through these analyses, the IOM helps to reshape the way medicine is practiced in the real world for the benefit of the American people.

#### THE PROBLEM OF PRETERM BIRTH

In 2005, more than 12 percent of babies in the United States were born preterm after fewer than 37 wefis' gestation. Although babies born before 32 wefis are at the greatest risk of dying, near-term or late-preterm babies—those born between 32 and 36 wefis—are at high risk for a host of health and developmental

problems as well. There is great cost involved also: caring for preterm babies costs the U.S. health care system more than \$26 billion annually. Despite great strides in improving the survival of preterm infants once they are in the hospital, too little is known about preventing these preterm births in the first place.

Preterm Birth: Causes, Consequences, and Prevention (2007) identified the troubling disparities that exist in preterm birth rates among different racial and ethnic groups. In 2003, nearly 18 percent of pregnant African American women gave birth to a preterm baby, compared with less than 12 percent of Caucasian, Asian, and Hispanic women. In addition, a host of socio-

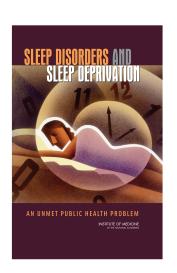


economic, biological, environmental, and other factors—often in combination—increase a woman's risks of preterm delivery. Adolescents less than 16 years old are twice as likely as women over 18 to deliver preterm, and women 35 and older are at an increased risk as well. Maternal history is also a factor: if a woman has delivered preterm, she is more likely to do so in future pregnancies.

The IOM committee recommended that federal agencies commit to sustained funding of research on the causes of preterm births. A multidisciplinary research agenda is needed to improve the prediction and prevention of preterm labor and to better understand the health and developmental problems that plague preterm infants. The report recommended that guidelines be issued to further reduce the number of multiple births resulting from infertility treatment, which is a significant risk factor for preterm birth.

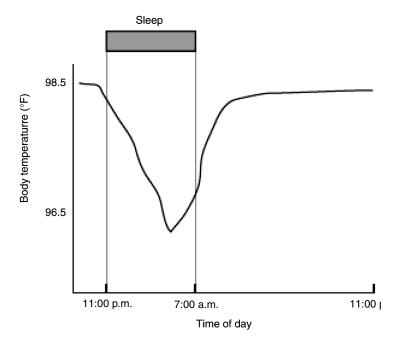
Release of the IOM report attracted nationwide media attention, including the major networks CBC, NBC, and ABC, as well as impacting legislation at the state and federal levels. The report's recommendations led to the enactment of the PREEMIE Act, legislation designed to reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications, as well as reduce infant mortality caused by prematurity. In the state of Indiana, legislation was introduced to expand and coordinate research on the prevention of preterm birth and the most effective care for preterm babies.

#### SLEEPLESS IN AMERICA



Between 50 million and 70 million Americans suffer from chronic sleep disorders such as insomnia, sleep apnea, and restless leg syndrome. Not only can a sleep disorder impinge on daily functioning and quality of life, it also adversely affects people's health and longevity. The cumulative long-term effects of sleep loss and sleep disorders have been associated with a wide range of health consequences, including an increased risk of hypertension, diabetes, obesity, depression, heart attack, and stroke. Nearly 20 percent of all serious car crash injuries in the general population are associated with driver fatigue and sleepiness independent of alcohol effects. As a result of all the various effects of sleep disorders, hundreds of billions of dollars are spent every year on direct medical costs associated with doctor visits, hospital services, prescriptions, and overthe-counter medications.

#### Clinical Medicine: Best Practices for Better Health



Body temperature in relation to time of day. SOURCE: Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem, p. 44.

The American Academy of Sleep Medicine, the National Center on Sleep Disorders Research at the NIH, the National Sleep Foundation, and the Sleep Research Society requested that the IOM conduct a study that would examine the public health significance of sleep disorders and identify opportunities for improving and stimulating interdisciplinary research, education, and training in sleep medicine.

Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem (2006) concluded that a coordinated strategy is needed to continue clinical and scien-

tific advances in sleep research. To lessen the public health and economic burden caused by sleep loss and sleep disorders, the workforce required to meet the clinical and scientific demands in this field must be expanded. Health care workers as well as the general public must be made aware of the serious nature of sleep loss and sleep disorders, and surveillance and

Nearly 20 percent of all serious car crash injuries in the general population are associated with driver fatigue and sleepiness independent of alcohol effects.

monitoring of the public health effects should be improved. In addition, more diagnostic and therapeutic technologies for identifying and treating sleep disorders are needed.

The report received coverage in newspapers and other media outlets across the country, including a feature on CBS's Early Show in a Healthwatch segment. The report's recommendations led to the development of guidelines by the American Academy of Sleep Medicine to accredit academic sleep centers.

#### LIFE AFTER CANCER

In the United States, half of all men and one-third of all women will develop cancer in their lifetimes. Advances in the detection and treatment of cancer, combined with an aging population, mean that "cancer survivor" will be a demographic category of its own in the near future. Despite this increase, primary care physicians and other health care providers often are not familiar with the secondary consequences of cancer or cancer treatments and seldom receive explicit guidance from oncologists. Furthermore, the lack of clear evidence of what constitutes best practices in caring for patients with a history of cancer contributes to wide variations in care.

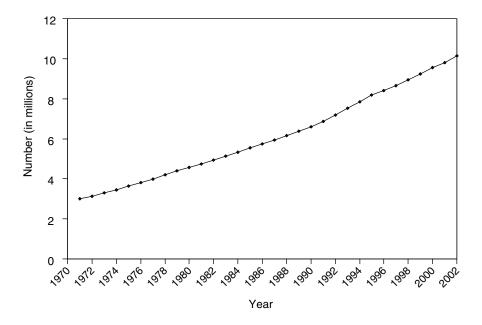
The transition from active treatment of cancer to post-treatment care is essential to long-term health. In addition to being at risk for cancer recurrence and

... primary care physicians and other health care providers often are not familiar with the secondary consequences of cancer or cancer treatments and seldom receive explicit guidance from oncologists. for developing other cancers, survivors may also face psychological distress, sexual dysfunction, infertility, impaired organ function, cosmetic changes, and limitations in mobility, communication, and cognition. In part, this is a direct result of treatment: many cancer treatments—including surgery, chemotherapy, hormone therapy, and radiation therapy—may have long-term

effects on tissues and organ systems. If care is not planned and coordinated, survivors are left without knowledge of their heightened risks or appropriate follow-up plans for action.

