INCIDENCE AND FACTORS ASSOCIATED WITH FAILED PLANNED EXTUBATION AT MOI TEACHING AND REFERRAL HOSPITAL INTENSIVE CARE UNIT, ELDORET.

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MOI UNIVERSITY

DECLARATION

Declaration by candidate:

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DEDICATION

I dedicate this work to my family as well as my teachers, through whose effort and sacrifice over the years, I have become a better person and Doctor.

DISCLOSURE

The researcher did not receive any outside funding or grant in support of this study. Neither he nor members of his immediate family received payment or other benefits or commitment or agreement to provide such benefits from a commercial entity.

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ABSTRACT

Background: Failed extubation is associated with increased morbidity and mortality. In addition to acute airway complications, re-intubated patients have higher mortality rates, prolonged hospital length of stay and higher costs. Despite planning, up to 25 % of patients fail extubation within 72 hours. Optimizing weaning using protocols reduces incidence of failed planned extubation when compared with standard physician-directed approach utilized at Moi teaching and referral hospital (MTRH). While the factors associated with extubation failure are modifiable, its burden at MTRH remains unknown.

Objective: To establish the incidence proportion and describe factors associated with failed planned extubation at MTRH Intensive care unit (ICU)

Methods: This was a prospective observational study done at MTRH ICU. A total of 104 patients who had undergone planned extubation were enrolled through systematic sampling between March 2019 and February 2020. Once eligible patients were extubated their biodata, intubation, mechanical ventilation and extubation details were collected using interviewer administered structured questionnaire and those requiring re-intubation within 72 hours were considered to have failed extubation.

Data analysis: Continuous data was summarized as median and categorical data as frequencies and proportions. Fisher's Exact Test was used to assess associations between categorical variables and non-parametric Kruskal-Wallis Test was used for continuous independent variables. A p-value < 0.05 was considered statistically significant.

Results: About half of the participants had been admitted postoperatively and majority were neurosurgical patients. Fifty eight percent were male and the median age was 38 years. The median age for participants who had failed extubation was 66 compared to 32 years for those extubated successfully. The median severity of illness on admission measured using the Simplified Acute Physiological Score II (SAPS II) among patients who had failed extubation was 50 compared with 17 for those extubated successfully. Thirty two percent of all the participants had comorbidities and among this group, 76% had failed extubation. The Duration of ventilation was longer with a median of 10 days for those who failed compared to 4 days for those who were successfully extubated. Eighteen percent of the participants had an Arterial partial pressures of Oxygen/Fraction of inspired oxygen (PaO2/ FiO2**)** ratio <100 prior to extubation and among them 90% failed extubation. Four out of ten (39%) of all the participants had failed extubation. The factors statistically significantly associated with failed planned extubation were prolonged mechanical ventilation and a PaO2/ FiO2 ratio <100 prior to extubation.

Conclusions: Incidence proportion of failed planned extubation was 39%, a figure higher than global average. The most significant factors associated with failed planned extubation were prolonged ventilation and a PaO2/ FiO2 ratio <100 prior to extubation.

Recommendations: There is need to develop and implement standardized weaning protocols at MTRH to optimize patients' readiness for extubation.

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LIST OF ABREVIATION AND ACRONYMS

ACV	Assisted Control Ventilation
ATC	Automatic Tube Compensation
CO2	Carbon Dioxide
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
ETT	Endotracheal Tube
FiO2	Fraction of inspired oxygen
ICU	Intensive care Unit
IREC	Institutional Research Ethics Committee
LOS	Length of Stay
MTRH	Moi Teaching and Referral Hospital
NACOSTI	National Commission for Science, Technology and Innovation
NIV	Non-Invasive ventilation
PaO2	Arterial partial pressures of Oxygen
PEEP	Positive End Expiratory Pressure
PSV	Pressure Support Ventilation
RR	Respiratory Rate
RSBI	Rapid Shallow Breathing Index
SBT	Spontaneous Breathing Trial
SIMV	synchronised Intermittent Mechanical Ventilation
VAP	Ventilator Acquired Pneumonia
VILI	Ventilator Induced Lung Injury
VT	Tidal Volume

PAO2/FIO2 RATIO (P/F RATIO)	The ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired oxygen (FiO2) expressed as a fraction
SAPS II	Simplified Acute Physiology Score II

OPERATIONAL DEFINITION OF TERMS

Tracheal intubation- This is the insertion of a flexible plastic tube into the trachea to maintain an open airway or to serve as a conduit through which to administer certain drugs.

Mechanical ventilation- is artificial ventilation where mechanical means is used to assist or replace spontaneous breathing

Weaning- refers to the gradual process of preparing a patient for liberation from mechanical ventilator support.

Endotracheal extubation- Refers to the removal of an endotracheal tube from the trachea.

Planned extubation- refers to endotracheal tube removal by a physician or nurse according to a schedule or protocol.

Unplanned extubation- is defined as accidental or patient-induced endotracheal tube removal

Accidental extubation- This is a form of unplanned extubation where the endotracheal tube is inadvertently removed especially during patient manipulation and procedures.

Self extubation- This is removal of the endotracheal tube by deliberate action of the patient. It may also be referred to as patient-induced unplanned extubation.

Extubation failure- is usually defined as a need for re-intubation within 72 hours following extubation.

Pressure support ventilation- also known as **pressure support**, is a spontaneous mode of invasive ventilation. The patient initiates every breath and the ventilator delivers support with the pre-set low (5-8cmH2O) pressure value. With support from the ventilator, the patient also regulates his own respiratory rate and tidal volume.

T-piece Trial- is the disconnection of the patient from the ventilator and giving supplemental oxygen via a T-piece. T-shaped tubing connected to an endotracheal tube and is used to deliver oxygen to an intubated patient.

Tracheostomy- creation of an opening into the trachea through the neck, with insertion of an indwelling tube to facilitate ventilation and evacuation of secretions. The procedure may be an emergency measure or done electively.

Outcome- the condition of a patient at the end of therapy or a disease process, including the degree of wellness and the need for continuing care, medication, support, counselling, or education.

CHAPTER ONE: INTRODUCTION

1.1 Background

Despite advances in mechanical ventilation and respiratory support, the science of determining if the patient is ready for extubation is still not well defined and as a result the incidence of extubation failure vary from low as 2% to 25% depending on the ICU population being studied (Stawicki, 2017). Delays in weaning and extubation has been associated with increased complication rates which include Ventilator induced lung injury (VILI), ventilator associated pneumonia (VAP), and ventilator induced diaphragmatic dysfunction, higher mortality and increased hospital costs(Thille et al., 2017). On the other hand, premature discontinuation of ventilator support carries its own set of risks, including difficulty in re-establishing an airway, compromised gas exchange, aspiration, respiratory muscle fatigue and increased mortality (Zein et al, 2016).

Extubation failure is defined as a need for re-intubation within 72 hours after extubation (Thille et al., 2017). It is the inability to tolerate removal of the endotracheal tube and it is generally treated with tracheal re-intubation (Cavallone & Vannucci, 2016). In ICU patients, the impact of extubation failure and need for re-intubation on the overall outcome is often measured in terms of increased ICU and hospital length of stay and mortality (Cavallone & Vannucci, 2013). Various studies have ascertained that there is some evidence that extubation failure, re-intubation, and/or prolongation of mechanical ventilation adversely affect outcomes independently of the underlying illness severity and is associated with mortality rates as high as fifty percent (Artime & Hagberg, 2018).

Despite planning extubation through weaning process involving robust patient assessment with daily sedation holds and spontaneous breathing trials (SBT),

extubation failure has continued to be a significant challenge, with re-intubation rates remaining as high as 25%(Thille et al., 2017).This implies that a SBT alone is not the sole consideration when making the decision to extubate, and it is equally important to attempt to identify patients at a high risk of extubation failure prior to discontinuing mechanical ventilation(Glover & Glossop, 2017).

Factors associated with an increased risk of extubation failure in ICU include advanced age, prolonged duration of mechanical ventilation, anaemia, higher severity of illness, use of continuous intravenous sedation (Artime & Hagberg, 2018). Regardless of the setting, certain coexisting medical conditions may lead to difficulty at the time of extubation and may include hypoventilation disorders, neuromuscular conditions and depressed levels of consciousness, chronic respiratory or cardiovascular disorders as well as metabolic derangements among others can also complicate extubation (Miu et al., 2016). Recognition of these factors allows early identification of patients at a high risk of extubation failure and thus enables clinicians to dedicate more attention and resources to such patients during weaning and extubation to reduce the incidence of extubation failure (Cavallone & Vannucci, 2017).

Driven by the desire to reduce the duration of mechanical ventilation and consequently decreasing incidence of extubation failure, research in the recent years has focused on the use of weaning protocols and studies have shown that protocol directed weaning is safe and resulted in a shorter duration of mechanical ventilation compared with the traditional practice of physician-directed weaning (Chaiwat et al., 2010). Automated computer-driven weaning protocols have also been studied and appear to enable a more efficient weaning process than those that rely upon clinician-directed weaning protocols and are associated with improved patient outcomes as

compared with standard care (Lellouche et al., 2016). These systems may result in clinically meaningful reduced durations of mechanical ventilation, weaning and reduced rates of extubation failures. Overall, these systems appear to be safe and can be considered a reasonable approach in the management of weaning and appears to reduce the incidence failed extubation (Belliato, 2016).

At Moi Teaching and Referral Hospital ICU, the process of liberating patients from mechanical ventilation is largely dependent on the traditional practice of physician/clinician-directed weaning. This practice has been shown to prolong the duration of mechanical ventilation hence contributing to high incidence of extubation failure (Rafael et al., 2021). The recommended standard of care currently is the utilization of weaning protocols Studies have shown that protocol directed weaning is safe and resulted in a shorter duration of mechanical ventilation compared with the traditional practice of physician-directed weaning(Schmidt et al., 2017). It yields clinically meaningful reduction in the duration of mechanical ventilation and reduces incidence of extubation failures (Belliato, 2016).

1.2 Problem Statement

Failed extubation is an outcome to be avoided since it is associated with increased morbidity and mortality. In addition to immediate complications including loss of airway, airway trauma, cardiac arrest and even death, re-intubated patients have prolonged ICU length of stay which increases incidence of other complications such as ventilator associated pneumonia and ventilator induced lung injury. These patients also have greater need for tracheostomy which is not without complications. All these factors contribute to significantly higher mortality and increased cost.

Anecdotal reports indicated high incidence of failed planned extubation at MTRH ICU and that this could have been attributed to the fact that the process of weaning

patients from mechanical ventilation is largely physician/clinician-directed. This traditional standard practice when compared with protocol directed weaning has been associated higher incidence of extubation failure. With proper management of the weaning and extubation process, some of the risk factors of extubation failure can be modified hence improving extubation outcomes. In developing countries like Kenya, many challenges are encountered in managing critically ill patients and outcomes remain poor (Riviello et al., 2011).

While the general process liberation from mechanical ventilation has been widely researched and published in different parts of the world, developing countries have contributed little to this body of knowledge. In line with this, only scanty data is available on the incidence and factors associated with failed planned extubation in these patients managed in different hospitals in Kenya.

Despite the MTRH offering critical care for many years, the magnitude of failed planned extubation remains unknown. There is no data recorded or published on the incidence and factors associated with extubation failure in MTRH. This study aimed to bridge this gap.

1.3 Justification/Rationale

With the current scarcity of intensive care beds, maximising the use of limited intensive care resources is an important goal of providing care to critically ill patients (Masterson, 2015). One way to achieve this goal is to institute measures that lowers the incidence of failed extubation and its attendant complications hence reducing ICU and hospital LOS and overall health care cost.

Moi teaching and referral hospital intensive care unit (MTRH ICU) is a 21 bed mixed population unit serving as a regional centre for critical care and it is expected to lead

in provision of current evidence based care. There is an urgent need for rationalized and appropriate usage of MTRH ICU resources and decreasing extubation failure rates goes a long way as an invaluable measure to conserve this increasingly limited resource.

The magnitude of extubation failure and associated factors at MTRH ICU remained unknown, this study aimed to bridge this gap and the findings would identify target areas for critical care staff in the effort to reduce the incidence of failed planned extubation. It would also guide hospital policy improvement on management of mechanically ventilated patients.

1.4 Research Questions

i. What is the incidence of failed planned extubation at MTRH ICU?
ii. What are the factors associated with failed planned extubation at MTRH ICU?

1.5 Objectives

1.5.1 General Objective

To establish incidence and describe factors associated with failed planned extubation at MTRH ICU.

1.5.2 Specific Objectives

i. To establish the incidence proportion of failed planned extubation at MTRH ICU
ii. To describe factors associated with failed planned extubation at MTRH ICU

1.6 Conceptual Framework

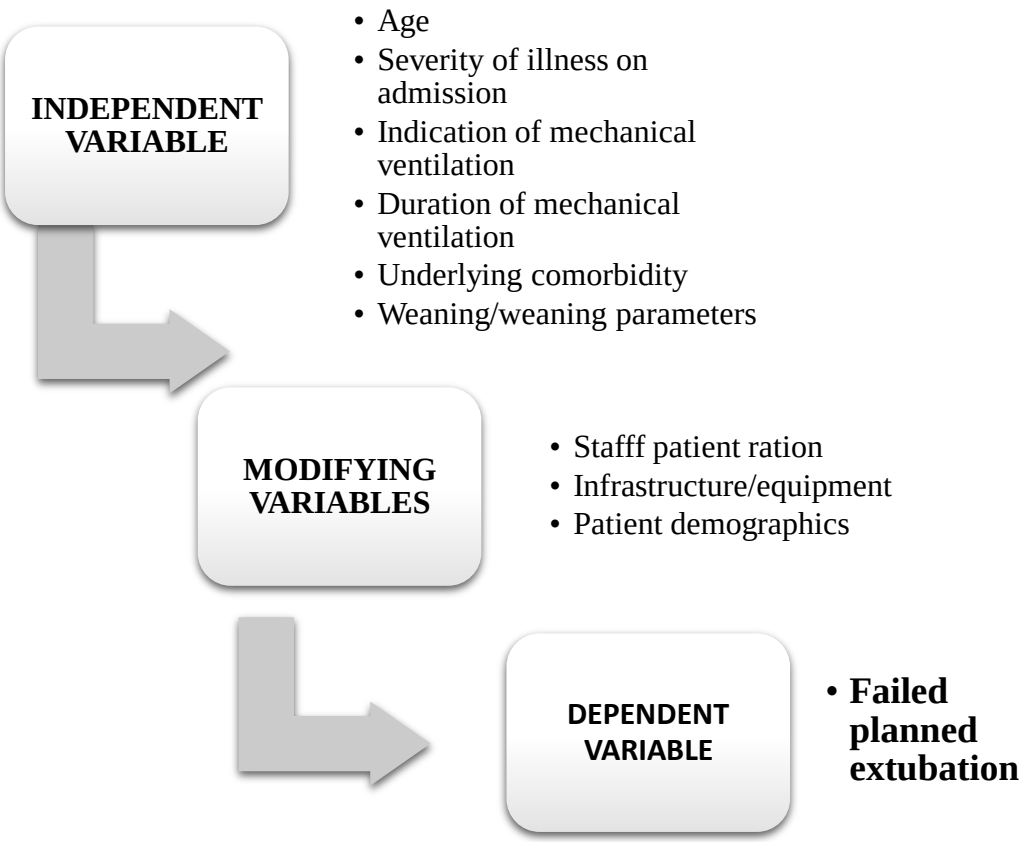

Figure 1: Conceptual Framework

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Extubation in the critical care setting is not only an important milestone for patient recovery, but also a procedure that carries a considerable risk of complication or failure. The decision to discontinue invasive mechanical ventilation involves weighing the benefits of avoiding the morbidity associated with prolonged mechanical ventilation against the risk of morbidity from extubation failure (Miu et al., 2014). Occurrence of extubation failure necessitating re-intubation varies from as low as 2% to 25% and patients who require re-intubation have been noted to have a significantly higher mortality rate (26%–50%) than those who are successfully extubated (Stawicki, 2017).

