Beyond surgical care improvement program compliance: antibiotic prophylaxis implementation gaps

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Antibiotic prophylaxis; SCIP; Surgical site infection; Implementation fidelity; Compliance; Adherence

Abstract

BACKGROUND: Despite increased compliance with Surgical Care Improvement Project infection measures, surgical-site infections are not decreasing. The aim of this study was to test the hypothesis that documented compliance with antibiotic prophylaxis guidelines on a pediatric surgery service does not reflect implementation fidelity or adherence to guidelines as intended.

METHODS: A 7-week observational study of elective pediatric surgical cases was conducted. Adherence was evaluated for appropriate administration, type, timing, weight-based dosing, and redosing of antibiotics.

RESULTS: Prophylactic antibiotics were administered appropriately in 141 of 143 cases (99%). Of 100 cases (70%) in which antibiotic prophylaxis was indicated, compliance was documented in 100% cases in the electronic medical record, but only 48% of cases adhered to all 5 guidelines. Lack of adherence was due primarily to dosing or timing errors.

CONCLUSIONS: Lack of implementation fidelity in antibiotic prophylaxis guidelines may partly explain the lack of expected reduction in surgical-site infections. Future studies of Surgical Care Improvement Project effectiveness should measure adherence and implementation fidelity rather than just documented compliance.

Surgical-site infections (SSIs) are associated with significant patient morbidity and cost. Approximately 750,000 to 1 million SSIs occur yearly, resulting in an excess of 2.5 million hospital days and $1 billion in cost. The Centers for Medicare and Medicaid Services, in collaboration with the Centers for Disease Control and Prevention, developed the Surgical Care Improvement Project (SCIP) in 2006 to reduce perioperative related morbidity and mortality. SCIP recommends evidence-based measures such as appropriate timing, type, and discontinuation of prophylactic antibiotics to prevent SSIs.

The results of studies evaluating the effectiveness of SCIP measures in reducing SSIs have been mixed. Some single-institution series have demonstrated that increased compliance was associated with a decrease in SSIs; however, these were uncontrolled before-and-after studies, which are subject to methodologic flaws such as regression.
to the mean and temporal confounding. Larger database studies have found that increased compliance was associated with either no change or an increase in SSIs, leading many surgeons to question the effectiveness of SCIP.7–10

There are several reasons why SCIP compliance may not consistently reduce SSIs. One reason is that SCIP measures may be necessary but not sufficient to prevent SSIs11; other prevention measures may also be necessary. Another possible explanation is that SCIP measures are effective only if all components are followed.10 Thus, outcomes are correlated with compliance with all SCIP measures rather than compliance with individual measures. Additionally, there may be a discrepancy between SCIP compliance and adherence. Compliance indicates that the intervention has been executed, but adherence indicates that the intervention was carried out as it was designed. Implementation fidelity is an overall measure of adherence for all aspects of an intervention.12 Documented compliance is routinely used to evaluate SCIP, but adherence and implementation fidelity are frequently not evaluated. It is possible that despite strict documentation of compliance, it is a poor reflection of adherence. Last, contextual factors such as organizational safety culture may influence the effectiveness of strategies to reduce SSIs.13,14

Children’s Memorial Hermann Hospital adopted SCIP-based antibiotic prophylaxis guidelines modified for pediatric surgery in 2009. The 3 specific aims of this investigation were (1) to assess current guideline adherence; (2) to compare documented guideline compliance with guideline adherence; and (3) to explore how practices and communication relating to antibiotic administration relate to adherence. We hypothesized that despite routine administration and documentation of antibiotic prophylaxis in pediatric surgery patients, implementation fidelity and adherence to the guidelines are poor.

Methods

Context

This study was performed at Children’s Memorial Hermann Hospital, a 240-bed university-affiliated children’s hospital in the Texas Medical Center. Operating room teams include attending physicians, fellows, and residents from surgery and anesthesia, as well as nursing staff members. Multiple pediatric surgery subspecialties are represented, including otolaryngology, plastic surgery, neurosurgery, ophthalmology, orthopedic surgery, and cardiovascular and thoracic surgery. This study qualified for institutional review board exemption.

