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Perioperative Antibiotic Use for Spinal Surgery Procedures in US Children's Hospitals

Lisa M. McLeod, MD, MSCE,* Ron Keren, MD, MPH,*† Jeffrey Gerber, MD, PhD,*‡ Benjamin French, PhD,† Lihai Song, MS,* Norma R. Sampson, MS,§ John Flynn, MD,§ and John P. Dormans, MD§

Study Design. Retrospective cohort study using the Pediatric Health Information System database.

Objective. To describe longitudinal patterns of prophylactic antibiotic use and determinants of antibiotic choice for spinal fusion surgical procedures performed at US children's hospitals.

Summary of Background Data. Surgical site infections (SSIs) account for a significant proportion of post–spinal surgery complications, particularly among children with complex conditions such as neuromuscular disease. Antimicrobial prophylaxis with intravenous cefazolin or cefuroxime has been a standard practice, but postoperative infections caused by organisms resistant to these antibiotics are increasing in prevalence. Studies describing the choice of antibiotic prophylaxis for pediatric spinal surgery are lacking.

Methods. We included children 6 months to 18 years of age discharged from 37 US children's hospitals between January 1, 2006, and June 30, 2009, with (1) an *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) procedure code indicating a spinal fusion and (2) combinations of diagnosis codes indicating adolescent idiopathic scoliosis (AIS) (n = 5617) or neuromuscular scoliosis (NMS) (n = 3633). After identifying antibiotics ordered on the operative day, we described variation in broad-spectrum antibiotic use over time and measured associations between patient/surgery characteristics and antibiotic choice.

Results. Prophylactic antibiotic choice varied across hospitals and over time. Broad-spectrum antibiotics were used in 37% of AIS and 52% of NMS operations. Seven (19%) hospitals used broad-spectrum coverage for more 80% of all cases. For NMS procedures, broad-spectrum antibiotic use was associated with patient characteristics known to be associated with high SSI risk. Use of vancomycin and broad gram-negative agents increased over time.

Conclusion. Broad-spectrum antimicrobial prophylaxis varied across hospitals and was often associated with known risk factors for SSI. These results highlight the need for future studies comparing the effectiveness of various prophylaxis strategies, particularly in high-risk subgroups. This research can inform the development of best practice for SSI prevention in spinal fusion procedures.

Key words: antimicrobial prophylaxis, surgical site infection, scoliosis, practice variation, spinal fusion. **Spine 2013;38:609–616**

Level of Evidence: 3

Surgical site infections (SSIs) result in more than 8000 deaths in US hospitals each year, costing the health-care system $3.5 to $10 billion annually.[1,2] For children who have undergone spinal fusion procedures, SSIs are particularly devastating and costly. Treatment of these infections often requires multiple readmissions, additional surgical procedures for wound debridement or device removal, and prolonged antibiotic therapy, in some cases resulting in $80,000 to $100,000 in additional cost per surgery.[3]

The majority of SSIs after orthopedic procedures are caused by contamination of the surgical site with naturally occurring skin flora, primarily *Staphylococcus aureus* and *Staphylococcus epidermidis*.[4,5] As such, antimicrobial prophylaxis with drugs such as cefazolin, which have activity against these organisms, has been accepted as an effective practice for SSI prevention.[5,6] However, the proportion of infections caused by methicillin-resistant Staphylococci has risen to more than 20% in some centers.[6] In addition, the microbiology of SSIs in medically complex surgical patients—often colonized by flora from the intestinal and urinary tracts—has shifted toward organisms with higher levels of resistance to cefazolin such as *Enterococcus spp*. and gram-negative bacilli, including *Escherichia coli*, *Pseudomonas aeruginosa*, and *Proteus mirabilis*.

Despite the standard use of perioperative cefazolin in pediatric spinal fusion procedures, 1% to 3% of operations involving healthy children with idiopathic disease and 1 in 6 (17%) operations involving children with neuromuscular disease are complicated by SSIs.[7–17] Being more prone to infections with gram-negative bacilli, medically complex children are

From the *Department of General Pediatrics, Center for Pediatric Clinical Effectiveness, Children's Hospital of Philadelphia, Philadelphia, PA; †Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia, PA; ‡Division of Pediatric Infectious Diseases, Children's Hospital of Philadelphia, Philadelphia, PA; and §Division of Orthopaedic Surgery, Children's Hospital of Philadelphia, Philadelphia, PA.

