Informing the Future: Critical Issues in Health, Sixth Edition

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Informing the Future
Critical Issues in Health

SIXTH EDITION

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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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

INSTITUTE OF MEDICINE
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Advising the Nation. Improving Health.

Contents

Forging Connections in a Disconnected World

> The part can never be well unless the whole is well.
>
> —Plato, *Charmides, or Temperance*

Plato's ancient dictum, written in 380 BCE, remains relevant today. The good health and well-being of any individual comprises the health of many different elements of the body, from the central nervous system to the skin. The health of a community similarly depends on such elements as walkability and access to healthcare services or play spaces. Likewise essential is a robust healthcare system that can effectively care for all people, healthy or infirm, old or young, rich or poor, without discrimination. And in an interconnected world, everyone's health depends on containing infectious diseases, mutual progress against chronic diseases, and building capacity and sustainable systems, especially in countries with fewer resources.

The Institute of Medicine (IOM) works at each of these levels, from the individual to the global, frequently bringing to light the ways in which meeting a need in one area can simultaneously serve other good ends. For example, among the recommendations in a 2010 IOM report on reducing sodium intake was a call for food manufacturers to reduce sodium in processed foods. In response, America's largest food retailer announced in January 2011 a commitment to reformulate many packaged foods, including national brands and its own brand, to reduce sodium. This decision could have many consequences—for the thousands of individuals and families who shop for groceries there, as well as those who shop elsewhere for the same food products that have been modified to include less sodium. Reducing sodium consumption may result in fewer cases of hypertension,

or high blood pressure, which affects nearly one in three American adults and is one of the nation's leading causes of death. A global reduction in sodium intake, in part spurred by reports such as this, could help reduce cardiovascular disease, which now accounts for nearly 30 percent of deaths in low- and middle-income countries each year and produces major economic repercussions. The IOM often generates just this type of ripple effect—a single recommendation by a committee of experts can result in behavior change and systems change worldwide.

The IOM is an independent, nonprofit organization that serves as adviser to the nation to improve health. Established in 1970 under the charter of the National Academy of Sciences, the IOM provides independent, objective, evidence-based advice to policy makers, health professionals, business and civic leaders, and the public.

Every report from the IOM aims to untangle complicated health matters of great importance. Including both consensus studies, in which expert committees deliberate until coming to agreement on the recommendations they will make, and workshop summaries, which highlight the themes and presentations from working meetings, the IOM issues more than five dozen reports a year.

Some of IOM's consensus studies begin as specific mandates by Congress; others are requested by federal agencies or suggested by independent organizations. Work is conducted by committees that are carefully composed of the foremost thought leaders to ensure the requisite expertise and to avoid conflict of interest. Coming together from various fields of study, these national and international experts grapple with vexing problems and use science-based evidence to reach conclusions and recommendations.

Valuable connections across different disciplines and perspectives—from government, academia, business, the professions, and the public—are made through the IOM's forums and roundtables. These bring together diverse stakeholders who share common interests in a specific area of health policy. The conversation and collaboration that take place within the forums and roundtables foster mutual understanding, unexpected insights, and creative solutions.

The IOM is both a research and an honorific organization. Its 1,800 elected members and foreign associates bring a plethora of experience and donate their time and expertise to IOM activities. Membership in the IOM is an honor, presented to 70 accomplished individuals each year. The members are drawn from the health professions and from the natural, social,

and behavioral sciences, as well as from law, ethics, engineering, administration, and the humanities. Election to the IOM represents both high professional recognition and a commitment to service.

As part of its educational effort, the IOM houses 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 midcareer health professionals in academic and community-based settings to assume leadership roles in health policy and management. The more recently instituted Anniversary Fellowship Program, created to celebrate the 35th anniversary of the IOM's establishment, enables talented, early-career health science scholars to participate actively in the work of the IOM and to further their careers as future leaders in the field.

This book highlights the work that IOM volunteers and staff have completed in recent years, followed by a description of IOM's collaborative activities and fellowship programs. The final section provides a comprehensive bibliography of IOM reports published since 2009. We hope this collection provides insight into the nature of our work and the distinctive, valuable role in health and health policy played by the IOM.

Building a Sustainable, High-Quality Healthcare System

More than a decade has passed since the Institute of Medicine (IOM) issued its influential reports, *To Err Is Human: Building A Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century*. These reports marked an important milestone in the IOM's continued efforts to improve our nation's health and healthcare system. In order to deliver the best possible health care to all Americans, and to do so in an efficient and cost-effective manner, the United States needs to reshape and strengthen its healthcare system. The current system undoubtedly has improved the lives of many individuals and made the nation healthier by a number of measures. But it also is falling short in critical ways. Many people, especially among minority and rural populations, do not have easy access to health care. Gaps among various types of healthcare practitioners put seamless care out of reach. The information that patients and healthcare providers rely on can be biased and untrustworthy, and many of the system's incentives are misaligned.

The IOM continues to confront these deficiencies and to press government, healthcare institutions and practitioners, and other stakeholders to improve the healthcare system.

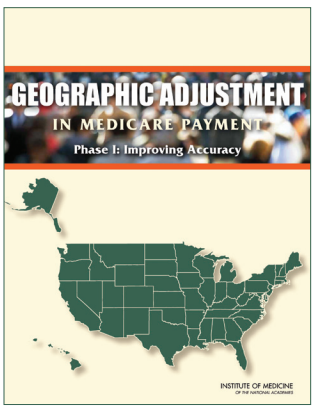
Making health care fairer and better

As the nation's largest health insurer, Medicare has a huge impact on the healthcare system. The program covers 39 million people aged 65 years and older and 8 million people with disabilities. Although it is a national pro-

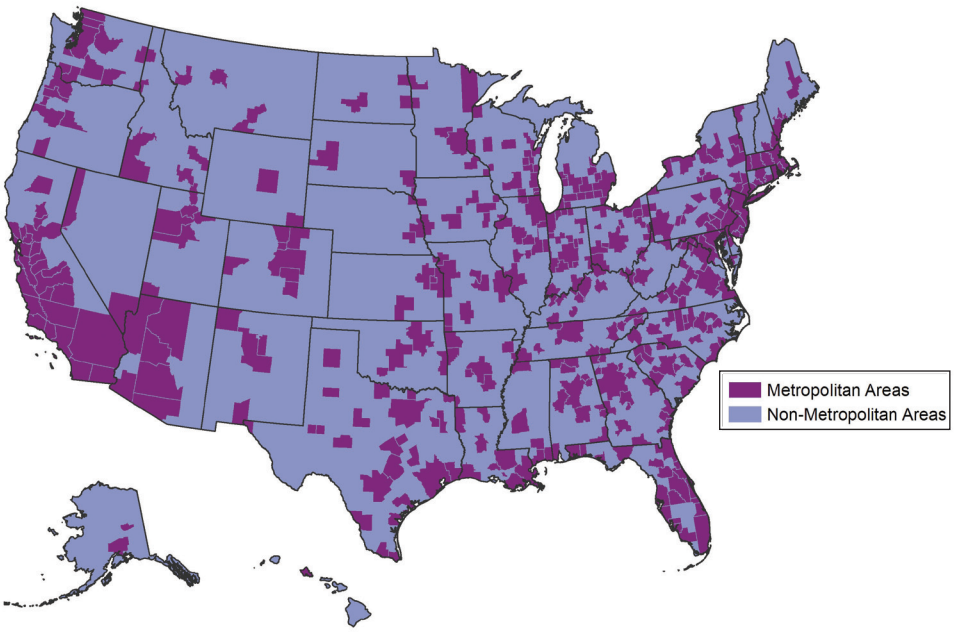
gram, Medicare adjusts its fee-for-service payments to hospitals, physicians, and other clinical practitioners based on their geographic location. The adjustments are intended to account for the differences in the costs of doing business, such as for staff compensation and payments for hospital or office space, in different regions as well as between urban and rural areas within a region. However, there are disagreements in the provider community and among policy makers about how best to make the adjustments.

Taken together, the recommendations would improve the accuracy of geographic adjustments in payment, streamline the payment process for a broader range of providers, and decrease the burden of cost reporting.

The U.S. House of Representatives called for a study by the IOM in Section 1157 of the Affordable Health Care for America Act, and although it did not end up in the final law, the Department of Health and Human Services (HHS) sought advice from the IOM on how to improve the accuracy of the data sources and methods used for making the geographic adjustments. The IOM's resulting report, *Geographic Adjustment in Medicare Payment* (2011), provides a technical assessment of the data sources and methods used to make adjustments to the hospital wage index and the geographic practice cost indexes.



Based on this assessment, the report recommends that Medicare adopt a more comprehensive approach that would unify the geographic boundaries used for both types of indexes, rely on one source of wage and benefits data for both, and expand the range of occupations covered in the indexes. Taken together, the recommendations would improve the accuracy of geographic adjustments in payment, streamline the payment process for a broader range of providers, and decrease the burden of cost reporting. Implementing the changes will require a phased-in process that invites public comment and combines legislative, rule-making, and administrative actions. A second edition of the report, released in September 2011, makes four additional recommendations on methods to set the work adjustment, calculate labor expenses in the practice expense, and use cost share weights.



SOURCE: RTI Analysis of FY 2011 Wage Index Files, Centers for Medicare and Medicaid Services.

In April 2012, the IOM committee responsible for the first geographic adjustment report will issue a second report that evaluates the effects of the adjustment factors on the distribution of the healthcare workforce, on the quality of care provided to patients, on population health, and on the ability of Medicare to provide efficient, high-value care.

Similarly arising from debates during the passage of the Affordable Care Act was a companion study on the value and costs of health care. This IOM study is aimed at understanding which factors contribute to variation and how lessons from existing variation may increase the value of health care in all geographic areas. Already under way, the results of this study are expected in Spring 2013.

Also at the request of Congress, the IOM examined another key aspect of how the healthcare system performs: the use of systematic reviews of the effectiveness of health interventions and the clinical practice guidelines derived from such reviews.

Patients rely on the expertise and judgment of their doctors to help select the best treatment. Patients can reasonably expect their doctors

and other caregivers to have access to reliable, up-to-date information on health interventions. In making treatment decisions, health professionals commonly consult clinical practice guidelines, which offer an evaluation of the quality of scientific evidence underlying a particular treatment and an assessment of its likely benefits and harms. This information helps a doctor and patient choose the best course based on the individual's needs and preferences. Clinical guidelines typically are derived from systematic reviews that identify, select, assess, and synthesize the findings of pertinent studies that can help clarify what is known and not known about the potential benefits and harms of drugs, devices, and other healthcare services.

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Congress sought assistance in the Medicare Improvement for Patients and Providers Act of 2008 by calling for the IOM to recommend standards for conducting systematic reviews and for developing clinical practice guidelines. The IOM formed two committees to respond to each part of this charge.

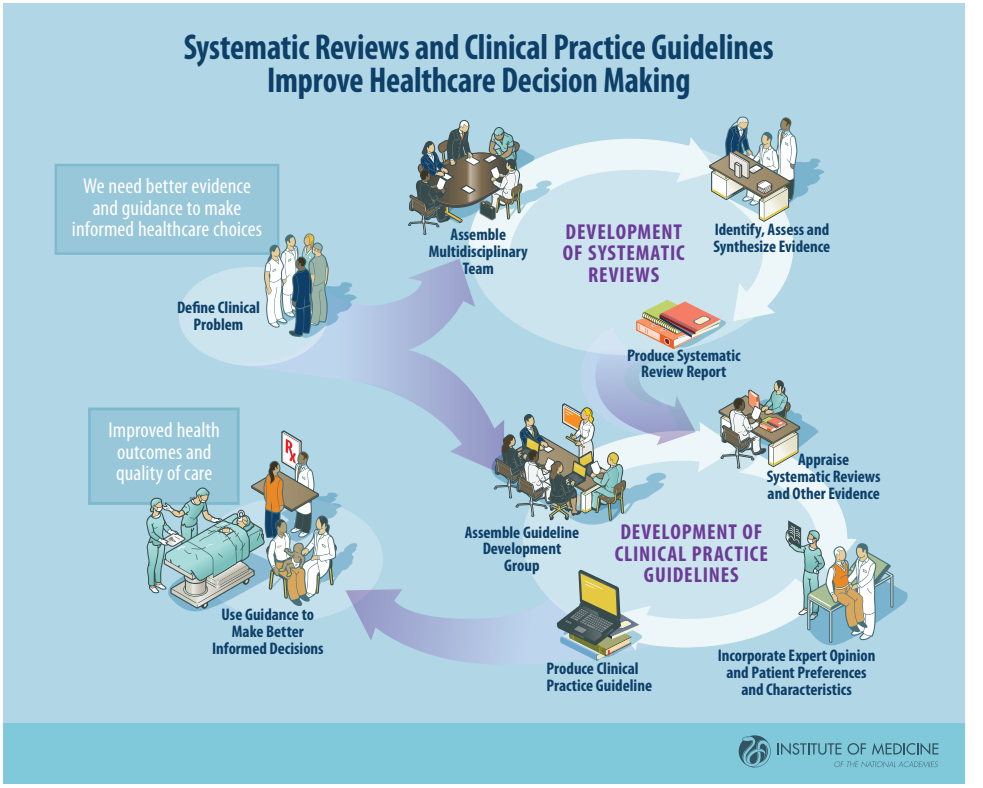
One of the ensuing reports, *Finding What Works in Health Care: Standards for Systematic Reviews* (2011), presents a set of 21 methodological standards and 82 elements of performance to be used in systematic reviews. Developing better systematic reviews has the potential to improve decisions made by clinicians, help patients make informed choices about their own care, and provide a more trustworthy basis for decisions by payers and policy makers. Improved systematic reviews also will aid professional medical societies and other organizations that develop clinical practice guidelines.

The proposed standards span the entire process, from formulating the topic and building a review team, to collecting and evaluating evidence, and finally to developing and using the systematic review and communicating results to others. Although they represent current best practices, the proposed standards are not meant to be the last word. Rather, they should be considered provisional, pending better empirical evidence about their scientific validity, feasibility, efficiency, and ultimate usefulness in healthcare decision making.

The report also concludes that the environment surrounding the development of systematic reviews lacks adequate funding and coordina-

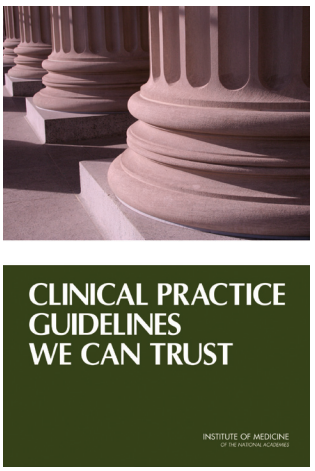
tion. Many organizations conduct systematic reviews, but typically they do not work together. Greater collaboration is needed among government agencies, medical professional societies, researchers, and patient interest groups. Together, these groups have the potential to improve the rigor and transparency of systematic reviews, encourage standardization of methods and processes, set priorities for selection of clinical topics of interest to clinicians and patients, reduce unintentional duplication of efforts, and more effectively manage conflicts of interest.

The other committee's report, *Clinical Practice Guidelines We Can Trust* (2011), presents a set of eight standards for rigorous, reliable clinical practice guidelines. Of the several thousand guidelines now on the books, most suffer from shortcomings in development, including failure to include a variety of disciplines in the development process, lack of transparency in how recommendations are derived and evaluated, and omission of a thor-



ough external review process. As a result, healthcare practitioners often find it challenging to determine the quality and trustworthiness of most guidelines.

The proposed standards reflect the latest scientific evidence, expert consensus, and public input, and they apply across the entire process of guideline development. Using the standards, institutions and researchers who are involved in guideline development will be better able to generate clinical practice guidelines that will earn the trust of healthcare practitioners and ultimately improve healthcare decision making and health outcomes for patients. To be trustworthy, guidelines should be based on a systematic review of the evidence, developed by a multidisciplinary panel of experts and representatives from key affected groups, consider important patient subgroups and patient preferences, and provide a clear explanation of care options and their expected health outcomes, among other factors. Additionally, development groups should optimally comprise members without any conflicts of interest, or at a minimum, members with a conflict should not represent more than a majority of a group.



To promote adoption of the standards, HHS should create a guide that identifies trustworthy guidelines and that will help healthcare practitioners and patients alike in choosing among treatment alternatives. In addition, the institutions and groups that implement clinical practice guidelines should develop and employ multifaceted strategies targeting both health systems and individuals in order to promote adherence to trustworthy guidelines. Wider adoption of electronic health records and computer-aided clinical decision support systems will open new opportunities to rapidly promote the use of clinical practice guidelines.

Reducing health disparities

The nation's healthcare system also faces challenges in delivering high-quality care in an equitable manner. The Agency for Healthcare Research and Quality (AHRQ) produces the National Healthcare Quality Report (NHQR) and the National Healthcare Disparities Report (NHDR) annually

at the request of Congress. The reports have revealed that even as healthcare performance has improved, health disparities persist across socioeconomic groups, racial and ethnic populations, and geographic areas. After 5 years of producing the NHQR and NHDR, AHRQ asked the IOM for guidance on how to improve the next generation of reports.

Future Directions for the National Healthcare Quality and Disparities Reports (2010) identifies a number of ways the NHQR and NHDR can be modified to be even more influential in promoting change in the healthcare system. In addition to being sources of data on past trends, the reports can provide more detailed insight into current performance, establish the value of closing gaps in quality and equity, and project the time required to bridge those gaps at the current pace of improvement. The IOM report recommends that AHRQ do the following:

The reports can provide more detailed insight into current performance, establish the value of closing gaps in quality and equity, and project the time required to bridge those gaps at the current pace of improvement.

- Align the NHQR and NHDR with nationally recognized priority areas.
- Select measures that reflect healthcare attributes or processes that have the greatest positive effect on population health.
- Affirm that achieving equity is an essential part of quality improvement.
- Increase the reach and usefulness of AHRQ's family of report-related products.
- Analyze and present data in ways that will inform policy and promote best-in-class achievement for all actors.
- Identify data needs to set a research and data collection agenda.

The IOM offers a set of national priority areas to enhance quality and eliminate disparities, and it provides a more quantitative and transparent method to evaluate measures for inclusion in the reports. The report also recommends that AHRQ make the extensive compendia of data in the NHQR and NHDR more user friendly in order to engage readers and spur action. The reports should convey what different audiences or stakeholders can do, what levels of performance have been achieved, and where readers can find information on effective interventions that might facilitate prog-

The Committee's Eight Recommended National Priority Areas for Healthcare Quality Improvement

The IOM Committee on Future Directions for the National Healthcare Quality and Disparities Reports recommends a set of eight national priority areas for healthcare quality improvement for use in the NHQR and NHDR; it believes these priorities can guide the national healthcare reports. The recommended areas include six priority areas identified by the National Priorities Partnership (NPP, 2008), as well as two additional priorities that the committee believes are important to highlight.

The six NPP priority areas included in the committee's set of national priority areas are:

1. **Patient and family engagement:** Engage patients and their families in managing their health and making decisions about their care.
2. **Population health:** Improve the health of the population.
3. **Safety:** Improve the safety and reliability of the U.S. healthcare system.
4. **Care coordination:** Ensure patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care.
5. **Palliative care:** Guarantee appropriate and compassionate care for patients with life-limiting illnesses.
6. **Overuse:** Eliminate overuse while ensuring the delivery of appropriate care.

The two additional priority areas in the committee's set are:

7. **Access:** Ensure that care is accessible and affordable for all segments of the U.S. population.
8. **Health systems infrastructure capabilities:** Improve the foundation of healthcare systems (including infrastructure for data and quality improvement; communication across settings for coordination of care; and workforce capacity and distribution among other elements) to support high-quality care.

SOURCE: *Future Directions for the National Healthcare Quality and Disparities Reports,* p. 3.

ress. Incorporating benchmarks that illustrate the best known levels of performance that have been obtained will enable various entities—states, for example—to compare their current performance against the best in class.

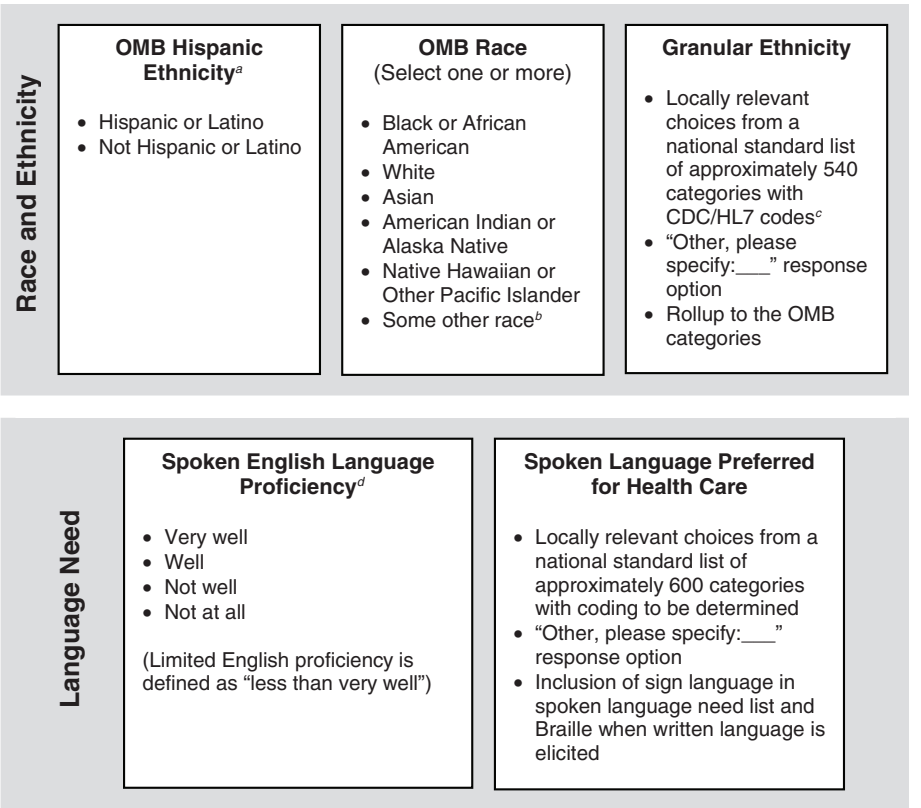
Another IOM study committee examined the health disparities found in AHRQ's reports from a different perspective. To reduce disparities, it is important to identify which populations are most at risk. One key way of doing this is to collect data on race, ethnicity, and English-language proficiency among various populations, as these factors have been demonstrated to affect the quantity and type of health care that they receive.

To reduce disparities, it is important to identify which populations are most at risk.

At AHRQ's request, the IOM committee examined ways to collect and use such specialized data. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (2009) offers a number of recommendations. The report recommends that AHRQ align its data classifications with the categories used by the Office of Management and Budget (OMB) and also develop more fine-grained categories of ethnicity (referred to as granular ethnicity) based on one's ancestry and language need. The OMB uses only five categories, sorted by race: Black or African American, White, Asian, American Indian or Alaska Native, and Native Hawaiian or Other Pacific Islander. But these are not always sufficiently descriptive to target interventions most effectively to various ethnic populations, especially to those of Hispanic ethnicity. Further, there is no way to distinguish whether a Hispanic child, for example, has a Mexican or Cuban background, even though such distinctions can be associated with differences in use of healthcare services and health outcomes.

Collecting more detailed, granular ethnicity data can help in tailoring healthcare delivery to local populations. Hospitals, health plans, and physician practices can use the data to understand the population being served, ameliorate disparities in care, and monitor improvements. States and health plans also can use the data for cross-institutional comparisons to detect variations in quality of care between entities serving similar populations. Legislation supports the collection of these data to improve quality and reduce disparities, and the data need to continue to be handled properly to maintain the public's trust.

HHS can help promote an expanded role for data collection by developing and distributing lists of categories for granular ethnicities and language needs, and by incorporating the collection of such data in all federally funded healthcare-related programs and electronic health record stan-



Recommended variables for standardized collection of race, ethnicity, and language need.

NOTE: Additional categories for health information technology tracking might include whether respondents have not yet responded (unavailable), refuse to answer (declined), or do not know (unknown), as well as whether responses are self-reported or observer-reported.

[a] The preferred order of questioning is Hispanic ethnicity first, followed by race, as OMB recommends, and then granular ethnicity.

[b] The U.S. Census Bureau received OMB permission to add "Some other race" to the standard OMB categories in Census 2000 and subsequent Census collections.

[c] Additional codes will be needed for categories added to the CDC/HL7 list.

[d] Need is determined on the basis of two questions, with asking about proficiency first. Limited English proficiency is defined for healthcare purposes as speaking English less than very well.

SOURCES: CDC, 2000; Office of Management and Budget, 1997b; Shin and Bruno, 2003; U.S. Census Bureau, 2002.

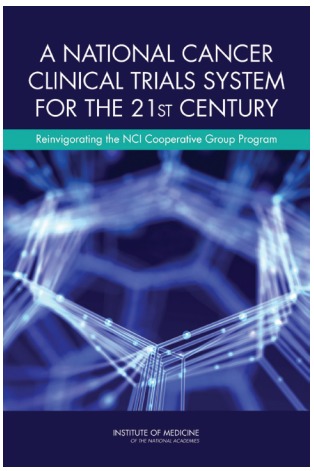
SOURCE: *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement,* p. 3.

dards. States, professional organizations, and other public and private entities involved in the provision of healthcare services should follow this lead.

Reinvigorating cancer clinical trials

Advances in biomedical research yield new opportunities to improve cancer prevention, detection, and treatment. Translating such discoveries into meaningful advances in cancer care depends on an effective clinical trials system. The National Cancer Institute (NCI) supports the nation's largest network for clinical trials of any type. The network's main component is the Clinical Trials Cooperative Group Program, whose 10 separate research groups work collaboratively with thousands of institutions and investigators to enroll more than 25,000 patients in clinical trials each year.

Despite its long record of accomplishment, however, the Cooperative Group Program is at a critical juncture. Numerous challenges—financial, bureaucratic, and scientific—threaten its ability to conduct the timely, large-scale, innovative clinical trials needed to improve patient care. In this light, the NCI asked the IOM to assess the state of cancer clinical trials, review the Cooperative Group Program, and provide advice on improvements.



The resulting committee's report, *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program* (2010), calls for preserving and strengthening the unique capabilities of the program while improving components that are not working well. The program needs to reorganize its structures and operations to become a truly national clinical trials network. The NCI should lead in instituting the necessary changes, but other federal agencies, such as the Food and Drug Administration, as well as academic centers, community practices, and the pharmaceutical industry, will need to be involved as well.

To guide this transformation, the report identified four main areas for improvement, noting that improvements will be needed in all of the areas; modifying any single element of the Cooperative Group Program will not suffice:

- Improve the efficiency of clinical trials, and reduce the average time for the design and launch of trials.

Summary of the Committee's Goals and Recommendations

Goal I. Improve the speed and efficiency of the design, launch, and conduct of clinical trials

1. Review and consolidate some front office operations of the Cooperative Groups on the basis of peer review
2. Consolidate back office operations of the Cooperative Groups and improve processes
3. Streamline and harmonize government oversight
4. Improve collaboration among stakeholders

Goal II. Incorporate innovative science and trial design into cancer clinical trials

5. Support and use biorepositories
6. Develop and evaluate novel trial designs
7. Develop standards for new technologies

Goal III. Improve prioritization, selection, support, and completion of cancer clinical trials

8. Reevaluate the role of NCI in the clinical trials system
9. Increase the accrual volume, diversity, and speed of clinical trials
10. Increase funding for the Cooperative Group Program

Goal IV. Incentivize the participation of patients and physicians in clinical trials

11. Support clinical investigators
12. Cover the cost of patient care in clinical trials

SOURCE: *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program,* p. 11.

- Make optimal use of innovations in science and trial design.
- Adequately support the clinical trials that have the greatest possibility of improving survival and quality of life for cancer patients, and increase the rate of clinical trial completion and publication.
- Incentivize the participation of patients and physicians in clinical trials by providing adequate funds to cover the costs of research and by reimbursing the costs of standard patient care during the trial.

In March 2011, the IOM's National Cancer Policy Forum and the American Society of Clinical Oncology held a workshop to pursue ways to achieve the goals and implement the recommendations from the 2010 IOM report. Speakers discussed how to work toward increasing the efficiency and productivity of the clinical trials system.

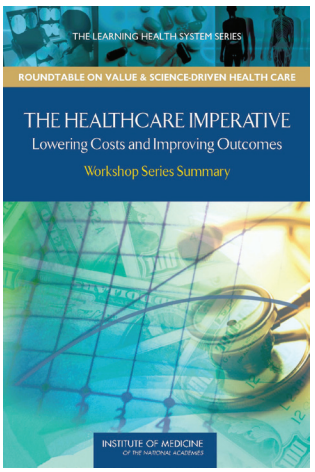
Reducing costs while enhancing the value of health care

In addition to examining ways to improve particular healthcare initiatives, the IOM, through its Roundtable on Value & Science-Driven Health Care, has explored ways to save money and improve health outcomes across the healthcare landscape. Healthcare cost increases continue to outpace the price and spending growth rates for the rest of the economy by a considerable margin. At $2.5 trillion and 17 percent of the nation's gross domestic product in 2009, health spending commanded twice the per capita expenditures of the average for other developed nations. Moreover, there are compelling signals that much of the additional health spending does little to improve health.

Healthcare cost increases continue to outpace the price and spending growth rates for the rest of the economy by a considerable margin.

With the support of the Peter G. Peterson Foundation, the IOM roundtable hosted a series of meetings of experts under the umbrella theme "The Healthcare Imperative: Lowering Costs and Improving Outcomes." Participants discussed the nature of excess health costs, current evidence on the effectiveness of approaches to their control, opportunities for improving health outcomes, and policy options for achieving these aims. The overarching goal was to explore ways to reduce healthcare costs by 10 percent within 10 years without compromising patient safety, health outcomes, or valued innovation.

The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary (2010) encapsulates the discussions. Workshop participants considered the nature and size of excess costs stemming from problems in six domains: unnecessary services, services inefficiently delivered, prices that are too high, excess administrative costs, missed prevention opportunities, and medical fraud. This comprehensive framework examined and compared all the sources of excess costs in a detailed way, highlighting the factors that drive excess costs. They also considered factors that give rise to unnecessary costs, including scientific uncertainty; perverse economic and practice incentives; system fragmentation; opacity as to cost, quality, and outcomes; changes in the population's health status; lack of patient engagement in decisions; and underinvestment in population health.



Discussions of strategies and policies to lower costs and improve health outcomes centered on a number of key levers. These included:

- streamlined and harmonized health insurance regulation;
- administrative simplification and consistency;
- payment redesign to focus incentives on results and value;
- quality and consistency in treatment, with a focus on treatments that are medically complex;
- evidence that is timely, independent, and understandable;
- transparency requirements as to cost, quality, and outcomes;
- clinical records that are reliable, sharable, and secure;
- data that are protected, but accessible for continuous learning;
- culture and activities framed by patient perspective;
- medical liability reform; and
- prevention at the personal and population levels.

In addition to its concern with cost savings, the Roundtable on Value & Science-Driven Health Care also has examined the promise and application of digital technologies in health and health care. Progress in computa-

tional science, information technology, and biomedical and health research methods have made it possible to foresee the emergence of an adaptive "learning health system" that enables both the seamless and efficient delivery of best care practices and the real-time generation and application of new knowledge. With sponsorship from the Office of the National Coordinator for Health Information, part of HHS, the roundtable convened a series of meetings of experts to explore strategies for accelerating this transformation. This marked the latest roundtable workshop in the Learning Health System Series, which dates to 2006 and has resulted in nearly a dozen reports intended to outline the conceptual foundation of the learning health system.

In *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care: Workshop Series Summary* (2010), participants from a variety of fields explored a system in which healthcare providers and patients will have access to timely, accurate, and comprehensive health information that can be used to deliver services effectively and efficiently. Information technology will serve as the functional engine for the system. The digital infrastructure would enable data to be collected during activities in various settings—clinical, research, and public health. These data would then be integrated, analyzed, and broadly applied to inform and improve clinical care decisions, promote patient education and self-management, design public health strategies, and support research and knowledge development efforts in a timely manner.

The digital infrastructure would enable data to be collected during activities in various settings—clinical, research, and public health.

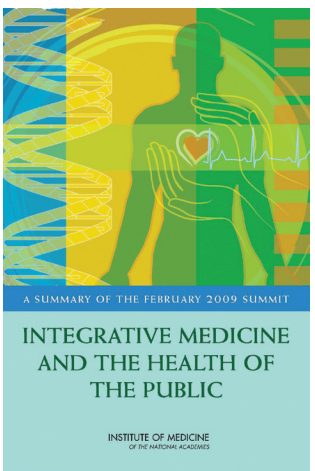
Workshop participants examined the vision of such a learning health system, the current state of the system, the key priorities for future work, and the strategic elements for accelerating progress toward a continuous learning health system. Collectively, the discussions captured an unprecedented promise for innovation and progress in health and health care. At the same time, bringing this potential to fruition will require coordinated efforts by many stakeholders to create the conditions necessary for seamless interoperability, to build the protocols for enhanced access and use of available information for knowledge generation, and to nurture a culture of engagement and support around a digital platform to promote continuous learning and improvement.

