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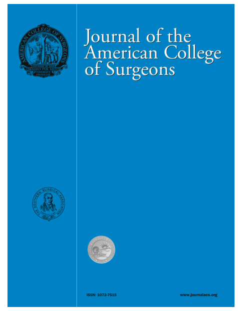

Development and Evaluation of the American College of Surgeons NSQIP Pediatric Surgical Risk Calculator

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Development and Evaluation of the American College of Surgeons NSQIP Pediatric Surgical Risk Calculator

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Running Title: NSQIP Pediatric Risk Calculator

ABSTRACT

Background: There is an increased desire of patients and families to be involved in the surgical decision making process. A surgeon's ability to provide patients and families with patient-specific estimates of postoperative complications is critical for shared decision making and informed consent. Surgeons can also use patient-specific risk estimates to decide whether or not to operate and what options to give to patients. Our objective was to develop and evaluate a publicly available risk estimation tool that would cover many common pediatric surgical procedures across all specialties.

Study Design: ACS NSQIP Pediatric standardized data from 67 hospitals were used to develop a risk estimation tool. Surgeons enter 18 preoperative variables (demographics, comorbidities, procedure) that are used in a logistic regression model to predict nine postoperative outcomes. A surgeon adjustment score is also incorporated to adjust for any additional risk not accounted for in the 18 risk factors.

Results: A pediatric surgical risk calculator was developed based on 181,353 cases covering 382 CPT codes across all specialties. It had excellent discrimination for mortality (c-statistic=0.98), morbidity (c-statistic=0.81), and 7 additional complications (c-statistics>0.77). The HL statistic and graphical representations also showed excellent calibration.

Conclusions: The ACS NSQIP Pediatric Surgical Risk Calculator was developed using standardized and audited, multi-institutional data from the ACS NSQIP Pediatric and provides empirically derived, patient-specific postoperative risks. It can be used as a tool in the shared decision making process by providing clinicians, families, and patients with useful information for many of the most common operations performed on pediatric patients in the U.S.

Key words: ACS NSQIP; Pediatric; Surgical Risk Calculator; Calibration

INTRODUCTION

Informed consent in pediatric surgery involves a shared decision making process between the surgeons and the family of the child.[1-4] Shared decision making has the potential to increase satisfaction with care, reduce decisional conflict and regret, improve understanding of and participation in care, and thereby improve health related quality of life.[5] Families report having less decisional conflict when they are involved in the decision making process.[6] For these reasons, and others, it is important that the surgeon be able to accurately estimate and describe the risks of the proposed surgery to the family. Risk assessment tools are one way to communicate these patient-specific risks to the patient and family in order to help them make decisions.[7-11] Risk assessment tools can also guide the surgeon's decision in whether or not operate, or what surgical options to present to the patient and family.

Until recently, there has not been sufficient pediatric data to support a risk calculator that could cover a broad selection of Current Procedural Terminology (CPT) codes© and outcomes for children's surgery. However, several risk calculators have been built for specific procedures and outcomes.[7,12-13] The American College of Surgeons' National Surgical Quality Improvement Program Pediatric (ACS NSQIP Pediatric) collects high quality, standardized clinical data including preoperative risk factors and postoperative outcomes from more than 70 pediatric hospitals.[14-15] These data have been used to provide participating sites with risk adjusted 30-day outcome comparative reports that can aid in quality improvement efforts. The program has now collected three years of data that can be used to construct a risk calculator that covers the majority of ACS NSQIP Pediatric eligible CPT codes.

The pediatric surgical risk calculator described in this paper will satisfy a growing need for, and interest in, being able to estimate patient specific risk for a wide range of procedures and outcomes within the pediatric patient population.[16] Surgeons will be able to use it as a tool in the office or inpatient settings to inform patients and families of the estimated risks associated with both elective and emergent/urgent procedures. Our objective was to develop and evaluate a publicly available risk estimation tool that would cover many common pediatric surgical procedures across all specialties.

METHODS

Data Source and Patients

Data were obtained from the ACS NSQIP Pediatric. The ACS NSQIP Pediatric collects patient-level clinical data including demographics, comorbidities, laboratory values, and outcomes, and identifies cases by CPT. These data are reliable, as they are rigorously defined, and collected and recorded by trained Surgical Clinical Reviewers (SCRs) who undergo training and examination in variable definitions. In addition, the program performs random audits to check for data validity and definition compliance. Cases are systematically sampled across all specialties (general, neurosurgery, urology, otolaryngology, plastic, and orthopedic) at each participating hospital following an 8-day cycle.[14] All cases are followed for 30 days using the medical record or patient outreach to verify the presence or absence of adverse events at the 30-day postoperative time point. In order to reliably estimate procedure risk, the dataset was restricted to only those cases whose CPT code is currently being collected by ACS NSQIP Pediatric and occurred at least 25 times in the dataset.

