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Standardizing preoperative preparation to reduce surgical site infections among pediatric neurosurgical patients

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OBJECTIVE Surgical site infections (SSIs) are costly to patients and the health care system. Pediatric neurosurgery SSI risk factors are not well defined. Intraoperative protocols have reduced, but have not eliminated, SSIs. The effect of preoperative intervention is unknown. Using quality improvement methods, a preoperative SSI prevention protocol for pediatric neurosurgical patients was implemented to assess its effect on SSI rate.

METHODS Patients who underwent a scheduled neurosurgical procedure between January 2014 and December 2015 were included. Published evidence and provider consensus were used to guide preoperative protocol development. The Model for Improvement was used to test interventions. Intraoperative and postoperative management was not standardized or modified systematically. Staff, family, and overall adherence was measured as all-or-nothing. In addition, SSI rates among eligible procedures were measured before and after protocol implementation.

RESULTS Within 4 months, overall protocol adherence increased from 51.3% to a sustained 85.7%. SSI rates decreased from 2.9 per 100 procedures preintervention to 0.62 infections postintervention ($p = 0.003$). An approximate 79% reduction in SSI risk was identified (risk ratio 0.21, 95% CI 0.08–0.56; $p = 0.001$).

CONCLUSIONS Clinical staff and families successfully collaborated on a standardized preoperative protocol for pediatric neurosurgical patients. Standardization of the preoperative phase of care alone reduced SSI rates. Attention to the preoperative in addition to the intraoperative and postoperative phases of care may lead to further reduction in SSI rates.

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KEY WORDS pediatrics; surgical wound infection; improvement science

Surgical site infections (SSIs) are common health care–associated infections that increase patient morbidity and mortality rates and cost the US health care system billions of dollars annually.[32,53] Neurosurgical SSIs in pediatric patients are particularly devastating.[12,58] Published risk factors for SSIs following pediatric neurosurgical procedures have focused predominantly on ventricular shunt procedures and have identified a variety of factors that affect the occurrence of SSIs.[1,23,51,54,56,61] Similarly, numerous risk factors for SSIs in adults following neurosurgery have been identified.[10,55,59] However, the identification of key factors that can prevent SSIs has been elusive. Numerous protocols have been published, and in the absence of a national consensus, current practice is probably institution specific, derived from experience and available evidence.[23,30,36] The Centers for Disease Control and Prevention SSI prevention guidelines define a care continuum for all surgical patients including preoperative evaluation, day of surgery preparation, the procedure itself, and postoperative care (hospital and home).[39] Despite the importance of preoperative attention, our center has not implemented standardized preoperative interventions systematically.

We developed an SSI prevention protocol to address preoperative patient risk factors. Our goal was to standardize practice and to engage families directly in the SSI prevention process. Standardization and family engagement have been shown to improve care among orthopedic surgery patients.[5,13] We hypothesized that standardization of practice and direct family involvement in the preoperative phase of care would generate high protocol adherence and prevent SSIs in our pediatric neurosurgical population.

Methods

Setting and Population

Cincinnati Children's Hospital Medical Center is a 523-

ABBREVIATIONS CHG = chlorhexidine gluconate; SSI = surgical site infection.

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bed academic, freestanding children's hospital. At any point during the study period, the neurosurgical service had up to 4 surgeons who performed approximately 750 routine and complex procedures during calendar year 2014.

Preintervention Care Coordination

A standard intraoperative bundle was implemented in 2009 that recommended preoperative bathing. Surgical candidates were provided with a bottle of baby shampoo when seen in the clinic and were instructed to bathe the night before and the morning of surgery. Adherence to this provision or recommendation was not tracked. The remainder of the bundle included wiping the patient at the anticipated incision site(s) with a chlorhexidine gluconate (CHG)–impregnated cloth prior to operating room transfer, proper intraoperative antibiotic timing, and maintenance of the patient's oxygenation and body temperature.[50] Additionally, many postoperative patients were instructed to cleanse the surgical incision daily with soap and water; this practice was not standardized among all patients or surgeons, and adherence was not tracked.

