Medical Errors—Is Total Quality Management for the Battlefield Desirable?

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There has recently been a great deal of discussion in both the lay press as well as the medical press regarding the incidence of errors that occur during medical practice. There have been many discussions of how quality control measures from industry can be applied to the health care system. Indeed both civilian and "brick and mortar" military medical treatment facilities are adapting these techniques. It is important that we understand the principles behind Total Quality Management (TQM) as well as its techniques and limitations. TQM is based on limiting deviation from an accepted standard of practice. These principles may be as applicable to our military health care facilities in a field environment as they are to our fixed facilities, although the standards used for measurement may have to be modified to adapt to different constraints of environment and resources. TQM techniques can nonetheless be applied in virtually any facility to ensure the best possible care and outcomes for our soldiers.

Introduction

Medical Errors—Is Total Quality Management for the Battlefield Desirable?

"*More errors found in emergency surgery–Study looks at cases in which equipment was left in patients.*"[1] This headline, accompanied by an X-ray showing a clamp left in a patient's abdomen, suggests that 1,500 similar cases occur in the United States each year. This would seem to be an appalling risk that demands public outrage and probably government action. In truth, this story in the *Boston Globe* reports an article from the *New England Journal of Medicine*[2] and the photograph is copied from that article. The article is part of the medical profession's effort at self-study and self-policing by evaluating its own practices and publicizing its findings. How did the authors determine that there were 1,500 similar cases in the United States annually and are their methods accurate and reasonable? How big a problem are medical errors in the United States today? Has the medical profession developed techniques to seek out and eliminate these errors? Is there anything that society, the media, and government needs to do to ensure these errors are eliminated?

In the original article mentioned above, the authors examined the records of all claims or incident reports filed with a large malpractice insurance company in Massachusetts, which covers 22 hospitals and approximately one-third of all physicians in the state. Fifty-four patients, with a total of 61 retained foreign objects, were identified. The denominator of patients at risk is not well defined, but the authors estimate that the incidence of retained objects lies between 1:8,801 and 1:18,760 inpatient operations. Clearly there are potential biases in the way these index cases were identified and in determining the denominator of cases at risk. Nonetheless the study is instructive. During the study period, 1985–2001, there were more than 28 million surgical procedures performed in this country. Although the risk of leaving a foreign body behind at surgery is very uncommon, there are a lot of patients at risk. The results of this type of complication are serious. In 37 of these 54 cases, surgery was required for removal of the foreign body. Twelve of these 37 cases resulted in major complications. There was one death. One would think that leaving a sponge or instrument behind at surgery would be completely avoidable; however, in 88% of cases there was reported a "correct" sponge count. Our intention is not to delve deeper into this particular type of risk although the authors suggest ways to decrease the incidence. Instead, we hope to examine the best way for society and the medical profession to deal with the very important issues of medical risk, including that which results from medical errors. Should the physician who commits an error be placed in public stocks and pilloried—this original report, after all, was from New England? Should he or she be sued and/or have his/her license to practice medicine revoked—in either case causing severe damage to the physician's livelihood? Should there be widespread publicity which would cause the public to lose trust in their health care providers and systems? Rather than punishment and vengeance, are there better ways to deal with errors in the medical system that might lead to improvements in care and a decrease in mistakes? Finally, what is the applicability of a Total Quality Management process to military hospitals functioning in difficult, dangerous, and austere environments?

Surgeons in particular have taken great pride in their efforts for upholding high patient care standards. Since the time of Halstead at Johns Hopkins Hospital in the early 20th century, surgeons have conducted peer review morbidity and mortality conferences. All members of the surgical staff were traditionally required to meet once a week. All complications and deaths were presented by the chief resident or in private hospitals by the attending surgeon to the chief of surgery. The staff surgeon was cross-examined by the rest of the staff and forced to defend his/her actions or admit the mistake. It was a difficult and sometimes brutal experience. The result was supposed to prevent recurrence, teach best methods, serve as an emotional catharsis, and motivate the surgeon to never foul up again, since surgeons of course should be infallible. "Blame and pun-

