Chapter 55. Legislation, Accreditation, and Market-Driven and Other Approaches to Improving Patient Safety

Robert Trowbridge, MD
Robert M.Wachter, MD
University of California, San Francisco School of Medicine

Background

Although conventional approaches to health care quality improvement based on educating providers and offering feedback have been proposed, the tremendous public and professional concerns raised by the Institute of Medicine's report on medical errors[1] have led to an unusual amount of interest in regulatory and legislative efforts to improve safety. Given the traditional American dependence on education, competition, and other non-coercive mechanisms of change, the shift toward a regulatory approach is evidence of the depth of concern this issue has engendered. As these regulatory and legislative approaches are considered, it is also worthwhile to consider the role of health care payers, hospital accreditation organizations, and professional societies, all of whom have also led safety initiatives.[2-4] This chapter considers the potential advantages and disadvantages of legislative, regulatory, professional society, and market-oriented approaches to implementing patient safety efforts, and reviews the evidence regarding their effectiveness.

Government Legislation and Regulation

The concept of patient safety has been championed by several prominent legislators in both major political parties and has become the topic of a great deal of national debate. Proposals to date include the establishment of voluntary and mandatory error reporting systems, the publication of outcomes data, and the development of several Health Care Financing Administration (HCFA) programs to prevent medical errors.[5] In addition, in 2000 the Agency for Healthcare Research and Quality (AHRQ) established a Center for Quality Improvement and Patient Safety, whose mandate in part is to fund research and demonstration projects in patient safety. Though most of these Federal efforts are in the formative stages,[6] successful Federal agency and regulatory efforts outside of medicine, most notably in workplace safety and commercial airline travel, may herald medicine's success. In these fields, the Occupational Safety and Health Administration (OSHA) and the Federal Aviation Administration (FAA) are credited with catalyzing significant improvements in safety over the past 30 years.[7, 8]

Despite a paucity of data regarding the effect of State legislation on medical errors and patient safety, there is some evidence regarding the effectiveness of State regulatory efforts to improve health care quality.[9-11] Among the most prominent set of regulations are the New York State enactments as a result of the death of Libby Zion.

The daughter of a prominent reporter, Ms. Zion died soon after being admitted to the medical service of a New York City hospital. A detailed investigation of the circumstances of her death subsequently raised concerns regarding working conditions and the supervision of resident physicians. The Bell Commission, formed at the behest of the New York State Health Commissioner, later recommended major reform in these areas and several regulations were enacted mandating dramatic changes in working conditions and supervisory oversight.[12]

These regulations markedly altered resident physician education in New York State. Although they anecdotally resulted in an improvement in resident morale and quality of life,[13]

their effect on patient safety is less certain. One retrospective cohort study demonstrated that patients treated after the work-hour limitations were instituted were more likely to suffer from complications and delays in the performance of diagnostic tests.[11] A second retrospective analysis of patient transfer-of-care, a bi-product of restricting resident work-hours, showed increased lengths of stay and utilization of laboratory testing for patients that were "handed off."[10] A third study, however, revealed exactly contradictory results. It found the work-hours limitations led to shorter lengths of stay and fewer medication errors.[9] These studies have been criticized for concentrating on the work-hour regulations when the main finding of the Bell Commission was that increased supervision of resident physicians was a more important initiative.[14] (See Chapter 46 for a more complete discussion of fatigue and work hours).

Although regulations to improve patient safety might be a more efficient way of changing practice than less coercive methods such as education or feedback, the use of government regulation in the assurance of patient safety has limitations. A primary concern is that regulations may be crafted by legislators who lack intimate knowledge of the health care system. In addition, health care in the United States is extremely heterogeneous - what may be feasible and appropriate in one setting may be inapplicable in another. The differences between the delivery of care in urban and rural settings may be particularly troublesome in this regard. Finally, it is unclear whether government agencies would provide adequate funding to assist health care organizations to comply with new regulations. For example, a cash-starved institution faced with a resident work-hours mandate might need to decrease nurse staffing or defer purchase of a computerized order entry system to meet the mandate.