Predictors and Outcomes

The factors that were considered for calculating patient-specific risk of surgical outcomes were demographic and preoperative clinical variables. The final variables were chosen based on their predictive value, clinical face validity, and regular availability to the surgeon prior to the operation (Table 1). Predictive value was determined by examining past ACS NSQIP Pediatric Semi-Annual Reports (SARs). Predictors that had entered at least 20 models with a median step of fifth or earlier in the selection process were considered. In addition to these patient-specific risk factors, a procedure-specific risk variable based on CPT code was also included. This procedure-specific risk was created by taking a linear transformation of the predicted probabilities from preliminary hierarchical models where CPT was used as a random effect to predict each outcome.[15]

The outcomes that were modeled were: mortality, composite morbidity (any defined morbidity), surgical site infection (SSI), venous thromboembolism (VTE), reintubation, cardiac event, pneumonia, renal insufficiency/failure, and urinary tract infection (UTI), all defined as binary variables indicating the absence or presence of the event within 30 days of the operation. The composite morbidity outcome was defined as having one or more of the following intra-operative or post-operative adverse events: pneumonia, reintubation, pulmonary embolism, renal insufficiency, renal failure, urinary tract infection, central line associated blood stream infection, coma >24 hours, seizure, peripheral nerve injury, any cerebral intra-ventricular hemorrhage, CVA/Stroke or intracranial hemorrhage, cardiac arrest requiring CPR, venous thrombosis requiring therapy, graft/prosthesis/flap failure, sepsis, surgical site infection (superficial, deep, or organ/space), blood transfusion ≥ 25ml/kg, deep wound disruption, or superficial wound disruption. Some of these morbidity events and their corresponding outcomes were adjusted for, or negated by, pre-existing conditions: pneumonia with preoperative pneumonia, reintubation with ventilator dependence, renal insufficiency or renal failure with preoperative renal failure or dialysis. The SSI outcome includes superficial, deep, and organ space SSIs.

Statistical Analysis

Hierarchical, random effects modeling, which accounts for clustering of cases within hospitals and imposes an empirical Bayes type shrinkage estimate to adjust for small sample sizes, was used throughout (SAS PROC GLIMMIX).[15] Each model included the demographic and preoperative clinical variables listed in Table 1, as well as the CPT linear risk variable and a random effect for hospital. Although hospital was used in the modeling, only the fixed effects estimates, patient level factors, were used for risk prediction.

Model Performance

Two metrics were used to evaluate model performance: the c-statistic and the Hosmer-Lemeshow (HL) statistic. First, the models' discriminative ability was measured using the c-statistic, also referred to as the area under the receiver operating characteristic (AUROC) curve (the plot of sensitivity vs. 1-specificity). The c-statistic indicates how well the model does in predicting membership in one of two groups (the binary response). It takes values from 0.5 to 1.0, with 0.5 indicating the model is no better than chance and 1.0 indicating perfect prediction. In general, models with a c-statistic greater than 0.7 are considered reasonable and models are considered strong when it exceeds 0.8. Although the c-statistic is useful in evaluating model performance, it may not be the best metric, as it does not directly evaluate the accuracy of the prediction and it suffers when a population is homogenous.

Second, the Hosmer-Lemeshow (HL) statistic was used as a measure of calibration. It attempts to detect bias in predicting risk over the range of risk. The data are ordered by predicted risk and then divided into ten risk groups of equal size. If there is a tendency for the model to over or under estimate risk based on the risk group, the HL statistic will be statistically significant. Unfortunately, the HL statistic varies depending on the (arbitrary) number of groups the data is divided into and finds smaller deviations to be statistically significant when the sample size becomes large due to its inherent reliance on the chi-square distribution.[17] To avoid these issues, graphical representations of fit are provided, in addition to the statistic, in which the mean predicted probability is plotted versus the mean observed probability for each of the ten risk groups.

Surgeon risk adjustment

The Pediatric Surgical Risk Calculator does not capture all possible comorbidities and there is uncertainty surrounding any estimate. To address this issue, Bilimoria et al[8] incorporated a Surgeon Adjustment Score (SAS) for the Universal ACS NSQIP Surgical Risk Calculator. The SAS provides clinicians with the opportunity to increase a patient's risk of surgery within a reasonable range for each specific CPT code. The default estimated risk from the model is assigned a SAS of 1. The surgeon can increase this to a SAS of 2 (median + 1 standard deviation of predicted risk) or SAS of 3 (median + 2 standard deviations). If an individual patient's estimated risk is greater than the SAS, then the estimated risk from the model remains unmodified, as the patient's predicted risk is already higher than the SAS modification. This adjustment is to be used only if the surgeon feels the patient has significant risk factors for surgery that are not already captured by the predictors that have been entered.

