Safety, Quality and the National Surgical Quality Improvement Program

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ABSTRACT

The Institute of Medicine 1999 publication, To Err is Human, focused attention on preventable provider errors in surgery, and prompted numerous new national initiatives to improve patient safety. It is uncertain whether these initiatives have actually improved patient safety, mainly because of the lack of a quantitative metric for the assessment of patient safety in surgery. A 15-year experience with the National Surgical Quality Improvement Program (NSQIP), which originated in the Veteran’s Administration (VA) in 1991 and was recently made available to the private sector, prompts the surgical community to place patient safety in surgery within a much larger conceptual framework than that of the IOM report, and provides a quantitative metric for the assessment of patient safety initiatives. This conceptual framework defines patient safety in surgery as safety from all adverse outcomes (not only preventable errors and sentinel events); regards safety as an integral part of quality of surgical care; recognizes that adverse outcomes, and hence patient safety, are primarily determined by quality of systems of care; and uses comparative risk-adjusted outcome data as a metric for the identification of system problems and for the assessment and improvement of patient safety from adverse outcomes.

The landmark publication of the Institute of Medicine (IOM) report To Err is Human in 1999, focused the attention on preventable provider errors and cast patient safety in terms of safety from iatrogenic injury.1 For surgeons, such errors and sentinel events would include surgery on the wrong site or side, retained foreign materials, transfusion mismatch, medication errors, mishaps in the operating room, and accidents in care, in and outside the operating room. Considered by some as the most influential healthcare publication in two decades,2 this publication created a major national concern about patient safety and prompted a wide variety of constituencies in healthcare to engage in efforts to improve patient safety. The anesthesia and surgery communities, in part through the efforts of the Anesthesia Patient Safety Foundation, the American College of Surgeons, and the Veterans Health Administration (VA) have expended laudable efforts on developing new structures and processes that would enhance the safety of the surgical patient.3

The IOM report set as a goal for these national efforts a 50% reduction in error-related deaths over five years. But today, more than 7 years since the publication of this report, there is no concrete evidence to suggest that any of these national efforts that had been spurred by the IOM report have resulted in an overall reduction in error-related deaths.4 An important reason for the failure to properly evaluate the impact and efficacy of all of these patient safety initiatives is the lack of a proper metric for the assessment of patient safety.

The development of the National Surgical Quality Improvement Program (NSQIP), first in the VA3 and then in the private sector (www.acsnsqip.org), has provided the surgeons with new tools to assess and improve the quality of surgical care. A 15-year experience with the NSQIP has thrown new light on patient safety in surgery, and prompts the surgical community to view patient safety in surgery in a different and more quantitative conceptual framework, a full understanding of which requires an understanding of the NSQIP and its achievements to date.

The NSQIP

The National Surgical Quality Improvement Program (NSQIP) is a validated state-of-the-art system for the comparative measurement and continuous improvement of the quality of major surgery nationwide.5-7 The comparative metric employed is risk-adjusted outcome, focusing initially on risk adjusted 30-day morbidity and mortality. Continuous improvement is achieved through two paradigms. The first is feedback to participating hospitals of data that include patient risk factors and risk-adjusted outcomes, allowing the healthcare providers and managers at these hospitals to compare their respective performance (and the characteristics of their respective patient populations) to those of their peers nationwide.

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The second paradigm through which quality improvement is achieved is the provision of an infrastructure allowing researchers to conduct, competitively and in a peer reviewed fashion, observational studies based on the program’s rich database, which, to date, contains prospectively collected information on more than 1.5 million patients/operations. These studies, for example, identify outcome-related risk factors in a wide variety of surgical conditions and treatments, and explore the relationship of specific structures, processes and costs of surgical care to risk-adjusted outcomes. Knowledge gained from these observational studies enhances our understanding of patient management, thus improving the welfare and outcome of the surgical patient.

