A Statewide Collaborative to Reduce Pediatric Surgical Site Infections

abstract

BACKGROUND: Surgical site infections (SSIs) are preventable events associated with significant morbidity and cost. Few interventions have been tested to reduce SSIs in children.

METHODS: A quality improvement collaboration was established in Ohio composed of all referral children’s hospitals. Collaborative leaders developed an SSI reduction bundle for selected cardiac, orthopedic, and neurologic operations. The bundle was composed of 3 elements: prohibition of razors for skin preparation, chlorhexidine-alcohol use for incisional site preparation, and correct timing of prophylactic antibiotic administration. The incidence of SSIs across the collaborative was compared before and after institution of the bundle. The association between 1 of the bundle elements, namely correct timing of antibiotic prophylaxis, and the proportion of centers achieving 0 SSIs per month was measured.

RESULTS: Eight pediatric hospitals participated. The proportion of months in which 0 SSIs per center was recorded was 56.9% before introduction of the bundle, versus 81.8% during the intervention ($P < .001$). Correct timing of preoperative prophylactic antibiotics also significantly improved; 39.4% of centers recorded correct timing in every eligible surgical procedure per month (“perfect timing”) before the intervention versus 78.7% after ($P < .001$). The achievement of 0 SSIs per center in a given month was associated with the achievement of perfect antibiotic timing for that month ($P < .003$).

CONCLUSIONS: A statewide collaborative of children’s hospitals was successful in reducing the occurrence of SSIs across Ohio. Pediatrics 2014;134:e1174–e1180

AUTHORS: Philip Toltzis, MD,a Maryanne O’Riordan, PhD,a Dennis J. Cunningham, MD,b Frederick C. Ryckman, MD,c Tracey M. Bracke, BS,c Jason Olivea, MS, MPA,c and Anne Lyren, MD, MSac

aRainbow Babies and Children’s Hospital, Cleveland, Ohio; bNationwide Children’s Hospital, Columbus, Ohio; and cCincinnati Children’s Hospital Medical Center, Cincinnati, Ohio

KEY WORDS quality improvement, surgical site infection, nosocomial infections, prophylactic antibiotics

ABBREVIATIONS CDC NHSN—Centers for Disease Control and Prevention National Healthcare Safety Network OCHSPS—Ohio Children Hospital Solutions for Patient Safety OR—odds ratio RTC—randomized controlled trial SSI—surgical site infection

Dr Toltzis was a site participant in the SSI reduction program and was responsible for data analysis and the organization and composition of the manuscript; Dr O’Riordan was the statistician principally responsible for conducting the analyses; Dr Cunningham co-led the implementation of the SSI reduction program design and reviewed the manuscript drafts; Dr Ryckman participated in the conceptualization and development of the SSI reduction program and reviewed manuscript drafts; Ms Bracke provided statistical support throughout the implementation of the SSI reduction program and during manuscript preparation; Mr Olivea participated in the development of the design of the SSI reduction program and during manuscript preparation; Mr Lyren participated in the development of the SSI reduction program and its implementation and reviewed manuscript drafts; Dr Lyren was a program leader for the statewide OCHSPS and conceptualized the quality assurance program and assisted in data collection at the statewide level and in the design of the manuscript; and all authors approved the final manuscript as submitted.

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Address correspondence to Philip Toltzis, MD, Rainbow Babies and Children’s Hospital, 11100 Euclid Ave, Cleveland, OH 44106.

E-mail: pxt2@case.edu

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Since the publication of the sentinel report on hospital-associated adverse events by The Institute of Medicine in 1999, it has been a dramatic increase in the attention given to hospital-based quality improvement. Nevertheless, actual progress in reducing adverse events in patients admitted to the hospital has been slow. It is now clear that to be successful, quality improvement requires an orchestrated effort, including strong administrative leadership willing to commit energy and financial resources to the task at hand, a scientific approach to improvement, and a sophisticated understanding of health care delivery systems and human behavior. The potential for success in these endeavors has been improved by the establishment of collaboratives, composed of groups of hospitals with shared goals for patient safety, which promote cumulative learning through the frequent exchange of ideas and results.