RESULTS

From January 1, 2012 through December 31, 2014, there were 183,233 patients entered into the database that underwent procedures at 67 participating ACS NSQIP Pediatric hospitals. All patients were under 18 years of age. Only CPT codes with at least 25 cases were utilized, resulting in 382 CPT codes, or 63% of the CPT codes in the full dataset, being used in modeling and available in the risk calculator. The final dataset consisted of 181,353 cases spanning these 382 CPT codes for the three-year period, representing these sub-specialties: general surgery, cardiothoracic, neurosurgery, orthopedics, otolaryngology, gynecology, urology, and plastic surgery.

The pediatric risk calculator reports on nine 30-day post-operative outcomes using a fixed set of 18 predictors (Table 1). Event rates ranged from 0.08% for renal failure to 5.91% for composite morbidity (Table 2). The c-statistics ranged from 0.77 for SSI to 0.98 for mortality, with eight of the nine models having c-statistics greater than 0.8 (Table 2). HL statistics were variable – several reached significance due to sensitivity to sample size (Table 2). However, fit was excellent when portrayed graphically with mean predicted probability plotted versus mean observed probability. Figure 1 displays fit for data grouped by CPT codes for three outcomes (mortality, morbidity, SSI). The diagonal line indicates perfect prediction (mean predicted rate = mean observed rate). Lines denoting ±25% are also shown. Points lie close to the diagonal line with very few outside the ±25% error lines suggesting that the model provides predictions that are consistent with the observed values. Figure 2 displays fit for all 9 outcomes across the observed risk spectrum. For most outcomes, there is a small tendency to under predict risk in the highest risk groups.

While all the data were used to create the calculator's prediction equations, we also split the data into two mutually exclusive datasets for model validation. A simple random sample of two-thirds of the three years of data was used as the training dataset with the remaining one-third being the test set. A random allocation was considered superior to splitting the data by year, since there could be time trends in the data and minor changes in variable definitions over time. The average c-statistic in the training and test datasets were 0.912 and 0.869, respectively, though one model (reintubation) showed a more dramatic reduction of 0.949 to 0.652 . These results confirm expectations for stable discrimination across training/test datasets typical of large sample sizes.

DISCUSSION

The desire of patients and families to be more involved in the surgical decision making process has led to a need for surgeons to be able to provide more information and information that is tailored to an individual patient's circumstances. There is currently no tool available to help surgeons estimate the surgical risk for a pediatric patient across multiple specialties. The ACS NSQIP Pediatric now has sufficient standardized, high-quality data to develop a risk calculator with excellent calibration and discrimination. This tool will assist clinicians, patients, and families in estimating the risks of surgery on an individual basis and making informed decisions. The pediatric risk calculator was made publicly available as a web application at http://riskcalculator.facs.org/peds in July of 2016 (Figure 3).

Other pediatric risk calculators have been developed, but they have several limitations. First, they are often for a single surgical procedure, complication, or specialty.[7,12-13] Second, they use only one to two years of data, or data from a single institution, which can limit accuracy and generlizability.[12-13] Third, they have not typically been made publicly available in a user-friendly format. In order to aid in the decision-making process, clinicians and families need the risk estimation available during their surgical consultations.

There are also several limitations to this study and the pediatric risk estimation effort. First, the data utilized come from only 67 ACS NSQIP Pediatric hospitals. This could lead to bias, as participation in the program is voluntary and although ACS NSQIP Pediatric currently has a mix of both large research hospitals and smaller hospitals, the hospitals that choose to participate may share certain other characteristics, including a focus on quality and safety, increased resources, and different case mix. This bias may become less of an issue as the program continues to grow, and the pediatric risk calculator is updated. Second, only the preoperative variables collected by ACS NSQIP Pediatric were available to estimate postoperative risk. Although it may seem that additional variables are clinically important, it has been shown that the majority of risk adjustment can be done with a limited set of variables.[18] This work focused on variables that would be known to surgeons and families prior to intervention to truly assist in decision making, and also focused on controlling the data entry burden to optimize usability. Third, some of the variable definitions have been evolving since the beginning of the ACS NSQIP Pediatric. However, we recognized this and since most of the major changes were made in the first program year, the first year of program data (2011) was not included in the development of the pediatric risk calculator. The majority of the definition changes that have been made since then have been clarifications and exclusions. These types of changes would not cause significantly more variation in the data than the variation that we would expect to see between data abstractors. Fourth, as with any statistical model, the results of the pediatric risk calculator are estimates and have some amount of error. The calculator should be used by clinicians in combination with their clinical expertise to aid all parties involved in the process of making informed decisions.

