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THE WITS PAEDIATRIC SURGICAL OUTCOMES STUDY (WiPSOS): a prospective multicentre observational study in four academic hospitals in Johannesburg

Dr. Anisa Zeenat Bhettay

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirements for the degree

of

Master of Medicine in the branch of Anaesthesiology

Johannesburg, 2019

Declaration

I, Anisa Zeenat Bhettay, declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

_____

30th May 2019.

Abstract

Background: There is limited data on perioperative outcomes in children in South Africa. The South African Paediatric Surgical Outcomes Study, a national multicentre study of perioperative morbidity and mortality in children, reported a postoperative complication rate of 9.7% and an in-hospital mortality rate of 1.1%. The Wits Paediatric Surgical Outcomes Study disaggregated the subset of data in the above study pertaining to the four referral hospitals that comprise the University of the Witwatersrand Academic Hospital Complex to allow meaningful comparison to the national data and other studies.

Aim: To describe the incidence of in-hospital perioperative complications including mortality and critical care admission in paediatric surgical patients at the Wits Academic Hospital Complex, and identify associated risk factors.

Methods: The Wits Paediatric Surgical Outcomes Study was a prospective observational multicentre cohort study that collected perioperative data for patients < 16 years undergoing non-obstetric surgery during a designated 14-day period.

Results: Between 22 May 2017 and 5 June 2017, 399 children received general anaesthesia for a surgical procedure. The median age was 4.42 years and the median American Society of Anaesthesiologists Physical Status 1. The incidence of perioperative respiratory adverse events was 10.3%. The incidence of perioperative cardiovascular adverse events was 4%. The postoperative admission rate to critical care units was 11.5%. Risk factors for adverse events include age under three years and higher ASA PS scores. The all-cause 30-day in-hospital mortality was 1.5%.

Conclusions: The paediatric perioperative risk profile differs substantially between high and middle-income countries. While the patient profile seen in this study is similar to the national cohort, the higher complication and mortality rate cannot be accounted for purely by the difference in age and ASA PS, and may be reflective of a healthcare system under stress.

Keywords

Perioperative morbidity; perioperative mortality; perioperative respiratory adverse events; paediatric anaesthesia; University of the Witwatersrand hospitals

Acknowledgements:

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Contents

Declaration ii

Abstract iii

Acknowledgements: iv

Nomenclature/Research Assumptions vii

List of Tables ix

Section 1: Literature Review 1

Introduction, background and rationale for this study 1

References 5

Section 2: Authors guidelines 7

Section 3: Draft Article 24

Introduction 26

Methods 27

Results: 28

Discussion: 30

Limitations: 31

Funding: 31

Conflicts of interest: 31

References: 31

Table 1 WiPSOS patient cohort descriptors 33

Table 2 Intraoperative Adverse Events 34

Table 3 Critical care admission cohort 35

Table 4 Details of patients who died in the perioperative period 37

Table 5 Key differences between SAPSOS and WiPSOS 38

Section 4: Appendices 39

Appendix 1: Permission from Principal Investigator to use data 39

Appendix 2: Approval from postgraduate committee 40

Appendix 3: Ethics clearances 41
Appendix 3: Turnitin report 43
Section 5: Proposal 44
5.1 Introduction, background and rationale for the study 46
5.2 Aim of the Study 49
5.3 Objectives of the study 49
5.4. Research Assumptions: 50
5.5. Demarcation of the study field 51
5.6. Ethical considerations 51
5.7. Research methodology 52
5.8. Significance of the study 54
5.9. Potential limitations 55
5.10. Projected Outline 55
5.11 Appendices 56
Appendix 1: SAPSOS Operating room case record form 58
Appendix 2: WiPSOS Operating room case record form 60
Appendix 3: SAPSOS post-operative case record form 61
Appendix 4: SAPSOS critical care case record form 62
Appendix 5: Patient information letter 64
Appendix 6: Parent information letter 65
Appendix 7: Consent form 66
5.12 References 67

Nomenclature/Research Assumptions

The following definitions and abbreviations will be used in the documentation of the study.

Anaesthetist: an anaesthesiologist, registrar or medical officer in the Department of Anaesthesiology.

APRICOT: Anaesthesia PRactise In Children Observational Trial

ARDS: Acute Respiratory Distress Syndrome

ASA-PS: American Society of Anaesthesiologists Physical Status. This describes the preoperative state of the patient, represented as I-V with I being fit, healthy patients, and V being an organ donor.

CCU: Critical Care Unit

CHBAH: Chris Hani Baragwanath Academic Hospital

CHD: Congenital Heart Disease

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

CRFs: Case Record Forms

CvAE: Cardiovascular Adverse Events

FCA (SA): Fellow of the College of Anaesthetists of South Africa

GA: General Anaesthesia

GDP: Gross Domestic Product

HJH: Helen Joseph Hospital

LMICs: Low-income and Middle-income countries

LIC: Low-income country

MIC: Middle-income country

PRAE: Perioperative Respiratory Adverse Events

RMMCH: Rahima Moosa Mother and Child Hospital

SASOS: South African Surgical Outcomes Study

SAPSOS: South African Paediatric Surgical Outcomes Study

SCAE: Severe Critical Adverse Events

URI: Upper Respiratory tract Infection

WAHC: Wits Academic Hospital Complex

WiPSOS: Wits Paediatric Surgical Outcomes Study

Wits: University of the Witwatersrand

List of Tables

Table 1 – WiPSOS patient cohort descriptors……32

Table 2 – Intraoperative adverse events……33

Table 3 – Critical care admission cohort descriptors……34

Table 4 – Details for patients that died in the perioperative period……36

Table 5 – Key differences between SAPSOS and WiPSOS……37

Section 1: Literature Review

Introduction, background and rationale for this study

The Lancet Commission on Global Surgery 2015 report announced that globally, 5 billion people lack access to safe, affordable surgical and anaesthesia care. Low and middle-income countries (LMICs) fare worst, while shouldering an increasing, multi-faceted burden of disease. In order to prevent death and disability, an additional 143 million surgical procedures need to be performed annually. This requires significant up-scaling of surgical services.[1] This extends to South Africa, but the surgical disease burden, scope of disease and disparity in perioperative care needs proper study and definition.

While South Africa has been classified as a high-Middle Income Country (MIC) in keeping with its GDP, it operates with a dual economy, and consistently has one of the highest rates of inequality in the world. Fifty eight percent of the population live below the national poverty line.[2, 3] This inequality extends to the complex healthcare system, where there are great disparities in access to and quality of care.

The South African Surgical Outcomes Study (SASOS)[4] was a landmark study across 50 government-funded hospitals across the country. It investigated the perioperative mortality and need for critical care admission in patients undergoing inpatient non-cardiac surgery in South Africa. When compared to results from the European Surgical Outcomes Study (EuSOS),[5] patients were found to be younger, had fewer non-communicable risk factors, and underwent significantly more urgent and emergent surgery. HIV was the commonest co-morbidity, but did not contribute to in-hospital mortality. Patients had lower admission rates to critical care units, but higher unplanned admission rates. Mortality was higher when admission to critical care units was unplanned. The authors concluded that a proactive strategy to increase surgical and critical care resources must be adopted, and that SASOS provides crucial information that has significant implications that can be used by clinicians to guide perioperative care, as well as policy makers to guide resource allocation. This study examined an adult population (>16 years old), and, while the results were important, they cannot be extrapolated to children.

The surgical needs of children differ from adults. Limited data extrapolated from other sub-Saharan countries indicate that injury contributes disproportionately and is the commonest surgical problem facing African children.[6] Inadequate or inappropriate care of these injuries can lead to permanent disability, where the economic implications are not inconsequential. A large study conducted in a rural South African hospital uncovered a high incidence of congenital anomalies, particularly neural tube defects and Down's syndrome.[7] These conditions are preventable with appropriate antenatal screening. The authors reasonably concluded that it was necessary to include prenatal, genetic and other appropriate paediatric facilities into the primary healthcare system of rural areas. Without access to appropriate and safe surgical services, death and disability are a tragic outcome. Health care policy in developing countries is not aligned with these unique surgical needs, possibly because these have not been well established and defined.

Serious critical incidents related to anaesthesia are rare, and occur in 1.4 per 1000 anaesthetics in developed countries.[8] In MICs this figure is two to threefold higher, and in LICs it is estimated to be almost 100 times higher. Anaesthesia-related critical events are 3 times more common in children, occurring in 3-8% of all anaesthetics. In neonates and infants, a particularly vulnerable group, the incidence of adverse events rises exponentially. While adverse events often have multiple contributing factors and are closely related to the presence of co-morbidities and pre-operative disease state, it is estimated that up to 75% are preventable. Identifying these contributing factors and preventable causes specific to our local context is of paramount importance, in seeking to address concerns around patient safety.

Results recently published from the Anaesthesia PRactice In Children Observational Trial (APRICOT) – which examined the incidence of severe critical adverse events (SCAE) in paediatric anaesthesia across Europe – highlighted a comparatively high rate of severe critical events (5.2%). This is in comparison to adult data, as well as previous reports in the literature from limited paediatric studies. Respiratory-related SCAE were the most common, especially in infants and pre-school children. Cardiovascular SCAE occurred more frequently in neonates. The study showed higher rates of SCAE with general anaesthesia vs sedation and significantly higher rates associated with higher American Society of Anaesthesiologists (ASA) risk categories. As indicated by previous studies, age remains an important risk factor.

