American College of Surgeons National Surgical Quality Improvement Program Pediatric: A Phase 1 Report

Mehul V Raval, MD, MS, Peter W Dillon, MD, FACS, Jennifer L Bruny, MD, Clifford Y Ko, MD, MS, MSHS, FACS, Bruce L Hall, MD, PhD, MBA, FACS, R Lawrence Moss, MD, FACS, Keith T Oldham, MD, FACS, Karen E Richards, BS, Charles D Vinocur, MD, FACS, Moritz M Ziegler, MD, FACS, on behalf of the ACS NSQIP Pediatric Steering Committee

BACKGROUND: There has been a long-standing desire to implement a multi-institutional, multispecialty program to address surgical quality improvement for children. This report documents results of the initial phase of the American College of Surgeons National Surgical Quality Improvement Program Pediatric.

STUDY DESIGN: From October 2008 to December 2009, patients from 4 pediatric referral centers were sampled using American College of Surgeons National Surgical Quality Improvement Program methodology tailored to children.

RESULTS: A total of 7,287 patients were sampled, representing general/thoracic surgery (n = 2,237; 30.7%), otolaryngology (n = 1,687; 23.2%), orthopaedic surgery (n = 1,367; 18.8%), urology (n = 893; 12.3%), neurosurgery (n = 697; 9.6%), and plastic surgery (n = 406; 5.6%). Overall mortality rate detected was 0.3% and 287 (3.9%) patients had postoperative occurrences. After accounting for demographic, preoperative, and operative factors, occurrences were 4 times more likely in those undergoing inpatient versus outpatient procedures (odds ratio [OR] = 4.71; 95% CI, 3.01−7.35). Other factors associated with higher likelihood of postoperative occurrences included nutritional/immune history, such as preoperative weight loss/chronic steroid use (OR = 1.49; 95% CI, 1.03−2.15), as well as physiologic compromise, such as sepsis/inotrope use before surgery (OR = 1.68; 95% CI, 1.10−1.95). Operative factors associated with occurrences included multiple procedures under the same anesthetic (OR = 1.58; 95% CI, 1.21−2.06) and American Society of Anesthesiologists classification category 4/5 versus 1 (OR = 5.74; 95% CI, 2.94−11.24). Specialty complication rates varied from 1.5% for otolaryngology to 9.0% for neurosurgery ($p < 0.001$), with specific procedural groupings within each specialty accounting for the majority of complications. Although infectious complications were the predominant outcomes identified across all specialties, distribution of complications varied by specialty.

CONCLUSIONS: Based on this initial phase of development, the highly anticipated American College of Surgeons National Surgical Quality Improvement Program Pediatric has the potential to identify outcomes of children's surgical care that can be targeted for quality improvement efforts. (J Am Coll Surg 2011;212:1–11. © 2010 by the American College of Surgeons)

Dr Raval is supported by the John Gray Research Fellowship and the Daniel F and Ada L Rice Foundation.

Disclosure Information: Nothing to disclose.

Results were presented at the American College of Surgeons National Surgical Quality Improvement Program Annual Meeting, Chicago, IL, July 2010.

Received July 5, 2010; Revised August 20, 2010; Accepted August 23, 2010.

From the Division of Research and Optimal Patient Care, American College of Surgeons(Raval, Ko, Hall, Richards), Department of Surgery, Northwestern University Feinberg School of Medicine (Raval), Chicago, IL, Department of Surgery, Division of Pediatric Surgery, Pennsylvania State University School of Medicine, Hershey, PA (Dillon), Department of Pediatric Surgery, University of Colorado, The Children's Hospital, Denver, CO (Bruny, Ziegler), Department of Surgery, University of California Los Angeles David Geffen School of Medicine and the VA Greater Los Angeles Healthcare System, Los Angeles, CA (Ko), John Cochran Veterans Affairs Medical Center, Department of Surgery, Washington University in St Louis, and Barnes Jewish Hospital, Center for Health Policy, and the Olin Business School at Washington University in St Louis, St Louis, MO (Hall), Department of Surgery, Yale University, Yale New Haven Children's Hospital, New Haven, CT (Moss), Department of Surgery, Medical College of Wisconsin, Milwaukee, WI (Oldham), Division of Pediatric Surgery, Thomas Jefferson University, A. I. DuPont Hospital for Children, Wilmington, DE (Vinocur), and ACS NSQIP Pediatric Steering Committee: American College of Surgeons, Chicago, IL (Mira Shiloach, MS, Charles Fischer, BS, Susan Shore, RN), The Children's Hospital, Aurora, CO (Debra Liebrecht, RN), Children's Hospital of Wisconsin, Milwaukee, WI (Yvonne Anderson, RN, MS), Yale New Haven Children's Hospital, New Haven, CT (Marilyn Hirsch, RN, Debbie Ferrigno, RN), A. I. DuPont Hospital for Children, Wilmington, DE (Michael Marchildon, MD, Christine Schuck, RN), Colorado Health Outcomes Program, Denver, CO (Karl Hammermeister, MD, William Henderson, PhD, Elaine Morrato, DrPH, MPH), QC Metrix (Kathy Rowell, MS, Janet Steeger, RN).

