# EFFECTIVENESS OF CEFOTAXIME IN PREVENTING SURGICAL SITE INFECTIONS IN CHILDREN UNDER 8 YEARS UNDERGOING ELECTIVE INGUINAL SURGERY AT THE UNIVERSITY TEACHING HOSPITALS, LUSAKA, ZAMBIA

By

**Azad Patel**

A Dissertation submitted to the University of Zambia in partial fulfillment of the requirements for the degree of Master of Medicine in Paediatric Surgery.

University of Zambia.

Lusaka.

2021

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# DECLARATION

I, **Azad Patel**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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## SUPERVISOR

This dissertation has been submitted with my approval.

Signature_____ Date_____

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# APPROVAL

This dissertation of Dr Azad Patel has been approved as fulfilling the requirements for the award of the degree of Master of Medicine in Paediatric Surgery by the University of Zambia.

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## Abstract

Inguinal operations are the most commonly performed surgeries in children. There is a divergent view on use of pre-operative antibiotic prophylaxis to prevent surgical site infections (SSI) after these surgeries. The aim of this study was to detect if the use of cefotaxime had a significant impact on prevention of SSI in children under 8 years undergoing elective inguinal surgery at the University Teaching Hospitals, Lusaka.

This was a cohort study. A total of 170 patients below 8 years of age undergoing elective inguinal herniotomy, orchidopexy or patent processus vaginalis (PPV) ligation at UTHs were enrolled. 85 of these received pre-operative cefotaxime while 85 did not receive any antibiotics based on surgeons preference. A data collection sheet was used to record pre-operative demographic details. Intraoperative variables and post-operative outcomes. No patient received post-operative antibiotics. Follow up to look for Surgical site infection was done at 2 weeks and 30 days according to Center for Disease Control (CDC) definition of SSI.

Out of 170 patients, 11(6.47%) had SSI. Six of the 85 that received surgical antibiotic prophylaxis (SAP) had SSI while 5 of the 85 that did not receive SAP had SSI (P=0.551). Deep SSI were seen in 2 patients that did not receive SAP (p=0.155) and grew Staphylococcus aureus in their cultures. Only 1 adverse allergic reaction to preoperative antibiotics was noted.

Despite a low risk of adverse reactions, there is no benefit of using pre-operative antibiotics to prevent SSI in children undergoing elective inguinal surgery.

**Keywords:**

Surgical site infections, Surgical antibiotic prophylaxis, Inguinal surgery, PPV ligation, Herniotomy, Orchidopexy

# Dedication

I dedicate this work to the children who took part in this study and look forward to use this work and future studies for the betterment of Paediatric surgery.

# ACKNOWLEDGEMENTS

I would like to recognise the invaluable contributions of my supervisor, Dr Bruce Bvulani. His dedicated guidance and tenacious efforts are without parallel.

I would like to thank my fellow colleagues in the paediatric surgical unit that helped me in the conduct of this research.

I would like to pay a special tribute to the many patients who have placed their faith and trust in me during the conduct of the study.

Special thanks go to the faculty of the Department of Surgery at the UTH, Adult Hospital, for all the help rendered to the fruition of this research project.

I also acknowledge the role of Prof Patrick Kaonga for his valuable input in statistical analysis.

Finally, I would like to thank my family especially my wife, who have been the well of support from which the water of this dissertation has been drawn. I could not have completed the task without them.

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# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| CDC | Center for Disease Control. |
| CI | Confidence Interval. |
| ERES | Excellence in Research Ethics and Science |
| Hb | Haemoglobin |
| M/C/S | Microscopy Culture and Sensitivity |
| MIC | Minimum Inhibitory Concentration |
| OR | Odds Ratio. |
| PPV | Patent processus Vaginalis. |
| RCT | Randomized Control Trial. |
| SAP | Surgical Antibiotic Prophylaxis. |
| SSI | Surgical Site Infection. |
| STATA | Software for Statistics and Data Science |
| UTH | University Teaching Hospitals. |
| WHO | World Health Organization. |

# DEFINITIONS

**Surgical Site Infection:** The CDC definition was used as below:

**Superficial incisional SSI-** Date of event for infection occurs within 30 days after surgical procedure AND involves only skin and subcutaneous tissue of the incision AND patient has at least one of the following:

a. Purulent drainage from the superficial incision.

b. Organisms identified from an aseptically-obtained specimen

c. Superficial incision that is deliberately opened by a surgeon or attending physician or other designee and culture or non-culture based testing is not performed. AND Patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat.

d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee.

**Deep incisional SSI-** Date of event for infection occurs within 30 days after the surgical procedure AND involves deep soft tissues of the incision AND patient has at least one of the following:

a. Purulent drainage from the deep incision.

b. A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon or attending physician or other designee and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purpose of clinical diagnosis or treatment or culture or non-culture based microbiological method is not performed patient has at least one of the following symptoms: fever (>38oC); localized pain or tenderness.

c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test.

**Organ/Space SSI** -Date of event for infection occurs within 30 days after the surgical procedure AND infection involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure AND patient has at least one of the following:

a. Purulent drainage from the drain that is placed into the organ/space

b. Organism identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method

c. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

**Adverse reaction:**

For the purpose of this study, we defined adverse drug reaction as:

A sudden and sustained change in vitals after administration of Antibiotic with or without a rash and may or may not need administration of antihistamines or systemic corticosteroids or sympathomimetic drugs.

**Surgical Antibiotic Prophylaxis:**

Prevention of infectious complications by administration of antimicrobial agent prior to exposure to contamination during surgery.

# CHAPTER ONE: INTRODUCTION

### 1.1.1: Inguinal surgery

Herniotomy for inguinal hernias is the most commonly performed operation in paediatric surgery worldwide (Holcomb, Murphy and Ostlie, 2014). Hydrocoeles are also common and are corrected using the same procedure in children, though referred to as ligation of a patent processus vaginalis. Orchidopexy for undescended testes also involves ligation of patent processus vaginalis followed by an additional procedure to fix the testes in the scrotum.

### 1.1.2: Surgical site infections

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site (Berríos *et al.*, 2017).

SSIs are potential complications of any type of surgical procedure. Although SSIs are among the most preventable healthcare-associated infections, they still represent a significant burden in terms of patient morbidity, mortality, and additional costs to health systems and service payers worldwide (World Health Organization, 2016). For these reasons, the prevention of SSIs has received considerable attention from surgeons, infection control professionals, health care authorities, the media and the public.

### 1.1.3: Surgical Antibiotic Prophylaxis

CDC guidelines state that ‘administer preoperative antimicrobial agents only when indicated based on published clinical practice guidelines and timed such that a bactericidal concentration

of the agents is established in the serum and tissues when the incision is made' (Category IB–strong recommendation; accepted practice.) (Berríos *et al.*, 2017).

