Washington State's approach to variability in surgical processes/ Outcomes: Surgical Clinical Outcomes Assessment Program (SCOAP)

David R. Flum, MD, MPH, Nancy Fisher, MD, MPH, Jeffery Thompson, MD, MPH, Miriam Marcus-Smith, RN, MHA, Michael Florence, MD, *and* **Carlos A. Pellegrini, MD,** *Seattle, Washington*

From the Department of Surgery and the Surgical Outcomes Research Center, and the Department of Health Services, University of Washington, Seattle, Washington; Washington State Health Care Authority, Seattle, Washington; Washington State Medical Assistance Administration, the Foundation for Health Care Quality, Seattle, Washington; and the Swedish Medical Center, Seattle, Washington

SURGEONS AND other stakeholders in healthcare share the perception that there is significant variation in both the outcomes of surgical care and the processes used to achieve those outcomes among hospitals and surgeons. Industry has long recognized that variability in process and performance is a threat to the quality of its products and has devoted considerable effort to the management and containment of this phenomenon. Working together with industry, regulatory groups also play a role in addressing variability. For example, while there is significant variation in aviation safety around the world (Fig 1), in regions where there are strong relationships between regulatory groups and industry sponsored safety programs these adverse outcomes are minimized and public confidence has been assured. In the United States this confidence comes in part from the longstanding oversight activities of the Federal Aviation Association (FAA). Through its use of a "complete" surveillance system and by regulating performance "outliers" the FAA and the aviation industry have limited the impact of this variability. There is no FAA for surgery, and while there will always be variability in surgical care, the perception of widespread gaps in surgical quality between centers has gone unchecked. In fact, both the perception and the reality of this variability have undermined confidence in the healthcare system and many stakeholders are demanding a system-level approach to address it.

Over the last three years surgeons and other healthcare stakeholders in Washington State have been working together to create such a system; Surgical Clinical Outcomes Assessment Program (SCOAP). As part of a new wave of quality improvement projects for general surgery SCOAP is unique in its mission, funding and functioning (Table I). This report outlines the background for the development of SCOAP, the rationale for its existence, the choices of procedures for evaluation, the elements of data collection and risk stratification, the alternatives to SCOAP and a discussion of the barriers to and limits of the project.

BACKGROUND

The development of SCOAP was coordinated by the Foundation for Health Care Quality (FHCQ), a non-profit organization serving as "safe-harbor" for the multiple groups involved in healthcare improvement projects. Beginning in 2002 the FHCQ brought together practicing surgeons, the leadership of the Washington State Chapter of the American College of Surgeons, investigators from the University of Washington Department of Surgery's Surgical Outcomes Research Center (SORCE), hospital quality improvement leaders and other important stakeholders in healthcare to develop options for surgical quality improvement (QI). The developmental funding for this work came from statewide purchasers and payers of healthcare and in particular the Washington State Health Care Authority

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Reprint requests: David R. Flum, MD, MPH, Department of Surgery, University of Washington, BB 431, 1959 N.E. Pacific St., Box 356410, Seattle, WA 98195-6410. E-mail: daveflum@u.washington.edu.

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Fig. 1. Worldwide regional variation in airplane hull-loss accidents per million departures 1995-2004. With permission, The Boeing Company.

(HCA), a state organization that purchases healthcare for nearly one in five Washington State residents. These stakeholders have demonstrated substantial interest in supporting optimum care and outcomes and took a leadership role in sponsoring SCOAP and SCOAP's predecessor, the Clinical Outcomes Assessment Program (COAP).

COAP is a quality improvement project that conducts universal surveillance of percutaneous cardiologic interventions and coronary artery bypass graft (CABG) surgery in Washington State.[1-3] Since its inception in 1997, COAP has collected prospective, patient-level process and outcome data on every patient undergoing these procedures at every hospital in the state. COAP provides regular reports to hospitals that allow for comparisons between hospitals while protecting the identity of the institution. The data are also protected from disclosure to third-parties by Washington State statutes that limit their distribution to QI purposes. COAP tracking on process measures has helped hospitals identify undesirable variation (e.g. prolonged ventilator use after CABG) and to provide actionable activities for their local QI staff. COAP tracking of process has also helped to identify outcome outliers (e.g. new dialysis after CABG in risk adjusted patients) that have assured stakeholders that no significant outliers persist in multiple years. The COAP program depends on local QI activities to address variability in process and outcome. This approach and has been successful in accomplishing reductions in variability of important measures (Fig 2) and assuring that variability in rates of adverse outcome after CABG (Fig 3) and percutaneous intervention is minimal.