Antibiotic prophylaxis guidelines

SCIP provides guidelines for antibiotic prophylaxis in adult patients. Consequently, the pediatric surgery and infectious disease departments at Children’s Memorial Hermann Hospital developed and instituted SCIP-based antibiotic prophylaxis guidelines for all pediatric operations (Table 1). These guidelines were developed from an

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Preferred regimen</th>
<th>Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiothoracic</td>
<td>Vancomycin* 15 mg/kg/dose IV, maximum dose 1 g</td>
<td>Vancomycin* 15 mg/kg/dose IV (if penicillin allergic or MRSA colonized)</td>
</tr>
<tr>
<td>Upper gastrointestinal, including Nissen, Whipple, biliary tract (not laparoscopic)</td>
<td>Cefazolin† 25 mg/kg/dose IV, maximum dose 2 g</td>
<td>Ceftriaxone† 50 mg/kg/dose IV, maximum dose 1 g, and metronidazole† 10 mg/kg/dose, maximum dose 1 g, IV</td>
</tr>
<tr>
<td>Lower gastrointestinal: appendectomy and colorectal</td>
<td>Cefoxitin† 40 mg/kg/dose IV, maximum dose 2 g</td>
<td>For penicillin-allergic patients, use gentamicin† 2 mg/kg/dose IV and metronidazole† 10 mg/kg/dose IV</td>
</tr>
<tr>
<td>Neurosurgery: ventriculoperitoneal shunt</td>
<td>Vancomycin* 15 mg/kg/dose IV, maximum dose 1 g, and cefazolin† 25 mg/kg/dose IV, maximum dose 2 g</td>
<td>Vancomycin* 15 mg/kg/dose IV (if penicillin allergic or MRSA colonized)</td>
</tr>
<tr>
<td>Neurosurgery: craniotomy and other clean neurosurgical</td>
<td>Cefazolin† 25 mg/kg/dose IV, maximum dose 2 g</td>
<td>Clindamycin† 10 mg/kg/dose IV, maximum dose 900 mg</td>
</tr>
<tr>
<td>Head and neck: incision through oropharyngeal mucosa</td>
<td>Cefazolin† 25 mg/kg/dose IV, maximum dose 2 g</td>
<td>Vancomycin* 15 mg/kg/dose IV (if penicillin allergic or MRSA colonized)</td>
</tr>
<tr>
<td>Orthopedic: insertion of hardware or prosthetic joint</td>
<td>Cefazolin† 25 mg/kg/dose IV, maximum dose 2 g</td>
<td></td>
</tr>
</tbody>
</table>

IV = intravenous; MRSA = methicillin-resistant *Staphylococcus aureus.
*Administer 60 to 120 minutes before incision.
†Administer 10 to 60 minutes before incision.
evidence-based investigation of the literature after reviewing existing guidelines for adult surgery as well as independent studies in pediatrics. The current guidelines were instituted in July 2009. The same guidelines and measures of adherence were followed for patients on scheduled therapeutic antibiotics; however, the antibiotic type was considered adherent if the therapeutic antibiotic covered the same organisms as the antibiotic recommended in the guideline.

Initial dissemination of guidelines

After the creation and adoption of the pediatric surgery antibiotic prophylaxis guidelines in 2009, the antibiotic guidelines were posted in every pediatric surgery operating room and provided to all rotating residents in a pediatric surgical resident handbook. The handbook is only provided to general surgery residents rotating on the pediatric surgery service. Pediatric surgical and anesthesia faculty members were also provided with copies of the guidelines (Table 1). This dissemination was not accompanied by any formal teaching or other educational initiatives.

