



THE FLORIDA SURGICAL CARE INITIATIVE

A Closer Look – May 2011

The Florida Surgical Care Initiative (FSCI), developed through a partnership between the Florida Hospital Association (FHA) and the American College of Surgeons (ACS), and endorsed by the Florida Chapter of the ACS, will focus initially on four outcome measures of the ACS National Surgical Quality Improvement Program (NSQIP). It will use a narrow set of key predictive clinical variables so as to concentrate resources and facilitate meaningful analysis and more rapid improvement in surgical care outcomes (all Florida hospitals may participate in the full ACS NSQIP, or choose to focus on the four FSCI measures).

ACS developed the four measures in 2009 in partnership with the Centers for Medicare and Medicaid Services (CMS) with the goal of creating outcomes-based measures that would help hospitals achieve significant quality improvements resulting in improved patient outcomes. ACS submitted these four surgical outcome measures to the National Quality Forum (NQF) for endorsement. If the measures receive NQF endorsement and are subsequently selected by CMS for implementation, FSCI participants will have a valuable head start in implementing these measures and using them to improve quality.

This article provides an overview of the surgery outcome measures, data-collection process, risk-adjustment methods, results reporting, and auditing process involved in the FSCI program.

Surgical Outcome Measures

The four surgical outcome measures of FSCI – surgical site infection (SSI), urinary tract infection (UTI), colorectal outcomes and elderly surgery outcomes – were developed out of the standard ACS NSQIP measures that are followed from pre-op to 30 days post-discharge (see Table 1). ACS NSQIP has been well documented to significantly decrease patient mortality and morbidity rates (*Annals of Surgery*, 250:363-376, September 2009), and the FSCI program also is expected to significantly impact patient outcomes because it was developed based on ACS NSQIP measures.

Each outcome measure has been individually validated by statistical models developed from the ACS NSQIP national database, which includes more than one million patient cases to date and more than 300,000 new cases each year:

The four measures of the FSCI program were selected because:

- They are applicable to hospitals of all sizes and types, including urban and rural, large and small, and teaching and non-teaching hospitals;
- They are able to evaluate quality for a wide range of patients including elderly patients whose outcomes often are not specifically measured and tracked in other measurement programs;
- They focus on high-impact, common procedures associated with high morbidity and mortality rates thus providing a significant opportunity for quality improvement.



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Table 1: FSCI Variables and Outcome Measures

Surgery Outcome Measures	Number of Predictor Variables	Number of Outcome Measures
Surgical Site Infection (SSI) Outcome	4	1
Urinary Tract Infection (UTI) Outcome	5	1
Colorectal Outcomes Measure	7	12
Elderly Surgery Outcomes Measure	3	12
Outcome Measures	<ol style="list-style-type: none"> 1. Death 2. Reoperation 3. SSI (Deep or Organ Space) 4. Wound Dehiscence 5. UTI 6. Pulmonary Embolism 7. Deep Vein Thrombosis 8. Pneumonia 9. Renal Failure/Insufficiency 10. Cardiac Arrest 11. Myocardial Infarction 12. Unplanned Reintubation 	

FSCI Data Collection

Each patient assigned to FSCI is evaluated to determine if they experienced one or more of the defined outcomes within 30 days of the operation. Specifically, this evaluation includes:

- Review of the final medical record.
- Screening of cases for readmission within 30 days of the operative record. If readmission has occurred, the record should be evaluated to determine if any of the designated outcomes occurred post-discharge.
- Post discharge assessment for complications occurring within 30 days of the operative procedure.

FSCI data is collected by a trained Surgical Clinical Reviewer (SCR), through a standardized process to optimize the accurate collection of data. An ideal minimum number of cases is collected annually for each outcome, as shown in Table 2. An ACS-validated sampling system called the eight-day cycle is used to minimize bias in choosing cases for assessment. This sampling system divides the work year into eight-day cycles; the first 40 consecutive cases that meet the inclusion criteria, beginning on a different day of the week for each cycle, are selected. The process ensures that cases have an equal chance of being selected from each day of the week. Case selection and case mix are monitored by the program on a weekly basis to ensure the sampling is appropriate. **NOTE:** FSCI will use a similar eight-day cycle methodology; the exact sampling methodology will need to be individualized to each hospital based on its case mix and volume.