SCOAP builds on the success our state has achieved with these procedures and different communities of physicians. Some of the fundamental COAP components retained in SCOAP include physician leadership, use of a third party (FHCQ) to create a "safe environment" for the candid exchange of sensitive performance data, the requirement for high-quality, accurate data regarding both process and outcomes, and reports that recognize the variability in patient risk at different institutions. Most importantly, by universally capturing data at all statewide hospitals performing selected procedures, both COAP and SCOAP strive to be a "tide that lifts all boats" to improve healthcare for all members of our community. SCOAP is in the process of initial data gathering at hospitals across the state and we expect universal participation in short order. The first targeted procedures for SCOAP are colon and rectal resection, bariatric surgery, and appendectomy.

Table I. Characteristics of the Surgical Clinical Outcomes Assessment Program (SCOAP)

Mission
- Improve quality of care for general surgical procedures performed in all hospitals across the state- "a tide that raises all boats".
- Focus on actionable process measures and relevant risk stratified outcomes data gathered on a patient-level but reported on a hospital-level.
- Data reports to hospitals and surgeons that are blinded to the identity of other hospitals Initial procedures include colon and rectal resection, appendectomy and bariatric surgery.

Function
- Surgeon leadership.
- Universal participation (by hospitals and surgeons across the state).
- Created by utilizing the "safe harbor" of a not-for-profit foundation (Foundation for Healthcare Quality) and Washington State statute protecting QI data.
- Data acquisition by trained personnel and subject to periodic audit.
- Information gathered protected (as QI) by State Statute.
- Partnership with Washington State Chapter of the American College of Surgeons.

Funding
- Sponsored by multiple stakeholders including purchasers, payers and hospitals.
- Major purchasers of healthcare in the state encourage participation through hospital contracts.

RATIONALE

Starting in 2000 investigators at the University of Washington's SORCE performed a series of analyses using Washington State's hospital discharge dataset to describe variation in adverse outcomes and components of care for procedures commonly

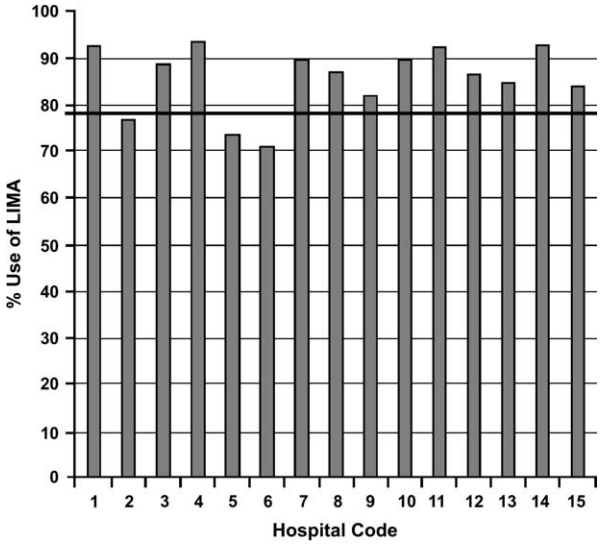

Fig. 2. Cardiac Outcomes Assessment Program (COAP) data[10] on hospital use of internal mammary artery for coronary artery bypass grafting, by hospital. The bar represents a national average. Reprinted, with permission, from Dabal RJ, Goss JR, Maynard C, Aldea GS. The effect of left internal mammary artery utilization on short-term outcomes after coronary revascularization. *Ann Thorac Surg* 2003;76:464-470.

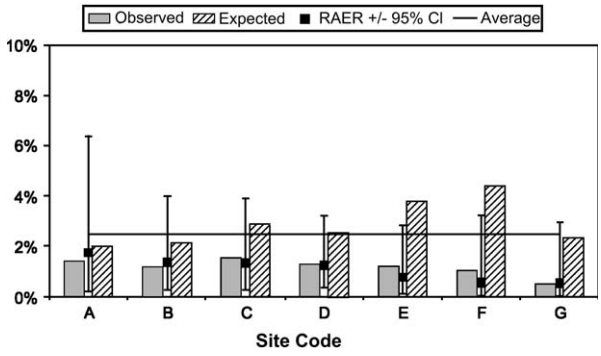

Fig. 3. Mock-up of a cardiac outcomes assessment program (COAP) report of expected and observed risk-adjusted 30-day mortality rates.

performed by general surgeons.[4-6] These data were also used to describe the potential financial benefits of reduction in variation of adverse outcomes across the state using a modeled cost analysis. For example, among the more than six million residents of Washington State approximately $300 million per year is spent on inpatient abdominal surgery inclusive of ~73,000 patient days. Analysis of "complications" (using administrative codes) following procedures commonly performed by general surgeons reveals that an estimated $30 million/year comprising 1200 complications/year and 7,000-8,000-hospital days/year could be avoided if variability in rates of these events was minimized.