Study design

A 7-week observational study was performed at Children’s Memorial Hermann Hospital to assess antibiotic prophylaxis guideline adherence and implementation fidelity compared with documentation of compliance. The electronic medical records were reviewed to evaluate antibiotic compliance as documented by the operating room nurse. The nurse is required to document antibiotic prophylaxis compliance for each case as an “all or none” measure. This measure was referred to as antibiotic compliance because it does not provide enough detail to evaluate if all aspects of the guidelines were followed. Antibiotic prophylaxis adherence, however, was evaluated on the basis of 5 aspects including appropriate administration, type, timing, weight-based dosing, and redosing of antibiotics. Elective pediatric surgical operations occurring in the operating room, neonatal intensive care unit, or pediatric intensive care unit were observed by 4 research students who were trained to assess adherence to the guidelines (Table 2). They recorded the actual times that antibiotics were administered and that incisions were made. They obtained the dose of antibiotics from the notation of the anesthesiologist in the electronic medical record. Redosing information (time and dose) were also obtained from the electronic medical record. Indication for and appropriateness of antibiotics were determined by the students and principal investigator on the basis of the guidelines. Adherence to all 5 guidelines was evaluated weekly and at the end of the observational period. The operating room team was aware of the students’ presence, but their purpose was not explained. Compliance and adherence with individual antibiotic guidelines are reported as proportions. A chi-square test were used to compare differences in results; significance was defined as \( P < .05 \).

To evaluate practices and communications relating to antibiotic administration, discussions among operating room team members (circulating nurse, surgeon, or anesthesiologist) were directly observed. Each case was observed to determine which team member initiated antibiotic discussion (if at all), if antibiotics were discussed by the team before or after they were administered, and if the discussion demonstrated knowledge of the antibiotic guidelines by the team members. Examples of discussion phrases that exemplified inadequate knowledge of the antibiotics guidelines included “Which antibiotic do you want?” “Does this case need antibiotics?” and “What is the dose of antibiotics?”

Results

Over the 7-week study, 143 cases were directly observed; 139 (97%) took place in the operating room, and the remaining (3%) occurred in the neonatal or pediatric intensive care unit. Convenience (during daytime hours) and purposeful stratified sampling was used so that all of the pediatric surgical subspecialties were represented (Table 3). Antibiotics were given or withheld appropriately in 141 of observed cases (99%). Unnecessary antibiotics were given in 1 case, and indicated antibiotics were inappropriately withheld in the other case. Antibiotics were indicated in 100 of the observed cases (70%). These cases were used to evaluate antibiotic prophylaxis guideline adherence. The

<table>
<thead>
<tr>
<th>Case type</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Gastrointestinal</td>
<td>32</td>
</tr>
<tr>
<td>Skin or soft tissue</td>
<td>21</td>
</tr>
<tr>
<td>Head and neck</td>
<td>18</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>10</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>9</td>
</tr>
<tr>
<td>Neurologic</td>
<td>4</td>
</tr>
<tr>
<td>Thoracic</td>
<td>4</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>1</td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td>1</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Guideline component</th>
<th>Adherent if</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration</td>
<td>Withheld in clean cases and given in all other cases</td>
</tr>
<tr>
<td>Type</td>
<td>Follows Table 1</td>
</tr>
<tr>
<td>Dose</td>
<td>Within 10% of weight-based dose (Table 1)</td>
</tr>
<tr>
<td>Timing</td>
<td>Vancomycin 60–120 min and all other antibiotics 10–60 min before incision</td>
</tr>
<tr>
<td>Redosing</td>
<td>Antibiotics given every 3 h in ongoing cases</td>
</tr>
</tbody>
</table>
type of antibiotic was consistent with guidelines in 97% of observed cases. Antibiotic administration was adherent to (within 10% of the calculated dose) weight-based dosing in 77% of cases. Of the 23 cases with incorrect dosing, the dose was off by 12% to 110% (median, 25%). Antibiotic timing was appropriate according to our guidelines in 73% of cases. Among the 27 timing fallouts, antibiotics were given too long before incision time in 30% (average, 179 minutes), too close to incision time in 55% (average, 4.5 minutes), and after incision time in 15% (average, 100 minutes) of cases. Among cases in which the dose was given too long before incision, the patient was on scheduled antibiotics in 5 cases, and the most recent dose was outside the dosing interval. Surgical preparation, such as arterial line and central line placement, prolonged the duration to skin incision after dosing in the remaining 3 cases. Repeat doses were indicated in 14 cases, and they were administered appropriately in only 1 of those cases (7%). Repeat doses were 1 hour early in 7%, 1 hour late in 36%, and not administered at all in 50% of indicated cases.

