

FOSTERING RAPID ADVANCES IN HEALTH CARE

LEARNING
FROM
SYSTEM
DEMONSTRATIONS



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Fostering Rapid Advances in Health Care

Learning from System Demonstrations

Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery
Systems

Janet M. Corrigan, Ann Greiner, Shari M. Erickson, *Editors*

Board on Health Care Services
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“Knowing is not enough; we must apply.

Willing is not enough; we must do.”

—Goethe



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REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **ELAINE L. LARSON**, Professor of Pharmaceutical and Therapeutic Research, Columbia University, School of Nursing and **BRADFORD H. GRAY**, Editor, The Milbank Quarterly and Director, Division of Health & Science Policy, New York Academy of Medicine. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Foreword

In June 2002, Health and Human Services Secretary, Tommy Thompson, met with leaders from The National Academies, including the Presidents and selected members from the Institute of Medicine, the National Academy of Sciences and the National Academy of Engineering. Paramount among his concerns were the serious problems confronting the health care delivery system, including rapidly rising health care costs, serious quality and safety shortcomings, growing numbers of uninsured, racial and ethnic disparities in access and quality of care, and workforce shortages.

The Secretary challenged the National Academies to identify several bold ideas that might change conventional thinking about the most serious problems facing the health care system. Throughout our history, the Academies have welcomed tough assignments. Since our founding in 1863, we have called upon leading scientists to examine difficult problems and produce original insights or solutions. The recent report, *Making the Nation Safer*, describes a wide range of threats to homeland security and recommends actions to protect the nation against terrorism. The current crisis confronting the nation's health care delivery system is no less important to our long-term national interests.

The IOM responded to the Secretary's challenge through the Committee on Rapid Advance Demonstration Projects: Health Care Finance and Delivery Systems. The committee was charged with identifying a set of demonstration projects that have the potential to lead fundamental change in the health care system. The ideas presented are bold, and testing them will require resources. However, the scale of the problem requires not only paradigm shifting ideas, but a rigorous and full scale testing of those ideas before they are considered for national implementation. Under current assumptions, the Medicare trustees project that in 75 years, health care could account for 40 percent of GNP. Changing that trajectory will require wide ranging reforms and changes on the part of consumers, employers and health care professionals alike. The Secretary's request to the National Academies and others to think creatively and unconventionally is an important step in creating alternative paths to assure quality health care for the American people without preempting other vital national interests.

Sharing the Secretary's sense of urgency, the IOM committee has moved expeditiously to identify a set of demonstration projects intended to produce model delivery systems within 5 years. As a country, we must now begin the challenging task of building a health care system for the 21st century.

Harvey V. Fineberg, M.D., Ph.D.
President, Institute of Medicine
November 2002

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Several other individuals also made important contributions to the committee's work. They include David Doolan of Hunter Health in New South Wales, Australia; Christopher Koppen of the National Association of Community Health Centers; Freda Mitchem of the National Association of Community Health Centers; Patricia Rutherford of the Institute for Healthcare Improvement; David M. Stevens, Health Resources and Services Administration; Kenneth E.Thorpe of the School of Public Health at Emory University; Tricia Trinite of the Health Resources and Services Administration; Nancy Whitelaw of the Henry Ford Health System and the National Council on Aging. We would also like to thank the following Institute of Medicine staff members for their valuable contributions: Philip Aspden; Wilhelmine Miller; and Dianne Wolman.

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Executive Summary

ABSTRACT

In response to a request from the Secretary of the Department of Health and Human Services, the Institute of medicine convened a committee to identify possible demonstration projects that might be implemented in 2003, with the hope of yielding models for broader health system reform within a few years. The committee is recommending a substantial portfolio of demonstration projects: 10–12 chronic care demonstrations, a primary care demonstration with 40 participating sites, 8–10 information and communications technology infrastructure demonstrations, 3–5 state health insurance coverage demonstrations, and 4–5 state liability demonstrations. As a set the demonstrations address key aspects of the health care delivery system and the financing and legal environment in which health care is provided. The launching of a carefully crafted set of demonstrations is viewed as a way to initiate a “building block” approach to health system change.

The American health care system is confronting a crisis. The cost of private health insurance is now increasing at an annual rate in excess of 12 percent, while at the same time individuals are paying more out of pocket and receiving fewer benefits (Edwards et al., 2002; Kaiser Family Foundation and Health Research and Educational Trust, 2002). One in seven Americans is uninsured, and the number of uninsured is on the rise (U.S. Census Bureau, 2001, 2002). Many states are confronting serious financial constraints that are likely to result in a narrowing of the eligibility criteria and benefits of public insurance programs (Desonia, 2002). Tens of thousands die from medical errors each year, and many more are injured (Institute of Medicine, 2000). Quality problems, including underuse of beneficial services and overuse of medically unnecessary procedures, are widespread (Leatherman and McCarthy, 2002; Schuster et al., 2001). And disturbing racial and ethnic disparities in access to and use of services call into question our fundamental values of equality and justice for all (Institute of Medicine, 2002e).

The health care delivery system is incapable of meeting the present, let alone the future needs of the American public (Institute of Medicine, 2001b). The vast majority of the nation's health care resources is now devoted to the ongoing management of chronic conditions (Anderson and Knickman, 2001a). Yet despite some laudable examples of integrated care, the delivery system consists of silos, often lacking even rudimentary information capabilities to exchange patient information, coor

dinate care across settings and multiple providers, and ensure continuity of care over time (Gandhi et al., 2000). Fixing the personal health care delivery system must be a high priority, but will not be enough. In recent years, it has become increasingly apparent that health outcomes are determined to a great extent by factors in addition to health care, including behavioral patterns, genetic predispositions, social circumstances, and environmental exposures (McGinnis et al., 2002). In the 21st century, the health care system must focus greater attention on helping people improve their health-related behaviors, including diet, exercise, and use of nicotine and alcohol.

As health care providers struggle to address these concerns, they confront sizable obstacles in the external environment, including regulatory, payment, and legal barriers, among others. The patchwork of federal and state regulatory requirements that has evolved over several decades is organized around various types of institutions (e.g., hospitals, nursing homes, home health agencies) and professionals (e.g., physicians, nurses, pharmacists). Many insurance programs fail to provide coverage for services that are critical to the care of the chronically ill, such as outpatient prescription drugs, patient education and support services, and interactions between health professionals and patients via e-mail and telephone (Anderson and Knickman, 2001b). The legal liability system does not adequately fulfill either of its two main objectives—to encourage enhanced safety and quality, and to provide timely and fair compensation to injured patients. Not surprisingly, the frustration of health care professionals is at a high level, further exacerbating the tight labor market, especially in nursing (Health Resources and Services Administration, 2000, 2002).

STUDY PURPOSE

It was in this context that the Secretary of Health and Human Services asked The National Academies to identify possible demonstration projects that could be implemented in 2003, with the hope of yielding viable models for broader health care system reform within a few years. In response to this request, the Institute of Medicine (IOM) initiated the Rapid Advance Demonstration Project in June 2002 to identify demonstration projects that have the potential to be transformative. In carrying out its charge, the committee has striven to identify a set of demonstration projects that would be ground-breaking and yield a very high return on investment in terms of dollars or health. Like all demonstrations, these projects should be viewed as experiments, with carefully designed evaluation components to test the effects of different interventions.

AMERICANS DESERVE SO MUCH MORE

In an earlier report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, the IOM called for a health system that would achieve six major aims or dimensions of quality—health care should be safe, effective (i.e., science-based), patient-centered, timely, efficient, and equitable (Institute of Medicine, 2001b). The current system falls far short with regard to each of these aims.

The country that put the first man on the moon and invented the microchip is surely capable of ensuring that children are immunized, that patients who suffer heart attacks receive life-saving drugs, that diabetics receive the education and support they need to manage their insulin levels, that terminally ill patients receive adequate pain management, and that patients who smoke tobacco receive the counseling and assistance they need to quit. Nevertheless:

- More than one-quarter of American children aged 19 to 35 months are deficient in immunizations (Centers for Disease Control and Prevention, 2001).
- An estimated 18,000 people die each year from heart attacks because they were eligible for but did not receive medication to

prevent recurrent heart attack (Chassin, 1997).

- Two in five diabetics do not receive an annual eye examination to check for signs of disease that can lead to blindness, and almost half do not get a foot examination to check for nerve damage (Centers for Disease Control and Prevention, 2000).
- Among oncology patients, 56 percent report moderate to severe pain (Von Roenn et al., 1993).
- Patients who smoke do not receive smoking cessation counseling during three-quarters of all visits to physicians (Thorndike et al., 1998).

This level of performance (Leatherman and McCarthy, 2002) is unworthy of the wealthiest nation in the world.

DEMONSTRATION PROJECTS AS A STRATEGY FOR HEALTH SYSTEM REDESIGN

The committee views the demonstration projects proposed in this report as the first step in advancing a more substantial process of health system redesign. In other words, the committee is hopeful that its work will lead to much more than a few demonstration projects, and accordingly has attempted to identify demonstrations that, if pursued as a set, have the potential to sow the seeds of fundamental health reform.

There is no accepted blueprint for redesigning the health care sector, although there is widespread recognition that fundamental changes are needed in health care and the financial and legal environment that shape it. The sheer size and complexity of the health care sector, with tens of thousands of health care providers and a myriad of public and private insurance and delivery arrangements, makes wholesale change difficult. For many important issues, we have little experience with alternatives to the status quo.

For these reasons, the committee sees the launching of a carefully crafted set of demonstrations as a way to initiate a “building block” approach to health system change. The recommended demonstration projects should as a group address the critical aspects of a reform strategy, including coverage, insurance benefits, provider payment incentives, and liability. The committee also believes that special attention should be focused on building stronger information and communications technology (ICT) infrastructures to support care delivery and many other important priorities, such as bioterrorism surveillance, public health, and research (Institute of Medicine, 2001b, 2002d; National Research Council, 2000). All or nearly all of the demonstration projects should involve public and private partnerships and collaborative efforts, recognizing that the federal and state governments and private-sector stakeholders all have important authorities and responsibilities, and that most health care markets are influenced by both competitive and cooperative forces.

For this strategy to result in broad-based health system reform, however, we must both plant the seeds of innovation and create an environment that will allow success to proliferate. Steps must be taken to remove barriers to innovation and to put in place incentives that will encourage redesign and sustain improvements. For example, emphasis must be placed on fashioning payment policies that recognize methods of e-health delivery (e.g., virtual visits, telemedicine) and reward high-quality care. If the federal government fails to play a proactive role in creating an environment that nurtures change and success, the ambitious demonstration agenda proposed in this report will have minimal impact on the overall health care sector.

PLANTING THE SEEDS

The committee has striven to identify bold and transformational demonstration projects with the potential to contribute to a major redesign of health care processes. These demonstration projects are intended to be the seeds of innovation, and to evolve into the first genera

tion of 21st-century community health care systems.

To guide the process of identifying the most promising demonstration projects, the committee developed two sets of criteria: those related to the intended results of demonstrations, and those related to the likelihood of successful implementation (see [Box ES-1](#)).

As a result of its deliberations, the committee identified five major categories of demonstrations (see [Box ES-2](#)). For four of these categories—chronic care, ICT infrastructure, state health insurance, and liability—demonstration sites would likely be states, or in a few instances, sizable markets within states or multistate collaborations. The remaining category—primary care—focuses on the provision of stellar care at a subset of about 40 of the country's community health centers.

In identifying the set of demonstration projects shown in [Box ES-2](#), the committee assumed that there would be only modest, if any, increases in health care expenditures. With one exception, then—state health insurance—the demonstration projects are intended to be budget neutral over the long term (while substantially increasing the benefits derived from expenditures on health care). All of the projects have initial start-up costs, most of which will need to be assumed by the federal government. In the case of the ICT demonstration projects, these initial capital investments will be sizable.

BOX ES-1 CRITERIA FOR SELECTING BOLD AND TRANSFORMATIONAL DEMONSTRATIONS

Criteria related to intended results of demonstrations

- *Improved health status of patients and populations*
- *System improvements*
- *Reduced waste*
- *Stimulus for continued innovation*

Criteria related to likelihood of successful implementation

- *Resonates with public and policy makers*
- *Broad base of support*
- *Recognizes and addresses barriers*
- *Builds on existing competencies*

Chronic Care: Reducing the Toll of Chronic Conditions

Demonstration projects in this category are intended to improve the quality of care provided to the chronically ill and to reduce the burden of disease and disability in a community. Navigat

BOX ES-2 FIVE CATEGORIES OF DEMONSTRATIONS

Chronic Care: Reducing the Toll of Chronic Conditions on Individuals and Communities

Primary Care: 40 Stellar Community Health Centers

Information and Communications Technology Infrastructure: A “Paperless” Health Care System

State Health Insurance: Making Affordable Coverage Available to All Americans

Liability: Patient-Centered and Safety-Focused, Nonjudicial Compensation

ing the health care system is often complex for individuals with chronic illnesses, who require ongoing treatment involving multiple providers and sites of care. For many people, chronic disease could have been avoided or delayed had educational and other supportive interventions been provided to assist them in modifying health behaviors.

These demonstration projects would involve the following components:

- *Coordinating structure*—During the first year, the grant recipient would be responsible for establishing a broad-based coordinating structure with participation from all stakeholders. This coordinating structure should have (or develop) the capability to provide strong leadership for the demonstration, to create the needed ICT infrastructure, to provide knowledge support and sponsor learning collaboratives, and to sponsor community-wide educational and other efforts.
- *Chronic care management programs*—Each demonstration site would establish chronic care management programs that would provide evidence-based treatment of chronic diseases, services to detect and minimize the consequences of common geriatric syndromes, services to meet the preventive and acute care needs of the enrolled chronically ill population, and extended outreach and coordination with social and environmental services. Effective chronic care programs employ systematic approaches, make extensive use of multidisciplinary teams having ready access to clinical knowledge and specialists, and provide information and other support to patients to encourage self-management.
- *Information and communications technology*—A major component of these demonstrations should be the expanded use of ICT to improve care for the chronically ill. All demonstration projects should involve major advances in Internet-based communication (e.g., dissemination of information to clinicians and patients, e-mail, telemedicine, access to patient records), chronic care registries, and medication order entry systems.
- *Benefits, Copayments, Provider Payments, and Accountability*—Demonstration sites should be given the flexibility under Medicare and other insurance programs to innovate in such areas as benefits coverage, beneficiary copayments, provider payments, and accountability. Some of the current benefit packages fail to provide coverage for certain services needed by the chronically ill (e.g., prescription drugs, educational and support services), and in some instances, copayments may be prohibitively high (Montenegro-Torres et al., 2001). The Medicare fee-for-service payment system provides compensation for face-to-face encounters, but does not recognize services such as e-mail or patient educational and support services, which in certain circumstances may be more beneficial to the patient and more cost-effective. Demonstration sites should be encouraged to experiment with provider payment methods that reward performance achievement and beneficiary copayment designs that encourage self-management.
- *Learning collaborates and community-wide educational efforts*—Each demonstration site, with assistance from the National Library of Medicine and the Agency for Healthcare Research and Quality (AHRQ), should engage in efforts to assist clinicians and patients in gaining access to scientific knowledge, practice guidelines, certified protocols, identified best practices, and decision support tools.

From among the responses to a Request for Proposals (RFP) issued by the Department of Health and Human Services (DHHS), a limited number of demonstration sites (10–12) would be selected. Demonstration sites would receive a 1-year planning grant, followed by a 3-year implementation grant. As noted, these demon

stations are intended to be budget neutral over the long term (exclusive of up-front federal capital investments in ICT).

It is anticipated that the demonstration projects would initially be limited to Medicare beneficiaries, but over time would likely expand to include all payers and possibly even the uninsured. About one of six of Medicare beneficiaries qualifies for Medicaid, so state participation would also be important (Gluck and Hanson, 2001).

Primary Care: 40 Stellar Community Health Centers

Well-organized and accessible primary care settings are an essential part of an effective health care system. The majority of patients enter the health system through primary care settings and receive the bulk of their care there, making such settings critical for achieving preventive, health promotion, and chronic care goals (Institute of Medicine, 1996).

Demonstration projects in this category are intended to reinvent and substantially enhance primary care. A subset of the nation's community health centers (CHCs) would be selected to participate in this program aimed at constructing model primary care practices. CHCs already have a strong track record in chronic care management, electronic patient registries, and performance measurement. These demonstrations would build on existing competencies to:

- *Implement new models of care delivery*—Demonstration sites would be encouraged to experiment with systemic approaches to care delivery that would make use of interdisciplinary teams, ICT support, enhanced communication, lay health workers, new roles for patients and their families, and enhanced coordination across other health care settings and with social and other community-based services (e.g., mental health, housing, education and training, and employment).
- *Create sustained partnerships between patients and clinicians*—Through frequent communication by e-mail, telephone, and visits, patients should establish ongoing and supportive relationships with clinicians.
- *Provide support for patient self-management*—Patients should have access to tailored care guides (in either hardcopy or electronic form) including their treatment plan, reminders and monitoring charts, and educational materials. In leading-edge CHCs, Internet-based communication should also be available for e-visits, prescription refills, and scheduling of appointments (including same-day appointments).
- *Build a robust ICT infrastructure*—The most ICT-advanced CHCs should, over a period of a few years, become “paperless.” Electronic medical records should be readily accessible to CHC clinicians at the point of care, and eventually to all of a patient's providers in the community as broader ICT platforms develop (see the discussion below of ICT infrastructure projects). Scientifically based protocols and decision support systems should support decisions by patients (e.g., Internet-based tools to assist patients in tracking key indicators, such as blood pressure and hemoglobin A1c for diabetics) and clinicians.
- *Enhance care system design and supports*—Improvements in safety and effectiveness should be achieved through the conscious design of care processes to apply knowledge and tools from the human factors and engineering sciences.
- *Provide supportive financing*—Flexible payment modalities would be needed to allow CHCs (which currently receive primarily visit-based payments) to offer group counseling and education visits, Internet-based communication and care delivery, and more extensive care coordination. Demonstration sites should establish robust cost accounting systems capable of quantifying ongoing costs and savings

(associated with improvements in care processes and efficiency) for patients with various conditions, combinations of conditions, or specific health care needs.

DHHS would issue an RFP to the nation's approximately 859 CHCs and select about 40 to participate in projects in this category. Demonstrations would be 3 years in duration, with the expectation that measurable improvements in care processes would be achieved within 18 months. Demonstrations in this category are intended to be budget neutral over the long term, although federal support would be necessary to invest in ICT, establish and support the learning collaborative, and develop cost accounting systems. By 2006, the demonstration sites should open their doors to health care professionals from across the United States and even worldwide who would like to see primary care at its best.

ICT Infrastructure: A "Paperless" Health Care System

The establishment of an information and communications technology (ICT) infrastructure is fundamental to achieving the six quality aims enumerated earlier (Institute of Medicine, 2001b):

- In the area of *safety*, the availability of computer-based clinical information at the time of care delivery, together with clinical decision support systems, such as those for medication order entry, can prevent many errors from occurring (Bates et al., 1997, 1998, 1999).
- Care can be made more *effective* through the use of computer-based reminder systems that facilitate adherence to protocols (Balas et al., 2000) and computer-assisted diagnosis and management programs that improve clinical decision making (Durieux et al., 2000; Evans et al., 1998; Intermountain Health Care, 1996).
- With regard to *patient-centeredness*, the Internet has opened up many opportunities to assist consumers in playing a more active role in staying healthy and in making health care decisions by providing access to clinical knowledge through understandable and reliable Web sites, online support groups, customized health education, and disease management messages (Cain et al., 2000; Goldsmith, 2000).
- Internet-based communication (e.g., e-mail, telemedicine) between patients and clinicians and among clinicians can make care less episodic and more *timely*.
- More immediate access to computer-based clinical information, such as the results of laboratory and radiology tests, can reduce redundancy and improve both effectiveness and *efficiency*.
- There are also opportunities to improve *equity*, for example, through the use of electronic insurance enrollment programs that facilitate the enrollment of uninsured children eligible for coverage under the State Children's Health Insurance Program (SCHIP).

ICT is also a matter of national security (Tang, 2002). Computer-based clinical records, combined with Internet-based communication, can enable the following:

- Early detection and rapid response to bioterrorism attacks.
- Dissemination of up-to-date information to clinicians and patients on the clinical presentation of various chemical and biological threats, as well as practice guidelines for responding.
- Organization and execution of large-scale inoculation campaigns.
- Ongoing monitoring, detection, and treatment of complications arising from

exposure to biochemical agents or from preventive measures, such as immunizations.

The federal government has provided support for infrastructure development in the past. Following World War II, the federal government supported the development of the Interstate highway system, and years later, the Defense Advanced Research Projects Agency funded the work that led to the modern Internet (National Research Council, 1999; Weingroff, 1996). Similar to these prior national efforts, an ICT infrastructure is needed to enable fundamental reform of the public health and health care delivery systems, and the federal government will need to play a role in providing the necessary capital investment.

Demonstration projects in this category are intended to result in the establishment of a state-of-the-art health care ICT infrastructure in a state, sizable market, or multistate region that interconnects all providers and consumers. The ICT infrastructure would support the following:

- *Communication*—Internet-based communication between patients and clinicians and among clinicians, including e-mail, home monitoring, and teleconsulting.
- *Access to patient information*—For each patient, computer-based health and clinical information that is complete, organized, and available in real time to the patient and the patient's providers, while at the same time being confidential and secure.
- *Knowledge management*—Access to reliable, up-to-date information from the science base in forms that are useful to clinicians and patients.
- *Decision support*—Computer-aided decision support tools for patients and clinicians, such as reminder systems, prompts, medication order entry systems, and chronic disease management systems.

All demonstration projects in this category would involve three phases:

- A planning phase (months 1–6)—formation of a public-private partnership and development of an operational plan.
- An infrastructure building phase (months 7–24)—establishment of a secure platform for communication and sharing of clinical and other data between patients and providers and among providers.
- Expansion of applications (months 7-ongoing)—steady migration of administrative and business processes to the platform, development and application of knowledge management and decision support tools, and development of new e-health delivery modes.

These demonstration projects are intended to provide the initial nodes of a national health information infrastructure. A total of 8 to 10 demonstration projects should be funded in this category, with the expectation that a second generation would be funded in 2005.

One-time-only federal financial support would be required to establish the public-private partnership and the infrastructure. Health care providers should commit to making the necessary financial investments in support of ongoing maintenance and enhancement of the ICT infrastructure, and to redesigning care processes to take maximal advantage of this infrastructure. Public and private purchasers should offer the appropriate financial incentives to encourage and reward providers for making ongoing investments in ICT (e.g., higher fee-for-service payments or reduced regulatory burden for providers with computer-based records) and redesigning care processes. Some combined federal and state assistance to safety net providers would be needed to enable their full participation in the ICT infrastructure. The transition to computer-based clinical and other information would also have ripple effects through various administrative systems (e.g., enhancements

in coding and classification systems, utilization management processes), and these effects should be anticipated.

