Designing a Surgical Quality Improvement Project at Eastern State Medical Center

In June of 2012, Dr. Marshall Giles, Chief of General Surgery was about to design his first surgical quality improvement project at Eastern State Medical Center (ESMC), a large academic medical center. ESMC was a participant in the National Surgical Quality Improvement Program (NSQIP©), and Dr. Giles, the NSQIP “Surgical Champion,” was hoping to use the hospital’s most recent NSQIP Semi-Annual Report (SAR) as the basis for focusing his intervention, working with his Surgical Clinical Reviewer 1.

He first consulted with the hospital’s resident statistician, Joan Dutrow, PhD, about how he should interpret the SAR for General Surgery (See Exhibit 3 for the specific page in the report he was looking at). Dr. Dutrow said,

*This plot presents a lot of data very efficiently but I’m suspicious of the very high odds ratios – they make me worry that there’s a lot of noise in this data. Of course, I don’t know the methods they used or the context for the graph, but my first reaction is to be skeptical of taking it too literally.*

Dr. Giles was left wondering whether the SAR should be the basis for focusing his QI effort, and if so, what else he needed to know to ensure that he was interpreting the report in a way that would properly target his quality improvement efforts. He realized that nothing was perfect, but he wanted to be armed with the best understanding possible before he began to work with his surgical colleagues to improve surgical outcomes.

1 A hospital-based Surgical Champion and Surgical Clinical Reviewer are required in order for the hospital to participate in NSQIP; they are trained with tool kits, webinars, and monthly conference calls.

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Background on NSQIP

NSQIP was developed as a tool to evaluate surgical quality with patient risk adjustment by the Department of Veterans Affairs in the late 1990s, and expanded by the American College of Surgeons to non-VA hospitals in 2005 (ACS NSQIP). As of 2013, there were more than 525 participating hospitals in ACS NSQIP. Hospitals receive reports twice a year, in January/February and in July, based on a year’s worth of cases collected 6 months prior to the reports. The six-month lag time between the end of the case period and the issuance of the report allows for 30-day post-operative observation and report processing. The direct costs of participation in NSQIP for ESMC were over $150,000/year which includes the salary of the surgical clinical reviewer and the annual fee of $30,000 to the American College of Surgeons.

Each “model” or surgical area (e.g., General Surgery) has its own case-mix adjusters (also called predictors), outcomes (adverse events), and comparison group of hospitals. To identify “outcomes” (the presence or absence of a specific adverse event) as well as variation in patient characteristics (“case-mix”), each participating hospital is responsible for hiring one FTE Surgical Clinical Reviewer (SCR) to abstract a sample of patient demographic and specific clinical data from medical records. (See Exhibits 1 and 2.) ACS NSQIP takes the raw data submitted by the participating hospitals and runs it through sophisticated statistical regression modeling procedures to predict the “expected probability” of the outcome of a given patient. If a case-mix variable is missing, the models will impute its value using standard statistically valid techniques. Each model has its own version of “predictor” variables, which are selected based on their statistical impact on effective prediction of the outcome, rather than on clinical judgment.

The Odds Ratio (OR) quantifies the ratio of the odds of the adverse outcome for each individual hospital to the odds of adverse outcomes in all the other hospitals combined, after statistical adjustments to address the characteristics of the hospitals. It is similar to, but not the same as, an Observed/Expected (O/E) ratio. For an O/E ratio, the “observed” rate for each hospital is divided by the “expected” rate, which is the aggregate rate for all participating hospitals. The OR is making the same comparison using statistical methods to adjust for case-mix and other participating hospital characteristics. Like the O/E ratio, an OR=1 means that the hospital has the same odds of experiencing adverse events as the other hospitals. A 95% Confidence Interval is then constructed to show a margin of error for the estimate of the OR.

The report provides two ways of interpreting the hospital’s performance. The first method uses the 95% Confidence Interval (CI) for the OR of each hospital for each outcome. If the lower CI is above 1, then a hospital is considered to have performed “worse than average.” Conversely, if the upper CI is below 1, then the hospital is considered to have performed “better than average.”
The second way of reporting the hospital’s performance uses each hospital’s OR rank, relative to the other participating hospitals. Good performance is defined as being in the best decile or, in lay terms, the “top 10%.” Poor performance is defined as being in the worst decile or “bottom 10%.”