Advancing integrative medicine

Integrative medicine is emerging as a promising, multidimensional approach to protect and promote good health. Integrative medicine can be described as orienting the healthcare system to engage patients and caregivers in the full range of physical, psychological, social, preventive, and therapeutic modalities and elements known to preserve and restore optimal health. Integrative medicine focuses on efficient, evidence-based practice, prevention, wellness, and patient-centered care, creating a more personalized, predictive, and participatory healthcare experience.

Integrative medicine is emerging as a promising, multidimensional approach to protect and promote good health.

With support from The Bravewell Collaborative, the IOM convened the Summit on Integrative Medicine and the Health of the Public in February 2009. At the meeting, one of the largest and most diverse ever at the IOM, speakers and attendees examined the science and practice of integrative medicine, including successes from clinical settings across the country, and suggested elements of an agenda to help improve the prospects for integrative medicine's contributions to better health and health care.



Integrative Medicine and the Health of the Public: A Summary of the February 2009 Summit, presents a variety of speakers' and participants' suggestions for advancing the field, including redesigning study protocols to better accommodate multifaceted and interacting causal factors; developing pilot projects to identify effective integrated approaches that demonstrate value, sustainability, and scalability; and strengthening and redirecting education and training programs. Throughout the summit, speakers highlighted the need for public policy incentives that would support the necessary developments in research, education, and practice, in particular those that encourage care coordination, team care, patient engagement, and an orientation to prevention and well-being.

Improving Food Safety, Nutrition, and Health

The problems have grown all too familiar. Too many Americans are overweight or obese. Too many children do not eat healthy meals at school. Many people consume too much of some foods or nutrients, or too little of others. Information overload confounds some nutritional claims. The nation's food supply, though generally safe, periodically suffers outbreaks of contamination that cause food-borne illnesses.

All told, the nation has considerable room for improvement in ensuring that the foods available to consumers are safe, that people eat enough of what they should to be healthy, and that they minimize or eliminate their intake of potentially harmful foods. To help meet these goals, the Institute of Medicine (IOM) regularly examines the nation's nutritional well-being and offers measures for improvement.

Improving food programs

In February 2010, as part of the launch of Let's Move!, First Lady Michelle Obama's program to reduce childhood obesity, the secretary of the U.S. Department of Agriculture (USDA), Tom Vilsack, spoke of his department's commitment to have all schools offer nutritious meals to their students. He said this stand is based in part on the IOM report *School Meals: Building Blocks for Healthy Children* (2010), which "sounded an alarm about the nutritional value of school meals," and added that his department "is working as aggressively as possible" to build on the report's findings. In 2011, the USDA issued new interim rules for its

school breakfast and lunch programs that incorporate many of the IOM's recommendations.

The report referenced by the secretary was written at the request of the USDA. The agency asked the IOM to review the food and nutritional needs of school-aged children in the United States and offer guidance on updating the regulations, which had been established in 1995. The National School Lunch Program and the School Breakfast Program provide nutritionally balanced, low-cost or free meals each school day. The lunch program served more than 31 million children in 2009. In its report, the IOM offers recommendations that focus clearly on providing meals that are consistent with the *Dietary Guidelines for Americans*, the foundation of the government's nutrition policies. The report calls on the USDA's Food and Nutrition Service to adopt standards for menu planning that increase

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Key Recommended Changes in School Lunch Requirements

Type of Specification	Current Requirements	Recommendations
Fruits	Considered together as a fruit and vegetable group. No specifications for the type of vegetable.	Required daily amount increased
Vegetables		Two servings required daily, amount increased. Must include dark green, bright orange, legumes, starchy, and other vegetables each week
Grains/breads	No requirement for whole grains	At least half must be whole grain rich
Milk	Whole, reduced-fat, low-fat, fat-free milks (plain or flavored)	Fat-free (plain or flavored) and plain low-fat milk only
Calories	Must meet minimum level	Must be within minimum and maximum level
Sodium	None (decreased level recommended)	Gradually but markedly decrease sodium to the specified level by 2020

The committee recommends a single approach to menu planning—one that includes a meal pattern plus specifications for minimum and maximum calorie levels, maximum saturated fat content, and maximum sodium content.

SOURCE: *School Meals: Building Blocks for Healthy Children.*

the amount and variety of fruits, vegetables, and whole grains; set a minimum and maximum level of calories; and place greater focus on reducing the amounts of saturated fat and sodium provided. Other recommendations are intended to ensure not only that schools offer nutritious meals but that students select healthful foods from the menu.

The IOM report generated a response not just by government but also from the business community. In February 2010, several major food services companies that provide students with breakfasts and lunches at schools nationwide announced that they would meet the IOM's recommended school meal standards for fat, sugar, and whole grains over the next 5 years, and meet the standards for sodium over the next 10 years. The companies—ARAMARK, Sodexo, and Chartwells—also agreed to include more fruit, vegetables, and low-fat and fat-free milk in their school meals. Specifically, they pledged to work to double the amount of produce offered over the next 10 years.

In another study of federal food and nutrition initiatives, the IOM examined USDA's Child and Adult Care Food Program (CACFP), which supports the nutrition and health of the nation's most vulnerable individuals—more than 3 million infants and children and more than 114,000 impaired or older adults, primarily from low-income households. To receive federal reimbursement, CACFP meals and snacks must meet regulations designed to ensure that participants receive high-quality, nutritious foods. But the current standards, called Meal Requirements, are based in part on nutrition and health information from 1989. For assistance in updating the program, the Food and Drug Administration (FDA) asked the IOM to review and assess the nutritional needs of the populations served by the CACFP and to provide recommendations to revise its Meal Requirements.

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In *Child and Adult Care Food Program: Aligning Dietary Guidance for All* (2010), an IOM committee provided recommendations that cover all age groups and could be implemented by a variety of providers, including those in family homes and large centers. The recommendations are based on current dietary guidance, including the *Dietary Guidelines for Ameri-*

cans, and take into account such practical considerations as the need for appealing menus, the capabilities of the providers, and cost.

The recommendations target three age groups—infants, children, and adults 19 years and older. (The first two groups are broken down into several subgroups, based on age.) For each group, the committee recommended new Meal Requirements, including both revised daily and weekly meal patterns and additional food specifications. The meal patterns are the types and amounts of foods that are to be offered for breakfast, lunch/supper, and snacks. The requirements will promote intakes of healthy foods from five food groups: fruits, vegetables, milk, grains/bread, and lean meats or meat alternates, and seek consistency with the *Dietary Guidelines for Americans*.

Today, almost 10 percent of infants and toddlers carry excess weight for their length, and slightly more than 20 percent of children between the ages of 2 and 5 years are already overweight or obese.

The effectiveness of the Meal Requirements will be determined in large part by the manner in which they are implemented and monitored for compliance. Key implementation strategies should include engaging families, food industry stakeholders, and community members; providing nutritional education to participants; and training state agency staff and program providers. To aid in implementation, the committee recommended that the USDA offer extensive technical assistance to CACFP providers and work with stakeholders to develop an effective system for monitoring and reimbursing CACFP meals.

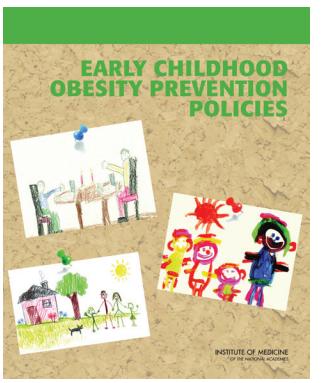
Combating the obesity epidemic

Improving school lunches and meals served by child care providers will be one tool in reducing obesity among Americans. The hope is that by learning and practicing good nutritional habits early, children can avoid becoming overweight or obese later in life. And these behaviors must begin among even the youngest of children. Because early obesity can track into adulthood, efforts to prevent obesity should begin long before a child enters school. Today, almost 10 percent of infants and toddlers carry excess weight for their length, and slightly more than 20 percent of children between the ages of 2 and 5 years are already overweight or obese.

In 2010, the IOM appointed a committee to review factors related to overweight and obesity from birth to age 5, with a focus on nutrition, physi-

cal activity, and sedentary behavior. In its report, *Early Childhood Obesity Prevention Policies* (2011), the committee recommends actions that healthcare professionals, caregivers, and policy makers can take to prevent obesity in children 5 years old and younger.

Parents see pediatricians, primary care physicians, and other healthcare professionals as child care authorities. Thus, these professionals have an important opportunity to increase parents' awareness about healthy weight early on to allow time for prevention or intervention. The IOM recommends that healthcare professionals measure weight and height or length in a standardized way, as well as pay attention to obesity risk factors, such as rate of weight gain and parental weight, at routine pediatric visits. In addition, the IOM recommends that parents and child care providers keep children active throughout the day and provide them with diets rich in fruits, vegetables, and whole grains, and low in energy-dense, nutrient-poor foods. Caregivers also should limit young children's screen time and ensure that children sleep an adequate amount each day.



Finally, the committee recommends that the USDA and the Department of Health and Human Services (HHS) establish dietary guidelines for children from birth to age 2. Currently, the *Dietary Guidelines for Americans* do not include recommendations for children under the age of 2. Such guidelines are necessary for setting nutrition recommendations for public and federal programs.

Another IOM study committee looked at options outside of school for helping children and adolescents avoid weight problems. In *Local Government Actions to Prevent Childhood Obesity* (2009), the committee identified numerous actions that show potential for use by local governments. Of course, parents and other adult caregivers play a fundamental role in teaching children about healthy behaviors, in modeling those behaviors, and in making decisions for children when needed. But those positive efforts can be undermined by local environments that are poorly suited to supporting healthy behaviors—and may even promote unhealthy behaviors.

Local governments have many opportunities to promote children's health. Given their jurisdiction over aspects of land use, food marketing, community planning, transportation, health and nutrition programs, and

other community concerns, local governments also are ideally positioned to promote behaviors that will help children and adolescents reach and maintain healthy weights.

As a blueprint for action, the IOM committee recommended nine healthy eating strategies and six physical activity strategies for local government officials to consider in planning, implementing, and refining childhood obesity prevention efforts. The committee also recommended a number of specific action steps for each strategy and highlighted 12 steps overall judged to have the most promise. One general message is clear: Promoting children's healthy eating and activity will require the involvement of an array of government officials, including mayors and commissioners or other leaders of counties, cities, or townships. Many departments, including those responsible for public health, education, public works, transportation, parks and recreation, public safety, planning, economic development, and housing, also need to be involved.

In addition, community involvement and evaluation are vital to childhood obesity prevention efforts. It is critical for local government officials and staff to involve constituents in determining local needs and identifying top priorities. Engaging community members in the process will help identify local assets, focus resources, and improve implementation plans. And, as obesity prevention actions are implemented, such actions need to be evaluated in order to provide important information on what does and does not work.

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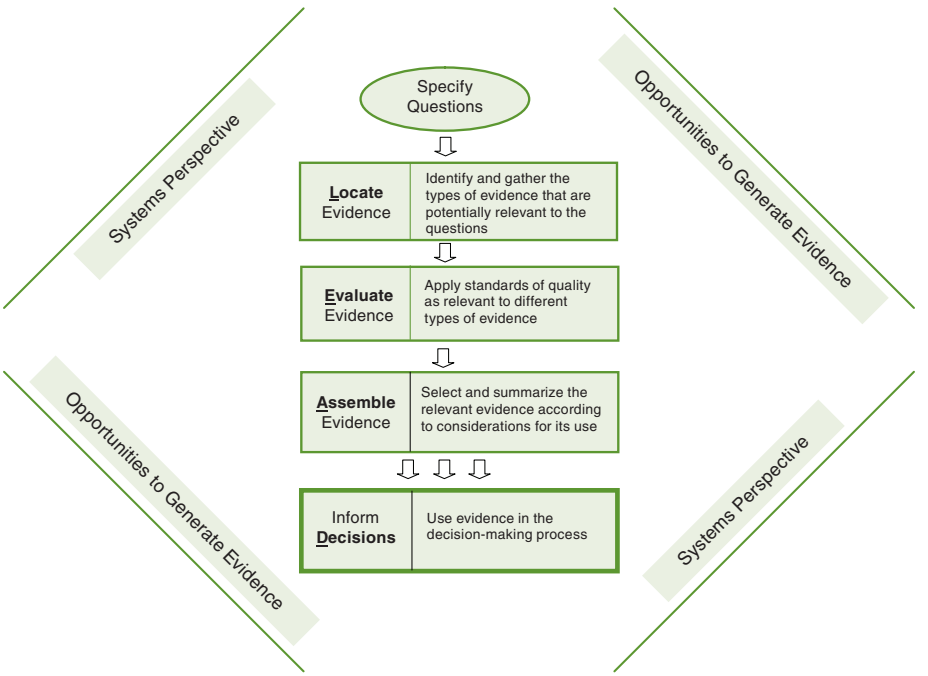
The IOM also has dealt with the obesity epidemic across broader society. Approximately 68 percent of adults in the United States aged 20 years or older are either overweight or obese. Among children and adolescents aged 2 through 19 the rate is nearly 32 percent. To respond most effectively, policy makers, public health professionals, and other decision makers need relevant and useful evidence on promising obesity prevention actions for the populations they serve.

In 2008, Kaiser Permanente asked the IOM to develop a practical,

action-oriented framework to guide the use of evidence in decision making about obesity prevention policies and programs and to guide the generation of new and relevant evidence. The IOM convened a committee that sought the answers to two fundamental questions:

- How can evidence that is currently available and potentially relevant to decisions about obesity prevention be identified, evaluated, and compiled in ways that will best inform decisions?
- How can more evidence be developed that is of high quality and framed to be directly relevant to decision making on obesity prevention?

The committee developed the L.E.A.D. framework process—short for Locate evidence, Evaluate it, Assemble it, and inform Decisions—to help in answering these questions. Presented in the committee's report, *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making* (2010), the framework encourages decision makers and researchers to look at obesity from a systems perspective in order to under-



The L.E.A.D. framework.

SOURCE: *Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making,* p. 5.

stand it as a complex, population-based health problem. The framework provides guidelines for assembling and compiling evidence in an open and transparent way, placing it in a real context in order to inform decisions. It offers opportunities to generate useful, high-quality evidence for decision making at every step, and encourages learning from a variety of sources, including ongoing policies and practices and alternatives to randomized experiments. It also provides a way for assessing how well research results can be applied to other individuals, settings, contexts, and time frames.

The (L.E.A.D.) framework provides guidelines for assembling and compiling evidence in an open and transparent way, placing it in a real context in order to inform decisions.

The IOM continues to tackle the obesity epidemic through many different avenues. Its Standing Committee on Childhood Obesity Prevention, sponsored by the Robert Wood Johnson Foundation, serves as a focal point for national and state-level policy discussions about obesity prevention, and it has guided the development of previous and upcoming studies on various aspects of obesity prevention, among them the legal strategies that have an effect on obesity. The standing committee hosted a workshop to highlight current and potential legal strategies and other public health initiatives in October 2010.

In addition, the IOM recently partnered with HBO Documentary Films on *The Weight of the Nation*, a project that will incorporate multiple documentary films, publications, and a web component. More about this project can be found in the chapter on collaboration.

Strengthening food safety

Approximately 76 million food-borne illnesses—caused by a variety of bacteria, viruses, parasites, or chemical residues—occur each year in the United States, resulting in more than 300,000 hospitalizations and 5,000 deaths. While food safety is regulated by several agencies, the FDA oversees approximately 80 percent of the nation's food supply, including all produce, seafood, and cheeses. But experts and the public have criticized the FDA's food safety system and questioned whether it properly safeguards the public from food-borne diseases. In response, Congress asked the IOM to examine the gaps in the current food safety system under the

purview of the FDA and to identify the tools needed to improve food safety.

In *Enhancing Food Safety: The Role of the Food and Drug Administration* (2010), the IOM study committee concludes that the FDA lacks a comprehensive vision for food safety and should change its approach in order to properly protect the nation's food. The agency should use a risk-based approach to evaluate food safety problems rather than its current reactive approach, which addresses problems only on a case-by-case basis and may fail to account for all the factors involved in making a decision. Adopting a risk-based approach will enable decision makers to evaluate the food safety system in a comprehensive way and follow a systematic process for addressing and preventing problems. Components of a risk-based food safety system include conducting strategic planning; ranking public health risks; targeting information gathering efforts, such as surveillance, on identified risks; analyzing and selecting interventions; designing an intervention plan; and monitoring and reviewing implementation efforts.

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The committee outlines a set of actions that are needed to implement a risk-based food safety system. For example, the FDA should hire or train additional staff with expertise in risk management and analysis; develop a comprehensive strategic plan that identifies public health goals and metrics to measure success; and define the roles of all parties in the food system, including suppliers, farmers, retailers, consumers, and government agencies, among others. The agency also should lead efforts to integrate federal, state, and local safety programs so they work in a seamless manner; improve food safety inspections; and expand and sharpen communications programs to inform the public of risks in a timely and useful manner.

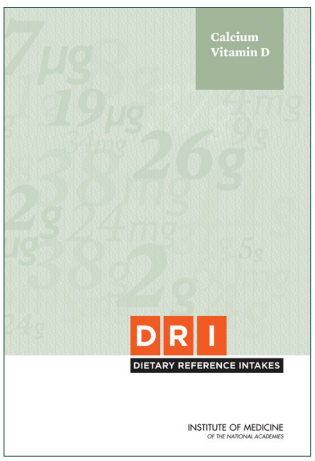
Finally, the committee called on Congress to help, by considering legislative action to provide the FDA with the authority it needs to fulfill its food safety mission. In November 2010, the Senate passed legislation that aligned with many of the IOM's recommendations, and in January 2011, President Obama signed into law the FDA Food Safety Modernization Act, which is aimed at ensuring the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

Fostering good nutrition

Consumers need sound information about food and nutrition in order to make choices that promote and protect their health and well-being. The IOM has helped by developing and disseminating Dietary Reference Intakes (DRIs) that specify how much of a given nutrient should be consumed for good nutrition and how much is unsafe or unwarranted, with the levels specified according to an individual's age, gender, and life stage. Now available for more than 40 nutrient sources, the DRIs are intended to serve as a guide for good nutrition and provide the basis for the development of nutrient guidelines in both the United States and Canada.

The IOM has compiled these DRIs into a single listing for easy viewing. A summary guide to the DRIs also is available, along with a number of focused, in-depth publications to help users understand the important considerations in applying the values for planning and assessing diets. Through these and other avenues, the DRIs are used by a range of health professionals and policy makers, including federal nutrition officials who develop policies and programs, dietitians and health practitioners who counsel individuals and groups, and researchers who are working to advance the state of nutrition knowledge.

Dietary Reference Intakes for Calcium and Vitamin D (2010) is the most recent report in the IOM series. These two nutrients have long been known for their role in bone health. Over the past 10 years, however, the public has heard conflicting messages about other benefits of these nutrients—especially vitamin D—and about how much of the nutrients must be consumed for good health. The new DRIs are based on much more information and higher-quality studies than were available when the reference values were first set in 1997.



The report's authoring committee concluded that a strong body of evidence from rigorous testing substantiates the importance of vitamin D and calcium in promoting bone health. The evidence for other health benefits, however, is mixed and inconclusive, and targeted research is needed to assess these possible health benefits. The committee also found that consuming vitamin D and calcium at levels higher than recommended does not confer greater benefits. In fact, elevated consump-

Dietary Reference Intakes for Calcium and Vitamin D

	Calcium			Vitamin D		
Life Stage Group	Estimated Average Requirement (mg/day)	Recommended Dietary Allowance (mg/day)	Upper Level Intake (mg/day)	Estimated Average Requirement (IU/day)	Recommended Dietary Allowance (IU/day)	Upper Level Intake (IU/day)
Infants 0 to 6 months	*	*	1,000	**	**	1,000
Infants 6 to 12 months	*	*	1,500	**	**	1,500
1–3 years old	500	700	2,500	400	600	2,500
4–8 years old	800	1,000	2,500	400	600	3,000
9–13 years old	1,100	1,300	3,000	400	600	4,000
14–18 years old	1,100	1,300	3,000	400	600	4,000
19–30 years old	800	1,000	2,500	400	600	4,000
31–50 years old	800	1,000	2,500	400	600	4,000
51–70 year old males	800	1,000	2,000	400	600	4,000
51–70 year old females	1,000	1,200	2,000	400	600	4,000
>70 years old	1,000	1,200	2,000	400	600	4,000
14–18 years old, pregnant/ lactating	1,100	1,300	3,000	400	600	4,000
19–50 years old, pregnant/ lactating	800	1,000	2,500	400	600	4,000

*For infants, Adequate Intake is 200 mg/day for 0 to 6 months of age and 260 mg/day for 6 to 12 months of age.
**For infants, Adequate Intake is 400 IU/day for 0 to 6 months of age and 400 IU/day for 6 to 12 months of age.

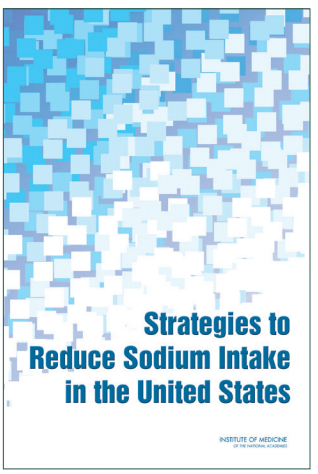
SOURCE: *Dietary Reference Intakes for Calcium and Vitamin D.*

tion has been linked to various health problems, such as kidney stones caused by excessive calcium intake—challenging the concept that "more is better." These findings may raise important concerns as North Americans take more supplements and eat more foods that have been fortified with vitamin D and calcium, increasing their risk of consuming far too much of these otherwise important nutrients.

In another study, the IOM looked at a common food ingredient that can cause health problems: sodium. Americans consume unhealthy amounts of sodium in their food, increasing their risk for high blood pressure, a serious health condition that can lead to a variety of diseases. While numerous stakeholders have initiated voluntary efforts to reduce sodium consumption during the past 40 years, they have not succeeded. Challenges arise because salt—the primary source of sodium in the diet—and other sodium-containing compounds are widely used in the food industry, including restaurants, to enhance the flavor of foods.

Consuming vitamin D and calcium at levels higher than recommended does not confer greater benefits.

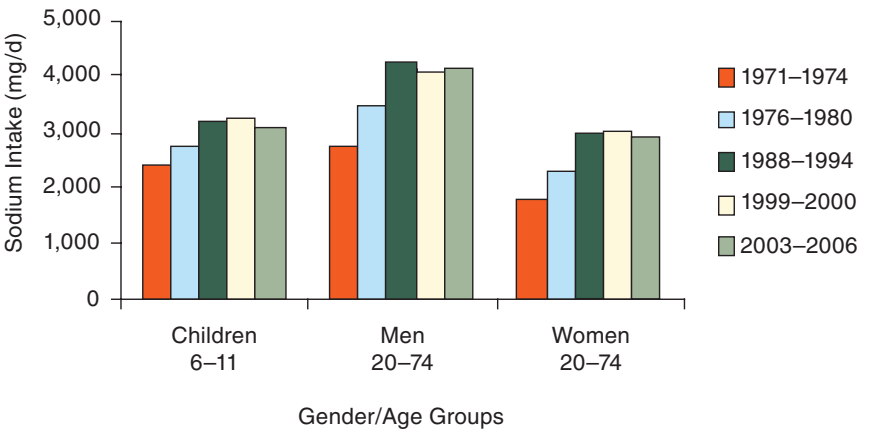
To help in meeting this concern, Congress asked the IOM to recommend strategies for reducing sodium intake to levels recommended in the *Dietary Guidelines for Americans*—currently no more than 2,300 milligrams per day for persons 2 or more years of age. This amounts to about a teaspoon of salt per day, while the average person consumes about 50 percent more than that. In *Strategies to Reduce Sodium Intake in the United States* (2010), the authoring study committee concluded that a new, coordinated approach is needed to reduce sodium content in food, requiring new government standards for the acceptable level of sodium.



Manufacturers, restaurants, and other food-service operators should be required to meet these standards so all sources in the food supply are involved and so consumers' taste preferences can be changed over time to the lower amounts of salt in food. The goal is to slowly, over time, reduce the sodium content of the food supply in a way that goes unnoticed by most consumers as individuals' taste sensors adjust to the lower levels of sodium.

A range of stakeholders will need to cooperate in this effort. HHS should act in cooperation with other government and private groups to design and implement a nationwide campaign to reduce sodium intake and should set a timeline for achieving recommended sodium intake levels. Consumers have an important role to play by making healthy food choices and selecting lower-sodium foods. In addition, government agencies, public health and consumer organizations, health professionals, the health insurance industry, the food industry, and public-private partnerships should support the implementation of the sodium standards for foods and also support consumers in reducing their sodium intake. Finally, better monitoring of sodium intake and of the progress toward changing salt taste preference are essential so the reduction efforts can be tracked and evaluated, and improvements can be made as needed.

In response to the IOM report, some companies in the food industry have begun to act. And Walmart, which sells more food than any other grocery store chain in the nation, announced in January 2011 that it would work with its suppliers to provide healthier food choices and make those foods more affordable to consumers. The company referred to the IOM in making its announcement. Walmart plans to reformulate many of its packaged foods to reduce sodium—as well as added sugars and *trans* fats—by



Trends in mean sodium intake from food for three gender/age groups, 1971–1974 to 2003–2006.

NOTES: Analyzed using 1-day mean intake data for the National Health and Nutrition Examination Survey (NHANES) 2003–2006 to be consistent with earlier analyses and age-adjusted to the 2000 Census; includes salt used in cooking and food preparation, but not salt added to food at the table. d = day; mg = milligram.

SOURCE: Briefel and Johnson (2004) for 1971–2000 data; NHANES for 2003–2006 data.

SOURCE: *Strategies to Reduce Sodium Intake in the United States,* p. 5.

2015. The company said it also intends to ask its suppliers to reduce sodium by 25 percent in some foods and to report on their progress.

Meeting the needs of an aging population

The nation's population is increasingly an older population, and IOM's Food Forum held a workshop in October 2009 to discuss food safety and nutrition in older adults. One general concept that emerged was that there is no single "elder" population. Rather, there are many different aging populations defined by age range as well as by such factors as race, socioeconomic status, level of family support, disability, and chronic health conditions. Meeting the differing needs of these groups rapidly becomes a complex task. Workshop participants from government, academia, industry, and other sectors discussed the variety of ways that different stakeholders are embracing the challenge of improving food safety and nutrition in aging populations.

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This challenge is made more difficult by a lack of information in many key areas. For example, although high-quality diets and nutrient optimization are understood to be necessary for maintaining good health in older adults, several questions remain about exactly what constitutes a high-quality diet and what types of obstacles, such as poor oral health and loss of appetite, keep people from obtaining optimal diets. Another challenge in differentiating among multiple aging populations is the lack of health-monitoring data and the consequent inability to generate enough statistical power to make conclusions about the health conditions and needs of those varied populations. Also, although industry has developed new food-processing techniques and novel packaging that minimize many food safety problems, there are still important unanswered questions about how food processing, formulation, and packaging can be improved to better meet the needs of older adults.

In October 2011, the IOM held another workshop to explore nutritional interventions and services for older people staying in community settings. This workshop outlined the scope of nutrition needs; the importance, strengths, and weaknesses of nutrition services; and future research needs related to nutrition and healthy aging in the community.

Strengthening the Healthcare Workforce

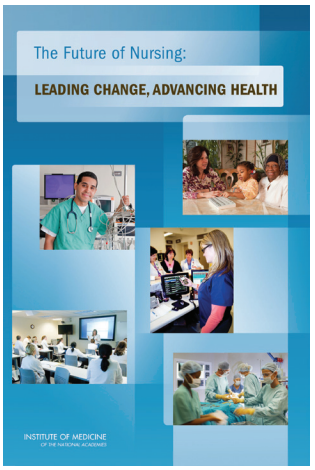
The workforce of healthcare professionals—the backbone of the nation's healthcare system—labors under many pressures. Some care providers have difficulty coping with a rapidly evolving healthcare system. Doctors are increasingly challenged to keep up with advances in science and medicine. Global health problems create shared responsibilities for health workers everywhere. New and emerging diseases raise safety concerns for frontline care providers. Rising patient expectations and increasing demand from more widespread insurance coverage will heighten the challenges.

The Institute of Medicine (IOM) has examined many aspects of the healthcare workforce—delineating problems, identifying solutions, and charting paths forward. Government policy makers, healthcare and education leaders, individual care providers, and a range of other stakeholders can draw on this knowledge to ensure that the nation takes full advantage of a skilled, adaptive, and well-protected healthcare workforce.

The future of nursing

With more than 3 million members, the nursing profession is the largest segment of the nation's healthcare workforce. But even as nurses are the primary professional caregivers for many patients, a number of barriers prevent nurses from being able to keep up with changes in where and how health care is delivered and in the skills required to keep pace with today's evolving healthcare system.

In 2008, the Robert Wood Johnson Foundation (RWJF) and the IOM launched a 2-year study to respond to nurses' needs and transform the nursing profession. Called the Robert Wood Johnson Foundation Initiative on the Future of Nursing, at the Institute of Medicine, the project followed a methodical course to ensure comprehensive analysis. Over 2 years, the study committee held three national forums focused on critical aspects of health, including acute care; community health, primary care, and long-term care; and nursing education. The meetings enabled stakeholders to share their knowledge and express their concerns about the roles of nurses in the current healthcare system, and the IOM published summaries of each forum. The committee also held several technical workshops at which members further explored challenges facing the nursing profession.



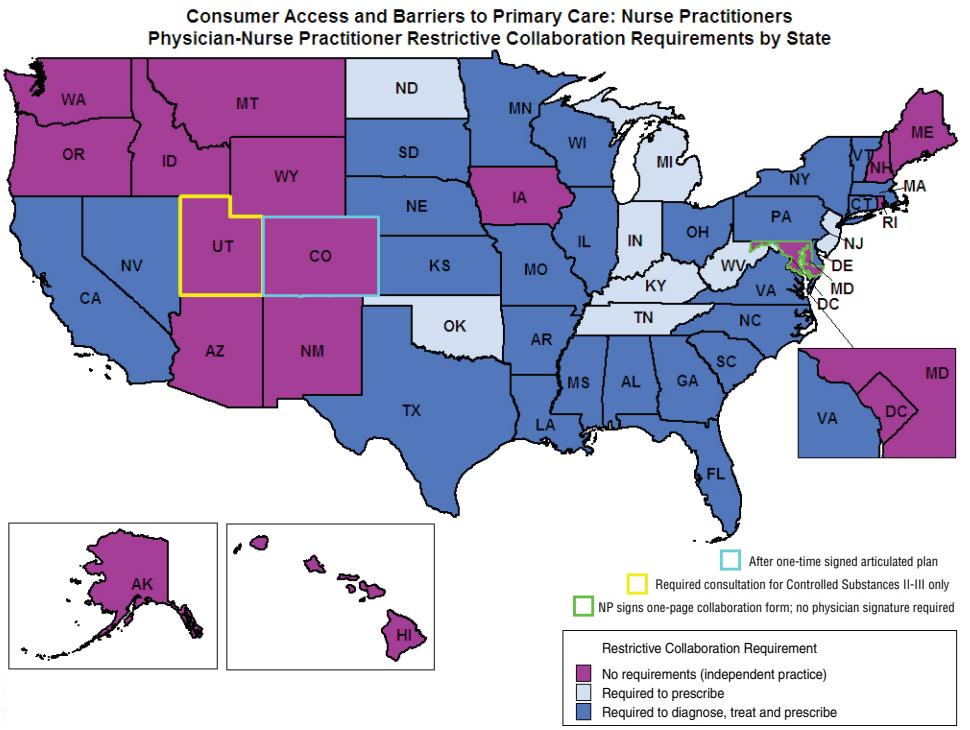
From these efforts, the committee produced *The Future of Nursing: Leading Change, Advancing Health* (2010). The report describes the committee's vision for health care and the essential role of nurses in realizing this vision, concluding that a fundamental transformation of the nursing profession is needed if nurses are to fulfill this role. The report presents a blueprint for action in the form of recommendations and related research priorities. Transformations are needed in three broad areas—nursing practice, education, and leadership—and within this framework, the committee developed four key messages that structure its recommendations.

The report describes the committee's vision for health care and the essential role of nurses in realizing this vision.

First, nurses should practice to the full extent of their education and training. Because licensing and practice rules vary across states, the regulations regarding scope of practice—that is, the activities that a qualified nurse may perform—have varying effects on different types of nurses in different parts of the country. Consequently, the tasks that nurses are allowed to perform are often determined not by their education and training but by the unique state laws under which they work. The report calls on a variety of stakeholders—from state legislators to the Centers for Medicare and Medicaid Services to the Congress—to ensure that nurses

can practice to the full extent of their education and training. The federal government is particularly well suited to promote reform of states' scope-of-practice laws by sharing and providing incentives for the adoption of best practices.

Second, nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression into higher-degree programs. Patient needs have become more complicated, and nurses need to achieve requisite competencies to deliver high-quality care in a variety of settings and in partnership with teams of health professionals. Needed competencies include system improvement, research and evidence-based practice, and teamwork and collaboration,



Requirements for physician–nurse collaboration, by state, as a barrier to access to primary care.

NOTE: Collaboration refers to a mutually agreed upon relationship between nurse and physician.

SOURCE: AARP, 2010b. Courtesy of AARP. All rights reserved. This figure combines Map 1, Overview of Diagnosing and Treating Aspects of NP Practice and Map 2, Overview of Prescribing Aspects of NP Practice, both developed by Linda Pearson (2010).