Correspondence address: Mehul V Raval, MD, American College of Surgeons, 633 N Saint Clair St, 22nd Floor, Chicago, IL 60611-3211. email: m-raval@md.northwestern.edu

ISSN 1072-7515/11/$36.00
doi:10.1016/j.jamcollsurg.2010.08.013

Abbreviations and Acronyms

ACS NSQIP = American College of Surgeons National Surgical Quality Improvement Program
ASA = American Society of Anesthesiologists
OR = odds ratio

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) has provided risk-adjusted, reliable outcomes and sparked improved outcomes and increased safety for adult patients undergoing surgical procedures.[1] The ACS has partnered with the American Pediatric Surgical Association since 2005 to develop the ACS NSQIP Pediatric.[2,3] The ACS NSQIP Pediatric was developed with several distinguishing features as compared with the adult program. First, the ACS NSQIP Pediatric was designed as a multispecialty program with cases sampled from pediatric general/thoracic surgery, pediatric otolaryngology, pediatric orthopaedic surgery, pediatric urology, pediatric neurosurgery, and pediatric plastic surgery. Second, many standard variables and definitions adopted by the ACS NSQIP were redefined and modified to apply to the pediatric patient population. Last, complication rates were known to be lower among pediatric patients compared with adult populations, raising novel challenges for risk-adjusted comparison of institutions and creating uncertainty as to whether there would be demonstrable variation in outcomes.

Launched in October of 2008, the goal of Phase 1 of the ACS NSQIP Pediatric was to serve as a data collection trial to test and refine data collection software, data elements, and procedures. Feasibility of ACS NSQIP Pediatric implementation in terms of the technological platform development, uniform data collection, and completeness of data collection with 30-day follow-up has been demonstrated previously.[4] The purpose of this report is to provide a summary of complete Phase 1 results, identify variables associated with postoperative occurrences, and outline potential areas of focus as the ACS NSQIP Pediatric moves toward the use of data for surgical quality improvement.

METHODS

The specific variables and outcomes collected in the ACS NSQIP Pediatric have been described previously.[2,4] Cases were selected for inclusion based on Current Procedural Terminology codes using a standard ACS NSQIP 8-day cycle-based systematic sampling of approximately 35 procedures per cycle. Several high-volume, low-risk procedures, such as pyloromyotomy and tonsillectomy, had accrual limits of 5 cases or fewer per cycle. Approximately 121 variables were prospectively collected: 6 demographic, 8 surgical profile, 46 clinical preoperative, 13 laboratory, 16 intraoperative and 32 postoperative.[2] In addition, variables of interest were collected for special populations, such as neonates, undergoing surgical procedures. In several cases preoperative variables were combined into composite variables. The preoperative composite variables studied included congenital malformations (including neonates $<$1,500 g at the time of surgery or any diagnosis of congenital malformation), neurological history (including cerebrovascular accident, stroke, brain injury, coma, central nervous system tumor, cerebral palsy, or intraventricular hemorrhage for neonatal patients), pulmonary history (including asthma, cystic fibrosis, bronchopulmonary dysplasia or chronic lung disease, pneumonia, and ventilator-dependence), cardiac history (including previous cardiac surgery intervention as well as minor, major, or severe cardiac risk factor status), renal history (including dialysis for renal failure and acute renal failure), gastrointestinal history (includes liver, biliary, pancreatic, esophageal, or intestinal disease causing functional abnormality), nutritional/immune history (including weight loss, supplemental nutritional support, chronic steroid use, or earlier bone marrow or organ transplantation), hematological history (including blood transfusions within 48 hours of surgery and underlying hematological/bleeding disorders), oncologic history (including underlying malignancy, chemotherapy within 30 days, and radiotherapy within 90 days), endocrine or wound history (including diabetes mellitus requiring therapy with oral agents or insulin or open wounds), and physiologic compromise (including systemic sepsis within 7 days of surgery, inotropic support at surgery, or cardiopulmonary resuscitation within 7 days of surgery). Thirty-day outcomes of interest ranged from mortality to specific end points, including surgical site infection, pneumonia, urinary tract infection, sepsis, respiratory/airway issues, wound disruption, neurologic events, renal failure, deep vein thrombosis, cardiac events, and graft/prosthesis/flap failures. These postoperative occurrences were studied individually as well as combined to create an overall postoperative occurrence composite. Although initial data collection also included blood transfusion and postoperative seizure as outcomes of interest, redefinition of these outcomes during program development excluded these outcomes from analysis. Data were clinically abstracted by data collectors who received extensive training before data collection.[5]

Phase 1 was conducted at 4 sites: Yale New Haven Children's Hospital (New Haven, CT), A.I. DuPont Hospital for Children (Wilmington, DE), The Children's Hospital (Aurora, CO), and Children's Hospital of Wisconsin (Milwaukee, WI). All sites underwent audit of data accuracy

and completeness and had an overall inter-rater reliability disagreement rate of 1.9%, well below the established 5% ACS NSQIP limit.[4,6]

Patients with and without postoperative occurrences were compared based on demographics, preoperative risk factors, preoperative laboratory values, and operative factors. Postoperative occurrences were categorized as infectious, airway-related, wound disruptions, neurologic events, deep vein thrombosis, renal failure, and cardiac events. Infection occurrences included superficial, deep, or organ-space surgical site infections, sepsis or septic shock, pneumonia, and urinary tract infections. Neurologic events included nerve injury, stroke, cerebral-vascular accidents, and coma. Outcomes were subsequently compared by surgical specialty. The most frequent procedures captured for each surgical specialty are described. Within each specialty, cases were placed in clinically related groups based on expert opinion of anatomic- and procedure-related considerations. Complication rates within the groups were subsequently compared. Variability in outcomes was demonstrated across the 4 participating centers, but no attempt at risk adjustment was made in this study because of the limited sample sizes.

Preliminary inferential statistics were calculated for all variables using chi-square tests for categorical data, Student's *t*-test to compare means, and Mann Whitney rank-sum test to compare medians. Logistic regression models were used to identify factors associated with any postoperative occurrence other than mortality secondary to the uniqueness and rarity of this event, as well as postoperative transfusions and seizures for definition-related issues previously noted. All factors were entered into the multivariable model based on significance of $p < 0.20$ in univariate analyses. Model quality was evaluated through assessment of the Hosmer-Lemeshow goodness-of-fit statistic and the c-statistic. The ACS NSQIP Pediatric was conducted at each site after either full IRB review or under the auspices of a quality improvement program exempt from formal IRB review. Phase 1 participants have each approved contribution of the existing, site deidentified data shared in this report. This analysis was retrospectively performed using deidentified data and was deemed not to qualify as human subjects' research after review of protocols by the Northwestern University IRB. Statistical analyses were performed using SPSS 18 (SPSS Inc).