The scientific rationale for antibiotic prophylaxis is to inhibit or eliminate contaminating microorganisms that gain access to the surgical site during the procedure, which reduces the probability of an established infection. Thus, the goal of administering preoperative antibiotics is to allow for adequate tissue (blood, soft tissue, and bone) concentrations by the time of incision. These antibiotics should exceed the minimum inhibitory concentration (MIC) for the organisms likely to be encountered for the duration of the operation. The MIC depends on the antibiotic used (Hansen *et al.*, 2014).

Few RCT's have been described comparing SSI with use of pre-operative antibiotics for herniotomy in particular. Most of these studies have not been able to recommend or reject the use of pre-operative antibiotics for herniotomy. Children above 8 years of age require repair of a defect in their abdominal wall after a herniotomy and this procedure has proven benefit from pre-operative cephalosporin use (Boonchan *et al*, 2017).

WHO has recommended surveillance of SSI by having national databases. CDC has a standard SSI information sheet that is useful for surveillance and establishment of guidelines (WHO, 2016).

### 1.1.4: Local Perspective

At the University Teaching Hospitals paediatric surgery unit no guidelines exist with regards to pre-operative antibiotic use and there is no documentation of complications from inguinal surgeries done.

Currently, there is no level 1 evidence that encourages or discourages use of antibiotics pre operatively for these operations from lower and middle income countries. The existing

literature in these regions have previously shown contrasting results. The literature from developed countries however discourage antibiotic use pre operatively as SSI is not common in those regions.

A study in 2016 supports that a quality-improvement intervention should take into account local contexts, with development of hospital policies, education on SAP recommendations, and dissemination of data on adherence to recommendations (Giusti *et al.*, 2016).

Children above age of 8 years have repair of the posterior wall during herniotomy hence benefit from SAP.

### 1.1.5 Overall Purpose of the Study

The aim of this study was to assess the benefit of using cefotaxime in prevention of surgical site infections for elective inguinal surgery in children at the UTHs, Lusaka.

## 1.2: Statement of the problem

There is a scarcity of RCTs for SSI in the paediatric population (Vaze, Samujh and Rao, 2014). Systematic reviews on the topic have no clear guidelines for SAP use in paediatric inguinal surgery and advice for larger studies. (Ameh *et al.*, 2012)

Anecdotal data shows that theater notes at the UTHs do not mention if SAP was given or not. The current surgeons in the department (consultants and registrars) have divided opinions on use of SAP for herniotomy.

SSIs are seen in the outpatient review clinics in UTH but there is no documentation of infection rates, other complications and the type of SSI.

Adverse reactions to SAP have been reported but no clear documentation on the exact type of adverse reactions.

Most developed country literature does not recommend SAP for herniotomy, orchidopexy and PPV ligation while literature from developing countries is divided on SAP use for these operations.

## 1.3: Study justification

This study is part of a trending topic that has attracted the attention of many researchers, authorities in health economics and the public. With the large number of patients expected to be included in this study, it is hopeful to find a scientific answer to the question on benefit of SAP for paediatric herniotomies, orchidopexies and ligations of PPV.

The study will enable us to identify the incidence of adverse reaction to SAP in this population and to identify if the adverse effects outweigh prevention of SSI if found.

Cefotaxime, a third generation broad spectrum antibiotic is cheap, easily accessible and has been proven effective as SAP in various operations (Gohil *et al.*, 2016). It is currently the antibiotic of choice for SAP for general paediatric surgical operations at the UTHs.

Previous studies have recommended more studies need to be done with regards to SAP and prevention of SSI to come up with more definite evidence.(Ameh *et al.*, 2012; Shirimpaka E, 2007).

## 1.4: Research questions

Does the administration of pre-operative cefotaxime reduce the incidence of SSI among children undergoing elective inguinal surgery in the Children's Surgical theater at University Teaching Hospital, Lusaka, Zambia.

## 1.5: Objectives

### 1.5.1: Main objective

To evaluate the benefit of pre-operative antibiotic prophylaxis with cefotaxime in the prevention of postoperative SSI in patients undergoing herniotomy, orchidopexy and PPV ligation.

### 1.5.2: Specific objectives.

1. To determine the rate of SSI and associated factors for herniotomy, orchidopexy and PPV ligation at UTH.
2. To compare the rate of SSI amongst patients that receive pre-operative cefotaxime and those that don't.
3. To characterise the adverse effects of preoperative cefotaxime in patients that receive SAP.

# CHAPTER 2: LITERATURE REVIEW

**2.1.1: Prevention of Surgical Site Infections:** The similarity of the operations for treatment of inguinal hernia, hydrocoeles and cryptorchidism allows for comparisons across the operations in terms of post-operative outcomes as seen in many previous studies (Morecroft *et al.*, 1993; Vaze *et al.*, 2014; Erdoğan *et al.*, 2013; Clarke, 2010).

Adherence to a strict surgical care intervention program that includes use of antibiotic prophylaxis when appropriate has been shown to reduce SSI (Ameh *et al.*, 2012). This is in agreement with the WHO guideline with regards to antibiotic use for procedures where literature does not support SAP nor does it disapprove SAP (Hawn *et al.*, 2011).

A landmark systematic review in 2012 of interventional studies for prevention of surgical site infections in sub-Saharan Africa concluded that there is extremely limited research from sub-Saharan Africa on interventions to curb the occurrence of SSI. Although some of the existing studies are weak, several high-quality studies have been published in recent years. Standard methodological approaches to this subject are needed (Aiken *et al.*, 2012). The main limitation noted were nonstandard definition of SSI, weak randomization techniques, and lack of the use of sample size calculations (Ameh *et al*, 2012).

Prevention of SSI is key in performing inguinal surgery in neonates. The occurrence of infection has been associated with atrophy of the testes and this has an impact on the fertility on the patient in future (Phelps *et al.*, 1997; Leung *et al.*, 1999). Infection has also been associated with recurrence of hernia. A recurrent hernia poses difficulty to treat and can be prevented by preventing infection (Grosfeld *et al.*, 1991).

A systematic review of preoperative practice found that preoperative bathing with soap, chlorhexidine or plain water did not affect rates of SSI in patients undergoing clean elective surgeries (Webster *et al.*, 2015)

### 2.1.2: Adverse reactions of Pre-Operative Antibiotics:

A retrospective review in USA found that SAP did not reduce the risk of postoperative SSI, readmissions, or hospital visits. Patients who received SAP had significantly increased odds of perioperative allergic reaction. This demonstrated that the risks of SAP outweigh the benefits in children undergoing Orchiodpexy. Peri-operative reactions to the antibiotics were seen in 1.4 percent of patients included (Rensing *et al.*, 2018).

Antibiotics have been shown to be responsible for 12 to 15 percent of perioperative anaphylaxis reactions in a French series (Mertes *et al.*, 2010). Studies in the United States of America showed that antibiotics accounted for over 50 percent of all anaphylaxis reactions (Gurrieri *et al.*, 2011; Kuhlen Jr *et al.*, 2016; Trautmann *et al.*, 2016). Hence their use should be restricted to when they have been shown to be effective and not for all operations (WHO , 2016).