SOURCE: *The Future of Nursing: Leading Change, Advancing Health,* p. 99.

among others, as well as competencies in specific content areas, including community and public health and geriatrics. Nurses also should be educated with physicians and other health professionals both as students and throughout their careers in lifelong learning opportunities. And to improve the quality of patient care, a greater emphasis must be placed on making the nursing workforce more diverse, particularly in the areas of gender, race, and ethnicity.

Third, nurses should be full partners with physicians and other healthcare professionals in redesigning health care. Being a full partner will involve taking responsibility for identifying problems and areas of system waste, devising and implementing improvement plans, tracking improvement over time, and making necessary adjustments to realize established goals. In the health policy arena, nurses should participate in, and sometimes lead, decision making and be engaged in healthcare reform-related implementation efforts. Nurses also should serve actively on advisory boards on which policy decisions are made to advance health systems and improve patient care. To ensure that nurses are ready to assume leadership roles, nursing education programs need to embed leadership-related competencies throughout training.

Nurses should be full partners with physicians and other healthcare professionals in redesigning health care.

Fourth, planning for fundamental, wide-ranging changes in the education and deployment of the nursing workforce will require comprehensive data on the numbers and types of health professionals—including nurses—currently available and required to meet future needs. Once an improved infrastructure for collecting and analyzing workforce data is in place, systematic assessment and projection of workforce requirements by role, skill mix, region, and demographics will be needed to inform changes in nursing practice and education.

Building on this report, the RWJF and the IOM convened the National Summit on Advancing Health through Nursing. Held in late 2010, it brought together more than 500 stakeholders from multiple sectors to discuss implementing the report's recommendations. Thousands more participants joined via webcast and more than 120 satellite meetings in 45 states.

At the summit, RWJF, in collaboration with AARP, the advocacy group for older people, announced the launch of the Initiative on the Future

of Nursing Campaign for Action. Using the IOM report as a framework, the campaign works in partnership with numerous healthcare groups and professionals on a variety of activities, such as data collection and dissemination of educational tools, aimed at ensuring that nurses are prepared to meet the demands of the 21st-century health system.

Lifelong learning

Every segment of the healthcare workforce must comprise professionals who provide high-quality health care and assure patient safety. However, the nation lacks a comprehensive, effective system of continuing education in the health professions, and that this gap contributes to knowledge and performance deficiencies at the individual and system levels. Many stakeholders have called for a national interprofessional continuing education institute that would advance the science of continuing education. With support from the Josiah Macy Jr. Foundation, the IOM examined options for bridging the education gap.

The IOM study committee's report, *Redesigning Continuing Education in the Health Professions* (2009), described the merits and drawbacks of current programs, explored development of a national continuing education institute, and offered guidance on the establishment and operation of such an institute. To add perspective to its deliberations, the committee evaluated a number of possible alternatives to an institute. They included maintaining the status quo, developing a government program within an existing agency, forming a coalition of continuing education stakeholders and other organizations focused on healthcare quality and patient safety, and creating a new entity drawn from professional societies. The committee judged each alternative to be feasible, but concluded that a public-private institute held the most promise for fostering collaboration among all stakeholders that would improve the nation's system of continuing education for all health professionals.

There are major flaws in the way continuing education is conducted, financed, regulated, and evaluated, and the science underpinning continuing education for health professionals is fragmented and underdeveloped.

The report identifies a set of key messages that should help guide reforms. Among them, there are major flaws in the way continuing education is conducted, financed, regulated, and evaluated, and the science

Overview of Current Continuing Education Financing in Medicine

	Current System
Industry funding?	Yes, ~58% of total
Out-of-pocket cost to physicians	~42% of total, or $1,200 per physician per year
Mode of delivery	Primarily in-person lectures and workshops, with a small amount of simulation training and performance improvement exercises taking hold
Educational value, impact on patient care	Unclear

SOURCE: *Redesigning Continuing Education in the Health Professions,* p. 67.

underpinning continuing education for health professionals is fragmented and underdeveloped. Continuing education efforts should bring health professionals from various disciplines together in carefully tailored learning environments. And in an overarching shift, the nation should develop a comprehensive new vision of professional development to replace the culture that now envelops continuing education in health care.

The new vision should be based on an approach called continuing professional development, in which learning takes place over a lifetime and stretches beyond the classroom to the point of care. Unlike today's more structured approach, this holistic approach would incorporate a broad variety of learning methods and theories, and it would be learner driven, allowing learning to be tailored to individuals' needs.

To help in reaching these goals, the Department of Health and Human Services (HHS) should commission a blue-ribbon panel to oversee the design and implementation of an independent public-private Continuing Professional Development Institute. As a neutral body, not embedded within any agency, the institute could promote and catalyze stakeholder collaboration. The IOM report presents a detailed action plan for the institute. Among other actions, the institute should develop and prioritize a national research agenda in continuing education, work toward harmonizing the complex web of regulations covering continuing education, and explore new financing mechanisms that

The nation should develop a comprehensive new vision of professional development to replace the culture that now envelops continuing education in health care.

will support a broader-based continuing professional development system while avoiding potential conflicts of interest.

Guarding worker safety

Given that professionals across the healthcare workforce grapple regularly with a variety of medical threats, including new and emerging diseases, it is important to protect them where they work. One such risk emerged with the recent outbreak in the United States and other nations of a new type of influenza, called H1N1 influenza A. At the request of the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA), the IOM convened an expert committee to rapidly develop recommendations on how best to provide respiratory protection for healthcare workers who might be exposed to the virus on their jobs.

In *Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report* (2009), the committee recommends that personnel in hospitals and other care settings who are in close contact with individuals with H1N1 influenza A or influenza-like illnesses use an N95 respirator (or one equally effective) that is adjusted for proper fit. Employers should ensure that the use and fit testing of N95 respirators be conducted in accordance with OSHA regulations, and healthcare workers should use the equipment as required by regulations and employer policies.

The committee also calls for the CDC and other federal agencies, as well as private health groups, to fund or conduct additional research to resolve unanswered questions about the relative contribution of various routes of influenza transmission; explore the effectiveness through randomized clinical trials of personal respiratory protection technologies in a variety of clinical settings; and design and develop the next generation of personal respiratory protection technologies for healthcare workers to enhance safety, comfort, and ability to perform work-related tasks.

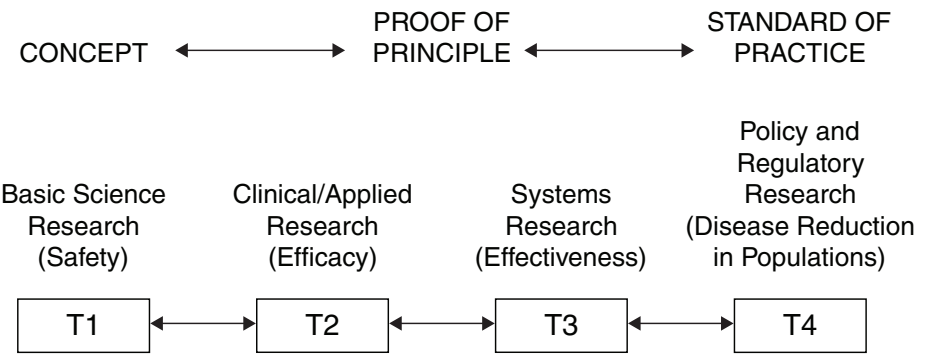
While this study answered some particularly pressing health questions raised by the emergence of a new influenza virus, the healthcare community clearly faces broader challenges in dealing with influenza pandemics and other viral diseases. To help in efforts to better protect the healthcare workforce, the National Personal Protective Technology Laboratory at the National Institute for Occupational Safety and Health

(NIOSH) asked the IOM to assess the personal protective equipment (PPE) on which workers rely. PPE may include respirators, face masks, gloves, gowns, eye protection, and face shields. The IOM previously had examined this issue and reported the findings in *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers* (2008). The new IOM study focused on updating progress in research and identifying future directions for PPE for healthcare personnel.

The healthcare community clearly faces broader challenges in dealing with influenza pandemics and other viral diseases.

In *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel—Update 2010*, the committee proposes an integrated approach that embraces the full spectrum of research (from basic research to policy research) and translates research findings into improvements in healthcare practice. Feedback loops will be critical, with adaptations made along the way as new equipment and processes are developed and tested in real-world settings. Such an integrated approach will call for collaboration and discourse among scientists, clinicians, policy makers, and other stakeholders who may not have had previous interactions.

Among research needs, basic questions remain about how the various modes of influenza transmission—droplet spray, aerosol, and direct or indirect contact—contribute to the overall spread of illness. Improvements



An integrated system moving research into practice, depicting the translation of research from basic science (T1) through policy and regulatory research (T4).

SOURCE: *Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel—Update 2010*, p. 8.

also are needed in equipment design. For example, safety devices known as filtering facepiece respirators are widely used and much improved in recent years, but new technologies are needed to improve their fit and reduce inward leakage of potentially contaminated air. In addition, better understanding is needed of how safety equipment and processes are used in various types of healthcare settings where a number of factors—the user, the device, the task, and the general work and organizational context—come into play. Paying greater attention to interactions among such contextual factors will better align research on PPE use in health care with other branches of occupational safety and health research.

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But the committee said that even as research continues, enough is known to implement a number of new approaches and technologies immediately, and it recommended a four-pronged strategy. There should be deliberate planning and preparation at the leadership and organizational levels; comprehensive training of personnel, including supervisors and managers; widespread and convenient availability of appropriate PPE devices; and accountability at all levels of the organization. Policies for PPE use by healthcare personnel need to be carefully planned at the organizational and institutional level to ensure a culture of safety, compliance, and buy-in at all levels. Managers and frontline workers alike need to understand and accept their roles and responsibilities, and using PPE needs to be as easy and convenient as possible for all healthcare personnel.

Occupational health nursing (OHN) is one healthcare profession particularly focused on PPE in the workplace. Occupational health nurses (OHNs) work in a variety of workplace environments, including agriculture, construction, health care, manufacturing, and public safety. In these environments, OHNs have a wide range of roles and responsibilities that span management and organization, worker health assessment and direct healthcare services, and prevention and research. In many settings where OHNs work, employees require protective measures to safeguard them from a range of respiratory hazards—for example, respirable dust in construction and chemical sprays in agriculture. As key members of the occupational health and safety workforce, OHNs need adequate education and

training in respiratory protection in order to ensure both their own safety and the safety of America's workers.

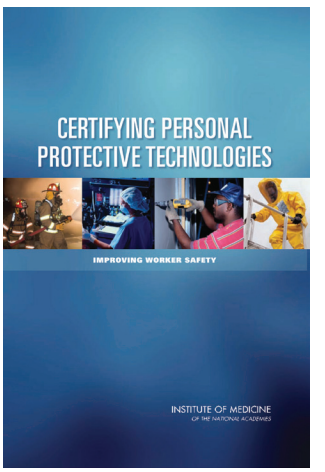
At the request of NIOSH's National Personal Protective Technology Laboratory, the IOM examined existing respiratory protection curricula in occupational health nursing programs and made recommendations to improve the education and training of OHNs. The IOM identified essential content that should be included in education and training programs for OHNs and the best approaches to teaching that content. The report, *Occupational Health Nurses and Respiratory Protection: Improving Education and Training—Letter Report* (2011) finds that current respiratory protection education for OHNs receives varying amounts of dedicated time and resources and is taught using a variety of approaches. The report makes several recommendations to occupational health nursing education and training programs and the National Personal Protective Technology Laboratory, such as expansion of respiratory protection information provided across all levels of nursing education and training; consistent integration of essential content into graduate curricula and continuing education programs for OHNs; continued and expanded use of innovative teaching methods, such as online courses, use of simulation and case studies, and field observation and practice; and exploration of the development of core competencies in respiratory protection.

As key members of the occupational health and safety workforce, occupational health nurses need adequate education and training in respiratory protection in order to ensure both their own safety and the safety of America's workers.

Millions of workers rely on a variety of personal protective technologies (PPT) to keep them safe. PPT encompass a range of specialized clothing and equipment, including gloves, hearing protection, fall arrest harnesses, respirators, and eye protection. To ensure that PPT will perform as intended, government agencies, manufacturers, testing laboratories, workers, and other stakeholders participate in an array of activities collectively called conformity assessment. Activities include testing to ensure that the product meets specific design or performance criteria, examining the test results to declare conformity to the specifications, inspecting manufacturing sites, and conducting postmarket evaluations.

Millions of workers rely on a variety of personal protective technologies to keep them safe.

The National Personal Protective Technology Laboratory asked the IOM to appoint an expert committee to examine PPT conformity assessment issues and recommend improvements. The committee's report, *Certifying Personal Protective Technologies: Improving Worker Safety* (2010) concluded that current approaches to evaluating occupational PPT, often by job sector, are fragmented and vary in rigor. The committee recommends as a first step that a comprehensive framework be established for PPT conformity assessment. The framework would categorize products into tiers, based on the degree of risk to the safety and health of the user, while also considering various pragmatic factors, such as the cost or feasibility of developing a new product and the size of the intended target population.



Within the framework, risks would be rated as high, medium, or low, with each category requiring different levels of conformity assessment. When risks are low, manufacturers would need only to attest that their products meet certain standards recognized by the federal government. When risks are medium, products would need to be tested and assessed by an independent testing laboratory and certifying organization to ensure that they meet federal standards. When risks are high, third-party testing and certification would be required, coupled with intensive government involvement at all stages, from design to manufacture and follow-up testing in the workplace.

Numerous stakeholders must participate in developing, implementing, and supporting this new framework. The National Personal Protective Technology Laboratory at NIOSH can play a lead role, and it should work with other federal agencies, certifying and accrediting organizations, manufacturers, and workers who use PPT. Other efforts also will be needed to improve communications between government and employers and workers about the availability and effectiveness of PPT, and to expand federal surveillance programs to monitor the effectiveness of PPT products in the workplace. With such a comprehensive system in place, the government and others will be better able to direct conformity assessment efforts, identify remaining gaps in assessment, and prioritize resources to ensure that workers receive the best protection possible on their jobs.

Fighting HIV/AIDS in Africa

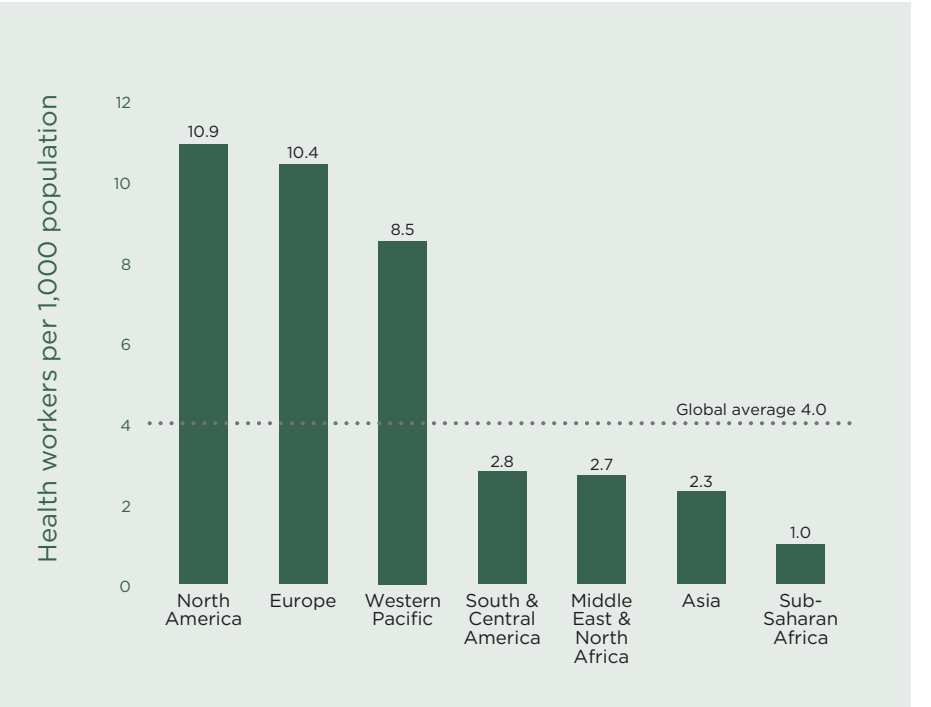
In addition to working to improve the health and well-being of Americans, the U.S. workforce of healthcare professionals, by necessity, tackles international health challenges as well. No challenge is greater than combating HIV/AIDS in sub-Saharan Africa, which in 2009 accounted for 68 percent of cases worldwide and 69 percent of new infections. In a major U.S. effort, the President's Emergency Plan for AIDS Relief has provided approximately $32 billion to HIV/AIDS-related programs since it was established in 2003. But this and other assistance efforts are being overwhelmed as the epidemic continues to spread.

No challenge is greater than combating HIV/AIDS in sub-Saharan Africa, which in 2009 accounted for 68 percent of cases worldwide and 69 percent of new infections.

In this context, the IOM appointed a committee of experts to recommend affordable, sustainable strategies that both African nations and the United States can implement to reduce the long-term burden of HIV/AIDS. The committee's report, *Preparing for the Future of HIV/AIDS in Africa: A Shared Responsibility* (2010), concludes that the burden of morbidity and mortality in Africa cannot be alleviated through treatment alone. Treatment can reach only a fraction of those who need it, and its costs are unsustainable. Greater emphasis must be placed on preventing new infections. The report identifies a number of specific, tailored strategies for building African capacity—including human, scientific, technological, organizational, institutional, and/or resource capabilities—to prevent, treat, and care for HIV/AIDS.

African countries, with the support of international donors, including the United States, should develop and implement methods for measuring the level of and change in new HIV infections to enable better planning and evaluation of prevention programs. The nations also should focus on strengthening their healthcare systems by making the most of existing capacities, such as healthcare workers on the ground and local institutions. Needed actions include making use of management and support staff from outside the clinical health sector to free up time for healthcare providers to perform clinical work; delegating tasks of health professionals, when appropriate, to health workers with less-specialized training; tapping the potential of modern information and communications technology, such as smart phones and distance learning; and forming partnerships between developing countries and creating regional collaborations to exchange technical assistance.

For the United States, strategies should focus on supporting partnerships—particularly institutional partnerships—that can help Africa move forward independently in HIV/AIDS treatment and prevention. Such partnerships can be formed in the public and private sectors and include collaborations among academic institutions, faith-based organizations, and the militaries of the United States and African nations. Among other actions, the White House and the Office of the Global AIDS Coordinator should develop a U.S. roadmap for HIV/AIDS in 2020 that incorporates a model of U.S.-African shared responsibility. This roadmap should give priority to HIV/AIDS prevention and strike an optimal balance between bilateral and multilateral funding mechanisms. Likewise, HIV/AIDS coordinating groups in Africa should develop a 20-year roadmap for combating the epidemic, including sufficient investment in prevention and the development of more efficient models of care and treatment.



Health worker density by region.

SOURCE: JLI, 2004, compiled from WHO, 2004.

SOURCE: *Preparing for the Future of HIV/AIDS in Africa: A Shared Responsibility*, p. 108.

Measuring America's Health

Healthcare programs and policies depend on timely, accurate, and thorough information. Yet the nation's systems to collect and analyze key health data fall short of their potential. The Institute of Medicine (IOM) has conducted a number of studies in recent years to guide collection and analysis of health information. How healthy is the population as a whole, or subgroups within the population? What measures provide the best indicators of health, for individuals and society? The answers to such questions hold the key to judging performance and improving the health of all Americans.

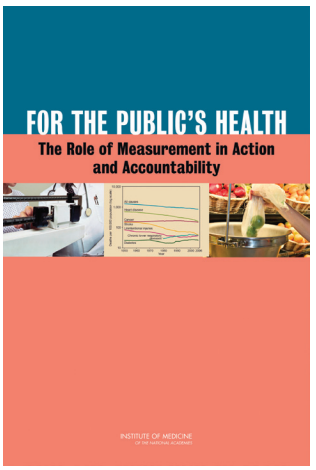
Health and the nation

America has the costliest healthcare system in the world, but many countries get better results for less money. Recent international comparisons show that dozens of less affluent nations boast higher life expectancy and lower infant mortality than the United States.

Looking beyond such statistics, the Robert Wood Johnson Foundation saw a more fundamental problem: the nation lacks a comprehensive system for gathering, analyzing, and communicating health information about the population. The foundation turned to the IOM for guidance on filling this gap, commissioning a 2.5-year study on three key aspects of public health—measurement, laws, and funding.

In its first report, *For the Public's Health: The Role of Measurement in Action and Accountability* (2010), the committee concluded that social and environmental factors, rather than delivery of clinical care, are the most powerful shapers of health outcomes in the population, yet the nation lacks a cohesive strategy and measurement tools for tracking and responding

to these critical influences. For example, health outcomes now are listed under categories such as "infant mortality" or "myocardial infarction," but the environmental or social failures—as when community residents lack easy access to healthful foods or to safe sidewalks and parks for exercise—that could have mitigated these conditions are less obvious and therefore go unnoticed. These nonmedical factors are not routinely measured, so harmful trends and disparities often go unrecorded.



Achieving gains in the nation's health will require actions across many domains, including communities and their organizations, the clinical care delivery system, employers and businesses, the media, and other public and private stakeholders whose policies and actions affect the longevity and quality of life of every person. In a detailed roadmap for the nation, this report describes needed changes in the processes and tools used to gather information about health outcomes and their determinants and shows how such measures can be used to assess and enhance accountability on the part of governmental and other entities that bear responsibility for the population's health.

The report urges the Department of Health and Human Services (HHS) to lead development of one core set of standardized indicators focused on priority health outcomes. The numerous health indicator sets developed in recent years and deployed in different contexts make assessment and comparison difficult for policy makers and other decision makers by highlighting similar information in different ways. The standard indicators should reflect national, state, and local priorities and enable an "apples to apples" comparison of jurisdictions.

America has the costliest healthcare system in the world, but many countries get better results for less money.

HHS also should develop and promote a single summary measure of population health to serve as an equivalent to the gross domestic product in the economic sector. This measure could be used to track trends, mark progress, and encapsulate an overall picture of the health of communities and the nation, improving the ability of decision makers to monitor health status, make forecasts, and set priorities. In addi-

tion, HHS should issue an annual report on the social and environmental factors that influence the population's health as a means of helping Americans better understand what shapes their well-being at the local, state, and national levels. A report of this kind potentially could galvanize actions that lead to better outcomes and could increase the likelihood that health implications be considered not only in health policy but in all policy.

The committee's second report, *For the Public's Health: Revitalizing Law and Policy to Meet New Challenges*, describes how public policy can more effectively protect and improve the health of the population. This report is described later in the chapter on public health. In its third report, expected late in 2011, the committee will propose recommendations for funding state and local public health systems within the healthcare landscape expected to evolve as the Affordable Care Act of 2010 is implemented.

Working in concert with HHS, the IOM helped to develop and promote a new national Health Data Initiative (HDI). Described in more detail in the chapter on IOM's collaborations, the HDI is an effort to make use of health data to raise awareness and spark community action to improve health.

National health indicators

Improving health measurement stands at the center of a major HHS program to chart the health of the nation's population. For the past three decades, HHS has issued a national agenda aimed at improving the health of all Americans over each 10-year span. Under each of these *Healthy People* initiatives, HHS established health targets and monitored how well people were reaching them over time. *Healthy People 2020* lays out the proposed agenda for the current decade. At the request of HHS, the IOM convened a committee of experts to review the agenda and recommend ways to sharpen its focus.

Healthy People 2020, like previous versions, lays out a number of topics and objectives that collectively provide a blueprint for improving the nation's health. In the context of the *Healthy People* blueprints, a topic is a general category relevant to health (such as chronic illness), and an objective is movement toward a quantitative health goal (such as reducing the prevalence of cardiovascular disease by 10 percent). With the steady advance of science and medicine, each decade's agenda has grown increasingly detailed. *Healthy People 2020* lists 42 topics and nearly

Topics, Indicators, and Objectives

Topics	Indicators	Objectives
Access to Care	Proportion of the population with access to healthcare services	1. Increase the proportion of persons with health insurance (AHS 1). 2. Increase proportion of persons with a usual primary care provider (AHS 3). 3. (Developmental) Increase the proportion of persons who receive appropriate evidence-based clinical preventive services (AHS 7).
Healthy Behaviors	Proportion of the population engaged in healthy behaviors	4. Increase the proportion of adults who meet current federal physical activity guidelines for aerobic physical activity and for muscle-strengthening activity (PA 2). 5. Reduce the proportion of children and adolescents who are considered obese (NWS 10). 6. Reduce consumption of calories from solid fats and added sugars in the population aged 2 years and older (NWS 17). 7. Increase the proportion of adults who get sufficient sleep (SH 4).
Chronic Disease	Prevalence and mortality of chronic disease	8. Reduce coronary heart disease deaths (HDS 2). 9. Reduce the proportion of persons in the population with hypertension (HDS 5). 10. Reduce the overall cancer death rate (C 1).
Environmental Determinants	Proportion of the population experiencing a healthy physical environment	11. Reduce the number of days the Air Quality Index (AQI) exceeds 100 (EH 1).
Social Determinants	Proportion of the population experiencing a healthy social environment	12. (Developmental) Improve the health literacy of the population (HC/HIT 1). 13. (Developmental) Increase the proportion of children who are ready for school in all five domains of healthy development: physical development, social-emotional development, approaches to learning, language, and cognitive development (EMC 1). 14. Increase educational achievement of adolescents and young adults (AH 5).
Injury	Proportion of the population that experiences injury	15. Reduce fatal and nonfatal injuries (IVP 1).
Mental Health	Proportion of the population experiencing positive mental health	16. Reduce the proportion of persons who experience major depressive episodes (MDE) (MHMD 4).
Maternal and Infant Health	Proportion of healthy births	17. Reduce low birth weight (LBW) and very low birth weight (VLBW) (MICH 8).
Responsible Sexual Behavior	Proportion of the population engaged in responsible sexual behavior	18. Reduce pregnancy rates among adolescent females (FP 8). 19. Increase the proportion of sexually active persons who use condoms (HIV 17).
Substance Abuse	Proportion of the population engaged in substance abuse	20. Reduce past-month use of illicit substances (SA 13). 21. Reduce the proportion of persons engaging in binge drinking of alcoholic beverages (SA 14).
Tobacco	Proportion of the population using tobacco	22. Reduce tobacco use by adults (TU 1). 23. Reduce the initiation of tobacco use among children, adolescents, and young adults (TU 3).
Quality of Care	Proportion of the population receiving quality healthcare services	24. Reduce central line-associated bloodstream infections (CLABSI) (HA 1).

NOTE: The numbering of the objectives is directly from *Healthy People 2020*.

SOURCE: *Leading Health Indicators for Healthy People 2020: Letter Report,* p. 6.

600 objectives. By comparison, *Healthy People 2000* listed 15 topics and 226 objectives.

As part of its charge, the IOM committee was asked to identify 12 key topics and 24 objectives that are critical to the nation's health needs, and also to identify 24 leading indicators, or measurements of health-related concepts, that reflect major public health concerns. The committee presented its recommendations in *Leading Health Indicators for Healthy People 2020: Letter Report* (2011).

Improving health measurement stands at the center of a major Health and Human Services program to chart the health of the nation's population.

The committee arrived at its recommendations by using, among other things, a life-course health model that takes into account specific risk factors and determinants of health that mark various stages of life and combines them to produce a health trajectory that spans a person's lifetime. The trajectory can be improved by reducing risk factors and promoting health through actions at both individual and society levels, applied at specific points or during specific stages of the life course, especially during the early years of life. In choosing its recommended objectives, the committee applied additional criteria. For example, the objectives should be actionable—that is, responsive to policies or initiatives by public or private health agencies. They also should be based on the latest scientific evidence and, to the extent possible, should have annual data sources, with comparable data available at the state and county level.

Overall, the committee concludes that *Healthy People 2020* is likely to prove valuable in eliciting interest and awareness among the general population, motivating diverse population groups to engage in activities that will improve their health, and providing feedback on progress toward improvements on specific health indicators. Advances in these areas will help the nation achieve health equity and eliminate disparities; create social and physical environments that promote good health; and promote quality of life, healthy development, and healthy behaviors across life stages.

Measuring health among understudied populations

Information gaps also occur among subgroups within the larger U.S. population, including among children and adolescents. In the Children's Health Insurance Program Reauthorization Act of 2009, Congress directed the

IOM and the National Research Council to convene an expert committee to evaluate current efforts to measure child and adolescent health and the quality of their healthcare services.

The committee found that despite federal support for hundreds of data sets and measures through federal surveys and administrative data systems, the nation lacks robust national- and state-level information about the health status or healthcare quality of children and adolescents. In its report, *Child and Adolescent Health and Health Care Quality: Measuring What Matters* (2011), the committee pointed to a lack of standardized data in key areas—such as race and ethnicity, socioeconomic status, primary language spoken at home, and parental English proficiency—and said these information gaps hinder policy makers, researchers, and others who use data to identify, monitor, and resolve persistent health and healthcare quality disparities among children and adolescents. Measurement in these areas is especially important given the growing ethnic and racial diversity of children and adolescents and the increasing number of children who live in poverty.

The nation lacks robust national- and state-level information about the health status or healthcare quality of children and adolescents.

To guide improvements, the committee recommended the following five-step action plan:

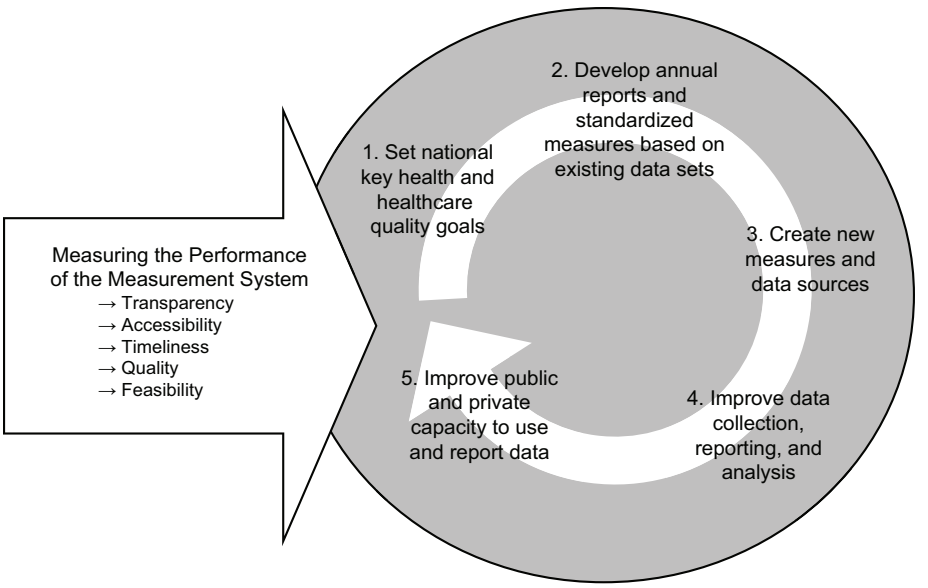
1. Set shared health and healthcare quality goals for children and adolescents.
2. Develop annual reports and standardized measures for existing data sets of health and healthcare quality that can be collected and used to assess progress toward those goals.
3. Create new measures and data sources in priority areas.
4. Improve methods for data collection, reporting, and analysis.
5. Improve public and private capacities to use and report data.

This approach will require both government-funded and private initiatives and should include continuous evaluation of the measurement system itself for transparency, accessibility, timeliness, quality, and feasibility.

Within this framework, the report calls for adopting a "life-course" approach to measurement that considers how events at each stage of life influence subsequent health and healthcare quality. The approach places

greater emphasis on social, behavioral, and physical factors that influence the health status of children and adolescents and their use of healthcare services. The approach focuses on the needs of the "whole child" as opposed to individual clinical concerns, and will better meet the distinct needs of younger populations, including their unique patterns of morbidity and mortality, their dependent status, and their developmental stages.

The committee also endorsed the use of innovative measurement practices that can adapt to changing conditions, changing populations, and opportunities for health improvement. This will require efforts that track key child and adolescent populations over time to ensure that groups with the greatest risk for poor outcomes are included in data sources. Electronic data collection—done in ways that ensure privacy and confidentiality—offers opportunities to enhance future measurement activity by capturing important state-level policy and community-level characteristics and enabling analysis of the variability and impact of coverage, eligibility, and payment policies.



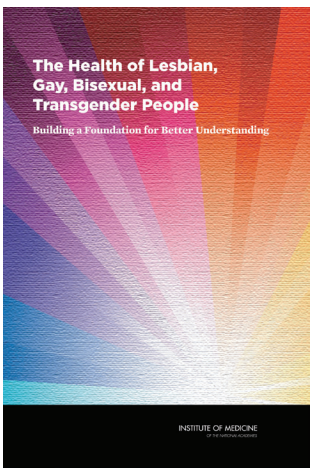
A stepwise approach to measuring health and healthcare quality for children and adolescents.

SOURCE: *Child and Adolescent Health and Health Care Quality: Measuring What Matters,* p. 185.

In another study, the IOM considered the health status and health needs of a population subgroup that historically has been overlooked—lesbian, gay, bisexual, and transgender individuals, often referred to under the umbrella acronym LGBT. Even as LGBT people are becoming more socially acknowledged, clinicians and researchers are faced with incomplete information about their health status. In this light, the National Institutes of Health (NIH) asked the IOM to appoint an expert committee to assess current knowledge of the health of LGBT populations, identify research shortcomings and opportunities, and outline an agenda to help the NIH focus its research in this area.