RESULTS

From October 2008 to December 2010, a total of 7,287 patients were prospectively evaluated in the program. There were 22 deaths captured (0.3%). Overall 420 (5.8%) patients had postoperative complications/occurrences. After excluding blood transfusions and seizure as occurrences, secondary to redefinition of these variables, 287 (3.9%) patients had one or more postoperative complications/occurrences. Occurrence rates by pilot site ranged from 3.1% to 5.6%. Table 1 provides a comparison of patients with and without postoperative occurrences across demographics, preoperative risk factors, and operative information. Occurrences were higher in male patients compared with female ($p = 0.03$) and for inpatient cases compared with outpatient cases ($p < 0.001$). Race, ethnicity, and payor status were not associated with variation in occurrence rates. Although the vast majority of patients were admitted from home (82.5%), only 2.7% of these patients had occurrences. Higher occurrence rates were noted for patient admissions from emergency department (10.0%) or transfer from outside wards (11.8%) or outside intensive care settings (17.3%, overall $p < 0.001$). General/thoracic cases were the most frequent surgical specialty captured (30.7%) followed by otolaryngology (23.3%), and orthopaedic surgery (18.8%). Despite being the second most common sampled specialty, otolaryngology had the lowest occurrence rate of all specialties (1.5%). Conversely, neurosurgery cases represented 9.6% of the cases sampled and had the highest occurrence rate at 9.0%. Figure 1 demonstrates the contribution of each specialty to both the total cases captured as well as the total burden of complications identified. The presence of a wide variety of preoperative risk factors including congenital malformations and history of neurological, pulmonary, cardiac, renal, gastrointestinal, nutritional/immune, hematological, oncologic, endocrine/wound, or physiologic disease were all associated with higher occurrence rates (Table 1; all $p < 0.001$). Although 60.8% of patients had a single procedure recorded, 39.2% underwent either additional procedures performed by the original surgical team or concurrent procedures performed by an alternate surgical team. Patients with a single procedure performed had a lower postoperative occurrence rate (2.9%) compared with those with multiple procedures performed (5.5%; $p < 0.001$). Patients undergoing urgent/emergent cases had a higher postoperative occurrence rate than those undergoing elective procedures (8.7% versus 3.0%; $p < 0.001$). Increasing American Society of Anesthesiologists (ASA) physical status classification rates were associated with higher postoperative occurrence rates from ASA 1 having a 1.2% occurrence rate to ASA 4/5 having a 26.1% rate ($p < 0.001$).

Preoperative laboratory tests captured are displayed in Table 2. Frequency of capture ranged from 12.1% for partial thromboplastin time to 34.9% for white blood count. When considering only patients with data reported, patients with postoperative occurrences had slightly higher

Table 1. Demographics, Preoperative Risk Factors, and Operative Information for Patients with and without Postoperative Occurrences in the American College of Surgeons National Surgical Quality Improvement Program Pediatric

	n	%	% Without occurrences	% With occurrences	p Value
All cases	7,287		96.1	3.9	—
Gender					0.029
Female	2,881	39.6	96.5	3.5	
Male	4,392	60.4	95.5	5.5	
Neonatal patient					<0.001
No	7,060	96.9	96.4	3.6	
Yes	227	3.1	85.5	14.5	
Race					
White	5,031	69.0	95.9	4.1	0.37
Other	2,256	31.0	96.4	3.6	
Hispanic ethnicity					0.24
Yes	1,157	15.9	95.2	4.8	
No	6,069	83.3	96.2	3.8	
Unknown	61	0.8	96.7	3.3	
Admission status					<0.001
Outpatient	3,819	52.8	99.2	0.8	
Inpatient	3,419	47.2	92.5	7.5	
Admission source					<0.001
Home	6,012	82.5	97.3	2.7	
Emergency department	858	11.8	90.0	10.0	
Outside hospital transfer	152	2.1	88.2	11.8	
Outside intensive care transfer	173	2.4	82.7	17.3	
Other	87	1.2	80.5	19.5	
Payor status					0.54
Private	3,988	54.7	96.2	3.8	
Government/other	3,299	45.3	95.9	4.1	
Specialty					<0.001
General/thoracic surgery	2,237	30.7	95.1	4.9	
Otolaryngology	1,687	23.2	98.5	1.5	
Orthopaedic surgery	1,367	18.8	95.8	4.2	
Urology	893	12.3	97.9	2.1	
Neurosurgery	697	9.6	91.0	9.0	
Plastic surgery	406	5.6	96.6	3.4	
Congenital malformation					<0.001
No	4,519	62.3	97.2	2.8	
Yes	2,734	37.7	94.3	5.7	
Any neurological history					<0.001
No	5,256	72.1	97.4	2.6	
Yes	2,031	27.9	92.7	7.3	
Any pulmonary history					<0.001
No	6,277	86.1	96.9	3.1	
Yes	1,010	13.9	90.9	9.1	
Any cardiac history					<0.001
No	6,726	92.3	96.5	3.5	
Yes	561	7.7	90.4	9.6	

(continued)

