

# Expanded Surgical Time Out: A Key to Real-Time Data Collection and Quality Improvement

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Some of the *concepts* contained here have been discussed and incorporated in another publication, but the data are entirely unique to this manuscript. (See: Transforming the Surgical “Time-Out” Into a Comprehensive “Preparatory Pause.” Backster A, Teo A, Swift M, MD, Polk HC Jr, MD, FACS, Harken AH, MD, FACS. *J Cardiac Surg*, in press.)

- BACKGROUND:** The increasing push for quality improvement coincides with the slowly growing use of surgical time out (STO) to lessen the likelihood of wrong-site operation. We believe that the use of STO as a reflective pause or a preoperative briefing has broader value. The purpose of this article is to describe one institution’s experience with this technique and to validate its potential use by others.
- STUDY DESIGN:** An enhanced use of STO was conducted in a 400-bed teaching hospital in calendar year 2006. Before and after conducts and constructs were rated.
- RESULTS:** The institution found the technique to be of value, and substantially clarified and improved its performances with respect to prophylactic antibiotic choice and timing; appropriate maintenance of intraoperative temperature and glycemia; and institution of secondary issues, such as maintenance of  $\beta$ -blockade and appropriate venous thromboembolism prophylaxis. Surgeon leadership and real-time data collection became essential and helpful components.
- CONCLUSIONS:** Prompt feedback to surgeons is vital; identification of future targets for performance improvement is feasible, although useless measures are eliminated. Because surgeons grapple with pay-for-performance, STO is a useful safety, data, and quality improvement tool. (*J Am Coll Surg* 2007;204:527–532. © 2007 by the American College of Surgeons)

Rare but worrisome reports of wrong-site operations in North America have led to the implementation of a surgical time out (STO), which is an improved method to verify patient identity and intended-site operations. A National Time Out Day was sponsored by the American College of Surgeons and highlighted the universal protocol approved by the Joint Commission on Accreditation of Healthcare Organizations in July 2004 (<http://www.facs.org/ahp/>

[testimony/patientsafety.html](http://www.facs.org/ahp/testimony/patientsafety.html)). The STO, as such, is being progressively accepted in surgical practice. Once the STO event occurs, it is simple to add a limited list of other safety or practice parameters, which can be used as a device and data platform for other quality measures.

For nearly a decade, the quality of, and safety in medical practices has been a growing public issue. This issue has, to some degree, been driven by media reports, but also by a troublesome frequency of untoward events in many families.<sup>1</sup> Interestingly, many of these studies have focused on chronic diseases and their medical management, but the 85,000 Americans who undergo elective procedures daily have, to this point, been largely ignored. Nuances of hemoglobin A1c,  $\beta$ -blocker use, and vision examinations for diabetes mellitus are being studied in detail. An elective operation surely offers many measures of quality surgical and institutional practices, and finite outcomes to which those measures are more or less directly linked. This STO concept imports momentum to the surgical quality and safety movement.

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### Abbreviations and Acronyms

SCIP = Surgical Care Improvement Project  
 STO = surgical time out  
 VTE = venous thromboembolism

In 2003, through a competitive proposal process, the Centers for Medicare and Medicaid Services selected Quality Surgical Solutions, PLLC, through the Quality Improvement Organization in Kentucky, to pilot the Surgical Care Improvement Project (SCIP). Quality Surgical Solutions recruited 15 of 20 invited hospitals and more than 200 surgical specialists to study hysterectomy, total hip or knee replacement, colon or rectal resections, laparoscopic cholecystectomy, and nonaccess vascular and cardiac operations in 2004. Results of our work with 5,285 patients provided a genuine field test of the parameters (Tables 1, 2) for elective surgical patients, many of whom were Medicare beneficiaries. Data from SCIP were derived both from trained hospital chart abstractors and from the surgeons themselves from more than 1,100 patient charts maintained in the private office of the surgeon. During this process, which demanded numerous collaborations among surgeons, nurses, administrators, and other health care professionals, it became clear that real-time data collection during STO was feasible, and patently more accurate and timely to overall quality improvement. Data from SCIP and some aspects of its work have been published.

Independently, the University of Louisville Hospital began to test the usefulness of the STO as a reflective pause or preoperative briefing. The purpose of this report is to describe the experience as an example of early efforts in a more uniform involvement of surgical specialists in all aspects of the quality and safety movement.

## METHODS

The core components of STO are patient identification and verification of operative site. We chose to add five components to that process, which are denoted below, with a brief statement of rationale and limited references to pertinent literature.

