Compliance with surgical antibiotic prophylaxis guidelines: a prospective descriptive study at a tertiary level hospital in Cape Town, South Africa.

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Contents

Declaration Page

I, Dr. Delia Schuster, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university.

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I. Literature Review

1. Introduction

Within the health care setting, there exists a delicate balance between causing and preventing harm: the risk-benefit ratio. In the case of surgical antibiotic prophylaxis (SAP), the risks of adverse drug reactions and microbial resistance must be weighed against the benefit of reduced incidence of surgical site infection (SSI).Therefore, addressing the issue may lead to cost saving benefits and improved patient outcomes; as well as contribute towards responsible antibiotic stewardship.

SAP entails the prevention of infectious complications by administering an appropriate antimicrobial agent prior to exposure to contamination during surgery. Efficacy depends on delivery of the antibiotic in sufficient concentrations before contamination of the surgical site occurs.(1) Microbial contamination may be endogenous or exogenous in origin. Pathogens commonly responsible for SSI include *S. aureus, E. coli, Enterococcus* spp. and coagulase negative staphylococci.(2)

As such, the available literature emphasises the benefit of routinely using SAP, amongst other strategies, to prevent SSI during non-clean and implant surgery. In this context, "compliance" refers to the administration of a drug when indicated; whilst "adherence" is defined as correct practice in all aspects, namely: indication (whether to administer or withhold SAP); choice of drug (spectrum of antimicrobial activity); dosage; timing of injection; re-dosing intervals and appropriate continuation of SAP beyond the perioperative period where indicated. However, these terms are often used interchangeably both in the existing literature and clinical setting.

The term SSI encompasses the surgical wound and associated infections occurring within 30 days after a surgical procedure; or up to a year later in case of an implant. It is classified as superficial infection, deep infection, organ space infection or sepsis.(2)

2. Problem Globally and in South Africa

To quote the APACHE study group, “Adherence to current recommendations is hard to achieve”,(3) yet arguably important, as preventing SSI without adding to the worldwide burden of antimicrobial antibiotic resistance is imperative.

The worldwide incidence of SSI is 2 – 5% with a peak incidence of 20% for colon surgery.(4) It is the third most common cause of nosocomial infection and the most common among surgical patients,(5) contributing to the burden of disease by increasing duration of hospitalisation, morbidity, mortality and consequently cost.

According to the American College of Surgeons and Surgical Infection Society, SSI incurs the highest cost of all nosocomial infections, extending length of stay by 9.7 days on average(4) and increasing the risk of mortality by a factor of 2 to 11.(2)

Effective SAP amounts to preventing SSI by administering a drug that targets the microbes most likely to contaminate the surgical site, achieving adequate and timeous tissue levels and maintaining this for the duration of the surgery; whilst reducing adverse effects and microbial resistance by employing the narrowest possible spectrum of antibiotic for the shortest possible period (or omitting where appropriate).(1)(2)(6)(7)

The purpose of SAP guidelines is to establish such sound practices, but in 2018 a prospective descriptive study conducted at a South-African Academic hospital demonstrated that anaesthetists’ utilisation and knowledge of SAP guidelines were lacking: only 15.6% followed any given guideline in their practice and the mean score for knowledge was 56.2%. The study involved testing anaesthetists’ knowledge of SAP by employing a self-administered questionnaire. The study population consisted of anaesthetic consultants and registrars from a university affiliated Anaesthesiology Department in Johannesburg, South Africa.(8)

Examples of international, national and local guidelines include: the Scottish Intercollegiate Guideline Network (SIGN) – Antibiotic Prophylaxis in Surgery;(1) the South Australia Expert Advisory Group on Antibiotic Resistance (SAAGAR) – Surgical antibiotic Prophylaxis Guideline;(7) the American Society of Health-systems Pharmacists (ASHP) – Clinical practice guidelines for antimicrobial prophylaxis in surgery;(9) the South African Society of Anaesthesiologists (SASA) – Guidelines for Infection Control in Anaesthesia in South Africa;(6) Guidelines for the management of nosocomial infections in South Africa(10) and the National Health Laboratory Service (NHLS) – Western Cape academic hospitals antimicrobial recommendations.(11)

From these guidelines emerge six defining aspects of SAP compliance, namely:

- indication (to administer or withhold)
- choice/selection (appropriate spectrum of antimicrobial activity)
- dosage
- timing
- re-dosing and
- duration (correct continuation/ discontinuation) of SAP.

Several studies, globally and within the African context, have been aimed at determining clinician adherence to existing SAP guidelines. However, none of these studies are from South Africa.

A prospective investigation of three paediatric hospitals in Italy found that where SAP was indicated, perfect adherence in terms of antibiotic choice, timing and duration was 8%, with first dose timing and duration of prophylaxis being the biggest contributors to error. Under-use when SAP was indicated (81%) and over-use when not (18%) was also noted.(3)

Similar findings have been reported by numerous investigators.

A retrospective monocentric study from France again showed that timing of injection (to close to surgical incision) was the most common mistake (34.8% non-compliance), with β-lactam allergy and obesity leading to non-compliance with choice and dose of antibiotic in 45% and 96% respectively.(12)

In Australia, analysis of prospectively collected SSI surveillance data from an academic hospital demonstrated issues with drug selection, timing and duration of SAP; and an increase in extended-spectrum-β-lactamase producing bacteria.(13)

Conversely, a Northern American observational study concluded that compliance with timing, choice and dose of SAP did not lower the incidence of SSI, but diabetes and elevated body mass index were implicated in a higher rate of SSI.(14)

A Brazilian review from 2015 found that appropriate indication of antibiotic prophylaxis ranged from 70.3% to 95%; inappropriate indication from 2.3% to 100%; correct timing 12.73% to 100%; correct choice 22% to 95%; adequate discontinuation 5.8% to 91.4% and adequate antibiotic prophylaxis 0.3% to 84.5%.(15)

Reasons for non-compliance revolve around issues with clinicians' knowledge, attitude, beliefs, team communication and allocation of responsibilities; as well as institutional promotion, support and monitoring of SAP.(16)

A prospective, international, multicentre cohort study by the GlobalSurg Collaborative highlights several issues of concern around SAP and SSI: most notably the relatively greater

risk of SSI and higher rates of microbial resistance against SAP, compounded by the paucity of high quality research emerging from countries with a low Human Development Index (HDI) as opposed to those with a middle- or high HDI. It was further demonstrated that patients form low HDI countries were more likely to receive pre-operative courses of antibiotics, SAP and post-operative antibiotics, yet the rates of SSI and microbial resistance were also higher. Organ space infection, a second nosocomial infection, re-intervention and death were also more likely in patients with SSI that those without.(17)

3. The Problem in South Africa

As mentioned, Jocum et al has demonstrated a lack of awareness of SAP guidelines and consequently poor knowledge of SAP administration.(8)

We postulate that a similar problem exists at Groote Schuur Hospital, resulting in erroneous SAP practices. Furthermore, there appears to be no other published studies of SAP practices in South Africa. This paucity of research poses a major problem and obscures the true extent to which faulty SAP practices may be contributing to SSI, adverse drug reactions and microbial antibiotic resistance.

