Fostering Rapid Advances in Health Care

Learning from System Demonstrations

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

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Board on Health Care Services

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu
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.
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
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**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

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.

- **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 reallocated 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-
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.

**REFERENCES**


Fostering Rapid Advances in Health Care: Learning from System Demonstrations (2002)


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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 non-judicial 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 non-judicial 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 no-fault 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., pre-injury), 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-
Liability

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.

REFERENCES


