The incidence of perioperative critical events in paediatric patients at a Johannesburg Academic Hospital

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530158

A research report submitted to the Faculty of Health Sciences,

University of the Witwatersrand, Johannesburg,

in the partial fulfilment of the requirements for the degree of

Master of Medicine in the branch of Anaesthesiology

Johannesburg, 2024

Declaration

I, Anne-Mart Viljoen, herewith declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

Signed

On this 13th day of March 2024

Dedication

To my family, you are the absolute best. Thank you for all your patience with me and always supporting me. Harshal and Hilde, thank you for always being there when I need you. I am forever grateful.

Abstract (words:300)

Background

Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death. South African paediatric research on risk factors and critical events is limited. The aim of this study was to describe the perioperative critical events in paediatric patients at Rahima Moosa Mother and Child Hospital in Johannesburg. The objectives were to determine the incidence and management of perioperative critical events, risk factors, and to describe immediate postoperative outcomes.

Methods

A prospective observational cross-sectional study was conducted. It included 206 patients up to the age of 12 undergoing anaesthesia for elective and emergency procedures.

Results

The median age of patients with critical events was four years with a weight of 13kg. The cumulative incidence of critical events was 34% (95% CI, 27-40) with hypoglycaemia having the highest incidence of 21% (95% CI,16-27). The incidence of respiratory critical events was 11% (95% CI, 7-16), emergence delirium 2.4% (95% CI, 0.90-5.9%), cardiovascular events 1.9% (95% CI,0.62-5.2%) and temperature abnormalities was 0.5% (95% CI, 0.03-3.1). Risk factors associated with respiratory events included younger age [OR (95% CI) = 0.63 (0.40, 1.00), p = 0.049] and the use of endotracheal tubes [endotracheal tube vs facemask: OR = 0.07 (0.00, 0.42), p = 0.016; endotracheal tube vs supraglottic: OR = 0.18 (0.03, 0.77), p = 0.041]. Management of the events varied according to physician preferences. Of the patients included, 87% were discharged to the ward.

Conclusion

The cumulative incidence of critical events was almost seven times higher than that reported in high income countries, and more than double than in a large South African multi-centre study. Hypoglycaemia was the biggest contributor emphasising the importance of correct implementation of preoperative fasting guidelines. Attention should be given to improve in-service training and continuous medical education to improve patient outcomes.

Acknowledgements

Janine Wagner and Shafeeqa Mayet, thank you for your input, guidance, and support.

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List of Abbreviations

ASA	American Society of Anaesthesiologists
BMV	Bag mask ventilation
ENT	Ear, nose, and throat
ETT	Endotracheal tube
HGT	Haemoglucose test
OPA	Oropharyngeal airway
RMMCH	Rahima Moosa Mother and Child Hospital
SACRI	Severe Anaesthetic-Related Critical Incident
SGAD	Supraglottic airway device
Wits	University of the Witwatersrand

Statement

The Research Report consists of a literature review, draft article, study proposal, and appendices. The literature review and study proposal are included for background reference and are not for examination.

The formatting of this Research Report, but not the draft article, complies with the University of the Witwatersrand's Style Guide for Theses, Dissertations, and Research Reports.

The formatting of the draft article is in keeping with the author guidelines stipulated by the South African Journal of Anaesthesia and Analgesia, the journal to which it is intended to be submitted.

Section 1: Review of the Literature

1. Introduction

The National Guideline for Patient Safety Incident Reporting and Learning defines a "patient safety incident" as an unplanned or unintended event or circumstance that could have resulted, or did result, in harm to a patient while in the care of a health facility (1). This event is thus not due to the underlying health condition or natural progression of disease. An incident can be a near miss (which did not reach the patient), no harm incident, or harmful incident (adverse event). Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death (2). Care should be taken to avoid critical events in the vulnerable paediatric population to avoid morbidity and mortality.

Critical events in anaesthesia include a variety of conditions that involve a range of physiological systems in the body. Respiratory events include difficult bag mask ventilation, difficult or failed intubation, broncho- and laryngospasm, hypoxia, aspiration, and post anaesthetic stridor. Cardiovascular events include arrhythmias, bradycardia, hypotension, hypertension, myocardial ischemia, and cardiac arrest. Seizures and loss of neurological function may occur. Hypoglycaemia and temperature derangements are not uncommon in paediatrics. Different drug doses are used for paediatrics, which predisposes these patients to drug errors. These include administering the wrong dose, wrong drugs, and administration at the wrong site. Fluid extravasations, anaphylaxis, and emergence agitation can also occur (2,3).

According to Habre et al (2) risk factors for severe critical events include patient, anaesthetic, and surgical risk factors. Risk factors include a higher ASA score, the younger patients less than 6 years of age with the highest being in the neonatal population, and sensitised airways (airways with acute or chronic inflammation). Physical conditions such as prematurity, current fever, having a physical or mental disability, history of snoring, and medication use were also identified as risk factors. Anaesthetic related risk factors include less experienced anaesthetists, using inhalational induction, airway manipulation such as endotracheal intubation, as well as the use of supraglottic airways (2,4).

Some studies have found that intubation without muscle relaxants are a risk factor (5). Surgical procedures have been found to have a higher incidence of critical events than non-surgical procedures, and emergency cases have also been identified as an independent risk factor (2).

A study conducted in Australia, showed that risk factors for respiratory complications include a history of a night-time cough, exercise induced wheezing, and history of wheezing more than three times in the past year. An upper respiratory tract infection less than two weeks prior to the procedure, family history of atopy, asthma and eczema, and smoking were also identified as factors that increase respiratory adverse events (4).

Critical events in anaesthesia could result in catastrophic sequelae if the anaesthetic team doesn't respond timeously in an adequate manner. In the United Kingdom it has been reported that the overall incidence of critical events is approximately 5% with the majority being made up by respiratory (59.6%) and cardiovascular (36.5%) events (2). A study conducted by Kurth et al (6) in the United states has shown that 0.1% of anaesthetics result in life threatening injuries with disabilities, incapacity, or even death.
A study conducted by Murat et al (7) showed that the majority of critical events (53%) were respiratory in nature.

A study conducted in Nigeria by Agbamu et al (8) has found that the incidence of critical events was 6.1%. In contrast to studies conducted in high income countries, the highest incidence of critical events was recorded in elective procedures supervised by specialists. These were cardiovascular in nature. The critical incidents reported in the study were as follows: cardiovascular (41.1%), respiratory (23.25%), vascular access (15.1%), airway/intubation (6.85%), equipment errors (6.85%), difficult/failed regional technique (4.11%), and others (2.74%) (8).

The results of these studies may differ as the definitions of perioperative critical and adverse events are not standardised. The international data can also not be extrapolated to the South African setting due to the diversity in the South African population and health care system, as well as the challenges that South African hospitals face with regards to infrastructure, funding, staffing, equipment, and other resources.

There is a paucity of South African data concerning critical events in South Africa. A study conducted by Cronje et al (3) in 2017 examined severe anaesthetic-related critical incidents (SARCI) and perioperative cardiac arrests. This study found that the incidence of SARCI was 15.9%, and that critical incidents were three times higher than in high income countries and perioperative cardiac arrests were 10 times more common. However, despite the inclusion of 43 hospitals, the study was only conducted over a two-week period. The authors did not state how many patients were included per hospital, nor was there reference made with respect to specific surgical disciplines.

In contrast to Cronje's study, this study will be conducted over a four-month period only at one hospital (RMMCH). This will ensure that the data will be more representative of practise specifically at RMMCH. This study will also specify the different surgical disciplines and the critical events per discipline in the intra-operative period. The observation and outcomes will only be from the theatre complex. It will not follow patients up in the ward for any complications post operatively.

There is no specific data available regarding perioperative critical events in the paediatric population at Rahima Moosa Mother and Child Hospital (RMMCH). This data will assist with identifying risk factors for patients' poor outcome, will provide insight into current service provision, establish a baseline from which interventions can be assessed, assist with protocol and guideline development, and improve strategies for in-service training.

Problem statement

Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death The incidence of perioperative severe critical events for all paediatric anaesthetic sub-specialities at RMMCH has not yet been established. It is necessary to establish status quo with regards to critical events in a paediatric setting to provide insight into current service provision at RMMCH, and to measure the effect of any intervention that may be instituted in the future.

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Section 2: Author's Guidelines

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The incidence of perioperative critical events in paediatric patients at a Johannesburg Academic Hospital

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Keywords: paediatric, critical events, anaesthesia, perioperative, risk factors

Abstract (word count:300)

Background

Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death. South African paediatric research on risk factors and critical events is limited. The aim of this study was to describe the perioperative critical events in paediatric patients at Rahima Moosa Mother and Child Hospital in Johannesburg. The objectives were to determine the incidence and management of perioperative critical events, risk factors, and to describe immediate postoperative outcomes.

Methods

A prospective observational cross-sectional study was conducted. It included 206 patients up to the age of 12 undergoing anaesthesia for elective and emergency procedures.

Results

The median age of patients with critical events was four years with a weight of 13kg. The cumulative incidence of critical events was 34% (95% CI, 27-40) with hypoglycaemia having the highest incidence of 21% (95% CI,16-27). The incidence of respiratory critical events was 11% (95% CI, 7-16), emergence delirium 2.4% (95% CI, 0.90-5.9%), cardiovascular events 1.9% (95% CI,0.62-5.2%) and temperature abnormalities was 0.5% (95% CI, 0.03-3.1). Risk factors associated with respiratory events included younger age [OR (95% CI) = 0.63 (0.40, 1.00), p = 0.049] and the use of endotracheal tubes [endotracheal tube vs facemask: OR = 0.07 (0.00, 0.42), p = 0.016; endotracheal tube vs supraglottic: OR = 0.18 (0.03, 0.77), p = 0.041]. Management of the events varied according to physician preferences. Of the patients included, 87% were discharged to the ward.