2.2 Planned Extubation

Extubation is performed by a physician, respiratory therapist or critical care nurse after a successful spontaneous breathing trial (SBT) in a patient fulfilling all weaning criteria for liberation from mechanical ventilation and represents the final step in liberation from mechanical ventilation (Zein et al., 2016). Planned extubation is the removal of the endotracheal tube according to a schedule or protocol (T. W. Lee et al., 2015).

Extubation success is the desired outcome for all mechanically ventilated patients (Ismaeil et al., 2014). Despite having successfully passed a weaning readiness test, 10-15 % of patients on average and up to 20–25 % of those at high risk may need re-intubation (Thille et al., 2013). Of greatest importance, the re-intubated patients have a higher incidence of poor outcomes with mortality rates of 26%–50%(C.-C. Lai et al., 2016). One local study done at Kenyatta National Hospital (KNH) found that the overall incidence of extubation failure in the KNH ICU was 39% while that of failure

after planned extubation was 21% (Mathangani, 2010). This value in other studies varies widely from 2 - 25% depending on the difference in study populations, medical facility types and time period used to determine extubation failure (Chang et al., 2011)

Weaning parameters such as Rapid shallow breathing index (RSBI), PaO2/FiO2 (P/F ratio) and SBT among others have been recognized as useful markers in predicting successful weaning and extubation. However, they are imperfect, and clinicians always incorporate other factors for final extubation decision (Tu et al., 2018). Some have incorporated several parameters, including thoracic compliance, arterial oxygenation, maximum occlusion pressure, and dynamic changes of these indices through the course of a SBT for differentiating patients who are successfully extubated from patients who failed extubation(Liu et al., 2015). A large scale study in Taiwan aimed at establishing predictors for successfully planned extubation, which can be followed by medical personnel and it identified three independent risk factors of extubation success after a successful SBT. These predictors included a Cuff Leak Test =2+, a Mean Expiratory Pressure of 55cmH2O or more, and an RSBI less than 68breath/min/ml. Indeed, these measures represent the patency of the upper airway, cough strength, and respiratory capacity, respectively (Lai et al., 2016).

2.2.1 Determination of Weaning and extubation readiness

Weaning is the process of decreasing the degree of ventilator support and allowing the patient to assume a greater proportion of their own ventilation ultimately resulting in a patient breathing spontaneously and being extubated (Zhou et al., 2020). This process can be achieved rapidly in about 80% of patients when the original cause of the respiratory failure has improved. The remaining cases will require a more gradual method of withdrawing ventilation(Zhou et al., 2020).

Liberation from mechanical ventilation is an important process in recovery of critically ill patients in the intensive care unit. It is a three-step process, consisting of readiness testing, weaning, and extubation. Patients who wean successfully have less morbidity and mortality and use fewer resources than patients who require prolonged mechanical ventilation (Rafael et al., 2021).

The goal of readiness testing is to identify patients who are to wean from mechanical ventilation. Identifying those who are ready to wean avoids unnecessary mechanical ventilation and thereby, also avoids the risk of death and complications related to mechanical ventilation. Similarly, identifying patients who are not ready to wean protects patients from the risks of premature weaning and extubation hence reducing odds of failure(Zhou et al., 2020).

According to the American Thoracic Society (ATS)/American College of Chest Physicians (ACCP)/ American College of Critical Care Medicine (ACCM) 2017 evidence based practice guidelines on weaning and discontinuation of mechanical ventilation , some of the objective parameters used in determining whether a patient is able to come off the ventilator include the following (Schmidt et al., 2017);

a) The cause of the respiratory failure has improved
b) PaO2 /FiO2 ratio >150-200
c) Level of positive end expiratory pressure (PEEP) 5-8 cmH2O
d) FiO2 level <50%
e) pH > 7.25; 7.25
f) Ability to initiate spontaneous breaths.

Some of the subjective parameters used in determining the ability to liberate from mechanical ventilation include(Schmidt et al., 2017);

a) Hemodynamic stability
b) Absence of active myocardial ischemia
c) Absence of clinically significant, vasopressor-requiring hypotension
d) Mental status awake and alert or easily reusable
e) Adequate muscular strength allowing the capability to initiate/sustain the respiratory effort.

2.2.2 Weaning Protocols

Driven by the desire to reduce the duration of weaning from mechanical ventilation and consequently decreasing incidence of extubation failure, research in the recent years has focused on the use of weaning protocols and studies have shown that protocol directed weaning is safe and resulted in a shorter duration of mechanical ventilation compared with the traditional practice of physician-directed weaning(Rose et al., 2014). Automated computer-driven weaning protocols have also been studied and appear to enable a more efficient weaning process than those that rely upon clinician-directed weaning protocols and are associated with improved patient outcomes as compared with standard care (Lellouche et al., 2016). These systems may result in clinically meaningful reduced durations of mechanical ventilation, weaning and reduced rates of extubation failures. Overall, these systems appear to be safe and can be considered a reasonable approach in the management of weaning and appears to reduce rates of failed extubation (Belliato, 2016).

Protocols are institution specific but follow same general principle and are written with sufficient detail that different clinicians with various clinical expertise will arrive

at the same decision for the same clinical scenario (Schmidt et al., 2017). The common focus for weaning protocols include the following:

a) Daily assessment for liberation potential based on a criteria that includes: evidence of reversal of the underlying cause of respiratory failure, adequate oxygenation on PEEP <8 and FiO2 <0.50, hemodynamic stability, and ability to initiate an inspiratory effort among others.
b) Once a patient meets the liberation criteria, a spontaneous breathing trial (SBT) should be conducted before determining whether extubation can occur. Generally, the SBT should last 30-120 minutes.
c) SBT is conducted while the patient is undergoing a sedation awakening trial (SAT). Conducting the SBT while the patient is minimally sedated has been associated with improved outcomes, including reduced incidence of extubation failure.
d) Generally, if the patient fails the SBT, he should be placed back on previous settings or a comfortable level of pressure support and reassessed the following day for liberation potential.
e) Cuff leak test is performed prior to extubation in patients who have met extubation criteria and are deemed high risk for post-extubation stridor (PES).If there is insufficient leak (failed test), it is recommended that systemic steroids be administered at least 4 hours before extubation. A repeat cuff leak test prior to extubation is not required.
f) Prophylactic NIV post-extubation for patients ventilated for >24 hours who pass an SBT and are at high risk for extubation failure (e.g., patient with hypercarbia, COPD, CHF, or other co-morbidities) is recommended. It should be applied immediately after extubation to realize outcome benefits.

A manual protocol is one where, following a daily assessment of readiness to wean, healthcare staff manually alter the ventilator settings so that the patient undergoes a weaning trial as described above. Such protocols are usually respiratory therapist or nursing-driven. While effective, manual protocols are labor-intensive and compliance can be challenging, especially in a busy environment(Ouellette et al., 2017).

Automated systems use proprietary, computerized, closed loop weaning software packages that automate weaning by pressure support (Nugent & Edriss, 2017). Once the patient is deemed ready for weaning by ICU staff, the automated weaning program adjusts levels of pressure support during the weaning trial to keep the patient in a normal range of intermittently-monitored respiratory rate, tidal volume, and exhaled carbon dioxide. Once the patient is stable at a specific level of pressure support, the program automatically reduces the pressure support level and reassesses respiratory stability(Nitta et al., 2019).

2.3 Unplanned Extubation

Unplanned extubation is defined as accidental or patient-induced premature endotracheal tube removal and occurs in 3%–22% of patients on mechanical ventilation(T. W. Lee et al., 2015). Accidental extubations occur when patients are moved or manipulated during procedures such as during a nursing intervention, radiographic taking, removal of secretions and coughing whereas patient induced extubations occur when the patient deliberately pulls out the endotracheal tube. Reasons for self-extubation include discomfort or pain caused by the artificial airway, and anxiety due to patients' inability to talk or breathe on their own(Yeh et al., 2004).

Unplanned extubation is a potentially serious accident since in the acute setting about 31–78% of cases requires reintubation and/or is complicated by laryngeal or vocal cord trauma due to removal of the tube with the cuff still inflated, bleeding, prolonged

respiratory distress, respiratory arrest, arrhythmias, hypotension, emesis with possible bronchial aspiration and difficulty in reintubation or even death (J.-H. Lee et al., 2014). Locally however the rates for reintubation were significantly higher at 93% (Mathangani, 2010). Studies have shown a higher mortality for patients with failed unplanned extubation 28–51% as compared to those who have successfully tolerated the unplanned extubation 0–12% (Ismaeil et al., 2014). Unplanned extubation may have detrimental effects on patient outcomes because of the higher risk of extubation failure, which is known to be associated with a poor clinical prognosis when compared with planned extubation (Cavallone & Vannucci, 2013). These unfavourable outcomes include prolonged duration of mechanical ventilation following reintubation, longer ICU and Hospital length of stay (Thille et al., 2011). A higher rate of nosocomial pneumonia has also been documented both after unplanned extubation and after reintubation (Peñuelas et al., 2015). It is however notable that patients who did not need reintubation after an unplanned extubation have shorter length of ICU stay and hospital stay, shorter duration of total intubation time, and less ICU and hospital mortality compared with mechanically ventilated controls and unplanned extubation patients who required reintubation (Chuang et al., 2015).

Various factors have been associated with increased risk for unplanned extubation. Increased levels consciousness associated with restlessness and agitation has been identified as a risk factor for unplanned extubation(Chao et al., 2017). The role of sedatives in preventing unplanned extubation remains unclear. Studies have shown that more than half of patients were sedated at the time of unplanned extubation, suggesting inadequate sedation(Singh et al., 2013). Some studies have particularly associated the use of benzodiazepines, especially midazolam, with an increased occurrence of unplanned extubations. Although a paradoxical excitatory effect or

delirium associated with midazolam has been identified as a probable explanations for this finding(Paulo Sergio Lucas Da Silva & Fonseca, 2012). Physical restraints have been historically used to prevent self-extubation; however, it actually appears to be associated with self-extubation. Studies have reported that 65% of patients who self-extubated were restrained either at the time of self-extubation or within 24 hours of self-extubation (Selvan et al., 2014).

There are any number of ways to secure an endotracheal tube, the two most widely used methods of securing the endotracheal are the use of waterproof tape around the tube, upper lip, and face and secu1ring the endotracheal tube via a cloth or Velcro/gauze tie around the back of the head(Shimizu et al., 2011). Various studies have shown that securing the endotracheal tube using adhesive tape was superior in preventing unplanned extubations and maintaining oral mucosa and facial skin integrity(Carlson et al., 2007). In fact, standardizing the method for securing the endotracheal tube (twill tape method) in studies involving quality improvement programs reduced the incidence of endotracheal tube displacement(Schroeder et al., 2017).

Unplanned extubation is considered a marker of poor quality of care and understanding the factors associated with unplanned extubation is crucial for identifying patients at risk of this complication and thus for developing interventions to reduce the frequency of this complication(Endo et al., 2012). Some aspects such as the use of weaning protocols, adoption of sedation protocols, improving nurse workload and standardization of procedures such as the method of securing the endotracheal tube and the use of hand restraints have been reported to be useful in reducing the incidence of unplanned extubation (Kwon & Choi, 2017).

2.4 Extubation failure

Extubation success defined as the ability to sustain spontaneous breathing without the need for reintubation while extubation failure is defined as a need for re-intubation within hours to days after extubation (Ismaeil et al., 2014). It is the inability to tolerate removal of the endotracheal tube and it is commonly treated with tracheal re-intubation (Cavallone & Vannucci, 2013).There is lack of consensus on the time interval used in the definition and it ranges from 48- 72 hours and some authors have extended this period to one week (Thille et al 2017). In this study, extubation failure was defined as the need for re-intubation within 72 hours after extubation. This informed by the fact that in ICU re-intubation after extubation failure usually occurs within 2 hours of extubation and rarely after 24 hour (Artime & Hagberg, 2014).

2.4.1 Incidence of extubation failure

Determining if a patient is ready for extubation is one of most challenging decision made daily in the ICU and despite continuing research, the optimal timing of extubation is still not well defined and as a result, the incidence of extubation failure necessitating re-intubation vary from as low as 2% to 25% depending on the ICU population being studied, study design, and the different inclusion criteria (Stawicki, 2017). This wide variation could also be explained in part because of differences in the severity of illness as well indications for mechanical ventilation for the patients studied, the duration of mechanical ventilation prior to planned extubation, and the interventions that were instituted. Medical, pediatric, and multidisciplinary ICU (such as MTRH ICU), patients have the highest incidence of extubation failure. Another factor associated with higher re-intubation rates is the presence of comorbid conditions and comorbid congestive heart failure (CHF) is frequently associated with higher rates of extubation failure this is attributable to the abrupt burden to the

cardiovascular system resulting from the transition to spontaneous breathing in patients with poor cardiovascular reserves. Among patients admitted post-operatively to the ICU, higher extubation failure rates have been reported in neurosurgical patients higher extubation failure rates 33% (Godet et al., 2017). ICU physician staffing and nurse-to-patient ratios also have been shown to influence reintubation rates and specifically the recommended critical care nurse to patient ratio is 1:1 (Schmidt et al., 2017).