The guideline for the management of nosocomial infection in South Africa emphasises the need for infection control, considering the resource restricted environment in which the healthcare system operates. With this in view, it is recommended that measures taken to curb antimicrobial spread should be combined with effective and deliberately restrictive antibiotic usage.(10)

4. Investigation of The Problem

Whilst international audits of SAP practices abound, to the author's knowledge, the only South African study is the test of anaesthetists' awareness and knowledge of SAP guidelines by Jocum et al.(8)

According to reviews led by the WHO, developing countries run a much higher risk of SSI than high-income countries for equivalent procedures, yet far fewer interventional studies emerge from the higher risk group.(18)

A systematic review of sub-Saharan interventional studies aimed at preventing SSI, reports that research may be confounded by inconsistent definitions of SSI and wound classification. Nevertheless, it was clearly demonstrated that once-off pre-operative

antibiotic prophylaxis decreases the risk of SSI. For example, in Tanzania the introduction of a single dose of pre-operative amoxicillin/clavulanate was associated with a reduction in risk of SSI from 21.6% to 4%. On the other hand, avoiding the use of post-operative antibiotic "prophylaxis", was not associated with an increase in SSI or other adverse events. In fact, a South African study found that there is no benefit in prescribing a prolonged course of cefoxitine (versus placebo) following caesarean section. The reviewers concluded that very little research from sub-Saharan Africa has been aimed at reducing the prevalence of SSI, but recently some high-quality studies have emerged.(18)

Unfortunately, the South African national and provincial SAP guidelines are lacking in detail: not all surgical procedures are addressed in terms of indication, required spectrum of antimicrobial activity, timing of first injection, redosing intervals or duration of SAP. Although it is universally recommended that local and institutional microbial patterns must be considered when SAP is selected, information regarding these patterns is scant.(1)(5)(6)(10)(11)

Conversely, clinicians may be overwhelmed by a barrage of inconclusive and sometimes contradictory evidence gleaned from of international SAP guidelines. For example, the ideal time lag from first injection of antibiotic to surgical incision is generally accepted to be between 0 and 60 minutes (with the exception of vancomycin and fluoroquinolones which require infusion over 2 hours), but some studies recommend a more exact period while others show no statistically significant difference in SSI rates with more specific time frames.(2)(19) The only consensus regarding timing of SAP appears to be that the time lag should not exceed 1 hour;(1)(2) and administering SAP after incision is of no benefit and may even be harmful in terms of predisposing towards SSI and antimicrobial resistance.(1) Some procedures require various combinations of topical, oral and parenteral antibiotic prophylaxis(2), adding to the confusion.

Regarding the ideal duration of SAP, post-operative continuation of antibiotic administration predisposes towards *C. difficile* infection(2), but some procedures warrant extended SAP for 24 to 48 hours (arthroplasty, implant – and cardiac surgery).(1)(2)(5)

5. Management Of The Problem

Strategies aimed at improving compliance with SAP guidelines include implementing the use of personalised surgical antibiotic prophylaxis kits (SAPKs) at a University hospital in Nice;(20) educating surgical staff by introducing an antimicrobial stewardship program at

acute care hospitals in Egypt;(21) and incorporating standardised computerised order entries for perioperative antibiotic prophylaxis at a university hospital in Philadelphia, USA.(22)

In sub-Saharan Africa, cost constraints, minimal staff and limited facilities number among the challenges faced by clinicians, but a systematic review of interventions aimed at reducing the rate of SSI in this context postulates that improving the use of SAP may reduce the risk of SSI and help conserve scarce (antibiotic) resources. It is recommended that antibiotic spectrum appropriate to local pathogens must be identified at duly administered.(18)

The American College of Surgeons and Surgical Infection Society estimates that as much as 60% of SSI can be prevented if evidence-based methods are correctly implemented. This entails the stratification of risk factors for SSI into modifiable or non-modifiable intrinsic (patient) factors and extrinsic factors; and addressing these risk factors where possible. In terms of SAP, this means:

- Administering prophylactic antibiotics only when indicated (i.e. not for clean surgery).
- Choice of antibiotic is determined by the procedure and pathogens that will most likely cause SSI.
- SAP must be administered within an hour before surgical incision; or within 2 hours for vancomycin and fluoroquinolones, as these drugs are administered by slow infusion.
- Prophylactic antibiotic dose should be appropriate for weight.
- Antibiotic redosing should be aimed at maintaining adequate tissue levels based on the half-life of the drug and for every 1.5l of blood loss (in an adult).
- SAP should be discontinued at closure of incision (barring a few exceptions where the ideal duration of SAP remains elusive, namely: implant based breast reconstruction, arthroplasty and cardiac surgery.(2)

6. Conclusion

There appears to be a lack of high-quality evidence on SSI and associated antibiotic use.(17) Clinicians are further confounded by poor awareness and knowledge of existing SAP guidelines.(8) As part of a broader strategy of SSI prevention and antibiotic stewardship, we recommend the following:

- regular auditing of institutional SAP practices.
- comparison to guidelines.
- implementation of SAP awareness campaigns.

- clinician education.
- focused antibiotic stewardship programs.
- Implementation fidelity studies and randomised controlled trials to elucidate whether SAP related interventions curb the rate of SSI.

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II. Full Text Journal Article For Submission

1. Cover Letter

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Title: Compliance with surgical antibiotic prophylaxis guidelines: a prospective descriptive study at a tertiary level hospital in Cape Town, South Africa

2. Abstract

Background:

The aim of surgical antibiotic prophylaxis (SAP) is to prevent surgical site infection (SSI) by administering an appropriate antimicrobial agent perioperatively. However, SAP may be associated with adverse effects and incurs added costs.