Conclusion

The cumulative incidence of critical events was almost seven times higher than that reported in high income countries, and more than double than in a large South African multi-centre study. Hypoglycaemia was the biggest contributor emphasising the importance of correct implementation of preoperative fasting guidelines. Attention should be given to improve in-service training and continuous medical education to improve patient outcomes.

Introduction

Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death.[1] Critical events in anaesthesia are not uncommon and care should be taken to avoid critical events in the vulnerable paediatric population to avoid morbidity and mortality.

Patient, surgical, and anaesthetic risk factors predisposing patients to critical events have been identified in numerous studies.[1-3] Risk factors include higher American Society of Anaesthesiologists (ASA) scores[4], patients less than six years of age with the highest risk being in the neonatal population, and patients with sensitised airways with inflammation. Physical conditions such as prematurity, history of snoring, having a fever, taking treatment, and having a mental or physical disability were also identified as risk factors. Anaesthetic related risk factors include less experienced anaesthetists, using inhalational induction, airway manipulation such as endotracheal intubation, and the use of supraglottic airways.[1,2] Some studies have found that intubation without muscle relaxants are a risk factor.[3] Emergency cases have been found to have a higher incidence of critical events.[1]An upper respiratory tract infection less than two weeks prior to the procedure, a history of night-time coughing, wheezes, a family history of atopy, asthma and eczema, and secondary smoking can increase respiratory adverse events.[2]

Studies to determine the incidence of critical events have been conducted globally.[1,5-8] The results of these studies may differ as the definitions of perioperative critical and adverse events are not standardised. There is a paucity of data concerning critical events in South Africa. A study conducted by Cronje et al in 2017 examined severe anaesthetic-related critical incidents (SARCI) and perioperative cardiac arrests in paediatrics.[8] This study found that the incidence of SARCI was 15.9%, and that critical incidents were three times higher than in high income countries.[8]

It is necessary to establish status quo with regards to critical events in a paediatric setting to provide insight into the current service provision. The aim of this study was to describe the perioperative critical events in paediatric patients undergoing anaesthesia for surgical procedures at Rahima Moosa Mother and Child Hospital (RMMCH).

The objectives were to determine the incidence of the critical events, to determine the patient, surgical, and anaesthetic factors that are associated with severe critical events, and to describe the management and immediate postoperative outcomes of patients where critical events under anaesthesia occurred.

Methods

This was a prospective observational cross-sectional study conducted on 206 paediatric patients at Rahima Moosa Mother and Child Hospital (RMMCH), a regional hospital in Johannesburg South Africa. The study was conducted over a four-month period (October 2022 to February 2023).

A questionnaire based on the study conducted by Habre et al[1] was adapted with permission and underwent face and content validation by 10 specialist anaesthetists at the University of Witwatersrand (Wits). The questionnaires were left in the theatre complex and the anaesthetists conducting the anaesthesia were asked to complete this form. The definitions of critical events were explained to the anaesthetists, but not included in the original information sheet. Appendix 1 contains the definitions and could be provided should the study be repeated. Anaesthetic charts were traced by the primary researcher and used to fill in missing data. Where missing data couldn't be found on the charts, the participant was removed from the sample.

The study was approved by the senior clinical executive of RMMCH and registered on The National Research Database (NHRD) GP_202208_068. Ethical clearance was obtained from The Human Research Ethics Committee (Medical) from the University of the Witwatersrand (M220813). Consent for participation in the study was obtained from the parent or legal guardian of all the children. For children older than seven years, assent was also obtained from the children themselves.

Biases were prevented by having a well-designed protocol that clearly outlined the data collection and analysis thereof. There was representation of outliers in the data, and an independent biostatistician were used for the analysis of the data. Negative findings were also reported in this report.

The sample size was calculated for the primary outcome, which was descriptive. Thus, the required sample size was not calculated to achieve a specific power.

An adequate sample size of 205 was calculated using the formulas reported in Sharma et al,[9] using the cumulative incidence data from Cronje et al,[8] assuming an incidence of 15.9%, and allowing for a 5% margin of error.

Non-probability consecutive convenience sampling was used.

The study included all children (age 0-12 years old) who received an elective or emergency anaesthetic for a procedure in theatre. The study included ASA I-IV patients undergoing sedation, regional and general anaesthesia for paediatric gastroenterology, dental, urological, plastic surgical, orthopaedic, and general surgical procedures.

Children that were already intubated prior to arrival to theatre and remote site anaesthesia were excluded from this study.

Critical events were defined as respiratory (difficult bag mask ventilation, multiple intubations, laryngospasm, bronchospasm, aspiration, severe hypoxia, post-operative stridor), cardiac events (bradycardia, other arrhythmias, hypotension, cardiac arrest), metabolic (hypoglycaemia, hypothermia, hyperthermia) as well as neurological events, emergence delirium and drug errors. Emergence delirium was included as part of the definition of critical events based on review of a previous study done in South Africa examining the same outcome.[8]

The 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)' guideline were used to report.

Data analysis

After recruitment, the data from the questionnaires were entered anonymously into an electronic spreadsheet and analysed using R v4.2.2. Continuous data are reported as medians (interquartile range, IQR). Categorical data are reported as counts and percentages.

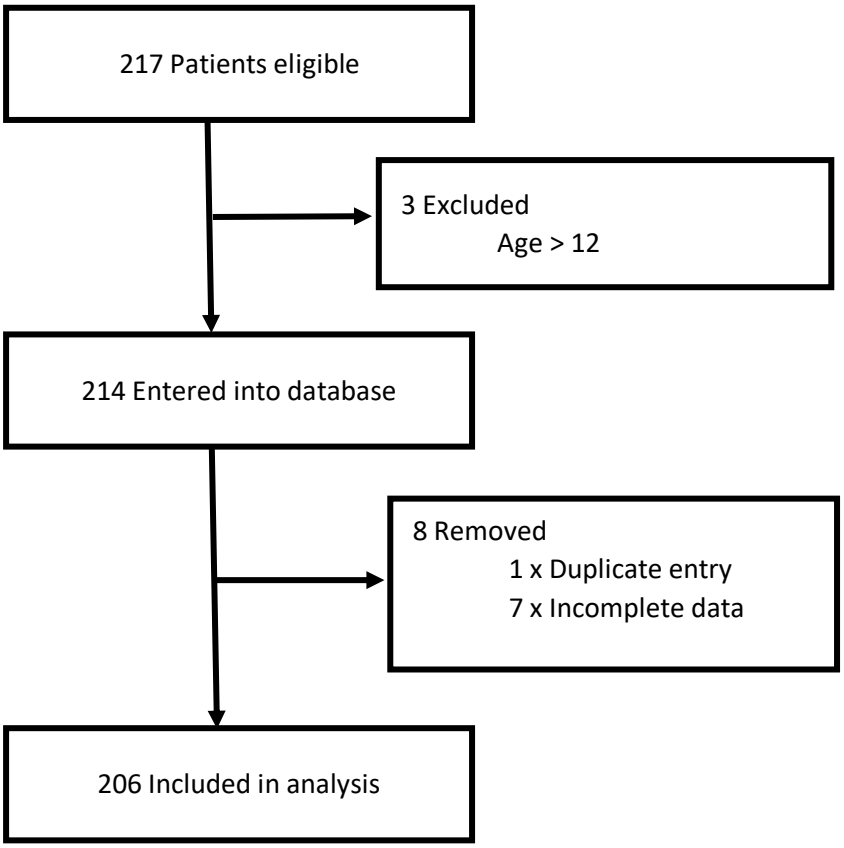
Cumulative incidence of critical events was calculated as the number of patients with at least one critical event during surgery divided by the total number of patients in the cohort. A bootstrap confidence interval (99 999 resamples) was calculated for the cumulative incidence. For univariate comparisons, Wilcoxon rank sum tests were used to compare between the critical event(s) and no critical event groups for continuous variables, while Fisher's Exact or Chi-squared tests (test chosen based on expected frequencies) were used to compare between the critical event(s) and no critical event groups for categorical variables.

Multivariable logistic regression was used to model risk factors for having a critical event; independent variables included: age (years), weight (kg), ASA status, and surgical discipline. Multivariable logistic regression was also used to assess associations between the immediate postoperative outcome and surgical discipline, age, weight, and ASA status. Descriptive statistics were used to document the management responses to critical events. P-values < 0.05 were considered statistically significant.

Results

A total of 217 patients were recruited, three patients were excluded due to the age restriction and eight removed due to incomplete questionnaires or duplicate records. A total of 206 cases were analysed (Figure 1).

Figure 1: Flow chart of sample realisation



The patient, anaesthetic and surgical characteristics of participants are summarised in Table 1 below. A total of 206 surgeries were assessed. The median (IQR) age for the study was four years (2.2-5.8). All but one patient received a general anaesthetic. Regional techniques were used in combination with general anaesthesia in 13 (6.3%) patients.

Caudal blocks were done in seven patients, supraclavicular block in three, followed by one fascia iliaca block, penile block and wrist block each.

The airway management included 125 (61%) endotracheal tube (ETT) intubations, 49 (24%) with supraglottic device insertions and 32 (16%) of the patients received a general anaesthetic with a facemask technique. A muscle relaxant was used for one patient for intubation and 122 (70%) patients were extubated awake. From the theatre complex 25 (12%) patients went directly home and 181 (88%) went to the ward to be discharged from the hospital at a later stage. Discharge dates and post operative complications in the ward were not studied.