The calculator, as has been described, is being released to the general public, but will be subject to continual modifications based on feedback from users. In addition, we anticipate that later versions of the calculator will include more granular composite measures (e.g. infection rather than overall morbidity), which should offer advantages for clinical risk evaluation and decision-making, and therefore be more informative and useful for providers and families.

CONCLUSIONS

There is an increased desire for patients and families to be more involved in the surgical decision making process. Surgeons need a quick and easy way to provide individualized information on surgical risk during consultations in the office and hospital settings. The ACS NSQIP Pediatric Surgical Risk Calculator will equip surgeons with an easy-to-use tool for providing patients and parents with empirically-derived, patient-specific estimates of post-operative complication risks. This additional information will enhance shared decision making, which should lead to better patient outcomes and patient care.

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Table 1. American College of Surgeons NSQIP Pediatric Variables Utilized in the Pediatric Surgical Risk Calculators

Variable	**Categories**
Age group	0-28 d, 29 d-<1 y, 1-<2 y, 3-5 y, 6-7 y, 8-12 y, 13-<18 y
Sex	Male, female
Transfer status	Admitted home, admitted ER, chronic care, transferred ICU, other
Case type	Elective, emergent, urgent
American Society of Anesthesiologists class	1, 2, 3, 4, or 5
Wound class	Clean, clean/contaminated, contaminated, dirty/infected
Inpatient/outpatient	Inpatient, outpatient
Systemic sepsis within 48 h prior to operation	None, systemic inflammatory response syndrome, sepsis, septic shock
Ventilator dependent	Yes, no
Neuromuscular disorder	Yes, no
Hematological disorder	Yes, no
Oxygen support	Yes, no
Cardiac risk factor	Yes, no
Structural CNS abnormality	Yes, no
Nutritional support	Yes, no
Developmental delay	Yes, no
Neonate	Yes, no
CPT-specific linear risk	382 values

Table 2. Complication Rates and Model Statistics for the Pediatric Surgical Risk Calculator Models (N=181,353)

Outcomes	**No. events and rate (%)**	**C-statistic**	**HL (p value)**
Mortality	62 (0.34)	0.9780	0.4821
Morbidity	10,834 (5.91)	0.8063	0.0000
Pneumonia	652 (0.36)	0.8984	0.0000
Cardiac	264 (0.14)	0.9606	0.4860
Surgical site infection	3,598 (1.96)	0.7714	0.0004
Urinary tract infection	955 (0.52)	0.8818	0.0001
Venous thromboembolism	205 (0.11)	0.9424	0.1844
Renal Failure	138 (0.08)	0.9502	0.7243
Reintubation	827 (0.45)	0.9386	0.0121

Higher C-statistics are more predictive; non-significant Hosmer-Lemeshow (HL) P-values (>0.05) are more predictive.