### Prophylactic antibiotics

Surgical-site infections are a major cause of postoperative morbidity and even mortality. Recent publication of the National Surgical Infection Prevention Project en-

**Table 1.** Quality Parameters Studied in Surgical Care Improvement Project 2004

Process measures in surgical infection module
On-time prophylactic antibiotic administration
Appropriate selection of prophylactic antibiotic
Discontinued antibiotics within 24 h after operation wound closure
Controlled perioperative serum glucose ( $\leq 200$ mg/dL) in major cardiac surgical patients
Surgical site hair removal in major surgical patients
Maintained normothermia ( $36^{\circ}$ – $39^{\circ}$ C) in major colorectal surgical patients during the perioperative period
Controlled perioperative serum glucose ( $\leq 200$ mg/dL) in major surgical diabetic patients
Process measures in cardiovascular module
Major noncardiac vascular surgical patients, without contraindications, who received $\beta$ -blockers during the perioperative period
Patients with known coronary artery disease or other atherosclerotic cardiovascular disease diagnoses, without contraindications, who received $\beta$ -blockers during the perioperative period
Major surgical patients, maintained on $\beta$ -blockers before operations, who received a $\beta$ -blocker during the perioperative period
Process measures in VTE module
Major surgical patients who received any perioperative prophylaxis for VTE
Major surgical patients who received appropriate perioperative prophylaxis based on the surgical level of risk for VTE
Process measures in respiratory complications module
Major surgical patients on a ventilator, whose postoperative orders included elevating the head of the bed $\geq 30$ degrees
Major surgical patients on a ventilator, in any intensive care or step-down unit, who received PUD prophylaxis
Major surgical patients on a ventilator who are placed on a ventilator-weaning protocol

Modified from Polk HC Jr, Lewis JN, Garrison RN, et al. Process and outcome measures in specialty surgery: early steps in defining quality. *Bull Am Coll Surg* 2005;90, with permission.

PUD, peptic ulcer disease; VTE, venous thromboembolism.

dorses well-established guidelines for preoperative parenteral antimicrobial prophylaxis in properly targeted patients.<sup>2</sup> Timeliness of antibiotic administration is not regularly achieved, either in initiation or termination, nor is choice of drug always proper.

### Normothermia

Maintenance of intraoperative normothermia has been convincingly related to reduced blood loss.<sup>3</sup> Correction of perioperative hypothermia reduces sepsis mortality rates and decreases clinical wound infections.<sup>4</sup> This is especially appropriate for major or prolonged operations.

**Table 2.** Outcomes Measures and Risk Data Elements Studied in Surgical Care Improvement Project 2004

Outcomes measures
Postoperative wound infection diagnosed during index hospitalization
Intra- or postoperative acute myocardial infarction
Intra- or postoperative cardiac arrest
Intra- or postoperative pulmonary embolism
Intra- or postoperative deep venous thrombosis
Postoperative ventilator-assisted pneumonia diagnosed
30-d admissions/readmission
Mortality within 30 d of operation
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% in 6 mo
Serum creatinine
Smoking history

Modified from Polk HC Jr, Lewis JN, Garrison RN, et al. Process and outcome measures in specialty surgery: early steps in defining quality. *Bull Am Coll Surg* 2005;90, with permission.

ASA, American Society of Anesthesiologists.

### Euglycemia

The association between hyperglycemia and adverse surgical outcomes is well-documented, but, more importantly, strict blood glucose control attenuates these risks.<sup>5,6</sup> Hyperglycemia is common in both diabetic surgical patients and in patients with no recognized history of glucose dyshomeostasis.<sup>7</sup> There is documentation of a benefit for intensive insulin therapy in critically ill patients, and the mechanisms of protection have been recently reviewed.<sup>8</sup> Diabetes mellitus is not the sole determinant of the need to monitor glucose intraoperatively.<sup>9</sup>

### $\beta$ -Adrenergic blockade

A dominant culprit responsible for perioperative mortality is atherosclerotic cardiovascular disease.  $\beta$ -Adrenergic blockade reduces the cardiac rate–pressure product, decreases myocardial oxygen consumption, and limits cardiac ischemia.<sup>10</sup> Preoperative  $\beta$ -adrenergic blockade reduces 30-day mortality rates in vascular surgical patients.<sup>11</sup> In a Dutch study of high-risk vascular surgical patients, preop-

erative  $\beta$ -blockade decreased the primary study end point of 30-day death from cardiac causes or nonfatal myocardial infarction from 34% to 3.4%.<sup>12</sup>

### Venous thromboembolism

The clinical benefit and cost efficacy of perioperative venous thromboembolism (VTE) prophylaxis has been stressed in moderate- and high-risk patients.<sup>13</sup> The definition of VTE risk status is less clear. The entire complex subject is being reviewed monthly, and industry-supported publications abound.<sup>14</sup>

Certain aspects of these focal points and their contemporary validity will be discussed subsequently. The procedures selected were a function of relatively high volume at the hospital and the interest of attending surgeons in gynecologic, orthopaedic, colorectal, and general surgery.