To make up for shortfalls in the care currently provided to the 10 million cancer survivors in the United States, the IOM report *From Cancer Patient to Cancer Survivor: Lost in Transition* (2006) recommended that each cancer patient receive a "survivorship care plan." Such plans should summarize information critical to the individual's long-term care, including a history of the cancer diagnosis, treatment, and potential consequences; the recommended timing and content

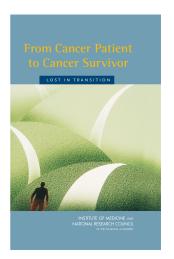
#### Clinical Medicine: Best Practices for Better Health



Estimated number of cancer survivors in the United States from 1971 to 2002. SOURCE: From Cancer Patient to Cancer Survivor: Lost in Transition, p. 25.

of follow-up visits; advice on maintaining a healthy lifestyle and preventing recurrent or new cancers; legal rights affecting employment and insurance; and the availability of psychological and support services. Details of survivorship care plans were specifically reviewed in a follow-up workshop *Implementing Cancer Survivorship Care Planning: Workshop Summary* (2007).

Cancer survivorship should be recognized as a distinct phase of cancer care. Participants in the care planning workshop called for health care providers, patient advocates, and other stak-olders to raise awareness of the needs of cancer survivors. For example, leadership organizations for physicians, nurses, and other health care providers should collaborate to improve care, and insurance companies should improve access to necessary services through more generous reimbursement policies. Policies should



be enacted to improve cancer survivors' quality of life, such as ensuring access to psychosocial services, fair employment practices, and health insurance.

To ensure that the 2006 report's message was widely disseminated, a FREDDIE award—winning video was produced to accompany it. After the report's release, Congress introduced the Comprensive Cancer Care Improvement Act of 2007 (H.R. 1078) to implement its recommendations. The bill provides for coverage of comprensive care planning under the Medicare program and would improve the care furnished to individuals diagnosed with cancer by establishing a Medicare hospice care demonstration program and grants programs for cancer palliative care and symptom management, provider education, and related research.

# MENTAL OR SUBSTANCE-USE PROBLEMS: QUALITY OF CARE

Each year more than 33 million Americans receive health care for mental or substance-use problems and illnesses. The diagnoses and severity of mental and substance-use problems vary widely—from distress caused by a life-changing event to severe depression to physical dependence on alcohol. These conditions

are the leading cause of combined disability and death in women, and the second highest in men.

Improving the Quality of Health Care for Mental and substance-Use Conditions

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Effective treatments do exist for many of these problems, and they continually improve. However, as with general health care, deficiencies in the way these treatments are delivered prevent many from receiving appropriate care. This has serious consequences for people who have the conditions; for their loved ones; for the workplace; for the education, welfare, and justice systems; and for the nation as a whole.

The IOM report *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001) set forth a strategy for improving health care in general. The report described quality issues and defined six aims—care should be safe, effective,

patient-centered, timely, efficient, and equitable—and ten rules for care delivery redesign. Health care for mental and substance-use conditions has a number of distinctive characteristics, however—including the greater use of coercion into treatment, separate care delivery systems, a less developed infrastructure for measuring the quality of care, and a differently structured marketplace. These and other differences have raised questions about whether the same quality measurement and remediation approach are applicable to health care for mental and substance-use conditions.

#### Clinical Medicine: Best Practices for Better Health

Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series (2006) built on previous reports by laying out a multifaceted strategy for incorporating the recommended general health framework into mental and substance-use health care. The strategy addresses the essential role that

health care plays for mental and substance abuse conditions in improving overall health. To that end, the report identified actions that should be required of clinicians, health care organizations, health plans, purchasers, all levels of government, and all other parties involved in health care for mental and substance-use conditions.

Health care for mental and substanceuse conditions has a number of distinctive characteristics, however including the greater use of coercion into treatment, separate care delivery systems, a less developed infrastructure for measuring the quality of care, and a differently structured marketplace.

The IOM received a *forWARDS*™ award in 2006 from the National Mental Health Association (NMHA) for its latest *Quality Chasm* report. The NMHA developed the program to pay tribute to the people, actions, and events that advance the cause of mental health each year. Additionally, the Johns Hopkins Bloomberg School of Public Health offered a class during the summer of 2006, "The IOM Blueprint for Improving Mental Health and Substance Use," based on the Quality Chasm report.

#### **EVIDENCE-BASED MEDICINE**

The IOM is founded on the principle of using sound scientific evidence to drive policy and research. The health of Americans has greatly benefited from the rapid growth of medical research and technology over the years, but multiple studies have shown that too few of the medical services supported by the stron-

gest evidence are actually delivered and that far too much health care spending is devoted to activities that do not improve health. In fact, little time or money has been invested in understanding the advantages of different interventions. This gap in knowledge will continue to increase as the pace of technology development quickens and the benefits of genetic research

This gap in knowledge will continue to increase as the pace of technology development quickens and the benefits of genetic research and other revolutionary areas of inquiry evolve into therapies and medications.

and other revolutionary areas of inquiry evolve into therapies and medications. Bridging this divide is fundamentally important to the efforts to improve the efficiency and efficacy of health care in America.

To address these issues, the IOM convened the Roundtable on Evidence-Based Medicine. The roundtable brings together key stak-olders from multiple sectors—healthcare providers, patients, insurers, employers, manufacturers,

policy makers, and researchers—for cooperative discussions and consideration of the ways in which evidence can be better developed and applied to improve the effectiveness of medical care. Thus far, participants have discussed efforts to move toward a "learning" healthcare system, in which evidence is applied and developed as a natural product of patient care. Another focus has been on advancing the capacity to generate clinical evidence for medical care that is most effective and provides the greatest value. Participants are also examining how to improve public understanding of evidence and its dynamic nature. This work is critically important to the IOM's mission of providing well-founded advice to the public, including medical practitioners.