FIGURE LEGENDS

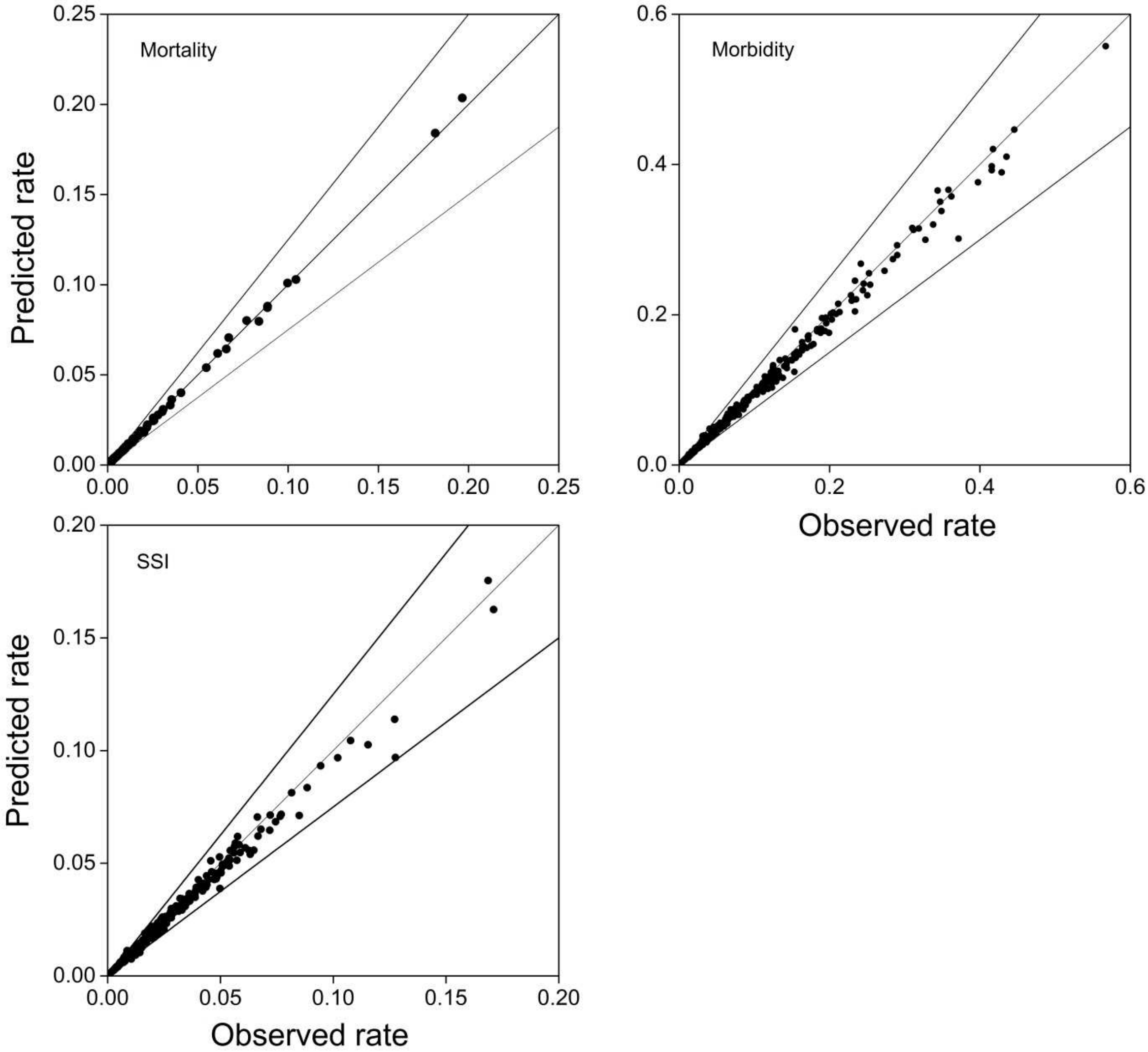
Figure 1. Plots of mean observed rates vs mean predicted rates for Current Procedure Terminology (CPT) codes. The diagonal line represents perfect prediction (mean observed = mean predicted). SSI, surgical site infection.

Figure 2. Mean observed vs mean predicted probabilities for 10 risk deciles. SSI, surgical site infection; UTI, urinary tract infection; VTE, venous thromboembolism.

Figure 3. Screenshots of the American College of Surgeons NSQIP pediatric surgical risk calculator (http://riskcalculator.facs.org/peds). (A) Risk factor entry screen; (B) report screen.

Precis

The pediatric risk calculator can be used as a tool in the shared decision-making process by providing clinicians, families, and patients with useful information about common surgeries.


