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Authors
Eisenstein, Samuel
Stringfield, Sarah
Holubar, Stefan D

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Using the National Surgical Quality Improvement Project (NSQIP) to Perform Clinical Research in Colon and Rectal Surgery

Samuel Eisenstein, MD[1] Sarah Stringfield, MD[1] Stefan D. Holubar, MD, MS, FACS, FASCRS[2]

[1] Section of Colon and Rectal Surgery, Rebecca and John Moores Cancer Center, University of California San Diego Health, La Jolla, California
[2] Department of Colon & Rectal Surgery, Cleveland Clinic, Cleveland, Ohio

Address for correspondence Samuel Eisenstein, MD, Section of Colon and Rectal Surgery, Rebecca and John Moores Cancer Center, University of California, San Diego Health System, La Jolla, CA 92093 (e-mail: seisenstein@mail.ucsd.edu).

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Abstract

The American College of Surgeons' National Surgical Quality Improvement Project (ACS-NSQIP) is probably the most well-known surgical database in North American and worldwide. This clinical database was first proposed by Dr. Clifford Ko, a colorectal surgeon, to the ACS, and NSQIP first started collecting data ca. 2005 with the intent of comparing hospitals (benchmarking) and for hospital-level quality improvement projects. Since then, its popularity has grown from just a few participating hospitals in the United States to more than 708 participating hospitals worldwide, and collaboration allows regional or disease-specific data sharing. Importantly, from a methodological perspective, as the number of hospitals has grown so has the hospital heterogeneity and thus generalizability of the results and conclusions of the individual studies. In this article, we will first briefly present the structure of the database (aka the Participant User File) and other important methodological considerations specific to performing clinical research. We will then briefly review and summarize the approximately 60 published colectomy articles and 30 published articles on proctectomy. We will conclude with future directions relevant to colorectal clinical research.

Keywords

- ► National Quality Improvement Program
- ► American College of Surgeons
- ► outcomes
- ► clinical research
- ► colectomy
- ► proctectomy
- ► biostatistics
- ► data analysis

Early in the 21st century, the American College of Surgeons' (ACS), in a movement championed by a colorectal surgeon Dr. Clifford Ko, MD, National Surgical Quality Improvement Program (NSQIP) was founded. Since then it has grown into an immense program encompassing more than 708 hospitals and approximately 16 specialty modules (►**Table 1**; https://www.facs.org/quality-programs/acs-nsqip). A full review of NSQIP is beyond the scope of this article. The first half of this review will focus on the use of NSQIP at the local level for *clinical research* using either national PUF or local PUF data, the database structure (known as the Participant User File ([PUF]), strengths, and weakness. We will then present a summary of select published scientific literature within our field of colon and rectal surgery.

Institutional Commitment to Quality Improvement: Once an institution understands what a powerful Quality Improvement (QI) and clinical research tool NSQIP is and makes the decision to join NSQIP, there is an annual subscription fee of approximately $80,000, as well as the salary and benefits associated with hiring and sustaining the surgical clinical reviewer(s) (SCRs) who collect the data from the chart retrospectively within 90 days. The size of the institution will dictate the percentage of full-time employee (FTE) SCR work they will require, with small institutions requiring less than 1.0 FTE, and large institutions requiring multiple FTE SCRs. The SCRs work closely with a surgeon champion (SC) and there is usually a cost associated with the SC—either a clinical offset (e.g., 0.2 FTE) or stipend.

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Table 1 Example of the sampling methodology

Multispecialty procedure	Example Sampling Method
Colectomy	All
Proctectomy	All
Ventral hernia repair	Four cases/cycle
Pancreatectomy	All
Hepatectomy	All
Thyroidectomy	Essentials only
Hyst/Myomectomy	Two cases/cycle
Bladder suspension	All
Brain tumor	Essentials only
Prostatectomy	Essentials only
Nephrectomy	All
Cystectomy	All
Flap	One case/cycle
Breast reduction	One case/cycle
Breast reconstruction	One case/cycle

Finally, the institution needs to decide if they will follow the Essentials and Multispecialty sampling.

Categories of Variables: Strengths and Weaknesses

The NSQIP PUF has several strengths, and most importantly it is a defined clinical database with robust data collection of demographics, preoperative risk assessment, preoperative laboratories, surgical case profile, operative information (►**Table 2**), postoperative occurrences, and discharge information including readmission (►**Table 3**). Note these databases listed in the tables are not absolute, as the exact number of variables included in the PUF varies by year, but in general it is greater than 295. The reason for this large number of variables is that some of the data are metadata; for example, lab tests have both the value and the date of collection prior to surgery, and complications include which postoperative day (POD) the complication occurred (e.g., venous thromboembolism [VTE], POD 10). The reason for the variable number of included data points is based on retrospective analysis, for example alcohol use was rarely collected, it may be dropped, and as NSQIP's priorities change, new variables are deemed applicable to a broad range of procedures (such as body surface area) it could be introduced. This fluctuating number of variables does cause some difficulty in the preanalysis phase when trying to combine PUFs from multiple years (theoretical; e.g., 2007 may have 300 variable, 2008 may have 310, and 2009 may have only 295) such that the different PUFs "do not fit together" readily, but this can usually be overcome by a seasoned data analyst.

Preoperative Variables

Preoperative variables include height and weight, such that the body mass index must be calculated locally during the preanalysis phase, laboratories (e.g., albumin), preoperative comorbidities (e.g., cardiopulmonary and renal disease), preoperative medications (i.e., chronic steroids), and treatments according to preoperative condition (e.g., preoperative chemotherapy [within 30 days] and radiotherapy [within 90 days]). The obvious weakness of these variables is that if the preoperative laboratories were not ordered within the specified time frame (i.e., creatinine within 30 days of operation), they will not be available. Likewise, if the preoperative history and physical and medical record do not contain documentation of a specific comorbidity, such as chronic renal insufficiency, it will not be available for analysis and furthermore may lead to an overestimation of the rate of postoperative acute renal failure (ARF; if neither a creatinine nor history of insufficiency is documented preoperatively). Another area of concern might be if a patient received chemotherapy preoperatively at another institution and it was not properly documented locally, these data may be missing. Several studies in our field have been published on preoperative comorbidities, such as cirrhosis and chronic renal failure.