Some studies have described an average extubation failure rate to be 8-15% in most well run speciality ICUs and a target of 0% may be unrealistic and often could lead to prolongation of mechanical ventilation (Krinsley et al., 2012). Other authors suggest an optimal rate of 5–10%, however, this suggestion has not undergone a rigorous review and remains controversial (Rafael et al., 2021). It would seem reasonable that the optimal rate should be determined based on weighing the adverse outcomes and economic cost of extubation failure and those associated with delayed extubation (Rafael et al., 2021).

One local study done at Kenyatta National Hospital (KNH) found that the overall incidence of extubation failure in the KNH ICU was 39% while that of failure after planned extubation was 21% (Mathangani, 2010). Another study in the same institution demonstrated that specific sub-groups of patients had higher incidence of extubation failure and they included male gender with a failure rate of 50%, paediatric patients 70% and neurosurgical patients 67% (Ayala et al., 2015). Another study sought to establish extubation failure rates specially in neurosurgical patients and demonstrated a significantly failure rate of 37.5% (Gitonga, 2020).

2.4.2 Outcomes of extubation failure and re-intubation

Regardless of the strategy of weaning from mechanical ventilation employed in the ICU, early identification of patients capable of breathing spontaneously is associated with better clinical outcomes following extubation (Thille et al 2017).

Extubation failure can occur following successful weaning and planned extubation as well as a consequence of unplanned extubation. Post extubation respiratory failure after elective discontinuation of mechanical ventilation is a common event associated with significant morbidity and mortality (Thille et al 2017). Reintubation, which occurs in 10% to 25% within 48 to 72 hours after planned extubation, is a relevant consequence of respiratory failure after extubation(C.-C. Lai et al., 2016). Unplanned extubations account for approximately 10% (range, 3% to 16%) of extubations and require reintubation in 35% to 75% of the cases. A high "success" rate is attributable to delayed weaning process suggesting that mechanical ventilation could be unduly prolonged in a minority of the self extubating patients whereas high failure rate may be attributed to accidental unplanned extubations and that consistently require reintubation(Thille et al., 2017).

Other complications experienced acutely following extubation may include post extubation stridor (PES), laboured breathing, desaturation, hypoxia, Hypercapnea, aspiration, hypotension, cardiac arrest and even death. Some of these complications may be overcome by instituting measures such as Non-invasive ventilation and high flow nasal oxygen therapy (HFNOT) while others may contribute to extubation failure.

Patients who require reintubation have been noted to have a significantly higher mortality rate (26%–50%) than those who are successfully extubated on the first attempt.

In addition, unsuccessful extubation significantly prolongs the duration of mechanical ventilation with its attendant complications, lengthens ICU and hospital stay and causes greater need for tracheostomy(Chen et al., 2018) . All these factors contribute to higher healthcare costs(Chen et al., 2018).

2.5 Factors associated with extubation failure

Several studies investigated the possible risk factors for extubation failure. The strongest predictors of planned extubation failure were upper airway obstruction, inability to clear abundant secretions , ineffective cough, duration of mechanical ventilation longer than 1 week prior to extubation, general disease severity, primary reason for intubation, and severe systolic LV dysfunction (Ornico et al., 2013). Other factors include neurologic disorders, use of continuous sedation and anaemia. Patients older than 65 years and those with an underlying chronic cardiac or respiratory disease are also at risk for extubation failure. Some additional factors are delirium causing altered mental status, ICU-acquired paresis affecting both peripheral and respiratory muscles leading to delayed extubation. Higher extubation failure rates have also been reported in patients intubated for heart failure or having positive fluid balance the day before extubation (Thille et al., 2017)

2.5.1 Indication for mechanical ventilation

Intensive care has been defined as “a service for patients with potentially recoverable conditions who can benefit from more detailed observation and invasive treatment than can safely be provided in general wards or high dependency areas.” It is usually

reserved for patients with potential or established organ failure (Schmidt et al., 2017). The most commonly supported organ is the lung, but facilities should also exist for the diagnosis, prevention, and treatment of other organ dysfunction.The need for ventilatory support is one of the commonest indications for admission to the ICU (Ramachandra Bhat et al., 2013). The indications for mechanical ventilation are varied and have traditionally been grouped into hypoxic and hypercapnic respiratory failures (Silva et al., 2009). Some conditions that predispose to respiratory failure include respiratory distress, airway obstruction, reduced or poor respiratory drive, abnormal chest wall and respiratory muscle fatigue (Tobi et al., 2017). It must be noted however that the primary indication for ventilatory support must be reversible to allow for early weaning and extubation and outcomes depend not only on the indication for mechanical ventilation, but also on development of complications and patient management in the ICU (Anzueto et al., 2012). Clear criteria may help to identify those at risk and to trigger a call for help from intensive care staff. Early transfer to ICU improves the chances of recovery, reduces the potential for organ dysfunction (both extent and number), may reduce length of stay in intensive care and hospital, and may reduce the costs of intensive care (Tobi et al., 2017)..

2.5.2 Duration of mechanical ventilation

Mechanical ventilation is a life-saving intervention, but it is also associated with complications. Therefore, it is desirable to liberate patients from mechanical ventilation as soon as the underlying cause that led to the mechanical ventilation has sufficiently improved and the patient is able to sustain spontaneous breathing and adequate gas exchange (Ouellette et al., 2017). Many advances have been made regarding the optimal methods of early weaning and extubation because mechanical ventilation is not without complications (Rose, 2015). Delays in this process has been

associated with increased complication rates, higher incidence of extubation failure, higher mortality and increased hospital costs (Thille et al., 2017). On the other hand, premature discontinuation of ventilator support carries its own set of risks, including extubation failure with difficulty in re-establishing an airway, compromised gas exchange, aspiration, respiratory muscle fatigue and increased mortality (Zein et al, 2016). Premature discontinuation of mechanical ventilation contributes to increased incidence of failed extubation, nosocomial pneumonia, or increased mortality (Chaiwat et al., 2010). Therefore timing of extubation involves weighing the benefits of avoiding the morbidity associated with prolonged mechanical ventilation against the risk of morbidity from extubation failure (Miu et al., 2014). This association between longer duration of ventilation and higher incidence of extubation failure as been attributed the combination of complete diaphragmatic inactivity and mechanical ventilation results in atrophy of diaphragm myofibers (Ouellette et al., 2017). Such atrophy has been reported even after only 18 hours of mechanical ventilation (Rose, 2015). The longer the duration of mechanical ventilation, the higher the risk of ventilator-associated complications which further compound the problem and lowers the chance of success in weaning and extubation (Ouellette et al., 2017).

The standard physician/clinician dependent weaning has been shown to prolong duration of mechanical ventilation when compared with the use of weaning protocols which helps optimize patient's readiness for extubation (Schmidt et al., 2017). Many studies have demonstrated that when compared with the standard physician/clinician directed weaning, Protocolized weaning resulted in shorter duration of ventilation and lower incidence of extubation failure. Multiple Clinical Practice Guidelines (CPGs) have endorsed the concept of a ventilator liberation protocol, most recently the American Thoracic Society/American College of Chest Physicians 2017 CPG on

liberation from mechanical ventilation in critically ill adults (Schmidt et al., 2017). They reviewed seventeen trials that compared weaning protocols with traditional physician-directed practice among critically ill adults. It was demonstrated that duration of mechanical ventilation was reduced by up to 25 hours and ICU stay was reduced by one day among patients whose readiness for extubation was assessed with a ventilator weaning protocol (Schmidt et al., 2017)

However, it should also be noted that patient factors could contribute to longer duration of ventilation and the associated higher incidence of extubation failure. Higher extubation failure rates are frequently reported in some subsets of patients. Thirty to 40% of traumatic brain injury (TBI) patients admitted to ICU postoperatively ultimately fail extubation and this has been attributed to longer durations of ventilation the often required (Godet et al., 2017). A Kenyan study done at Kenyatta National Hospital sought to establish extubation failure rates specially in neurosurgical patients and demonstrated a failure rate of 37.5% (Gitonga, 2020). Another patient factor that could contribute to longer duration of ventilation and high incidence of extubation failure is greater severity of illness which is often associated higher rates of complications and longer duration of ventilation. Adherence to ICU admission criteria has been shown to aid in prioritization of patients and avoid frequent admission of patients that were too sick to benefit (Thille et al., 2017). However this remains controversial because triage decisions can give rise to conflicts between the ethical principles of fairness in the distribution of limited resources and obligations to individual patients (Thille et al., 2017).

2.5.3 Weaning

Successful weaning and liberation from mechanical ventilation remain critical stages of a patient's intensive care unit (ICU) stay. The standard test for extubation readiness is the spontaneous breathing trial (SBT). It is often performed to assess the patient's ability to breathe while receiving minimal or no ventilator support (Thille et al, 2017).Tolerance of a spontaneous breathing trial is an evidence-based strategy to predict successful weaning from mechanical ventilation (Zein et al, 2016). These trials have traditionally been performed while the patient receives varying levels of ventilator support, including, continuous positive airway pressure (CPAP), a T-tube circuit or low-level pressure support ventilation (PSV) (Cohen et al., 2009). There is no current evidence suggesting that one of these approaches is superior to the others. Few randomized studies have evaluated the best technique for performing SBT before extubation and there is no clinical evidence of a higher reintubation risk between these methods (Rose, 2015).

Driven by the desire to reduce the duration of weaning from mechanical ventilation research, in the recent years has focused on the use of weaning protocols and studies have shown that protocol directed weaning is safe and resulted in a shorter duration of mechanical ventilation compared with the traditional practice of physician-directed weaning (Chaiwat et al., 2010). Automated computer-driven weaning protocols have been studied and appear to enable a more efficient weaning process than those that rely upon clinician-directed weaning protocols and are associated with improved patient outcomes as compared with standard care (Lellouche et al., 2006). These systems may result in clinically meaningful reduced durations of mechanical ventilation, weaning and reduced rates of extubation failures. Overall, these systems

appear to be safe and can be considered a reasonable approach in the management of weaning and appears to reduce rates of failed extubation (Belliato, 2016).

Several weaning parameters have undergone assessment and use in clinical studies and they are helpful when taken into account with the overall clinical picture, but they are not very sensitive or specific when considered individually (Thille et al., 2016). One of such weaning parameters examined in this study was the PaO2/FiO2 (P/F) ratio defined as the ratio between arterial oxygen partial pressure (PaO_2) and the fraction of inspired oxygen (FiO_2). The severity of the acute respiratory distress is defined by the degree of hypoxemia, which is calculated as the ratio of arterial oxygen tension to fraction of inspired oxygen (P/F). It can be mild (P/F 200-300), moderate (P/F 100-199) or severe P/F < 100) as clarified by the Berlin definition of Acute Respiratory Distress Syndrome (ARDS) (Ranieri et al., 2012) .Progressive hypoxemia after extubation is frequently associated with failed extubation and might be predicted prior to extubation by a reduced P/F ratio (Nitta et al., 2019). According to critical care societal evidence based practice guidelines on weaning and discontinuation of mechanical ventilation , some of the objective parameters used in determining whether a patient is able to come off the ventilator include among others a PaO2 /FiO2 ratio >150-200 (Ranieri et al., 2012.

Another significant weaning parameter is the Rapid shallow breathing index (RSBI). Yang and Tobin described RSBI as the ratio of respiratory rate (RR) to tidal volume (VT), with a threshold value of >105 breaths/min/L being highly predictive of weaning failure, while RSBI <105 breaths/min/L is associated with weaning success. In this study, majority of the participants had RSBI value of less than a hundred and five 60 (57.7%).

Successful weaning cannot be achieved without optimizing sedation and limiting the use of paralytics. Protocolized targeted sedation or daily sedative interruption have been associated with shorter duration of MV in both medical and surgical patients in comparison with no protocols (Jung et al., 2020), and are currently recommended by international guidelines (Ouellette et al., 2017).

2.5.4 Age

Elderly patients with critical illness often have significant functional limitations, and studies indicate that advanced age is a risk factor for ICU death(Carson, 2003). Ely et al 2013 showed that mechanically ventilated patients ≥70 years of age with acute lung injuries had mortality rates nearly twice those of younger patients. Compared to a younger age group (less than 70 years old) matched for severity of illness, inability to handle secretions was the most common reason of airway causes leading to extubation failure in the elderly while upper airway obstruction was the predominant cause in the control group (Lai et al., 2016). As for non-airway causes, COPD related hypercapnic respiratory failure accounted for the majority of cases in both groups. After adjusting for severity of illness, elderly patients who required reintubation had a higher risk of developing nosocomial pneumonia (Lai et al., 2016).

Occurrence of unplanned extubation is of concern primarily in paediatric patients on mechanical ventilation. It accounts for 3% to 14% incidents per 100 ventilation days in paediatric intensive care unit (PICU) in hospitals worldwide (Loughead et al., 2008). Paediatric patients are particularly at high risk for unplanned extubation due to their short tracheal length, the use of uncuffed endotracheal tubes and their developmental immaturity often limit their cooperation with health workers (Seikgato Getrude Molekoa, 2015). Unplanned extubations often leads to emergent, less-controlled endotracheal reintubation. Repeated intubations, especially those

performed as an emergency, increase the risk of laryngeal or tracheal injury and scarring, pulmonary injury from excessive ventilation, and ventilator-associated pneumonia (Paulo Sérgio Lucas da Silva et al., 2017). Improvements in routine practice have primarily targeted inadequate sedation, ineffective restraint, and insecure tube fixation (Loughead et al., 2008).

2.5.5 Severity of illness on admission

Severity of illness on admission to ICU has not only been associated with prolongation of duration of mechanical ventilation, weaning and extubation failure but also increased ICU mortality rates(C.-C. Lai et al., 2016). Illness severity scoring systems (SSs) are used to provide information about the patients' severity of illness, to facilitate resource allocation, for comparing outcomes in different Intensive Care Units (ICUs) and to predict possible patient outcomes in terms of mortality and ICU/hospital length of stay (LOS)(Bansal et al., 2017). Scoring systems must only be used with understanding of their limitations and users must be cognizant that no scoring system is ideal(Bansal et al., 2017). These systems can be broadly divided into those that are specific for an organ or disease (for example, the Glasgow Coma Scale (GCS)) and those that are generic for all ICU patients(Vincent & Moreno, 2010)(Bouch & Thompson, 2008) Most critical care severity scores are calculated from the data obtained on the first day of ICU admission [e.g. the APACHE, the SAPS, and the mortality prediction model (MPM)]. Other scoring systems are repetitive and collect data sequentially throughout the duration of ICU stay or over the first few days. Examples of repetitive systems are the Sequential Organ Failure score (SOFA) and Multiple Organ dysfunction Score (MODS)

Simplified Acute Physiologic Score (SAPS II) is among other scoring models in this field, proposed by Le Gall et al. This model consists of 17 variables including 12

physiologic factors, age, type of admission, and 3 variables regarding underlying diseases (Vincent & Moreno, 2010). The SAPS II score was validated using data from consecutive admissions to 137 ICUs in 12 countries (Jean-Roger Le Gall,Stanley Lemeshow, Fabienne Saulnier, 1993) Predictive value of this model has been confirmed in different clinical conditions Dysfunction Score (Aminiahidashti et al., 2017).