Mortality
Predicted rate
0.25
0.20
0.15
0.10
0.05
0.00
0.00
0.05
0.10
0.15
0.20
0.25
Morbidity
0.6
0.4
0.2
0.0
0.0
0.2
0.4
0.6
Observed rate
SSI
Predicted rate
0.20
0.15
0.10
0.05
0.00
0.00
0.05
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0.15
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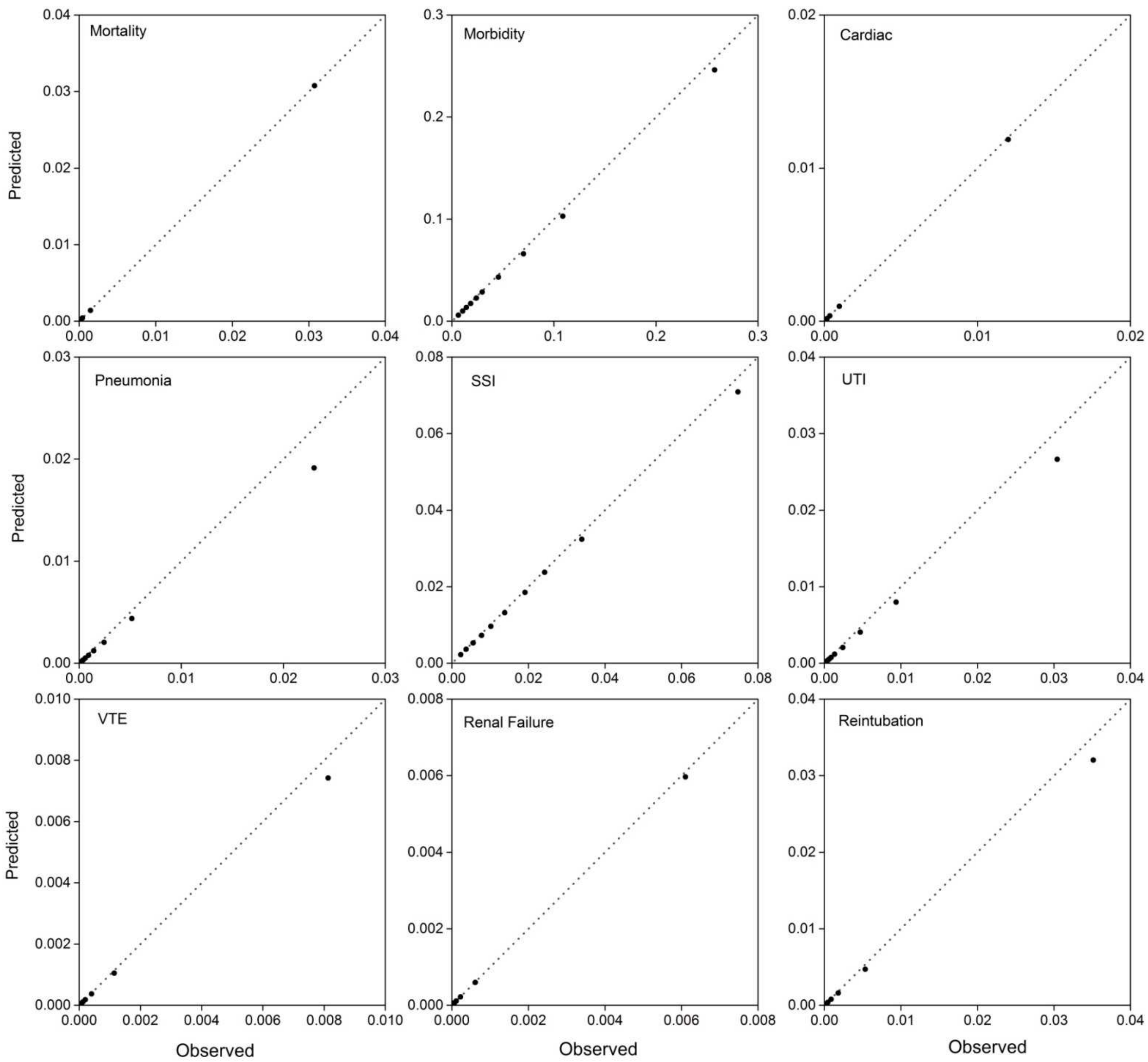
Observed rate