Inclusion/Exclusion Criteria and Operational Definitions

All patients undergoing elective neurosurgery (defined as surgery planned in advance through the outpatient clinic) between January 1, 2014, and December 31, 2015, were eligible for inclusion. Patients undergoing cerebral angiography, surgery for acute trauma, emergent adverse events (e.g., infection, shunt revision, and so on), and those scheduled for a procedure as inpatients were excluded. Suspected postoperative infections were identified and reviewed by the hospital's infection control program. SSIs were defined using National Healthcare Safety Network definitions and were counted by procedure date.[8] For pre- and postimplementation comparisons, procedures were placed in 1 of the following categories: craniotomy (craniotomy for epilepsy, tumor, third ventriculostomy, posterior fossa decompression, and invasive craniofacial procedure); shunt (any procedure for which the purpose was to place or modify a shunt or extraventricular drain); vascular (craniotomy for arteriovenous malformation resection or revascularization following moyamoya); implant (placement, revision, or removal of vagal nerve stimulator, intrathecal baclofen pump, or deep brain stimulator); spine (laminectomy, tethered cord release, dorsal rhizotomy, or spinal fusion); and other (dermoid cyst excision or noninvasive craniofacial procedure). This quality improvement initiative was submitted and considered exempt from formal review by the Cincinnati Children's Hospital Medical Center IRB.

Protocol Development

A multidisciplinary improvement team was created to apply the model for improvement method to develop and implement a preoperative SSI prevention protocol.[35] The team discussed existing practice, published evidence, and provider preference to determine the 5 protocol components assigned to 3 groups of stakeholders: neurosurgery clinic nurses, patients/families, and preoperative unit nurses (Table 1).

Adherence Measurement

Adherence measurements were made according to the stakeholder responsible for component completion. There were 3 neurosurgery clinic nurse measures, up to 3 patient/family measures, and 2 preoperative unit nurse measures. The number of patient/family measures varied depending on skin integrity and *Staphylococcus aureus* screening results. In addition to bathing, families were expected to mitigate skin issues and/or undergo *S. aureus* decolonization only if skin issues and/or colonization were identified.

Intraphase Communication

Prior to this project, we observed that information gathered and actions prescribed by the clinic nurses did not reach the preoperative nurses reliably. Additionally, preoperative activities were not tracked in a standard fashion, such that it was unclear whether practices were being followed and by what percentage of patients. To streamline the information shared and to produce analyzable data, a tracking document was developed to compile all adherence data sequentially from each of the stakeholder groups. Clinic nurses completed documentation of the measures for which they were responsible (Table 1). On Friday, the forms were scanned and emailed to the preoperative area for patients who were scheduled for surgery the following week. Preoperative nurses documented adherence to the remainder of the measures through patient and family questioning and self-report.

Patient/Family Reminders

Initial failure analysis revealed that patient bathing was the most common failure. We hypothesized that reminders provided through printed materials and telephone conversations would improve patient/family bath adherence. We modified the protocol to include reminders at 3 different time points: 1) At approximately 3 months postimplementation, we added a telephone call by neurosurgery staff to patients/families when the date of surgery was set (preoperative telephone call); 2) at approximately 4 months postimplementation, we revised our printed bathing instructions for clarity and to target individual patients based on age and *S. aureus* colonization status; and 3) at approximately 5 months postimplementation, we added an additional telephone call when *S. aureus* screening results were available (*S. aureus* result telephone call).

