

PATIENT SAFETY: WHAT'S HAPPENED SINCE THE IOM REPORT?

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The Institute of Medicine's (IOM) 1999 report published in 2000 entitled "To Err is Human: Building a Safer Health System" raised the national awareness to this major issue facing physicians and the entire health care system¹. This report on medical errors and patient safety has catalyzed public and payer concerns about the quality of health care in the United States. Estimates of up to 98,000 preventable deaths each year in hospitals startled everyone. Debates followed about the accuracy of the data. But the Medical Practice Study reported similar numbers and recently a HealthGrades Quality study reported over 260,000 deaths in the two-year period 2000 to 2002². Berwick, the President of the Institute for Health Care Improvement, stated "100 patients die in hospitals each day because of injuries of treatment, not their diseases."³ He went on further to say "patients will suffer injuries from care until someone decides otherwise." In the five years since the Institute of Medicine's report many are asking what has happened to improve patient safety during this five-year period. Berwick stated that there are pockets of progress but no national commitment. The Commonwealth Fund recently reported Robert Wachter's informal survey of practicing hospitalists and found that 55% believe their hospitals had a "culture of safety"⁴. Wachter's own evaluation of the changes since the IOM report is:

- Regulation: A-
- Error Reporting Systems C
- Information Technology: B-
- Malpractice System D+
(& other vehicles for accountability)
- Workforce and Training Issues: B
- OVERALL GRADE: C+

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Karen Davis, in her Commonwealth Fund's President's Report stated the following positive changes have occurred since the IOM report: More hospital physicians and policy-makers are openly discussing the need to address medical errors; twenty-two states have mandatory reporting; the Leapfrog patient safety program is a major incentive system for participating hospitals; the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) requires hospitals to report errors to patients and requires a time out and sign your surgical site program; more hospitals are reporting quality of data to the Center for Medicare and Medicaid Services (CMS); there has been an increase in the pay for performance (P4P) movement for both hospitals and physicians⁴. On the negative side, however, 40% of consumers feel that the quality of health care has declined in the past five years. Fifty percent of consumers are concerned about the care they or their families have received.

The Leapfrog Group with Medstat recently reported mixed results on hospital practices that protect the patients from harm in a national survey of hospitals using National Quality Forum standards⁵: 8/10 hospitals implemented changes to avoid wrong-site surgeries; 7/10 hospitals require pharmacist to review medication orders before given to patient; 39% fully implement one of Leapfrog Patient Safety Practices; BUT 7/10 hospitals have no protocol to ensure adequate nursing staff and no policy to check that patients understand risks of their procedure; 6/10 hospitals lack procedures for preventing malnutrition in patients; 5/10 hospitals have no procedures in place to prevent bed sores; 4/10 hospitals lack policies requiring workers to wash hands before and after seeing a patient; only 4% implemented CPOE (20% by 2006); only 19% have intensivists on ICU staff (32% by 2008); and high-risk procedures are referred only 3% to 17% of the time.

At the JCAHO Symposium entitled "Prescription for Patient Safety and Medical Liability Reform" it was reported that: Safety issues that have been accomplished in the last five years have changed the conversation so that our health care system is no longer in denial on whether or not medical errors occur, but is now asking the question how do they occur⁶? People are beginning to realize that it is not always bad people making errors but errors more often represent results of bad systems. Resources are beginning to be mobilized from regulators, purchasers, professional organizations, coalitions, the federal government, as well as grass roots efforts. Standards of practice have been developed by the National Quality Forum (NQF) - list

of safe practices - which the JCAHO has adopted. More recently the pay for performance agenda has expanded to include both hospitals and patients. It has participants from both the CMS and the private sector.

However, according to Leape there are many areas where there have not been significant accomplishments. These include: not obtaining legislative protection from discovery; mandatory voluntary reporting; implementation nation-wide of an electronic medical record; universal use of computerized physician order entry systems; and not being effective in having our health care professionals working in teams. We have not involved most physicians and importantly we have not received commitment to patient safety from hospitals, health care professionals, and importantly CEO's. Therefore we have not changed the current culture to one of safety⁷. HealthGrades recently published a quality study from the cooperative efforts of the Kaiser Foundation, the Agency for Health Care and Quality, and the Harvard School of Public Health that evaluated the health care system in reference to patient safety five years after the IOM report². The report focused on four areas: health care quality, making decisions about health care, medical errors and special populations and thoroughly reviews the current status of each.