Intraoperative Variables

NSQIP is also particularly robust at collecting procedural data, as defined by Current Procedural Terminology (CPT) codes. Specifically each case is assigned a primary or index CPT code, for example, a laparoscopic total proctocolectomy with ileal pouch-anal anastomosis (IPAA), as well as up to 10 "other" CPT codes (performed by the same surgical team; e.g., extensive adhesiolysis), and 10 "concurrent" CPT codes (not performed by the primary surgical team; e.g., ureteral stents). Note that since NSQIP data are not collected for billing purposes, where multiple CPT codes are all rolled under the primary CPT code, inclusion of the additional other CPT codes is dependent on the individual surgical teams and/or local SCRs to record. Nonetheless, these additional CPT codes are a fertile ground for inquiry, and may provide insights into the complexity and intensity of care.

Other intraoperative variables of interest include American Society of Anesthesiology's (ASA's) classification, number of intraoperative transfusions, operative time, and length of time under anesthesia. These latter variables are typically obtained from both the electronic health record, which may be a highly reliable data source, and the anesthesia records which are subject to the same limitation as the pre- and postoperative variables: if it is not documented it will not be available for analysis.

Postoperative Variables (Outcomes)

The other area that the NSQIP is particularly strong in is 30-day outcomes. These include traditional outcomes, such as postoperative length of hospital stay, readmission, reoperation, and mortality rates and also robust adverse outcomes including wound complications, complications associated with end-organ damage such as renal failure, cardiopulmonary complications, and neurologic complications. Of note

Table 2 ACS-NSQIP essentials module included variables

Demographics	Pre-op risk assessment	Pre-op labs + date	Surgical profile	Operative information
ID number	*General*: height, weight, smoker, dyspnea, functional status	Sodium	Primary CPT code, text, wRVU	Emergency case
Age	*Pulmonary*: severe COPD, ventilator dependent	BUN	Operation date	Wound classification
Female gender	*Hepatobiliary*: ascites within 30 d	Creatinine	Origin status (multiple choices)	Surgical wound closure type
Race	*Cardiac*: CHF within 30 d, HTN requiring meds, MI, prior PCI, angina in past 30 d	Albumin	Elective case?	ASA classification
Ethnicity	*Renal*: acute renal failure, currently on dialysis	Bilirubin	Patient status (inpatient vs. outpatient)	Total operation time, in min
Admission date	*Vascular*: history of PVD, rest pain	SGOT	Surgeon, specialty (many choices)	Other CPT code, wRVU x9
	Immune/Nutrition/Other: disseminated cancer, open wound, steroid for chronic condition, >10% weight loss with in 6 mo, bleeding disorders, no. of transfusions with 72 h pre-op	Alk phos	Resident involvement	Concurrent CPT code, wRVU x10
	Sepsis within 48 h	WBC	Primary anesthesia (10 choices)	
	Chemotherapy in last 30 d	Hematocrit	Other anesthesia (10 choices)	
	Radiotherapy in last 90 d	Platelets	No. of intra-op RBC transfusion	
	Systemic sepsis: none, SIRS, sepsis, septic shock	PT/PTT/INR	Duration of anesthesia, in min	

Abbreviations: ACS-NSQIP, American College of Surgeons' National Surgical Quality Improvement Project; BUN, blood urea nitrogen; CHF, congestive heart failure; CNS, central nervous system; COPD, chronic obstructive pulmonary disease; CPT, Current Procedural Terminology; HTN, hypertension; INR, international normalized ratio; MI, myocardial infarction; OR, operating room; PCI, percutaneous coronary intervention; PT, prothrombin time; PTT, partial thromboplastin time; PVD, peripheral vascular disease; SGOT, Serum glutamic oxaloacetic transaminase; wRVU, work relative value units, RBC, red blood cell; SIRS, systemic inflammatory response syndrome; UTI, urinary tract infection; WBC, white blood cells.

Table 3 ACS-NSQIP post-op occurrences (plus date of occurrence) and discharge information

Post-op occurrences	Discharge information
Wound occurrences: surgical site infections (superficial, deep incisional, organ space), wound disruption	Discharge date, length of stays (admission to discharge, surgery to discharge)
Respiratory outcomes: pneumonia, reintubation, intra-op pulmonary embolism, ventilator >48 h post-op	Discharge destination (multiple choices)
Urinary tract occurrences: UTI, progressive renal insufficiency, acute renal failure	Post-op ICD-9 code (i.e., diagnosis)
CNS: cerebrovascular accident, coma	Still in hospital for >30 d
Cardiac: cardiac arrest, myocardial infarction (either intra-op or post-op)	*Death*: intra-op, <30 d, date of death >30 d
Other occurrences: transfusions 72 h post-op, venous thrombosis requiring therapy, post-op *Clostridium difficile* colitis, sepsis, septic shock	End of life/withdrawal of care
Unplanned return to the OR (1st, 2nd, >2) with associated CPT codes	*Readmissions* within 30 d, choice-associated occurrence or ICD-9 code
	Other: estimated probability of morbidity and mortality

Abbreviations: ACS-NSQIP, American College of Surgeons' National Surgical Quality Improvement Project; CNS, central nervous system; OR, operating room; UTI, urinary tract infection.

some of these conditions, such as wound infection, may be present at the time of admission and thus would not be considered a postoperative adverse event. One weakness of the postoperative adverse outcomes is they are not presently graded by severity, that is, according to the Clavien-Dindo classification, which has essentially become the ad hoc preferred method for reporting postoperative outcomes as the severity of the complication, and its implications, is typically more important than the specific complication itself.

Sampling Methodology

The case mix will differ for the Essentials and Multispecialty sampling, but in general follows an 8-day cycle, such that the first X number of essential cases (which include targeted procedure as well) are reviewed every 8 days, while for targeted cases (specialty) sampling may occur at a variable rate ranging from 0 to 100%. Zero means that target procedure is collected only as part of essentials, while 100% is the most robust sampling, especially for otherwise low- to medium-volume procedures. At this time, one FTE translated to approximately 40 cases per cycle, more than 620 essential cases, and more than 1,000 targeted cases per year. As additional modules come online at the institutional level, the number of cases per cycle an SCR can review will go down given the increased number of variables associated with the targeted modules. ►**Table 4** is a list of the additional variables collected in the targeted colectomy dataset and the Enhanced Recovery in NSQIP (ERIN) targeted dataset.