Even as lesbian, gay, bisexual, and transgender people are becoming more socially acknowledged, clinicians and researchers are faced with incomplete information about their health status.

In *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), the committee identifies a number of challenges that researchers face in understanding the health needs of LGBT populations, including a lack of data. To correct this, the committee recommended that HHS and other federal agencies use their health surveys to collect data on sexual orientation and gender identity, in the same way that race and ethnicity data are collected. In June 2011, a few months after the report's release, HHS Secretary Kathleen Sebelius announced plans to begin collecting health data on LGBT populations in an effort to help researchers, policy makers, health providers, and advocates to identify and eliminate health disparities afflicting these communities.



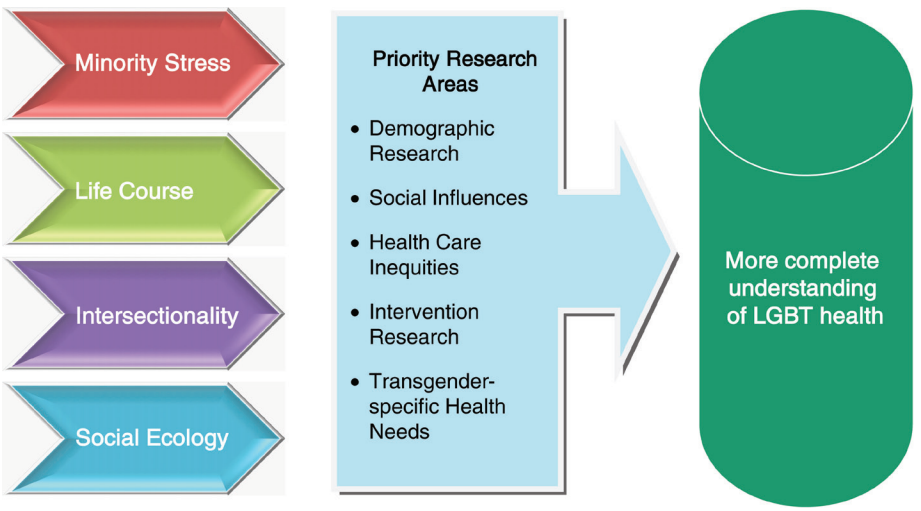
In addition, the report recommends that questions about sexual orientation and gender identity be standardized to allow for the comparison and combination of data across large studies. Such data should be collected as well in electronic health records in various settings, with appropriate privacy and security protections.

The committee also urges the NIH to avoid repeating past disparities in research, which has not been conducted evenly across sexual and gender minority populations. More research has focused on gay men and lesbians

than on bisexual and transgender people, for example, and research has not adequately examined subpopulations, particularly racial and ethnic groups. Also, most research has been conducted among adults, with a modest number of studies on adolescents and less attention on LGBT elders.

In its recommended research agenda for the NIH, the committee focuses on five priority areas: demographic research, social influences, healthcare inequities, intervention research, and transgender-specific health needs. The NIH also should support methodological research aimed at developing innovative ways to conduct research with small populations—to reduce the costs of such research—and determining the best ways to collect information on sexual and gender minorities in research, health care, and other settings.

To encourage more research on LGBT health issues, the NIH should create a comprehensive research training program that would raise awareness of LGBT health issues among researchers. The NIH also should encourage researchers in a range of institutions to include sexual and gender minorities explicitly in their samples, using the NIH policy on the inclusion of women and racial and ethnic minorities in clinical research as a model. This would prompt researchers to consider these groups more frequently when applying for research grants and ultimately increase the body of information on the health status and needs of LGBT populations.



Research agenda.

SOURCE: *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding,* p. 6.

Military and Veterans: Protecting the Protectors

The men and women of the U.S. military face many health threats. Combat carries risks of injury or death. Personnel serving away from battle zones may also encounter toxic chemicals or other hazardous materials that are used in or arise from warfare or the environment. Deployment in dangerous areas can generate extreme stress. The health effects of these and other threats may be immediate or develop later, even long after a service member has returned home. Some effects can last a lifetime.

The Department of Defense (DoD) bears the primary responsibility for protecting service members on active duty and providing them with high-quality health care. The Department of Veterans Affairs (VA) provides health care to service members after they leave the military. To help in carrying out their missions, the DoD and the VA regularly request that the Institute of Medicine (IOM) study and recommend actions on a range of health-related topics.

Health effects of serving in Iraq and Afghanistan

Protecting the health and well-being of the military personnel who are serving or have served in Afghanistan and Iraq stands as an immediate challenge to the federal government. Roughly 2.1 million men and women, including those drawn from military reserve units and the National Guard, have served in Iraq during Operation Iraqi Freedom and in Afghanistan during Operation Enduring Freedom, often experiencing multiple deployments.

At the end of their deployments, most of the troops successfully readjust to life away from war. But others have difficulty in returning or transitioning to family life, to their jobs, and to living in their communities after deployment. Numerous media reports have suggested that for many service members, the challenge of readjustment is made worse by various health problems, including post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI).

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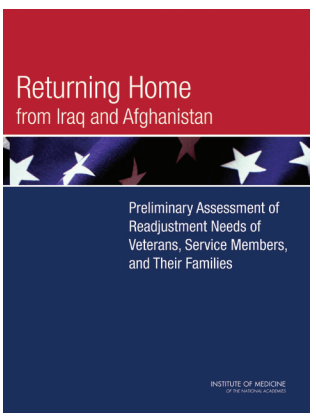
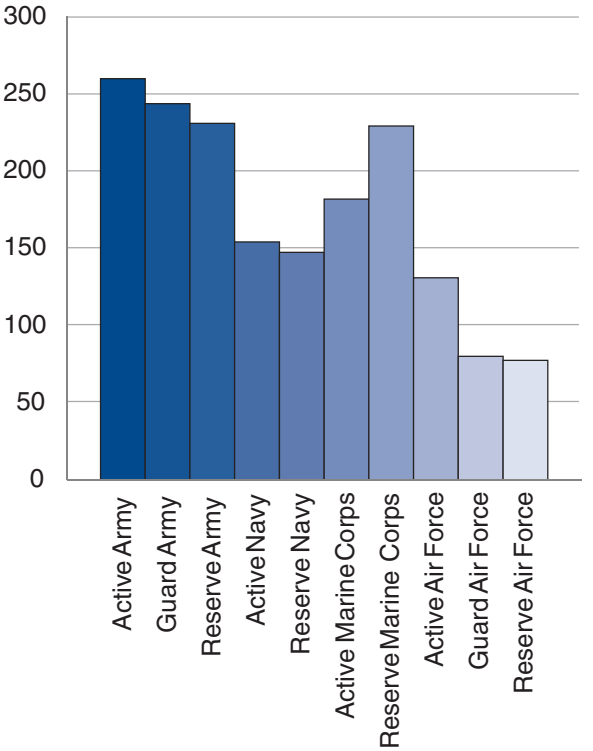
In response to these concerns, Congress, in the National Defense Authorization Act for Fiscal Year 2008, directed the DoD, in consultation with the VA, to sponsor an IOM study of the physical and mental health and other readjustment needs of current and former service members deployed to Iraq and Afghanistan and their families. The IOM appointed a committee of experts to conduct the study, which would be done in two phases.

In its report on the first phase, *Returning Home from Iraq and Afghanistan: Preliminary Assessment of Readjustment Needs of Veterans, Service Members, and Their Families* (2010), the committee identified the most pressing needs of this population, based in large part on a review of the scientific literature and on testimony from veterans and their families at several town-hall meetings across the country. The report commended the DoD and the VA for their efforts to help returning troops and their families but concluded that critical gaps remain.



One key need is to improve scientific understanding of long-term management of TBI, which has been called the signature wound of the fighting in Iraq and Afghanistan. The VA established a comprehensive system of rehabilitation services for TBI, focused on needs that arise in the initial months and years after injury. But protocols to manage the lifetime effects of TBI have not been studied in either military or civilian populations. The committee recommends that the VA sponsor research to determine the efficacy and cost effectiveness of potential protocols for managing TBI—as well as other types of injuries resulting from multiple traumas—over the long term.



Average time spent deployed in days by branch of military subdivided by active component and reserve component and reserve component.

SOURCE: *Returning Home from Iraq and Afghanistan: Preliminary Assessment of Readjustment Needs of Veterans, Service Members, and Their Families,* p. 27.

The DoD and the VA also need to ensure there are enough mental health professionals in the healthcare systems serving current and former military personnel and their families to provide treatment to those who suffer from PTSD, substance abuse, and other mental health problems, and that these providers are located where they are needed. On an overarching level, the VA needs to institute a process for forecasting the amount and types of resources necessary to meet health requirements of the veterans and their families well into the future. Requests for disability care and compensation by veterans of previous wars did not peak until 30 years or more after their service ended, and this pattern may hold for Iraq and Afghanistan military personnel and their families as well. The VA currently lacks a mandate and resources to make such long-range projections, limiting the

agency's ability to plan for the infrastructure, workforce, and other needs when demand is likely to be greatest.

In the report, the committee also presents a framework for the second phase of its study. The aim is to provide a systematic review of interventions to ease readjustment to civilian life, to identify gaps in research, and to identify challenges in accessing care. The second report is expected in spring 2013.

Concurrently, the IOM is looking at the long-term health effects of exposure to burn pits, used to dispose of waste in Iraq and Afghanistan. Using the Balad Burn Pit in Iraq as an example, an IOM committee is examining the feasibility and design issues of an epidemiologic study of veterans exposed to the burn pit and their health outcomes as well as exploring background information on the use of burn pits in the military. A final report is expected in fall 2011.

The IOM also is studying ongoing efforts in the treatment of PTSD. The two-part study, mandated by Congress, will collect and analyze data on DoD and VA programs and methods available for the prevention of PTSD and the screening, diagnosis, treatment, and rehabilitation of members of the Armed Forces and veterans diagnosed with PTSD. The first of two reports is expected in summer 2012.

Treating Traumatic Brain Injury

As *Returning Home from Iraq and Afghanistan* and other reports have made clear, TBI is common among soldiers who have fought in Iraq and Afghanistan. By one estimate, 10 to 20 percent of veterans returning from those conflicts have sustained a traumatic brain injury. The IOM has substantial experience in this area, having published—sometimes with other units of the National Academies—at least eight reports dealing with TBI in both military and civilian contexts over the past decade.

10 to 20 percent of veterans returning from those conflicts have sustained a traumatic brain injury.

In recent studies of methods for treating TBI, there is evidence that nutritional interventions in the minutes or hours following injury may be effective in improving health outcomes and may even offer some degree of resilience to TBI. In light of such findings, the DoD asked the IOM to convene an expert committee to review the potential role of nutritional interventions.

In *Nutrition and Traumatic Brain Injury: Improving Acute and Subacute Health Outcomes in Military Personnel* (2011), the committee describes what is known—and unknown—about a number of potential interventions. Given the complexity of TBI and the current gaps in scientific knowledge, the committee could identify only one method that can immediately improve treatment efforts: early feeding of patients with severe TBI. This approach involves giving patients specified levels of energy and protein within the first 24 hours and continuing the course for at least 2 weeks. Early feeding is likely to limit the person's inflammatory response, which typically is at its peak during the first 2 weeks after an injury, and thereby improve the ultimate health outcome. The committee recommends that the DoD take the lead in developing feeding protocols that require standardized early nutrition delivery for patients with severe TBI, and that hospital intensive care units that treat military personnel should include these protocols in their critical care guidelines.

Early feeding is likely to limit the person's inflammatory response, which typically is at its peak during the first 2 weeks after an injury, and thereby improve the ultimate health outcome.

Although not as far advanced, a number of other nutritional interventions show therapeutic promise as well. The interventions target specific physiological processes involved in TBI, and they act by restoring cellular energy processes, reducing inflammation and oxidative stress, or repairing brain functions by regenerating neurons or revascularizing damaged tissue. Researchers within the DoD and elsewhere should expand studies of these interventions to demonstrate their effectiveness and safety.

Outside of the laboratory, the DoD should improve assessment of the nutritional status of military personnel, especially those deployed in combat areas, to determine whether there are nutrients that need to be added to their diets to help provide at least some resistance to TBI.

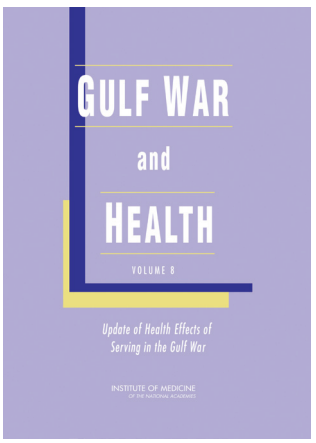
Beyond nutritional interventions, the IOM continues to study TBI and consider treatment options. A study currently under way is tasked with designing a methodology to review, synthesize, and assess the available evidence and experience from the field to determine the efficacy of cognitive rehabilitation therapy (CRT) for the treatment of TBI. The DoD asked the IOM to convene a committee to determine the effects of specific CRT treatment on improving attention, language and communication, memory, visuospatial perception, and such executive functions as problem solving and awareness. The IOM's final report is expected in fall 2011 and

will include recommendations pertaining to the safety, efficacy, and effectiveness of CRT.

Health effects of the Gulf War

The federal government also conducts programs to monitor and protect the health of military personnel who served in the Persian Gulf War. Following Iraq's invasion of Kuwait, the United States led an international coalition of armed forces in Operation Desert Shield, which began in January 1991 and ended roughly 3 months later with a ceasefire agreement. Almost 700,000 U.S. troops, including many members of the Reserves and National Guard, took part in the conflict.

On returning home, a substantial number of the troops reported health problems that they believed to be connected to their service. At the request of Congress, the IOM has conducted a series of studies that have examined the scientific and medical evidence on the health effects of the various agents to which military personnel may have been exposed. Beginning in 2000, the IOM has reported on numerous health outcomes related to possible exposures in the Gulf; that work has resulted in the studies in the Gulf War and Health series, which currently includes eight volumes.



As part of this effort, the Department of Veterans Affairs in 2005 asked the IOM to appoint an expert committee to review what was known about the current status of veterans' health. In its report, *Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War* (2006), the committee found that many veterans reported that they were troubled by a combination of medically unexplained symptoms, often including chronic fatigue, muscle and joint pain, sleep disturbance, difficulty with concentration, and depression. Veterans also reported numerous other health problems, including chronic pain, gastrointestinal disorders, skin disorders, and respiratory disorders.

Research on the conditions continued, and in 2009 the VA asked the IOM to update its earlier work, based on the latest scientific literature. In

Summary of Findings Regarding Associations Between Deployment to the Gulf War and Specific Health Outcomes

Sufficient Evidence of a Causal Relationship
- PTSD.

Sufficient Evidence of an Association
- Other psychiatric disorders, including generalized anxiety disorder, depression, and substance abuse, particularly alcohol abuse. These psychiatric disorders persist for at least 10 years after deployment.
- Gastrointestinal symptoms consistent with functional gastrointestinal disorders such as irritable bowel syndrome and functional dyspepsia.
- Multisymptom illness.
- Chronic fatigue syndrome.

Limited/Suggestive Evidence of an Association
- ALS.
- Fibromyalgia and chronic widespread pain.
- Self-reported sexual difficulties.
- Mortality from external causes, primarily motor-vehicle accidents, in the early years after deployment.

Inadequate/Insufficient Evidence to Determine Whether an Association Exists
- Any cancer.
- Diseases of the blood and blood-forming organs.
- Endocrine, nutritional, and metabolic diseases.
- Neurocognitive and neurobehavioral performance.
- Multiple sclerosis.
- Other neurologic outcomes, such as Parkinson's disease, dementia, and Alzheimer's disease.
- Incidence of cardiovascular diseases.
- Respiratory diseases.
- Structural gastrointestinal diseases.
- Skin diseases.
- Musculoskeletal system diseases.
- Specific conditions of the genitourinary system.
- Specific birth defects.
- Adverse pregnancy outcomes such as miscarriage, stillbirth, preterm birth, and low birth weight.
- Fertility problems.

Limited/Suggestive Evidence of No Association
- Peripheral neuropathy.
- Mortality from cardiovascular disease in the first 10 years after the war.
- Decreased lung function in the first 10 years after the war.
- Hospitalization for genitourinary diseases.

SOURCE: *Gulf War and Health, Volume 8: Update of Health Effects of Serving in the Gulf War,* p. 8.

Gulf War and Health, Volume 8: Update of Health Effects of Serving in the Gulf War (2010), the committee notes there is considerable evidence that deployment is associated with the type of chronic, multisymptom illness reported by many veterans, as well as with various other conditions and diseases, including gastrointestinal disorders such as irritable bowel syndrome; substance abuse, particularly alcoholism; chronic fatigue syndrome; and some psychiatric disorders, including anxiety disorder and depression. In addition, there is suggestive, though limited, evidence for an association with amyotrophic lateral sclerosis (ALS), fibromyalgia and chronic widespread pain, sexual difficulties, and death from external causes, including automobile accidents, in the early years after deployment.

For the many other diseases with a suggested possible link to deployment—including various cancers, Parkinson's disease, Alzheimer's disease, and dementia—the committee judged the evidence to be insufficient for making a determination. For a very few health outcomes, including death from cardiovascular disease within 10 years of the war, the committee found some evidence that deployment has no impact, though data are far from complete.

Concluding that there is a pressing need to answer lingering questions, the report offers a detailed action plan. On one front, the government should continue its surveillance of deployed and nondeployed Gulf War veterans. This effort should include assembling methodologically robust cohort groups and carefully tracking their development of a number of diseases, including ALS, multiple sclerosis, brain cancer, and psychiatric conditions, as well as health problems that occur at a later age, such as other cancers, cardiovascular disease, and neurodegenerative diseases.

Renewed effort is needed to better understand the multisymptom illness that affects an estimated 250,000 Gulf War veterans.

On another front, renewed effort is needed to better understand the multisymptom illness that affects an estimated 250,000 Gulf War veterans. Researchers should undertake studies comparing genetic variations and other differences in veterans with and without symptoms. It is likely that the illness results from interactions between genes and environmental exposure, with genetics predisposing some individuals to illness. A consortium involving the VA, the DoD, and the National Institutes of Health could coordinate this effort and contribute the necessary resources. Similarly, expanded clinical trials are needed to develop more

effective methods to treat or even cure multisystem illness—and, ideally, to find ways to prevent such disorders from affecting troops in future deployments.

The VA took quick action. Citing the IOM report, in July 2010 the agency announced a national research program to identify and adopt more effective treatments for multisymptom illnesses in Gulf War veterans. The $2.8 million program, which incorporates recommendations of the VA's Gulf War Veterans' Illnesses Task Force, will feature three new research projects. Included will be a 5-year study to evaluate the impact of resistance exercise training in treating chronic musculoskeletal pain and related symptoms, a 4-year study using an animal model of multisymptom illness to assess therapies designed to enhance mood and memory, and a 2-year pilot study to compare the effectiveness of certain stress-reduction therapies with conventional care in treating Gulf War veterans. In addition to funding new research, the VA has asked the IOM to evaluate treatments being used to manage chronic multisymptom illness and to recommend those that seem to offer the most benefit and improved health outcomes in those veterans experiencing chronic symptoms.

Tracking the health effects of Agent Orange

From 1962 to 1971, the U.S. military sprayed herbicides, including a mixture called Agent Orange, over parts of southern Vietnam and surrounding areas in order to achieve a number of military goals. Most large-scale sprayings were conducted from airplanes and helicopters, but herbicides were also dispersed from boats and ground vehicles and by soldiers wearing back-mounted equipment. Following the war, many veterans and their families began attributing various chronic and life-threatening diseases to exposure to Agent Orange or to its toxic contaminant, dioxin.

In 1991, Congress directed the IOM to study the veterans' claims. *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (1994) provided the first comprehensive, unbiased review of the epidemiological evidence regarding links between such exposure and the full spectrum of adverse health effects, including various cancers, reproductive and developmental problems, and neurobiological disorders. Since then, the IOM has published a series of biennial updates. Collectively, these reports—integrating all the peer-reviewed published literature—provide the scientific basis on which the VA awards disability compen-

sation to Vietnam veterans. The reports also recommend research that could provide more definitive conclusions about possible health effects.

Veterans and Agent Orange: Update 2008 was released in 2009. Among key findings, the report concluded that there is suggestive but limited evidence that exposure to Agent Orange and other herbicides is associated with an increased chance of developing ischemic heart disease and Parkinson's disease in Vietnam veterans. Ischemic heart disease is characterized by reduced blood supply to the heart that can lead to heart attack and stroke. Parkinson's disease is a degenerative disorder of the central nervous system that can cause movement-related problems and, in later stages, behavioral and cognitive problems.

There is suggestive but limited evidence that exposure to Agent Orange and other herbicides is associated with an increased chance of developing ischemic heart disease and Parkinson's disease in Vietnam veterans.

In response to a request for clarification by the VA, the committee that conducted the study also affirmed that hairy cell leukemia should be classified with chronic lymphocytic leukemia (CLL) and lymphomas for compensation purposes. Previous reviews in the series had found sufficient evidence to state that there is an association between herbicide exposure and increased risk for CLL and lymphomas.

But many health questions remain, and the study committee identified a number of areas where continued research is needed. For example, development of animal models of various chronic health conditions and their progression would be useful for understanding whether and how Agent Orange and other herbicides contribute to problems in aging Vietnam veterans. Work also needs to be undertaken promptly to resolve questions regarding several health outcomes, most urgently tonsil cancer, melanoma, and paternally transmitted transgenerational effects.

As a result of the IOM report, Secretary of Veterans Affairs Eric Shinseki announced plans in October 2009 to add Parkinson's disease, ischemic heart disease, and hairy cell leukemia to the list of conditions presumed to be associated with exposure to Agent Orange. These plans became final August 31, 2010. The change makes it substantially easier for thousands of veterans to claim that those ailments were the direct result of their service in Vietnam, thereby smoothing the way for them to receive monthly disability checks from the VA. *Veterans and Agent Orange: Update 2010,* the latest report in the series, will be released in fall 2011.

In another study, the IOM examined whether Navy personnel who served aboard deep-water vessels operating off Vietnam might face increased health risks from exposure to Agent Orange or other herbicides. Several recent studies have raised the possibility that these sailors might have been exposed to Agent Orange and its dioxin contaminant, perhaps via onboard distillation systems that converted seawater into potable water. If so, the sailors might face the same health risks as ground troops or sailors in the Brown Water navy who served on vessels that operated in Vietnam waters and along the coastline. Such concerns prompted the VA to commission an IOM study.

During its deliberations, the IOM study committee considered many data sources, including published peer-reviewed literature, models for assessing environmental concentrations of Agent Orange and dioxin, memoirs and other anecdotal information from veterans about their experiences during and after the war, government documents, and ships' deck logs. The committee also held several open meetings to gather testimony directly from Navy veterans about their experiences with Agent Orange while they served in the Vietnam War.

In its report, *Blue Water Navy Veterans and Agent Orange Exposure* (2011), the committee concludes that the available evidence is not sufficient to reasonably determine exposure of these sailors to Agent Orange or dioxin. Thus, it is currently impossible to judge whether Blue Water Navy Vietnam veterans might be at higher, lower, or similar risk of long-term adverse health effects associated with Agent Orange exposure than shore-based veterans or Brown Water Navy veterans.

Safeguarding mental health

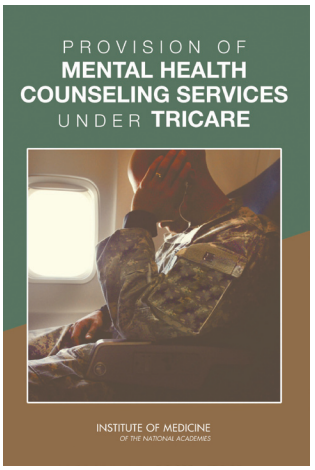
Combat troops in today's wars in Iraq and Afghanistan face exposure to a range of traumatic events that can cause immediate or delayed mental health conditions.

Combat troops in today's wars in Iraq and Afghanistan, as well as their counterparts in other wars, face exposure to a range of traumatic events that can cause immediate or delayed mental health conditions. The DoD provides an array of mental health services, along with other types of health care, through TRICARE, a single-payer program that combines the resources of military treatment facilities with networks of civilian healthcare professionals and medical facilities. A variety of men-

tal health professionals, with differing education, training, and expertise, provide care through the program.

This cadre includes mental health counselors, professionals who typically hold master's degrees and who are obligated by state licensure and other requirements to have demonstrated clinical experience in order to practice. Under current TRICARE rules, counselors are required to practice under a physician's supervision, and their patients must be referred to them by a physician in order for their services to be eligible for reimbursement.

In the National Defense Authorization Act for Fiscal Year 2008, Congress requested that the IOM convene a committee to examine the credentials, preparation, and training of licensed mental health counselors. In *Provision of Mental Health Counseling Services Under TRICARE* (2010), the committee reports that it found no compelling evidence that distinguishes mental health counselors from other classes of practitioners in their ability to serve in an independent capacity or to provide high-quality care. Accordingly, the committee recommends that TRICARE change its policy to permit mental health counselors to practice independently in circumstances where their education, licensure, and clinical experience have helped to prepare them to diagnose and, where appropriate, treat conditions in the beneficiary population. It offered a set of guidelines for determining when these circumstances were fulfilled. The committee recommends that counselors who do not meet the proposed requirements still be allowed to practice within the system to maintain the continuity of care, and that TRICARE consider supervising them in a manner that provides for successively greater levels of independent practice as experience and demonstrated competence increase.



The committee also recommends a more fundamental step, that TRICARE implement a comprehensive quality management system for all of its mental health professionals. This recommendation is built on other IOM reports that suggest that the best way for healthcare providers to deliver high-quality care is by setting appropriate standards of education and training for providers and then promoting evidence-based care standards and the monitoring of results.

After the report's release, the IOM, at the request of the DoD, held a 3-day workshop in October 2010 to explore the possible structure and implementation of the recommended quality management system. The workshop brought together participants from a variety of groups and with a range of interests, and the discussions are expected to inform efforts to improve the way that TRICARE serves the mental health needs of its beneficiaries.

Public Health: Protecting the Population

Strategies to promote the health and well-being of an entire population can preserve the health of every individual and family. In diverse ways, ranging from environmental protection to response to natural disasters to nutrition labeling, the field of public health affects the health of people from every walk of life and in every part of the country.

Because of its multiple facets, public health is the most diverse area that the Institute of Medicine (IOM) investigates. An array of government agencies and private organizations concerned with public health regularly depend on the IOM's findings and recommendations to guide their decisions and actions.

Protecting the nation's security

Among the broadest challenges the nation faces is protecting its security—and the safety of the population—from both natural disasters and threats linked to hostile human actions. One threat that has emerged in recent years is the possibility that enemies of the nation will attack using biological agents. In response, the Department of Homeland Security (DHS) introduced BioWatch, a federal monitoring system intended to speed detection of specific biological agents in the air. BioWatch air-sampling devices are deployed in more than 30 major cities. The samples typically are tested daily for signs of the agents, and if further laboratory testing confirms their presence, the system generates a signal.

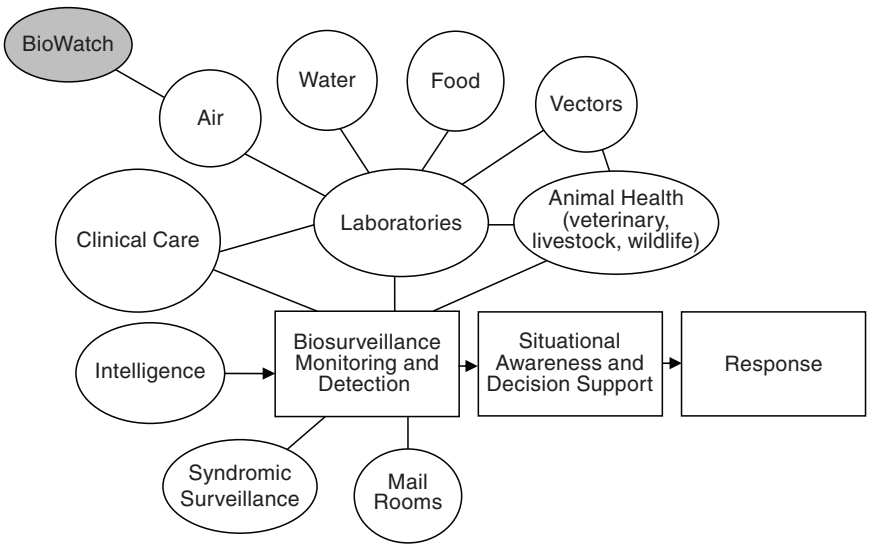
In 2008, Congress directed DHS to ask the IOM and National Research Council (NRC) to convene a committee to evaluate the merits

and costs of both the current BioWatch and the plans for a new generation program, and also to examine more traditional infectious disease surveillance conducted through hospitals and public health agencies.

The current BioWatch system requires better testing to establish its effectiveness and better collaboration with public health systems to improve its usefulness.

In its report, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats* (2010), the committee concludes that the current BioWatch system requires better testing to establish its effectiveness and better collaboration with public health systems to improve its usefulness. Also, the proposed enhancements to BioWatch are likely to be possible only if significant and long-standing scientific and technical challenges can be overcome. The report offers a detailed outline of needed actions.

Among actions to improve BioWatch, DHS should lead efforts to systematically test and evaluate current and planned technology to establish a more systematic, scientifically sound, and stakeholder-approved approach to technology acquisition, development, testing, and deployment than was possible when the program began. DHS and other federal agencies also should work to strengthen the relationship between BioWatch and the



A schematic illustration of the relation between the BioWatch program and other sources of information needed for infectious disease surveillance in the public health and healthcare systems.

SOURCE: *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats*, p. 174.

state and local jurisdictions in which it operates. Attention should be given as well to making BioWatch more responsive to user needs and better able to aid the timely response to a biological attack, beyond just successfully detecting suspicious materials in the air.

On the public health side, the Department of Health and Human Services (HHS), which has key responsibility in this area, should work with other agencies to develop and evaluate new opportunities in infectious disease surveillance and detection. Also, since early detection of a bioterrorism event may depend on astute clinicians' ability to recognize suspicious cases, HHS should promote the development, testing, and evaluation of technologies that strengthen the clinical diagnosis of significant infectious diseases and facilitate timely reporting of outbreaks to public health authorities. At a broader level, HHS and DHS should give high priority to building and sustaining sufficient public health workforce strength and competencies, along with associated laboratory and information management capacities, needed by all states and communities to detect a bioterrorism attack or other public health emergency.

With improvements in both BioWatch and public health infectious disease detection systems, a crucial step will be to link them into a national biosurveillance framework that will provide state and local public health authorities and the healthcare system with the information needed to determine the appropriate response to biological threats.

Preparing for health emergencies

In a major health emergency, whether caused by humans or occurring naturally, thousands or even hundreds of thousands of people across the country may suddenly require and seek medical care. In such emergencies, state and public health officials will turn to crisis standards of care policies that cover how to allocate scarce resources and how care is provided. But standards of care for crisis situations in different jurisdictions tend to be weak, fragmented, or nonexistent. At the request of the Office of the Assistant Secretary for Preparedness and Response in HHS, the IOM convened a committee of experts to consider this problem.

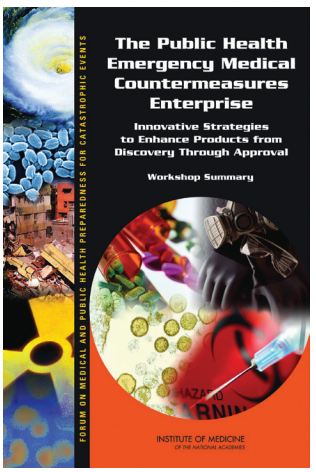
In a major health emergency, whether caused by humans or occurring naturally, thousands or even hundreds of thousands of people across the country may suddenly require and seek medical care.

In *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report* (2009), the committee first defines the conditions under which "crisis standards would be used." Crisis standards of care represent a substantial change in usual healthcare operations made necessary by a pervasive or catastrophic disaster. A state government must declare that crisis standards of care are in effect, and likely to be effect for a long period, thereby enabling specific legal and regulatory powers and protections for healthcare providers in allocating and using scarce medical resources and implementing alternate care facility operations.

Crisis standards of care represent a substantial change in usual healthcare operations made necessary by a pervasive or catastrophic disaster.

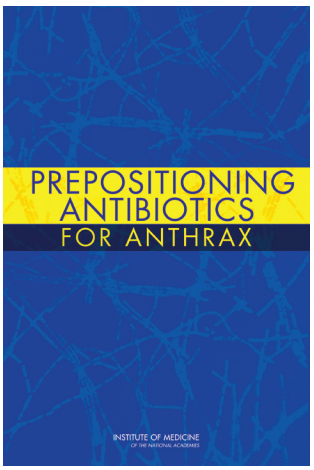
With this foundation, the committee proposes a national framework for developing crisis standards of care, identifies key elements that should be included in the standards, and provides detailed guidance that state and local public health officials can use to establish and implement crisis standards of care. The proposed roadmap encompasses the full spectrum of the health system, including emergency medical services and dispatch, public health, hospital-based care, home care, primary care, palliative care, mental health, and public health.