# Forums and Roundtables: The Power of Convening

The fundamental work of the Institute of Medicine (IOM) is not simply the creation of documents and reports. It is the act of bringing people together to share and advance knowledge. While creation of a common ground can occur through formal committees with specific reporting objectives and mandated areas of study, it often takes place through forums, roundtables, and symposia, all of which provide opportunities for serendipitous discovery and critical, cross-disciplinary thinking.

Symposia are most often held as part of the dissemination activities for an IOM report on a narrowly defined topic. A series of symposia on the subject of childhood obesity, for example, has served to bring the subject and the IOM's report to the attention of regional media markets and stak-olders.

In contrast, forums and roundtables, the IOM's convening activities, offer a different approach to the exploration of issues in science and public policy than traditional consensus studies. They draw together diverse parties who have shared interests in the health sciences in a neutral setting.

Forums and roundtables bring together a community of stak-olders interested in a broad area of health 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 of consumer and public interest groups.

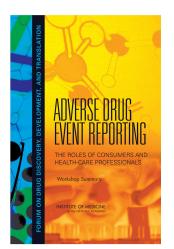
The purpose of these gatherings is to illuminate issues through discussion and debate across sectors and institutions rather than to resolve pressing issues and make specific, actionable recommendations. Bringing together these individuals can be a powerful force in creating the shared knowledge, trust, and understanding necessary to enable progress in the most difficult areas of health and science policy.

Forums and roundtables bring together a community of stakeholders interested in a broad area of health science policy for a long-term, evidence-based dialogue.

#### **FOOD FORUM**

Since 1993, the Food Forum of the Food and Nutrition Board has engaged science and technology leaders in the food industry, top administrators from federal agencies in the United States and Canada, representatives from consumer interest groups, and academics in discussing food-related issues. The dialogue established during Food Forum meetings is intended to explore approaches to address emerging issues in the broad areas of food science, food safety, and nutrition, including technologies and regulations. The Food Forum's most recent workshop explored the varying approaches, methodologies, and challenges in assessing nutritional risk.

# FORUM ON DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION



The Forum on Drug Discovery, Development, and Translation (DDDT Forum) was created in 2005 by the Board on Health Sciences Policy to provide an opportunity for leaders from government, academia, industry, and other stak-olders to meet and discuss issues in pharmacology several times each year. In addition, the DDDT Forum commissions research papers to synthesize the literature on selected topics. The DDDT Forum's workshops thus far have looked at a range of issues from adverse drug event reporting to better understanding of the benefits and risks of pharmaceuticals.

#### FORUM ON MICROBIAL THREATS

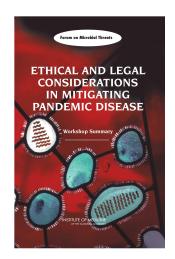
The Forum on Microbial Threats (FMT), formerly the Forum on Emerging Infections, was established in 1996 to provide a structured opportunity for stak-older discussions of the prevention, detection, and management of infectious diseases. The FMT's membership includes individuals from a wide range of disciplines and organizations in the public and private sectors, including the public health, medical, pharmaceutical, veterinarian, plant pathology, academic science, agricultural, national security, and environmental communities. In recent years, the FMT dialogue has resulted in the illumination of priority issues in infectious disease research and public health policy; the use of new scientific and policy tools; and opportunities for more effective collaboration between the private and the public sectors. The FMT's recent workshops have focused on the ethical and legal components of strategies to thwart pan-

## Forums and Roundtables: The Power of Convening

demic disease as well as the best methods for the surveillance and detection of infectious disease.

# FORUM ON NEUROSCIENCE AND NERVOUS SYSTEM DISORDERS

Established in the fall of 2006, the Forum on Neuroscience and Nervous System Disorders (FNNSD) focuses on building partnerships to better understand the brain and nervous system disorders in their structure and function as well as to share effective clinical prevention and treatment strategies. The FNNSD concentrates on six themes to better educate the public, press, and policy makers: nervous system disorders, mental illness and addiction, genetics of nervous system disorders, cognition and bavior, modeling and imaging, and



ethical and social issues. The FNNSD brings together leaders from private-sector sponsors of biomedical and clinical research, federal agencies sponsoring and regulating biomedical and clinical research, foundations, the academic community, and consumers. The two most recent workshops hosted by the FNNSD were dedicated to neuroscience biomarkers and the environmental and research challenges of autism. In addition, to help identify the long-term priorities of neuroscience field, the FNNSD is beginning a new initiative focused on identifying the grand challenges facing the field and the infrastructure needs required to meet these challenges.

#### NATIONAL CANCER POLICY FORUM

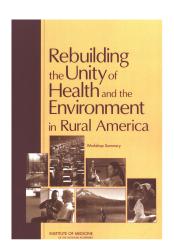
The IOM established the National Cancer Policy Forum (NCPF) in May 2005 to succeed the National Cancer Policy Board (1997-2005). The NCPF continues the work of the Board in providing a focus within the National Academies for the consideration of issues in science, clinical medicine, public health, and public policy relevant to the goals of preventing, palliating, and curing cancer. The NCPF's two most recent workshops examined cancer in elderly people and the genetic testing and counseling issues related to cancer patients.

## **ROUNDTABLE ON HEALTH LITERACY**

Building on the 2004 IOM report *Health Literacy: A Prescription to End Confusion*, the IOM convened a Roundtable on Health Literacy. According to the 2004 report, nearly half of all American adults—90 million people—have difficulty understanding and using health information, and there is a higher rate of hospitalization and

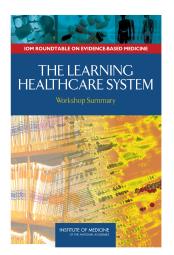
use of emergency services among patients with limited health literacy. Limited health literacy may lead to billions of dollars in avoidable health care costs. The Roundtable brings together leaders from academia, industry, government, foundations, and associations and representatives of patient and consumer groups who have an interest and role in improving health literacy. The Roundtable has held a number of workshops to address specific concerns relevant to health literacy, including the organizational changes necessary to improve health literacy and the role of health literacy in transforming health care quality.