Table 1. Participant demographic characteristics

Characteristic	Overall n (%)	No critical event n (%)	Critical event n (%)	p-value
Patient factors				
Weight				0.11
< 10 kg	34 (17%)	24 (18%)	10 (14%)	
10-20 kg	115 (56%)	69 (51%)	46 (66%)	
≥ 20 kg	57 (28%)	43 (32%)	14 (20%)	
ASA classification				0.6
I	156 (76%)	104 (76%)	52 (74%)	
II	37 (18%)	25 (18%)	12 (17%)	
III	13 (6.3%)	7 (5.1%)	6 (8.6%)	
IV and V	0 (0%)	0 (0%)	0 (0%)	
Anaesthetic and Surgical factors				
Anaesthetist level of experience				0.3
Consultant	182 (88%)	119 (88%)	63 (90%)	
Senior registrar (years 3 and 4)	13 (6.3%)	11 (8.1%)	2 (2.9%)	
Junior registrar (years 1 and 2)	10 (4.9%)	5 (3.7%)	5 (7.1%)	
Medical officer	1 (0.5%)	1 (0.7%)	0 (0%)	
Urgency of surgery				0.013
Elective	177 (86%)	111 (82%)	66 (94%)	
Emergency	29 (14%)	25 (18%)	4 (5.7%)	
Time of surgery				0.7
In hours (07:00-16:00)	200 (97%)	131 (96%)	69 (99%)	
After hours (16:00-07:00)	6 (2.9%)	5 (3.6%)	1 (1.4%)	
Surgical discipline				0.3
Dental	40 (19%)	24 (18%)	16 (23%)	
Ear-Nose-Throat (ENT)	63 (31%)	41 (30%)	22 (31%)	
Gastroenterology	21 (10%)	11 (8.1%)	10 (14%)	
Gynaecology	1 (0.5%)	1 (0.7%)	0 (0%)	
Orthopaedic	43 (21%)	33 (24%)	10 (14%)	
Plastic surgery	25 (12%)	19 (14%)	6 (8.6%)	
Urology	13 (6.3%)	7 (5.1%)	6 (8.6%)	

Critical events

Of the 206 surgeries, 70 (34%) were associated with the occurrence of at least one critical event. Details pertaining to critical events are presented in Table 2.

Table 2: Cumulative incidence of critical events

Characteristic	**n (%) (N=70)**	**Cumulative incidence* % (95% CI) (N=206)**
Number of critical events		
1	61 (30%)	30% (23-36%)
2	7 (3.4%)	3% (1-6%)
3	2 (1%)	1% (0.5-1.9%)
Hypoglycaemia (HGT < 3.6 mmol.l^{-1})	43 (61%)	21% (16-27%)
Respiratory	27 (39%)	13% (8.7-18%)
Laryngospasm	15 (21%)	7.3% (4.3-12%)
≥ 2 attempts at intubation	5 (7.1%)	2.4% (0.90-5.9%)
Bronchospasm	4 (5.7%)	1.9% (0.62-5.2%)
Difficult BMV	2 (2.9%)	1% (0.17-3.8%)
Stridor	1 (1.4%)	0.5% (0.03-3.1%)
Aspiration	0 (0%)	0% (0.0-2.3%)
Hypoxia	0 (0%)	0% (0.0-2.3%)
Cardiovascular	4 (5.7%)	1.9% (0.62-5.2%)
Bradycardia	3 (4.3%)	1.5% (0.38-4.5%)
Hypotension	1 (1.4%)	0.5% (0.03-3.1%)
Arrythmia	0 (0%)	0% (0.0-2.3%)
Cardiac arrest	0 (0%)	0% (0.0-2.3%)
Drug error	0 (0%)	0% (0.0-2.3%)
Temperature abnormality	1 (1.4%)	0.5% (0.03-3.1%)
Neurological event	0 (0%)	0% (0.0-2.3%)
Emergence delirium	5 (2.4%)	2.4% (0.9-5.9%)
Other (Unable to obtain IV access)	1 (1.4%)	0.5% (0.03-3.1%)

N=206

*Number of patients with events / number of patients

Abbreviations: BMV = bag mask ventilation. CI = confidence interval. HGT = haemoglucose test. Kg = kilogram. IV = intravenous.

Management of critical events

The treatment strategies of critical events are summarised in Table 3 below. The categories to present hypoglycaemia were chosen to represent the various ways in which hypoglycaemia was treated at RMMCH, to emphasise the diversity in practice.

Table 3. Management of critical events

Critical event management strategy	**n (%)**
Hypoglycaemia	n=43
2% dextrose	19 (44%)
1% dextrose solution	9 (21%)
2% dextrose + 1ml/kg 10% dextrose bolus	7 (16%)
10% dextrose bolus only	3 (7.0%)
1% dextrose + 2ml/kg 10% dextrose bolus	1 (2.3%)
1% dextrose + 1ml/kg 10% dextrose bolus	1 (2.3%)
3% dextrose + 2ml/kg 10% dextrose bolus	1 (2.3%)
4% dextrose	1 (2.3%)
Nil	1 (2.3%)
Emergence Delirium*	n=5
Parental presence	2 (40%)
Fentanyl and propofol	2 (40%)
Propofol only	1 (20%)
Reassurance	1 (20%)
Cardiovascular Critical Events	n=4
Bradycardia treated with atropine	3 (75%)
Hypotension treated with vasopressors	1 (25%)
Hyperthermia (> 38℃)	n=1
Bair hugger switched off	1 (100%)
Hypothermia (<36℃)	n=0
Treatment	0 (0%)

*Count adds to greater than 5 because one patient received two interventions.

The management of the respiratory events is summarised in Table 4 below.

Table 4: Treatment of respiratory events

	Difficult BVM n=2	**Difficult intubation n=5**	**Laryngospasm n=15**	**Bronchospasm n=4**	**Stridor n=1**
Treatment n (%)					
Positive pressure	..	2 (40%)	11 (73%)	1 (25%)	..
Oropharyngeal airway (OPA)	1 (50%)	3 (60%)	8 (53%)	..	1 (100%)
Anaesthesia deepening	1 (50%)	5 (100%)	8 (53%)	4 (100%)	..
Propofol	1 (50%)	5 (100%)	12 (80%)	2 (50%)	..
Ketamine	..	..	2 (13%)	2 (50%)	..
Magnesium sulphate	..	..	1 (6.7%)	1 (25%)	..
Intubation	1 (50%)	2 (40%)	5 (33%)	..	..
Bronchodilators	..	..	1 (6.7%)	1 (25%)	..
Adrenaline nebulisation	..	..	..	..	1 (100%)
Suctioning	1 (50%)	1 (20%)	4 (27%)	1 (25%)	..
Steroids	1 (50%)	2 (40%)	4 (27%)	2 (50%)	..
Change laryngoscope blade/handle	..	1 (20%)	1 (6.7%)	..	..
Change ETT	..	2 (40%)	..	..	..
Bag mask ventilation	..	2 (40%)	..	..	..
Consultant to take over airway	..	1 (20%)	..	..	..
Escalate level of expertise	..	1 (20%)	..	..	..

Abbreviations: BVM = bag-valve-mask. ETT = endotracheal tube

The patient, surgical and anaesthetic factors associated with critical events.

Patient factors

When analysing all the critical events, lower weight was found to be significantly associated with critical events ($p<0.05$). However, when a multivariable logistic regression (including ASA class, surgical discipline, weight, and age) was performed, this relationship between critical events and weight was no longer statistically significant (OR = 0.96; 95% CI= 0.88-1.02; p = 0.2.

Surgical factors

There were no statistically significant differences between the critical event group and the no critical event group for the timing of surgery ($p=0.7$) or the distribution of surgeries across the various disciplines ($p=0.3$).

Anaesthetic factors

No anaesthetic factors were found to be significantly associated with critical events. Factors assessed included: Anaesthetist training level ($p=0.3$), ASA class ($p=0.6$), anaesthetic methods ($p=0.9$), method of airway management ($p=0.14$), and muscle relaxant use ($p=0.9$). There was also no association between deep or awake extubation and the occurrence of a critical event ($p=0.4$).

These results relating to factors associated with critical and respiratory events are presented in Table 5 below. Although no anaesthetic factors were found to be significantly associated with critical event occurrence, a multivariable logistic regression performed to assess respiratory events alone showed a significant association between age and the incidence of a critical respiratory event ($p<0.05$), such that increasing age was associated with a lower odds of having an event compared to lower ages. In addition, there was a significant association between the airway management method and the occurrence of respiratory critical events, such that there was a lower odds of having an event when using a facemask ($p<0.05$) or supraglottic device ($p<0.05$) compared to when using an endotracheal tube. However, the confidence intervals for the odds ratio were very wide, indicating a lack of precision in the estimate (probably owing to the low frequency of use of the two methods), making it difficult to interpret the importance of this finding.

Table 5. Logistic regression summary of all the critical events and respiratory events

Characteristic	OR	95% CI	p-value
Logistic regression summary of all the critical events			
Anaesthetist category			
Consultant	—	—	
Medical Officer	0.00		>0.9
Junior registrar (years 1 and 2)	2.11	0.52, 8.76	0.3
Senior registrar (years 3 and 4)	0.66	0.1, 2.90	0.6
ASA class			
I	—	—	
II	0.91	0.37, 2.14	0.8
III	1.02	0.20, 4.75	>0.9
Age (years)	0.95	0.76, 1.19	0.7
Weight (kg)	0.96	0.88, 1.02	0.2
Surgical discipline			
ENT	—	—	
Dental	1.09	0.47, 2.50	0.8
Gastroenterology	1.30	0.33, 5.17	0.7
Orthopaedic	0.43	0.16, 1.07	0.078
Plastic surgery	0.40	0.12, 1.18	0.11
Urology	1.54	0.43, 5.48	0.5
Log likelihood= -124.362 (df =10) n=205			
Logistic regression summary for the respiratory events			
Age (years)	0.63	0.40, 1.00	0.049
Weight (kg)	0.99	0.83, 1.11	0.9
ASA class			
I	—	—	
II	0.23	0.01, 1.29	0.2
III	2.52	0.57, 10.6	0.2
Airway management method			
Endotracheal tube	—	—	
Facemask	0.07	0.00, 0.42	0.016
Supraglottic	0.18	0.03, 0.77	0.041
Log likelihood= -54.468 (df =7) n=206			

Abbreviations: ASA = American Society of Anaesthesiologists. CI = Confidence Interval. df = Degrees-of-freedom. OR = Odds Ratio. Kg = Kilogram.

