Surgical Antibiotic Prophylaxis in Children- Adherence to Guidelines: A Cohort Study

Key words: Antibiotic Prophylaxis; Surgery; Paediatrics; Infectious Diseases

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Abstract

Background: Surgical antimicrobial prophylaxis (SAP) is an important measure to reduce post-operative infections. Guidelines exist, but their efficacy and performance in children is poorly understood, compared with that in adults.

Aims: To review adherence to SAP guidelines, assess risk factors for non-adherence and rate of early post-surgical infections.

Methods: A retrospective cohort study of paediatric surgical cases (0 to < 18 years) at a tertiary children's hospital was performed. Patient characteristics, surgical factors, and antimicrobial details were evaluated against hospital guidelines for overall adherence and domains of: antimicrobial choice, dose, re-dosing, timing and duration. Multiple regression analysis was used to determine risk factors for non-adherence. Hospital records were reviewed for post-operative infections at 7 and 30 days.

Results: Among 326 cases, overall guideline adherence was 39.6% but varied by domain and surgical subspecialty. Incorrect wound classification was

associated with overall non-adherence on multivariate regression (OR: 2.59; $p < 0.001$). Incorrect antimicrobial choice was more likely in children with penicillin hypersensitivity (OR 138.34, $p = 0.004$) and incorrect dosing more likely in adolescent patients (OR 4.33; $p = 0.004$). Presence of invasive devices was associated with prolonged duration of antimicrobials (OR 2.92, $p = 0.016$). Only 2 post-operative infections were documented by 30 days but data were insufficient to exclude mild infections managed in the community.

Conclusions: SAP was suboptimal in children, with areas for improvement including better guidance on wound classification, allergy management and care for adolescent patients. Documented infections were rare but mild infections were unable to be excluded due to limited post-discharge information.

Brief Points:

What is known?

- Surgical antimicrobial prophylaxis (SAP) reduces post-operative infection rates if adhered to correctly
- Poor adherence to SAP is an issue in surgeries in adult populations as it can lead to insufficient cover or antimicrobial overuse
- Paediatric populations have different risk factors and most guidelines rely on extrapolation from adult guidelines

What does this paper add?

- Our study is one of the largest paediatric cohort studies available that assesses risk factors for SAP non-adherence in detail for each domain (correct choice, timing, dose, duration)
- Incorrect wound classification was one of the most important factors in determining non-adherence, and along with other specific risk factors, these results provide opportunities for future improvement in clinical practice
- Adds important new knowledge to improve paediatric specific SAP guideline development

Introduction

An estimated 235 million surgical procedures are conducted worldwide annually. Complications include surgical site infections (SSIs), post-operative pneumonia and sepsis (1). SSIs are among the most common healthcare-associated infections (HAI) worldwide and the most common type in surgical patients. Post-operative stays may be lengthened by 5 to 20 days, at significant cost to patients and care providers (2).

Surgeons classify wounds according to level of contamination and risk of infection, with SSI risk increasing with the level of contamination at the surgical site (3, 4). Surgical antimicrobial prophylaxis (SAP) has been shown to reduce SSI rates for procedures associated with a substantial risk of infection (3). Antimicrobials are given before first incision in the operating room and re-dosed where necessary in longer procedures. Guidelines generally recommend prophylactic antimicrobials are not continued post-operatively, or should be halted within 24 hours after the procedure, depending on type of surgery (5). However there is often poor adherence to these guidelines with regard to timing, dose, and antimicrobial type (6). Whilst children undergo a similar number of surgical procedures requiring prophylaxis as adult patients, paediatric-specific SAP studies are limited (3). Most paediatric guidelines extrapolate recommendations from adult guidelines, with adjustments in drug dosage, typically calculated according to weight in children (3, 7). The risk of infection may also be different for children undergoing similar procedures.

Although children typically have fewer comorbidities than adults e.g. smoking and alcohol related diseases, conversely neonates and young infants may be more susceptible to infection for reasons including immunological immaturity and relative lack of adaptive immunity.