# ROUNDTABLE ON ENVIRONMENTAL HEALTH SCIENCES, RESEARCH, AND MEDICINE



In 1998, the IOM established the Roundtable on Environmental Health Sciences, Research, and Medicine to provide a convening mechanism for environmental health stak-olders from academia, industry, environmental, and federal research perspectives to meet to discuss sensitive and difficult issues. Presently, the Roundtable has three areas of emphasis: the human-impacted environment, gene—environment interactions, and monitoring of environmental health. Two recent workshops held by the Roundtable have looked at the environmental public health impacts of disasters, with a focus on Hurricane Katrina, and the various aspects and economics of green health care institutions.

# ROUNDTABLE ON EVIDENCE-BASED MEDICINE



The Roundtable on Evidence-Based Medicine was convened in 2006 to help reexamine the way in which evidence on clinical effectiveness is generated and used to improve health and health care. Roundtable members come from a variety of sectors including consumers and patients, health professionals, health care delivery organizations, evaluators and clinical researchers, employees and employers, health information technology developers, health care manufacturers, insurers, and regulators. They work with their colleagues to identify issues that are not being adequately addressed, the nature of the barriers and possible solutions, and priorities for action. Much of the work is oriented around three ongoing interests: evidence development, evidence applica-

#### Forums and Roundtables: The Power of Convening

tion, and sustainable capacity. Several of the Roundtable's recent workshops have focused on the "learning" health care system—how it might better capture and apply insights generated in the course of care.

# FORUM ON THE SCIENCE OF HEALTH CARE QUALITY IMPROVEMENT AND IMPLEMENTATION

Formed in 2006, the Forum on the Science of Health Care Quality Improvement and Implementation brings together leaders in quality improvement research, foundations, federal agencies sponsoring and conducting such research, the academic community, medical journals, and implementers of quality improvement. The goals of the Forum are to advance the understanding of the value and appropriate role of research philosophies, cultures, and methods and to develop greater awareness of and support for suitable approaches and methods on the part of key stak-older groups. The first workshop sponsored by the Forum focused on how quality improvement research might be advanced by looking at the current state of the research and the various barriers in the health care industry.



Informing the Future: Critical Issues in Health, Fourth Edition http://www.nap.edu/catalog/12014.html

# Fellowships at the Institute of Medicine: Tomorrow's Health Leaders

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 provide exposure to the health policy processes of Congress and the executive branch, and some fellows are able to work with the IOM's committees and other activities as well.

# ROBERT WOOD JOHNSON HEALTH POLICY FELLOWSHIPS

For more than 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 bavioral scientists. Through a unique and comprensive orientation program designed and administered by the IOM, followed by high-level work assignments in Congress or the administration, more than 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 have been frequently cited by members of Congress, the administration, and the health policy community as significantly improving the outcomes of the health policy-making process. For example, Mario Pacheco (2000–2001) came to his congressional assignment with a concern about obesity in the Hispanic population and 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 each fellow possesses makes valuable contributions to the deliberations of federal policy makers. Consequently, fellows are in great demand during their year in Washington, D.C., and beyond. They are recruited for congressional staff positions, 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, along with professional organiza-

tions and associations, also enlist alumni for their insight and experience to serve in leadership roles.

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 maintain their connections to the workings of government, and some alumni have become official liaisons in government relations for their universities and professional societies. For example, Kristofer Hagglund (2000-2001) and Karen Edison (1999-2000) are the co-directors and cofounders of the Center for Health Policy at the University of Missouri, Columbia.

#### IOM ANNIVERSARY FELLOWS PROGRAM

To celebrate its thirty-fifth anniversary in 2005, the IOM created a new fellowship program to enable talented health science scholars who are early in their careers to participate in the work of the IOM and to further their careers as future leaders in the health field. IOM boards, committees, and roundtables provide exceptional—and in many ways unique—learning environments that can offer early-career scholars extensive opportunities to interact with eminent researchers, policy experts, and clinicians from across the country on a range of important health issues.

The two-year program is open to individuals who hold nontenured faculty positions in any university. It welcomes applications from underrepresented minority candidates. Fellows continue with their main academic responsibilities while engaging part-time in various IOM activities. A one-wefi 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 benefits of gaining new knowledge, professional connections, and broad exposure to policy leaders attracts an outstanding pool of applicants from a range of health-related disciplines.

## **DISTINGUISHED NURSE SCHOLAR PROGRAM**

The Distinguished Nurse Scholar Program is designed to assist outstanding nurse leaders in playing a more prominent role in health policy development at the national level. The program sefis individuals who have the capacity and skills to help increase policy makers' awareness and understanding of critical issues related to nursing. As part of the program, the scholar is asked to produce a policy-oriented paper based on her or his area of special interest or to become actively involved in an IOM study related to his or her area of expertise.

## Fellowships at the Institute of Medicine: Tomorrow's Health Leaders

The program, initiated in 1992, is supported by the American Academy of Nursing and the American Nurses Foundation and conducted by the IOM. Each year, one senior nurse scholar is selected from an eligible institution or organization to come to Washington, D.C., to participate in a one-year program of orientation and work at the IOM.

Informing the Future: Critical Issues in Health, Fourth Edition http://www.nap.edu/catalog/12014.html

This chapter lists reports released by the Institute of Medicine from 2005 through 2007 as well as select older reports, grouped by subject area. Following the reports, are upcoming reports expected to be released through 2008.

denotes a congressionally mandated study.

## **RECENT REPORTS** (2005–2007)

#### AGING AND ELDERLY PEOPLE

- **Approaching Death: Improving Care at the End of Life**, Health Care Services, 1997.
- **Cancer in Elderly People: Workshop Proceedings**, National Cancer Policy Forum, 2007.
- 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.
  Improving the Social Security Disability Decision Process, Military and Veterans Health, 2007.

#### CHILD/YOUTH HEALTH

- Adequacy of Evidence for Physical Activity Guideline Development: Workshop Summary, Food and Nutrition Board and Population Health and Public Health Practice, 2007.
- America's Children: Health Insurance and Access to Care, Health Care Services and Board on Children, Youth, and Families, IOM/NRC, 1998.
- Confronting Chronic Neglect: The Education and Training of Health Professionals on Family Violence, Board on Children, Youth, and Families, IOM/NRC, 2001.
- Emergency Care for Children: Growing Pains, Health Care Services, 2007. Ethical Considerations for Research on Housing-Related Health Hazards Involving Children, Board on Children, Youth, and Families, IOM/NRC, 2005.

