EFFECTS OF EXTUBATION GUIDELINE ADHERENCE ON EXTUBATION FAILURE RATE AMONG MECHANICALLY VENTILATED PAEDIATRIC PATIENTS AT THE KENYATTA NATIONAL HOSPITAL.

DR. KAGUONGO RACHEL KABUI
MBChB, Nairobi
H58/81887/2015

SUPERVISORS:

Dr. Rashmi K. Kumar, MBBS, M.Med (Paediatrics), Fellowship (Paediatric Critical Care).

Prof. Ruth W. Nduati, MBChB, M.Med (Paediatrics), MPH (Epidemiology).

Dr. Beatrice C. Mutai, MBChB, M.Med (Paediatrics).

Dr. Idris N. Chikophe, MBChB, M.Med (Anaesthesia).

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DECLARATION

This dissertation is my original work and has not been presented elsewhere. References to work done by others have been clearly indicated.

Signature……..... Date…….

Dr. Rachel Kabui Kaguongo

APPROVAL

This dissertation has been submitted with our approval as university supervisors.

Dr. Rashmi Kumar

Lecturer, Department of Paediatrics and Child Health,

University of Nairobi.

Signature……..... Date…….

Prof. Ruth W. Nduati

Professor, Department of Paediatrics and Child Health,

University of Nairobi.

Signature……..... Date…….

Dr. Beatrice Mutai

Lecturer, Department of Paediatrics and Child Health,

University of Nairobi.

Signature……..... Date…….

Dr. Idris N. Chikophe

Department of Anaesthesia,

Kenyatta National Hospital.

Signature……..... Date…….

DEDICATION

Prof. Kaguongo Wambari and Mrs. Wanjiru Wambari, my parents: You were my first teachers, and remain my mentors. I couldn't have done this without you. I thank God for you!

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LIST OF ABBREVIATIONS

CPAP	Continuous positive airway pressure
CROP	Compliance, rate, oxygenation and pressure (index)
DAS	Difficult Airway Society
EF	Extubation Failure
FiO_2	Fraction of inspired oxygen
GCS	Glasgow Coma Scale
ICU	Intensive Care Unit
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
MUAC	Mid Upper Arm Circumference
PEEP	Positive end expiratory pressure
PICU	Paediatric Intensive Care Unit
PIM	Paediatric Index of Mortality (score)
PIP	Peak Inspiratory Pressure
RSBI	Rapid shallow breathing Index
SBT	Spontaneous Breathing Trial
SIMV	Synchronised mandatory intermittent ventilation
V_T	Tidal volume
WAZ	Weight for Age Z (score)
WHO	World Health Organisation
WHZ	Weight for Height Z (score)

DEFINITIONS OF TERMS

- Weaning – transition from ventilatory support to completely spontaneous breathing. During this process, the patient is allowed to take on more of the work of breathing while the ventilatory support is gradually withdrawn.(1)
- Extubation – removal of the endotracheal tube from the trachea.
- Spontaneous breathing trial (SBT) – when the intubated patient is allowed to breathe spontaneously either through a T-piece or while on a pressure support mode such as Continuous Positive Airway Pressure (CPAP) so as to assess readiness for extubation.(2)
- Extubation failure – patient presenting in respiratory distress or respiratory failure (significant respiratory acidosis or hypoxemia on blood gas analysis) requiring reintubation within 48 hours of extubation or complications requiring tracheostomy insertion within 48 hours of extubation. A systematic review of weaning and extubation readiness among pediatric patients defined early extubation failure as occurring within 6 hours of extubation, intermediate extubation failure occurring at 6 to 24 hours post-extubation and late extubation failure between 24 and 48 hours post-extubation.(1)
- Successful extubation – patient able to maintain spontaneous respiration without features of respiratory distress or respiratory failure for more than 48 hours post extubation.

ABSTRACT

BACKGROUND

Children, especially those under 5 years of age, are especially at risk of death from preventable and/or reversible causes particularly in resource-limited settings, which generally have sparse critical care resources. There is no accepted gold standard on extubation practice, and only minimal literature from Africa. At the Kenyatta National Hospital, guidelines based on international literature are utilised, but timing of extubation continues to rely heavily on clinical judgement. Little is known regarding the prevalence of extubation failure (EF) in our setting, or the effect of following our current guidelines on the extubation failure rate.

STUDY OBJECTIVE

This study sought to determine the rate of adherence to extubation guidelines and the prevalence of extubation failure among paediatric patients extubated at the Kenyatta National Hospital main and paediatric ICUs. The third objective was to describe the effect of extubation guideline adherence on extubation failure rate among these mechanically ventilated paediatric patients at the Kenyatta National Hospital.

METHODS

The study was a hospital based, retrospective, observational cohort study set in the main ICU and paediatric ICU at Kenyatta National Hospital. The participants were children aged 1 month to 12 years admitted to the ICU/PICU from November 1, 2017 to February 28, 2018 who received mechanical ventilation via endotracheal tube and have an attempted extubated during their stay in the ICU. An informed consent was obtained for all participants enrolled in the study. A standard data collection tool was used for data collection. Data was stored in MS-EXCEL and analysed using STATA 12® software.

RESULTS

The study enrolled 56 out of 84 possible eligible participants aged between 1 month to 12 years, with a total of 62 extubation attempts recorded. Of the participants, 57.2% were male, and majority of them (89.3%) were below the age of 5 years, with median age of 13.5 months (IQR 2 months – 82 months). Respiratory and neurological diagnoses were a common reason for intubation in these patients. More than half of the extubations (59.7%) were carried out in PICU with the rest being in the main ICU. A high incidence of

unplanned extubations (22.6%) was noted. Only 3 to 8 of the 9 criteria were followed for each extubation. None of the extubations were carried out in adherence to all 9 criteria of the guidelines, and most of the extubations (74%) met between 5 to 7 of the guidelines. The overall extubation failure (EF) rate was 11.3%. EF rate was not significantly different when comparing planned and unplanned extubations. Use of adrenaline nebulisation, control of underlying disease and hemodynamic stability evidenced by no inotropic support in the 24 hours pre-extubation were the 3 parameters shown to be associated with reduced risk of EF after bivariate analysis. Multivariate analysis however did not show a significant association.

CONCLUSION

The KNH paediatric extubation guidelines are only partly adhered to in planning for extubation in the ICUs. Despite this however, our EF rate of 11.3% is comparable to documented rates worldwide. Of the 9 criteria, 2 (control of underlying disease and hemodynamic stability) were shown to be protective against EF even in a small population. The high rate of unplanned extubations and low EF rate in unplanned extubations suggests that our approach to assessing extubation readiness may be too conservative.

RECOMMENDATIONS

There is need to improve awareness of the healthcare workers in these ICUs on the extubation guidelines, particularly those that have been shown to have significant effect on EF. Early weaning and extubation of our paediatric patients may have benefit. Clinical judgement of a trained and experienced ICU specialist remains vital in determining the best time to extubate patients, but the guidelines remain useful for less experience healthcare workers in an ICU setting. Further studies assessing post extubation use of adrenaline nebulization as an independent variable are indicated in our setting.

CHAPTER ONE: INTRODUCTION

The first paediatric critical care unit was opened in 1955 at the Children's Hospital of Goteborg in Sweden. Since then, there have been rapid and significant developments in the field, making it a recognized subspecialty worldwide. The organization, types, available resources and team composition of paediatric intensive care units (PICUs) varies widely from country to country, even in resource-rich countries.(3)

The World Health Organization estimates that one third of annual deaths in children under the age of 5 years can be attributed to acute respiratory failure and shock, both of which are preventable and/or reversible.(4) In resource-limited settings, critical care resources are sparse, intensivists are few, and intensive care unit (ICU) equipment more difficult to access.(5) In addition, there is a general lack of ICU beds in low income countries, as well as little reliable published local data on critical care topics.(6) This is in spite of the high burden of disease reported in the paediatric age group in these countries.(7) The demand for critical care services thus outstrips the available resources in resource-limited settings.

One of the most successful measures taken towards improving care of seriously ill children in hospitals in low-income countries has been the introduction of training for health care workers in areas such as the Emergency Triage Assessment and Treatment plus admission care (ETAT+) course that was developed in Kenya from existing WHO guidelines.(8) This aims to make recognition and emergency management of the critically ill child more effective, and improve prioritisation of patients for admission. However, ETAT+ does not address the details of specialised care should these children be admitted into a critical care unit.

A large part of critical care in both paediatric and adult ICUs is mechanical ventilation. Khemani et. al. who studied 16 United States PICUs, found that approximately one in three patients admitted into PICU (30%) will require mechanical ventilation. The frequency of intubation however varied widely, from 20 to 64% in the different units. Almost 50% of those mechanically ventilated had respiratory disorders as the primary diagnosis and 30% suffered from cardiovascular conditions.(9)

In one Brazilian study, 35.7% of PICU patients were mechanically ventilated for 24 hours or more. The major indication for mechanical ventilation was acute respiratory failure, usually associated with severe sepsis or septic shock.(10) Zamzam et. al., at EL-Mahalla Chest Hospital ICU in Egypt, found a similar prevalence (31%) of mechanical ventilation in adult ICU patients in their setting.(11) In a prospective observational cohort study of adult patients from 40 ICUs in 16 countries, Vincent et. al., found that 32% of ICU patients were admitted in acute respiratory failure, while 24% developed acute respiratory failure during their ICU stay.(12) Esteban et. al., in a 1-day point prevalence study in 412 medical-surgical ICUs in North America, South America, Spain and Portugal, found that acute respiratory failure was the indication for mechanical ventilation in 66% of the ventilated patients. Of these patients, 75% were ventilated via endotracheal tube.(13) Thus, management of the endotracheal tube is a vital part of critical care.

Endotracheal extubation is the removal of the endotracheal tube from the trachea.(14) Rather than being a single event, extubation is a process, and has the potential for significant morbidity and even mortality if not carried out successfully.(15–17) While there are various guidelines worldwide that aim to guide extubation, there is no gold standard guiding current practice, and no validated protocol in resource poor settings such as ours. As seen in Table 1 below, some of the guidelines specifically address extubation following anaesthesia, while others focus on extubation in an ICU setting following mechanical ventilation. The guidelines are generally written by expert members of professional organisations in various countries, and thereafter published in a peer-reviewed journal for dissemination purposes.

Table 1: Existing extubation guidelines and their origins and target populations

Organisation	Country	Target Population	Year of last update
American College of Chest Physicians (CHEST) and American Thoracic Society (ATS) (18)	United States of America	Critically ill adults	2016
All India Difficult Airway Association (AIDAA) (19)	India	Patients with difficult extubation.	2016
American Society of Anaesthesiologists (ASA) (20)	United States of America	Patients with difficult extubation	2012
Difficulty Airway Society(DAS) (21)	United Kingdom	Patients post-anaesthesia	2011
American Association for Respiratory Care (AARC) (22)	United States of America	Adult, pediatric and neonatal patients following mechanical ventilation.	2007

There exists minimal literature on pediatric extubation practice or guidelines in Africa, and none from Kenya. However, one South African study described unplanned extubations in an academic intensive care unit.(23)

This paucity of data is reflected in a systematic review of intensive care unit capacity in low-income countries, reviewing studies published between 2004 and 2014 that had data on ICU capacity in low-income countries as defined by the World Bank criteria. 43 studies were included, collating data from different continents, including 13 African countries and

4 Kenyan studies. Overall, only 3 of the studies discussed topics related to mechanical ventilation, and none focused on extubation practice(6).