Table 4 Additional variables in the targeted colectomy and Enhanced Recovery in NSQIP (ERIN)

	Targeted colectomy	ERIN
Pre-op	Indication (free text + ICD-9)	Preadmission counseling
	Steroids	Shortened fluid fast
	Chemotherapy	Use of thoracic epidural
	Mechanical bowel prep	Multimodal pain management
	Oral antibiotics	
Peri-op	Emergent	Goal-directed therapy use and intra-op cc's fluid
	Mode	Use of multimodal antiemetic prophylaxis
		Normal temperature in PACU
Post-op	Anastomotic leak—type	Mobilization once on POD 0
	Anastomotic leak—treatment	Mobilization BID on POD 1 and 2
	Ileus	Clears on POD 0
	Margins	Solid food on POD 1
	T, N, M stage	Foley out on POD 1
	Nodes, no.	IVF discontinued on POD 1

Abbreviations: BID, twice a day; IVF, intravenous fluids; NSQIP, National Surgical Quality Improvement Project; PACU, postanesthesia care unit; POD, postoperative day.

Additional Weaknesses

Additional potential weaknesses of NSQIP are as follows: (1) Only 708 hospitals (as of 2017) out of approximately 5,000 hospitals nationwide participate; thus the results of any individual study may not be generalizable to non-NSQIP participating hospitals. Nonparticipating hospitals may be more likely to be community based and smaller, and not able to afford participation or hire a FTE or even part-time SCR. (2) Variables are "set in stone"; if a particular data point is not documented (e.g., CPT codes) or captured (such as Remicade or actual milligram of steroids), it is not available for subsequent retrospective inclusion in the PUF. Exceptions include additional variables that may contain targeted procedures (such as rectal cancer stage in the proctectomy module), variables that are only collected as part of a disease-specific collaborative (such as infliximab in the nascent IBD Collaborative), ad hoc locally collected variables, and using a local PUF as the framework for subsequent additional internal retrospective review. (3) There are no long-term outcomes; outcomes are limited to 30 days postoperatively. (4) There is limited cancer staging information in the PUF, although this is addressed by the targeted variables such that additional colon cancer and rectal cancer data are available. (5) There are overpowered studies; NSQIP studies of very common conditions and procedures, such as colon cancer and ileocolostomy, are often overpowered such that there is precise statistical significance (e.g., age: 50.2 vs. 51 years old, $p < 0.0001$) *but not clinically significant differences*. Note that to abstract reviewers and journal editors, this is particularly irritating and may result in type 3 statistical error—that conclusions are not supported by results.

How to Get Started with a NSQIP Clinical Research Study

Assuming your institution participates in NSQIP, the following are steps in starting a new NSQIP research project:

1. What is your research question: for example, does preoperative radiation increase complications? Discuss with your research mentor.
2. Rephrase as a testable hypothesis: preoperative radiation is associated with increased 30-day composite wound complications. The infrequent exception to this is *a priori* noncomparative descriptive only in case series, for example, elucidation of outcomes after rare procedures such as Kock pouches.
3. Search PubMed to make sure it is not done already, following the old adage, "*a month in the library will save a year in the laboratory*." Ideally one also searches for

abstracts and oral presentations using tools such as WebCrawler, as these will often be associated with as yet unpublished manuscripts.
4. Review the more than 295 NSQIP variables to ensure relevant variables are included: radiation within the last 90 days (definitions are in NSQIP PUF annual user guides).
5. Define your study population (diagnosis and/or procedures): rectal cancer (ICD9 = 154.1) + proctectomy (CPT 451xx).
6. Request a "chunk" of the PUF, limited to your criteria, from your SCR, SC, or data manager. Note unless one is facile with biostatistical programming, "unlimited" PUF datasets are unwieldy to analyze without either a relational database structure (because each patient encountered can have multiple associated CPT codes) or a dedicated data analyst. However, smaller datasets are much easier to use when getting started.
7. Alternatively individuals at participating institutions can directly request permissions and PUF datasets using the NSQIP Web site. All persons using local or national PUF data are required to submit a Data Use Agreement (DUA) to NSQIP. Also note that in general only the SC, SCR, and/or chief of surgery or section/division chiefs will have access to surgeon-level data. NSQIP was designed to compare hospitals to each other, not surgeons at the local level. This is because the statistics breakdown due to low numbers. For example, if surgeon A performs 100 J-pouches per year, and surgeon B performs only 5, surgeon B may not have enough data to analyze using traditional statistics but perhaps with QI methods (Statistical Process Control).

Preanalysis: PUF Data Cleaning and Preparation: Once the PUF is obtained, assuming it is obtained directly from NSQIP, the data files are accessed using a biostatical software package. These include SAS, STATA, SPSS, R, and others. All of these programs are relatively expensive and require prior statistical knowledge and specific programming skills. An alternative is JMP—a user-friendly graphical "version" of SAS, which requires relatively little prior training, and YouTube and other online resources are available. Note there are plugins for Excel and online statistical tools, but they are generally not robust enough to handle the amount of data from a PUF unless it is very small (< several hundred patients). Also note *Excel is not a database*, but a spreadsheet, meaning that each row and column are independent of each other and it is easy to mix them up while sorting, potentially wasting weeks of work, while in a database each column is dependent on the "indicator" row—in other words each row represents one patient and the rows are locked when sorting. Finally, if your project encompasses more than 1 year, PUFs from each year are generally combined into one master dataset, or a relational database used. Note that for NSQIP PUF files, this step can be very time consuming and prone to error, so typically requires a dedicated data manager or data analyst.

Once one can actually look at the data (in most cases as a flat file, or very large table) to use the right statistical test, one needs to go through ideally each and every included variable to assure it has been imported properly (e.g., numeric fields may be imported as categorical) and recoded as needed, from numeric to categorical (e.g., length of stay [LOS] >12 days). Also some variables will ideally be analyzed by constructing a composite variable (e.g., any wound complication = any superficial, deep, or organ space infections; dehiscence); composite variables maybe more clinically meaningful and generally have more statistical power. The variables should then be double checked by distribution analysis to make sure the data are in the proper format and the output analysis will be what you expect, and columns that are not of interest or missing (e.g., albumin if it were missing in 70% of the cases) should be hidden or deleted (former preferred) to ease analysis. Finally, one must consider which patients may have been inadvertently included and excluded. For example if you are focusing on patients aged 18 to 90 years, and some outlying centurions are included and may skew the data, these should be excluded in the preanalysis phase.

After the PUF data are cleaned in the aforementioned manner, the analysis of baseline differences between the groups is performed, as is the analysis of the primary and secondary outcomes. Further analytic discussion is not unique to NSQIP and is beyond the scope of this article.

