The SAGES Manual of Quality, Outcomes and Patient Safety

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Second Edition

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Preface

The idea that we can continually improve our outcomes in the delivery of healthcare is intrinsic in the nomenclature of calling what we do being in "practice." The concept of improving quality in the practice of medicine dates back to the nineteenth century. From Ignaz Semmelweis' seminal work on handwashing to prevent puerperal sepsis to Florence Nightingale associating high death rates of soldiers in Army hospitals with poor living conditions, physicians and other healthcare providers have often endeavored to find novel ways to improve the delivery of patient care. In surgery, Ernest Codman is credited with the first efforts in quality improvement, recognizing that surgeons could learn from each other and share science to lead to better outcomes for patients, and so he helped found the American College of Surgeons (ACS). Dr. Codman helped to start the Hospital Standardization Program at the ACS, which created and oversaw hospital standards. Today, this is known as the Joint Commission, which is ubiquitous in the healthcare quality arena. He also is the father of implementation of strategies to improve healthcare outcomes. Surgical quality, outcomes, and safety owe a debt of gratitude to this unique surgeon with remarkable foresight over a century ago.

While surgical societies such as ACS or the Society of Thoracic Surgeons (STS) have often led the charge to quality improvement, SAGES, too, has long had a role in this space. SAGES proudly developed the Fundamentals of Laparoscopic Surgery (FLS), the Fundamentals of Endoscopic Surgery (FES), and the Fundamentals of the Use of Safe Energy (FUSE); these programs were borne of the concept of

education and accreditation of surgeons as "safe" for their patients; both FLS and FES are requirements for all graduating surgical residents. The SAGES Quality, Outcomes, and Safety (QOS) Committee was formed as a Task Force on Outcomes in 1997, and it eventually led to the creation of the Outcomes Committee in 2003. This committee was expanded into the QOS Committee in 2008, and it leads the society and its 7000+ surgeons and members as more public attention is devoted to healthcare quality. The first edition of the SAGES Quality, Outcomes, and Safety Manual was groundbreaking as it combined didactic study with expert opinion, venturing outside the clinical arena with important writings on topics such as systems improvement, perioperative safety, error analysis, simulation as an educational tool, team training, and an emphasis on the SAGES Fundamentals programs. Published in 2011, this manual edited by David Tichansky, John Morton, and Daniel B. Jones was one of the first scholarly texts to collect these thoughts into one book, and it was well received by the SAGES membership and surgeons around the world.

Much has transpired in the last decade, and the editors of the second edition of the SAGES Quality, Outcomes, and Safety Manual sought to include these topics for discussion. So, while we sought to keep and update some of the fine work of the first edition, we added new sections that are timely and relevant to the surgeon in practice today. We explored areas of enhanced recovery pathways and the avoidance of postoperative opioid use, as the crisis of the abuse of the drugs is widespread and perhaps preventable to some degree. We examined threats to quality, such as healthcare disparities, disruptive behavior, physician wellness and burnout, physicians as second victims of bad outcomes, ergonomics of surgery, and training new surgeons in the era of work hour limitations. We discussed pathways towards quality, such as mentoring, teleproctoring, training to proficiency, and creating procedural benchmarks. We debated controversial issues such as the use of the robot in minimally invasive surgery, prevention of bile duct injury, super-specialization of general

surgery and what it means for patients, and non-clinical concerns such as enforced OR attire and consistent operating room teams. And wherever possible, we highlighted the role that SAGES plays in the quality, outcomes, and safety space.

Lastly, it would be remiss of me personally and professionally not to acknowledge the incredible work of Erin Schwarz. Erin is the administrative staff member who ensures that Quality, Outcomes, and Safety continues its important role in SAGES. A textbook project of this magnitude simply would not be possible without her indefatigable efforts to keep the momentum going to complete this project. Erin is a key member of BSC, who are the framework upon which SAGES thrives. My heartfelt gratitude goes to the whole of BSC, but to Erin, I can only humbly say "thank you."

On behalf of my co-editors, Jonathan Dort, Rebecca Kowalski, and Prashant Sinha, I thank you for reading this book and hope it helps you to consider important concepts to improve the care of your surgical patients.