Local literature is important because our patient population is unique in several ways. Our setting has a high prevalence of tropical and infectious diseases. Unlike the developed world where non-communicable diseases are responsible for a significant proportion of mortality, in sub-Saharan Africa, the leading causes of mortality in all age groups are communicable diseases such as HIV-AIDS, lower respiratory infections, diarrheal diseases and malaria. Globally, lower respiratory tract infections, diarrhoeal diseases and malaria remain a leading cause of under 5 mortality, together causing 57% of deaths in children aged 1 month to 59 months(7).

In our setting, the prevalence of malnutrition is relatively high. According to the 2014 Kenya Demographic Health Survey (KDHS), 4% of children under 5 were wasted, weighing less than expected for their height, and 26% of Kenyan children were stunted, with height less than expected for age(24). Malnourished children have lower immunity and are at higher risk of severe illness, thus at higher risk of requiring ICU admission. Because malnutrition affects muscle bulk, including that of respiratory muscles, (25) it is conceivable that this may affect the success of extubation in our setting. These factors as well as the small ICU capacity in Africa may have implications on the applicability of data from the developed world to our setting. It is therefore crucial that clinicians in Africa generate and disseminate to each other research findings on critical care practice in our setting.

CHAPTER TWO: LITERATURE REVIEW

The Difficult Airway Society (DAS) Extubation guidelines recommend that when planning an extubation, an assessment and as much as possible, optimisation of airway and general risk factors be done. This optimisation includes normalising cardiovascular, respiratory, metabolic and neuromuscular parameters, ensuring adequate monitoring and equipment availability, as well as ensuring the availability of skilled assistance in case of any complications.(26) The American Association for Respiratory Care Guidelines for Removal of the Endotracheal Tube indicate that for successful extubation, a patient should have an adequate central inspiratory drive, good cough and laryngeal function, optimised nutritional status, and clearance of the effects of medications such as sedatives and neuromuscular blockers from the system.(22)

Endotracheal intubation and mechanical ventilation, though life-saving, may also be associated with risks including ventilator-induced lung injury, airway injury and nosocomial pneumonia(1) as well as increased costs associated with these complications. The desire therefore is to minimise the duration of intubation as much as possible, balancing this with the risks of extubation at any given time.

Many studies have assessed weaning from ventilation(2,27–30). The process includes assessment of the child's hemodynamic stability, neurological status and level of sedation, blood gas parameters, respiratory measurements such as the minimum positive end expiratory pressure that the child can comfortably tolerate and other relevant indices such as the rapid shallow breathing index (RSBI). This is done sometimes in conjunction with a spontaneous breathing trial where the patient is taken off the ventilator completely, for example by use of a T-piece, or placed on a pressure support mode such as continuous positive airway pressure (CPAP) but remains intubated as an assessment of the effectiveness of respiratory effort and readiness for extubation(27,29,31). However, there is no clear evidence on which weaning strategy is ideal, and contrary to evidence from adult studies, a weaning protocol in the paediatric age group may not be beneficial in reducing patient ventilator days.(32) In fact, it has been suggested that this gradual withdrawal of mechanical ventilation may actually prolong the duration of ventilation

unnecessarily in some patients(27). A South African study on unplanned extubations in adults found that only 25% of the patients who suffered an unplanned extubation needed re-intubation(23). This suggests that for the 75% whose unplanned extubations were successful, the patients were actually ready for extubation though no decision had been made to extubate them. A randomised controlled trial conducted in PICUs in 10 North American children's hospitals found that more than a third of children who were determined to be ready for weaning actually already fit the criteria for extubation, and most were then successfully extubated within 24 hours.(32) Weaning these children further would therefore only prolong their duration of intubation unnecessarily.

Although extubation failure (EF) can be defined as the need for reintubation and revertion to ventilatory support within 72 hours of extubation,(33,34) multiple studies define the time period as within 48 hours of extubation.(2,15,28,31,35,36) A systematic review of weaning and extubation readiness among pediatric patients defined early EF as occurring within 6 hours of extubation, intermediate EF occurring at 6 to 24 hours post-extubation and late EF between 24 and 48 hours post-extubation.(1)

EF has been found to be associated with a significant increase in mortality rate,(16,35,37) whereas the patients who tolerate extubation longer than 24-72 hours generally have favourable outcomes.(17) There have been conflicting results however. Baisch et al., found that patients who failed extubation had increased morbidity, with a longer hospital stay and duration of ventilation, potentially ending in tracheostomy insertion, but did not have a statistically significant increase in mortality rate.(15) Preparation for extubation means taking into consideration the associated risks and benefits for each individual patient, and optimising each patient's condition for the best possible outcome.

2.1 Epidemiology of Extubation Failure

Extubation failure is an important part of critical care and thus an important area of research. Despite the available guidelines, the prevalence of EF varies significantly from unit to unit. Kulkarni and Agarwal, in their 2008 review found a wide range of EF incidence reported in various ICUs, ranging from 6% to 47%.(33) Aetiology of failed extubation has

been found to be multifactorial(15,32,38) and in many cases was related to upper airway obstruction including obstruction secondary to airway edema as well as pulmonary pathology causing impaired oxygenation and ventilation. Other factors from these studies include excessive airway secretions, apnea, inadequate cough, encephalopathy or cardiac dysfunction.

An extremely low EF rate suggests that many patients may be remaining on mechanical ventilation longer than they require, whereas a high EF rate suggests that many patients are being extubated before they are ready. In a review of the reported range of failed extubations in literature, the mean extubation failure rate in 96 observational studies included was found to be 15%, while a mean extubation failure rate of 15.7% was calculated from 55 interventional studies included in the review. Krinsley et al., the authors of this review, also report on their case control study of 2,012 mechanically ventilated patients in a 16 bed medical-surgical ICU over a 5 year period. Their EF rate was 6.6%. From this large study as well as their review of literature, an ‘optimal’ EF rate of 5-10% is proposed.(34)

2.2 Summary of Existing Guidelines

Table 2: Scope of existing extubation guidelines

	CHEST /ATS	AIDAA	ASA	DAS	AARC	KNH PICU
Specific guidelines for paediatric patients included					✓	✓
Difficult extubation post anaesthesia addressed		✓	✓	✓		
Extubation in patients intubated for more than 24 hours addressed	✓		✓		✓	✓
Spontaneous breathing trial recommended as part of establishing extubation readiness	✓				✓	✓
Extubation to non-invasive ventilation recommended for patients at high risk of extubation failure	✓		✓		✓	
Adequate level of consciousness or minimising sedation recommended	✓		✓	✓		✓
Use of steroids recommended	✓*	✓	✓		✓**	✓
Use of supplemental oxygen recommended		✓		✓		✓
Cuff-leak test on ventilator recommended prior to extubation	✓	✓	✓		✓	
Cough test recommended prior to extubation			✓		✓	
Aspects of post-extubation care addressed	✓	✓	✓	✓	✓	✓

Steroid use recommended: *for adults who fail the cuff-leak test **in certain age groups.

2.3 Risk Factors for Extubation Failure

Various studies have given conflicting results on predicting successful extubation. One study looking at predictors of successful extubation in children found that risk factors for failed extubation included younger age, longer duration of mechanical ventilation,

increased ventilator demand, reduced compliance of the respiratory system and defects in oxygenation and ventilation, compared to children who underwent successful extubation. Epstein suggests that the best predictors of successful extubation include successful completion of a spontaneous breathing trial together with minimal airway secretions, patency of the upper airway and adequate cough reflex.(39)

The rapid shallow breathing index (RSBI), and compliance, rate, oxygenation and pressure (CROP) indices were first described by Yang and Tobin in 1991. RSBI is measured using a spirometer attached to the endotracheal tube while the patient is breathing spontaneously and is a ratio comparing the respiratory rate to tidal volume. The CROP index is more technical and includes measures of dynamic compliance, oxygenation, maximal inspiratory pressure as well as respiratory rate.(38) Thiagarajan et al., found that these predictive indices, previously used in adults, were predictive of extubation success in children.(40) Khan et al., however had previously found that the CROP index was not a reliable predictor of EF in children.(41) It is therefore clear, that evidence on extubation in adults may not reliably be extrapolated to extubation in children.

In our setting, due to the lack of clear evidence as well as a shortage of required equipment and trained personnel, use of such predictive indices in planning for extubation is impractical and in many cases not possible. Purely clinical guidelines for extubation are also not validated.

2.3.1 Age of Patient

Multiple studies have shown that young age is associated with a higher risk of extubation failure(15,40,42). Infants in particular are therefore at risk, with the ages of 1 to 3 months being quoted as being associated with higher risk of extubation failure.(32,42) Baisch et al., report a median age of 6.5 months among patients who failed extubation compared with 21.3 months in those who had successful extubation(15).

2.3.2 Sex of Patient

Males were found to have greater risk of extubation failure than females in Randolph's study of one hundred and eighty two children across ten North American paediatric ICUs(32).

2.3.3 Lung Compliance, Oxygenation and Ventilation

Thiagarajan et. al., in a study of 227 patients undergoing mechanical ventilation, found that patients who successfully underwent extubation had better lung compliance, receiving larger tidal volumes (V_T) from mechanical ventilation on lower ventilator peak airway inspiratory pressures. Higher arterial partial pressure of oxygen (Pa_{O2}), higher positive end expiratory pressure (PEEP), and lower mean airway pressures on mechanical ventilation were also found in patients who were successfully extubated. On similar levels of fraction of inspired oxygen (FI_{O2}), successfully extubated patients had a higher Pa_{O2}/FI_{O2} ratio, significantly lower partial pressures of carbon dioxide (Pa_{CO2}) and lower respiratory rates during spontaneous breathing trials on CPAP of 4 cm H_20. Overall, successful extubation was associated with better lung compliance, oxygenation and ventilation.(40)

2.3.4 Duration of Mechanical Ventilation

In a Brazilian prospective cohort study of 124 mechanically ventilated children, Fontela et. al., established prolonged ventilatory support (mechanical ventilation for more than 15 days) to be associated with EF.(42) Thiagarajan et. al. also found that duration of mechanical ventilation was independently associated with extubation failure. Successful extubation was associated with significantly shorter duration on mechanical ventilation.(40)

2.3.5 Hemodynamic Stability

The DAS Extubation guidelines consider hemodynamic instability as a risk factor for extubation failure, and recommend normalisation of cardiovascular parameters prior to attempting extubation.(21) Fontela et al. found that patients who received inotropes dopamine and dobutamine were at higher risk for extubation failure.(42)

2.3.6 Neurological Status

The patient's level of consciousness is a variable of interest with higher levels of sedation being shown to increase the risk of extubation failure.(32) Randolph studied 358 critically ill paediatric patients undergoing extubation. Patients who suffered extubation failure were more likely to have had prolonged ventilation and used intravenous sedation.(42) Mokhlesi found that patients who had hypercapnia with either a Glasgow Coma Scale (GCS) score $\leq$10 or with moderate or copious secretions had an EF rate of 69%, compared to 2% when the 3 risk factors were all absent. In his study, a low GCS was found to also be an independent predictor of EF.(43)