Examples of NSQIP Clinical Research

The ACS-NSQIP, in its current form, has been in existence since 2005. The first NSQIP analysis of colon and rectal procedures was published in 2008 using the 2005–2006 dataset. Bilimoria et al compared 30-day outcomes for laparoscopic and open colectomies across the 121 institutions participating in NSQIP at that time.[1] They demonstrated that, after multivariable regression, patients undergoing laparoscopic colectomies had a lower risk of overall complications (OCs), surgical site infections (SSIs), urinary tract infections (UTIs), and pneumonia, and had a shorter LOS.

Since the publication of this article, many peer-reviewed articles have been written and colon and rectal surgeries have been closely evaluated to determine how to obtain high-quality surgical outcomes, with clinical research being the nidus for quality improvement at the surgeon level. The targeted colectomy dataset began in 2011–2012 with 121 institutions and has grown to include 285 hospitals in the 2017 dataset. While the targeted colectomy data are relatively new and have not been published on extensively, it has become clear that the data are crucial to understanding what goes into quality outcomes in colon and rectal surgery. Below is a review of all articles published to date that have used the NSQIP database to analyze outcomes in colon and rectal surgery. Targeted protectomy began in 2016 and now has 8,739 cases from 166 hospitals.

Perioperative Factors and Outcomes

A variety of factors, which are known from smaller studies to contribute the surgical outcomes, have been included in both the NSQIP PUF and the targeted colectomy dataset. These robust data allow for a careful description of a variety of perioperative factors and their relationship on colon and rectal surgery outcomes. Ricciardi et al looked at more than 54,000 patients in the NSQIP PUF undergoing colon and rectal surgery and found that superficial SSI, sepsis, and deep space SSI were the most common adverse events after colon and rectal surgery.[2] They were able to describe, at length, the complications of these types of procedures and how they can prolong postoperative LOS. Mortality increased with the number of postoperative adverse events, and the events most likely to lead to mortality included cardiac arrest, septic shock, stroke, myocardial infarction (MI), and ARF.

There are several articles comparing outcomes from emergent and nonemergent colon and rectal procedures. Ingraham et al looked at the 2005–2007 PUF dataset and demonstrated that nonemergent colon and rectal surgery had a 23.9% complication rate and a 1.9% mortality rate, while emergency surgery carried a 43% complication rate, 15.3% mortality rate, and higher rates of almost every complication.[3] This was one of the first groups to compare the data by institution, and found that good outcomes with elective surgery were not associated with quality outcomes for emergency surgery. From these data, they advocated for more quality improvement initiatives for emergency cases. Ballian et al also looked at laparoscopic versus open colectomy for emergency colorectal surgery with primary anastomoses and found that there were no major differences in morbidity or mortality, but laparoscopic procedures had a longer operative time and shorter LOS.[4] However, this study, as with many NSQIP studies, should be interpreted through the lens of selection bias, which we may never be able to truly remove despite multivariate regression analysis. Propensity score matching, sometimes referred to as pseudorandomization, is a relatively new statistical method that can help further reduce the influence of selection and other biases.[5]

Preoperative bowel preparation is another popular topic that can now be analyzed more clearly because of the targeted colectomy dataset. In their seminal paper, which has since led to significant changes in bowel preparation utilization across the country, Scarborough et al analyzed the effect of type of bowel prep on infectious outcomes.[6] Utilizing the 2012 targeted colectomy dataset, they demonstrated that in 4,999 patients, those who had mechanical bowel prep with antibiotics preoperatively had a significant decrease in postoperative superficial SSI (3.2 vs. 9.0%), anastomotic leak (2.8 vs. 5.7%), and readmission (5.5 vs. 8.0%) when compared with no bowel prep. They also demonstrated that mechanical and antibiotic bowel preps alone did not improve outcomes.[6] Despite this, Haskins et al did demonstrate that having a bowel prep, both mechanical and mechanical with oral antibiotics did not affect the severity of the leak or the need for reoperation in patients who experienced an anastomotic leak after surgery for colon cancer.[7] Finally, in a 2015 NSQIP study, Kiran et al reported on more than 8,000 patients in the targeted colectomy dataset; they found the group that had MBP (mechanical bowel prep) with OA (oral antibiotics) had a nearly 50% reduction in SSI, anastomotic leak, and even ileus (►**Fig. 1**).[8]

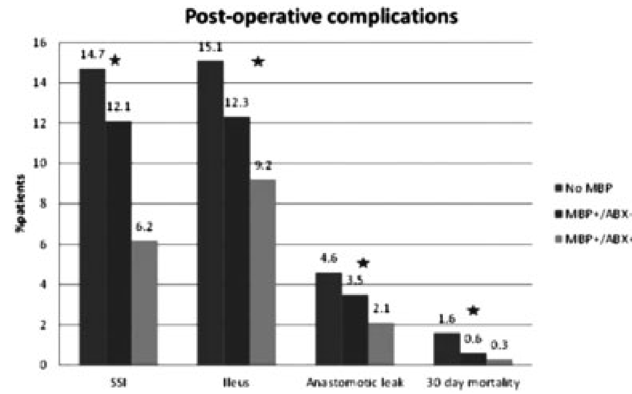

Fig. 1 Postoperative complications according to type of bowel preparation. *Statistical significance, $p < 0.0001$. (Reproduced with permission from Kiran et al,[8] by Wolters Kluwer Health, Inc.)

Another great advantage of employing such a robust database to examine surgical outcomes is the detail to which data can be analyzed. Several studies have examined postoperative gastrointestinal dysfunction, also known as ileus, after colorectal surgery in NSQIP. Using the 2012–2013 PUF, Moghadamyeghaneh et al found that the overall rate of prolonged ileus (7 days) after colorectal surgery was 12.7%, and that ileocolic anastomoses had a higher rate than colorectal anastomoses; they also cited an association between ileus and intra-abdominal sepsis and anastomotic leak, emphasizing the importance of considering secondary causes of ileus.[9] Tevis et al examined the relationship between ileus and further downstream complications using the 2012–2013 PUF.[10] They found that over half (59%) of those who developed an ileus had another complication, while those without ileus (25%) had one or more complications. Older age and multiple comorbidities were identified as risk factors for poor outcome after an ileus.