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ish" were the operative principles, but they may inadvertently have encouraged some to hide their errors. As litigation has increased, the morbidity and mortality conference has lost its bite, since there is individual and institutional fear that information could get out and lead to lawsuits. For better or for worse, the morbity and mortality conference has become a symbolic and toothless exercise when it is practiced at all. As we will later discuss, this may actually be for the best. In contrast to surgeons, practitioners of other medical specialties have never even attempted to have a formal quality review effort of this type. In fact, surgeons historically looked down upon their medical colleagues because they did not "formally" practice introspection and self-criticism in a morbidity and mortality format.

Today with the rise of interventionalists outside of traditional surgical disciplines, there is a growing need for other practitioners to discuss complications, which would include interventional cardiologists, interventional vascular radiologists, interventional gastroenterologists, and anesthesiologists managing pain clinics. All of these practitioners are performing, procedures that in the past might have been in the province of the surgeon. Recently, correct site surgery audits suggest that problems in the operating rooms have been dealt with and the next area of concern is procedures outside of the operating room, in the clinic, on the ward, and in other patient care environments.

As early as 1964, Schimmel[3] reported that 20% of patients admitted to a university hospital medical service suffered iatrogenic injury and that 20% of those injuries were serious or fatal. Public and professional concern for the problem of medical error really did not surface, however, until a landmark study by Leape and colleagues[4,5] showed that 4% of patients in New York state suffered an injury due to their treatment or due to an error that "prolonged their hospital stay or resulted in measurable disability. This added up to 98,609 patients in New York state in that year. Nearly 14% of these injuries were fatal. If these numbers were extrapolated to the entire U.S. population, then an estimated 180,000 people die each year from complications of iatrogenic injury, which means injury caused by medical treatment or errors. Other groups have found similar rates of iatrogenic injuries.[6,7]

In this same study, Leape[4] demonstrated that most of the iatrogenic injuries were caused by preventable errors."Drug complications were the most common type of adverse event (19%), followed by wound infections (14%) and technical complications (13%). Nearly one-half of the adverse events (48%) were associated with a surgical procedure. Adverse events during surgery were less likely to be caused by negligence (17%) than nonsurgical ones (37%). The proportion of adverse events due to negligence was highest for diagnostic mishaps (75%), noninvasive therapeutic mishaps or errors of omission (77%), and events occurring in the emergency room (70%)."[5] Clearly, there was overlap of categories, and some adverse events such as wound infections are iatrogenic but not necessarily caused by an error. Others have confirmed the high incidence of medication errors.[8–11]

The high rate of medical errors, both those leading to significant complications and those that fortuitously did not, were a great surprise to the medical profession when these studies were initially published. The surgical community and the nursing community were especially shocked because both prided themselves on intolerance of deviation from high standards and for a willingness to enforce a high degree of discipline on the practitioners in their fields. The surgical "morbidity and mortality conference" was described above. The nursing profession dealt traditionally and, to some extent currently, through "incident reports," investigation of errors, assignment of individual responsibility, and disciplinary actions. Both physicians and nurses as groups have extremely high levels of responsibility. They are rarely lazy or unconscientious. They are often willing to accept blame even when not individually responsible under the "captain of the ship" philosophy. As groups they tend to hold themselves to high standards. Why were these errors occurring, particularly among such dedicated groups?

"Efforts at error prevention in medicine have characteristically followed what might be called the perfectibility model: if physicians and nurses could be properly trained and motivated, then they would make no mistakes. The methods used to achieve this goal are training and punishment (p 1852)."[12] In fact, however, medical care is a very complex system. "All humans err frequently. Systems that rely on error-free performance are doomed to fail. The medical approach to error prevention is also reactive. Errors are usually discovered only when there is an incident—an untoward effect or injury to the patient. Corrective measures are then directed toward preventing a recurrence of a similar error, often by attempting to prevent that individual from making a repeat error. Seldom are underlying causes explored (p 1852)."[12]