To meet public health needs in large-scale emergencies, the nation also requires adequate amounts of safe and effective chemical, biological, radiological, and nuclear medical countermeasures (MCM)—including vaccines, drugs, and diagnostics. But the public health enterprise has inadequate research, development, and production of needed countermeasures. Recognizing this, HHS directed its Office of the Assistant Secretary for Preparedness and Response to lead a review of its public health emergency medical countermeasures enterprise, and the office turned to the IOM to assist with this task. The IOM convened a workshop in 2009, bringing together representatives from government agencies and the private sector to examine the federal policies and activities that affect MCM discovery, development, and approval and to explore potential opportunities to enhance the medical countermeasures enterprise. The discussions, reported in *The Public Health*



Emergency Medical Countermeasures Enterprise: Innovative Strategies to Enhance Products from Discovery Through Approval: Workshop Summary (2010), highlighted a number of key points, among them how to achieve the greatest health impact in the face of diminishing resources, regulatory aspects of the enterprise, and product discovery and development.

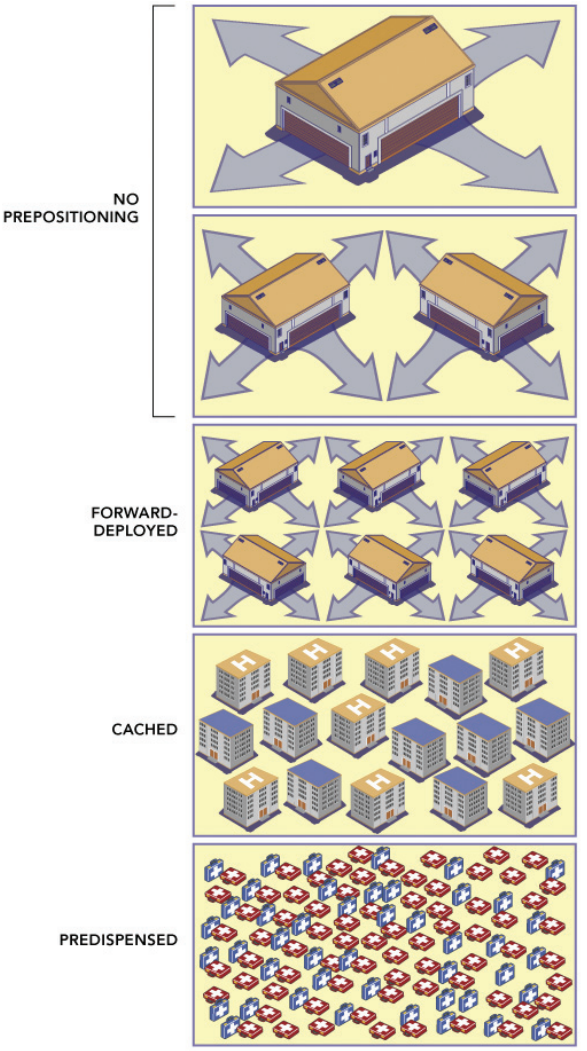
In addition to the research, development, and production of MCM, it is critical to be able to deliver them to those in need. As part of efforts under way nationwide to improve the nation's ability to rapidly distribute and dispense MCM, the Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS commissioned the IOM to examine the potential uses, benefits, and disadvantages of strategies for prepositioning antibiotics. Prepositioning involves storing antibiotics close to or in the possession of the people who would need rapid access to them should an attack occur. These prepositioning strategies—intended to help ensure timely access to antibiotics in the event of an attack—would complement existing plans that rely heavily on more centralized stockpiles.



In *Prepositioning Antibiotics for Anthrax* (2011), the IOM committee appointed to this task finds that the earliest sign of inhalational anthrax symptoms will likely occur four days or later after an attack. It may take a day or two—if not more—to detect that an attack has occurred and for public health officials to decide that antibiotics should be dispensed to people who may have been exposed. Since antibiotics are most effective at preventing anthrax if taken before symptoms begin to occur, to prevent illness, public health officials must act quickly to distribute and dispense antibiotics in the remaining time.

The Centers for Disease Control and Prevention (CDC) and state and local jurisdictions currently aim to dispense antibiotics to the entire population within 48 hours after the decision is made to dispense antibiotics. The committee finds—given the limited evidence available—that this goal appears to be appropriate as long as the attack is detected soon after it occurs.

The backbone of current distribution plans is the Strategic National Stockpile (SNS)—a national repository of medicine and medical supplies



Medical countermeasures storage locations needed to provide eqivalent coverage.

SOURCE: *Prepositioning Antibiotics for Anthrax*.

maintained by the CDC—which can be deployed rapidly around the country as a supplement to state and local antibiotic stockpiles. State and local public health authorities dispense antibiotics from all of these stockpiles to the public primarily via points of dispensing that are set up throughout the community. The committee defines three categories of prepositioning strategies that could complement more centralized stockpiling strategies:

- Forward-Deployed MCM: MCM stored *near* the locations from which they will be dispensed.
- Cached MCM: MCM stored *at* the locations from which they will be dispensed, such as workplaces and healthcare facilities.
- Predispensed MCM: MCM stored *by the intended users* or by heads of households or other nonmedical caregivers for use by those in their care.

Further, because communities differ widely in their needs and capabilities, the committee offers a framework to help state, local, and tribal public health officials determine which prepositioning strategies could benefit their communities, if any.

In another examination of major medical emergencies, the IOM explored ways to improve the nation's ability to respond to mass casualty incidents (MCIs) that occur in rural settings, where healthcare resources often are limited. One incident occurred in January 2008 in Utah when a chartered bus carrying 56 passengers crashed, killing 9 passengers and injuring 43 others, as well as the driver. The crash crystallized the need for an integrated infrastructure capable of responding to MCIs that occur in rural areas. In response, the Federal Interagency Committee on Emergency Medical Services, with support from the National Highway Traffic Safety Administration, asked the IOM's Forum on Medical and Public Health Preparedness for Catastrophic Events to hold a workshop to explore the issue.

Many rural areas are medically underserved with regard to both prehospital services, including emergency medical service units, and hospital services, which often face day-to-day shortages of equipment, supplies, or personnel.

The workshop brought together experts from a variety of fields and included an open panel discussion. *Preparedness and Response to a Rural Mass Casualty Incident: Workshop Summary* (2011) captured the discussions, which revealed a number of common themes. For example, MCIs are common in rural areas and likely will become more frequent in coming decades as more people use trains, buses, and airplanes to traverse these regions. Many rural areas, however, are medically underserved with regard to both prehospital services, including emergency medical service (EMS) units, and hospital services, which often face day-to-day shortages of equipment, supplies, or personnel.

Responding to MCIs in these areas also is hampered by limited 9-1-1 access and broadband services. In addition, the vast distances often involved can delay response to the scene and transport of patients to care facilities. Once on the scene, rural EMS providers may have radios for communication, but there are numerous "dead areas," particularly in mountainous regions and expansive land areas with limited communication towers. When multiple EMS teams respond, their radio systems are not necessarily compatible.

Common themes also emerged on possible improvements. Developing mechanisms to identify and share best practices in planning for and responding to MCIs will help federal, state, and local governments. Better communications and patient tracking also can be a tremendous asset to everyone involved in a disaster response. Leveraging existing federal programs can provide an opportunity to improve access to broadband technologies. For all responders, providing communications interoperability, including across state lines, can be critically helpful.

Developing mechanisms to identify and share best practices in planning for and responding to mass casualty incidents will help federal, state, and local governments.

Promoting regional cooperation among stakeholders, including governments, the private sector, and local military bases, may help in efforts to better assess the risks in various areas and their response capabilities. Although some concerns arose about possible loss of local control, there was considerable agreement that regionalization, especially when supported by increased federal funding support, can facilitate partnerships and sharing of resources that result in greater flexibility to plan and respond at the local level.

Revitalizing public health laws and policy

In national efforts to protect and improve the health of the population, public policies have a major role to play. Sound laws and regulations are particularly important in a time of scarce resources, because they can diminish or preclude the need for other, more costly and potentially less efficient interventions. As part of a 2.5-year study requested and supported by the Robert Wood Johnson Foundation (RWJF), the IOM convened a committee of experts to examine the legal and regulatory authority for public health activities, identify past efforts to develop model public health legislation, and describe the implications of the changing social and policy

context for public health laws and regulations. This analysis comprises the second phase of a three-part study, which also will examine measurement and funding issues that are critical to public health.

In its report, *For the Public's Health: Revitalizing Law and Policy to Meet New Challenges* (2011), the IOM finds that public health law warrants systematic review and revision, given the enormous transformations in the practice, context, science, and goals of public health agencies and changes in society as a whole, especially in the past 2 to 3 decades. Both federal and state policy makers should takes steps to ensure that public health laws adequately meet current health needs. State laws should provide health agencies with broad authority to deal with chronic diseases and conditions such as obesity, inju-

The 10 Essential Public Health Services

1. Monitor health status to identify and solve community health problems.
2. Diagnose and investigate health problems and health hazards in the community.
3. Inform, educate, and empower people about health issues.
4. Mobilize community partnerships and action to identify and solve health problems.
5. Develop policies and plans that support individual and community health efforts.
6. Enforce laws and regulations that protect health and ensure safety.
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. Assure a competent public and personal healthcare workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
10. Research for new insights and innovative solutions to health problems.

SOURCE: *For the Public's Health: Revitalizing Law and Policy to Meet New Challenges,* p. 4.

ries, and substance abuse, and to develop immunization registries and surveillance systems that could help detect bioterrorist attacks or disease outbreaks. Whenever possible, federal and state governments should set minimum public health standards and develop regulations to allow lower levels of government to enact further restrictions when necessary.

Among other actions, states should increase the capability and capacity of health departments. States also should require health agencies to provide the 10 essential public health services as the standard of practice and make certain that adequate funding and staffing are in place to provide these services, the report says. Previously developed by a consortium of public health groups, the list of services includes basic functions such as monitoring the health status of communities, diagnosing and investigating community health hazards, mobilizing community action, enforcing laws that protect health, and evaluating population-based services.

States also should require health agencies to provide the 10 essential public health services as the standard of practice and make certain that adequate funding and staffing are in place to provide these services.

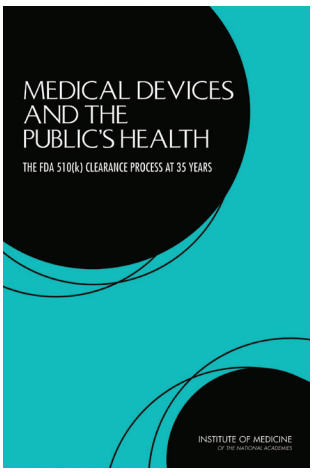
Policies and regulations that lie outside the health sector can have a significant impact on people's health as well. For example, government agricultural subsidies can influence the availability and affordability of certain foods, zoning policies can encourage the creation of green space, and education policies can support the intellectual and physical growth of young people. Governments at all levels should examine the potential positive and negative effects of such cross-sector laws and policies and identify improvements that can boost public health.

The committee's first report generated in the RWJF-sponsored study, *For the Public's Health: The Role of Measurement in Action and Accountability* (2010), is described in more detail earlier in this book, in the chapter on measurement. In its third report in the series, projected for fall 2011, the committee will propose recommendations for funding state and local public health systems within the healthcare landscape expected to evolve as the Affordable Care Act of 2010 is implemented.

One area in which public policy is integral to the health and well-being of the public is the clearance of medical devices. Medical devices play a critical role in the health care of Americans. They can range from simple tools, such as tongue depressors and bandages, to complex or life-saving

equipment, such as pacemakers, magnetic resonance imaging machines, and heart–lung machines. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires a "reasonable assurance of safety and effectiveness" before a device can be marketed, and the U.S. Food and Drug Administration (FDA) is responsible for enforcing this requirement. Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA. Devices that are subject to the 510(k) process include such devices as blood pressure cuffs as well as some types of contact lenses and pacemakers. The FDA receives several thousand 510(k) submissions each year.

Some policymakers and patients have expressed concern about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective. Other policy makers and patients, as well as the medical-device industry, have asserted that the process has become too burdensome and time-consuming and that it is delaying important new medical devices from entering the market.



The FDA turned to the IOM to review the 510(k) process and answer two questions:

- Does the current 510(k) process protect patients optimally and promote innovation in support of public health?
- If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process optimally?

In its report, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (2011), the IOM finds that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old 510(k) process, the IOM concludes that the FDA's finite resources would be better invested in developing an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle. This new framework should:

- be based on sound science;
- be clear, predictable, straightforward, and fair;

- be self-sustaining and self-improving;
- facilitate innovation that improves public health by making medical devices available in a timely manner and ensuring their safety and effectiveness throughout their lifecycle;
- use relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness; and
- be risk-based.

Current information is not adequate to design a new framework, and the FDA should begin to obtain the needed information. Once adequate information is available to design an appropriate medical-device regulatory framework, the report recommends, Congress should enact legislation to do so.

Aiding women, children, and families

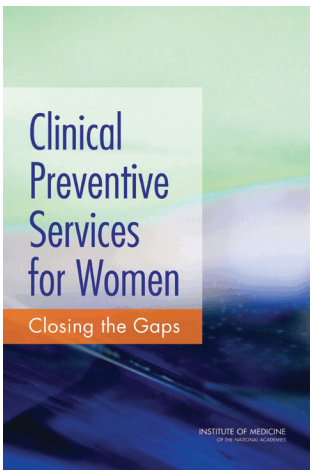
Several segments of the population face particular health and healthcare risks and needs. Among these are women, children, and families. Over the years, the IOM has focused on the health needs facing these populations and offered research and policy paths for protecting and improving their health and well-being.

In one study, the IOM examined what changes mandated in the Patient Protection and Affordable Care Act of 2010 will mean for women. The legislation requires that certain preventive services be covered at no cost to patients. HHS is charged with determining precisely what services will be covered.

Given this responsibility, HHS asked the IOM to appoint a committee of experts to comprehensively examine women's health needs and the potential impact of the new preventive health mandates. In *Clinical Preventive Services for Women: Closing the Gaps* (2011), the committee reviews the list of currently approved preventive services, examines additional screenings and services that have been shown to be effective in improving women's health, and recommends services that should be considered for inclusion in the guidelines. The proposed services have the potential to improve the health and well-being of women, and are supported by high-quality scientific evidence.

Women stand to benefit greatly by expanded access to preventive ser-

vices. With longer life expectancies than men, as well as reproductive and gender-specific conditions and a greater burden of chronic diseases and disability, women traditionally pay significant out-of-pocket expenses for preventive services. Also, women have disproportionately lower incomes, often putting the screenings, tests, and treatments that support women's health financially out of reach.



The preventive services recommended by the committee cover a range of needs and health conditions. They include a number of services and screenings that support and improve women's sexual, reproductive, and emotional health. For example, women should have access to contraceptive education, counseling, and services so they can better avoid unwanted pregnancies and space their pregnancies to promote optimal birth outcomes. Screening also should be available for gestational diabetes in early pregnancy for women at high risk of diabetes, and all pregnant and postpartum women should receive lactation counseling and equipment to ensure successful breastfeeding, which benefits the mother, the child, and society. Over time, HHS should regularly review and update the approved preventive services to stay current with science and changing health needs.

Protecting and improving the health of children presents another major challenge to the nation generally and the public health community in particular. Child health is important not only in its own right but to future health as well; the quality of health and health behaviors laid prenatally and in early childhood contribute significantly to lifelong health. Research from a variety of fields demonstrates that the social and economic conditions under which children live greatly influence their health in ways that continue through their life spans. Further, disparities in socioeconomic conditions among children contribute to the health disparities observed among some racial and ethnic adult populations across the nation. These factors raise the importance of using community-level activities and interventions to positively affect key determinants of health.

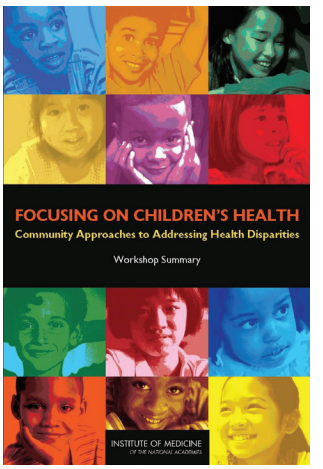
The quality of health and health behaviors laid prenatally and in early childhood contribute significantly to lifelong health.

Recommendations for Preventive Healthcare Services for Women That Should Be Considered by the U.S. Department of Health and Human Services

Recommendation 5.1: Screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.	**Recommendation 5.6:** Comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Recommendation 5.2: The addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.	**Recommendation 5.7:** Screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.
Recommendation 5.3: Annual counseling on sexually transmitted infections for sexually active women.	**Recommendation 5.8:** At least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.
Recommendation 5.4: Counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.	
Recommendation 5.5: The full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.	

SOURCE: *Clinical Preventive Services for Women: Closing the Gaps.*

At a workshop convened by the IOM's Roundtable on Health Disparities, experts from a variety of fields, including academia, community development, health care, business, and philanthropy, examined the relationship between socioeconomic conditions early in life and later health outcomes, discussed how community approaches can help, and explored a number of successful models that engage both community factors and health care to affect life course development.



Focusing on Children's Health: Community Approaches to Addressing Health Disparities: Workshop Summary (2009) describes a number of common threads that emerged. Participants generally agreed, for example, that it is time for action. Although more can be learned about the roles of social, racial, and economic determinants of health, the success of model programs shows that disparities in health are not insurmountable. Successful interventions involve the community as a full partner in the process. Identification of health challenges and priority concerns, and development of intervention strategies suited to a community's needs and culture, cannot be done without the input of the community members.

Families, of course, also greatly influence children's health. The American family is a complicated institution—and rapidly becoming more so. Demographic changes, immigration, economic upheavals, and changing societal mores are creating new and altered structures, processes, and relationships in families. As a result, the lives of infants, children, and adolescents differ in fundamental ways from those of past generations.

As families undergo rapid change, so is family science, which is spawning a large and growing body of findings from various disciplines. The science of family research cuts across demography, anthropology, psychology, sociology, economics, education, genetics, neuroscience, and developmental biology. Researchers, often working in multidisciplinary teams, are generating a better understanding of how to improve the health and well-being of children.

The American family is a complicated institution—and rapidly becoming more so.

In light of advances and ongoing changes in family science, the IOM

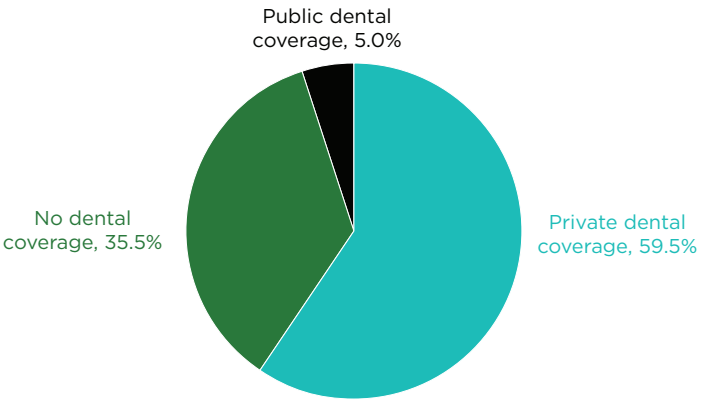
and the NRC convened a workshop where researchers, funders, and users of research results on families explored current and emerging issues, and their discussions and presentations were presented in *Toward an Integrated Science of Research on Families: Workshop Report* (2011). Among areas of common agreement, participants suggested that advances in family research will require approaches that can move beyond problem-oriented studies to identify positive family strengths and functioning that contribute to the well-being of family members, especially during times of social disruption and adversity. Also, more efforts need to be devoted to clarifying the structures, processes, and relationships within families that contribute to the resilience, well-being, school readiness, and healthy development of children, in order to inform the next generation of programs and policies to support children and families.

Oral health: A silent epidemic

For the nation as a whole, one major—and often overlooked—challenge to public health is the poor oral health of much of the population. Contributing to the problem, millions of people lack routine access to basic oral health care. This gap is particularly acute among racial and ethnic minorities, older adults, children, pregnant women, people with special needs, people of lower socioeconomic status, and people living in medically underserved rural and urban areas, among others. At the request of the Health Resources and Services Administration (HRSA) and the California HealthCare Foundation, the IOM and the NRC convened a committee of experts to examine these issues.

Millions of people lack routine access to basic oral health care.

In *Improving Access to Oral Health Care for Vulnerable and Underserved Populations* (2011), the committee describes current levels of access to oral health care for vulnerable and undeserved populations, identified problem areas, and proposed a sweeping new vision for oral health care. In this vision, everyone has access to quality oral health care across their life spans. Further, the oral healthcare system will be based on sound scientific evidence; eliminate barriers that contribute to oral health disparities; prioritize disease prevention and health promotion; provide oral health services in a variety of settings; make use of a diverse and expanded array of providers who are competent, compensated, and authorized to provide



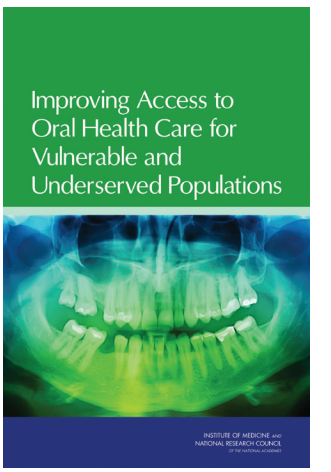
Percentage of adults 21–64 according to dental coverage status: U.S. civilian noninstitutionalized population, 2007.

SOURCE: Manski and Brown, 2010.

SOURCE: *Improving Access to Oral Health Care for Vulnerable and Underserved Populations*.

evidence-based care; include collaborative and interdisciplinary teams working across the healthcare system; and foster continuous improvement and innovation.

The system also must ensure that oral health care is incorporated as an integral component of comprehensive health care. With proper training, nondental healthcare professionals, such as nurses, pharmacists, physician assistants, and physicians, could screen for oral diseases and deliver preventive care services. While several nondental healthcare education programs have made great strides in improving the oral health education and training of their students, these efforts have not spread widely through the professions.



Other efforts to improve access to oral health care should include developing and promulgating optimal regulations and policies that determine who may provide care and how it may be provided. Also, the dental education system should be improved to ensure that current and future generations of dental professionals can deliver quality care to diverse populations, in various settings. Financial and administrative barriers to oral health care should be modified as well, including barriers within public programs such

as Medicaid and the Children's Health Insurance Program, which are the primary funders of healthcare coverage for underserved and vulnerable individuals.

Given the lingering—and pervasive—problems among many segments of the population, HRSA also asked the IOM to convene a committee of experts to assess the current oral healthcare system and recommend strategic improvements in light of the role that HHS can play.

In *Advancing Oral Health in America* (2011), the committee found that HHS's efforts to improve oral health and oral health care have been wide ranging, but the priority placed on these endeavors, including financial support, has been inconsistent. Areas needing expanded support and attention include research on best practices in oral health care and behavior change, oral health literacy, quality measurement, integration and standardization of data, oral healthcare financing, and workforce innovations.

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HHS already had recognized that its programs needed improving, and in 2010 the department launched an Oral Health Initiative—a cross-agency effort to improve oral health care nationwide. As part of its deliberations, the IOM committee examined the plans and recommended improvements in a number of areas. The recommendations collectively comprise what the committee called a New Oral Health Initiative (NOHI), to distinguish it from and build on the current initiative.

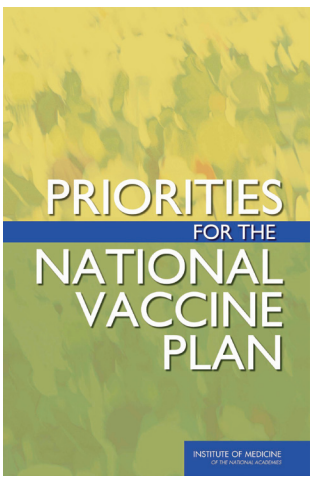
The proposed agenda rests on a set of core organizing principles based on the areas in greatest need of attention and the approaches that have the most potential for creating improvements. The principles include establishing high-level accountability within HHS, emphasizing disease prevention and oral health promotion, improving oral health literacy and cultural competence, reducing oral health disparities among underserved populations, exploring new models for payment and delivery of care, enhancing the role of nondental healthcare professionals, expanding oral health research and improving data collection, promoting collaboration among private and public stakeholders, and measuring progress toward short-term and long-term goals and objectives. A final principle, address-

ing evaluation, calls on HHS to use the goals of *Healthy People 2020*—an existing set of benchmarks for achieving better health for the country—rather than creating new goals that would be redundant.

Vaccinations aiding public health

A fundamental component in the nation's public health and preventive care system, vaccinations prevent the spread of infectious and potentially deadly diseases. In recognition of their importance, the federal government in 1994 established a National Vaccine Plan, and in 2008 the government proposed an updated national plan. The National Vaccine Program Office (NVPO), created by Congress and located in HHS, oversees the plan, and the NVPO asked the IOM to review the proposed new plan and identify priority areas for improvement.

In *Priorities for the National Vaccine Plan* (2009), the IOM committee that conducted the review concludes that the NVPO has not functioned as intended and that the proposed plan has numerous shortcomings. The NVPO falls short, in particular, in meeting a key responsibility, that of coordinating vaccine activities within government agencies and across the larger immunization system. The system engages many partners—including multiple government agencies and departments, vaccine researchers, manufacturers, public health officials, healthcare providers, and the public—in identifying vaccine needs, researching and developing new products, assessing safety, and getting people immunized. But the stakeholders do not regularly or effectively work together to advance collective goals. HHS can take an important step forward by clarifying the NVPO's role as the central coordinator for critical immunization activities and giving it the necessary funding to fulfill this mission.



Among recommended improvements for the proposed plan update, a greater proportion of vaccine research and development should be directed at specific goals, such as producing vaccines against diseases for which there are none or developing a single vaccine that would work against all influenza viruses. The majority of vaccine research and development currently stems from

the interests of individual researchers rather than a set of priority targets identified through a centralized planning process.

The plan should set a more aggressive agenda for research on vaccine safety, with sufficient funding, and should include establishing a permanent group to advise the government on safety issues. A new vaccine safety advisory group could guide efforts to address potential safety concerns and the development of a research agenda with clear priorities. The plan should include a strategy to eliminate financial barriers to immunization, such as lack of health plan coverage for all recommended vaccines and insufficient reimbursements that do not cover all of a clinic's costs of providing vaccines, as well as the development of a national communications strategy that engages the latest techniques and methods, such as social networking. In addition, it should promote the use of health information technology, including electronic health records, to monitor disease incidence, rapidly detect potential safety signals, and measure vaccine coverage.

One of the key aims of developing a National Vaccine Plan is to prevent adverse reactions to vaccines. Though generally very rare or minor, there are side effects, or "adverse effects," associated with some vaccines. Importantly, some adverse events following a vaccine may be due to coincidence and are not caused by the vaccine. To make this distinction, researchers use evidence to determine if adverse events following vaccination are causally linked to a specific vaccine; if so, these events are referred to as adverse effects. HRSA asked the IOM to review a list of adverse events associated with eight vaccines—varicella zoster, influenza (except 2009 H1N1), hepatitis B, HPV, MMR, hepatitis A, meningococcal, and those that contain tetanus—and evaluate the scientific evidence about the vaccine–adverse effect relationship. The IOM committee appointed to this task was not asked to assess the benefits or effectiveness of vaccines but only the risk of specific adverse events.

In its report, *Adverse Effects of Vaccines: Evidence and Causality*, the committee presents 158 causality conclusions, one for each pair of vaccine–adverse effect pairing. The committee finds that evidence convincingly supports a causal relationship between some vaccines and some adverse events. However, for the majority of cases—135 vaccine–adverse event pairs—the evidence was inadequate to accept or reject a causal relationship. Overall, the committee concludes that few health problems are caused by or clearly associated with vaccines.

Few health problems are caused by or clearly associated with vaccines.

Summary of Causality Conclusions

Vaccine	Adverse Event	Causality Conclusion
Varicella	Disseminated varicella infection (widespread chickenpox rash shortly after vaccination)	Convincingly Supports
Varicella	Disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis	Convincingly Supports[a]
Varicella	Vaccine strain viral reactivation (appearance of chickenpox rash months to years after vaccination)	Convincingly Supports
Varicella	Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (inflammation of the brain)	Convincingly Supports
MMR	Measles inclusion body encephalitis	Convincingly Supports[a,b]
MMR	Febrile seizures (a type of seizure that occurs in association with fever and is generally regarded as benign)	Convincingly Supports
MMR	Anaphylaxis (a very rare but sudden allergic reaction)	Convincingly Supports
Varicella	Anaphylaxis	Convincingly Supports
Influenza	Anaphylaxis	Convincingly Supports
Hepatitis B	Anaphylaxis	Convincingly Supports[c]
Tetanus Toxoid	Anaphylaxis	Convincingly Supports
Meningococcal	Anaphylaxis	Convincingly Supports
Injection-Related Event	Deltoid bursitis (frozen shoulder, characterized by shoulder pain and loss of motion)	Convincingly Supports
Injection-Related Event	Syncope (fainting)	Convincingly Supports
HPV	Anaphylaxis	Favors Acceptance
MMR	Transient arthralgia (temporary joint pain) in women	Favors Acceptance[d]
MMR	Transient arthralgia in children	Favors Acceptance
Influenza	Oculorespiratory syndrome (a mild and temporary syndrome characterized by conjunctivitis, facial swelling, and upper respiratory symptoms)	Favors Acceptance[e]
MMR	Autism	Favors Rejection
Influenza	Inactivated influenza vaccine and Bell's palsy (weakness or paralysis of the facial nerve)	Favors Rejection
Influenza	Inactivated influenza vaccine and asthma exacerbation or reactive airway disease episodes in children and adults	Favors Rejection
MMR	Type 1 diabetes	Favors Rejection
DT, TT, or aP containing	Type 1 diabetes	Favors Rejection

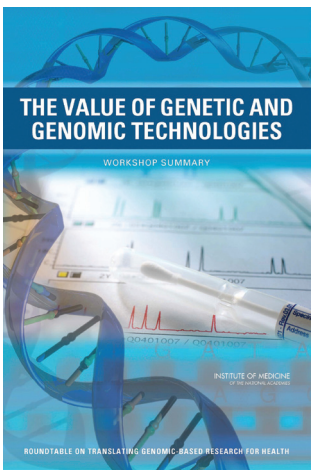
[a] The committee attributes causation to individuals with demonstrated immunodeficiencies.
[b] The committee attributes causation to the measles component of the vaccine.
[c] The committee attributes causation to yeast-sensitive individuals.
[d] The committee attributes causation to the rubella component of the vaccine.
[e] The committee attributes causation to two particular vaccines used in three particular years in Canada.
All other causality conclusions are the evidence is inadequate to accept or reject a causal relationship.

SOURCE: *Adverse Effects of Vaccines: Evidence and Causality.*

Emerging genetic technologies

Genetic and genomic technologies also offer broad promise for improving health care and health outcomes for many people. It is well established that alterations in genes—collectively comprising the genome—sometimes can cause any number of diseases or make an individual more prone to particular diseases. A variety of genetic and genomic laboratory tests are now available for a range of purposes, including for disease testing, guiding personalized drug therapy, and screening for markers of increased risk of disease.

These new technologies, however, have not been widely integrated into clinical practice, and questions remain as to how they are valued in the healthcare setting. The IOM, through its Roundtable on Translating Genomic-Based Research for Health, held a workshop that brought together experts from a variety of fields, as well as patients and other laypeople, to explore such questions. As one basis for discussion, participants examined three case examples of current tests that span a range of potential applications.



Their discussions, reported in *The Value of Genetic and Genomic Technologies: Workshop Summary* (2010), ranged across a number of topics related to the perceived value of genetic and genomic technologies, both present and future, in clinical practice. They considered, for example, how different stakeholders define the value of genetic and genomic technologies; how stakeholders prioritize various aspects of genetic tests when determining value; how people assess the relative value of genetic tests when making personal healthcare decisions; and how perceived values relate, or do not relate, to the monetary cost of the technologies. The aim was not to assess the value of any specific test, but rather, to identify broader issues of how individual stakeholders derive their personal or professional opinions of the value of using these technologies.

Examining the value of cancer care

One challenge facing all parts of the healthcare system centers on costs—and perhaps no area of health care feels more pressure than oncology, or

cancer care. Oncology spending is growing at more than 15 percent annually, faster than total health spending. In oncology, there are certain factors that discourage consideration of evidence concerning safety, effectiveness, and cost-effectiveness. Many cancer patients, for example, have a grim prognosis and are facing imminent death, so patients and healthcare professionals feel a sense of urgency to try every possible treatment in the hopes of at least potentially prolonging life, and patients and physicians in this situation may discount the potential harms of treatments. In addition, the healthcare delivery system's incentives favor aggressive treatment over many other important steps, such as providing patients with accurate information about prognosis, comfort care measures that can improve the quality of life for patients with cancer and even prolong life, or end-of-life planning, and these may take second place to costly interventions.

Oncology spending is growing at more than 15 percent annually, faster than total health spending.

The IOM's National Cancer Policy Forum held a workshop to explore subjects related to the value of cancer care from multiple perspectives, including those of patients and patient advocates, providers, insurers, healthcare researchers, federal agencies, and industry. Their discussions, reported in *Assessing and Improving Value in Cancer Care: Workshop Summary* (2009), ranged across a variety of issues, including the lack of a single description of *value* on which everyone currently agrees. Many descriptions of value, in general, have been proposed, with descriptions often focusing largely on a return for a cost in terms of goods or services. These descriptions parallel themes at issue for value in oncology—relative worth, fair return, costs, and measures of quality.