In their study on postoperative deep venous thrombosis (DVT) and pulmonary embolus (PE) after colon and rectal surgery, *Moghadamyeghaneh* et al showed that the VTE rate was 2%, with a 0.2% PE rate.[11] Furthermore, approximately 30% of VTEs were diagnosed after discharge from the hospital and that the rate seemed to drop off around the 30-day postoperative time period. This demonstrated the need for prolonged VTE prophylaxis, even after discharge from the hospital. Subsequently, Greaves and Holubar used the 2005–2012 PUF to examine the relationship between preoperative LOS and risk of postoperative VTE, and they did find a strong association (dose–response curve, ►**Fig. 2**) between longer times in the hospital before surgery and higher risk of postoperative VTE.[12] NSQIP has also allowed researchers to analyze the effect of anemia on outcomes in colon and rectal surgery. Leichtle et al divided their patients into categories of severe, moderate, mild, and no anemia and found increased rates of poor outcomes including stroke, MI, ARF, increased LOS, and death across all subgroups of anemia (odds ratios [ORs]: 1.83, 2.19, 1.49, respectively) compared with those without anemia.[13] These NSQIP studies can clearly be practice changing, and anemia should be routinely screened for and treated preoperatively.

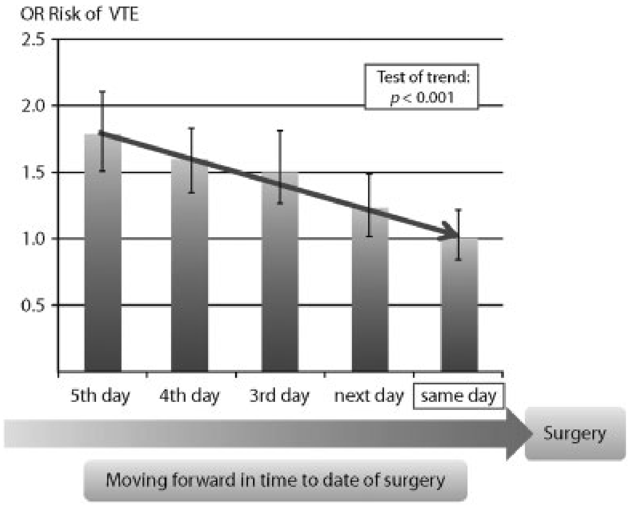

Fig. 2 Presurgical hospitalization length of stay on the risk of VTE using a multivariable logistic regression model. (Reproduced with permission from Greaves and Holubar,[12] by Wolters Kluwer Health, Inc.)

Another study by Sippey et al focused on resident involvement in colon and rectal surgeries for malignancy.[14] Interestingly, their study demonstrated that resident involvement led to increased operative time, readmission rates, and serious, minor, and overall morbidity. However, they also demonstrated that lack of resident involvement led to higher mortality and failure to rescue rates. This decrease in mortality was attributed to resident involvement in the postoperative care of the patient. While their involvement may have directly contributed to an increased complication rate, it may also be possible that either residents were more helpful in identifying and reporting complications, or potentially allowed patients who would have otherwise died with lesser care to survive and accrue more complications. Finally, resident involvement may be a surrogate for level of case complexity, with more complex cases being performed at tertiary referral centers.

Minimally Invasive Surgery

Laparoscopy has become one of the most common perioperative factors analyzed using NSQIP. Kiran et al used 10,979 patients who underwent colon and rectal surgery from the 2006–2007 dataset to show that after multivariable logistic regression, laparoscopic surgery demonstrated significantly lower overall infection, superficial SSI, deep incisional SSI, organ space SSI, and wound dehiscence rates, similar to the study of Bilimoria et al.[1,15] In 2012, Stefanou et al used a novel statistical analysis to confirm that open colectomy when compared with laparoscopic, as well as frailty index, ASA score, male gender, and African American race significantly increased the patient's risk for a prolonged LOS.[16] The same group also looked at Clavien grade 4 and 5 complications and found that, after controlling for preoperative comorbidities and risk factors, laparoscopic surgery was protective for these types of complications (OR = 1.74 for all type 4 and 5 complications, 1.54 for mortality).[17] In 2012, Mustain et al showed that obesity correlated with increased operative time and wound complications during laparoscopic surgery.[18] Isik et al showed that laparoscopic colectomy was associated with a decreased rate of incidental splenectomy (OR: 6.58 for open procedures), which in turn was shown to decrease postoperative ventilator dependence, transfusion, reoperation, and sepsis.[19] Hand-assisted laparoscopy has also been reviewed and demonstrated to have a lower morbidity and mortality than open colectomy, but similar mortality and increased morbidity (adjusted OR: 1.29) when compared with laparoscopic colectomy.[20] This allowed the authors to advocate for hand assistance in laparoscopic cases that would otherwise be converted to open.

More recently, in 2016, Bhama et al compared laparoscopic to robotic procedures. They found that laparoscopy led to shorter operative times, but robotic surgery was associated with a decreased LOS and rates of conversion to open surgery (10.0–13.7%).[21] At that point of time, there were, however, only a handful of robotic colon and rectal cases included—299 compared with 7,790 laparoscopic procedures, creating unbalanced groups. Miller et al looked at a slightly larger group of cases (653 robotic, 11,267 laparoscopic) and again demonstrated an increase in operative time and decrease in LOS with robotic cases.[22] Likely there will be more robust data on robotic colon and rectal surgery in the coming years, as more recent data are released.

Colon and Rectal Cancer

One of the most frequently discussed conditions in NSQIP literature on colon and rectal disease–specific publications is cancer. In fact, 8 of the 23 targeted colectomy variables are specific to colon cancer. Thus, when reviewing the NSQIP literature on colon and rectal cancer, it is important to determine if the authors are including the colectomy-targeted variables which provide a much more robust dataset for colon and rectal cancer, or if they are simply using the standard PUF which does not include details such as margin status, nodes harvested, and anastomotic leak rate.