Statistical Analysis

Adherence data were collected prospectively and managed using REDCap electronic data capture tools hosted by the University of Cincinnati Center for Clinical and Translational Science and Training.[22] Each protocol component was counted as a success if completed and as a failure if not completed. If all data for a patient were missing from a given stakeholder (clinic nurse, patient/family, preoperative nurse), that patient was excluded from adherence calculations for that phase. Process all-or-nothing measures included protocol adherence for clinic nurses, families, preoperative nurses, and overall (all measures combined). Process data were validated prior to adherence calculations by manual review of any identified failure. Run charts were

TABLE 1. Preoperative protocol components

Component	Stakeholder	Task	Basis for Inclusion
Skin integrity assessment	Clinic nurse	Nurse screens for acne, eczema, & other potential barriers to proper healing. Nurse refers patient for further assessment based on results.	Acute wound healing is enhanced by removing barriers to proper healing, including low-pathogenicity organisms such as *S. epidermidis* & *Propionibacterium acnes*.[11,20,49]
	Family	Patient follows recommended actions to mitigate identified barriers.	
S. aureus screening/decolonization	Clinic nurse	Patient is screened in 2 body sites for both MSSA & MRSA.	Patients known to have *S. aureus* colonization preop have an increased risk of SSI.[33] Decolonization protocols targeting *S. aureus* have been shown to reduce *S. aureus* SSIs among adult patients undergoing hip & knee replacement procedures.[4,31,44,47]
	Family	Patient who has MRSA or MSSA colonization undergoes a decolonization protocol.	
CHG baths	Clinic nurse	Nurse provides family w/ baby shampoo, 2% CHG solution, & written instructions for bathing.	Multiple baths or showers w/ CHG can reduce organisms present on the patient's skin.[7,25,43]
	Family	Patient is bathed w/ shampoo &/or 2% CHG the night before & the morning of surgery.	
CHG wipes	Preop nurse	Nurse wipes patient's anticipated surgical site(s) w/ 2% CHG wipe.	See above.
Patient warmer	Preop nurse	Nurse places a forced-air warming blanket on patient & documents temperature prior to transfer to operating room.	Hypothermia is a risk factor for SSI.[34,40]

MRSA = methicillin-resistant *S. aureus*; MSSA = methicillin-sensitive *S. aureus*.

generated using SAS 9.3 (SAS Institute) for each phase to assess the effect of interventions over time.

Data were analyzed for all eligible patients per 2-week period. Preliminary median rates for each stakeholder group were established based on the first 8 points on the chart. Special cause (a pattern of performance that was not part of the existing system as a result of a change in the system) analysis was used to identify a statistically significant change in adherence rate, defined as ≥ 8 consecutive points greater than or less than the median.[46] We sought to achieve 90% protocol adherence for staff, families, and overall. This goal was set based on an expectation of 10^{-1} performance (≤ 10 errors per 100 opportunities), which we believed would be sufficient to affect the SSI rate.[35]

For pre- and postimplementation comparisons, we derived two cohorts who met inclusion criteria from our institution's surgical database. To examine cohort differences by demographic data, procedure type, and surgeon, we used 2-tailed t-test and chi-square calculations. To examine differences in SSI by procedure type and surgeon, we used chi-square tests to compare the proportion of procedures performed that resulted in SSIs in each period. For the SSI rate comparison, we calculated a Pearson chi-square value and risk ratio to compare preimplementation (January 1, 2012, to December 31, 2013) and postimplementation (January 1, 2014, to December 31, 2015) rates using SAS 9.3. Fisher's exact test was used to calculate p values, with $p < 0.05$ considered statistically significant.

Results

Protocol Adherence

Adherence data were available for 683 of the estimated 801 eligible procedures (85.3%). The preliminary median protocol adherence for clinic nurses was 92.9% and improved to 100% in January 2015; clinic nurse adherence for the 24-month period was 95.9% (data not shown). The median protocol adherence for preoperative nurses was sustained at approximately 100% throughout the study period; preoperative nurse adherence for the 24-month period was 94.8% (data not shown). The preliminary median protocol adherence for patients/families was 83.8% and improved to 100% in March 2014 following introduction of the preoperative telephone call. The process showed a high degree of variability and shifted to 85.7% in February 2015; family adherence for the 24-month period was 89.5% (data not shown). Combining measurements from all 3 phases yielded an overall preliminary median protocol adherence of 56.3%. Adherence began to increase following introduction of the preoperative telephone call (Fig. 1A) and demonstrated special cause with introduction of the revised bathing instructions (Fig. 1B) and *S. aureus* result telephone call (Fig. 1C). Adherence ultimately reached 87.9% within 6 months of implementation and was sustained for 18 months. Overall adherence for the 24-month period was 80.6%.

