Commentary

Medical errors: how the US Government is addressing the problem

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Abstract

November's Institute of Medicine (IOM) report on medical errors has sparked debate among US health policy makers as to the appropriate response to the problem. Proposals range from the implementation of nationwide mandatory reporting with public release of performance data to voluntary reporting and quality-assurance efforts that protect the confidentiality of error-related data. Any successful safety program will require a national effort to make significant investments in information technology infrastructure, and to provide an environment and education that enables providers to contribute to an active quality-improvement process.

Keywords: Institute of Medicine (USA), legal liability, legislation, mandatory reporting, medical errors

Introduction

Medical errors have become an important topic in current discussions of health care policy in the USA. A well-publicized November 1999 report from the IOM [1] summarized the existing data on mortality from medical errors, discussed potential sources of error, and proposed strategies to reduce these errors. While the report addresses medical practice as a whole, rather than trials in particular, its findings and recommendations are directly applicable to the practice of cardiology. Error-tracking systems, while still in their infancy, have already been implemented in the study of bypass surgery. From its review of the medical literature, the report found that medical errors are pervasive in the health system and are a major cause of death in the USA. The report concludes, however, that most errors result from systematic problems in health care delivery rather than poor performance by individual providers.

Using examples from outside of the health care industry, the report suggested that errors can be reduced through systems approaches, including the development of error-tracking mechanisms, extensive investigations and root cause analyses of errors, and allocation of sufficient resources for error-protection initiatives. Although the health care industry shares characteristics with other industries in its dependence on the interaction of people and technology to achieve a single goal, fragmentation in the health care system and lack of financial support for a comprehensive information technology infrastructure have limited the implementation of effective error-reduction systems across clinical practice sites.

The IOM report outlined a four-part approach in response to its findings: establish a national effort to expand knowledge about medical safety; identify and learn from errors

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IOM = Institute of Medicine; QuIC = Quality Interagency Coordination Task Force.

through mandatory and voluntary reporting systems; raise safety standards and expectations for improvement in safety through the involvement of professional and accrediting organizations; and create delivery-level safety systems within health care organizations.

Quality Interagency Coordination Task Force recommendations

Shortly after the release of the IOM report, President Clinton directed the Quality Interagency Coordination Task Force (QuIC) to develop a plan of action to reduce the incidence of medical errors. The QuIC coordinates the efforts of 12 federal agencies to ensure that the bureaus that are involved in purchasing, providing, researching, or regulating health care services work together to improve the quality of health care.

In its report, the QuIC agreed that error-reporting systems should be established in all 50 states [2]. First, the QuIC recommended that a mandatory system be implemented in all Department of Defense hospitals and clinics in order to collect information on medical errors. Second, mandatory reporting requirements should be expanded to blood banks and other establishments that work with blood. Third, the QuIC will identify a set of patient safety measures that are critical to the identification of medical errors, practices that help to reduce the incidence of errors, and other issues related to the implementation of a mandatory reporting system. Finally, the federal government will work to determine the most effective way to present public information on the incidence of medical errors. A voluntary error-reporting system will be implemented nationwide for Veterans Affairs hospitals by the end of 2000, and the QuIC will examine existing mandatory and voluntary reporting systems at the federal and state levels in order to develop recommendations for a federal role in data collection and oversight.

The QuIC also recommended that all hospitals participating in Medicare and all health plans participating in the Federal Employees Health Benefits Program develop patient safety programs. The Department of Labor will begin to include medical error data in its Health Benefits Education campaign as a way of incorporating patient safety into health plan purchasing decisions. Within 1 year, the US Food and Drug Administration will develop new standards to prevent errors caused by similar-sounding brand names and packaging, and the QuIC report called for the development of new drug labeling standards by the end of 2000. Finally, the QuIC proposed steps to improve access to patient information and to improve order entry within federal health care systems.

Recent legislation

Legislation addressing medical errors has been introduced in both houses of Congress. The *Medical Errors Reduction Act of 2000* [3] called for the implementation of 15 demonstration projects in order to determine optimal strategies for gathering medical error data and to determine the impact of mandatory and voluntary reporting mechanisms and public disclosure of reports. The bill also called for demonstration projects to test technologic means of reducing the incidence of errors.