Targeted colectomy data began only in 2011–2012. The first use of NSQIP to look at rectal cancer outcomes predates this, employing the PUF from 2005 to 2009. Greenblatt et al demonstrated that among the 5,420 patients undergoing proctectomy for rectal cancer, 19.2% underwent laparoscopic procedures.[23] Laparoscopy demonstrated a lower morbidity (OR: 1.41 for open surgery), shorter LOS, less need for transfusion, and longer operating time. However, using the "generic" PUF, it is difficult to tease out some issues specific to rectal cancer, such as margins, lymph nodes, and anastomotic leak rates (which initially could only be inferred from patients having intra-abdominal abscesses or sepsis postoperatively). Another study, in which it became apparent that it would be necessary to collect targeted colon and rectal data, was by Nurkin et al in 2013.[24] They analyzed the effects of fecal diversion in patients who underwent low anterior resection (LAR) and demonstrated that there was a significant risk of sepsis, reoperation, and longer LOS in patients with undiverted coloanal anastomoses. However, in patients undergoing LARs, diversion only lead to a higher rate of ARF. There are significant weaknesses in the selection of patients because the authors were forced to separate patients by CPT codes, which are fraught with inadequacies when it comes to specificity of the procedure performed. The authors selected CPT 45113 (ileal anal pouch with or without ileostomy) to fall on the no-diversion side and the only two subsets listed for diversion were CPT 44146 (LAR with colostomy) and 45119 (colonic J-pouch with enterostomy). Compared with other NSQIP studies, the numbers were small to begin with, only 1,791 patients, and therefore even a few patients miscategorized by coders could have potentially skewed the data.

While these studies demonstrate the weaknesses of the generic PUF, there was still a significant amount to be learned from these patients. Kwaan et al looked at the 2005–2008 data and compared right and left side colectomies for cancer, demonstrating that there was similar utilization of laparoscopy between the groups.[25] They demonstrated a greater risk of superficial SSI in the left colectomy group (8.2 vs. 5.9%), but otherwise the outcomes were similar. These findings are interesting because a later study by Nfonsam et al, providing some validation of the Kwaan study findings, looked at the NSQIP PUF from 2005 to 2010 and asked the same question of patients undergoing only laparoscopic resections.[26] Again, they demonstrated a similar increase in superficial SSI in the left side group, but they also identified an increased rate of ureteral injury, conversion to open, and LOS in the left side group. In another interesting study looking at wound complications after rectal cancer surgery using the generic PUF and propensity score matching (a schematic of propensity score matching is shown in ►**Fig. 3**), Holubar et al found no association between recent preoperative radiotherapy and a composite outcome of any wound complications.[5] This study underscores that there are still many questions that can be answered using the nontargeted PUF, and studying the same topic using the targeted dataset would provide validation of their findings.

Another interesting finding from another publication was that being underweight was the greatest predictor of readmission in patients older than 85 years undergoing surgery for colon and rectal cancer.[27] This same study also demonstrated that in patients between 65 and 84 years old, recent chemotherapy was the greatest predictor of readmission. Another interesting study from the targeted colectomy dataset comes from Causey et al, who looked at Model for End-stage Liver Disease (MELD) scores, regardless of whether the patients had liver disease, and outcomes from colon and rectal cancer surgeries.[28] International normalized ratio, creatinine, and sodium levels are all standardly recorded in the NSQIP database and they supply a risk calculator that could potentially be applicable across all patients. They demonstrated that complications increased with MELD score proportionately (OR increase of 1.05 with every 1 point MELD increase). They also demonstrated that MELD was associated with an increase in mortality, but not in the same linear manner.

The targeted colectomy dataset has added significantly to the robustness of the literature on colon and rectal cancer. Papageorge et al looked at this dataset from 2012 to 2013 and compared outcomes of minimally invasive and open surgery for colon cancer.[29] They demonstrated significantly fewer postoperative complications for patients undergoing minimally invasive procedures, including anastomotic leak (3.0 vs. 5.0%), and they were able to control for colon cancer–specific variables including the patient's T stage. Haskins et al

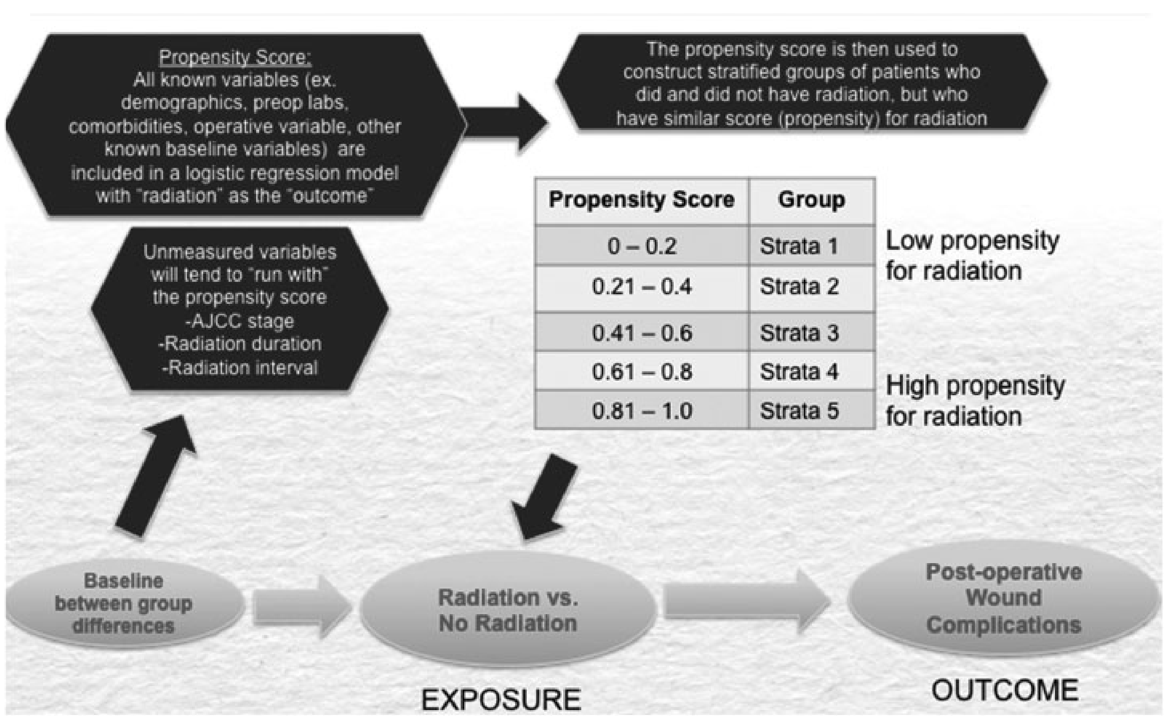

Fig. 3 Schematic representation of propensity score stratification used in this study.

used targeted colectomy data to analyze the effect of preoperative hypoalbuminemia on colon cancer surgery outcomes. They demonstrated a significant inverse association with an increase in a variety of adverse postoperative events in patients with albumin levels less than 3.5 g/dL as well as increased mortality.[30] These effects were much more pronounced in patients undergoing open surgery and those having an anastomosis, and complication rates increased the most below a cutoff of 3.1 g/dL.