There are many barriers to successfully changing our current culture to one that does not tolerate medical errors ensuring that our health care system is safe for all patients. One of the major issues in the United States is the legal constraint that prevents voluntary confidential disclosure of errors so that analysis of the causes for the error can be discovered allowing changes to be implemented to avoid repeating these same errors. There is obviously concern about voluntary disclosure of errors because of the risk of malpractice litigation. Until Congress passes legislation giving peer review protection for mandatory reporting of errors any understanding of their causes and how to avoid future similar errors will be minimal throughout our health care system. We also live in a culture of blame where someone has to take the responsibility for the error. There is lack of priority for patients' safety and insufficient funding. Other issues include the complexity of our fragmented health care system, the lack of experience of qualified researchers (which is improving), the lack of clear definitions (also improving) and the lack of agreed nomenclature for reporting.

Physicians remain skeptical that the most common prescribed interventions to reduce medical errors will be effective. In fact, in a recent survey of over 1,300 physicians only 34% felt that interventions that had published evidence for their efficacy were effective; whereas 20% felt that interventions without published evidence for that effectiveness were effective⁸. There was little difference between physicians' opinion about proven interventions to reduce medical errors over those that have not been proven. For those interventions with proven evidence the following percent of physicians believed they were effective: increasing the number of nurses in hospitals 51%; limiting certain high-risk procedures to hospitals that perform many of them 40%; Improving the training of health professionals 36%;

using only physicians with intensive care training on intensive care units 34%; increasing the use of computers to order drugs and medical tests 23%; including a pharmacist on hospital rounds when physicians review patient care 20%.

Recently concern has been raised about veteran doctors not staying current. According to a recent report measuring outcomes as well as other performance measures such as knowledge, therapy, diagnosis and screening, over fifty percent of those surveyed by Choudry et al experienced a decrease in performance with increased years in practice^c. Interestingly, the physicians who have been reluctant to sign the surgical site have been in the older age groups. Choudry et al recommended there must be a quality improvement intervention for physicians and that continuing medical education alone is not effective. The recent Maintenance of Certification (MOC) program instituted by the Accreditation Council for Graduate Medical Education (ACGME) addresses this issue by requiring recertification on a timely basis along with a continued self-learning program, periodic self-assessment and practice performance evaluations. Choudry et al also recommended an increased use of evidence-based medicine and disease management to reverse this trend amongst physicians.

Hospitals and their CEO's have been slow to move forward on patient safety issues. A recent survey of health care executives reported that it is not one of the top priorities facing hospitals today¹⁰. The major issues are financial challenges and care of the uninsured. Patient safety is seventh on their top ten issues of concern:

ISSUE	% CEO'S	CHANGE
Financial Challenges	71	No change
Care of Uninsured	36	Increase
Personnel Shortages	33	Decrease
MD/Hospital Relations	32	Increase
Government Mandates	19	No change
Quality	18	No change
Patient Safety	16	Increase
Capacity	16	Decrease
Technology	14	No change
Patient Satisfaction	13	Increase

There is no doubt that physicians as well as hospital leaders are not incented to reduce medical errors. For example, computerized physician order entry systems (CPOE), which have been shown to reduce medication errors by 50 to 85%, are in less than 10% of hospitals^{11,12}. Leapfrog also has made CPOE one its major initiatives for all of its participating hospitals. However, the number of hospitals in the United States that had CPOE five years ago averaged around 3%; now it is about 7 to 10% - not a major change⁵. Hospitals continue to add bricks and mortar to their facilities making room for more inpatients and operating rooms for more surgical procedures, both to improve their bottom line. A hospital in New Jersey was

reported to be building a deluxe maternity wing for new moms. Their CEO publicly commented that safety and quality are important but upscale amenities sell - “patients tend to believe they are getting quality care when they see hotel service.”¹³ The Massachusetts Technology Collaborative has recommended CPOE for all Massachusetts hospitals¹⁴. The installation and operating costs are high:

	500 Beds	250 Beds	<150 Beds
Installation (Capital and Operating)	\$7.9 M	\$5 M	\$3.1 M
Operating Costs (Annual)	\$1.35 M	\$700,000	\$300,000

Many hospitals will have difficulty paying these costs; several years of experience are needed before they realize savings from a decrease in errors. Currently in Massachusetts only 10% of hospitals have CPOE with another 20% in the process of implementing CPOE. Seventy percent of Massachusetts’s hospitals do not; most under 500 beds. The barriers to 100% utilization include the overwhelming challenge of major information technology costs and installation, lack of clear specifications and standards (which are often not available), the lack of guidelines for best practices for installation and implementation and importantly the resistance by physicians and administrative staff. The Massachusetts Technology Collaborative has recommended that all payers provide 50% of the cost in their so-called Mass-E Collaborative by partnering with the hospitals. They are currently working on an implementation plan.