At the University of Louisville Hospital, patients scheduled for elective hysterectomies, laparoscopic cholecystectomies, colon or rectal resections, or major lower extremity orthopaedic operations were studied. Extensive meetings among the primary admitting surgeons, the anesthesiology staff, and operating room and holding area nurses were held, and procedures and order sets were agreed on. An experienced nurse-observer recorded the process preoperatively and intraoperatively. Each patient was followed 48 hours postoperatively, with a special interest in termination of antibiotic prophylaxis and postoperative initiation of VTE prophylaxis. Real-time data were recorded for most patients, but all other data were identified and enrolled no later than the first postoperative day. Practices revealed that exact times of antibiotic initiation and cessation were determined, and only a few antibiotics were considered acceptable for prophylaxis;  $\beta$ -blockers were mandated only for maintenance (ie, only if the patient had been taking the drug preoperatively); a few patients received new  $\beta$ -blockers intraoperatively at the discretion of the anesthesiologist; and VTE prophylaxis was studied only in lower extremity orthopaedic patients. Monthly reports were provided to the principal surgeons and to the nursing, anesthesiology, and administrative staff.

### RESULTS

Initial data are recorded in Table 3 and show that 99% of STOs were performed properly. An acceptable antibiotic for surgical-site infection was ordered in 97% of patients and administered within 60 minutes of incision in 95%

**Table 3.** Results of Surgical Time Out Pilot Trial

	Properly performed	Total patients with data
Surgical time out	288	290
Antibiotic prophylaxis, acceptable choice	253	281
First dose < 60 min	245	281
Last dose > 48 h	163	182
Temperature monitored > 96.6°F	260	260
Blood glucose monitored	39	39
$\beta$ -blockers maintained/initiated	66	290
Venous thromboembolism prophylaxis		
None needed	68	275
Postoperative medicines and/or devices	207	275
Preoperative medicines and devices	176	288

of patients. Discontinuation of antibiotic prophylaxis was accomplished within 48 hours of wound closure in 78% of patients.

Intraoperative temperature was monitored and maintained at > 95°F in 96% of patients. Only 21 of 203 patients for whom the presence of diabetes was determined were indeed diabetic; all of them had blood glucose monitored intraoperatively. Of 211 patients in whom preoperative  $\beta$ -blocker use was defined, all 48 receiving the drugs preoperatively had it maintained throughout the perioperative period.

Prophylaxis of VTE was determined to be unnecessary in 29%, some of whom were outpatient laparoscopic cholecystectomy patients. A combination of medications and devices was used to prevent VTE in 71% of patients postoperatively, most of those were begun preoperatively as well.

## DISCUSSION

Many surgical specialists are focused on poor and worsening reimbursement and rising professional liability premiums. Elected officials, the media, and the public appear to believe that quality, safety, and transparency are more important. Anesthesiology is a shining example of how enhanced quality and safety finally led to lower malpractice insurance premiums, but one that is little noticed or understood by surgeons at present.<sup>15</sup> Perhaps it is best to return to what is good for our patients as guides to surgical contemporary priorities, rural or urban.<sup>16</sup> Medicine is ever-more complex, and the 80-hour duty week for trainees demonstrates daily that the old guardrails are not sufficient.

The STO (no matter what it is labeled) should be compulsory. For the purpose of this report, we chose six events,<sup>17</sup> even though at least two are highly debatable and others imprecise. The priorities of antibiotic use are very old.<sup>18</sup> The first dose needs to be within 60 minutes, and there is almost certainly no need for drugs after the first day, unless complex practices and central lines complicate the case. The sudden unavailability of cefotetan complicates drug choices, but durable second-generation cephalosporins still work in most hospitals.

Maintaining  $\beta$ -blockade is also not debatable. What has become obscured is whether or not new use should be initiated in some high-risk cardiovascular operations. The subject is complex and well-referenced here and elsewhere.<sup>10-12</sup> Confusing directives from the Centers for Medicare and Medicaid Services and the Joint Commission of Accreditation of Healthcare Organizations abound with inconsistent reference to sound evidence-based medicine. Note, for example, the persisting prohibition of razors for preoperative shaving of the operative site. The most persuasive data are 40 years old and applied only when performed the night before operation, which seldom applies any more.<sup>19</sup> Elevation of the head of the bed to minimize aspiration is off-again and on-again, despite its wide use and generally agreed-on value, and very limited costs and risks.