<sup>&</sup>lt;sup>1</sup>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.

- **Food Marketing to Children and Youth: Threat or Opportunity?**, Food and Nutrition Board, 2006.
- Future of Emergency Care: Dissemination Workshop Summaries, Health Care Services, 2007.
- 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: 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.
- Joint U.S.-Mexico Workshop on Preventing Obesity in Children and Youth of Mexican Origin, Food and Nutrition Board, 2007.
- **Making Better Drugs for Children with Cancer**, National Cancer Policy Board, 2005.
- From Neurons to Neighborhoods: The Science of Early Childhood Development, Board on Children, Youth, and Families, IOM/NRC, 2000.
- Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth, Food and Nutrition Board, 2007.
  - **Preterm Birth: Causes, Consequences, and Prevention**, Health Sciences Policy, 2007.
- Preventing Childhood Obesity: Health in the Balance, Food and Nutrition Board and Board on Health Promotion and Disease Prevention, 2005.
  - Preventing Teen Motor Crashes: Contributions from the Bavioral and Social Sciences, Board on Children, Youth, and Families, IOM/NRC/ Transportation Research Board, 2007.
  - Progress in Preventing Childhood Obesity: Focus on Communities—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Industry—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Schools—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.

- **Progress in Preventing Childhood Obesity: How Do We Measure Up?**, Food and Nutrition Board, 2007.
- 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.
- The Richard and Hinda Rosenthal Lectures 2004: Perspectives on the Prevention of Childhood Obesity in Children and Youth, Institute of Medicine, 2005.
- **Safe Medical Devices for Children**, Health Sciences Policy, 2005.
  - A Study of Interactions: Emerging Issues in the Study of Adolescence: A Workshop Summary, Board on Children, Youth, and Families, IOM/NRC, 2006.
  - WIC Food Packages: Time for a Change, Food and Nutrition Board, 2005.

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

- The Anthrax Vaccine: Is It Safe? Does It Work?, Medical Follow-Up Agency, 2002.
  - **Asbestos: Selected Cancers**, Population Health and Public Health Practice, 2006.
  - Assessing the Quality of Cancer Care: An Approach to Measurement in Georgia, National Cancer Policy Board, 2005.
  - Assessment of Future Scientific Needs for Live Variola Virus, Global Health, 1999.
  - Battling Malaria: Strengthening the U.S. Military Malaria Vaccine Program, Medical Follow-Up Agency and Board on Military and Veterans Health, 2006.
  - Biological Threats and Terrorism: Assessing the Science and Response Capabilities, Global Health, 2002.
  - From Cancer Patient to Cancer Survivor: Lost in Transition, National Cancer Policy Board, 2005.
  - **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, 2005.
  - Emerging Infections: Microbial Threats to Health in the United States, Health Sciences Policy, 1992.

- 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, 2005.
- **Food Marketing to Children and Youth: Threat or Opportunity?,** Food and Nutrition Board, 2006.
- **Gulf War and Health, Volume 5: Infectious Disease**, Population Health and Public Health Practice, 2007.
  - 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.
  - Implementing Cancer Survivorship Care Planning: Workshop Summary, National Cancer Policy Forum, 2007.
  - Improving Palliative Care for Cancer—Summary and Recommendations, National Cancer Policy Board, IOM/NRC, 2001.
  - Learning from SARS: Preparing for the Next Disease Outbreak, Workshop Summary, Global Health, 2004.
  - **Marijuana and Medicine: Assessing the Science Base**, Neuroscience and Bavioral Health, 1999.
- Noise and Military Service: Implications for Hearing Loss and Tinnitus, Medical Follow-Up Agency, 2005.
- Preventing Childhood Obesity: Health in the Balance, Food and Nutrition Board and Board on Health Promotion and Disease Prevention, 2005.
  - Progress in Preventing Childhood Obesity: Focus on Communities—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Industry—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Schools—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.

- **Progress in Preventing Childhood Obesity: How Do We Measure Up?**, Food and Nutrition Board, 2007.
- Reusability of Facemasks During an Influenza Pandemic: Facing the Flu, Health Sciences Policy, 2006.
- Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem, Health Sciences Policy, 2006.
- The Smallpox Vaccination Program: Public Health in an Age of Terrorism, Population Health and Public Health Practice, 2005.
- Veterans and Agent Orange: Herbicide/Dioxin Exposure and Acute Myelogenous Leukemia in the Children of Vietnam Veterans, Health Promotion and Disease Prevention, 2002.
- Veterans and Agent Orange: Herbicide/Dioxin Exposure and Type 2
  Diabetes, Health Promotion and Disease Prevention, 2000.

## DRUGS, DEVICES, AND BIOLOGICS

- Adverse Drug Event Reporting: The Roles of Consumers and Health Care Professionals: Workshop Summary, Health Sciences Policy, 2007.
- The Anthrax Vaccine: Is It Safe? Does It Work? Medical Follow-Up Agency, 2002.
  - **Assessment of Future Scientific Needs for Live Variola Virus**, Global Health, 1999.
  - Developing a National Registry of Pharmacologic and Biologic Clinical Trials: Workshop Report, Health Sciences Policy, 2006.
  - 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, 2005.
  - The Future of Drug Safety: Promoting and Protecting the Health of the Public, Population Health and Public Health Practice, 2007.
- Gulf War and Health, Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines, Health Promotion and Disease Prevention, 2000.
  - Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War, Population Health and Public Health Practice, 2006.
  - 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 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.
- **Making Better Drugs for Children with Cancer**, National Cancer Policy Board, 2005.
- **Marijuana and Medicine: Assessing the Science Base**, Neuroscience and Bavioral Health, 1999.
- Marijuana as Medicine?: The Science Beyond the Controversy, Neuroscience and Bayorioral Health, 2000.
- Microbial Threats to Health: The Threat of Pandemic Influenza, Global Health, 2006.
- **Posttraumatic Stress Disorder: Diagnosis and Assessment,** Population Health and Public Health Practice, 2006.
- Preventing Medication Errors: Quality Chasm Series, Health Care Services, 2007.
- Safe Medical Devices for Children, Health Sciences Policy, 2005.
  - Understanding the Benefits and Risks of Pharmaceuticals: Workshop Summary, Health Sciences Policy, 2007.
  - Vaccine Safety Research, Data Access, and Public Trust, Population Health and Public Health Practice, 2005.