In this study we assessed adherence to local surgical antimicrobial prophylaxis guidelines in children, analysed risk factors for non-adherence to these guidelines, and monitored early post-operative infections in relation to the above to inform practice.

Material and Methods

Setting

The study was performed in a 170-bed tertiary referral paediatric hospital in Australia, co-located with an adult and obstetric hospital with newborn intensive care facilities. Over 10,000 paediatric surgical procedures are performed at this hospital annually. A hospital-wide SAP guideline had been previously developed and is readily available to staff in the operating theatre via the hospital intranet, as well as via posters displayed in all paediatric operating room anaesthetic bays. In addition, hospital doctors have online access to widely-used, comprehensive national SAP recommendations from *Therapeutic Guidelines: Antibiotic* (eTG) via the hospital intranet but these protocols are not specific to the hospital, or to paediatric patients (5).

Data collection

A retrospective patient chart review was conducted over a period of 6 weeks from 5 April 2016 to 10 May 2016. Consecutive paediatric patients who underwent surgical procedures in the study period were identified from hospital electronic medical records. All patients aged from 0 days to less than 18 years who had a procedure involving surgical incision were included. Exclusion criteria were: age ≥ 18 years, procedures not including a surgical incision (e.g. non-invasive endoscopies or closed reduction of fractures), patients with documented allergies to antimicrobials other than penicillins, use of non-parenteral dosage forms (e.g. oral antimicrobials for dental surgery as endocarditis prophylaxis), and patients receiving empiric or targeted antimicrobial treatment prior to surgery (e.g. for septic arthritis).

Information collected was divided into 4 categories: 1) patient demographics: age, sex, weight, documented penicillin hypersensitivity, and comorbidities categorised according to organ system; 2) surgical factors: surgical subspecialty, seniority of surgeon and anaesthetist (trainee versus specialist), procedure type, procedure duration; 3) antimicrobial details: indication, timing of initial administration, drug, dose, timing of re-dosing (if required), duration of therapy; and 4) post-operative infection at/after 7 and 30 days. The data was collected and analysed by ZM, and reviewed and discussed weekly with Infectious Diseases Specialists, PP and BM. Any discrepancies about data classifications were resolved by consensus between PP and BM.

Adherence to guidelines was evaluated with reference to established hospital SAP guidelines (7). If guidance for specific scenarios was not available in these hospital guidelines, the online *Therapeutic Guidelines: Antibiotic* (eTG) (5) were used for assessment. SAP was stratified as “indicated” or “not indicated”, according to local hospital guidelines, with reference to surgical wound classification and type of procedure (7). Overall adherence required the following parameters be met: correct choice of antimicrobial(s) administered for the procedure type, correct dose according to body weight (within +/- 10%), correct timing: dose given < 1 hour prior to skin incision, correct re-dosing at appropriate intervals for longer surgical procedures (>4 hours), and correct duration, with SAP given for no longer than 24 hours, even in the presence of post-surgical devices. Adherence was deemed to be correct, incorrect or indeterminable as per Figure 1. A Senior Medical Officer (SMO), surgeon or anaesthetist, was defined as those with specialist qualifications, whilst a Junior Medical Officer (JMO) was defined as a doctor in a specialist-training program.

Statistical/Data Analysis

Descriptive analysis was conducted using Microsoft Excel (2016).

Multivariable logistic regression models were determined using SPSS Statistics (IBM Corp. 2015, Version 23.0. NY, USA). These were used to identify potential risk factors for overall SAP non-adherence, and subcategories of non-adherence: antimicrobial choice, dosage, incorrect timing and prolonged duration. Explanatory variables: age group, penicillin

hypersensitivity, comorbidity, incorrect wound classification, surgical subspecialty, emergency or elective, experience level of surgeon or anaesthetist and the presence of post-surgical devices, were computed with a stepwise backward method (likelihood ratio test $p < 0.05$). In our regression model, the largest subgroups were chosen as the reference group from the beginning, such as paediatric surgery (general surgery) in subspecialty analysis.