Occurrence of SSIs

Preimplementation, the mean age of patients was slightly older; sex and race did not differ. Types of procedures performed differed only for vascular procedures. Four of the 6 surgeons had a different proportion of eligible procedures performed (Table 2). The proportion of shunt procedures resulting in an SSI decreased in the postimplementation period, and 1 provider had a lower SSI rate (Table 3). The SSI rate prior to protocol implementation was 2.9 per 100 procedures. Following protocol implementation, the rate decreased to 0.62 infections per 100 procedures (Fig. 2) (Pearson chi-square 11.5; $p = 0.003$), with an approximate 79% reduction in SSI risk (risk ratio 0.21, 95% CI 0.08–0.56; $p = 0.001$) (Table 4).

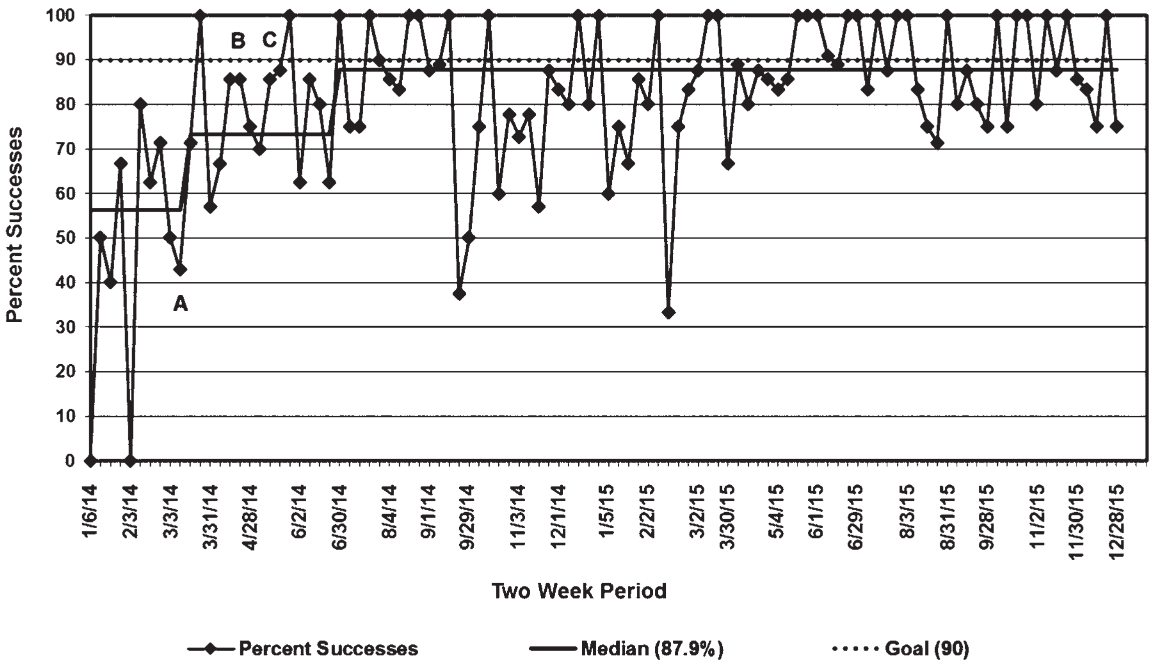

FIG. 1. Overall protocol adherence rate. *Diamonds* represent percentage of adherent procedures per 2-week period; the horizontal axis is labeled approximately monthly. *Thick black line* represents median percentage of adherence; *dotted gray line* represents goal percentage of adherence. *Letters* denote timing of protocol modifications. A = preoperative reminder telephone call; B = revised patient education and instructions; C = *S. aureus* result reminder telephone call.