When Lucien Leape was asked what has to happen to improve patient safety since the IOM report he replied: “there have not been big improvements.” He suggested “three musts” for change: public outrage must increase; there must be regulation by JCAHO and advocated by the IOM and the Agency for Healthcare Research and Quality (AHRQ) and a business case must be made for patient safety¹⁵. The current reimbursement system must change. Leape and others are now advocating for pay for performance (P4P), or pay for quality (P4Q) programs for both hospitals and physicians. A pilot program has been initiated by CMS for hospitals (“Pay for Performance”), another is being planned by CMS for physicians and pay for quality programs have begun in the private sector (Leapfrog’s “Bridges to Excellence” program). Don Berwick’s Institute for Health Care Improvement has developed a plan to reduce medical errors - “save 100,000 lives campaign” beginning this year³. The Institute’s goals are to save 100,000 patients from fatal medical errors and poor care in 18 months - by July 2006 in 1,000 hospitals. Berwick is recommending that each of these 1,000 hospitals adopt at least one of the six safety measures listed below:

1. Deploying rapid response team – at first sign that a patient’s condition is declining
2. Deliver evidence-based care for heart attack patients by appropriate use of aspirin and beta blockers

3. Develop accurate lists of patient’s medications to prevent overdoses and allergic reactions
4. Prevent IV line infections with 5 steps, including hand washing
5. Prevent surgical site infections with 3 steps, including preoperative antibiotics
6. Prevent pneumonia in ICU’s with measures like elevating the head of a bed by 30 degrees

In addition, the JCAHO has recently published its goals for 2005⁶:

1. Use ≥ 2 patient identifiers
2. Verbal/telephone orders: “read back” required
3. Standardize list of abbreviations not to be used in institution
4. Measure, access and if necessary take action to improve timeliness of reports
5. Remove concentrated electrolytes from patient care units
6. Standardize and limit number of drug concentrations available
7. Identify and at least annually review and take action to prevent errors of sound alike/look alike drugs.
8. Ensure free flow protection on all PCA/IV infusion pumps
9. Comply with CDC hand hygiene guidelines
10. Manage as sentinel events – unanticipated deaths or major permanent loss of function
11. Develop process to obtain and document all medications by each patient
12. Complete list of patient’s medications is to be communicated to next provider/institution of care
13. Staff education regarding control of heat sources, fuels and guidelines to summarize O₂ concentration under drapes

However, they did not mandate use of bar codes or bed alarms.

Pay for performance programs are increasing. CMS has a pilot program in hospitals throughout the United States. CMS has chosen five clinical situations¹⁶ (25 measures), to monitor for quality: acute MI, CABG procedures, heart failure, pneumonia and hip and knee replacement. The measures for THR and TKR are: prophylactic antibiotic within 1 hour preoperatively, antibiotics discontinued within 24 hours post-operatively, incidence of hemorrhage/hematoma, incidence of post-operative metabolic derangement, number of readmissions within 30 days of discharge, and number of discharges home or to home health programs. These measures will be used to potentially increase payment to the top performing hospitals by means of a bonus (top 10% receive a 2% bonus). After three years the lower performing hospitals will have to return some of their DRG payment (bottom 10% returns 2% of their payment).

Leapfrog has initiated a pay for quality program called “Bridges to Excellence” for both physicians and hospitals; the program includes physicians in the Boston area⁵. Numerous health care insurers throughout the United States are adopting similar programs. Interestingly, HealthPartners in Minnesota recently announced it will refuse to pay for what they call “never events”¹⁷. Included in “never events” are wrong site surgery, wrong patient surgery, retained instruments or sponges, and others. Another project - a 10-site pilot project - will pay providers for “better care”. They will reward physicians with a bonus, relying on 32 quality measures adopted by the AMA and NCQA. The problem, however, is that some of these bonus programs withhold a portion current payments to physicians. If certain quality measures are met, the physician can receive a bonus up to the withheld amount at the end of the fiscal period. Doesn't this sound similar to the withholds that managed care implemented and eventually failed? These projects are based on quality measures, but are increasingly being tied to cost reductions and other “efficiency” measures.

In summary, there have been minimal changes to improve patient safety and reduce medical errors in the United States since the IOM's report five years ago. Changes have occurred, but they don't go nearly far enough. There remain many significant barriers to successful change our current culture to one of safety: fear of disclosure and its legal consequences, the costs, the lack of understanding of the significance of the overall problem of medical errors in our health care system and a commitment by physicians and hospitals to change. The problem will not going to go away, however, as it has seemed to in the past. Public pressure for improvement will continue. Physicians need to lead; to take charge to ensure their patients' safety. If not there will be continued regulatory efforts, schemes for payment for quality, lack of our patients' needed support for professional liability reform, as well as a continued erosion of patients' and society's trust in the medical profession.

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