Government agencies may also influence patient safety practices through means other than direct legislation. For example, the National Nosocomial Infections Surveillance (NNIS) system may serve as a template for the development of a government-sponsored safety program. Established and administered by the Centers for Disease Control and Prevention (CDC), the NNIS is a voluntary nationwide consortium of 300 hospitals that regularly report the incidence of specified nosocomial infections.[15] Through analysis of the aggregate data, benchmarks are set for the expected rates of nosocomial infection that hospitals may then strive to meet or better. There is some evidence that the NNIS has contributed to a substantial decline in the rate of nosocomial infections over the past several decades.[16] It is conceivable that a similar program could be established for broader patient safety issues. Although voluntary and lacking enforcement power, NNIS-like patient safety benchmarking could significantly improve safety, especially if the data were made available to the public or accreditation agencies.

Infection control officers, another aspect of the CDC-championed infection control movement, may also be applicable to the patient safety movement. Presently, infection control officers employed by medical centers focus on improving the system and changing practices to decrease the institutional rates of serious infections. An institutional "patient safety officer" might assume an analogous function with regard to decreasing adverse events and errors. The establishment of a patient safety officer or committee is one of the new Joint Commission on Accreditation of Healthcare Organization's (JCAHO) safety standards (discussed below). To date, there are no data regarding the effectiveness of these practices in patient safety.

Accreditation Organizations

Accreditation organizations represent another sector of the health care industry that is assuming new responsibilities in the field of patient safety. JCAHO, an outgrowth of accreditation programs initiated by the American College of Surgeons several decades ago, is the best known of these organizations. JCAHO conducts meticulous inspections of medical centers,

hospitals and other health care institutions on a triennial basis. Survey results are subsequently used in the process of obtaining Medicare certification and State licensure and to obtain bond ratings and managed care contracts. Although such inspections had previously included some elements relating to the field of patient safety (including infection control and the prevention of medication errors), they tended to focus on organizational topics including information management, institutional leadership and strategic planning.[17] In response to concerns regarding patient safety, however, JCAHO has recently launched a major patient safety initiative and implemented an entirely new set of standards in July 2001.[18]

The new JCAHO standards place a much greater emphasis on the prevention of medical errors and the process of responding to medical errors once they occur. A particular focus of the new initiative is the development of organization-specific patient safety programs. Such programs, which will undoubtedly require substantial resources to implement, are expected to have well-defined leadership, to proactively determine areas where errors are likely to occur, and to be capable of effecting significant organizational change when necessary. The key elements of these standards are listed in Table 55.1.

Although there is no published evidence that the patient safety standards previously required by JCAHO have reduced medical errors, it seems reasonable to assume they have had some salutary effect.[6] Because JCAHO reports are now publicly available and are used by a wide variety of credentialing agencies and health care purchaser organizations, many hospitals and other medical institutions will make serious and concerted efforts to meet the new standards. Although lacking the enforcement power of Federal regulations, the agencies' knowledge of, and contacts within the medical community may produce change more efficiently. Moreover, the process of accreditation involves frequent site visits between the agencies and health care organizations. These visits, in turn, may allow for interactions between institutions and accreditors which, under ideal circumstances, could allow for user input in to modifications of regulations. How often this ideal is realized is not known, and some observers have questioned JCAHO's overall effectiveness.[19-21]

Health Care Purchaser Initiatives

The business community has also reacted to the perceived crisis of safety in health care. The most prominent example is the Leapfrog Group.[3] Sponsored by a consortium of major corporate chief executive officers known as the Business Roundtable, the Leapfrog Group's stated commitment is "to mobilize employer purchasing power to initiate breakthrough improvements in the safety of health care for Americans."[22] Large volume purchasers of health care, including Aetna, ATT, IBM and many other Fortune 500 companies, have joined the group. Combined, their annual health care outlay is over $45 billion. Using their considerable financial influence, the group hopes to impact medical care by requiring or incentivizing health care providers to adhere to certain standards for the process and delivery of care.[22]

