Making Patient Safety the Centerpiece of Medical Liability Reform

Hillary Rodham Clinton and Barack Obama

We have visited doctors and hospitals throughout the country and heard firsthand from those who face ever-escalating insurance costs. Indeed, in some specialties, high premiums are forcing physicians to give up performing certain high-risk procedures, leaving patients without access to a full range of medical services. But we have also talked with families who have experienced errors in their care, and it has become clear to us that if we are to find a fair and equitable solution to this complex problem, all parties — physicians, hospitals, insurers, and patients — must work together. Instead of focusing on the few areas of intense disagreement, such as the possibility of mandating caps on the financial damages awarded to patients, we believe that the discussion should center on a more fundamental issue: the need to improve patient safety.

We all know the statistic from the landmark 1999 Institute of Medicine (IOM) report that as many as 98,000 deaths in the United States each year result from medical errors.¹ But the IOM also found that more than 90 percent of these deaths are the result of failed systems and procedures, not the negligence of physicians. Given this finding, we need to shift our response from placing blame on individual providers or health care organizations to developing systems for improving the quality of our patient-safety practices.²

To improve both patient safety and the medical liability climate, the tort system must achieve four goals: reduce the rates of preventable patient injuries, promote open communication between physicians and patients, ensure patients access to fair compensation for legitimate medical injuries, and reduce liability insurance premiums for health care providers. Addressing just one of these issues is not sufficient. Capping malpractice payments may ameliorate rising premium rates, but it would do nothing to prevent unsafe practices or ensure the provision of fair compensation to patients.³

Studies show that the most important factor in people’s decisions to file lawsuits is not negligence, but ineffective communication between patients and providers.⁴ Malpractice suits often result when an unexpected adverse outcome is
Main Provisions of the National Medical Error Disclosure and Compensation (MEDiC) Bill

Office of Patient Safety and Health Care Quality
This legislation would create an Office of Patient Safety and Health Care Quality within the Department of Health and Human Services. The director of this office will be responsible for establishing a National Patient Safety Database, conducting data analyses to inform policy and practice recommendations, establishing and administering the National Medical Error Disclosure and Compensation (MEDiC) program, and supporting studies related to MEDiC and the medical liability system.

MEDiC Program
The MEDiC program would promote open communication between patients and providers; reduce the rates of preventable medical errors; ensure patient access to fair compensation for medical injury, negligence, or malpractice; and reduce the cost of medical liability insurance.

The MEDiC program would provide federal grant support and technical assistance for doctors, hospitals, and health systems that disclose medical errors and problems with patient safety and offer fair compensation for injuries or harm. Participants would submit a safety plan and designate a patient-safety officer, to whom these disclosures and notices of related legal action would be reported. If a patient was injured or harmed as a result of medical error or a failure to adhere to the standard of care, the participant would disclose the matter to the patient and offer to enter into negotiations for fair compensation.

The terms of negotiation for compensation ensure confidentiality, protection for any disclosure made by a health care provider to the patient in the confines of the MEDiC program, and a patient’s right to seek legal counsel; they also allow for the use of a neutral third-party mediator to facilitate the negotiation. Any apology offered by a health care provider during negotiations shall be kept confidential and could not be used in any subsequent legal proceedings as an admission of guilt if those negotiations ended without mutually acceptable compensation.

Participating insurance companies and health care providers would be required to apply a percentage of the savings they achieve from lowered administrative and legal costs to the reduction of premiums for physicians and toward initiatives to improve patient safety and reduce medical errors.

Grants
The director would develop and oversee grant programs to encourage participation in the MEDiC program and support patient-safety initiatives. Funding may be used to develop and implement communication training programs for health care providers; to improve the use of information technology for the reporting, collection, and analysis of patient-safety data; to facilitate the tracking and analysis of local and regional patient-safety trends; and to develop and disseminate safety training guidelines and recommendations.

Studies
The Office of Patient Safety and Health Care Quality would conduct three studies: an analysis of the patient-safety data from its new database and other sources to determine performance and systems standards, as well as safety tools and best practices for health care providers; an analysis of the medical liability insurance market to determine historical and current legal costs related to medical liability, factors leading to increased legal costs, and which, if any, state liability insurance reforms have led to stabilization or reduction in medical liability premiums; and a database study of cases that were not successfully negotiated through the new program, to determine the reasons, trends, and effects of such outcomes.
met with a lack of empathy from physicians and a perceived or actual withholding of essential information. Stemming the causes of medical errors requires disclosure and analysis, which create tension in the current liability climate.

The current tort system does not promote open communication to improve patient safety. On the contrary, it jeopardizes patient safety by creating an intimidating liability environment. Studies consistently show that health care providers are understandably reticent about discussing errors, because they believe that they have no appropriate assurance of legal protection. This reticence, in turn, impedes systemic and programmatic efforts to prevent medical errors.