SAPS II was applied in this study to estimate severity of illness on admission. This is informed be the fact that the variables included in this scoring system are readily available within 24 hours of admission and these can be done at no extra cost to the patient. SAPS II score provides reliable prediction of mortality without having to specify a primary diagnosis. The variables in SAPS II score are readily available. No special venous or arterial blood samples are required. Calculation of the score is simple and rapid (Prakash et al., 2006)

2.5.6 Underlying comorbidity

Chronic comorbid medical conditions are common in critically ill patients and may influence the acute illness, the types and intensity of care delivered, and outcomes in the intensive care unit(Esper & Martin, 2011). With the increases in the aging population and patients with multiple comorbidities, more patients will require invasive mechanical ventilator for management of acute respiratory failure(Chen et al., 2018). Although many of these patients may survive through the acute stage of critical illness, approximately 3–13% experience difficulty weaning and extubation and thus require prolonged mechanical ventilation(PMV; the use of MV for at least 21 days)(C. Lai et al., 2016). Some of the common chronic comorbid conditions encountered in ICU population include Diabetes Mellitus, COPD, cancer, end-stage renal disease, end-stage liver disease, HIV, and obesity and they associated with a

significant impact on the course of critical illness, complications, and outcomes(Mackay et al., 2014).

2.5.7 Means of restraint

Chemical and physical restraints are frequently used in the intensive care unit (ICU) to control agitated patients and to prevent self-harm and unplanned extubations(Chuang et al., 2015). Adequate sedation, a chemical form of restraint, has been proposed to decrease the incidence of unplanned extubation(Trivedi et al., 2014). However continuous intravenous sedation has been associated with prolonged duration of mechanical ventilation and sedation minimization strategies, including protocalized sedation, have been demonstrated to reduce incidence of extubation failure by significantly shortening duration of ventilation. They have also been shown to decrease ICU and hospital length of stay (Shehabi et al., 2013).

Physical restraints have been historically used to prevent self-extubation; however, it actually appears to be associated with self-extubation. Studies have reported that 65% of patients who self-extubated were restrained either at the time of self-extubation or within 24 hours of self-extubation(Selvan et al., 2014).This is compounded by the fact that restraints are often used with agitated or delirious patients, whose risk for self-extubation is already increased.

Self-extubation has the potential to damage the larynx and cause severe airway complications due to removing the tube with the cuff still inflated. Hypotension, arrhythmias, bronchospasm, aspiration, and laryngeal bleeding or oedema can also occur. In addition, up to 20% of patients have a difficult re-intubation following self-extubation (Selvan et al., 2014).

2.5.8 Timing of extubation

Following successful weaning trials, extubation should occur as soon as possible to prevent known complications of mechanical ventilation such as pneumonia, which occurs in up to 28% of ventilated patients (Peberdy et al., 2008). Increased time of mechanical ventilation also increases the incidence of complications such as extubation failure and also lengthen ICU stay. However, there is concern that better outcomes observed for medical procedures conducted during the day might also apply to extubation (Tischenkel et al., 2014). It has been observed that ICU patients extubated at night may have higher likelihood of reintubation, increased LOS, or increased mortality compared to those extubated during the day and this largely related to staffing variations at night leading to increased risk of medical errors at night (Mohammed & Ali, 2018).

The incidence of self-extubation particularly is higher during the night shift (76%), which could reflect a higher risk for patient delirium at night or decreased patient surveillance(Biehl, Sloan, Malinchoc, & Gajic, 2012). The effect of decreased patient surveillance on self-extubation is also demonstrated by the higher an frequency of self-extubations occurring within the hour before and after shift changes, when patients are often monitored less. In a in tertiary care ICU in Egypt, Mohammed and his colleagues reported that self-extubation during shift changes between 7:00 am and 8:30 am and 7:00 pm and 8:30 pm accounted for almost 50% of the self-extubations in over a one year period (Mohammed, 2018)

2.6 Post extubation care

Ten to 15% of patients have been demonstrated to need reintubation within 72 hours after extubation. Standard oxygen therapy is routinely used in low risk patients with no or few extubation failure risk factors. On the other hand, in high-risk patients, the combination of high-dose non-invasive ventilation (NIV) with high-flow nasal oxygen (HFNO) is associated with less reintubation in comparison with HFNO alone. In low- to moderate-risk patients, prophylactic HFNO has been associated with a lower rate of reintubation than standard oxygen therapy in medical but not surgical patients. Likewise, HFNO is probably not inferior to NIV alone in preventing post-extubation respiratory failure and may be considered as a first-line prophylactic respiratory support option in patients with a moderate risk of weaning failure. In expert centres, NIV may also be used as a weaning strategy in patients who failed the SBT, as a way to provide positive pressure without the side effects of the tracheal tube and sedation.

2.6.1 Non -Invasive ventilation

Non-invasive ventilation (NIV) refers to the administration of ventilator support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of non-invasive ventilation has markedly increased over the last few decades, and it has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in the critical care unit (Ferrer, Sellares, & Torres, 2014). Non-invasive ventilation in some appropriate clinical situations has been used as a replacement for invasive ventilation, and its flexibility also allows it to be a valuable complement in patient management. Its use in acute respiratory failure is well accepted and widespread. The role of non-invasive

ventilation in those with chronic respiratory failure is not as clear and remains to be defined (Guy W Soo Hoo, MD, 2017).

Non-invasive ventilation has been recently applied as an adjunct therapy to weaning from mechanical ventilation and can be used as a preventive measure to all extubated patients, or as a rescue therapy for patients who develop post-extubation acute respiratory failure, the main goal decrease the duration of mechanical ventilation and to prevent or avoid reintubation and subsequent complications (Girault et al., 2011). It is an effective modality particularly for patients with chronic obstructive pulmonary disease (COPD), early non-invasive ventilation weaning is associated with the decrease of mortality, ventilator-associated pneumonia, length of stay in the intensive care unit and hospital, total duration of mechanical ventilation, and duration of invasive ventilation (Ornico et al., 2013b). Studies have also demonstrated that non-invasive ventilation, if used immediately after planned extubation, reduced the reintubation rate in mixed ICU patients with respiratory failure in need of mechanical ventilation for more than 72 hours (Kea et al., 2010). Therefore experience to date suggests that non-invasive ventilation can help facilitate weaning and discontinuation of mechanical ventilation in selected patients. Patients with underlying hypercapnic acute respiratory failure like those with COPD are the best candidates, but other groups may also benefit from an early-extubation approach followed by noninvasive ventilation support. COPD patients who develop respiratory distress after meeting criteria for extubation are most likely to benefit from noninvasive ventilation, but this is not established and use of noninvasive ventilation in these patients as well as any other patient who develops post-extubation respiratory distress (ARF)should be done with caution(Zhou et al., 2020).

Recently, however, in selected patients recovering from hypoxemic ARF, the application of NIV, immediately after early extubation, demonstrated to reduce the length of invasive mechanical ventilation, as opposed to standard weaning (Cammarota et al., 2021). Retrospective studies have suggested that COVID-19 patients may also benefit of this approach to weaning. In these COVID-19 patients early extubation followed by NIV was able to significantly decrease the rate of extubation failure and reintubation, compared to standard weaning (Cammarota et al., 2021).

2.6.2 High Flow Nasal Oxygen Therapy (HFNOT)

HFNOT has been available for over a decade, but refinements and increasing clinical experience have made it a solid alternative for management that exists in the spectrum of options before noninvasive and invasive mechanical ventilation (Park et al., 2015). This modality was initially developed for neonatal patients, and refinements have permitted its use in adults. Conventional oxygen therapy is not well tolerated at high flow rates because of problems with unheated and non-humidified oxygen (Ischaki et al., 2017). The high-flow nasal cannula oxygen systems are able to heat and humidity, improving patient tolerance and comfort. HFNOT is increasingly used as part of both ward-based and critical care management of respiratory failure (Gonzalo et al., 2016). Respiratory failure is distressing for patients and treatment modalities currently in use may be associated with discomfort from upper airway drying, tightly fitting facemasks, and resultant complications such as skin breakdown. Invasive ventilation is also associated with a number of complications including ventilator-associated pneumonia (Ni et al., 2017).

This system basically works with an air oxygen blender allowing delivery of FiO2 of 21% to 100% and generates up to 60L/min flow rates (Edic et al., 2016). The gas is

heated and humidified through an active heated humidifier and delivered via a single limb heated inspiratory circuit (to avoid heat loss and condensation) to the patient through nasal cannula of large diameter, the ‘‘high flow nasal cannulas’’ (Schwabbauer et al., 2014). HFNOT now not only allows constant FiO2 during peak inspiratory flow but also confers benefits such as a low level of continuous positive airway pressure with increased end-expiratory lung volume and reduced work of breathing, partly through intrinsic positive end-expiration pressure compensation and dead space washout (Parke & McGuinness, 2013). The inspired gases are warmed and humidified, improving comfort and possibly reducing airway inflammation, leading to improved drainage of respiratory secretions.

Oxygenation and ventilation impairment after extubation is frequent. Post-extubation respiratory management aims to decrease the risk of early acute respiratory failure and reintubation, which is associated with a poor prognosis. The use of HFNOT in Post-extubation period in the ICU has been studied and compared to conventional oxygen therapy the application of HFNOT achieved a higher success rate of oxygen therapy within 24 hour (Song, Gu, Xiu, Cu i, & Ii, 2014). HFNOT is a well-tolerated and an effective device for oxygen therapy in mild to moderate hypoxic respiratory failure and bridges the gap between conventional oxygen applicators, NIV, and invasive mechanical ventilation (Schwabbauer et al., 2014). However the indications and contraindications for HFNC have to be further clarified in additional clinical outcome studies (Song et al., 2014).

CHAPTER THREE: MATERIAL AND METHODS

3.1 Design

This was a prospective observational study. Once eligible patients were extubated, their biodata, intubation, mechanical ventilation and extubation details were collected using interviewer administered structured questionnaire. These patients were then followed up for a period of 72 hours and those who required re-intubation within this period were considered to failed extubation.

3.2 Study site

The study was conducted in the intensive care unit of Moi Teaching and Referral Hospital located in Eldoret town, Uasin-Gishu County. It is a National referral Hospital with a bed capacity of 1000. It has a 21 bed mixed/general population Intensive Care Unit and as such it serves a variety of patients including paediatrics, surgical and medical among others. The hospital has a catchment population of 13 to 15 million people from over 15 counties in the Rift valley and western part of Kenya forming about 40% of the Kenyan population (Tenge et al, 2009). It also receives referrals from neighbouring countries particularly Uganda and South Sudan. A significant proportion of the referrals from the counties are critically ill patients requiring ICU care.

3.3 Study population

The study population consisted of patients who had undergone planned extubation between March 2019 and February 2020. MTRH ICU is a mixed population unit and therefore subjects of the study included adults as well as children with varied diagnosis.

3.3.1 Inclusion criteria

- Patients who had undergone planned extubation
- Patients whose consent was obtained from the patients or their next of kin

3.3.2 Exclusion criteria

- Patients whose arterial blood gas analysis (ABGs) results were unavailable on admission and Prior to extubation. ABGs are required for calculation of SAPS II score and P/F ratios both of which were significant independent variables.

3.3.3 Study population schematic diagram

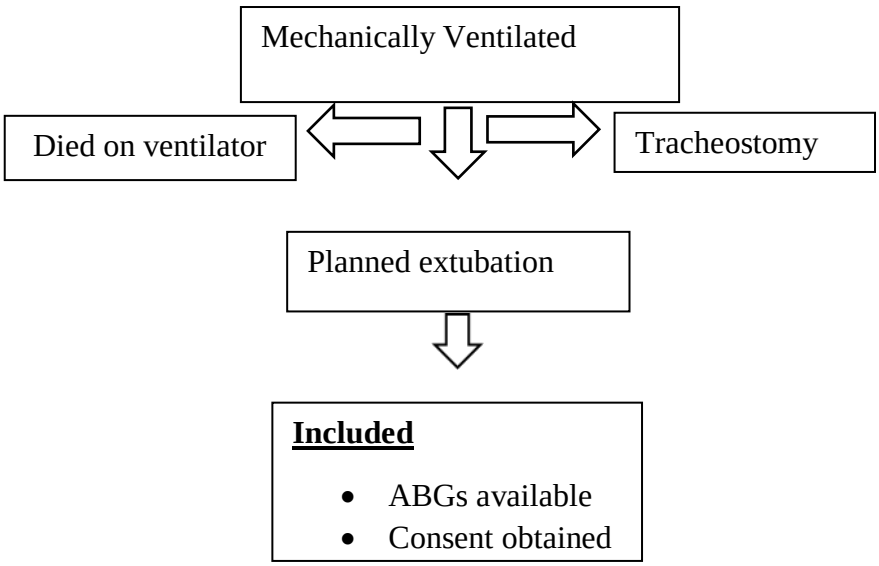

Figure 2: Study population

3.4 Sample size

This study aimed to establish the incidence and describe factors associated with extubation failure. Data from a study done in KNH found the incidence of failure after planned extubation was 21% (Mathangani, 2010). Thus we needed a sample size that was sufficient to describe this outcome. In order to be 95% sure that we reported this failure rate to within plus or minus 5%, we determined the required sample size as follows (Cochran, 1963).

$$n = \left(\frac{Z_{1-a/2}}{d}\right)^2 \times P \times (1-P)$$

$$= \left(\frac{1.96}{0.05}\right)^2 \times 0.21 \times (1-0.21)$$

$$= 255$$

Where

n is sample size

Z_c is the quartile of the standard normal distribution corresponding to $c \times 100\%$ percentile,$c = \left(1 - {}^{a}/_{2}\right)$, and a = 5%.

P is the extubation failure rate

d is the margin of error, and is equal to 5%.