Mortality
Morbidity
Cardiac
Pneumonia
SSI
UTI
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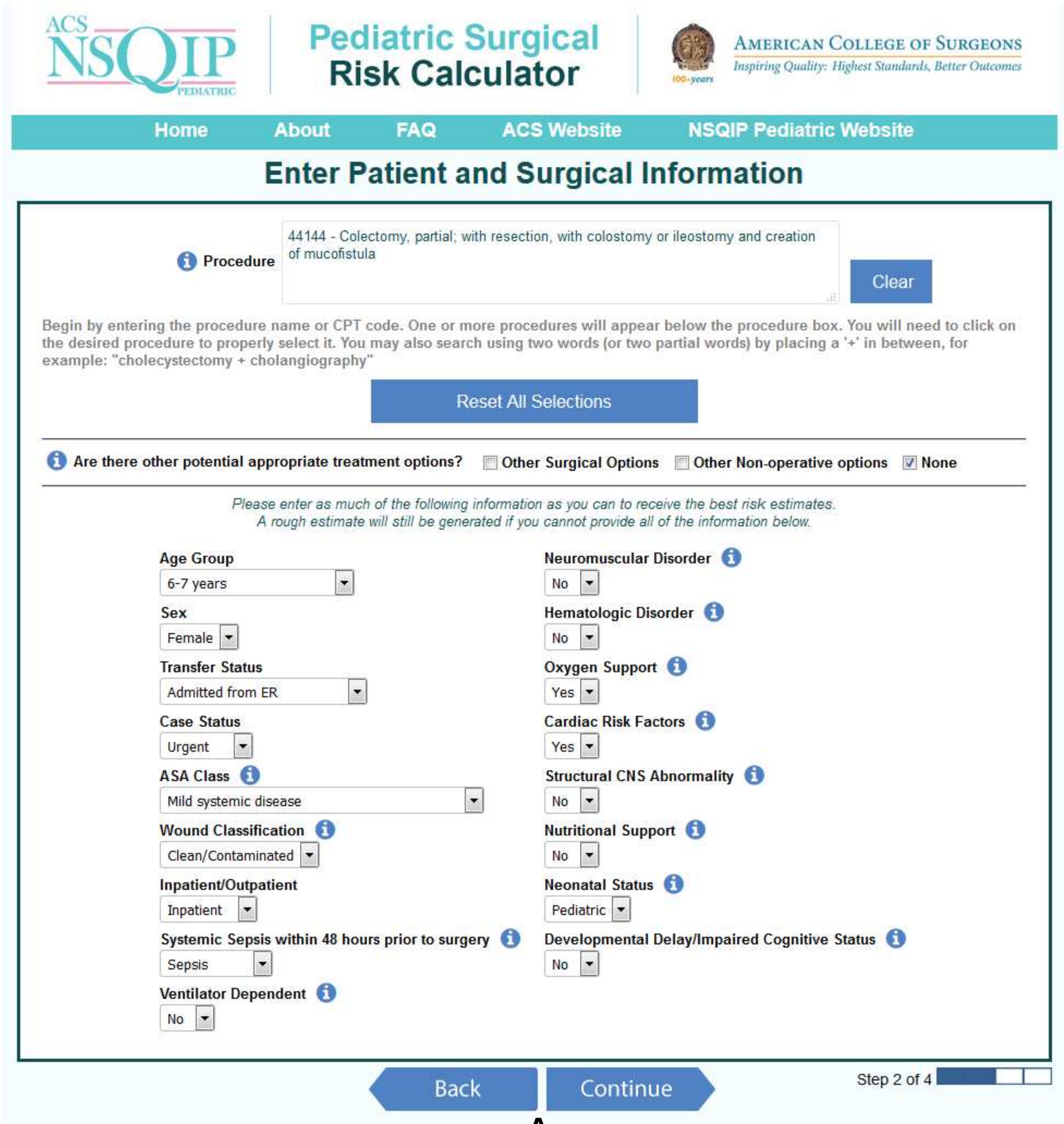
Observed


ACS NSQIP PEDIATRIC
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Inspiring Quality: Highest Standards, Better Outcomes
100+years
Home
About
FAQ
ACS Website
NSQIP Pediatric Website
Enter Patient and Surgical Information
Procedure
44144 - Colectomy, partial; with resection, with colostomy or ileostomy and creation of mucofistula
Clear
Begin by entering the procedure name or CPT code. One or more procedures will appear below the procedure box. You will need to click on the desired procedure to properly select it. You may also search using two words (or two partial words) by placing a '+' in between, for example: "cholecystectomy + cholangiography"
Reset All Selections
Are there other potential appropriate treatment options?
Other Surgical Options
Other Non-operative options
None
Please enter as much of the following information as you can to receive the best risk estimates.
A rough estimate will still be generated if you cannot provide all of the information below.
Age Group
6-7 years
Sex
Female
Transfer Status
Admitted from ER
Case Status
Urgent
ASA Class
Mild systemic disease
Wound Classification
Clean/Contaminated
Inpatient/Outpatient
Inpatient
Systemic Sepsis within 48 hours prior to surgery
Sepsis
Ventilator Dependent
No
Neuromuscular Disorder
No
Hematologic Disorder
No
Oxygen Support
Yes
Cardiac Risk Factors
Yes
Structural CNS Abnormality
No
Nutritional Support
No
Neonatal Status
Pediatric
Developmental Delay/Impaired Cognitive Status
No
Back
Continue
Step 2 of 4