There is some evidence that a higher caseload and more experience of the anaesthesia team could be more relevant than the institution itself, as this was associated with a lower incidence of respiratory and cardiac SCAE. The study was conducted across 261 centres in 33 European countries, and the investigators found significant variation in both the nature and frequency of severe critical incidents between the participating countries, possibly due to the extreme variability in anaesthesia management. The hope is that quality improvement campaigns will be embarked upon to standardise care and reduce the incidence of SCAE. After analysis of the findings, the recommendations are that all children under the age of 3-3.5 years should be managed by tertiary care providers, or anaesthesiologists with specific paediatric training and experience. The same recommendation was extended to children who snore, have reactive airways, and have been assigned an ASA score of ≥ 3.[9]

Currently ongoing and recruiting patients is the NEonate-Children sTudy of Anaesthesia pRactice IN Europe (NECTARINE)[9] – examining the epidemiology of morbidity and mortality in neonatal anaesthesia. This study is examining the most vulnerable subset of paediatric patients, identified as unique and at higher risk perioperatively. While we look forward to the results, the realities of neonatal perioperative care in South Africa are vastly different from those in Europe. Although the rate of premature births is similar in South Africa and many European countries, our survival rates are significantly lower, especially for extremely premature neonates. Access to neonatal Intensive Care Units is limited, as is the number of qualified and experienced neonatal intensivists, as well as other resources.

The South African Perioperative Research Group recently identified, as one of its top ten priorities for national research, the need for a 'national prospective observational study of the outcomes associated with paediatric surgical cases'[10].

The South African Paediatric Surgical Outcomes Study (SAPSOS)[11] makes strides towards addressing the paucity of data in the South African context around perioperative morbidity and mortality in paediatric patients. This study identified the incidence of in-hospital postoperative complications and mortality rate, as well as contributing factors. It described the spectrum of paediatric disease (comorbidities), the scope of surgical procedures being performed, and identified risk factors for

morbidity and mortality. This is another landmark study in South Africa and confers vitally important information, which can be used by relevant educators, policy-makers as well as healthcare providers to plan resource allocation with the aim of improving the quality of care and ultimately patient outcomes.

GlobalSurg-1[12] was a multicentre, prospective cohort study (much like SAPSOS) which was conducted internationally. It included six South African hospitals. The study aimed at identification of outcome variations across international settings, specifically for emergency intra-abdominal surgery. A follow-up study analysed the data for the six local hospitals, found significant inter-hospital variation, and determined that the hospital is an independent risk factor for adverse outcomes for emergency intra-abdominal surgery.

To date, one of the most important studies conducted in South Africa was a prospective audit of paediatric perioperative mortality over a period of 1 year at the Red Cross War Memorial Children's Hospital (RCWMCH)[13]. Not surprisingly, the study showed that age < 1 year and cardiac procedure (cardiac catheterisation and cardiac surgery) were independent predictors for increased risk for 30-day mortality. The study showed only slightly higher mortality rates than reported in other tertiary paediatric centres, but also recognised that the RCWMCH is well resourced, equipped and in the fortunate position of retaining a highly skilled, experienced staff of clinicians. This is not necessarily the case in other hospitals in South Africa.

Gauteng is South Africa's most densely populated province, with a recorded population of over 13.4 million people (24% of the total population)[14]. Within Gauteng's population, 19.7% is under the age of 15 years (vs. 30% nationally), and 3% are orphans. The province continues to grow rapidly, fuelled by migration both from other provinces, as well as from outside the country. This is projected to continue, with an expected influx of 1.1 million over a 5-year period. 0.3% of households are headed by children. The rate of unemployment stands at slightly lower than the national rate, however 13% of households have inadequate food access. Despite being on the decline, 19.8% of households reside in informal dwellings, making Gauteng the 2nd highest concentration of informal dwellings in the country. This results in poor conditions and overcrowding, which has important health implications. The percentage of the population reliant on public health care

has risen to 71.3% (2013). In addition to the burden of HIV/AIDS and other infectious diseases, the contribution of diseases of lifestyle to premature mortality in the province is rising consistently, and continues to displace some of the communicable diseases as the main causes of mortality. Rates of physical disability have risen sharply, possibly in keeping with accidental and non-accidental trauma.[15] What the contribution of unmet surgical need is to this, has not been studied or defined. Additionally, Gauteng Department of Health faces significant challenges with its workforce, with funding constraints, as well as other cited challenges, resulting in high vacancy rates, particularly among clinical workers[15].

In urban Johannesburg, paediatric surgical services are rendered by the University of the Witwatersrand (Wits) Academic Hospital Complex – comprising the Chris Hani Baragwanath Academic Hospital (CHBAH), the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), and the Rahima Moosa Mother and Child Hospital (RMMCH). The Wits Donald Gordon Medical Centre falls under the academic hospital complex umbrella, but is a private hospital and provides limited paediatric surgical services to paying patients. In addition to serving the local population, these hospitals serve as referral centres for other provinces, as well as other African countries. The patient population is diverse, the burden of disease significant, and the spectrum of pathology broad, but this has not been well studied or documented.

Following on from those results, it seems relevant to analyse the SAPSOS data relevant to the local hospitals. The Wits Paediatric Surgical Outcomes Study (WiPSOS) would involve disaggregating the subset of data from SAPSOS pertaining to the Wits Academic Hospitals. This would allow analysis of the data to allow comparison to the national data, as well as using the conclusions to draft protocols and guidelines, risk factor criteria for critical care admission more specific to local hospitals, guide resource allocation, develop outreach programmes, and draft public health policy relevant to the province.

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Section 3: Draft Article

Title: The Wits Paediatric Surgical Outcomes Study (WiPSOS)

Type of article: A research report

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What is known: South Africa is a high-middle income country with high levels of inequality, mirrored in the healthcare system, with unequal access to surgical care. Little is known about the cohort of paediatric perioperative patients and their outcomes.

What this report adds: This research report provides data around paediatric surgical outcomes, adverse events related to anaesthesia, the spectrum of surgical pathology, indications for surgery, and the disease profile of surgical patients in four busy referral hospitals in urban Johannesburg.

The Wits Paediatric Surgical Outcomes Study (WiPSOS); a prospective multicentre observational study in four academic hospitals in Johannesburg.

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Introduction

In the wake of large surgical outcomes studies conducted across Africa, North America and Europe, the South African Perioperative Research Group in 2016 identified the need for a national prospective observational study of the outcomes associated with paediatric surgical cases [1]. The South African Paediatric Surgical Outcomes Study (SAPSOS) thus sought to address the paucity of data in the local context around perioperative morbidity and mortality in paediatric patients [2].

The Anaesthesia PRactice In Children Trial (APRICOT) [3], conducted in mainly high-income European countries, highlighted a relatively high rate of perioperative severe critical adverse events (SCAE) (5.2%). Identified risk factors were congruent with previous literature and included younger age and higher American Society of Anaesthesiologists Physical Status (ASA PS) scores. Despite the higher incidence of SCAE, mortality remained low at 0.05% and none of the deaths were deemed to be attributable to anaesthesia.

The South African Surgical Outcomes Study (SASOS) [4] described perioperative mortality and critical care admission in patients older than 16 years undergoing inpatient non-cardiac surgery. Compared to the European Surgical Outcomes Study (EuSOS) [5] patients were younger, had fewer non-communicable risk factors, and underwent more urgent and emergent surgery. HIV was the commonest co-morbidity. Admission rates to critical care units (CCU) were lower, but unplanned admission rates were higher, and associated with higher mortality. These results highlight important differences in adult data compared to high income countries (HICs), but cannot be extrapolated to paediatric practice.

An audit of paediatric perioperative mortality at a tertiary children's hospital in Cape Town showed that age under one year and cardiac procedure were independent risk factors for 30-day mortality [6]. This study showed only slightly higher mortality rates (0.1%) than reported in other tertiary paediatric

centres, but recognised that the institution is well resourced, equipped and in the fortunate position of retaining a highly skilled, experienced staff of clinicians.

The dichotomy between the private and public healthcare sectors in South Africa is well described. Additionally, there are significant historically-rooted regional differences in care due to staffing, funding, management and access to resources[7]. This made it necessary to evaluate the data pertaining to the regional population. Gauteng is the most densely populated province with 13.4 million people (24% of the total population)[8]. Children under 15 years comprise 19.7% of the population (vs. 30% nationally), and 3% are orphans. The population reliant on public health care has risen to 71.3% (2013). Rates of physical disability have risen sharply, possibly in keeping with accidental and non-accidental trauma[9]. The Gauteng Department of Health faces significant challenges with its workforce, with funding constraints and other cited challenges resulting in high vacancy rates particularly among clinical workers[9].

This study was designed to identify the incidence and nature of adverse events and their outcomes in children undergoing anaesthesia at the University of the Witwatersrand Academic Hospital Complex (WAHC).

Methods

Study Design

This study was part of a larger national, prospective observational multi-centre study called SAPSOS. SAPSOS collected data for all children under 16 years undergoing a non-obstetric surgical procedure over a designated 14-day period. Data for 2024 patients across 43 hospitals were obtained. The Wits Paediatric Surgical Outcomes Study (WiPSOS) disaggregated the subset of data pertaining to the four referral hospitals that comprise the University of the Witwatersrand Academic Hospital Complex: three tertiary hospitals and one secondary hospital.

Ethical approval was granted by the University of the Witwatersrand Human Research Ethics Committee (Reference: M170112). Between 22 May 2017 and 5 June 2017, all patients under 16 years presenting for a non-obstetric surgical procedure under general anaesthesia were included in the study. Patients were followed up for 30 days postoperatively, until death or discharge from hospital (whichever came first). Patients undergoing diagnostic procedures were excluded. Data collected were all part of routine clinical care. Data were collected on paper case record forms (CRF) and entered anonymously into a secure internet-based electronic case record form (RedCap™). Only the local teams had access to individual patient information. Access to RedCap™ was username and password protected.