Guidance from the NSQIP organization\(^2\) regarding where hospitals should focus their quality improvement efforts included these two points:

- Hospitals should give more credence to high statistical outliers (95% CI above 1) than to the decile ranking.
- All other things being equal, hospitals should focus their efforts on improving areas where there is the largest range in odds ratios (longest background box in Exhibit 3)

**Moving Forward**

While every surgeon wanted the best possible outcomes for their patients, they did not all agree that the NSQIP report was the best way to identify where quality improvement interventions should take place. One commented that, “Benchmarking outcome data in the absence of process measures could potentially cause us to put our efforts into something that will end up being a waste of time.” Another surgeon countered, saying that “without knowing how our outcomes compare, we have no idea if we are providing good or bad quality. Plus the NSQIP data is the only validated source for measuring surgical outcomes in general surgery.” Others were still not convinced that quality improvement interventions were even necessary, especially when adverse event rates were very low. It was critical that Dr. Giles start off with the most credible and relevant data possible to inform his QI effort.

Dr. Giles was also aware that the Centers for Medicare and Medicaid Services (CMS) had recently indicated its intention to incorporate clinical, risk-adjusted outcome measurement for surgeries into its value-based purchasing initiatives for hospitals in 2015. It might not be long before the hospital was financially rewarded or penalized for how it did on the NSQIP measures. Unless he had a good understanding of what the data could and could not be used for, he was very worried that the hospital might ramp up pressures for his service to spend time and resources to “chase noise.”

\(^2\) Evaluating Models and Interpreting Results, Kristopher Huffman, MS, Division of Research and Optimal Patient Care, Continuous Quality Improvement, American College of Surgeons, July 14th, 2013

Exhibit 1:

Overview of NSQIP Classic Variables for Abstraction

Surgical Profile variables
- Principle Operative Procedure, Procedure Code (CPT), In/Out Patient Status, Elective Surgery, Origin of Status, Hospital Admin Date, Operation Date, Level of Supervision, Principal Anesthesia, Surgical Specialty

Preoperative Risk Assessment:
- Height, Weight, Diabetes, Current Smoker, Pack-year History, Alcohol use, Dyspnea, Do Not Resuscitate Status, Functional Health Status
- Pulmonary: Ventilator Dependent, Chronic obstructive pulmonary disease (COPD), Pneumonia
- Hepatobiliary: Ascites
- Gastrointestinal: Esophageal varices
- Cardiac: Congestive heart failure, myocardial infarction (MI), percutaneous coronary intervention, Cardiac Surgery, Angina, hypertension
- Vascular: Revascularization, Amputation for peripheral vascular disease, Rest Pain/Gangrene
- Renal: Renal Failure, Dialysis
- Central Nervous System: Impaired Sensorium, Coma, Hemiplegia/Hemiparesis, Transient Ischemic Attacks, cerebrovascular accident (CVA), Tumor involving central nervous system, Paraplegia/paraparesis, Quadraplegia/quadraparesis
- Nutritional/immune/oncology/other: Disseminated Cancer, Open wound, Steroid /Immunosuppressant Use, > 10% of weight, Bleeding disorders, Pre-operative Transfusions, Chemotherapy, Radiotherapy, Systemic inflammatory response syndrome (SIRS), Sepsis, Septic Shock, Pregnancy, Prior Operation
- Preoperative Laboratory Data: Preoperative Lab Value Info.

Operative Info:
- Additional Operative Procedures: Other Procedure, Concurrent Procedure

Occurrences:
- Intraoperative Occurrences: Cardiac Arrest, Death, MI, Unplanned Intubation, Other Intra-Operative
- Postoperative Occurrences: present at time of surgery (PATOS)
- Wound Occurrences: Superficial Incisional SSI, Superficial Incisional SSI PATOS, Deep Incisional SSI, Deep Incisional SSI PATOS, Organ/Space SSI, Organ/Space SSI PATOS, Wound Disruption
- Respiratory Occurrences: Pneumonia, Pneumonia PATOS, Unplanned Intubation, Intraop/Postop Intubation, Pulmonary Embolism, On Ventilator> 48 Hours, On Ventilator> 48 Hours PATOS