There average number of mechanically ventilated patients at MTRH ICU per year was 400 (MTRH Records). In the study done in KNH, it was reported that 43.71% of intubated patients where extubated while 44.37% died while intubated and the remaining 12% progressed from endotracheal intubation to tracheostomy (Mathangani, 2010). Thus correcting for a finite population size 43.71% (extubated patients) of 400 (mechanically ventilated patients per year at MTRH) is 175, the required representative sample size is

$$\left(\frac{n}{1 + {}^{n}/_{N}}\right) = \left(\frac{255}{1 + {}^{255}/_{175}}\right) = 104$$

3.5 Sampling procedure

All patients who had undergone planned extubation were assessed and those among them who qualified for the study were enrolled. Selection of patients for inclusion in the study was done using systematic random sampling method. The first patient included was selected using simple random sampling method. The subsequent patients were selected systematically at an interval of 2 (i.e. $k = (175/104) = 1.68 \approx 2$). Data was collected between March 2019 and February 2020

3.6 Measures

3.6.1 Dependent variables

The dependent variable for this study was failed planned extubation. Extubation failure is defined as a need for re-intubation within 72 hours after extubation(C.-C. Lai et al., 2016). It is the inability to tolerate removal of the trans-laryngeal tube and it is generally treated with tracheal re-intubation.

3.6.2 Independent variables

The independent variables for this study included various factors associated with extubation failure. Demographic characteristics such as age and its association with extubation failure was examined. Elderly patients with critical illness often have significant functional limitations, and studies indicate that advanced age is a risk factor for extubation failure and ICU death (Carson, 2003).

Severity of illness on admission to ICU has not only been associated with prolongation of duration of mechanical ventilation, weaning and extubation failure but also increased ICU mortality rates(C.-C. Lai et al., 2016). Severity of illness on admission was quantified using SAPS II Score.

Another factor is the primary indication for mechanical ventilation, it must be reversible to allow for early weaning and extubation. Extubation outcomes depend not only on the indication for mechanical ventilation, but also on development of complications and patient management in the ICU (Anzueto et al., 2012)

Many advances have been made regarding the optimal methods of early weaning and extubation because mechanical ventilation is associated with considerable morbidity, mortality and cost (Rose, 2015). However, premature discontinuation of mechanical ventilation can contribute to the incidence of failed extubation, nosocomial pneumonia, or increased mortality, hence duration of mechanical ventilation has been demonstrated to influence outcomes of extubation significantly (Chaiwat et al., 2010). Adequacy of weaning was examined by observing its duration as well parameters such as RSBI and P/F ratios.

Chronic comorbid medical conditions are common in critically ill patients and may influence the acute illness, the types and intensity of care delivered, and outcomes in the intensive care unit(Esper & Martin, 2011). Although many of these patients may survive through the acute stage of critical illness, approximately 3–13% experience difficulty weaning and extubation and thus require prolonged mechanical ventilation (PMV; the use of MV for at least 21 days)(C. Lai et al., 2016).

Chemical and physical restraints are frequently used in the intensive care unit (ICU) to control agitated patients and to prevent self-harm and unplanned extubations(Chuang et al., 2015). Ideally patients should undergo daily sedation holds to allow for examination of their mental status and eligibility for SBT trials. In this study we recorded and analysed the duration between the last sedative/muscle

relaxant administration and extubation. The timing of extubation and its association with extubation failure was also assessed.

3.7 Data Collection Tool

An interviewer administered structured questionnaire was designed with three sections. The first section captured the patient's demographic data and intubation details such date and time of intubation, SAPS II score, GCS and place of intubation. The second section recorded extubation details i.e. duration of weaning, SBT strategy, duration of ventilation, time of administration of last sedative/muscle relaxant prior to extubation, weaning parameters such as pre-extubation P/F ratios and RSBI. This section also captured details on the level or mode of respiratory support the patient received prior to extubation as well as date and time of extubation. The third section was only filled in the event of a failed extubation i.e. when the extubated patient required re-intubation within 72 hours. It was used to record date and time of re-intubation and captured contained details on acute manifestations of extubation failure and any challenges experienced in its initial management.

3.8 Study Execution

Data collection commenced after approval from Moi University/Moi Teaching and Referral hospital Institutional Research and Ethics Committee (IREC). Data was collected from March 2019 to February 2020 by the Principal Investigator and three research assistants. The research assistants included one ICU medical officer, ICU clinical officer and ICU nutritionist. They were selected on the basis of availability and being conversant MTRH ICU. The Principal Investigator trained the research assistants on patient enrolment, ethics and data collection.

The Principal Investigator and research assistants then identified patients who had been extubated following successful SBT trials and checked for eligibility. The decision to extubate a patient was made by clinicians of various cadres including consultants, residents, medical and clinical officers. Subsequently, informed consent was obtained from conscious patients while for children and cognitively impaired adults, consent was sought from their respective guardians (designated next of kin in the patient record)

Once eligible patients had been enrolled, they were followed up and when a patient required re-intubation within seventy two (72) hours of an extubation it was classified and recorded as failed extubation. Those who did not require re-intubation within that period were considered to have had successful extubation. This allowed us to address our first objective.

The second objective was addressed by subjecting various factors (independent variables) to statistical analysis to asses association between them and extubation failure (dependent variable). These independent variables included severity of illness on admission, age, comorbidities, duration on mechanical ventilation, weaning parameters including PaO2/FiO2 (P/F) ratio, RSBI among others.

3.9 Data Management, Analysis and Presentation

3.9.1 Data Management

Data collected was reviewed for completeness and coded accordingly. Once confirmed the data was entered into IBM® SPSS® version 24 Statistics package for storage and back up. Upon completion of data entry the record was verified for missing and anomalous values and corrected. Then, data was exported to R version 3.6.0 (R Core Team, 2019) statistical software for analysis. Strict patient

confidentiality was maintained at all times with no use of identifiers on the questionnaires. The questionnaires were kept in a safe cabinet under a lock. The key was retained by the lead investigator. The database was also be backed up using external data drives and kept in separate safe location to cushion against data loss.

3.9.2 Data Analysis

3.9.2.1 Descriptive Statistics

Continuous data is summarized as mean, standard deviation and median with inter-quartile range while categorical data is summarized as frequency and proportions.

3.9.2.2 Inferential Statistics

Fisher's Exact Test was used to assess associations between categorical variables and Kruskal-Wallis Test was used for continuous independent variables. After subjecting the independent variables to bivariate analysis, multiple logistic regression was done to account for confounding effects among the covariates. A *p* value of less than 0.05 was considered statistically significant.

3.9.3 Data Presentation

Results are presented in prose, tables and figures.

3.10 Ethical Considerations

The study was done after approval from Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC). Permission to carry out the study was also obtained from Moi Teaching and Referral Hospital. Only patients/next of kin who had given voluntary informed written consent participated in the study. A third party (designated next of kin on the patients' record) consented on behalf of critically ill patients/ cognitively impaired adults and children who were unable to give consent.

All patients received routine care with no direct financial benefit. Additional costs on medical care were not meted on the patients for the purpose of this study. No coercion or payment was done to influence patients join the study.

There were no risks associated with the study. Neither incentives nor inducements were used to coerce patients into the study. The patients were free to withdraw from the study at any point in time with no consequences.

3.11 Dissemination of findings

The research findings from this study will be disseminated through relevant channels, thesis defense, scientific conferences and publications in peer reviewed journals. Bound copies of thesis will be submitted to the department, supervisors and the Moi University library.

3.12 Study limitations

On some occasions MTRH laboratory was unable to carry out daily arterial blood gas analysis (ABGs) due to erratic supply of reagents. ABGs are required for calculation of SAPS II score and P/F ratios both of which were significant independent variables hence this led to exclusion of some patients who would have otherwise qualified for the study. On such occasions unavailability of this test was reported immediately to the laboratory managers for prompt action.

The results for most the independent variables were not normally distributed. For instance the results for age and SAPS II score were skewed to the right. Additionally, the sample size was not large enough and for the categorical variables, some of the cells in the contingency table had count values less than 5. These two factors limited the choice of the statistical tests to non-parametric therefore limiting the generalizability of the findings.

CHAPTER FOUR: RESULTS

4.0 Introduction to the chapter

This chapter consists of results presented in prose, tables and figures according to the study objectives any other significant findings during the study.

4.1 Socio-demographic characteristics

There were a total of 104 participants included in the analysis. Figures 3 and 4 their socio demographic characteristics. The median age was 38 years (IQR: 22.5, 63.5) with a slightly higher proportion of males 60 (57.7%) compared to females 42.3% as shown in figures 3 and 4 below.

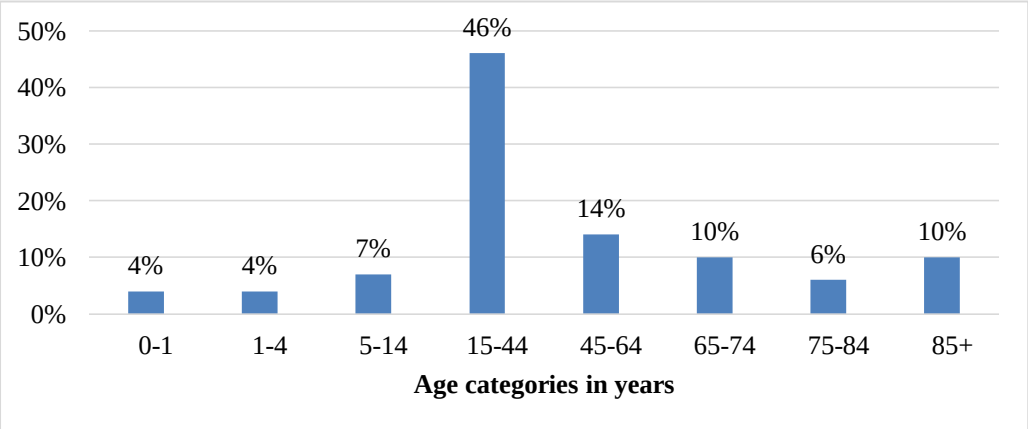

Figure 3: Age categories in years

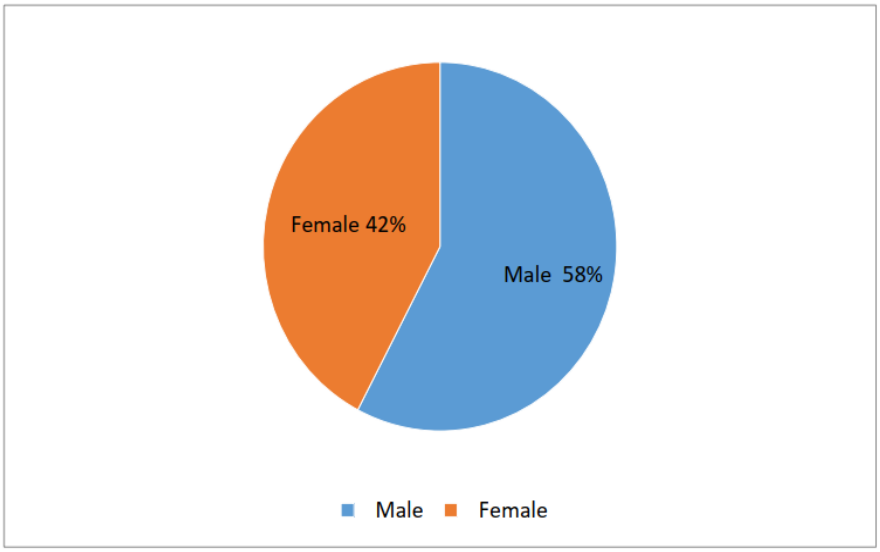

Figure 4: Gender

4.2 Severity of illness on admission

Slightly less than half of the participants had a GCS score of eight and below 51 (49.5%) while 36 (35.0%) scored 9-12 and 16 (15.5%) scored 13-15. The median SAPSII score was 24.35 (IQR: 12.6, 47.1).

Table 1: Severity of illness on admission 1

SAPSII	
Mean (SD)	31.61 (24.23)
Median	24.35 (IQR: 12.6, 47.1)
GCS	
N-Miss	1
8 and below	51 (49.5%)
9-12	36 (35.0 %)
12-15	16 (15.5 %)

4.3 Indications for mechanical ventilation

There were a total of 51 (49.0%) patients who were admitted to ICU for mechanical ventilation post operatively. Majority of these postoperative admissions were neurosurgical patients 22 (43.1%). Other indications for mechanical ventilation included acute respiratory failure 31 (29.8%), coma12 (11.5%), chronic respiratory illness 4 (3.8%) and renal failure 5 (4.8%) with majority being acute kidney injury 4 (80.0%).

Table 2: Indications 1

	Overall (N=104)
Post-operative	
NA	53
Neurosurgical	22 (43.1%)
General surgery	10 (19.6%)
Cardiothoracic	10 (19.6%)
Orthopedics	3 (5.9%)
Obstetrics	6 (11.8%)
Acute respiratory failure	N=31
Pneumonia	13 (41.9%)
Heart failure	1 (3.2%)
Sepsis/septic shock	13 (41.9%)
ALI/ARDS	1 (3.2%)
Trauma	3 (9.7%)
Coma	N=12
Metabolic	2 (16.7%)
Stroke	4 (33.3%)
Meningioencephalitis	3 (25.0%)
Traumatic brain injury	3 (25.0%)
Chronic respiratory	N=4
COPD	2 (50.0%)
Asthma	2 (50.0%)
Renal failure	N=5
Acute	4 (80.0%)
Chronic	1 (20.0%)
Others	N=7
Neuromuscular	1 (14.3%)
OPP	4 (57.1%)
Potassium poisoning	1 (14.3%)
Severe malaria	1 (14.3%)

4.4 Comorbidities

Of all the patients who were mechanically ventilated for various indications, 33 (31.7%) had associated comorbidities with congestive heart failure being the most prevalent 8 (24.2%) followed by diabetes and hypertension both of which had equal occurrence 5 (15.2%) as shown in figure 5 below.