Recruitment and follow up was performed by local site investigators. For each patient, information was recorded on an intraoperative CRF and a postoperative CRF which was completed at 30 days postoperatively, death or discharge. A critical care CRF was completed for all patients admitted to CCU. These forms were based on the dataset from EuSOS and SASOS with minor adaptations relevant to paediatric patients.

Full details of the patient history, nature of the procedure, anaesthetic conduct and experience of the anaesthetist and surgeon in charge were recorded. Significant adverse events were predefined and included laryngospasm, bronchospasm, pulmonary aspiration, severe hypoxia, difficult bag-mask ventilation, difficult or failed intubation, severe hypotension, bradycardia, arrhythmia, cardiac arrest, hypo/hyperthermia, hypoglycaemia, emergence agitation and the presence of postoperative stridor.

Postoperative complications of an infectious, cardiovascular or miscellaneous nature were included and categorised as mild, moderate or severe according to predefined criteria. Miscellaneous complications included gastro-intestinal bleeding, acute kidney injury, postoperative bleeding, acute respiratory distress syndrome, anastomotic breakdown or other. Patients who required reoperation and/or CCU admission after developing complications were noted.

Data analysis:

Relevant parts of the document were used to corroborate information where the data were missing. Where no complications were recorded it was entered as none having occurred.

Statistical analysis:

Categorical variables were described as percentages and associations were done using $\chi 2$ and Fisher's exact tests. Continuous variables were described as means and standard deviations, and the comparisons were done using the t-test. We used a generalised linear regression model (logistic regression model) to fit the binary outcomes to identify the risk factors. We performed statistical analysis with STATA (version 14).

For the logistic regression models, results were reported as adjusted odds ratios (ORs) with 95% confidence intervals (CIs). All factors with a *p* value of < 0.2 were included in the multivariable model.

Results:

The study included 399 eligible patients across the four hospitals who underwent surgery over the 14 - days. The majority were male (223; 55.9%). The median age was 4.42 years. The median ASA PS score was 1. The most common acute comorbidity was a current/recent URI (5.5%) while the most common chronic comorbidities were congenital syndromes (8.3%), congenital heart disease (5.8%) and cancer (5.5%). Most surgical procedures performed were elective (272/398; 68%), 55/398 (13.8%) were urgent, and 71/398 (17.8%) were emergent. Only 41 (10.3%) surgeries were performed after hours. Most surgeries were categorised as minor (240/398; 60.3%), while 125/398 (31.4%) were intermediate and 33/398 (8.3%) major. The most frequent indication for surgery was a congenital disorder/anomaly (149; 37.7%), followed by non-communicable diseases (126; 31.9%) and trauma (77; 19.3%). Patient cohort descriptors are tabulated in Table 1.

Perioperative Respiratory Adverse Events (RAE) occurred in 41 patients (10.3%; 95% CI 7.5-13.7%). RAE that occurred in the intraoperative period and recovery room included difficult airway management, laryngospasm, bronchospasm, hypoxia, aspiration and postoperative stridor. These occurred in 34 (8.52%; 95% CI 6 -11.7%) patients. Risk of developing these RAE was higher for

patients with a current/recent URI (OR 3.42; 95% CI 1 – 12; $p = 0.055$). Patients with 'other' comorbid diseases, which included burns, chronic lung disease, laryngeal papillomas, osteogenesis imperfecta, pulmonary tuberculosis and sickle cell disease, were at higher risk of RAE occurring intraoperatively or in the recovery room (OR 3.18; CI 1.42-7.12; $p = 0.005$). RAE in the postoperative period included pneumonia (5; 1.2%) and ARDS (2; 0.5%).

Cardiovascular adverse events (CvAE) in the intraoperative period and recovery room included arrhythmias, bradycardia, severe hypotension and cardiac arrest. These occurred in 12 (3%; 95% CI 1.6 – 5.2%) patients. The median age of patients who developed CvAE was 1.1 years, and the mean ASA PS III. Risk of developing CvAE was higher in patients with congenital heart disease (CHD) (OR 69.11; 95% CI 16.26 – 293.68; $p < 0.001$). Children with cancers were also at higher risk (OR 7.40; 95% CI .72 – 75.78; $p = 0.092$).

Other intraoperative complications included difficult IV access, difficulty increasing oxygen saturation, failed caudal anaesthesia, postoperative pain, massive haemoptysis, delayed emergence and dental trauma (see Table 2). Most patients had no intraoperative complications. Fifty-eight patients (14.5%) experienced one complication, 14 (3.5%) had two complications and one patient had five intraoperative complications.

Postoperatively, 46 (11.5%; 95% CI 8.6-15.1%) patients required CCU admission. Most were accommodated (43/46; 93.5%). Most admissions were planned (35/43; 81.4%). Indications for admission included respiratory support in 25 (6.3%) patients, cardiovascular support in 10 (2.5%), and 'other' reasons in 11 (2.7%) patients. The latter included sepsis, metabolic derangement, and combined respiratory and cardiovascular support. The three patients who were not admitted returned to the ward for postoperative care. One of these patients subsequently developed sepsis and acute kidney injury and was still in hospital at the close of the study period. The other two patients recovered and were discharged home (see Table 3).

Most patients who had surgery during this period had an uneventful postoperative course. There were 74 complications which occurred in 47 patients, resulting in a postoperative complication rate of 11.8% (95% CI 8.8 - 15.3%). Most complications (39.2%) were categorised as mild, 36.5% were moderate and 24.3% were severe. The most common complications were infectious (55/74; 74.3%). There were 55 infectious complications in 25 patients with a postop infection rate of 6.3%. Bloodstream infections accounted for the majority of these (17/55; 30.9%), followed by superficial surgical site infections (13/55; 23.6%) and deep surgical site infections (10/55; 18.2%). Other complications in the postoperative period included cardiovascular complications 4 (1%), and 16 (4%) miscellaneous complications, which included ARDS, bleeding, acute kidney injury and anastomotic breakdown. There were 20 (5.1%) patients who required further surgery secondary to a postoperative complication. Sixteen of these were already in the CCU and returned to the unit postoperatively. Mean length of stay in hospital postoperatively was 3.97 days (SD 6.94) (12 data missing). The longest postoperative stay was 52 days (patient was alive at close of study period).

In the perioperative period 6 patients died. The mortality rate at 30 days was 1.5% (95% CI 0.5 – 3.2%). No one died in the operating theatre. Three patients died in the CCU. Patients with congenital cardiac disease were 9 times more likely to die (95% CI 1.36 – 63.16) (p = 0.023). One patient was discharged home for palliation and likely died within the study period, but was not included in this data (see Table 4).

Discussion:

This study reports an in-hospital 30-day perioperative mortality of 1.5%, higher than that described in the national data (1.1%) and in Europe (0.05%). Achieving lower mortality rates approximating that of developed countries is possible as shown in Cape Town, in an institution rendering a specialist paediatric perioperative service. This lends credibility to establishing dedicated children's hospitals that are well funded and have access to better resources, facilitating the retention of skilled staff.

The disease profile seen in WiPSOS mirrors the national cohort, with congenital syndromes and CHD the most common chronic comorbidities. The evidence shows consistently that these patients are at higher risk for perioperative morbidity, cardiac arrest and death [10-12]. SAPSOS identified that a congenital indication for surgery was a risk for postoperative complications. In WiPSOS 37.3% of surgeries were performed for this indication compared to 27.6% (p < 0.001) in SAPSOS (see Table 5). Data from Sub-Saharan Africa suggests that injury is the most common surgical problem in children on the continent [13]. Despite high levels of crime in South Africa, trauma was only the third most common indication for surgery. The burden of disease is largely congenital and is likely unanticipated, which raises questions around effective antenatal screening programs and the allocation of resources for this purpose.

The incidence of perioperative RAE in this study was more than three times that seen in the APRICOT. However, included in these data were difficult airway management and hypoxia, case definitions which were more expansive than those used in APRICOT. Anaesthesia-related RAE occurred mainly intraoperatively and in the recovery room. Difficult airway management accounted for 17 (50%) of these. Possible reasons for this include a high incidence of current/recent URIs and a lack of specialised/experienced paediatric anaesthetists, two well described factors associated with increased perioperative RAE and difficult airway management [14, 15]. Many of the comorbid diseases listed as 'other' were diseases affecting the respiratory system (e.g. pulmonary tuberculosis, laryngeal papillomatosis), possibly resulting in these patients being at higher risk.

The definitions for CvAE were similar to APRICOT and thus this comparison is more meaningful. The incidence of CvAE was more than double that for APRICOT (4% vs 1.9%). In accordance with other literature, patients in this group were younger and sicker. It is unsurprising that patients with CHD were at higher risk.

The incidence of infectious complications is high (6.3%). This is alarming and suggests that a review of institutional infection control programs including surgical antibiotic prophylaxis protocols, audit of

adherence to these and other protocols for prevention of iatrogenic infections, handwashing techniques and use of other barrier precautions, is required. The contribution of decaying infrastructure[7], inadequate maintenance of hospital facilities and lack of implementation of infection control policies warrants further study and review.

Other key contributing factors to the higher morbidity and mortality compared to the national data include younger age (4.42 vs 5.9 years) and higher ASA PS scores (59.7% ASA PS I vs 66.4%) (p =0.004). Each of these variables was identified as an independent risk factor for postoperative complications by SAPSOS, but don't in their entirety account for this high incidence. These results emphasise that added vigilance is warranted when anaesthetising children under three years and those with higher ASA PS scores, specifically related to congenital syndromes, CHD and cancers. The recommendation is that a dedicated anaesthetist experienced in paediatric perioperative care is present throughout these procedures, but also begs for the training and recognition of paediatric anaesthetists as sub-specialists.