Inflammatory Bowel Disease

Inflammatory bowel diseases (IBDs) including Crohn's disease (CD), chronic ulcerative colitis (CUC), and indeterminate colitis, has also been studied extensively. NSQIP has provided a platform to look at large numbers of patients where formerly there were only retrospective single institution studies. By analyzing IBD outcomes, we have seen many of the strengths of NSQIP as well as many of the weaknesses.

The first major IBD-related NSQIP publication examined the rates of VTE after surgery for IBD.[31] They found that in more than 10,000 cases in the 2004–2010 PUF, there was a 2.3% incidence of VTE with a mean of 10.8 days postoperatively (usually after discharge), and risk factors related to developing a VTE were bleeding disorder, steroid use, anesthesia time, emergency surgery, hematocrit less than 37%, malnutrition, and functional status; some of these (bleeding, anemia) are likely related to chemoprophylaxis being held. Additionally, patients undergoing surgery for CUC had a higher incidence of VTE than CD. VTE was again analyzed by Wilson et al across 96,000 colon and rectal surgeries for various disease processes and they validated the aforementioned findings and that the CUC group had a higher incidence of VTE than CD, but used colon cancer as a comparison group and the CUC group still had the higher rate of VTE.[32]

Surgical site infection after IBD surgery is an important topic that has been investigated. Wideroff et al analyzed the 2006–2011 PUF for outcomes after segmental colectomy for CD, diverticular disease, and cancer (CUC was excluded as these patients underwent nonsegmental/total colectomies).[33] They showed that while diverticulitis and cancer patients had a very similar risk of postoperative SSI, CD imparted an increased risk of any SSI, deep organ space SSI, deep incisional SSI, and UTI, although not superficial SSI. Nguyen et al demonstrated the significant increase in infectious complications for patients on steroids undergoing surgery for IBD.[34] They looked at the 2005–2012 PUF and found that patients with IBD on steroids had significantly higher rates of all complications, intra-abdominal infections, sepsis, and VTE; however, there was no increased risk for mortality. Geltzeiler et al looked at complication rates after stricturoplasties in CD in the 2005–2012 PUF, and found that while complication rates remained the same, the incidence of this procedure decreased from 5.1% of all CD operations to 1.7% over this time. They attributed this decrease either to sampling error—as more nonspecialized centers entered NSQIP over time, the procedure actually being performed less frequently—or to improved medical therapy for CD.[35]

Racial disparities in surgical outcomes can often be identified through large database studies. In one study which used the targeted colectomy dataset from 2012 to 2013, black race was associated with a 60% higher postoperative readmission rate than white race after IBD surgery when controlling for other factors, demonstrating the effects of race and possibly socioeconomic status on outcomes in IBD surgery.[36] Arsoniadis et al further showed that African Americans had a higher complication rate after surgery for CD and that this disparity only disappeared when controlling for comorbidities and ASA score, underscoring some of the health issues associated with racial disparities.[37]

The inadequacies of NSQIP, in its current state, are laid most bare when analyzing the outcomes after ileal pouch–anal anastomosis (IPAA) surgery for CUC. The many nuances of this surgery—whether the surgery was done in 1, 2, or 3 stages, whether they had mucosectomy or double-stapled anastomosis, and whether they were on anti-tumor necrosis factor (TNF) medications preoperatively—are either unavailable or difficult to tease out from the generic PUF. Ileostomy status is also difficult to determine as the CPT code for IPAA includes the phrase "with or without ileostomy." Still, there have been some attempts to explore IPAA outcomes using the generic PUF. Wertzberger et al looked at the 2006–2011 PUF for short-term outcomes of IPAA patients who had undergone pelvic radiation. They demonstrated that there did not appear to be an increase in short-term complications for these patients.[38] From this, they concluded that long-term functional problems associated with ileal pouches in irradiated pelvises were not related to 30-day complications.

Diverticular Disease

As with several other disease processes, early diverticulitis NSQIP studies looked at differences across mode of surgery. Kakarla et al used the PUF from 2005 to 2008 and demonstrated that, after adjusting for a variety of risk factors, laparoscopic colectomy for diverticular disease was associated with a lower risk of morbidity, wound complication, and shorter LOS than open procedures for the same diagnoses.[39] They also demonstrated that for all surgeries for diverticular disease, peripheral vascular disease, history of percutaneous coronary intervention, hypertension requiring medication, and steroids imparted an increase in both morbidity and mortality while chronic obstructive pulmonary disease and smoking led to increased wound complications. Another study by Wise et al looked at outcomes from patients undergoing proximal diversion after elective surgery for diverticular disease across the 2005–2011 PUF.[40] They demonstrated that these patients were older and sicker and had increased rates of SSI, DVT, ARF, sepsis, and readmission, and had prolonged LOS. Interestingly, understanding the potential selection bias, they did not advocate against stoma creation in this setting, but rather urged a high index of suspicion for postoperative complications, as these patients tend to be high risk. A recent study by Papageorge et al looked at overall trends in diverticular surgery from 2005 to 2013 and found that the rate of laparoscopic procedures increased from 48 to 70% and that stoma creation rates remained flat.[41] During the study period, the risk of any postoperative complication decreased by 5.8% despite the fact that patients were becoming more complex. While they do attribute a small improvement in outcomes to the increased use of laparoscopy, they conclude that there are likely numerous factors that have contributed to improved outcomes, including the changing paradigm for treatment of diverticular disease as well as systemic healthcare improvements.

An interesting subset of patients with diverticulitis is the immunosuppressed patients. Al-Khamis et al used the 2005–2012 PUF to look at these patients and compare them to their immune competent peers across emergency and elective procedures.[42] They showed that for elective cases, immunosuppression increased the risk of major morbidity (OR: 1.46) and wound dehiscence (OR: 2.69) but not mortality; however, in the emergent setting, immunosuppression did increase mortality (OR: 1.79) but not morbidity. These data could be interpreted to demonstrate that immunosuppressed patients should undergo elective diverticular procedures before they have the opportunity present in an emergency setting.

Another controversial issue in the setting of perforated diverticulitis is the use of Hartmann's procedure anastomosis with diverting loop ileostomy (DLI). Using the NSQIP PUF from 2005 to 2009, Gawlick and Nirula demonstrated that there were no significant differences in outcomes if the wound class was less than 4; however, for dirty/infected cases, there was a twofold increase in mortality for DLI.[43] This again demonstrates some of the weaknesses of the NSQIP database, as the data rely heavily on surgeon classification at the time of the procedure, which can be somewhat subjective between the two extremes of complete fecal peritonitis and minimal soiling.