Springfield, MA, USA John R. Romanelli

Preface

Approximately a decade following the publication of the first edition of this manual, the world of surgery continues to dramatically change. The focus on the quality of care provided by surgeons, the safety of the patients we treat, and the clinical outcomes we see as a result of our care, by both the surgical community and the public, has never been stronger. SAGES remains committed to leading in these areas, and the work and expertise presented in this manual will hopefully serve as a comprehensive resource to all of our SAGES members, as well as to the broader surgical community. This manual covers a wide range of critical topics, from the language and basics of quality, outcomes, and patient safety to education, mentorship, new technologies, and different approaches to care. It is crucial for the care of their patients that surgeons understand all of the elements of how quality is measured, how care outcomes are reviewed, and what the best practices available to them are on how to provide that care. On behalf of the SAGES Quality, Outcomes, and Patient Safety Committee, I am indebted to the time and efforts of the committee members and authors who have helped to create this manual. I also wish to thank my co-editors, John Romanelli, Rebecca Kowalski, and Prashant Sinha, as well as to Erin Schwarz, who has provided all of the administrative support to this endeavor, for all of their hard work in producing this second edition. I hope that you find it to be informative, comprehensive, and useful.

Falls Church, VA, USA — Jonathan M. Dort, MD

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Part I
Surgical Quality

Chapter 1
Defining Quality in Surgery

Ryan Howard and Justin B. Dimick

Introduction

With recognition of wide variations in surgical performance, demand for information on surgical quality is at an all-time high. Patients and families are turning to their physicians, hospital report cards, and the Internet to identify the safest hospitals for surgery [1]. Payers and purchasers are using efforts to reward high quality (e.g., pay for performance) or steer patients toward the highest quality providers (e.g., selective referral) [2]. In addition to responding to these external demands, providers are becoming more involved in leveraging their own quality measurement platforms to improve surgical care, such as the National Surgical Quality Improvement Program (NSQIP) [3]. Finally, professional organizations are now accrediting hospitals based on their ability to meet certain metrics believed to be associated with better outcomes [4].

Despite the need for good measures of quality in surgery, there is very little agreement about how to best assess surgi-

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cal performance. According to the widely used Donabedian paradigm, quality can be measured using various aspects of structure, process, or outcome [5]. In addition, many widely recognized quality measurement efforts, such as those by the Leapfrog group, use composite, or "global," measures of quality, which combine one or more elements of structure, process, and outcome [6]. In this chapter, we consider the advantages and disadvantages of each type of quality measure. We close by making recommendations for choosing among these different approaches.

Structure

The structure of surgical care refers to measurable attributes of a hospital (e.g., size and volume) or its providers (e.g., specialty training and years in practice) (Table 1.1). Measures of structure are extensively used in the measurement of surgical quality, owing to their widespread availability. The American College of Surgeons (ACS) and the American Society of Metabolic and Bariatric Surgeons (ASMBS) accredit hospitals for bariatric surgery based largely on measures of structure, including hospital volume, surgeon volume, and other structural elements necessary for providing multidisciplinary care for the morbidly obese [4].

Structural elements have several key strengths as quality measures. First, they are relatively easy to ascertain. Often, structural elements such as volume can be obtained from readily available administrative data. Second, many structural measures are strong predictors of hospital and surgeon outcomes. The most well-known example of this relationship was described by Birkmeyer et al., who observed a fivefold difference in mortality between low- and high-volume hospitals for high-risk surgical procedures [7]. This same relationship holds true for individual surgeon volume as well [8]. Since the early 2000s, the volume-outcome relationship has been demonstrated for dozens of operations [9].

Table 1.1 Approaches to measuring the quality of care for aortic surgery with advantages and disadvantages of each approach

Type of measure	Example	Advantages	Disadvantages
Structure	Hospital or surgeon volume	Inexpensive and readily available Good proxy for outcomes	Not actionable for quality improvement Not good for discriminating among individual providers
Process	Prophylactic antibiotics given on time Adherence to venous thromboembolism prevention guidelines	Actionable as targets for improvement Less influenced by patient risk and random errors	Known processes relate to unimportant or rare surgical outcomes Very few "high leverage" processes of care are known
Outcomes	Anastomotic leak rates with bariatric surgery Wound infection with ventral hernia repair	Seen as the bottom line of patient care Enjoy good "buy-in" from surgeons	Sample sizes often too small at individual hospitals Need for detailed data for risk adjustment
Composite	Leapfrog group's "Survival Predictor"	Addresses problems with small sample size Makes sense of multiple conflicting measures	Not granular enough to identify specific clinical areas that need improvement

However, there are certain limitations of using structural quality measures. Most importantly, they are proxies for quality rather than direct measures. As a result, they only hold true on average. For example, while high-volume surgeons are better than low-volume surgeons on average, there are likely to be some high-volume surgeons with bad outcomes and low-volume surgeons with good outcomes [5]. What's more, structural measures are not meaningfully actionable for quality improvement. Hospitals cannot easily change their operative volume, although regionalization of high-risk care may offer a solution to centralize care at more specialized centers and leverage the volume-outcome relationship.