Surgical site infections (SSIs) are largely preventable hospital-acquired events and are associated with substantial morbidity and mortality, but to date, few quality improvement programs have been established that have focused on reduction of SSIs in children. Such programs are hindered by the limited published experience defining risk factors and preventative strategies for pediatric SSIs. The principal children’s hospitals in Ohio, with significant leadership and encouragement at the state level, developed a collaborative to address the challenge of SSIs among pediatric inpatients, extrapolating from measures that had been tested in adult patients. The analysis of that program, described herein, asked whether contemporary quality improvement techniques and the collaborative model can reduce the frequency of SSIs among children.

**METHODS**

**Collaborative Model**

The collaborative was comprised of the 8 referral children’s hospitals in Ohio, all members of the Ohio Children’s Hospital Association, as described elsewhere. In 2009, the Association launched the Ohio Children’s Hospitals Solutions for Patient Safety (OCHSPS), a learning and improvement program designed to reduce the incidence of adverse events among pediatric inpatients. Reduction of pediatric SSIs was among the program’s first goals. The collaborative was supported by 3 primary principles: (1) unequivocal commitment to the program by the top administrators of each participating hospital, (2) a spirit of full transparency that encouraged individual teams to share their experience and outcome data without concern for liability, enabled by Ohio legislature that expressly provided peer review protection for OCHSPS activities, and (3) promotion of a culture of change within each institution. Participation in OCHSPS quality improvement projects was approved by each hospital’s Institutional Review Board.

**Planning the Intervention**

Each hospital developed an SSI reduction leadership team. Team members were trained in the Model for Improvement as described in the Institute for Healthcare Improvement Break-Through Series. Group learning was promoted through monthly conference calls and biannual face-to-face meetings in Columbus, Ohio, a city centrally located in the state and easily accessible to all participants. The OCHSPS targeted SSI reduction in 3 groups of clean surgical procedures, namely, cardiac surgery requiring cardiopulmonary bypass, orthopedic surgery involving the spine, and primary placement of an internalized cerebrospinal fluid shunt, recognizing that the consequences of SSI in each of these procedures were particularly significant. An SSI reduction bundle was devised that was composed of 3 elements whose efficacy had been established in studies of adult patients or which possessed biological rationale, namely (1) the elimination of razors for preparation of the surgical site, (2) the preferential use of chlorhexidine-alcohol for skin disinfection before incision in children older than 2 months of age, and (3) the administration of preoperative prophylactic antibiotics infused at the recommended time before incision. Regarding this last element, antibiotics were scored as correctly administered if they were infused between 60 minutes before incision and the time of incision, except for vancomycin, which was scored as correctly administered if dosed between 120 and 60 minutes before incision. Nine months after the intervention had commenced, program leaders began to emphasize re-dosing of prophylactic antibiotics every 3 hours until skin closure for prolonged cases, but antibiotic timing was judged “correct” based only on the timing of preincisional drug. A table developed by team leaders recommended antibiotics and doses for SSI prophylaxis, depending on whether the patient had a history of allergy to β-lactams or was known to be a carrier for methicillin-resistant *Staphylococcus aureus*. The choice of antibiotic, however, ultimately was left to the discretion of the attending surgeon, as was the duration of administration postoperatively.

**Methods of Evaluation**

Adherence to the bundle was prospectively monitored by program staff through daily review of all operative records of eligible procedures. Program personnel immediately alerted the surgical and anesthesiology team in the event of a breach in the application of the bundle. SSIs were identified by each hospital’s Infection Prevention team using their customary real-time processes, using diagnostic criteria established by the Centers for Disease Control and Prevention National Healthcare Safety Network (CDC NHSN). Children subjected to cardiac surgery who had delayed sternal closure were excluded,
as the CDC NHSN categorized such infections as organ space infections rather than surgical site infections. Each occurrence of SSI prompted a root cause analysis, using processes and formats developed at each center, in an attempt to identify and correct systems issues that may have predisposed to the infection, and the results of these analyses were shared during the monthly conference calls.