The data which has emerged confirms the importance of disaggregating large multicentre studies to develop deeper local insights and possibly inform more locally applicable solutions. Heterogeneity between sites regarding workforce and access to resources remain important factors that require greater exploration. The analysis of this data may inform practise in a manner that is locally relevant. This facilitates the development of evidence-based practise and improvement initiatives towards reduced perioperative morbidity and mortality.

Limitations:
Differing definitions between SAPSOS and other international studies restrict direct comparison.

Funding:
This research was carried out with personal funding.

Conflicts of interest:
No conflicts of interest declared.

Word count: 2465

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Table 1 WiPSOS patient cohort descriptors

Variable	Hospital			
	CMJAH	**CHBAH**	**RMMCH**	**HJH**
Functional operating rooms *n*	37	28	5	8
CCU paediatric beds* *n*	17	27	6	0
Total number of patients *n*	135	210	50	4
Median age (years)	3.5	5.96	3.125	3.42
ASA grade *Mean (SD)*	1(1.1)	2 (2.2)	1.1 (0.5)	1 (2.5)
Elective surgeries *n* (%)	97 (71.9)	125 (59.5) *	47 (94)	3 (75)
Grade of surgery				
Minor *n* (%)	70 (51.8)	119 (56.7)	48 (96)	3 (75)
Intermediate *n* (%)	46 (34.1)	76 (36.2)	2 (4)	1 (25)
Major *n* (%)	19 (14.1)	14 (6.7)	0	0
Surgical speciality *n* (%)				
Orthopaedic	16 (11.8)	60 (28.6)	4 (8)	-
ENT	3 (2.2)	16 (7.6)	20 (40)	-
GIT (incl. HPB)	32 (23.7)	33 (15.7)	5 (10)	1 (25)
Plastics	12 (8.9)	20 (9.5)	5 (10)	-
Cardiac	16 (11.8)	3 (1.4)	-	-
Maxillofacial/Dental	4 (3)	4 (1.9)	16 (32)	-
Ophthalmology	7 (5.2)	22 (10.5)	-	3 (75)
Neurosurgery	8 (5.9)	6 (2.9)	-	-
Urology	18 (13.3)	13 (6.2)	-	-
Thoracic	3 (2.2)	2 (0.9)	-	-
Burns	1 (0.7)	16 (7.6)	-	-
Vascular	1 (0.7)	1 (0.5)	-	-
Other	14 (10.4)	13 (6.2)	-	-
Primary Indication for surgery *n* (%)				
Non-communicable	36 (26.7)	53 (25.2)	37 (74)	0
Infective	8 (5.9)	30 (14.3)	4 (8)	1 (25)
Injury	20 (14.8)	56 (26.7)	1 (2)	0
Congenital	70 (51.8)	69 (32.9)	7 (14)	3 (75)
Missing data	1	2	1	-

* number of CCU beds varies according to availability of suitably qualified nurses.

Table 2 Intraoperative Adverse Events

Adverse event category	Number of adverse events	%	Number of patients	%	Median age (years)	Median ASA
Respiratory	44	11	34	8.52	2.2	II
CVS	14	3.50	12	3	1.1	III
Other	30	9				

Table 3 Critical care admission cohort

Variable	Elective CCU admission, n (%) n=35	Non-elective CCU admission, n (%) n=8	*p* Value
Age (mean in years)	3.28 (SD 3.92)	1.67 (SD 2.7)	0.29
ASA (mean)	2.6 (SD 0.2)	3.33 (SD 0.8)	0.08
Grade of surgery			
Minor	0	1 (12.5)	
Intermediate	13 (37.14)	3 (37.5)	0.106
Major	22 (62.86)	4 (50)	
Urgency of Surgery			
Elective	20 (57.14)	1 (12.5)	
Urgent	5 (14.28)	2 (25)	0.057
Emergent	10 (28.57)	5 (62.5)	
Surgical speciality			
Cardiac	14 (40)	2 (25)	
ENT	5 (14.28)	0	
Thoracic	2 (5.71)	1 (12.5)	
Upper GIT	2 (5.71)	1 (12.5)	0.63
Lower GIT	4 (11.42)	3 (37.5)	
Maxillofacial/dental	1 (2.86)	0	
HPB	1 (2.86)	0	
Burns	4 (11.42)	1 (12.5)	
Other	2 (5.71)	0	
Indication for surgery			
NCD	5 (14.28)	3 (37.5)	
Infective	3 (8.57)	2 (25)	0.08
Traumatic	6 (17.14)	1 (1)	
Congenital	21 (60)	2 (2)	

Comorbid disease		
CHD	15	3
Congenital syndrome	6	1
Cancer	1	-
LRI	6	2
URI	2	-
Pulmonary hypertension	3	1
HIV/AIDS	1	-
Asthma/Atopy	1	-
OSA	1	-
Other	7	3

Table 4 Details of patients who died in the perioperative period

Age	ASA	Comorbid disease	Procedure	Periop SCAE	Plausible cause	Location
10m	III	Congenital Heart Disease	VSD repair	Sepsis, Acute Kidney Injury, Cardiac Arrest	Sepsis	CCU
2y	III	Congenital Heart Disease, Atopy, Acute Liver Disease, Down's Syndrome	DL + dilatation subglottic stenosis			CCU
12y	III	Acute Lymphoblastic Leukaemia	BMAT		Neutropaenic Sepsis	Oncology ward
9m	IIIE	Congenital Hydrocephalus	EVD insertion		Intracranial bleed, apnoea	Paediatric surgical ward
1y9m	IIIE	Burns	Sloughectomy	Pneumonia, Sepsis	Sepsis	CCU
3y9m	II	Burns	Skin grafting			Unknown

Table 5 Key differences between SAPSOS and WiPSOS

Variable	SAPSOS	WiPSOS
Age (median in years)	5.9	4.42
ASA PS (%)		
I	66.4	59.7
II	20.7	21.3
III	10.8	16.2
IV - V	2.1	2.8
Urgency of Surgery (%)		
Elective	64.8	68
Urgent	20.2	13.8
Emergent	15.1	17.8
Severity of Surgery (%)		
Minor	54.9	60.3
Intermediate	37.6	31.4
Major	7.5	8.3
Indication for Surgery (%)		
Congenital	27.6	37.7
Non-communicable disease	31.9	31.9
Injury	22.3	11.1
Infection	18.3	19.3
Postoperative complication rate (%)	9.7	11.8
Mortality rate (%)	1.1	1.5

Section 4: Appendices

Appendix 1: Permission from Principal Investigator to use data

Dear Dr Bhettay,

Re: South African Paediatric Surgical Outcomes Study (SAPSOS)

I hereby grant you permission to use the subset of anonymized data gathered from all hospitals associated with WITS university from the SAPSOS study. Your institution will be able to use this anonymized data for any purpose you see fit, provided you have fulfilled all local ethical and regulatory regulations required for local projects which use the data. The anonymized data will be released following the primary publication of the whole study. The SAPSOS Steering Committee must approve the final version of all manuscripts relating to the SAPSOS dataset prior to submission.

Please ensure that there is recognition of the SAPSOS study in any publications you produce from this data.

Yours sincerely



Dr A Torborg

Principal Investigator

South African Paediatric Surgical Outcomes Study (SAPSOS)

Office of the Head of Discipline – Anaesthesiology & Critical Care School of Clinical Medicine

Postal Address: Private Bag 7, Congella, Durban, 4013, South Africa

Appendix 2: Approval from postgraduate committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

19 July 2017
Person No: 315738
PAG

Dr AZ Bhettay
28 Saxonwold Manor
cnr Eastwold Way & Oxford Road
Saxonwold
Johannesburg
2196
South Africa

Dear Dr Bhettay

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Wits Paediatric Surgical Outcomes Study (WiPSOS)* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 3: Ethics clearances

R14/49 Dr Anisa Bhettay et al

HUMAN RESEARCH ETHICS COMMITTEE

CLEARANCE CERTIFICATE NO. M1

NAME: (Principal Investigator)	Dr Anisa Bhettay et al
DEPARTMENT:	Anaesthesiology Rahima Moosa Mother and Child Hospit Helen Joseph Hospital Chris Hani Baragwanath Academic Hosp Charlotte Maxeke Johannesburg Acade
PROJECT TITLE:	South African Paediatric Surgical Outco Fourteen-day, South African National M Prospetive Cohort Study of Paediatric P undergoing Surgery
DATE CONSIDERED:	27/01/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	
APPROVED BY:	Professor P. Cleaton-Jones, Chairperso
DATE OF APPROVAL:	05/04/2017

This clearance certificate is valid for 5 years from date of approval. Extensi

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Se floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the fully understand the the conditions under which I am/we are authorised to carry ou research and I/we undertake to ensure compliance with these conditions. Should from the research protocol as approved, I/we undertake to resubmit to the Commi **yearly progress report**. The date for annual re-certification will be one year after meeting where the study was initially reviewed. in this case, the study was initially therefore be due in the month of January each year. Unreported changes to the a the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL E

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

23 October 2017

Dr Anisa Bhettay
Specialist Anaesthetist
Department of Anaesthesiology
Faculty of Health Sciences
University of the Witwatersrand
Parktown
2193

Sent by email to: anisabhettay@gmail.com

Dear Dr Bhetty

Re: **Protocol Ref No: M170112**
Protocol Title: Wits Paediatric Surgical Outcomes Study
Fourteen-day, Regional, Multi-centre Prospective Cohort Study of Paediatric Patients (<16 Years) Undergoing Surgery
Principal Investigator: Dr Anisa Bhettay et al
Differed Consent

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has approved the differed consent for the abovementioned study, as detailed in your document.