Table 1. Continued

	n	%	% Without occurrences	% With occurrences	p Value
Any renal history					<0.001
No	7,260	99.6	96.1	3.9	
Yes	27	0.4	77.8	22.2	
Any gastrointestinal history					<0.001
No	6,279	86.2	96.8	3.2	
Yes	1,008	13.8	91.7	8.3	
Any nutritional/immune history					<0.001
No	6,529	89.6	97.2	2.8	
Yes	758	10.4	86.4	13.6	
Any hematological history					<0.001
No	7,061	69.9	96.3	3.7	
Yes	226	3.1	87.2	12.8	
Any oncologic history					<0.001
No	7,193	98.7	96.2	3.8	
Yes	94	1.3	87.2	12.8	
Any endocrine or wound history					<0.001
No	7,155	98.2	96.2	3.8	
Yes	132	1.8	89.4	10.6	
Any physiologic compromise history					<0.001
No	6,996	96.0	96.5	3.5	
Yes	291	4.0	84.9	15.1	
Multiple/concurrent procedures					<0.001
No	4,432	60.8	97.1	2.9	
Yes	2,855	39.2	94.5	5.5	
Case type					<0.001
Elective	6,123	84.2	97.0	3.0	
Urgent/emergent	1,152	15.8	91.3	8.7	
ASA classification					<0.001
1 Normal	2,258	31.1	98.8	1.2	
2 Mild disease	3,334	45.9	97.5	2.5	
3 Severe disease	1,494	20.6	91.6	8.4	
4/5 Life-threatening/moribund	176	2.4	73.9	26.1	

Missing values: gender (n = 14), admission status (n = 20), admission source (n = 5), congenital malformation (n = 34), case type (n = 12), American Society of Anesthesiologists (ASA) Classification (n = 25).

blood urea nitrogen, creatinine, and alkaline phosphatase levels as well as lower sodium levels, albumin levels, and platelet counts (all $p < 0.05$). Patients with postoperative occurrences also had longer partial thromboplastin times and higher international normalized ratios (both $p < 0.01$). Total bilirubin levels, transaminase levels, white blood cell counts, hematocrit, platelet counts, and prothrombin times did not vary significantly between those with and without postoperative occurrences (all $p > 0.05$).

Table 3 displays several important risk-adjusted odds ratios (ORs). After taking demographic, preoperative, as well as operative factors into consideration in a multivariable logistic regression model, postoperative occurrences were 4 times more likely in patients undergoing inpatient as opposed to outpatient procedures (OR = 4.71; 95% CI, 3.01−7.35). Patients with nutritional deficiency or immunological compromise had a higher likelihood of postoperative complications compared with those without (OR = 1.49; 95% CI, 1.03−2.15). Patients with physiologic derangement before surgery, such as those requiring inotropic support or with sepsis or cardiopulmonary resuscitation within 7 days of surgery had a 68% higher likelihood of postoperative complications compared with those without physiologic derangement (OR = 1.68; 95% CI, 1.10−2.57). Patients undergoing multiple/concurrent procedures had a 58% higher likelihood of a postoperative occurrence (OR = 1.58; 95% CI, 1.21−2.06). Higher ASA classification category was also highly associated with postoperative occurrences: pa-

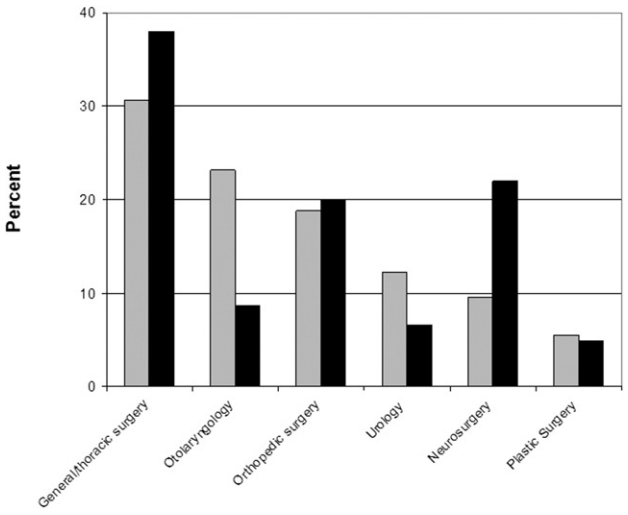

Figure 1. Percent of cases (gray bar) and percent of postoperative occurrences (black bar) by children's specialty.

tients with ASA classes 4/5 had nearly 6 times the likelihood of postoperative occurrences compared with ASA class 1 (OR = 5.74; 95% CI, 2.94−11.24). On multivariable analysis gender, neonatal age, surgical specialty, urgent/emergent case status and history of congenital malformations, neurologic disease, pulmonary disease, cardiac disease, renal disease, gastrointestinal disease, hematological disease, or oncologic disease did not increase the likelihood of postoperative occurrences.

Table 4 compares specific morbidities and mortality captured in the ACS NSQIP Pediatric by surgical specialty. Mortality ranged from 0% for plastic surgery and urology to 1.4% for neurosurgery. Morbidity ranged from 1.4% for otolaryngology to 9.0% for neurosurgery. Individual complications studied included surgical site infection (1.3% of all patients), pneumonia (0.3%), urinary tract infection (0.3%), sepsis (0.5%), airway/respiratory events (0.5%), wound disruption (0.5%), neurologic injury (0.3%), renal insufficiency/failure (0.1%), deep vein thrombosis/thrombophlebitis (<0.1%), cardiac arrest (<0.1%), and graft/prosthesis/flap failure (<0.01%). With regard to specific postoperative occurrences, there are observable variations in rates by specialty. For example, urinary tract infections constituted 42.1% of all urology occurrences, airway/respiratory events constituted 25.0% of all otolaryngology occurrences, and wound disruption constituted 42.9% of all plastic surgery occurrences. Surgical site infections were ubiquitous across all specialties ranging from 20.8% of otolaryngology occurrences to 45.6% of orthopaedic surgery occurrences. Graft/prosthesis/flap failure represents a narrowly focused postoperative occurrence and, although the overall rate was low at 0.7% of all occurrences, it was detected in specialties such as otolaryngology at 4.2% and plastic surgery at 7.1%. Table 5 provides the most common procedures with occurrences captured for each specialty. Procedures were grouped in terms of anatomic- and procedure-related considerations. For general/thoracic surgery, neonatal patients were grouped together regardless of the specific procedure performed. Remaining general/thoracic procedures were grouped by anatomic location. More than 85% of all postoperative occurrences were noted in the abdominal (61.5%) and neonatal (23.9%) groups. Although the hernia grouping comprised 28.4% of all general/thoracic surgery cases, this group accounted for only 4.6% of complications. Figure 2 displays the proportion of cases and complications captured by general/thoracic surgery subgroup.