Objectives:

- The primary objective of this prospective study is to establish whether clinicians are adhering to existing perioperative antibiotic prophylaxis guidelines in terms of indication, dosage and timing of SAP.
- Secondary objectives are to determine the proportion of patients receiving inappropriate antibiotics; and to evaluate correct practice concerning re-dosing and duration of SAP.

Methods:

A cross-sectional prospective audit of the anaesthetic records and prescription charts of surgical patients was conducted at Groote Schuur Hospital, a tertiary level teaching hospital in Cape Town, South Africa, over a period of one week. Data were collected by anaesthetists – blinded to the study objectives – and the investigators; then captured on Excel spread sheets and compared to existing SAP guidelines. Descriptive statistics and binary logistic regression were used for analysis.

Results:

Of the 192 patients consented, 180 questionnaires were completed for data analysis. The median age of participants was 44.5 years (IQR: 31.5-58), with a preponderance of females (58.7%). SAP was administered in 149 cases (82.8%) and withheld in 31 (17.2%). This was appropriate in 91.9% (137/149) and 77.4% (24/31) respectively. Twelve patients (6.7%) received inappropriate antibiotics and in seven (3.9%) it was inappropriately withheld. Of the 156 patients who should have received SAP, choice of drug was correct in 121 (77.6%), dosage in 110 (70.5%) and timing in 87 (55.8%). Absolute compliance was achieved in 44.4% (80/180). Errors were mostly related to timing, re-dosing and duration of SAP.

Conclusion:

Anaesthetists and surgeons at Groote Schuur Hospital demonstrate variable adherence to surgical antibiotic prophylaxis guidelines. Interventions aimed at improving compliance are warranted.

Keywords:

Surgical antibiotic prophylaxis, adherence, compliance, guidelines, surgical site infection.

3. Introduction

Surgical site infection (SSI) is associated with a significant increase in morbidity and mortality.(1)(2)(5) The role of surgical antibiotic prophylaxis (SAP) as part of a broader strategy of SSI prevention has been well described in the literature.(1)(2)(5)(17)(23) However, establishing the exact impact of adherence to SAP guidelines on the incidence of SSI has proven to be difficult.(1)

In South Africa, the paucity of published, comprehensive national and local guidelines may contribute towards clinicians' lack of knowledge, understanding and utilisation of correct perioperative antibiotic prophylaxis (PAP). In a prospective, descriptive study of

anaesthetists' knowledge of SAP, only 20% of participants were able to name any guidelines. A questionnaire was employed to test the anaesthetists' knowledge of indication for prophylaxis, spectrum of cover, timing of first dose and exceptions, re-dosing intervals and duration of SAP for various antibiotics. The mean score was 56.2%. This appears to be the only existing study of clinicians' awareness and utilisation of SAP and SAP guidelines in this country.(8)

While there have been many retrospective and prospective studies published on SAP compliance internationally,(3)(12)(14) (24)(25) to the author's knowledge, none have been conducted in South Africa.

As there appears to be an urgent need for both research and intervention as far as the SAP practice of South African clinicians is concerned, the primary objective of this study was to establish the compliance with existing SAP guidelines in terms of indication, selection, dosage and timing of SAP. Secondary objectives were to determine the proportion of patients receiving antibiotics inappropriately; and evaluate re-dosing and duration of SAP.

In view of the minimal local and national guidelines,(6)(11)(10) we also employed international guidelines(1)(5)(7)(23) in our evaluation of clinicians' adherence to SAP guidelines.

4. Research Methods and Study Design

4.1.1. Study design

A cross-sectional prospective descriptive research design was used for this facility-based study.

4.1.2. Setting

The study population consisted of adult patients over eighteen years of age presenting to Groote Schuur Hospital for surgery. All surgical subspecialties were included. Recruitment took place during one week from 07h00 on Monday until 19h00 on Friday.

4.1.3. Data collection

The anaesthetists were tasked with recruiting patients, obtaining their consent and recording the following information: date; patient number, age and weight; surgical procedure, whether emergency or elective; diagnosis; surgical wound classification†; time

of surgical incision; duration of surgery; known allergies and recent prescription of antibiotics. The investigator subsequently reviewed the anaesthetic records and prescription charts to document information regarding SAP: whether administered or withheld (indication); choice (selection/ antimicrobial spectrum) and dosages of drugs; time of injection; re-dosing (drug, dosage, time) and whether further antibiotics were prescribed for twenty-four hours or longer.

These data were then captured on Excel spreadsheets.

Because awareness of observation might give rise to changing practice (Hawthorne effect), the anaesthetists assisting with data gathering were not informed of the purpose of the study.

At Groote Schuur hospital, antibiotics are administered by the anaesthetists perioperatively. This is mostly done in conversation with the operating surgeon. Post-operative antibiotics are usually prescribed by the surgeons.

4.1.4. Data analysis

This SAP audit was based on the Scottish Intercollegiate Guidelines Network (SIGN) recommendations for a minimum data set*(see supplementary file 1).

The data were evaluated by an intensivist and specialist medical microbiologist and compared to international and national SAP guidelines: SIGN,(1) South Australian expert Advisory Group on Antimicrobial Resistance (SAAGAR),(7) American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines,(2) South-African Society of Anaesthesiologists (SASA),(6) National Health Laboratory Service Western cape academic hospitals antimicrobial recommendations (NHLS);(11) and the only (unpublished) local guideline made available, from the Groote Schuur Department of Urology. However, the SASA and NHLS recommendations lack detail, hence the inclusion of international guidelines. According to the European Centre for Disease Control (ECDC), the defining aspects of SAP compliance are correct indication; selection; dosage; timing, and duration of antibiotic treatment.(23) Redosing was also included. These criteria were analysed as follows:

Indication

Administration of SAP was considered appropriate for clean-contaminated, contaminated and dirty surgeries or where surgical prostheses were implanted, and inappropriate for clean surgeries. Omission/ withholding of SAP was considered appropriate for clean surgeries (that did not include surgical prosthetic implantation).

Selection

Spectrum of antimicrobial activity was evaluated by a microbiologist and intensivist from Groote Schuur Hospital in consideration of both their knowledge of local patterns of microbial sensitivity and recommendations from existing guidelines.