The AVPU mnemonic (A: alert, V: responsive to verbal stimulation, P: responsive to painful stimulation, U: unresponsive) is taught as part of the ETAT+ course in our setting for rapid assessment of the neurological status of a child and is incorporated in Kenya's Basic Paediatric Protocols.(44) The AVPU scale is simpler to use than the GCS, and has been shown to have good correlation to the paediatric GCS(pGCS) in both pre-hospital and in-hospital settings, with an AVPU of A and V correlating to a pGCS of 10-15 in paediatric ICU patients aged 2 months to 12 years.(45,46)

Figure 1: Paediatric modification of Glasgow Coma Scale (pGCS).(46)

Eye opening	Spontaneous To voice To pain None		**4** **3** **2** **1**	
Best motor response	Targeted grabbing on request, obeys commands Targeted defense to pain stimulus Flexion to pain stimulus Abnormal flexion to pain (decortication) Extension to pain (decerebration) No motor response to pain		**6** **5** **4** **3** **2** **1**	
Best verbal response	**Non-verbal children (<4 yrs.)**	**Verbal children (> 4 yrs.)**		
	Fixes, follows, recognizes objects and persons, laughs, adequate interaction	Alert, speakswords or sentences normally	**5**	
		Confused, dissoriented, speaks incoherently	**4**	
	Fixes and follows inconsistently, recognition of people uncertain, irritable cry			
		Inadequate words or sentences, inappropriate words	**3**	
	Arousable at times, cries inconsolable to pain			
	Motor restless, moans, irritable	Incomprehensible sounds	**2**	
	No response to pain	No response to pain	**1**	
Total GCS score			**15**	

2.3.7 Haemoglobin Level and History of Blood Transfusion

Several studies have shown that anemia increases the risk of extubation failure.(47–49) Khamiees et al., showed that adult patients with haemoglobin levels below or equal to 10g/dL had a more than five-fold increased risk for unsuccessful extubation.(47) However, in addition to the negative effect of anemia, blood transfusions are considered to have a negative effect on duration of mechanical ventilation.(49)

2.3.8 Use of Steroids

A Cochrane review by Markovitz and Randolph of 7 studies found on the topic of steroid use during extubation concluded that while steroid use in children reduced the incidence of stridor following extubation, there was not enough evidence for its benefit in reducing the rate of reintubation in this age group. In neonates however, dexamethasone tended to have a positive effect in reducing reintubations.(50) Newth et al. note that studies which successfully showed benefit of steroids started the steroid administration 6 – 24 hours prior

to extubation, while those that did not administered the steroid within 6 hours of extubation.(1)

2.3.9 Nutritional Status

Although Fontela et. al., working in a developing country, suspected that nutritional status may affect EF in their patients, their study did not show a statistically significant association between the two.(42) Animal models however have proven respiratory muscle weakness as a result of malnutrition.(25) Measurement of the mid-upper arm circumference (MUAC) is taught as part of the ETAT+ course and normal values for ages 6 months to 5 years documented in the Kenya Basic Paediatric Protocolas as a rapid way to assess for acute malnutrition correlating well with WHZ scores.(44)

Table 3: Correlation of MUAC and WHZ score as per Kenya Basic Paediatric Protocol

Classifying malnutrition
(for WHZ values see pg 51 to 52)

Acute Malnutrition *(severity)*	MUAC *(cm)*	WHZ
None	>13.5	> - 1
At Risk	12.5 to 13.4	> - 2 to ≤ 1
Moderate	11.5 to 12.4	> - 3 to ≤ - 2
Severe	< 11.5	≤ - 3
	Kwashiorkor	

In addition, MUAC has been shown to be an effective measure of risk of mortality due to undernutrition in local studies, and charts of normal ranges are available for children aged 5 months to 19 years.(51)

2.3.10 Use of CPAP

Patients who are ventilated on continuous positive airway pressure (CPAP) immediately prior to extubation have been found to have a higher risk of extubation failure.(42) It is

thought that progressive lung derecruitment during CPAP with resultant atelectasis and respiratory distress leads to the EF in these patients. This is interesting in light of the fact that other studies recommend a spontaneous breathing trial (SBT) usually leaving the patient on CPAP or a T-piece for at least 2 hours to assess readiness for extubation.(1)

2.3.11 Spontaneous Breathing Trial

Effectiveness of weaning and readiness for extubation can be assessed through a spontaneous breathing trial where the patient is taken off the ventilator completely, for example by use of a T-piece, or placed on a pressure support mode but remains intubated as an assessment of the effectiveness of respiratory effort and readiness for extubation.(27,29,31) Newth et al. suggest criteria for failure of SBT during 2 hours on CPAP at less than 5cm H_20 or on T-piece in two categories. Clinical criteria include diaphoresis, nasal flaring, increased work of breathing, heart rate rising by more than 40 beats per minute, cardiac arrhythmias, hypotension or apnoea. Laboratory criteria include worsening acidosis (as indicated by $P_{ET}CO_2$ > 10 mmHg, arterial pH < 7.32 or a reduction in pH of >0.07) and hypoxemia (PaO_2/FiO_2 ratio < 150 or PaO_2 < 60 mmHg at FiO_2 > 0.40 or reduction in SPO_2 of >5%).(1)

Johnston and da Silva describe objective parameters of adequate gas exchange, hemodynamic and ventilatory stability, and subjective clinical parameters of mental state, ventilatory distress and work of breathing in determining success of a SBT.(2)

2.3.12 Adrenaline Nebulisation Following Extubation

Laryngeal edema is a common cause of upper airway obstruction following extubation and when severe, can lead to re-intubation. Nebulised adrenaline acts through stimulation of α-adrenergic receptors on vascular smooth muscle cells. The resultant vasoconstriction reduces blood flow and hence reduces edema in the airway.(52) Aerosolized adrenaline has been shown to be equally effective as aerosolized budesonide in treatment of post-extubation stridor, and is in fact superior due to its more sustained effect.(53)

2.4 Protocol Based Approaches to Extubation

It is intuitively expected that planned extubations would have better outcomes than those that are unplanned. Mpe et al., found a 10.35% rate of unplanned extubations among adult patients in a South African ICU, 25% of whom required reintubation. Unplanned extubations were defined in this study as those resulting from self extubation by the patient or accidental extubation by staff during bedside procedures. The investigators in this study however, did not compare the rate of reintubation in these patients to the reintubation rate in those patients who had planned extubations(23). Compared to the average reintubation rate of 15% quoted previously in observational studies,(34) a higher rate of reintubation was therefore found in unplanned extubations.

While there is evidence of benefit for protocol use in adults, the evidence is less clear in paediatrics.(1) Johnston and da Silva, in their 2012 review article, reported on three studies assessing protocol based approaches to weaning from mechanical ventilation. Some studies also assessed the performance of set measures for extubation readiness. Unfortunately, none of these studies were able to find a significant difference in the outcome measures (including extubation failure rate) compared to standard care.(2)

What has been proven however, is that use of a protocol driven by cadres of staff other than experienced physicians can significantly improve patient care amongst intubated patients in the ICU, including reduction of EF rates. Dries et al., found this through examining a protocol driven by nurses and respiratory therapists.(27) This data could be extrapolated to our setting where the PICU is manned by nurses, paediatric residents and medical officers with support from paediatric intensivists who are on call 24 hours a day.
The algorithm suggested by Johnson and da Silva in their review article referred to above, forms the basis of the guidelines that used in the KNH PICU, and considers 10 criteria to determine extubation feasibility. The KNH PICU guidelines vary from these recommendations in only a few aspects. Pimax and RSBI are not measured in our unit thus not utilised as a measure of extubation readiness. In addition, it is recommended that all of our patients receive at least 2 doses of steroids, with one given more than 6 hours prior to extubation.

Table 4: Comparison of Johnson and da Silva recommendations to KNH PICU guidelines

Johnson and da Silva	KNH PICU guidelines
• Controlled underlying disease • No need for vasoactive drugs • Adequate level of consciousness • Successful spontaneous breathing trial (SBT) • $FiO_2 \leq 40\%$ with $SPO_2 > 92\%$ or $PaO_2/FiO_2 > 150$ • PEEP = 5cmH_20 and PIP < 30cmH_2O • Blood pH of 7.32 to 7.47 • Hemoglobin level above 10g/dL • Force and respiratory muscle resistance appropriate for age and underlying disease (assess Pimax and RSBI) • Effective cough	• Controlled underlying disease • No need for vasoactive drugs for at least 24 hours prior to extubation • Adequate level of consciousness • Successful spontaneous breathing trial (SBT) • $FiO_2 < 40\%$ with $SPO_2 > 92\%$ or $PaO_2/FiO_2 > 150$ • PEEP = 5 cmH_2O and PIP $\leq$ 30 cmH_2O • Acceptable blood gas analysis results • Hemoglobin level above 10g/dL • Steroid administration at least 6 hours prior to extubation

These recommendations are in line with the evidence detailed above in the section on risk factors for extubation failure. The authors comment that while corticosteroids may be beneficial, there is a lack of definitive evidence. However, after analysing the literature on clinical markers related to extubation, no single physiological indicator was found to predict extubation success in children.(2)

2.5 Study Justification and Utility

Although mechanical ventilation is a crucial part of paediatric critical care, there is no consensus worldwide on the best practice for extubation of the paediatric ICU patient. In

addition, there is a paucity of literature on any critical care topic from resource limited settings.

Extubation failure has been shown to vary widely in prevalence from institution to institution even in resource-rich settings, and is associated with increased morbidity and mortality. There is however no literature available on the prevalence and risk factors for paediatric extubation failure in Kenya. In addition, it is not clear what effect the existing extubation guidelines have on extubation outcomes in our setting.

Our analysis of extubation practice in the main and paediatric ICUs in Kenyatta National Hospital will shed light on the prevalence of extubation failure in our setting, as well as investigating possible risk factors associated with this failure of extubation. It will also provide evidence on the efficacy and utilization of our current extubation guidelines and what effect (if any) these guidelines have on our extubation failure rate. In addition to adding to the body of knowledge on paediatric critical care in resource limited settings, this study will provide baseline data, paving the way for future research into the topic of extubation. Information obtained will also be useful in guiding changes in local institutional protocols and policy that may help standardise extubation practice within the ICUs and potentially reduce morbidity and mortality in critically ill paediatric patients in KNH.

CHAPTER THREE: RESEARCH QUESTIONS AND OBJECTIVES

3.1 Research Questions

1. What is the rate of adherence to extubation guidelines in paediatric patients extubated at the Kenyatta National Hospital main and paediatric ICUs?
2. What is the prevalence of extubation failure among paediatric patients extubated at the Kenyatta National Hospital main and paediatric ICUs?
3. What is the effect of extubation guideline adherence on extubation failure rate among mechanically ventilated paediatric patients at the Kenyatta National Hospital?

3.2 Objectives

1. To determine the rate of adherence to extubation guidelines in paediatric patients extubated at the Kenyatta National Hospital main and paediatric ICUs.
2. To determine the prevalence of extubation failure among paediatric patients extubated at the Kenyatta National Hospital main and paediatric ICUs.
3. To describe the effect of extubation guideline adherence on extubation failure rate among mechanically ventilated paediatric patients at the Kenyatta National Hospital.