W. E. Deming,[13] an engineer, pioneered the systematic study of quality control in industry and developed many techniques to increase the quality of industrial products and processes. These methods included standardization, simplification, worker input into industrial processes, and many others.[13] We have already mentioned that medication errors are the most common form of medical errors in hospitals, despite intensive efforts at checking and double-checking by nurses and pharmacists. In industry, however, reliance on inspection, at least alone, as a mechanism of quality control was long ago discredited. Use of computerized order entry, bar coding of prescription packages to check medications before they are administered, and unit dose packaging are the types of innovations that Deming and other engineers would have approved to reduce the incidence of medication errors.

Such human factor specialists, who are for the most part engineers, have been concerned with the design of the man-machine interface in complex environments such as airplane cockpits and nuclear power plant control rooms.[14] Many errors, particularly those in medicine, result from mistakes in mental functioning. Much mental functioning is rapid and automatic. It is possible because of a vast array of experiential patterns to which we have been previously exposed. Rassmussen and Jensen[15] have developed a model of human performance based on three levels of activity: skill-based, rule-based, and knowledge-based. Cognitive errors occur at each level. "Slips" are unconscious glitches in automatic activity that occurs when attention is diverted. "Mistakes" are rule-based errors that occur when the wrong rule is chosen, either because of a misperception of the situation or because of a misapplication of a rule that seems to fit adequately. Finally, "latent errors" are errors caused by poor system design. They are "accidents waiting to happen."[14]

In the year 2000, the Institute of Medicine issued a report on

Medical Errors entitled *To Err is Human*.[16] This report made "four major points: the problem of accidental injury is serious; the cause is not careless people but faulty systems; we need to redesign our systems; and patient safety must become a national priority (p 1273)."[17] "The concept that errors result largely from the failures of systems, not from individual carelessness or inadequacy, is fundamental to the new effort to address safety and runs counter to the traditional focus of medical training on individual performance. . . . Achieving safety requires more than a reliance on individual carefulness." (NEJM, v. 347, p 1273)[17]

There is an increasing movement to apply techniques of industrial quality control to health care. These efforts go under a variety of names such as Quality Assurance, Quality Improvement, and Total Quality Management. Quality Assurance is a system of retrospective case review, usually of problem cases. Quality Improvement is a prospective case review process. Total Quality Management is an effort to examine an entire system with the idea of minimizing variation from a given standard. Underlying these efforts is the realization that health care is a system and that safety and quality require a systematic approach. Latent errors which were mentioned above are "deficiencies in design, organization, maintenance, training, and management that create conditions in which persons are more likely to make mistakes (p 1273)."[17] An example would be a resident training and on-call schedule that makes it likely that fatigue will contribute to poor decision-making. In a properly run system, errors will be recognized and analyzed so that techniques can be implemented such as: critical-incident analysis, standardization of processes, use of checklists, changes in training and supervision, implementation of new monitoring techniques, and design of processes with computer checks or fail-safe mechanisms to prevent critical errors. These types of activities have been particularly successful in both the aviation industry and in the nuclear industry in reducing errors and accidents.

To implement such a system, there must be a comprehensive reporting of adverse events, errors, and close calls. The system of punishment and retribution used traditionally in medical care, although laudable in intent, is actually counterproductive. Fear of punishment, retribution, litigation, and public humiliation lead to underreporting of incidents and, in the worst case, they lead to outright cover-up. An effective reporting system such as that used in the aviation industry has three factors: (1) it is safe, offering pilots immunity from disciplinary action if they report promptly; (2) it is simple to file, using a short report; and (3) it is worthwhile, providing expert evaluation of the problem and feedback concerning potential solutions.[18] It is important that these reviews be used for improvement and not for judgment or punishment.