These population-level analyses reveal significant variation in processes of care and outcomes for procedures that might provide opportunities for targeted quality improvements. These opportunities include patients undergoing appendectomy (rates of negative appendectomy and the use and accuracy of diagnostic testing), cholecystectomy (common bile duct injury and the use of intraoperative cholangiogram) and surgical weight loss procedures (highly variable rates of early mortality between hospitals). The significant variability in outcomes following colorectal resection among Washington state hospitals (Fig 4) dramatically explains the rationale for a program like SCOAP.

Administrative datasets are significantly limited by the fidelity of the data they include, the lack of clinical variables to allow for meaningful comparisons based on patient illness and clinical conditions and their timeliness. It is because of these limitations that surgeons should be concerned by attempts to profile their performance using these techniques. This is why a program such as SCOAP that provides risk stratified, clinical data on processes and outcomes is valuable. What surgeon would not want to know what Figure 4 would like for their practice and hospital, especially if it were based on "real" clinical data and with an accounting for varying patient risk profiles? Quite simply, the surgical community's desire to improve patient care is the motivation behind SCOAP.

THE PROCEDURES EVALUATED IN SCOAP

Based on this rationale, an argument could be made that all procedures should be "SCOAPed". The management committee of SCOAP decided to include colorectal resections, bariatric surgery and appendectomy in the first iteration of the program. The procedures to be evaluated in this first version of SCOAP were selected for a combination of practical reasons. The first criterion for inclusion was that the procedure occurs in the inpatient setting and that a significant percentage of their adverse outcomes occur while an inpatient. The second criterion for inclusion was that the procedure occurs frequently enough to be able to quickly capture sufficient cases to demonstrate success (i.e. approximately 5,000 colorectal resections and 6,000 appendectomies are performed per year in the state). The third criteria for inclusion was that procedures should be important either from a cost perspective (e.g. bariatric surgical procedures cost ~$25,000/case and the costs of

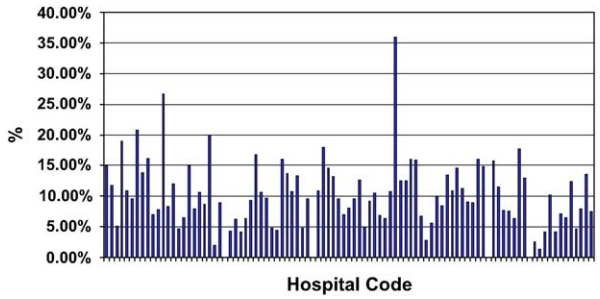

Fig. 4. Variability in rates of 90-day reintervention (operative or percutaneous) following colon and rectal resections across Washington State, by hospital (1987-2003).

care associated with an anastomotic breakdown can easily exceed $100,000) or from a clinical perspective (e.g. variability in the use and accuracy of diagnostic information provided for surgical diseases like appendicitis has recently become a highly debated issue). Finally as in most states, the general surgical community of Washington has little experience candidly sharing information about process and outcomes. Even in a confidential and anonymous setting these first procedures were selected in part because surgeons agreed that these were either important enough (bariatric surgery and colorectal resection) or sufficiently "non-threatening" enough (e.g. appendectomy) such that early success would be likely.

THE ELEMENTS OF DATA COLLECTION AND RISK STRATIFICATION

The SCOAP data collection instrument has three components; risk stratification, general and specific (to each procedure) process and outcome measures. The full dataset is available through the website: http://www.scoap.org, as is the data dictionary used for abstractors.