The immediate postoperative outcomes

All patients were either discharged home directly from theatre or to the ward. None of the patients were admitted to high care facilities, or an intensive care unit. No mortalities were reported during the study period. There was no statistically significant difference between the critical event and no critical event groups for being discharged home versus discharged to the ward (p=0.8).

Discussion

The results of this paediatric anaesthesia study showed a higher cumulative incidence of critical events (34%) in comparison to a similar large multicentre cohort study conducted in Europe in 2014.[1] However, this large difference may be attributed to the fact that the European study did not include hypoglycaemia (a commonly occurring critical event in this study) in their definition of major critical events.

The incidence of critical events in this study was also found to be more than double that reported in a large South African multi-centre study published by Cronje et al in 2021, where the overall incidence of critical events was reported to be 15.9%.[8] This difference is mostly attributed to the high incidence of hypoglycaemia in this study (21% compared to 1%). This study reported a similar incidence of respiratory (11% compared to 9%) and cardiovascular events (2% compared to 3%).

The questionnaire in this study specifically evaluated the haemoglucose test (HGT) in every case and required details concerning the treatment implemented. At RMMCH it is routine for glucose levels to be tested for every paediatric patient undergoing a procedure in theatre. In the study by Cronje et al, the operating room case record form did not specify HGT levels, but rather recorded only if the patient had hypoglycaemia, and therefore it is not known if the HGT levels were routinely performed for all cases included in the study.[8] It is a possibility that some of the hypoglycaemic events could have been missed in the study by Cronje et al if the HGT levels, especially those of children undergoing short procedures, were not routinely performed.

The reason for the high incidence of hypoglycaemia at RMMCH is most likely multifactorial. RMMCH has a large patient burden.[10] RMMCH is also an academic hospital where the procedural times are often longer or unpredictable due to teaching. The order of theatre lists is constantly changing.

This may be attributed to problems with equipment failure or shortages, patients not arriving, and invalid consent according to the departmental statistics.[11,12]

South Africa has an unemployment rate of 32.9%, and the inability of patients to afford own transport or using unreliable transport often contribute to them not presenting to theatre when booked for a procedure.[13]

When patients arrive at the hospital there are also often administrative delays, and long waiting times to obtain files. It is also common for children not to present with their legal guardian, or to not have the same surname as both of their parents. Mothers with different surnames to their child are required to provide a police affidavit stating that they are the parent in order to give consent for a procedure. According to clinicians working in theatre, the lists are often amended or delayed giving parents an opportunity to go to the police station to get this affidavit. High patient to nursing staff ratios may result in difficulties implementing guidelines.[10,11] Poor communication and a lack of education of nursing staff and surgeons may result in incorrect preoperative fasting orders.

Understanding the reasons for poor guideline uptake is complex. Saluja et al published a review article to establish the challenges that influence guideline uptake in low- and middle-income countries.[14] The findings were summarised in four broad categories. This included inadequate infrastructure, limited funding, the lack of experience and training of healthcare workers and the lack of national regulations or legislation. The implementation of fasting guidelines can be done without additional infrastructure or funding. A large tertiary paediatric teaching hospital in the United Kingdom reduced patient fasting times by means of quality improvement programs and education only.[15]

The results of the study show that RMMCH is still following an approach of fasting children from 22h00 on the night prior to surgery which is outdated and not in alignment with the latest guidelines. The latest guidelines for preoperative fasting in children published in 2022 by the European Society of Anaesthesiology and Intensive Care recommend the intake of clear fluid in healthy individuals up to one hour prior to elective procedures. Breastmilk is recommended up to three hours, and formula milk and a light meal allowed up to four hours prior to anaesthesia.[16]

The management of critical events varied and was not standardised. This can be explained by the fact that more than one critical event occurred in the same patient.

Corticosteroids are often prescribed for its analgesic properties as well as the prevention of postoperative nausea and vomiting. Magnesium can also be used as an adjunct to analgesia, and a differential diagnosis of bronchospasm was possibly considered.

Non-standardised management strategies are common in settings that don't have management protocols in place.[17] Individual practise results in critical events being managed in a non-standardised manner.

Poor or non-adherence to protocols may adversely affect patient outcomes as seen at other hospitals.[18,19] Continuous medical education (CME) is a way to improve clinicians' performance by changing their behaviour in the clinical setting.[20] It is also a way of keeping up to date with the latest evidence-based knowledge, anaesthetic skills, emerging technology, and safety practices to decrease the risk of adverse events and to deliver quality anaesthetic care to our patients, and minimise critical events.

Systematic reviews done on continuous medical education concluded that it improves clinician performance and patient outcomes.[21]

The results of this study show that management of critical events is not standardised at RMMCH and therefore the development and implementation of departmental specific guidelines, CME initiatives, and the evaluation of such interventions is recommended.

Limitation

This study was contextual and therefore the results of this study cannot be extrapolated to other healthcare settings regionally or globally. The definitions for this study were adopted from the South African multicentre study done by Cronje et al.[7]

There may also have been an overestimation of critical events due to the subjectivity of the interpretation of the critical event definitions. The measurement of emergence delirium was a subjective assessment done by the anaesthetist.

The correctness of the data on the collection sheet, that was filled by the anaesthetic provider, was not compared to the original anaesthetic charts.Literature of critical events are important to establish the quality of care that is provided. This could be missed if morbidity and mortality alone are assessed.

Conclusion

The incidence of critical events at RMMCH is substantially higher than that reported internationally and in other South African studies. Non-standardised treatment of critical events may result in increased morbidity and mortality and have financial implications for an institution. In order to reduce the incidence of critical events in our setting, ongoing education and protocol development with implementation thereof is needed.

Continuous medical education (CME) for the detection and management of critical events and especially hypoglycaemia is vital. These results can be used as a baseline for future studies that could possibly examine interventions to improve patient care and the quality of anaesthetic practices. The management choice of critical events is an area for future research.

The institution of local as well as international accepted definitions for critical events by anaesthetic as well as surgical societies to standardise research on critical events is recommended. This will facilitate accurate comparisons with future clinical audits and the measurement of the effect of implemented interventions.

Declaration

The authors declare that they have no conflict of interest. This research was done in partial fulfilment of a Master of Medicine degree. No funding was received for completion of this study.

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Appendix 1:

The following definitions were used in the study:

Critical event: An event that require immediate intervention to prevent major disability or death.[1]

Neonate: Birth to 28 days inclusive (first four weeks after birth).[2]

Infant: A young child from birth to 12 months of age.[2]

Paediatric Patient: Patient younger than 12 years of age.[3]

Elective procedure/surgery: Not immediately lifesaving; planned within months or weeks.[4]

Emergency procedure/surgery: Performed without delay; the patient has no choice other than to undergo immediate surgery if permanent disability or death is to be avoided.[5]

After hours: 16h00-07h30.

American Society of Anaesthesiologists (ASA) physical status score:[6]

I: A normal healthy patient.

II: A patient with mild systemic disease without substantive functional limitations.

III: A patient with severe systemic disease with substantive functional limitations.

IV: A patient with severe systemic disease that is a constant threat to life.

V: A moribund patient who is not expected to survive without the operation.

Anaesthetist: Any qualified doctor performing anaesthesia who works in the Wits Department of Anaesthesiology including medical officers, registrars, and consultants**.**

Medical officer: A qualified doctor practising in the Wits Department of Anaesthesiology under specialist supervision.

Career medical officer: A medical officer with more than 10 years of experience who is regarded as a consultant.

Registrar: A qualified doctor who is registered with the Health Professions Council of South Africa (HPCSA) as a trainee anaesthetist**.**

Junior Registrar: A registrar in their first or second year.

Senior Registrar: A registrar in their third, fourth, or subsequent years.

Consultant: A qualified doctor who is registered with the HPCSA as a specialist anaesthetist capable of independent practice, or a career medical officer.

Difficult BMV: The inability of an unassisted anaesthesiologist to maintain oxygen saturation of > 92% or to prevent or reverse signs of inadequate ventilation during positive-pressure mask ventilation under general anaesthesia.[7]

Hypoglycaemia: Levels below the following blood glucose levels.[8]
First 24 hours of life <1.65 mmol/l
Neonates (>24hours old) <2.5mmol/l
Infants and children <3.6mmol/l

Multiple intubation attempts: Two or more attempts with a laryngoscope.

Laryngospasm: The sustained closure of the vocal cords resulting in the partial or complete loss of the patient's airway.[9]

Bronchospasm: an abnormal contraction of the bronchi resulting in restriction of the airway with one or more of the following: expiratory wheeze, prolonged expiration, increased inflation pressures, desaturation, hypercapnia, upsloping capnograph trace, silent chest. It can occur alone, or as part of another problem.[8]

Aspiration: Regurgitation or vomiting of gastric contents which has passed through the larynx into the trachea or tracheobronchial tree.[8]
Post-operative stridor: A symptomatic (varying severity) form of laryngotracheal narrowing in an extubated patient. It is clinically diagnosed by an inspiratory crowing sound.

Severe hypoxia: Hypoxia with a peripheral saturation of < 80% on pulse oximetry, or clinical impression of hypoxia in the absence of a pulse oximeter.[8]

Arrhythmias: Electrocardiograph (ECG) evidence of cardiac rhythm disturbance.[8]

Bradycardia: Defines as a heart rate below lowest normal value for age.[8]

AGE	Normal HR bpm
Newborn – 3 months	80 - 205
3 months – 2 years	75-190
2 - 10 years	60-140
>10 years	50-100

Hypotension: Blood pressure reading below the lowest value for the patient's age.

Cardiac arrest: The cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest.[8]

Drug error: A mistake made surrounding administering of a drug.

Neurological event: Any event with neurological involvement or symptoms.