Demonstration projects in this category would be greatly facilitated by an immediate emphasis on the development of national data standards. All demonstrations should be required to conform to national standards where they exist. There should also be an expectation that these projects would lend their expertise to and share their technology with other states, and would provide valuable feedback on the robustness of national standards.

State Health Insurance: Making Affordable Coverage Available to All Americans

Contrary to popular belief, those without health insurance do not receive the medical care they need (Institute of Medicine, 2001a). The uninsured are less likely to receive preventive and screening services, are less likely to receive appropriate care to manage their chronic health conditions, exhibit consistently worse clinical outcomes, and are at increased risk of dying prematurely (Institute of Medicine, 2002a). Having one or more uninsured members in a family can have adverse consequences for everyone in the household and can negatively affect the financial, physical, and emotional well-being of all family members (Institute of Medicine, 2002c). As the numbers of uninsured grow, the effects, in terms of poorer overall health status, reduced productivity, increased disability, and possibly increased social services expenditures, are likely felt at the community level.

Demonstration projects in this category are intended to result in the availability of affordable insurance coverage to all Americans in a state. Each demonstration would involve two components:

- *Coverage expansions*—Demonstration projects might expand insurance coverage through either tax credits to be applied to an insurance plan, expanded eligibility for public insurance programs, or a combination of the two. Under the tax credit approach, the federal government would provide support to a demonstration site to be used for premium assistance, and the state would provide state tax credits to uninsured individuals. The state tax credit would likely be based on a sliding scale tied to income, and would need to be adequate to enable the individual to purchase a good insurance package. Under the approach of expanded eligibility for public insurance programs, the federal government would provide federal matching support for a significantly expanded eligibility program under a state Medicaid or SCHIP program.
- *Statewide electronic enrollment clearing-house*—During the first 18 months of a project, state governments would work in partnership with private insurers, DHHS, and others to establish an electronic clearinghouse for verification of insurance program eligibility and immediate enrollment of uninsured individuals. Although one of the principal objectives of establishing the clearinghouse would be to allow for immediate enrollment of uninsured individuals in one of the insurance programs developed through coverage expansion, the clearinghouse should yield benefits to all insured individuals and providers in a community. For example, in years 2–3, this electronic clearinghouse might be used for billing and payment of providers.

DHHS would issue an RFP to state governments, and a limited number of demonstration sites (three to five) would be selected. Demonstration projects should be 10 years in duration. DHHS would need to make this extended commitment to encourage states to undertake the very significant efforts envisioned in the areas of building public-private partnerships, developing ICT infrastructure, and redesigning public insurance programs.

Demonstration projects in this category are not budget neutral. Sustained funding would be required indefinitely, and both the federal and state governments would be expected to contribute resources. Recognizing the currently severe financial constraints of many states (Desonia, 2002), the federal government may need to provide the majority of additional resources necessary to conduct these demonstrations at least in the near term. There may be some offsets to the insurance expansion program, such as reduced need for Medicare disproportionate-share hospital payments and lower uncompensated care tax write-offs for for-profit providers.

Liability: Patient-Centered and Safety-Focused, Nonjudicial Compensation

The current liability system hampers efforts to identify and learn from errors, and likely encourages “defensive medicine.” Many instances of negligence do not give rise to lawsuits, and many legal claims do not relate to negligent care (Bovbjerg et al., 2001). Judgments are sometimes inconsistent with the medical evidence base (Eisenberg, 2001; Havighurst et al., 2001; Rosoff, 2001), and compensation is highly variable (Urban Institute, 1995). Legal fees and administrative expenses consume upwards of half the cost of liability insurance premiums (Cantor et al., 1997; Kakalik and Pace, 1986). Volatility in liability insurance markets has led to escalating malpractice premiums in certain geographic areas, precipitating closure of practices and shortages of certain types of specialists and services (American Hospital Association, 2002; Hopper, 2002; Price, 2002). The committee believes that changes in the liability system are a critical component of health care system redesign. Medical liability issues are technically complex, and policy debates have been dominated by powerful stakeholders. State-level demonstrations offer an opportunity to experiment with alternative models to the current judicial system.

Demonstration projects in this category would create injury compensation systems outside of the courtroom that would provide timely, fair compensation to injured patients and promote apologies and nonadversarial discussions between patients and clinicians. The demonstrations are also intended to create an environment that encourages providers to report and analyze medical errors and to involve patients in safety improvement activities. The financial exposure of providers would also be limited, thus contributing to stabilization of malpractice insurance premiums. This approach would replace the existing tort liability system with an alternative system for compensating patients who have experienced avoidable injuries, allow quicker payments to be made to many more injured patients, and reward providers who put effective programs in place to reduce medical injuries.

DHHS would issue an RFP to states, and a limited number of demonstration sites (four to five) would be selected. States would choose one of two nonjudicial claims resolution systems:

- *Provider-based early payments*—Offers predetermined limits on noneconomic damages, including pain and suffering, and federally subsidized reinsurance to self-insured provider groups that promptly identify and compensate patients for avoidable injuries.
- *Statewide administrative resolution*—Grants all health care professionals and facilities, however organized, immunity from tort liability under most circumstances in exchange for mandatory participation in a state-sponsored, administrative system for compensating avoidable injuries.

Demonstration projects would likely build on existing liability reform proposals, such as “avoidable classes of events” (Tancredi and Bovbjerg, 1991, 1992), “early offers of settlement” (O’Connell, 1982), and “scheduled ranges

of allowable noneconomic damages (Bovbjerg et al., 1989). States should engage in efforts to educate the public about trade-offs involved in liability reform, and help providers communicate more effectively with patients when errors occur.

Demonstration projects in this category would require modest federal start-up funds and appropriate state legislation. Within 1–2 years, benefits in terms of administrative efficiency should be realized. Longer-term benefits should include improvements in patient safety and malpractice insurance market stabilization.

NURTURING SUCCESS

The nation's mounting health care problems—rapidly rising costs, growing numbers of uninsured, safety and quality gaps, workforce shortages—threaten to destabilize the system, making it imperative to move expeditiously to achieve quality improvements. This is one of the reasons the committee is proposing a substantial portfolio of demonstration projects: 10–12 chronic care demonstrations, a primary care demonstration with 40 participating sites, 8–10 ICT infrastructure demonstrations, 3–5 state insurance coverage demonstrations, and 4–5 state liability demonstrations. The demonstrations involved in this initiative should reach out to large numbers of communities from all geographic regions and rural and urban areas, and engage them in finding solutions to these varied and complex challenges.

Efforts should also be made to identify and include in the demonstrations those sites that are today at the cutting edge in use of ICT infrastructure, adherence to 21st-century care delivery models, and administrative and clinical efficiency, and to spur them to evolve to higher levels of excellence. Communities that are currently more advanced in terms of ICT infrastructure might be ideal locations for multiple demonstrations, such as a hybrid demonstration encompassing the chronic care and uninsured categories, aimed at establishing highly effective e-health chronic care management programs, removing waste from the system, and rechanneling these resources to cover the uninsured.

The committee envisions that by 2005, the nation should have instituted the first generation of 21st-century community health systems, and by the end of the decade, should have made a decisive advance in reinventing health care delivery. For this to happen, the federal and state governments will need to do much more than plant seeds. Rather, the federal and state governments must work collaboratively with leaders from the private sector to nurture innovation and disseminate new discoveries.

Learning Collaboratives

To speed the process of change, DHHS should provide support to appropriate private or public organizations to establish learning collaboratives. The committee encourages DHHS to consider establishing demonstration-specific collaboratives given the complexity of the issues being addressed. The collaboratives would provide support to demonstration sites, in such forms as the following:

- Sponsoring forums for the exchange of information and joint problem solving across demonstration sites (e.g., traditional meetings and a full array of Internet-based audiovisual communication techniques).
- Providing access to knowledge and literature syntheses on the effectiveness of various services in support of local efforts to make evidence-based coverage and care delivery decisions.

Once demonstration projects were under way and knowledge and experience had begun to accumulate, the collaboratives would be responsible for disseminating what had been learned so that all could benefit.

Reshaping the Health Care Environment

In tandem with the demonstrations, federal and state efforts to reshape the broader health care environment would be essential. The current health care environment often confounds efforts to redesign health care. Nowhere is this more apparent than in the area of ICT.

Many environmental forces—including regulation, benefit and payment policies, and legal liability—fail to facilitate and sometimes block the adoption of 21st-century ICT (Overhage et al., 2002). For example, regulations stand in the way of progress when the federal and state governments fail to adapt old rules (e.g., state-based licensure of health professionals) to accommodate innovations (e.g., the practice of telemedicine across state borders). But perhaps even more important than barriers stemming inadvertently from outdated regulatory structures is the failure to put in place new ground rules for the emerging marketplace. Many believe that the absence of a strong federal role in establishing national data standards for health information has contributed to the sluggish pace of adoption of ICT in the health care sector (National Committee on Vital and Health Statistics, 2000). Another IOM committee addressing the issue of data standards will be releasing a report in fall 2003 (Institute of Medicine, 2002b).

Similar impediments to ICT exist in other areas. As noted, the benefit and payment policies of many health insurance programs fail to recognize and provide compensation for various e-health delivery modes (e.g., e-visits, e-consultations, remote monitoring of intensive care units). Moreover, uncertainty about liability implications has raised some concern about the use of e-mail communication between patients and clinicians (American Medical Association, 2001).

There is a critical need to examine existing environmental structures with an eye to removing such barriers, aligning incentives, and establishing new policies that would enable a rapid transition to a 21st-century ICT infrastructure. This work should proceed expeditiously in parallel with the conduct of demonstrations. If it does not, rapid upscaling from the initial set of demonstration projects would be impossible.

Evaluation, Transparency, and Accountability

As the country embarks on a radical transformation of what comprises one-seventh of the national economy (Levit et al., 2002), there should be a steadfast commitment to transparency and accountability. Although the committee strove to apply sound principles in identifying the demonstrations proposed in this report, the nation is embarking on a period of experimentation in health care delivery, and there will be a need to adjust course from time to time.

Ongoing evaluation is critical to understanding what does and does not work and why. Indicators of success should be defined before the demonstration projects begin. Planning for evaluation must begin in parallel with planning for the demonstrations.

The evaluative effort should identify which of the demonstrations within a given category are most successful and why. In addition, there should be an evaluation across the five demonstration categories. This global evaluation would help participating organizations, policy makers, researchers, and the broader practice community determine which demonstrations should be selected, and in what order, for rapid replication across the country. Another objective of the overall evaluation initiative should be to identify synergies among the various demonstration categories and strategies for combining the demonstration “building blocks” to achieve the strongest 21st-century health system.

Transparency—the sharing of information on strategies, tools, and techniques and their impact on performance—encourages the rapid spread and adoption of innovative technologies. Breakthrough knowledge and technology are rarely initiated on the first attempt. Important knowledge can also be gained from the sharing of information on community-based interventions that were less successful than expected.

Lastly, the sharing of cross-sectional and longitudinal performance information is the bottom line. It is through the ongoing tracking of the impact of various demonstrations on the six quality aims—safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity—that policy makers, health care professionals, and others would be able to determine whether their efforts to retool health care systems have been successful. And ultimately, the health system must be held accountable for demonstrating that resources are being used wisely to reduce the burden of illness, injury, and disability and to improve the health and functioning of the American people.

With both evaluation and accountability activities, there is a vital role for dissemination through formal and informal channels, and adequate financial support must be provided for these activities. Researchers should communicate their findings through journals and other publications. Presentations, speeches, and communication by means of policy-oriented briefs can provide a window into these demonstrations before they appear in scholarly journals.

WHAT SHOULD PATIENTS EXPECT?

In identifying a set of demonstration projects, the committee has been guided by a common vision of what care in the 21st century should be like from the perspective of patients.

These demonstrations should lead to a health care system in which patients' experiences would be very different from today's norm. For a typical patient with one or more chronic conditions requiring ongoing management, as well as preventive and acute care needs, the system should provide a continuous relationship with a personal clinician who functions with the support of a multidisciplinary team. Patients should be able to access care over the Internet, by telephone, and by other means in addition to face-to-face visits. There should be few concerns about safety, but in the event that a patient is harmed, the clinician should inform the patient immediately, apologize, and take action to mitigate the consequences. Care should not vary illogically from clinician to clinician or place to place. Each patient should receive the best that science has to offer, whether for ongoing treatment of a chronic condition or care for an acute episode. This does not imply one-size-fits-all care. Patients will have different preferences (e.g., watchful waiting versus surgical intervention for prostate cancer), differing needs for education and support, and differing constraints (e.g., a need for home care with family support versus short-term rehabilitative care).

Perhaps the greatest difference between the envisioned future system and the present reality is the role of patients themselves (Coulter, 2002). Profound cultural changes are necessary to allow patients to play as active a role in treatment decisions as they desire and to engage in effective self-management of chronic conditions. Such involvement will require a supportive environment—one that offers ready access to reliable and understandable sources of clinical knowledge and actively encourages health literacy by providing relevant information to patients (e.g., a primary care practice that forwards the most up-to-date information on practice guidelines, medication options and risks, and self-management to its patients with asthma).

In short, the 21st-century health care system should deliver far greater value than is currently the case. Patients have a right to demand—and health care leaders have an obligation to act now to ensure that they receive—care that is safe, effective, patient-centered, timely, efficient, and equitable. The committee believes the proposed demonstration projects would represent a substantial step in that direction.

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The Time for Change Has Come

In March 2001, the Institute of Medicine (IOM) released the report *Crossing the Quality Chasm: A New Health System for the 21st Century*, calling for fundamental change in the health care system (Institute of Medicine, 2001b). Responding to widespread and persistent, systemic shortcomings in health care quality, that report challenges the nation to undertake a major redesign of both the health care delivery system and the policy environment that shapes it. The recommendations in the *Quality Chasm* report did not come altogether as a surprise. The safety and quality of health care in the United States had been brought to the forefront with a renewed sense of urgency starting in 1998 through the release of three major reports on the quality of care. The IOM's National Roundtable on Health Care Quality had concluded that “the burden of harm conveyed by the collective impact of all of our health care quality problems is staggering” (Chassin and Galvin, 1998, p. 1004). The Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998, [Chapter 1](#)) called for a national commitment to improve quality after concluding that “today in America, there is no guarantee that any individual will receive high-quality care for any particular health problem.” And the conclusions of both of these national panels had been supported by the results of an extensive literature review conducted by researchers at the RAND Corporation, which encompassed publications in peer-reviewed journals between 1993 and mid-1997 and revealed evidence of systemic quality problems throughout the health care sector (Schuster et al., 1998). Moreover, these findings had been corroborated by studies that looked in more detail at the treatment of specific diseases (e.g., cancer) or focused on particular types of quality problems (e.g., errors) (Institute of Medicine, 2000; Institute of Medicine and National Research Council, 1999; Leatherman and McCarthy, 2002).

In an effort to chart a direction for health system improvement, the *Quality Chasm* report identified six national quality aims: health care should be safe, effective, patient-centered, timely, efficient, and equitable (see [Box 1–1](#)). These aims address not only the serious quality challenges noted above, but also the need to use resources more wisely.

BOX 1–1 QUALITY AIMS FOR THE 21ST-CENTURY HEALTH CARE SYSTEM

- *Safe*—avoiding injuries to patients from the care that is intended to help them.
- *Effective*—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse).
- *Patient-centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely*—reducing waits and sometimes harmful delays for both those who receive and those who give care.
- *Efficient*—avoiding waste, in particular waste of equipment, supplies, ideas, and energy.
- *Equitable*—providing care to all who could benefit that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

SOURCE: Institute of Medicine (2001b, p. 39–40).

In the 2 years since the release of the Quality Chasm report, the challenges confronting the health care system have probably worsened. Overall, national health spending has increased as a portion of gross domestic product and is expected to continue to do so for the remainder of the decade—from 13.2 percent in 2000 to approximately 17 percent in 2011 (Heffler et al., 2002). Employers are expected to see a 13 to 15 percent increase in their health care premiums in 2002, which will be the sixth straight year of rising premiums (Alliance for Health Care Reform, 2002; Center for Studying Health System Change, 2001). Medicaid is also experiencing cost increases—an average of 25 percent over the 2 years between 2000 and 2002 (Alliance for Health Care Reform, 2002).

These rising costs, in combination with the recent economic downturn, are expected to have a number of consequences. Increases in employers' health care premiums are likely to result in employers narrowing benefits and/or shifting a larger portion of costs to workers in the form of premiums or copayments. More employees may choose not to participate in employer-sponsored plans, and more employers, especially small businesses, may choose not to offer health insurance altogether.

Overall the number of uninsured people in the United States has been increasing for more than a decade—about one in six Americans is without coverage today (Institute of Medicine, 2001a). The uninsured do not receive the health services they need, and this gap has serious health, financial, and other consequences for both the uninsured individuals and their families (Institute of Medicine, 2002a, 2002b). Moreover, the growing numbers of uninsured place increased demand on public hospitals, academic health centers, community health centers, and other safety net providers that offer a sizable proportion of services to those who lack health insurance and cannot afford to pay.

There are also serious inequities in health care. A significant body of research reveals disturbing disparities in health care access and quality, especially for racial and ethnic minorities (Institute of Medicine, 2002c). Minorities receive a lower quality of health care than non-

minorities, even after controlling for such factors as insurance status and income.

The Quality Chasm report calls for changes at four levels—patient experiences, small-practice settings or microsystems that deliver care (e.g., provider groups, multidisciplinary teams), health care organizations that house the microsystems (e.g., hospitals), and the health care environment (e.g., payment policies, legal liability, regulatory processes) (Berwick, 2002). There is little doubt that change of this magnitude will be difficult to accomplish, but it is imperative that the process begin. This report sets forth a strategy for health system reform in which states are used as laboratories for the design, implementation, and testing of alternative redesign strategies. The set of demonstrations called for by this strategy addresses critical leverage points at each of the above four levels.

ORIGINS OF THIS REPORT

The disturbing trends in health care summarized above have not gone unnoticed by health care leaders. In June 2002, the Secretary of Health and Human Services met with representatives of The National Academies and expressed his concerns about the need to reverse these trends. It was agreed that workable solutions must be found quickly. Almost immediately, the IOM initiated a fast-track study with the objective of identifying interventions and approaches that showed promise for solving key problems, and recommending a set of demonstration projects to test these solutions. The Secretary expressed a strong interest in demonstration projects that might be conducted in collaboration with states starting in 2003.

To conduct this study, the IOM established the Committee on Rapid Advance Demonstrations in June 2002. The committee began by developing a set of criteria for use in selecting potential demonstration projects. Working groups for each of the five categories of demonstrations (enumerated below) were then convened to delineate the specifics of the potential demonstration projects. The full committee then met to finalize the set of proposed demonstrations.

CRITERIA FOR SELECTION OF DEMONSTRATIONS

The committee went through a multi-step process to identify potential demonstration projects. Each committee member was asked to identify potential demonstration categories. These categories were then discussed with overlapping or related areas being combined, resulting in a list of seven categories. Small working groups were formed to develop detailed descriptions of these seven categories. The full committee then discussed the seven categories further and narrowed the list to five. Categories that were considered, but not selected, are discussed later in this chapter.

The committee concluded that the demonstration projects as a set, and individually if possible, must be *bold and transformational*. Recognizing the gravity of the problems confronting the health care sector, as well as the need for a major redesign of health care processes, the committee focused on projects that would address the fundamental building blocks of the health care system.

To guide its work, the committee generated a list of criteria encompassing factors that would lead to a successful demonstration initiative (see [Box 1-2](#)). These criteria fall into two categories: those related to the intended results of demonstrations and those related to the likelihood of successful implementation.

The demonstration projects are intended to produce four results:

- *Improved health status for patients and populations*—The health care system of the 21st century should maximize the health and functioning of both individual patients and communities. To accomplish this goal, the system should balance and integrate needs for personal health care with broader community-wide initiatives that target the

entire population (e.g., prevention initiatives to address obesity). The health care system must have well-defined processes for making the best use of limited resources.

BOX 1–2 CRITERIA FOR SELECTING BOLD AND TRANSFORMATIONAL DEMONSTRATIONS

- **Criteria related to intended results of demonstrations**

- *Improved health status of patients and populations*
- *System improvements*
- *Reduced waste*
- *Stimulus for continued innovation*

- **Criteria related to likelihood of successful implementation**

- *Resonates with public and policy makers*
- *Broad base of support*
- *Recognizes and addresses barriers*
- *Builds on existing competencies*

- *System improvements*—In the 20th century, “bricks and mortar” constituted the basic infrastructure of the health care delivery system. To deliver care in the 21st century, the system must have a health information and communications technology (ICT) infrastructure that is accessible to all patients and providers. Over the past several decades, the health care needs of the population have been shifting from acute to chronic care (The Robert Wood Johnson Foundation, 1996). Although infectious diseases and acute care are still important, the vast majority of health care resources are now devoted to the ongoing management of chronic conditions. The processes used by the health system must be redesigned to emphasize the prevention and ongoing management of such conditions, and this redesign will require integration across sites of care and more sophisticated interfaces between the health care and social service sectors. Ready access to electronic medical records will be essential as well.
- *Reduced waste*—The 20th-century health care system is extremely wasteful, characterized both by clinical waste (e.g., unnecessary procedures, redundant laboratory tests) and administrative waste (e.g., compliance with the requirements of multiple insurance programs, which have not been standardized). Waste in the system must be reduced so resources can be rechanneled to meet the needs of patients and populations.
- *Stimulus for continued innovation*—The 21st-century health care system must have the built-in capacity to continuously change and accommodate innovations in knowledge and technology.

The change process will not be easy, and the demonstrations must be able to withstand many challenges. In identifying promising demonstration projects, then, attention must be paid to implementation issues, including the need to:

- *Resonate with the public and policy makers*—The demonstration projects must be understandable to the lay public and policy makers and must address their immediate concerns. The demonstrations should be structured to produce some tangible results in the short run.
- *Develop a broad base of support*—While a start-up investment may be necessary to assist in initiating change, most demonstrations should be budget neutral to the federal government over the long term or at least budget conscious. Careful thought should be given to the benefits and costs of the demonstrations to each of the major stakeholders, including patients, payers, and

providers. Financial and other incentives should be offered to key stakeholders, recognizing that major change is difficult to initiate and to sustain over long periods of time. Both the public sector (i.e., federal and state governments) and the private sector (e.g., philanthropic foundations) should provide up-front support for the conduct of the demonstrations.

- *Recognize and address barriers*—There will be many barriers to change—political, cultural, organizational, regulatory, and others. To be successful, demonstrations must identify and eliminate (or at least mitigate) these barriers.
- *Build on existing competencies*—There is no time to lose. The set of demonstration projects initiated in 2003 should produce the building blocks of a model 21st-century community health care system by 2006. The Department of Health and Human Services should select demonstration sites that have a high likelihood of making rapid progress.

The committee identified five major categories of demonstrations—chronic care, primary care, ICT infrastructure, state health insurance, and liability. These demonstration categories are discussed in turn in Chapters 2 through 6. For each category, multiple demonstration projects or sites are proposed for two reasons. First, within any given category, there would likely be a good deal of variability in design characteristics, which in turn will influence the likelihood of success or failure. For example, an ICT demonstration project in a predominantly rural state would likely have different characteristics than one in a large metropolitan area. Much can be learned from assessing the variability in design characteristics across different types of demonstration sites, and the effects of different designs on impact. Second, a sizable number of sites will be needed for this strategy to begin to have a measurable impact on the health system overall.