#### **ENVIRONMENTAL AND OCCUPATIONAL HEALTH**

- Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users, Health Sciences Policy, 2007.
- Does the Built Environment Influence Physical Activity? Examining the Evidence—Special Report 282, Population Health and Public Health Practice, 2005.
- **Ensuring Safe Food From Production to Consumption,** Food and Nutrition Board, 1998.
- Environmental Public Health Impacts of Disasters: Hurricane Katrina, Workshop Summary, Population Health and Public Health Practice, 2007.
- Estimating the Contributions of Lifestyle-Related Factors to Preventable Death: A Workshop Summary, Population Health and Public Health Practice, 2005.
- Ethical Considerations for Research on Housing-Related Health Hazards Involving Children, Board on Children, Youth, and Families, IOM/NRC, 2005.

- Genes, Barior, and the Social Environment: Moving Beyond the Nature/ Nurture Debate, Health Sciences Policy, 2006.
- Global Environmental Health in the 21st Century: From Governmental Regulation to Corporate Social Responsibility, Workshop Summary, Population Health and Public Health Practice, 2007.
- Green Healthcare Institutions; Health, Environment, and Economics, Workshop Summary, Population Health and Public Health Practice, 2007.
- Gulf War and Health, Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines, Health Promotion and Disease Prevention, 2000.
- Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants, Health Promotion and Disease Prevention, 2005.
  - Implications of Nanotechnology for Environmental Health Research, Workshop Summary, Population Health and Public Health Practice, 2005.
  - Rebuilding the Unity of Health and the Environment in Rural America: Workshop Summary, Population Health and Public Health Practice, 2006.
  - Rebuilding the Unity of Health and the Environment, the Greater Houston Metropolitan Area: Workshop Summary, Population Health and Public Health Practice, 2005.
  - Review of NASA's Space Flight Health Standards-Setting Process: Letter Report, Health Sciences Policy, 2007.

# FOOD, NUTRITION, AND DIET

- Addressing Foodborne Threats to Health: Policies, Practices, and Global Coordination, Workshop Summary, Global Health, 2006.
- Diet and Health: Implications for Reducing Chronic Disease Risk, Food and Nutrition Board, 1989.
- 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: Proposed Definition of Dietary Fiber,** Food and Nutrition Board, 2001.
- Dietary Reference Intakes: The Essential Guide to Nutrient Requirements, Food and Nutrition Board, 2006.
- Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride, Food and Nutrition Board, 1997.

- Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, Food and Nutrition Board, 2002.
- Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Food and Nutrition Board, 1998.
- Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Food and Nutrition Board, 2001.
- Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Food and Nutrition Board, 2000.
- Dietary Reference Intakes Research Synthesis: Workshop Summary, Food and Nutrition Board, 2007.
- **Dietary Risk Assessment in the WIC Program**, Food and Nutrition Board, 2002.
- Eat for Life: The Food and Nutrition Board's Guide to Reducing Your Risk of Chronic Disease, Food and Nutrition Board, 1992.
- **Ensuring Safe Food: From Production to Consumption**, Food and Nutrition Board, joint with the NRC Board on Agriculture, 1998.
  - Escherichia coli O157:H7 in Ground Beef: Review of a Draft Risk Assessment, Health Promotion and Disease Prevention, Food and Nutrition Board, 2002.
  - Evolution of Evidence for Selected Nutrient and Disease Relationships, Food and Nutrition Board, 2002.
  - **Food Chemicals Codex: First Supplement to the Fifth Edition,** Food and Nutrition Board, 2006.
  - **Food Chemicals Codex: Third Supplement to the Fourth Edition**, Food and Nutrition Board, 2001.
  - **Food Marketing to Children and Youth: Threat or Opportunity?,** Food and Nutrition Board, 2006.
  - Influence of Pregnancy Weight on Maternal and Child Health: A Workshop Report, Board on Children, Youth, and Families, IOM/NRC, 2007.
  - **Integrating Employee Health: A Model Program for NASA**, Food and Nutrition Board, 2005.
  - Joint U.S.-Mexico Workshop on Preventing Obesity in Children and Youth of Mexican Origin, Food and Nutrition Board, 2007.
  - Letter Report on the Dietary Reference Intakes for Trans Fatty Acids, Drawn from the Report on Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids, Food and Nutrition Board, 2001.

- Mineral Requirements for Military Personnel: Levels Needed for Cognitive and Physical Performance During Garrison Training, Food and Nutrition Board, 2006.
- Nutrient Composition of Rations for Short-Term, High-Intensity Combat Operations, Food and Nutrition Board, 2005.
- Nutrigenomics and Beyond: Informing the Future, Workshop Summary, Food and Nutrition Board, 2007.
- Nutrition During Lactation, Food and Nutrition Board, 1991.
- Nutrition During Pregnancy: Part 1: Weight Gain, Part 2: Nutrient Supplements, Food and Nutrition Board, 1990.
- Nutrition During Pregnancy and Lactation: An Implementation Guide, Food and Nutrition Board, 1992.
- **Nutrition Services in Perinatal Care: Second Edition**, Food and Nutrition Board, 1992.
- Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth, Food and Nutrition Board, 2007.
- Preventing Childhood Obesity: Health in the Balance, Food and Nutrition Board and Board on Health Promotion and Disease Prevention, 2005.
  - Progress in Preventing Childhood Obesity: Focus on Communities—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Industry—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - Progress in Preventing Childhood Obesity: Focus on Schools—Brief Summary: Institute of Medicine Regional Symposium, Food and Nutrition Board, 2006.
  - **Progress in Preventing Childhood Obesity: How Do We Measure Up?**, Food and Nutrition Board, 2007.
  - **Seafood Choices: Balancing Benefits and Risks**, Food and Nutrition Board, 2007.
  - Weighing the Options: Criteria for Evaluating Weight-Management **Programs**, Food and Nutrition Board, 1995.
  - WIC Food Packages: Time for a Change, Food and Nutrition Board, 2005.