Dosage

Dosage: as prescribed by guidelines.(1)(6)(7)(9)(11)

Table 1: Summary of SAP dosages considered correct

Drug	**Dosage (Adult only)**
Cefazolin	2g (1g acceptable if weight ≤ 80kg)
Gentamycin	5 – 7mg/kg
Metronidazole	500mg
Clindamycin	600mg
Amoxycillin/Clavulanic acid	1.2g

Timing

Timing of initial injection was considered correct if 15 to 60 minutes had elapsed prior to surgical incision or tourniquet insufflation for Cefazolin, Metronidazole, Gentamycin, Clindamycin, Ampicillin and Amoxycillin/clavulanic acid (fluoroquinolones and glycopeptides require infusion over one to two hours).(9)

Re-dosing

Redosing was considered appropriate if the duration of surgery exceeded two half-lives of the given antibiotic; or blood loss exceeded 1.5 l (in an adult).The time lag between the first and subsequent injections was considered correct if two half-lives had elapsed (4 hours for Cefazolin). The dose should be appropriate for weight or consistent with the initial dose in case of unknown or estimated weight.

Duration

Prolonged SAP for up to 24 hours was deemed correct for arthroplasty and orthopaedic implant surgery; and up to 48 hours for cardiac surgery. Allowances were made where complicated surgery, intra-operative spillage of bowel content or pre-existing infections necessitated antibiotic treatment beyond SAP.

Statistical analysis

Data were entered into a Microsoft excel database and analysed using Stata version 15. (Stata Corp). Since most of the variables were categorical, the Fisher's exact test was used to assess associations between the variables, disaggregated by whether SAP was withheld or given. For the continuous variables the comparison between those who received SAP and those who had it withheld, was via Mann-Whitney U test, as the variables were skewed. A p-value of <0.05 was considered statistically significant.

4.1.5. Ethical considerations

Ethical approval was obtained from the Human Resources Ethics Committee (HREC) of the University of Cape Town, South-Africa (HREC 757/2017).

5. Results

Over a 1-week period, 194 patients were approached and 192 granted consent. Their anaesthetic records and prescription charts were reviewed, and these data were captured on data sheets. Of these, 180 were included for data analysis, as 12 sheets were unintelligible.

The median age of study participants was 44.5 years (IQR: 31.5-58), with a preponderance of females at 57.8%. The median estimated weight was 74kg (IQR: 61-90).

Most patients presented for elective surgery (79.4%, 143/180) with the highest proportion of procedures coming from the Orthopaedic department (20.6%, 37/80). The surgical characteristics are summarised in Table 2.

Table 2: Descriptive data for baseline surgical characteristics for the study sample (n = 180)

Characteristic	Total (n=180)
Surgical department	n (%)
Cardiothoracic	13 (7.2)
Colorectal	6 (3.3)
ENT	16 (8.9)
General	14 (7.8)
Gynaecology	19 (10.6)

Head, Neck & Breast	7 (3.9)
Hepatobiliary	8 (4.4)
Maxillo-fascial	9 (5.0)
Neurology	4 (2.2)
Obstetrics	14 (7.8)
Ophthalmology	6 (3.3)
Orthopaedics	37 (20.6)
Renal	4 (2.2)
Trauma	1 (0.6)
Urology	13 (7.2)
Vascular	9 (5.0)
Wound classification, n (%)	
I	71 (39.4)
II	70 (38.9)
III	25 (13.9)
IV	14 (7.8)
Surgery	n (%)
Elective	143 (79.4)
Emergency	37 (20.6)
Duration of surgery, median (IQR)	75 (42-150)
Range (minutes)	5-435

A total of 28 patients had been receiving antibiotic treatment prior to presenting for surgery, as summarised in Table 3.

Table 3: Antibiotic treatment prior to surgery (n=180)

Prior antibiotics	n (%)
None	152 (84.4)
Ofloxacin	1 (0.6)
Azithromycin and Ceftriaxone	1 (0.6)
Cefazolin	2 (1.1)
Ceftriaxone	2 (1.1)
Ciprofloxacin and Cefuroxime	1 (0.6)
Ciprofloxacin and Metronidazole	1 (0.6)

Amoxycillin/Clavulanic acid	14 (7.8)
Ertapenem and imipenem	1 (0.6)
Metronidazole	1 (0.6)
Nitrofurantoin	1 (0.6)
Amikan, Piptaz and Ciprofloxacin	2 (1.1)
Vancomycin and Ceftriaxone	1 (0.6)

The various choices/ combinations for SAP are illustrated in Table 4.

Table 4: SAP drug choice (n=180)

Antibiotic prophylaxis	n (%)
Cefazolin	107 (59.4)
Cefazolin, Gentamycin and Metronidazole	3 (1.7)
Cefazolin and Amoxycillin/Clavulanic acid	1 (0.6)
Cefazolin and Gentamycin	4 (2.2)
Cefazolin and Metronidazole	12 (6.7)
Ceftriaxone	2 (1.1)
Chloromycetin (topical)	2 (1.1)
Clindamycin	2 (1.1)
Gentamycin	9 (5)
Metronidazole	3 (1.7)
Amoxycillin/Clavulanic acid	4 (2.2)

In terms of the primary objectives:

Indication and Selection

SAP was appropriately administered or withheld in 161 cases (89.44%). Of the 149 patients who received SAP, it was appropriately administered in 137 cases (92%) and appropriately withheld in 24 of the 31cases that did not (77%). Consequently, SAP was incorrectly administered in 12 (clean) cases (12/180 = 6.67%) and incorrectly withheld in 7 (7/180 = 3.89%). An appropriate antibiotic was selected in 121/156 cases (77.6%).

Dose

The dose was appropriate to weight in 110 of the 156 patients who received SAP (70.5%). There was consistent under-dosing of Gentamycin.

Timing

Timing of initial injection was incorrect in 44.2% of the 156 participants that received SAP (n = 69), the time lag being too short (< 15min) in 33 cases (21.2%); too long (> 60min) in 13 (8.3%); unknown in 9 (5.8%) and administered after surgical incision in 7 cases (4.5%) .

Regarding secondary objectives:

Re-dosing

Sixteen cases required a second dose of SAP, but it was administered only 14. Of these 14, only 3 (21.4%) received an appropriate dose at an appropriate time. Under-dosing for weight occurred in 6 cases (42.9%), re-dosing too late in 3 (21.4%) and too early in 2 (14.3%). The second dose was incorrectly omitted in 2/16 cases (12.5%).

Duration

Antibiotics were prescribed for 24 hours in 57 cases (31.7%) but justified in only 41 (71.9%); and for 48 hours or more in 38 cases (21.1%). Extended duration was appropriate in 33 (86.8%) of these cases, as they were on antibiotic treatment for previously existing or suspected infection. SAP was inappropriately extended for 72 hours in 2 cardiac cases (5.3%) and 48 hours for 2 orthopaedic cases (5.3%) respectively. One obstetric patient received oral amoxycillin/clavulanic acid for 1 week, as this was thought to be warranted should the duration of a caesarian section exceed 1 hour, but this practice is not supported by the literature. Maxillofacial cases were correctly prescribed an extended course of oral or topical antibiotic, as per the WHO recommendations.

These findings are summarised in Table 5.

Table 5: Rate of adherence in terms of antibiotic choice, dose, timing and re-dosing.

Characteristic	Total (n=180)
Appropriate prophylaxis choice	n (%)
Yes	121/156 (77.6)
No	35/156 (22.4)

Appropriate dose Yes No	 110/156 (70.5) 46/156 (29.5)
Appropriate timing Yes No	 87/156 (55.8) 69/156 (44.2)
Re-dose received Yes Appropriate re-dose Yes No	 14 (7.8) 3/14 (21.4) 11/14 (78.6)
Antibiotic to incision time, median (IQR) Range	25 (15-35) -45 – 90

6. Discussion

Adherence to all the criteria of SAP compliance was achieved in 44.4% (n = 80). Breakdown by department is shown in figure 1.

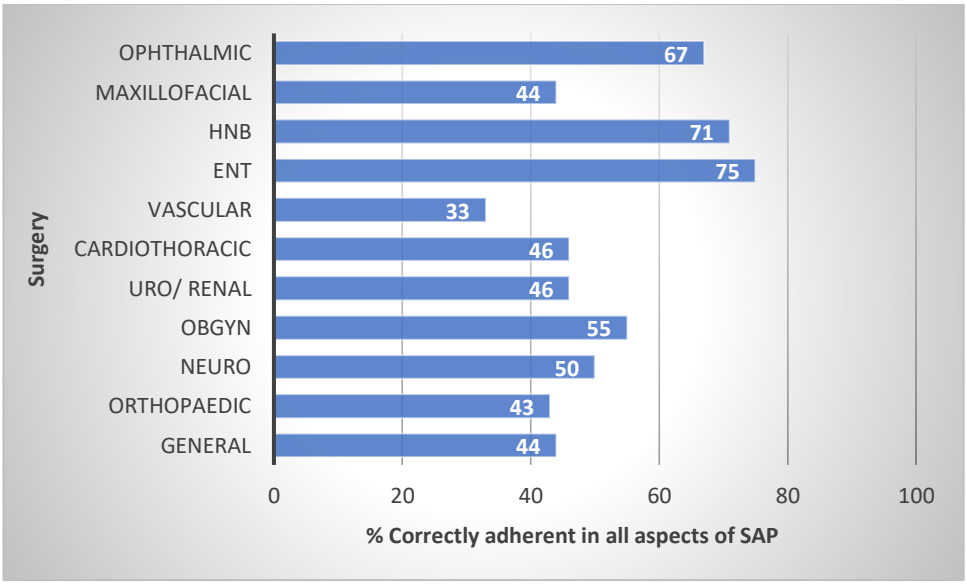

Figure 1: Percentage of cases where adherence to SAP guidelines was achieved in all aspects, by surgical department.

(HNB: head, neck, breast; ENT: ear, nose, throat; Uro: Urology; OBGYN: obstetrics and gynaecology; General: colorectal-, hepatobiliary-, and upper gastro-intestinal surgery)

Erroneous omissions appear to be due to clinicians' assumption that previously prescribed antibiotics negate the need for SAP, regardless of the spectrum or half-life of those drugs. The reasons for incorrect timing may vary from logistical issues (many activities being performed at the same time around induction of anaesthesia and surgical incision) to lack of awareness of guidelines and inconsistencies in the available literature. While there is agreement in the literature that adequate tissue levels of the antibiotic must be attained prior to surgical incision or tourniquet insufflation, the ideal time lag has not been elucidated.(1)For example, the Belgian recommendation is 15 to 60 minutes,(12) but the SIGN recommends 0 to 60 minutes, (1) and the WHO safety checklist reads, "antibiotic administered within 30 to 60 minutes prior to surgical incision". There is low quality evidence that administering SAP after surgical incision is harmful with a significantly increased risk of SSI, but due to the severity of morbidity associated with SSI, the recommendation against such a dosing strategy is strong.(1) (5)

The under dosing of Gentamycin may be due to anaesthetists being unfamiliar with the antibiotic, as it is prescribed less often and mostly for surgeries involving the urinary tract. Concerning duration of SAP, there appears to be consensus amongst the sources quoted by the WHO that SAP should not exceed a single pre-operative dose, with the possible exceptions of arthroplasty, open cardiac surgery and complicated maxillofacial surgery. The Royal College of Physicians of Ireland recommends prolonged SAP for up to 24 hours for open reduction and internal fixation of compound mandibular fractures, orthognathic surgery, complicated septorhinoplasty and head and neck surgery; and 24 to 48 hours for open cardiac surgery. According to the USA Institute for Health Care Improvement: surgical site infection, SAP must be discontinued within 24 hours or 48 hours for cardiac patients.(5).

6.1.1. Strengths and limitations:

The main strength of this study lies with its prospective nature, as opposed to the retrospective data analysis described in many of the larger studies. It appears to be the first

audit of SAP practice undertaken in South-Africa; and as such highlights many shortcomings in this arena.

Limitations to this study include a small sample size, which prohibits generalisation and may impact on the reported results. For example, the impact of drug allergies on SAP compliance could not be elucidated, as none of the participants had a history of β-lactam allergy. Convenience sampling may also have led to selection bias. Furthermore, only some aspects of the data were directly observed and recorded by the anaesthetists, but to avoid the Hawthorne effect, information directly pertaining to the primary and secondary objectives were obtained from paper records in patient folders – which may have contained inaccurate information. The weight was known in only 83 (46.1%) and estimated in 97 (53.9%) cases. Wound classification may have been inaccurate, but this was addressed during a case by case re-evaluation of the data and should not have a significant effect on the analysis, as each procedure was carefully considered on its own merit.

6.1.2. Implications or recommendations

The awareness and knowledge of SAP guidelines have been shown to be lacking amongst anaesthetists at a tertiary hospital in South-Africa.(8) Globally, there is considerable variability in SAP compliance, with several studies demonstrating poor compliance.(3)(12)(13)(15)(25) Such findings are reproduced in our study, with a non-compliance rate of 55.6% (p-value < 0.001). The most frequently observed errors included incorrect timing of first dose, issues with re-dosing and inconsistencies in prolonged continuation of SAP.

7. Conclusion

Given the devastating consequences of SSI in terms of morbidity and mortality, measures to raise awareness and educate clinicians regarding SAP guidelines are warranted. We recommend that regular audits of SAP practice should be followed by studies of adherence and implementation fidelity.

8. Declarations

We have no financial or personal relationship(s) that may have inappropriately influenced this paper. Thanks to Doctor Riezaah Abrahams for assistance with data evaluation; Doctor Justin Howlett for providing access to the SAP guidelines of the Department of Urology,

Groote Schuur; and to Professor Bruce Biccard and Ms Lizel Loo for their invaluable advice in the preparation of this document.

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10.Supplementary Files

Supplementary File 1

*The SIGN recommendations for a minimum data set for SAP audit:(1)

Date and operation performed

Classification of operation†

Elective or emergency

Patient weight

Previous adverse reactions or allergies to antibiotics

Justification for prophylaxis; justification for not giving prophylaxis

Time, name and dosage of antibiotic administrated

Time of surgical incision

Duration of surgery

Whether a second dosage is indicated and/ or given

Whether postoperative antibiotic prophylaxis is indicated and/ or given

Whether antibiotic prophylaxis is continued for longer than 24 hours

Clear documentation

Supplementary File 2

†Surgical wound classification (abridged from the ECDC)(23)

I. Clean surgery: no break in aseptic technique and the respiratory, gastrointestinal and genitourinary tracts are not breached.
II. Clean-contaminated surgery: this extends to the oropharynx, sterile genitourinary or biliary tract, the gastrointestinal or respiratory tracts, or if there has been a minor breech in the aseptic technique.
III. Contaminated surgery: the presence of acute inflammation, infected bilious secretions, infected urine, or gross contamination from the gastrointestinal tract.
IV. Dirty surgery: if an established infection exists, and therapeutic antibiotics are administered based on the susceptibility of bacterial isolates grown from culture