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Table 2: FSCI Ideal Sample Sizes (Note: It is expected that certain cases will be applicable to multiple measures).

Surgery Outcome Measures	Ideal Sample Size/Year (I)
1. Surgical Site Infection (SSI) Outcome	430
2. Urinary Tract Infection (UTI) Outcome	290
3. Colorectal Outcomes Measure	80%-100% of total cases performed
4. Elderly Surgery Outcomes	180

FSCI Sample Sizes

For each measure, sample sizes were chosen to achieve a reliability of 0.4. In this context, reliability describes how well one can confidently distinguish the performance of one hospital from another. Reliability is influenced by measurement error (noise), real differences between hospitals (signal), and sample size, but only the latter can be adjusted. Reliability ranges from 0 (meaning that all variability in a measure is due to measurement error) to 1 (all variability is due to real differences in performance). Depending on the signal-to-noise ratio estimated for any particular measure, different sample sizes will be required to meet a specified reliability criterion. The attached table shows estimated required samples sizes for each measure.

Sample Size Limits and Sample Sizes per 8-Day Cycle

While some FSCI participating hospitals may wish to focus in on a particular procedure or issue for their quality improvement activities, sampling procedures have been established to ensure reliability of the outcome models. It is important to adhere to the prescribed methodology because over or undersampling can impact risk adjustment.

If a hospital limits participation to a single measure, then it could provide many more cases, compared to other hospitals participating in all four measures. If the total, all-hospital, sample size is very large, then no single hospital – even one participating in only a single measure – will comprise a very large percentage of the data. However, if the total sample size is small, then a single hospital may over-define “average” performance. For this scenario, ACS retains the prerogative to randomly sample cases from over-contributing hospitals, so that a single hospital or small set of hospitals does not set the *de facto* standard.

For hospitals participating in the elderly surgery measure, based on a sample size approaching 880 we expect that 177 elderly patients would automatically be pulled in participating hospitals over the course of a year, because the elderly typically compose more than 20 percent (177/880) of the surgical population. Minor increases in sampling during one 8-day cycle to compensate for under-sampling in another should not pose an undue risk for bias.

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FSCI Sample Sizes per Measure

SSI Reliability Estimate	Procedures Req. to Meet Spec. Reliability	% of U.S. Hospitals Meeting Volume Req.*	% of ACS NSQIP Hospitals Meeting Volume Req.+
0.3	275	94.0	94.8
0.4	428	89.3	92.4
0.5	641	84.8	82.0
0.6	961	79.7	65.9
0.7	1495	73.1	32.7

UTI Reliability Estimate	Procedures Req. to Meet Spec. Reliability	% of U.S. Hospitals Meeting Volume Req.*	% of ACS NSQIP Hospitals Meeting Volume Req.+
0.3	187	94.0	96.2
0.4	290	93.9	94.3
0.5	435	89.2	92.4
0.6	653	84.5	82.0
0.7	1015	78.5	59.7

Elderly Reliability Estimate	Procedures Req. to Meet Spec. Reliability	% of U.S. Hospitals Meeting Volume Req.*	% of ACS NSQIP Hospitals Meeting Volume Req.+
0.3	114	93.3	92.4
0.4	177	90.8	84.8
0.5	265	86.8	72.5
0.6	397	80.9	46.5
0.7	617	70.7	13.3

Colorectal Reliability Estimate	Procedures Req. to Meet Spec. Reliability	% of U.S. Hospitals Meeting Volume Req.*	% of ACS NSQIP Hospitals Meeting Volume Req.+
0.3	41	55.8	79.6
0.4	63	42.9	68.7
0.5	94	31.6	53.5
0.6	141	20.1	27.5
0.7	219	9.6	3.8



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Staffing: The Surgical Clinical Reviewer

SCRs play a key role in collecting data and championing quality improvement efforts. Since FSCI is a focused program, most hospitals will require only the equivalent of a half-FTE staff time or less to collect data. In some cases, hospitals will find that they are already collecting much of this data for other purposes.