Adherence to all 5 antibiotic guidelines occurred in only 48% of cases in which antibiotics were indicated (Fig. 1). Weekly overall adherence was evaluated to assess for any appreciable Hawthorne effect (Fig. 2). Weekly overall compliance did not show any significant change during the study period, with a range of 25% to 67% (P > .05). Documented compliance with antibiotic prophylaxis was 100% for all cases during the observational period.

During the observational period, 92 discussions among the operating room team were observed pertaining to antibiotic prophylaxis. Despite the discussions, 48 cases did not adhere to the guidelines. Discussions occurred before antibiotic administration in only 52% of cases. When discussions occurred, they were initiated most often by anesthesiologists (48%). Surgeons (17%) were less likely to initiate discussion compared with circulating nurses (33%). Observation of discussion content suggested that 50% of total antibiotic discussions did not demonstrate prior knowledge of or familiarity with the antibiotic guidelines.

Comments

Our study is the first to measure implementation fidelity with antibiotic prophylaxis guidelines and to demonstrate the lack of correlation with documented compliance. Nonetheless, the high level of correct administration and withholding of antibiotics as indicated at our center may be a reflection of the increasing awareness of the importance of antibiotic prophylaxis and the penetration of adult SCIP initiatives into pediatric surgery. Such high levels of adherence are not universal. In 2011, Rangel et al reported that among 22 children’s hospitals, there was significant variation in the administration of antibiotic prophylaxis in pediatric surgery; an average of 82% of children received antibiotics when indicated, but an average of 40% of children received them when they were not. Although compliance with antibiotic prophylaxis and other perioperative measures recommended by SCIP has been at the forefront of the adult surgical community since the mid-2000s, tracking of SCIP compliance and SSIs has only more recently been facilitated in pediatric surgery. National collaboratives such as the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) have resulted in the widespread availability of outcome data; however, a pediatric equivalent (ACS NSQIP Pediatric) has only recently been launched. The initial report noted that although the overall incidence of SSIs was low (1.3%), they constitute one-third of all morbidity from pediatric surgical procedures.

Despite increased SCIP compliance in adult surgery, SSIs have failed to decrease. One reason may be that there is an “all-or-none” phenomenon, in that all appropriate antibiotic prophylaxis measures must be followed; compliance with individual measures is insufficient to prevent SSIs. Our data demonstrated that fewer than half of sampled pediatric surgery patients received appropriate prophylactic antibiotics when all guidelines were considered together. Another potential reason for the lack of correlation between SCIP compliance and SSI reduction is the lack of implementation fidelity, measured by adherence. The degree of implementation fidelity can influence the relationship between intervention and outcome; failure to successfully implement an intervention may reduce its effectiveness. Despite the importance of assessing implementation fidelity, it is infrequently done. Our study demonstrates that despite 100% documented compliance with antibiotic prophylaxis measures, overall guideline adherence was only 48%. Documented compliance, which is typically what is reported to

Figure 1 Surgical antibiotic prophylaxis adherence for all guidelines and each guideline.

Figure 2 Adherence with all guideline components by study week.
nation databases, may be a poor marker of guideline adherence. Future studies evaluating the effectiveness of SCIP or other preventive interventions should measure implementation fidelity, not just compliance.