CHAPTER FOUR: RESEARCH METHODOLOGY

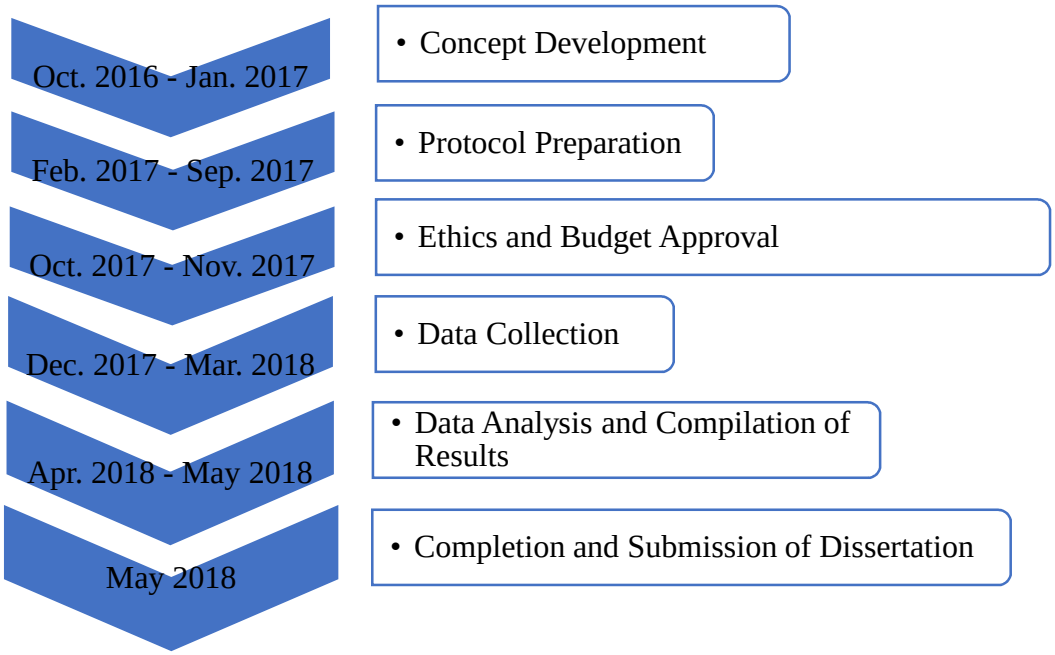
4.1 Study Design

This study was a single centre cohort study of patients undergoing an extubation attempt in the Kenyatta National Hospital during admission in either the main ICU or the PICU.

4.2 Study Period

The timeline for this study is illustrated in the figure below.

Figure 2: Study timeline



4.3 Study Site

The Kenyatta National Hospital(KNH) is one of two national teaching and referral hospitals in Kenya and has a capacity of 1800 beds. It is located about 4km from the Nairobi City Centre. There are four general paediatric wards admitting patients aged 0 – 12 years. These have a capacity of 240 patients. Each paediatric ward has an acute room, in which the sickest patients on the ward are monitored. Patients who need intensive care may then be admitted to the Paediatric Intensive Care Unit (PICU). The PICU at KNH opened in 2015 and has a capacity of five beds. It is led by a team of pediatric intensivists. Pediatric patients requiring intensive care may also be admitted in the Main Intensive Care Unit (ICU) which primarily cares for adult patients and is anaesthesiologist led. This is

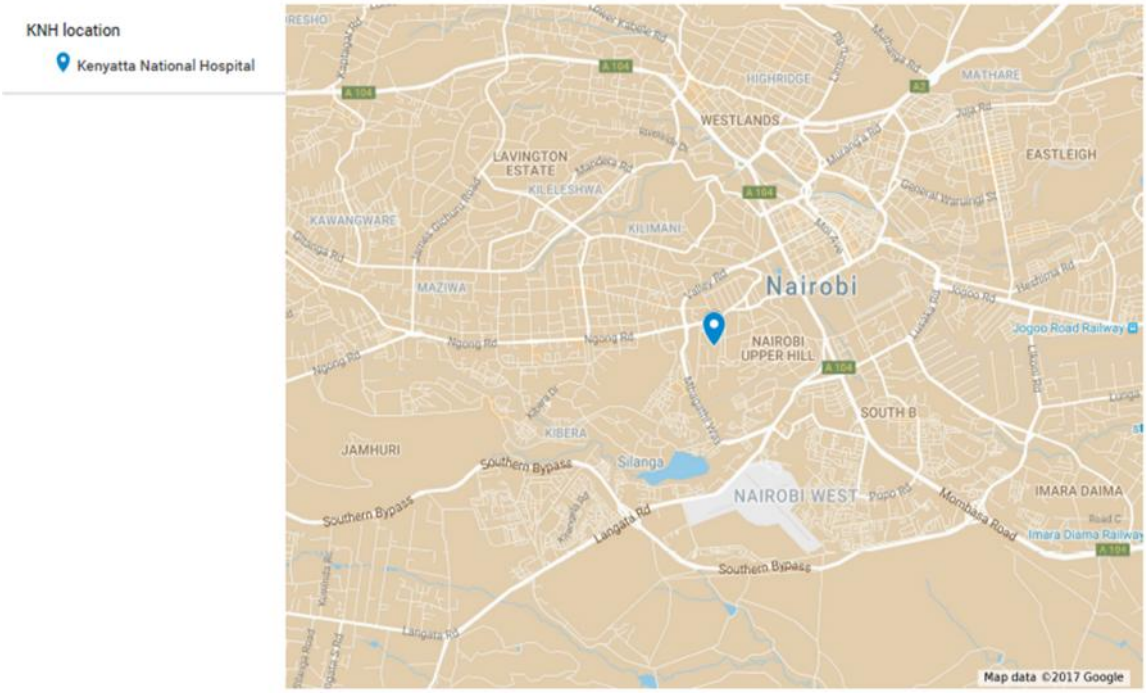
especially true for post-surgical paediatric patients who require intensive care and continue under the management of the anaesthesiologists who cared for them intra-op. The paediatric ICU team however is generally consulted, and reviews paediatric patients when they are admitted in the main ICU. Neonatal patients are however admitted to the Neonatal ICU, part of the Newborn Unit at the facility and led by a team of neonatologists.

As a national teaching and referral hospital, the KNH sees a wide variety of cases referred from all over the country. As a public hospital, costs are tailored to cater to people of all socio-economic status and this allows for a wide variety of diagnoses in the patient population. One of the most common reasons for pediatric admissions to the ICU is the need for mechanical ventilation. In some cases, the condition of patients in the paediatric ward acute rooms require PICU admission, but there is limited bed space.

From a baseline review of admission records, we were able to determine that in 2016, the KNH PICU alone admitted over 200 patients. This is independent of the paediatric patients admitted in the main ICU of the hospital. Of these PICU patients, more than 95% were intubated.

The map in figure 2 shows the location of the Kenyatta National Hospital within the Nairobi area.

Figure 3: Location of Kenyatta National Hospital in Nairobi



The guideline currently in use in the KNH PICU for establishing extubation readiness contains the criteria listed in the table below.

Table 5: KNH PICU guidelines for establishing extubation readiness

Criteria for establishing paediatric patients' readiness for extubation
1. Controlled underlying disease 2. No need for vasoactive drugs for at least 24 hours prior to extubation 3. Adequate level of consciousness (A or V on AVPU scale / GCS > 10) 4. Successful spontaneous breathing trial (SBT) 5. FiO_2 <40% with SPO_2 >92% or PaO_2/FiO_2 >150 6. PEEP = 5 cmH_2O and PIP $\leq$ 30 cmH_2O 7. Acceptable blood gas analysis results 8. Hemoglobin level above 10g/dL 9. Steroid administration at least 6 hours prior to extubation

4.4 Study Population

Our case definition for this study was a paediatric patient between the ages of 1 month and 12 years admitted into ICU at Kenyatta National Hospital between November 1, 2017 and February 28, 2018, intubated and with an attempted extubation during the PICU admission. Neonates were excluded from the study due to the differences in their respiratory physiology and pathology compared to the older child(54), which is likely to affect ventilation and extubation outcomes. The upper age limit for paediatric admissions at KNH is 12 years. Patients older than this are admitted into the medical wards under the care of physicians, and were thus excluded from this study.

4.4.1 Inclusion Criteria

1. Patients aged 1 month to 12 years at the time of entry into the study
2. Patients admitted into KNH main ICU or PICU and intubated for mechanical ventilation during their hospital stay

4.4.2 Exclusion Criteria

1. Patients who underwent tracheostomy insertion prior to any attempt at extubation being made or were ventilated via tracheostomy from the beginning of their ICU admission.
2. Patients who were transferred to another unit prior to an attempt at extubation.

4.5 Sample Size

The Sample Size was determined using the Formula for calculating sample size when comparing 2 proportions as below:

$$n = \frac{[\, Z_\alpha \sqrt{(2pq)} - Z_\beta \sqrt{p_1 q_1 + p_2 q_2}\,]^2}{(p_1 - p_2)^2}$$

$$= \frac{[1.96\sqrt{(2 \times 0.325 \times 0.675)} - (-0.84)\sqrt{(0.15 \times 0.85) + (0.5 \times 0.5)}\,]^2}{(0.15 - 0.5)^2} = 26.87$$

$$= 27\ patients\ in\ each\ cohort\ (Total\ 54\ patients\ in\ the\ study)$$

- n = calculated sample size for each cohort
- Z_α = standardized critical value for a 95% Confidence Interval; set at 1.96.
- Z_β = standardized critical value for 80% power; set at -0.84

- p_1 = apriori estimated proportion of failed extubations in cohort with adherence to extubation guidelines, value set as 0.15 – based on average extubation failure rate in systematic review of observational studies.(34)
- q_1 = apriori estimated proportion of successful extubations in cohort with adherence to extubation guidelines (i.e. $q_1 = 1 - p_1$)
- p_2 = apriori estimated proportion of failed extubations in cohort with failure to adhere to extubation guidelines, value set as 0.5 – based on systematic review by Newth et al., in 2009 that reported that 50% of unplanned extubations result in extubation failure.(1)
- q_2 = apriori estimated proportion of successful extubations in cohort with failure to adhere to extubation guidelines (i.e. $q_2 = 1 - p_2$)
- $p = \frac{p_1+p_2}{2}$
- q = 1 - p

4.6 Study Variables

4.6.1 Independent Variables

Adherence to the KNH PICU extubation guidelines was assessed as follows:

1. *Controlled underlying disease*

   General improvement of the patient was established by reviewing the patient's clinical notes as documented by the doctors in the unit.

2. *No need for vasoactive drugs for at least 24 hours prior to extubation*

   Use of inotropes within 24 hours prior to extubation was established by reviewing the clinical notes, fluid charts and treatment sheets of each patient.

3. *Adequate level of consciousness*

   Level of consciousness was considered adequate if AVPU scale is at A or V, or GCS $\geq$ 10 as documented in the clinical notes in the 24 hours prior to extubation.

4. *Successful spontaneous breathing trial (SBT)*

   An SBT was considered successful if a patient was able to maintain adequate spontaneous respiration for at least 2 hours on CPAP or T-piece and was established from the clinical notes and charts.