SCRs have a bachelor's degree and at least one year of experience in the surgical department. They may be nurses or other appropriate professionals, such as a medical records staff member. Training is provided by the ACS. Then, over the next four months, ACS provides additional follow-up courses via webinar and conference calls for SCRs, as well as online exams to test the skills of the SCR. During this time, ACS monitors data collection more carefully for accuracy. After the training period, ongoing education programs and networking opportunities are available to all SCRs.

Risk-Adjusted Outcomes

Risk-adjusted 30-day morbidity and mortality outcomes are computed for each participating hospital and are reported as observed versus expected (O/E) ratios, a well-validated measure of quality (*Journal of the American College of Surgeons*, 185:341-351, October 1997). The O is the number of observed events (the four adverse outcomes described in Tables 1 and 2) and E is the estimated (risk-adjusted) number of such events based on the logistic prediction models developed for each outcome. Among institutions whose patient populations generally have poor preoperative health, E will be relatively high; among those whose patient populations have better preoperative health, E will be relatively low.

Because the O/E ratio is based on a sample of cases at each site, the estimated O/E ratio might not exactly equal a site's "true" O/E ratio. Therefore, a confidence interval (CI) is calculated for the O/E ratio within which a site's "true" O/E ratio lies. As the number of submitted cases increases, the width of the CI generally decreases. As long as a site abides by the ACS-validated sampling system, a decrease or increase in the number of cases should not affect the point estimate of the O/E ratio.

If the O/E ratio and the upper bound of the O/E confidence interval is < 1.0 , the hospital's outcomes are statistically better than expected – or "exemplary." Conversely, if the O/E ratio and the lower bound of the O/E confidence interval is > 1.0 , the hospital's outcomes are statistically worse than expected and are reported as "needs improvement."





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Reporting

Hospitals enrolled in the FSCI have data presented to them in two kinds of quantitative reports in addition to access to ad hoc reporting:

- **Semiannual Reports** – A comprehensive report is prepared twice a year for administrators and surgical services staff to compare their risk-adjusted surgical outcomes to other participating sites. To supplement the Semiannual Reports, sites are provided with an Individual Site Summary Report and PowerPoint presentation, each with pre-populated site-specific data.
- **Online Reports** – Authorized users can view daily center-specific reports as well as those comparing their metrics to national averages. In this way they can monitor continuous improvement on an ad hoc basis between the more formal report cycles. FSCI member reports will be tailored to fit the four focused measures of the program.

Data Reliability and Auditing

The ACS goes to great lengths to ensure data reliability. SCRs receive consistent, detailed initial training prior to starting data collection. Throughout the program, SCRs participate in continuing education modules, weekly online case studies, regular conference calls, and an annual conference to discuss and review aspects of the program and the data-collection process.

To ensure the data collected are of the highest quality, ACS conducts Inter-Rater Reliability (IRR) Audits of participating sites on a random basis. In addition, hospitals that are flagged by internal diagnostics performed by ACS will also be audited to uncover any data reliability concerns. The audit process involves the review of 20 charts, some of which are selected randomly, while others are selected based on criteria designed to identify potential reporting errors. For example, cases with five or more preoperative risk factors and no reported mortality or morbidity or cases with two or fewer preoperative risk factors and reported mortality or morbidity will be selected for chart review. Operating room logs are also audited to ensure correct sampling of cases.

The ACS NSQIP training, data collection and auditing process has been shown to be highly reliable. A study in the January 2010 *Journal of the American College of Surgeons* found the training and audit procedures ACS uses have been reliable since ACS NSQIP's inception and that reliability has improved each year.





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Conclusion

The Florida Surgical Care Initiative, an adaptation of the well-regarded and highly effective ACS NSQIP, concentrates resources on gathering a minimal set of key clinical data elements to facilitate meaningful analysis and rapid improvement. The outcome measures include surgical site infection, urinary tract infection, surgery in the elderly, and colectomy. Florida's hospitals that participate in the FSCI will be involved in a surgical quality improvement program based on the respected ACS NSQIP, which has been proven to reduce complications and mortality and improve surgical patient outcomes in participating hospitals.

To enroll in FSCI, please contact:

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