Table 2. Specific Laboratory Test Values Captured in the American College of Surgeons National Surgical Quality Improvement Program with Comparison of Mean Values between Patients with and without Postoperative Occurrences

Laboratory test	With data		Overall mean (SD)	Mean without occurrences	Mean with occurrences	p Value
	n	%				
Sodium	1,724	23.7	138.7 (3.6)	138.7	138.2	0.05
Blood urea nitrogen	1,653	22.7	12.4 (8.8)	12.1	15.1	<0.01
Creatinine	1,653	22.7	0.6 (0.8)	0.6	0.7	0.06
Albumin	893	12.3	4.1 (0.8)	4.1	3.6	<0.01
Total bilirubin	1,033	14.2	1.3 (2.3)	1.3	1.3	0.93
Aspartate transaminase	969	13.3	43.6 (48.2)	43.3	46.5	0.54
Alkaline phosphatase	960	13.2	216.7 (136.7)	213.3	248.2	0.02
White blood count	2,541	34.9	10.5 (5.2)	10.4	10.8	0.30
Hematocrit	2,529	34.7	37.5 (5.6)	37.5	37.6	0.82
Platelet count	2,517	34.5	333.7 (127.8)	335.0	319.1	0.09
Partial thromboplastin time	880	12.1	30.9 (9.3)	30.5	33.9	<0.01
Prothrombin time	908	12.5	13.3 (4.7)	13.3	13.7	0.35
International normalized ratio	911	12.5	1.1 (0.2)	1.1	1.2	<0.01

Table 3. Factors Associated with Postoperative Occurrences in Phase 1 of the American College of Surgeons Surgical Quality Improvement Program Pediatric (n = 7,196*)

Factors	Odds ratio (95% confidence intervals)
Gender	
Female	1.0 (Referent group)
Male	0.84 (0.65−1.08)
Neonatal patient	
No	1.0 (Referent group)
Yes	1.26 (0.75−2.11)
Admission status	
Outpatient	1.0 (Referent group)
Inpatient	4.71 (3.01−7.35)
Admission source	
Home	1.0 (Referent group)
Emergency department	1.29 (0.84−1.99)
Outside hospital transfer	1.42 (0.77−2.61)
Outside intensive care transfer	1.50 (0.84−2.68)
Other	2.14 (1.10−4.18)
Specialty	
General/thoracic surgery	1.0 (Referent group)
Otolaryngology	0.79 (0.48−1.30)
Orthopaedic surgery	1.21 (0.80−1.84)
Urology	1.43 (0.82−2.50)
Neurosurgery	1.38 (0.91−2.09)
Plastic surgery	1.84 (0.97−3.49)
Congenital malformation	
No	1.0 (Referent group)
Yes	0.82 (0.61−1.10)
Any neurological history	
No	1.0 (Referent group)
Yes	1.20 (0.87−1.67)
Any pulmonary history	
No	1.0 (Referent group)
Yes	1.05 (0.74−1.49)
Any cardiac history	
No	1.0 (Referent group)
Yes	1.00 (0.68−1.46)
Any renal history	
No	1.0 (Referent group)
Yes	2.41 (0.86−6.73)
Any gastrointestinal history	
No	1.0 (Referent group)
Yes	0.87 (0.61−1.24)
Any nutritional/immune history	
No	1.0 (Referent group)
Yes	1.49 (1.03−2.15)
Any hematological history	
No	1.0 (Referent group)
Yes	1.09 (0.69−1.74)
Any oncologic history	
No	1.0 (Referent group)
Yes	1.47 (0.73−2.95)
Any endocrine or wound history	
No	1.0 (Referent group)
Yes	1.04 (0.54−1.98)
Any physiologic compromise history	
No	1.0 (Referent group)
Yes	1.68 (1.10−2.57)
Multiple/concurrent procedures	
No	1.0 (Referent group)
Yes	1.58 (1.21−2.06)
Case type	
Elective	1.0 (Referent group)
Urgent/emergent	1.19 (0.81−1.74)
ASA classification	
1 Normal	1.0 (Referent group)
2 Mild disease	1.56 (0.99−2.45)
3 Severe disease	2.55 (1.54−4.24)
4/5 Life-threatening/moribund	5.74 (2.94−11.24)

Hosmer-Lemeshow test = 0.897, c-statistic = 0.821.
*91 cases excluded secondary to multiple missing values.
ASA, American Society of Anesthesiologists.