Arkenbosch et al compared laparoscopic and open Hartmann reversals using the 2005–2012 PUF.[44] They demonstrated that while only 18% of these procedures were done laparoscopically, patients undergoing laparoscopic surgery had shorter LOS by 1 day, lower morbidity rates (18.4 vs. 27%), and lower rates of incisional SSI, organ space SSI, UTI, sepsis, and reoperation.

Other Colon and Rectal Procedures

Rectal prolapse surgery has also been evaluated using NSQIP. Clark et al used the 2006–2009 PUF to evaluate 816 rectal prolapse surgeries.[45] They showed the likelihood of a patient undergoing a perineal approach increased with age and ASA score; however, after logistic regression, the only independent predictor for postoperative complication was open abdominal surgery (OR: 6.29), and advocated for more laparoscopic abdominal procedures in elderly patients. That same year, Fang et al looked at the PUF from 2008 to 2009 to evaluate the differences in mortality between abdominal and perineal repairs for rectal prolapse.[46] They found that mortality was exceedingly rare after rectal prolapse surgery (7 cases out of 1,621); however, only 1 of these deaths was for an abdominal procedure and the remaining 6 were after perineal repairs. They further substratified by ASA score and found that this trend held up with significance. From this, they advocated for greater utilization of laparoscopic abdominal approaches—although one can argue that since mortality was such a rare event in this series, it is ultimately inconclusive. These two studies both demonstrate some of the difficulties encountered when carefully constructing a large database analysis, because almost any finding can be significant and it can be extremely difficult to weed out selection bias for a surgery when using a label as broadly applied as ASA score or age. It is easy to see how these rare events can easily be influenced by selection bias and potentially lead readers to false conclusions.

Endometriosis has also been studied using NSQIP. Thiels et al wrote a descriptive analysis of the 268 patients who underwent elective colorectal resections for endometriosis using the PUF from 2005 to 2014.[47] They found that the patients tended to be healthy and had a relatively low major complication rate (9.0%). When comparing the laparoscopic and open cases in this set, the only differences were LOS (1 day shorter for laparoscopic) and operating time.

To date, there have also been several studies that have examined the increased risk brought about by doing a colectomy at the time of another major surgical procedure.[48–52] The general consensus is that there is a significant increase in morbidity and mortality by adding significant other procedures to a colon and rectal resection. For example, when comparing patients who underwent *en bloc* pancreatectomy and colectomy to propensity-matched controls, Paquette et al found that there was a 10-fold increase in pulmonary complications, blood transfusions, and wound dehiscence, and approximately threefold increase in SSI.[52] These effects were also analyzed by Kwaan et al in patients undergoing pelvic exenteration.[49] Interestingly, they demonstrated that while adding organ resections increased the risk of SSI, when the cases were controlled for overall operative time there ultimately was no difference in SSI, implying that the risk of SSI increases as a function of the length of surgery. Shubert et al looked at simultaneous hepatectomy and colectomy and compared the observed results of synchronous procedures with the expected results of asynchronous.[48] As expected, there is significant increase in morbidity for simultaneous colectomy and major hepatectomy. They did, however, show that minor hepatectomy (partial hepatectomy) did not add any morbidity and potentially was less morbid than doing the two procedures separately when they factored in the adjusted risk additively of two separate procedures.

Finally, the recently introduced ERIN module has been constructed. The pilot studies, although complete, have not been published as of yet, but the module including variables (►**Table 2**) as well as definitions is available for use at all NSQIP participating institutions.

Validation

One of the keys to maintaining a large dataset is validation. It is vitally important that the data collected be representative of the population as a whole and be accurate so as to be applicable across all practices. It is also necessary that flaws inherent to the system, whether data collection or the various biases, which may be difficult to tease out of the system, are brought to light and addressed so that they do not snowball into greater and greater inaccuracies. There are many ways that this validity has been tested.

Several studies have employed the NSQIP database to help create predictive models from the data and validate these models using known outcomes—such as other databases or previous years' NSQIP data. Kwok et al used the 2007–2008 PUF to create a mortality risk prediction model for emergency colon surgery in the elderly.[53] They demonstrated that the score generated from the NSQIP data was more accurate at predicting outcomes from the 2005–2006 dataset than the ACS Colorectal Surgery Risk Calculator, as well as more accurate than ASA score or Surgical Risk Scale alone. When Neale et al used a similar method to look at outcomes for laparoscopic and open colectomies in all patients, they found that patient comorbidities affected the outcomes significantly more than intraoperative factors, and that the data were not particularly accurate for open colectomy and very inaccurate for laparoscopic colectomies.[54] They felt that the dataset as a whole was less useful for colon and rectal surgery, as it did not include the intraoperative factors that were already known to impact outcomes in colon and rectal surgery. Interestingly, these two studies demonstrated a similar accuracy in NSQIP at predicting outcomes and demonstrated that it can be up to the author and the reader to determine how accurate a database actually is. This deficiency has since been addressed through the addition of targeted variables for colectomy and proctectomy.

It is also possible to compare NSQIP to already validated models for specific outcomes. Ju et al compared postoperative colon surgery SSI in NSQIP to the National Healthcare Safety Network (NHSN), a center for disease control program that evaluates postoperative infection.[55] They showed that NSQIP was much more sensitive at identifying postoperative SSI (13.5 vs. 5.7%) and that NSQIP was more likely to pick up postoperative infections which were being managed on an outpatient basis.

Applying the data to already existing outcomes within a single institution is another accepted way to validate predictive models based on a dataset. Bergquist et al compared predictive models for SSI after colon and rectal surgery based on the NSQIP dataset to their own outcomes between 2006 and 2014.[56] They also compared three other validated models. They found there was actually fairly poor correlation between the predicted and actual outcomes. It should be noted that these data were acquired from the general PUF and do not include the colon- and rectal-targeted data.

Conclusions

Over the last decade, much had been learned about colon and rectal surgery through the data analyzed via NSQIP. Important studies have altered everything from preoperative bowel preparation to postoperative anticoagulation. Despite this, there is still much to be learned. The addition of the targeted colectomy and proctectomy data has only expanded our understanding of the variables which impact outcomes in these procedures, and NSQIP will likely to continue to grow its dataset, as there is increasing demand for more granular information.

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