5. FiO_2 $\leq$40% with SPO_2 >92% or PaO_2/FiO_2 >150

6. *PEEP = 5 cmH_2O and PIP $\leq$ 30 cmH_2O*
7. *Acceptable blood gas analysis*

   Compliance to these three guidelines above was established from the ventilation chart and vital signs documented as well as any arterial or venous blood gas results during the 24 hours prior to extubation. Arterial blood gas was considered acceptable if pH is 7.32 to 7.47 or a venous gas with pH 7.28 to 7.43 with bicarbonate of above 20 mmol/L in both arterial and venous samples.
8. *Haemoglobin level above 10g/dL*

   The haemoglobin(Hb) level at the time of extubation was established from the documented Hb in any blood gas analysis done within 24 hours before extubation. This was only excluded if there was documented evidence of bleeding after the time of the last documented Hb and before 48 hours post extubation.
9. *Steroid administration at least 6 hours prior to extubation*

   This was established from the child's treatment sheet. At least two doses of steroids should have been administered with one dose at least 6 hours prior to extubation.

4.6.2 Dependent Variable

Extubation failure

Patients who were re-intubated within 48 hours of the extubation attempt were deemed to have had a failed extubation. Any patient who did not require re-intubation in this time period was considered to have undergone successful extubation.

4.6.3 Precision Variable

Sex of patient was documented as part of biodata but also as a precision variable.

4.6.4 Potential Confounders

Data was collected on the following variables which were identified as potential confounders:

1. Age

Patient's age at the time of extubation was established from the clinical record.

2. Weight

Child's weight at admission was documented. While it was the intention of the researchers to also document MUAC, it was found that MUAC was not measured for paediatric patients admitted into the ICU and PICU.

3. Primary and Secondary Diagnosis

The primary ventilation was considered as that which was documented as the major diagnoses at the time of initiation of mechanical ventilation, and specifically that diagnosis which likely led to the requirement for mechanical ventilation. Any other diagnoses were documented as secondary diagnoses. This information was obtained from the doctor's notes in the clinical record.

4. Duration of illness

Length of admission as well as length of ICU stay at the time of extubation were obtained from the clinical record.

5. Use of adrenaline nebulisation post extubation

Any use of adrenaline nebulisation post extubation was established from the clinical record.

4.7 Study Personnel

1. Principle investigator – was in charge of the study team. Her role was to ensure research procedures were followed as per protocol with the assistance of the research assistant. She also double checked all entries into the research database for accuracy and where discrepancies arose, clarified these with the hospital patient record. As part of this, she double checked 12 of the 54 patient files accessed (22%).

2. Research assistant – assisted in data collection under supervision. The research assistant was trained in use of the data entry tool.

Qualifications of research assistant: The research assistant was a qualified PICU nurse, and was provided with the study protocol, which contained the study procedures as well as all the study definitions.

4.8 Sampling Procedure

A screening log was maintained of all patients who fit the inclusion criteria for this study. Once patients were identified who fit the entry criteria, consecutive enrolment after written informed consent was done until the desired sample size is achieved.

4.9 Patient Recruitment Procedure

Patients who met the inclusion criteria were identified based on their admission to the PICU or main ICU. Any patient meeting the exclusion criteria was excluded from the study. Parents/Guardians of patients meeting the inclusion criteria were contacted either in person while their child was in the hospital or if necessary by phone.

Once an extubation attempt was made, the study was explained verbally to the parent or guardian by the principal investigator or research assistant, and a copy of the consent form given to the parent/guardian. It was emphasized that since this was a purely observational study, there was minimal risk to the child as a result of the study procedures.
All data was entered into the data collection tool only after obtaining informed consent.

4.10 Data Management

4.10.1 Data Collection and Storage

Data regarding the child's status prior to extubation was obtained from doctor and nurse's notes in the official patient record and inserted into the data collection tool (Appendix 1) at the point of enrolment (at or after extubation attempt). A patient was categorized as having been extubated in adherence to the guidelines only if all 9 components of the guidelines had been adhered to. Each guideline was considered adhered to only when documentation to this effect was found in the patient record. Patients who were found to have been extubated without following the guidelines were categorised into groups for stratification based on how many items of the guidelines were not adhered to. The child was then followed up for 48 hours post extubation to determine whether the outcome for this child would be considered extubation success or extubation failure.

Data was collected retrospectively by the research assistant from the patient record once informed consent has been obtained. Data was stored in MS-EXCEL files with password protection to maintain confidentiality. All data entered was verified manually by the principal investigator to ensure accuracy. Data was protected at all points to prevent unauthorised sharing. The principle investigator was responsible for maintaining the security of the data and restricting access.

4.10.2 Data Analysis

Data analysis was carried out using STATA 12® software. Descriptive statistics of baseline characteristics of study participants are presented using means (with standard deviations) or medians (with interquartile ranges) based on data distribution for continuous variables and frequencies and proportions for categorical variables. Graphical displays are presented on baseline characteristics using pie charts and bar graphs as appropriate.

Chi-square test or Fisher's exact test were used in bivariate analysis to examine for significant associations between the outcome variable and predictor variables. Continuous variables were compared to the outcome variable by means of a Student's T-test. To control for potential confounding by age, diagnosis, duration of illness, nutritional status and use of adrenaline nebulisation post extubation, we stratified data by these variables before analysis. Continuous variables like age were categorized into age groups for bivariate analysis. Data was also stratified to control for precision variables such as sex of the patient. Logistic regression was carried out to compare the outcome variables to all independent variables. Pairwise comparison was carried out to determine if nutritional status impacted extubation outcomes. A composite variable generated to compare outcome variable to the multiple prequalification criteria for extubation.

4.11 Control of Bias and Error

4.11.1 Sampling Bias

Only patients who meet the eligibility criteria were included in this study. For the time period identified, there were 84 eligible patients at first screening. After retrieving medical

records, a further 8 were identified as not meeting the eligibility criteria. All eligible patients whose parents/guardians gave consent were included in the study.

4.11.2 Selection Bias

There was potential for selection bias since the parent or guardian needed to give consent prior to the child's enrolment into the study. Every effort was made to obtain informed consent from the parents or guardians of all eligible patients. However, 8 parents / guardians could not be reached for consent, and of those approached, a further 4 out of 76 denied consent.

4.11.3 Information Bias

The research assistant was familiarised with the study protocol and data collection tools prior to beginning data collection. A copy of the protocol, case definitions and definitions of technical terms was also provided. Supervision and support were provided by the principal investigator with weekly discussions of any challenges encountered by the research assistant.

4.12 Ethical Considerations

Ethical consent was sought from the KNH/UON Ethics Review Committee to conduct the study. Written informed consent or consent by thumbprint sign were sought before enrollment from each child's parents or caregivers for inclusion of the child's data into the study. Consent forms were available (Appendix 2) in both national languages, English and Kiswahili, and were kept by the principal investigator / research assistant for the duration of the study. The caregivers were free to withdraw consent at any time during the study period without any discrimination. A copy of the signed consent form was also made available to caregivers who consented for enrolment.

The study was a retrospective and purely observational study and the researcher anticipates no greater than minimal risk to study participants as no interventions that may affect patient outcomes or cause adverse effects to the patient were undertaken by the investigator or research assistants.

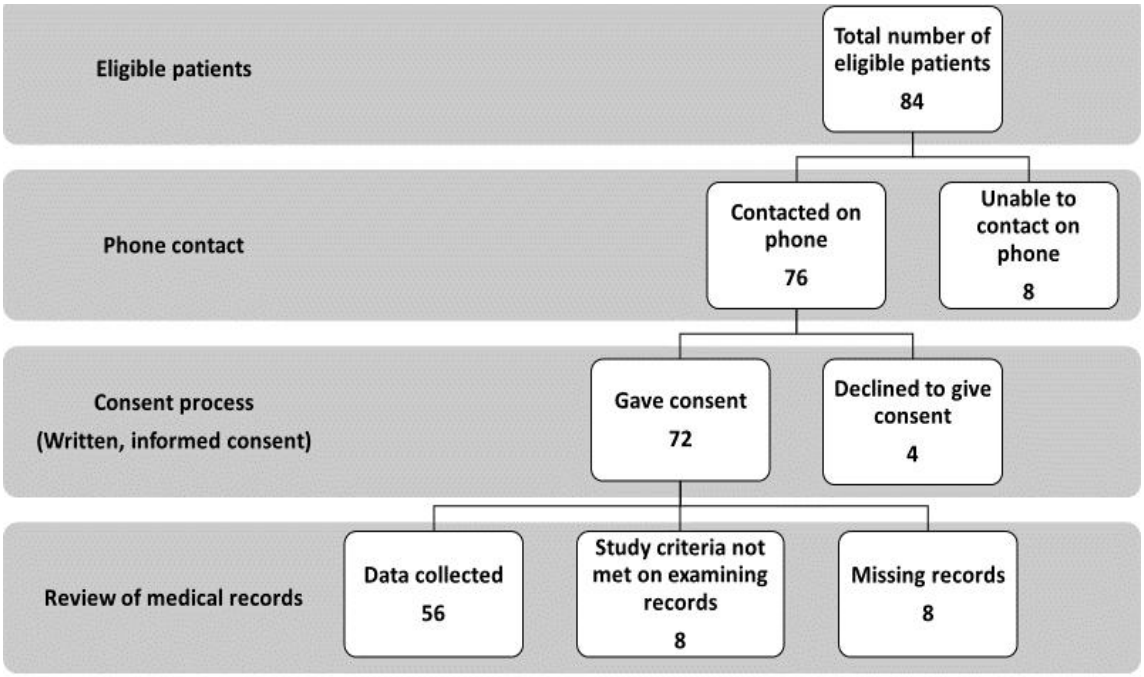
Data confidentiality was ensured by collecting and documenting data using a unique serial number as the patient identifier. The primary investigator has a master list linking the serial numbers to the to the patient's identity.

CHAPTER FIVE: RESULTS

5.1 Population Characteristics

By screening admission records, 84 eligible patients were identified. The recruitment procedure is summarised below.

Figure 4: Summary of recruitment and data collection procedures



This study included 56 patients aged between 1 month to 12 years, with a total of 62 extubation attempts recorded. Of these patients, 57.2% (32 patients) were male, and 42.8% (24 patients) were female. Majority of the patients included in this study (89.3%) were below the age of 5 years with a median age of 13.5 months (IQR 2 months – 82 months). Mean age was 23.6 months (SD 26.4 months) and this was not significantly different when comparing successful extubations to failed extubations.

The most common primary diagnosis and indication for mechanical ventilation was found to be respiratory conditions, commonly pneumonia, accounting for 37.1% of the patients in the study. Neurological diagnoses (19.3%) such as meningoencephalitis were also a significant reason for intubation among the patients in this study.