In one common theme, participants noted that value in cancer care encompasses numerous complex topics, including evidence for treatment effectiveness, clinical discussions of healthcare costs, and quality end-of-life care, among other factors. Considering these and other issues, participants sought to provide an objective concept of value that could be considered by anyone faced with difficult decisions regarding developing, evaluating, prescribing, and paying for cancer care. A better understanding of value also may help policy makers and other decision makers in developing and using new policy tools that can lead to improvements in the value of cancer services provided to patients.

Shaping Research Priorities

The late Paul G. Rogers, known as "Mr. Health" when he served in the U.S. Congress, and who later chaired Research!America, used to say, "Without research, there is no hope." To get the most out of every research dollar, researchers must focus on critically important health priorities and proceed in the most efficient manner. Prioritizing research is especially critical in tight economic times when even fewer dollars may be available to fund valuable scientific investigations.

The Institute of Medicine (IOM) has a long history of helping governments at all levels and private groups in many quarters shape their health research programs. IOM studies have offered research blueprints for tackling stubborn challenges that call for innovative approaches as well as new questions that demand immediate attention.

Assessing the oil spill in the Gulf of Mexico

When the Deepwater Horizon offshore drilling rig in the Gulf of Mexico exploded on April 20, 2010, it killed 11 workers and unleashed one of the largest oil spills in U.S. history. The resulting cleanup efforts came to mark the nation's largest and most demanding on-water response ever, with many thousands of commercial workers and volunteers often working under harsh conditions for days and weeks on end. The spewing oil raised both environmental and health concerns.

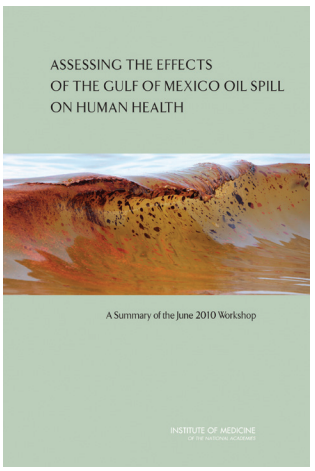
The potential effects on human health were both immediate and long term. Worries arose about exposure to the oil itself, to the chemical dispersants used to break up the oil, and to the fumes generated by fires set to burn off oil slicks, among other physical threats. Adverse social, economic,

and psychological effects also may threaten the mental health of diverse Gulf Coast populations, which includes uniquely at-risk groups, including such groups as those in the fishing community who may temporarily or permanently lose their livelihoods.

Adverse social, economic, and psychological effects also may threaten the mental health of diverse Gulf Coast populations, which includes uniquely at-risk groups.

Even before the ruptured oil well was capped in July, the federal government initiated a number of efforts to protect the health and well-being of individuals and communities in the affected regions. Officials recognized early on that monitoring and surveillance would be key in detecting the spill's physical and behavioral health effects on individuals and in identifying and assessing appropriate preventive and healthcare services. Accordingly, the Department of Health and Human Services (HHS) asked the IOM to convene an urgent workshop to examine the role and possible organization of monitoring and surveillance programs.

The IOM convened the first workshop in June 2010, bringing together more than 350 federal, state, and local government officials; scientists from varied disciplines; policy experts; healthcare providers; public health advocates; and community representatives and residents from affected areas. Presenters reviewed current knowledge and identified gaps regarding the human health effects of exposure to oil and chemical dispersants. Presenters considered information about the specific populations that might be at increased risks for adverse health effects. Presenters discussed communication strategies to convey information about health risks to at-risk populations, accounting for culture, health literacy, language, technology, and geographic barriers. They explored research methodologies and data collection needs. And as a final objective, they discussed the potential components of a framework for short- and long-term surveillance to monitor the spill's potential adverse health effects.



Many participants observed that assessing the effects on human health of oil spills and response activities is complex, involving such factors as the chemical composition and environmental degradation of the oil and

dispersants, as well as the unique characteristics of affected populations. Similarly, human health is multidimensional: physical, psychological, and socioeconomic factors influence the overall well-being of individuals and communities. A number of workshop participants predicted that the oil spill disaster will likely have an even greater effect on the psychological health of affected communities because of serious and prolonged disruptions to the social environment and local economies. They noted that community involvement is essential when designing surveillance systems and related activities. Local residents and communities have unique experience and expertise that can improve surveillance-related activities, especially if community engagement begins early. Speakers also described how coordination between and among all interested parties—public and private—can strengthen existing and developing surveillance and monitoring systems.

As called for in its commitment to HHS, the IOM also has conducted several other related studies, under the auspices of a specially appointed Committee to Review the Federal Response to the Health Effects Associated with the Gulf of Mexico Oil Spill. In one study, the committee examined the proposed plans for a new program to be run by the National Institute of Environmental Health Sciences, which is part of the National Institutes of Health (NIH). Called the Gulf Long-Term Follow-Up Study for oil spill clean-up workers and volunteers—or the GuLF Study—its aim is to fill some fundamental gaps in knowledge about the health effects of oil spills. Such new information may lead to improved understanding of the Gulf oil spill and help in identifying ways to prevent adverse health outcomes today and in any similar disasters in the future.

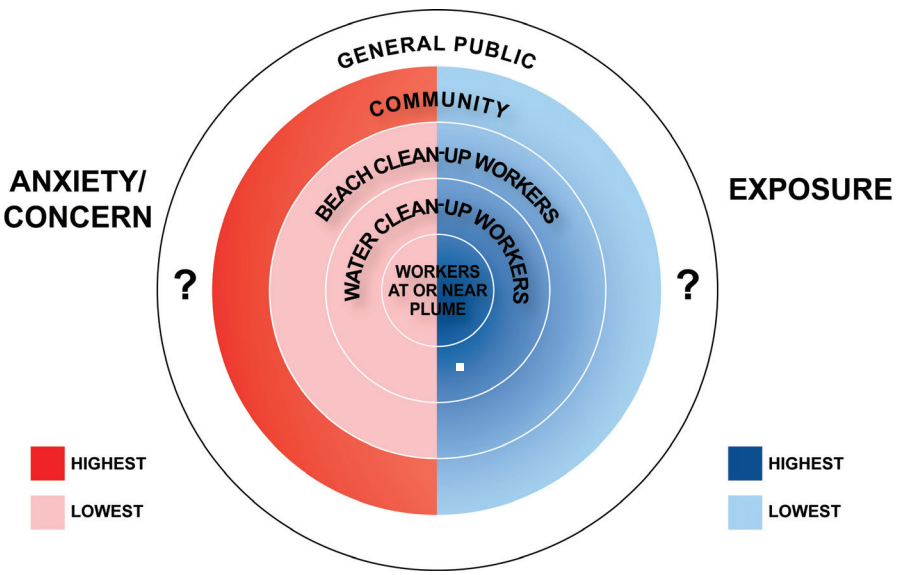
Local residents and communities have unique experience and expertise that can improve surveillance-related activities, especially if community engagement begins early.

The IOM convened a daylong workshop in September 2010 to gather scientific and community comments on the design and methodology to be used in the GuLF study. As explained by its principal investigator, the study will follow two groups. One group will include adults 18 years of age or older who worked or volunteered for 1 or more days in any cleanup task and therefore were exposed to potential health threats; the other group will include adults who completed safety training but did not perform cleanup work and therefore were not directly exposed, along with other unexposed community members, such as friends and relatives of the work-

ers, if needed. These groups will be examined or monitored in various ways for a range of physical and psychological health symptoms that affect or may yet affect these populations.

Discussions at the workshop are presented in *Review of the Proposal for the Gulf Long-Term Follow-Up Study: Highlights from the September 2010 Workshop: Workshop Report* (2010). Participants explored a number of suggested approaches for improving the study, while at the same time recognizing the time, legal, and resource limitations that may impede the improvements from being made. For example, study officials can make greater use of resources and expertise available both at the federal level and locally, and they can provide more specific, focused outcomes or concrete hypotheses that can be used to guide decisions about the data to be collected. In addition, the study would benefit by including more health outcomes, such as additional psychosocial measurements and gathering of data from pregnant women affected by the oil spill.

Other suggestions focused on recruitment and outreach. For example, study officials can give careful consideration of how to maximize the enrollment and retention of study participants, while also planning for



Levels of population exposures and anxiety or concern as defined by proximity to the oil leak.

SOURCE: *Assessing the Effects of the Gulf of Mexico Oil Spill on Human Health*, p. 32.

enrollment lower than predicted in the protocol. Fostering collaboration with the community will be important as well, and communications with all members of the community should be culturally sensitive and take health literacy into account.

The IOM's recommendations go beyond the GuLF study alone. Based on its information-gathering process, which included the daylong workshop in September 2010, the IOM committee tasked with this work identified a number of potentially useful areas of research. In *Research Priorities for Assessing Health Effects from the Gulf of Mexico Oil Spill: A Letter Report* (2010), the committee singled out five areas that are most promising:

- Research to generate evidence about the psychological and behavioral effects of the oil spill. Policymakers and health officials can use such evidence to guide efforts to improve the health status of individuals affected by the spill, as well as to contribute to the prevention and treatment of similar health outcomes in future disasters.
- Research to obtain information that is as comprehensive as possible about exposure to the oil, dispersants, and by-products of the controlled burns.
- Research on assessing seafood safety in both the near term and long term. The findings should be clearly communicated to the affected communities.
- Research to evaluate and compare communication and engagement methods to determine which would be most effective in disaster-preparedness efforts.
- Research to determine the framework needed to deploy a rapid research response for future oil spills and other potential disasters.

Evaluating federal worker safety programs

In an ongoing commitment, the federal government supports a variety of research efforts to protect and improve the health and safety of the nation's millions of workers. The National Institute for Occupational Safety and Health (NIOSH) is the lead agency for such research. NIOSH has research programs in eight main areas—hearing loss; mining; agriculture, forestry, and fishing; respiratory diseases; personal protective technology; traumatic injury; construction; and health hazard evaluation.

At the request of NIOSH, the IOM and the National Research Council (NRC) jointly have conducted a series of studies since 2004 to evaluate the relevance and impact of the research programs. As a first step, a lead IOM/NRC committee developed a common framework to be used in the evaluations. The framework is based on a model that is widely used in program evaluation and planning. Called the logic model, it organizes program efforts into four basic categories: inputs, activities, outputs, and outcomes. Eight separately appointed committees then used the framework over several years to assess the individual programs, and each committee issued a report on its findings.

At the conclusion of the studies, the IOM/NRC framework committee held a public workshop where discussions focused on the experiences gained in the evaluation process. From these discussions and other deliberations, the committee produced *Evaluating Occupational Health and Safety Research Programs: Framework and Next Steps* (2009). The report details the evaluation framework developed and used for the evaluations; summarizes lessons learned along the way; and presents a revised framework, along with a related set of recommendations, for NIOSH and other federal agencies to use in future research evaluation efforts.

Among its recommendations, the committee says that NIOSH should establish a system for periodic external evaluation complemented by internal self-assessments on a regular basis. NIOSH also should continue to build and improve research translation to effectively move research into practice. As part of the translation process, the institute should listen to people in the workplace and beyond to identify intervention needs that should be targeted with additional research.

In other steps, NIOSH should increase and improve surveillance of work-related injuries, illnesses, exposures, and working conditions so that information needed to assess program relevance and impact will be available for future evaluations. Enhanced surveillance should prove informative in balancing research priorities. Also, future evaluations should systematically consider intramural and extramural research activities, in terms of both evaluating the impact and relevance of each type of research and assessing the extent to which intramural and extramural research are integrated in strategic planning.

In addition to these wide-ranging evaluations of research on worker safety, the IOM has reviewed NIOSH's research plans for addressing health concerns raised by a single class of workplace hazards: asbestos fibers and similar mineral particles. Prior and ongoing exposures to asbestos con-

tinue to contribute to respiratory diseases—including mesothelioma, lung cancer, and asbestosis—despite the fact that asbestos is no longer mined in the United States.

To help in responding to ongoing questions and concerns in this field, NIOSH released a detailed research plan in January 2009, *Asbestos Fibers and Other Elongated Mineral Particles: State of the Science and Roadmap for Research*. At the request of NIOSH, the IOM and the NRC jointly appointed a committee to review the scientific and technical quality of the proposed plans. In *A Review of the NIOSH Roadmap for Research on Asbestos Fibers and Other Elongate Mineral Particles* (2009), the committee reports that overall, NIOSH put together a comprehensive plan that likely would yield important results. The committee also offers recommendations that could boost the expected knowledge and practical returns from the research programs.

Among recommended actions, NIOSH should clarify the vision and rationale for the roadmap. The vision statement should point toward research that will differentiate effects from exposure to a range of elongate mineral particles and help determine the influence of size, shape, and other physical and chemical characteristics of these particles on human health. The rationale should clearly articulate the influence that ongoing and future research can have on improving public and occupational health. In addition, NIOSH should revise the roadmap to emphasize the need for collaboration and integration of research among the mineralogical, toxicological, epidemiological, and exposure-assessment disciplines.

On a broader scale, NIOSH should continue to work with other federal agencies, as well as with private-sector groups and nonprofit organizations, in developing an overarching strategy for research. Such a strategy might include several elements in addition to the framework and goals set forth in the proposed roadmap, among them an interdisciplinary system for prioritizing research activities to ensure maximum efficiency in an environment of limited funding; an approximation of the resources needed to carry out high- and middle-priority efforts; and a plan for review, evaluation, and accountability for individuals and institutions receiving support for research.

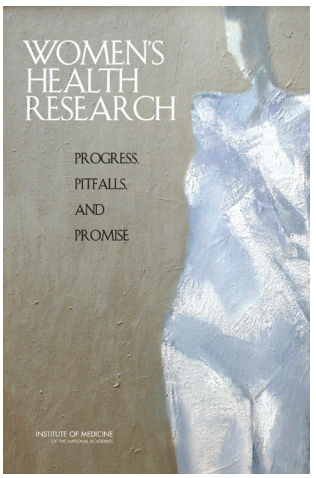
The National Institute for Occupational Safety and Health should continue to work with other federal agencies, as well as with private-sector groups and nonprofit organizations, in developing an overarching strategy for research.

Advancing women's health research

Among other populations that the federal government targets for research, women comprise more than 50 percent of the U.S. population but historically have gotten short shrift as subjects of biomedical research. Over the past 2 decades, however, there have been major changes in government support of women's health research—in policies, regulations, and the organization of research efforts. To assess the impact of these changes, Congress in 2008 directed HHS to ask the IOM to examine what has been learned from that research and how well it has been put into practice and communicated to both providers and women.

Women comprise more than 50 percent of the U.S. population but historically have gotten short shrift as subjects of biomedical research.

The IOM committee appointed for the task defined women's health broadly, encompassing health conditions that are specific to women, are more common or more serious in women, have distinct causes or manifestations in women, have different outcomes or treatments in women, or have high morbidity or mortality in women. In *Women's Health Research: Progress, Pitfalls, and Promise* (2010), the committee reports that research has contributed to significant progress in reducing the morbidity and mortality associated with some conditions, while other conditions have seen only moderate progress at best. Gaps remain, both in research and in the application of results to benefit women in general and across multiple population groups, and the committee proposes a number of recommendations for improvements.



The NIH should emphasize research on common determinants and risk factors that underlie multiple diseases that affect women. Research to date has paid inadequate attention to the social and environmental factors that, along with biologic risk factors, influence women's health. In addition, researchers should pay greater attention to assessing quality-of-life issues, such as mobility or presence of pain, and promoting wellness.

In addition to conducting women-only research as appropriate, the research community should strive to integrate women's health considerations into all health research, such that sex- and gender-based differences between men and women are routinely and consistently assessed. Toward this end, the government and other funding agencies should ensure adequate participation of women and reporting of sex-stratified analyses in health research. More attention also needs to be paid to finding the most effective ways of moving research findings into clinical practice and public health policies.

Improved public communications are needed as well. Many people often are confused by conflicting findings and opposing recommendations emerging from health research, including women's health research. The committee calls on HHS to appoint a task force to develop strategies to effectively communicate research-based health messages to women. The federal government can support improved communications by requiring all federally funded studies to include a plan for disseminating findings to the public, providers, and policymakers.

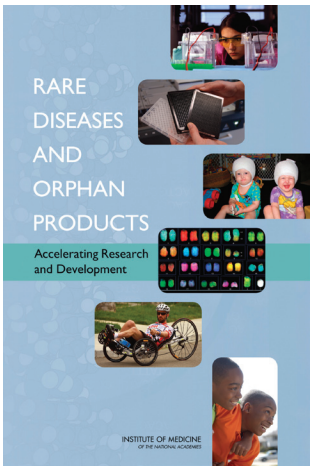
Conditions Discussed by Committee, Categorized by Extent of Progress

Conditions on Which Research Has Contributed to Major Progress
Breast Cancer
Cardiovascular Disease
Cervical Cancer
Conditions on Which Research Has Contributed to Some Progress
Depression
HIV/AIDS
Osteoporosis
Conditions on Which There Has Been Little Progress
Unintended Pregnancy
Maternal Morbidity and Mortality
Autoimmune Diseases
Alcohol and Drug Addiction
Lung Cancer
Gynecological Cancers Other than Cervical Cancer
Non-Malignant Gynecological Disorders
Alzheimer's Disease

SOURCE: *Women's Health Research: Progress, Pitfalls, and Promise,* p. 4.

Boosting research on rare diseases

While many diseases affect large numbers of people and attract research attention, some diseases strike relatively few individuals and often go neglected. As a result, researchers lack even a basic understanding of many rare—or "orphan"—diseases. Also, effective therapeutics are available for only a small fraction them, and even when available, some are extraordinarily expensive. In light of these realities, the NIH, with support from the Food and Drug Administration (FDA), asked the IOM to appoint a committee of experts to examine the opportunities and obstacles in developing drugs and medical devices for treating rare diseases.



In *Rare Diseases and Orphan Products: Accelerating Research and Development* (2010), the committee calls for implementing an integrated national strategy that would include seven key elements. In simplified form, these elements are:

1. active involvement and collaboration by a range of public and private interests;
2. timely application of advances in science and technology;
3. creative strategies for sharing research resources and infrastructure;
4. appropriate use and further development of trial design and analytic methods for conducting research on small populations;
5. reasonable rewards and incentives for private-sector innovation, coupled with prudent use of public resources for product development when necessary to respond to important unmet needs;
6. adequate support for public agencies that fund research on rare diseases and regulate drugs and medical devices; and
7. mechanisms for weighing priorities for rare diseases research and product development, establishing collaborative as well as organization-specific goals, and assessing progress toward these goals.

Components of these elements already exist, some more robust than others, and the committee recommends a number of specific steps to foster

their further development and implementation. Steps for the NIH include developing a comprehensive action plan for rare diseases research that covers all institutes and centers and working with the FDA to ensure that NIH-funded drug studies are designed to meet FDA standards for product approval. Other steps include identifying unmet needs for medical devices to treat rare conditions and improving understanding of how public and private insurance programs have an effect on access to drugs and medical devices for such conditions.

To help build on the recommendations and existing activities, HHS should establish a national task force on accelerating rare diseases research and product development. To operate for perhaps 4 to 8 years, the task force would bring together leaders from government, industry, academic and other research institutions, and advocacy groups. Its aim would be to promote, coordinate, monitor, and assess the implementation of public and private initiatives on rare diseases and orphan products and to support additional opportunities for public-private collaboration.

Ethical issues in studying drug safety

Although federal regulations call for drugs under development to be tested for safety and kept off the market if problems are detected, adverse health effects often are discovered only after drugs have been in widespread use. Historically, most of the FDA's authority and activity related to drugs has centered on approval prior to entering the market. In 2007, Congress expanded the FDA's authorities and responsibilities over drugs during the postmarketing period. The new authorities, many of which were recommended by the IOM in *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007), provided the FDA with a range of additional regulatory tools.

With its expanded powers, the FDA recognized that it faced a number of new challenges and questions, both ethical and scientific, regarding the study of drugs after approval. It turned to the IOM for help, and the IOM appointed a committee of experts to evaluate a number of questions submitted by the FDA on how best to conduct studies of the safety of approved drugs.

As a first task, the committee was directed to undertake only one of the FDA's questions—What are the ethical and informed consent questions that must be considered when designing randomized clinical trials to eval-

uate potential safety risks?—and to submit a report by July 2010, in time for a joint meeting of two scientific advisory committees to the FDA examining the testing and safety of a particular drug.

In that preliminary report, *Ethical Issues in Studying the Safety of Approved Drugs: A Letter Report* (2010), the IOM committee describes a conceptual framework that the FDA should use for evaluating ethical and informed consent issues related to its postmarketing evaluations. The framework consists of four classes of considerations: the public health context of drug safety, regulatory science and public accountability, design considerations, and additional ethical obligations to research participants. Within each category, the committee explores a number of key issues that the FDA might be expected to face in determining whether and how to conduct postmarketing studies. The committee will issue a subsequent report on the remaining questions in late 2011.

The Persistence of Chronic Diseases

Chronic diseases are among the most common of all health problems in the United States. They cause about 70 percent of deaths and account for an estimated 75 percent of healthcare costs each year. Although they are more common among older adults, chronic diseases affect people of all ages.

Even as they are so damaging to health, chronic diseases often are among the most preventable health problems. But in many cases, prevention has proved difficult. Effective steps often require fundamental changes in people's lifestyles and behaviors. Structural factors across society, including within government and the health system, also create barriers. Facing such obstacles, the federal government and various private organizations frequently call on the Institute of Medicine (IOM) for advice on how to better understand and manage a range of chronic diseases.

Combating cardiovascular disorders

Hypertension is one of the nation's most common chronic conditions—and one of the most vexing. Nearly one-third of adults have hypertension, more commonly known as high blood pressure. Chronic hypertension is a key risk factor for stroke, heart attack, and heart failure, among other health problems, and it accounts for about one in six adult deaths annually. Yet hypertension is relatively easy to prevent, simple to diagnose, and inexpensive to treat.

To help guide nationwide efforts to reduce the impact of hypertension, the Centers for Disease Control and Prevention (CDC), through its

Division for Heart Disease and Stroke Prevention (DHDSP), developed a strategic plan that identified a broad array of action areas and goals. At the CDC's request, the IOM convened an expert committee to assess the plan and identify a smaller set of high-priority areas on which the DHDSP and other public and private groups should focus in the near term.

Nearly one-third of adults have hypertension, more commonly known as high blood pressure. Chronic hypertension is a key risk factor for stroke, heart attack, and heart failure, among other health problems, and it accounts for about one in six adult deaths annually.

In *A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension* (2010), the committee reports that in today's era of tightening budgets, the DHDSP should shift the balance of its hypertension efforts from healthcare interventions directed at individuals to population-based strategies and systems approaches that can reach large numbers of people and improve the well-being of entire communities—at the lowest possible costs. This shift should extend as well to state and local health departments and to various other organizations and providers across the health enterprise.

Under this operational umbrella, the DHDSP should collaborate with state and local public health jurisdictions on a variety of behavioral and lifestyle interventions that target risk factors known to contribute substantially to hypertension. These risk factors include eating an unhealthful diet, consuming too much salt and too little potassium, being overweight or obese, and engaging in too little physical activity. Public health jurisdictions should integrate hypertension prevention and control interventions into their policies and programs in ways that will support healthy eating, active living, and obesity prevention across their respective communities. Jurisdictions also should align their efforts with populations most likely to be affected by hypertension, such as older populations, which often are not the target of these programs.

It also will be necessary to improve how physicians serve their patients. Today, many physicians do not provide treatment for hypertension that is consistent with generally accepted practice guidelines. The DHDSP should conduct research to understand the reasons behind their poor performance, and then lead in developing strategies to increase the likelihood that primary providers will screen for and treat hypertension appropriately.

Prevalence of Hypertension (averaged measures), Overweight, Obesity, and Average Intake of Dietary Sodium per 1,000 Adults, 1960-2006

	1960-1962	1971-1974	1976-1980	1988-1994	1999-2000	1999-2002	2001-2004	2003-2006
Hypertension	38.1*	39.8*	40.4*	25.5	32.8	30.0	30.9	31.3
Overweight[a]	44.8*	44.7*	47.4*	56.0	64.5	65.1	66.0	66.7
Obesity	13.3*	14.3*	15.1*	22.9	30.5	30.4	31.4	33.4
Sodium (mg/day)[b]		2,200*	2,900*	3,600*	3,500*			

[a] Includes obesity.

[b] Sodium intake estimates are based on the average of salt intake from 24-hour recalls for men and women from NHANES data. Data from NHANES 1971-1974 include naturally occurring sodium in foods and that added by processors. Data for NHANES 1999-2000 includes naturally occurring sodium in foods and that added by processors and discretionary salt usage.

* For ages 20-74, other data for ages 20 and over.

SOURCES: Briefel and Johnson, 2004; NCHS, 2003, 2009, 2010.

SOURCE: *A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension,* p. 69.

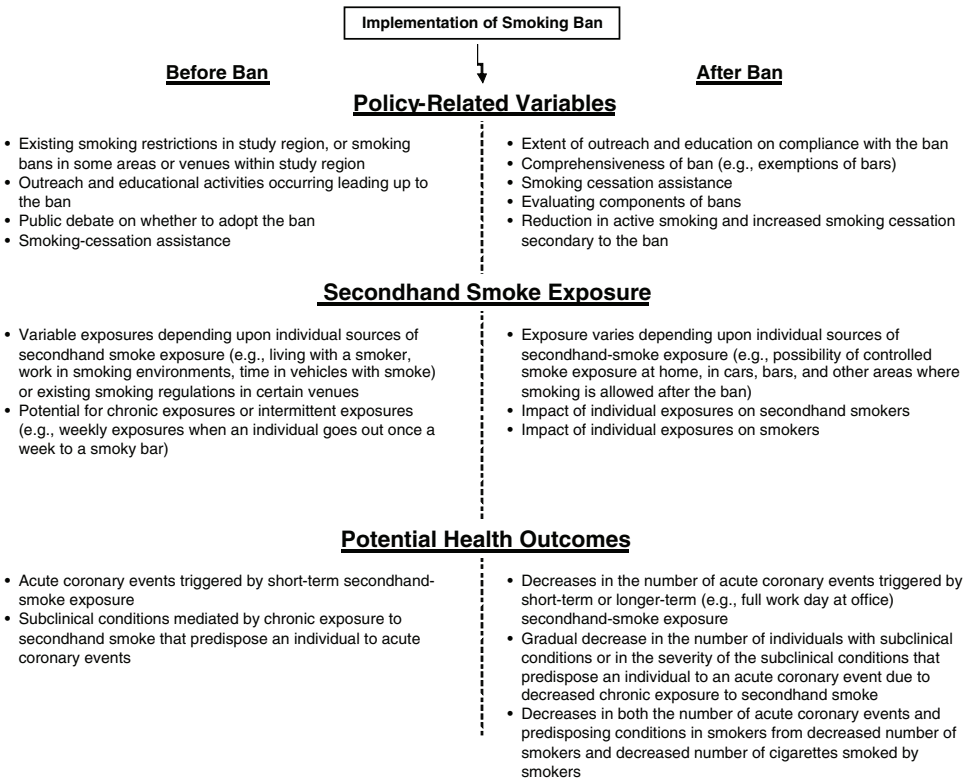
To effectively carry out current and recommended programs, the DHDSP will need additional federal support. The hypertension program is underfunded, relative to the preventable burden of hypertension. In today's climate of healthcare reform and the increasing attention being directed to prevention, there is no better time to rise to the challenge. The committee therefore calls on Congress to provide the DHDSP with adequate resources for implementing a broad suite of population-based policy and system approaches at the federal, state, and local levels that have the greatest promise to prevent, treat, and control hypertension.

One important—and widespread—risk factor for cardiovascular disorders is smoking. There also is evidence that exposure to secondhand smoke—that is, smoke from burning cigarettes, cigars, and pipe tobacco, as well as smoke exhaled by smokers—can be damaging to nonsmokers. At the CDC's request, the IOM convened a committee to assess the evidence on the relationship between exposure to secondhand smoke and effects on the heart, as well as the evidence on how smoking bans affect rates of heart attacks.

In *Secondhand Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence* (2009), the committee reports that the bulk of studies

supports the current consensus that exposure to secondhand smoke increases the risk of coronary heart disease among both men and women. The evidence is not sufficient, however, for determining the precise magnitude of the increased risk—that is, the number of cases of disease that are attributable to secondhand-smoke exposure.

The committee also finds that numerous studies support an association between smoking bans and a decrease in the incidence of heart attacks, with observed decreases ranging from 6 percent to 47 percent. However, none of the studies included information on how long or how often individuals were exposed to secondhand smoke before or after implementa-

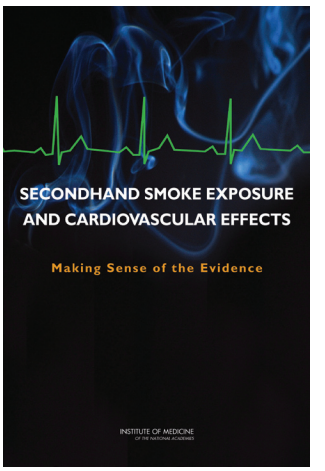


NOTE: Factors that can affect the impact of smoking bans on cardiovascular outcomes.

A number of policy-related variables can differ among locations and affect the impact of a smoking ban. The concentration of secondhand smoke can also differ among locations both before and after a ban is implemented. Outcome-related factors can differ and affect study results.

SOURCE: *Secondhand Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence,* p. 23.

tion of smoking bans. For example, it is not known whether individuals were exposed to high concentrations sporadically for short periods, to low concentrations more consistently, or both. Without this information, the committee could not determine whether heart attacks were triggered by acute exposures, whether they were the eventual result of chronic exposures that caused chronic damage, or both.



In light of current knowledge gaps, the committee calls for additional research and outlines priority needs. Studies on smoking bans, for example, should examine the time between an intervention and observed health effects, measure the magnitude of the effects, and take various social factors into account. They also should include direct observations on individuals—including their history of cardiac disease, exposure to other environmental chemicals, and other risk factors for cardiac events—to assess the impact of those factors on study results. Further, assessment of smoking status is needed to distinguish between the effects of secondhand smoke in nonsmokers and the effects of a ban that reduces cigarette consumption or supports smoking cessation in smokers.

The bulk of studies supports the current consensus that exposure to secondhand smoke increases the risk of coronary heart disease among both men and women.

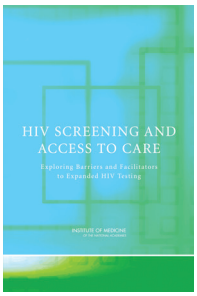
In addition, the committee finds only sparse data on the prevalence and incidence of cardiovascular disease and heart attacks at the national level in general, compared with other health endpoints, such as cancer, for which there are central data registries and surveillance of all events. A large prospective cohort study could be very helpful in more accurately estimating the magnitude of the risk of cardiovascular disease and heart attacks posed by exposure to secondhand smoke.

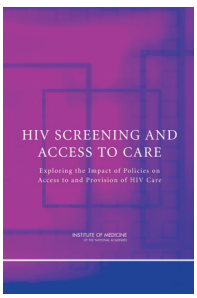
Shaping a national HIV/AIDS plan

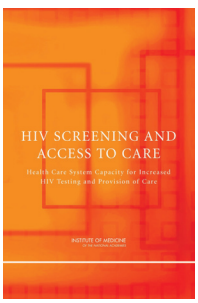
HIV/AIDS only recently joined the list of chronic diseases on the national stage. In the early decades of the epidemic, HIV infection was considered to be ultimately fatal. But new, advanced methods of care, including anti-

retroviral therapies, have transformed HIV/AIDS into a chronic—and manageable—condition that people can live with for many years. Ensuring that people know their HIV status and receive adequate care—starting early and continuing for life—can improve clinical outcomes, extend lives significantly, and reduce the transmission of HIV.

In July 2010, the White House Office of National AIDS Policy, which coordinates government efforts to stem the HIV epidemic, released its National HIV/AIDS Strategy. To help guide implementation, the office asked the IOM to appoint a committee to evaluate the extent to which federal, state, and private health insurance policies and practices pose barriers to expanding HIV testing and treatment; examine the current capacity of the healthcare system to administer more HIV tests and accommodate new HIV diagnoses; and identify options for overcoming existing barriers and ensuring adequate system care capacity.







Over the course of its study, the committee issued three reports:

1. *HIV Screening and Access to Care: Exploring Barriers and Facilitators to Expanded HIV Testing* (2010)
2. *HIV Screening and Access to Care: Exploring the Impact of Policies on Access to and Provision of HIV Care* (2011)
3. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care* (2011)

Among barriers to expanded HIV testing, the committee identified conflicting federal agency guidelines on who should be tested, low federal and private insurance reimbursement rates that can discourage providers from conducting tests, restrictive laws in some states on how HIV tests should be conducted and who can do the testing, and a widespread lack of programs to combat the stigma and discrimination that often is associated with HIV and that can discourage people from being tested.

Expanding programs to notify partners of HIV-positive individuals, linking HIV testing with other healthcare and social services, and mounting media and social network outreach efforts all could help to promote testing. Expanding the use of "rapid" HIV tests

may help as well. Unlike conventional tests that take days to yield results, rapid tests provide results immediately and thus may reduce the number of people who fail to receive their test results. Streamlining the administration of HIV tests also may make them easier to administer in busy clinics, and it may be possible to simplify and expand HIV testing in prisons and other correctional facilities, where HIV often is prevalent.