SUPPORTING AND EVALUATING THE DEMONSTRATIONS

As the demonstrations are launched, there must be comprehensive parallel efforts to support exchange among organizations undertaking the projects within a given demonstration, to evaluate the effectiveness of the approaches and interventions being practiced, and to broadly disseminate best practices thus identified. Such efforts are critical so that the demonstrations can achieve their full potential, and those that show the most promise can be rapidly replicated across the country.

The committee believes that learning collaboratives are the best mechanism for providing support for the demonstrations, and that such collaboratives should be formed for each of the five areas enumerated above. The learning collaboratives would be modeled after similar efforts at both the national and state levels, in which provider organizations have defined common goals and related performance measures and collaborated successfully—exchanging ideas and information—to improve clinical care for patients with diabetes, heart disease, and other conditions (Institute for Healthcare Improvement, 2002; Oswald, 2002). In the process, these organizations have successfully reengineered delivery systems to meet their quality improvement targets. These demonstration-specific collaboratives—which would exist virtually but would need some staff support—would be created by various organizations, depending upon interest and existing capacity. For example, the Health Resources and Services Administration might take responsibility for establishing the primary care collaborative, and the Centers for Medicare and Medicaid Services the chronic care collaborative. Of course, either or both agencies might choose to conduct the collaborative directly or to contract with a private-sector organization.

In addition to the learning collaboratives, the committee believes there needs to be a national evaluation and dissemination effort that would span all five demonstration categories and would include an advisory council with representatives from each of the areas. Given

the previous, related work of the Agency for Healthcare Quality and Research (AHRQ), it would be logical for this agency to take the lead in creating and nurturing such an effort. There would need to be adequate support to carry out this critical activity. Planning for the evaluation should begin at the same time as planning for the demonstrations. The criteria, performance measures, and data to be used in assessing progress must be defined in advance. Those involved in the effort would, over time, rigorously review quantitative and qualitative performance data from all of the demonstrations to assess effectiveness, and then extensively disseminate the best practices identified. They also would be able to discern how the five demonstration categories—potential building blocks for a reformed health care system— might fit together in the future. In addition, they would be well poised to identify the specific environmental obstacles that need to be addressed if demonstrations that prove successful are to be replicated on a larger scale.

Learning Collaboratives

As the demonstrations were being designed and initiated, the learning collaboratives would play an important supporting role in enabling the sharing of information about strategies, tools, and techniques (see [Box 1–3](#)). Such arrangements allow implementing organizations to benefit from the creativity and experiences of others, help guard against reinventing the wheel, and foster continuous learning. Learning collaboratives rely on regular contact, mainly electronic, and regular reporting of agreed-upon performance measures and qualitative progress reports. The collaboratives for these demonstrations would also provide informal and, to a lesser degree, formal technical assistance to the projects.

Once performance could be assessed, the collaboratives would provide a venue for discussions about what does and does not work, generating information necessary for midcourse corrections. This kind of transparency and accountability across the demonstration organizations could help foster a culture of change in a health care system that has firmly entrenched interests and has over the decades stubbornly resisted reform.

Evaluation and Dissemination

A critical step, whether carried out by AHRQ or another organization, is to identify up front what would constitute success in each of the five demonstration categories and to trans

BOX 1–3 COMPONENTS OF A LEARNING COLLABORATIVE

- Multiple organizations that make a commitment, signed by the top leader, to achieve measurable improvements on a given set of metrics and to support staff in their efforts to do so
- Shared goals and related performance measures
- Education and training on how a collaborative functions
- A coordinated, supportive network through which demonstration project staff can actively learn from each other
- Informal coaching for project staff
- Reporting of performance measures back to the collaborative and to the larger evaluation effort

SOURCE: Adapted from Oswald (2002).

late these ideas into quantifiable measures and associated data requirements. This effort is important because limited documentation exists on approaches that represent alternatives to the traditional ways in which care is delivered and financed. With such measures, a rigorous evaluation can be performed, including, where possible, a business case and economic analysis. This business case would help determine whether the demonstration benefits—as measured by clinical quality indicators and other measures—outweigh the costs, after accounting for up-front investment, particularly in the case of the ICT infrastructure demonstrations. It is essential to identify the interventions that are and are not successful and to understand what factors contributed to their success or failure. Such an evaluation can go a long way toward convincing powerful stakeholders about why and how they need to change.

The evaluative measures should help provide a strategic focus for the participating organizations that emphasizes the objectives of enhancing quality of care and reducing waste. To the extent possible, these clinical measures should be aligned with the process and outcome measures included in the National Health Care Quality Report, which is to be published by AHRQ in September 2003. As a conceptual framework, the National Health Care Quality Report will use the six quality aims enumerated earlier (i.e., safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity). Specific measures falling into one or more of these domains have been selected—for example, the percentage of diabetics with hemoglobin A1c under control and the percentage of heart failure patients prescribed an angiotensin-converting enzyme (ACE) inhibitor at discharge are measures of effectiveness (Agency for Healthcare Research and Quality, 2002). AHRQ is also developing the National Disparities Report, and measures from this report might be highly useful in assessing efforts to address racial, ethnic, and geographic disparities. If demonstration sites apply some or all of the same measures, it will be possible to gauge their progress in comparison with that of the nation as a whole.

At the close of the demonstrations, when it is clear which approaches and interventions have yielded best practices and on what specific dimensions, it will be time to get the word out to the broader community. The information disseminated should include all the documentation and analysis generated over the course of a project, including costs incurred, gains realized (particularly in the clinical realm), and operational issues confronted and overcome.

This would also be an appropriate time to identify environmental obstacles that must be confronted for best practices to take hold, including those that cut across a number of different demonstrations and therefore necessitate priority action. It is clear that future wide-scale implementation of the best practices resulting from the demonstrations will require more than Medicaid waivers, Medicare demonstration authority, or communities and states that are uniquely supportive of a given demonstration.

Those individuals involved in evaluating and disseminating demonstrated best practices will have an important vantage point. They will understand not only which of the demonstration building blocks are effective, but also how to combine them into a more comprehensive, synergistic reform model. They will understand where gaps exist and how to fill them. Finally, they will have detailed knowledge about environmental obstacles that need to be overcome and areas in which new ground rules need to be articulated for the seeds of the successful demonstrations to be sown and to take hold across the country, transforming the landscape of the health care system in the process.

OTHER POSSIBLE DEMONSTRATION AREAS

The committee believes that the five demonstration categories enumerated above represent a reasonable starting point from which to stimulate fundamental change in the health system, but they are not the only promising areas. The following are summaries of the two other areas that were seriously considered but

not selected, which may also represent good candidates:

- *Making America's hospitals safe and effective and a decent place to work*—Many if not most of the country's hospitals were built decades ago. Since that time, a great deal has been learned about how best to design work environments to promote patient and worker safety and improve efficiency. There have been many advances in information technology and medical devices that have specific space and other physical requirements. There have also been innovations in architectural design that result in environments more conducive to the provision of patient-centered care and workforce satisfaction. It should be noted that although the committee did not ultimately choose this category, some of the categories selected—particularly ICT infrastructure—could well lead to improvements in hospital care and environments.
- *Evidence-based, patient-centered pharmacy management*—Medications, both prescription and over-the-counter, represent one of the fastest-growing components of health care services. Safety is a serious concern, with many suffering preventable adverse drug events that could have been avoided through the use of computerized medication order entry systems (Bates et al., 1999). Cost is a major issue, given that Medicare and some other insurance plans provide little or no insurance coverage for prescription drugs. Numerous options exist for promoting evidence-based prescribing of medications and improving efficiency. Although pharmacy management was not selected as one of the five categories, the committee believes that projects in some of the selected categories—including chronic care, primary care, and ICT infrastructure—will have a highly positive impact in this area.

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2

Chronic Care: Reducing the Toll of Chronic Conditions on Individuals and Communities

SUMMARY DESCRIPTION

Demonstration projects in this category are intended to improve the quality of care for individuals with one or multiple chronic conditions in a particular geographic area. The projects are expected to result in changes at two levels: (1) redesign of the delivery system to provide care that is ongoing, is coordinated across multiple providers (both acute and long-term care providers and social services), and supports patient self-management; and (2) implementation of community-wide educational and other initiatives designed to improve population health. Changes in both areas will involve extensive use of 21st-century information and communications technology (ICT).

The committee suggests that demonstrations initially focus on Medicare beneficiaries, with the objective of expanding to all payers and even the uninsured over time. These demonstrations would be community-based (although some may be state-wide or even multistate efforts). Regardless of the geographic area, state collaboration would be important because many Medicare beneficiaries are also eligible for Medicaid. The Department of Health and Human Services (DHHS) would issue a Request for Proposals (RFP), and a limited number of demonstration sites (10–12) would be selected from the applicants. Applicants might be a consortium of providers (e.g., medical groups, hospitals), a health plan, an academic health center, a professional or trade association, or other established health care organization. Each selected applicant would receive a 1-year planning grant to accomplish two objectives: establishment of a public-private partnership and development of a 3-year implementation plan. The public-private partnership should encompass all major stakeholders, including consumer groups, health care professionals, health care and social service organizations, the public health community, state government, and others.

The demonstration projects would be 4 years in duration (including the 1-year planning period). Measurable improvements in care delivery should be achieved within 2 years. Over the long haul, the objective is to achieve a lessening of chronic illness burden in a community. These demonstrations are intended to be budget neutral over the long term (exclusive of up-front federal capital investments in ICT).

BACKGROUND

A chronic condition is defined as “a condition that requires ongoing medical care, limits what one can do, and is likely to last longer than one year” (Partnership for Solutions, 2002a, p. 1). An estimated 120 million Americans have one or more chronic conditions; more than half of these people have multiple such conditions. People with chronic conditions account for the majority of overall health care spending. Chronic illness affects all age groups and also leads to reduced worker productivity and lost time from school for children (National Academy on an Aging Society, 2000). Some chronically ill patients have inadequate or no health insurance, and these individuals receive less care and have higher out-of-pocket expenditures than they should (Partnership for Solutions, 2002b).

Some patients with chronic conditions experience disability and functional limitations (e.g., hearing loss, visual impairment, loss of mobility), including cognitive impairment and other geriatric syndromes that severely undermine quality of life and pose a threat to independence. The 5 million Medicare beneficiaries who are under age 65 and disabled fall into this category, as does an increasing proportion of over-65 Medicare beneficiaries, sometimes referred to as the “frail elderly” (Gluck and Hanson, 2001) (see [Table 2–1](#)).

These individuals require ongoing treatment of a specific disease(s), but this treatment is not sufficient. Careful management of geriatric

TABLE 2–1 Prevalence of Chronic Conditions, Disability, and Functional Limitations

Age	65–74	75–84	85+
None of the Three Problems	17%	10%	4%
Chronic Conditions Only	51%	37%	17%
Disability Only	2.1%	2.1%	3%
Functional Limitations Only	*	0.4%	*
Any Two of the Three Problems	22%	32%	32%
All Three Problems	8%	19%	44%

SOURCE: Partnership for Solutions, Johns Hopkins University analysis of 1996 Medical Expenditure Panel Survey, unpublished data; also in American Association of Retired Persons (2002).

NOTE: This table makes use of the following definitions to estimate the prevalence of three types of health problems—chronic conditions, disability and functional limitations. Chronic condition—has lasted or is expected to last 12 months or longer and either (1) involves ongoing medical care or (2) places limitations on age-appropriate task performance, basic self-care, independent living skills, or social interactions. Functional limitation—the need for help or supervision with any activities of daily living or instrumental activities of daily living. Disability—includes any one of the following characteristics: (1) the use of assistive technology; (2) difficulty walking, climbing stairs, grasping objects, reaching overhead, lifting, bending or topping, or standing for long periods of time; (3) any limitation in work, housework, or school; (4) social/recreational limitations; (5) cognitive limitations, such as confusion or memory loss, or decision-making problems that lead to interference with daily activities or require supervision to ensure one’s safety; (6) vision problems; and (7) deafness or difficulty in hearing.

syndromes (e.g., cognitive decline, lack of resilience, undernutrition, loss of mobility) and attention to the patient's social and environmental circumstances are needed to preserve maximum levels of independence and slow the progression of disability (Buchner and Wagner, 1992; Welch et al., 1996).

For many with chronic conditions, navigating the complex health care system can be difficult, sometimes even distressingly so. The chronically ill typically require care from multiple clinicians (both primary care providers and specialists) and across multiple sites (e.g., hospital, nursing home, in the community with or without home care), and this care is generally not well coordinated. Moreover, in the current highly decentralized, paper-driven health care system, clinical information (e.g., diagnoses, test results, medications, specialty consults) is frequently unavailable when needed.

The chronically ill experience many problems with access to care and avoidable complications of care. In a recent survey of chronically ill individuals, about three of four respondents reported difficulty with obtaining medical care; specifically, many experienced difficulty getting care from a primary care physician (72 percent) or a medical specialist (79 percent), as well as obtaining prescription drugs (74 percent) (Partnership for Solutions, 2002c). Nearly 20 percent of Americans report problems communicating with their clinicians (Collins et al., 2002). The lack of coordinated care results in chronically ill people receiving inconsistent and contradictory information and experiencing many avoidable complications (Partnership for Solutions, 2002a, 2002c). All of these problems are likely exacerbated for those chronically ill who are disabled, frail, and/or have cognitive impairments.

Improving care for people with chronic conditions must be a high priority, but improved care alone is not enough. The health care system must focus far more attention and resources on community-wide interventions aimed at preventing or at least slowing the onset and progression of these conditions. About 95 percent of health care expenditures is currently devoted to direct medical care services, mainly for the treatment of people with chronic diseases (McGinnis et al., 2002). Very few resources are devoted to reducing the unhealthy behaviors that currently contribute to about 40 percent of deaths in the United States (McGinnis et al., 2002), including poor dietary habits, lack of physical activity, smoking, and excessive alcohol consumption.

The health care delivery system must take greater responsibility for promoting healthy lifestyles. The personal health care system has a role to play in educating individual patients and providing supportive interventions (e.g., counseling, nicotine patches), but the personal health care system reaches only those who seek health services, many of whom have already suffered serious and irreparable damage as a result of poor health behaviors. Broader-based interventions are needed to reach the entire population of a community before harm has occurred.

It is unrealistic and inefficient to expect providers acting individually to address all population concerns. They do not have the financial resources, incentives, or expertise to do so. Some health plans have attempted to focus greater attention on the prevention of chronic diseases for their members, but many people are not enrolled in comprehensive health plans. In many communities, moreover, the frequent turnover of enrollees attenuates incentives to focus on interventions that can produce substantial long-term benefits in terms of improved health status. Collaborative community-wide efforts are needed, as are specific interventions to align provider financial incentives in ways that reward the provision of high-quality care.

GOALS

The primary objective of the demonstration projects in this category is to improve the quality of care provided to the chronically ill and to reduce the burden of disease and disability in a community. Specific goals include the following:

1. The right care at the right time in the right setting

- State-of-the-art, science-based care for the patient's condition or conditions
- Elimination of underuse (i.e., the failure to provide services from which the patient would likely have benefited) and overuse (i.e., the provision of services that expose patients to more harm than good)
- Emphasis on primary, secondary, and tertiary prevention
- Enhanced management and coordination of chronic conditions (e.g., ease of access to appropriate providers)

2. Improved patient safety

- Decrease in errors
- Decrease in avoidable hospitalizations
- Improved medication management

3. Enhanced patient role and satisfaction

- Promotion of shared responsibility for health (e.g., support for healthy behaviors and lifestyles)
- Improved self-management of chronic conditions
- Increased health literacy and understanding of care plans
- Informed decision making
- Improved satisfaction of patients and informal caregivers (including managing burden and providing respite for informal caregivers)
- Customized care—not one size fits all, but care that takes account of patient preferences, culture, family circumstances, and needs

4. Enhanced workforce productivity

- Development of effective multidisciplinary teams
- Improved communication among team members and between patients and team members
- Shared values and goals among team members
- Increased satisfaction on the part of health professionals

5. Reduced clinical waste

- Decrease in overuse
- Reduced use of services to treat complications arising from errors

6. Improved coverage

- More appropriate benefit package for the chronically ill (e.g., coverage of prescription drugs, educational and support services)
- Coverage of benefits for which there is evidence to substantiate effectiveness
- Coverage for some chronically ill individuals who otherwise would have been uninsured

7. Establishment of a strong public-private partnership

- Healthier community—measurable decrease in the incidence of chronic conditions and the associated disease burden
- Improved capabilities at the state and community levels to address health care issues and to collaborate and invest in health system improvements

DEMONSTRATION ATTRIBUTES

It is anticipated that demonstration projects in this category would focus initially on a subset of Medicare beneficiaries, perhaps those with one or more conditions requiring intensive ongoing management. Over time, however, the projects would expand to include all of the chronically ill. Demonstrations would include interventions falling into two broad categories: (1) redesign of the personal health care delivery

system, and (2) establishment of community-wide health promotion initiatives. Initially, most attention will likely be focused on the first category. Over time, the demonstration sites should shift attention and resources to the second category, which has much potential to reduce the burden of chronic illness in a community.

In the area of personal health care, demonstration sites would be expected to establish comprehensive chronic care management programs including the following elements:

- Evidence-based treatment programs for all of the leading chronic conditions that affect the population being served. Many individuals involved in the demonstration project will have more than one condition requiring active management.
- Services to detect and minimize the consequences of geriatric syndromes, including a decline in cognitive (e.g., loss of memory) and physical (e.g., visual loss, hearing impairment) functioning.
- Services to meet the preventive, acute, long-term care, and other health care needs of patients with chronic conditions.
- Extended outreach and coordination with social and environmental services, provided through formal (e.g., meals on wheels, senior centers, transportation services, assisted-living environments) and informal (e.g., faith-based institutions, family and friends) means.

With regard to population-level health interventions, prevention and management of chronic conditions often involve modifications in behavior (e.g., proper diet, exercise, avoidance of nicotine, moderate use of alcohol). Community-wide educational campaigns and other population-level interventions may be the most effective way of accomplishing these objectives.

Each demonstration project would involve five components: (1) establishment of a coordinating structure (or strengthening of an existing one), (2) development of chronic care management programs, (3) ICT support, (4) innovative approaches to payment and to recognizing and rewarding achievement, and (5) learning collaboratives and community-wide educational efforts. These components are discussed in turn below

Establishment of a Coordinating Structure

As discussed above, demonstration projects in this category are intended to lead to the establishment of exemplary chronic care management programs for individuals and community-wide initiatives focused on improving population health. Accomplishing these objectives will require new structures that extend beyond the traditional personal health care delivery system.

During the first year of the project, grant recipients would be responsible for establishing a broad-based coordinating structure with participation from all important stakeholders, including consumer groups; the medical community; hospitals; health plans; the public health community; local, state, and federal governments; the business community; and others. This coordinating structure should have (or develop) the capability to (1) provide strong leadership for the demonstration, (2) work with providers to organize chronic care management programs, (3) develop necessary ICT infrastructure, (4) implement payment and quality monitoring programs, and (5) provide knowledge management support and sponsor learning collaboratives.

The committee recognizes that 1 year is an ambitious time frame for building a coordinating structure, and encourages DHHS to consider selecting sites where some form of coordinating structure already exists. For example, a collaborative effort aimed at achieving sizable improvements in cancer care has been established in the state of Georgia (Georgia Cancer Coalition, 2002), and a diabetes initiative is

under way in New York State (IDEATel, 2002). In other communities, an initial grant recipient may be an academic health center, a consortium of providers, or a professional or hospital association with the potential to provide leadership and a commitment to establishing a broader-based structure; in these instances, however, the planning phase may need to be longer.

In communities where medical groups, health plans, or other providers have developed or are seeking to develop chronic care management programs, such programs might serve as a strong foundation for broader community-wide efforts. The Centers for Medicare and Medicaid Services (CMS) also has disease management and coordinated care demonstration projects under way that focus on improved care delivery for specific beneficiaries through changes in payment, benefits, and organization of care (Centers for Medicare and Medicaid Services, 2002; U.S. Department of Health and Human Services, 2001). These efforts, too, might represent a strong foundation for a more expansive, community-wide effort. These types of health care delivery programs alone would not qualify as a demonstration. However, they might well constitute the first step toward establishing community-wide efforts with the capacity to provide coordinated health and social services, as well as community-wide educational and public health campaigns, and to cultivate a learning environment with the potential to contribute to greater health care redesign within a community (and ultimately nationwide).

During the first year, grant recipients would also be responsible for developing a comprehensive plan for the 3-year implementation phase of the project. This planning effort should result in a detailed operational plan specifying the patients to be enrolled, services to be provided, subcontracts to be initiated with vendors, clinicians and institutions to be involved, payment mechanisms, and community outreach and educational endeavors. If waivers from various state or federal regulatory requirements will be required (e.g., waivers from states' licensure requirements for health professionals to enable telecommunications services across a two-state demonstration project, or waivers from state scope-of-practice acts to allow for multidisciplinary team management), these should be identified and secured within the first 12 months.

Strong leadership will be critical to the success of all the demonstration projects given the profound cultural and organizational changes that must occur within the health care community. There should also be a willingness on the part of health care professionals and organizations to develop new relationships, especially ones that go beyond the boundaries of the traditional medical care system. The mission and operations of health care organizations would need to reflect a greater commitment to both individual health care and population health initiatives. In many communities, health care providers would need to strike a new balance between collaboration and competition. It would be the responsibility of the leadership of the coordinating structure to identify community-specific barriers and to identify solutions (e.g., establishing coordination across insurance plans, forging relationships between existing disease management programs and the overall chronic care initiative).

Development of Chronic Care Management Programs

Unlike much acute, episodic care, effective care for the chronically ill is a collaborative process, best carried out through a systematic approach (Von Korff et al., 1997). Wagner et al. (1996) have identified five important elements of chronic care programs:

- *Evidence-based, planned care*—Guidelines and protocols applicable to each of the leading chronic conditions that affect the population being served must be incorporated into practice.
- *Multidisciplinary team approach*—Delivery of care is generally through a multidisciplinary team (both health and social services) with well-defined relationships and responsibilities. Members of the team must have

flexibility in allocating time and resources to meet the needs of each patient for education and support.

- *Patient information*—There must be systematic approaches to providing counseling, education, information feedback, and other support to patients (Brown, 1990; DeBusk et al., 1994; Mullen et al., 1987).
- *Clinical knowledge and expertise*—Both patients and clinicians should have ready access to knowledge and specialized expertise through such means as teleconferencing, referrals to specialists, computer decision support systems, and collaborative care models (in which primary care providers and specialists practice together at least some of the time) (Barton and Schoenbaum, 1990; Katon et al., 1995; Litzelman et al., 1993; McCulloch et al., 1994; Vinicor et al., 1987).
- *Supportive information systems*—Effective mechanisms for sharing information among team members and between patients and team members (e.g., computer-based records, registries) are critical. Also helpful are systems that provide reminders for preventive care and necessary follow-up, and track patient compliance with treatment plans (Dickey and Petitti, 1992; Turner et al., 1990).