TABLE 2. Cohort characteristics

Variable	Preimplementation	Postimplementation	p Value
Mean age in yrs (range)	9.4 (0–35.3)	8.4 (0–31.6)	0.01
Female sex	262 (42.6)	391 (48.8)	0.21
Race			0.63
White	502 (81.6)	652 (81.4)	
Black or African American	56 (9.1)	68 (8.5)	
Other*	57 (9.3)	81 (10.1)	
Procedure type			
Craniotomy	281 (45.7)	349 (43.6)	0.67
Implant	117 (19.0)	101 (12.6)	0.10
Spine	97 (15.8)	171 (21.4)	0.13
Shunt	74 (12.0)	68 (8.5)	0.27
Vascular	0 (0)	23 (2.9)	<0.01
Other	46 (7.48)	89 (11.1)	0.17
Surgeon			
A	64 (10.4)	9 (1.1)	<0.01
B	295 (48.0)	297 (37.1)	0.03
C	3 (0.5)	0 (0)	0.54
D	239 (38.9)	269 (33.6)	0.28
E	10 (1.6)	137 (17.1)	<0.01
F	4 (0.7)	89 (11.11)	<0.01

Values are number of patients (%) or mean (range).

* Other races include Asian, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, unknown, and other.

Discussion

The prevention of SSIs in pediatric and adult settings has focused mainly on the intraoperative phase of care. Although effective at reducing SSI rates in many settings, these measures alone have not shown consistent control, nor elimination of SSIs.[29,30,52,57] We had an a priori belief that to achieve further reduction, and possibly elimination, of SSIs, attention must be paid to the entire surgical care continuum, namely the pre-, intra-, and postoperative phases of care. Others have shown that a multidisciplinary approach to SSI prevention can reduce rates in adult colorectal and pediatric orthopedic contexts.[2,21,28] Based on Centers for Disease Control and Prevention guidance,[39] we developed and implemented a standardized preoperative protocol for patients undergoing elective surgery. Subsequently, our SSI rate decreased significantly.

Protocol Composition

Our choice of protocol components was driven by high-quality, rigorous evidence when available. Because such evidence is limited for prevention of pediatric neurosurgical SSIs, the relevant pediatric literature was used with adult literature from neurosurgical and other surgical specialty areas (Table 1). We were careful to choose only those measures we thought would be most appropriate for pediatric populations.

Preoperative bathing that includes multiple CHG cleansings has been shown to affect SSI rates positively.[15,18,26] When subjected to meta-analysis, benefit for cleansing with CHG when compared with other cleansing was not observed, although study variability and quality probably affected the analysis.[14] CHG cleansing has be-

TABLE 3. SSIs by procedure type and provider

Variable	Preimplementation		Postimplementation		p Value*
Procedure type	No.	SSI (%)	No.	SSI (%)	
Craniotomy	281	4 (1.4)	349	1 (0.3)	0.35
Implant	117	6 (5.1)	101	2 (2.0)	0.16
Spine	97	5 (5.2)	171	2 (1.17)	0.07
Shunt	74	3 (4.1)	68	0 (0)	0.04
Vascular	0	0 (0)	23	0 (0)	—
Other	46	0 (0)	89	0 (0)	—
Surgeon					
A	64	1 (1.6)	9	0 (0)	0.20
B	295	8 (2.7)	297	2 (0.67)	0.22
C	3	0 (0)	0	0 (0)	—
D	239	9 (3.8)	269	2 (0.7)	0.10
E	10	1 (10)	137	1 (0.73)	<0.01
F	4	0 (0)	89	0 (0)	—

* The p values were calculated using the percentage of procedures that resulted in an SSI.

TABLE 4. SSI risk ratio

Variable	Preimplementation	Postimplementation
No. of procedures	597	796
No. of infections	18	5
Infection rate, %	2.9	0.62
Risk ratio (95% CI)	0.21 (0.08–0.56); $p < 0.01$	

come a standard preoperative practice across many surgical specialties, in part due to a belief that preoperative bathing reduces skin bacterial load and therefore protects against SSIs.[17,24,25,45,60] Our group shared this belief, and thus we included CHG cleansing in our protocol.