In recent years, structural measures of care have also been found to be lacking when implemented as real-world quality metrics. For example, after certain high-risk cancer operations, there was no mortality difference in hospitals that met the Leapfrog group's minimum volume standards and those that did not [10]. Similarly, even among hospitals designated as bariatric centers of excellence based on volume standards, there is still a 17-fold difference in rates of serious complications [11].

Process

Processes of care are the steps and details of a patient's care that can lead to good (or bad) outcomes. Although processes of care can represent details of care in the preoperative, intraoperative, and postoperative phases, the most familiar process measures focus on details in the immediate preoperative phase of patient care. For example, the Center for Medicare and Medicaid Services (CMS) Surgical Care Improvement Project (SCIP) measures utilization of preoperative antibiotic and venous thromboembolism prophylaxes. Along these lines, one of the most familiar approaches to improving the process of care in surgery is the use of a presurgical checklist, which verifies that a number of best practices (confirming patient name, procedure laterality, administration of antibiotics, etc.) have been performed [12]. This has now become standard practice in the United States.

Process measures have several strengths as quality measures (Table 1.1). First, processes of care are extremely actionable in quality improvement. When hospitals and surgeon are "low outliers" for process compliance (e.g., patients not getting timely antibiotic prophylaxis), they know exactly where to target improvement. Second, in contrast to risk-adjusted outcomes measurement, processes of care do not need to be adjusted for differences in patient risk, which limits the need for data collection from the medical chart and saves valuable time and effort.

However, using processes of care has several significant limitations in surgery. First, most existing process measures are not strongly related to important outcomes. For example, the SCIP measures, which are by far the most widely used process measure in surgery, are not related to surgical mortality, infections, or thromboembolism [13]. Similarly, after implementing the preoperative checklist in 101 hospitals in Ontario, Canada, there was no measurable change in postoperative complications or mortality [14]. The lack of a relationship between process improvement and surgical mortality can be explained by the fact that the complications they aim to prevent are secondary (e.g., superficial wound infection) or extremely rare (e.g., pulmonary embolism). However, there is also a very weak relationship between process measures and the outcome they are supposed to prevent (e.g., timely administration of prophylactic antibiotics and wound infection) [15]. This finding is more difficult to explain. It is possible that there are simply multiple other processes (many unmeasured or unmeasurable) that contribute to good surgical outcomes. As a result, it is likely that adherence to process best practices is necessary but not sufficient for good surgical outcomes.

Outcome

Outcomes represent the end results of care. In surgery, the most commonly evaluated outcomes are mortality, serious complications, and hospital readmissions. For example, the

NSQIP, the largest clinical registry focusing on surgery, reports risk-adjusted morbidity and mortality rates to participating hospitals [3]. While morbidity and mortality have long been the "gold standard" in surgery, patient-reported outcomes such as functional status and quality of life are also critically important.

Direct outcome measures have several strengths (Table 1.1). First, everyone agrees that outcomes are important. Measuring the end results of care makes intuitive sense to surgeons and other stakeholders. For example, the NSQIP has been enthusiastically championed by surgeons and other clinical leaders [16]. Second, outcomes feedback alone may improve quality. This so-called Hawthorne effect is seen whenever outcomes are measured and reported back to providers. For example, the NSQIP in the Veterans Affairs (VA) hospitals and private sector has documented improvements over time that cannot be attributed to any specific efforts to improve outcomes [17].

However, outcome measures have key limitations. First, when the event rate is low (numerator) or the number of cases is small (denominator), outcomes cannot be reliably measured. Small sample size and low event rates conspire to limit the statistical power of hospital outcomes comparisons. For most operations, surgical mortality is too rare to be used as a reliable quality measure [18]. For example, a study examining seven operations for which mortality was advocated as a quality measure by the Agency for Healthcare Research and Quality (AHRQ) found that only one of the seven operations – coronary artery bypass surgery – had high enough caseloads to reliably measure quality with surgical mortality [19].

Accurately measuring and comparing outcomes as a quality improvement instrument is also confounded by many factors. Surgical outcomes are influenced not only by quality of care but also by random variation, sample size, and case mix. Whereas structure and process measure are fixed elements of care, outcomes require additional risk and reliability adjust-