Supplementary File 3

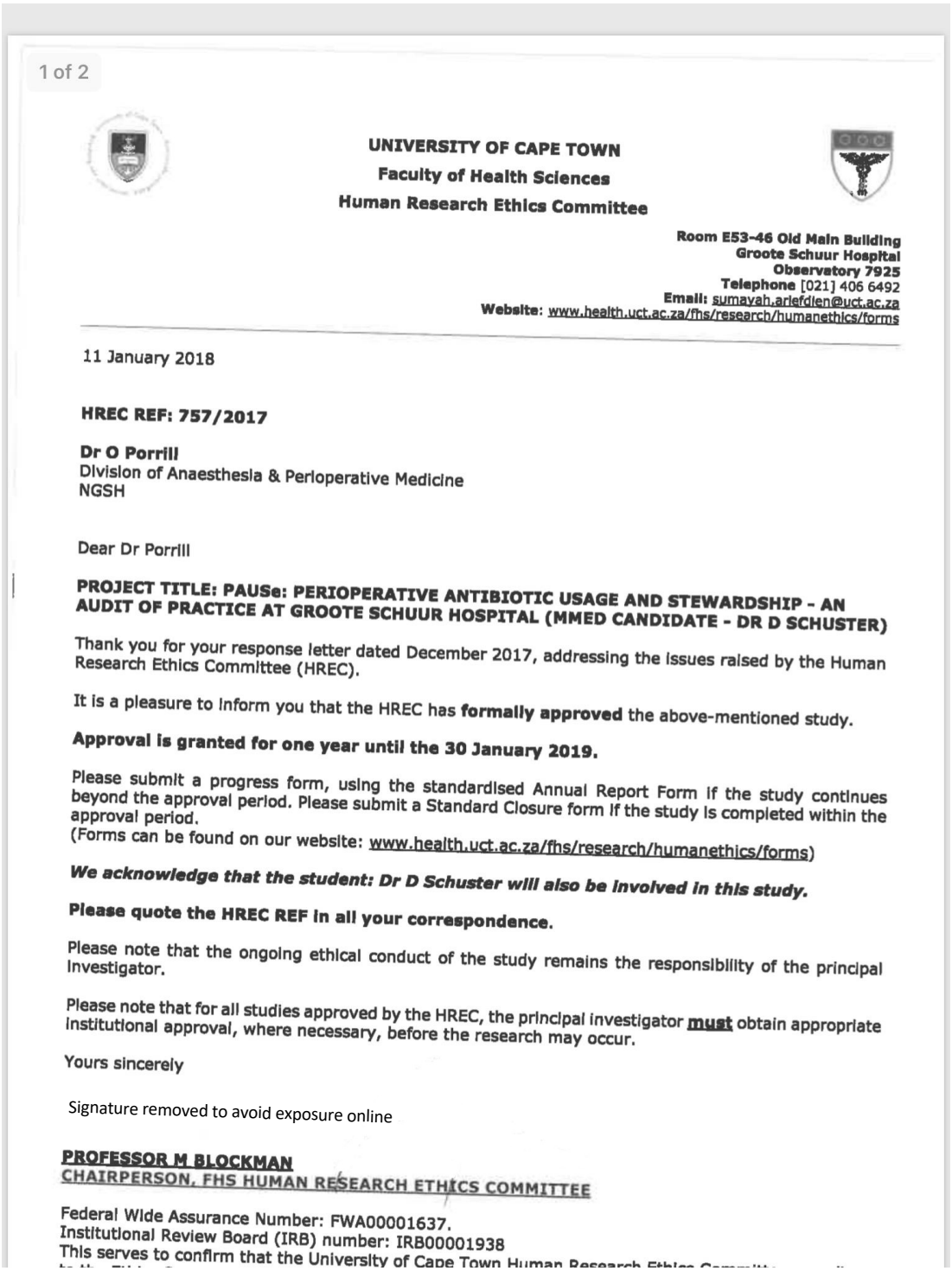
Statistical Analysis

Variable	SAP withheld n=31	SAP given n=149	Total n=180	p-value
Age in years, median (IQR)	43 (30-56)	45 (32-60)	44.5 (31.5-58)	0.55
Sex, n (%)				
Female	16 (51.6)	88 (59.1)	104 (57.8)	0.45
Male	15 (48.4)	61 (40.9)	76 (42.2)	
Weight (kg), median (IQR)	76 (61-85)	74 (61-90)	74 (61-90)	0.97
Surgical department, n (%)				
Cardio-thoracic	0	13 (8.7)	13 (7.2)	<0.001
Colorectal	0	6 (4.0)	6 (3.3)	
ENT	12 (38.7)	4 (2.7)	16 (8.9)	
General	3 (9.7)	11 (7.4)	14 (7.8)	
Gynecology	6 (19.4)	13 (8.7)	19 (10.6)	
Head, Neck & Breast	3 (9.7)	4 (2.7)	7 (3.9)	
Hepatobiliary	1 (3.2)	7 (4.7)	8 (4.4)	
Maxillofacial	0	9 (6.0)	9 (5.0)	
Neurology	0	4 (2.7)	4 (2.2)	
Obstetrics	0	14 (9.4)	14 (7.8)	
Ophthalmology	0	6 (4.0)	6 (3.3)	
Orthopaedic	4 (12.9)	33 (22.2)	37 (20.6)	
Renal	0	4 (2.7)	4 (2.2)	
Trauma	0	1 (0.7)	1 (0.6)	
Urology	0	13 (8.7)	13 (7.2)	
Vascular	2 (6.5)	7 (4.7)	9 (5.0)	
Surgery, n (%)				
Elective	25 (80.7)	118 (79.2)	143 (79.4)	0.86
Emergency	6 (19.3)	31 (20.8)	37 (20.6)	
SAP appropriately given, n (%)	-	137 (92.0)	-	-

SAP appropriately withheld, n (%)	24 (77.4)	-	-	-

III. Addenda

1. Ethics approval



1 of 2

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

11 January 2018

HREC REF: 757/2017

Dr O Porrill
Division of Anaesthesia & Perioperative Medicine
NGSH

Dear Dr Porrill

PROJECT TITLE: PAUSe: PERIOPERATIVE ANTIBIOTIC USAGE AND STEWARDSHIP - AN AUDIT OF PRACTICE AT GROOTE SCHUUR HOSPITAL (MMED CANDIDATE - DR D SCHUSTER)

Thank you for your response letter dated December 2017, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 January 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr D Schuster will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE
06 JAN 2020
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.01.2021
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	signature removed	Date Signed	8/1/2020

Comments to PI from the HREC
Thank you for the deviation received

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	30th December 2019		
HREC REF Number	757/2017	Current Ethics Approval was granted until	30 January 2019
Protocol title	PAUSe: Perioperative Antibiotic Usage and Stewardship: A cross-sectional observational prospective study		
Protocol number (if applicable)			

Are there any sub-studies linked to this study?	☐ Yes ☑ No
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	

Principal Investigator	Jenna Piercy
Department / Office Internal Mail Address	jenna.piercy@uct.ac.za

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

UNIVERSITY OF CAPE TOWN FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)			
This serves as acknowledgement of a protocol deviation as described below.			
Chairperson of the HREC signature	signature removed	Date	8/1/2020

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	30 December 2019
HREC REF Number	757 | 2017
Project Title	Peri-operative Antibiotic Usage and Stewardship
Protocol number (if applicable)	
Principal Investigator	Dr Jenna Pierry
Department / Office Internal Mail Address	jenna.pierry@uct.ac.za

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation occurred.
Duration of study has gone beyond 30 January 2019

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants.
As this is an observational study, the delay has not had an effect on the above
3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future
The MMed student will have to abide by the time granted.

4. Principal Investigator's acknowledgement of responsibility

This signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.			
Signature of PI	signature removed	Date	30 December 2019

2. **Submission preparation checklist (SAJAA)**

SAJAA

Southern African Journal of Anaesthesia and Analgesia

Official Journal of The South African Society of Anaesthesiologists

As part of the submission process, authors are required to check off their submission's compliance with all of the following items, and submissions may be returned to authors that do not adhere to these guidelines.

- This manuscript has currently only been submitted to SAJAA and has not been published previously.
- This work is original and all third party contributions (images, ideas and results) have been duly attributed to the originator(s).
- Permission to publish licensed material (tables, figures, graphs) has been obtained and the letter of approval and proof of payment for royalties have been submitted as supplementary files.
- The submitting/corresponding author is duly authorised to herewith assign copyright to the South African Society of Anaesthesiologists (SASA).
- All co-authors have made significant contributions to the manuscript to qualify as co-authors.
- Ethics committee approval has been obtained for original studies and is clearly stated in the methodology as well as provided as a supplementary file.

- A conflict of interest statement has been included where appropriate.
- The submission adheres to the instructions to authors in terms of all technical aspects of the manuscript.
- Plagiarism: The submitting author acknowledges that the Editorial Board reserves the right to use plagiarism detection software on any submitted material.

Author Guidelines

Submitted manuscripts that are not in the correct format and without the required supporting documentation specified in these guidelines will be returned to the author(s) for correction and will delay publication.

AUTHORSHIP

Named authors must consent to publication **by signing a covering letter** which should be submitted as a supplementary file. Authorship should be based on substantial contribution to:

(i) conception, design, analysis and interpretation of data;

(ii) drafting or critical revision for important intellectual content; and

(iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**); and

(iv) exact contribution of each author must be stated.

DECLARATION OF CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute a conflict of interest. If there is no conflict of interest to declare please include the following statement: The authors declare no conflict of interest.

FUNDING SOURCE

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated as follows: No funding source to be declared.

RESEARCH ETHICS COMMITTEE APPROVAL

The submitting author must provide written confirmation of Research Ethics Committee approval for all studies including case reports. The ethics committee as well as the approval number should be included.

STATISTICAL ANALYSIS

Authors are advised to involve medical statisticians at the protocol stage of their research project: to plan sample size, and the selection of appropriate statistical tests for analysis and presentation.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

ETHNIC CLASSIFICATION

The rationale for analysis based on racio-ethnic-cultural categorisation should be indicated.

CATEGORIES OF SUBMISSIONS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Original articles

Original articles on research relevant to anaesthesia and analgesia should not exceed 3 200 words, no more than 30 references, with up to 6 tables or figures. A structured abstract under the following headings, Background, Methods, Results, and Conclusions is a requirement and should not exceed 300 words.

Clinical Review articles

Review articles relevant to anaesthesia and analgesia should not exceed 2 400 words, with a maximum of 20 references and no more than 6 tables or figures. A summary of 300 words or less is required.

Case reports

Case reports should not exceed 1 800 words with no more than 10 references. Figures are limited to 2 figures and may include images or photographs. The case report should have three headings: Summary (not exceeding 100 words), Case report (with no introduction) and Discussion. Case reports will be published online only. The summary and the URL will appear in the printed version.

Scientific Letters

Scientific Letters should not exceed 2 400 words with a maximum of 10 references. Only one table or illustration is permissible. A structured abstract under the following headings, Background, Methods, Results, and Conclusions, is a requirement and should not exceed 250 words.

Letters to the editor

Letters to the editor should be 800 words or less with only one image or table.

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

Qualification, affiliation and contact details

This information must be provided for ALL authors and must be submitted as a supplementary file.

Email addresses of all author must be provided.

ORCID number of **ALL** authors must be provided – if authors do not have ORCID, please register at https://orcid.org/

Abbreviations

All abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements

Scientific measurements must be expressed in SI units except blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age) should also be preceded by a space e.g. > 20 years. No spaces should precede ± and °, i.e. '35±6' and '19°C'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting

The manuscript must be in Microsoft Word or RTF document format. Text must be 1,5-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, except for Tables). *The manuscript must be free of track changes.*

Disclaimers should follow the Conclusion and it should be in the following order: Acknowledgements, Declaration conflict of interest, Funding source, Ethics declaration and ORCID.

ILLUSTRATIONS AND TABLES

If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Tables may be embedded in the manuscript file **and** provided as **'supplementary files'**. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g. 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e. not constructed with text boxes, tabs or enters) and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

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REFERENCES

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All references should be listed at the end of the article in numerical order of appearance in the **Vancouver style** (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus. Names and initials of all authors should be given; if there are more than six authors, the first four names should be given followed by et al. First and last page, volume and issue numbers should be given. **Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central ID (PMCID).** Authors are encouraged to use the DOI lookup service offered by **CrossRef**. Crossref DOIs should always be displayed as a full URL link in the form https://doi.org/10.xxxx/xxxxx

Journal references:

1. Jun BC, Song SW, Park CS, Lee DH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3-dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):429-34.
2. Polgreen PM, Diekema DJ, Vandeberg J, Wiblin RT, et al. Risk factors for groin wound infection after femoral artery catheterization: a case-control study. Infect Control Hosp Epidemiol [Internet]. 2006 Jan [cited 2007 Jan 5];27(1):34-7. Available

from: http://www.journals.uchicago.edu/ICHE/journal/issues/v27n1/2004069/2004069.web.pdf.

Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101. *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: publisher name, year; pages. Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'. Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

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3. **Consent**

Dear Colleagues,

We are looking to audit current clinical practice/ management of surgical wounds.

As we will be using data that reflect your clinical practice, we kindly request your consent to do so.

Please note that participation is anonymous and voluntary; and that all information will be password protected. This data will not be used evaluate individual performance, but rather to obtain a broad view of clinical practice in general.

For any queries, please contact:

Dr Delia Schuster:

- Cell: 0846160382
- Speed dial: 77391
- E-mail: deaschuster@gmail.com

Or

Dr Owen Porril

- Cell: 0827840607
- Speed dial: 76788
- E-mail: owen.porrill@uct.ac.za

*I hereby grant consent to be included in the study***.**

*I **DO NOT** wish to participate in this study.*

(Please tick the appropriate option)

Name:

……

Signature:

…….

Date

……

Dear Sir/ Madam

We are looking to audit current clinical practice as pertains to the prevention of wound infections during or following surgery.

This study will not change your management/ treatment in any way; nor will any personal information be divulged. All information will be kept anonymous.
Please be advised that NOT participating in this study WILL NOT affect your treatment either.

Thank you kindly for your time.
Warmest regards,

Dr Delia Schuster
Registrar in Anaesthetics and Peri-operative Medicine
Groote Schuur Hospital
deaschuster@gmail.com

*I hereby grant consent to be included in the study***.**

*I **DO NOT** wish to participate in this study.*

(Please tick the appropriate option)

Name:

……

Signature:

…….

Date:
……..

4. **Questionnaires**

Dear Colleagues,

Please take a moment to complete the following questionnaire on surgical antibiotic prophylaxis.

In terms of antibiotic administration:

Date

Patient number

Patient age

Procedure

Diagnosis

Weight of patient (please record "unknown" if the patient has not been weighed)		
Emergency or elective (Emergency surgery defined as surgery which cannot be delayed for more than six hours)	Elective	Emergency
Surgical wound classification (see addendum)	I II III IV	
Please list any antibiotics administered in the 24 hours preceding surgery		
Time of surgical incision		
Duration of surgery		

Thank you for your co-operation!

Dr Delia Schuster

MMed research project

Addendum

I. Clean surgery: no break in aseptic technique and the respiratory, gastrointestinal and genitourinary tracts are not breached.

II. Clean-contaminated surgery: this extends to the oropharynx, sterile genitourinary or biliary tract, the gastrointestinal or respiratory tracts, or if there has been a minor breech in the aseptic technique.

III. Contaminated surgery: the presence of acute inflammation, infected bilious secretions, infected urine, or gross contamination from the gastrointestinal tract.

IV. Dirty surgery: if an established infection exists, and therapeutic antibiotics are administered based on the susceptibility of bacterial isolates grown from culture

For the investigator:

Date

Patient number

Patient age

Procedure

Diagnosis

Prophylactic antibiotic given?	Yes	No	
Drug and doses			
Time of antibiotic administration			
2nd Dose administered? Please record time and dose, as well as the drug(s)			
Antibiotic prescribed post-operatively?	No	24hrs	>24hrs