RISK STRATIFICATION

SCOAP measures include a detailed but easily extractable (from charted information) risk stratification strategy based on demographic components, comorbid medical conditions, use of certain medications and serum laboratory measures. Despite many attempts over the years to determine a meaningful risk stratification strategy for general surgical care the goal of adequate risk adjustment (for all but cardiac surgical patients) has remained elusive. Certainly for the procedures and relevant outcomes being evaluated in SCOAP there is no accepted strategy to guarantee an "apples to apples" comparison. SCOAP has aimed for risk stratification rather than risk adjustment based on a group of commonly found data elements selected by a panel of surgeon experts gathered for this purpose. The adequacy of this risk stratification will only be testable after SCOAP evolves but ultimately the test of its adequacy will be made by the community of surgeons using SCOAP and based largely on its face validity and its predictive characteristics when tested.[2]

Process and Outcomes Measures. The overall emphasis of SCOAP data collection is on process of care more than outcomes. Process analysis may be a more productive approach to QI projects than outcomes oriented approaches. While adverse outcomes for most procedures performed by general surgeons are infrequent or even rare events, "best practice" process measures should be nearly universally applied. The use of process measures as a metric allows for more meaningful comparisons between hospitals using statistical tests. Deviations from accepted process measures are also actionable items that should result in improved outcomes. Conversely, a report that only details increased mortality compared to one's peers requires a different, "reinvent the wheel" response that may not be as easily actionable. This type "outcomes only" approach may unfortunately shift the focus from improving quality to one of selecting patients likely to have good outcomes and that may compromise access to care. Indeed, limiting procedures to healthier patients might result in improved mortality without a parallel improvement in quality. Process focused approaches may also be less threatening in the nascent collaboratives that surgeons are forming across the country. Variability in training, experience, beliefs, and interpretation of evidence has led to highly variable clinical practice and all surgeons think their results are above average. Tracking on outcome alone may challenge these notions but may also reinforce this variability because individual components of practice (that may have nothing to do with outcome) may be justified by an assessment of outcomes alone. SCOAP is beginning a conversation about the variability in surgical process that will help to incorporate evidence-based process measures into practice. Specific process measures to be included in SCOAP include all the evidence-based measures for intraoperative and operative care and a set of exploratory variables that have not risen to the level of "best practices" but that an expert panel thought was likely to become "best practices" over time.

SCOAP data elements also track adverse outcome. These include measures such as in-hospital

survival, percutaneous and/or operative reinterventions, negative appendectomy, severe hospital acquired pneumonia and length of hospitalization. Given the problematic definition of anastomotic complications, intra-abdominal abscess and deep surgical site infection (SSI) we devised a strategy for adverse outcome detection that defines complications by the treatments used to address them. For example, at different institutions anastomotic complications might be defined variably by radiologic or clinical grounds but all will likely treat those using variations of antibiotics, intensive care unit observation, percutaneous drainage or reoperation. SCOAP will capture all these events independent of whether the causative event was characterized as an anastomotic leak.

Early on in the development of SCOAP the issue of whether or not this was intended as a research or a QI database was considered. Although SCOAP will be used to describe variability in process and outcome and apparent relationships between outcome and features of patients and processes, fundamentally this dataset was designed for QI purposes. The main distinction between the two types of datasets relates to data fidelity. QI data like that used for SCOAP are extracted from clinical chart reports using a standard data dictionary. Data included in clinical records may not have the same rigor as data derived for research. For example, in clinical care a patient's self-reported diagnosis of diabetes may be used to define the presence of that disease while for research purposes biochemical criteria may be more appropriate. A research dataset of any rigor requires that data used to describe a patient or a procedure be generated by research staff or practitioners using standardized metrics. This standard for the source of data in thousands of patients is beyond the scope of most QI initiatives and limits their use for addressing many research questions.

OPERATIONAL ISSUES

Data collection for SCOAP occurs in the hospital and it is done by trained abstractors who obtain relevant information from medical records. Data collection is audited externally and submitted to a central data repository where they are "cleaned", analyzed and the results of these analyses are prepared in quarterly reports. The FHCQ disseminates these reports and assures that hospitals are blinded to the identity of all but their own results. SCOAP and COAP measures are reported without surgeon identifiers. Hospitals have access to this surgeon-level information, but hospital-level reporting was considered by the SCOAP leadership to be more appropriate because the focus of the program is on system-level processes of care, the numbers of procedures by any one surgeon are likely to be small, and hospitals are better suited to approach QI issues that relate to a given individual.

Hospitals are charged fees to participate in SCOAP and these fees are supplemented by investments from the stakeholders outlined above. The HCA and payers have further supported SCOAP by including language encouraging and ultimately requiring participation in SCOAP in their healthcare contracts. The SCOAP leadership is also working with payers to develop a billing code that will allow for third party payer reimbursement for this QI activity that will further reduce SCOAP fees.