Patient/Family Adherence

Our most common failure was patients failing to complete preoperative skin cleansing. Our reminder interventions helped increase family adherence to bathing and probably influenced overall protocol adherence. Reminders such as telephone calls and text messaging have improved adherence to care protocols among patients with chronic illness[19] and most recently among adults specifically for preoperative bathing.[16] When asked to describe barriers to bathing, most families reported difficulty with the morning bath (given long travel distances), young or developmentally delayed patients, and early report times (not shown). It is unclear whether a single bathing the night before surgery is sufficient to affect SSI prevention. Further study is necessary to determine how many baths and with what agents are the minimal effective combination to maximize SSI prevention.

Prevention of SSIs

Pre- and postimplementation cohorts were similar in most characteristics examined. Where they differed is unlikely to have significantly influenced our SSI rate. Patients in the postimplementation cohort were younger, which would have increased their SSI risk.[54] Vascular procedures were performed in the postintervention period only, but none resulted in an SSI (not shown). Of the 6 providers, 4 had a different proportion of eligible procedures performed. This was due to personnel turnover, with Surgeons A and C leaving and Surgeons E and F joining the group. The difference in SSI rate observed for Surgeon E is probably a function of a > 10-fold increase in case load, while having 1 SSI in each period. We do not believe that the decrease in overall SSI rate is due to the change in personnel, because when the same calculations were per-

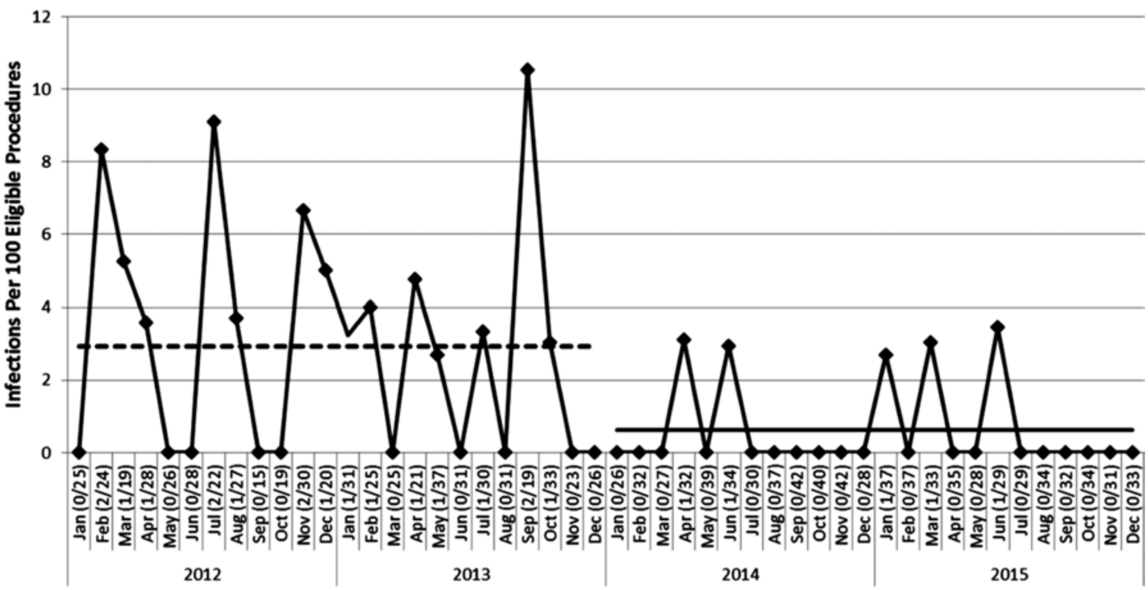

FIG. 2. The SSI rate per 100 eligible procedures. The *dotted line* denotes the SSI rate prior to protocol implementation, and the *solid line* denotes the SSI rate following protocol initiation in January 2014.

formed for Surgeons B and D, who performed the majority of procedures in both periods, a significant decrease in rate was observed (not shown).