Among barriers to care, many patients lack access to a provider with expertise in treating HIV, or they cannot afford treatment, even with insurance. Problems also arise from the lack of integration of state and federal government programs meeting the complex needs of HIV-positive individuals and the intertwined medical and social problems often associated with HIV. Such fragmentation, coupled with multiple funding sources with different eligibility requirements, causes many individuals to shift in and out of eligibility for HIV care.

New, advanced methods of care, including antiretroviral therapies, have transformed HIV/AIDS into a chronic—and manageable—condition that people can live with for many years.

To overcome such barriers, strategies may include making eligibility criteria for public and private coverage consistent with the guidelines issued by HHS for initiating antiretroviral therapies, providing cost-sharing assistance for lower-income populations, imposing monthly and annual caps on a patient's overall out-of-pocket expenses, ending the practice of denying coverage for failure to pay for services, and eliminating annual or lifetime coverage limits for treatment.

Developing and promoting coordinated care and integrated delivery systems also can help. Healthcare providers and public health officials will need to be increasingly flexible and willing to employ a variety of approaches to meet the needs of HIV-positive individuals, especially given the financial and capacity strains facing the healthcare system. Providers likely will need to collaborate on care of patients and often divide tasks among providers to the extent permitted by state regulations. Approaches to expanding HIV testing and treatment should take account of the setting in which they are being implemented, so as to fit as seamlessly as possible into the workflow.

As an underlying problem, the United States lacks enough providers skilled in HIV/AIDS care, as well as primary care providers more generally, to handle the number of people who need to be tested and treated. To meet

workforce demands, all health professionals, both during their training and through continuing education programs, should be exposed to outpatient HIV care. It also may be desirable to provide better financial and other incentives to encourage more health professionals to enter and remain in HIV care. There is a need as well to reach beyond the primary care physicians and infectious disease specialists who now provide most HIV care. Registered nurses, physician assistants, dentists, pharmacists, and social workers are among those who can help in providing quality HIV care in a variety of settings.

Viral hepatitis: A silent epidemic

Affecting even more people than HIV/AIDS, chronic viral hepatitis—hepatitis B and hepatitis C—causes significant health problems in the United States and is responsible for about 15,000 deaths each year. Yet because viral hepatitis typically causes few if any obvious symptoms, many people do not know they are infected until they develop liver cancer or liver disease many years later. Few among the populations most at risk—including immigrants from Asia and the Pacific islands, where hepatitis B is endemic, and their U.S.-born children, as well as injection-drug users—seek testing or information on how to protect themselves from infection.

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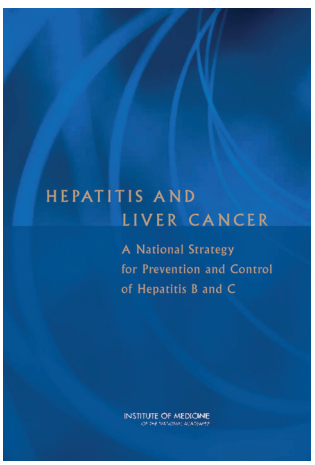

With support from several government and private sponsors, including the CDC, the IOM convened a committee to assess current prevention and control activities for hepatitis B and C and identify ways to reduce new cases of infections and lower illnesses and deaths from them. In *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (2010) the committee identified several priority action areas.

Steps are needed, for example, to develop and provide more comprehensive services for viral hepatitis. Services should have five core components: outreach and awareness, prevention of new

infections, identification of infected people, social and peer support, and medical management of chronically infected people. Stakeholders also should work together to better coordinate their services, which currently are sparse and fragmented among providers and organizations, leading to missed opportunities to prevent the spread of infection and lessen the impact of chronic infections.

New public awareness initiatives are needed along the lines of those that succeeded in increasing recognition, prevention, and treatment of HIV/AIDS. Toward this end, the CDC can work with stakeholders to develop and evaluate innovative hepatitis B and C educational programs for healthcare and social service providers, the general public, and specific populations at higher risk of contracting viral hepatitis.

Stepped-up vaccination efforts are needed for hepatitis B. (There is no vaccine for hepatitis C as yet.) All full-term newborns whose mothers test positive for hepatitis B should receive the vaccine before leaving the delivery room, rather than up to 12 hours after birth as is currently recommended.

Burden of Selected Serious Chronic Viral Infections in the United States

Virus	Prevalence[a,b]	Percentage of Population Unaware of Infection Status[c,d,e]	Deaths in 2006 Related to Infection[a,b]	Vaccine-Preventable	Transmission Routes	Percentage of CDC NCHHSTP FY 2008 Budget[f]
HBV	0.8–1.4 million	About 65%	3,000	Yes	Birth, blood, sex	2% combined
HCV	2.7–3.9 million	About 75%	12,000	No	Birth, blood, sex	
HIV/AIDS	1.1 million	About 21%	14,016	No	Birth, blood, sex	69% (domestic activities)

Abbreviations: CDC NCHHSTP, Centers for Disease Control and Prevention National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Prevention; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV/AIDS, human immunodeficiency virus/acquired immunodeficiency syndrome.

SOURCES: [a]CDC, 2009b; [b]CDC, 2009d; [c]Lin et al., 2007; [d]Hagan et al., 2006; [e]CDC, 2008b; [f]Ward, 2008a.

SOURCE: *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C,* p. 26.

In addition, all states should make hepatitis B vaccination a requirement for school attendance, and health plans should fully cover the costs.

Improved surveillance of viral hepatitis is needed because current data do not provide accurate estimates of the disease burden and are insufficient for program planning and evaluation. Among recommended steps, the CDC should develop agreements with state and territorial health departments to support core surveillance for hepatitis B and C, along with targeted surveillance to monitor incidence and prevalence of the diseases in at-risk populations not fully captured by core surveillance.

The IOM's report set off a cascade of responses. The CDC launched a new website—www.KnowHepatitis.org—to provide frontline community healthcare providers with current and accurate information, with a featured session focused on the report's recommendations. In addition, HHS organized the Viral Hepatitis Interagency Working Group, which released a blueprint of priorities, called *Combating the Silent Epidemic of Viral Hepatitis*, for HHS agencies and other government and private partners. Announced in May 2011, the plan is organized by topics that map directly to the IOM recommendations. Finally, in his budget request to Congress for fiscal year 2012, President Obama recommended a $5.2 million increase for the prevention of viral hepatitis in the United States.

Evaluating biomarkers for use in foods

Statements about the healthfulness of foods are commonplace in the media and the marketplace; statements tout various health benefits, including reducing the risk of a variety of chronic diseases. It is well established that diet can raise or lower the risk of developing chronic diseases such as diabetes and heart disease, and food manufacturers want consumers to know when their foods may lower those risks.

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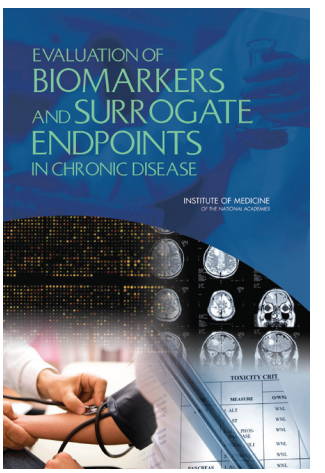
The FDA regulates statements about health and nutrition on food labels. As part of this process, the FDA often must assess manufacturers' data on how the food or ingredient affects so-called biomarkers, which are characteristics that indicate biological processes. For example, low-density lipoprotein (LDL) cholesterol level is a widely used biomarker in cardiovascular disease. Some bio-

markers, called surrogate endpoints, are used as substitutes for actual clinical outcomes, such as incidence of disease or death. Surrogate endpoints are intended to predict benefit or harm based on scientific evidence, and they are used in practice when it is difficult to collect data based on clinical endpoints.

As the gatekeeper for entry of foods, drugs, and many other products into the marketplace, the FDA examines data and makes decisions about whether biomarkers or surrogate endpoints can be used for regulatory reviews. In recent years, the FDA's Center for Food Safety and Applied Nutrition found that it was reviewing significant numbers of applications for food health claims based on stated effects on biomarkers, and the FDA asked the IOM to convene a committee to study the evaluation process for biomarkers, focusing on biomarkers and surrogate endpoints in chronic disease.



In *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease* (2010), the committee recommends that the FDA adopt a consistent framework for biomarker evaluation in order to achieve a rigorous and transparent process for all stakeholders. The proposed framework consists of three steps, involving validating the performance of the biomarker test (analytical validation), assessing the strength of the evidence supporting the link between the biomarker test and the disease (qualification), and considering the purposes for which they will be used (utilization). These steps often will be interrelated, and conclusions in one step may require revisions or additional work in other steps.

For biomarkers with regulatory impact, the IOM committee suggests the FDA go further, convening expert panels to evaluate biomarkers and biomarker tests. Initial evaluation of analytical validation and qualification should be conducted separately from a particular context of use. In addition, the expert panels should reevaluate analytical validation, qualification, and utilization on a continual and a case-by-case basis.

In its regulatory operations, the FDA should use the same degree of scientific rigor for evaluating biomarker use in foods and dietary supplements as it does across other regulatory areas, including drugs and medical devices. Currently, when the FDA reviews drugs, it considers the safety and efficacy of the entire product. But when the agency reviews foods, it con-

siders the safety of individual ingredients rather than the food as a whole. Despite the common perception that foods present fewer risks to consumers than drugs, foods and food ingredients may pose even greater risks because the reach of food is so vast. Even minor risks become clinically consequential when the majority of the population is exposed to them.

In pursuit of chronic disease

Chronic disease continues to be an area of interest for health experts and policy makers, particularly in light of budget constraints. In the spring of 2010, the IOM held a meeting to review the state of research and clinical practice associated with chronic disease illnesses such as cancer, brain tumors, sickle cell disease, epilepsy, diabetes, and congenital heart disease in children. An IOM report on one of the world's most deadly chronic diseases, cardiovascular disease (CVD) was issued in March 2010. That report, *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health*, discussed the worldwide threat, and it is discussed in more detail in the chapter on global health.

In a report sponsored by the CDC, HHS, and the Arthritis Foundation, the IOM is examining the burden of chronic disease. In its report, expected to be released in fall 2011, the IOM will recommend which chronic diseases should be the focus of public health efforts, which populations should be the focus of interventions, and which interventions can help achieve outcomes that maintain or improve quality of life, functioning, and disability.

Advancing Health Around the World

Health threats recognize no political or geographic borders. Indeed, given today's increasingly interconnected world, diseases in any part of the world can easily reach into the U.S. population. Beyond individual illness, the social and economic consequences of global disease, especially in developing nations, often can be felt in many ways in the United States.

In this era of globalization, the United States has an important role to play in maintaining health and mitigating risk, and the Institute of Medicine (IOM) regularly examines these responsibilities from a number of perspectives. The IOM has considered how the nation can best protect its residents from global health threats and also how it can help other countries with limited resources to tackle health problems within their own borders.

Helping fight cardiovascular disease

A growing challenge worldwide is cardiovascular disease (CVD). Once considered mainly a problem in industrialized nations, CVD, especially coronary heart disease and stroke, has emerged as a major health threat in developing countries. CVD now accounts for nearly 30 percent of deaths in low- and middle-income countries each year and is accompanied by significant economic repercussions. Yet most governments, global health institutions, and development agencies have largely overlooked CVD as they have made investments in health in developing countries.

In response to this lack of attention, the National Heart, Lung, and Blood Institute (NHLBI) asked the IOM to convene a committee of experts

to assess current knowledge and strategies for meeting the challenge of CVD, offer guidance to the NHLBI in setting priorities for its investments in global CVD control, and, more broadly, identify ways in which the global health agenda can be made more inclusive of chronic diseases, including cardiovascular disease.

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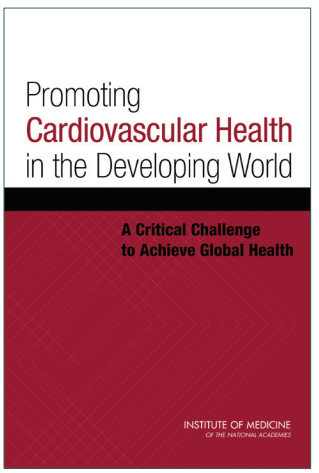
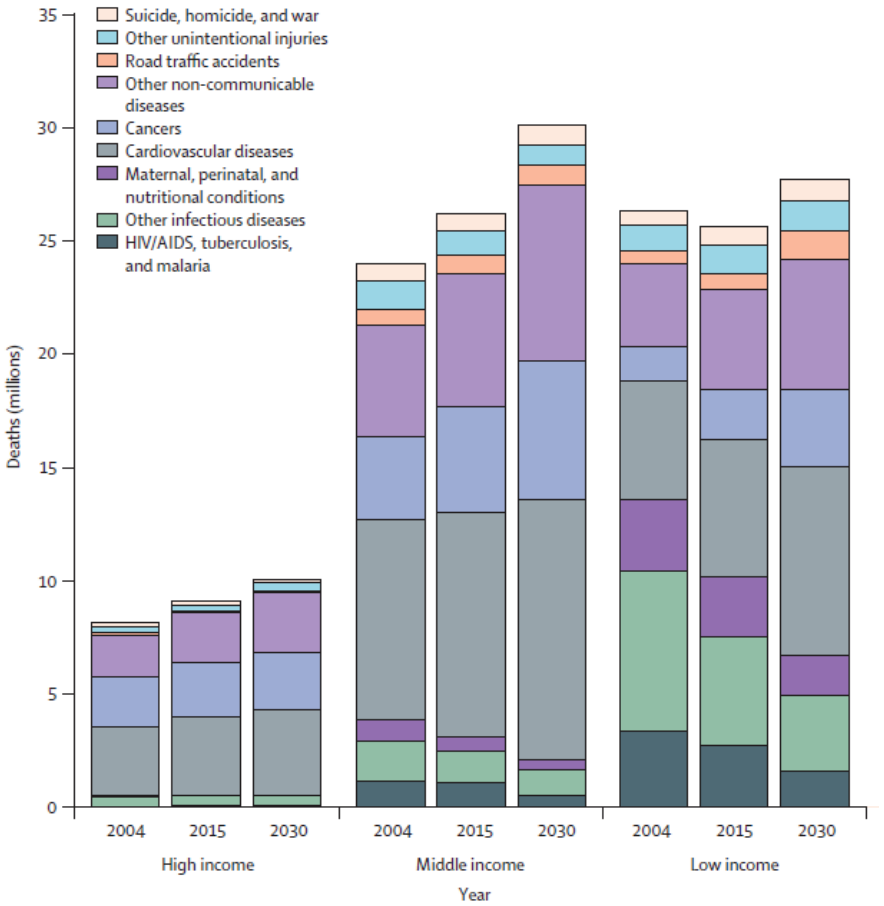
In its report, *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health* (2010), the committee provides an up-to-date assessment of the state of CVD around the world and lays out a detailed vision for how to curb the rapid growth of CVD and related chronic diseases in low- and middle-income nations. The report emphasizes that success will depend on a wide array of stakeholders taking action at the global, regional, and local levels. The report offers specific recommendations and guidance for both short-term and long-term actions for a number of important target audiences, including governments, international health and development agencies, academic and research institutions, the private sector, and nongovernmental groups.



To ensure that these critical audiences receive the key messages of the report and are prompted to begin concrete planning for implementing the recommendations, the IOM has undertaken a 2-year communications effort with the support of several private donors. Activities include widespread distribution of the report and summary materials, presentations of the report at scientific meetings and global health events, publication of editorials and articles building on the report, and tailored briefing events in Geneva and Washington. In addition, the announcement of a United Nations (UN) high-level meeting on noncommunicable diseases held in conjunction with the UN General Assembly in September 2011 triggered a wide range of communications and advocacy events focusing on global chronic diseases by other organizations, many of which have drawn on the report as a resource.



Projected global deaths by cause.

SOURCE: *Promoting Cardiovascular Health in the Developing World: A Critical Challenge to Achieve Global Health,* p. 50.

The report emphasizes the need to create environments that promote lifestyle choices that help protect heart health, and this requires public health infrastructure and health systems with the capacity to conduct programs that will effectively detect and reduce risk and manage CVD. It identifies the following essential functions that will be required to meet these goals:

- Exercise leadership and advocacy to tackle chronic diseases, including CVD.

- Build evidence-based and locally relevant solutions.
- Assess what works, and disseminate innovative interventions.
- Promote solutions through collaboration among key stakeholders based on clearly defined goals.
- Work toward global progress in reducing the global burden of cardiovascular disease.

Successfully carrying out these functions will require resources—financial, technical, and human—and the combined efforts of multiple players sustained over many years.

Private industry should work to reduce people's consumption of salt, sugar, saturated fats, and *trans* fats—all contributors to cardiovascular disease. Policy makers in each country, working with their partners, will need to determine how best to carry out risk-reduction initiatives in light of the particular conditions, infrastructure, and resources within the country. Research organizations and government agencies should prioritize research, assessment of current CVD interventions, and information sharing among all parties. It will be important as well for all parties to help improve healthcare facilities, build the medical work force, and strengthen primary healthcare services in low- and middle-income nations, and to ensure that health service providers include prevention and care for cardiovascular disease and other chronic diseases as a focus.

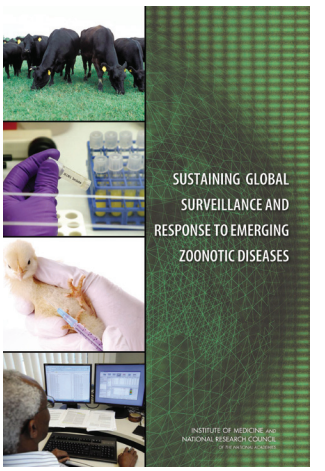
Infectious diseases crossing borders

The United States and the world face threats from a number of emerging infectious diseases. Zoonotic pathogens—infectious agents transmitted from animals to humans—are now responsible for most new infectious disease events. The conditions that can promote the spread of zoonotic pathogens and diseases, such as international travel and global shipments of animals and animal products, are becoming ever more common, raising the chances that new outbreaks will emerge with devastating health, economic, environmental, agricultural, and sociopolitical consequences.

Zoonotic pathogens—infectious agents transmitted from animals to humans—are now responsible for most new infectious disease events.

In response to such concerns, the U.S. Agency for International Development (USAID) asked the IOM and the National Research Council

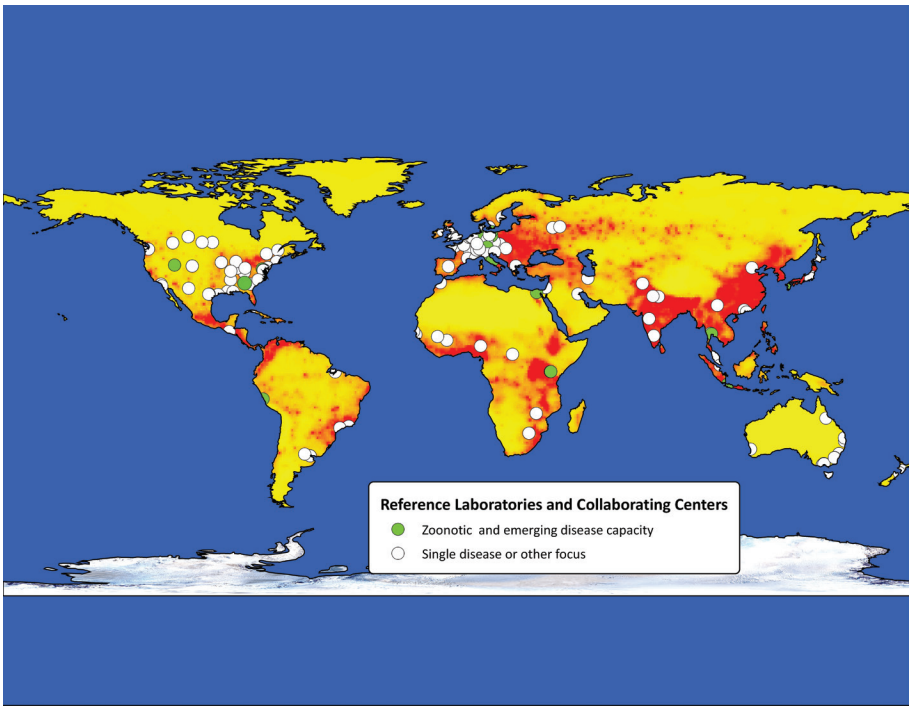
for advice on how to improve global capacity for surveillance and response to emerging zoonotic diseases. After detailing what is known about the transmission of zoonotic disease, exploring the current capacity for zoonotic disease surveillance, and outlining research and other needs to improve global surveillance and responses efforts, the committee appointed to this task continued to pursue many remaining questions about how best to protect humans worldwide from the transfer and spread of diseases from animals. In *Sustaining Global Surveillance and Response to Emerging Zoonotic Diseases* (2009), the committee offers a detailed plan for establishing and funding a comprehensive, globally coordinated system to identify novel zoonotic disease threats as early as possible wherever they arise so appropriate responses can be implemented.



U.S. federal agencies, including USAID, should spearhead efforts to develop this system and work with international partners to provide funding and technical assistance to build the expertise, equipment, and other components of zoonotic disease surveillance and response capabilities in countries worldwide. Greater integration of the human health and veterinary medicine sectors should be a key feature of this new system, because the current lack of coordination and communication between these groups results in missed opportunities to detect potential species-crossing pathogens and leads to less effective measures to contain diseases. There also should be a fundamental shift in surveillance away from urgent, time-constrained reactions to new individual diseases and toward a sustained focus on preventing the conditions for zoonotic agents to emerge and detecting possible threats on an ongoing basis.

International travel and commerce—most notably the explosive growth of commercial air transportation over the past 50 years—drives the rapid, global distribution of microbial pathogens and the organisms that harbor them.

The IOM, through its Forum on Microbial Threats, also took a broader look at the spread of infectious diseases, largely from human activities, across national borders and around the world. Today, international travel and commerce—most notably the explosive growth of commercial air trans-



Zoonotic disease hotspots and selected reference laboratories by location.
SOURCE: *Sustaining Global Surveillance and Response to Emerging Zoonotic Diseases,* p. 10.

portation over the past 50 years—drives the rapid, global distribution of microbial pathogens and the organisms that harbor them. Human travel and migration have been implicated in the spread of numerous diseases, including influenza and severe acute respiratory syndrome.

In response to such concerns, the forum held a public workshop to explore a variety of topics associated with the emergence, detection, and surveillance of infectious diseases globally. The expert presentations and group discussions are presented in *Infectious Disease Movement in a Borderless World: Workshop Summary* (2010). Topics discussed included the historical role of human migration and mobility in the movements of pathogens and organisms that carry them; the complex interrelationship of travel, trade, tourism, and infectious disease emergence; national and international biosecurity policies related to globalized pathogens; the limitations and potential benefits of the latest round of International Health Regulations, enacted by the World Health Organization (WHO) in 2005; and obstacles

and opportunities for detecting and containing pathogens early, thereby reducing the potential burden of emerging infectious diseases.

One of the most devastating diseases ever to plague humanity was smallpox, now eradicated. Today, all known live stocks of the disease's causative agent, variola virus, are stored in two repositories sanctioned by WHO, one in the United States and one in Russia. Since eradication, the World Health Assembly (WHA)—WHO's decision-making body—has debated whether to retain or destroy these stocks of live variola virus.

To help prepare for this decision, the U.S. Department of Health and Human Services's Biomedical Advanced Research and Development Authority and the Centers for Disease Control and Prevention asked the IOM to review the most recent decade of research and determine what unmet needs still exist that require the use of live variola virus. The resulting report, *Live Variola Virus: Considerations for Continuing Research* (2009), found that developing medical countermeasures against this deadly pathogen remains an essential need because of the potential for an accidental or deliberate release, and that having access to stocks of live variola virus will critically aid researchers in reaching these goals.

At a January 2011 meeting, WHO's executive board supported the retention of smallpox virus stocks in the authorized repositories for research purposes, a position in line with IOM recommendations. Also, in May 2011 the WHA met to discuss retention versus destruction of the variola virus, and it strongly reaffirmed the organization's previous decisions that the remaining stocks should be destroyed only when crucial research has been completed. At a meeting scheduled for 2014, the WHA plans to again review the state of variola virus research and discuss a date for destruction of the remaining virus stocks.

In another forum workshop focused on infectious diseases, participants examined the growing phenomenon of antimicrobial resistance (AMR). Today, some strains of bacteria and viruses are resistant to all but a single drug, and some may soon have no effective treatments left in the medicine chest. Drug-resistant pathogens have become a global challenge, aided and abetted by the use, misuse, and overuse of once highly effective antibiotics and other antimicrobial drugs. *Antibiotic Resistance: Implications for Global Health and Novel Intervention Strategies: Workshop Summary* (2010) captures the discussions.

Assessing federal HIV/AIDS programs

Although the United States continues to confront an HIV/AIDS epidemic that has affected millions of residents, the challenges are even greater in many other nations, including many that lack adequate resources to fight back. For years, the federal government has played a leading role in efforts to reduce the impact of HIV/AIDS in countries around the world. In a major commitment, President George W. Bush in 2003 launched the President's Emergency Plan for AIDS Relief (PEPFAR), providing $15 billion in relief. Congress, through the Lantos-Hyde Reauthorization Act of 2008, expanded program funding to $48 billion, to treat not only AIDS but tuberculosis and malaria as well. The reauthorizing legislation also called upon the IOM to assess the performance of PEPFAR and the impact of the program's activities on health, and to make recommendations to improve the government's response to global HIV/AIDS.

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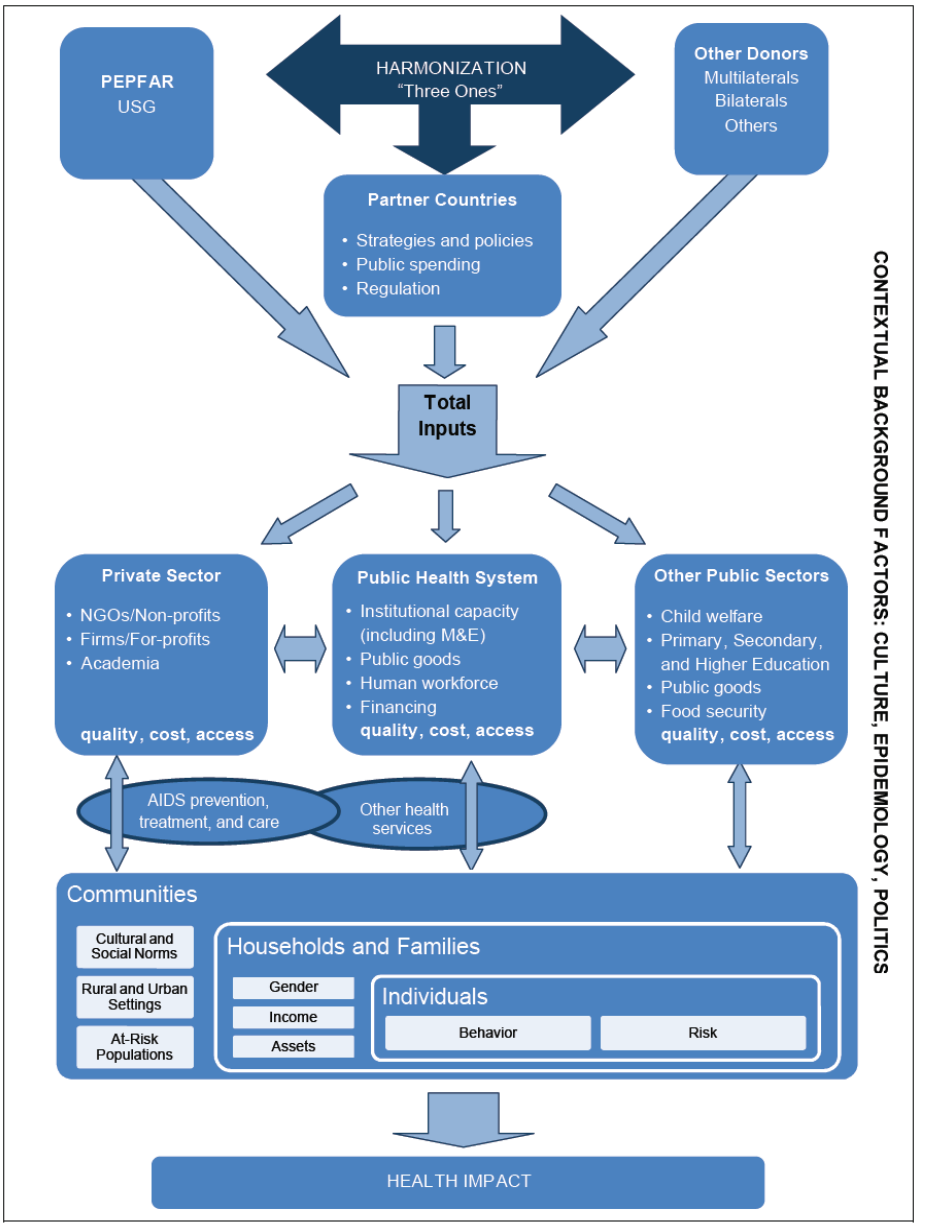
The IOM committee conducted the study in two stages. First, the committee was charged to develop a plan for the evaluation and to issue a short report to Congress. In *Strategic Approach to the Evaluation of Programs Implemented Under the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008* (2010), the committee presented an overview of the strategic approach and conceptual framework for the assessment and evaluation of PEPFAR. The proposed approach was designed to support an assessment of whether the program is performing in the way it is intended along the full range of its implementation, rather than simply an evaluation of its ultimate impact. This would allow for refined conclusions about elements of the program that are functioning well or that could be improved to result in a greater impact on health.

Within countries that receive PEPFAR support, the evaluation was to cover a range of factors that can affect the implementation of the program and health outcomes, including cultural, societal, geographical, and political factors and influences, as well as the presence of investments and activities from a range of other external and country-level sources that are aimed at achieving the same health impact. Given the multiplicity of factors that



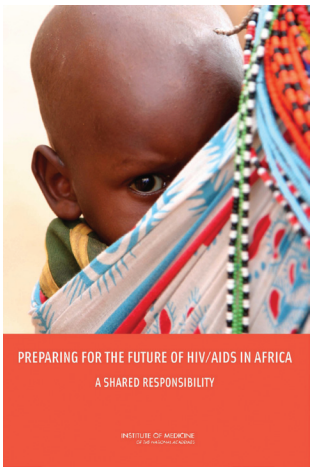
Context for PEPFAR program implementation.

NOTES: M&E = monitoring and evaluation; NGOs = non-governmental organizations; USG = U.S. government.

SOURCE: *Strategic Approach to the Evaluation of Programs Implemented Under the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008,* p. 26.

influence outcomes, the goal of the analysis was to assess PEPFAR's contribution to changes in health impact, as determining direct attribution will not be possible.

In the second phase of the study, the IOM began its evaluation of PEPFAR in the fall of 2010 and is scheduled to release a report in 2012. Based on the conclusions of the evaluation, the IOM will make recommendations that focus on improving the government's response to global HIV/AIDS, including support for and alignment with global and local responses at the country level. The report is intended to inform decisions about how to identify, disseminate, and scale up the most effective and efficient strategies in order to make the best use of limited resources to accomplish PEPFAR's goals for a transition to a sustainable, country-owned response to the pandemic.



PEPFAR has provided approximately $32 billion to HIV/AIDS-related programs since it was established in 2003. The epidemic in Africa is catastrophic and further amplified because the region lacks sufficient resources to meet the need for life-saving antiretroviral therapy (ART). In *Preparing for the Future of HIV/AIDS in Africa: A Shared Responsibility* (2010), the IOM identifies strategies for both African nations and the United States to build African capacity—including human, scientific, technological, organizational, institutional, and/or resource capabilities—to prevent, treat, and care for HIV/AIDS. More information about this report can be found in the chapter on the healthcare workforce.

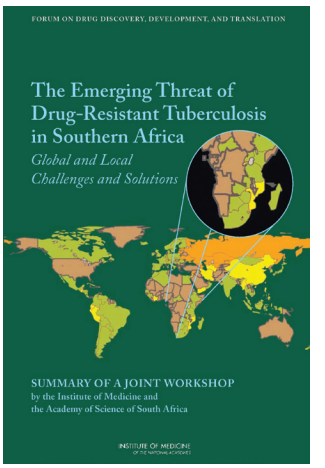
Challenges of drug-resistant tuberculosis

An estimated 2 billion people, one-third of the global population, are infected with the bacterium that causes tuberculosis (TB). Spread through the air, this infectious disease kills 1.8 million people each year. Exacerbating this devastation is the growing threat of drug-resistant strains of the disease in many parts of the world. The year 2008 saw an estimated 440,000 new cases of drug-resistant TB and 150,000 deaths from drug-resistant strains of TB. The increasing burden of drug-resistant TB introduces significant new challenges to traditional control and treatment programs.

In recognition of this emerging threat, the IOM Forum on Drug Discovery, Development, and Translation launched an initiative focused on drug-resistant TB. It began with a workshop in Washington, DC, in November 2008 and continued with a series of workshops held in countries with a very high burden of drug-resistant TB. The international workshops, taking place between 2010 and 2012, are intended to enable participants to learn from the historical and contemporary experiences of each nation's public health community in controlling and combating the spread of drug-resistant TB, and to draw lessons about best practices and novel approaches that can be applied in the regions and across the globe. The presentations and discussions among workshop speakers and guests also are intended to help forge new linkages and collaborations across multiple disciplines and countries and facilitate the sharing of scientific knowledge to benefit TB control efforts.