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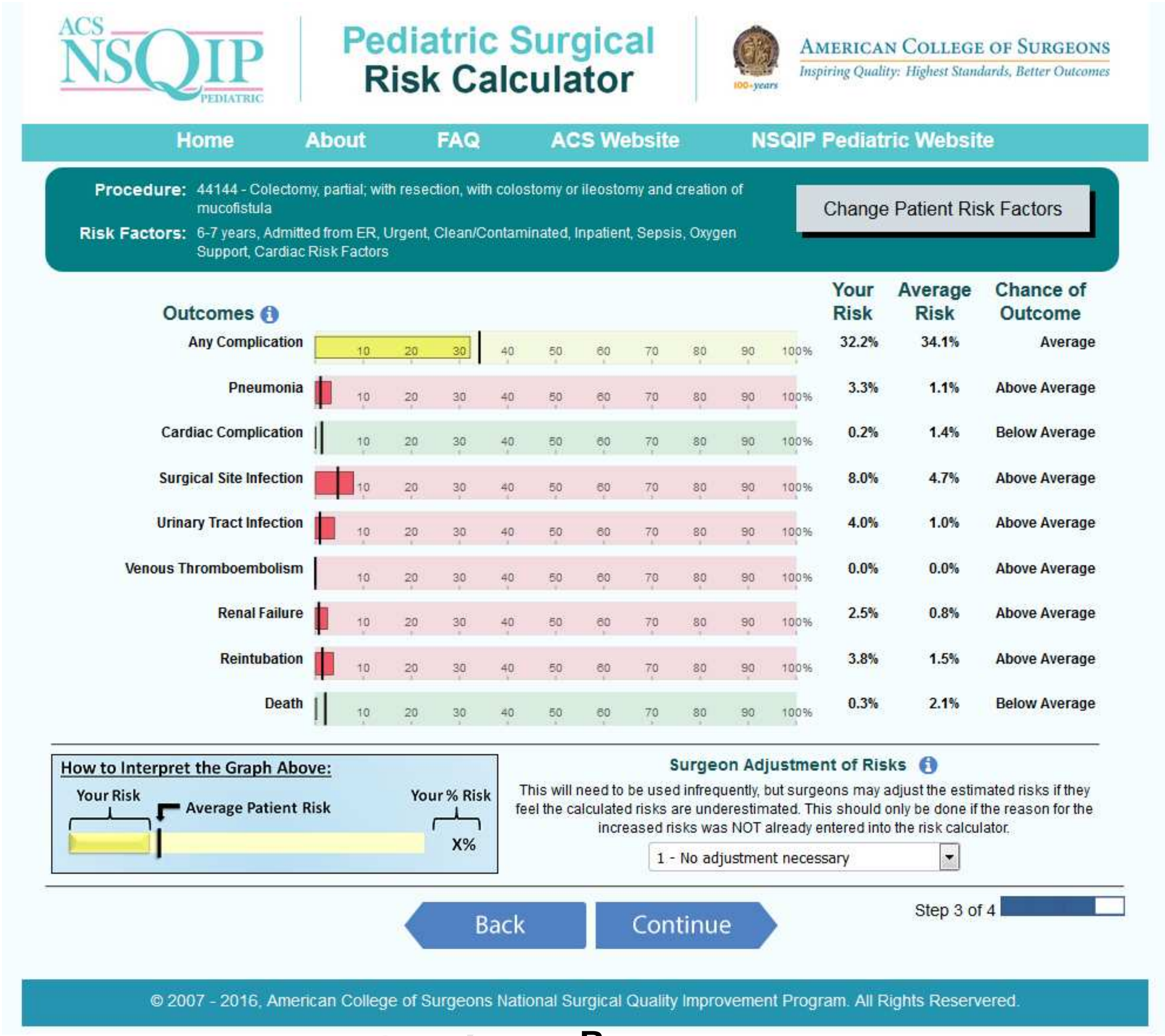
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Inspiring Quality: Highest Standards, Better Outcomes
Home
About
FAQ
ACS Website
NSQIP Pediatric Website
Procedure: 44144 - Colectomy, partial; with resection, with colostomy or ileostomy and creation of mucofistula
Risk Factors: 6-7 years, Admitted from ER, Urgent, Clean/Contaminated, Inpatient, Sepsis, Oxygen Support, Cardiac Risk Factors
Change Patient Risk Factors
Outcomes
Your Risk
Average Risk
Chance of Outcome
Any Complication 32.2% 34.1% Average
Pneumonia 3.3% 1.1% Above Average
Cardiac Complication 0.2% 1.4% Below Average
Surgical Site Infection 8.0% 4.7% Above Average
Urinary Tract Infection 4.0% 1.0% Above Average
Venous Thromboembolism 0.0% 0.0% Above Average
Renal Failure 2.5% 0.8% Above Average
Reintubation 3.8% 1.5% Above Average
Death 0.3% 2.1% Below Average
10 20 30 40 50 60 70 80 90 100%
How to Interpret the Graph Above:
Your Risk
Average Patient Risk
Your % Risk
X%
Surgeon Adjustment of Risks
This will need to be used infrequently, but surgeons may adjust the estimated risks if they feel the calculated risks are underestimated. This should only be done if the reason for the increased risks was NOT already entered into the risk calculator.
1 - No adjustment necessary
Back
Continue
Step 3 of 4
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