DISCUSSION

The ACS NSQIP Pediatric was developed as the first multicenter, multispecialty quality improvement effort targeting children's surgical care. The goal of ACS NSQIP Pediatric Phase 1 was trial data collection, test collection software, and refine data elements and procedures captured. The feasibility of the program in terms of initial implementation and uniform data collection among pilot sites was reported in an interim assessment of the program.[4] This report shares results of 7,287 cases abstracted during 14 months of data collection at 4 tertiary pediatric pilot sites representing completion of Phase 1. Based on a systematic sampling of cases at participating sites that mirrors ACS NSQIP methodology, an overall mortality rate of 0.3% and a postoperative occurrence rate of 3.9% were identified. The ACS NSQIP Pediatric represents children's surgery through capture of general/thoracic surgery (30.7%), otolaryngology (23.2%), orthopaedic surgery (18.8%), urology (12.3%), neurosurgery (9.6%), and plastic surgery (5.6%). Variability in outcomes was demonstrated across participating sites as well as across surgical specialties, supporting the potential of the ACS NSQIP Pediatric to identify qual-

Table 4. Specific Postoperative Occurrences Captured in the American College of Surgeons Quality Improvement Program Pediatric Stratified by Surgical Specialty

	All	General/thoracic surgery	Otolaryngology	Orthopaedic surgery	Urology	Neurosurgery	Plastic surgery
Mortality, n (%)	22 (0.3)	9 (0.4)	2 (0.1)	1 (0.1)	0 (0)	10 (1.4)	0 (0)
Morbidity, n (%)	287 (3.9)	109 (4.9)	25 (1.4)	57 (4.2)	19 (2.1)	63 (9.0)	14 (3.4)
Surgical site infection,* %	32.4	34.9	20.0	45.6	26.3	23.8	28.6
Pneumonia, %	7.7	5.5	16.0	14.0	5.3	3.2	7.1
Urinary tract infection, %	7.7	5.5	0.0	7.0	42.1	6.3	0.0
Sepsis,† %	12.9	21.1	16.0	1.8	5.3	11.1	7.1
Airway/respiratory events,‡ %	12.2	16.5	25.0	5.3	5.3	9.5	7.1
Wound disruption, %	12.2	6.4	12.0	21.1	10.5	7.9	42.9
Neurological injury,§ %	7.7	3.7	0.0	1.8	0.0	27.0	0.0
Renal insufficiency/failure (%)	3.1	3.7	4.0	0.0	5.3	4.8	0.0
Deep vein thrombosis/ thrombophlebitis (%)	1.7	1.8	0.0	1.8	0.0	3.2	0.0
Cardiac arrest (%)	1.7	0.9	0.0	1.8	0.0	3.2	0.0
Graft/prosthesis/flap failure (%)	0.7	0.0	4.0	0.0	0.0	0.0	7.1

Column percents might not equal 100% secondary to rounding error.
*Surgical site infection includes superficial incisional, deep incisional, and organ/space surgical site infection.
†Sepsis includes catheter-related sepsis and systemic sepsis.
‡Airway/respiratory events include unplanned reintubation and respiratory failure.
§Neurological injury includes stroke, cerebrovascular accidents, nerve injury, and intraventricular hemorrhage.

ity improvement targets in the future, although risk-adjusted performance evaluation of the small number of pilot sites was not attempted.

There are several challenges to developing a quality improvement program in children's surgery. First, mortality and morbidity event rates after surgery are low in the pediatric patient population. One method to manage this obstacle is to combine events and create a composite outcomes measure. This approach has been employed within the ACS NSQIP with the reporting of risk-adjusted 30-day morbidity rates.[7] A similar composite was created using ACS NSQIP Pediatric pilot data. Our initial analysis revealed an overall postoperative occurrence rate of 5.9%. After excluding the need for postoperative transfusion and postoperative seizures as occurrences, the rate was 3.9%. These specific outcomes were excluded because of extensive redefinition throughout the course of Phase 1 development. For example, a postoperative seizure in a patient with presurgical seizure disorder and recorded history of seizures while on medical management was excluded early in the program. Using the composite of any postoperative occurrence, we were able to demonstrate differences between patient populations captured in the program. As expected, the majority of preoperative factors captured in the program ranging from the presence of congenital malformations to physiologic derangement secondary to sepsis before surgery were associated with poor outcomes. After controlling for preoperative and operative factors, inpatient procedures compared with outpatient procedures, patients with nutritional deficiency or immunological compromise, patients with physiologic derangement before surgery, patients undergoing multiple/concurrent procedures, and those with higher ASA classifications had considerably higher likelihood of a postoperative occurrence. Several of these variables have been previously demonstrated in adults to be associated with poor outcomes.[8-10] When moving forward with ACS NSQIP Pediatric development and future efforts to provide risk-adjusted hospital-level feedback to participating institutions, these variables will be important. It should be noted that there are limitations to employing a composite outcomes measure, such as difficulty elucidating the specific quality improvement target. In addition, not all morbidity events are clinically regarded as equal. For example, our composite provides equal weight for low morbidity occurrences such as a superficial surgical site infection and a high morbidity occurrence such as postoperative cardiac arrest or stroke. There are ongoing efforts within the ACS NSQIP to address severity grading of complications. Specific outcomes of interest that might be more applicable to pediatric populations and children's surgical specialties are being identified. These specific outcomes might facilitate development of quality improvement interventions.

A second challenge to measuring surgical quality in children is that the procedures for which morbidity and mortality are high are uncommon. The vast majority of procedures performed at children's centers remain low-risk. With this limitation in mind, the ACS NSQIP Pediatric

Table 5. Evaluation of Procedures with Postoperative Occurrences within the American College of Surgeons National Surgical Quality Improvement Program Pediatric by Specialty Specific Procedural Groupings

Procedure grouping	Frequency	%
General/thoracic surgery	109	100.0
Abdominal	67	61.5
Neonatal	26	23.9
Other	8	7.3
Hernia	5	4.6
Thoracic	3	2.8
Otolaryngology	25	100.0
Tumor/cyst excision	7	28.0
Tracheostomy/tracheotomy	6	24.0
Tonsillectomy/ adenoidectomy	4	16.0
Other	3	12.0
Reconstruction	2	8.0
Sinus-related procedure	2	8.0
Tympanoplasty	1	4.0
Orthopaedic surgery	57	100.0
Spinal arthrodesis/fusion	30	52.6
Osteotomy/osteoplasty	7	12.3
Other	5	8.8
Open fracture fixation	4	7.0
Removal of implant	3	5.3
Abscess drainage	3	5.3
Tendon-related procedure	2	3.5
Secondary wound closure	2	3.5
Fasciotomy	1	1.8
Urology	19	100.0
Ureteral anastomosis	5	26.3
Enterocytoplasty	4	21.1
Hypospadias	4	21.1
Nephrectomy	3	15.8
Orchiopexy/torsion	2	10.5
Other	1	5.3
Neurosurgery	63	100.0
Craniotomy/craniectomy	29	46.0
Ventricular catheter/shunt	21	33.3
Other	7	11.1
Spinal arthrodesis/fusion	4	6.3
Myelomeningocele repair	2	3.2
Plastic surgery	14	100.0
Cleft palate/lip repair	6	42.9
Tissue transfer	4	28.6
Lesion excision	2	14.3
Mandibular reconstruction	1	7.1
Craniosynostosis management	1	7.1

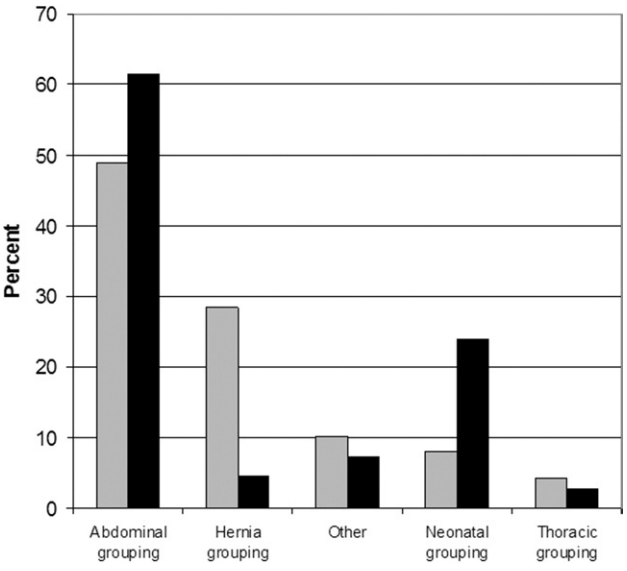

Figure 2. Percent of cases (gray bar) and percent of postoperative occurrences (black bar) by procedural grouping within general/thoracic surgery.

specifically constrained the number of appendectomy, hernia repair, laparoscopic cholecystectomy, pyloromyotomy, gastrostomy, tonsillectomy, and adenoidectomy cases sampled. Hernia repair still constituted 28% of all general/thoracic cases captured. Within each of the surgical specialties represented in the program, procedural groupings were identified that might serve as future areas for focus. For general/thoracic surgery, the neonatal population requiring surgical intervention was identified as a potential area for focus. Although this group represented only 8% of all general/thoracic cases, it represented nearly 24% of all postoperative occurrences. When evaluating the surgical specialties in the program, neurosurgery represented $<10\%$ of cases but $>20\%$ of complications. Conversely, otolaryngology represented nearly a quarter of cases, yet $<10\%$ of complications. Identifying specific procedural groupings that are of clinical importance to each specialty will be crucial as the ACS NSQIP Pediatric moves forward. This type of focused approach has been outlined and is under development in the adult ACS NSQIP as well.[11] It is believed that focusing attention on procedure groupings that are of clinical importance to each specialty can have beneficial effects, such as improving efficiency of data collection, improving specificity of information and reducing data burden, improving the validity of risk adjusted assessments, and facilitating directed quality improvement. To assist in developing focus, procedural groups associated with postoperative occurrences in this phase of the pediatric program were provided for each surgical specialty. Clinical partnerships with

surgical specialty societies and leaders in the respective fields are ongoing.

A third challenge to measuring surgical quality in children involves the data burden associated with variable collection, the number of variables needed for risk adjustment, and the duration of follow-up. Data abstractors in Phase 1 reported an increased complexity of abstracting data points in the pediatric (versus adult) population. Therefore, the number of cases sampled was decreased. As more complex, high-risk procedures are targeted for inclusion, the data burden is expected to increase. With this expected increase in the burden of data collection, the number of variables collected per case will need to be decreased. Earlier research within the adult ACS NSQIP has shown that a relatively small number of variables can be used to provide robust risk-adjusted comparisons.[12] As specific procedures to focus on are identified, more clinically meaningful and procedure-specific preoperative and operative variables, as well as postoperative outcomes, will be defined and incorporated into the program. Potentially, these variables will replace others currently being collected.

As an exercise, laboratory results were analyzed in this report. There were high rates of missing data for all laboratory variables examined. In addition, laboratory variables are clearly not independent. Many are linked together in clinically available "panels" as evident in Table 2. When present, several laboratory variables, including albumin, blood urea nitrogen, and coagulation studies, revealed associations with postoperative outcomes. Specific laboratory results such as albumin have been demonstrated to be associated with substantial outcomes in adult populations.[13] Other laboratory values, when collected, were not associated with occurrences and can be considered for elimination or replacement. Although laboratory values are often linked to electronic medical records and therefore represent very little burden for data collectors, this type of value assessment of variables is critical in the early stages of program development. As is true in the adult ACS NSQIP, moving forward more attention will be devoted to investigating the explanatory power of laboratory variables and the handling of missing data.