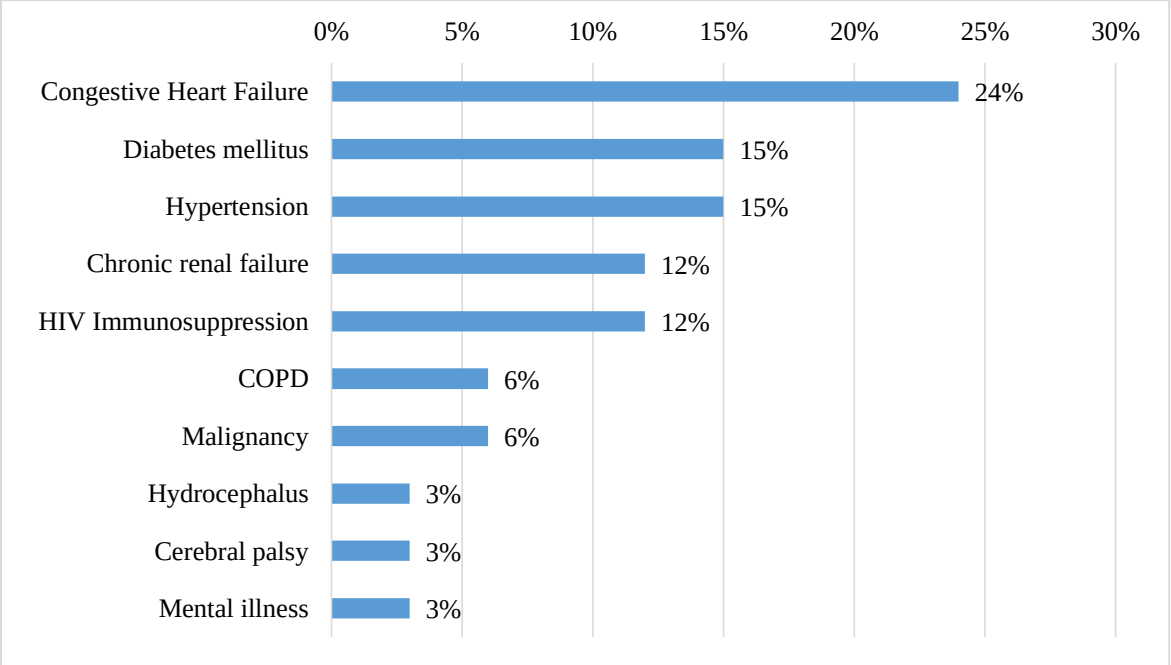

Figure 5: Comorbidities

4.5 Weaning

The duration on mechanical ventilation ranged from 1 to 23 days with the mean being 6.97 (std =4.93) days. The mean duration of weaning in days was 2.2 (std =1.2). In almost all patients the SBT strategy employed for weaning was PSV 101 (97.1%) and 40 (38.5%) were on SBT form more than 2 hours. Majority of the participants had their last sedatives and/or muscle relaxant more than 12 hours prior to extubation as shown in Table 5 below.

Table 3: Weaning 1

Variable	N=104 Freq (%)
Ventilator days	
Mean (SD)	6.97 (4.93)
Range	1.00 - 23.00
Duration of weaning	
Missing	1
Mean (SD)	2.18 (1.25)
Range	1.00 - 6.00
SBT strategy	
T-piece	1 (1.0%)
CPAP	2 (1.9%)
PSV	101 (97.1%)
Duration of SBT	
0.5hr	10 (9.6%)
2hr	54 (51.9%)
>2hr	40 (38.5%)
Last sedative	
<12h	2 (1.9%)
>12h	102 (98.1%)
Last muscle relaxant	
<12h	3 (2.9%)
>12h	101 (97.1%)

4.6 Timing of Extubation

Most of the participants in this study 67(67.7%) were extubated in the morning. Prior to extubation almost all patients 97 (93.3%) were ventilated with PSV/CPAP and majority of them had RSBI value of less than a hundred and five 60 (57.7%). Most of the patients had PF ratio of between two hundred and three hundred 36 (34.6%) while 19 (18.3%) had PF ratio less than a hundred. The most reported complication following extubation was desaturation 47 (45.2%)

Table 4: Extubation 1

Prextubation Mode	
ACV	2 (1.9%)
SIMV	5 (4.8%)
PSV/CPAP	97 (93.3%)
RSBI	
<105	60 (57.7%)
>105	44 (42.3%)
PFratio	
>300	19 (18.3%)
200-300	36 (34.6%)
100-200	30 (28.8%)
<100	19 (18.3%)
Extubation time	
Morning	67 (67.7%)
Afternoon	26 (26.3%)
Evening/night	6 (6.1%)
Complications	
None	12 (11.5%)
Laboured breathing	16 (15.4%)
Hypotension	10 (9.6%)
Bradycardia	10 (9.6%)
Hypercapnea	7 (6.7%)
Desaturation	47 (45.2%)
Stridor	1 (1.0%)
Aspiration	1 (1.0%)

Objective 1: Incidence proportion of extubation failure

A total of 41 (39.4%) had extubation failure at 95%CI (30.0, 49.5).

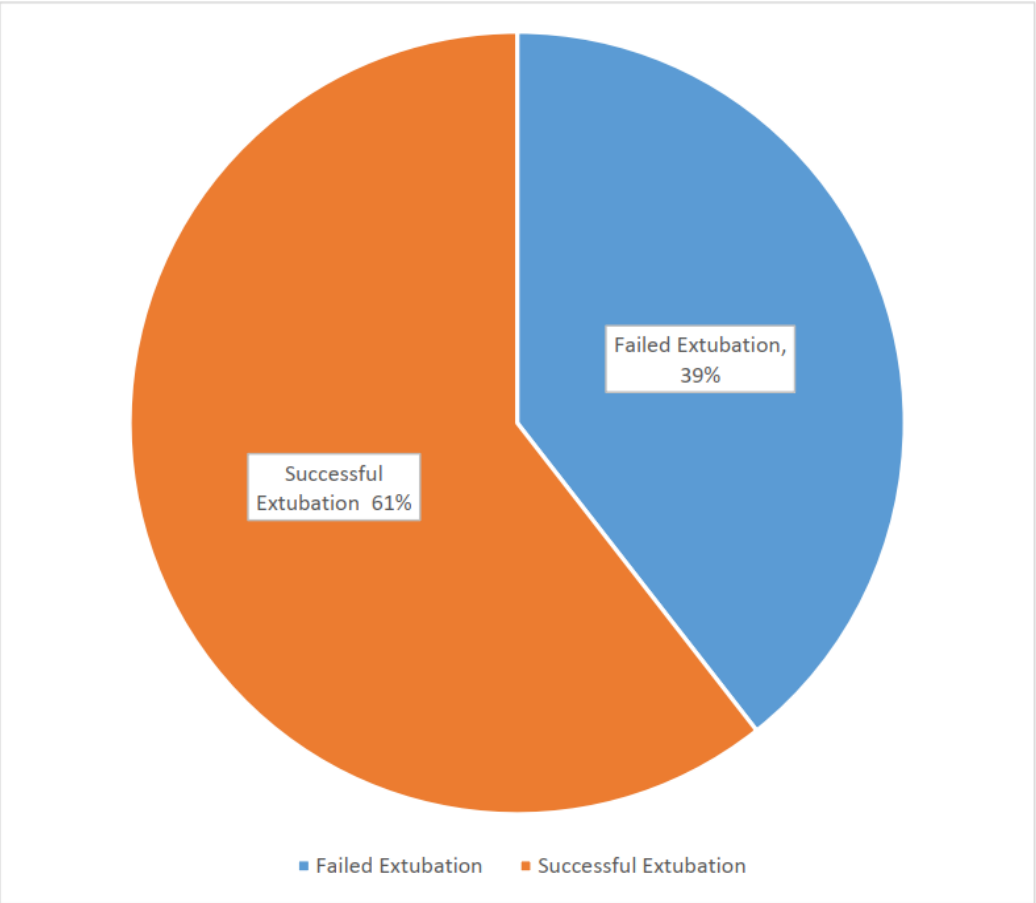

Figure 6: **Incidence proportion of extubation failure**

Objective 2: Factors associated with extubation failure

We observed that Age, SAPSII, having a comorbidity , duration on ventilator, duration of weaning and PF ratio were statistically significantly associated with failure.

Table 5: Factors associated with extubation failure 1

	Success (N=63)	Failure (N=41)	
Variable	**Freq (Row %)**	**Freq (Row %)**	**p value**
Age in (yrs)			< 0.001[1]
Median	32.00	66.00	
Q1,Q3	20.50, 41.50	30.00, 84.00	
Gender			1.000[2]
Male	36 (60.0%)	24 (40.0%)	
Female	27 (61.4%)	17 (38.6%)	
SAPSII			< 0.001[1]
Count	63	41	
Median	17.00	50.00	
Q1,Q3	7.90, 29.40	30.000, 72.00	
GCS			0.164[2]
8 and below	28 (54.9%)	23 (45.1%)	
9-12	22 (61.1%)	14 (38.9%)	
13-15	13 (81.2%)	3 (18.8%)	
Indication			0.841[2]
Respiratory	1 (25.0%)	3 (75.0%)	
Non respiratory	0 (0.0%)	1 (100.0%)	
Comorbidities			< 0.001[2]
No	55 (77.5%)	16 (22.5%)	
Yes	8 (24.2%)	25 (75.8%)	
Ventilator days			< 0.001[1]
Count	63	41	
Median	4.00	10.00	
Q1,Q3	3.00, 6.00	7.000, 14.00	
Duration of weaning			< 0.001[1]
Count	62	41	
Median	1.50	2.00	
Q1,Q3	1.00, 2.00	2.00, 4.00	
Extubation time			0.474[2]
Morning	41 (61.2%)	26 (38.8%)	
Afternoon/night	14 (53.8%)	12 (46.2%)	
Evening	5 (83.3%)	1 (16.7%)	
SBT strategy			0.059[2]
T-piece	0 (0.0%)	1 (100.0%)	
CPAP	0 (0.0%)	2 (100.0%)	
PSV	63 (62.4%)	38 (37.6%)	
Mode of prextubation			0.571[2]
ACV	1 (50.0%)	1 (50.0%)	
SIMV	2 (40.0%)	3 (60.0%)	
PSV/CPAP	60 (61.9%)	37 (38.1%)	
PFratio			< 0.001[2]
>300	19 (100.0%)	0 (0.0%)	
200-300	31 (86.1%)	5 (13.9%)	
100-200	11 (36.7%)	19 (63.3%)	
<100	2 (10.5%)	17 (89.5%)	
Age in categories			< 0.001[2]
<1	3 (75.0%)	1 (25.0%)	
1-4	3 (60.0%)	2 (40.0%)	
5-14	3 (50.0%)	3 (50.0%)	
15-44	41 (85.4%)	7 (14.6%)	
45-64	9 (60.0%)	6 (40.0%)	
65-74	1 (10.0%)	9 (90.0%)	
75-84	3 (50.0%)	3 (50.0%)	
85+	0 (0.0%)	10 (100.0%)	

1. Kruskal-Wallis rank sum test
2. Fisher's Exact Test for Count Data

We fit a logistic regression where we included variables that were significant in the bivariate analysis. We observed that there was correlation between ventilation time and duration of weaning thus we couldn't include both in the analysis.

Adjusting for age, SAPSII and comorbidity duration of ventilation and P/F ratio were statistically significantly associated with failure. Specifically holding all other factors constant one day increase in ventilation was associated with 1.2 increase in the odds of failure. Holding all other factors constant a decrease in the P/F ratio by one was associated with 8.6 times increase in the odds of failure.

Table 6: Bivariate analysis of factors associated with extubation failure 1

Characteristic	**AOR**	**95% CI**	**p-value**
Age	1.02	1.00, 1.05	0.084
SAPSII	0.99	0.95, 1.03	0.700
Comorbidity			
No	1		
Yes	3.70	0.64, 23.6	0.150
Ventilator days	1.21	1.04, 1.43	0.014
PFratio	8.62	3.39, 29.3	<0.001

CHAPTER FIVE: DISCUSSION

5.0 Introduction to the chapter

This chapter covers the discussion of the study results.

5.1 Socio-demographic characteristics

A male predominance was observed with males being about one and half times the females. This is comparable to the conclusion that gender distribution in intensive care units is consistently found to be around 60% men and 40% women (Zettersten et al., 2019). However there has been no difference in admittance rate that could be attributed to the gender of the patient nor has it been sufficiently demonstrated that there is a gender bias between male and female ICU admitting physicians (Zettersten et al., 2019)

5.2 Incidence of extubation failure

Despite advances in mechanical ventilation and respiratory support, the science of determining if the patient is ready for extubation is still not well defined and as a result, the incidence of extubation failure necessitating re-intubation vary from as low as 2% to 25% depending on the ICU population being studied, study design, and the different inclusion criteria. (Stawicki, 2017). Though controversial, some interventional and observational studies have described the average extubation failure rate to be 8-15% (Krinsley et al., 2012).

In this study a total of 41 patients (39.4%) had extubation failure 95%CI (30.0, 49.5). This extubation failure rate is significantly higher compared to the generally demonstrated and accepted rates. This could be partly explained by the fact that the MTRH ICU is a mixed/general population unit and as such it serves a variety of patients including paediatrics, surgical and medical among others. Extubation failure rates have been shown to be significantly higher in some sub-sets of ICU patient

population. In our study paediatric patients aged 5 years and younger formed about 8% of the study population and among them we reported slightly higher incidence of failed planned extubation (42%) whereas older children had failure rates comparable to our adult population (39.4%). This is in contrast with the findings of Simonassi & Sanso, 2019 where they demonstrated an extubation failure rate of 25% in a tertiary paediatric centre despite including those children who had undergone unplanned extubation in their study. This contrast is attributable to the lack of standardized ventilation protocols at MTRH ICU as well as patient factors such as indication for mechanical ventilation and greater severity of illness on admission contributing to longer duration of ventilation and ultimately higher incidence of failed extubation.

Post-operative neurosurgical patients with traumatic brain injury (TBI) requiring mechanical ventilation formed 24% of our study population and among them we reported incidence of failed planned extubation of 48%. This is higher than rates reported in India (33%) by Godet et al., 2017. One Kenyan study at KNH sought to establish extubation failure rates specially in neurosurgical patients and demonstrated a failure rate of 37.5% (Gitonga, 2020). This contrast can be explained by the fact that in the institutions where those studies we done, pre-emptive early tracheostomies were done for neurosurgical patients objectively expected to require longer duration of mechanical ventilation. Early tracheostomies are also done at MTRH ICU but delays occasioned by unavailability of theatre space among others, contributes to the inconsistency of the practice. Therefore the high rate of failure shown at MTRH ICU could be partly attributed to the fact that it is a mixed population unit serving both adults and children with a significant proportion of the adult admissions being neurosurgical patients.

The decision to extubate is one of the relatively complex judgments made in intensive care units on a daily basis. The approach to weaning and extubation at MTRH ICU is the standard physician-directed practice. In this unit the attending physicians are tasked with all aspects of management of critically ill patients including decisions on weaning and liberation from mechanical ventilation. Physician/clinician dependent weaning is relatively subjective since it is dependent on the particular physician's clinical acumen and experience and it has been associated with either premature extubation or unnecessary prolongation of ventilation both of which have associated with higher incidence of extubation failure. Studies have shown that protocol directed weaning is safe and resulted in a shorter duration of mechanical ventilation and reduced incidence of extubation failure compared with the traditional practice of physician-directed weaning (Chaiwat et al., 2017). In our study, the duration on mechanical ventilation ranged from 1 to 23 days with the mean being 6.97 (std =4.93) days. The mean duration of weaning in days was 2.2 (std =1.2). We demonstrated that holding all other factors constant one day increase in the duration of ventilation was associated with 1.2 increase in the odds of extubation failure. Perhaps utilization of weaning protocols would have reduced duration of ventilation and hence lower the incidence of extubation failure.