Emergence agitation: Restlessness, disorientation, excitation, non-purposeful movement, inconsolability, thrashing, and incoherence during early recovery from general anaesthesia.[10]

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Section 4: Proposal

Perioperative critical events in paediatric patients at a Johannesburg Academic Hospital

Dr Anne-Mart Viljoen

Student Number: 530158

Annemartviljoen.av@gmail.com

Supervisor: **Dr Janine Wagner**

Department of Anaesthesiology, University of the Witwatersrand

Co-Supervisor: **Dr Shafeeqa Mayet**

Department of Anaesthesiology, University of the Witwatersrand

2. Introduction

The National Guideline for Patient Safety Incident Reporting and Learning defines a "patient safety incident" as an unplanned or unintended event or circumstance that could have resulted, or did result, in harm to a patient while in the care of a health facility (1). This event is thus not due to the underlying health condition, or natural progression of disease. An incident can be a near miss (which did not reach the patient), no harm incident, or harmful incident (adverse event). Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death (2). Care should be taken to avoid critical events in the vulnerable paediatric population to avoid morbidity and mortality.

Critical events in anaesthesia include a variety of conditions that involve a range of physiological systems in the body. Respiratory events include difficult bag mask ventilation, difficult or failed intubation, broncho- and laryngospasm, hypoxia, aspiration, and post anaesthetic stridor. Cardiovascular events include arrhythmias, bradycardia, hypotension, hypertension, myocardial ischemia, and cardiac arrest. Seizures and loss of neurological function may occur, and hypoglycaemia and temperature derangements are not uncommon in paediatrics. Different drug doses are used for paediatrics, which predisposes these patients to drug errors which include administering the wrong dose, wrong drugs, and administration at the wrong site. Fluid extravasations, anaphylaxis, and emergence agitation can also occur (2,3).

According to paediatric anaesthesia research done by Habre et al (2) risk factors for severe critical events include patient, anaesthetic, and surgical risk factors. Risk factors include a higher ASA score, the younger patients less than 6 years of age with the highest being in the neonatal population, and sensitised airways (airways with acute or chronic inflammation). Physical conditions such as prematurity, current fever, being handicapped, history of snoring, and medication use were also identified as risk factors. Anaesthetic related risk factors include less experienced anaesthetists, using inhalational induction, airway manipulation such as endotracheal intubation, as well as the use of supraglottic airways (2,4). Some studies have found that intubation without muscle relaxants are a risk factor (5). Surgical procedures have been found to have a higher incidence of critical events than non-surgical procedures, and emergency cases have also been identified as an independent risk factor (2).

A study conducted in Australia, showed that risk factors for respiratory complications include a respiratory history of a night-time cough, exercise induced wheezing, and history of wheezing more than three times in the past year. An upper respiratory tract infection less than two weeks prior to the procedure, family history of atopy, asthma and eczema, and smoking were also identified as factors that increase respiratory adverse events (4).

Critical events in anaesthesia are not uncommon and could result in catastrophic sequelae if the anaesthetic team doesn't respond timeously in an adequate manner. In the United Kingdom it has been reported that the overall incidence of critical events is approximately 5% with the majority being made up by respiratory (59.6%) and cardiovascular (36.5%) events (2). A study conducted by Kurth et al (6) in the United states has shown that 0.1% of anaesthetics result in life threatening injuries with disabilities, incapacity, or even death. A study conducted by Murat et al (7) in showed that the majority of critical events (53%) were respiratory in nature.

A study conducted in Nigeria has found that the incidence of critical events was 6.1%. In contrast to studies conducted in high income countries, the highest incidence of critical events was recorded in elective procedures supervised by specialists and were cardiovascular events. The critical incidents reported in the study were as follows: cardiovascular (41.1%), respiratory (23.25%), vascular access (15.1%), airway/intubation (6.85%), equipment errors (6.85%), difficult/failed regional technique (4.11%), and others (2.74%) (8).

The results of these studies may differ as the definitions of perioperative critical and adverse events are not standardised. The international data can also not be extrapolated to the South African setting due to the diversity in the South African population, and health care system, as well as the challenges that South African hospitals face with regards to infrastructure, funding, staffing, equipment, and other resources.

There is a paucity of South African data concerning critical events in South Africa. A study conducted Cronje et al (3) in 2017 examined severe anaesthetic-related critical incidents (SARCI) and perioperative cardiac arrests. This study found that the incidence of SARCI was 15.9%, and that critical incidents were three times higher than in high income countries and perioperative cardiac arrests were 10 times more common.

However, despite the inclusion of 43 hospitals, the study was only conducted over a two-week period, and the authors did not state how many patients were included per specific hospital, nor was there reference made with respect to specific surgical disciplines.

In contrast to Cronje's study, this will be done only at one hospital this will ensure that the data will be more representable of RMMCH itself. It will be done over a longer period. This study will also specify the different surgical disciplines and the critical events per discipline. The observation and outcomes will only be from the theatre complex and would not be following the patients up for post-op complications such as post operative cardiac events.

There are no specific data available regarding perioperative critical events in the paediatric population at Rahima Moosa Mother and Child Hospital (RMMCH). This data will assist with identifying risk factors for patients' poor outcome, will provide insight into current service provision, establish a baseline from which interventions can be assessed, assist with protocol and guideline development, and improve strategies for in-service training.

3. Problem statement

Critical events in anaesthesia have been defined as events that require immediate intervention to prevent major disability or death The incidence of perioperative severe critical events for all paediatric anaesthetic sub-specialities at RMMCH has not yet been established. It is necessary to establish status quo with regards to critical events in a paediatric setting to provide insight into current service provision at RMMCH, and to measure the effect of any intervention that may be instituted in the future.

3. Aim

The aim of this study is to describe the perioperative critical events in paediatric patients undergoing anaesthesia at RMMCH.

4. Objectives

Primary Objectives:

- To determine the incidence of perioperative critical events in paediatric patients undergoing paediatric gastroenterology, dental, urological, plastic surgical, orthopaedic, and general surgical procedures at RMMCH.

Secondary objectives:

- To determine the patient, surgical, and anaesthetic factors that are associated with severe critical events under anaesthesia.
- To describe the management of critical events that occurred under anaesthesia.
- To describe the immediate postoperative outcomes of patients where critical events occurred (in-hospital mortality, and admission to HCU and ICU).

5. Research assumptions

The following definitions will be used in the study**:**

Critical event: An event that require immediate intervention to prevent major disability or death (2).

Neonate: Birth to 28 days inclusive (first four weeks after birth) (9).

Infant: A young child from birth to 12 months of age (9).

Paediatric Patient: Patient younger than 12 years of age (10).

Elective procedure/surgery: Not immediately lifesaving; planned within months or weeks (11).

Emergency procedure/surgery: Performed without delay; the patient has no choice other than to undergo immediate surgery if permanent disability or death is to be avoided (12).

After hours: 16h00-07h30.

American Society of Anaesthesiologists (ASA) physical status score (13):

I: A normal healthy patient.

II: A patient with mild systemic disease without substantive functional limitations.

III: A patient with severe systemic disease with substantive functional limitations.

IV: A patient with severe systemic disease that is a constant threat to life.

V: A moribund patient who is not expected to survive without the operation.

Anaesthetist: Any qualified doctor performing anaesthesia who works in the Wits Department of Anaesthesiology including medical officers, registrars, and consultants**.**
Medical officer: A qualified doctor practising in the Wits Department of Anaesthesiology under specialist supervision.

Career medical officer: A medical officer with more than 10 years of experience who is regarded as a consultant.

Registrar: A qualified doctor who is registered with the Health Professions Council of South Africa (HPCSA) as a trainee anaesthetist**.**

Junior Registrar: A registrar in their first or second year.

Senior Registrar: A registrar in their third, fourth, or subsequent years.

Consultant: A qualified doctor who is registered with the HPCSA as a specialist anaesthetist capable of independent practice, or a career medical officer.

Difficult BMV: The inability of an unassisted anaesthesiologist to maintain oxygen saturation of > 92% or to prevent or reverse signs of inadequate ventilation during positive-pressure mask ventilation under general anaesthesia (14).

Hypoglycaemia: Levels below the following blood glucose levels (16).
First 24 hours of life <1.65 mmol/l
Neonates (>24hours old) <2.5mmol/l
Infants and children <3.6mmol/l

Multiple intubation attempts: Two or more attempts with a laryngoscope.

Laryngospasm: The sustained closure of the vocal cords resulting in the partial or complete loss of the patient's airway (15).

Bronchospasm: an abnormal contraction of the bronchi resulting in restriction of the airway with one or more of the following: expiratory wheeze, prolonged expiration, increased inflation pressures, desaturation, hypercapnia, upsloping capnograph trace, silent chest. It can occur alone, or as part of another problem (16).

Aspiration: Regurgitation or vomiting of gastric contents which has passed through the larynx into the trachea or tracheobronchial tree (16).

Post-operative stridor: A symptomatic (varying severity) form of laryngotracheal narrowing in an extubated patient. It is clinically diagnosed by an inspiratory crowing sound.

Severe hypoxia: Hypoxia with a peripheral saturation of < 80% on pulse oximetry, or clinical impression of hypoxia in the absence of a pulse oximeter (16).

Arrhythmias: Electrocardiograph (ECG) evidence of cardiac rhythm disturbance (16).
Bradycardia: Defines as a heart rate below lowest normal value for age (16).

AGE	Normal HR bpm
Newborn – 3 months	80 - 205
3 months – 2 years	75-190
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Hypotension: Blood pressure reading below the lowest value for the patient's age.

Cardiac arrest: The cessation of cardiac mechanical activity, as confirmed by the absence of signs of circulation. ECG changes may corroborate the incidence of cardiac arrest (16).

Drug error: A mistake made surrounding administering of a drug.

Neurological event: Any event with neurological involvement or symptoms.

Emergence agitation: Restlessness, disorientation, excitation, non-purposeful movement, inconsolability, thrashing, and incoherence during early recovery from general anaesthesia (17).

6. Demarcation of study field

The study will be conducted in the Department of Anaesthesiology at RMMCH, which is affiliated with the University of the Witwatersrand.