#### GLOBAL AND INTERNATIONAL HEALTH

- Addressing Foodborne Threats to Health: Policies, Practices, and Global Coordination, Workshop Summary, Global Health, 2006.
- America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests, International Health, 1997.

- **Assessment of Future Scientific Needs for Live Variola Virus**, Global Health, 1999.
- Cancer Control Opportunities in Low- and Middle-Income Countries, Global Health, 2007.
- Emerging Infections: Microbial Threats to Health in the United States, Health Sciences Policy, 1992.
- Ending Neglect: The Elimination of Tuberculosis in the United States, Health Promotion and Disease Prevention, 2000.
- Ending the War Metaphor: The Changing Agenda for Unraveling the Host-Microbe Relationship, Workshop Summary, Global Health, 2006.
- Ensuring an Infectious Disease Workforce: Education and Training Needs for the 21st Century, Workshop Summary, Global Health, 2006.
- Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary, Global Health, 2007.
- **Globalization**, **Biosecurity**, **and the Future of the Life Sciences**, Global Health, 2006.
- Healers Abroad: Americans Responding to the Human Resource Crisis in HIV/AIDS, Global Health, 2005.
- Human Resources at U.S. Ports of Entry to Protect the Public's Health. Interim Letter Report, Global Health, 2005.
- The Impact of Globalization on Infectious Disease Emergence and Control: Exploring the Consequences and Opportunities, Workshop Summary, Global Health, 2006.
- An International Perspective on Advancing Technologies and Strategies for Managing Dual-Use Risks: Report of a Workshop, Global Health, 2005.
- Joint U.S.-Mexico Workshop on Preventing Obesity in Children and Youth of Mexican Origin, Food and Nutrition Board, 2007.
- Microbial Threats to Health: The Threat of Pandemic Influenza, Global Health. 2006.
- **PEPFAR Implementation: Progress and Promise**, Global Health, 2007.
- Plan for a Short-Term Evaluation of PEPFAR Implementation: Letter Report #1, Global Health, 2006.
  - Preventing HIV Infection Among Injecting Drug Users in High Risk Countries: An Assessment of the Evidence, Global Health, 2006.
  - Quarantine Stations at Ports of Entry Protecting the Public's Health, Global Health, 2005.
  - **Review of the HIVNET 012 Perinatal HIV Prevention Study**, Population Health and Public Health Practice, 2005.

## HEALTH CARE PROFESSIONAL TRAINING, EDUCATION, AND WORKFORCE

- Adverse Drug Event Reporting: The Roles of Consumers and Health Care Professionals, Workshop Summary, Health Sciences Policy, 2007.
- Confronting Chronic Neglect: The Education and Training of Health Professionals on Family Violence, Board on Children, Youth, and Families, IOM/NRC, 2001.
- **Emergency Care for Children: Growing Pains**, Health Care Services, 2007.
- Emergency Medical Services at the Crossroads, Health Care Services, 2007.
  The Future of the Public's Health in the 21st Century, Health Promotion
  - and Disease Prevention, 2002.
  - Healers Abroad: Americans Responding to the Human Resource Crisis in HIV/AIDS, Global Health, 2005.
- Hospital-Based Emergency Care: At the Breaking Point, Health Care Services, 2007.
  - Human Resources at U.S. Ports of Entry to Protect the Public's Health: Interim Letter Report, Global Health, 2005.
  - **Integrating Employee Health: A Model Program for NASA**, Food and Nutrition Board, 2005.
  - Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, Institute of Medicine, IOM/NRC, 2002.
  - **The Learning Healthcare System: Workshop Summary,** Institute of Medicine, 2007.
  - Nursing Staff in Hospitals and Nursing Homes: Is it Adequate? Health Care Services, 1996.
- **PEPFAR Implementation: Progress and Promise**, Global Health, 2007.
  - The Richard and Hinda Rosenthal Lectures 2005: Next Steps Toward Higher Quality Health Care, Institute of Medicine, 2006.
  - The Right Thing to Do, The Smart Thing to Do: Enhancing Diversity in Health Professions—Summary of the Symposium on Diversity in Health Professions in Honor of Herbert W. Nickens, M.D., Institute of Medicine, 2001.
- Training Physicians for Public Health Careers, Population Health and Public Health Practice, 2007.

# HEALTH CARE SERVICES, QUALITY OF CARE

- Advancing Quality Improvement Research: Challenges and Opportunities, Workshop Summary, Health Care Services, 2007.
- America's Health Care Safety Net: Intact but Endangered, Health Policy Programs and Fellowships, 2000.

- America's Health in Transition: Protecting and Improving Quality, Council of the Institute of Medicine, 1994.
- Assessing the Quality of Cancer Care: An Approach to Measurement in Georgia, National Cancer Policy Board, 2005.
- Building a Better Delivery System: A New Engineering/Health Care Partnership, Health Care Services, 2005.
- Care Without Coverage: Too Little, Too Late, Health Care Services, 2002.
- The Computer-Based Patient Record: An Essential Technology for Health Care, Revised Edition, Health Care Services, 1997.
- **Coverage Matters: Insurance and Health Care**, Health Care Services, 2001.
- Crossing the Quality Chasm: A New Health System for the 21st Century, Committee on Quality of Health Care in America, 2001.
- **Emergency Care for Children: Growing Pains,** Health Care Services, 2007.
- **Emergency Medical Services at the Crossroads**, Health Care Services, 2007.
  - **To Err Is Human: Building a Safer Health System**, Health Care Services, 2000.
  - **Evaluating the HRSA Traumatic Brain Injury Program**, Health Care Services, 2006.
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### **UPCOMING REPORTS**

#### AGING AND ELDERLY PEOPLE

The Future Health Care Workforce for Older Americans, Health Care Services

#### CHILD/YOUTH HEALTH

- Addressing the Barriers to Pediatric Drug Development: Workshop, Health Sciences Policy
- Adolescent Health Care Services and Models of Care for Treatment,
  Prevention, and Healthy Development, Board on Children, Youth, and
  Families, IOM/NRC