SCOAP is administered by the FHCQ and a management committee comprised of surgeons and QI leaders with advisors from the HCA and the medical directors of Medicaid and Medicare. Although these payer stakeholders serve as advisors the data derived from SCOAP cannot be used by anyone other than the hospitals. Yearly meetings of all SCOAP participants tied to the annual meeting of the Washington State Chapter of the American College of Surgeons will allow for comparisons of local QI activities and further development of the program.

ALTERNATIVES TO SCOAP

Hospitals across the nation are balancing their interest in several national and regional QI alternatives. These programs include Surgical Site Infection Prevention Program (SIP) which is a shared initiative by Medicare and the Joint Commission on Accreditation of Hospitals Organization (JCAHO). SIP tracks 3 process measures that are either involved in prevention of SSI (timely initiation and appropriate choice of antibiotics) or antibiotic resistance (cessation of antibiotics within 24 hours). A similar program extended from SIP and initiated by Medicare and other involved parties is the Surgical Complication Improvement Project (SCIP). SCIP aims to improve the use of DVT prophylaxis and to reduce perioperative myocardial infarction and pneumonia by identifying a list of procedures that should always be performed in tandem to prophylactic measures and then tracking on their use In Washington State a program like SCOAP has appeal because approximately half of our hospitals do not or cannot participate in JCAHO and because many of these hospitals are rural. Small hospital participation in expensive or burdensome data reporting projects may not be feasible when the procedures are performed infrequently.

There are also a series of initiatives being proposed and led by professional societies (American College of Surgeons-NSQIP and American Society of Bariatric Surgery) or insurance carriers and payers that may be viewed as competing projects. Because of their cost and because, by definition not every hospital can be a "Center of Excellence" these programs will likely not include all hospitals in the state. The appeal of SCOAP over these projects is that through its universal inclusion of all statewide hospitals performing these procedures SCOAP will help improve the quality of all care delivered in the state. Rather than identifying "Centers of Excellence" this approach will assure an adequate standard of care across the entire state. In this way the SCOAP project is really a public health initiative that is aimed at improving the surgical care of all residents in the state. Furthermore, in its present incarnation NSQIP records no information about processes of care.

In the absence of SCOAP there may be an advantage for a hospital to be involved in more than one of the available surgical QI projects. For example a hospital might want to be involved in both a project that is exclusively outcome oriented (i.e., NSQIP) and one that focuses only on perioperative process (i.e., SCIP). We believe that future evolutions of these seemingly competing projects will look more like SCOAP by combining actionable process measures and relevant and credible outcome measures. Perhaps one of the most appealing components of SCOAP is that as a regional project it takes advantage of the established relationships of QI managers and leadership to address the needs of our community.

BARRIERS AND LIMITATIONS TO SCOAP

There are several potential barriers to these projects. For example, surgeons may feel threatened by tracking on process and outcome data on their patients and to have their beliefs and experience challenged by data showing their actual use of evidence-based process measures. Furthermore, it is challenging to find out that our outcomes may not "measure up" without getting defensive and when we as individuals cannot control all the elements being tracked. When challenged with data demonstrating variability often the first challenge is to the adequacy of the data or data collection techniques. For this reason, projects like SCOAP need some time to develop and to gather "buy in" from surgeons to the data and data collection process. Early SCOAP reports will therefore be considered exploratory until there is confidence among the stakeholders that the data and variability observed is real.

There are also competing initiatives that in some cases have overlapping data reporting requirements. SCOAP has dealt with this by using identical data definitions where there is overlap and working to streamline reporting processes. Other initiatives also appeal to competing hospital interests that may have little to do with improving patient care. For example, Centers of Excellence programs are often viewed by the marketing departments of hospitals as an opportunity for advertising their hospital's excellence. A program like SCOAP that requires the candid sharing of data cannot exist in the setting of these "billboard" approaches to quality. In fact, COAP has flourished in our state primarily because of the state statutes that protect its findings both from discovery and dissemination for non-QI activities (e.g. billboards, contracting). We acknowledge that there are important competing demands on hospitals. Hospitals' willingness to participate in SCOAP is dependent on their belief that the public health approach will be better for our state. These competing demands also require competing financial and human resources and the limited pool of these is another challenge to programs like SCOAP. SCOAP hopes to reduce this barrier, by creating a reimbursable code for this QI activity and demonstrating costs saving opportunities through reduction in variability.