The *Stop All Frequent Errors in Medicare and Medicaid Act of 2000* [4] would establish a Center for Patient Safety within the Agency for Healthcare Research and Quality, following the recommendations of the IOM report. The focus of the bill, however, is on the establishment of medical error detection and prevention systems for hospitals operating within the Medicare and Medicaid programs. The bill would require health facilities to establish error-detection systems, perform root-cause analyses, and establish strategies to correct errors. The information would be reported to either state public health departments, Medicare peer-review organizations, or accrediting organizations. Noncompliant facilities (ie those with poor safety performance for more than 2 years) would be reported to federal officials, who would release the facilities' medical error records to the public.

The *Medication Error Prevention Act of 2000* [5] encouraged use of a voluntary reporting system known as Med MARx, a national, Internet-based, anonymous database established for health care professionals to share field experiences regarding medical errors.

Finally, the *Patient Safety and Errors Reduction Act* [6] and the *Voluntary Error Reduction and Improvement in Patient Safety Act* [7] called for the institution of a Federal Center for Quality Improvement and Patient Safety. Neither bill called for mandatory reporting of medical errors, and both bills would protect health care providers against litigation and provide for patient confidentiality in medical error databases.

Challenges

Several aspects of the campaign to reduce medical errors have generated controversy. Nancy Dickey, immediate past president of the American Medical Association, criticized President Clinton's call for mandatory reporting of errors, noting that a "number of states have mandatory reporting, and there's no evidence that they have greater safety or fewer errors" [8]. However, preliminary evidence from New York hospitals suggests that mandatory reporting may improve quality of health care. New York hospitals have been required to report medical errors to the state's Department of Health since 1985. The Department also collects information on all patients undergoing heart bypass surgery in the state, regardless of whether an error occurred, and publishes death rates for all hospitals performing the procedure. The death rate for bypass surgery in New York has dropped more than 30% since the state began publishing the data in 1989 [8]. Of course, these uncontrolled data merit further analysis, but the key task for the future effectiveness of the program will be to identify quality assurance practices that could respond effectively to these data. Even states with a long history of error reporting, such as New York, have not implemented comprehensive programs to correct problems once they are identified. This step is central to the goals of the IOM and QuIC reports.

Also, information about new medical technologies should be included in programs to reduce the incidence of medical errors. Although the medical literature has focused primarily on medication- and procedure-related errors, there is little information on the potential benefits and hazards associated with the use of new medical technologies. Neither the IOM report nor the QuIC recommendations address the sharing of information about medical technologies, although such information may be of use to many providers.

Additional concerns arise from the legal dilemmas that mandatory reporting systems are likely to generate. When the reporting of errors concerns death or other serious detriment to patients, accountability will become an issue. Not only might malpractice claims rise with increased error reporting, but hospitals and health care professionals may be less likely to report mistakes if they are not protected from litigation arising from the reporting process. A successful reporting system should ensure that health care organizations are able to examine medical errors without fear of punishment. Although the White House has played down the risk of increased malpractice lawsuits resulting from error reporting, the issue of liability will be a major concern for many providers [9].

Improving the quality of services available to the public is a primary responsibility of all health professionals, so a broader question for the medical profession is why medical errors, which have been described for over a decade, have not previously been approached on a systematic basis. First, the lack of integration across health care delivery sites reduces the likelihood that comprehensive data on patient care will be maintained at a single site or on a single computer system. Lack of integration also fractures responsibility for the monitoring and reporting of errors across several sites, and prevents standardization of information systems and investment in the information infrastructure required to achieve the goals articulated by the IOM. Greater integration may be achievable, but it would require much greater investment in infrastructure, systems, and monitoring than has been available to date in health care settings.

Conclusion

Although the federal government is beginning to find ways to reduce medical errors, the implementation of safety and reporting systems is still in its infancy. Many of the recommendations of the IOM and QuIC reports have not yet come to fruition, and some critics have questioned the need for legislation to reduce errors. Lucian Leape, a noted researcher in this field, felt that new federal regulations could be avoided if expert medical safety panels quickly developed and implemented best practices [10]. Leape also felt that medical errors could be reduced by 50% over 5 years if the President provided more funding for patient safety research. Although appropriate responses to the IOM report are being debated, it is clear that a systematic effort to understand and reduce medical errors will be the cornerstone of health care providers' professional responsibility in coming years. Concerned providers acting in concert cannot accomplish this goal, however, without appropriate investments in infrastructure, analysis capability, and education.

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