The coordinating structure would be responsible for working with groups of providers in the community to organize chronic care management programs. In nearly all cases, extensive team building would be required to forge closer and more collaborative working relationships among various types of health care professionals. A high priority should be placed on designing care processes that are sensitive and accommodating to the needs of health care professionals. The greatest success would come from the alignment of well-designed systems accompanied by financial and other incentives to motivate providers. Attention should also be focused on the design of programs and care processes that have the potential to reduce health disparities.

In some communities, disease management programs sponsored by medical groups, health systems, or health plans may serve as initial building blocks. However, the chronic care management programs in these demonstration projects are intended to differ from typical disease management programs in several important ways. First, these programs are intended to serve beneficiaries with many different chronic conditions (and often with multiple conditions), while disease management programs tend to be limited to a specific disease. Second, these programs should provide for all of patients' preventive, acute, and chronic care needs, not just services for the treatment of a specific disease. Finally, those who develop programs would be required to participate in collaborative community-wide efforts focused on prevention and health promotion.

Information and Communications Technology Support

A major component of these demonstrations should be the expanded use of ICT to improve care for the chronically ill. Specifically, ICT would enable the following improvements:

1. Better communication

- Web-based dissemination of knowledge (relative to both specific diseases and chronic care management)
- Sharing of learning experiences between patients and clinicians, among clinicians, and among patients
- E-mail communication between patients and clinicians and among clinicians
- Telemedicine, including the use of home monitoring devices (e.g., for glucose monitoring) that transmit results via the Web

- Provision of Web-based reminders (e.g., for flu shots, physical activity, and diet) to patients and clinicians
- Electronic health risk appraisal and feedback reports
- Ongoing patient communication with support groups
- Electronic access to patient records (as information becomes computerized), with appropriate safeguards for patient confidentiality

2. Chronic care registries

- Central repository for patients' care plans and other important health, clinical, and service information
- Patients' access to their care plans in hardcopy or electronic form
- Real-time access to all information in the repository by patients and their providers to improve coordination and care delivery
- Tracking and monitoring of patients' progress

3. Medication order entry systems—computerized prescriptions with centralized repository of information for patients

4. Creation of a “paperless” clinical environment

- Reporting of results from laboratories and imaging centers
- Consults with specialists
- Emergency encounters
- Clinicians notes

5. Advanced decision support systems for clinicians and patients

Development of this ICT infrastructure would likely take place in phases over the duration of the demonstration, but there should be a comprehensive plan and timeline for the development and deployment of various capabilities. All demonstrations should involve major advances in the first three areas listed above during the 3-year project.

Some consideration should also be given to building on efforts already under way. Potential applicants that have already made progress in the first three areas would be expected to develop more advanced ITC capabilities in the last two areas above during the demonstration period. There might also be some opportunity to transfer the knowledge and technology developed in a specific location to new demonstration projects starting up in other locales.

One example of an initiative already under way is the diabetes telemedicine collaborative in New York State (IDEATel, 2002). This project is led by Columbia University and includes several major medical centers, hospitals, and a home for the aged located in New York City and upstate New York; CMS; and the American Diabetes Association. CMS has provided a \$28 million grant in support of this project, and various commercial vendors have made in-kind contributions, including home monitoring equipment and high-speed Internet lines. A total of 1,500 patients have been enrolled in this randomized controlled trial; one-half are in the intervention group and the other half in a control group. Computers with devices that read blood sugar, take pictures of skin and feet, and check blood pressure are placed in the homes of those in the intervention group. Patients are responsible for checking their blood sugar, blood pressure, and other factors. They receive educational material on diabetes and specific recommendations, reminders, and instructions for managing their disease. The program builds on Columbia University's Web-based clinical record technology and uses an automated care guideline system to analyze patient data and issue automated alerts to clinicians when certain information varies from predetermined values. Patients have access to their own clinical information.

Innovative Approaches to Benefits, Copayments, Provider Payment, and Accountability

Initially, these demonstration projects should focus on Medicare beneficiaries. Each site would establish eligibility criteria for participation in its demonstration project (e.g., beneficiaries with one or more of the five most common chronic conditions). Some sites may prefer to include all beneficiaries with chronic conditions from the beginning, while others may wish to start with a smaller subpopulation and expand at a later date.

A major component of all of the demonstration projects in this category would be the flexibility to innovate in such areas as benefits coverage, beneficiary copayments, provider payments, and accountability. Careful design, ongoing evaluation, and sharing of learning experiences in these areas of program design would be critical.

Within the overall constraint of budget neutrality, demonstration sites should be given the flexibility to use Medicare funds in ways that would yield the greatest benefits in terms of improved patient and population health. One financing approach would be for CMS to provide the coordinating structure, with a capitation payment to cover all the care needs of the participating patients (i.e., preventive, acute, and chronic care). The coordinating entity should have the flexibility to provide the expanded benefits necessary for chronic care management.

Regular Medicare does not cover certain services that are often important for care of the chronically ill, including patient education and support, telemedicine (e.g., e-mail, home monitoring), and prescription drugs. For example, it may be possible through the coverage of prescription drugs and frequent monitoring of patients via e-mail to decrease office encounters and hospital episodes. In establishing an appropriate capitation payment rate for a demonstration site, CMS should strive to achieve budget neutrality and to correct geographic inequities in payment. The committee cautions CMS not to attempt to address cost concerns by setting capitation rates at levels that are unreasonably low or below current fee-for-service (FFS) expenditure rates. Participation of health plans in Medicare + Choice program, which also uses capitated payments, has been declining and this may be because payment rates are lower than FFS expenditures and these plans are expected to provide enhanced benefits. CMS might also consider establishing a national payment rate for chronic care demonstration sites, with a geographic adjustment for differences in the cost of practice. This would correct for geographic variability in payment rates that is not tied to differences in cost of practice.

The coordinating entity in each demonstration site would be responsible for (1) determining the amount of funds to be used for community-wide prevention and other initiatives, and (2) establishing payment methods for chronic care management programs. It would be important for each demonstration site to establish robust cost accounting systems at the level of both the coordinating entity and the providers of care.

Demonstration sites would be encouraged to experiment with various provider payment methods, especially ones that reward performance achievement. Numerous options have been identified for motivating providers to improve their performance (Bailit Health Purchasing, 2002). For example, a capitation payment to a chronic care management program that enrolls beneficiaries with diabetes might be contingent, in part, upon achievement of certain predetermined performance thresholds (e.g., more than 85 percent of beneficiaries have had an annual eye and foot exam; 75 percent have LDL cholesterol levels below 100; less than 20 percent have hemoglobin A_{1c} above 8). Another option is to provide chronic care management programs with annual bonuses (e.g., 2–5 percent of capitation payments) based on achieving certain performance goals. Each demonstration site should also ensure that payments to providers are properly risk-adjusted to reflect the more extensive care needs of the

frail elderly, the disabled, and those with multiple chronic conditions.

Demonstration sites should consider providing stronger incentives to patients to encourage self-management. To a great extent, patients play a critical role in the ongoing management of chronic conditions, which frequently require major lifestyle changes, including improved diet, exercise, and smoking cessation. Patient incentives might include variable cost sharing, such as discounted Medicare Part B premiums for those who follow care plans. Of course, all chronic care management programs should provide patients with the tools and medical and social support necessary to encourage healthy behaviors.

Demonstration projects should engage in various forms of public reporting of progress and quality data. Each demonstration project should produce a progress report describing programmatic accomplishments. Each project should also be accountable to the public for showing improvements in the functioning and satisfaction of the chronically ill enrolled in the program, and over the long run, reductions in the state-wide (or community-wide) incidence and prevalence of chronic conditions. Demonstrations might also involve public reporting of comparative performance information on organized chronic care management programs and providers. Although much of the focus of the chronic care demonstrations should be on redesigning care delivery, the committee believes these efforts would be more effective if undertaken in an environment that provides ongoing feedback to clinicians and patients.

Learning Collaboratives and Community-Wide Educational Efforts

Each demonstration project should include efforts to assist clinicians and patients in gaining access to scientific knowledge, practice guidelines, certified protocols, identified best practices, and decision support tools. Some consideration should be given to whether the National Library of Medicine and the Agency for Healthcare Research and Quality might provide special knowledge management assistance to demonstration sites in the form of syntheses of the evidence in selected areas, special chronic care Web sites for clinicians and patients, and a rapid response system for key clinical or treatment questions that might arise during the demonstration project.

DHHS, in collaboration with private foundations, should ensure that each demonstration site has the resources necessary to establish a state-wide learning collaborative for clinicians involved in the care of patients with selected chronic conditions. In such collaboratives, participating members would commit to common goals and related performance measures for improving chronic care. DHHS should also provide resources needed to sponsor public education efforts targeted at both consumers and clinicians, with an emphasis on primary prevention, early identification, and slowing of the rate of progression of chronic diseases. Special attention should be focused on cultivating patient- and clinician-led quality improvement efforts. The Robert Wood Johnson Foundation is providing support for a limited number of regional chronic care learning collaboratives, and there might be an opportunity to build on this synergistic effort already under way (Improving Chronic Illness Care, 2002).

POSSIBLE DEMONSTRATION EXPANSIONS

Although the primary focus of these demonstrations is on Medicare beneficiaries, all demonstration projects should have a tentative plan from the beginning for expansion beyond Medicare to other public and private payers. The structures and programs developed by the demonstration projects are intended to benefit all people in the community—both those with chronic conditions and those without who might delay or avoid the onset of such conditions through primary prevention. It is also important to note that many people with chronic conditions are covered by more than one insurance program (e.g., dual eligibilities under Medicare and Medicaid) or will move from one insurance

plan to another during the course of a project with changes in eligibility status (as regards age, income, and employment). The goal is to develop community-wide care delivery programs and supports that are available to all people, thus minimizing or avoiding some of the disruptions in care delivery and patient-clinician relationships that often result from changes in insurance coverage.

Some demonstrations might also expand beyond insured populations to provide coverage or services to certain uninsured individuals (e.g., uninsured cancer patients). Studies consistently document that sizable amounts of health care resources represent overuse (i.e., about 20 to 30 percent of patients receive services that expose them to more potential harm than good) (Schuster et al., 1998). Medical errors, another type of quality problem, also consume health care resources—resources used to treat those who are harmed as a result of those errors. One objective of some of the demonstration projects in this category may be to identify ways to remove “quality waste” (i.e., overuse and errors) from the system, and redistribute these resources to care of the uninsured (who frequently experience underuse, whereby patients do not receive services from which they would likely have benefited). DHHS and state governments should also consider providing grants or other financial incentives to encourage demonstration expansions aimed at the uninsured.

Although such expansion to all payers and/ or the uninsured would be difficult for most demonstration sites to accomplish within the 4-year demonstration time frame, it may be possible to identify some sites that have already taken steps in this direction and to build quite rapidly on these previous accomplishments. For example, an initiative in Maine—Healthy Future Partnership for Quality—is now in its 5th year (Healthy Futures and the Maine Center for Public Health, 2002). This community-based health reform initiative serves six small towns in central Maine. Patients enrolled in the program include both insured and uninsured individuals, with services for the uninsured being covered by a 10 percent surcharge on the fee for each insured participant. The surcharge is paid by the participating insurers, which include Anthem Blue Cross/Blue Shield, Cigna HealthCare, MaineCare (the state Medicaid program), and Hannaford Brothers. Thus far, the initiative has focused on patient education (regarding health behaviors, prevention, and disease management) and improved access to primary care and preventive services.

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3

Primary Care: 40 Stellar Community Health Centers

SUMMARY DESCRIPTION

Through implementation of proven models for redesigning care delivery, select community health centers (CHCs) would reinvent and substantially enhance primary care—encompassing preventive, acute, and chronic care—for all CHC patients. These CHCs would then serve as national models for practices across the country for the delivery of stellar primary care. The Department of Health and Human Services (DHHS) will issue a Request for Proposals (RFP) to the nation's approximately 859 community health centers and select 40 of these for demonstration projects in this category (see [Box 3-1](#)).¹

The demonstrations would be 3 years in duration, with the expectation that measurable improvements in care delivery processes would be realized within 18 months. All the demonstrations would include support for CHC leaders and clinicians to redesign care delivery and evaluate subsequent quality improvements and cost reductions. Each demonstration would provide the information and communications technology (ICT) infrastructure necessary to bring about this wholesale transformation and align financial incentives to support the care delivery changes instituted. Finally, the demonstration sites would be provided the resources necessary to disseminate what has been learned to other CHCs, primary care practices across the country, and the policy community.

¹The authors use the term CHCs, defined when this type of entity was first established. This term encompasses CHCs that do and do not receive Section 330 grants (see [Box 3-1](#)). In 1992, an alternative term, federally-qualified health centers (FQHCs) was established and refers to CHCs eligible to receive Medicare payment for services provided (these same CHCs may or may not receive section 330 grants) (*Federal Register*, 1992). In this chapter, the term CHCs is intended to encompass FQHCs.

BACKGROUND

Primary care is a logical focus for demonstrations because it is an essential part of an effective health care system, a system that ideally emphasizes patient-centered, high-quality care while using resources efficiently (Institute of Medicine, 2001). Specifically, research has shown that higher levels of primary care in a geographic setting are associated with lower mortality rates, probably because primary care enables patients to obtain needed services before they are seriously ill, can improve health by helping patients control chronic conditions, and can provide sustained relationships between patients and clinicians (Gonnella et al., 1977; Shi, 1992). In addition, primary care settings are where the large majority of patients enter the health system and receive the bulk of their care, making such settings critical for achieving key preventive, health promotion, and chronic care goals (Bureau of Primary Health Care, 2002d; Institute of Medicine, 1996).

All CHCs—those that do and do not receive Section 330 grants—would be eligible to apply for a demonstration grant, with up to 40 CHCs being selected as demonstration sites. If more than one CHC in a given state received a demonstration grant, they could channel a portion of their funds to the state-level primary care association. Association staff could provide services such as data collection and reporting, infrastructure services, and patient education materials for CHCs within their state.

Selecting CHCs as a mechanism to enhance primary care makes sense for a variety of reasons. CHCs are an established network of primary care practices. They have a strong base of innovation upon which to build that includes well-developed programs for the management of chronic disease; an existing ICT infrastructure that supports the collection and reporting of performance measures; recognition of the importance of wraparound services, such as patient education and self-management; and established relationships with government,

BOX 3–1 HOW CHCS ARE PAID

Most CHCs receive Section 330 grants to enable them to provide services to the medically underserved, including the uninsured (*Federal Register*, 1996), with a small number of those that do not still meeting Section 330 eligibility requirements. These CHCs do not receive such grants because of funding constraints or because they do not want to meet increased reporting and financial requirements (Institute of Medicine, 2000).

Both types of CHCs, however, receive funding under the same Medicare and Medicaid formulas (Bureau of Primary Health Care, 2002c). They are paid on the basis of reasonable cost for providing services to Medicare beneficiaries. With respect to Medicaid, they are paid, at a minimum, on a per visit basis under a prospective payment system (PPS) that went into effect in 2001 as part of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act. Using 1999 and 2000 CHC cost information, each state calculates a minimum rate that is 100 percent of the average of each CHC's reasonable costs. While each CHC has a unique rate, annual adjustments to this rate are tied to the Medicare Economic Index factor (Bureau of Primary Health Care, 2002a; Koppen, 2001).

If CHCs contract with Medicaid managed care plans, they receive payments as

communities, and public health organizations. These features likely contribute to CHCs providing care that is at least as good as, and in many cases superior to, the overall health system in terms of better quality and lower costs (Falik et al., 1998; Institute of Medicine, 2000; Partridge, 2001; Regan et al., 1999; Starfield et al., 1994).

does any other provider, which may take the form of capitated payment, discounted fee for service, or other arrangements. However, the Balanced Budget Act provides a wraparound payment to CHCs equal to the difference between their cost of providing care to Medicaid patients and the amount they receive from the plans (Koppen, 2002).

A revenue profile for the nation's CHCs in 2000 is shown in the following table, but excludes those CHCs that do not receive Section 330 grants. Of the nation's 859 CHCs, 111 do not receive such grants.

Type of Revenue	Percentage of CHCs*
Medicaid	34
Medicare	6
Section 330 and other Federal Grants	25
Nonfederal grants (state, foundations)	14
Self-pay	6
Other (public and private payers)	15
Total	100

SOURCE: Adapted from Bureau of Primary Health Care (2002d). *Excludes CHCs that do not receive Section 330 grants.

CHCs have a shared mission and shared clinician values, attributes well suited to a spirit of collaboration (Berwick, 2002; Stevens, 2002a). And the fact that about two-thirds of CHC resources come from either federal grants, Medicare, or Medicaid provides leverage for policy makers seeking to implement change. CHCs are located across the country in both urban and rural settings (Bureau of Primary Health Care, 2002a) and serve a high proportion of low-income and poor patients. They are community-based and are required to have a majority of active CHC clients as board members (McAlearney, 2002). Consequently, they are in a position to understand and respond to local and patient needs.

CHCs are highly variable in terms of geographic location; funding mix; and involvement in chronic care collaboratives, which relates to their ICT capacity. They also vary in particular populations served (e.g., poor families, migrant workers, the homeless, school-age children), although in general CHCs serve a high proportion of the poor (two-thirds of patients are at or below the poverty line) and two-thirds are racial/ethnic minorities (Bureau of Primary Health Care, 2002d). Given this patient mix, overall improvements in care delivery should help to close the nation's existing racial and socioeconomic gaps in care.

Finally, the Administration has focused on CHCs as a way of providing services to the uninsured and other vulnerable populations. The Administration has stated that it plans to add 1200 new or expanded CHC sites² over the next 5 years and to increase the number of people served from 11 to 16 million (U.S. Department of Health and Human Services, 2002). The Administration also recognizes the role of CHCs in providing important emergency response programs in urban settings. This year, the Health Resources and Services Administration (HRSA) received \$175 million to create new CHCs, expand existing ones, and enhance emergency response programs (U.S. Department of Health and Human Services, 2002).

In implementing proven models to redesign care delivery, demonstrations in this category would build upon and significantly expand the efforts of leading CHCs that are actively and successfully managing a select number of chronic conditions so that their care management approaches can be applied to all conditions and all health center patients.³ The demonstrations would help extend existing innovations, detailed below, to the next level so that all CHC patients will have ready access to high-quality, science-based, state-of-the-art care that is patient-centered and safe and allows for patient decision making and self-management. Ultimately, these demonstrations should lead to improved primary care across the country, as well as strengthen the nation's health care safety net.

Existing Innovations at CHCs

The demonstrations will build upon CHCs' existing innovations in redesigning care delivery, which are supported by information technology and rely upon reporting and monitoring related performance measures.

- *Chronic care management*—Starting in 1998, five CHCs began using the Chronic Care Model (Wagner et al., 2001) and the Institute for Healthcare Improvement (IHI) models to redesign care for patients with diabetes. This initial effort has provided a springboard for CHCs to redesign care for patients with a number of chronic conditions, including cardiovascular conditions, asthma, depression, and HIV. [Box 3–2](#) describes an example of a successful CHC program that used these models in improving care for patients with asthma. One of the central aspects of these models is a learning collaborative, whereby diverse organizations define common goals and share ideas, strategies, and methods—including redesign of care processes—for achieving improvements in clinical care for a specific condition. To date, about 500 CHCs have been involved in a collaborative of some kind (National Coalition on Health Care and Institute for Healthcare Improvement, 2002a; Stevens, 2002b).
- *Electronic patient registries*—Electronic patient registries—which at a minimum include an individual care plan for a specific disease, health status information, visit notes, and the capacity to generate summary statistics related to the individual and population—exist in about 500 CHCs and support the collaboratives noted above. The latest generation of registries, in place in over 140 CHCs and known as the Patient Electronic Care System, adds the ability to manage multiple chronic diseases, the latest

² CHCs may have one or more sites, with the average having three or more (Institute of Medicine, 2000).

³ If the center's patient population reflects the population as a whole, at least 45 percent have one or more chronic conditions (Partnership for Solutions, 2001). In addition, studies have shown that adult low income CHC users have a higher prevalence of certain chronic conditions, such as hypertension and diabetes, than adult low income persons in the general population (Bureau of Primary Health Care, 2002a; Mathematica Policy Research, 1998a; Mathematica Policy Research, 1998b). The number of uninsured served by CHCs is 3.9 million, but this figure does not include those served by CHCs that do not receive Section 330 grants. Therefore, the total number of uninsured served by CHCs is likely larger.

evidence-based guidelines and related prompts, and the capacity to generate lists of patients in need of care (e.g., follow-up visits, laboratory tests). The system is available free of charge to CHCs that have already been involved in the Bureau of Primary Health Care's chronic disease programs. The registries are seen as a stepping stone to computer-based patient records currently in place in just a few CHCs (Langley, 2002a, 2002b).⁴

- *Performance measures*—Data collection and reporting performance measures were initiated in the early 1990s and encompassed a small number of preventive care measures; now performance measures are mostly linked to the collaboratives. They include some core, standardized measures to allow for comparison and learning across CHCs, as well as organization-specific measures. In the future, the CHCs plan to make their performance data available to the public (Stevens, 2002b).

BOX 3–2 CHCS DEMONSTRATE SUCCESS IN MANAGING CHRONIC ILLNESSES: A CASE EXAMPLE

The Hill Health Center in New Haven, Connecticut, began an asthma improvement program in 2000 with one clinician and 30 patients (National Coalition on Health Care and Institute for Healthcare Improvement, 2002b). The program has now grown to serve over 900 patients in both the main clinic and eight school-based and primary care satellite clinics. The program has resulted in significant reductions in emergency department visits and school absenteeism. It has also increased the number of days that patients are free of asthma symptoms, outstripping national averages. Hill Health Center adapted existing models (see [Box 3–4](#)) to aid in the redesign of care delivery that led to these improvements.

The asthma program was initiated with the development of a patient registry to identify patients. The registry allows for tracking of measures related to individual patients and the population as a whole, more flexible scheduling of appointments, and identification of patterns. Responsibilities for care, such as taking of histories and patient education, are now divided among interdisciplinary teams, which include physicians, community health workers, and registered nurses. The Hill Health Center also includes patient education in groups in its improvement model. Patients are encouraged to manage their conditions through the development of an action plan, which incorporates a patient goal. They are also provided self-management tools, such as videos, comic books, peak flow meters, and brochures.

Continuing education of providers has been a priority as well. The center conducts in-service meetings to reinforce the use of the latest evidence-based guidelines and protocols for asthma care. It also uses an asthma assessment and treatment plan flow sheet and posts guidelines in color-coded laminated charts in easily accessible locations.

⁴ The term “computer-based patient record” encompasses electronic medical records and is used for consistency throughout this report.

The Hill Health Center has partnered with multiple community organizations to address the environmental factors that can trigger the disease, such as pests, mold, and ventilation systems, as well as to provide educational materials, activities, and equipment for its patients. These organizations have included school nurses, the Visiting Nurses Associations, the local public Community Action Agency, the American Lung Association, and pharmaceutical companies.