Thus far the Leapfrog consortium has chosen to promote 3 patient safety practices: the use of computerized physician order entry (Chapter 6), the involvement of critical care physicians in the care of intensive care unit patients (Chapter 38), and the use of evidence-based hospital referral systems (Chapter 18).[23] The latter practice refers to the referral of patients to hospitals with the highest volume and best outcome figures for certain elective medical procedures and treatments. These initiatives were selected because there is substantial evidence that they enhance quality of care and their implementation is both feasible and easily assessed. Initial research sponsored by the group suggests that implementing just these 3 strategies could prevent almost 60,000 deaths per year and avoid over 500,000 errors in medication

administration.[24, 25] It is anticipated that other quality-related practices (some directed at patient safety targets) will be added to the list as evidence for their effectiveness is accumulated.

The Leapfrog Group has also begun to outline a program to improve compliance with the target practices. Plans include rewarding complying providers with an increased number of patients, increasing remuneration for specific services, and providing public recognition. General quality will be assessed and publicized through the use of rankings, including those assigned by JCAHO and other accreditation organizations.[23] In addition, the employees of participating companies will be encouraged to become more active in choosing providers that meet the Leapfrog standards.

Although the Leapfrog initiative is in its nascent stages and there is presently no objective evidence that it will favorably impact patient safety, the sheer financial clout of the involved corporations may catalyze rapid and meaningful change. As with government regulation, it is unclear which sector of the health care industry will bear the brunt of the implementation costs. The institution of computerized order entry systems, for example, will require substantial financial outlays (several million dollars in hardware, software and training for the average hospital; see Chapter 6) that hospitals and medical groups may find extremely difficult to absorb without assistance. Additionally, physicians and other health care providers may resist changes forced upon them from outside medicine, or may "game the system" to create the appearance of change simply to meet the standards.[26] Finally, purchaser initiatives may create disparities in the level of patient safety among socioeconomic groups if the changes they promote are only required of health care institutions that provide care to insured members of the group.

Other Approaches

Professional Societies

Some of the earliest efforts to improve patient safety were actually directed by medical professional societies rather than outside regulators, accreditors, or legislative bodies. The American Society of Anesthesiologists (ASA), for example, formed the Anesthesia Patient Safety Foundation in 1984 and has since promulgated a number of reforms that have substantially changed the routine practice of anesthesia. Safety measures such as continuous electrocardiographic monitoring, pulse oximetry and preoperative evaluation were strongly championed by these organizations through the dissemination of quality standards and newsletters.[1] While no evidence directly links these initiatives to improved patient safety, there is little doubt that these reforms resulted in substantial advances. In fact, the standards of care promoted by the ASA have been widely adopted and now represent the recognized minimum level of appropriate care.[4] It is nonetheless difficult to separate the effects of these standards from secular trends associated with technological and clinical advances.

Although medical professional societies do not possess the regulatory might of the Federal government or the financial power of large health care purchasers, their standing in the medical community and collective clinical experience are great advantages. It is well established that physicians are more apt to follow practice guidelines sponsored by respected medical societies than those issued by the government or industry.[27] Society-based programs are also likely to allow for more provider input and may be more amenable to frequent modification. Unfortunately, because they lack the power to compel, society recommendations cannot be the sole agent of change, especially when the evidence supporting a practice is extremely strong and the stakes are high. It is important to recognize that society recommendations carry a potential

for bias, particularly when the recommended changes may have an economic impact on society members.