The anaesthetic department is comprised of 21 staff members, five full time anaesthetic consultants, one consultant employed in a part-time post, seven registrars, five medical officers plus two medical officers, and three community service doctors (Kleyenstuber T, email communication, March 2022). The theatre complex has five theatres of which one is allocated to paediatric cases.

7. Ethical considerations

Approval to conduct the study will be obtained from the Human Research Ethics Committee (HREC) (Medical) and the Graduate Studies Committee of the University of the Witwatersrand. Permission to conduct the study at RMMCH will be obtained from the CEO of RMMCH (Appendix A) as well as the Medical Advisory Committee prior to commencement of the study (Appendix B). Permission will also be obtained from Professor Motshabi, the Head of Department (HOD) of Anaesthesiology at the university of Witwatersrand (Appendix C) and from Dr Kleyenstuber, HOD of Anaesthesiology at RMMCH (Appendix D).

An information letter (Appendix E) will be distributed to the parent/guardian and the child, and consent would be obtained from the parent or guardian and assent will be obtained if the child is between 7 and 12 years old (Appendix F).
The study will not, and is not intended to, assess anyone, and will not be used as part of any disciplinary undertaking against anyone involved. A questionnaire regarding the patients' demographics, surgical procedure, and anaesthesia will be utilised in this study. The anaesthetic team involved in the case will be requested to complete a questionnaire on a voluntarily basis and will be given an information sheet (Appendix G). Questionnaires will be completed anonymously, and no identifying information will be collected on the questionnaire. Confidentiality will be ensured as only the researcher and supervisor will have access to the raw data.

The data collected will be stored on a password protected computer for six years once the study is completed as per the HREC regulations. The study will be conducted according to the principles of the Declaration of Helsinki and the South African Good Clinical Practice guidelines (18,19).

8. Research Methodology

The study will be conducted as a prospective observational study. The data collection dates will be determined by the date of ethics approval. Anaesthetists conducting anaesthesia at RMMCH over a 6-month period (dates to be confirmed after ethics approval has been obtained) will be asked to complete a study questionnaire to ascertain whether a critical event occurred and to describe the event.

The researcher will also apply to do a rotation at HJH/RMMCH complex, to be able to be on site for the beginning months of the study. This will ensure compliance and in this way the researcher would be able to answer and assist with any questions or problems encounter. After this, subsequently the consultants mainly doing paediatric anaesthesia at RMMCH will assist with the process.

The study will include patients that have undergone anaesthesia for paediatric gastroenterology, dental, urological, plastic surgical, orthopaedic, and general surgical procedures.

8.1 Research design

This will be a prospective observational cross-sectional study.

8.2 Study population

The study will be conducted in the RMMCH anaesthetic department. The study will include all children (age 0-12 years old) who receive an elective or emergency anaesthetic for a procedure in theatre (10). The study will include patients undergoing anaesthesia for paediatric gastroenterology, dental, urological, plastic surgical, orthopaedic, and general surgical procedures.

The anaesthetic team allocated to the paediatric theatre will be requested to complete a questionnaire with regards to the patient demographics, type of surgery, the anaesthetic done, the occurrence of critical events, as well as the management thereof.

8.3 Study sample

Sample size

Sample size was calculated using the formulas reported in Sharma et al (20). Using the cumulative incidence data from Cronje et al (3) assuming an incidence of 15.9%, and allowing for a 5% margin of error, the estimated sample size is 205. According to records, 900-1000 paediatric theatre cases as performed per annum at RMMCH. It is therefore estimated that it will be necessary to collect the data for a 6-month period or until sample realisation is met.

Sampling method

The researcher will use non-probability consecutive convenience sampling over a period of 6-months or until the researcher comes to a sample size realisation (21).

Inclusion criteria

The study will include:

- All children (age 0-12 years old) who receive an elective or emergency anaesthetic.
- Children undergoing gastroenterological, dental, urological, plastic surgical, orthopaedic, and general surgical procedures.
- All paediatric patients receiving regional and general anaesthesia.
- ASA I-IV patients.

Exclusion criteria

- Patients already intubated on arrival in theatre.
- Procedures done remotely and not in theatre.

8.4 Data collection

A paper based or electronic questionnaire based on the study conducted by Habre et al will be used. The original questionnaire has been adapted specifically for the RMMCH setting and has been reviewed by 10 anaesthetists with a special interest in paediatric anaesthesia to ensure content and face validity.

The questionnaire focuses on the following aspects:

- Patient demographics (age, date of birth, weight, ASA classification).

- Procedural information (date, discipline, type of procedure).
- Critical incidents (difficult BMV, multiple intubations, laryngospasm, bronchospasm, aspiration, post-operative stridor, severe hypoxia, arrhythmias, bradycardia, hypotension, cardiac arrest, drug error, temperature abnormalities, neurological events, emergence agitation, and HGT abnormalities).
- Management of the critical event that occurred.
- Patient's outcome (discharged to the ward, to monitored care which includes High Care Unit or Intensive Care Unit, in hospital mortality).
- Anaesthetic experience of the anaesthetist in charge.

The study will be explained to the anaesthetic working the department at RMMCH during the 6-month period at a departmental meeting. Anaesthetists will be provided with an information letter (Appendix G). The anaesthetists will be requested to participate on a voluntarily basis. Every week the anaesthetic team involved will be reminded about the questionnaires that need to be filled in after all the cases and any queries can then be resolved. The link as well as the QR code of the electronic questionnaire (Appendix H) will be visible on a poster in the paediatric theatre and will also be sent to the anaesthetists allocated to the paediatric theatre. A sealed box will be placed in the recovery room should anaesthetists choose not to complete the form electronically.

8.5 Data analysis

Continuous data will be reported as medians and interquartile ranges (e.g., age, duration of anaesthesia). Categorical data will be reported as percentages (e.g., types of critical event, types of management, and patient immediate outcome).

Cumulative incidence (with bootstrapped 95% confidence intervals) will be calculated as the number of patients with at least one critical event during surgery divided by the total number of patients.

Only the results from the first surgery will be included if a patient has more than one surgery in the data collection period.

Univariable and multivariable analyses will be used to test for factors associated with the endpoint (at least one critical event during a surgical procedure).

Logistic regressions will be used to analyse the data (univariable and multivariable), thus allowing for the assessment of continuous and categorical independent variables on the dependent variable (did a critical event occur; yes or no). Independent variables included in the modelling will be surgical discipline (e.g., orthopaedic, gastroenterological), age (years), weight (kg), ASA status (treated as an ordinal variable) and type of anaesthesia (e.g., general anaesthesia, sedation).

In patients who had at least one critical event, associations between the timing of the event (e.g., induction, maintenance, recovery) and surgical discipline, age, ASA status, and type of anaesthesia will be assessed using multinomial logistic regression. In patients who had at least one critical event, associations between the immediate postoperative outcome (e.g., in-hospital mortality, admission to HCU or ICU) and surgical discipline, age, weight, ASA status, and type of anaesthesia will be assessed using multinomial logistic regression.

8.6 Significance of the study

The findings of the study will establish the status quo for critical events for the department and will provide insight into current service provision at RMMCH. The established benchmark could be used to determine if interventions are required, and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training, and the development and dissemination of management protocols/ guidelines, which may be implemented to improve patient outcomes.

9. Validity and reliability of the study

Validity and reliability of this study will be ensured by the following:

- Applying an appropriate study design.
- Having a representative sample population.
- Using a standardised questionnaire either paper based or electronically.
- Clear explanation to the anaesthetists how to fill the form.
- Analysing data in consultation with a biostatistician.

10. Potential limitations of the study

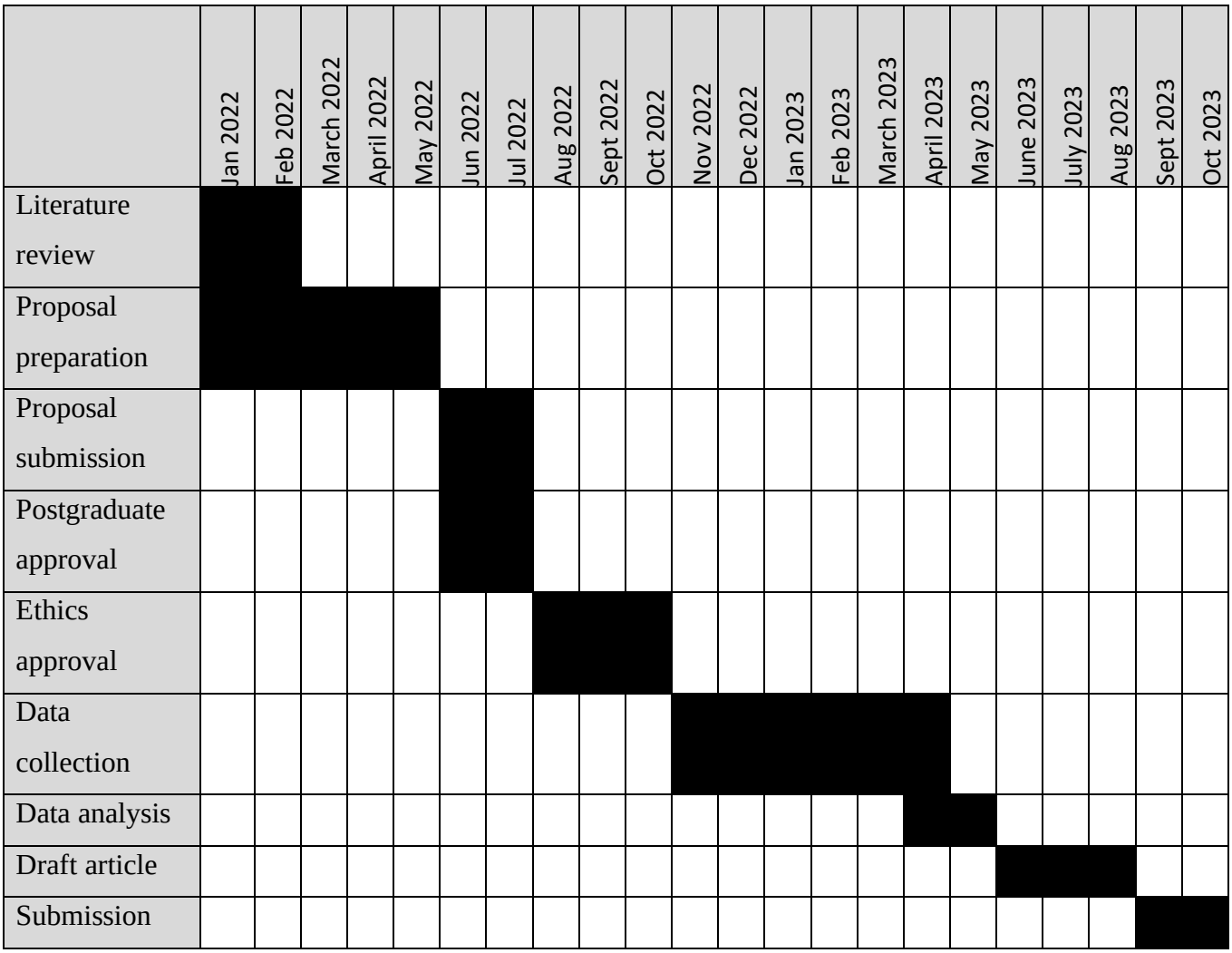
The study is contextual by nature. The results will only represent the paediatric anaesthesia practices at RMMCH, and therefore cannot be generalised to other departments or institutions.