To overcome the impasse in the debate on medical liability, we have introduced legislation, the National Medical Error Disclosure and Compensation (MEDiC) Bill (S. 1784), to direct reform toward the improvement of patient safety (see box). Our proposed MEDiC program provides grant money and technical assistance to doctors, hospitals, insurers, and health care systems to implement programs for disclosure and compensation. The MEDiC model promotes the confidential disclosure to patients of medical errors in an effort to improve patient-safety systems. At the time of disclosure, compensation for the patient or family would be negotiated, and procedures would be implemented to prevent a recurrence of the problem that led to the patient’s injury.

Under our proposal, physicians would be given certain protections from liability within the context of the program, in order to promote a safe environment for disclosure. By promoting better communication, this legislation would provide doctors and patients with an opportunity to find solutions outside the courtroom. In return, MEDiC program grantees would be required to use savings achieved by reducing legal defense costs to reduce liability insurance premiums and to foster patient-safety initiatives.

Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a withholding of essential information.

The MEDiC program is based on model programs around the country that have demonstrated successful approaches to protecting both patients and doctors while improving the quality of care. A number of hospital systems and liability insurance providers have already adopted a policy of robust disclosure of medical errors. These programs have been successful in reducing administrative and legal costs for providers, insurers, and hospitals. Surveys also show greater trust in and satisfaction with health care providers on the part of patients. Ultimately, through these programs, disclosure of medical errors has resulted in the filing of fewer malpractice suits, a reduction in litigation costs, and accelerated provision of compensation to patients, and increases in the numbers of patients who are compensated for their injuries.

The link between the medical liability environment and patient safety has been illustrated by a number of these programs. In 2002, the University of Michigan Health System launched a program with three components: acknowledge cases in which a patient was hurt because of medical error and compensate these patients quickly and fairly; aggressively defend cases that the hospital considers to be without merit; and study all adverse events to determine how procedures could be improved. Before August 2001, the organization had approximately 260 claims and lawsuits pending at any given time. As of August 2005, the number had dropped to 114 (see graph). The average time from the filing of a claim to its resolution was reduced from approximately 21 months to less than 10 months. Annual litigation costs dropped from about $3 million to $1 million. The health care system has begun to reinvest these savings in the automation of its patient-safety reporting systems. Since the implementation of this program, the University of Michigan Health System has expanded the number of practicing clinicians and faculty members in high-risk fields such as obstetrics–gynecology and neurosurgery.

In 1987, after two malpractice cases that together cost it more than $1.5 million, the Veterans Affairs (VA) Hospital in Lexington, Kentucky, adopted a policy of robust disclosure of medical errors, with early offers of compensation to its injured patients. As a result of its 19 years of ex-
experience with this approach, the hospital has liability costs well below those of comparable VA hospitals. Data show that average settlements were approximately $15,000 per claim, as compared with more than $98,000 at other VA institutions. The policy has also decreased the average duration of cases, previously two to four years, to two to four months, as well as reduced costs for legal defense. These are just two examples of such programs, but their results are consistent with those of other organizations that have adopted a similar model.

We realize that the implementation of the MEDiC model will not come without effort. A safe and appropriately confidential environment must be created that allows open communication between physicians and patients about adverse outcomes. Initially, medical-error transparency may be difficult to foster. However, organizations that have put disclosure programs into practice have been effective in resolving disputes in a less adversarial manner, providing fair compensation, and improving patient care. We believe that the MEDiC Bill provides a commonsense solution that avoids the political pitfalls that have hampered other efforts to reform the medical liability system.

An interview with Richard Boothman of the University of Michigan Health System can be heard at www.nejm.org.

Senator Clinton (D-N.Y.) and Senator Obama (D-Ill.) are coauthors of the MEDiC bill.

4. Liebman CB, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. Health Aff (Millwood) 2004;23(4):22-32.

FOCUS ON RESEARCH

Lymphocytic Choriomeningitis Virus — An Old Enemy up to New Tricks

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Lymphocytic choriomeningitis virus (LCMV) was among the first human pathogenic viruses to be isolated. In the mid-1930s, Armstrong and Lillie obtained a filterable agent thought to be from the brain of a man who died during an epidemic of St. Louis encephalitis. Traub discovered a chronic infection in a mouse colony, and Rivers and Scott isolated a virus from the cerebrospinal fluid of patients with aseptic meningitis (see image).¹ All three of these viruses were shown to have the same properties and serologic features, and LCMV became the type species characterizing the virus family Arenaviridae, established in 1970. In nature, each of the approximately 20 known arenaviruses chronically infects a single rodent species, with long-term shedding of virus, but with minimal or no overt disease.

The study of mice infected with LCMV has led to Nobel Prize–win-