To measure the improvement achieved through the program, the center developed a set of tracking indicators, but unfortunately did not report (or perhaps even collect) baseline data. These indicators have revealed the following:

- Medication used to control asthma has increased to 100 percent.
- School absenteeism has been reduced to less than 1 day per 2 weeks since January 2001.
- Emergency visits due to asthma have been reduced to less than 1 percent on average per 2 weeks since February 2001.
- Peak flow rate performance has increased to greater than 80 percent.
- An asthma action plan is provided to 100 percent of patients.
- The number of symptom free days has increased to almost 80 percent (the national standard is 70 percent).

Through these improvements, the Hill Health Center has reduced costs as a result of fewer hospitalizations and emergency visits. This cost reduction has enabled the center to negotiate with managed care organizations to cover key medications and medical equipment and to make the reimbursement process smoother, although the center itself has not benefited financially from the improvements achieved.

Given the growing experience of CHCs with redesigning care delivery and measuring the results—500 CHCs have participated in a learning collaborative, with many being able to point to impressive results (National Coalition on Health Care and Institute for Healthcare Improvement, 2002b)—private primary care practices could likely benefit from what CHCs have learned along the way. Chronic care collaboratives based outside of CHCs have included private primary care practices and hospitals as well as CHCs (Wagner et al, 2001, 2001), and organizers point to the value of this cross-fertilization (Berwick, 2002). CHCs have also developed models for providing effective interdisciplinary and culturally competent care to patient populations that have a high proportion of ethnic/racial minorities, including those reliant on supportive services (Politzer et al., 2001)—models that private primary care practices could perhaps adapt as they work to implement and support care teams and attempt to close existing equity gaps (Institute of Medicine, 2002). Finally, CHCs have a history of integrating physical and mental health services, which leading primary care experts have long advocated to enhance quality (Institute of Medicine, 1996).

GOALS

Demonstration projects in this category are intended to achieve the following goals for all patients as appropriate:

1. High-Quality, patient-centered care

- Redesigned preventive, acute, and particularly chronic care that results in measurable decreases in severity of illness and increased use of preventive/ primary care, eventually leading to reductions in incidence and disease burden
- Care responsive to patients' wishes and social circumstances
- Effective clinical care teams that meet varied patient needs

2. Participatory care

- Patients sharing actively in all clinical decisions that affect them
- Patients supported in learning how to care for themselves and, if they wish, to manage their own conditions

3. Open access

- Access to appointments without delay, including same-day appointments
- Patient access to care through varied and convenient mediums

4. Evidence-based, safe care

- Science-based, high-quality, state-of-the-art care that is safe and reliable
- Expert systems for quality improvement, including error detection and reporting
- Patients' confidence that they will not be subjected to invasive, harmful care that will not help them

5. Shared best practices

- Sharing of best practices related to care delivery redesign and other learning across CHCs
- Patients' confidence that the best known approaches to care will be used to help prevent, address, and manage their illnesses, particularly in the case of chronic conditions
- Evaluation of CHC demonstration efforts and communication of results to the larger practice community

6. Efficient, effective care

- Reduction in inappropriate hospital visits
- Other care delivery mechanisms that are less costly and equally or more effective, such as group visits, e-mail consults and lay health worker visits
- Improved medication management

7. Equitable care

- Targeting of populations to meet diverse patient needs and reduce disparities
- A community orientation that gets diverse stakeholders involved in creative solutions for reducing ethnic and racial disparities

DEMONSTRATION ATTRIBUTES

The goal is for CHC demonstrations to become models for exemplary primary care practices over the next 3 years. Given this short timeframe, in all likelihood it will be prudent to select CHCs with an established track record in successfully implementing care delivery innovations. There is, however, no one size fits all approach to innovation. Each demonstration site would take into account its unique history, capacity, existing relationships, location, and distinct populations served while emphasizing four basic attributes:

- a patient-centered focus;
- investment in and implementation of ICT;
- shared learning and accountability; and
- a supportive financial environment.

By way of example, [Box 3–3](#) presents a chart that illustrates what a leading CHC— which has already achieved innovation in all four of these areas—could accomplish over the 3-year demonstration period. Given this rela

tively short time frame and the ambitiousness of the goals outlined above, most CHCs would be limited to accomplishing these results in fewer domains.

BOX 3–3 POTENTIAL ACCOMPLISHMENTS OF AN CHC

Key Attributes	Current Reality	Demonstration Vision
Patient-centered focus	Chronic care collaboratives in place for two conditions, selected providers.	Care delivery redesigned for all conditions, all patients; full participation of all providers.
Information and communications technology	Patient registry for two conditions; work under way to transition to electronic medical records (EMRs).	Computerized decision support integrating EMRs, secondary databases, and protocols at point of care.
Shared learning and accountability	Participation in two condition-specific learning collaboratives; collection and reporting of select process and outcome measures.	Participation in demonstration-wide collaboratives; reporting of performance measures that show lower indications of disease severity, reduced emergency department/hospital use, increased use of preventive/primary care, and progress on other quality indicators.
Financial environment	Visit-based payment, except for the uninsured; staff on salary; achieve some cost savings resulting from innovations, but all accrue to payers.	Payment innovations to support more extensive care coordination and alternative care delivery vehicles; experimentation with rewarding teams and individuals, and centers for exemplary performance.

Patient-Centered Focus

As noted, demonstration CHCs would redesign and transform the way care is delivered for all patients so that eventually care for all conditions as well as routine preventive care is transformed. By adding collaboratives, the demonstrations may extend existing models they have been using—the Chronic Care Model and the IHI models for health care organizations and clinical office practices (see [Box 3–4](#))—to other conditions or consider other approaches. These existing models are predicated on a well-developed ICT infrastructure, stress enhancing care delivery through better integration and coordination, and involve patient self-management and sharing of best practices and data across the organizations involved. The demonstrations would also need to make effective use of interdisciplinary teams, maximizing clinician and paraprofessional skills in the process (Milstein, 2002).

Each CHC patient would receive a care guide to help in navigating and planning for care within and outside of the CHC. These care guides would reside in the electronic patient registry or computer-based patient record; include data from other organizations from which the patient receives care (e.g., laboratory or

hospital); and have built-in supports, such as electronic and phone reminders, to help clinicians and patients in monitoring care against an agreed-upon plan. The care guides should serve to educate patients, would help foster patient self-management, and should aid in integrating and coordinating care, so that a patient can easily move from one setting to another without a great deal of disruption.

Two existing efforts provide some guidance on how CHCs have been integrating care across settings, and may serve as models for CHCs that have not yet focused on enhancing care delivery beyond their centers. The first is the Integrated Service Development Initiative (ISDI), which began in 1994 and is focused on integrating services across Bureau of Primary Health Care (BPHC)-supported programs and other safety net providers. In addition to integrating administrative and financial functions, the ISDI projects have also focused on clinical integration, such as creation of specialty referral networks and standardized disease management protocols and integration of management information systems (Health Resources and Services Administration, 2002). Another BPHC-initiated

BOX 3–4 CARE DELIVERY MODELS ADAPTED BY CHCS

CHCs have adapted and integrated leading models for the redesign of care delivery, including the Chronic Care Model (CCM), developed at Group Health Cooperative of Puget Sound, and improvement models designed by the Institute of Healthcare Improvement (IHI). Approximately 500 CHCs have used these or other models to form collaboratives that have redesigned and further integrated care.

The CCM, intended to improve the care provided to patients with chronic illness and their families, is a population-based approach that emphasizes evidence-based, planned, and integrated collaborative care (National Coalition on Health Care and Institute for Healthcare Improvement, 2002a; Wagner et al., 2001; 1996). The model relies on decision support technology, such as a computerized patient registry, and the support of community organizations, such as schools, government, nonprofits, and other organizations. A primary goal of the CCM is interaction between an informed, active patient and a proactive, prepared practice team.

A second improvement model, developed by IHI, is called the PDSA (Plan-Do-Study-Act) rapid-cycle improvement model (Institute for Healthcare Improvement, 2002b). This model complements the CCM, and the two can be implemented together by multidisciplinary practice teams. The PDSA cycle involves planning a change, trying it, observing the results, and acting on what is learned. The initial step is to set a clear aim for improvement and form a team that represents all of the areas of expertise that will be involved in the effort, including members with leadership positions, technical expertise, and day-to-day experience. This team then works to develop measures that can be used to determine whether a specific change has actually led to an improvement. Once the aim, team, and measures have been established, a change can be tested in the real work environment using the PDSA model.

In addition, IHI is undertaking another initiative, Idealized Design of Clinical Office Practices (IDCOP) (Institute for Healthcare Improvement, 2002a), with the aim of significantly improving the performance of clinical office practices through dramatic and sustained system-level changes. IDCOP may become a third improvement model that practice teams can adapt to improve and integrate care.

effort is the Community Access Program, which currently supports 136 community-wide efforts in urban, rural, and tribal areas. These efforts are focused both on building integrated health care delivery systems across sectors in a community so as to create seamless care, and on reducing unnecessary and duplicative functions. Savings that result from such waste reduction are currently captured by the CHCs and reinvested in the system (Health Resources and Services Administration, 2002).

CHC patients should also have access to alternative ways of communicating with their clinicians and receiving needed services. A limited number of CHCs currently provide patient education and counseling in group settings (Stevens, 2002a). Such approaches have been shown to increase patient compliance with care plans, enhance patient satisfaction, and reduce costs (Henry, 1997; Kilo et al., 2000; Masley et al., 2000). All of the demonstrations will be encouraged to offer such an option.

Some CHC patients, albeit a limited number, currently communicate with their clinicians by e-mail or through lay health workers, who are recruited from the community for outreach and treatment follow-up, home visits, and other duties. Demonstrations should be encouraged to extend e-mail as an option to all patients interested in such arrangements, with the provision that reimbursement will support these e-consults. Although some clinicians may be initially uncomfortable with communicating by email, many will likely find that it saves time, and if the financing mechanism is supportive, will not cause a loss of revenue to the CHC because they are foregoing an office visit. Lay health workers, supported by demonstration funds, will be called upon to help in the implementation of demonstration goals. For example, they might visit asthmatic patients' homes to provide tips on ways to reduce allergens (National Coalition on Health Care and Institute for Healthcare Improvement, 2002a) or provide follow-up education for new mothers on preventative baby care.

Demonstrations also should be encouraged to give patients the option of scheduling same-day appointments, which have been shown to reduce no-shows, increase patient visits, and enhance gross revenue without requiring additional staff (Darves, 2002; Gordon, forthcoming; Murray and Tantau, 2000; White, 2001). Finally, depending upon the population(s) served, CHCs should consider using demonstration funds to further tailor and customize care so they can meet the needs of racial/ethnic minority patients more effectively. This goal might be accomplished by translating patient education materials into appropriate languages, working with community groups to address the health needs of difficult-to-reach populations, or undertaking other strategies that can help the CHC provide culturally sensitive care.

Investment in and Implementation of Information and Communications Technology

The longer-term goal for the demonstrations would be to have computerized decision support systems that integrate computer-based patient records, secondary databases, and scientifically based protocols at the point of care so that patients receive state-of-the-art, reliable, high-quality care. The computer-based patient record should be accessible to patients and clinicians on an as-needed basis, and will promote effective care delivery, education, and shared decision making. The CHCs, as they have in the past, would be encouraged to work together in further developing ICT; such technology should conform to national data standards where they exist (see [Chapter 4](#)).

As noted, few CHCs currently have computer-based patient records, although existing electronic patient registries and the Patient Electronic Care System provide an important building block by capturing care plans, protocols, and patient information and allowing for ongoing monitoring. A computer-based patient record is the next step, enabling integration of all of a patient's clinical information and the exchange of such information with patients and, when warranted, with outside organizations.

Such exchange would be predicated on having appropriate privacy protocols in place.

With the computer-based patient record as a foundation, CHCs would be able to transition to an environment that no longer relies so substantially on paper transactions. Ultimately, the goal is to have a Web-based system whereby information, as appropriate, is accessible to all the CHCs and the relevant organizations in a given community. For example, such a system allows for electronic order entry for medications and automated monitoring of contraindications and allergens; exchange of patient information, such as hospital and emergency department discharge information, with other institutions; receipt and integration of laboratory and imaging center data; integration of information from specialty consults; and access to protocols for major therapeutic decisions (Milstein, 2002).

CHCs in California are currently working to implement a computer-based patient record system (Bureau of Primary Health Care, 2002b). A number of California-based health centers that received funding from the Tides Foundation for ICT investments, including those designed to advance the use of computer-based patient records, have reported that they have been able to increase reimbursement, improve immunization rates, and enhance follow-up for patients with chronic disease as a result (Brailer, 2002; The California Endowment, 2002).

Demonstration CHCs could continue to work with private vendors to evolve current products into computer-based patient records— an example being the Aristos Group, which developed the Patient Electronic Care System—or choose to partner with other organizations that have the necessary expertise. On the local level, hospitals within the Veterans Health Administration (VHA), which has developed and implemented a computer-based patient record system, might serve as a local resource for CHCs in this regard.

In addition to the automation of clinical records, CHCs would need to establish a digital connection between clinicians and patients for those who desire this form of communication, including e-mail and fax communication, Web-based dissemination of information, and electronic same-day scheduling and reminders. Although few CHCs currently have such connections, and the populations served may be less likely to use such forms of communication as compared with the general population (Newburger, 2001), such linkages are an important component of an exemplary primary care practice, and provide important tools for providing preventive care information and managing patients with chronic illnesses.

How rapidly an ICT infrastructure can be developed would depend in large part on each CHC's existing capacity. New CHC should, at a minimum, develop a highly evolved Patient Electronic Care System. The goal for others would be development and use of a computer-based patient record system. For those that have such a system in development or in place, migrating to a “paperless” environment should be the focus.

Shared Learning and Accountability

An important foundation of the existing condition-specific collaboratives is the sharing of information across CHCs through electronic and face-to-face meetings, site visits, informal and formal assessments, and periodic reports. With more collaboratives coming on line, the aggregation and reporting of this information only grows in importance so that CHCs can understand what works, assess the benefits for patients, and determine the cost of such efforts. To this end, there needs to be a national CHC learning collaborative that spans all conditions—likely housed at HRSA—that collects data from the demonstrations and provides some direction to the participants in an advisory capacity.

The kinds of performance data currently reported by the CHCs provide a good foundation for the more extensive data collection and reporting envisioned for this demonstration category. Each demonstration CHC should build upon its current reporting activities and set benchmarks for improvement, with the goal of

demonstrating to the public that CHCs can substantially reduce the severity of many conditions (e.g., heart disease, diabetes, asthma); increase the numbers of patients who avail themselves of scientifically established screening and health behavior counseling programs; and reduce the use of emergency departments and hospitals, thereby reducing costs. The national learning collaborative should establish a set of core performance measures to be reported by all the demonstrations—building upon existing CHC core performance measures—to allow for comparisons and benchmarking.

In addition to the collaborative, the Agency for Healthcare Research and Quality (AHRQ), which has a grant to test and compare two different models for improving diabetes care in 40 CHCs in the Midwest (Agency for Healthcare Research and Quality, 1999), should receive further support for taking a comprehensive look at all 40 demonstrations; evaluating their efforts individually and collectively; and discerning whether there is a business case to be made for the overall effort, in other words, whether the benefits derived from the demonstration outweigh the costs.

Finally, the national learning collaborative, with support and evaluative information from AHRQ, should take the lead in disseminating the innovations and best practices resulting from the demonstrations to the broader primary care and policy communities. This dissemination function should be provided adequate support, given that it is the mechanism through which primary care practices can learn from CHCs about how to redesign and improve care. In addition to leaders from the CHCs, those involved in the dissemination efforts should include leaders in primary care who can help in translating learning from CHCs to traditional primary care practices.

Financial Environment

Some of the demonstration components would require innovation with respect to payment, which is now mainly visit-based except in the case of the uninsured. In the case of Medicaid, waivers may be required and necessitate state involvement. Payment innovations would support CHCs in their efforts to provide group counseling and education visits, more extensive care coordination, and other care that does not result in a billable clinician visit (e.g., e-mail consults). Organizations must also experiment with paying for services rendered outside of the CHC, perhaps by lay workers, where evidence suggests that such services could enhance quality, by, for example, systematically reducing allergens in homes of patients with asthma. Currently, CHCs either are not compensated for providing such services or receive less-than-adequate support by relying on Section 330 grants.

CHCs also should be provided incentives to include hospitals, health plans and insurers in the collaboratives because of the importance of managing care across settings, particularly care for those with chronic conditions. Including institutions outside of the CHCs will allow for sharing of data, problem solving about how to improve care coordination and integration, and how to reduce costs, e.g., emergency department and overall hospital use. See [Box 3–2](#) and [Box 3–5](#) for examples of a CHC managing care across settings.

CHC staff, the health centers themselves, and other institutions that serve CHC patients should also share in the rewards when they demonstrably enhance the quality of and reduce costs of patient care. At present this is generally not the case. The expectation for the demonstrations is that through redesign of care delivery, patients would receive better-quality care that is less costly because waste will be eliminated. Public programs would certainly benefit from those savings, but as an incentive and as a matter of equity, so should CHCs and the clinicians who work there. With respect to CHCs, such incentives may be at the CHC team or clinician level and could also encompass conference attendance, assistance with research, and other nonmonetary rewards. [Box 3–5](#) describes a case example of CHC efforts to reduce health care costs.

BOX 3–5 REDUCING COSTS: A CASE STUDY IN MISSISSIPPI

In Hinds County, Mississippi, CHCs are working with four local hospitals to reduce emergency department and hospital use by uninsured persons. The program, supported by The Robert Wood Johnson Foundation and the Health Resources and Services Administration, includes follow-up with an uninsured person who has made a hospital visit to determine its appropriateness, provides counsel on what is an appropriate visit, and links the individual to a regular source for primary care. Program leaders hope that if the program can demonstrate savings, the hospitals can be convinced to support its operating costs. In 2003, the program will be rolled out to Medicaid beneficiaries (Jackson Medical Mall Foundation, 2002). The Medicaid agency has reportedly said that if costs can be kept budget neutral, CHCs and local hospitals will be able to share in the savings (Shirley, 2002).

Finally, to permit analysis of the business case for redesign as well as assessment of any related gains and how they should be distributed, there should be a robust cost accounting system for each CHC that separates out start-up costs for the demonstrations and ongoing costs and benefits, as measured by clinical quality indicators and other measures. Use of such a system would go a long way toward helping policy makers assess whether the demonstrations should be replicated across all CHCs, and enable primary care practices across the nation to decide whether to embark upon CHC-inspired redesign efforts focused on delivering stellar primary care.

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4

Information and Communications Technology Infrastructure: A “Paperless” Health Care System

SUMMARY DESCRIPTION

The wise use of information and communications technology (ICT) has the potential to improve the quality and safety of health care while at the same time enhancing access and reducing waste, unnecessary delays, and administrative costs. Some degree of improvement results from use of the recent rapid and dramatic advances in moving information among a variety of clinicians and experts. Even more important over the long run, however, is the capacity of ICT to make it possible to work differently and better.

The provision of health care consists of very complex processes, including initiating efforts to diagnose or treat a patient's problem; receiving and acting on the results of laboratory, radiology, and other diagnostic tests; communicating with patients about results and progress; and monitoring patient progress and ensuring appropriate follow-up (Middleton et al., forthcoming). At every step of the way, communication among providers and between clinicians and patients is critical, and information and knowledge must be made available to users when they need it.

Demonstration projects in this category would be 5 years in duration and are intended to result in the establishment of a state-of-the-art health care ICT infrastructure in a state, community, or a multistate region that is accessible to all providers and all consumers. Most patient information should be computer-based, virtually eliminating processes based on moving, finding, or filing paper. There would still be some situations in which paper is used (for example, an attending physician may find it useful to carry a concise summary of patients' clinical information when making rounds or to make handwritten notes that are subsequently scanned into the computer-based record). However, the volume of paper would be significantly reduced. More important, ambulatory practices, hospitals,

ancillary providers, and others would be inter-connected, and the availability of patient and other information to support decision making at the time of care delivery would be dramatically improved.

All demonstration projects in this category would include the formation of some form of public-private partnership. In general, the demonstrations would encompass three phases:

1. A planning and preparation phase, which includes the establishment of a public-private partnership.
2. Establishment of a secure platform for communication and sharing of clinical and other data between patients and providers and among providers. This infrastructure-building phase is intended to allow rapid movement of computer-based information to multiple sites on a need-to-know and right-to-know basis.
3. Rapid incorporation of the information made accessible through the platform to support (1) the steady migration of administrative and business processes to the platform (e.g., appointment scheduling, insurance eligibility checking, billing and payment), (2) development and application of knowledge management and decision support tools, and (3) development of new e-health delivery modes. Critical to accomplishing this phase is the computerization of all or nearly all types of patient data.

Phase 1 should be accomplished within 6 months and phase 2 between months 7 and 24. During phase 2, the community would begin to reap tangible benefits from the demonstration project. Phase 3 would proceed in parallel with phase 2 and continue indefinitely, producing stepwise benefits with enhancements to the applications performed using the platform.

Demonstration projects in this category would be greatly facilitated by an immediate emphasis on accelerated development of national data standards in certain key areas. All projects should be required to conform to national standards where they exist and to feed back experience on the use and utility of these new standards, thus facilitating the development of even more robust standards. Furthermore, there should be an expectation that the projects will lend their expertise to and share their technology with other geographic areas.

The initial demonstration projects should serve as the first generation or starter nodes of a national health information infrastructure. The committee recommends that a total of 8 to 10 demonstration projects be funded in this category, with the expectation that a second generation will be funded in 2005.

One-time-only federal financial support would be required to carry out phases 1 and 2. In general, private-sector health care providers should commit to making the ongoing financial investments necessary to carry out the developmental activities in phase 3. Payment structures would need to be realigned so that providers will benefit financially from the ongoing investments required to sustain the ICT infrastructure. Some combined federal and state assistance to safety net providers would be needed to enable their full participation in the ICT infrastructure.

BACKGROUND

The potential for information technology to improve the quality and safety of health care is enormous (Institute of Medicine, 1991, 1997, 2001). A strong ICT infrastructure can help patients be more informed and better prepared to engage in decision making and to carry out their treatment plan. From a clinician's perspective, ICT includes many powerful tools that are useful in applying scientific evidence to clinical decision making and in providing care that is safe. Specifically, the ICT infrastructure can contribute to improvements in the following areas:

- *Communication*—Web-based interactions between patients and clinicians and among

members of the care team, including e-mail, home monitoring, teleconsulting, and other applications.

- *Access to patient information*—Computer-based health and clinical information for each patient that is complete, organized, and available in real time to the patient and the patient's providers, while at the same time being confidential and secure.
- *Knowledge management*—Easy access to reliable information from the science base in forms that are useful to both clinicians and patients (and accommodate both English- and non-English-speaking patients and different levels of health literacy).
- *Decision support*—Computer-aided decision support tools for both patients and clinicians, such as reminder systems targeted at clinicians or patients, medication order entry systems, and chronic disease management systems.