Thank you for keeping us informed and updated.

Yours Sincerely,

L.Moeng

Mr Lebohang Moeng
Administrative Assistant
Human Research Ethics Committee (Medical)

UNIVERSITY OF THE WITWATERSRAND
OFFICE OF THE DEPUTY VICE CHANCELLOR RESEARCH
23 OCT 2017
RESEARCH OFFICE HREC (Medical)
JOHANNESBURG

Appendix 3: Turnitin report

315738:forturnitin.docx

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Section 5: Proposal

Wits Paediatric Surgical Outcomes Study (WiPSOS)

Name: Anisa Bhettay

Student Number: 315738

Degree: Master of Medicine – Anaesthesia

Supervisor: Ass. Professor Lionel Green-Thompson

Assistant Dean: Teaching and Learning

Co-supervisor: Dr. Thomas Kleyenstuber

Head of Anaesthesia – Rahima Moosa Mother and Child Hospital

TABLE OF CONTENTS:

1.0 Introduction, background and rationale for the study

2.0 Aim of the Study

3.0 Objectives of the Study

- 3.1 Primary Objectives
- 3.2 Secondary Objectives

4.0 Research Assumptions

5.0 Demarcation of the Study Field

6.0 Ethical Considerations

7.0 Research Methodology

- 7.1 Study Design
- 7.2 Study population
- 7.3 Study Sample
  - 7.3.1 Sample Size
  - 7.3.2 Sampling Method
  - 7.3.3 Inclusion and Exclusion Criteria
- 7.4 Data Collection
  - 7.4.1 Data Collection Instrument
  - 7.4.2 Data Collection Method
- 7.5 Data Analysis

8.0 Significance of the Study

9.0 Potential Limitations

10.0 Projected Outline

- 10.1 Timeframe
- 10.2 Outline

11.0 Appendices

12.0 References

5.1 Introduction, background and rationale for the study

The Lancet Commission on Global Surgery 2015 report announced that globally, 5 billion people lack access to safe, affordable surgical and anaesthesia care. Low and middle-income countries (LMICs) fare worst, while shouldering an increasing, multi-faceted burden of disease. In order to prevent death and disability, an additional 143 million surgical procedures need to be performed annually. This requires significant up-scaling of surgical services(1). This extends to South Africa, but the surgical disease burden, scope of disease and disparity in perioperative care needs proper study and definition.

While South Africa has been classified as a high – Middle Income Country (MIC) in keeping with its GDP, it operates with a dual economy, and consistently has one of the highest rates of inequality in the world. Fifty eight percent of the population live below the national poverty line(2, 3). This inequality extends to the complex healthcare system, where there are great disparities in access to and quality of care.

The South African Surgical Outcomes Study (SASOS)(4) was a landmark study across 50 government - funded hospitals across the country. It investigated the perioperative mortality and need for critical care admission in patients undergoing inpatient non-cardiac surgery in South Africa. When compared to results from the European Surgical Outcomes Study (EuSOS)(5), patients were found to be younger, had fewer non-communicable risk factors, and underwent significantly more urgent and emergent surgery. HIV was the commonest co-morbidity, but did not contribute to in-hospital mortality. Patients had lower admission rates to critical care units, but higher unplanned admission rates. Mortality was higher when admission to critical care units was unplanned. The authors concluded that a proactive strategy to increase surgical and critical care resources must be adopted, and that SASOS provides crucial information that has significant implications that can be used by clinicians to guide perioperative care, as well as policy makers to guide resource allocation. This study examined an adult population (>16 years old), and, while the results were important, they cannot be extrapolated to children.

The surgical needs of children differ from adults. Limited data extrapolated from other sub-Saharan countries indicate that injury contributes disproportionately and is the commonest surgical problem facing African children(6). Inadequate or inappropriate care of these injuries can lead to permanent disability, where the economic implications are not inconsequential. A large study conducted in a rural South African hospital uncovered a high incidence of congenital anomalies, particularly neural tube defects and Down's syndrome(7). These conditions are preventable with appropriate antenatal screening. The authors reasonably concluded that it was necessary to include prenatal, genetic and other appropriate paediatric facilities into the primary healthcare system of rural areas. Without access to appropriate and safe surgical services, death and disability are a tragic outcome. Health

care policy in developing countries is not aligned with these unique surgical needs, possibly because these have not been well established and defined.

Serious critical incidents related to anaesthesia are rare, and occur in 1.4 per 1000 anaesthetics in developed countries(8). In MICs this figure is two to threefold higher, and in LICs it is estimated to be almost 100 times higher. Anaesthesia-related critical events are 3 times more common in children, occurring in 3-8% of all anaesthetics. In neonates and infants, a particularly vulnerable group, the incidence of adverse events rises exponentially. While adverse events often have multiple contributing factors and are closely related to the presence of co-morbidities and pre-operative disease state, it is estimated that up to 75% are preventable. Identifying these contributing factors and preventable causes specific to our local context is of paramount importance, in seeking to address concerns around patient safety.

Results recently published from the Anaesthesia PRactice In Children Observational Trial (APRICOT)(9) – which examined the incidence of severe critical adverse events (SCAE) in paediatric anaesthesia across Europe – highlighted a comparatively high rate of severe critical events (5.2%). This is in comparison to adult data, as well as previous reports in the literature from limited paediatric studies. Respiratory-related SCAE were the most common, especially in infants and pre-school children. Cardiovascular SCAE occurred more frequently in neonates. The study showed higher rates of (SCAE) with general anaesthesia vs sedation and significantly higher rates associated with higher American Society of Anaesthesiologists (ASA) risk categories. As indicated by previous studies, age remains an important risk factor. There is some evidence that a higher caseload and more experience of the anaesthesia team could be more relevant than the institution itself, as this was associated with a lower incidence of respiratory and cardiac SCAE. The study was conducted across 261 centres in 33 European countries, and the investigators found significant variation in both the nature and frequency of severe critical incidents between the participating countries, possibly due to the extreme variability in anaesthesia management. The hope is that quality improvement campaigns will be embarked upon to standardise care and reduce the incidence of SCAE. After analysis of the findings, the recommendations are that all children under the age of 3-3.5 years should be managed by tertiary care providers, or anaesthesiologists with specific paediatric training and experience. The same recommendation was extended to children who snore, have reactive airways, and have been assigned an ASA score of ≥ 3.

Currently ongoing and recruiting patients is the NEonate-Children sTudy of Anaesthesia pRactice IN Europe (NECTARINE)(10) – examining the epidemiology of morbidity and mortality in neonatal anaesthesia. This study is examining the most vulnerable subset of paediatric patients, identified as unique and at higher risk perioperatively. While we look forward to the results, the realities of neonatal perioperative care in South Africa are vastly different from those in Europe. Although the rate of premature births is similar in South Africa and many European countries, our survival rates are significantly lower, especially for extremely premature neonates. Access to neonatal Intensive Care Units is limited, as is the number of qualified and experienced neonatal intensivists, as well as other resources.

The South African Perioperative Research Group recently identified, as one of its top ten priorities for national research, the need for a 'National prospective observational study of the outcomes associated with paediatric surgical cases'(11).

The South African Paediatric Surgical Outcomes Study (SAPSOS)(12) seeks to address the paucity of data in the South African context around perioperative morbidity and mortality in paediatric patients. The study aims to identify the incidence of in-hospital postoperative complications as well as contributing factors. It will identify the burden of paediatric diseases (comorbidities) which may contribute to perioperative morbidity and mortality, and extract important information around the categories of surgical procedures being performed. It is well established in paediatric anaesthesia that the experience of the anaesthetist specifically with paediatric cases impacts on morbidity and mortality. SAPSOS will allow us to identify the level of training of perioperative caregivers – surgical and anaesthetic. This is another landmark study in South Africa and will confer critically important information, which can be used by relevant educators, policy-makers as well as healthcare providers to plan resource allocation with the aim of improving the quality of care and ultimately patient outcomes.

GlobalSurg-1(13) was a multicentre, prospective cohort study (much like SAPSOS) which was conducted internationally. It included six South African hospitals. The study aimed at identification of outcome variations across international settings, specifically for emergency intra-abdominal surgery. A follow-up study analysed the data for the six local hospitals, found significant inter-hospital variation, and determined that the hospital is an independent risk factor for adverse outcomes for emergency intra-abdominal surgery.

To date, one of the most important studies conducted in South Africa was a prospective audit of paediatric perioperative mortality over a period of 1 year at the Red Cross War Memorial Children's Hospital (RCWMCH)(14). Not surprisingly, the study showed that age < 1 year and cardiac procedure (cardiac catheterisation and cardiac surgery) were independent predictors for increased risk for 30-day mortality. The study showed only slightly higher mortality rates than reported in other tertiary paediatric centres, but also recognised that the RCWMCH is well resourced, equipped and in the fortunate position of retaining a highly skilled, experienced staff of clinicians. This is not necessarily the case in other hospitals in South Africa.