Ethics approval was obtained from the Sydney Children's Hospital Network Human Research Ethics Committee.

Results

In our study period, 379 records were reviewed and 53 cases were excluded, leaving 326 cases included for analysis [Figure 2]. In 8 cases where SAP was administered, missing records on some antimicrobial details meant SAP adherence was deemed 'indeterminable'.

Patient demographics

There was a predominance of male patients (64.1%), and median age was 5.6 years (range 0 days to 17.5 years). Median weight was 20 kilograms (range 2.4kg to 117.9kg) [Table 1].

The majority of patients had no recorded comorbidity (72.1%) but a range of comorbidities were reported [Table 1].

Procedural Factors

The largest number of procedures were performed by the general surgery team (n = 122, 37.4%) followed by plastic surgery (n=64, 19.6%) and orthopaedics (n =53, 16.3%) [Table 1]. Most cases were elective rather than emergency (n=192, 58.9%), but this varied by speciality. Notably, Ear, Nose and Throat (ENT) and urology procedures were predominantly elective procedures (93% and 100% respectively). The primary surgeon was an SMO in 52.5% of procedures; in comparison, anaesthetic SMOs were primary in 75.2%.

Adherence to Guidelines

Overall adherence to SAP guidelines (requiring adherence to all parameters) was 39.6%. Adherence to individual parameters for adherence varied: the

lowest adherence was for correct dose at 59.2% and the highest for correct timing at 85.6% [Table 2]. Only 1 case required re-dosing due to prolonged procedure time, and this was appropriately performed. Adherence to guidelines varied by specialty and was highest for ophthalmology and ENT and lowest for urology [Figure 3].) Incorrect wound classification on the operation report occurred in 46.3% of cases.

On multiple regression analysis, incorrect wound classification was a significant risk factor for overall non-adherence (OR 2.59; 95% CI 1.45-4.61). Adherence also varied by surgical speciality but the only significant difference in adherence by speciality with general surgery as reference group was ENT (more adherent $p < 0.001$). Risk factors for sub-categories of non-adherence are shown in Table 3. Incorrect antimicrobial selection was more common in elective cases and also varied by surgical sub-speciality. It was also more likely in cases where there was a documented penicillin hypersensitivity, but this was a very small number of cases and confidence intervals were wide (OR 138.34; 95% CI 4.89 - 3911.69). Incorrect dose was more likely with adolescents than younger children. For patients with post-surgical devices *in-situ*, SAP duration was more likely to be inappropriately prolonged (incorrect duration OR 2.29; $p = 0.016$), and timing of SAP incorrect, though dosage more likely to be correct.

Post-operative infection at 7 and 30 days

Early discharge and lack of further documentation was common: documentation in hospital records was absent for 68.7% cases (n=224) at 7 days and 81.3% of cases (n=265) at 30 days. Thus for most cases there was insufficient information to exclude mild post-operative infections treated as outpatients or by primary care doctors in the community.

Post-operative infection was recorded in 0.6% of overall cases (2 /326) and these were both urinary tract infections due to *Pseudomonas* species in children who underwent urological surgery and received inadequate SAP, according to guidelines.

Discussion

We report here the first study on adherence of recommended SAP in Australian children. Among 326 cases, we found low overall adherence to hospital SAP guidelines. Risk factors for non-adherence included incorrect wound classification, surgical speciality, adolescent patients, penicillin hypersensitivity and presence of post-operative devices. Reported post-operative infections were uncommon, but we were unable to exclude milder infections that may have been managed in the community, and this is an important limitation of our study.

Overall adherence in our study, although suboptimal, was among the highest rates reported in children compared to other observational studies of SAP in children (8-12). A 2016 Australian point prevalence survey of antimicrobial prescribing National Antimicrobial Prescribing Survey, which included information on 12,634 adults and children from 248 Australian hospitals, reported inappropriate use of antimicrobial in 40% of cases of SAP, but did not include detailed analysis of SAP criteria as we have reported or paediatric-specific data (13). The same group developed another survey tool (SNAPS) to collect more detailed information for surgical antimicrobial prophylaxis and published results of a pilot survey in 2016, with overall inappropriate surgical antimicrobial prophylaxis at just over 43%, but again did not publish paediatric-specific data (14).