The program originated in the Veterans Health Administration in 1991, prompted by a 1987 Congressional mandate that required the VA to report outcomes of major surgery as per national average, and risk-adjusted for severity of patient illness. In 1994, the Program was expanded to include all 133 VA medical centers that performed major surgery. In 2004, the American College of Surgeons (ACS) made the Program available to the private sector by establishing the ACS-NSQIP. At the time of this writing, more than 95 hospitals are fully enrolled in the ACS-NSQIP, and an average of 6 new hospitals per month is being accrued into the Program. The distinguishing feature of the NSQIP is that it applies to outcome-based quality measurement the same scientific rigor that is normally applied to clinical trials and fundamental research. Hence trained dedicated clinical nurse reviewer at each medical center collects prospectively preoperative, intraoperative, and 30-day outcomes variables on most patients undergoing major surgery. Data collection methodology is standardized and nurse competency and inter-rater reliability are periodically ascertained through site visits, a Web-based competency assessment program, and annual meetings of all the clinical nurse reviewers. Data are transmitted from each medical center to a national data coordination center where they are cleaned and subjected to statistical analyses. On an annual basis, these analyses identify the independent predictors of various 30-day outcomes for all operations in a hospital, and for the various surgical subspecialties, calculating a Beta coefficient for each predictive variable in a respective model. This coefficient is then used to calculate the expected 30-day outcome of a patient, or of a specific population of patients, based on the severity of illness of that patient or population. The ratio of the observed to the expected outcome, which is termed the O/E ratio, is the risk adjusted metric for that outcome, which is used by the NSQIP to compare the performance of the institutions partaking in it. The NSQIP has validated its O/E ratios for morbidity and mortality as reliable measures of quality within its institutions, based on an extensive site visits study.

Feedback of comparative data for the purpose of QI

As mentioned above, the NSQIP affects quality improvement through an extensive feedback to the providers of comparative preoperative and risk-adjusted outcome data, which are then used locally to drive and monitor process improvement. Significant reductions in morbidity and mortality O/E ratios, as a result of local QI efforts at various surgical centers, are repeatedly observed in the NSQIP. During the decade following the inception of the NSQIP, 30-day mortality rate in the VA following major surgery has decreased by 31% and 30 day postoperative morbidity rate has decreased by 45%. A 2002 Institute of Medicine report, entitled “Leadership by example: Coordinating government roles in improving health care quality,” cited the VA Health System as “best in the nation” in part because of NSQIP, which it referred to as “one of the most highly regarded VHA initiatives employing performance measures.”

Applicability of the NSQIP to the Private Sector

To ascertain the applicability of the NSQIP to the private sector, the NSQIP started its Private Sector Initiative (PSI) in 1998, by collaborating with three academic non-VA surgical departments that volunteered to provide a full-time nurse and to participate in the NSQIP in a manner identical to the VA hospitals. A special Web-based system for the collection of data from these three sites and their transmission to the VA data coordinating/analysis center was created. Data collection in the PSI was limited to general and vascular surgery. Analysis of the first year of data collection from these three “alpha” sites (Emory University Hospital in Atlanta, University of Kentucky in Lexington Medical Center, and University of Michigan in Ann Arbor Medical Center) showed that the processes, methodology, and 30-day outcome predictive models, developed by the VA NSQIP, were fully applicable to the private sector, at least in general and vascular surgery. Based on this encouraging result, the VA and the American College of Surgeons collaborated together in applying for, and ultimately conducting, the Patient Safety in Surgery study, which was funded by the Agency for Healthcare Research and Quality (AHRQ). Also limited to general and vascular surgery, this study allowed the participation in the NSQIP of 14 non-VA large academic medical centers and 4 smaller community hospitals (i.e. 18 “Beta” sites) over a 3-year data collection period that terminated on September 30, 2004. The study met its objectives and demonstrated that the NSQIP was equally applicable to private sector hospitals as to the VA hospitals: The methodology could be easily implemented in the private sector, the predictive models were similar, and the variation in risk-adjusted outcomes was equally wide, reflecting similar variation in quality of surgical care. As in the VA, application of the NSQIP to the private sector prompted local QI initiatives that resulted in improvement of outcomes in those facilities. The positive results of the PSS study, which are currently being prepared for publication, are what prompted the American College of Surgeons to establish the ACS-NSQIP, thus making it possible for private sector hospitals to partake in the program.
What Have We Learned About Patient Safety From the NSQIP?