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

- Assessment of DoD-GEIS Influenza Surveillance and Response Program, Global Health
- Autism and the Environment: Challenges and Opportunities for Research, Workshop, Health Sciences Policy
- Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs, Health Care Services
- **Cancer-Related Genetic Testing and Counseling: Workshop,** National Cancer Policy Forum
- Gulf War and Health: Brain Injury in Veterans and Long-Term Health Outcomes, Population Health and Public Health Practice
- Gulf War and Health: Deployment-Related Stress and Health Outcomes, Population Health and Public Health Practice
- **Improving the Quality of Clinical Cancer Trials: Workshop,** National Cancer Policy Forum
- Infectious Disease Surveillance and Detection: Assessing the Challenges, Finding Solutions, Workshop, Global Health
- Making Best Use of the Agent Orange Exposure Reconstruction Model, Military and Veterans Health
- The Natural History of Celiac Disease, Medical Follow-Up Agency
- Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers, Health Sciences Policy
- **Treatment of Posttraumatic Stress Disorder**, Population Health and Public Health Practice

## Drugs, Devices, and Biologics

Addressing the Barriers to Pediatric Drug Development: Workshop, Health Sciences Policy

Challenges for the FDA: The Future of Drug Safety, Workshop, Health Sciences Policy

### ENVIRONMENTAL AND OCCUPATIONAL HEALTH

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## FOOD, NUTRITION, AND DIET

Dietary Reference Intakes Review Workshop, Food and Nutrition Board
Dietary Supplement Use by Military Personnel, Food and Nutrition Board
Nutritional Risk Assessment: Bridging Perspectives, Sharing
Methodologies, Identifying Data Challenges, Workshop, Food and
Nutrition Board

**Nanotechnology in Food and Nutrition Workshop**, Food and Nutrition Board

#### GLOBAL AND INTERNATIONAL HEALTH

Assessment of DoD-GEIS Influenza Surveillance and Response Program, Global Health

Infectious Disease Surveillance and Detection: Assessing the Challenges, Finding Solutions, Workshop, Global Health

Methodological Challenges in HIV Prevention Trials, Global Health

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Violence Prevention in Low- and Middle-Income Countries: Finding a Place on the Global Agenda Workshop, Global Health

## HEALTH CARE PROFESSIONAL TRAINING, EDUCATION, AND WORKFORCE

The Future Health Care Workforce for Older Americans, Health Care Services

# HEALTH CARE SERVICES, QUALITY OF CARE

Adolescent Health Care Services and Models of Care for Treatment,
Prevention, and Healthy Development, Board on Children, Youth, and
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Building a Foundation for Effective Health Care, Health Care Services
Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs,
Health Care Services

Leadership Commitments to Improve Value in Healthcare: Toward Common Ground, Workshop, Institute of Medicine

The State of Quality Improvement and Implementation Research: Workshop, Health Care Services

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Addressing the Barriers to Pediatric Drug Development: Workshop, Health Sciences Policy

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Conflicts of Interest in Medical Research, Education, Patient Care, and Institutional Management, Health Sciences Policy

Emerging Safety Science, Workshop, Health Sciences Policy

The HIPAA Privacy Rule, Health Sciences Policy

Judging the Evidence: Standards for Determining Clinical Effectiveness, Workshop, Institute of Medicine

Need to Know: Contending with the Expanding Evidence Divide, Workshop, Institute of Medicine

Neuroscience Biomarkers: Converging Technologies, Emerging Partnerships, Workshop, Health Sciences Policy

NIOSH Research Programs: Traumatic Injury, Population Health and Public Health Practice

Practice-Based Research: Redesigning the Clinical Effectiveness Research Paradigm, Workshop, Institute of Medicine

Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers, Health Sciences Policy

Securing the Public Good: Clinical Data as the Basic Staple of Healthcare Improvement, Workshop, Institute of Medicine

## MENTAL AND BEHAVIORAL HEALTH, NEUROSCIENCE

Autism and the Environment: Challenges and Opportunities for Research, Workshop, Health Sciences Policy

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Building a Foundation for Effective Health Care, Health Care Services Cancer-Related Genetic Testing and Counseling: Workshop, National Cancer Policy Forum

Challenges for the FDA: The Future of Drug Safety, Workshop, Health Sciences Policy

The HIPAA Privacy Rule, Health Sciences Policy

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Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers, Health Sciences Policy

President's Emergency Plan for AIDS Relief [PEPFAR] Implementation: Progress and Promise Workshop, Global Health

### CONTACT US . . .

#### **INSTITUTE OF MEDICINE**

500 Fifth Street, N.W. Washington, DC 20001 (202) 334-2659 www.iom.edu

#### **Executive Office**

President: Harvey V. Fineberg, NAS-323, (202) 334-3300

Interim Executive Officer: Clyde J. B>ney, KC-848, (202) 334-2177; cb>ney@nas.edu

Foreign Secretary: Jo Ivey Boufford, NAS-315, (202) 334-3366

Home Secretary: Stephen J. Ryan, NAS-316, (202) 334-2174

#### Office of Reports and Communications

Director of Communications: Bethany Hardy, KC-837, (202) 334-2258; bhardy@nas.edu

#### **Health Policy Educational Programs and Fellowships**

Director: Marie Michnich, KC-759, (202) 334-1296; mmichnich@nas.edu

#### **Board on African Science Academy Development**

Director: Patrick Kelley, KC-850, (202) 334-2650; pkelley@nas.edu

#### Board on Children, Youth, and Families

Director: Rosemary Chalk, KC-1157, (202) 334-1230; rchalk@nas.edu

#### **Food and Nutrition Board**

Director: Linda Meyers, KC-740, (202) 334-3153; lmeyers@nas.edu

#### **Board on Global Health**

Director: Patrick Kelley, KC-850, (202) 334-2650; pkelley@nas.edu

#### **Board on Health Care Services**

Acting Director: Michele Orza, KC-758a, (202) 334-3142; morza@nas.edu

#### **Board on Health Sciences Policy**

Director: Andrew Pope, KC-829, (202) 334-1739; apope@nas.edu

#### Board on Military and Veterans Health and Medical Follow-Up Agency

Director: Rick Erdtmann, KC-773, (202) 334-1925; rerdtmann@nas.edu

#### **Board on Population Health and Public Health Practice**

Director: Rose Marie Martinez, KC-855, (202) 334-2655; rmartine@nas.edu

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