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Address correspondence and reprint requests to Lisa M. McLeod, MD, MSCE, 3535 Market St, Ste 1509, Philadelphia, PA 19104; E-mail: lisa.mcleod@me.com

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theoretically ideal candidates for broad-spectrum antibiotics.[7,12,13,18,19] However, adequate comparative effectiveness studies of broad-spectrum *versus* cefazolin-only prophylaxis have not been performed, and the cost *versus* benefit of such practices is unknown. Consequently, antimicrobial prophylaxis practice patterns vary. Understanding current antimicrobial prophylaxis practice patterns and exploring factors that may influence decisions about antibiotic choice are essential first steps toward establishing standards of care for SSI prevention practices in spinal fusion procedures.

Therefore, we performed a retrospective cohort study using the administrative records of all children with adolescent idiopathic scoliosis (AIS) and neuromuscular scoliosis (NMS) who had a spinal fusion performed at 1 of 37 US children's hospitals from 2006 to 2009. We described the variation in perioperative antibiotic use across hospitals and over time and measured associations between patient- and procedure-specific characteristics and the use of broad-spectrum antibiotic prophylaxis.

MATERIALS AND METHODS

Study Design

Retrospective cohort study.

Data Source

The Pediatric Health Information System (PHIS) contains detailed hospital administrative and billing data from 43 freestanding children's hospitals affiliated with the Children's Hospital Association (CHA). Contributing hospitals are located in 17 of the 20 major metropolitan areas in the United States and represent a significant proportion of centers that perform spinal surgery on children. PHIS data include patient demographics; admission and discharge date, pre- and postoperative lengths of stay, insurance type, primary and secondary diagnoses and procedures, and all itemized charges, including pharmacy charge data. Data are quality checked by CHA before being published for use.

Selection Criteria

We first excluded all years of data from 4 of the PHIS/CHA hospitals and 4 quarters of data from each of 2 hospitals because of missing pharmacy charge data. We then selected records from the database with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) procedure code for spinal fusion procedure and diagnostic code indicating nontraumatic spinal deformity (13,826 procedures on 13,252 children). If spinal fusion was not listed as the primary procedure, we confirmed that primary and secondary procedures were related to spinal fusion operations (*e.g.*, bone graft, chest wall incision, or vertebral resection).

We excluded admissions with concurrent procedures, such as dental extractions, which may require specific antibiotic prophylaxis. To ensure that operative day antibiotics were initiated only for procedural prophylaxis, we also excluded any admission with a preoperative length of stay longer than 2 days and/or age less than 6 months at the time of admission, leaving 11,471 procedures on 11,105 children.

We reviewed all diagnosis and procedure codes for all hospitalizations of the remaining patients and defined 2 cohorts—AIS and NMS. The NMS cohort was defined by selecting any child with a diagnosis of neuromuscular disease (*e.g.*, Duschenne muscular dystrophy or spinal muscular atrophy), neurological impairment, spina bifida, or cerebral palsy.[20] From the remaining 7472 non-NMS admissions, the AIS cohort was defined by excluding children with (1) diagnoses and procedures indicating chronic medical or surgical conditions[21]; (2) diagnoses or procedures suggestive of non-idiopathic disease, including rod lengthening, hemivertebrae, Klippel-Fiel Syndrome, and spondylolisthesis; or (3) age at index operation less than 10 years.[22]

To identify the presence of gastrointestinal ostomies (colostomies and gastrostomy tubes), tracheostomies, and ventricular drainage devices (shunts), we used only *ICD-9-CM* codes recorded for the index admissions and admissions prior to the index hospitalization. In order to account for the possibility that antibiotic choice might be dictated by prior SSIs, we included only the first surgical admission for each child. Children with less than 6 months of prior data were excluded from the study. Two hospitals performed many fewer procedures per year relative to the other centers (<5 *vs.* >22 procedures per year) and were excluded from the study (n = 49, 0.5%).