Properly structured ICT also has great potential to reduce some administrative costs and burden. Administrative costs are estimated to account for 20 to 30 percent of the nation's health care expenditures (Evans and Roos, 1999; Woolhandler, 1997; Woolhandler and Himmelstein, 2002). The development of a secure ICT platform to support clinical, administrative, and financial transactions, as well as the use of computer-based clinical records, should over time reduce some administrative costs and dramatically improve the effectiveness, safety, and timeliness of the health care system.

As the ICT infrastructure expands beyond the boundaries of a single or several organizations to span a community, a state, and eventually the nation, there is the potential for it to support many additional clinical, research, professional education, and public health applications (National Research Council, 2000). A community-wide infrastructure can facilitate access to far more complete clinical information by all of the patient's providers, not just those within a given institution (e.g., hospital or health system). This interconnectedness offered by a Web-based platform, accompanied by protocols for data exchange, has great potential to improve quality and efficiency, especially in communities where health care delivery is highly decentralized. Clinical research applications include the development of large-scale biomedical databases that can support population-based, longitudinal studies. Professional education applications include improved access to the knowledge base, virtual conferences, and other distance-learning applications.

Of particular importance in light of heightened concerns about chemical and biological terrorism are the public health applications of an ICT infrastructure. These applications include improved tracking and surveillance for bioterrorism and other public health threats, and rapid dissemination of important health and medical information to providers and possibly citizens (Tang, 2002).

With the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104–191) and the Department of Health and Human Services' recent promulgation of regulations to protect data privacy and security, one major impediment to the establishment of an ICT infrastructure has been removed. The time is right for widespread adoption of computer-based clinical records.

A health information infrastructure as envisioned by the National Committee on Vital and Health Statistics (2001) involves three dimensions:

1. *Personal health dimension*—Creation of a personal health record by an individual (and his or her family or caregivers), which includes both information from the clinical record that is relevant to patients and non-clinical information, such as self-care trackers and directories of health care and public health service providers.
2. *Health care provider dimension*—Creation of a computer-based clinical record includ

ing such information as clinical orders, prescriptions, and clinician notes; ready access to practice guidelines and the science base; and the application of decision support tools.

3. *Population health dimension*—Collection of information on the health of the population and the salient influences, making it possible to identify and track health threats, assess population health, sponsor targeted health education campaigns, and conduct research. Much of the necessary data can come from deidentified personal and patient records that are accessed on a right- and need-to-know basis.

Although the potential applications and benefits likely increase logarithmically as the boundaries of the ICT infrastructure expand, so, too, does the complexity of implementation. Establishing such an infrastructure involves the development of data standards, laws, regulations, business practices, and technologies (National Committee on Vital and Health Statistics, 2000). Payment policies must be modified to recognize new methods of care delivery (e.g., e-visits, remote consultations, remote monitoring of patients). In many of these areas, federal leadership will be needed to move forward, because numerous issues of clinical data ownership, security, and privacy have yet to be addressed.

The up-front capital investments required to establish the ICT infrastructure will be quite sizable. The United States has successfully confronted similar challenges, however. Following World War II, the federal government supported the development of the Interstate highway system, and years later, the Defense Advanced Research Projects Agency funded the work that led to the modern Internet (National Research Council, 2000; Weingroff, 1996). Today, the challenge is not just one of ensuring access to public health data for homeland security, but also one of ensuring national health and economic productivity through a healthy workforce. The committee is confident that over time the return on investment in terms of dollars and health will rival the success of these other major national infrastructure investments, and that Americans of all socioeconomic levels will benefit (U.S. Department of Commerce, 2000).

GOALS

Demonstration projects in this category are intended to result in a practice environment that relies on computer-based patient records, and allows clinicians and patients immediate access to evidence and other information needed to support decision making. The goal is for the following capabilities to be available, for the most part, in real time:

1. Ready access to information by clinicians and patients on a right- and need-to-know basis
 - Eligibility, appointment, and account status information
 - Computer-based patient records; for example, a summary of current problems, medications, and allergies, together with all results, notes, and summaries
 - Disease management guidelines
2. Support tools for patients
 - Educational materials
 - Tools to monitor individual health status and needs
 - Tools to track progress in meeting clinical goals and compliance with treatment plans
 - Tools to model preferences and the impact of alternative treatment decisions and outcomes
 - Tools to access patient records and to contribute information to these records
3. E-mail and audiovisual communication between patients and clinicians and among clinicians

- Nonepisodic care (e.g., short questions and answers)
- Home monitoring
- Remote consultation

4. Data capture and decision support tools for clinicians

- Reminder systems
- Computer-based order entry and prescription writing, with dosage and interaction checking
- Note capture with immediate coding for billing
- Individual registries for chronic disease management

5. Management

- Appointment scheduling and admissions
- Workload scheduling and staffing
- Automated charge capture
- Contract modeling
- Enrollment in insurance programs
- Claim submission, with immediate verification of completeness and eligibility for payment

6. Performance measurement data for ongoing assessment of quality and safety improvements

7. Accountability

- Compliance with performance reporting requirements in the areas of safety and quality
- Demonstration of improvements in safety and quality
- Reporting of relevant data to public health authorities

DEMONSTRATION ATTRIBUTES

Demonstration projects in this category would likely include the three phases enumerated earlier. The work in phases 1 and 2 should establish an initial track record of stakeholders working together on a substantial statewide undertaking that has enormous potential to benefit patients and the community, but also requires extensive collaboration and shared decision making. Although critical, these phases would accomplish only a subset of the goals listed above. Phase 3 would entail extensive change within every health care organization. Emphasis is on the computerization of many types of patient and other data that currently are paper-based in most health care settings. This phase would also involve doing work differently. The increasing computerization of clinical data and the availability of knowledge management and other decision support tools would open up new opportunities to redesign care processes in ways that would improve safety, effectiveness, and efficiency and be more responsive to patient preferences and needs. Phase 3 would continue indefinitely as advances in medicine, science, and technology offer new possibilities, but by year 5, each demonstration site should be within reach of the goal of a near “paperless” health care system. Each of the three phases is discussed in detail below.

Phase 1: Planning and Preparation

During this phase, a lead organization, such as a state agency, an academic health center, a consortium of providers, or a state hospital/ health system association, would be responsible for establishing a broad-based public-private partnership. It is critical that the commitment of all major stakeholders in the community be secured at this stage. The demonstration projects would directly impact patients, physicians, nurses, hospitals, nursing homes, home health agencies, free-standing clinical laboratories, imaging centers, and others. Careful attention should be paid to ensuring that each of these stakeholders derives both near- and long-term benefits from the ICT infrastructure. Strong leadership from professional and hospital associations, academic health centers, the state government, and consumer groups would be needed.

This first phase would also involve the development of a detailed operational plan for carrying out the 5-year demonstration project. The operational plan should include proposed contractual agreements with all participants and vendors; a business and financial plan; and policies and procedures for data access and management, including security and authentication.

Phase 2: Data Exchange Platform

The primary advantage of establishing a data exchange platform is that it facilitates access to computer-based patient information in real time regardless of the form in which that information is currently being collected, coded, and classified by the provider or ancillary service organization. Establishment of a platform for sharing data poses a reasonably low risk of failure because it does not require providers (e.g., hospitals, health systems, physician groups) or other participating organizations (e.g., laboratories, imaging centers) to make major changes in their existing systems. Effecting the collaboration required for such data exchanges can be challenging, however, and hence leadership from the federal government could be quite useful in this regard.

Perhaps the best-known example of a data exchange platform for patient information is operated by CareScience in Santa Barbara County, California (CareScience, 2001). Care Data Exchange was initiated in 1991 as a low-cost public utility model that would allow participating organizations to share data through an Internet-based system. About 25 participating organizations accounting for the majority of care provided in Santa Barbara County include hospitals and health systems, physician practices, laboratories and ancillary providers, clinics and outpatient facilities, public health agencies, health plans and payers, pharmacies, and employers. The key characteristics of the system are as follows:

- Users (i.e., clinicians, hospitals, laboratories) need only a Web browser and an Internet connection to participate.
- Patient data remain at their original sources (e.g., hospital legacy system, imaging center data system), but authorized users are allowed to view the data.
- Participants determine who can and cannot access patient data according to protocols. For instance, when a participant requests patient information, the data exchange verifies the requester's digital credentials.
- Patients do not have unique identifiers; rather, the data exchange maintains a file with patient demographic data and correlates these data with those maintained by the provider organization to produce a validated patient search. The locations of the patient records are then stored with the patient's demographic data as "pointers" or "locators."
- The data exchange maintains a secure portal through which data may be exchanged "peer-to-peer."
- The data exchange maintains audit logs of all requests (i.e., who, when, what data requested).

There are other examples of data sharing networks. With support from the National Library of Medicine (NLM), the Regenstrief Institute has developed a community-wide electronic medical record system called the Indiana Network for Patient Care (INPC) (Regenstrief Institute, 2002). The INPC is being used by 11 geographically separated hospitals in the Indianapolis metropolitan area to improve care for patients presenting to their emergency departments. In Winona, Minnesota, Cerner Corporation and Hiawatha Broadband Communications initiated a partnership with Winona Health to create Winona Health Online, a network connecting the local health system, clinics, physicians, and patients (Chin, 2000). In addition, the Patient Safety Institute (PSI), a nonprofit organization that has developed a secure com

munications network for real-time access to clinical information at the point of care, has selected two hospital sites in Washington State to demonstrate this network (Patient Safety Institute, 2002). One of the major benefits of a data exchange is that it makes more complete clinical data available at the point of service. The availability of this information should result in fewer medical errors, less waste in terms of redundant services, and improved timeliness of services.

The magnitude of benefits derived from a data exchange depends on the extent to which patient data are computer-based. The types of transactions and applications that can be carried out over the network expand dramatically with the availability of more computer-based clinical and other patient data. The committee expects that the mere existence of a data exchange within a community would generate momentum to add other types of data.

Phase 3: Comprehensive ICT Infrastructure

All of the demonstration projects are intended to result in a health care system that relies on computer-based patient records. The committee recognizes that not all sites will achieve this goal by year 5, but believes that most can make considerable progress in computerizing key aspects of the patient record, such as laboratory, imaging, and prescription drugs.

The immediate objective of these demonstrations is to provide electronic access to those portions of a patient's clinical record that are computerized, and to encourage steady progress towards more complete computerization of patient information. Of course, access would be limited to authorized users (e.g., clinicians, ancillary service organizations, patients and their families). The ICT infrastructure should facilitate Internet-based communication between patients and clinicians, between patients and patient groups, and among clinicians. Over time, the infrastructure should be capable of securely supporting a wealth of applications, including (1) insurance enrollment and eligibility verification, (2) claims processing and payment, (3) clinical knowledge management for clinicians and patients (e.g., guidelines, chronic disease management sites), (4) decision support tools (e.g., reminders, provider order entry systems), (5) telemedicine (e.g., specialist consults, in-home monitoring), (6) disease surveillance, and (7) a public health rapid alert system.

The demonstration sites selected should be ones for which there is a reasonable expectation that this more extensive ICT infrastructure can be established within 5 years. This may mean selecting sites in geographic areas in which some investments in building an ICT infrastructure have already been made, the necessary expertise exists, and there is strong interest in working toward the accomplishment of community-wide goals. Sites that already have some building blocks in place will be able to move more expeditiously and will be more likely to achieve the 5-year goal. The potential for resistance to change from one or more important stakeholders should not be underestimated. Applicants should also be asked to detail the benefits that each major stakeholder is expected to derive from the demonstration project during the first few years.

In many geographic areas, there are pockets of innovation where strong ICT infrastructures are already available. A number of academic health centers, health systems, and large multispecialty groups have developed strong ICT capabilities (Doolan and Bates, 2002; McDonald et al., 1999; Overhage et al., 2000; Teich et al., 1999), and it should be possible for some communities and regions to build upon these successful efforts. In the public sector, the Veterans Health Administration (VHA) has one of the largest and most sophisticated health information systems in the nation, serving about 5 million veterans annually in 22 designated regions. The VHA system includes an architecture that supports information exchange across multiple clinical disciplines and lines of business, a computer-based patient record system for clinical documentation and information

retrieval, and an e-health communications system to provide veterans with online access to their medical records and other health information (Christopherson, 2002).

Careful consideration should be given to the best means of creating a public-private partnership in a geographic area to leverage existing resources and to ensure that no providers or consumers are excluded. One possibility might be for the state government, VHA, and private-sector health care organizations and vendors to work in partnership to establish the ICT infrastructure. Additional support might be provided to VHA so it can offer safety net providers (e.g., public hospitals, community health centers) the opportunity to participate in its ICT system and receive technical assistance for that purpose. Another possibility for providing assistance to safety net providers would be to allow a state Medicaid program to work collaboratively with such providers (who generally receive a sizable proportion of their revenues from Medicaid and the State Children's Health Insurance Program) to establish the necessary ICT infrastructure, and for the federal government to provide a 90 percent federal matching rate for these expenditures in the same way it pays for state-level Medicaid Management Information System development expenditures under Medicaid (Congressional Research Service, 1993).

MAKING PROGRESS TOWARD A NATIONAL ICT INFRASTRUCTURE

There is a good deal of truth to the saying that "all health care is local." For the most part, health care is provided by local institutions and clinicians. Communities take great pride in their health systems, and efforts to develop ICT infrastructure would best build on this foundation.

As important as grassroots support may be, however, a strong federal role in setting standards for ICT infrastructure is critical for several reasons. First, patient care-seeking behavior does not respect strict geographic boundaries, and this will likely be the case increasingly in the future. An estimated 25 percent of the U.S. population resides in a metropolitan area that crosses state boundaries (Salinsky, 2002), and many likely receive services in more than one state. The Internet has opened up many opportunities for telemedicine, a method of health care delivery that often crosses state and sometimes national boundaries. A patient's computer-based record should be accessible to all health care providers regardless of geographic location.

Second, the capability to monitor and respond to infectious disease outbreaks and bioterrorist attacks requires a national if not global ICT infrastructure. The ICT infrastructures developed by the various demonstration sites should be able to interface with each other, and over time these state- or community-based systems should become part of a nationwide infrastructure.

Third, the return on investment in knowledge management and other clinical decision support tools would be much greater if the software can be readily used in multiple geographic settings. The promulgation of national standards in some areas is critical to achieving this objective.

Fourth, many health care administrative functions, such as insurance and federal regulatory requirements, are national in scope. National data standards in certain areas are important to lessen the burden associated with provider compliance with these requirements.

The committee wishes to emphasize the importance of viewing the state- or community-based ICT demonstrations as part of a broader strategy intended to result in the establishment of a national ICT infrastructure. Specifically, demonstration projects in this category are intended to accomplish two objectives:

- Each individual demonstration project should result in the establishment of a community- or state-wide ICT infrastructure that begins to yield benefits to the community in the near term.
- Collectively, the demonstration projects in this category should within 3 years consti

tute primary or starter nodes of what will be expanded to constitute a national ICT infrastructure.

One impediment to establishing an ICT infrastructure either locally or nationally is the difficulty of getting all participating health care providers and vendors to agree on uniform data standards (i.e., the methods, protocols, and terminology adhered to by everyone for the purpose of allowing disparate information systems to interoperate successfully). The term "uniform data standards" is not intended to imply that all clinical and other information in the patient record must be coded and classified in exactly the same way, although in some instances strict adherence to what is known as "controlled vocabulary" may be desirable. In many cases, the development of "reference standards or terminology" may be adequate, with all participants agreeing to code data at a sufficient level of detail to allow mapping of local data to the national reference standard (Stead et al., 2000).

It will be critical for the Secretary of Health and Human Services, working with the President and Congress, to pursue an aggressive agenda for the adoption of national health data standards. Some degree of standardization is important to improve the interoperability of ICT systems; the comparability and usefulness of the data; and the quality, accountability, and integrity of the data. Numerous expert panels have recommended a stronger federal role in the promulgation of standards to be used nationwide (National Committee on Vital and Health Statistics, 2001; National Research Council, 2000), but to date, progress in this area has been slow. The proposed demonstration projects are unlikely to thrive in the absence of progress in establishing data standards. The American public will reap a far greater return on investments in these demonstration projects if they are pursued in tandem with national and global efforts to establish data standards.

The Secretary of Health and Human Services can immediately move this agenda forward by implementing the standards recommended by the National Committee on Vital and Health Statistics in reports sent to the Secretary in the past 3 years. In particular, the report entitled *Uniform Data Standards for Patient Medical Record Information* contains a number of standards that deserve prompt use in the Medicare and Medicaid programs and within all portions of the federal government that utilize health data standards (National Committee on Vital and Health Statistics, 2000). A partial list of these standards is Health Level 7 (HL7), Version 2; Digital Imaging and Communications in Medicine (DICOM); National Council for Prescription Drug Programs (NCPDP); and for early adoption, Institute of Electrical and Electronics Engineers, Series 1073 (IEEE 1073) Medical Device Communications and HL7, Version 3.

Of particular importance is the work of HL7, one of the largest private-sector standards-setting organizations, focusing on Version 3 standards for data interchange. With some additional financial resources, the work of this group could be accelerated, thereby completing some important aspects of standards setting within about 18 months (Hammond, 2002). The completion of this work would greatly facilitate the development of the ICT demonstration projects proposed in this report and perhaps even reduce the costs of such demonstrations.

There are some important standards-setting efforts in the federal government as well. The work of the Consolidated Health Informatics Initiative (CHII) and NLM is particularly note-worthy and can be leveraged. CHII was created under the auspices of the White House Office of Management and Budget in 2001 to facilitate the development of standards that would ensure compatible ICT systems across the government health programs (Office of Management and Budget, 2002). NLM has made extensive efforts through the Unified Medical Language System project to consolidate the various controlled vocabularies used in medicine and to provide tools needed to make the relationships among terms clear to human and machine alike (Humphreys et al., 1998; Lindberg et al., 1993).

These groups are well positioned to play important roles in the further development of clinical data standards.

Recent private-sector efforts also present an excellent opportunity for the federal government to collaborate in and obtain broad-based support for national standards-setting initiatives. Specifically, the Markle Foundation's Connecting for Health Initiative is focused on building consensus on and accelerating the rate of adoption of clinical data standards within health care. The group has already obtained general agreement among a broad stakeholder group on several clinical data standards that are ready for adoption, and more work is under way. An early product of this effort is an inventory of standards domains necessary to support computer-based records; these include reference information models, data types, terminology, clinical documents, clinical templates, data interchange, implementation manuals, rules, tool sets, terminology services, security, unique identifiers for patients and clinicians, and guidelines (Markle Foundation, 2002). The IOM Committee on Patient Safety Data Standards, scheduled to release a report in fall 2003, is currently working to identify the types of standards needed for monitoring safety and quality, and is providing guidance to the federal government on actions it might take to facilitate the development of such standards.

Although a more intensive effort at the national level to establish data standards is desirable, the committee does not intend to imply that the development of ICT infrastructures at the state or community level should be postponed until national standards are promulgated. The setting of national standards will be an ongoing process for many years if not decades to come. All information systems will need to accommodate frequent updates in standards. Also, as discussed above, some national data standards provide room for local sites to map their coding systems to a national reference standard.

The goal of having these initial demonstration projects serve as the hubs of a national ICT infrastructure has implications for the selection of demonstration sites. Consideration should be given to ensuring balanced geographic representation when selecting the demonstration sites. All major regions of the country (northeast, south, central, northwest, and southwest) and both urban and rural areas should be represented since the issues involved in implementing ICT capabilities differ greatly depending on the size and ICT sophistication of clinical groups. All participants in the demonstration program should be willing to sponsor site visits so others can learn from their experiences.

The Agency for Healthcare Research and Quality should be charged with establishing a central coordinating unit for the demonstrations in this category. Such a unit might be established in an academic or other applied research setting. The coordinating unit should be tasked with the following:

- Monitoring and evaluating the progress of the demonstrations
- Documenting successful and unsuccessful change management strategies pursued by the various demonstration sites
- Establishing ongoing communication among demonstration sites to share learning experiences and to discuss how best to overcome challenges
- Quantifying the benefits and costs associated with the demonstrations, and identifying and communicating best practices in care redesign

This last point deserves special attention. Reaping a return on investment in the ICT infrastructure will require changes in care processes. The costs associated with making these changes should be captured and included in the cost-benefit analysis. Another complicating factor is that benefits from investing in ICT accrue to many stakeholders, and not necessarily those who made the investment. Substantiating who benefits and who pays should be part of the evaluation.

The coordinating unit should have a strong communication capacity. It should be responsible for reaching out to various stakeholders, such as professional societies, health care associations, academic health centers, and others, to assist in disseminating knowledge gained from the demonstrations and in building a strong base of support for the establishment of a national ICT infrastructure.

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5

State Health Insurance: Making Affordable Coverage Available to All Americans

SUMMARY DESCRIPTION

Demonstration projects in this category are intended to result in insurance coverage for nearly all residents of a state. The Department of Health and Human Services (DHHS) would issue a Request for Proposals (RFP) to state governments (and U.S. territories) for undertaking two major activities: (1) achieving increased availability of affordable insurance coverage through public and/or private insurance programs, and (2) establishing a statewide electronic insurance enrollment clearinghouse. A limited number of demonstration sites—perhaps three to five—would likely be selected from the applicants. The demonstration projects should be 10 years in duration, but with the expectation that there will be measurable accomplishments within 18 months.

The committee believes that a 10-year commitment by DHHS to these demonstration projects would be necessary to encourage states to undertake the very significant efforts envisioned in the areas of building public-private partnerships, developing information and communications technology (ICT) infrastructure, and redesigning public insurance programs. Furthermore, in light of currently severe state budget limitations, the federal government may need to contribute all or nearly all of the increased funds required to conduct these demonstrations.

BACKGROUND

The number of people in the United States who were without health insurance during the entire year of 2001 was 41.2 million, or approximately 14.5 percent of the population (U.S. Census Bureau, 2002). Although there was a slight drop in the number of uninsured people in the late 1990s,

probably as the result of a particularly strong economy, the number has been increasing overall for more than a decade (Institute of Medicine, 2001).

When one considers the number of U.S. residents who experience breaks in insurance coverage of at least 1 month during a year, the magnitude of the uninsured problem becomes even greater. In 1996, 27.1 percent of nonelderly residents, or 62 million individuals, lacked coverage at some point during the year (Monheit et al., 2001).

Since Medicare provides nearly universal coverage for the elderly, almost all of the uninsured are individuals under age 65 (U.S. Census Bureau, 2001). The majority (67.3 percent) of residents under age 65 who have some form of health insurance obtain that insurance through their employer (Fronstin, 2001). Another 14.1 percent are enrolled in public insurance programs, such as Medicaid and the State Children's Health Insurance Program (SCHIP) (Fronstin, 2001). Eligibility requirements for Medicaid and SCHIP vary from state to state, but most have maximum income thresholds of 200 percent of the federal poverty level (FPL) or less (Centers for Medicare and Medicaid Services, 2000). There is also a small proportion (6.6 percent) of people who purchase individual insurance policies (Fronstin, 2001).