Table 6: Characteristics of study population

Patient characteristics (total 56)			
		Number of patients	Proportion (%)
Age	1 – 12 months	30	53.6
	12 – 59 months	20	35.7
	5 years – 12 years	6	10.7
Sex	Male	32	57.2
	Female	24	42.8
Characteristics of extubation attempts (total 62)			
Primary diagnosis	Respiratory	24	38.7
	Neurological	11	17.7
	Neuromuscular	7	11.3
	Gastro-intestinal	10	16.1
	Multi-systemic	4	6.5
	Post-surgical	6	9.7
Site	PICU	37	59.7
	Main ICU	25	40.3
Type of extubation	Planned	48	77.4
	Unplanned	14	22.6
Adrenaline nebulisation post extubation	Done	57	91.9
	Not done	5	8.1
Nutritional status (WAZ)	Normal	29	46.8
	Obese	7	11.3
	Underweight	19	30.6
	Severe underweight	7	11.3

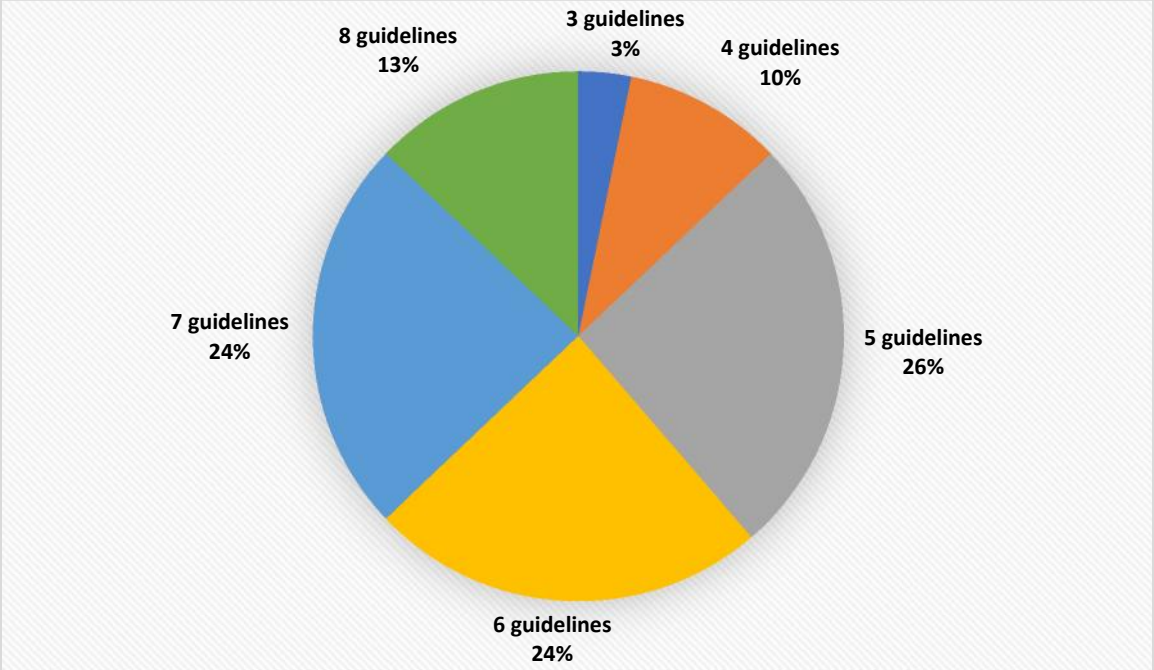
Of the extubation attempts, 59.7% of them were carried out on patients admitted in the PICU, while 40.3% were on patients in the main ICU. Overall, 22.6% of the extubation attempts were documented as unplanned extubations. Adrenaline nebulisation was carried out in 91.9% of the extubated patients.

Weight for age Z scores were normal in 46.8% of the extubation attempts. Of the remainder, 11.3% were overweight or obese and 41.9% were underweight. The mean weight was 11 kg (SD 5.3kg) with a median weight of 9.35 kg (IQR 4.9 – 20 kg).

5.2 Adherence to the KNH PICU Extubation Guidelines

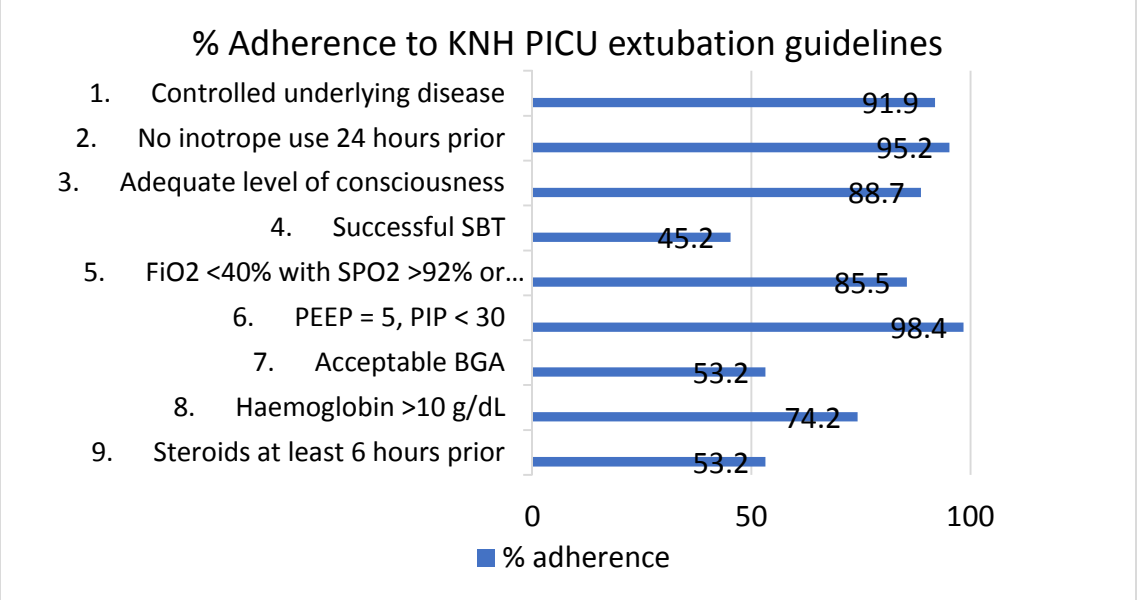
Overall, none of the extubations were carried out in adherence to all 9 criteria of the guidelines. Overall adherence to the guidelines varied at each extubation attempt. The highest rate of compliance seen was 8 out of the 9 guidelines being adhered to, and the lowest had only 3 out of the 9 parameters adhered to. Majority of the extubations (74%) met between 5 to 7 of the guidelines. Adherence to 8 guidelines was considered good (13%), 5 to 7 guidelines was fair (74%) and adherence to 4 or less guidelines was considered poor (13%).

Figure 5: Summary of number of guidelines adhered to at extubation



The adherence to each individual criterion of the guideline is described below. Again, there was incomplete adherence for each of the criteria, with the highest compliance being 98.4% for PEEP=5 and PIP <30 and the lowest being that only 45.2% of patients had a successful spontaneous breathing trial (SBT) prior to extubation.

Figure 6: Graph depicting adherence to each of the 9 KNH PICU Extubation Guidelines.



5.2.1 Controlled Underlying Disease

In 57 (91.9%) of the cases (95%CI 81.7 – 96.7%), the underlying disease had been controlled and the patient stabilised before the extubation attempt took place.

5.2.2 No Need for Vasoactive Drugs for at least 24 hours Prior to Extubation

Majority of the patients were hemodynamically stable at the time of extubation. In 59 of the cases (95.2% with 95%CI 85.6 – 98.5%), the patient had not been on inotropic support for at least 24 hours prior to extubation. However, 3 of the extubation attempts did not meet this criterion.

5.2.3 Adequate Level of Consciousness

It was found that 88.7% (95%CI 77.8 – 94.6%) of the extubation attempts (55 out of 62) were carried out when the patient had an adequate level of consciousness defined as a GCS above 10 or an AVPU score of A or V.

5.2.4 Successful Spontaneous Breathing Trial (SBT)

In more than half of the extubation attempts, an SBT was either not done, not documented, or was unsuccessful. A successful SBT was only found in 28 of the patients (45.2% with 95%CI 33 – 57.9%).

5.2.5 FiO_2 <40% with SPO_2 >92% or PaO_2/FiO_2 >150

The study found that 53 of the extubation attempts were in patients who met this criterion, giving an adherence rate of 85.5% (95%CI 74 – 92.4%).

5.2.6 PEEP = 5 cmH_2O and PIP < 30 cmH_2O

Of the 62 extubation attempts, 61 (98.4% with 95%CI 88.9 – 99.8%) met this criterion. Only one patient did not have documented ventilator settings in the medical record in the 24 hours prior to extubation.

5.2.7 Acceptable Blood Gas Analysis

Acceptable blood gases were documented for 33 of the extubations, giving a 53.2% adherence rate to this criterion (95%CI 40.5 - 65.5%). In 3 cases (4.8%), no blood gas had been done in the 24 hours prior to extubation, and there were 26 (41.9%) abnormal blood gases.

5.2.8 Haemoglobin Level Above 10g/dL

In 46 (74.2% with 95%CI 61.6 – 83.7%) of the extubation attempts, Haemoglobin (Hb) was documented within 24 hours of extubation as being above 10g/dL, thus meeting this criterion. In 2 of the extubations, the patient did not have a documented Hb done within the 24 hours prior to extubation. The remaining 14 patients had a documented low Hb.

5.2.9 Steroid Administration at least 6 hours Prior to Extubation

Although steroids were administered in 46 of the extubation attempts (74.2%), only 33 of the extubation attempts met the full criterion, having at least 2 doses of steroids administered with at least one of the doses administered 6 or more hours prior to extubation. This was an adherence rate of 53.2% (95%CI 40.5 – 65.5%).

5.3 Incidence of Extubation Failure

Overall, the extubation failure(EF) rate in our patients was 11.3%. Extubation failure amongst patients in the PICU was 8.1% and among patients in the main ICU was 16%. This difference in EF rates was however not statistically significant with a P-value of 0.3. The rate of unplanned extubations was found to be 22.6%. Use of adrenaline nebulisation post extubation, although not part of the extubation guidelines assessed, was found to have a significant association with reduced risk of extubation failure (P = 0.000). However, multivariate analysis did not show a significant association.

Table 7: Effect of patient characteristics on extubation failure rate.

Patient Characteristic		Number of extubations	Number of failed extubations	EF Rate	P-value
Sex	Male	36	5	13.9	0.4
	Female	26	2	7.7	
Primary diagnosis	Respiratory	24	2	8.3	0.4
	Neurological	11	1	9.1	
	Neuromuscular	7	0	0	
	Gastro-intestinal	10	3	30	
	Multi-systemic	4	0	0	
	Post-surgical	6	1	16.7	
Site	PICU	37	3	8.1	0.3
	Main ICU	25	4	16	
Type of extubation	Planned	48	5	10.4	0.7
	Unplanned	14	2	14.3	
Adrenaline nebulisation	Done	57	3	5.3	0.0
	Not done	5	4	80	
Nutritional status (WAZ)	Normal	29	3	10.3	0.4
	Obese	7	2	28.6	
	Underweight	19	1	5.2	
	Severe underweight	7	1	14.3	

5.4 Effect of Guideline Adherence on Extubation Failure

Two criteria were shown to have a significant association with extubation failure in our study population. These were control of the underlying disease and hemodynamic stability, where the patient had no need for inotropic support in the 24 hours prior to extubation.