Although there was reasonably high adherence with the correct type of antibiotics (97%), there was significant fallout in all other measures. Incorrect dosing was seen in 23% of cases. This may be attributable to the general lack of experience and knowledge with weight-based dosing in the pediatric population. Because anesthesia and surgical trainees are involved in every operation, there may be a general lack of familiarity with pediatric dosing as well as the impetus for concise dosing calculations because of the poor dissemination strategies. Similarly, other fallouts, such as the timing of antibiotics (73% adherent) and appropriate redosing (7%), suffer from the same dissemination shortcomings.

The lack of implementation fidelity at our institution may be related to the strategies for dissemination and implementation of the guidelines and/or to the context. The observations of the discussions about antibiotic prophylaxis revealed a general lack of awareness and knowledge of the guidelines among operating room team members, suggesting that the guideline dissemination and implementation strategies were ineffective. A dissemination strategy refers to the method with which information pertaining to a particular intervention is distributed. An implementation strategy helps integrate the intervention into practice. The antibiotic prophylaxis guidelines were disseminated passively using educational materials only; the guidelines were given to all team members and posted in each operating room without any associated educational initiatives or other formal implementation strategies. Systematic reviews of dissemination and implementation have suggested that multiple strategies can be effective in improving guideline compliance; however, there is not enough evidence to determine which strategy or strategies are most effective and efficient in which contexts. In general, the distribution of educational materials and educational outreach (often in combination with other interventions) are only modestly effective at improving compliance. In moving forward, the proposed benefits in awareness and knowledge must be balanced against the resources and efforts required for such educational outreach. Single-center studies of implementation of antibiotic prophylaxis measures in adult surgical patients have suggested other potential strategies for implementation, such as the institution of a protocol for instituting a time or location for antibiotic administration, establishing a reminder system for redosing, or delegating responsibility of antibiotic prophylaxis to a specific team member.

Lack of effective implementation at our center may also be related to context. A study of ACS NSQIP–participating hospitals identified several contextual factors that predicted good performance with low rates of SSIs. For example, a positive safety culture, strong leadership support for quality improvement initiatives, and an environment that fostered ease of communication were identified at hospitals with low SSI rates. A recent study by Wick et al demonstrated that a surgery-based comprehensive unit-based safety program, along with other targeted interventions, reduced SSIs. We are currently instituting several initiatives to improve the infrastructure for quality improvement and the safety culture at the children’s hospital in conjunction with our efforts to standardize perioperative practices.

One potential limitation of our study is that there may have been a Hawthorne effect, or an improvement in antibiotic prophylaxis administration due to the presence of observers. However, the presence of a Hawthorne effect would be unlikely to change the conclusions of the study regarding the lack of implementation fidelity. Furthermore, although there was an initial increase in compliance after the 1st week of study, there was little change throughout the remainder of the study period. Another limitation is that this study focused on process rather than outcome measures. The low incidence of SSIs in pediatric surgery limits the feasibility of demonstrating an association between guideline adherence and SSIs in our patients, even with a larger sample size. In addition, process measures are considered to be more sensitive to and more direct measures of quality of care. Studies in other patient populations have demonstrated that improving processes of care have improved population health as measured by patient outcomes. Ultimately, no quality measure is perfect. Studies evaluating the impact of implementation fidelity and adherence on SSIs would require multicenter collaboration, which may become feasible as ACS NSQIP Pediatric gains traction.

Our study demonstrates the importance of measuring implementation fidelity when evaluating the effectiveness of evidence-based guidelines, such as for antibiotic prophylaxis for prevention of SSIs. As we have learned, the creation of guidelines does not necessarily ensure robust implementation fidelity or the establishment of process. The plan to improve implementation fidelity at our institution includes the development of a protocol, the introduction of educational outreach, and the enhancement of safety culture with the formation of a patient safety council and other targeted initiatives. Future study should be directed at identifying the best strategy or combination of strategies for disseminating and implementing guidelines, not just within our local context. Although the identification of preventive measures other than antibiotic prophylaxis is also necessary to further address the problem of SSIs, continued efforts should be directed at measuring and ensuring implementation fidelity before giving up on SCIP antibiotic prophylaxis measures.

References