### 2.1.3: Current evidence heterogeneity

Although the CDC definition of SSI is up to a period of thirty days, a prospective study in 2016 showed that 2 weeks is an acceptable duration for follow up as short term complications are likely to occur before 2 weeks from time of surgery for inguinal hernias (Dhakne *et al.*, 2016). A RCT done in India suggests that there is no statistically significant difference in the proportion of early post-operative wound infection between the patients who received single dose of pre-operative antibiotic vs those that did not. In this study, no group received post-operative antibiotics. The operations included were herniotomy and orchidopexy (Vaze *et al.*, 2014).

Analysis of surgical aspect of bacterial infection in paediatric populations found that up to 20% of clean surgeries are infected in Africa (Ameh *et al.,* 2012). This is in contrast to literature from developed countries that showed infection rates of between 0.6 to 2.4% for paediatric inguinal herniotomy, with or without antibiotic use (Rensing *et al.*, 2018; Erdoğan *et al.*, 2013). A study in 2008 in Nigeria with 104 patients found pre-operative Gentamycin to significantly reduce SSI in herniotomy; Staphylococcus aureus was the most common organism isolated in that study (Usang *et al.*, 2008). Another study in 2015 showed incidence of SSI of 9.27% without using SAP (Ibrahim *et al.*, 2015).

A study in Zambia in 2007 found no significant benefit of SAP in preventing SSI in adult patients undergoing clean abdominal surgeries when compared to post-operative antibiotic use. Patients receiving SAP had infection rates of 7.3% while those that did not receive SAP had infection rates of 10.1% (Shirimpaka E, 2007). This study did not include any paediatric patient and was only comparing pre op antibiotic use in the two groups. Both groups received same regimen of post-operative antibiotic prophylaxis.

# CHAPTER 3: RESEARCH METHODS

**3.1 Study design**: This was a Cohort study

**3.1.2 Study site:** The study was conducted in the Department of Paediatric Surgery; at the University Teaching Hospitals, Lusaka.

**3.1.3 Study duration:** The study was done from June 2018 to June 2019.

**3.1.4 Study end point:** The end point was at 30 days after the time the operation. At this point, any surgical site infection is expected to be established if present.

Surgical site infection was classified as per WHO guidelines:

- Superficial incisional SSI - Infection involves only skin and subcutaneous tissue of incision
- Deep incisional SSI - Infection involves deep tissues, such as fascial and muscle layers; this also includes infection involving both superficial and deep incision sites and organ/space SSI draining through incision
- Organ/space SSI - Infection involves any part of the anatomy in organs and spaces other than the incision, which was opened or manipulated during operation

**3.1.5 Target population**: Children under 8 years of age presenting to paediatric surgery department of the UTHs.

**3.1.6 Study population:** Patients under 8 years with inguinal hernia, hydrocoeles and cryptorchidism scheduled for elective surgery.

### 3.2: Inclusion criteria

- All patients under age of 8 years presenting to the department of paediatric surgery for management of clinically confirmed inguinal hernias, hydrocoeles and cryptorchidism scheduled for surgery and were included.
- Patients who had consented and/or ascented to participate in the study.

### 3.3: Exclusion criteria

- Patients with non-reducible hernia, including those with a recent (48 hrs.) incarceration and testicular torsion (emergency operations)
- Patients that had known allergy to Cefotaxime
- Patients that had an intraoperative complication that warrants antibiotic use
- Patients with a recurrent hernia or those due for staged orchidopexy were excluded.

### 3.4: Sampling strategy

Systematic sampling was done. Every second patient due for the concerned operations was recruited till the sample size was achieved. Being an observational study, the selection criteria to determine which patient receive antibiotics was determined by the preference of the operating surgeon on their use of SAP for these operations.

### 3.5: Procedure

#### 3.5.1 Enrolment:

Patients were recruited by the main principle investigator, after consent to operation was obtained and the patient was included on the operating list. The study was explained to the parents and caregiver and a written consent to participate in the study was obtained. Children between age 7 to 8 were also be told about the study when obtaining ascent.

#### 3.5.2 Operations:

Standard operations of herniotomy, PPV ligation, and orchidopexy were done according to current practice in paediatric surgery at UTH. Patients had a regular morning bath with warm water. A single brand of Cefotaxime (Erixime) was used for all patients that received antibiotics during the study. Operations were performed by consultants, senior registrars, and registrars. Registrars could only operate independently when assessed as competent to perform these procedures by the consultant. Adverse reaction to pre-operative antibiotic were recorded in the data collection tool and patient's file. The adverse reaction was managed by the anaesthesiologist providing anesthesia according to their perioperative anaphylaxis management practice. Pre-op cleaning with povidone iodine was done in theater. All wounds were dressed with sterile dressing post-operative.

#### 3.5.3 Post-operative

Patients were told to remove the dressing on day 2 and to clean the wound with soap and water. A phone call to care givers on day 2 post operation was made to remind them hence ensure this is done on the specified day.

No oral antibiotic was given after the procedure as is the current practice in the department. Only analgesics in the form of paracetamol was given.

Patients were counselled of signs and symptoms of complications of the operations including infection and when they should seek earlier medical attention than the review date.**3.5.4 Follow up**

Reviews were done by surgeons to assess for surgical site infection as defined in this study. When a SSI was identified, patients were treated as per current treatment practices of SSI in the department and swabs for microscopy, culture and sensitivity (M/C/S) obtained.

**3.6 Sample size:** 166

Sample size was calculated using open Epi sample size calculator for Cohort studies.

**Sample Size: X-Sectional, Cohort, & Randomized Clinical Trials**

| | |
|---|---|
| Two-sided significance level(1-alpha): | 95 |
| Power(1-beta, % chance of detecting): | 80 |
| Ratio of sample size, Unexposed/Exposed: | 1 |
| Percent of Unexposed with Outcome: | 9.3 |
| Percent of Exposed with Outcome: | 0.1 |
| Odds Ratio: | 0.01 |
| Risk/Prevalence Ratio: | 0.01 |
| Risk/Prevalence difference: | -9.2 |

Resultant sample size: 166 patients

### 3.7 Data analysis

Statistical software STATA version 13 was used to analyse the Data.

Rates of surgical site infections were calculated for those that received SAP and those that did not receive SAP.

The rate of adverse reactions was also calculated for those that received SAP.

Bivariate analysis (using chi square test) of SAP with post-operative infection and occurrence of adverse effects was done.

Univariate and multivariate logistic regression was done. Independent variables included age, weight, haemoglobin, WBC count, care giver education level, type of suture, type of incision, time of surgery and bilateral hernia. Dependent variables were SSI and adverse reactions to antibiotic.

### 3.8 Ethical considerations

This study was conducted in full compliance with ethical principles. Ethical approval from ERES Converge Ethics Committee (Ref- 2018-OCT-026) was sought before the study was commenced. Permission to access the study site was also sought from the U T Hs management. Data collected was only handled by the researcher, and confidentiality was ensured.

# CHAPTER 4: RESULTS

## 4.1 Background

A total of 170 participants were enrolled in the study between November 2018 and July 2019.

**Table 4.1: Baseline Characteristics of study participants undergoing inguinal surgery**

| Characteristic | Category | Proportion n (%) |
|---|---|---|
| Gender | Male | 154(90.6) |
| | Female | 16(9.4) |
| Residence | Low Density | 52(30.6) |
| | High Density | 118 (69.4) |
| Caregiver education level | Primary | 67(39.4) |
| | Secondary | 53(31.2) |
| | Tertiary | 50(29.4) |
| HIV status | Positive | 3(1.8) |
| | Negative | 167(98.2) |
| Z-Score (nutrition status) | -3 | 8(4.7) |
| | -1 | 13(7.7) |
| | 0 | 120(70.6) |
| | 1 | 16(9.4) |
| | 3 | 13(7.6) |

The majority of patients were males, with only 16 females with inguinal hernia. The majority of patients were residents of low cost areas of Lusaka accounting for 69.4% of study participants. The Primary care giver had completed tertiary education in 29.4% of participants while only 39.4% and 31.2% had attended primary and secondary school respectively. The majority of participants were HIV negative. Only 1.8% were positive and on treatment. The majority of children were in the normal weight for age charts accounting for 87.7% of participants. Only 7.6% were overweight for their age while 4.7% were under weight for their age.

The patients in the study were between 5 and 96 months as shown in figure 4.1 below. The median age for males was 27 months (IQR 18-48 months) while the median age for females was 26 months (IQR 26-38 months) as shown in figure 4.1 below.

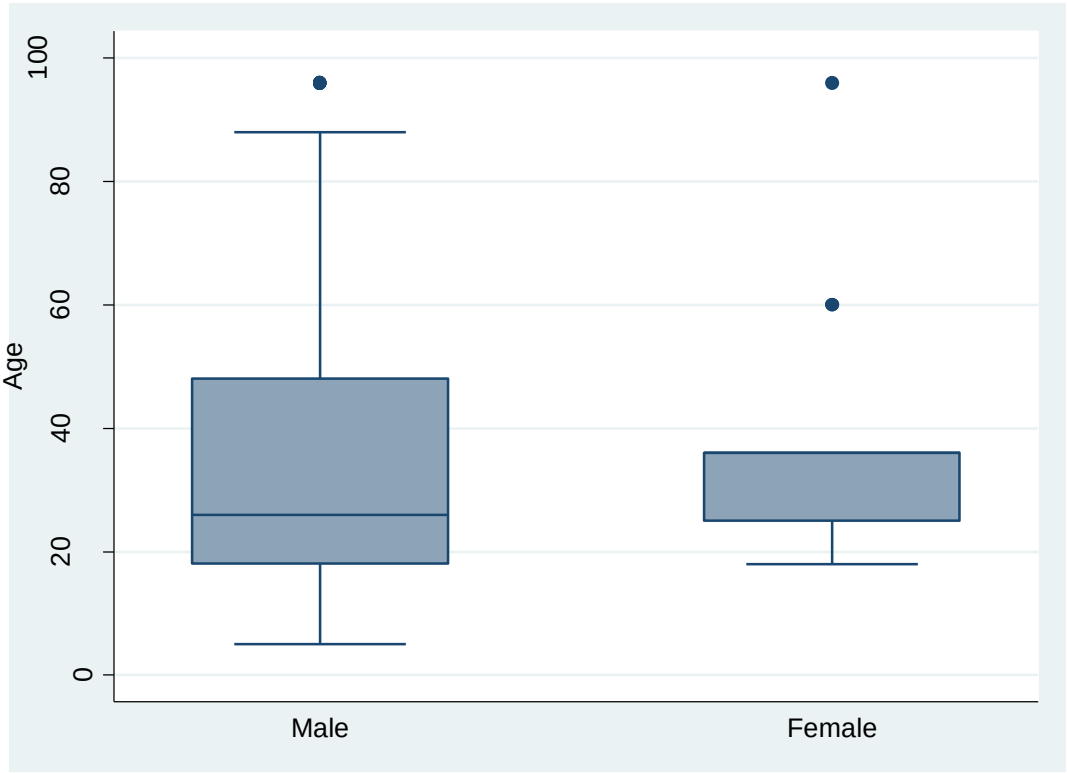


**Figure 4.1: Age distribution between male and females in months**

Inguinal hernias were the most common diagnosis accounting for 121 patients seen of which 66 were right sided, 29 left sided and 26 bilateral. There were 21 cases of hydrocoeles of which 13 were right sided, 6 left sided and 2 bilateral. A total of 28 cases of undescended testes were seen of which 13 were right sided, 8 left sided and 7 bilateral. This information is shown in figure 4.2 below. 60% of the undescended testes were palpable in the inguinal canal before surgery while 40% were palpable at or below the superficial ring. There were no cases of intra-abdominal testes in the study.

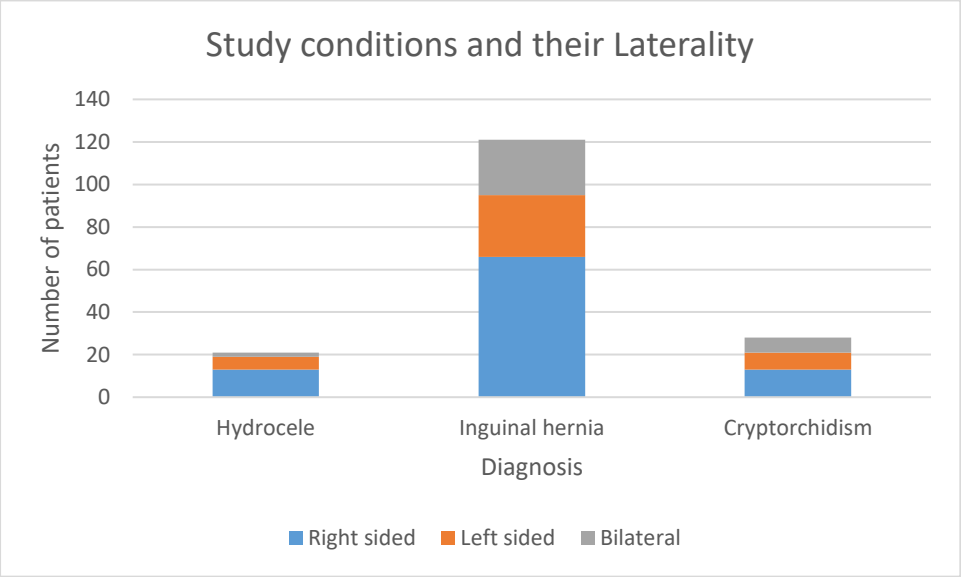


**Figure 4.2: Study conditions with Laterality**

There were 11 patients that developed SSI in this study giving an overall infection rate of 6.47% as shown in figure 4.3 below. The infection rate in the group that received SAP was 7.05% while it was 5.89% in the group that did not receive SAP. This difference was not statistically significant on chi square analysis with p value of 0.551.

**Rates of SSI**

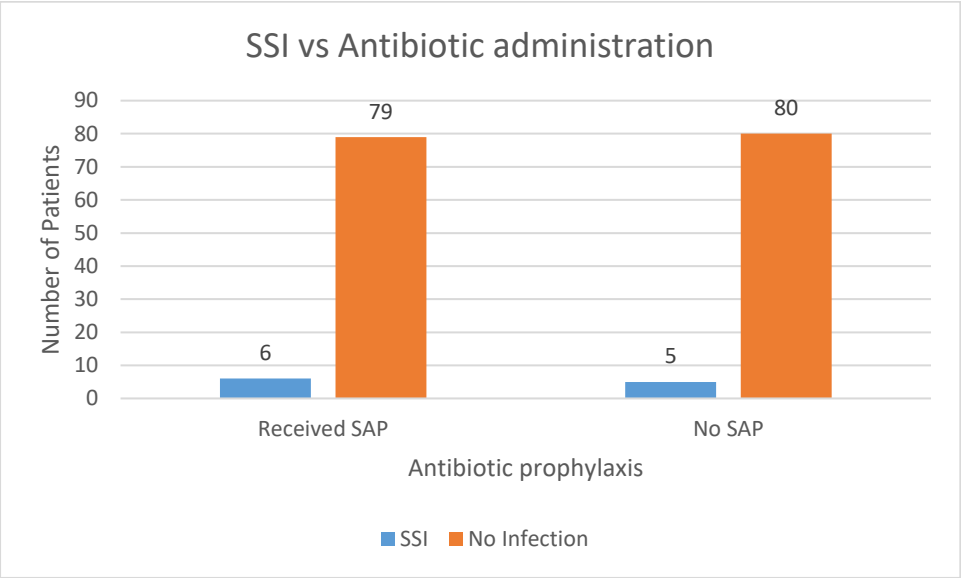


**Figure 4.3: Association between SAP administration and presence of SSI**

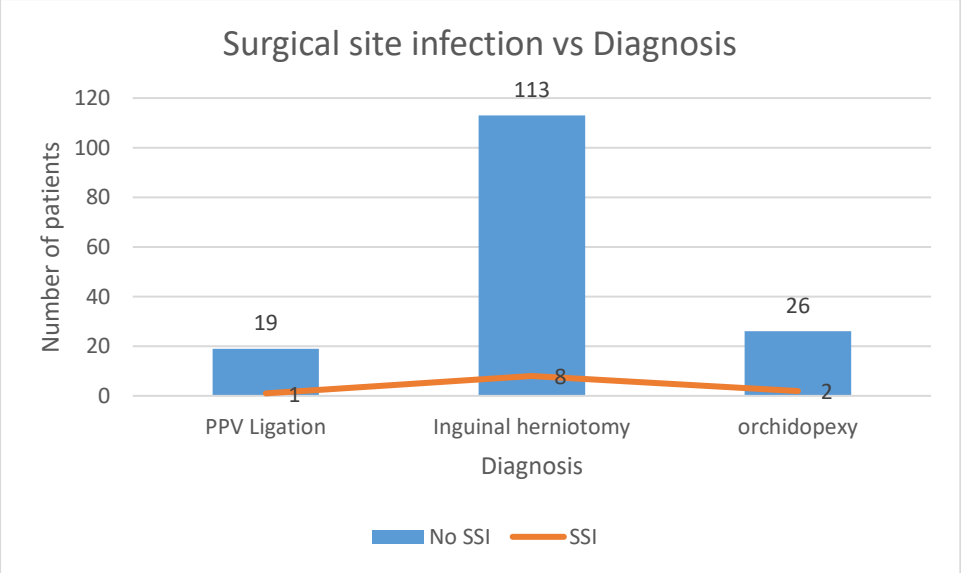


**Figure 4.4: SSI among the various surgical procedures done.**

The infection rate was the highest in the patients that had orchidopexies done with an overall infection rate of 7.1%. The infection rate for PPV ligation was 5.26% while it was 6.6% in patients with inguinal hernias as shown in Figure 4.4 above.

**Table 4.2: Association between types of SSI and SAP.**

| | No infection | Superficial SSI | Deep SSI | Organ space | Total |
|---|---|---|---|---|---|
| Received SAP | 79 | 6 | 0 | 0 | 85 |
| No SAP | 80 | 3 | 2 | 0 | 85 |
| | 159 | 9 | 2 | 0 | 170 |

Pearson Chi Square 2.98 P Value Overall: 0.225

P Value Deep SSI: 0.155

Of the 11 cases of SSI seen, 9 were superficial surgical site infections and 2 were deep infections. The patients that had deep infections did not receive SAP. However, there was no significant association between deep SSI and lack of antibiotic administration. The two deep SSI were due to *Staphylococcus aureus* that was sensitive to Cefotaxime and Penicillin on culture.

All patients that had a SSI were males. No female patients with hernias developed a SSI. All the cases of SSI were in HIV negative patients. There were few patients with HIV in the study (3/180). Thus, gender and HIV status had an odds ratio of 1 in predicting SSI as shown in table 4.3 below.

Age was a significant factor associated with SSI on univariate analysis with p value of 0.02. Nine of the 11 patients that developed a SSI were between ages 6 and 7 months' age. This association was not significant on multivariate analysis.

There were statistically significant increased infections in patients staying in a low density area (13.4%) compared to high density area that had a surgical site infection rate of 4.2%. This was noted as shown on both univariate and multivariate analysis in table 4.3.

The Hb was significantly associated with SSI at an Hb of less than or equal to 10.4g/dl. This was however not significant on multivariate analysis.

There was no association seen between SSI and nutrition status through Z score (P 0.294), diagnosis/ surgical procedure (P= 0.342), bilateral pathology (P= 0.192), position of testes (P=0.159) and the volume of fluid in the hydrocele (p= 0.176)

**Table 4.3: Multiple logistic regression analysis of the association between SSI and pre-operative variables.**

| Variable | Univariate | | | Multivariate | |
|---|---|---|---|---|---|
| | OR | 95% CI | P value | 95% CI | P Value |
| Gender | 1 | - | - | -.08-0.18 | 0.439 |
| Age | 1.075 | 1.14-4.77 | **0.020** | -0.08-0.18 | 0.439 |
| Address | 6.5 | 0.37-1.33 | **0.012** | 0.11-0.32 | **0.000** |
| Education Status | 2.04 | 0.85-4.87 | 0.109 | 0.01-0.12 | 0.11 |
| Z score | 0.72 | 0.41-1.24 | 0.239 | -0.56-0.17 | 0.294 |
| Hb | 2.1 | 1.32-3.34 | **0.035** | -0.01-0.68 | 0.157 |
| WBC | 1.05 | 0.97-1.14 | 0.254 | -0.53-0.08 | 0.379 |
| HIV Status | 1 | - | - | -0.53-0.07 | 0.144 |
| Diagnosis | 1.05 | 0.14-1.68 | 0.255 | -0.11-0.04 | 0.342 |
| Laterality | 0.56 | 0.14-2.20 | 0.407 | -0.16-0.33 | 0.192 |
| Position of Testes | 2.3 | 0.71-7.8 | 0.159 | -0.42-0.22 | 0.081 |

**Table 4.4: Multiple logistic regression analysis of the association between SSI and intra perioperative variables**

| Variable | Univariate | | | Multivariate | |
|---|---|---|---|---|---|
| | OR | 95% CI | P value | 95% CI | P Value |
| Antibiotic | 1.43 | 0.43-4.7 | 0.551 | -0.646-0.085 | 0.646 |
| Time of day | 2.25 | 0.27-18.1 | 0.447 | -0.056-0.22 | 0.237 |
| Time Interval | 0.99 | 0.87-1.12 | 0.905 | -0.011-0.007 | 0.623 |
| Type of skin incision | 0.14 | 0.003-5.7 | 0.298 | -0.43-0.02 | 0.081 |
| Aponeurosis incision | 0.17 | 0.003-7.5 | 0.356 | -0.23-0.16 | 0.731 |
| Suture on sac | 2.52 | 0.4-15.2 | 0.313 | -0.04-0.12 | 0.308 |
| Sac excision | 1.15 | 0.11-12.3 | 0.906 | -0.14-0.22 | 0.643 |
| Duration of surgery | 1.06 | 096-1.17 | 0.220 | -0.004-0.007 | 0.613 |

Table 4.4 above shows that there was no significant association between SSI in the group that got SAP vs those that did not get SAP (P= 0.551). There was no significant association between SSI and operative variables including time of day (Morning or afternoon) (P=0.447) and oblique vs transverse skin incision (P=0.298). There was no difference in SSI rates between canalicular and extra canalicular approach (P=0.731). There was also no significant association between SSI and the duration of surgery (P=0.613) and whether the sac was excised or not (P=0.643). These associations are shown in table 4.4 above.

### 4.2 Adverse reactions.

There was only one case of an adverse reaction to SAP representing rate of 1.17% among the 85 patients that received SAP. This was an allergic reaction post administration of cefotaxime identified as a rash around the IV cannula and left hand just after the drug was given. This was treated with hydrocortisone and simple observation. The patient was discharged the same day after surgery after a post-operative review by the attending clinician assessed patient fit for discharge. The patient did not present with a SSI at review. There was no statistical significance at bivariate analysis (P= 0.699 95% CI) of occurrence of adverse reaction and reduction SSI prevention in the patients that received antibiotics.

# CHAPTER 5: DISCUSSION

## 5.1 Background

This was a cohort study conducted in the department of surgery at the UTH. It was done to assess the benefit of administering Cefotaxime as a preoperative prophylactic antibiotic in children under 8 years undergoing elective inguinal surgery. This was an essential study as the literature on this topic has divided recommendations as well as divided local opinions among surgeons in the department (Usang *et al.*, 2008; Osuigwe*et al.*, 2006). In this study, we found an overall infection rate of 6.47%. There was no significant difference in infection rates between the groups that received SAP with those that did not receive. Patients that stayed in a low density areas and patients with age less than 7 months were at higher risk of developing a SSI in this study.

## 5.2 Baseline patient characteristics

A total of 170 patients were included in the study. The male to female ratio was 9:1, which was similar to studies done by Jhadav et al. This, like in other studies combining pathologies such as hydrocoeles, inguinal hernias and undescended testes, is attributable to the higher incidence in males than females. Studies looking at inguinal hernias only have a male to female ratio of 8:2 (Javaid *et al.*, 2018).

The majority of patients (69.4%) were residents of high density areas that are generally have low cost housing facilities. With regard to education status of the primary caregiver, only 29.4% had tertiary education while the majority (39.4%) had only attended primary school. This was much

less than the participants in a study by Ekpemo et al that had 61% of care givers with tertiary education in Nigeria (Ekpemo *et al.,* 2018).

All our patients that are admitted for elective surgery take an HIV test on an opt-out basis from the Children's surgical outpatient unit or during the admission . Only 1.8% of patients in the study had HIV and all these were already on antiretroviral treatment. This was much lower than described by Ameh et al who noted HIV prevalence of 67% in children undergoing surgery in African countries (Ameh *et al*, 2012). One of the reasons for this low incidence of HIV in the study population could be because of the robust Prevention of Mother to Child Transmission programs in Zambia (Chi *et al.*, 2018).

Most patients in the study had a good nutritional status based on a Z score. Only 4.7% had a Z score of less than -3. Togo et al reported a malnutrition rate of 10.7% in their study (Togo *et al.*, 2011).

### 5.3 Overall infection rate

The overall rate of surgical site infection in the study was 6.47%. This was comparable to studies done by Ekpemo et al who had an overall infection rate of 6.35% (Ekpemo *et al.,* 2018). Our infection rate was much lower than Ibrahim et al that had an infection rate of 9.27% for inguinal surgeries in children (Ibrahim *et al.,* 2015b). It was also much less than the review by Ameh et al that showed children in Africa undergoing clean elective surgeries having infection rates up to 14.3% (Ameh *et al*, 2012). It was lower when compared to Shirimpaka et al that showed SSI of 8.7% at our institution in clean surgeries in adults (Shirimpaka E, 2007).

Our infection rate was higher than most other studies in developing countries. Vaze et al from India, Kekre et al, Dhakne from India, Joda from Iraq and Osuigwe from Nigeria that had infection rates of 2.89%, 0.4%, 2%, 3.3% and 4.7% respectively (Vaze *et al.*, 2014; Kekre *et al.*, 2018; Dhakne *et al.*, 2016; Osuigwe *et al.*, 2006; Joda, 2018). Of note, most of these studies did not use the WHO or CDC definitions of SSI in their studies hence may have led to some variations in recoding of outcomes as highlighted in a review by (Ameh *et al.*, 2012). Lee et al reported no SSI in their study (Lee *et al.*, 2014).

The studies from developed countries showed much lower SSI rates. Rensing et al found and SSI rate of 0.1% and Kwok et al found an infection rate of 2% (Rensing *et al.*, 2018; Kwok *et al.*, 2016).

Most of the SSI in this study were superficial surgical site infections. Only 2 of the 170 patient developed deep SSI. This comparison was difficult to make with other studies as most did not classify infections as superficial and deep (Vaze *et al.*, 2014; Ekpemo *et al.*, 2018).

### 5.4 Benefit of SAP

The SSI rate in the group that received pre-operative cefotaxime was 7.05% compared with 5.89% in the group that did not receive cefotaxime. There was no statistical significance in this difference hence no overall benefit was noted in prevention of SSI with use of pre-operative cefotaxime in inguinal surgery in children. This finding was in keeping with literature from developed countries as well as some in African studies with similar demographic characteristics of participants (Javaid *etal.*, 2018; Vaze *et al.*, 2014; Rensing *et al.*, 2018; Osuigwe *et al.*, 2006; Joda, 2018; Gangopadhyay *et al.*, 2005). Our results were in contrast to Usang et al in Nigeria who had noted

a benefit in reduction of SSI when using pre-operative antibiotics for herniotomies (Usang *et al.*, 2008a). This could have been due to an overall lower rate of SSI of 4.8% and a smaller sample size of 88 patients in their study.

Nine patients in the study had superficial surgical site infections. These were treated without antibiotics with emphasis given to parents on wound care. They all healed with minimal scaring at 30 day review.

There were 2 cases of deep SSI occurring in the group that did not receive pre-operative antibiotics. These patient received a course oral Cloxacilllin upon making the diagnosis of the surgical site infection. Swabs that were collected in these two patients found *Staphylococcus aureus* as the causative organism and were sensitive to penicillins, and cefotaxime. *Staphylococcus aureus* was also the causative organism in other similar studies (Usang *et al.*, 2008; Mawalla *et al.*, 2011; Shirimpaka, 2007).

Our choice of antibiotic was Cefotaxime. A single brand was used in the study patients that received this antibiotic. It is broad spectrum antibiotic that is the current choice of antibiotic for SAP at UTH in patients undergoing clean general surgical operations. Cephalosporins have been used in other studies for the inguinal surgeries in other studies (Ekpemo *et al.*, 2018). Some studies used Ampiclox and Gentamycin (Osuigwe *et al.*, 2006; Usang *et al.*, 2008b).

### 5.5 Factors associated with infection

The main controlled factor in the study-antibiotics- did not show any significance in reduction of SSI in the study population (P= 0.551).

On univariate regression analysis, age was a significant factor (P=0.02) that was associated with the occurrence of SSI. Age less than or equal to 7 months was a higher risk for developing SSI in our study. This observation was not significant on multivariate analysis however. This finding was similar to Usang et al that showed more SSI in pre-school children compared to school going children, though exact ages were not specified (Usang *et al.*, 2008).

The residence of patients was significantly associated with SSI. Patients that stayed in high density areas were less susceptible to SSI than those that stayed in low density areas. This showed that the social class of patients did not correlate to SSI. A possible explanation for this could be due to less antibodies in patients from low density areas as they have had very few exposures to infecting organisms in the past. This was in contrast to Ekpemo et al, however was in agreement with the study showing that SSI were unrelated to caregivers education level (Ekpemo *et al.*, 2018). In this study, SSI were not significantly associated with the education level of the primary care giver.

The pre-operative haemoglobin of less than 10.4g/dl was significantly associated with SSI on univariate analysis. The sensitivity and the specificity of having a SSI with an Hb of less than 10.4g/dl was 81% and 62% respectively.

The difference in infection rates amongst the specific surgical procedures, i.e., herniotomy, orchidopexy and PPV ligation was not significant P=0.255. This lack of association was noted in other studies as well (Vaze *et al.*, 2014; Javaid *et al.*, 2018). The laterality and presence of bilateral

hernia was also not associated with SSI P=0.40 There was no association between SSI and the position of undescended testes as well P=0.159

The average duration of surgery in this study was 40 minutes (95% CI 38.0-43.7). This was higher than Ekpemo et al who had an average of 34.8 minutes (Ekpemo *et al.*, 2018). This difference could be as the later study did not include orchidopexies that take a slightly longer duration.

The interval between antibiotic administration and incision ranged from 1 to 33 minutes. The mean was 10.7 minutes (95% CI 9.1-12.4 minutes). This was within WHO recommendation of SSI to be within 2 hours of incision (WHO, 2016). The exact duration of antibiotic administration prior to incision was not significantly associated with SSI in this study P=0.905. Studies have been done to show there is no difference in SSI between patients that receive antibiotics between 0 to 30 minutes or 30 to 60 minutes prior to incision (de Jonge *et al.*, 2017; Koch *et al.*, 2013; Wu *et al.*, 2014).

No significant difference was noted between intraoperative variations in procedure and occurrence of SSI. Whether a transverse skin crease incision or an oblique para inguinal incision was made was not associated with SSI P=0.298. The surgical approach as canalicular or extra canalicular was not associated with SSI P= 0.356. The suture material used to tie the inguinal sac was vicryl, ranging from 3/0 to 5/0/- in size. The size of suture used was not associated with SSI. Excision of the sac vs not excising the sac also did not have a significant association with SSI P=0.313 This was similar to other studies comparing intraoperative techniques to SSI in inguinal surgery. (Ibrahim *et al.*, 2015).

### 5.6 Adverse reactions

There was one case of adverse reaction to pre-operative cefotaxime representing an adverse reaction rate of 0.59% in the study population. The study was designed to look out for immediate adverse reactions that are of an allergic type only. The particular adverse reaction did not increase length of post-operative stay for the patient. The incidence in this study was much lower than the 1.4% found by Rensing et al (Rensing *et al.*, 2018). This difference could be because of long term adverse reaction monitoring that was included in their study.

Rangel et al found that up to 40% of surgical patients get SAP with no indication (Rangel *et al.*, 2011).

### 5.7 Study Limitations

One of the limitations of this study was that only anaphylactic adverse reactions to cefotaxime were investigated. Long term adverse effects such as Clostridium difficile diarrhoea were not investigated.

The lack of a formal randomization of patients in the study was a limiting factor as well.

The study did not asses the impact of the surgeon performing the procedure to occurrence of SSI.

# CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

## 6.1 Conclusions

The rate of surgical site infections in patients that received pre-operative antibiotic prophylaxis with cefotaxime was 7.06 % while it was 5.9% in those that did not receive cefotaxime. There was a higher rate of deep SSI in the patients that did not receive SAP with cefotaxime. These associations were not statistically significant. In conclusion, SSI rates were not reduced by the use of SAP with cefotaxime and their routine use is unwarranted in our environment.

There was no significant anaphylactic reaction when using cefotaxime as an antibiotic for pre-operative prophylaxis.

The factors that's were significantly associated with an increased incidence of SSI were patients that lived in low density areas and patients with an age of less than 7 months.

## 6.2 Recommendations

I. Given the extra cost of using cefotaxime and that there was no proven benefit of its use in prevention of SSI, antibiotics should not be used for these clean elective inguinal operations.

II. Further studies should be done to monitor for delayed adverse effects of cefotaxime use such as Clostridium difficile diarrhea.

III. Complications such as Superficial SSI and haematoma are self-resolving and do not need be treated with antibiotics in clinically stable children.

IV. Surgery should be delayed after age of 7 months in view of increased chances of infection, when no urgent indication is present.

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## Appendices:

### 1. PARTICIPANTS INFORMATION SHEET

My name is Dr Azad Patel, a medical doctor pursuing a master degree in paediatric surgery in the department of Surgery at the University Teaching Hospitals. As part of my academic qualification I am conducting a study to establish if antibiotics given before surgery for hernia, hydrocele and undescended testes help reduce infections after operation. The antibiotic used is not a new one but one that is commonly used in the hospital; Cefotaxime.

Currently at UTH, some patients may receive antibiotics while others may not. This is dependent on the surgeon operating.

During this study, your child may receive antibiotic whilst under general anesthesia in theatre. You shall then be required to return for clinical review after 2 weeks and at 1 month after operation. Signs of complications will be explained to you to enable you come for earlier review if needed. You may be availed the findings of the study when completed about a year later.

Your child's identity and all information collected during this study will be kept confidential. The study will not affect your child's treatment in any way different than the current practice nor will it have any added benefit outside the standard management of this condition.

Possible complications that may occur during this study are local pain/discomfort after the operation, swelling at operation site, redness of skin, superficial skin infection or abscess formation. In the unlikely event that any of the above occurs, prompt action shall be taken by the medical staff upon your return. Child may also have an adverse effect of the antibiotic and appropriate action will be taken if this occurs.

Participation in this study is voluntary and a written consent will be obtained from you, as their parent/ guardian indicating that you understand the procedure and are agreeable for your child to be included in the study. If at any time during the study you feel inconvenienced or for whatever reason you feel the need to withdraw your child from the study, you shall be permitted and treatment will not be withheld.

Any queries or clarifications can be directed to me, Dr Azad Patel, 0976153559, department of Surgery, P/bag RW1X, UTH, and Lusaka. Or you may contact The Chairperson, ERES Converge IRB, 33 Joseph Mwilwa Road, Rhodes Park, Lusaka. Tel: 0955 155633, 0955155634, 0966 765503. Email: eresconverge@yahoo.co.uk

## 2. CONSENT FORM

I_____, being the parent/guardian to ..... have read the above information, or it has been read to me. I have had the opportunity to ask questions concerning the study and these have been answered to my satisfaction. I consent voluntarily for my child to participate in this study.

Signature of parent/ guardian _____Date_____

Thumb print of parent/ guardian

**STATEMENT BY RESEARCHER**

I have accurately read out the information sheet to the participant's parent/guardian and to the best of my ability made sure that they understand what shall be done.

I confirm that the parent/ guardian was given an opportunity to ask questions about the study and all the questions asked have been answered correctly and to the best of my ability. I confirm that the parents/ guardians have not been coerced into giving consent and that it has been given freely and voluntarily.

Name of researcher _____

Signature of researcher _____Date _____

**WITNESS FORM**

I have witnessed the accurate reading of the information and consent form to the participant's parent/guardian and they have had the opportunity to ask questions. I confirm that the parent/guardian have given consent freely.

Name of witness _____

Thumb print of witness

Signature of witness _____ Date _____

## 3. CHILD ASSENT FORM

I am Dr Azad Patel from the University Teaching Hospital. I am doing a study to find out if a certain medicine, is helpful to reduce infections after operation. I also want to know how many children have reactions to this drug. This is not a new medicine but one that is commonly used in the hospital

You will receive an injection just before your operation. You will not feel any pain during this process as you will be put to sleep in theatre.

You will need to come back for a check-up after 2 weeks after the operation and after another 2 weeks.

If you do not want to take part in this study, you do not have to, and if you feel as though you would like to stop at any point during the study, you are free to do so.

You should discuss with your parent/guardian before you agree to take part. Your parents will be spoken to and will be asked for permission for you to participate, but if you do not want to, you do not have to.

If you have any questions, feel free to ask them, now or later, and I will do my best to answer them. If you think of a question later, you or your parents can contact me at 0976153559, or find me at the UTH in the department of surgery.

Sign this form only if you:

- Have understood what will happen to you during the study
- Have had all your questions answered
- Have talked to your parents/ guardian about the study
- Agree to take part in this study

I _____ (Participants name) in the presence of my parents/guardian and with their consent, do agree voluntarily to participate in this study.

Signature/thumb print: _____

Date _____

Investigators name: _____

Signature/thumb print: _____

Date: _____

## 4. Data Collection sheet

**A: Pre op details**

1. Participant Number:……. 2. Date enrolled: …….

3 Age:…… 4 Sex:……. 5 Weight:……kg. 6 Height……..cm

7.

Address:……
……

8. Contact Number: ……..

9. Mother/care giver level of education:

a. Primary
b. Secondary
c. Tertiary

10 Hemoglobin:……g/dl 11. White cell count:……

12. HIV status a. Positive b. Negative

13. Allergy to cephalosporin: a. Yes b. No

14. Diagnosis: a. Hydrocele b. Inguinal hernia c. Undescended testes

145. Volume of fluid from hydrocele

16. Position of testes: a. abdominal b. Inguinal canal c. At external ring d. Retractile

17. Is condition bilateral: a Yes b. No

**B Intra-operative and Peri-operative data:**

1. Antibiotic given: a.Yes b.No
2. Time antibiotic given:…….hrs
3. Incision time:……..hrs
4. Type of skin incision: a. Tranverse b. Oblique
5. Type of incision on aponeurosis: a. None b. Window c. Fully opened.
6. Suture used to tie sac: a. Chromic b. Vicryl c. PDS
7. Size of suture on sac:……..
8. Skin closure: a. Subcut b. Interrupted
9. Skin suture: a. Vicryl b. Prolene c. Silk d. Nylon
10. Size of suture on skin: ……
11. Sac excised : a.Yes b. No
12. Duration of surgery:…….minutes
13. Adverse antibiotic reaction: a. Yes b. No
14. Type: a. rash: b. Severe tachycardia c. Hypotension d. Arrhythmias
15. Action taken…… ……
16. Outcome of adverse reaction: a. Reaction controlled b. Prolonged admission needed

**(A) Two weeks review (tick or complete)**

1. Temperature:…….°C 2. Pulse rate:……../min 3. Day after operation……days

4. Clean healthy wound: a. Yes b. No

5. Swelling: a. Haematoma b. Hydrocele c. Abscess d. Recurrence.

**Infection screen:**

**a. No infection**

**5. Superficial SSI**

1. Redness/erythema

2. Purulent discharge

3. Swelling

4. Heat

**6. Deep SSI**

1. Infection involving the fascia or muscles with purulent discharge

2. Wound breakdown

**7. Organ space SSI**

1. Collection of pus in abdomen 2. Collection of pus in scrotum

**(B) At 30 days review**

**a. No infection**

**8. Superficial SSI**

1. Redness/erythema

2. Purulent discharge

3. Swelling

4. Heat

**9. Deep SSI**

1. Infection involving the fascia or muscles with purulent discharge

2. Wound breakdown

**10. Organ space SSI**

1. Collection of pus in abdomen 2. Collection of pus in scrotum

If Swab taken, Organism Identified:……

Sensitive drugs:…… Resistant drugs:……..