Gauteng:

Gauteng is South Africa's most densely populated province, with a recorded population of over 13.4 million people (24% of the total population)(15). Within Gauteng's population, 19.7% is under the age of 15 years (vs. 30% nationally), and 3% are orphans. The province continues to grow rapidly, fuelled by migration both from other provinces, as well as from outside the country. This is projected to continue, with an expected influx of 1.1 million over a 5 year period. 0.3% of households are headed by children. The rate of unemployment stands at slightly lower than the national rate, however 13% of households have inadequate food access. Despite being on the decline, 19.8% of households reside in informal dwellings, making Gauteng the 2nd highest concentration of informal dwellings in the

country. This results in poor conditions and overcrowding, which has important health implications. The percentage of the population reliant on public health care has risen to 71.3% (2013). In addition to the burden of HIV/AIDS and other infectious diseases, the contribution of diseases of lifestyle to premature mortality in the province is rising consistently, and continues to displace some of the communicable diseases as the main causes of mortality. Rates of physical disability have risen sharply, possibly in keeping with accidental and non-accidental trauma.(16) What the contribution of unmet surgical need is to this, has not been studied or defined. Additionally, Gauteng Department of Health faces significant challenges with its workforce, with funding constraints, as well as other cited challenges, resulting in high vacancy rates, particularly among clinical workers(16).

In urban Johannesburg, paediatric surgical services are rendered by the University of the Witwatersrand (Wits) Academic Hospital Complex – comprising the Chris Hani Baragwanath Academic Hospital (CHBAH), the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), and the Rahima Moosa Mother and Child Hospital (RMMCH). The Wits Donald Gordon Medical Centre falls under the academic hospital complex umbrella, but is a private hospital and provides limited paediatric surgical services to paying patients. In addition to serving the local population, these hospitals serve as referral centres for other provinces, as well as other African countries. The patient population is diverse, the burden of disease significant, and the spectrum of pathology broad, but this has not been well studied or documented.

Following on from those results, it seems relevant to analyse the SAPSOS data relevant to the local hospitals. The Wits Paediatric Surgical Outcomes Study (WiPSOS) would involve disaggregating the subset of data from SAPSOS pertaining to the Wits Academic Hospitals. This would allow analysis of the data to allow comparison to the national data, as well as using the conclusions to draft protocols and guidelines, risk factor criteria for critical care admission more specific to local hospitals, guide resource allocation, develop outreach programmes, and draft public health policy relevant to the province.

5.2 Aim of the Study

Research Question:

1. To determine the incidence of perioperative morbidity and mortality in patients under the age of 16 years, presenting for a non-obstetric procedure under general anaesthesia, at the University of the Witwatersrand (Wits) Academic Hospitals.

5.3 Objectives of the study

5.3.1 Primary objective

1. To describe the incidence of in-hospital perioperative complications including mortality and critical care admission in paediatric surgical patients in the Wits Academic Hospitals.

5.3.2 Secondary objectives

1. To identify factors associated with in-hospital perioperative complications in paediatric surgical patients in Wits Academic Hospitals.
2. To describe the profile of paediatric surgical procedures performed at different levels of hospitals in Wits Academic Hospitals.
3. To describe the proportional contribution of communicable, non-communicable diseases, congenital and traumatic injuries to in-hospital mortality and critical care admissions in paediatric surgical patients in Wits Academic Hospitals.

5.4. Research Assumptions:

The following definitions and abbreviations will be used in the documentation of the study.

Anaesthetist: an anaesthesiologist, registrar or medical officer who belongs to the Department of Anaesthesiology.

Anaesthesiologist: a medical doctor who is a specialist in the field of anaesthesiology.

ASA: American Society of Anaesthesiologists. The ASA status describes the preoperative state of the patient, represented as I-V with I being fit, healthy patients, and V being an organ donor.

CRFs: Case Record Forms

EuSOS: European Surgical Outcomes Study

FCA (SA): Fellow of the College of Anaesthetists of South Africa

GA: General Anaesthesia

GDP: Gross Domestic Product

Junior consultant: an anaesthesiologist with less than 5 years' experience as a specialist anaesthetist.

Junior registrar: a registrar who has not yet passed the FCA (SA) Part I examination.

LMICs: Low-income and Middle-income countries

LIC: Low-income country

MIC: Middle-income country

Medical officer: a medical doctor who is post-community service.

Registrar: a medical doctor who is receiving advanced training in a specialist field i.e. anaesthesiology in order to qualify as an anaesthesiologist.

SASOS: South African Surgical Outcomes Study

SAPSOS: South African Paediatric Surgical Outcomes Study

Senior registrar: a registrar who is has passed the FCA (SA) Part I examination, and is currently doing or has already completed the senior rotations in anaesthesiology.

WAHC: Wits Academic Hospital Complex

WiPSOS: Wits Paediatric Surgical Outcomes Study

Wits: University of the Witwatersrand

5.5. Demarcation of the study field

The study will be conducted within the Departments of Anaesthesiology and Critical Care at the Chris Hani Baragwanath Academic Hospital (tertiary), Charlotte Maxeke Johannesburg Academic Hospital (tertiary), Rahima Moosa Mother and Child Hospital (secondary), and Wits Donald Gordon Medical Centre (tertiary).

5.6. Ethical considerations

Ethics approval will be obtained from the University of the Witwatersrand Human Research Ethics Committee. Each participating hospital will be approached to provide site approval for the study.

Section 71(3)(a)(ii) of the National Health Act (NHA) states that consent must be obtained from the Minister of Health for 'non-therapeutic' health research involving minors. (17) Four criteria must be met. The Minister has delegated authority to provide this consent to fully registered research ethics committees (RECs). I believe that this study fulfils these four criteria.

Criterion 1: *The research objectives cannot be achieved except by the participation of minors.*

> As explained above, data from adult surgery cannot simply be extrapolated to paediatric patients. Paediatric patients represent unique challenges when compared to adults, as they differ physiologically, anatomically and have different pharmacokinetics. The spectrum of disease differs significantly, and the surgical procedures that they undergo are congruent with the disease profile. Risk factors for perioperative complications and poor perioperative outcomes deviate from those relevant for adults. In ascertaining what these are, it is crucial that research be conducted on the relevant patient population – in this case, minors.

Criterion 2: *The research is likely lead to an improved scientific understanding of certain conditions, diseases or disorders affecting minors.*

> The burden and spectrum of disease affecting minors in South Africa, and more locally, Gauteng, is unknown. Also lacking is local and centre-specific data on perioperative outcomes. Children under the age of 15 constitute 19.7% of Gauteng's population. Minors are disproportionately affected by the burden of untreated surgical disease. Globally, the

established priority is access to safe surgery, and in order to accomplish this goal, appropriate resources need to be allocated, at a national and provincial level. This study can be used to guide resource allocation.

Criterion 3: *Any consent given to the research is in line with public policy.*

In South Africa, children are protected as a vulnerable research population and as such require individual informed consent. Thus, informed consent will be obtained, where necessary with the use of interpreters, in a language that is developmentally appropriate for the child.

Criterion 4: *The research does not pose a significant risk to minors; and if there is some risk, the benefit of the research outweighs the risk.*

This study is conducted by collecting data. This data is routinely obtained, and as such there is no risk posed to the patient.

5.7. Research methodology

5.7.1 STUDY DESIGN

The SAPSOS study, from which the subset of relevant data will be obtained, will be based on the methodology of the EuSOS and SASOS studies. This is a descriptive, South African national multi-centre prospective cohort study of paediatric patients (<16 years) undergoing surgery. Data will be collected during the course of the study, which will take place over fourteen days. The relevant data is the subset of data that pertains to the University of the Witwatersand Academic Hospital Complex.

5.7.2 STUDY POPULATION

All consecutive paediatric patients presenting for general anaesthesia for a surgical procedure, at the above-mentioned hospitals between 22 May 2017 and 5 June 2017.

5.7.3 STUDY SAMPLE

The study population is comprised of all consecutive patients under the age of 16 years, who will undergo a general anaesthetic for a surgical procedure.

5.7.3.1 SAMPLE SIZE

The intention is to recruit all the patients as is possible within the fourteen-day period. Based on limited anecdotal data from participating sites, I estimate that the sample size may be close to 400. This is based on the regular caseload at these sites. The inferences which may be made from this data may be limited by the number of cases done, however, the descriptive statistics would be of value.

5.7.3.2 SAMPLING METHOD

5.7.3.3. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

All consecutive patients under 16 years of age, admitted to participating centres during the study period who undergo elective and non-elective surgery. All patients undergoing operative procedures will be included – this extends to day case surgery and operative procedures occurring in 'remote' theatres, outside the main operating theatre complex. Recruitment will commence during the fourteen-day study cohort period which will run from 07h00 on 22 May 2017 to 06h59 on 5 June 2017.

Exclusion criteria:

1. Patients undergoing radiological or other procedures not requiring general anaesthesia, or where general anaesthesia is performed but no procedure is done e.g. GA during a magnetic resonance imaging (MRI).

2. Obstetric surgical procedures.

5.7.4 DATA COLLECTION

5.7.4.1 DATA COLLECTION INSTRUMENT

Each patient will have information recorded on either an electronic or paper case record form (CRF). These CRFs were created by the SAPSOS principal investigators, based on the dataset from EuSOS and SASOS with minor adaptations relevant to paediatric patients. For the purposes of this study, I have made amendments (approved by the SAPSOS investigators), to the Operating Room CRF. While intended to be comprehensive, it is important not to make the forms too cumbersome, which may limit compliance. The other CRFs are taken directly from the SAPSOS.

For each patient there are potentially 3 CRFs:

1. Operating Room Case Record Form will be completed for every patient eligible to form part of the study within the fourteen-day period. (Appendix 1)

2. All patients enrolled will be followed up for 30 days. A Post-operative follow-up Case Record Form will be completed for every patient enrolled in the study upon discharge, death or 30 days post-op (whichever comes first). (Appendix 2) (12)

3. A Critical Care Case Record Form will be completed for all patients enrolled in the study who require admission to a critical care unit post-operatively within the follow-up period. (Appendix 3) (12)

In addition, a Hospital Data Record Form will be completed for each site.