Publication of Performance Data

Each of the large entities described above (legislatures, accrediting bodies, purchasers, payers, and professional societies) may choose to disseminate performance data to the public as part of its quality improvement strategy. To date, most such report cards have focused on discrete quality outcomes for single diseases or procedures (eg, mortality after coronary angioplasty) rather than patient safety targets such as error or nosocomial infection rates. Nonetheless, implicit in the vigorous debate regarding mandatory error reporting systems is the question of whether public reporting of performance data is effective in either motivating provider change or facilitating informed choices by patients.

Marshall and colleagues recently reviewed the evidence regarding the impact of public reporting systems.[28] They found that such systems had a relatively small impact on patients (the potential users of the data), but a greater impact on the hospitals (the sources of the data). They posit that the impact is growing as the public becomes increasingly comfortable with both the concept and interpretation of quality reports. Although some have claimed that public reporting systems, such as New York State's Cardiac Surgery Data System (which has reported risk-adjusted coronary bypass outcomes since 1990), have led to major improvements in quality,[29] this remains controversial.[30] Proponents point to New York's falling bypass mortality rate as evidence of the value of public reporting, but there is some evidence that the fall in the rate was due to outmigration of high-risk patients to other states rather than true quality improvement.[31]

Comment

Concerns about medical errors have spurred many organizations and institutions to launch major patient safety initiatives. Perhaps because they represent a relatively recent development or because empirical measurement of such macro-changes is difficult (isolating the effects of individual interventions vs. other confounding influences), there is little objective evidence either to determine if they will result in meaningful change or to consider their relative advantages and disadvantages (Table 55.2). Yet Federal and State governments, accreditation agencies such as JCAHO, and health care purchasers such as the Leapfrog Coalition, in combination and independently, may eventually be highly effective champions of patient safety initiatives. In addition, professional medical societies, given their influential role in the medical community, are effective agents of change in certain circumstances. The work and involvement of these diverse, powerful organizations and institutions may prove to be valuable adjuncts to the more traditional mechanisms of change represented by practice guidelines, continuing medical education programs, and decision support systems.

Table 55.1. New JCAHO safety standards

-Development of a leadership individual or group to devise and implement a comprehensive patient safety program
-Development of a proactive error prevention program that includes means of identifying potentially high risk areas
-Development of systems for the reporting of errors
-Development of an error-response system including protocols for root cause analysis
-Requirement for an annual report discussing errors, the response to errors and the programs initiated to prevent future errors
-Requirement for hospital leaders to set “measurable objectives” for patient safety programs
-Requirement for educational initiatives for employees, stressing the concept of patient safety

Table 55.2. A comparison of non-local methods to promote patient safety practices

Approach	Example	Advantages	Disadvantages
Legislation	"Libby Zion" laws limiting resident work hours	-potential for widespread implementation -supported by government enforcement ability	-inflexible -limited acceptance by health care providers -potential to be developed with inadequate input from providers and experts -may be politically driven with limited applicability -may not provide for costs of implementation, leading to cost-shifting away from other beneficial patient safety practices
Accreditation	JCAHO patient safety standards	-may be more flexible and more easily modified than legislation -implemented at the level of the health care organization -health care providers may have the opportunity for input	-dependent on voluntary participation in the accreditation process -limited enforcement ability -generally assessed only every few years
Market-based	The Leapfrog Group	-uses the power of the market to induce change (may be more acceptable for many providers than regulatory solutions) -may involve carrot (eg, higher payments for better practices or outcomes) rather than stick alone to achieve impact	-potential to cause disparity in care among groups not covered by initiatives -limited acceptance by health care providers -potential for standards to develop with inadequate input from health care providers -change is not required, and therefore implementation may be limited
Professional Societies	Anesthesia Patient Safety Foundation	-readily accepted by health care providers -developed by providers themselves, leading to better "buy in" -more easily modified when new evidence or changes in practice emerge	-minimal enforcement potential; depends largely on voluntary participation by practitioners -potential for bias by professional societies

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