Normothermia seems essential when operations last longer than 2 hours or blood transfusions are set up or given. SCIP 2004 Kentucky pilot data found hypothermic (< 95°F) patients 4.5 times more likely to die after colon or rectal resection than normothermic patients.<sup>20</sup> Temperature monitoring is now a thoughtless ritual, even for very brief operations in many operating rooms; active correction of intraoperative hypothermia needs much more attention.

Initiation of new  $\beta$ -blockade in higher-risk cardiovascular patients is being widely debated. Until that debate evolves to a feasible conclusion, individuals constructing their own STOs should make their own best choices. Similarly debatable, although not so visible, is the other side of the massive push for VTE prophylaxis. Industry-sponsored journal supplements and Web casts are everywhere, and surgeons who are not undertaking vigorous VTE prophylaxis are said, by some, to be guilty of malpractice. Once again, the 2004 SCIP Kentucky pilot data sheds some light on real-world practices. An unpublished report stresses that there are wide variations in the definition of risk status for VTE; most surgical spe-

cialists carried out the same VTE prophylaxis irrespective of risk status; most regimens or combinations of which are very expensive to conduct or monitor. Among 5,285 elective procedures, only 20 deep vein thromboses were diagnosed; and of those patients, only 15 pulmonary emboli occurred (none fatal). In addition, of these pulmonary emboli, only 2 occurred within the 3,594 gynecologic, general, and cardiovascular patients; 13 occurred in the 1,691 patients undergoing total hip or knee replacement or colorectal resections; and all these had received some form of prophylaxis.

We have been accused of having achieved a very good degree of prophylaxis. This is hard to accept when the VTE prevention practices were so diverse and unrelated to established VTE risk, and no methods were used in 29% of the patients. Admittedly, many of these were genuinely low-risk outpatient cholecystectomy patients. Until this entire process has more unequivocal evidence, the University of Louisville Hospital has chosen to study this matter only in major lower-extremity orthopaedic operations and colorectal resection patients.

Irrespective of these imperfect solutions to some issues, we propose that every hospital should practice STO uniformly and add quality and safety parameters of their choosing to events studied. It is best, we believe, to enlist all persons involved: surgical specialists, anesthesiologists, nurses, administrators, and quality-control specialists. Feedback is important, as are the sequential modifications of goals and raising of the bar in areas when practices improve. Both of these experiences involved real-time data collection in the operating room. We believe that is a strength unto itself.

The costliness of this reflective pause and data collection are real. It is easy to project savings from wound infections or arrhythmias prevented. Premier Health Systems has provided several impressive Web casts to demonstrate that application of “bundles” of practices substantially lessens target events with a frequency that is actually cost beneficial to the hospital. How well that saving is shared with the physicians remains to be seen. The bundling concept is interesting, in the sense that several measures used uniformly are often required to actually lessen the undesired event. Using surgical wound infection as an example, a bundle could include ideal antibiotic selection, initiation, and termination, coupled with maintenance of normoglycemia and normothermia. Additional refinements of ideal antibiotic prophylaxis are ongoing.<sup>21</sup> Patients receiving 100% of

the bundle components, for example, have much better outcomes than those with only 80% or 60%.

We hold that STO is a usual and vital step in such a process, and that real-time data collection permits frequent and regular feedback to all concerned. At least two recent reports<sup>22-24</sup> stress that the STO process is helpful but imperfect in preventing wrong-site operations. Involvement and concurrence among surgeons, anesthesiologists, and nurses are essential to ongoing refinement of this process and to the continuing improvement of each parameter of measurable quality care. This pilot report is intended to encourage other surgeons and colleagues to use STO for enhanced contemporary surgical quality improvement.

The relationship between measurable quality and safety measures and outcomes has been debated most recently and broadly during the proceedings of an invitational conference.<sup>25</sup> This constitutes a good platform of suggestions that every hospital and every surgical specialty can implement and improve on to develop a process for improving outcomes of surgical specialty care.<sup>26</sup>

## Author Contributions

Study conception and design: Altpeter, Polk

Acquisition of data: Altpeter, Lewis

Analysis and interpretation of data: Altpeter, Lewis

Drafting of manuscript: Altpeter, Harken, Polk

Critical revision: Harken, Polk

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