Outcomes

Identification of Perioperative Antibiotics

Using the daily pharmacy billing data, we identified all antibiotics given to a patient on each day of their hospitalization. We characterized the operative day antibiotic regimen as the intravenous antibiotic(s) ordered on the day of the procedure (for 99% of the patients, this was the first or second hospital day). We then grouped prophylaxis strategies into 4 categories on the basis of the most frequently ordered antibiotics: (1) cefazolin only, (2) any vancomycin, (3) any clindamycin, or (4) any broad-spectrum gram-negative coverage with aminoglycosides, third or fourth generation cephalosporins, carbapenems, monobactams, or quinolones.

Statistical Analysis

We described the patient population and use of each SSI prophylaxis strategy within and across hospitals using means and percents.

Univariable and Multivariable Analyses

To account for the clustering of patients within hospitals, we used multilevel logistic regression for both univariable and multivariable analyses. We estimated the independent associations between perioperative antibiotic choice and patient/surgery characteristics, using the above-defined categories as binary outcome variables. Separate models were created for (1) all spinal surgery patients, (2) AIS only, and (3) NMS only. Discharge year, sex, government insurance, and age were included in all models *a priori*. Other covariates were retained in the models if (1) the association with the outcome was statistically significant ($P < 0.05$), (2) inclusion altered the estimated effects of other covariates by more than 10%, or (3) inclusion resulted in better model fit based on likelihood ratio testing. Certain covariates, such as prior admissions, neurological impairment, malnutrition, obesity, and anterior surgical approach were highly collinear with other covariates; therefore, we retained in the models only the covariate with the largest effect in univariable analyses.

Estimating Marginal Probabilities

Using logistic regression and accommodating the clustering of patients within hospitals, we estimated marginal probabilities of receiving a particular category of antibiotic for each level of each covariate. The marginal probability is the likelihood that a child will be prescribed a particular antibiotic given a particular characteristic or combination of characteristics, controlling for all other characteristics.[23] All data management and analyses were conducted using Stata12.0 (Stata Corp, College Station, TX).

Our study was considered not to constitute human subjects research by The Children's Hospital of Philadelphia Institutional Review Board according to 45 CFR 46.101(b4), because the participants in PHIS are not readily identifiable. A data use agreement between the CHA and The Children's Hospital of Philadelphia addresses Health Information Privacy and Accountability Act and participant privacy requirements.

RESULTS

Patient Characteristics

We identified 5617 AIS and 3633 NMS index operations at 37 hospitals. Patient and surgery characteristics for the AIS and NMS cohorts are described in Table 1. AIS procedures accounted for 60% of admissions in the cohort. Children with AIS were predominantly female (78%) and rarely had admissions prior to the index surgery. The median ages of the NMS and AIS groups were not significantly different. Forty-one percent of children with NMS had at least 1 admission prior to the index hospitalization and 86% were identified as neurologically impaired. Children with spina bifida and cerebral palsy made up the largest proportion of NMS procedures (42%). Nearly half of children with NMS had a diagnosis indicating a gastrointestinal ostomy, tracheostomy, and/or shunt either on the index hospitalization or on prior hospitalization. Children with spina bifida were the most likely to have shunts (50%), a diagnosis indicating bladder dysfunction (50%), and procedures involving sacral fusions (28%). Posterior fixation was the only predominant surgical approach for both AIS and NMS (88% and 68%). Anterior fixations were rarely identified in children with AIS.

Hospital Characteristics

Hospitals performed a median of 80 spinal surgical procedures per year (22–224) (Figure 1). The proportion of procedures performed for NMS varied from 20% to 60% across hospitals.

Variation Across Hospitals in Broad-Spectrum Prophylaxis

Figure 2 illustrates the variation in antibiotic use for AIS (Figure 2, panel A) and NMS (Figure 2, panel B) procedures performed at each of the 37 children's hospitals from 2006 to 2009. Forty-three percent of all children received at least 1 broad-spectrum agent. Five hospitals accounted for 90% of the vancomycin and clindamycin ordered for procedures during the study period. Nineteen hospitals (51%) used only 1 antibiotic regimen for more than 75% of all spinal fusions performed during the study period: 16 (43%) cefazolin only, 2 (5%) clindamycin (primarily as a single-drug regimen), and 1 (3%) broad-spectrum coverage for both gram-positive and gram-negative organisms. Drugs other than cefazolin, clindamycin, vancomycin, aminoglycosides, and third-/fourth-generation cephalosporins made up less than 1% of all operative day antibiotics ordered.

Characteristics Associated With Broad-Spectrum Prophylaxis

Age and sex were not associated with the use of broad-spectrum coverage in either population. Children with NMS were more likely than those with AIS to receive all forms of broad-spectrum coverage (Table 2). Within the NMS cohort, children with tracheostomies and gastrointestinal ostomies had significantly greater odds of receiving vancomycin (both odds ratio [OR]: 1.6, $P < 0.001$), and children with shunts had the highest odds of receiving clindamycin (OR: 1.8, $P < 0.001$). Independent of other comorbidities, children with spina bifida had 3-fold greater odds of receiving any broad-spectrum coverage. Procedures involving sacral fusion and/or anterior fixation were not associated with greater odds of broad-spectrum prophylaxis.

Variation in Broad-Spectrum Prophylaxis Over Time

Predicted probabilities for the use of each type of antibiotic coverage changed over time for both AIS and NMS procedures (Figure 3). Prophylaxis with vancomycin increased steadily from 2006 to 2009 ($P < 0.01$). Clindamycin use peaked in early 2008 and then decreased significantly ($P < 0.01$) through the remainder of the study period. Conversely, use of broad gram-negative prophylaxis was lowest in early 2008 and subsequently increased throughout the remainder of the study period ($P < 0.01$).

Among children in the NMS cohort, vancomycin prophylaxis was associated only with the presence of tracheostomies (OR: 1.6, confidence interval [CI]: 1.1–2.4) and/or gastrointestinal ostomies (OR: 1.6, CI: 1.2–2.2), and the odds of receiving clindamycin were highest in children with shunts (OR: 1.8, CI: 1.4–2.4). The presence of gastrointestinal ostomies, tracheostomies, and bladder dysfunction had significant associations with the use of broad gram-negative prophylaxis. Independent of other comorbidities, children with spina bifida

TABLE 1. Patient and Procedure Characteristics for Adolescent Idiopathic Scoliosis and Neuromuscular Scoliosis Spinal Fusion Operations Performed at 37 US Children's Hospitals From 2006 to 2009

	Total (n = 9250)	AIS (n = 5617)	NMS (n = 3633)
Patient characteristics			
Age in yr, median (range)	14 (6 mo to 19 yr)	15 (10 mo to 19 yr)	14 (6 mo to 19 yr)
Female, n (%)	6218 (67)	4394 (78)	1824 (50)
Prior admissions, n (%)			
None	7368 (80)	5211 (93)	2157 (59)
1 or more	1882 (20)	406 (7)	1476 (41)
Malnutrition, n (%)	400 (4)	23 (0.4)	377 (10)
Neurological impairment, n (%)	…	…	3134 (86)
Seizure disorder, n (%)	…	…	1075 (30)
Gastrointestinal ostomy, n (%)	…	…	968 (27)
Tracheostomy, n (%)	…	…	263 (7)
Shunt, n (%)	…	…	819 (23)
Bladder dysfunction, n (%)	…	…	451 (12)
Spina bifida, n (%)	…	…	390 (11)
Cerebral palsy, n (%)	…	…	1131 (31)
Other myopathies, n (%)	…	…	828 (23)
Procedure characteristics			
Sacral fusion, n (%)	974 (11)	336 (5)	638 (18)
Approach, n (%)			
Posterior	7435 (80)	4964 (88)	2471 (68)
Posterior/anterior	1542 (17)	627 (11)	915 (25)
Not specified	273 (3)	26 (0.5)	247 (7)
Prophylactic antibiotics*			
Cefazolin only	5306 (57)	3563 (63)	1743 (48)
Any broad spectrum	3944 (43)	2054 (37)	1890 (52)
Any vancomycin	1323 (14)	647 (12)	676 (19)
Any clindamycin	1522 (16)	942 (17)	580 (16)
Any broad gram-negative coverage	1786 (19)	627 (11)	1159 (32)

**With the exception of cefazolin only, each category represents any administration of a particular antibiotic. Patients may receive multiple perioperative antibiotics and therefore totals will not add to 100%.*

had 3-fold greater odds of receiving one of these drugs. Neither sacral fusions nor anterior/posterior *versus* posterior only fixations were independently associated with broad-spectrum antibiotic use.

DISCUSSION

Our study provides a detailed illustration of perioperative antibiotic use in spinal fusion procedures performed at US children's hospitals. We observed significant variation across hospitals and an increase over time in the use of both vancomycin and broad-spectrum gram-negative coverage. In addition, we found that broad-spectrum prophylaxis was associated with patient characteristics related to high SSI risk.[8,17,19,24] However, 63% of hospitals did not use broad-spectrum coverage for the majority of operations involving children with NMS, and we found no association between high-risk sacral fusions and prophylactic antibiotic choice.[13,25] These findings reflect the high degree of uncertainty surrounding which prophylaxis strategies provide the safest care to patients, balancing the risks associated with antibiotic exposure (drug resistance,

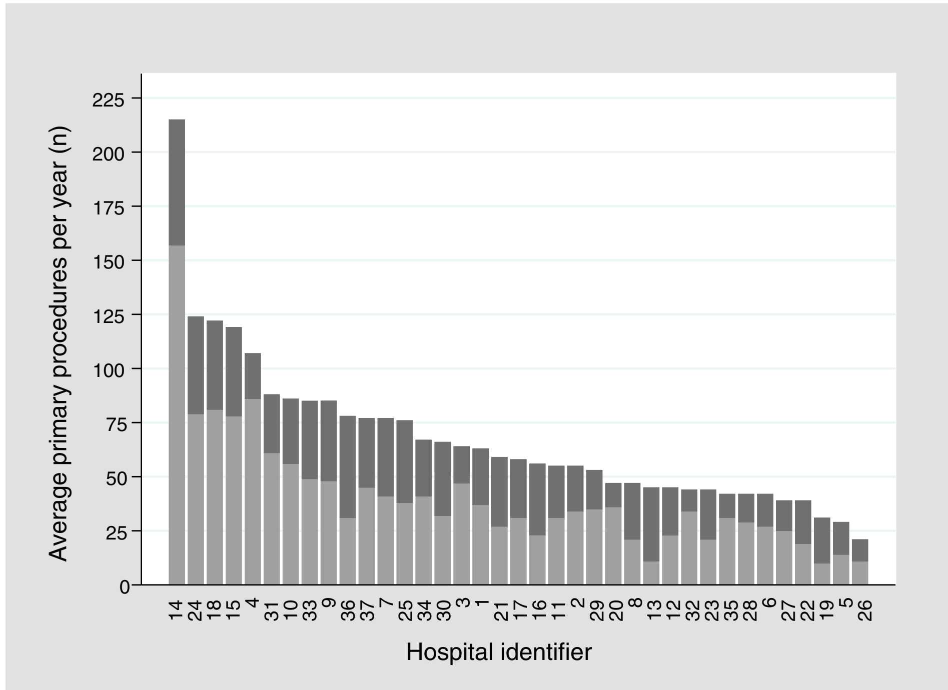

Figure 1. Average annual primary procedures involving children with adolescent idiopathic scoliosis (light gray segments) and neuromuscular scoliosis (dark gray segments) performed across 37 US children's hospitals. Each bar represents a single hospital. Height of each bar is the total number of procedures performed at a particular hospital per year.

adverse effects) with the potential for reducing the risk of SSIs.

The observed practice variation for antimicrobial prophylaxis in spinal surgical procedures likely stems from a lack of evidence to support best practice as well as differing interpretations of the literature by both surgeons and hospital policy makers. Although there are many publications reporting risk factors for SSIs—including spina bifida diagnosis and lower-level fusions—only 1 retrospective study of 176 pediatric spinal fusions found an association between antibiotic choice (clindamycin *vs*. others) and higher SSI risk.[12] There is also limited evidence that broad-spectrum prophylaxis reduces the incidence of SSIs from cefazolin-resistant organisms, in particular. One orthopedic study examining antimicrobial

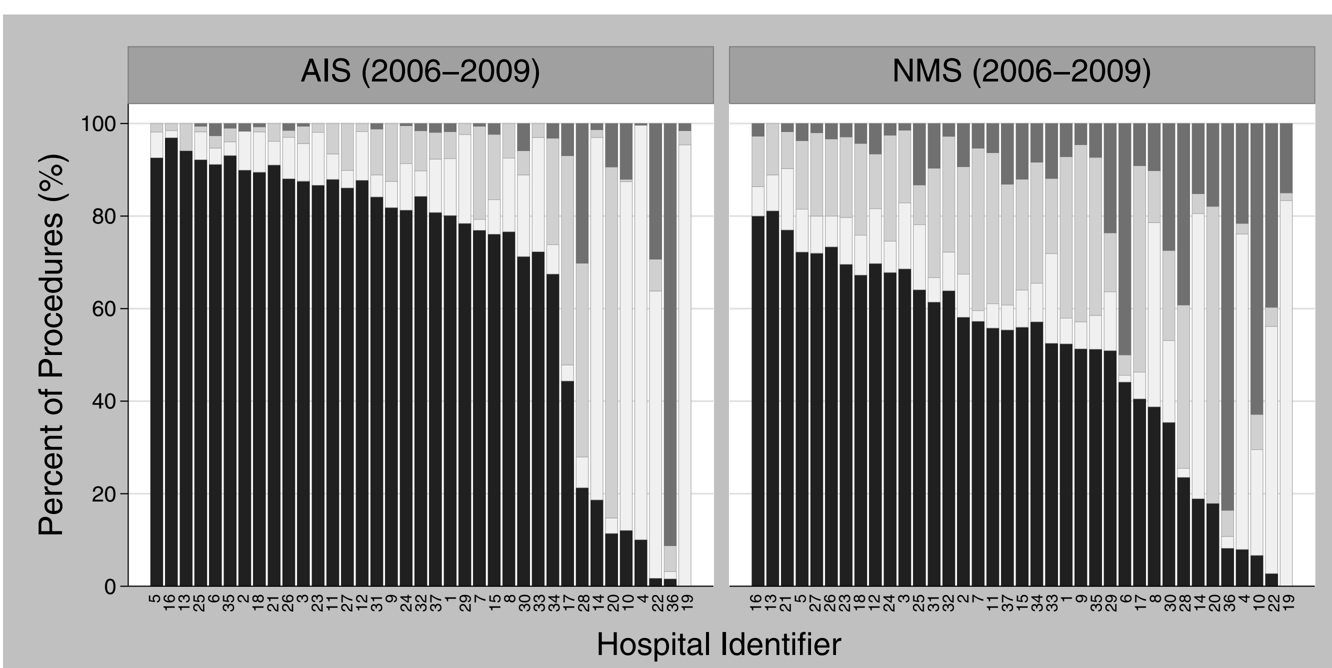

Figure 2. Patterns in prophylactic antibiotic choice for AIS and NMS procedures performed at 37 children's hospitals from 2006 to 2009. Each bar represents a single hospital. Bar segments represent the percent of procedures for which each antibiotic regimen was ordered, including: (1) cefazolin only (black), (2) addition of methicillin-resistant *Staphylococcus aureus* coverage with vancomycin or clindamycin (white), (3) addition of broad-spectrum gram-negative coverage (light gray), or (4) addition of both methicillin-resistant *S. aureus* coverage and broad-spectrum gram-negative coverage (dark gray). Bar height equals 100%. AIS indicates adolescent idiopathic scoliosis; NMS, neuromuscular scoliosis.

TABLE 2. Associations Between NMS Patient and Surgery Characteristics and the Use of Broad-Spectrum Antimicrobial Prophylaxis for Spinal Fusion Procedures

	Vancomycin		Clindamycin		Broad Gram-Negative Coverage	
Covariate	OR* (95% CI)	Predicted Probability†	OR (95% CI)	Predicted Probability	OR (95% CI)	Predicted Probability
All NMS‡	2.1 (1.8–2.5)	0.18	1.6 (1.3–1.9)	0.19	5.5 (4.7–6.4)	0.30
Sacral fusion	0.9 (0.6–1.2)	0.18	0.9 (0.6–1.2)	0.17	1.0 (0.8–1.3)	0.33
Seizures	1.2 (0.9–1.5)	0.21	1.3 (0.9–1.7)	0.18	1.4 (1.2–1.8)	0.36§
Shunt	1.0 (0.7–1.3)	0.20	1.8 (1.4–2.4)	0.21§	1.3 (1.0–1.6)	0.36
Bladder dysfunction	1.4 (0.9–2.0)	0.23	1.3 (0.9–1.9)	0.19	1.6 (1.2–2.1)	0.39§
Tracheostomy	1.6 (1.1–2.4)	0.24§	0.7 (0.4–1.1)	0.14	1.7 (1.2–2.3)	0.39§
Gatrointestinal ostomy	1.6 (1.2–2.2)	0.23§	1.2 (0.9–1.6)	0.18	2.0 (1.5–2.4)	0.40§
Spina bifida	1.2 (0.8–1.7)	0.22	1.1 (0.7–1.7)	0.17	3.1 (2.3–4.1)	0.51§

**Odds ratios measure the relative change in odds of receiving each antibiotic when compared with a child who does not have a particular characteristic and controlling for all other covariates in the model.*

†Predicted probabilities are the likelihood that a child will receive a particular antibiotic given a particular characteristic or combination of characteristics, controlling for all other characteristics. Statistical significance of the differences in these probabilities from the subgroup averages is determined by the significance of the corresponding ORs from the multivariate models.

‡Reference group for change in odds of prophylactic antibiotic use among children with NMS is the AIS cohort.

§Odds ratios and probabilities were statistically significant.

OR indicates odds ratio; CI, confidence interval; NMS, neuromuscular scoliosis.

prophylaxis in adult arthroplasties found that vancomycin use was associated with fewer methicillin-resistant *S. aureus* infections; but in this study, overall rates of SSI remained stable, and numbers needed to treat were high—ranging from 100 to more than 2000 patients.[26,27] No similar studies have been performed in the pediatric surgical population, making it difficult to quantify the risks *versus* benefits of implementing broad-spectrum prophylaxis protocols.