The use of convenience sampling is also considered a limitation as this may result in the sampling bias (22).

The data collection, and quality of data collection, is dependent on the anaesthetic team allocated to the paediatric theatre for that day. This team changes daily, and data collection may be incomplete, or missing. To limit this effect, the researcher contacts the anaesthetic team allocated to the list the day before surgery to remind them about the study process. The researcher will also place a poster on the wall in the theatre with a link to the questionnaire.

11. Project outline

11.1 Time frame



11.2 Financial plan

Description	Price per item	Number of pages	Number of copies	Total
Printing proposal	R1	30	6	R180
Printing questionnaire	R1	6	400	R2400
Final	R1	100	2	R200
Total				R2780

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13. Appendices

Appendix A: Request to the CEO of RMMCH

Dear Dr Nozuko Mkabayi

My name is Anne-Mart Viljoen. I am one of the registrars in Department of Anaesthesiology. I am planning to do my MMed research, titled "Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital".

May I please have your permission to conduct a research study in the anaesthetic department at Rahima Moosa Mother and Child Hospital. I will distribute a questionnaire to the members of the anaesthetic team conducting paediatric anaesthesia. This questionnaire will help me to determine what the incidence of critical events during anaesthesia is.

Participation in the study is voluntary and anonymous. Consent will be implied by the completion and return of the questionnaire. Information will remain confidential and only my supervisors and myself will have access to the raw data.

The aim of this study is to describe the perioperative critical events in paediatric patients undergoing anaesthesia at RMMCH. The findings of the study will establish what the status quo is for critical events for the department and will provide insight into current service provision. The established benchmark could be used to determine if interventions are required and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training and the development and dissemination of management protocols or guidelines which may be implemented to improve patient outcomes.

Yours Sincerely

Anne-Mart Viljoen

0713542630

Annemartviljoen.av@gmail.com

Appendix B: Request to the Medical Advisory Committee

Dear Sir/Madam,

My name is Anne-Mart Viljoen. I am one of the registrars in Department of Anaesthesiology. I am planning to do my MMed research, titled "Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital".

May I please have your permission to conduct a research study in the anaesthetic department at Rahima Moosa Mother and Child Hospital. I will distribute a questionnaire to the members of the anaesthetic team conducting paediatric anaesthesia. This questionnaire will help me to determine what the incidence of critical events during anaesthesia is.

Participation in the study is voluntary and anonymous. Consent will be implied by the completion and return of the questionnaire. Information will remain confidential and only my supervisors and myself will have access to the raw data.

The aim of this study is to describe the perioperative critical events in paediatric patients undergoing anaesthesia at RMMCH. The findings of the study will establish what the status quo is for critical events for the department and will provide insight into current service provision. The established benchmark could be used to determine if interventions are required and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training and the development and dissemination of management protocols or guidelines which may be implemented to improve patient outcomes.

Yours Sincerely

Anne-Mart Viljoen

0713542630

Annemartviljoen.av@gmail.com

Appendix C: Permission from the Head of Department

Dear Prof Motshabi,

My name is Anne-Mart Viljoen. I am one of the registrars in Department of Anaesthesiology. I am planning to do my MMed research, titled "Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital".

May I please have your permission to conduct a research study in the anaesthetic department at Rahima Moosa Mother and Child hospital. I will distribute a questionnaire to the members of the anaesthetic team conducting paediatric anaesthesia. This questionnaire will help me to determine what the incidence of critical events during anaesthesia is.

Participation in the study is voluntary and anonymous. Consent will be implied by the completion and return of the questionnaire. Information will remain confidential and only my supervisors and myself will have access to the raw data.

The aim of this study is to describe the perioperative critical events in paediatric patients undergoing anaesthesia at RMMCH. The findings of the study will establish what the status quo is for critical events for the department and will provide insight into current service provision. The established benchmark could be used to determine if interventions are required and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training and the development and dissemination of management protocols or guidelines which may be implemented to improve patient outcomes.

Yours Sincerely

Anne-Mart Viljoen

0713542630

Annemartviljoen.av@gmail.com

Appendix D: Permission from the Head of Anaesthesiology RMMCH

Dear Dr Kleyenstuber,

My name is Anne-Mart Viljoen. I am one of the registrars in Department of Anaesthesiology. I am planning to do my MMed research, titled "Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital".

May I please have your permission to conduct a research study in the anaesthetic department at Rahima Moosa Mother and Child hospital. I will distribute a questionnaire to the members of the anaesthetic team conducting paediatric anaesthesia. This questionnaire will help me to determine what the incidence of critical events during anaesthesia is.

Participation in the study is voluntary and anonymous. Consent will be implied by the completion and return of the questionnaire. Information will remain confidential and only my supervisors and myself will have access to the raw data.

The aim of this study is to describe the perioperative critical events in paediatric patients undergoing anaesthesia at RMMCH. The findings of the study will establish what the status quo is for critical events for the department and will provide insight into current service provision. The established benchmark could be used to determine if interventions are required and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training and the development and dissemination of management protocols or guidelines which may be implemented to improve patient outcomes.

Yours Sincerely

Anne-Mart Viljoen

0713542630

Annemartviljoen.av@gmail.com

Appendix E: Information sheets

Information sheet for Parent

Dear Parent/Guardian

My name is Anne-Mart Viljoen, and I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I would like to invite you to participate in my MMED research project titled: Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital.

This study will be submitted towards my Master of Medicine degree with the University of the Witwatersrand. The results of the study will help in improving the anaesthetic care we give at RMMCH.

My research seeks to document the details of the anaesthetic that your child will undergo at Rahima Moosa Hospital. Occasionally problems arise during surgery, and I will seek to document this in my study aswell.

The anaesthetic team will fill in a form after the surgery to give us some important information around your child's physical condition (age, weight, other medical conditions) the surgery that took place as well as anaesthetic events. The questionnaire will be anonymous and at no stage will your child's name be filled in. Participation in the study is voluntary and anonymous. All information will remain confidential and only my supervisors and myself will have access to the raw data.

If your child is between 7 and 12 years old, your child will also have to agree to this. You are welcome to refuse participation in the study and it won't impact the planned treatment to your child in any manner. You are welcome to ask any questions, at any time, regarding this study. You can also withdraw your consent at any point of the
study.

My study has been approved by the Graduate Studies Committee and the Human Research Ethics Committee of the University of the Witwatersrand (Certificate number: M220813).
For any further information, you are welcome to contact me directly. For information regarding the way the study is being conducted, please contact the Chairperson of the Ethics Committee Professor Clement Penny on 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the committee secretaries are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za.

Signing the consent form means you agree for your child to partake in the study. You will be given a copy of this information sheet should you agree to participate.

Your time and consideration in this regard is much appreciated.
Kind regards

Anne-Mart Viljoen (Researcher), 011 470 9106

Patient information sheet for 7-12 year old

Patient information sheet for 7-12 year old

Paediatric Anaesthetic-Related Critical Events at a Johannesburg Academic Hospital

Dear Patient

My name is Anne-Mart, and I am studying to become a doctor to make people sleep for an operation. Will you help me with my studies?

I would like to look at all the forms we are filling in during your operation. I want to see what medication we have given you and how the operation and anaesthesia went.
I can only do this if you as well as your parent/guardian agree for me to look at your information.

You are welcome to ask any questions, at any time.

My study has been approved by the University of Witwatersrand and the ethics committee. For any further information, your mommy/daddy is welcome to contact me. All the contact details are on the form I've given to them.

Thank you for helping me. You are a star.

Anne-Mart Viljoen (Researcher), 011 470 9106

Appendix F: Consent and Assent form

Consent form Parent

Consent form Parent (children less than 7 years)

I (name & surname) _____

agree for my child (name & surname) _____
to participate in the study titled: Paediatric Anaesthetic-Related Critical Events at a Johannesburg Academic Hospital

- The study has been explained to me in a language that I understand.
- I understand that the care and management my child will receive is not in any way different for participation in this study.
- All my questions have been answered and I understand that I am free to ask any questions at any point during the study, which will be answered.
- I am agreeing for my child to participate and understand that I may withdraw from the study at any point.
- I understand that if I withdraw from the study, I will still receive the standard of care for my condition.