Multiple Clinical Practice Guidelines (CPGs) have endorsed the concept of a ventilator liberation protocol, most recently the American Thoracic Society/American College of Chest Physicians 2017 CPG on liberation from mechanical ventilation in critically ill adults(Schmidt et al., 2017). They reviewed seventeen trials that compared weaning protocols with traditional physician-directed practice among critically ill adults. It was demonstrated that duration of mechanical ventilation was reduced by up to 25 hours and ICU stay was reduced by one day among patients

whose readiness for extubation was assessed with a ventilator weaning protocol (Schmidt et al., 2017).

It should be noted however that while effective, manual weaning protocols are labor-intensive and compliance can be challenging, especially in a busy environment(Ouellette et al., 2017). Its implementation requires availability of adequate numbers of all critical care staff cadres. Staff to patient ratios are important, specifically the recommended critical care nurse to patient ratio is 1:1(Schmidt et al., 2017). During the study period, the critical care nurse to patient ratio at MTRH ICU was on average 1:4 and there was only one respiratory therapist in the entire unit (MTRH records). Therefore despite availability of established weaning protocols, the failure of their implementation at MTRH ICU could also be attributed to inadequate staff to patient ratios. Studies done in western countries with adequately staffed ICUs and are able to appropriately utilize weaning protocols report lower incidence of failed extubation, 8-15% on average (Krinsley et al., 2018).

5.3 Factors Associated With Extubation Failure

5.3.1 Duration of mechanical ventilation

Prolonged duration of mechanical ventilation has been sufficiently demonstrated to be an independent predictor of extubation failure (Rose, 2015). In our study, the duration on mechanical ventilation ranged from 1 to 23 days with the mean being 6.97 (std =4.93) days. The mean duration of weaning in days was 2.2 (std =1.2). In our bivariate analysis we demonstrated that the duration of ventilation was longer among those who failed extubation with a median of 10 days compared to 4 days for those successfully extubated. Furthermore, in the multiple logistic regression analysis where we were able to control for the confounding effects of the other covariates, it

was demonstrated that holding all other factors constant one day increase in ventilation was associated with 1.2 increase in the odds of extubation failure. This association between longer duration of ventilation and higher incidence of extubation failure as been attributed the combination of complete diaphragmatic inactivity and mechanical ventilation results in atrophy of diaphragm myofibers (Ouellette et al., 2017). Such atrophy has been reported even after only 18 hours of mechanical ventilation (Rose, 2015). The longer the duration of mechanical ventilation, the higher the risk of ventilator-associated complications which further compound the problem and lowers the chance of success in weaning and extubation (Ouellette et al., 2017).

The tendency to ventilate patients for longer durations at MTRH ICU as shown in this study could be attributed to the fact that the process of liberating patients from mechanical ventilation is largely the standard physician/clinician dependent practice. Perhaps utilization of weaning protocols would have optimized patient's readiness for extubation and reduced duration of ventilation ultimately lowering the incidence of extubation failure. Many studies have demonstrated that when compared with the standard physician/clinician directed weaning, Protocolized weaning resulted in shorter duration of ventilation and lower incidence of extubation failure (Schmidt et al., 2017).

It should also be noted that patient factors may have also contributed the longer duration of ventilation and associated higher incidence of extubation failure at MTRH ICU. About half of the participants were admitted postoperatively and majority were neurosurgical patients with traumatic brain injury. These patients included young to middle aged males who sustained road traffic accidents majority of which involved motorcycles. They sustained severe TBI with half of them having a GCS score of less than 8 on admission. Their injuries included skull fractures as well as intracranial

hemorrhage requiring craniotomies among others. Higher extubation failure rates could be attributable to the longer duration of ventilation frequently required by these neurosurgical patients (Godet et al., 2017). A local study conducted at Kenyatta National Hospital sought to establish extubation failure rates and demonstrated a failure rate of 37.5% in neurosurgical patients (Gitonga, 2020). Another patient factor that could have contributed to longer duration of ventilation and high incidence of extubation failure at MTRH is severity of illness. It was also noted that there was erratic adherence to ICU admission criteria and this lead to frequent admission of patients that were too sick to benefit. This is evidenced by the fact that 10% of our participants were above 85 years old and had multiple comorbid conditions and in this group of patients we reported 100% extubation failure rate. This ethical dilemma faced by admitting clinicians between giving an individual patient best possible chance to save their lives and the responsibility of promoting equitable access to scarce resources, could have been alleviated by adherence to ICU admission criteria within the context of available resource.

5.3.2 Weaning.

Successful weaning and liberation from mechanical ventilation remain critical stages of a patient's intensive care unit (ICU) stay. The standard test for extubation readiness is the spontaneous breathing trial (SBT). It is often performed to assess the patient's ability to breathe while receiving minimal or no ventilator support (Thille et al 2017).Tolerance of a spontaneous breathing trial is an evidence-based strategy to predict successful weaning from mechanical ventilation (Zein et al., 2016). These trials have traditionally been performed while the patient receives varying levels of ventilator support, including, continuous positive airway pressure (CPAP), a T-tube circuit or low-level pressure support ventilation (PSV) (Cohen et al., 2019. In almost

all patients included in this study, the SBT strategy employed for weaning was PSV (97.1%) and 38.5% were on SBT form more than 2 hours. Few randomized studies have evaluated the best technique for performing SBT before extubation and there is no clinical evidence of a higher reintubation risk between these methods (Rose, 2015)

It is desirable to liberate patients from mechanical ventilation as soon as the indication has sufficiently improved, and the patient is able to sustain spontaneous breathing and adequate gas exchange(Ouellette et al., 2017) Many advances have been made regarding the optimal methods of early weaning and extubation because mechanical ventilation is associated with considerable morbidity, mortality and cost(Rose, 2015).

Several weaning parameters have undergone assessment and use in clinical studies and they are helpful when taken into account with the overall clinical picture, but they are not very sensitive or specific when considered individually (Thille et al., 2016). One of such weaning parameters examined in this study was the PaO_2/ FiO_2 (P/F) ratio defined as the ratio between arterial oxygen partial pressure (PaO_2) and the fraction of inspired oxygen (FiO_2). The severity of the acute respiratory distress is defined by the degree of hypoxemia, which is calculated as the ratio of arterial oxygen tension to fraction of inspired oxygen (P/F). It can be mild (P/F 200-300), moderate (P/F 100-199) or severe P/F < 100) as clarified by the Berlin definition of Acute Respiratory Distress Syndrome (ARDS) (Ranieri et al., 2012)

Progressive hypoxemia after extubation is frequently associated with failed extubation and might be predicted prior to extubation by a reduced P/F ratio (Nitta et al., 2019). Most of the patients in our study (34.6%) had PF ratio of between two hundred and three hundred and notably 18.3% had PF ratio less than a hundred just prior to extubation. Of more importance however, we were able to demonstrate that

having a PF ratio<100 prior to extubation was statistically significantly associated with extubation failure in our patient population. Furthermore, in the multiple logistic regression analysis where we were able to control the confounding effects of the other covariates, it was demonstrated that holding all other factors constant an increase in the P/F ratio by one was associated with 8.6 times increase in the odds of failure.

According to the American Thoracic Society (ATS)/American College of Chest Physicians (ACCP)/ American College of Critical Care Medicine (ACCM) 2017 evidence based practice guidelines on weaning and discontinuation of mechanical ventilation , some of the objective parameters used in determining whether a patient is able to come off the ventilator include among others a PaO_2/ FiO_2 ratio >150-200. In this study 18.3% of the participants had PF ratio less than a hundred just prior to extubation and among them 90% failed extubation. Therefore this indicates that this proportion of the participants were extubated while they still had severe ARDS as described above. This puts emphasis on the need to utilize weaning protocols to optimize patient's readiness for extubation hence reducing the incidence of failed extubation at MTRH ICU.

Another weaning parameter examined is Rapid shallow breathing index (RSBI). Yang and Tobin described RSBI as the ratio of respiratory rate (RR) to tidal volume (VT), with a threshold value of >105 breaths/min/L being highly predictive of weaning failure, while RSBI <105 breaths/min/L is associated with weaning success. In this study, majority of the participants had RSBI value of less than a hundred and five 60 (57.7%). However this was not associated with extubation success with any statistical significance

Successful weaning cannot be achieved without optimizing sedation and limiting the use of paralytics. Protocolized targeted sedation or daily sedative interruption have been associated with shorter duration of MV in both medical and surgical patients in comparison with no protocols (Jung et al., 2020), and are currently recommended by international guidelines (Ouellette et al., 2017). In this study, despite absence of sedation protocols Majority of the participants had their last sedatives and/or muscle relaxant more than 12 hours prior to extubation hence there was no significant association sedation/muscle relaxation with extubation failure.

5.3.3 Severity of illness on admission to ICU

In this study Simplified Acute Physiological Score II (SAPS II) score was used as one of the measures of severity of illness on admission to ICU and in the findings the score ranged from 5 to 88 with a mean of 31. Severity of illness on admission has been shown to have a strong influence on extubation outcome. Robriquet et al., 2016, measured initial severity of illness by the SAPS II prognostic system and found that a SAPS II above 35 on ICU admission was associated with extubation failure. Severity of illness on admission measured by scoring systems has already been highlighted by several authors, it has been shown to result in a longer duration of mechanical ventilation and difficulties in weaning both of which are associated with higher rates of extubation failure. In our analysis we observed that adjusting for age, higher SAPSII scores were statistically significantly associated with extubation failure in the study subjects. SAPS II scores were higher among those who failed extubation with median score of 50 compared with 17 for extubated successfully. Anecdotal reports had indicated that there was erratic adherence to ICU admission criteria and this could have resulted to frequent admission of severely ill patients that would otherwise not benefit may have contributed to the high extubation failure rates observed. It is also

possible that these severely ill patients with higher scores and justified ICU admission required longer duration of ventilation that has been shown to be an independent predictor of extubation failure.

In this study majority of postoperative admissions were neurosurgical patients. In addition most of the other patients came into the ICU with some level of neurological impairment and this was quantified using the Glasgow Coma Scale (GCS). Patients with acute neurological illness often require endotracheal intubation and mechanical ventilation for airway protection and to achieve adequate ventilation and oxygenation(Adeel et al., 2016).. We found that Slightly less than half of the participants had a GCS score of eight and below 51 (49.5%) while 36 (35.0%) scored 9-12 and 16 (15.5%) scored 13-15. Despite its simplicity and ease of use GCS score is not without limitations and this has led to controversial findings on its utility in predicting extubation failure. In their multivariable model, McCredie et al., 2017 demonstrated that a GCS score 7–9 at the time of admission was associated with increased risk of extubation failure. In contrast, Coplin and co-workers did not find GCS score to be predictive of extubation failure in a group of 136 acutely brain-injured patients. In that study, 91% patients with GCS score <4 and 80% with GCS score < 8 on admission were successfully extubated. This study concurs with this findings since it was demonstrated that low GCS on admission was not significantly associated with extubation failure.

5.3.4 Age

The mean and median ages were 42.10 (SD 26.85) and 38 (IQR: 22.5, 63.5) years respectively with majority in their second, third and fourth decades of life. This is in contrast with studies done in the west where their general population is aging. Laporte et al., 2018 demonstrated that ICU patients have become older by 4.4

months/year in the United Kingdom. By 2013 the median age of ICU patients was 66 and now 15% of all patients are ≥80 years. The relatively younger ICU population demonstrated in this study could be attributed to fact that majority of the admissions were postoperative traumatic brain injury patients who were of relatively young age at which most people are socio-economically active and are prone to injuries. It is however noteworthy that a significant proportion of the subjects of this study were 85 years and older 10(9.6%) and 100% failed extubation at their first attempt. These findings agrees with several studies that have shown that advanced age is an important risk factor for failed extubation (Laporte et al., 2018). These studies demonstrated that 20% to 35% of elderly patients were re-intubated within 48 to 72 hours after extubation, this is higher than that in the general population (Suraseranivong et al., 2018). However most of these studies expanded the age bracket to include patients above 65 years old (Suraseranivong et al., 2018).

Elderly patients with critical illness often have significant functional limitations, and studies indicate that advanced age is a risk factor for ICU death(Carson, 2003). Ely et al 2013 showed that mechanically ventilated patients ≥70 years of age with acute lung injuries had mortality rates nearly twice those of younger patients. Compared to a younger age group (less than 70 years old) matched for severity of illness, inability to handle secretions was the most common reason of airway causes leading to extubation failure in the elderly while upper airway obstruction was the predominant cause in the control group. As for non-airway causes, COPD related hypercapnic respiratory failure accounted for the majority of cases in both groups. After adjusting for severity of illness, elderly patients who required reintubation had a higher risk of developing nosocomial pneumonia.

5.3.5 Comorbidities

Elderly patients are being increasingly admitted to the ICU for mechanical ventilation. They have multiple comorbidities as well as age-related physiologic changes and it has been demonstrated that 20% to 35% of elderly patients were re-intubated within 48 to 72 hours after extubation (Suraseranivong et al., 2018).

In this study, of all the patients who were mechanically ventilated for various indications, 32% had an associated comorbidities and among them 76% failed extubation. Congestive heart failure was the most prevalent comorbid condition at 24 %. Other comorbidities included diabetes and hypertension both of which had equal occurrence 15%. Patients with cardiac dysfunction are at high risk of extubation failure due to the abrupt burden to the cardiovascular system resulting from the transition to spontaneous breathing. Additionally, those with associated fluid overload or cumulative positive fluid balance, are at high risk of weaning-induced pulmonary oedema (WiPO) (Vignon, 2018).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.0 Introduction to the chapter

The chapter covers the conclusions emanating from the results and discussion followed by recommendations.

6.1 Conclusions

1. The incidence proportion of failed planned extubation was high (approximately 4 out of 10 patients within 72 hours)
2. The most significant factors associated with extubation failure were prolonged duration of mechanical ventilation and having PaO_2/ FiO_2 ratio of less than 100 prior to extubation.

6.2 Recommendations

Based on results and the stated objectives, the following recommendations are proposed:

- MTRH ICU should introduce measures aimed at decreasing the incidence of failed planned extubation. These may include:
    1. Develop and implement standardized weaning protocols for use in MTRH ICU. This will aid in optimizing patient's readiness for extubation hence reducing the incidence of extubation failure in the unit.
    2. There is need to emphasize implementation of existing standardized ICU and critical care admission criteria through continuous medical education (CME).