Table 8: Effect of adherence to KNH PICU Extubation Guidelines on Extubation Failure Rate

Criteria	Adherent group EF Rate	Non-adherent group EF Rate	P-value
Controlled underlying disease	7%	60%	0.008
No inotropes 24 hours prior	8.5%	66.7%	0.031
Adequate level of consciousness	9.1%	28.6%	0.2
Successful SBT	7.1%	14.7%	0.3
FiO_2 <40% with SPO_2 >92% / PF $\geq$150	13.2%	0%	0.3
PEEP = 5, PIP $\leq$30	11.5%	0%	0.9
Normal BGA (pH and HCO3)	12.1%	10.3%	0.6
Haemoglobin level > 10 g/dL	10.9%	12.5%	0.6
Steroids 2 doses, 1 at least 6 hours prior	9.1%	13.8%	0.4

Multivariate analysis was carried out using logistic regression. Independent variables were not significant when compared to outcome variable (P value ranging 0.6 to 1.0). A composite value representing the number of criteria in the extubation guidelines adhered to did not have a significant association with the extubation failure rate. There was no statistically significant difference in extubation failure rate between patients who had overall good, fair or poor adherence to the extubation guidelines.

CHAPTER SIX: DISCUSSION

The vast majority of our population was under the age of 5 years. With a median age of 13.5 months, approximately half of the extubations were in infants, who have been shown to be at higher risk for extubation failure.(15,32,40,42) However, in our population, age was not shown to have a significant effect on the rate of extubation failure. It has also been suggested that males may be at higher risk for extubation failure.(32) Although we had more extubations in males than females, the sex of the patient was also not shown to have any effect on extubation failure rates in our study.

The most common indication for intubation in our population was a respiratory diagnosis resulting in acute respiratory failure. This proportion corresponds to findings in studies around the world.(10–12) However, we also had a significant cohort of patients with neurological and neuromuscular conditions necessitating mechanical ventilation. Commonly, these were patients who presented with reduced level of consciousness, status epilepticus or acute flaccid paralysis necessitating mechanical ventilation. Since the primary indication for intubation had to be deduced from a retrospective review of patient notes, the classification of diagnoses was subjective rather than objective. Despite this, the diagnosis did not have a significant effect on the extubation failure rate. However, our sample size was not powered to investigate association between sample size and extubation outcome. It is possible that a larger sample size would provide more information.

Weight and duration of ICU admission had also been considered as potential confounders but were not shown to have any significant effect on extubation failure rate in our study. Overall, the only population characteristic that was shown to have a significant association with extubation failure was use of adrenaline nebulisation following extubation. This was shown to have a protective effect against extubation failure. This suggests that a significant cause of extubation failure in our setting is laryngeal edema, and there would be benefit in administering adrenaline nebulisation to every patient who is extubated. However, as these were not the primary risk factors under investigation, the study was not powered to detect this effect, and it is possible that with a greater sample size, these effects may be present.

Adherence to the KNH extubation guidelines was poorer than expected, since not even one patient had 100% adherence to the guidelines at extubation. Although this is the recommended criteria for extubation of paediatric patients at the Kenyatta National Hospital, it is not universally followed throughout the hospital ICUs, and extubation is guided largely by the attending doctor's (paediatric intensivists and anaesthesiologists) discretion and clinical judgement.

Despite this, the units had an acceptable overall extubation failure(EF) rate of 11.3%. While this is slightly higher than the suggested "optimal" EF rate of 5-10%, it is lower than the 15% average reported in a review of observational studies worldwide.(34) Although there was variation in the extubation failure rate in the main ICU compared to that in the PICU, this was not found to be significant. None of the units however complied fully to the extubation guidelines. This may be a result of poor awareness of the guidelines combined at least partially with poor documentation of compliance in the patient record.

In both units, planned extubations, which made up almost 80% of the data, were based partly on the clinical criteria, but also on the judgement of the consultant physician – whether this was an anaesthesiologist or a paediatric intensivist. This suggests that use of the protocol may not be as useful when experienced and ICU trained doctors are making the clinical decisions as it is when junior members of staff make the decisions. This is in keeping with the findings of Dries et al., who reported that protocol use significantly improved patient care amongst intubated patients in the ICU when driven by cadres of staff other than experienced physicians.(27)

Roughly one in every five extubations was unplanned, with accidental extubations accounting for 22.6% of all the extubations in this study. This is approximately double the incidence of unplanned extubations reported in one South African study in an adult ICU.(23) This rate of accidental extubations is quite high and represents an area for possible improvement of care in the ICU.

It is also possible however, that our units suffer from an abundance of caution in preparing patients for extubation. This is reinforced by the fact that our EF rate is relatively low compared to international literature, and patients who suffered accidental extubations only had an EF rate of 14.3% and were not at higher risk for failed extubation compared to patients who underwent planned extubations. This is contrary to the systematic review by Newth et al., who reported that 50% of unplanned extubations resulted in extubation failure.(1) In a review of literature from January 1966 to March 2009, reintubation rates ranged from 14% to 65% for unplanned extubations.(55) Our rate of 14.3% can thus be considered relatively low, and these patients who underwent accidental extubations can be presumed to have been ready for extubation, even though the doctors caring for them had not yet made the decision to extubate them. It may therefore benefit such patients to have a more aggressive approach to weaning and extubation than is our current practice. This may reduce ICU stay, complications of long-term ventilation, and increase bed availability for patients who truly need mechanical ventilation in a setting where there is a real shortage of ICU bed space.

Only two of the criteria were found to have a significant effect on extubation failure rate. However, since the sample size was based on overall effect of the guidelines together rather than individual components of the guidelines, it is possible that with a larger sample size, the other criteria could also be shown to have an effect on extubation outcome. The two criteria of the guidelines that were shown to be protective against extubation failure were control of the underlying disease prior to extubation, and hemodynamic stability as evidenced by no need for inotropic support for at least 24 hours prior to extubation. Under multivariate analysis however, the independent variables were not significant. A larger sample size may be better powered to determine whether these variables independently affected the outcome.

When a composite variable representing the number of guideline criteria adhered to was compared to extubation outcome, no significant effect was found. This suggests that these guidelines may not have increased effect when used as a bundle.

6.1 Study Strengths and Limitations

6.1.1 Strengths

This is the first study done in our ICUs addressing extubation practice in our paediatric patients.

We were able to collect data for 56 of 84 possible patients.

6.1.2 Limitations

Systematic bias was a possibility. Nevertheless, careful data extraction was carried out.

As none of the participants achieved 100% adherence to the extubation guidelines, it was not possible to achieve two cohorts of non-adherence vs. adherence to the guidelines as originally intended. This was mitigated by categorising adherence as good, fair or poor as previously described.

In addition, use of extubation guidelines can also be variable between units, and thus the results here may not apply to other units.

6.2 Conclusion

The KNH paediatric extubation guidelines are only partly adhered to in planning for extubation in the ICUs. Clinical judgement plays a large role in the case by case decision to extubate. Despite this however, our EF rate of 11.3% is comparable to documented rates worldwide. Of the 9 criteria, 2 (control of underlying disease and hemodynamic stability) were shown to be protective against EF even in a small population. The high rate of unplanned extubations and low EF rate in unplanned extubations suggests that our approach to assessing extubation readiness may be too conservative.

6.3 Recommendations

Based on our findings, we can make the following recommendations:

1. There is need to improve awareness of the healthcare workers in these ICUs on the extubation guidelines, particularly those that have been shown to have significant effect as well as the need for good documentation. Continuous medical education for all ICU staff would be useful in this regard.

2. It would be useful to further assess risk factors associated with the high rate of accidental extubations in our units. These may provide areas for intervention in improvement of patient care and outcomes. In addition, assessing post extubation use of adrenaline nebulisation as an independent variable will be useful since this study suggests that it may have some benefit in reducing extubation failure rates.
3. It may be beneficial to aggressively wean paediatric patients in the units off mechanical ventilation with a view to early extubation.
4. Clinical judgement of a trained and experienced ICU specialist remains vital in determining the best time to extubate patients. The protocol may be useful in guiding less experienced healthcare workers such as the registrars who rotate through the unit.
5. A prospective study with a larger sample size may shed more light on our current practice. It may also be useful to study the knowledge, attitudes and practices of ICU staff with regards to extubation.

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APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

Patient serial number	Age		Sex	Weight	MUAC	Primary diagnosis	Secondary diagnosis
	Years	Months	M/F	kg	cm		
1							
2							
3							
4							
5							
6							

Length of stay of admission at extubation	Length of ICU stay at extubation	AVPU	GCS	SBT success (Y/N)	FiO_2 pre-extubation
days	days			Y/N	

SPO_2 pre-extubation (%)	PEEP pre-extubation (cmH2O)	PIP pre-extubation (cmH2O)	PaO_2/FiO_2 ratio	BGA	pH
%	cmH_2O	cmH_2O		arterial/venous	

pCO_2	HCO_3	Hb	Number of steroid doses	Steroids ≥ 6 hours pre-extubation	Adrenaline nebulisation post-extubation	Extubation outcome
mmHg	mmHg	g/dL		Y/N	Y/N	success/failure

APPENDIX 2: INFORMED CONSENT

EFFECTS OF EXTUBATION GUIDELINE ADHERENCE ON EXTUBATION FAILURE RATE AMONG MECHANICALLY VENTILATED PAEDIATRIC PATIENTS AT THE KENYATTA NATIONAL HOSPITAL.

INFORMED CONSENT FORM

This informed consent form is for the parents of children between the ages of 1 month and 12 years of age who were admitted to the study units between the period of November 1, 2017 and February 28, 2018 and who we are asking to participate in the study titled **"***Effects of extubation guideline adherence on extubation failure rate among mechanically ventilated paediatric patients at the Kenyatta National Hospital."*

Principal Investigator:

Dr. Kaguongo, Rachel Kabui

University of Nairobi- School of Medicine, Department of Paediatrics and Child Health

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

We are conducting a study to assess the current guidelines on extubation (removing the tube that helps your child breathe on the ventilator) while in ICU. We would like to invite you and your child to take part in the research. Please read through this consent form and feel free to ask any questions. You may take as much time as you need as well as discuss the study with anyone you feel comfortable with before you agree to participate. If you have any questions later or are ready to make a decision you may contact the investigator(s) through the contacts provided above.

Purpose

Removal of the endotracheal tube (breathing tube) is called extubation. It is not always successful. Sometimes, the patient is not able to breathe on their own after it is removed and we have to return it (re-intubation). By studying children at the time of extubation, we would like to assess how helpful our current guidelines are, and describe the factors that may contribute to a child having to be reintubated. This will help us to care better for many other children in the years to come.

Type of Research Intervention

There is no direct intervention by the study team. However, we will be documenting information obtained from your child's hospital file.

Participant selection

This study is for children aged 1 month to 1 year who have used the endotracheal tube for ventilation while in the main or paediatric ICU at KNH. This is why your child has been selected to participate in the study.

Voluntary Participation

The decision to have your child participate in this study is voluntary. Your decision not to participate will not deny your child the care they need for their illness and will still benefit from all treatment options available to them at this facility. If you choose to take part in the study but later change your mind, you are free to inform the investigator as much and your child will still continue to receive their treatment.

Procedures and Protocol

Your child will be given the same care they would have been given even if they were not in the study. The study personnel will however obtain information from your child's hospital file regarding the period before, during and 48 hours after your child has been extubated. We will not record your child's name when we take this information, and when we share the results with our colleagues, we will take care that there will be nothing to identify your child specifically.

Duration

The research will be conducted from 1st November, 2017 to 28th February, 2018. Your participation will end 48 hours after your child is extubated.