_____

Signature/Fingerprint of Parent/Guardian:

_____

Signature of Health Care Provider:
Date: / /20

PATIENT ASSENT FORM

Assent form (children 7–12 years old)

I (name & surname) _____

Agree to participate in the study titled: Paediatric Anaesthetic-Related Critical Events at a Johannesburg Academic Hospital

- The doctor explained to me that they will only look at my forms.
- I understand that they will take good care of me.
- I know that I can ask any questions.
- I can say no at any time.
- I will still receive standard care even if I don't want to be a part of the study any-more.

_____ _____

Signature/Fingerprint of Parent/Guardian: Signature/Fingerprint of Patient:

_____

Signature of Health Care Provider:
Date: / /20

Appendix G: Information Sheet for Colleagues

Dear Colleagues

My name is Anne-Mart Viljoen, and I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. I would like to invite you to participate in my MMED research project titled: Paediatric Anaesthetic-Related Critical Events at a Regional Academic Hospital.

My research seeks to determine the cumulative incidence of perioperative critical events in paediatric patients undergoing paediatric gastroenterology, dental, urological, plastic surgical, orthopaedic, and general surgical procedures at RMMCH. The findings of the study will establish what the status quo is for critical events for the department and will provide insight into current service provision. The established benchmark could be used to determine if interventions are required and to measure the effect of such interventions. The findings of the study may highlight the need for continuous departmental in-service training and the development and dissemination of management protocols or guidelines which may be implemented to improve patient outcomes.

The study has been approved by the Human Research Committee (Medical). Ethics approval number: M220813. For any further information, you are welcome to contact me directly. For information regarding the way the study is being conducted, please contact the Chairperson of the Ethics Committee Professor Clement Penny on 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the committee secretaries are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za.

Please fill in the questionnaire for every child undergoing anaesthesia (general/regional/sedation) for the different surgical disciplines. This will include elective as well as emergency cases. The questionnaire must also be filled in even though the anaesthesia was uneventful for a specific case. If there was no critical incident, one will just mark “none” for that section.

Participation in the study is voluntary and anonymous. There are no personal identifiers included within the questionnaire. Consent is implied by the completion and return of the questionnaire. All information will remain confidential and only my supervisors and myself will have access to the raw data. There is no penalty for not filling the questionnaire.

No incentives will be provided for completing the questionnaires. The questionnaire should not take longer than 5 minutes per patient to complete. All questionnaires, whether completed or not, should please be returned and placed in the appropriately labelled box. If there are any questions prior to or during completion the survey, please feel free to ask.

Kind regards

Anne-Mart Viljoen (Researcher), 071 354 2630

Appendix H: Data Collection Sheet

The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital

Case information: Unique patient nr: _____

1. **Date of procedure:** ____/____/____ (DD/MM/YYYY)
2. **Urgency of surgery:** ☐ Elective ☐ Emergency ☐ 07:00-16:00 ☐ 16:00-07:00
3. **Discipline:**
   ☐ Dental ☐ Ophtal ☐ Paeds surgery
   ☐ ENT ☐ Orthopaedic ☐ Urology
   ☐ Gastroenterology ☐ Plastics ☐ Other_____
4. **Surgery/Procedure performed:** _____

Patient information:

5. **DOB:** ___/____/____ (DD/MM/YYY)
6. **Weight:** _____kg
7. **ASA classification:** ☐ I ☐ II ☐ III ☐ IV ☐ V

Anaesthesia:

8. **Anaesthetist in charge:**
   ☐ Consultant ☐ Senior registrar (year 3+4) ☐ MO >3 years' experience
   ☐ Junior registrar (year 1+2) ☐ MO <3 years' experience
9. **Type of anaesthesia:** ☐ GA ☐ Regional (type)_____ ☐ Sedation
10. **Airway:** ☐ Facemask ☐ Supraglottic (eg LMA) ☐ ETT ☐ Other:_____
11. **Muscle relaxant:** ☐ Yes ☐ No
12. **Extubation** ☐ Deep ☐ Awake
13. **Immediate outcome:** ☐ D/C home ☐ D/C to ward ☐ HighCare ☐ ICU

Events:

14. **HGT after induction:** _____(mmol/L)
15. **Treatment for HGT**
    ☐ Nil given ☐ 1% Dextrose solution ☐ 2% Dextrose solution ☐ Insulin
    ☐ Other (specify): _____
16. **If any of the following occurred, please continue to next page:** Difficult BVM, >2 attempts on intubation, Laryngospasm, Bronchospasm, Aspiration, Post-op stridor, Severe hypoxia, Arrhythmias, Bradycardia, Hypotension, Cardiac arrest, Drug error, Temp >38 or <36, Neurological events eg seizures or loss of function, Emergence agitation, or any event that required intervention to prevent disability or death
    ☐ None of the above occurred

Perioperative critical events in paeds anaesthesia

The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital

Unique patient nr: _____

ONLY FILL THE APPLICABLE SECTION, where an event occurred.

Respiratory critical Events:

17. How did you manage respiratory events?

	Difficult BMV	Multiple intubation (2 or more attempt)	Laryngospasm	Bronchospasm	Aspiration	Severe hypoxia	Post-op stridor	Other _____
Positive pressure								
OPA								
Deepening of anaesthesia								
Propofol								
Sux								
Intubation								
Bronchodilators								
Adrenaline								
Suctioning								
Antibiotics								
CPAP								
IV Steroids								
Other: Please specify								

Other event and/ or treatment:

_____

_____

_____

_____

The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital

Unique patient nr: _____

18. How did you manage cardiac events?

	Bradycardia	Arrhythmia(other than brady)	Hypotension	Cardiac arrest	Other _____
Fluid					
Adrenaline					
Atropine					
Defib					
Cardiovert					
Bloodproducts					
CPR					

Other:_____

19. Temperature abnormality?

☐ Temp <36°C ☐ Temp >38°C

20. How did you manage the temperature abnormality?

☐ Cold IV fluid ☐ Ice packs ☐ Cold saline irrigation

☐ Warm IV fluid ☐ Bair hugger ☐ Warm saline irrigation

☐ Other:_____

21. How did you manage emergence delirium?

_____

_____

22. Did any drug error occur?

☐ Wrong drug ☐ wrong dose ☐ Wrong site ☐ Extravasation

☐ Other: please specify_____

23. How did you treat the drug error:

_____

Annexures

Annexure A: MAC RMMCH Approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Rahima Moosa Mother and Child Hospital
Enquiries: Adjunct Professor Ashraf Coovadia
Tel: 011 470 9284/9100
Email: Karen.Marshall@wits.ac.za

TITLE OF RESEARCH PROJECT:
"PAEDIATRIC ANAESTHETIC-RELATED CRITICAL EVENTS AT A REGIONAL ACADEMIC HOSPITAL"

NAME OF SUPERVISOR:
Dr Janine Wagner

NAME OF RESEARCHER:
Dr Anne-Mart Viljoen
Department of Anaesthesiology
University of the Witwatersrand

NHRD REF NO: GP_202208_068

Dear Dr Viljoen,

Permission is granted for you to conduct the research as indicated in the title above.

The terms under which this permission is granted is contained in the Researcher Declaration form that you have signed. Failure to comply with these conditions will result in the withdrawal of such permission.

It is crucial for you to inform the Research Coordinator, Karen Marshall of the actual start and end dates of your study. This could be done by e-mail.

Should the study commence more than 12 months after receipt of this approval letter you will have to go through the process of applying again.

You are strongly advised to keep a signed copy of the declaration form to ensure that the terms of this agreement are always complied with.

Yours sincerely,

DR FREW BENSON
Senior Clinical Executive
Rahima Moosa Mother and Child Hospital
2022.09.23

Annexure B: Permission from the Head of Department

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES | WITS SCHOOL OF CLINICAL MEDICINE

DEPARTMENT OF ANAESTHESIOLOGY
Tel.(011)488 4344

08 August 2022

Postgrad Office

School of Clinical Medicine

Faculty of Health Sciences

University of the Witwatersrand

To Whom It May Concern

Permission To Conduct Research: Dr Anne-Mart Viljoen- Student Number: 530158

This is to confirm that I have read and given permission for **Dr Anne-Mart Viljoen** to conduct research at in the Department of Anaesthesiology towards his/her Mmed project titled *"Paediatric Anesthetic-Related Critical Events at a Regional Academic Hospital"*

Thank you.

Assoc. Prof. P Motshabi Chakane

Annexure C: Permission from the Head of Anaesthesiology RMMCH

Department of Anaesthesiology
Rahima Moosa Mother and Child Hospital
Tel: (011) 470-9106
E-mail: kleyenstuber@hotmail.com
Thomas.Kleyenstuber@wits.ac.za

8 August 2022

Attention: The Chair of the Human Research Ethics Committee

Permission to collect data in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital

I hereby grant permission for data to be collected in the Department of Anaesthesia at Rahima Moosa Mother & Child Hospital for the following MMED research project: Paediatric Anaesthesia-Related Critical Events at a Regional Academic Hospital.

Kind Regards

Dr T Kleyenstuber

Head: Clinical Unit – Anaesthesiology

Rahima Moosa Mother & Child Hospital

Annexure D: Human research ethics committee clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr A-M Viljoen

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M220813

NAME: (Principal Investigator)	Dr A-M Viljoen
DEPARTMENT:	School of Clinical Medicine Department of Anaesthesiology Medical School University
PROJECT TITLE:	*The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital* Change of study title noted on 2022/11/17
DATE CONSIDERED:	2022/08/26
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>
SUPERVISOR:	Drs J Wagner and S Mayet
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2022/10/14

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **August** and therefore reports and re-certification will be due in the month of **August** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator _____ Date _____

17/11/2022

Annexure E: Graduate studies approval

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

16 August 2022
Person No: 530158
PAG

Miss A Viljoen
32 van Graan Street
Oewersig
2531
South Africa

Dear Miss Anne-Mart Viljoen

Master of Medicine in Anaesthesia: Approval of Title

We have pleasure in advising that your proposal entitled *The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital* 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

Turnitin Report: