



# PROCESS AND OUTCOME MEASURES IN SPECIALTY SURGERY: *Early steps in defining quality*

by

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**P**roviding quality surgical care is not a new objective. Indeed, quality has been one of the quintessential expectations of surgery since Codman<sup>1</sup> espoused outcome measures and the assessment of quality practices at the beginning of the last century. Furthermore, the American College of Surgeons was founded on these concepts and has always promoted them.<sup>2</sup> Similarly, over the last two decades, the American Board of Surgery (ABS), through its examination process and the Residency Review Committee of the Accreditation Council for Graduate Medical Education (ACGME), has increasingly emphasized surgical quality improvement.

However, a new wave of concern and enthusiasm regarding medical practice quality and the avoidance of medical error has washed over the profession.<sup>3-5</sup> This movement has spawned entire specialties and an associated vocabulary in the field of health services research, in part supported by the Agency for Healthcare Research and Quality (AHRQ). For more than 10 years, the Centers for Medicare & Medicaid Services (CMS) has increasingly promoted improved quality as its primary mission<sup>6</sup> and has contracted with Medicare quality improvement organizations (QIOs) in each state to measure and improve quality in a variety of health care settings. Minimizing error in the health care industry has created a framework for these efforts.<sup>7</sup>

These and other efforts spurred the Institute of Medicine (IOM) to publish two important monographs, *To Err Is Human: Building a Safer Health System*<sup>8</sup> and *Crossing the Quality Chasm: A New Health System for the 21st Century*.<sup>9</sup> The first states the problem, while the second offers suggestions regarding its resolution. Interestingly, surgeons and surgery departments, for the most part, have been excluded directly or indirectly from this process. Only now is awareness growing about surgery as a major public health factor in the U.S. More than 42.5 million inpatient surgical procedures are performed in this country annually, representing a substantial number of individuals. By increasing specific standards for surgery and improving quality, some people believe that many postoperative deaths and complications could be avoided.

There also is a growing recognition that medical practice quality and patient safety are differ-

ent faces of the same coin. CMS's decision to focus on quality in surgical specialties is an outgrowth of the successful national Surgical Infection Prevention (SIP) program, which addresses the optimal use of prophylactic antibiotics to prevent infection in elective surgical operations.<sup>10,11</sup> From the earliest developmental stages of the SIP project, expansion beyond the use of prophylactic antibiotics was expected.

This expectation has proven accurate, resulting in the Surgical Care Improvement Project (SCIP), a partnership of CMS, the Centers for Disease Control and Prevention (CDC), the ACS, the Department of Veteran Affairs (VA), and a host of other governmental and nongovernmental organizations. Though SCIP is still under development, it uses some of the same principles as SIP, while setting broader goals and potential applications. At the heart of this endeavor is a plan to improve quality of surgical care and reduce morbidity and mortality nationally.

Ultimately, there will likely be a link to payment adjustment and public reporting on the quality of surgical care. Much of this can be attributed to the substantial accomplishments of the VA surgeons and their work with the National Surgical Quality Improvement Program (NSQIP), which has been published widely over the past decade.<sup>12-14</sup> Within the VA system, NSQIP culminated in a statistically significant reduction of more than 25 percent of risk-adjusted morbidity and mortality rates after surgical procedures.<sup>14</sup> It obviously is not a leap of faith to expand this effort into the broader private and public community of surgical specialty practice. This report describes the SCIP developmental work being performed in Kentucky.

### **Background**

In addition to serving as the Medicare QIO for Indiana and Kentucky, Health Care Excel (HCE) provides a variety of health quality services in four other states. HCE has transitioned from a peer review organization conducting individual case review to a facilitator of quality improvement in a number of settings.

HCE of Kentucky and Ohio KePRO, the Ohio QIO, contracted with CMS to implement the SCIP special study to explore a broader set of measures of surgical quality, develop a workable data collection system, and test the feasibility of their use in

surgical practice. HCE recruited Quality Surgical Solutions (QSS) to work collaboratively in the SCIP pilot, and Ohio KePRO recruited the Oklahoma Foundation for Medical Quality, the Oklahoma QIO, to conduct a portion of the pilot and provide administrative support for the executive committee.

Several surgical specialists developed QSS six years ago as a physician-led initiative in Kentucky. The surgeons were required to be certified by the American Board of Medical Specialties (ABMS) and to be Fellows of the ACS or of the American Academy of Orthopaedic Surgeons (AAOS), with at least volunteer faculty appointments in an appropriate medical school. The early experience with QSS has recently been described in the *Annals of Surgery*.<sup>15</sup> Table 1 on this page defines the specialties of the surgeons involved, the number of Current Procedural Terminology (CPT)-based protocols, and the initial number of surgical cases reported. The QSS framework served as a nucleus for the development of further quality studies.

### First steps

HCE and QSS chose to implement a two-pronged approach to recruit surgeons and hospitals to this study. A series of small face-to-face meetings followed initial contact via personal letters and telephone calls to leading surgical specialists and high-profile surgical leaders in Kentucky. Leaders of a select group of hospitals, including chief executive officers, directors of nursing, surgeons, quality teams, infection control nurses, and operating room managers and supervisors attended the meetings. Of the 20 hospitals invited to join the study, 15 agreed to participate. There was a tremendous advantage in having one of the Kentucky hospitals, an alpha test site for transitioning NSQIP from the VA to the civilian hospital setting, participate in SCIP. Furthermore, another participating Kentucky hospital has been actively involved in the surgical component of the National Nosocomial Infection Surveillance System (NNIS) with the CDC.

The surgical procedures selected are enumerated in Table 2 (this page). Although the SCIP is not limited to Medicare beneficiaries, these procedures are frequently performed on the Medicare population and are of sufficient magnitude to have appreciable complication and death rates. To bridge

**Table 1**

#### Profile of quality surgical solutions

66 surgical specialists

- General surgery
- Colorectal
- Digestive
- Endocrine
- Endoscopy
- Gynecologic
- Orthopaedic
- Otolaryngologic
- Surgical oncology
- Trauma
- Urologic
- Vascular

43 CPT-based protocols

16,028 surgical cases reported in first four years

**Table 2**

#### Procedures selected for study

- Cholecystectomy, including laparoscopic
- Hysterectomy
- Total hip replacement
- Total knee replacement
- Coronary artery bypass graft
- Other cardiac procedures
- Colorectal resection
- Vascular procedures

the artificial distinction between inpatient and outpatient procedures, laparoscopic cholecystectomy was added.<sup>16</sup>

Hospitals are expected to report a set of data on the procedures studied. Because high-volume hospitals have more than the requisite number of cases that could be included for the state as a whole (target, n=6,000), a smaller sequential or random sample from those institutions was selected. This stratification allowed better representation of small hospitals. Members of QSS are expected to perform approximately one-fourth of the operations studied and to provide separate surgeon-generated reports for comparison with the hospital-generated reports of the same cases. Each of these two distinct data sources has benefits and limitations. For example, the surgeon would be able to record office follow-up, patient ability to return to

**Table 3****Process measures****Surgical infection module**

Measure 1: Percent of surgical patients with on-time prophylactic antibiotic administration.

Measure 2: Percent of surgical patients with appropriate selection of prophylactic antibiotic.

Measure 3: Percent of surgical patients receiving prophylactic antibiotics, whose antibiotics were discontinued within 24 hours after surgery end time.

Measure 4: Percent of major cardiac surgical patients with controlled perioperative serum glucose ( $\leq 200$  mg/dL). (Perioperative is defined as the 24 hours preceding surgery through 48 hours following surgery.)

Measure 5 (test measure): Percent of major surgical patients with appropriate surgical site hair removal. No hair removal, or hair removal with clippers or depilatory is considered appropriate. Shaving is considered inappropriate.

Measure 6 (test measure): Percent of major colorectal surgical patients who maintained normothermia ( $36^{\circ}$ – $39^{\circ}$  C or  $96.8^{\circ}$ – $100.4^{\circ}$  F) during the perioperative period.

Measure 7 (test measure): Percent of major surgical diabetic patients with controlled perioperative serum glucose ( $\leq 200$ mg/dL). Perioperative is defined as the period beginning 24 hours prior to surgery and ending 48 hours after surgery.

**Cardiovascular module**

Measure 1: Percent of major noncardiac vascular surgery patients, without contraindications to receiving beta-blockers, who received beta-blockers during the perioperative period.

Measure 2: Percent of patients with known coronary artery disease or other atherosclerotic cardiovascular disease diagnoses, without contraindications to beta-blockers, who received beta-blockers during the perioperative period.

Measure 3: Percent of major surgery patients, maintained on a beta-blocker prior to surgery, who received a beta-blocker during the perioperative period.

**Venous thromboembolism (VTE) module**

Measure 1: Percent of major surgical patients who received any perioperative prophylaxis for VTE.

Measure 2: Percent of major surgical patients who received appropriate perioperative prophylaxis based on the surgical level of risk for VTE.

**Respiratory complications module**

Measure 1: Percent of major surgical patients on a ventilator, in any intensive care or step-down unit, whose postoperative orders included elevating the head of the bed greater than or equal to 30 degrees.

Measure 2 (test measure): Percent of major surgical patients on a ventilator, in any intensive care or step-down unit, without contraindications to PUD prophylaxis, who received PUD prophylaxis.

Measure 3 (test measure): Percent of major surgical patients on a ventilator, in any intensive care or step-down unit, who are placed on a ventilator-weaning protocol.

**Outcome measures**

Measure 1: Postoperative wound infection diagnosed during index hospitalization.

Measure 2: Intra- or postoperative acute myocardial infarction diagnosed during index hospitalization.

Measure 3: Intra- or postoperative cardiac arrest diagnosed during index hospitalization.

Measure 4: Intra- or postoperative pulmonary embolism diagnosed during index hospitalization.

Measure 5: Intra- or postoperative deep venous thrombosis diagnosed during index hospitalization.

Measure 6: Postoperative ventilator-assisted pneumonia diagnosed during index hospitalization.

Measure 7: 30-day admission/readmission.

Measure 8: Mortality within 30 days of surgery.

**Risk data elements**

Serum albumin

ASA class

Age

Operative complexity score

Functional status

Chronic obstructive pulmonary disease

Hemoglobin

Disseminated cancer

White blood cell count

Weight loss >10 percent in six months

Serum creatinine

Smoking history

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work, and other postoperative developments. These data are not typically available to hospitals or CMS. Based on prior experience with surgical measurements in Kentucky, confidence was placed in the reliability and confidentiality of the QSS data system and hospital data reported to HCE.

CMS and QIO SCIP study teams in Kentucky, Ohio, and Oklahoma developed a surgical processes and outcomes tool (SPOT) for hospitals to use in collecting data relevant to quality measures, outcomes, and risk adjustment. Analytic flowcharts for reporting purposes also were created. The data collection tool was adapted to be compatible with the NSQIP and NNIS systems, enabling hospitals to select a preferred version. For data abstraction by QSS surgeons, the procedure-specific tools in use by QSS were modified to include data elements needed for the study.

Participating hospitals were concerned about the burden of collecting a new set of data in addition to other ongoing quality initiatives. Since many institutions were already collecting usable surgery data, specific reporting forms were developed and staff was retrained to make current data collection compatible with SCIP requirements. To overcome discouragement about the high volume of material, the use of staff time, and a history of minimal feedback from many related initiatives, the participating hospitals were assured that frequent feedback and follow-up would be offered. Formal collaborative learning sessions have been held and interventions have begun, even though the clinical data collection is incomplete.

### *Discussion*

The concept of measuring surgical quality has been actively discussed for much of the past three decades, with the caveat that most surgeons believe they personally perform the more difficult cases and have an adverse case mix. This presumption has been discredited, according to NSQIP's pace-setting strategy of operative risk adjustment and data from the Society of Thoracic Surgeons (STS). Surgical specialists involved in this pilot agree it is critical to use a legitimate and fair estimate of operative risk. Postoperative death and other severe complications of surgery occur infrequently, even among older patients undergoing major elective operations. Death and complications

will be monitored, but with an expected total of fewer than 10,000 cases, those outcomes will be uncommon.

In line with other CMS and QIO quality initiatives, this study emphasizes a number of process measures that represent valid predictors of improved outcomes for each case. The outcomes studied include but are not limited to length of stay, readmission, morbidity rates, and mortality rates. Table 3 (page 11) details the general process measures as well as outcome measures.

Because this is a small pilot study, it should not be used as a scorecard comparison of performance by study participants on outcomes or processes. Some improvement in surgical care is expected, but the study primarily tests the feasibility and usefulness of measures of surgical quality for future implementation nationwide.<sup>17</sup>

To gain peer input, proposed measures, procedures, and necessary data elements were discussed with Kentucky surgeons during specialty-specific conference calls. These teleconferences included leaders in their fields. A high rate of participation, attention to detail, and outward concern for patients' interests demonstrated the invited surgeons' commitment.

Based on suggestions from surgeons in the state, additional data elements were added to the Kentucky version of the hospital data collection tool. Expansion of the QSS report forms, as they were revised and tested to include the SCIP performance measures, moved from grudging acquiescence to agreement and wide general use among QSS surgeons.

### *Interim conclusions*

In many cases, indications for surgery are subjective. In other cases, such as a hysterectomy, indications can be readily and easily referenced to American College of Obstetrics and Gynecology guidelines.<sup>18</sup> The prior work of this and other specialty groups make the actual parameters for quality performance relatively easy to agree upon.

In evaluating many risk factors as predictors of outcomes, both the STS work in cardiac surgery and the NSQIP studies in the VA clearly identified some important factors. For example, serum albumin, presumably an indicator of chronic disease or poor nutrition, is a marker very close to the ASA score as a prime predictor of risk.

Another high priority suggested by Kentucky specialty surgeons is patient education and documentation. Early data in this pilot study suggest that amazingly detailed and clear patient education activities, often supplemented by videos and brochures, are conducted in the physician's office but rarely documented in the hospital medical records. As a result, steps have been taken to improve the transfer of this information from the physician's office to the hospital medical record.

Attention to co-existing illnesses in older patient populations is a crucial aspect of surgical practice. Strict glucose control for patients with hyperglycemia is one example; use of beta blockade in patients undergoing vascular surgery or having a significant history of cardiovascular disease is another.

Appropriate, up-to-date, preprinted standardized orders address many patient safety issues and represent better practice in the best sense. Interestingly, the data collection showed that a number of preprinted orders in participating hospitals had not been updated in five years.

Antibiotic prophylaxis, including timing and choice of antibiotic, has been emphasized extensively and repeatedly. Many surgical specialty groups are finally developing guidelines that address proper termination of antibiotic prophylaxis within 24 hours after closure. Similar concerns exist regarding antibiotic management of community-acquired pneumonia.<sup>19,20</sup> Because specialty surgeons still fail to meet this performance measure 50 percent of the time, the guideline has recently been published in *Clinical Infectious Diseases*<sup>10</sup> and is being republished in the *American Journal of Surgery*. The AAOS has recently published a practice advisory that calls for no more than 24 hours of antibiotic prophylaxis following joint replacement surgery,<sup>21</sup> and the STS is currently reviewing evidence that supports the duration of prophylaxis in cardiac surgery.

Deep venous thromboembolism prophylaxis was one of the most interesting subjects discussed with surgeons, with virtually *no* agreement within any specialty group for any operation. Specialty opinions suggest that after taking patient-specific risk factors into account, any form of mechanical or pharmacologic prophylaxis, or none at all, is considered acceptable. There is a vast amount of fascinating evidence in this field, but the authors

agree with a recent National Institutes of Health (NIH) consensus conference on total knee replacement, which stated that "there is no persuasive evidence supporting or opposing prophylaxis of deep venous thrombosis in these patients."<sup>22</sup>

Regarding perioperative care, the importance of the precise, accurate, and minimally traumatic approach to the operation should not be forgotten. Clearly, the skill and experience of both surgeon and hospital remain important factors for all surgical procedures.

The traditional mortality and morbidity conference is a useful venue for quality improvement, but it can be further adjusted. For example, the University of Louisville mortality and morbidity conference was modified to be a quality improvement session with emphasis on "near-misses."<sup>23</sup>

Clinical pathways and protocols are sometimes abused, misused, and misunderstood as quality

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improvement tools. There is interest, however, in postoperative order sets in which each day of normal patient care in the hospital is defined with specific processes and medications. This lends confidence to the nursing staff when they have a high volume of similar cases.<sup>24</sup> Minor variations to adjust for patient needs may occur, but the capacity to put standard orders in print for repeated use has become a benchmark of the high standards encountered in prior clinical studies.

Office follow-up and return to work also are important factors in quality of care. They are outcomes that are not measured in the available CMS database.

### Summary

This study is currently under way in Kentucky, Ohio, and Oklahoma. So far, thousands of cases have been reported to HCE by participating Ken-

tucky hospitals, and hundreds of cases reported to QSS by its surgeons. Many standards of practice quality are being accepted and followed. A shining feature of the early observations of the pilot is how far surgical practitioners in the region exceed the anticipated norms for patient education. Collaborative meetings have been held in different parts of the state, uniformly attended by hospital representatives and a growing number of physicians, including some nonsurgeons. This study will conclude later this year and yield a significant report on the measures, standards, and capacity for ongoing improvement. It is perhaps most important to recognize that while actual data collection is unfinished, areas for improvement already have been identified. Hospital quality improvement teams and physicians are actively implementing several of these process improvement interventions. It has been said that perfection is an enemy of quality; the first step toward best practices is to implement, refine, and improve better practices. □



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