People may lose their coverage for all or part of a year for a number of reasons: loss of a job where insurance was offered; loss of Medicaid or SCHIP eligibility once children grow up or if the family income increases; loss of one's spouse because of separation, divorce, or death; loss of eligibility under a parents' plan upon turning 18 or graduating from college; situations in which one's insurer or employer goes out of business or an employer denies coverage; or an inability to pay increasing premium costs (Institute of Medicine, 2001).

State efforts to date to cover the uninsured have achieved some success in reducing the total number of people without coverage. With a large majority of states now offering public coverage to children up to 200 percent of the FPL, SCHIP has accomplished a significant expansion of coverage of low-income children (Centers for Medicare and Medicaid Services, 2002). In addition, at least 18 states now offer public coverage to parents up to the FPL, and a few, using federal waivers, extend coverage to low-income parents above the FPL (Broaddus et al., 2001). The experience of states such as Wisconsin, Massachusetts, New Jersey, and Rhode Island demonstrates that extending coverage to parents allows public programs to reach many more children as well (Dubay and Kenney, 2002; Institute of Medicine, 2002; Ku and Broaddus, 2000). Only a handful of states have significantly expanded coverage for low-income childless adults (Mann, 2002).

Eligibility for public programs is not enough to ensure coverage, especially for children. In 1999, three-quarters (6.8 million) of the estimated 9 million uninsured children who were eligible for Medicaid or SCHIP were not enrolled by their parents (Dubay et al., 2002). Some low-income parents (or guardians) may also lack information on public programs for which their children are eligible, or may find the enrollment procedures too cumbersome.

As part of their expanded coverage for adults, a small but growing number of states offer premium assistance to help low-income families afford the employee contributions needed for coverage by private employers. Rhode Island adopted a premium assistance program after finding that its public program expansion had reduced the state's uninsured rate, but also resulted in unaffordable shifts from private employer to public coverage (Rhode Island Department of Human Services, 2002). Oregon will use premium assistance as the central focus for its pending expansions (Crawford, 2002; Office for Oregon Health Policy and Research, 2001). There are also numerous proposals under consideration by federal policy makers to use tax credits to help uninsured residents buy individual health insurance; analyses indicate that this strategy would likely help some uninsured, but alone would not achieve coverage for all residents (Gabel et al., 2002a; Hadley and Reschovsky, 2002).

In spite of the many efforts made, states generally have not been able to develop approaches that facilitate stable, continuous coverage for their residents. Changes in a family's situation (new job, change to part-time status) can cause changes in program eligibility, coverage source, and consequently provider relationships. Federal program structures and eligibility rules sometimes require various family members to enroll in different programs offering different provider networks. Families may be willing to participate in one program but not another because of perceived differences in programs. And the complexity and fragmentation of private and public coverage sources and subsidies mean that many who need coverage do not enroll at all. Frequent changes in coverage can create significant costs for families and for the health care system as a whole as a result of discontinuities in care management and treatment, as well as administrative waste. State expansion initiatives are probably fiscally fragile because individual state economies are vulnerable to economic downturns that lead to a loss of private coverage (due to higher unemployment), while at the same time increasing demand for public programs and reducing tax revenues.

The committee believes that offering affordable insurance coverage to all residents should rank among the highest of health care priorities, even though it will not be easy to find solutions to achieve this goal. Numerous options exist, however, and should be explored (Meyer and Wicks, 2001). Strategies that maintain or even increase private contributions to insurance premiums will be needed, as will increased public expenditures. Efforts must also be made to stabilize or slow the rate of increase in the cost of insurance.

GOALS

Demonstration projects in this category are intended to achieve the following goals:

1. Coverage for all citizens and legal residents in a state
 - Affordable insurance coverage available to all citizens and legal residents in a demonstration state
 - Stable insurance coverage—no breaks in coverage and minimal switching from one insurance program to another
 - Consumers having some degree of choice of insurance carriers and plans and geographically accessible providers within a plan
 - Availability of comparative performance data for insurance carriers, plans, and providers to inform consumer decision making
 - Coverage that is family-centered, with parents and children having the opportunity to be covered under the same health plan
2. The right care at the right time
 - Shared responsibility for health (e.g., encouragement and support for healthy behaviors and lifestyles)
 - Improved use of primary preventive services (e.g., measurable improvements in screening, early-stage diagnosis)
 - Better management of chronic conditions (e.g., ongoing, coordinated care, with emphasis on secondary and tertiary prevention)
 - Improved patient satisfaction (e.g., fewer disruptions in clinician and patient relationships, ease of access to appropriate care providers)
3. Reduced clinical waste—reductions in redundant services (e.g., visits and ancillary tests) that result from the lack of a consistent source of care
4. Reduced administrative transactions
 - Fewer transactions resulting from changes in insurance coverage

- Reduced redundancy in clinical record keeping, resulting from fewer disruptions in clinician-patient relationships
- 5. Improved efficiency, resulting from an electronic clearinghouse for enrollment, eligibility verification, and billing and payment processes
- Reductions in paperwork
- Improved timeliness
- 6. Establishment of a strong public-private partnership that provides a foundation and mechanism for states to address other community health and health care issues

DEMONSTRATION ATTRIBUTES

Each demonstration would involve two components: expansions of affordable insurance coverage options through public and/or private programs, and establishment of a statewide electronic enrollment clearinghouse.

Coverage Expansions

Demonstration states would choose to expand insurance coverage through either tax credits to be applied to private insurance plans, Medicaid/SCHIP expansions to cover families and adults, or a combination of the two. Although there is much interest in coverage expansions (107th Congress, 2002), there has been limited experience with these approaches to date.

Tax Credit Approach. Under this approach, the federal government would provide support to a demonstration state to be used for premium assistance. The state would establish a program providing state tax credits to uninsured individuals based on a sliding scale tied to income. A demonstration state would determine individual eligibility based on state income tax filings, payroll taxes, or other information.

There are many different options for designing a state tax credit program (Fuchs et al., 2002). In general, there are two types of tax credits—nonrefundable and refundable. A non-refundable credit reduces the actual amount of tax paid by the individual. It provides a “dollar of subsidy for each dollar spent,” but only up to the amount of the individual's total income tax liability (Fuchs et al., 2002). A refundable credit is not limited by tax liability, but rather, amounts in excess of tax liability are payable to the individual.

The size of the population reached by a tax credit approach will depend on several factors, including the type of tax credit selected, the sliding income scale used to determine eligibility, and the design and amount of the tax credit. A refundable tax credit is recommended in that it has the ability to reach more uninsured individuals and to provide more assistance to those in greatest need. Credits can even be provided to individuals who do not have positive tax liability.

The number of people affected will also be influenced by the design of the tax credit and income range over which it is available. There are three basic designs: a fixed dollar amount (e.g., \$3000 per family as proposed by President Bush), a percent of premium (e.g., 65 percent of premium as contained in the COBRA Trade Adjustment Assistance Act just enacted), or a percent of income (e.g., premium in excess of 5 percent of income). The tax credit would typically be limited to those with incomes below a given level (e.g., up to 200 percent of poverty or, alternatively, those in the 15 percent tax bracket—\$27,000 for an individual and \$46,700 for a family). A tax credit that ensures no family pays more than 5 percent of income for a standard plan would likely achieve a modest participation rate, perhaps in the range of about 15 to 20 percent of those eligible (Ku and Coughlin, 1999). In the case of a fixed dollar amount, younger adults and families are more likely to participate than older people because premiums in the individual market would be much higher for older adults (Gabel et al., 2002b). About 65–75 percent of premium assistance (comparable to what employers contribute on average to employees plans) would also induce

fairly high participation rates (e.g., 60 percent of the unemployed uninsured) (Edwards et al., 2002).

To obtain a tax credit, individuals would be required to enroll in an insurance plan approved by the state. States should provide individuals with at least some choice of insurance plans. For example, a state might provide a choice of two or three of the following options: employee coverage, private or state purchasing pool, state employee health plan, and individual insurance plan. As a component of these demonstrations, states should be able to ask DHHS to give uninsured individuals aged 62 and older the opportunity to enroll in Medicare. The state tax credit accompanied by a Medicare buy-in option would minimize disruptions in coverage and provider relationships, and would afford DHHS an opportunity to assess the potential effects of broader-based policy proposals (Sheils and Chen, 2001).

Individuals who did not exercise their choice of options (and who did not indicate a desire to opt out) would be enrolled in a default plan offering reasonable geographic access to providers. Those individuals who received a tax subsidy covering some but not all of their premium would be expected to pay the remaining portion or be disenrolled. Demonstration states may need to establish a mechanism for discouraging individuals from moving to the state to obtain coverage (e.g., a requirement for a 6- or 12-month employment history in the state without coverage).

The tax credit approach has some appealing characteristics, but there are also limitations. Tax credits are a fairly flexible method of providing varying levels of assistance to individuals depending upon need. If designed properly, tax credits can also work in a complementary fashion with employer-based contributions to health insurance. However, one of the key challenges is to set the credits at levels that provide enough additional assistance to individuals to encourage them to enroll in a health insurance program, while not having the unintended consequences of reducing employer contributions to premiums or increasing the proportion of employers who choose not to offer insurance coverage.

The tax credit approach can also be structured to encourage continuity of patient relationships with health plans and providers. By allowing the tax credit to be used towards any one of several insurance options (e.g., Medicare buyin, employment-based coverage, individual insurance plan, COBRA, Medicaid/SCHIP or other state plan), changes in an individual's income or employment status are less likely to result in disruptions in insurance coverage or provider relationships.

Lastly, the tax credit approach may provide states with greater control and predictability over health care expenditures than is the case with expansions in public insurance programs. Tax credit programs do not require states to assume insurance risk or responsibility for the provision of certain benefits to beneficiaries. States can still afford some protections for beneficiaries by restricting the use of tax credits to the purchase of insurance from a selected set of approved plans that meet certain minimum requirements in terms of benefits, copayments, and quality requirements.

Medicaid/SCHIP Expansions to Cover Families. Under this approach, the federal government would provide federal matching support (at rates currently applied to SCHIP beneficiaries) for a significantly expanded eligibility program under a state Medicaid or SCHIP program. Initially, a state would expand eligibility for its Medicaid or SCHIP program to cover low-income parents of children enrolled in these public programs (an approach sometimes referred to as a family health insurance program). Coverage of other uninsured family members (older siblings) or family units (childless couples or adults) might follow. Individuals in these public programs should be enrolled for a minimum period of 12 months to encourage greater stability of coverage (i.e., fewer gaps in enrollment and less switching from one health plan to another).

Many factors would influence the approach selected by states. For example, states that do

not have income taxes (i.e., Alaska, Florida, Nevada, New Hampshire, South Dakota, Tennessee, Texas, Washington, and Wyoming) are less likely to pursue a premium assistance approach. Some pioneering states already have experience with demonstration projects that involve coverage of modest-income parents and children under Medicaid and SCHIP (Mann, 2002), and these states might choose to continue pursuing this strategy to cover larger numbers of the uninsured, including childless adults. Regardless of the approach selected, there should be a reasonable expectation for any given demonstration project that nearly all residents in the state will have obtained health insurance coverage within 3 years.

Although the intent is to give states a good deal of flexibility in developing innovative approaches to expanding coverage, all demonstration projects should be designed to encourage the following:

- *One plan per family*—There is evidence that both access and quality improve for children and adults when the family is enrolled in a single health plan (Institute of Medicine, 2002). Having a single health plan helps simplify administrative matters for both consumers and insurance programs, and increases the likelihood of multiple family members being able to obtain care at common delivery sites or provider groups. Demonstrations should be structured to encourage one plan per family through such options as enrollment of low-income parents in the same Medicaid and SCHIP program as their children, or use of premium assistance options toward employment-based family coverage.
- *Evidence-based insurance package*—States should be required to establish coverage policies that are science-based, specifying the types of services to be covered and under what circumstances. The Agency for Healthcare Research and Quality should be provided the resources necessary to work in a supportive capacity with the demonstration states, providing syntheses of the evidence on the effectiveness of various approaches. Each demonstration state will need to establish a mechanism to allow for public dialogue and input into decisions regarding coverage policies. Careful consideration should be given to the identification and inclusion of effective preventive, mental health, and developmental screening and treatment services.
- *A personal clinician*—Having a personal clinician (primary care physician, specialist, physician assistant, advanced practice nurse) increases the likelihood of patients obtaining the right care at the right time in the right setting (Bindman et al., 1995; Starfield, 1986, 1995). Insurance programs and health plans participating in the statewide demonstration project should be encouraged to ensure that each individual has access to a designated personal clinician capable of providing culturally appropriate services (e.g., simultaneous language translation services) (Youdelman and Perkins, 2002). Correspondingly, individuals should be informed of their responsibility to seek care in appropriate settings and to refrain from use of emergency departments for routine or urgent care that is best provided in other settings. Both patients and their personal clinicians should be made aware of their joint responsibility to ensure appropriate access to and wise use of resources.
- *Fair payment*—Each insurance program should provide adequate payments to providers, and states should take immediate steps to ensure that plans and providers participating in state-sponsored programs (i.e., Medicaid and SCHIP) receive adequate payment. If payments to providers are set too low, many may choose not to participate in public programs, thus impeding access, and others may participate but not provide all of the services from which patients would likely have benefited. Over time, the public and private insurers in the various demonstration sites should also be encouraged to identify innovative ways of

providing payments to clinicians that encourage and reward the provision of high-quality care.

Electronic Enrollment Clearinghouse

During the first 18 months of each project, the participating state would establish an electronic clearinghouse for eligibility verification and insurance program enrollment. One of the immediate benefits of the clearinghouse would be the ability to check whether individuals have insurance, and if not, to enroll them immediately in one of the insurance options made available through coverage expansions. The clearinghouse would not be the only method of enrolling uninsured individuals. States enrollment processes should also provide for applications to be submitted by telephone, fax, or other means.

The clearinghouse would likely yield benefits to consumers, clinicians, and insurers. Consumers would benefit immediately from faster and, in some cases, easier enrollment processes. Current enrollment processes rely to a great extent on the patient (or their provider office) completing paperwork, which is then mailed or faxed to state offices. The paperwork must be processed and a response sent to the individual. The electronic process would be faster and presumably less burdensome to consumers and providers. The streamlined eligibility process would result in more timely payment of providers, and over time, the clearinghouse might also be used for electronic billing and payment of claims. Lastly, insurers would likely derive some benefits from the clearinghouse, including ease of identification of dual eligibles, and possibly reduced administrative costs associated with the eligibility determination and other business functions that might be carried out using the electronic clearinghouse (e.g., provider payment, receiving and responding to benefits coverage and utilization review requests).

State governments should work in partnership with private insurers, DHHS, and others in designing and establishing the electronic clearinghouse. The clearinghouse is intended to be used by both public (i.e., Medicare, Medicaid, and SCHIP) and private insurance programs for eligibility verification, enrollment, claims processing, and payment. The return on investment in this infrastructure would increase if all insurance programs participate, and the likelihood of this happening would be higher if leading private and public insurers are involved in the design up front. During the first 6 months of the demonstration projects, public and private insurers would need to work closely on system design issues. Processes for safeguarding confidentiality and security would need to be established, and these processes should meet all legal and regulatory requirements for privacy imposed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other statutes. It is not necessary for all insurers to adopt uniform eligibility, claims processing, payment, and other processes, but some degree of standardization or mapping of key data elements to a reference standard would be necessary. DHHS should play a very active role in this process to promote the development and use of national standards where appropriate (see [Chapter 4](#) for a discussion of data standards).

The enrollment network should be capable of verifying eligibility for coverage under various insurance programs by accessing relevant sources of information, such as state income tax records and payroll records, as well as enrollment information submitted by individuals seeking coverage (with retrospective verification of income and other information). Health care delivery sites should have connectivity to the clearinghouse for purposes of eligibility verification and immediate enrollment of uninsured patients in insurance programs (although consumers, often with the assistance of their providers, would still have the option of seeking enrollment by telephone, fax, or mail).

Although the intent is to use the clearinghouse to enroll individuals in an insurance program automatically, each demonstration state should carefully consider options for providing consumers with some degree of choice of insurance carriers and plans. There should also be a mechanism for consumers to

opt out of insurance coverage for religious or other personal reasons; however, states should design policy approaches so that those without coverage will constitute a very small percentage of the currently insured population.

It is anticipated that over time, the electronic clearinghouse would evolve into a more general ICT platform and be used for many purposes. As noted above, electronic billing and payment functions might be added within a few years of demonstration start-up. The platform might also serve as a vehicle for providing clinicians and consumers with information on benefits, clinical evidence, and public health concerns. Ultimately, the platform might serve as a vehicle for accessing patient-level clinical information (e.g., laboratory and imaging results, prescription medications, emergency department visits, specialist encounters) and for ordering ancillary services, prescribing medications, referring patients to specialists, and admitting patients to hospitals (with appropriate confidentiality protections). Although the focus of these demonstrations is intended to be on expanding insurance coverage, participating states should give some consideration to these potential future applications of the clearing-house-during the planning phase (see [Chapter 4](#) for a discussion of the many applications of a comprehensive ICT infrastructure).

In establishing their clearinghouse, demonstration sites should be encouraged to learn from other programs already under way. One innovative project is the New England Healthcare EDI [electronic data interchange] Network (NEHEN), a consortium led by Computer Science Corporation that has been operational since 1998 (New England Healthcare EDI Network, 2002). Membership is open to providers, health plans, and payers in Massachusetts and Rhode Island. There are currently 14 members, including most of the region's largest insurers and health plans.

NEHEN provides members with access to a secure high-speed network for sending and receiving transactions. Members can either integrate NEHEN functions directly into their own management systems or access the NEHEN network using NEHENLite, a Web-based application. Members pay a flat monthly fee (which is not transaction-based) to cover the cost of managing and coordinating the consortium's activities and the development of common work products. All intellectual property created for NEHEN is shared among the members.

NEHEN's primary focus is on administrative simplification. The initial pilot project, which started in June 1998, involved checking insurance eligibility in real time for every patient encounter to reduce both claim denial rates and claim rework effort. A pilot is now under way to integrate Medicaid into the system. Another pilot project involves authorization for specialist referrals. Developmental efforts are also under way to address claims processing, including submission, inquiry, and remittance.

IMPLEMENTATION ISSUES

For the demonstration projects in this category to be successful, key implementation issues should be addressed. Specifically, the demonstrations should have adequate and stable long-range financial support and cooperation from both the public and private sectors.

Financial Support

Regardless of the approach selected by a demonstration site, increased federal and state financial support would be necessary. There should also be an ongoing federal commitment to the long-term goal of making affordable coverage available to all residents.

The executive branch has a considerable ability to restructure Medicaid and SCHIP programs through Section 1115 waivers (Kaiser Commission on Medicaid and the Uninsured, 2001). Over 20 percent of federal Medicaid spending is in support of Section 1115 demonstrations. Those demonstrations have been used to extend coverage to groups not eligible under current law (e.g., low-income nonelderly, non-disabled adults without children); provide

targeted benefits to specific groups (e.g., access of Medicare beneficiaries to Medicaid prescription drug discounts, family planning services for low-income women not otherwise eligible for Medicaid, and coverage for people with HIV who would not otherwise qualify for Medicaid because their disease has not progressed to the point where they are considered disabled); and implement changes in managed care and other delivery systems (e.g., mandatory managed care enrollment, substate programs that modify payment and care delivery, special management programs for those dually eligible under Medicare and Medicaid) (Kaiser Commission on Medicaid and the Uninsured, 2001).

It is quite likely that congressional enabling authority and financial support would be needed to conduct some or all of the proposed demonstrations. The proposed demonstration projects differ from earlier efforts in three ways:

- *Magnitude of change*—The objective of the proposed demonstration projects is to achieve coverage for all or nearly all residents in a state. Other demonstrations to date have been important in extending coverage to certain groups of the uninsured, but modest in scope overall.
- *Fundamental change in enrollment processes*—The proposed demonstration projects include the development of an electronic clearinghouse that will remove administrative barriers to enrollment and improve the timeliness and efficiency of processes for eligibility verification and enrollment.¹
- *Not budget neutral*—To date, nearly all Section 1115 waivers have been granted for budget-neutral demonstrations (Kaiser Commission on Medicaid and the Uninsured, 2001). Given the proposed scope of the demonstration projects, it is unrealistic to expect that they would be budget neutral.
- *Ongoing flexibility to achieve goals*—Approval for demonstration projects has traditionally been provided for detailed program policy structures that are inflexible once approved. Given the scale of the proposed demonstrations, it is unrealistic to expect a state to identify a priori the best combination of policies and approaches for achieving the demonstration goals within budget constraints. Participating states should have the latitude to adjust program policy structures to achieve overall coverage goals. To ensure accountability and facilitate evaluation, changes should be reported prospectively to DHHS.

Although it was beyond the scope of this project to provide detailed estimates of the impact of the proposed demonstration projects on expenditures, it is a virtual certainty that overall costs would increase at both the federal and state levels, and that these would be ongoing expenditures. Federal support for the electronic clearinghouse would represent one-time start-up funding (once operational, the clearinghouse could be supported by very modest user fees). Of far greater significance, the federal government would need to provide ongoing support for expanded enrollment in Medicaid and SCHIP (at the enhanced SCHIP matching rate) and/or to offset the cost of state tax credits to the uninsured for premium assistance. The federal government could provide this additional support in the form of a block grant to a state tied to a state commitment to expand coverage to a prespecified number of individuals, or through existing Medicaid funding channels accompanied by flexibility to use the federal matching dollars to assist with paying premiums for private-sector plans.

State Medicaid and SCHIP expenditures would increase as enrollment expands, and states would presumably bear some of the costs

¹ A bill (HR 5233) to promote Internet enrollment systems in SCHIP and Medicaid was introduced in the U.S. House of Representatives on July 25, 2002. If passed, the bill would make available \$50 million to the Secretary of Health and Human Services for providing grants to states to establish Web-based enrollment systems.

of providing premium assistance to the uninsured enrolled in private insurance plans. To secure state participation, it might also be necessary for the federal government to identify a mechanism for providing additional support to states during economic downturns (i.e., counter-cyclic funding). Extension of coverage to the uninsured would likely yield many benefits to the community, including improved health status (which in some cases may reduce health care costs) and increased worker productivity. In all likelihood, there would also be some offsets to the insurance expansion program, such as less need for disproportionate share hospital payments and reduced tax write-offs for uncompensated care on the part of for-profit providers (Garson, 2000).

Steps should also be taken to ensure that the necessary information is gathered to enable evaluation of the effects of these demonstrations. Additional investments in expanding coverage would be sizable. The committee believes that the benefits to individuals and communities would also be sizable, but this belief should be substantiated through rigorous evaluation of the impact of expanded and stable coverage on (1) health status improvements; (2) the health, social, and financial stability of families; (3) timely and appropriate use of preventive, acute, and chronic care; and (4) enhanced productivity of workers and school participation of children.