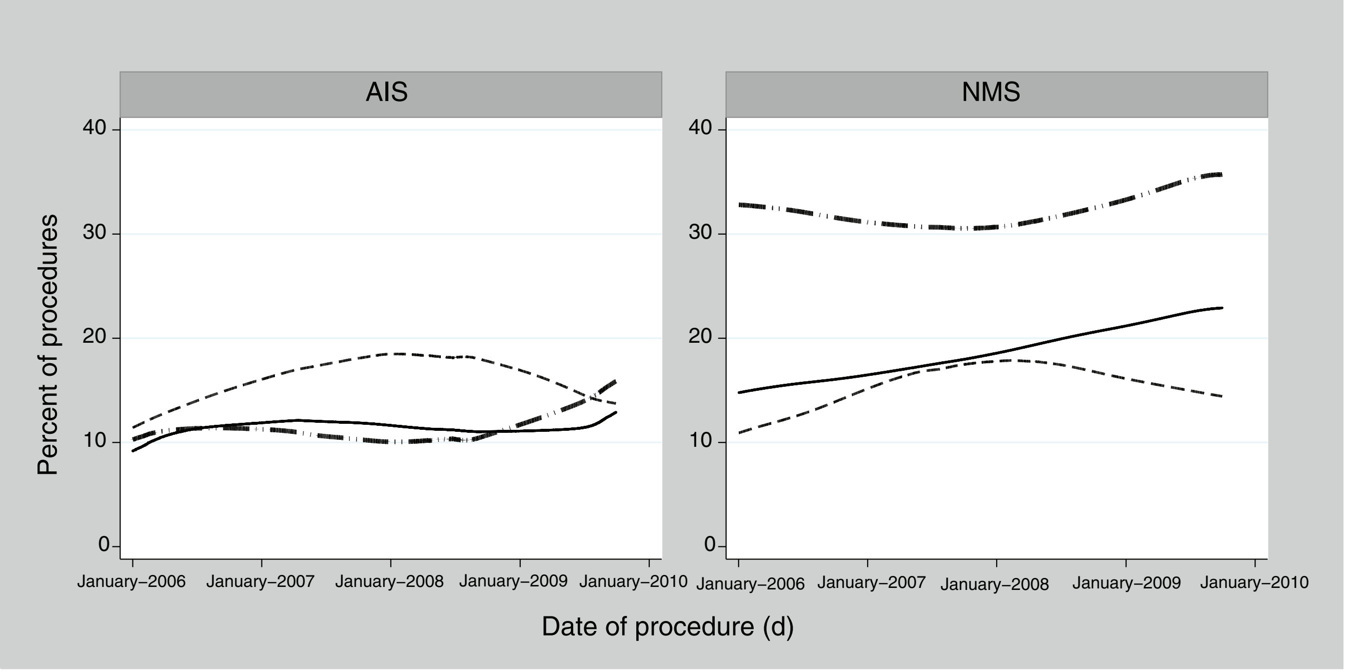

Figure 3. Changes over time in the use of vancomycin (solid line), clindamycin (dashed line), and broad gram-negative coverage (dashed/dotted line). Plotted lines represent the mean predicted proportion of patients receiving each type of prophylaxis as estimated from smoothed logistic regression models, which examine the association between patient-level antibiotic use and the date of each procedure. AIS indicates adolescent idiopathic scoliosis; NMS, neuromuscular scoliosis.

Our study has limitations. The use of *ICD-9-CM* codes to define procedures, patient characteristics, and antibiotic choice may have resulted in some degree of misclassification. However, for procedure identification, codes specific to orthopedic procedures, including hip and knee joint replacements, have been shown to be highly reliable, with positive and negative predictive values of 91% to 99%.[28] For patient diagnoses, we minimized the potential for misclassification by using all diagnoses assigned to each patient and selected the AIS cohort using a comprehensive set of exclusion criteria. To capture antibiotics intended only for prophylaxis, we identified antibiotics given only on the operative day and excluded concurrent procedures that might require specific prophylactic antibiotics, such as dental extractions. Importantly, the observed effect sizes were large, making it unlikely that potential misclassification or unmeasured confounding would alter our findings. However, these data could not reliably identify variables, such as intrawound antibiotic use, rod type, prior infections, and results of preoperative methicillin-resistant *S. aureus* screening, all of which are potential confounders of antibiotic choice and will be important to collect for subsequent comparative effectiveness studies.[29–32]

Our study also has 2 notable strengths. First, PHIS data provide a large sample size distributed across many hospitals. Although limited to 43 institutions, these over-represent the type of center that performs pediatric spinal surgery. Furthermore, although prior descriptions of variation in antimicrobial prophylaxis protocols were limited to small sample cross-sectional studies and physician surveys,[12,13,16,17] we captured all operations performed at each of the 37 hospitals during the study period, representing more than half of the average total procedures performed in the United States each year.[10] Similarly, we had sufficient sample size to stratify patients by specific characteristics, allowing us to describe antibiotic use for surgical procedures involving subgroups of patients with varying baseline SSI risk. Second, in contrast to the large national data sets previously used to describe the spinal fusion population, PHIS longitudinally captures data on uniquely identifiable patients within each hospital.[10,33] This provided an opportunity to explore changes over time in antimicrobial prophylaxis practices for surgical procedures involving specific patient populations within individual hospitals.

CONCLUSION

In summary, antimicrobial prophylaxis for pediatric spinal fusion procedures varied considerably across 37 major children's hospitals. By describing antimicrobial prophylaxis within distinct subgroups of children, this study lays the foundation for a broader research agenda focused on developing standards of care for SSI prevention in high- and low-risk pediatric spinal surgical procedures. Future comparative effectiveness research evaluating SSI rates between antibiotic regimens can identify the incremental value of prophylaxis protocols in specific patient populations; generating evidence for the most appropriate use of broad-spectrum prophylaxis for these procedures.

➢ Key Points

- ❑ Prophylactic antibiotic choice was not consistent among hospitals included in this study.
- ❑ Fourteen (63%) hospitals used cefazolin alone for more than 75% of procedures performed during the study period.
- ❑ Broad-spectrum prophylaxis was used in 43% of all procedures and was strongly associated with high-risk patient characteristics.
- ❑ Prophylaxis with vancomycin and broad-spectrum gram-negative agents increased over time, whereas use of clindamycin declined.

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