The effectiveness of the intervention was tested through an interrupted time-series design, with data recorded monthly. The study was divided into 3 periods. During the baseline period (January through September 2009), centers retrospectively assessed their incidence of SSIs within the 3 classes of procedures. The period October 2009 through January 2010 (run-in period) was used to familiarize surgery and anesthesia staff with the initiative and to begin application of the bundle. This was followed by the intervention period, which extended between February 1, 2010 and January 31, 2012. For the purposes of this study, only outcomes measured during the baseline and intervention periods were compared.

The goal of this quality improvement program was for each participating center to achieve a perfect outcome, namely, the total elimination of SSIs. When a center achieved this goal (that is, the number of SSIs for a given month was equal to 0), that center was said to have achieved “0 center-month” status. After eliminating center-months in which no eligible procedures were performed, a comparison then was made of the proportion of centers achieving 0 center-month status during the baseline versus the intervention period, using $\chi^2$ analysis. Adjusted analyses for this measure were carried out to account for possible correlation of results within center across time, assuming an autoregressive correlation structure and controlling for the magnitude of the denominator.

The secondary outcome was the frequency of correct timing of prophylactic antibiotics per center-month compared between the baseline and intervention periods. As with the primary outcome, the goal of the program was to achieve perfection, indicated as correct preincisional antibiotic timing in every candidate procedure per center-month (“perfect timing”). The association between perfect prophylactic antibiotic timing and achievement of 0 SSI status was tested by $\chi^2$. Additional analyses included a $\chi^2$ test for trend within each time period to determine that the assumption of a steady state was correct. All analyses were done using SAS v9.2 (SAS Institute, Inc, Cary, NC) and the level of significance was set to 0.05.

RESULTS
Primary Outcome Measure
There was a substantial reduction in the incidence of pediatric SSIs across the collaborative after introducing the intervention, as reflected in several measurements. During the baseline period, the frequency of SSIs was 4.48 per 100 surgical procedures; during the intervention period, this was reduced to 1.89 infections per 100 procedures, a 58% reduction (Fig 1). A reduction in SSI incidence was noted in all 3 categories of procedures: 44% reduction in orthopedic surgery cases, 67% in neurosurgery cases, and 72% in cardiothoracic surgery cases. After excluding the 6 center-months in which no eligible procedures were performed, 66 center-month observations were assessed during the baseline period; in 35 (53.0%) of these center-months, 0 SSIs were detected. By contrast, after excluding 18 center-months in which no eligible operations were performed, 0 SSIs were detected in 139 of...
174 (79.9%) center-month observations during the intervention period (Fig 2; \(P < .001\)). The unadjusted odds ratio (OR) of a center achieving 0 SSI status during the intervention period was 3.86 (95% CI; range, 2.46–6.11) compared with the baseline period, indicating a substantially greater likelihood of a center achieving the program goal of being SSI-free after the intervention was adopted. There were no trends toward reduced incidence when either the baseline or intervention period was considered alone (test for trend during baseline period, \(P < .78\), and during the intervention period, \(P < .24\)), suggesting that there were no secular trends toward reduced infections emanating from unmeasured factors outside the SSI reduction program.

Measured confounders that potentially could have influenced the study outcome appeared evenly distributed over the course of the study. Specifically, there were no apparent differences in the types and numbers of operations in each surgical category performed per month in the baseline and intervention periods (Table 1). Moreover, the intervention period remained independently associated with the achievement of 0 SSI status after adjusting for possible correlated data within site and for number of eligible cases performed per month (OR, 3.89; range, 2.45–6.18).

Improvement in the incidence of SSIs was detected in 7 of the 8 centers (Table 2); in the remaining hospital (Site 4) the incidence remained essentially unchanged. The proportion of months in which there were 0 SSIs during the baseline period ranged from 22.2% to 88.9% across the participating centers. The highest proportions (indicating the lowest occurrences of SSIs) were recorded in the 3 centers performing the fewest number of eligible procedures (Sites 4, 7, and 8 in Table 2; median, 1–5 operations per month). Between-center differences were much less apparent during the intervention period, in which all 8 centers performed at a high level (Table 2).