Risks, Stress, Discomfort

There will be no additional tests or interventions done by the study team. We will only use the information that the doctors and nurses have already written in the file about your child.

Benefits

There is no direct benefit to you or your child for participating in this research. However, the results of the study may be used in future to help improve the care of children who are as sick as your child in Kenya and in other countries like ours. Your participation in this study is therefore of great value in the advancement of medical practice in developing countries.

Reimbursement

Your participation in this study is entirely voluntary and there will be no money or other token given to you or your child for taking part in the study.

Confidentiality

We will take care to keep your child's name and identity confidential, and will not share that information when we release the study results.

Sharing of the results

Please feel free to get in touch with the principle investigator should your wish to find out the results of this study. We also intend to publish the study as a dissertation in the University of Nairobi, Department of Paediatrics and Child Health, and later in a medical journal as a way of sharing this with our colleagues in other countries.

This study proposal has been reviewed by the Kenyatta National Hospital/University of Nairobi Ethics and Review Committee (KNH/UON ERC) which is responsible for ensuring that ethical guidelines as well as the dignity, rights and safety of research participants are observed.

Any questions or concerns about the study may be communicated to the KNH-UON ERC through the following contacts:

Kenyatta National Hospital/
University of Nairobi Ethics and Review Committee,
College of Health Sciences ,
P.O.Box 19676-00202,
Nairobi, Kenya.
Telephone: +254 20 2726300-9 Ext 44355
E-mail: uonknh_erc@uonbi.ac.ke

PART II: Certificate of Consent

Investigator Contacts:

Dr. Kaguongo, Rachel Kabui +254720874488
P. O. Box 14964, 00800,
Nairobi, Kenya.
extubationstudy@gmail.com

I have read the information above concerning the study and it has also been explained to me. I have been able to ask the questions that I had and they have been answered to my satisfaction. I consent voluntarily for my child to participate in this study.

***Print Name of Participant*_____**

***Print Name of Parent or Guardian*_____**

***Signature of Parent or Guardian* _____**

Date _____

Day/month/year

If parent/guardian is unable to sign:

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

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

Print name of witness*_____** ***Thumb print of parent

***Signature of witness* _____**

***Relationship to parent* _____**

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately explained the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the study is voluntary and carries minimal risk to the patient.

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

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

FOMU YA KUPATA KIBALI CHA WAZAZI / WALEZI WA WASHIRIKI

Hii fomu ni kwa ajili ya wazazi wa watoto wenye umri kati ya mwezi 1 na miaka 12 ya umri ambao waliolazwa katika ICU kati kipindi cha Novemba 1, 2017 hadi Februari 28, 2018. Tunawaomba mshiriki katika utafiti wetu ambao unaangalia vile watoto ambao wametumia ile mashine ya kusaidia kupumua wanavyoendelea ile mpira ya kupumua inapotolewa.

Mpelelezi Mkuu:

Dr Kaguongo, Rachel Kabui

Chuo Kikuu cha Nairobi – Idara ya Madaktari wa Watoto

Fomu hii ya Ruhusa ya Ruhusa ina sehemu mbili:

- Karatasi ya Taarifa (habari kuhusu utafiti huu)
- Hati ya Ruhusa (Ikiwa umekubali mtoto wako kushiriki)

Utapewa nakala ya Fomu ya Ruhusa ya Ruhusa

SEHEMU YA I: Karatasi ya Taarifa

Utangulizi

Tunafanya utafiti kuchunguza miongozo ya sasa ya “extubation” (kuondoa ile mpira inayosaidia mtoto wako kupumua kwenye mashine) wakati amelazwa ICU. Tungependa kuwakaribisha wewe na mtoto wako kushiriki katika utafiti huu. Tafadhali soma fomu hii ya idhini na jisikie huru kuuliza maswali yoyote. Unaweza kuchukua muda mwingi unavyohitaji na pia kujadili masomo na mtu yeyote kabla ya kukubali kushiriki. Ikiwa una maswali yoyote baadaye au uko tayari kufanya uamuzi unaweza kuwasiliana na uchunguzi (s) kupitia anwani zilizotolewa hapo juu.

Kusudi

Kuondolewa kwa mpira unaosaidia mgonjwa kupumua inaitwa extubation. Wakati mwingine, mgonjwa hawezi kupumua vizuri mpira ukitolewa, na inabidi huo mpira

urudishwe ili aweze kuendelea kupumua. Kwa kuchunguza hali ya watoto wakati huu mpira unapotolewa, tungependa kuona kama miongozo tuliyo nayo kwa wakati huu ina manufaa, na kuchunguza ni mambo gani ambayo yanaweza fanya mtoto ahitaji kurudishwa kwenye mpira ya kupumua. Hii itatusaidia kutunza vizuri zaidi watoto wengine wengi katika miaka ijayo.

Aina ya Utafiti

Hatutabadilisha yale matibabu mtoto wako anayoyapata akiwa amelazwa kwenye ICU. Tutakavyofanya ni kuchunguza faili ya mwanao na kunakili yale mambo yaliyofanywa na kuandikwa humo nd

Uchaguzi wa washiriki

Utafiti huu ni kwa ajili ya watoto wenye umri wa mwezi 1 mwaka 1 ambao wamelazwa katika ICU ya KNH na wanapumua kwa usaidizi wa mpira wa kupumua. Ndiyo sababu mtoto wako amechaguliwa kushiriki katika utafiti.

Kushiriki kwa hiari

Uamuzi wako wa mtoto wako kushiriki katika utafiti huu ni hiari. Usipokubali kushiriki, mtoto wako bado atapata matibabu yote inayofaa na ambayo inapatikana katika ICU yetu. Ikiwa unachagua kushiriki katika utafiti lakini baadaye utabadili mawazo yako, wewe ni huru kumjulisha mpelelezi mkuu na mtoto wako ataendelea kupokea matibabu yake.

Taratibu na Itifaki

Mtoto wako atapewa huduma ile ile wangepata hata kama hawakuwa katika utafiti. Wafanyakazi wa utafiti watapata taarifa kutoka faili ya hospitali ya mtoto wako kuhusu wakati ule kabla ya mpira kutolewa, wakati unapotolewa na kwa masaa 48 baada ya mtoto wako kutolewa mpira wa kupumua. Sisi hatutaandika jina la mtoto wako tunapopata taarifa hii, na tunapojadiliana matokeo na wenzetu, tutatunza kwamba hakutakuwa na chochote cha kutambua mtoto wako hasa.

Muda

Utafiti huu utafanywa kuanzia tarehe Novemba 1, 2017 hadi Februari 28, 2018. Ushiriki wako utakamilika masaa 48 baada ya mtoto wako kutolewa mpira wa kupumua.

Hatari za Utafiti

Hakutakuwa na vipimo vya ziada au hatua zaidi zitakazofanywa na timu ya utafiti. Tutatumia tu habari ambazo madaktari na wauguzi wameandika tayari kwenye faili kuhusu mtoto wako.

Faida

Hakuna faida moja kwa moja kwako au mtoto wako kwa kushiriki katika utafiti huu. Hata hivyo, matokeo ya utafiti inaweza kutumika katika siku zijazo ili kusaidia kuboresha huduma ya watoto ambao ni kama mgonjwa kama mtoto wako huku Kenya na katika nchi nyingine kama yetu. Kushiriki kwako katika utafiti huu basi ni wenye thamani kubwa kwa kustawisha hali ya matibabu katika nchi zinazoendelea.

Malipo

Kushiriki kwako katika utafiti huu ni kabisa hiari na hakutakuwa malipo yoyote kwako au kwa mtoto wako kwa kushiriki katika utafiti.

Usiri

Tutajali kuweka jina la mtoto wako na utambulisho wake siri, hata tunapotoa matokea ya utafiti huu.

Kushiriki matokeo

Tafadhali jisikie huru kuwasiliana na mpelelezi mkuu ukitaka kupata matokeo ya utafiti huu. Tuna nia ya kuchapisha utafiti kama dissertation katika Chuo Kikuu cha Nairobi, Idara ya Madaktari wa Watoto, na baadaye katika jarida za matibabu kama njia ya kushiriki na wenzetu katika nchi nyingine.

Utafiti huu umekaguliwa na Kenyatta National Hospital/University of Nairobi Ethics and Review Committee (KNH/UON ERC) ambayo ina wajibu wa kuhakikisha kuwa miongozo ya kimaadili, heshima, haki na usalama wa washiriki wa utafiti imezingatiwa.

Maswali yoyote juu ya utafiti inaweza kuwasilishwa kwa KNH-UON ERC kwa njia ya mawasiliano yafuatayo:

Kenyatta National Hospital/
University of Nairobi Ethics and Review Committee,
College of Health Sciences,
SLP 19676-00202,
Nairobi, Kenya.
Simu: +254 20 2726300-9 Ext 44355
Barua pepe: uonknh_erc@uonbi.ac.ke

SEHEMU YA II: Hati ya Ruhusa

Mawasiliano ya Wachunguzi:

Dr Kaguongo, Rachel Kabui +254720874488
PO Box 14964, 00800,
Nairobi, Kenya.
extubationstudy@gmail.com

Nimesoma na kuelezwa maelezo iliyo hapo juu kuhusu utafiti. Nimekuwa na uwezo wa kuuliza maswali yangu na nikaridhika na majibu niliyopata. Ninakubali kwa hiari kwa mtoto wangu kushiriki katika utafiti huu.

***Jina la Mshiriki*_____**

***Jina la Mzazi/Mlezi*_____**

***Sahihi ya Mzazi/Mlezi* _____**

Tarehe _____

Siku/mwezi/mwaka

Ikiwa mzazi / mlezi hawezi weka sahihi:

Shahidi mwenye ujuzi wa kusoma lazima aweke sahihi (ikiwa inawezekana, mtu huyu lazima achaguliwe na mshiriki na asiwe na uhusiano na timu ya utafiti). Washiriki ambao hawajui kuandika wanapaswa kuweka alama yao ya kidole pia.

Nimeshuhudia maelezo ya fomu hii kwa mzazi wa mshiriki, na amepatiwa nafasi ya kuuliza maswali. Ninathibitisha kwamba mzazi/mlezi amekubali mtoto wake kushiriki kwa utafiti huu kwa hiari yake.

Jina la Shahidi*_____** ***Alama ya kidole ya Mzazi/Mlezi

***Sahihi ya Shahidi* _____**

***Uhusiano na Mzazi/Mlezi* _____**

Tarehe _____

Siku/mwezi/mwaka

Taarifa ya mtafiti / mtu mwenye kuchukua idhini

Nimeeleza sahihi mzazi wa mshiriki mambo yaliyo katika hii fomu, na kadri ya uwezo wangu nimehakikisha kwamba anaelewa kwamba ushiriki kwenye utafiti huu ni kwa hiari, na hatari kwa mshiriki ni nadra.

Ninathibitisha kuwa mzazi alipewa nafasi ya kuuliza maswali kuhusu utafiti, na maswali yake yamejibiwa kwa usahihi kadri ninavyoweza. Ninathibitisha kwamba mtu huyo hakulazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Nakala ya ICF hii imetolewa kwa mshiriki.

Jina la Mtafiti / anayechukua idhini_____

Sahihi ya Mtafiti / anayechukua idhini_____

Tarehe _____

Siku/mwezi/mwaka