3 ACS NSQIP – CLASSIC VARIABLES & DEFINITIONS, June 24, 2010, ACS NSQIP
- Urinary Tract Infection Occurrences (UTI): Progressive Renal Insufficiency, Acute Renal Failure Requiring Dialysis, UTI, UTI PATOS
- Central Nervous System Occurrences: Stroke/CVA, Coma > 24 Hours, Peripheral Nerve Injury,
- Cardiac Occurrences, Cardiac Arrest Requiring CPR, Intraop /Postop Cardiac Arrest, MI, Intraoperative/Postoperative MI
- Other Occurrences: Transfusion Intraop/ Postop, Graft/Prosthesis/Flap Failure, DVT requiring therapy, Sepsis, Sepsis PATOS, Septic Shock, Septic Shock PATOS, Other Postop Occurrences

**Laboratory Data**
- Postop Lab Value Information (various tests)

**Postoperative Information**
- Hospital Discharge/Readmissions/Mortality/Reoperations: Acute Hospital Discharge Date, Hospital Discharge Destination, Postoperative Diagnosis (ICD-9), Still in Hospital > 30 Days, Death postoperative within 30 days, Death intraoperative/postoperative within 30 days, Death Postoperative > 30 days, Death Date, Hospital Readmission, Unplanned Reoperation

**Follow-up**
- 30 Day follow-up, Patient Contact Management

**Glossary:**

- ASA classification: American Society of Anesthesiologists Physical Status classification system
- COPD: Chronic obstructive pulmonary disease
- CPT: Current procedure code
- CVA: Cerebrovascular accident (stroke)
- DVT: Deep vein thrombosis
- MI: Myocardial infarction
- PATOS: Present at time of surgery
- SSI: Surgical site infection
Exhibit 2:

How Adverse Events are Identified Using Surgical Site Infection as an Example

Excerpts from CDC instructions (23 pages) on how hospitals should undertake SSI surveillance:

SSI monitoring requires active, patient-based, prospective surveillance. Post-discharge and antedischARGE surveillance methods should be used to detect SSIs following inpatient and outpatient operative procedures. These methods include:

1) Direct examination of patients’ wounds during follow-up visits to either surgery clinics or physicians’ offices,
2) Review of medical records or surgery clinic patient records,
3) Surgeon surveys by mail or telephone, and
4) Patient surveys by mail or telephone (though patients may have a difficult time assessing their infections).

Any combination of these methods is acceptable for use; however, CDC criteria for SSI must be used.

Excerpt from CDC instructions on what constitutes a Superficial SSI:

Infection occurs within 30 days after any (eligible) operative procedure (where day 1 = the procedure date), including those coded as ‘OTH’* and involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

a. Purulent drainage from the superficial incision.
b. Organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision.
c. Superficial incision that is deliberately opened by a surgeon, attending physician** or other designee and is culture positive or not cultured and patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; redness; or heat. A culture negative finding does not meet this criterion.
d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician** or other designee.

Exhibit 3:

The NSQIP SAR Graph for ESMC General/Vascular Surgery

Each “box” represents the distribution of Odds Ratios (ORs) for all hospitals in the model; the bottom and top give the smallest and largest values, and the horizontal lines give decile demarcations. The dots represent the ORs and the bars represent the 95% CIs for Eastern State Medical Center for each outcome.

DVT/PE = deep vein thrombosis/pulmonary embolism
SSI = Surgical Site Infection
ROR = Return to the Operating Room
Exhibit 4:

The Detailed NSQIP SAR Report for ESMC General/Vascular Surgery

The total cases represent a sample of roughly 5500 general and vascular surgeries that meet criteria. The criteria for inclusion include: over the age of 18, ASA classification < 5 (i.e., not moribund), no trauma, no more than two breast cases, two laparoscopic cholecystectomy cases, or two inguinal hernia cases per 8-day cycle.

* Determined by Outlier status or by Decile status

** Predicted Observed Rate is the model-adjusted observed rate

*** C.I.: 95% Confidence Interval