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APPENDICES

APPENDIX I: DATA COLLECTION TOOL

INCIDENCE AND FACTORS ASSOCIATED WITH FAILED PLANNED EXTUBATION AT MOI TEACHING AND REFERRAL HOSPITAL INTENSIVE CARE UNIT

TOOL NO: ☐

SECTION A: To be filled in for **ALL** eligible extubated patients.

1.0 HOSPITAL NUMBER ☐

2.0 GENDER: Male ☐ Female ☐

3.0 AGE: ☐

4.0 INTUBATION: Place ☐ Date ☐ Time ☐

5.0 ETT securing method: Adhesive tape ☐ Cloth/Gauze ties ☐ None ☐ Other ☐

6.0 ICU Admission: Date ☐ Time ☐

7.0 ADMISSION SAPS II SCORE ☐

8.0 ADMISSION GLASGOW COMA SCALE ☐

9.0 INDICATION FOR MECHANICAL VENTILATION

9.1 Acute respiratory failure

9.1.1 Postoperative

- Neurosurgical ☐
- General surgery ☐
- Cardiothoracic ☐
- Orthopaedics ☐
- Obstetrics ☐

9.1.2 Pneumonia ☐

9.1.3 Heart failure ☐

9.1.4 Sepsis/septic shock ☐

9.1.5 ALI/ARDS ☐

9.1.6 Trauma ☐

9.1.7 Cardiac arrest ☐

9.1.8 Coma

- Metabolic/intoxication ☐
- Stroke ☐
- Meningioencephalitis ☐
- Traumatic brain injury ☐
- Status Epilepticus ☐

9.1.9 Exacerbation of chronic respiratory disease

- COPD ☐
- Asthma/status Asthmaticus ☐
- Chronic respiratory disease (non-COPD) ☐

9.1.10 Neuromuscular disease ☐

9.1.11 Renal disorders

- Acute renal failure ☐
- Chronic renal failure ☐

9.1.12 Hepatic disorders ☐

9.1.13 others (specify) ☐

10.0 CORMOBIDITY

- Diabetes mellitus ☐
- Hypertension ☐
- COPD ☐
- Congestive Heart Failure ☐
- Stroke ☐
- Chronic renal failure ☐
- Liver cirrhosis ☐
- Malignancy ☐
- HIV immunosuppression ☐
- Others(specify) ☐

11.0 INTUBATION END POINT:

- Extubation ☐
- Tracheostomy ☐
- Died intubated. ☐

SECTION B: To be filled **ONLY** when planned extubation occurs

Extubation: Place ☐ Date ☐ Time ☐

Duration of mechanical ventilation ☐

Duration of weaning ☐

SBT Trial strategy

T-piece trial ☐

CPAP ☐

PSV ☐

Use of physical restraints: NONE ☐ WRIST/HAND ☐ LEGS ☐ OTHER ☐

Administration of sedative drugs 1 hr. prior to extubation: YES ☐ NO ☐

Administration of muscle relaxants 1 hr. prior to extubation: YES ☐ NO

Tick any complications experienced within 2 hours of extubation

None	☐	Desaturation	☐
Laboured breathing	☐	Stridor	☐
Hypotension	☐	Aspiration	☐
Bradycardia	☐	Hypoxia	☐
Hypercapnea	☐	Cardiac arrest	☐
Death	☐	Others (specify)	☐
Respiratory acidosis	☐		

Ventilator mode preceding extubation:

ACV	☐	VC- SIMV	☐	BIPAP	☐
PSV	☐	PCV	☐	OTHER	☐
	☐		☐		

PC-SIMV CPAP

Level of: Pressure support ☐ PEEP ☐ Fi02 ☐

SECTION C: To be filled in only in the event of a failed panned extubation. (I.e. to be filled ONLY when this patient requires reintubation within 72 hours)

Reintubation: Date ☐ Time ☐ Place ☐

Complications experienced during emergency reintubation:

Aspiration ☐ Multiple intubation attempt ☐ Equipment malfunction ☐
Hypotension ☐ Failed intubation ☐ Equipment unavailability ☐
Bradycardia ☐ Airway trauma ☐ Cardiac arrest ☐
Death ☐ None ☐ Othe ☐

Ventilator mode after reintubation

ACV ☐ VC- SIMV ☐ BIPAP ☐
PSV ☐ PCV ☐ OTHER ☐
PC-SIMV ☐ CPAP ☐

Level of: Pressure support ☐ PEEP ☐ Fi02 ☐

APPENDIX II: SAPS II SCORE

Simplified Acute Physiology Score II (SAPS II)

Age (years)

<40	**0**
40-59	+7
60-69	+12
70-74	+15
75-79	+16
≥80	+18

Heart rate

If patient had both cardiac arrest (11 points) and extreme tachycardia (7 points), assign 11 points

<40	+11
40-69	+2
70-119	**0**
120-159	+4
≥160	+7

Systolic BP, mmHg

Worst value in 24 hours

<70	+13
70-99	+5
100-199	**0**
≥200	+2

Temperature ≥39ºC (102.2ºF)

Highest temperature in 24 hours

No	**0**
Yes	+3

GCS

Lowest value in 24 hours; if patient is sedated, record estimated GCS before sedation

14-15	**0**
11-13	+5
9-10	+7
6-8	+13
<6	+26

PaO_2/FiO_2, if on mechanical ventilation or CPAP

Use lowest value in 24 hours; if patient was extubated <24 hours ago, use lowest value while on mechanical ventilation

<100 mm Hg/% (13.3 kPa/%)	+11
100-199 mm Hg/% (13.3-26.5 kPa/%)	+9
≥200 mm Hg/% (26.6 kPa/%)	+6
Not on mechanical ventilation or CPAP within the last 24 hours	**0**

BUN, mg/dL or serum urea, mmol/L

BUN <28 or urea <10	**0**
BUN 28-83 or urea 10-29.6	+6
BUN ≥84 or urea ≥30	+10

Urine output, mL/day

If in ICU <24 hours, calculate for 24 hours (e.g. if 1 L in 8 hours, then mark 3 L in 24 hours)

<500	+11
500-999	+4
≥1000	**0**

Sodium, mEq/L or mmol/L

Worst value in 24 hours

<125	+5
125-144	**0**
≥145	+1

Potassium, mEq/L

Worst value in 24 hours

<3.0	+3
3.0-4.9	**0**
≥5.0	+3

Bicarbonate, mEq/L

Lowest value in 24 hours

<15	+6
15-19	+3
≥20	**0**

Bilirubin

Highest value in 24 hours

<4.0 mg/dL (<68.4 µmol/L)	**0**
4.0-5.9 mg/dL (68.4-102.5 µmol/L)	+4
≥6.0 mg/dL (≥102.6 µmol/L)	+9

WBC, x 10^3/mm^3

Worst value in 24 hours

<1.0	+12
1.0-19.9	**0**
≥20.0	+3

Chronic disease

None	**0**
Metastatic cancer	+9
Hematologic malignancy	+10
AIDS	+17

Type of admission

Scheduled surgical = surgery scheduled ≥24 hours prior; medical = no surgery within 1 week of admission; unscheduled surgical = surgery scheduled ≤24 hours prior

Scheduled surgical	**0**
Medical	+6
Unscheduled surgical	+8

APPENDIX III: CONSENT FORM

Study Title:

EXTUBATION FAILURE THE IN ICU: PREVALENCE AND RISK FACTORS AT MOI TEACHING REFERRAL HOSPITAL

Name of Principal Investigator:

Dr. Henry Kipyego Chebii

Registrar Anaesthesia and critical Care,

Moi University, School of Medicine

Department of surgery and anesthesiology

SM/PGACC/02/17

Informed Consent Form for:

All eligible extubated patients at MTRH ICU during the study period.

This Informed Consent Form has two parts:

• Information Sheet (to share information about the study with you)

• Certificate of Consent (for signatures if you choose to participate)

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

Part I: Information Sheet

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. You could still receive other treatments. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study

Purpose of the study:

The purpose of the study is to find out how often extubation failure occurs and describe factors associated with it in patients at MTRH ICU.

Type of Research Project/Intervention:

This is a descriptive observational study.

Why have I been identified to Participate in this study?

Subjects of this study will include all patients whose endotracheal tubes will be removed once their doctors have ascertained their readiness for doing so.

How long will the study last?

You will be in this study for a period not exceeding 72 hours after removal of the endotrachracheal tube.

What will happen to me during the study?

This study intends to observe and document:

- When and how the endotracheal tube currently inserted into your airway will be removed.
- Whether or not you will need to have the endotracheal tube re-inserted after its removal.
- Whether or not you or the attending doctor experiences any problems during removal or re-insertion of the endotracheal tube.

The study findings will be used to make recommendations geared at improving the management of intubated patients in MTRH ICU.

What side effects or risks I can expect from being in the study?

This study does not involve any risks to you neither does it entail the imposition, withholding or withdrawal of any treatment from you. Decisions concerning your management will be left to the MTRH ICU team, in consultation with you

Are there benefits to taking part in the study?

You may not benefit personally from this study however the study findings will be used to make recommendations geared at improving the management of mechanically ventilated patients in MTRH ICU.

Reimbursements:

Participation in this study is purely voluntary and no financial benefit will be gained

Who do I call if I have questions about the study?

- Questions about the study: Dr Henry Chebii

  Tel +254721526447

  Email: chebiihenry@yahoo.com

- Questions about your rights as a research subject:

You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information (private and confidential. Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr Henry chebii and his study team may share portions of your medical record, with the groups named below:

- The National Bioethics. Committee,
- The Institutional Review and Ethics Committee

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

The study results will be retained in your research record for at least six years after the study is completed. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr Henry Chebii in writing and let him know that you are

withdrawing your permission. The mailing address is PO BOX 4606 Eldoret. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

Your treatment, payment or enrolment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You will receive a copy of this form after it is signed

Part II: Consent of Subject:

I have read or have had the document read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

_____ _____ _____

Name of Participant Signature /thumbprint Date

_____ _____ _____

Name of person Obtaining Consent Signature Date

Dr Henry chebii _____ _____

Printed name of Investigator Signature Date

APPENDIX IV: GUARDIAN/ NEXT OF KEEN CONSENT FORM

Study Title:

EXTUBATION FAILURE THE IN ICU: PREVALENCE AND RISK FACTORS AT MOI TEACHING AND REFERRAL HOSPITAL.

Name of Principal Investigator:

Dr. Henry Kipyego Chebii

Registrar Anaesthesia and critical Care,

Moi University, School of Medicine

SM/PGACC/02/17

Informed Consent Form for:

Next of kin, guardians or caretakers of cognitively impaired adults and/or Children eligible for the study.

This Informed Consent Form has two parts:

• Information Sheet (to share information about the study with you)

• Certificate of Consent (if you choose to consent on behalf of your patient)

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

Part I: Information Sheet

Introduction:

You are being asked to consent for your patient to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to give consent, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to allow your patient to take part in the study. Your patient could still receive other treatments. Saying no will not affect his/her rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want your patient to stay in the study

Purpose of the study:

The purpose of the study is to find out how often extubation failure occurs and describe risk factors associated with it in patients at MTRH ICU.

Type of Research Project/Intervention:

This is a descriptive observational study.

Why has my patient been identified to Participate in this study?

Subjects of this study will include all patients whose endotracheal tubes will be removed once their doctors have ascertained their readiness for doing so.

How long will the study last?

He/she will be in this study for a period not exceeding 72 hours after removal of the endotrachracheal tube.

What will happen to my patient during the study?

This study intends to observe and document:

- When and how the endotracheal tube currently inserted into his/her airway will be removed.
- Whether or not he/she will need to have the endotracheal tube re-inserted after its removal.
- Whether or not he/she or the attending doctor experiences any problems during removal or re-insertion of the endotracheal tube.

The study findings will be used to make recommendations geared at improving the management of intubated patients in MTRH ICU.

What side effects or risks he/she can expect from being in the study?

This study does not involve any risks to your patient neither does it entail the imposition, withholding or withdrawal of any treatment from him/her. Decisions concerning his/her management will be left to the MTRH ICU team, in consultation with you

Are there benefits to taking part in the study?

He/she may not benefit personally from this study however the study findings will be used to make recommendations geared at improving the management of mechanically ventilated patients in MTRH ICU.

Reimbursements:

Participation in this study is purely voluntary and no financial benefit will be gained

Who do I call if I have questions about the study?

- Questions about the study: Dr Henry Chebii

Tel +254721526447

Email: chebiihenry@yahoo.com

- Questions about your patient's rights as a research subject:

You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?

All reasonable efforts will be made to keep the information protected (private and confidential. Protected Information is information that is, or has been, collected or maintained and can be linked back to your patient. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of his/her personal information. A decision to take part in this research means that one agrees to let the research team use and share their Protected Information as described below.

As part of the study, Dr Henry chebii and his study team may share portions of your patients medical record, with the groups named below:

- The National Bioethics. Committee,
- The Institutional Review and Ethics Committee,

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

The study results will be retained in the research record for at least six years after the study is completed. Any research information entered into your patient's medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your patient's Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr Henry Chebii in writing and let him know that you are withdrawing your permission. The mailing address is PO BOX 4606 Eldoret. At that time, we will stop further collection of any information about your patient. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

Your patient's treatment, payment or enrolment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You will receive a copy of this form after it is signed

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely consent for my patient to take part in this study.

(Caretaker/guardian to sign on behalf of cognitively impaired adult or Child)

_____	_____	_____	_____
Name of caretaker/Guardian	Relationship to Subject	Signature	Date

_____	_____	_____
Name of person Obtaining Consent	Signature	Date
Dr Henry chebii	_____	_____
Printed name of Investigator	Signature	Date

APPENDIX V: IREC APPROVAL

MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2019/03
Approval Number: 0003261

14th March, 2019

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
14 MAR 2019
APPROVED
P.O. Box 4606-30100 ELDORET

Dr. Henry Kipyego Chebii,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Chebii

RE: FORMAL APPROVAL

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

"Extubation Failure in the Intensive Care Unit: Prevalence and Risk Factors at Moi Teaching and Referral Hospital".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3261*** on 14th March, 2019. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 13th March, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

APPENDIX VI: HOSPITAL(MTRH) APPROVAL

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An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

19th March, 2019

Dr. Henry Kipyego Chebii,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Extubation Failure in the Intensive Care Unit: Prevalence and Risk Factors at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

19/03/2019
DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPPOVED
19 MAR 2019
SIGN
P. O. Box 3 - 30100, ELDORET

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM