

**MAGNITUDE OF POST- URETHROPLASTY URINARY
TRACT INFECTIONS IN CHILDREN WITH HYPOSPADIAS
AT KENYATTA NATIONAL HOSPITAL**

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DEDICATION

To my dear husband, Denver Mariga and son, Glenn Imani. Thank you for your endearing love and support throughout this period.

To my loving parents, Boniface Mutua and Justina Mutua for your constant encouragement and love, I'm grateful. God bless you.

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LIST OF ABBREVIATIONS

CFU	Colony forming unit
CLSI	Clinical and Laboratory Standards Institute
DMSA	Dimercaptosuccinic acid
EAU	European Association of Urology
GAP	Glans approximation procedure
KIU	Kampala International University
KNH	Kenyatta National Hospital
MAGPI	Meatal advancement and granuloplasty incorporated
MOI	Moi University
MCS	Microscopy, Culture, Sensitivity
MSU	Mid- stream urine
SPA	Suprapubic aspiration
UON	University of Nairobi
UTI	Urinary tract infection
VUR	Vesicoureteric reflux

OPERATIONAL DEFINITION OF TERMS

- a) Urinary tract infection was diagnosed based on positive culture results as:
- Urine specimen from suprapubic bladder puncture- any number of CFU/ml (at least 10 identical colonies)
 - Urine specimen from bladder catheterization- $\geq 1000 - 50\,000$ CFU/ml
 - Urine specimen from midstream void- $\geq 10^4$ CFU/ml with symptoms
- $\geq 10^5$ CFU/ml without symptoms
- b) Contaminated urine: ≥ 2 organisms cultured in a urine specimen.
- c) Asymptomatic bacteriuria- Attenuation of urogenic bacteria by the host or colonization of the bladder by nonvirulent bacteria that are incapable of activating a symptomatic response (no leucocyturia or symptoms).
- d) Asymptomatic UTI- Leucocyturia is present without any symptoms in children with significant bacteriuria
- e) Symptomatic UTI the patient presents with irritative voiding symptoms, fever or malaise and a positive urine culture.
- f) Pre-operatively - From birth until the primary urethroplasty procedure
- g) Peri-operatively - From the operation day and within 30 days of the operation
- h) Post- operatively - After 30 days from surgery day

ABSTRACT

Background:

Children who have undergone urethroplasty (reconstructive surgery) procedure for hypospadias are at a higher risk of getting urinary tract infections (UTI). This may be due to urethral scarring following urethroplasty that acts as a nidus for UTI. The risk is also attributed to urine stasis due to complications of urethroplasty such as urethral diverticulum, urethral stricture, meatal stenosis or breakdown of urethroplasty. Hypospadias is associated with mullerian duct remnants such as mullerian duct cysts and enlarged prostatic duct utricle which may lead to recurrent UTI. Hence the need to assess the magnitude of UTI post-urethroplasty in Kenyatta National Hospital (KNH).

Study Objective:

The aim of this study was to determine the magnitude of urinary tract infections after urethroplasty for hypospadias in children at KNH.

Study Setting:

The study was carried out at the Pediatric Surgical Outpatient Clinic and the urine specimens were analyzed in the Microbiology laboratory at KNH.

Study Population:

The study targeted 115 male children with hypospadias condition who had undergone urethroplasty procedure between January 2014 to December 2018 (5years) in KNH with an age range of 6 months to 17 years.

Study Design:

This was a prospective descriptive cross- sectional study.

Study Duration:

The study duration was four months within the year 2019

Data Collection:

A data collection sheet was utilized for data collection. The patient's history from the parent or guardian as well as the patient's clinical record was obtained. This informed us on the type of hypospadias the patient had and the surgery performed. Complications of surgery were documented. These included urethral stricture, meatal stenosis, urethral diverticulum or urethroplasty breakdown. The patient was assessed for symptoms and signs of urinary tract infections. The appropriate urine collection method was used to collect the urine specimen and microscopy, culture and sensitivity tests was carried out on the specimen at Kenyatta National Hospital Laboratory. The results were filled in the data collection sheet.

Data Analysis:

Data was analyzed using STATA 15. Quantitative data was summarized into percentages, frequencies, means and standard deviation. Appropriate univariate and bivariate analysis such as Chi- square test of association, Odds ratio and confidence interval were applied on the results. Significance of the results was considered at 95% confidence interval.

Results

The total number of patients seen and urine samples collected was 83 boys. The prevalence of UTI following urethroplasty for children with hypospadias was 6% (5/83). They all had UTI symptoms such as dysuria, suprapubic pain, dribbling, fever, urgency and frequency. Complication rate was 54.2% (45/83) with urethroplasty breakdown being the commonest at 44.6%. Of the patients who had UTI, 60% had Ecoli, 20% had Pseudomonas aeruginosa and 20% had Enterobacter cloaca complex. 80% of the patients with UTI had penoscrotal hypospadias and 60% of them had complications post- operatively.

Conclusion

Magnitude of urinary tract infection post- urethroplasty for children with hypospadias was 6% at KNH with 80% of the patients having peno- scrotal type of hypospadias. The most common organism cultured was E. Coli.

60% of patients with UTI had urethroplasty breakdown post- operatively.

Further anatomical evaluation should be done on these patients to rule out mullerian duct remnants.

1.0 CHAPTER ONE: INTRODUCTION

Hypospadias is defined as an abnormal ventral opening of the urethral meatus in a male.¹ Its prevalence is 1 in 100-300 live births.¹ It is classified as per the location of urethral meatus. Duckett (1996) classified hypospadias into anterior 50% (glanular, coronal, subcoronal), middle 30% (anterior penile, midshaft, posterior penile) and posterior hypospadias 20% (penoscrotal, scrotal, perineal).²

Urethroplasty procedure depends on the classification of hypospadias and this includes tubularised incised plate repair (Snodgrass modification), transverse preputial island flap technique, meatal advancement with glansplasty incorporated (MAGPI), glans approximation procedure (GAP), Mathieu procedure, On-lay Island flap and staged procedures like Bracka preputial and buccal graft repair.^{3,4}

Urinary tract infection (UTI) is the growth of significant number of organisms of a single species in the urine, in the presence of symptoms.⁵ It is one of the most common childhood illness and also a common complication following urological procedures. UTI has a prevalence rate of 2.4% - 20.1% in childhood.⁶ Asymptomatic colonization of the urinary tract can occur and thus, other features such as the presence of inflammatory markers and urine culture is important to diagnose UTI.⁷

Complications of urethroplasty that have been reported include meatal stenosis, breakdown of urethroplasty, urethral stricture and urethral diverticulum which leads to urinary tract infections due to urine stasis.³

Patients with hypospadias are predisposed to UTI pre-operatively, peri-operatively and post-operatively. In a study by Winberg et al, UTI was diagnosed pre-operatively (from birth until the primary urethroplasty procedure) in 2% of the cases, peri-operatively (from the operation day and within 30 days of the operation) in 1% of the cases and post-operatively (after 30 days from surgery day) 5% of the cases.⁸

It was reported by Desautel et al, that posterior hypospadias is associated with the occurrence of other genitourinary anomalies like mullerian duct remnants which cause recurrent urinary tract infections following urethroplasty for hypospadias.⁹

There was no data in Kenyatta National Hospital on post-operative urinary tract infections following urethroplasty for hypospadias. From this study, we aimed to determine the magnitude of UTI and to identify the microbiologic profile of urine in these children post-operatively in order to enable us formulate a protocol that would aid in the management of UTI in children who had undergone urethroplasty for hypospadias at KNH.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Classification of Urinary Tract Infections

Urinary tract infections in children is classified according to site, episode, symptoms and complicating factors.^{10,11}

Classification based on site can be either lower urinary tract infections or upper urinary tract infection. Lower urinary tract infections (Cystitis) presents with irritative symptoms in older children such as suprapubic pain, frequency, dysuria, incontinence, urgency, hematuria and malodorous urine. In neonates and infants, these irritative voiding symptoms are hard to diagnose. Upper urinary tract infections (Pyelonephritis) involves the renal parenchyma and pelvis. It presents with symptoms including fever of more than 38°C. Children however have non-specific signs like lethargy, irritability, vomiting, diarrhea, poor feeding or failure to thrive.

Asymptomatic UTI is when leucocyturia is present without any symptoms in children with significant bacteriuria while in symptomatic UTI, the patient presents with irritative voiding symptoms, fever or malaise. Asymptomatic bacteriuria is colonization of the bladder by nonvirulent bacteria or attenuation of urogenic bacteria by the host. These are incapable of activating a symptomatic response and thus no leucocyturia.

UTI can be classified also according to episode. First infection is the initially diagnosed UTI. This may be due to an anatomical anomaly in infants and children. Recurrent UTI is defined as two or more culture proven infections after the early post-operative period has elapsed and the stent is removed.¹² It is subcategorized into unresolved bacteriuria, bacterial persistence and reinfection. Unresolved bacteriuria results from sub-therapeutic level of antimicrobial agent, noncompliance, malabsorption, inadequate drug metabolism or presence of resistant pathogens unresponsive to current treatment. Bacterial persistence is mostly due to a nidus or an isolated portion or anomaly where bacteria resides and is shielded from current treatment causing the same pathogen to be identified in recurrent infection. Reinfection is when each episode of UTI is a new infection. Sometimes, different serotypes of *Escherichia coli*. Other risk factors for recurrent UTI include vesico-ureteric reflux (VUR) and bladder-bowel dysfunction which is marked by lower urinary tract symptoms, constipation and history of recurrent fever of undiagnosed origin.^{13,14}

Complicated UTI occurs in an individual in whom factors related to the host like immunosuppression or specific anatomical or functional abnormalities related to the urinary tract. Uncomplicated UTI is infection in a patient with functional and morphological normal lower and upper urinary tract and a competent immune system.¹⁵

Catheter-associated UTIs refers to UTIs occurring in a person whose urinary tract is currently catheterized or has been catheterized within the past 48hrs.¹⁵

2.2 Diagnosis

The gold standard for diagnosis of UTI is growth of pathogenic bacteria in a urine culture.⁶

Urinalysis consisting of both dipstick test and microscopy is the first line test to be done when UTI is suspected. Dipstick test frequent biochemical markers of infection are nitrite, leukocyte esterase or both. Nitrite is a degradation product of nitrate in Gram-negative bacteria metabolism and its test has a sensitivity of 45-60% and a specificity of 85-98%. Leukocyte esterase is produced by the activity of leukocytes. It is an indicator of pyuria. It has a sensitivity of 48-86% and a specificity of 17-93%. A combination of both these tests improves sensitivity and specificity.¹⁵

Microscopy will assess for pyuria and bacteriuria which are both not reliable parameters to diagnose or exclude UTI. Pyuria in centrifuged urine is 5 white blood cells per high power field (25 WBC/uL). In uncentrifuged urine >10WBC/uL is sensitive for UTI. A combination of pyuria and a positive nitrite test has a positive predictive value of 98% in children who are older than 6 months and is thus reliable for the diagnosis of UTI.¹⁵

Criteria for UTI in children as per the EAU is based on how the urine sample was collected and the colony forming units per milliliter (CFU/ml).¹⁵ Urine specimen from suprapubic bladder puncture, any number of CFU/ml (at least 10 identical colonies). Urine specimen from bladder catheterization, $\geq 1000 - 50\,000$ CFU/ml while urine specimen from midstream void-, $\geq 10^4$ CFU/ml with symptoms or $\geq 10^5$ CFU/ml without symptoms.

2.3 Urine Collection Methods

Several methods can be used for urine collection, depending on whether the child is toilet trained or not and all of them with varying contamination rates and invasiveness. This

includes: Suprapubic bladder aspiration done with ultrasound guidance (specificity- 100% in excluding UTI) with a contamination rate of 1%. Bladder catheterization (specificity- 100% in excluding UTI) with a contamination rate of 12%. Clean catch urine collection (Sensitivity- 89%, Specificity- 95%) with a contamination rate of 26%. A plastic bag attached to cleaned genitalia (Sensitivity- 77%, Specificity- 68%) with a contamination rate of 46%. For the toilet trained child, a clean voided mid-stream urine sample can be obtained (Sensitivity- 100%, Specificity- 100%).^{13,16}

2.4 Urinary Tract Infections Following Urethroplasty for Hypospadias

Urinary tract infections post urethroplasty is usually as a result of surgery complications which include meatal stenosis, urethroplasty repair that has broken down, urethral stricture and urethral diverticulum and is thought to be due to urine stasis.³

Posterior hypospadias is the severe form associated with an enlarged utricle which forms a nidus for UTI as reported in a study by Desautel et al where 10/13 patients with perineoscotal hypospadias had mullerian duct remnants. These are either prostatic utricle cysts or mullerian duct cysts.^{9,17} Enlarged prostatic utricle was seen in 11-14% of hypospadias patients.¹⁸ According to Krstic et al, there is a direct relationship between the utricle size and the degree of hypospadias. The mullerian duct remnants are diagnosed frequently after failed urethroplasty, recurrent UTIs, or even retention of urine.¹⁹

In a retrospective study by Winberg et al, the aim was to determine the frequency of UTI's in 174 boys with hypospadias in the pre-operatively, peri- operatively and post- operatively period. Post-operative UTI's was 5% compared to the pre- operative UTI's at 2% and peri-operative UTI's at 1%. The study concluded that the high incidence of UTI post-operatively could be due to urethral scarring following the operation and this scar acts as a nidus increasing susceptibility to UTI in these children.⁸ Some children with hypospadias undergo several urethroplasty procedures in order to achieve full function especially in severe forms of hypospadias.

The incidence was low peri- operatively since the children are on antibiotics till the urethral stent or catheter is removed. The antibiotics in this case is given to prevent catheter associated UTIs and wound infections which may cause wound dehiscence and formation of fistulas.⁸ In a study by David et al, evaluating the complication rate after hypospadias repair

in the peri- operative period with and without the use of antimicrobial prophylaxis, with group 1(52) receiving cephalexin from day 1 after surgery to 2 days after catheter removal and group 2(49) not receiving antibiotics post- operatively. Urinary tract infections occurred four times more in group 2 than in group 1 while urethroplasty breakdown developed three times more in group 2 than 1 and meatal stenosis occurred four times more in group 2 than group 1. The most common organism was *Klebsiella pneumoniae* in group 2 and *Pseudomonas aeruginosa* in group 1. They concluded that antimicrobial prophylaxis following hypospadias repair will reduce complications of urethroplasty breakdown and meatal stenosis and reduces the risk of complicated UTIs.²⁰

In another study by Wehbi et al, the development of recurrent UTI after hypospadias repair was 1.91% with a mean age of repair at 14 (6-24) months and a median follow up period of 6.5(1.5-11) yrs. Ultrasound done in 90% of cases in this study, identified hydronephrosis in 21% and post-operative voiding cysto-urethrogram done in 58% of cases showed distal stenosis in 40%, vesicoureteric reflux (VUR) in 33%, urethral diverticulum in 14% and enlarged utricle in 12%.¹²

UTIs have long term complications like renal scarring leading to hypertension, proteinuria and renal failure.¹³ In a study by Shaikh et al, DMSA (Dimercaptosuccinic acid) renal scan done in children with an initial episode of UTI, acute pyelonephritis changes was seen in 57% of cases and renal scarring occurred more in children with VUR: relative risk of 1.5 compared with children with no VUR.²¹

Typical UTI is caused by *Escherichia coli* species in 60-92% while atypical UTI is caused by other organisms rather than *E. coli* like *Proteus*, *Klebsiella*, *Enterobacter spp*, *Enterococcus*, *Pseudomonas*, *Staphylococcus aureus* and *Group B Streptococcus*.^{13,22} Fungal UTI caused by *Candida albicans* may occur in patients with an indwelling catheter and on antibiotics. *Aspergillosis*, a fungal infection occurs in immunocompromised patients. *Tuberculosis* may lead to strictures and *Schistosomiasis* parasite leads to bladder fibrosis a risk to bladder cancer.²³

It was interesting finding out the microbiologic profile of UTI's in patients following hypospadias repair in our set-up.

2.5 Problem Statement

The magnitude of post-operative urinary tract infections in children following urethroplasty for hypospadias repair was not known in Kenyatta National Hospital. The microscopic and bacteriologic profile of urine in these children was also not known in our set-up. Knowledge obtained from this study would enable us to formulate a management protocol for UTI post hypospadias repair.

2.6 Study Justification

Urinary tract infections are common in childhood. In children with hypospadias, it may occur pre-operatively, peri-operatively or post-operatively following urethroplasty. Recurrent UTIs in severe forms of hypospadias may be associated with mullerian duct remnants such as enlarged prostatic utricle cyst and mullerian duct cysts.

There was need to look at the occurrence of urinary tract infections following urethroplasty for hypospadias as well as the microscopic and bacterial profile of urine of children at Kenyatta National Hospital. There was paucity of this data in our local set-up as I had not come across any such study in Africa.

The knowledge gained from this study would enable us to formulate a management protocol on UTIs in children post hypospadias repair. This would provide evidence based treatment preventing renal scarring and the cost related to renal failure in these children.

Based on the results of this study, long term follow-up of these children post-operatively is necessary to prevent long- term sequel of post urethroplasty UTI and its complications.

This study will also form a basis for future prospective studies in the field of pediatric urology and in particular hypospadias surgery by developing significant hypothesis that can be tested in other study designs.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Objective

3.1.1 Broad Objective

To determine the magnitude of urinary tract infection post-operatively after urethroplasty for hypospadias in children at Kenyatta National Hospital (KNH).

3.1.2 Specific Objective

- a) To determine the prevalence of UTI following urethroplasty for hypospadias in the post-operative period at KNH.
- b) To assess the microbiologic profile of urine specimens through microscopy, culture and sensitivity after urethroplasty for hypospadias in the post-operative period at KNH.
- c) To analyze the relation between UTI and the different types of urethroplasty performed for hypospadias in the post-operative period at KNH.

3.2 Materials and Methods

3.2.1 Study Setting

The study was carried out at the Pediatric Surgical Outpatient Clinic and the urine specimens were analyzed in the microbiology laboratory at Kenyatta National Hospital (KNH). KNH is the national referral hospital in Kenya and the largest in East and Central Africa. Majority of the patients with hypospadias therefore underwent urethroplasty procedure at KNH hence it was the most appropriate study setting.

3.3 Inclusion Criteria

- Children who had undergone urethroplasty procedure for hypospadias at least 30 days to 5 years post-operatively.

3.4 Exclusion Criteria

- Children in the peri- operative period (less than 30 days post-operatively) following urethroplasty for hypospadias repair
- Children with urethral catheter or stent in-situ
- Children with a known bladder pathology that may increase the risk of UTI such as bladder diverticulum, bladder stones and neurogenic bladder.

3.5 Study Design

The purpose of this study was to determine the magnitude of UTI post- operatively through assessing the microbiologic profile of urine following urethroplasty for hypospadias repair at Kenyatta National Hospital. Based on this objective, the most appropriate design to achieve this was a descriptive cross-sectional study. This prospective study design allowed us to collect data at a defined point in time and to assess occurrence of a disease. This design also allowed us to examine a relationship between a health condition or a disease and other variables of interest in a defined sub set of a population over a certain period of time and to generalize the findings to the entire target population.

3.6 Study Duration

The duration of the study was four months within the year of 2019.

3.7 Study Sample

Data from KNH health information department showed there was an average of 23 cases of hypospadias condition admitted to KNH each year. The study population was thus 115 children who had undergone urethroplasty for hypospadias repair between January 2014 and January 2019 (5 years). We intended to collect data from all the 115 children who were operated within the 5 years.

3.8 Sampling Technique

The study selected all children who had urethroplasty for hypospadias within the study period. The sampling frame was obtained from KNH health information department.

3.9 Data Collection

A data collection sheet was utilized for data collection. It contained the demographic data of the patient, type of hypospadias as per the patient's clinical record, type of urethroplasty procedure done and the date it was done, any complications following the procedure, any irritative bladder symptoms and the urine collection method was entered in a pre-prepared data sheet.

Data was entered by the principal investigator or research assistant at the pediatric surgical outpatient clinic. Urine biochemistry, microscopy, culture and sensitivity results was entered on the data sheet by the microbiologist following analysis.

3.10 Procedure

The study was explained to the eligible patient in the company of a parent or guardian by the researcher or the research assistant. Informed and written consent was sought from the parent or guardian. An assent form was completed by the patient if he was 6-17 years old. The patient in the company of the parent or guardian was taken through the process of urine collection as per the patient's age and whether the child was toilet trained or not.

3.10.1 Urine Specimen Collection Methods

This included clean voided mid-stream urine for the toilet trained children, clean catch urine collection, suprapubic bladder aspiration and bladder catheterization for the non- toilet trained.

Mid-stream urine specimen was collected by the patient, researcher or research assistant. The patient washed their hands with soap and water, then cleaned the urethral meatus with cotton wool balls or gauze soaked in 0.9% of sodium chloride or liquid soap and water. This was done in a downward motion from front to back. He then passed the first part of urine stream into the toilet or bedpan, collected midstream urine in a sterile container taking care not to contaminate the specimen, then the patient voided the remainder of the urine into the toilet.

For clean catch urine collection, after cleansing procedure parents had a sterile urine container ready to collect urine taking care that the perineum did not touch the inside of the container.

Urine specimen was obtained in an aseptic technique when suprapubic aspiration or bladder catheterization was opted. This was done by the researcher or research assistant.

Suprapubic aspiration procedure was performed by the researcher or research assistant who donned sterile gloves. With patient in supine position, the suprapubic region was cleaned with betadine swab and draped aseptically. Lignocaine anaesthetic cream was applied on the suprapubic region for pain management. A 23G needle mounted on a 5ml syringe was inserted perpendicularly on the midline at the lower abdominal crease on the skin. Urine was aspirated as the needle was withdrawn. The urine was placed into a sterile urine container. A dry swab was strapped at the aspiration site.

Bladder catheterization technique via the urethra was performed by the researcher or research assistant who donned sterile gloves. With patient in supine position, the genitalia was cleaned with hibitine swab and draped aseptically. Using a 2ml syringe with no needle, lignocaine gel 2% was instilled into the urethra. 2-3 minutes was allowed for its anaesthetic effect before catheterization. 5- 10mls of KY gel was then instilled into the urethral meatus as a lubricant. The appropriate size of urethra catheter for age (6 Fr to 12 Fr) was be introduced into the urethral meatus and advanced up to the bladder. This was evidenced by urine draining from the larger port of the catheter. Urine was collected into a sterile urine container. The catheter was then removed.

The urine specimen accompanied with microbiology request forms was transported within 30minutes of collection to the microbiology laboratory in KNH for urinalysis. The cost of urinalysis, microscopy, culture and sensitivity of the urine specimen was met by the researcher. The dip stick test was conducted first for nitrate and leukocyte esterase. Then microscopy test for pyuria and bacteriuria. Culture of the urine specimen was also done. Urine was processed on cysteine-lactose-electrolyte-deficient (CLED) agar by standard loop method and incubated at 37° C overnight. Then the organism cultured was subjected to sensitivity test of various antibiotics according to the CLSI guidelines. Urine specimen cultured as contaminated was recorded as contaminated in the study.

Antibiotics were prescribed for the patients with symptomatic UTI based on culture and sensitivity results. For patients with asymptomatic UTI, close follow up was done.

3.11 Data Analysis

After data collection, all the schedules were entered into SPSS 22 and later exported into STATA 15 for further analysis. Quantitative data was summarized into percentages, frequencies, means and standard deviation.

The first objective which was to determine the prevalence of UTI following urethroplasty for hypospadias in the post-operative period at KNH was done using univariate analysis. The number of cases of UTI was expressed as a proportion of the total sample.

The second objective which was to assess the microbiologic profile of urine specimens through microscopy, culture and sensitivity after urethroplasty for hypospadias in the post-operative period at KNH, results were analyzed using descriptive statistics.

The third objective which was to analyze the relation between UTI and the different types of urethroplasty performed for hypospadias in the post-operative period at KNH, results were analyzed using bivariate analyses such as Chi- square test of association, Odds ratio and confidence interval. The critical values for the significance of the results was considered significant at 95% confidence interval.

3.12 Ethical Consideration

Informed Consent and Assent: The parents or legal guardian in the presence of the children in this study were informed by the researcher on the purpose and rationale of the study. Participation was voluntary and the participants were allowed to leave the study at any specified time according to their discretion. A consent form was signed by both the parent or legal guardian and the researcher. An assent form was signed by children aged 6-17 years once the patient agreed to participate in the study.

Confidentiality: All participants remained anonymous and identification was done by a unique patient identification number. Confidentiality and privacy was observed throughout the duration of the study.

Research Approval: Institutional consent was sought from the University of Nairobi, department of surgery and the Ethics and Research committee of KNH, reference number: KNH-ERC/A/308

3.13 Quality Assurance

This was ensured by adhering to the standard aseptic procedure during bladder catheterization. KNH medical laboratory is certified by International Organization for Standardization (ISO 15189: 2012) ensuring quality and competence in the laboratory. Urine samples were analyzed using the criteria established by Clinical and Laboratory Standards Institute (CLSI).

3.14 Limitation

- The scope did not analyze the anatomical status of the urethra at time of the study.

3.16 Dissemination of Results and Publication Policy

The results were disseminated to the University of Nairobi research library, KNH/UON Ethics and research committee and were available for review by participants. Recommendations were made to relevant policy makers.

The findings were presented for publication. In this context, the principal investigator took the lead in publication with supervisors and research assistants as co- researchers. The department of surgery in UON and KNH were affiliated in publications.

4.0 CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter presents the results from empirical data collected at KNH. The study targeted a total of 115 children who had undergone urethroplasty procedure for hypospadias at least 30 days to 5 years post-operatively between January 2014 and December 2018. The final study includes 83 children whose guardian/parents consented for the study hence sampling 72.3% of the target population hence sufficient for analyses.

4.2 Background Information of the Respondents

The study found that the median (range) age of the surveyed children was 7 (IQR: 5-12) years. The median (range) age of diagnosis was 1 day (IQR: 1day -14 days) and age at surgery was 2.6 (IQR: 1.8-6) years. The summary is presented in table 1 below.

Table 1: Age of the children

	N	Median (IQR)	Minimum	Maximum
Age (years)	83	7.0 (5-12)	1.1	18
Diagnosis age	83	1.0 (1 day-14 days)	1 day	15 years
Age at Surgery (Years)	83	2.6 (1.8-6)	0.5	17

From our study, the patients had the following types of hypospadias: penoscrotal (32.5%, n=27), subcoronal (28.9%, n=24), anterior penile (10.8%, n=9), mid penile (10.8%, n=9) and glanular (9.6%, n=8). The summary of other types of hypospadias are presented in the bar graph below.

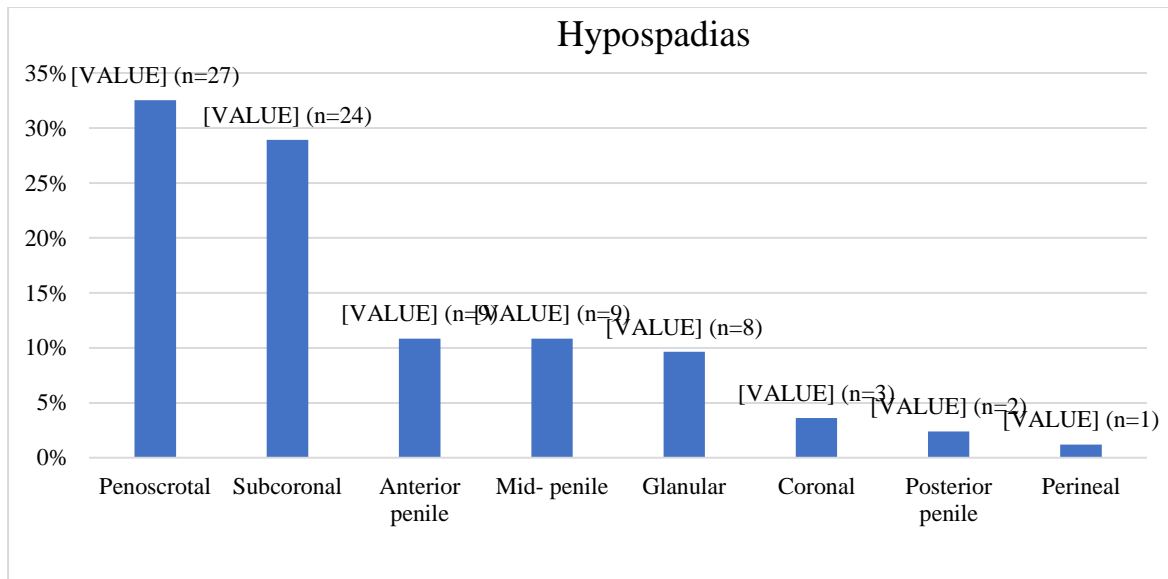


Figure 1: Hypospadias types

The surgical techniques used to correct hypospadias were TIP at 53% (44/83), staged preputial (Byar) flap at 22.9% (19/83), Magpi at 8.4% (7/83), Duckett procedure 6% (5/83), Bracka two stage buccal graft at 3.6% (3/83), Thiersch duplay procedure at 2.4% (2/83), Mathieu procedure at 2.4% (2/83) and Glans approximation procedure at 1.2% (1/83).

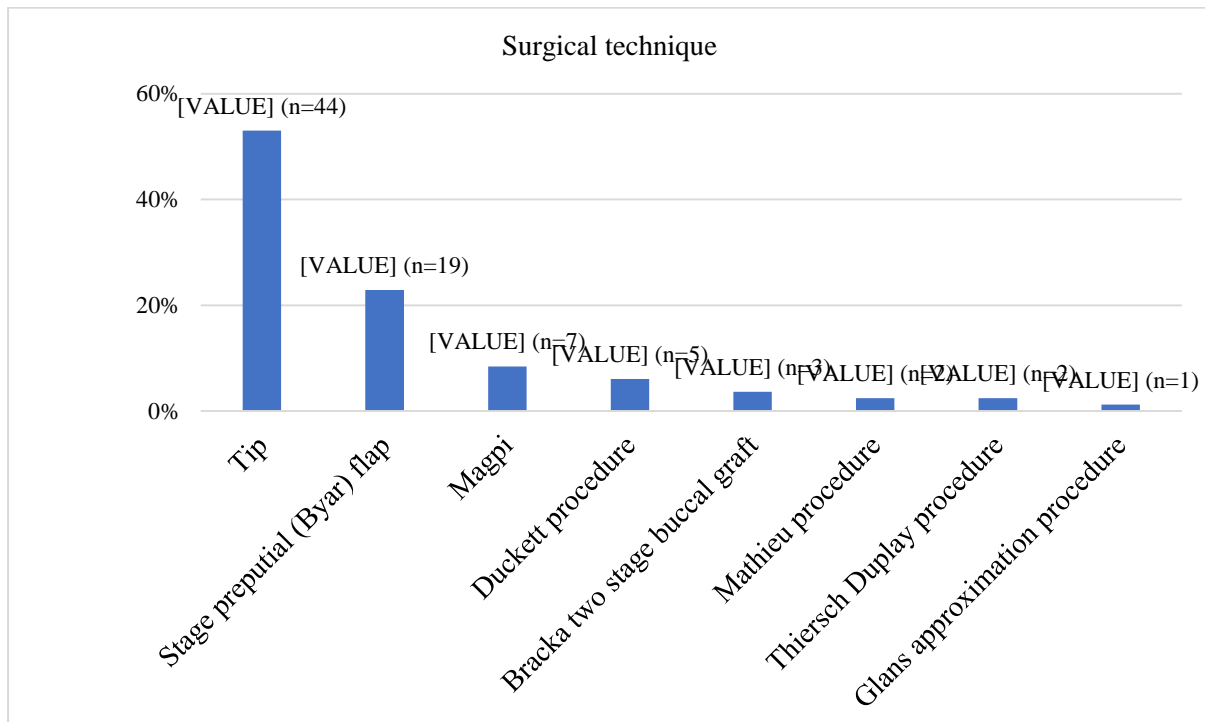


Figure 2: Surgical Technique

4.3 Prevalence of UTI following urethroplasty for hypospadias in the post-operative period at KNH

The study found that the prevalence of UTI following urethroplasty for hypospadias in the post-operative period at KNH was 6% (5/83). All cases had UTI symptoms such as dysuria, suprapubic pain, dribbling, fever, urgency and or frequency. The prevalence is presented in the pie chart below.

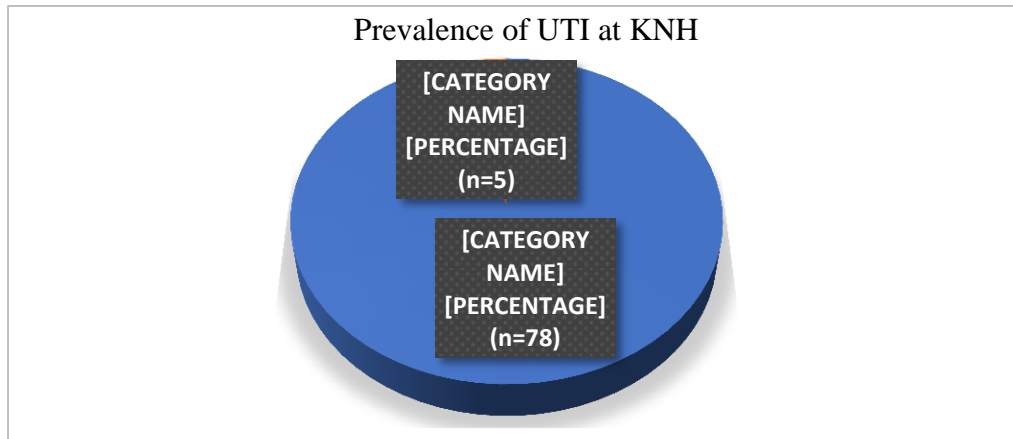


Figure 3: Prevalence of UTI

4.4 Microbiologic profile of urine specimens through microscopy, culture and sensitivity after urethroplasty for hypospadias in the post-operative period at KNH.

Pre-operative microscopy culture and sensitivity of the children was done on 15.7% (13/83) out of which 53.8% (7/13) were normal and 46.2% (6/13) were abnormal as follows: 4 patients had E. coli, 1 patient had Klebsiella Pneumonie and 1 patient had positive nitrate and leukocyte esterase on urine dip stick however urine culture was not done previously as per the patient's clinical records.

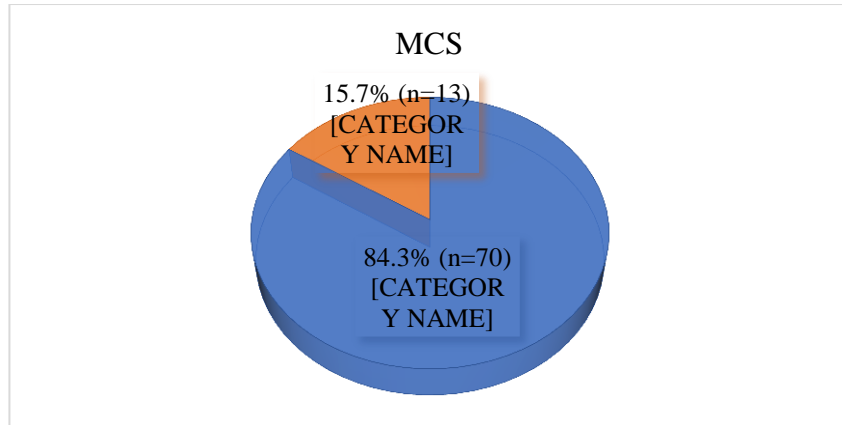


Figure 4: Pre-operative MCS

From the mid-stream urine samples that we obtained from the patients post-operatively, 6% (5/83) had UTI. Of these, 60% (3/5) had E. Coli, 20% (1) had Pseudomonas aeruginosa and 20%(1) had Enterobacter cloaca complex. This is demonstrated in the graph below.

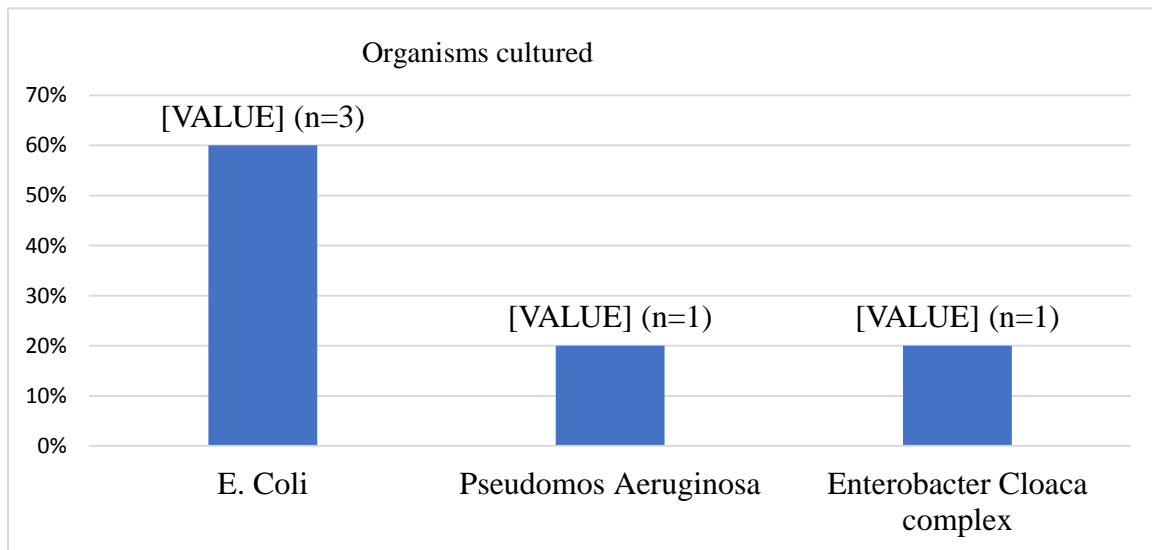


Figure 5: Organisms cultured

Table 2: The summary of E. coli sensitivity to different antibiotics

Sensitive antibiotic	Percentage
Amikacin	100%
Amoxicillin/ clavulanic acid	100%
Cefazolin	100%
Cefoxitin	100%
Meropenem	100%
Nitrofurantoin	100%
Piperacillin/tazobactam	100%
Aztreonam	66.6%
Cefepime	66.6%
Cefotaxime	66.6%
Ceftazidime	66.6%
Ceftriaxone	66.6%
Cefuroxime	66.6%
Cefuroxime Axetil	66.6%
Gentamicin	66.6%
Ampicillin	33.3%
Ampicillin/ sulbactam	33.3%
Ciprofloxacin	33.3%
Trimethoprim/ sulfamethoxazole	33.3%

- Enterobacter cloaca complex was sensitive to Piperacillin/Tazobactam, cefotaxime, ceftazidime, ceftriaxone, cefepime, aztreonam, meropenem, amikacin, gentamicin, ciprofloxacin, nitrofurantoin, trimethoprim/ sulfamethoxazole. It was resistant to ampicillin, amoxicillin/ clavulanic acid, Ampicillin/ sulbactam, cefazolin, cefuroxime, cefuroxime Axetil and cefoxitin.
- Pseudomonas aeruginosa was sensitive to Piperacillin/Tazobactam, ceftazidime, cefepime, meropenem, amikacin, gentamicin and ciprofloxacin. It was resistant to

Ampicillin, Amoxicillin/ clavulanic acid, Ampicillin/ sulbactam, cefazolin, Cefuroxime, Cefuroxime Axetil, Cefoxitin and cefotaxime.

The urine collection method used was bladder catheterization in 2 children, clean catch in 9 children, mid- stream urine in 72 children. All positive urine culture had mid-stream urine collection method used. All urine samples had no contamination on culture. The summary is presented in the table below.

Table 3: Urine collection method, positive urine culture, contamination

Urine collection method	Normal	Positive urine culture	Contamination	Total
Bladder catheterization	2	0	0	2(2.4%)
Clean catch	9	0	0	9(10.8%)
Mid- stream urine	67 (93.1%)	5 (6.9%)	0	72(86.8%)
Total		5	0	83

4.5 Relation between UTI and the different types of urethroplasty performed for hypospadias in the post-operative period at KNH

There were 27 cases of penoscrotal hypospadias most of which were corrected using Two stage preputial (Byar) flap, 24 cases of subcoronal hypospadias most of which were corrected using TIP, 9 cases of anterior penile and mid-penile hypospadias most of which were corrected using TIP, and glanular hypospadias most of which were corrected using Magpi. The summary of these findings is presented in the table below.

Table 4: Type of hypospadias and surgery performed

Type of hypospadias	Number of cases	Surgery performed
Penoscrotal	27	Staged preputial(Byar)flap (18/27), Tip (4/27), Bracka two stage buccal graft (2/27), Duckett procedure (2/27) and Thiersch Duplay procedure (1/27),
Subcoronal	24	Tip (22/24), Magpi (1/24) and Bracka two stage buccal graft (1/24)
Anterior penile	9	Tip (9/9)
Mid- penile	9	Tip (6/9), Duckett procedure (2/9) and Mathieu procedure (1/9)
Glanular	8	Magpi (5/8), Tip (2/8) and Glans approximation procedure (1/8)
Coronal	3	Magpi (1/3), Mathieu procedure (1/3), and Tip (1/3)
Posterior penile	2	Duckett procedure and Thiersch Duplay procedure

Perineal	1	Staged preputial(Byar)flap
Total	83	

The study found out of the 44 cases that were corrected using Tip 22 (50%) did not develop any complications, 19 (43.2%) developed urethroplasty breakdown, 2 children developed both UCF and meatal stenosis and 1 case of meatal stenosis was reported. The study found that all children that underwent Bracka two stage buccal graft developed complications similar to Mathieu procedure and Thiersch Duplay procedure. Of the 5 that underwent Duckett procedure 4 developed complications. The summary of the type of surgery and complication encountered is presented in the table below.

Table 5: Type of surgery and complications encountered

Type of surgery	Number of cases	Complications encountered
Tip	44	None (22/44), Urethroplasty breakdown (19/44), UCF and meatal stenosis (2/44) and meatal stenosis (1/44)
Staged preputial (Byar) flap	19	None (9/18), Urethroplasty breakdown (8/18), Urethroplasty breakdown and meatal stenosis (1/18), and Urethroplasty breakdown and urethral diverticulum (1/18)
Magpi	7	None (5/7), Meatal stenosis (1/7) and Urethroplasty breakdown (1/7)
Duckett procedure	5	Urethroplasty breakdown (4/5) and none (1/5)
Bracka two stage buccal graft	3	Urethroplasty breakdown (2/3) and Urethroplasty breakdown & urethral stricture (1/3)
Mathieu procedure	2	Urethroplasty breakdown(2/2)
Thiersch Duplay procedure	2	Urethroplasty breakdown(1/2) & Urethroplasty breakdown and urethral stricture(1/2)
Glans approximation procedure	1	None
Total cases	83	

The results revealed 54.2% (45/83) of children had complications post operatively while 45.8% (38/83) children had no complications. 44.6% (37/83) had Urethroplasty breakdown (UCF), 3.6% (3/83) had both UCF and meatal stenosis, 2.4% (2/83) had meatal stenosis only, 2.4% (2/83) had Ucf and urethral stricture, and 1.2% (1/83) had Ucf and urethral diverticulum. The summary is presented in the graph below.

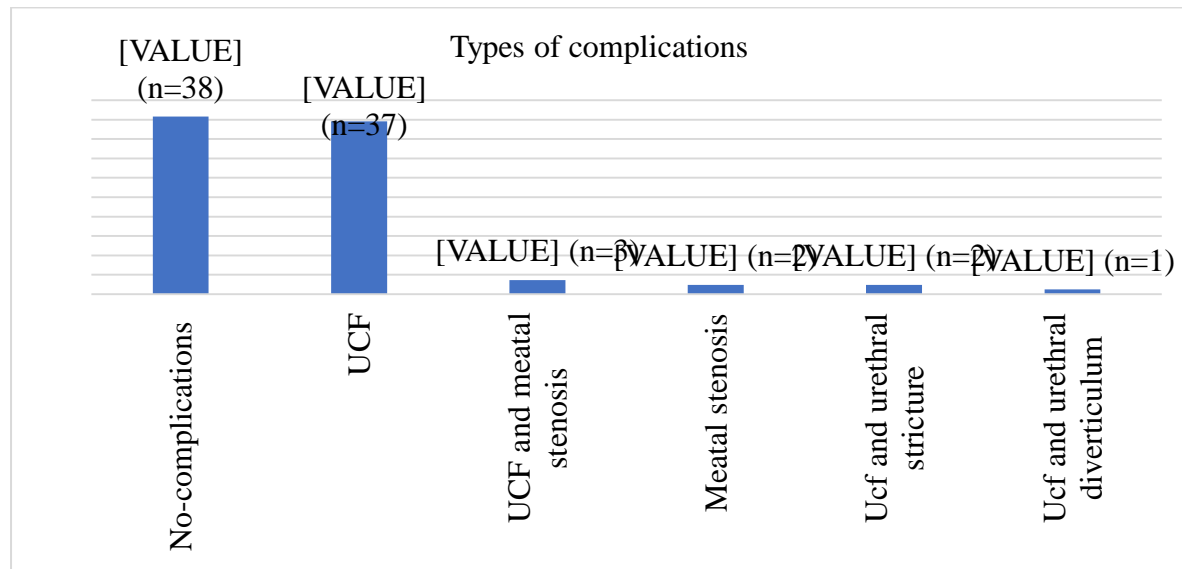


Figure 6: Complications post- operatively

Complications in relation to age at primary surgery occurred at 37.8% (17/45) in children aged 1-2 years, 20% (9/45) in children aged 3-5 years, 11.1% (5/45) in children aged 6-8 years and 8.9%(4/45) in children aged 5-12 months.

Table 6: Complications in relation to age at primary surgery

Age at primary surgery	No Complications	Had complications	Total cases
5-12 Months	2 (5.3%)	4 (8.9%)	6
1-2 years	21 (55.3%)	17 (37.8%)	38
3-5 Years	9 (23.7%)	9 (20%)	18
6-8 Years	3 (7.9%)	5 (11.1%)	8
9-11 Years	2 (5.3%)	2 (4.4%)	4
12-14 Years	0	3 (6.7%)	3
15-17 Years	1 (2.6%)	5 (11.1%)	6
Total	38 (100%)	45 (100%)	83

The study found that during urethroplasty, 66.3% (55/83) of children had tubularization done over a catheter while in 33.7% (28/83) a stent was used. The median use of catheter was 10 days and 7 days for stent. This is presented in the pie chart below.

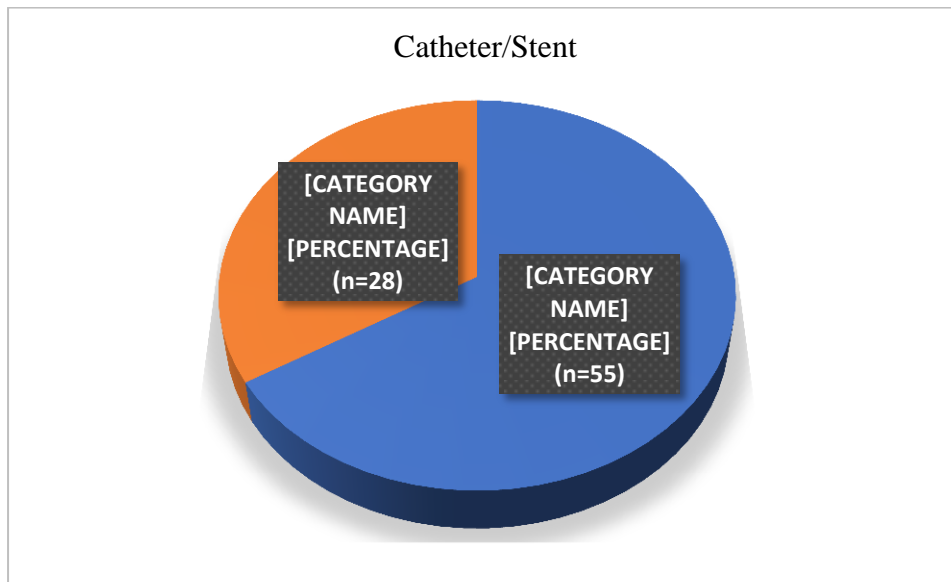


Figure 7: Catheter/stent

In our study, we found that only 31.3% (26/83) had antibiotics duration correctly administered in the peri- operative period. That is, when the catheter/ stent is in-situ plus 2 days following catheter/stent removal. Augmentin, ceftriaxone and septrin were administered from 5 days on average and cefuroxime was administered for 6 days on average. In children whom cefuroxime antibiotic was used, they had 31.3% complication rate compared to children who were administered augmentin at 62.5%, and ceftriaxone at 58.8%. All the UTI cases had antibiotics incorrectly administered. The results however revealed antibiotics does not have any significant effect on complications ($p>0.05$). The summary is presented in the graph below.

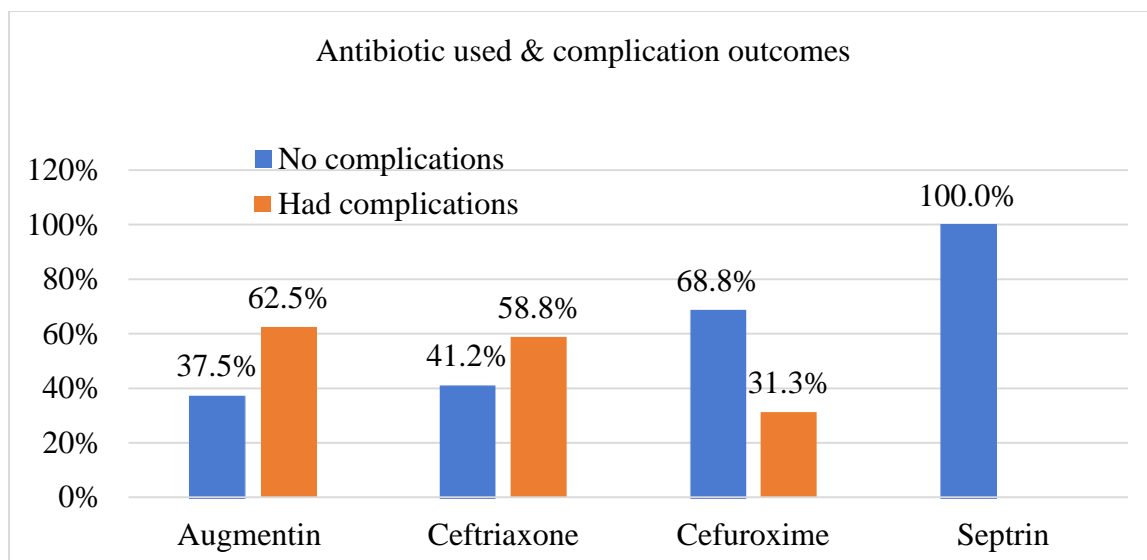


Figure 8: Antibiotic used peri- operatively & complication outcomes

Table 7: Summary of the children who had urinary tract infections post-operatively following urethroplasty for hypospadias. We had 5/83 cases of UTI and therefore not sufficient to do scientific associations.

Organism	Ecoli	Enterobacter cloaca complex	Pseudomonas aeruginosa
Number of UTI cases	3	1	1
Median age (Years)	5	15	5
Hypospadias	Peno-scrotal	Subcoronal	Penoscrotal
Age at primary surgery(years)	1.2, 2, 17	15	2
Type of surgery	Staged preputial flap and buccal graft	Tip	Stage preputial flap
Time between surgery and UTI	1mo- 3mo, 1yr-2yr	1mo-3mo	1yr-2yr
Catheter/ stent	Catheter	Catheter	Catheter
Antibiotics used	Ceftriaxone		
	Cefuroxime	Ceftriaxone	Augmentin
Antibiotics administration	Not correctly administered	Not correctly administered	Not correctly administered
Complications	UCF	None	UCF+ Urethral diverticulum

5.0 CHAPTER FIVE: DISCUSSION

From our study of 83 children, we found that the prevalence of UTI following urethroplasty for hypospadias in the post-operative period at KNH was 6%. This is similar to a study by Winberg et al to evaluate the frequency of UTI in 174 boys with hypospadias where UTI was diagnosed post-operatively in 5% of the cases.⁸

The organisms cultured from the urine samples was 60% E. Coli, 20% Pseudomonas aeruginosa and 20% Enterobacter cloaca complex. Pre-operative microscopy culture and sensitivity of the children was done on 15.7% (13/83) out of which 53.8% (7/13) was normal and 46.2% (6/13) was abnormal as follows: 4 patients had E. coli, 1 patient had Klebsiella Pneumonie and 1 patient had positive nitrate and leukocyte esterase on urine dip stick however urine culture was not done previously as per the patient's clinical records and following urethroplasty, the patient had recurrent UTI with a positive urine culture growing Pseudomonas aeruginosa. It would have been important to perform urine culture and sensitivity pre-operatively in order to rule out if it was unresolved bacteriuria, bacterial persistence or reinfection.

From our study E. coli was sensitive at 100% to nitrofurantoin, amoxicillin/ clavulanic acid, cefoxitin, cefazolin, amikacin, meropenem and piperacillin/tazobactam. It was sensitive at 66% to gentamicin and 33.3% to ciprofloxacin and trimethoprim/ sulfamethoxazole. Our results are similar to a study by Sudheendra et al where E. coli was sensitive to nitrofurantoin at 92.4%, amikacin at 90.9%, imipenem at 96.7% and piperacillin/tazobactam at 80.7%.²⁴ This was in contrast to a study done by Kiran et al where gentamycin was 100% sensitive and amoxicillin/ clavulanic acid was 4% sensitive to E. coli.⁵

Similar to a study by Viren et al, Pseudomonas aeruginosa from our study was sensitive to carbapenems and aminoglycosides but resistant to monotherapies of most of the cephalosporins and penicillins.²⁵ Enterobacter cloacae complex from our study was sensitive to cefepime, ceftriaxone, nitrofurantoin, and aminoglycosides while resistant to amoxicillin/ clavulanic acid and cefuroxime. This was similar to a study by Ann Pallett et al.²⁶

The urine collection method used was mid-stream urine in 72 children, clean catch in 9 children and bladder catheterization in 2 children. All positive urine culture had mid-stream urine collection method used. All urine samples had no contamination on culture. This

demonstrates that when the proper instructions on cleaning of genitalia and collection method are followed in children, contamination of urine sample is avoided.

From our study, most of the children had penoscrotal hypospadias at 32.5% (27/83). 80% (4/5) of the patients with UTI had penoscrotal hypospadias. It was reported by Desautel et al, that posterior hypospadias is associated with the occurrence of other genitourinary anomalies like mullerian duct remnants which cause recurrent urinary tract infections following urethroplasty for hypospadias.⁹ Our study was limited in that we did not analyze the anatomical status of the urinary tract.

The results revealed 54.2% (45/83) of children had complications post operatively with 44.6%(37/83) of them having urethroplasty breakdown (UCF). This is almost similar to a retrospective study done at KNH where the incidence of urethrocutaneous fistula was 47%.²⁷ 60%(3/5) of the children with UTI post-operatively had complications following urethroplasty. These were urethroplasty breakdown and urethral diverticulum which cause urine stasis which is a risk to UTI.

Complications in relation to age at primary surgery occurred at 37.8%(17/45) in children aged 1-2 years, 20%(9/45) in children aged 3-5 years, 11.1%(5/45) in children aged 6-8 years and 8.9%(4/45) in children aged 5-12 months. This demonstrates that in children between 5months to 1 year operated primarily for hypospadias, the complications post- urethroplasty are four times less compared to children operated between 1-2 years. 60%(3/5) of the patients with UTI from our study had the primary surgery when they were 1-2years of age and 60% had complications post-operatively. Manzoni et al on the timing of hypospadias surgery recommended that primary surgery should be done when the child is 6 months old as the anaesthetic risks are reduced and child tolerates surgery well. The penile length is 0.8cm less on average at 1 year than at pre-school.²⁸ According to EAU guidelines, primary surgery for hypospadias is recommended between 6-18 months.²⁹ Our study however did not take into account the age of primary surgery and complications in relation to the type of hypospadias and the urethroplasty technique used.

In our study, we found that only 31.3% (26/83) had antibiotics correctly administered in the peri- operative period. That is, when the catheter/ stent is in-situ plus 2 days following catheter/stent removal. In children whom cefuroxime antibiotic was used, they had 31.3% complication rate when compared to augmentin (amoxicillin/ clavulanic acid) and ceftriaxone

whose complication rate was two times more. All the UTI cases had antibiotics incorrectly administered. This is similar to a study by David et al, where urinary tract infections occurred four times more after hypospadias repair in the peri- operative period in children who did not receive antibiotics post- operatively.²⁰ Our results however revealed antibiotics does not have any significant effect on the complications ($p>0.05$).

6.0 CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

Magnitude of urinary tract infection post- urethroplasty for children with hypospadias was 6% at KNH with 80% of the patients having peno- scrotal type of hypospadias.

The most common organism cultured was E. Coli. 60% of patients with UTI had urethroplasty breakdown post- operatively. Further anatomical evaluation should be done on these patients to rule out mullerian duct remnants.

Timing of primary surgery should be between 6-12 months to reduce on complication rate.

Long term follow-up of children post-operatively is necessary to prevent long- term sequel of post urethroplasty UTI and its complications.

From this study, we can formulate a management protocol on UTIs in children post hypospadias repair.

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STUDY BUDGET

Particulars	Amount (Ksh)
Research fee for KNH- ERC	5,000
Statistician	35,000
Stationery	5,000
Printing and binding	5,000
Research assistant	25,000
Non- pharmaceuticals (Clean and sterile gloves, antiseptics, syringes, needles, cotton wool, gauze, strapping)	48,000
Pharmaceuticals (Lignocaine cream and gel, KY gel)	20,000
Sterile urine containers	2,500
Catheters	13,350
Urine bags	7,100
Urinalysis- Dipstick test	23,000
Urine Microscopy, Culture & Sensitivity	138,000
Total	326,950
Miscellaneous 10% of total	32,695
GRAND TOTAL	359,645

STUDY TIMELINE

Activity	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	June 2019	July 2019	Aug 2019	Sept 2019	Oct 2019	Nov 2019	Dec 2019
Proposal development												
Ethical Approval												
Data collection												
Data Analysis												
Dissertation Writing and presentation												

APPENDICES

Appendix I: Data Collection Tool

MAGNITUDE OF POST- URETHROPLASTY URINARY TRACT INFECTIONS IN CHILDREN WITH HYPOSPADIAS AT KENYATTA NATIONAL HOSPITAL

Serial number.....

A. Demographic data

- a) Current Age Years _____
- b) Sex-Male
- c) Age at diagnosis: Years _____Months _____ Weeks _____
- d) Age at time of first urethroplasty: Years _____Months _____

B. Type of hypospadias

- Glanular
- Coronal
- Subcoronal
- Anterior penile
- Mid- penile
- Posterior penile
- Peno- scrotal
- Scrotal
- Perineal

C. Type of surgery

- Tubularized incised plate repair
- Transverse preputial island flap technique
- Meatal advancement with glansplasty incorporated
- Glans approximation procedure
- Mathieu procedure
- On-lay island flap
- Two stage buccal graft repair
- Two stage Bracka procedure

D. What was used following urethroplasty:

Catheter

Stent

For how long was it maintained? _____

E. Which antibiotic was used peri-operatively? _____

For how long was it given? _____

F. From time of surgery

1 month to 3 months

4 month to 6 month

7 months to 1 year

1 year- 2 years

2 years- 3 years

3 years- 4 years

4 years- 5 years

G. Complications

Meatal stenosis

Urethroplasty breakdown

Urethral stricture

Urethral diverticulum

H. Previous urine micro- biologic profile

Yes

No

If yes,

- Was it indicative of UTI?

Yes

No

- Which organism was cultured? _____

- Which antibiotic was it sensitive to? _____

I. Urinary tract symptoms

Asymptomatic

Symptomatic-

Fever

- Dysuria
- Suprapubic pain
- Frequency
- Nocturia
- Incontinence
- Urgency
- Hematuria

J. Urine collection method

- Suprapubic aspiration
- Bladder catheterization
- Mid- stream urine
- Clean catch method
- Plastic bag method

K. Urine analysis

Specimen	Dipstick	Microscopy	Culture	Sensitivity	Contaminated
1	Nitrite	Pyuria \geq 10 WBC/uL	CFU		
	Leukocyte esterase	Bacteriuria	Organism		

Appendix II: Consent Form (English version)

MAGNITUDE OF POST- URETHROPLASTY URINARY TRACT INFECTIONS IN CHILDREN WITH HYPOSPADIAS AT KENYATTA NATIONAL HOSPITAL

This informed consent form is for parents or guardians with children who have undergone surgery for hypospadias. We are requesting these patients to participate in this research project whose title is “**Magnitude of post- urethroplasty urinary tract infections in children with hypospadias at Kenyatta National Hospital**”

Principal Investigator: Dr. Irene Mutua.

Institution: Department of Surgery, School of Medicine- University of Nairobi

Supervisors: Dr. F. Osawa, Dr. D. Kuria, Dr. J. Lessan

This informed consent has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)
3. Statement by the researcher

You will be given a copy of the full informed consent form.

Part 1: Information sheet

Introduction

My name is Dr. Irene Mutua, a postgraduate student in Pediatric Surgery at the University Nairobi. I am conducting a study on the magnitude of urinary tract infections for patients who have been operated on for hypospadias at Kenyatta National Hospital.

Purpose of the study

Urinary tract infections occur more in children who have undergone urethroplasty procedure for hypospadias as compared to the normal population. This study aims to assess the prevalence of urinary tract infections, the organisms causing the infection and the drug sensitive to that infection which will be prescribed for treatment.

Study Participation

I am inviting the child under your care to participate in my study. You will be given an opportunity to ask questions before you decide. Participation in this study is voluntary. If you agree to participate, you will be asked to sign a consent form. No payments will be made due to your participation in the study.

Benefits of participation

Participation in the study will help to assess whether your child has urinary tract infection and if so, which organism is causing it and the drug that is sensitive to treat the infection will be determined and prescribed.

Risk of Participation

Your child involvement in this research will be through filling of a data collection form and the collection of urine for analysis. You will not expose yourself to any risk if you consent to participate.

Right to decline or withdraw

You are free to withdraw from the study at any time. The refusal to participate or withdraw from the study will not in any way compromise the quality of care and treatment given to the patient.

Confidentiality

Any information that is obtained from you in this research will be treated with utmost confidentiality. The patients' name shall not be used.

Sharing of results

Knowledge gained from this study will be shared with other experts through conferences and publications. Confidentiality will be obtained.

Cost and Compensation

There shall be no extra cost incurred by you from participation in the study and there is also no compensation.

Contacts of relevant parties

1. Primary Investigator

Dr. Irene Mutua

Resident, Department of Surgery, University of Nairobi

P.O Box 19676 KNH, Nairobi 00202

Mobile Phone 0711261324

2. Research Assistant

Dr. Jeremiah Kamwetu

Resident, Department of Surgery, University of Nairobi

P.O Box 19676 KNH, Nairobi 00202

Mobile Phone 0722995701

3. Secretary,

KNH/UON ERC
P.O Box 20723-00202, Nairobi
Tel: 0202726300 Ext 44355
Email: KNHplan@Ken.Healthnet.org

4. Research Supervisors

Dr. Francis Osawa
Lecturer in Pediatric Surgery
Department of Surgery
University of Nairobi
P.O Box 19676-00202 KNH, Nairobi
Tel: 0202726300

Dr. Kihiko Kuria
Lecturer in Pediatric Surgery
Department of Surgery
University of Nairobi
P.O Box 19676-00202 KNH, Nairobi
Tel: 0202726300

Dr. Joel Lessan
Consultant Pediatric Surgery
Kenyatta National Hospital
P.O Box 19676-00202 KNH, Nairobi
Tel: 0202726300

Part 2: Consent form

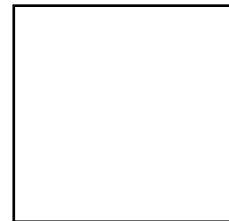
Statement of consent by parent or guardian

I.....freely give consent for my child
Name.....to take part in the study of
magnitude of urinary tract infections post- urethroplasty in children with hypospadias at
Kenyatta National Hospital. I have been informed and have understood that my child’s
participation is entirely voluntary. I understand the information given about the study and I
have had the opportunity to ask questions and all my concerns have been addressed.

I have the freedom to decline to participate in the study at any time

Signature or left thumb print (Parent/Guardian).....

Date.....



Statement by witness if parent or guardian is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the
individual has had the opportunity to ask questions. I confirm that the individual has given
consent freely.

Name of witness

Signature of witness.....

Date.....

PART III: Statement by the researcher

I have accurately read out the information sheet to the participant and to the best of my ability
made sure of the following:

- That the participant consent has been given voluntarily and free of duress.
- Refusal to participate or withdraw from the study will not in any way compromise the quality of care and treatment given to the patient.
- All information will be treated with confidentiality
- The results of this study might be published to enhance the knowledge of the subject of research.
- That I have answered all the questions asked by the participant to the best of my ability and knowledge.
- That a copy of this informed consent form has been provided to the participant.

Name of researcher/ person taking consent.....

Signature of researcher/ person taking consent

Date.....

Appendix III Consent Form (Swahili Version)

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

Fomu hii ya makubaliano ni ya wale watoto ambao wanahudumiwa kwenye kliniki ya upasuaji wa watoto katika hospitali ya Kenyatta na wamealikwa kujiunga na utafiti **MAGNITUDE OF POST- URETHROPLASTY URINARY TRACT INFECTIONS IN CHILDREN WITH HYOSPADIAS AT KENYATTA NATIONAL HOSPITAL**

Mtafiti mkuu: Dkt. Irene Mutua

Kituo: Kitengo cha Upasuaji, Shule ya Afya, Chuo kikuu cha Nairobi.

Fomu hii ya makubaliano ina sehemu tatu:

- Habari itakayo kusaidia kukata kauli
- Fomu ya makubaliano (utakapo weka sahihi)
- Ujumbe kutoka kwa mtafiti

Utapewa makala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Dkt. Irene Mutua na ninafanya utafiti wa shahada ya juu katika upasuaji wa watoto kwenye chuo kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, “**Magnitude of post- urethroplasty urinary tract infections in children with hypospadias at Kenyatta National Hospital.**”

Lengo Kuu la Utafiti

Ujumbe utakaodhihirika kutokana na utafiti huu utasaidia madaktari kujua hasa ni bakteria ipi inayo sababisha ugonjwa wa mkojo katika watoto waliofanyiwa operesheni kwa njia ya mkojo kwa sababu ya hali ya hypospadias.

Ushiriki wa hiari/ haki ya kukataa

Ningependa kukualika katika ushiriki wa utafiti huu. Utapata nafasi ya kuuliza maswali kuhusu utafiti huu, aidha kutoka kwangu au kutoka kwa msaidizi wangu. Baada ya kuelewa kabisa undani wa maelezo ya utafiti, ushiriki wako utakuwa wa hiari. Iwapo utaamua kutoshiriki katika utafiti, hautanyimwa matibabu. Isitoshe, ukishaamua kushiriki, ni haki yako kukataa kuendelea na ushiriki huo wakati wowote ule bila madhara yoyote.

Taadhimu ya siri

Ujumbe wote utakaotokana nawe utahifadhiwa kwa siri, na utatumika tu na wahusika wa utafiti kwa malengo ya utafiti pekee. Jina lako halitaorodheshwa popote katika utafiti huu; nambari spesheli itatumika katika utambulizi wako.

Utumizi wa matokeo ya utafiti

Nakala za matokeo ya utafiti huu zitahifadhiwa kwa siri katika maktaba ya Idara ya Upasuaji, Chuo Kikuu cha Nairobi. Kwa minajili ya kuendeleza ujuzi wa Sayansi ya Utabibu, huenda haja ya kuarifu wauguzi wengine kuhusu utafiti huu itokee. Cha muhimu ni kwamba, ruhusa itaombwa kutoka kwa Afisi ya Maadili ya Utafiti inayosimamia utafiti katika hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi, kabla ya kutumia matokeo ya utafiti huu katika warsha za Sayansi au kuyachapisha katika majarida ya Sayansi. Nyakati hizo, ujumbe wa kibinafsi hautafichuliwa kamwe.

Madhara

Utafiti huu hauna madhara yoyote kwako

Gharama/ Malipo

Hakuna gharama ya ziada wala malipo utakayopata kutokana na kushiriki kwako katika utafiti.

Anwani za Wahusika

Ikiwa uko na maswali ungependa kuuliza baadaye, unaweza kuwasiliana na:

1. Mtafiti Mkuu

Dkt. Irene Mutua,

Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0711261324.

2. Mtafiti Msaidizi

Dkt. Jeremiah Kamwetu

Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0722995701

3. Karani

KNH/ UON-ERC

SLP 20723 KNH, Nairobi 00202

Simu: +254-020-2726300-9 Ext 44355

Barua pepe: KNHplan@Ken.Healthnet.org

4. Wahadhiri wahusika

Dkt. Francis Osawa

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

Dkt. David Kuria

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

Dkt. Joel Lessan

Hopitali Kuu ya Kenyatta,

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

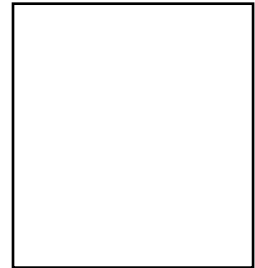
SEHEMU YA PILI: Fomu ya makubaliano

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumuuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki.....

Sahihi la shahidi/ Alama ya kidole cha mshiriki.....

Tarehe.....



Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nadhibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi.....

Sahihi la shahidi.....

Tarehe.....

SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo;

- Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kutibu bakteria katika mkojo.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo.

Ninahakikisha kuwa mshiriki alitoa ruhusa bila kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti.....

Sahihi ya mtafiti.....

Tarehe.....

Appendix IV: Assent Form (English)

This is for children aged 6-17 years

Study Title: MAGNITUDE OF POST- URETHROPLASTY URINARY TRACT INFECTIONS IN CHILDREN WITH HYPOSPADIAS AT KENYATTA NATIONAL HOSPITAL

Study Site: Kenyatta National Hospital

My name is Dr. Irene Mutua, a postgraduate student in Pediatric Surgery, Department of Surgery, University of Nairobi. I am conducting a study on the above topic. This means that following operations on the urinary tract, infections in urine are more likely to occur and we aim to know the magnitude of UTI and which bacteria if any is causing this infection and which drug will kill these bacteria.

If you agree to be part of this study, urine samples will be collected from you and analyzed in our laboratory for bacteria.

I will explain to you the procedure of urine collection so as to avoid contaminating it during collection.

Participation in this study is voluntary and you will not get any monetary benefit from participation in the study.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

You don't have to be in this study if you don't want to be. If you decide to stop after we begin, that is okay. Your parents will know about the study too.

If you decide you want to be in the study, please sign your name

Name.....Signature.....

Date.....

Name of Parent or Guardian.....

Statement by researcher

I have read the information to the participant and to the best of my ability made sure that the participant understands what the study entails.

A copy of this assent has been provided to the parents/ relative.

Name.....

Signature

Date.....

Appendix V: Assent Form (Swahili)

ASSENT FORM (SWAHILI)

FOMU YA IDHINI YA WATOTO WALIO NA UMRI WA MIAKA SITA HADI KUMI NA SABA.

Jina langu ni Dkt. Irene Mutua. Mimi ni daktari ninayesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, **“MAGNITUDE OF POST-URETHROPLASTY URINARY TRACT INFECTIONS IN CHILDREN WITH HYPOSPADIAS AT KENYATTA NATIONAL HOSPITAL.”**

Utafiti huu unamaanisha kuwa watoto waliofanyiwa operesheni katika njia ya mkojo hupata maambukizi ya mkojo na tugependa kujua ni bakteria lipi linalohusishwa na maabukizi haya. Pia, ni dawa lipi linaloweza kuangamiza bakteria hili.

Ukikubali kushiriki katika utafiti huu, mkojo wako utakusanywa na kupelekwa katika maabara la hospitali kuu ya Kenyatta ili kuchuguzwa kama lina bakteria.

Nitakueleza zaidi kuhusu utaratibu wa kukusanya mkojo ili usichafuke katika hali ile ya kuikusanya.

Kushiriki katika utafiti huu ni kwa hiari yako na hamna masharti yeyote ya lazima. Una haki ya kujiondoa kutoka ushiriki wa utafiti huu wakati wowote upendavyo na uamuzi huo hauwezi dhuru matibabu yako kwa vyovyote vile.

Hakuna hatari wala gharama ya ziada yeyote itakayo kukumba kutokana na kushiriki katika utafiti huu.

Tutakapo maliza utafiti huu, tutaandika ripoti kuhusu tulilojifunza. Hakuna popote pale nitakapotaja jina lako. Hivyo basi hamna atakaye tambua kwa majina walioshiriki.

Mzazi au mlezi wako atajulishwa kuhusu utafiti huu pia.

Nitakupa nakala ya fomu hii ukikubali kushiriki katika utafiti huu.

Kama umekubali kushiriki katika utafiti:

Jina lako.....

Sahihi yako

Tarehe

Jina la Mzazi au Mlezi.....

Mtafiti aliyekupa maelezo ya utafiti

Jina

Sahihi

Tarehe.....