5.7.4.2 DATA COLLECTION METHOD

Data will be collected at each individual centre, by the anaesthetist responsible for the case. Each site will have a local coordinator who will communicate with the Wits lead investigator (me).

Each individual centre will collect and record data on either an electronic or paper case record form (CRF) for every patient recruited. Paper CRFs will include identifiable data (to allow follow-up of clinical outcomes). Each patient's data will be anonymized by assigning them a generated, unique numeric code. This will then be transcribed by local investigators onto a secure, password-protected, internet based electronic CRF. Each patient will only be identified on the electronic CRF by their numeric code; thus, the coordinating study team cannot trace data back to an individual patient without contact with the local team. A patient list will be used in each centre to match identifier codes in the database to individual patients in order to record clinical outcomes and supply any missing data points. Access to the data entry system will be protected by username and password delivered during the registration process for individual local investigators. All electronic data transfer between participating centres and the coordinating centre will be encrypted using a secure protocol (HTTPS/SSL 3.0 or better).

Where individual centres are unable to access the internet-based case record form, I will collect the forms.

Each centre will maintain a secure trial file including a protocol, local investigator delegation log, ethics approval documentation, the participant list, and other additional documentation such as trial definitions.

A final summary printout of included patients with major variables should be produced for each centre together with final data submission to double check for completeness and accuracy.

5.7.5 DATA ANALYSIS

Primary outcome measure:

1. The incidence of in-hospital perioperative complications in paediatric surgical patients < 16 years at the Wits Academic Hospital Complex (WAHC).

Secondary outcome measures:

1. Mortality rate on the day of surgery for patients < 16 years undergoing surgery at the WAHC

2. The in-hospital mortality rate for patients < 16 years undergoing surgery at the WAHC

3. Rate of post-operative admission to critical care for patients <16 years at the WAHC

5.8. Significance of the study

WiPSOS hopes to better define the spectrum and burden of paediatric surgical disease within the greater Johannesburg area. By identifying which types of procedures and which kinds of patients are being operated on at different levels of care, it can make recommendations regarding appropriate distribution of cases, centre utilisation, as well as identify centres where it may be appropriate to upscale paediatric surgical care provided. In this way, it could help guide resource allocation at a

provincial level. By identifying deviations from evidence-based anaesthesia management, it can highlight which centres may benefit from outreach and ongoing training in paediatric anaesthesia. Given the exponential rise in litigation cases in recent years, the results or recommendations from WiPSOS could be used to draft clear and prescriptive guidelines as to which patients should be treated at certain levels of care in the province.

5.9. Potential limitations

The potential limitations to this study would be that of data loss. This may be addressed by cross-referencing with theatre registers.

5.10. Projected Outline

5.10.1 TIMEFRAME

	2017										2018
	March	April	May	June	July	August	Sept	Oct	Nov	Dec	Jan
Protocol	X										
Submission for ethics approval		X									
Submission for postgrad. approval		X									
Data collection			X	X							
Data analysis							X	X			
Write-up									X	X	
Submission											X

10.2 BUDGET FOR THE STUDY

Item	Cost per unit	Units	Total cost
Printing of Case Record Forms	R1.00	300	R300.00
Printing Information letters	R1.00	600	R600.00
Printing consent/assent forms	R1.00	600	R600.00
Printing of research report	R1.00	1000	R1000.00
Binding of final research report	R200.00	2	R400.00
		Total	**R2900.00**

The cost of the study will be funded privately by the researcher.

10.3 PUBLICATION PLAN

The SAPSOS steering committee will appoint a committee to compile a scientific report for publication. The scientific report for WiPSOS will only be allowed to be published after the SAPSOS report has been published and results disseminated.

5.11 Appendices

Appendix 1

SAPSOS Operating Room CRF

Appendix 2

WiPSOS Operating room CRF

Appendix 3

SAPSOS Post-operative case record form

Appendix 4

SAPSOS Critical Care case record form

Appendix 5

Information letter for parents

Appendix 6

Information letter for child

Appendix 7

Consent form for parent

Appendix 1: SAPSOS Operating room case record form

South African Paediatric Surgical Outcomes Study (SAPSOS)

Operating Room case record form

Patient information:

Age: ☐☐ **days** ☐☐ **months** ☐☐ **years** **Gender:** ☐ **M** ☐ **F**

Exposure to tobacco smoke: ☐ **Y** ☐ **N** **Vaccinations up to date:** ☐ **Y** ☐ **N**

Weight ☐☐☐.☐ **kg** **Height:** ☐☐☐ **cm**

ASA ☐ **I** ☐ **II** ☐ **III** ☐ **IV** ☐ **V**

Asian/ Indian ☐ **Black African** ☐ **Caucasian** ☐ **Coloured** ☐

Chronic or Acute CO-MORBID disease (tick *all* that apply):

☐ **Congenital heart disease**	☐ **Other cardiac disease**	☐ **Congenital syndrome**
☐ **Endocrine**	☐ **Cancer**	☐ **Cerebral Palsy**
☐ **Obstructive sleep apnoea**	☐ **Asthma/Atopy**	☐ **HIV/AIDS**
☐ **Pulmonary hypertension**	☐ **Current LRTI**	☐ **Recent LRTI**
☐ **Current URTI**	☐ **Recent URTI**	☐ **Muscle disorder**
☐ **Bronchiolitis**	☐ **Acute liver disease**	☐ **Chronic liver disease**

Most recent blood results (no more than 28 days before surgery):

Haemoglobin ☐☐☐.☐ **g/L Leucocytes** ☐☐☐.☐ **x10^9/L Platelets** ☐☐☐ **x10^9/L**

Albumin ☐☐ **Urea/BUN** ☐☐☐.☐ **mmol/L Creatinine** ☐☐☐☐.☐ **µmol/L**

Anaesthesia induction time (24h) & date: hh:mm dd 05 2017

Anaesthetic technique (tick *all* that apply):

Induction ☐ **IV** ☐ **Volatile** ☐ **HALO** ☐ **SEVO** ☐ **N_2O**

☐ **General** ☐ **Sedation**

Airway: ☐ **Mask** ☐ **LMA** ☐ **ETT**

Regional: ☐ **Epidural** ☐ **Caudal** ☐ **Local** ☐ **Other regional**

Analgesia: ☐ **Narcotic** ☐ **NSAID** ☐ **Ketamine** ☐ **Paracetamol**

Inotrope / Vasopressor: ☐ **A** ☐ **NA** ☐ **Dopamine** ☐ **Dobutamine** ☐ **Other**

SAPSOS unique patient ID ☐☐☐☐☐☐☐

✂

Patient name: _____ **DOB** dd mm yyyy

Patient hospital number : _____

Anaesthetic Complications:

☐ Laryngospasm ☐ Aspiration ☐ Severe hypoxia ☐ Severe hypotension

☐ Difficult BMV ☐ Difficult intubation ☐ Failed intubation ☐ Cardiac arrest ☐ Bradycardia

☐ Arrhythmia ☐ T > 38 ☐ T < 36 ☐ Low GM

Neonates

Gestational age at birth ☐☐ weeks Birth weight ☐☐☐☐ grams

Birth Asphyxia ☐ Y ☐ N

Surgical procedure category (select *single* most appropriate):

☐ Orthopaedic	☐ Cardiac	☐ ENT
☐ Gynaecological	☐ Vascular	☐ Kidney
☐ Upper gastro-intestinal	☐ Thoracic (lung and other	☐ Urological
☐ Hepato-biliary	☐ Plastics / Cutaneous	☐ Neurosurgery
☐ Lower gastro-intestinal	☐ Thoracic (gut)	☐ Ophthalmology

Urgency of surgery ☐ Elective ☐ Urgent ☐ Emergency

Severity of surgery ☐ Minor ☐ Intermediate ☐ Major

Primary indication for surgery:

☐ Non-communicable disease ☐ Infective ☐ Traumatic injury ☐ Congenital

Surgical checklist used (e.g. WHO checklist)? ☐ Y ☐ N

Blood loss during surgery: ☐☐☐☐ ml Transfusion ☐ Y ☐ N

Duration of surgery: ☐☐☐☐ minutes

Personnel

Most senior anaesthetist present in operating room

☐ Specialist ☐ MO/ registrar > 3 yrs ☐ Junior (<3 years in anaesthesia)

Most senior surgeon present in operating room

☐ Specialist ☐ MO/ registrar > 3 yrs ☐ Junior (<3 years in surgery)

Requires critical care (CC) after surgery: ☐ Y ☐ N

If Yes, did the patient get admitted to CC ☐ Y ☐ N

Primary indication for ICU: ☐ Cardiovascular ☐ Respiratory/Airway ☐ Other

SAPSOS unique patient ID ☐☐☐☐☐☐☐

✂

Patient name: _____ DOB d d m m y y y y

Patient hospital number : _____

Appendix 2: WiPSOS Operating room case record form

Wits Paediatric Surgical Outcomes Study (WiPSOS)

Operating room case record form

1. What was the procedure performed?

   _____

2. Was this case an emergency?

   □ Y □ N

3. Were there any other complications other than those listed on the SAPSOS case record form? If yes, list them.

   □ Y _____

4. Experience of the most senior anaesthetist in theatre:

   □ Specialist > 5 years □ Specialist < 5 years

   □ Senior registrar (post cardiac) □ Junior registrar

   □ Medical Officer (passed DA) □ MO (no DA)

5. Where did this anaesthetic and procedure take place?

   □ Main theatre complex □ ICU □ Remote theatre

SAPSOS unique patient ID □□□ □□□□

✂----------

Patient name: _____ **DOB** □□□□□□□□

Patient hospital number: _____

Appendix 3: SAPSOS post-operative case record form

South African Paediatric Surgical Outcomes Study (SAPSOS)