An estimated 2 billion people, one-third of the global population, are infected with the bacterium that causes tuberculosis.

The first international workshop was held in South Africa, cohosted by the Academy of Science of South Africa. It brought together disease experts, community leaders, policy makers, and patient advocates from that nation; other countries in southern Africa; and the United States, and their presentations and discussions are captured in *The Emerging Threat of Drug-Resistant Tuberculosis in Southern Africa: Global and Local Challenges and Solutions: Workshop Summary* (2011).



For the second international workshop, held in Russia in collaboration with the Russian Academy of Medical Sciences, participants came from that nation, the United States, South Africa, and China. Those discussions are presented in *The New Profile of Drug-Resistant Tuberculosis in Russia: A Global and Local Perspective: Workshop Summary* (2011). This workshop also was the first in a series of meetings of the U.S.-Russia Scientific Forum for Biomedical and Behavioral Research, which grew out of an agreement between Presidents Barack Obama and Dmitry Medvedev at their summit in July 2009, a date that also marked the 50th anniversary of collaboration between the Russian Academy of Sciences and the U.S. National Academy of Sciences.

Each of the workshops explored a number of common challenges. For example, many countries face an increasing incidence of drug-resistant TB. Also, drug-resistant TB is having an increasing—and devastating—impact among children, who pose unique challenges for prevention and treatment. There are numerous problems in monitoring and tracking the spread of drug-resistant TB, and many health systems lack the capacity, both technical and human, to deliver appropriate treatment for drug-resistant TB.

Drug-resistant tuberculosis is having an increasing—and devastating—impact among children.

There also are some common opportunities. Among them, the development and implementation of a point-of-care diagnostic test to detect drug-resistant TB would speed the effective diagnosis of patients and permit initiation of treatment as soon as possible. Such an innovation could reduce the period of a patient's infectivity and thereby help protect others in the community.

The forum held a third workshop in India in April 2011, in collaboration with the Indian National Science Academy and the Indian Council of Medical Research, and a report is forthcoming. Continuing the effort undertaken at the meetings in South Africa and Russia, participants in this third international workshop considered the current status of drug-resistant TB in India and across the globe, highlighted key challenges to controlling the spread of drug-resistant strains, and discussed innovative strategies to advance and harmonize local and international efforts to prevent and treat drug-resistant TB.

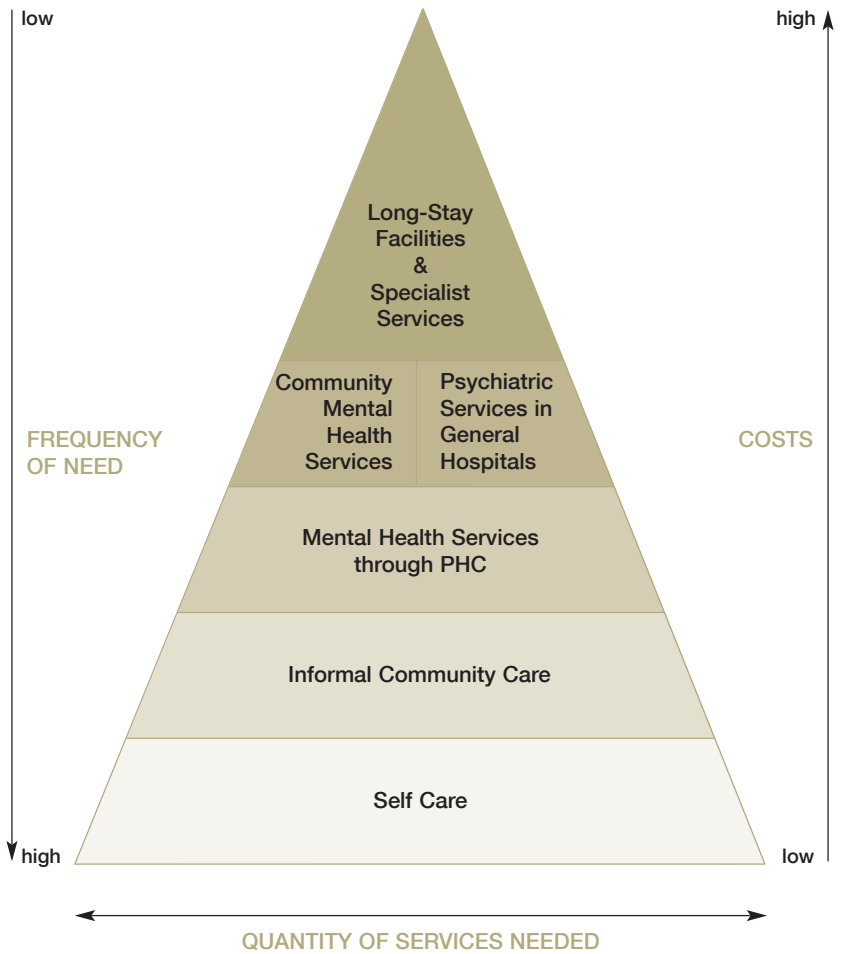
Plans are now under way for a fourth workshop, to be held in China.

Mental health needs in sub-Saharan Africa

Disorders of the nervous system are common to all countries and cause tremendous suffering. In sub-Saharan Africa—where the majority of the world's poorest countries with the least resources are found—the burden of mental health, neurological, and substance use disorders is especially significant. Epilepsy, depression, and drug and alcohol abuse affect the lives of millions of people, disrupting the daily course of life, challenging families, and weighing on the social and economic fabric of the region.

The IOM Forum on Neuroscience and Neurological Disorders, in conjunction with the Uganda National Academy of Sciences Forum on

Health and Nutrition, hosted a workshop in Kampala, Uganda, to discuss the current state of care for mental, neurological, and substance use disorders in the region. More than 150 researchers, providers, patient advocates, and policy specialists participated, and their presentations and discussions are presented in *Mental, Neurological, and Substance Use Disorders in Sub-Saharan Africa: Reducing the Treatment Gap, Improving Quality of Care: Workshop Summary* (2010).



The WHO's optimum mix of mental health services.

SOURCE: *Mental, Neurological, and Substance Use Disorders in Sub-Saharan Africa: Reducing the Treatment Gap, Improving Quality of Care: Workshop Summary,* p. 33.

Among the goals set for the workshop was to identify strategies to improve the quality and consistency of care delivered in sub-Saharan Africa, taking into account resource constraints, infrastructure limitations, and other realities. Toward this aim, participants examined opportunities to ensure continuity of care and provide sustainable care within a country's existing healthcare system; identified resources that are either currently available or could be made available in cost-effective and efficient ways to aid in the treatment and prevention of disease; assessed the need for national, evidence-based policies within national healthcare systems that consider the quality of care for mental, neurological, and substance use disorders; and explored ways to facilitate collaborations among a variety of stakeholders, including policy makers and healthcare professionals.

Beyond disease: The global burden of violence

The WHO estimates that more than 1.6 million people worldwide die each year as a result of violence, and millions more are injured physically or emotionally. But such violence is not unavoidable, and it can be stemmed. In 2010, the IOM launched the Forum on Global Violence Prevention to work to reduce violence worldwide by promoting research and encouraging evidence-based prevention efforts. Additional information about the IOM's newest forum can be found in the chapter on IOM's convening activities.

In 2010, the Institute of Medicine launched the Forum on Global Violence Prevention to work to reduce violence worldwide by promoting research and encouraging evidence-based prevention efforts.

Fostering Leadership: Fellowships at the Institute of Medicine

In addition to providing guidance on a range of health and policy issues, the Institute of Medicine (IOM) offers a number of fellowship opportunities for health professionals and behavioral and social scientists. The fellowships provide exposure to the health policy processes of Congress and the executive branch, as well as opportunities to engage with the IOM's committees and other activities.

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 behavioral and social scientists. Through a unique and comprehensive orientation program designed and administered by the IOM, followed by high-level work assignments in Congress and 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 frequently have been cited by members of Congress, the administration, and the health policy community as significantly improving the outcomes of the health policy-making process.

The scientific and clinical expertise that fellows possess makes

valuable contributions to the deliberations of federal policy makers. Consequently, fellows are in great demand during their year in Washington, DC, and beyond. They are recruited for congressional staff positions and have taken assignments in the administration, including in the Office of the Secretary of Health and Human Services, the Department of Defense, the Office of Management and Budget, and the White House Office of Domestic Policy. Federal and state agencies, along with professional organizations and associations, also enlist alumni of this program 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 enthusiastically maintain their connections to the workings of government, and some alumni have become official liaisons in government relations for their universities and professional societies.

IOM Anniversary Fellows Program

To celebrate its 35th anniversary in 2005, the IOM created a new fellowship program to enable talented health science scholars early in their careers to participate in the work of the IOM and to further their careers as future leaders in the 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 2-year program is open to individuals who hold nontenured faculty positions in any university. It especially welcomes applications from underrepresented minority candidates. Fellows continue with their main academic responsibilities while engaging part-time in various IOM activities. A 1-week immersion in the health policy arena in Washington, DC, a mentoring relationship with a senior IOM member, and a flexible research stipend enhance the value of the program. The IOM anticipates that the benefits of gaining new knowledge, professional connections, and broad exposure to policy leaders will attract an outstanding pool of applicants from a range of health-related disciplines.

An endowment from the American Board of Obstetrics and Gynecology (ABOG) has created the Norman F. Gant/American Board of Obstetrics and

Gynecology Fellowship. The fellowship, created to honor Norman F. Gant, M.D., a member of the IOM and the executive director of ABOG, is targeted to obstetricians and gynecologists early in their careers. In addition, the American Board of Internal Medicine Foundation has sponsored an IOM Anniversary Fellowship in honor of Dr. John Benson, an IOM member and past president and chief executive officer of the American Board of Internal Medicine. Finally, the American Board of Family Medicine established the James C. Puffer, M.D./American Board of Family Medicine Fellowship to enable talented, early-career health policy or health science scholars in the field of family medicine to participate in IOM's work and to further their careers as future leaders in the field.

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 seeks 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 or to become actively involved in an IOM study related to his or her area of expertise.

The program, initiated in 1992, is supported by the American Academy of Nursing, the American Nurses Association, and the American Nurses Foundation and is conducted by the IOM. Each year, one senior nurse scholar is selected from an eligible institution or organization to come to Washington, DC, to participate in a 1-year program of orientation and work at the IOM.

The Value of Collaboration: IOM's Role as a Convener

The Institute of Medicine (IOM) has a singular capacity to bring together various stakeholders to work together on health problems of shared interest. Through both its ongoing roundtables, sometimes called forums, and through unique partnerships, the IOM shapes the conversation around health and health care. Partnerships with outside organizations bring complementary strengths and enable the IOM to amplify the size and character of its audience and the impact of its work. The IOM has pursued a number of such new opportunities with outside organizations in recent years.

HBO Obesity Project

In association with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), the IOM has entered into an innovative collaboration with HBO Documentary Films aimed at helping to slow, arrest, and reverse the disturbing trend toward obesity in our country. The collaboration, titled *The Weight of the Nation*, is part of IOM's continuing commitment to ameliorate the nation's obesity epidemic. The IOM's work in this area began with the landmark 2005 study, *Preventing Childhood Obesity: Health in the Balance*. The expected spring 2012 publication *Accelerating Progress in Obesity Prevention* will add to this considerable body of work. *The Weight of the Nation* is expected to generate unprecedented national impact through the production, airing, and dissemination of five documentary films in 2012, along with companion publications, a video-rich website and social network presence,

and the free distribution of 40,000 screening kits to enable communities to screen the film locally.

The Health Data Initiative

The Health Data Initiative, launched by the IOM and the Department of Health and Human Services (HHS) in June 2010, is a public-private collaboration that encourages innovators to use health data to help power applications and services that can improve health and health care. Last year's launch, attended by 350 stakeholders, featured new "apps" that demonstrated highly innovative ways to employ community-level health data to improve health. This year the IOM and HHS enlarged the program, with a second meeting held in June 2011. The forum, held at the Natcher Conference Center at the NIH, was attended by more than 550 participants from information technology firms, healthcare delivery systems, academia, business, social sectors, public health communities, and all levels of gov-

Kathleen Sebelius, Secretary of the Department of Health and Human Services, addresses the Health Data Initiative Forum, June 9, 2011.

SOURCE: The National Academies.

ernment. It also was webcast nationally to more than 350 individuals and viewed by another 250 people at 10 satellite locations. The forum included an extensive "expo" and highlighted the work of nearly 50 companies and other organizations as well as the winning apps from the Collegiate Challenge, a national contest for college students to design a health app.

Forums, roundtables, and symposia

In the role of partner and convener, the IOM serves as a neutral meeting place where diverse groups of people can come together to share information and advance knowledge. Although creating common ground can occur through formal committees with specific objectives and areas of study, it often takes place through forums, roundtables, and symposia that provide opportunities for serendipitous discovery, mutual exchange, and critical, cross-disciplinary thinking.

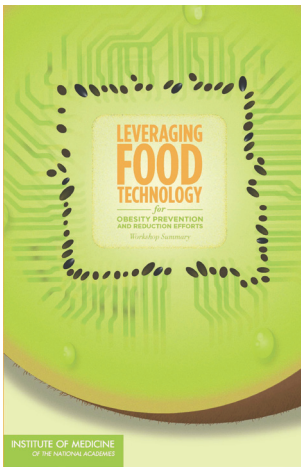
The IOM holds symposia, sometimes called summits or workshops, to foster awareness or focus attention on important issues, or to help broaden awareness about a recently released IOM report. In July 2010, for example, the IOM held a 2-day public workshop on emerging research needs for the Special Supplemental Nutrition Program for Women, Infants, and Children (commonly referred to as the WIC Program), in response to a request from the USDA's Food and Nutrition Service. In another example, the IOM assembled thought leaders in October 2010 to examine the critical needs and gaps in understanding prevention, amelioration, and resolution of Lyme disease and other tick-borne diseases.

Forums and roundtables offer a different approach, by drawing together an array of stakeholders interested in a broad area of health science or public policy for a long-term, dialogue. Members of forums and roundtables typically include experts from the scientific and practice communities; leaders from government, academia, and industry; and representatives of consumer and public interest groups, among others.

These gatherings are intended to illuminate issues through discussion and debate across sectors and institutions rather than to resolve a particular issue or make specific, actionable recommendations. Bringing together these individuals can create the shared knowledge, trust, and understanding necessary to foster progress in the most contentious areas of health and science policy.

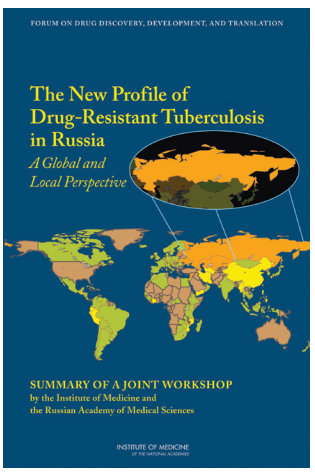
Food Forum

Since 1993, the Food Forum of the Food and Nutrition Board has engaged scientists, administrators, and policy makers from academia, government, industry, and public sectors on an ongoing basis to discuss problems and issues related to food, food safety, and regulation, as well as identifying possible approaches for addressing those problems and issues. The dialogue established during meetings deals with emerging issues in the broad areas of food science, food safety, and nutrition, including technologies and regulations. Most recently, the forum has held workshops on diverse issues including the safety of imported foods and the effect that technological advances in the food system could have on obesity.



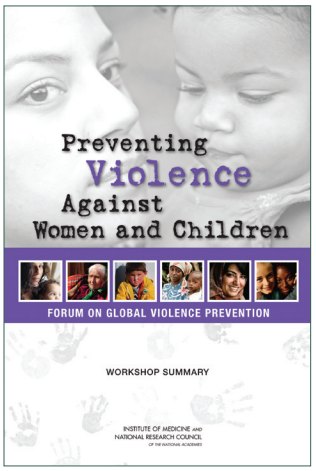
Forum on Drug Discovery, Development, and Translation

The Forum on Drug Discovery, Development, and Translation, created in 2005 by the Board on Health Sciences Policy, provides an opportunity for leaders from government, academia, industry, and other stakeholder groups to discuss ongoing and emerging issues in pharmacology. The forum brings ongoing attention and visibility to important issues in drug development; explores new approaches for resolving problem areas; helps define the scope of the field and thus sets the stage for future policy action; provides a catalyst for collaboration on topics where there is synergy among potential partners; and elevates the general understanding of drug discovery, development, and translation among the research, public policy, and broader communities. The forum recently has considered a vast array of issues, ranging from drug regulation and regulatory decision making to medical countermeasures during public health emergencies. In addition, the forum is collaborating with the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH to develop a series of international meetings on multidrug-resistant tuberculosis. Meetings in Russia and South Africa took place in 2010, and a meeting took place in India in April 2011.



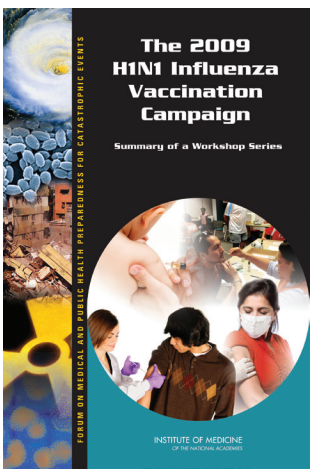
Forum on Global Violence Prevention

Violence—for example, child abuse, intimate partner violence, elder abuse, sexual violence, gang violence, and suicide—is a major public health problem worldwide. In 2001, violence accounted for 45 million disability-adjusted life years (DALYs) lost, with low- and middle-income countries bearing the largest burden. But violence can be prevented. The IOM's Forum on Global Violence Prevention, established in 2010, works to reduce violence worldwide by promoting research on both protective and risk factors and encouraging evidence-based prevention efforts. The forum aims to facilitate dialogue and exchange by bringing together experts from all areas of violence prevention, including behavioral scientists, policy makers, criminal justice professionals, social service providers, economists, legal experts, journalists, philanthropists, faith-based organizations, and corporate social responsibility officers. Recent workshops have explored the social and economic costs of violence as well as violence against women and children.



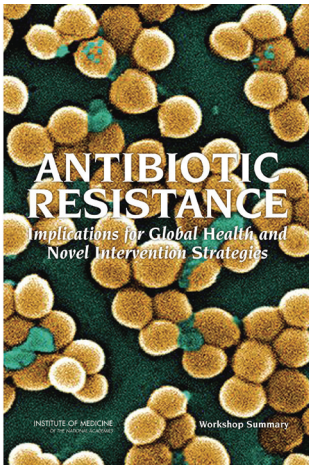
Forum on Medical and Public Health Preparedness for Catastrophic Events

The Forum on Medical and Public Health Preparedness for Catastrophic Events, established in 2007, focuses on strengthening the nation's medical and public health preparedness for acts of terrorism or natural disasters by improving communication and the coordination of activities among federal, state, and local government agencies as well as private-sector groups. Most recently, the forum held workshops that considered the 2009 H1N1 pandemic vaccination campaign, examined medical and public health preparedness and response in rural and frontier settings, and, in a workshop cosponsored with the Forum on Drug Discovery, Development, and Translation, discussed methods to improve how medical countermeasures are developed, tested, and approved.



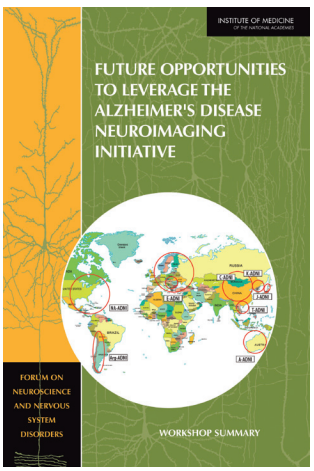
Forum on Microbial Threats

The Forum on Microbial Threats—formerly called the Forum on Emerging Infections, which was established in 1996—considers issues related to the prevention, detection, and management of infectious diseases. The forum's membership includes individuals from a 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, forum dialogues have illuminated priorities 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. Recent workshops have focused on the science and policy implications of neglected tropical diseases, the recent emergence of multidrug-resistant "superbugs," and the threat of fungal diseases.



Forum on Neuroscience and Nervous System Disorders

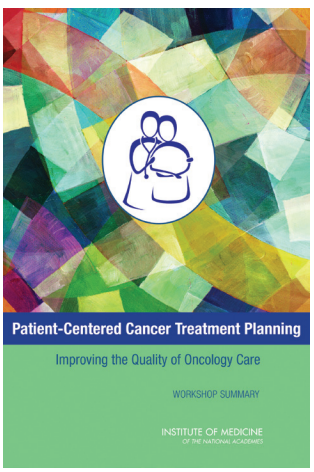
Established in 2006, the Forum on Neuroscience and Nervous System Disorders brings together leaders from private-sector sponsors and users of biomedical and clinical research, federal agencies sponsoring and regulating research, private foundations, the academic community, and public and consumer groups. The forum focuses on building partnerships to understand the brain and nervous system and disorders in their structure and function, as well as sharing effective clinical prevention and treatment strategies. The forum concentrates on six main areas: nervous system disorders, mental illness and addiction, the genetics of nervous system disorders, cognition and behavior, modeling and imaging, and ethical and social issues. Recent workshops have focused on a diverse array of topics, including the implications of recent cutbacks by top pharmaceutical companies in drug development for central nervous system disorders, and growth opportunities for the field,



including Representative Patrick Kennedy's "moon shot" effort to increase the funding and coordination of neuroscience research.

National Cancer Policy Forum

The National Cancer Policy Forum was established in 2005 to succeed the National Cancer Policy Board, which was formed in 1997. The forum considers a range of issues in science, clinical medicine, public health, and public policy relevant to the goals of preventing, palliating, and curing cancer. Its objectives are to identify emerging high-priority policy issues in the nation's effort to combat cancer and to examine those issues through convening activities that promote discussion about potential opportunities for action. These activities inform stakeholders about critical policy issues through published reports, and they often provide input for planning formal IOM consensus committee studies. The forum has held recent workshops on patient-centered cancer treatment planning and on technological advances in cancer research and care delivery.

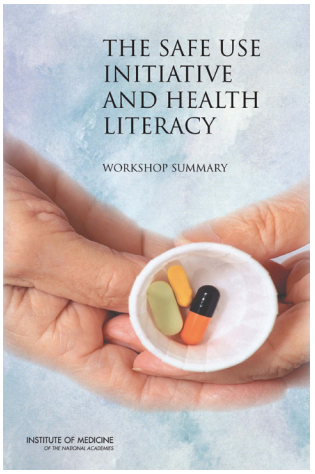


Roundtable on Environmental Health Sciences, Research, and Medicine

Established in 1998, the Roundtable on Environmental Health Sciences, Research, and Medicine brings together stakeholders from government, academia, industry, and environmental groups to discuss sensitive and difficult issues related to environmental health. Since its inception, the roundtable has focused on the state of environmental health science, research gaps, and policy implications. The roundtable has moved toward an increasingly global perspective in its discussions on nanotechnology, the interrelationship between trade and health, and corporate social responsibility in environmental health. It is currently examining issues of domestic and international importance such as climate change, sustainable drinking water, transportation-related energy use, and environmental health decision making.

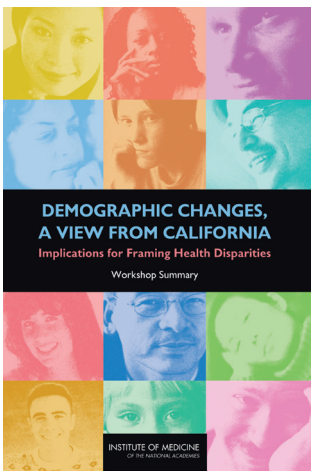
Roundtable on Health Literacy

The Roundtable on Health Literacy was created in 2004, in response to the IOM report *Health Literacy: A Prescription to End Confusion,* which found that nearly half of all American adults—90 million people—have difficulty understanding and using health information. The roundtable's mission is to support the evolution of the field of health literacy by translating research findings to practical strategies that can be implemented. To achieve this mission, the roundtable brings together leaders from academia, industry, government, foundations, and patient and consumer groups who have an interest and role in improving health literacy to discuss challenges facing health literacy practice and research, and to identify approaches to promote health literacy through mechanisms and partnerships in both the public and private sectors. Recent workshops have included a discussion on the Food and Drug Administration's Safe Use Initiative as well as a workshop to discuss how research and information technology can help improve health literacy.



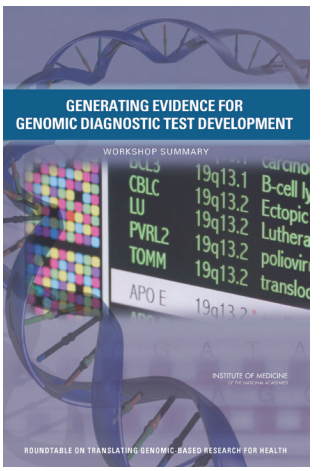
Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities

The Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities focuses on issues related to the visibility of racial and ethnic disparities in health and health care as a national problem, the development of programs and strategies to reduce disparities, and the need to encourage new leadership in a variety of fields. Roundtable members include experts from the health and social sciences, industry, and the community. Recent roundtable workshops included a discussion of the factors that influence life expectancy in the United States and a workshop on the effects of healthcare reform and the need for a more diverse healthcare workforce to serve the expected influx of patients from underserved communities of color.



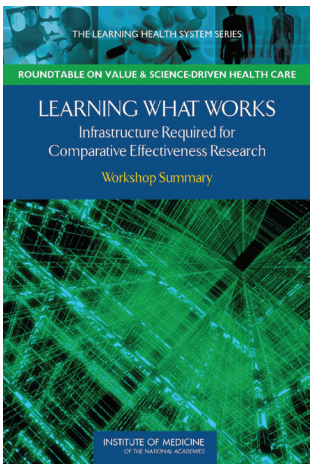
Roundtable on Translating Genomic-Based Research for Health

The Roundtable on Translating Genomic-Based Research for Health brings together leaders from academia, industry, government, foundations, and associations who have a mutual interest in the translation of genomic-based research. The mission of the roundtable is to advance the field of genomics and improve the translation of research findings to health care, education, and policy. Translating genomic innovations involves many disciplines, and it takes place within different economic, social, and cultural contexts, necessitating a need for increased communication and understanding across these fields. The ramifications of genomic innovations extend to clinical utility, economic implications, equal access, and public perspectives. The roundtable fosters dialogue across sectors and institutions and fosters collaboration among stakeholders.



Roundtable on Value & Science-Driven Health Care

The Roundtable on Value & Science-Driven Health Care, established in 2006 as the Roundtable on Evidence-Based Medicine, provides a trusted venue for national leaders in health care to work cooperatively toward their common commitment to effective, innovative health care that consistently adds value to patients and society. Members include clinicians, patients, healthcare organizations, employers, manufacturers, insurers, health information technologists, researchers, and policy makers. As leaders in their fields, roundtable members work with their colleagues to identify and engage the key challenges and opportunities for achieving better outcomes and greater value in health care. They then marshal the energy and resources of their respective sectors to work for sustained public-private cooperation.



The work of the roundtable is conducted through two types of activities. The first type is accelerating understanding and progress toward

the roundtable's vision of a learning health system, in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience. The second type of activity is the fostering of cooperative projects through the work of five stakeholder innovation collaboratives focused on (1) best clinical practices, (2) communication of medical evidence, (3) clinical effectiveness research, (4) health information technology, and (5) incentives for value in health care.

Recent and Upcoming Reports

This chapter lists reports released by the Institute of Medicine from 2009 through 2011 as well as select older reports, grouped by subject area and listed in more than one subject area where appropriate. Each report title is followed by the responsible board and the year the report was released. Following the recently released reports are upcoming reports expected to be released through 2012. A "  " denotes a congressionally mandated study.*

Recent reports

Aging

Future Opportunities to Leverage the Alzheimer's Disease Neuroimaging Initiative: Workshop Summary, Health Sciences Policy, 2010.

Glutamate-Related Biomarkers in Drug Development for Disorders of the Nervous System: Workshop Summary, Health Sciences Policy, 2011.

 **Improving the Quality of Long-Term Care**, Health Care Services, 2000.

Improving the Social Security Disability Decision Process, Military and Veterans Health, 2007.

* The Board on Select Populations was previously known as the Board on Military and Veterans Health and Medical Follow-Up Agency; 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; and the Roundtable on Value & Science-Driven Health Care was previously known as the Roundtable on Evidence-Based Medicine.

Mental, Neurological, and Substance Use Disorders in Sub-Saharan Africa: Reducing the Treatment Gap, Increasing Quality of Care: Workshop Summary, Health Sciences Policy, 2010.

Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches, Value & Science-Driven Health Care, 2009.

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- **A 21st Century System for Evaluating Veterans for Disability Benefits**, Military and Veterans Health, 2007.
- **Amyotrophic Lateral Sclerosis in Veterans: Review of the Scientific Literature**, Population Health and Public Health Practice, 2006.
- **Blue Water Navy Vietnam Veterans and Agent Orange Exposure**, Health of Select Populations, 2011.
- **Epidemiologic Studies of Veterans Exposed to Depleted Uranium: Feasibility and Design Issues**, Population Health and Public Health Practice, 2008.

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From Exposure to Human Disease: Research Strategies to Address Current Challenges: Workshop Summary, Population Health and Public Health Practice.

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Review of the California Institute for Regenerative Medicine, Health Sciences Policy.

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Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule, Population Health and Public Health Practice.

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From Neurons to Neighborhoods: Anniversary Workshop, Children, Youth, and Families.

Diseases

From Exposure to Human Disease: Research Strategies to Address Current Challenges: Workshop Summary, Population Health and Public Health Practice.

The Public Health Dimensions of the Epilepsies, Health Sciences Policy.

Valuing Community-Based, Non-Clinical Prevention Policies and Wellness Strategies, Population Health and Public Health Practice.

Workshop on Country-Level Decision Making for Control of Chronic Diseases, Global Health.

Environmental health

Occupational Information and Electronic Health Records, Health Sciences Policy.

Food and nutrition

Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase 2 Report, Food and Nutrition.

Fitness Measures and Health Outcomes in Youth, Food and Nutrition.

Nutrition and Healthy Aging in the Community, Food and Nutrition.

Strengthening Core Elements of Regulatory Systems in Developing Countries, Global Health; Health Sciences Policy; Food and Nutrition.

Global health

Strengthening Core Elements of Regulatory Systems in Developing Countries, Global Health; Health Sciences Policy; Food and Nutrition.

Workshop on Country-Level Decision Making for Control of Chronic Diseases, Global Health.

Health services, coverage, and access

Determination of Essential Health Benefits, Health Care Services.

Integrating Primary Care and Public Health, Population Health and Public Health Practice.

Personal Preparedness (BARDA), Health Sciences Policy.

Prevention, Diagnosis, Treatment, and Management of Substance Use Disorders in the U.S. Armed Forces, Health of Select Populations.

Healthcare workforce

The Mental Health Workforce for Geriatric Populations, Health Care Services.

Workforce Resiliency Programs: A Workshop Series, Health Sciences Policy.

Public health

Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule, Population Health and Public Health Practice.

Decision Making Under Uncertainty, Population Health and Public Health Practice.

From Exposure to Human Disease: Research Strategies to Address Current Challenges: Workshop Summary, Population Health and Public Health Practice.

Identifying and Prioritizing New Preventive Vaccines for Development, Population Health and Public Health Practice.

Information-Sharing Models and Guidelines for Collaboration: Applications to a National Integrated Biosurveillance Strategy: A Workshop, Health Sciences Policy.

Integrating Primary Care and Public Health, Population Health and Public Health Practice.

Review of the Appropriate Use of Armed Forces Institute of Pathology's Tissue Repository Following Its Transfer to the Joint Pathology Center, Health of Select Populations.

Scientific Standards for Studies on Modified-Risk Tobacco Products, Population Health and Public Health Practice.

Sex-Specific Reporting of Scientific Research: A Workshop, Health Sciences Policy; Population Health and Public Health Practice.

The Potential Impacts of Climate Change on Human Health: Workshop Summary, Population Health and Public Health Practice.

Valuing Community-Based, Non-Clinical Prevention Policies and Wellness Strategies, Population Health and Public Health Practice.

Workforce Resiliency Programs: A Workshop Series, Health Sciences Policy.

Workshop on Country-Level Decision Making for Control of Chronic Diseases, Global Health.

Quality and patient safety

Patient Safety and Health Information Technology, Health Care Services.

Substance abuse and mental health

Prevention, Diagnosis, Treatment, and Management of Substance Use Disorders in the U.S. Armed Forces, Health of Select Populations.

The Mental Health Workforce for Geriatric Populations, Health Care Services.

Veterans' health

Prevention, Diagnosis, Treatment, and Management of Substance Use Disorders in the U.S. Armed Forces, Health of Select Populations.

Review of the Appropriate Use of Armed Forces Institute of Pathology's Tissue Repository Following Its Transfer to the Joint Pathology Center, Health of Select Populations.

The Evaluation of Cognitive Rehabilitation Therapy for Traumatic Brain Injury, Health of Select Populations.

The Initial Assessment of Readjustment Needs of Military Personnel, Veterans, and Their Families: Phase 2, Population Health and Public Health Practice.

Women's health

Sex-Specific Reporting of Scientific Research: A Workshop, Health Sciences Policy; Population Health and Public Health Practice.

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