An area for possible expansion is tracking outcomes for longer than 30 days. There are many procedures for which 30-day outcomes might be of limited value. For example, in patients undergoing anorectal procedures, long-term continence is one of the key outcomes to measure.[14] Similarly, our results demonstrate that spinal procedures represented one of the key procedural groupings for focus among orthopaedic or neuorlogic specialties, and for these cases long-term functional status remains an important measure of successful surgery.[15] The added burden associated with longer follow-up must be weighed against the clinical and quality improvement use of long-term measures. Typically, quality improvement at the hospital level requires timely, frequent feedback and data analysis. Long-term outcomes and feedback can represent results of outdated practices in the rapidly evolving world of children's surgery. In addition, with real-world issues such as turnover of staff, practice patterns could change swiftly, making quality targets based on long-term outcomes difficult to approach. Long-term outcomes can be better tracked in disease-specific registries and might be beyond the purview of a quality improvement program such as the ACS NSQIP Pediatric.

Ultimately, the exact methodology and outcomes to be used in providing risk-adjusted feedback to hospitals participating in the ACS NSQIP Pediatric will be determined as the program continues to grow in terms of number of cases and refinement of targets and variables. There are 29 sites currently collecting data under the auspices of Phase 2 of the ACS NSQIP Pediatric. Variables and definitions used in the program have evolved since initial program conception and will continue to be refined. Critical assessment of data being collected so far will provide insight toward improving the program and feedback is actively being sought from various specialty groups.

This report serves as a summary of ACS NSQIP Pediatric Phase 1 results and provides information relevant to the various surgical specialties represented, including case volumes, overall and specific occurrence rates, procedure groupings captured, and areas for future focus. Variables associated with postoperative occurrences have also been identified. As the ongoing Phase 2 of the ACS NSQIP Pediatric continues at 29 sites, additional case volumes and program expansion will provide the basis for further program development. The ACS NSQIP Pediatric Phase 1 represents a successful step toward creating a multiinstitutional, multispecialty effort to begin to address surgical quality improvement in the pediatric population. Data collected in Phase 1 demonstrates the challenges specific to pediatrics that will be addressed in the ongoing development of the program.

Author Contributions

Study conception and design: Dillon, Ko, Hall, Moss, Oldham, Richards, Vinocur, Ziegler

Acquisition of data: Raval, Dillon, Bruny, Ko, Hall, Moss, Oldham, Richards, Vinocur, Ziegler

Analysis and interpretation of data: Raval, Dillon, Ko, Hall, Moss, Oldham, Richards, Vinocur, Ziegler

Drafting of manuscript: Raval, Dillon, Hall

Critical revision: Raval, Dillon, Bruny, Ko, Hall, Moss, Oldham, Richards, Vinocur, Ziegler

Acknowledgment: Dr Raval participates in the American College of Surgeons Clinical Scholars in Residence Program. The authors would like to thank members of the ACS NSQIP Pediatric Steering Committee for commitment to the successful development of this program and contribution of efforts leading to the preparation of this manuscript.

REFERENCES

1. Hall BL, Hamilton BH, Richards K, et al. Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. Ann Surg 2009;250:363–376.
2. Dillon P, Hammermeister K, Morrato E, et al. Developing a NSQIP module to measure outcomes in children's surgical care: opportunity and challenge. Semin Pediatr Surg 2008;17:131–140.
3. Morrato EH, Dillon P, Ziegler M. Surgical outcomes research: a progression from performance audits, to assessment of administrative databases, to prospective risk-adjusted analysis—how far have we come? Curr Opin Pediatr 2008;20:320–325.
4. Raval MV, Dillon PW, Bruny JL, et al. Pediatric ACS NSQIP: feasibility of a novel, prospective assessment of surgical outcomes. J Pediatr Surg in press.
5. American College of Surgeons National Surgical Quality Improvement Program. Surgical clinical nurse reviewer training. Available at: http://acsnsqip.org/main/program_nurse_training.asp. Accessed September 23, 2010.
6. Shiloach M, Frencher SK Jr, Steeger JE, et al. Toward robust information: data quality and inter-rater reliability in the American College of Surgeons National Surgical Quality Improvement Program. J Am Coll Surg 2010;210:6–16.
7. Fink AS, Campbell DA Jr, Mentzer RM Jr, et al. The National Surgical Quality Improvement Program in non-Veterans Administration hospitals: initial demonstration of feasibility. Ann Surg 2002;236:344–353; discussion 353−354.
8. Raval MV, Hamilton B, Ingraham A, et al. The importance of assessing both inpatient and outpatient surgical quality. Ann Surg in press.
9. Ingraham A, Bilimoria KY, Cohen ME, et al. Comparison of 30-day outcomes after emergency general surgery procedures: potential areas for targeted improvement. Surgery 2010; 148(2):217−238.
10. Cohen ME, Bilimoria KY, Ko CY, et al. Effect of subjective preoperative variables on risk-adjusted assessment of hospital morbidity and mortality. Ann Surg 2009;249:682–689.
11. Birkmeyer JD, Shahian DM, Dimick JB, et al. Blueprint for a new American College of Surgeons: National Surgical Quality Improvement Program. J Am Coll Surg 2008;207:777–782.
12. Dimick JB, Osborne NH, Hall BL, et al. Risk adjustment for comparing hospital quality with surgery: how many variables are needed? J Am Coll Surg 2010;210:503–508.
13. Gibbs J, Cull W, Henderson W, et al. Preoperative serum albumin level as a predictor of operative mortality and morbidity: results from the National VA Surgical Risk Study. Arch Surg 1999;134:36–42.
14. Levitt MA, Pena A. Outcomes from the correction of anorectal malformations. Curr Opin Pediatr 2005;17:394–401.
15. Kelly DM, McCarthy RE, McCullough FL, Kelly HR. Long-term outcomes of anterior spinal fusion with instrumentation for thoracolumbar and lumbar curves in adolescent idiopathic scoliosis. Spine (Phila Pa 1976) 2010;35:194–198.