Another principle, which has been learned from industrial quality assurance techniques, is that you cannot correct what you cannot measure. It is important to identify a benchmark, or a series of benchmark standards, and measure compliance with those standards. A benchmark in this case is a clinical indicator that is usually identified from the medical literature or occasionally through original research. Once compliance with a particular parameter is measured, for example, the length of time to prepare a patient for surgery, then changes in the system may be introduced and restudied to determine whether an improvement in outcome was demonstrated. The use of these types of techniques makes it imperative that health care providers understand statistical methods, limits of sample size, and error analysis. Even the process of measurement itself tends to improve performance and quality, an observation known as the Hawthorne effect.

It is popular to talk about "outcome analysis" as a means of identifying and reducing medical errors. Outcome analysis is really what we have always done in medicine. It is the application of scientific and quantitative techniques to evaluate medical questions. What is new is the recognition that we can apply the techniques traditionally used to answer large generic medical questions and apply them to problems encountered by local hospitals, local medical or surgical services, and even individual providers. These forms of analyses are similar to what engineers have always done. They break down a complex problem into simpler component problems. After they solve the component problems, they work backward to apply these solutions to the larger overarching issue. Medical care is an extremely complex system. Many of the errors, which Leape and others have identified, occur because we have treated health care as a cottage industry. We have not identified appropriate standards and techniques, minimized variation from those standards, nor have we analyzed the outcomes from the use of those techniques in a systematic way and then modifying them when necessary.

Society is indebted to the researchers who have characterized the nature of errors that occur in our health care system as well as to those who have demonstrated ways of reducing the number of these errors. It is incumbent on the medical profession to be proactive in self-analysis and self-improvement. I believe the profession has for the most part embraced the problem and the search for improvement in quality and safety. It is important for the public and the government to be vigilant through licensing and review organizations to hold the profession to this course.

Finally, is there a place for a Total Quality Management process in military Table of Organization and Equipment (TOE) hospitals? Frequently these hospitals are deployed in austere and dangerous locations. They are challenged by the need to be partially or totally mobile and may have rotating professional staffs. During the past decade, there has been a move at the U.S. Army Medical Command to ensure that the "quality of care" on the battlefield was equal to the "quality of care" in the Continental United States (CONUS) Medical Centers (MEDCENs). Today, quality is defined as establishing and minimizing the deviation from a standard. The earlier use of the word quality had more to do with a vague ill-defined sense of a general standard. In today's environment, if quality is the minimization of variance from a standard, it will be possible for various organizations to have equal quality even though their standards may be quite different. In this regard, it is possible to establish standards for care in a battle environment that are different from CONUS MEDCEN standards and yet if the variations are minimized from established battlefield health care standards, each hospital will have achieved the delivery of quality care. A first example would be the definition of an expectant patient in a triage scheme. In a CONUS MEDCEN, the sickest and most resource-consuming patient may be afforded full care, whereas in an austere battle environment with a mass casualty in process such a patient would probably be made expectant. Availability of antibiotics and the unavailability of microbiological culture and sensitivity

laboratories would also be differences, but if guidelines are established and variation from them minimized, quality care is still delivered. During Operation Desert Storm at the 31st Combat Support Hospital, there was a meeting right before the battle to discuss infection control. Many of the providers were concerned with establishing protocols to reflect their CONUS MEDCEN experience. With no resupply expected, however, the discussion quickly turned to a discussion of how to reuse endotracheal tubes, Foley catheters, operating room gloves, and other supplies. These are items that are never reused in the CONUS, but are frequently reused in third world countries with resource constraints. Fortunately, these plans were not needed, but it did appear that if Operation Desert Storm had gone on for 2 more days, there would have been severe resupply issues throughout the theater. The point here is that standard "best practices" can take into account the environment and constraints under which the organization is operating.

Developing best practices and evaluation of deviations from those practices can be applicable to any level of care on the battlefield. A few examples are included:

1. time from wounding to arrival at a forward surgical team or combat support hospital.
2. percentage of negative trauma laparotomies performed. It is important not to miss injuries, but a negative laparotomy takes the patient out of the battle. Is the use of noninvasive diagnostic techniques appropriate in a given medical treatment facility?
3. number of negative extremity X-rays in a given facility. Are too many or too few X-ray examinations being performed?
4. time to evacuate seriously wounded patients out of theater. Is the theater evacuation policy being appropriately followed?
5. the incidence of resuscitative versus definitive laparotomies. Are resuscitative laparotomies, especially at forward surgical teams, being used appropriately, i.e., too often or not often enough?
6. time to revascularization of extremity injuries either definitively or using vascular shunts. Are vascular shunts being appropriately used at the forward surgical team level?