We found that incorrect wound classification was the most likely factor to influence non-adherence to SAP guidelines overall. We considered wounds correctly classified if they were in accordance with the local guideline and the principles stated in the 2013 clinical practice guidelines devised by Bratzler et al (3). The system of classifying wounds along a spectrum from 'clean', with a risk of post-surgical infection of 2%, to 'clean-contaminated', then 'contaminated', then 'dirty', with a risk of infection of approximately 40%, is one of the most important factors informing prophylaxis. Information on this classification and its rationale is clearly explained in these documents, but these are unlikely to be read on a daily basis in a busy operating theatre.

Misclassifications may also arise in scenarios with complex patient factors that are not easily classified by the existing guidelines (4), or surgeons might be using alternate guidelines, resulting in different wound classifications, though we did not discover this in discussion with surgeons. Another reason could be inappropriate 'tick-box' or automatic documentation by operating theatre staff, for example documenting a wound as 'clean' inappropriately, since this is the default choice in our electronic record. This highlights potential unintended consequences of electronic system design. We had no way of determining in this audit which individuals were responsible for documenting wound classification or if misclassification was more a function of the computer system than a surgeon effect, which we acknowledge is a limitation and worthy of further investigation.

Patients undergoing ENT procedures were significantly more likely than those who had paediatric general surgical procedures to be recorded as adherent in our study ($p < 0.001$). This might in part be because the most common ENT procedures were ones where SAP is not indicated (e.g. adenotonsillectomies) and therefore not given. Thus, it was potentially easier to be adherent overall for these cases, as criteria such as antimicrobial choice/dose/duration were no longer relevant and assessed. Though not identified in our model, adherence to SAP was perfect for the small number of ophthalmology procedures. Emergency cases were more likely than elective cases to have correct SAP choice in our study. As most of these were recommended only single doses of

cefazolin for adherence, this may have been easier to achieve than some elective procedures where multiple antimicrobials are recommended. Although we identified penicillin hypersensitivity as another significant risk factor for non-adherence, this should be interpreted with caution, since it was a very small number of cases and confidence intervals were wide. While current SAP guidelines give alternative antimicrobial options in immediate penicillin hypersensitivity, prescribers needing to prescribe a less familiar antimicrobial may find this more difficult to do correctly. Nonetheless it is important to manage drug hypersensitivity correctly to prevent potentially serious reactions.

Correct antimicrobial choice in our study was high, at over 80%, and we also report higher adherence to correct timing and duration of SAP than other paediatric SAP studies to date (8-12). Reasons for these might include prominent placement of these parameters in our guidelines, which are displayed as colourful posters in operating theatres, and a well-established process in our hospital operating theatre for SAP administration (15) (Supporting Information 1).

Correct dosage was the SAP criterion with poorest adherence in our study at 59.2%, lower than in other paediatric SAP studies (8, 9, 11). Adolescents (12 to less than 18 years old) were significantly more likely to receive an incorrect dose of SAP than those aged 3 to 12 years old. These adolescents commonly received doses lower than recommended. Prescribers may have approximated lower doses: “rounded down” for adolescent patients rather than

calculating according to the guideline's weight-based dosing. To our knowledge, this is the first time this phenomenon in adolescent SAP has been reported. In contrast, adherence for correct timing in our study was high at 85.6%, superior to that described in several other studies (range 32-73%, (8-11).

In cases with post-surgical devices such as chest drains, urinary catheters and implants, we found evidence of guideline non-adherent extended post-procedural SAP use, in some cases for up to 4 days. This has been noted in other studies, despite lack of evidence supporting this practice and recommendations to the contrary (3, 10, 16, 17). There may be an exaggerated perception of SSI risk associated with devices and benefits of ongoing prophylaxis, leading to overuse of antimicrobials. Perceived consequences of potential infection appear to outweigh concerns about unnecessary antimicrobial use for some prescribers (18). This issue requires engagement between infectious diseases teams and surgeons and providers of post-operative care to optimise SAP.