The experience gained from the operational aspect of the NSQIP in both the VA and the private sector, and the knowledge gained from the numerous observational studies that have emanated from its database, prompt us to view patient safety in a totally different framework from that which was popularized by the IOM report To Err is Human. This view is based on three important observations made by the NSQIP:

Safety is indistinguishable from overall quality of surgical care and should not be addressed independent of surgical quality.

The wide variation in the morbidity and mortality O/E ratios among various institutions, and the demonstrated ability of local process improvement to significantly lower these ratios, clearly indicate that, during an episode of surgical care, certain populations of patients are safer than others. After all, all morbidity is injurious to the patient, and mortality is the ultimate lack of patient safety. Irrespective of whether it is preventable or not, an adverse outcome compromises patient safety. The NSQIP has demonstrated through its day-to-day operation, and in several observational studies, that rates of adverse outcomes, properly measured and risk-adjusted, can reflect the quality of surgical care. Placing patient safety within the rubric of quality and defining it in terms of safety from adverse outcomes allows us to use the same quantitative tools that the NSQIP has developed for assessment and improvement of quality in the assessment and improvement of patient safety. Improving the quality of surgical care reduces the incidence of adverse outcomes and improves patient safety. Within this rubric, prevention of errors is synonymous with reduction of adverse outcomes, and, as such, can be a reliable quality measure.

During an episode of surgical care, adverse outcomes, and hence patient safety, are primarily determined by quality of the systems of care.

Several times in the course of a year, the NSQIP conducts consultatory site visits to surgical departments with significantly higher than expected O/E ratios in mortality or morbidity. An experienced team comprised of a surgeon, a nurse, and an anesthesiologist conduct the site visit in accordance with a structured instrument that evaluates the structures and processes of care at the hospital. Invariably, structures and/or processes of care are found to be problematic at high-outlier hospitals, reflecting deficiencies in systems of care. Errors in these hospitals, although sometimes committed by specific providers, are more likely to be system errors than due to provider incompetence. The provider is important in as much as he or she contributes to the system. These site visits have underscored the importance of adequate communication, coordination, and team work in achieving quality surgical care, confirming publications from the National Surgical Risk Study that had addressed these issues.

Reliable comparative outcome data are imperative for the identification of system problems and the assurance of patient safety from adverse outcomes.

Surgeons in the VA have learned that while obvious iatrogenic and accidental provider errors can be easily detected through good local quality monitoring systems, the more subtle system errors that lead to a much larger body of adverse outcomes cannot be adequately appreciated or recognized without comparative data with other institutions and peer groups. Deficiencies and errors within a system of care can result in adverse outcome rates that might be considered “acceptable” by the local provider community, particularly when comparisons are made with unadjusted rates published in the literature. It is only when these rates are compared to similarly risk-adjusted rates at other peer institutions that the providers appreciate the increased adversity at their center, and are thus prompted to investigate and improve the quality of the adversity-related processes and structures.

A New Conceptual Framework For Safety in Surgery

The lessons learned from the NSQIP prompt us to view patient safety in surgery in a different conceptual framework from that advocated by the IOM publication To Err is Human, which focused on preventable provider errors.