Public- and Private-Sector Cooperation

Given the magnitude of change involved in these demonstrations, it would be important to build a broad base of private- and public-sector support. Prior to the start of the demonstration projects, efforts should be made to secure the support of the business community at the national, state, and local levels. DHHS and the Department of Labor, working with the National Governors Association, the National Business Coalition on Health, the Business Roundtable, and the Leapfrog Group, should convene leaders from the business community and state governments to discuss the importance of the demonstration projects. Other groups that might play an important role in building a broad base of support for and providing ongoing information about the demonstrations include the National Academy for State Health Policy, the National Association of Insurance Commissioners, and the National Conference of State Legislatures.

In each demonstration site, the support of the business community and private insurers would be critical to success. Regardless of the approach selected by a state, the insurance expansions should be accomplished in a way that preserves the current levels of contributions from private employers and employees. Reaping the full benefits of the electronic clearinghouse would require the full (or nearly full) participation of all insurers. Although the tax credit approach is not an employer mandate, the success of this approach would depend on the willingness of employers, both self-insured and non-self-insured, to work voluntarily with the state to encourage the enrollment of individual employees and their families in employer-sponsored plans.

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6

Liability: Patient-Centered and Safety-Focused, Nonjudicial Compensation

SUMMARY DESCRIPTION

Demonstrations in this category would create injury compensation systems outside of the courtroom that are patient-centered and focused on safety, while also addressing provider concerns about rapidly rising liability insurance premiums. Specific characteristics of this non-judicial approach to malpractice reform are replacing tort liability with alternative systems for ensuring that patients who have experienced avoidable injuries receive timely, fair compensation from responsible parties; limiting financial exposure for health care providers; promoting apology and non-adversarial discussions with patients; encouraging provider organizations to report and analyze medical errors; rewarding providers that put in place effective programs for reducing medical injury; and involving patients in safety improvement efforts.

Prompt federal action to provide incentives for adopting this approach—coupled with appropriate state legislation—has the potential to produce immediately measurable benefits in terms of provider access to affordable, high-dollar liability coverage; gains in administrative efficiency once criteria for compensation are fully developed, allowing quicker payments to be made to many more injured patients; and longer-term improvements in patient safety and stabilization of insurance markets. The Department of Health and Human Services (DHHS) would issue a Request for Proposals (RFP) to the states and select four to five of those that apply for demonstration projects in this category. The demonstrations would be designed to ascertain a reform's effect on the number and nature of claims filed and associated total costs, as well as to permit comparison of claim and cost information across all the demonstrations. All of these components would be part of the overall evaluation of the demonstrations. If successful, the reforms could continue indefinitely.

The committee suggests that participating states implement one of two options on a demonstration basis:

- *Option 1: Provider-Based Early Payment*—Under this approach, the federal government would provide reinsurance on a shared-cost basis to self-insured or experience-rated provider groups that voluntarily agreed to identify and promptly compensate patients for avoidable injuries. States would prospectively set limits on non-economic damages, including pain and suffering, for identifiable classes of avoidable injuries.
- *Option 2: Statewide Administrative Resolution*—Under this approach, states would grant all health care professionals and facilities, however organized, immunity from tort liability (under most circumstances) in exchange for mandatory participation in a state-sponsored, administrative system established to provide compensation to patients who have suffered avoidable injuries.

Both options are compatible with the Administration's recent proposal related to liability reform, which caps noneconomic damages and supports the concept of “early offers” of compensation (U.S. Department of Health and Human Services, 2002). However, both options also differ in certain respects from the Administration's proposal and do not depend on its enactment.

BACKGROUND

For the first time in nearly 20 years, the United States is facing a broad-based crisis in the availability and affordability of malpractice liability insurance for physicians, hospitals, and other health care providers. The American health care system has undergone dramatic changes since the last malpractice crisis two decades ago (Abraham and Weiler, 1994; Sage, 1997). Reforms to address the current situation should therefore take into account a number of new concerns and constraints: (1) increased sensitivity among providers and the public to substantial rates of medical error and the need to improve patient safety at a system level; (2) lower margins and reduced provider capacity resulting from private- and public-sector cost containment, which increases vulnerability to “liability shocks”; and (3) organizational and technical innovations in health care financing and delivery, including provider integration and consolidation, that have affected the dynamics of litigation as well as expanding the range of public policy responses to a liability insurance crisis.

There is widespread agreement that the current system of tort liability is a poor way to prevent and redress injury resulting from medical error (Bovbjerg et al., 2001). Most instances of negligence do not give rise to lawsuits, and most legal claims do not relate to negligent care (Localio et al., 1991). Many injured patients do not know they have suffered an injury resulting from error, and those who go through the legal process often do not even recover the cost of their continued health care (Sloan et al., 1991). A few plaintiffs and their attorneys, however, win large sums that may be disproportionate to their injuries or unrelated to the defendant's conduct. Prolonged, adversarial haggling over claims by plaintiffs' attorneys and liability insurers alienates both providers and patients, and generates legal fees and administrative expenses that consume more than half the cost of liability insurance premiums (Kakalik and Pace, 1986).

The apparent randomness and delay associated with this pattern of accountability not only prevent severely injured patients from receiving prompt, fair compensation, but destabilize liability insurance markets and attenuate the signal that liability is supposed to send health care providers regarding the need for quality improvement. Fear and distrust breed inefficient “defensive medicine,” and lead to missed opportunities for information exchange and apology that might avoid lawsuits in the first place. Unfavorable economic conditions and catastrophic events external to the health care

system add to the effects of legal uncertainty on liability insurance premiums, particularly for high-dollar coverage that depends on global reinsurance markets.

The shortcomings of the current malpractice system therefore come from three directions, all of which have contributed to the present crisis: inefficient and inequitable legal processes for resolving disputes, problematic responses by clinicians to the threat and cost of liability, and volatile markets for liability insurance. Although some states face greater insurance instability than others as the result of different legal standards, public expectations, and professional cultures, no state is immune to the threat of service interruptions affecting physicians, hospitals, and other health care providers.

The current liability insurance crisis provides a compelling case for reform. However, approaches that focus narrowly on reducing the number and value of legal claims (e.g., limiting damage awards) may lower liability insurance premiums but do nothing to improve patient safety or produce prompter and fairer compensation for patients who are injured. The systemic problems noted by the Institute of Medicine (IOM) in *To Err Is Human* and *Crossing the Quality Chasm* (Institute of Medicine, 2000, 2001) strongly suggests the need to create a legal environment that both fosters high-quality patient care and relieves financial strain and administrative burden for health care providers. The committee believes that replacing tort liability with a system of patient-centered and safety-focused non-judicial compensation— linking claims resolution to organization-based error disclosure and safety improvement processes—can best accomplish these goals. Such systems would cap providers' financial exposure at reasonable levels, both directly by limiting damages and indirectly by providing affordable umbrella coverage. They would also encourage and oversee health care organizations' efforts to identify, compensate, and reduce errors in cooperation with patients. In combination, these improvements should enhance patient safety and enable a greater number of patients with valid claims to receive compensation, while simultaneously stabilizing liability insurance markets by decreasing the unpredictability associated with high-dollar, outlier cases (Studdert and Brennan, 2001a; 2001b).

Approaches intended to compensate more injured patients by using a standard of “avoidability” rather than the narrower tort standard of “negligence” raise appropriate concerns about increased cost. Rigorously testing such systems on a demonstration basis would allow policy makers to determine the total cost of compensating medical injuries outside the courtroom. Further, by gathering, analyzing, and comparing claims and cost data across participating states, policy makers would gain insight into how definitions of avoidable injury and the generosity of the compensation packages selected influence total cost. Finally, policy makers would obtain important information about the possible dollar benefits of reducing the incidence of avoidable injuries.

Through the demonstrations in this category, states would have the opportunity—and the incentive—to select one of the two nonjudicial claims resolution options outlined above. All participating states will refine the technical and scientific underpinnings of such a system through an expert or participatory process, depending upon the state's preference. States would build on well-developed, but untested proposals such as “ACEs” (“avoidable classes of events,” also called “accelerated compensation events”), early offers of settlement, and scheduled ranges of allowable damages for pain and suffering. ACEs identify, in scientifically rigorous fashion, situations in which injuries that typically are preventable occur, such as giving a patient two drugs that are known to interact (Tancredi and Bovbjerg, 1991). Early offer systems protect defendants from additional liability if they reliably and promptly acknowledge problems and offer fair compensation (O'Connell, 1982). Damage schedules ascertain reasonable levels of compensation for pain and suffering on the basis of jury awards for injuries of defined severity and cap damages at those

amounts rather than imposing a one-size-fits-all limit (Bovbjerg et al., 1989).

States would need to create centralized mechanisms to ensure the identification, disclosure, and analysis of avoidable injuries, as well as voluntary, confidential reporting of “near misses.” The way in which such mechanisms would be operationalized will be left up to the states, necessitating resolution of important policy issues. The federal government might play a role by helping to develop consistent definitions and data reporting standards, thereby reducing the need for each state to reinvent the wheel and allowing for comparisons across states. States also would help health care providers communicate more effectively, both internally and with patients, when errors occur by encouraging apology and the use of facilitated discussion procedures such as mediation (Cohen, 2000; Sage, 2002). Finally, states would engage in sustained efforts to educate the public with respect to the trade-off involved in replacing tort liability with administrative remedies for avoidable medical injury: faster, fairer, surer compensation but forgoing a jury trial.

Some states might choose to phase in nonjudicial approaches to compensation, beginning with selected provider organizations (e.g., hospitals, large medical groups, and closed-panel health maintenance organizations [HMOs]) that have demonstrated their willingness and ability to detect, disclose, and prevent medical errors and have entered into voluntary contractual agreements with patients that establish the terms of compensation (Havighurst, 1995; O’Connell, 1986; Sage et al., 1994). Other states might want to move more quickly by establishing comprehensive state-wide systems of administrative claims resolution with mandatory participation by all health care providers in the state (e.g., physicians, nurse practitioners, hospitals, nursing facilities).

The former approach has the advantage of building on the IOM’s earlier recommendations regarding the optimal structure and conduct of high-quality health care organizations (Institute of Medicine, 2000, 2001). Specifically, this approach creates incentives for physicians and hospitals to join together to form well-managed clinical entities that bear primary financial responsibility for avoidable errors and have the medical know-how to minimize patient injury. The strength of the latter approach is that it gives all health care providers equal, immediate access to relief from the current liability crisis and does not depend upon particular organizational forms (e.g., integrated group practice) that may not be well developed in many jurisdictions.

The workers’ compensation system is the most familiar example of substituting administrative claims resolution for tort liability on a state-wide basis (Fishback and Kantor, 2000; Kramer and Briffault, 1991). Experience with workers’ compensation demonstrates that nofault systems can enhance predictability and improve access to compensation. It also confirms the importance of maintaining safety incentives (e.g., through self-insurance or experience rating) and establishing reasonable injury thresholds and clear categories of compensable injury that reduce waste and discourage fraud.

Non-judicial approaches to compensating unexpected medical injuries are the norm in New Zealand, Sweden, and elsewhere (Bovbjerg and Sloan, 1998; Danzon, 1985, 2000). Similar programs were debated intensively in Colorado and Utah in the mid-1990s, but were not adopted (American College of Physicians, 1995; Petersen, 1995). The committee believes the time is now ripe for successful implementation of such approaches in the United States because of two contributions by the emerging science of patient safety. First, human factors engineers have shown that non-punitive approaches encourage the detection of avoidable injuries and foster systems for continuous improvement, which suggests that resolving malpractice cases without a determination of fault will help rather than harm quality (Institute of Medicine, 2000). Second, as more health care providers accept their responsibility to disclose errors to patients, capping liability at defined amounts—an essential attribute of any affordable non-judicial system—will likely

result in more rather than fewer patients receiving compensation.

GOALS

The demonstration projects in this category would have the following goals:

1. Improve the malpractice system for patients
 - Make compensation for injury more predictable, timely, and fair.
 - Promote honesty, transparency, and trust in clinician-patient relationships.
 - Prevent liability concerns from compromising the availability of health care services for patients.
 - Put patients and physicians, not lawyers and courtrooms, at the center of a reformed system
2. Enhance patient safety
 - Promote robust reporting of errors in a safe environment.
 - Promote system-level responsibility for errors through organization-based financial incentives for improvement, such as self-insurance and experience rating.
 - Involve patients in safety improvement efforts.
3. Maintain access to liability insurance
 - Improve predictability of liability costs
 - Increase affordability of high-dollar liability coverage.
 - Decrease the administrative costs of resolving disputes.
4. Assess cost impact
 - Generate definitive data regarding error rates, claims rates, compensation costs, and administrative costs under various state systems for identifying avoidable errors and related compensation formulas.
 - Analyze and compare data within and across states.

DEMONSTRATION ATTRIBUTES

Both liability reform options outlined earlier require the following actions by participating states, with federal grants for up-front costs and technical assistance, as well as waiver authority if necessary:

- *Infrastructure*—The state would develop and maintain objective indicators of avoidable errors (ACEs), relying on experts, a broader and more participatory process, or a combination of the two. The state also would develop and maintain fair, consistent methods (schedules) for calculating economic harm and reasonable compensation for pain and suffering. Both the ACEs and the schedules would need to be updated on a regular basis, with ACE categories expanding over time to encompass the large majority of avoidable injuries. There also would need to be centralized collection of data related to the state-level demonstrations. To help states in developing ACEs and damage schedules, DHHS should provide support for related grants to the Health Resources and Services Administration (HRSA) or the Agency for Health Care Research and Quality (AHRQ).
- *Legal environment*—States would need to authorize statutory or contractual modifications of tort liability to reflect the terms of the option they select, as well as to create clear, narrow exceptions to the malpractice reform (e.g., intentional harm). The state would also need to protect from legal exposure individuals and organizations acting in good faith to implement the demonstration approach (e.g., health plans and employers negotiating group contracts on behalf of enrollees). And to make the demonstration affordable, states would need to prevent

health insurers, disability insurers, and other parties who pay costs incurred by patients suffering compensable injuries from suing health care providers to recover those payments (i.e., barring subrogation claims). Finally, states would need to ensure that apologies and other systematic communications, such as mediated discussions between providers and patients following the occurrence of an avoidable injury, do not increase providers' financial liability or legal exposure.

- *Patient safety reporting systems*—States would establish oversight mechanisms to verify the detection of injuries and disclosure to patients. The specifics of these mechanisms would depend on whether the claims resolution system operates at the state-wide or institutional level (i.e., upon the demonstration option selected). These mechanisms would build upon existing state reporting requirements. States would also need to establish mechanisms for collecting and analyzing patient safety data, including voluntary, confidential reporting of near misses. Federal legislation currently under consideration by Congress would aid this process if enacted. The collection and reporting of patient safety information would need to rely on computer-based monitoring systems within health care institutions. With time and experience, these systems could be linked to decision support and knowledge management systems that would help prevent errors from occurring in the first place. Federal technical assistance would be available for these activities.
- *Education*—The states would be charged with educating the public about the benefits and costs of liability reform, which offers faster, fairer, surer compensation on the one hand but requires waiving the right to a court trial on the other. States would also need to work with the principal stakeholder groups (e.g., consumer organizations, health care providers) to build familiarity with and trust in the public policy goals of the option selected, and to allay concerns about the constraints imposed by the demonstration.

Option 1: Provider-Based Early Payments

Eligibility

A variety of health care provider organizations could participate in such a demonstration, including hospitals, academic health centers, large medical groups, closed-panel HMOs, and skilled nursing facilities. Independent physicians might decide to affiliate with provider organizations (sometimes called “channeling”) in order to participate in a demonstration and receive liability protection.

Participating Provider Responsibilities

Provider organizations would first need to self-insure their liability risk, or purchase experience-rated primary coverage so that the organization benefits (or not) from how well they reduce the number of avoidable injuries. They would also need to inform patients about their participation in the demonstration, providing contractual notice of modified liability (perhaps through payers at the point of health insurance enrollment) (Moore and Hoff, 1986; O'Connell and Bryan, 2000–2001). It is likely that mandatory patient participation as a condition of treatment would best serve the goals of the demonstration for states adopting the provider-based early payment option. However, a state might choose, for legal, political, or other reasons, to allow patients to opt out of the reformed system at the time of health insurance enrollment or hospital admission (i.e., preinjury), or might modify the early payment system in special situations (e.g., emergency care).

Should a specific avoidable event (ACE) cause injury, providers would need to notify patients promptly; express regret; and tender payment for both net economic harm (medical care, lost wages, lost domestic production, with collateral source offset) and capped, scheduled noneconomic harm (pain and suffering). Provid

ers also would be permitted, but not required, to tender similar payments in other cases of avoidable medical injury that do not fit into an ACE category, thereby gaining immunity from suit. Because providers would be required to comply with external oversight and error reporting obligations, states would be able to monitor early payment practices to determine the circumstances under which providers are voluntarily tendering or not tendering early payment. In terms of patient safety, providers would need to offer patients meaningful opportunities to participate in efforts designed to reduce error (e.g., mediated discussions with patient safety committees regarding their experiences).

Government Responsibilities

The state would protect participating provider organizations from tort liability in cases where payment is promptly tendered. States, either directly or through intermediary organizations, would ensure that organizations reliably inform patients in all instances of avoidable injury. The federal government would provide reinsurance or other umbrella coverage as an incentive for provider organizations to self-insure and channel coverage for affiliated physicians, with shared-risk corridors or similar safeguards against moral hazard. The federal government should consider whether additional funds should be made available in the event that the early payment system is more expensive than the current system.

In addition to the general support described above, DHHS might provide technical assistance to states establishing oversight mechanisms for captive insurance companies or risk-retention groups formed by provider organizations. Finally, DHHS would create “safe harbor” protection under the antikickback statute so that hospitals and other provider organizations can offer shared, subsidized liability coverage to affiliated physicians.

Option 2: Statewide Administrative Resolution

Eligibility

All licensed health care providers (professional and institutional) within a state (or large geographic area within a state) would participate. States might explore including health plans and other potentially liable parties as well.

Provider Responsibilities

Providers, along with the state, would notify patients about the state's modified liability system and give them related information. No pre-injury opt-out would be available under this option. Providers also would need to set up systems to detect errors and disclose them to patients and to provide related apologies. For injuries to patients that fall within the scope of the demonstration, providers or their liability carriers would be responsible for paying amounts determined by the publicly administered adjudication system in the manner authorized by that system.

Government Responsibilities

States would need to create a publicly administered adjudication system, with each state having latitude to determine how it will do so. Key elements of such a system include the following:

- Compensation criteria based on avoidability (e.g., expansion over time of established ACEs categories)
- A definition of compensation that combines net economic harm (medical care, lost wages, lost domestic production, with collateral source offset) and capped, scheduled noneconomic harm (pain and suffering)
- Injury thresholds (days of hospitalization, days of disability, total economic loss)

- An administrative system of adjudication for determining eligibility and compensation in individual cases
- A consumer and provider appeals mechanism
- A multidisciplinary expert panel, including consumer representatives to oversee the system

DHHS would provide start-up funding for the administrative adjudication system, with the understanding that there will eventually be a transition to a provider surcharge with federal matching funds. This might be done using HRSA or AHRQ grants to states in amounts sufficient to cover the operating costs of calculating payments and resolving disputes, as well as initial expenses associated with defining compensable events and developing damage schedules.

As states develop the infrastructure needed for the demonstrations, they would need to work with stakeholder groups, including consumer advocacy groups, to anticipate and avoid state constitutional challenges and other implementation delays. The states would also need to put in place a system for funding compensation payments that maintains financial incentives for safety improvement within health care organizations, possibly modeled on workers' compensation systems that segment employers according to size and structure into tiers of class-rated individual risk, commercially insured (experience-rated) risk, and self-insured risk. Pooling of individual risks might best be handled in the long run by a state fund supported by physician surcharges and administered by private entities under contract to the state. For practicality, however, demonstration sites should encourage liability carriers that currently insure individual clinicians to accept essentially all applicants, with discounts for meaningful patient safety activities.

Finally, the federal government would guarantee fiscal neutrality from the state's and its providers' perspectives to account for the possibility that a comprehensive system that identifies and compensates avoidable injury may be more expensive than the current patchwork system of tort litigation. As part of this guarantee, appropriate maintenance-of-effort and other design safeguards would need to be in place.

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Glossary and Acronym List

GLOSSARY

- Chronic condition.** A condition that requires ongoing medical care, including monitoring, treatment, and coordination among multiple providers; limits what one can do; and is likely to last longer than 1 year. Examples include diabetes, cancer, and cardiovascular disease (Partnership for Solutions, 2002).
- Clinicians.** Individual health care providers, such as physicians, nurse practitioners, nurses, physician assistants, and others.
- Providers.** Refers to both institutional providers of health care services (e.g., health plans, health maintenance organizations [HMOs], hospitals, nursing homes) and clinicians (e.g., physicians, nurse practitioners, nurses, physician assistants).
- Quality.** The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Institute of Medicine, 1990).

Quality aims. Six dimensions of quality that constitute the goals of the health system (Institute of Medicine, 2001):

- *Safe*—avoiding injuries to patients from the care that is intended to help them.
- *Effective*—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
- *Patient-centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely*—reducing waits and sometimes harmful delays for both those who receive and those who give care.
- *Efficient*—avoiding waste, including waste of equipment, supplies, ideas, and energy.
- *Equitable*—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

Quality (or performance) measures. These include measures of patient perspectives on care, clinical quality, and patient outcomes:

- Measures of patient perspectives include patients' assessment of and satisfaction with their access to and interactions with the care delivery system (e.g., waiting times, information received from providers, choice of providers).
- Measures of clinical quality are specific quantitative indicators designated to identify whether the care provided conforms to established treatment goals and care processes for specific clinical presentations. Clinical quality measures generally consist of a descriptive statement or indicator (e.g., the rate of beta blocker usage after heart attack, the 30-day mortality rate following coronary artery bypass graft surgery), a list of data elements that are necessary to construct and/or report the measure, detailed specifications that direct how the data elements are to be collected (including the source of data), the population on whom the measure is constructed, the timing of data collection and reporting, the analytic models used to construct the measure, and the format in which the results will be presented. Measures may also include thresholds, standards, or other benchmarks of performance (McGlynn, 2002).
- Measures of patient outcomes include mortality, morbidity, and physical and mental functioning.

ACRONYM LIST

ACEs	avoidable classes of events or accelerated compensation events
AHRQ	Agency for Healthcare Research and Quality
BPHC	Bureau of Primary Health Care
CHC	Community Health Center
CHII	Consolidated Health Informatics Initiative
CMS	Centers for Medicare and Medicaid Services
DHHS	U.S. Department of Health and Human Services
DICOM	Digital Imaging and Communications in Medicine
FFS	fee-for-service
FPL	federal poverty level
FQHC	Federally-Qualified Health Center
HIPAA	Health Insurance and Portability Act of 1996
HL7	Health Level 7
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
ICT	information and communications technology
IEEE	Institute of Electrical and Electronics Engineers
INPC	Indiana Network for Patient Care
IOM	Institute of Medicine
ISDI	Integrated Service Development Initiative
NCPDP	National Council for Prescription Drug Programs
NEHEN	New England Healthcare EDI [electronic data interchange] Network
NLM	National Library of Medicine
PSI	Patient Safety Initiative
RFP	request for proposals
SCHIP	State Children's Health Insurance Program
VHA	Veterans Health Administration