During the pre- and postintervention periods, no systematic changes were made to intra- or postoperative practices. Of the 6 neurosurgical providers who were active during the 2 periods, many followed published evidence derived from a variety of sources. The addition of new surgeons to the group did not change the practice of the existing practitioners, and no one set of practices was shared by all surgeons. Adherence to the existing perioperative bundle was measured for antibiotic timing, hyperoxygenation, and normothermia, and did not change significantly (not shown). We therefore concluded that standardizing preoperative care affected the SSI rate. However, as a quality improvement initiative, we were unable to infer causality directly.

Previously published studies of protocols have shown SSI rate reduction for specific procedures, such as ventricular shunts or spinal fusions.[2,21,30] We purposefully implemented this protocol for all scheduled neurosurgical procedures to test whether an effect on the SSI rate would apply beyond procedures for which there is evidence of efficacy. Our results, along with published studies, suggest that preoperative standardization may improve SSI rates in multiple—possibly all—surgical procedure types. Broad standardization of patient preparation prior to surgery may lead to significant reduction in all SSIs, which recently have been found to be the most common health care–associated infections in the US.[38]

Limitations of the Study

As in any quality improvement project, context probably played a significant role in our success.[27] Our institution has a strong emphasis on safety culture, and quality transformation is embedded in its framework.[6] Additionally, we had strong leadership support from the neurosurgeon group, perioperative staff, and the institution's infection control program, all of which probably influenced our success.[48]

Our interpretation of project results is subject to limitations that are typical of quality improvement efforts. We were unable to conclude directly that preoperative protocol implementation caused a reduction in SSI rates. Adherence data were available for 85% of eligible procedures, and we were unable to determine if something different done for the remaining 15% affected our overall rates. This is unlikely because we found similar results when we compared pre- and postimplementation data using only patients for whom adherence data were available (data not shown).

Our results were potentially confounded by other SSI prevention efforts in our institution, among orthopedic spine and cardiothoracic patients. A meaningful effect on neurosurgical patients is unlikely because crossover of perioperative staff between the 3 specialties seldom occurs. Our adherence data may be confounded by the Hawthorne effect, where the measurement of activity increases the likelihood of activity completion.[9] We do not believe that this effect had a major influence on our process, because it generally dissipates over time,[3] and our reliability was sustained for > 12 months.

Furthermore, family adherence data are subject to social desirability (e.g., the patient telling the provider what he thinks the provider wants to hear) and recall bias.[42] Recall bias is unlikely because families were recalling actions they had taken the night before and the morning of the interview. To avoid social desirability bias, preoperative staff elicited adherence nonthreateningly, such as asking the patient, "Were you able to complete the bathing regimen?" Although we cannot rule out social desirability bias, we do know that many families were willing to tell us when they were not adherent.

Our project was not designed to determine if any components of the protocol provide greater protection than others. Adult studies have shown SSI reduction using a care protocol but could not demonstrate one component that rises above the rest.[57] Similarly, a recent publication by the Hydrocephalus Clinical Research Network found a significant association of antibiotic-impregnated catheter with fewer shunt infections, but the addition of antibiotic-impregnated catheters to a prevention bundle failed to decrease infection rates.[29] Our project was based on the belief that the standardization of processes with high reliability leads to safer care.[37,41] It is possible that the standardized approach played a significant role in the outcome improvement, perhaps to an equal or greater extent than the bundle components themselves. Finally, as a report of a single center's experience, and by excluding unplanned and urgent cases, our results may have limited generalizability.

Conclusions

We developed a reliable SSI prevention system in the preoperative phase of the surgical continuum. Standardization of the preoperative phase of care in the context of partial standardization of intra- and postoperative phases reduced SSI rates. Attention to the preoperative in addition to the intraoperative and postoperative phases of care may lead to a reduction in SSI rates.

Appendix

Preoperative SSI Prevention Team Members

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Disclosures

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Author Contributions

Conception and design: Schaffzin, Connelly, Mangano. Acquisition of data: Schaffzin, Simon. Analysis and interpretation of data: Schaffzin, Simon, Mangano. Drafting the article: Schaffzin. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Schaffzin. Statistical analysis: Simon. Study supervision: Connelly, Mangano.

Supplemental Information

Previous Presentations

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