**Association of Prophylactic Antibiotics and Achievement of 0 Center-Month Status**

The effect of the program specifically on 1 element of the bundle, namely, the correct administration of prophylactic antibiotics, was further examined. Program effect on this practice was assessed in 2 ways: first, by determining if the practice improved after the adoption of the bundle, and second, to determine if, during the intervention period, there was an association between perfect timing of prophylactic antibiotics and achievement of the program goal of 0 SSIs per center-month. After censoring those center-months in which no eligible procedures were performed, 100% adherence with correct administration of prophylactic antibiotics was recorded in 26 of 66 (39.4%) center-months during the baseline period. This practice improved significantly during the intervention period, during which perfect timing was noted in 137 of 174 (78.7%) center-months (\(P < .001\)). Adherence to correct pre-incisional prophylactic antibiotic administration practice was associated with reduced frequency of SSIs. In the intervention period there were 139 center-months during which 0 SSIs occurred; perfect timing of administration of prophylactic antibiotics was achieved in 116 (83.4%) of these center-months. By contrast, there were 35 center-months in which at least 1 SSI was recorded; during these center-months, perfect adherence to guidelines for prophylactic antibiotic administration was recorded in 21 (60.0%) instances (\(P < .003\)). The association between perfect prophylactic antibiotic administration and 0 SSIs per center-month remained significant after adjusting for possible correlated data within site and for number of eligible cases performed per month (OR, 3.89; range, 2.45–6.18).

**TABLE 1 Number of Cases per Month During the Baseline and Intervention Periods**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>46.0</td>
<td>48.0</td>
</tr>
<tr>
<td>Neurologic</td>
<td>15.5</td>
<td>12.5</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>43.0</td>
<td>42.5</td>
</tr>
<tr>
<td>Total cases</td>
<td>104.5</td>
<td>103.0</td>
</tr>
</tbody>
</table>

* The numbers represent the median number of eligible cases performed per month across all 8 participating centers.
data within site and number of cases performed per month (OR, 2.10; range, 1.14–3.87). When each class of procedures was assessed independently, however, the strength of association between perfect antibiotic timing and achieving 0 center-month status was weaker; for cardiac surgery, 89.9% of center-months recorded perfect timing during center-months in which 0 SSIs were recorded versus 87.5% during center-months in which at least 1 SSI was detected; for neurosurgery, 88.9% versus 78.6%; for orthopedic surgery, 88.2% versus 78.9%; all P > .05.

**DISCUSSION**

The OCHSPS collaborative program resulted in a dramatic, sustained reduction in the incidence of SSIs among children in all of the referral children’s hospitals in Ohio. The effectiveness of institutional collaboration to improve the health and wellbeing of children is well established. Successful collaborations have formed that have brought together interested individuals from a variety of pediatric health care organizations. Some of these collaborations have been motivated by a particular patient demographic, such as neonatal care; others have focused on a specific disease such as inflammatory bowel disease and congenital heart disease. Advocacy organizations such as the Children’s Hospital Association also have supported pediatric quality improvement projects executed by its members throughout the United States. Over the last several years, children’s hospitals in selected states have begun to recognize the value of collaboration at a statewide level. The partnerships that form within states have the advantages of proximity for meeting opportunities and shared state regulations for data transparency. The currently reported OCHSPS initiative embraced both of these advantages. The improved outcomes across essentially all study sites, with their different patient mixes and pre-existing cultures for quality improvement, lend credence to the program’s generalizability. To sustain their success in decreasing SSIs, teams from each center have continued to participate in monthly teleconferences to share data and lessons learned. Additionally, each hospital has adopted an additional bundle element, such as perioperative blood glucose and temperature control, to attempt to further decrease SSI rates. As a result, the incidence of SSIs among participating hospitals has remained at approximately the intervention rate through December 2013.