Patient safety in surgery is safety from all adverse outcomes, not only from iatrogenic provider errors and sentinel events. As illustrated in Figure 1A, there is an unsafe domain within every system caring for the surgical patient. This domain comprises the totality of the adverse outcomes experienced by patients being cared for within that system. Preventable errors, as conceptualized by the IOM report To Err is Human and causing “sentinel events” by JCAHO criteria (www.jcaho.org), form a very small part of the unsafe domain, which is dominated by the totality of the usual complications and adverse postoperative outcomes. Sentinel events are also not the only preventable adverse outcomes within the system. Preventability in the figure is represented by a spectrum with white on one end, representing preventable adverse outcomes, and black on the other, representing unpreventable adverse outcomes. Potentially, every adverse outcome should be preventable as quality improvement efforts intensify within a system of care and the size of the unsafe domain is reduced (Figure 1B). The better the quality, the less the adverse outcomes and the smaller the unsafe domain. Hence, the size of the unsafe domain is an inverse measure of the quality of care, making safety an integral part of quality. In a quality and safe system of surgical care (i.e. a system that is a statistically low-outlier by NSQIP criteria), the size of the unsafe domain would be small, and the ratio of preventable to unpreventable adverse outcomes would also be small. Conversely, in a poor and
unsafe system of surgical care (statistically high-outlier by NSQIP criteria), the size of the unsafe domain would be large as would be the ratio of preventable to unpreventable adverse outcomes. Quality improvement within a system of care reduces the unsafe domain by primarily reducing preventable adverse outcomes, thus resulting in a small unsafe domain that is primarily composed of unpreventable adverse outcomes (Figure 1B). One can appreciate from this construct the futility of addressing patient safety only in terms of sentinel events, and the error one would be committing by excluding from the definition of patient safety system errors that account for the majority of preventable adverse postoperative outcomes.

In light of the conceptual construct of safety described above, the failure of national safety efforts to reduce the incidence of iatrogenic errors over five years (or at least the uncertainty about it), may well be from: 1) The ipso facto separation in the IOM report of “accidental” and “preventable” errors from the wider domain of adverse outcomes; 2) the wrong assumption that most preventable errors are readily recognizable; 3) directing the safety focus to individual provider errors that might lead to an increase in the incidence of sentinel events, instead of directing it to system errors that are difficult to recognize and that might lead to increased incidence of much more frequent adverse postoperative outcomes. An unmistakably preventable provider error (such as a medication error) can still be a reflection of system error. If engineered properly, a quality system of care with proper checks and balances should prevent provider vulnerability to making an error in as much as it should prevent patient vulnerability to develop an adverse intra- or postoperative outcome. Focusing on preventable iatrogenic injury caused by the provider and quantified by the rate of sentinel events ignores the much larger domain of preventable iatrogenic patient injury caused by the system and quantified by the risk-adjusted rate of adverse outcomes.

Conclusion

Experience with the NSQIP to date, prompts us to place patient safety in surgery within a much larger conceptual framework than that of safety from preventable iatrogenic injury and sentinel events. The NSQIP, which was developed in the Department of Veterans Affairs and has been recently extended to the private sector through the American College of Surgeons, is the first national, validated, and peer-controlled program that employs risk-adjusted outcomes for the comparative assessment and improvement of the quality of surgical care. The program has demonstrated its efficacy in reducing postoperative complications in the VA, both nationally and at the local level in individual medical centers. The NSQIP experience prompts the redefinition of patient safety in terms of safety from all adverse postoperative outcomes, and supports four important paradigms related to patient safety in surgery: 1) Safety is an integral part of the overall quality of surgical care and should not be quantified independent of the quantification of surgical quality. 2) During an episode of surgical care, adverse outcomes, and hence patient safety, are primarily determined by quality of systems of care. The surgeon provider is important in as much as he or she contributes to the quality of the system. 3) Reliable comparative risk-adjusted outcome data are
imperative for the identification of system problems and provide a comparative metric for the assessment and improvement of patient safety from adverse outcomes, in as much as it provides a metric for the comparative assessment and improvement of the quality of surgical care. 4) Local quality improvement efforts in surgery should aim at reducing preventable system errors, and hence the unsafe domain caused by adverse postoperative outcomes.

References