Our study has several limitations: we were unable to confidently assess frequency of post-operative infections since most cases were discharged and information at 7 and 30 days post-operatively was often unavailable. Nonetheless, we believe serious infections requiring readmission or intravenous antimicrobial use would have been captured, as children are generally readmitted to our hospital in this case. Collecting this information is

more resource-intensive, but programs such as the National Surgical Quality Improvement Program (NSQIP) demonstrate that programs funded to capture more detailed surgical and postoperative information can be substantially improve outcomes for patients and reduce overall costs (19). Secondly, although we captured pre- and post-procedural antimicrobial use in hospital, there may have been unrecorded prescription of oral antimicrobials after hospital discharge as extended prophylaxis, not captured in our data. We were also unable to capture any adverse drug effect outcomes which may have happened after discharge. As a single-centre study in a tertiary setting, our results may not reflect prescribing for children in other hospitals with different guidelines and case-mix. However our study includes a broad mix of common paediatric conditions and would be considered a reasonable cross-section of the paediatric caseloads faced by surgeons in children's hospitals in comparable settings.

Conclusion

In this study, the first report of its type on surgical antimicrobial prophylaxis in Australian children, we found important gaps in practice and potential areas for improvement and intervention. Overall adherence to SAP in children is suboptimal, and a multidisciplinary approach, involving surgeons, anaesthetists, infectious diseases specialists, as well as nursing and pharmacy staff, focussed on practical implementation, is needed to

standardise wound classification, clarify appropriate dosing in adolescents and address motivations for prolonged SAP use. To this end, surveying surgeons' attitudes towards SAP may also provide insight into prescribing practice and culture and lead to a more cohesive approach. Future studies should focus on implementation and explore methods to enhance capture and reporting of post-operative complications.

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Tables (with title and footnotes) (Uploaded in separate file)

Figure Legends

Figure 1: Surgical antimicrobial prophylaxis evaluation methodology

Figure 2: Flowchart of patients included in study and evaluation

- * Exclusions: on empirical antimicrobial therapy (n=48); hypersensitivity to non-penicillin antimicrobials (n=5)

Figure 3: Overall SAP adherence by subspecialty

Supporting Information 1 – Poster for SAP: Choice of antimicrobial

JPC_14484_Figure3- Overall SAP Adherence by subspecialty REVISED.tiff

JPC_14484_Figure 1 SAP Evaluation.png

JPC_14484_Figure 2 - Flowchart of patients included in study and evaluation.tiff

Tables

Table 1 – Patient and Surgical Demographics

Characteristics	Population N=326 (% of total)
<u>Gender</u>	
Male	209 (64.1)
Female	117 (35.9)
<u>Median age (Range)</u>	
5.6 years (0.0 - 17.5 years)	
<u>Age groups</u>	
Neonate [< 28 days]	6 (1.8)
Infant [28 days to 1 year]	36 (11.0)
Toddler [1 year to 3 years]	58 (17.8)
Child [3 years to 12 years]	168 (51.5)
Adolescent [12 years to 18 years]	58 (17.8)
<u>Median weight (Range)</u>	
20 (2.4 – 117.9kg)	
<u>Comorbidity category</u>	
No comorbidity	235 (72.1)
Multi-system	17 (5.2)
Respiratory	16 (4.9)
Neurological	16 (4.9)
Cancer	10 (3.1)
Other [†]	32 (9.8)
Cases with documented penicillin hypersensitivity	9 (2.8)

<u>Subspecialty</u>	
General Surgery	122 (37.4)
Plastics	64 (19.6)
Orthopaedics	53 (16.3)
Ear Nose & Throat	46 (14.1)
Urology	19 (5.8)
Neurosurgery	13 (4.0)
Ophthalmology	6 (1.8)
Oncology	3 (0.9)
<u>Procedure Type</u>	
Elective	192 (58.9)
Emergency	134 (41.1)
Average duration of operation (h:m:s)	0:55:10
<u>Wound Class according to operation report</u>	
Clean	217 (66.6)
Clean-Contaminated	98 (30.1)
Contaminated	10 (3.0)
Dirty	1 (0.3)
<u>Primary Surgeon's Seniority</u>	
Senior Medical Officer	171 (52.5)
Junior Medical Officer [†]	148 (45.4)
Not Recorded	7 (2.1)
<u>Primary Anaesthetist's Seniority</u>	
Senior Medical Officer	245 (75.2)

Junior Medical Officer [‡]	62 (19.0)
Not Recorded	19 (5.8)
<u>Presence of post-surgical devices[§]</u>	
Yes	71 (21.8)
No	255 (78.2)

† “Other” category included cardiac (n=2), dermatological (n=4), endocrine (n=1), gastrointestinal (n=6), musculoskeletal (n=6), psychological (n=2) and renal (n= 4) disorders. Neonates (n=6) were also included as a comorbidity category due to their immunocompromised status.

‡ Junior Medical Officers are defined as those who are not consultants and include: Fellows, Registrars and Residents

§ Post-surgical devices include: drains, lines, indwelling catheters and prosthetics

Table 2 - Adherence to SAP criteria

Category	Percentage of cases with appropriate adherence (%)	Evaluable population (n = number of cases)
Correct overall adherence [†]	39.6	326
Indeterminable	2.5	326
Correct antibiotic choice	81.2	154
Correct dose	59.2	125
Correct timing	85.6	153
Correct duration	77.6	156

† Included cases where: 1) SAP was not indicated and was not administered; 2) SAP was indicated and all criteria were correctly adhered to.

Table 3 – Risk factors for SAP non-adherence

Outcome	Odds Ratio (95% CI)	p-Value
<u>Overall non-adherence</u>		
Incorrect wound classification	2.59 (1.45-4.61)	<0.001
Surgical Subspecialty		<0.001
• General Surgery	1.0	(ref)
• Ear, Nose & Throat	0.06 (0.02- 0.16)	<0.001
• Neurosurgery	0.56 (0.138 – 2.27)	0.416
• Other [†]	0.00	0.999
• Orthopaedics	0.49 (0.23 – 1.07)	0.072
• Plastics	0.58 (0.28 – 1.22)	0.149
• Urology	5.73 (0.71 – 46.5)	0.102
<u>Incorrect antibiotic choice</u>		
Penicillin Hypersensitivity	138.34 (4.89 - 3911.69)	0.004
Elective cases	5.26 (1.43 – 20.0)	0.012
Surgical Subspecialty		0.033
• General Surgery	1.0	(ref)
• Orthopaedics	0.038 (0.002 – 0.599)	0.020
• Plastics	0.028 (0.002 – 0.370)	0.007
• Ear, Nose & Throat	0.00	0.999
• Neurosurgery	0.00	0.999
• Other [†]	0.00	1.000
• Urology	5.51 (0.54 – 55.84)	0.149
<u>Incorrect dosage</u>		

Age Group		
• Child [3 - < 12y]	1.0	(ref)
• Adolescent [$\geq$ 12 years]	4.33 (1.60 – 11.67)	0.004
• Neonate [0 - < 28 days]	0.57 (0.05 – 6.09)	0.645
• Infant [28 days - < 1 year]	0.45 (0.09 – 2.36)	0.344
• Toddler [1 - < 3 years]	0.54 (0.14 – 2.04)	0.365
Presence of post-surgical devices [‡]	0.29 (0.12 – 0.70)	0.006
<u>Incorrect timing</u>		
Presence of post-surgical devices	6.84 (1.20 – 38.98)	0.030
<u>Incorrect duration</u>		
Presence of post-surgical devices	2.92 (1.22 - 7.01)	0.016

Significant values are bolded.

(ref): reference group

† Other includes: Ophthalmology and Oncology

‡ Post-surgical devices include: drains, lines, indwelling catheters and prosthetics

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