The OCHSPS SSI reduction program was challenged at its outset by the paucity of information regarding SSI risk factors and reduction strategies in children, requiring that the organizers develop interventions based on data extrapolated from adult studies or on biological plausibility. The bundle developed by this program included 3 elements, namely, the avoidance of razors for site preparation, the use of chlorhexidine-alcohol for incisional site disinfection, and appropriate timing of preoperative prophylactic antibiotics. All 8 participating centers had longstanding policies prohibiting the presence of razors in the operating room and compliance with this element approached 100% both before and after the intervention. Hence, the influence of this element of the bundle could not be determined. Chlorhexidine-alcohol use was recommended by the program leaders based exclusively on its combined rapid and sustained antibacterial effects and its superiority as a skin disinfectant in other clinical settings. Clinical trials testing its effectiveness in reducing SSIs were not published until after the program had commenced.

The evaluation of this element of the bundle, however, was hindered by incomplete recording of its use, by the reluctance of some surgeons to use this agent, by its combined use with a second disinfectant in some cases, and by its outright prohibition by 2 of the centers based on its fire-hazard risk; hence, its influence on the outcome of this program could not be confidently evaluated. The third bundle element, namely, correct timing of antibiotics, was accurately recorded for every candidate operation and was universally accepted at the institutional and individual-surgeon level, and it was variably applied, allowing it to be evaluated in the current study.

The positive impact of prophylactic preoperative antibiotics in adult patients has been supported by an extensive literature encompassing many randomized clinical trials (RCTs), including those confined to clean procedures such as those targeted by the OCHSPS. By contrast, almost all pediatric studies of SSI to date have focused on risk factors for development of infection, particularly after cardiac surgery, rather than the efficacy of selected interventions.
and the few observational studies that have tested the association of preoperative antibiotics and the development of SSI were unable to establish one.\textsuperscript{26,27} In 1 interventional trial to reduce SSIs in children, Adler and colleagues performed a retrospective, single-center analysis of a program initiated to target high rates of wound infections after cardiac surgery.\textsuperscript{32} The intervention, which included emphasis on correct timing of prophylactic antibiotics, resulted in a marked decrease in the incidence of postoperative wound infection.\textsuperscript{32} Our program likewise emphasized and closely monitored appropriate timing of preoperative antibiotics and inferred an association between correct antibiotic administration and achievement of the program goal of 0 SSIs per site-month across 8 pediatric referral centers.

This study was subject to several limitations. First, it used an interrupted time-series design, which by its nature may not detect unmeasured confounders. Although some principal factors known to affect the incidence of SSIs, particularly the type of surgery and individual center practice,\textsuperscript{53} did not appear to be operative, other factors known to affect the risk for SSIs in children, such as patient age,\textsuperscript{34} were not recorded and could not be evaluated. Secondly, we could not evaluate 2 elements of the bundle, as 1 of them (avoidance of razors) had been implemented before the intervention, and the second (use of chlorhexidine-alcohol for site disinfection) was beset by poor acceptance at both the individual-surgeon and institutional level. Third, the association between correct administration of prophylactic antibiotics and reduction of SSIs demonstrated by this study was indirect. Subject-specific data were not recorded in this quality assurance program, and hence we were able to demonstrate only that as prophylactic antibiotic practice improved at a given institution, there was a concomitant reduction in the incidence of pediatric SSIs, an association that became less apparent when each class of surgery was examined separately. Indeed, the program was very visible at each institution, and behaviors outside the intervention but beneficial to SSI reduction may have been embraced along with improved antibiotic practice. Ultimately, the effectiveness of prophylactic antibiotics in reducing SSIs in children would be best established by an RTC. The low incidence of SSIs in children, however; especially in clean procedures such as the ones examined in the current study, would render an RTC very difficult to perform; thus, it is likely that the effectiveness of this practice in pediatrics will be derived from adult RTCs and from inferential pediatric data such as those presented herein.

**CONCLUSIONS**

A statewide collaborative using Model for Improvement techniques was successful in substantially reducing the incidence of SSIs in children across Ohio.


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Philip Toltzis, Maryanne O'Riordan, Dennis J. Cunningham, Frederick C. Ryckman, Tracey M. Bracke, Jason Olivea and Anne Lyren

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