Post-operative follow-up case record form

Infection

Superficial surgical site	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Deep surgical site	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Body cavity	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Pneumonia	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Urinary tract	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Bloodstream	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐

Cardiovascular

Arrhythmia	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Pulmonary oedema	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Pulmonary embolism	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Cardiac arrest			**Severe** ☐	**None** ☐

Miscellaneous complications

Gastro-intestinal bleed	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Acute kidney injury	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Postoperative bleed	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
ARDS	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Anastomotic breakdown	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐
Other	**Mild** ☐	**Moderate** ☐	**Severe** ☐	**None** ☐

Postoperative Follow Up

Re-operation for complication ☐ **Yes** ☐ **No**

Critical care admission to treat postoperative complications ☐ **Yes** ☐ **No**

Days in critical care after surgery ☐☐

Days in hospital after surgery ☐☐

Status at hospital discharge or 30th postoperative in-hospital day ☐ **Alive** ☐ **Dead**

SAPSOS unique patient ID ☐☐☐☐☐☐☐

✂

Patient name: _____ **DOB** d d m m y y y y

Patient hospital number : _____

Appendix 4: SAPSOS critical care case record form

South African Paediatric Surgical Outcomes Study (SAPSOS)

Critical Care case record form

Patient information: Score within 1 hour of ICU ADMISSION

Admission date: ☐☐☐☐☐☐☐☐ **Admitted from same hospital:** ☐ **Yes** ☐ **No**

Elective ICU admission ☐ **Yes** ☐ **No**

Recovery from surgery or a procedure is main reason for ICU admission:

☐ **No** ☐ **Yes, recovery from non cardiac procedure**

☐ **Yes, recovery from bypass** ☐ **Yes, recovery from non-bypass cardiac procedure**

Low risk diagnosis as *main reason* for admission to ICU:

☐ **Asthma main reason** ☐ **Bronchiolitis main reason** ☐ **Croup**

☐ **OSA** ☐ **DKA** ☐ **seizure disorder** ☐ **None**

High risk diagnosis as *main reason* for admission to ICU:

☐ **Spontaneous cerebral hemorrhage** ☐ **CMO or myocarditis** ☐ **Necerotising enterocolitis**

☐ **Hypoplastic left heart syndrome** ☐ **Neurodegenerative disorder** ☐ **None**

Very High risk diagnosis as *main reason* for ICU admission

☐ **Severe combined immune deficiency** ☐ **Cardiac arrest preceding ICU admission**

☐ **Leukemia or lymphoma after first induction** ☐ **None**

Mechanical Ventilation in 1st hour ☐ **Yes** ☐ **No**

Pupillary reaction to bright light ☐ **> 3mm** ☐ **both dilated** ☐ **unknown**

Systolic BP **Highest:** ☐☐☐ **mmHg** **Lowest:** ☐☐☐ **mmHg**

PaO_2 **Highest:** ☐☐☐ **mmHg** **Lowest:** ☐☐☐ **mmHg**

FiO_2 **Highest:** ☐.☐ **Lowest:** ☐.☐

Base excess **Highest:** ☐☐ **mmol/L** **Lowest:** ☐☐ **mmol/L** **or** ☐ **unknown**

Temperature on admission in ^0C ☐☐.☐ **Heat Rate:** ☐☐☐

SAPSOS unique patient ID ☐☐☐ ☐☐☐☐

TRAUMA SCORING: **Score for any patient admitted with trauma**

Region	None	Injury Description
Head & Neck		
Face		
Chest		
Abdomen		
Extremity		
External		

Organ support during ICU stay:

☐ **Airway (ETT, tracheostomy)**
☐ **CVS/ hemodynamic (inotropes/vasopressors)**
☐ **Renal (RRT)**
☐ **Respiratory (invasive/non-invasive ventilation)**
☐ **Metabolic (Electrolytes/Glucose)**
☐ **Neurological (neuro-protection)**
☐ **G.I.T (enteral feed/ TPN, IAP)**
☐ **Other (specify)**

Discharge from ICU:

Date: ☐☐☐☐☐☐☐☐ (Y Y Y Y M M D D)

Survived ☐ **or** **Died** ☐☐☐☐☐☐☐☐ (Y Y Y Y M M D D)

☐ **Transferred to H/Care** ☐ **Transferred to ward / base hospital**

Primary Diagnosis:

☐ **Infectious** ☐ **Non Communicable** ☐ **Trauma** ☐ **Congenital**

Secondary Diagnosis (may be multiple:

Specify:

SAPSOS unique patient ID ☐☐☐☐☐☐☐

Appendix 5: Patient information letter

DEPARTMENT OF ANAESTHESIOLOGY
CHBAH, CMJAH, HJH, RMMCH

INFORMATION LETTER:

Title of Study: The South African Paediatric Surgical Outcomes Study and Wits Paediatric Surgical Outcomes Study

Hello, my name is Dr_____. I am a doctor in the Department of Anaesthesia. I would like to invite you to be part of the study: South African Paediatric Surgical Outcomes Study and Wits Paediatric Surgical Outcomes Study. These are happening in South Africa. I am collecting information for the University of the Witwatersrand, under the Department of Anaesthesia.

The reason for the study is to collect information about complications after surgery in children in South Africa. We would like to use your information to complete forms which will be part of the study.

You are going to have an operation at our Hospital. The Hospital not only provides treatment, but is also involved in research to make the treatment we provide for you better. Sometimes, this research means we use patient files to get information. We can only use this information if:

- The Committee for Research on Human Subjects at the University of the Witwatersrand approves it.
- Anonymity: Only the researcher will know who you are.

We would like to get your permission to use your information for our research. Being part of the study is completely up to you. You will not have to pay for anything.

If you choose not to agree to be part of the study, then it will not change your current or future treatment in any way.

If at any time, you don't want to be part of this study, you are free to leave, and this will again not change your current or future treatment in any way.

If you would like to contact us at any time about this permission, please contact the lead investigator in Johannesburg:
Dr. Anisa Bhettay 0829201190. OR

Human Research Ethics Committee (Medical), University of the Witwatersrand

HREC (Medical) contact details: Prof P Cleaton Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za
Ms Z Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Administrative Officers 011 717 2700/2656/1234/1252 zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za; and Lebo.moeng@wits.ac.za

Appendix 6: Parent information letter

DEPARTMENT OF ANAESTHESIOLOGY
CHBAH, CMJAH, HJH, RMMCH

INFORMATION LETTER:

Title of Study: The South African Paediatric Surgical Outcomes Study and Wits Paediatric Surgical Outcomes Study

Hello, my name is Dr_____. I am an anaesthetist in the Department of Anaesthesia. I would like to invite your child to participate in the studies: South African Paediatric Surgical Outcomes Study and Wits Paediatric Surgical Outcomes Study. This is a national multi-centre Prospective Cohort Study. I am collecting information for the University of the Witwatersrand, under the Department of Anaesthesia.

The purpose of the study is to collect information about complications after surgery in children in South Africa. We would like to use your child's information to complete forms which will form part of the study.

Your child is scheduled to have an operation at our Hospital. The Hospital not only renders treatment but is also actively involved in conducting research aimed at improving the quality of the care we deliver. From time to time such research involves the use of patient records from which information is extracted. The use of such information is subject to:

• Approval from the Committee for Research on Human Subjects (University of the Witwatersrand).
• Anonymity: in other words the identity of the patient from whose file information is extracted is never revealed to anyone but the researcher unless specific consent is obtained from the patient to do so.

We would like to obtain your consent to use your information for the purpose of our research, subject to the aforementioned conditions. Your participation is completely voluntary. There will be no cost to you, and your child will not undergo any additional procedures if he/she is involved in the study.

If you choose not to give your consent, then doing so will not compromise your current or future treatment in any way.

If at any time in the future, before or after your discharge from this Hospital, you choose to withdraw this consent, you are free to do so and this will again not prejudice your current or future treatment in any way.

Should you wish to contact us at any stage regarding this consent, please contact the lead investigator in Johannesburg:
Dr. Anisa Bhettay 0829201190. OR

Human Research Ethics Committee (Medical), University of the Witwatersrand

HREC (Medical) contact details: Prof P Cleaton Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za
Ms Z Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng Administrative Officers 011 717 2700/2656/1234/1252 zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za; and Lebo.moeng@wits.ac.za

Appendix 7: Consent form

DEPARTMENT OF ANAESTHESIOLOGY
CHBAH, CMJAH, HJH, RMMCH

CONSENT FORM: USE OF CLINICAL INFORMATION

TITLE OF STUDY: THE SOUTH AFRICAN PAEDIATRIC SURGICAL OUTCOMES STUDY AND WITS PAEDIATRIC SURGICAL OUTCOMES STUDY

Dear parent,

I confirm that I have been informed by Dr ……. about the nature of the study. I have also read/it was read to me and I understood the information sheet. I have had the opportunity to ask questions.

I understand that my child's participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that sections of any of my medical records may be looked at by Drs. Bhettay, Mogane, Semenya, Ravid and Dhanjee. I am aware that my child will not undergo any additional procedures. Any information and results will be anonymously processed into a computerized system. Data will be kept for two years if published or six years if not published, after this period the data will be destroyed.

Should you wish to contact us at any stage regarding consent, please contact Dr. Bhettay at 0829201190.

I agree that my child may take part in the above-mentioned study. I hereby give consent for his/her records to be used as per the above-mentioned conditions and for the purposes of research.

Name and Surname of Patient/Participant	Signature/Mark or Thumbprint	Date:

Translator/Other Person Explaining Informed Consent
(Designation)……:

Printed name	Signature	Date:

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