Public disclosure of QI activities is evolving as a standard for QI projects. However, the drive for complete transparency is not without unintended consequences, and in SCOAP's first iteration that degree of transparency will not be possible.[7,8] Complete transparency of data would not be appropriate if it made surgeons and hospitals less inclined to share the sensitive information that is required in a QI project. When SCOAP develops the full confidence of its stakeholders, discussions about the extent of public reporting will be appropriate. In Washington State the issue of complete disclosure may always be limited by the statute requirements that prohibit dissemination. One of the reasons that Washington State developed this statute is that the frank exchange of data on process and outcome variability may be impossible to accomplish if those data are subject to discovery during malpractice litigation. To bridge the competing interests of confidentiality and disclosure, SCOAP initially will report hospital participation status in the project and some elements of that participation. The drive for disclosure may represent a

barrier to this project but the SCOAP leadership believes that a balance of enough reporting to assure public confidence but not so much as to violate statute or to interfere in the development of this collaborative is a middle path that will satisfy these demands.

Another limitation of SCOAP is that it does not contain explicit QI functions beyond tracking of variability. As indicated above, legal statute both protects and prohibits the identification of individual hospital's data but at yearly meetings COAP members participate in the voluntary sharing of their hospital's practice patterns. We expect that the sharing of practice patterns, even if distinguished from the sharing of data regarding those practices will be a component of the SCOAP meetings. While the "Hawthorne effect" (measuring a problem improves the problem) has been a time honored approach to QI[9] there are limits to the success that can be achieved in this manner. Other QI interventions such as those sponsored by commercial QI groups have significant associated costs and high levels of "recidivism". SCOAP and COAP have approached QI by tracking on variability and having local QI activities and infrastructure respond to these data in the way that is most appropriate to the local institution.

Lastly, there is a limitation to the available data elements that are included in SCOAP. Aside from the limits of risk stratification strategies described above there is very little Class A data on process measures that make "best practices" to prevent anastomotic breakdown and other "operative" adverse outcomes that are most relevant to surgeons. The bulk of the process measures for which we have high levels of evidence involve perioperative care (i.e., myocardial infarction, DVT, SSI and pneumonia). In SCOAP we have dealt with this by gathering data on all known "best practices" process measures for perioperative care while also including a group of likely measures that clinicians feel are involved in optimal operative outcomes. Furthermore, outcome measures in SCOAP are limited by the feasibility of gathering such data. For its initial iteration SCOAP will gather data on in-hospital events only but we expect future versions to link to administrative data sources to allow for tracking of 30-day mortality and readmission to other hospitals.

CONCLUSION

For nearly every procedure performed there is significant variability in operative and periprocedural care and in associated outcomes between hospitals. From a health system perspective this variability often represents a lapse in quality and an opportunity to save in both human and financial costs. SCOAP is a developing Washington State initiative that was designed and implemented by practicing surgeons, the leadership of the statewide ACS chapter, the Washington State Hospital Association, and QI organizations across the state to track and reduce variability in abdominal surgical practice and outcomes. SCOAP is built on the success of an existing cardiac surgery/interventional cardiology care regional tracking system that has resulted in dramatic reductions in variability for those disciplines. SCOAP's initial clinical focus is on colon and rectal resections, appendectomy and bariatric surgery but will likely expand based on clinical interest and feasibility. The emphasis of data collection in SCOAP is on high-quality, reliable, evidence-based process measures gathered alongside measures of in-hospital outcome. This tracking of variability will be coupled with local QI activities aimed at improving performance by focusing on system level change rather than on individual behavior. In Washington State we look forward to this project helping to reduce the widespread variability in surgical practice and outcomes that is undermining confidence in the healthcare system. By including data on all hospitals in the state and not just "Centers of Excellence" SCOAP hopes to be a "tide that raises all boats". SCOAP aims to translate what we have learned through surgical outcomes research into improved surgical care across the state. While there are significant barriers to SCOAP we are optimistic that this program will improve the healthcare of our community and is worth the effort.

Surgeons have long considered themselves leaders in QI. This is best demonstrated by the incorporation of the morbidity and mortality conference into our weekly schedules and frank discussions about patient outcome into our professional culture. However, for years surgeons have focused almost exclusively on individual performance and may have missed an opportunity to evaluate and improve the system level factors that relate to adverse outcome. Activities like SCOAP are an attempt to correct this approach by instituting complete surveillance and shifting surgical QI to a system and process-level focus. This movement takes advantage of the experiences of other industries (i.e., airline and manufacturing) in making a better healthcare system. These systems do so not by eliminating variability but by tracking it, anticipating it and then building systems that protect against it. This is an exciting time for the surgical community as we

once again assert our role as leaders in improving quality of care.

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