The point is not to highlight specific questions but to emphasize that a process for developing appropriate standards and measuring deviation from those standards is a tool that can be of value at all levels of care from the battalion aid station to the CONUS MEDCEN. The standards may be appropriately different in different scenarios and at different levels of care.

It is also important that the public and the media place the problem of medical error in its proper perspective. Many of these studies are extrapolations from small samples to the national population at large. These extrapolations have some major statistical problems. The hospitals studied tended to be teaching hospitals that have unique characteristics that may not be translatable to the medical care system at large. Considering the complexity of the medical care system, errors that result in significant harm occur "relatively" infrequently. All iatrogenic injuries are not due to an error. Most important, we have learned that the punitive approach to rooting out medical errors by a system of blame and retribution are counterproductive and do not foster evaluation and improvement of the system. The fear of litigation and of adverse licensing actions is particularly perverse in this respect. We need to learn the lessons from the aviation and nuclear industries as to how to assess and improve potentially dangerous enterprises to decrease the risk of error to a miniscule level. Health care is no longer a cottage industry and it must apply the same standards to risk management as other essential but dangerous industrial activities.

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References

1. More Errors Found in Emergency Surgery—Study Looks at Cases in Which Equipment Was Left in Patients, *Boston Globe*, Thursday, January 16, 2003, p.A3.
2. Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MA: Patient safety: risk factors for retained instruments and sponges after surgery. N Engl J Med 2003; 348: 229–35.
3. Schimmel EM: The hazards of hospitalization. Ann Intern Med 1964; 60: 100–10.
4. Brennan TA, Leape LL, Laird N, et al: Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324: 370–6.
5. Leape LL, Brennan TA, Laird N, et al: The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med 1991; 324: 377–84.
6. Thomas EJ, Studdert DM, Newhouse JP, et al: Costs of medical injuries in Utah and Colorado. Inquiry 1999; 36:255–64.
7. Thomas EJ, Studdert DN, Burstin HR, et al: Incidence and types of adverse events and negligent care in Utah and Colorado in 1992. Med Care 2000; 38: 261–71.
8. Lessar TS, Briceland LL, Delcoure K, et al: Medication prescribing errors in a teaching hospital. JAMA 1990; 263: 2329–34.
9. Raju TN, Thornton JP, Kecskes S, et al: Medication errors in neonatal and paediatric intensive care units. Lancet 1989; 2: 374–9.
10. Classen DC, Pestonik SL, Evans RS, Burke JP: Computerized surveillance of adverse drug events in hospital patients. JAMA 1991; 266: 2847–51.
11. Folli HL, Poole RL, Benitz WE, Russo JC: Medication error prevention by clinical pharmacists in two children's' hospitals. Pediatrics 1987; 79: 718–22.
12. Leape L: Error in Medicine. JAMA 1994; 272: 1851–7.
13. Deming WE: Quality, Productivity, and Competitive Position. Cambridge, MA, MIT Press, 1982.
14. Reason J: Human Error. Cambridge, MA, Cambridge University Press, 1992.
15. Rasmussen J, Jensen A: Mental procedures in real-life tasks: a case study of electronic troubleshooting. Ergonomics 1974; 17: 293–307.
16. Kohn LT, Corrigan JM, Donaldson MS (editors): To Err Is Human: Building a Safer Health System. Washington, DC, National Academy Press, 2000.
17. Leape L, Epstein AM, Hamel MB: A series on patient safety. N Engl J Med 2002; 347: 1272–4.
18. Leape L: Reporting of adverse events. N Engl J Med 2002; 347: 1633–8.