UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICINE & PHARMACY

IMPLEMENTING THE ACTIONABLE PATIENT SAFETY SOLUTION (APSS) PRE-INTUBATION CHECKLIST IN THE EMERGENCY DEPARTMENT OF THE UNIVERSITY TEACHING HOSPITAL OF KIGALI: A PRE AND POST IMPLEMENTATION STUDY

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Emergency Medicine and Critical Care,

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DECLARATION

I, Dr. BIRAMAHIRE Joseph, declare that this dissertation entitled **"*Implementing the actionable patient safety solution (APSS) pre-intubation checklist in the emergency department of the university teaching hospital of Kigali: a pre and post implementation study*"** is the result of my own work and has not been submitted for any other degree at the University of Rwanda or any other institution.

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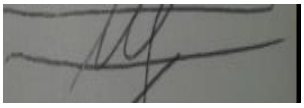
Signature: 

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ABSTRACT

Background: Airway management is one of the most important parts of practicing emergency medicine practice. Up to 1% of emergency patients may require intubation to treat conditions like respiratory failure, cardiac arrest and depressed mental status. Rapid sequence intubation (RSI) is one of the technics used to secure the airway. In the emergency department, it can be performed in a chaotic and stressful situation, which poses concerns about its safety. The generation of new policies and procedures can be implemented to generate transformative change for patient safety in airway management.

Methods: This was a pre- and post-intervention cross sectional study carried out over a period of 4 months and 1 week. It consisted of 3 phases; **Phase I:** Pre intervention**:** observation of routine practice on endotracheal intubations, **Phase II:** Intervention: Training and mentorship on the use of the pre-intubation checklist during 1 week and **Phase III:** Post intervention: Observation while using pre-intubation checklist before intubation. We recorded sociodemographic information of participants, steps of intubation, the time used for intubation, medication and devices used, tube placement confirmation, post intubation care and possible intubation related complications for pre and post intervention phase.

Results: Over the four months study period, seventy-seven (77) patients were enrolled in the study. 40 (51.9%) patients were intubated in Phase One and 37(48.1%) patients intubated during Phase Three. There was an increased adherence to steps of intubation during pre-intubation checklist use (post intervention phase). Overall, there was a reduction in ED patient intubated complications in Phase Three (35% VS. 24.7%), although this failed to reach statistical significance (p=0.306).

Conclusion: Within the UTHK ED, there was an increase in adherence to essential steps of intubation among emergency residents. In addition, the use of the pre-intubation airway checklist during rapid sequence intubations was associated with a reduction in intubation-related complications even though this reduction was not statistically significant.

Keywords: Airway complications, emergency department, airway checklist, Kigali.

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LIST OF SYMBOLS AND ACRONYMS

ABG: Arterial Blood Gas

APSS: Airway Patient Safety Solution

BVM: Bag Valve Mask

CMHS: College of Medicine and Health Sciences

DL/VL: Direct Laryngoscopy/ Video Laryngoscopy

ED: Emergency Department

EM: Emergency Medicine

EMCC: Emergency Medicine and Critical Care

ETI : Endotracheal Intubation

ETT : Endotracheal Tube

GCS: Glasgow Coma Scale

ICU: Intensive Care Unit

IQR: Interquartile range

IRB: Institutional Review Board

Kg: Kilogram

Mmhg: Millimeter of mercury

NGT: Nasogastric Tube

PGY: Post Graduate Year

PSMF: Patient Safety Movement Foundation

RSI: Rapid Sequence Intubation

SP02: Oxygen saturation

UR: University of Rwanda

USA: United States of America

UTHK: University Teaching Hospital of Kigali

VS: Vital sign

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I would like to thank the staff of the KUTH and my colleague residents, for having taught me a lot during my training in Emergency Medicine and Critical Care.

May God bless you.

DEDICATION

To God the Almighty for His love and blessings,

To my Beloved wife, and our sweet son

To my Beloved Parents, Brother and Sisters,

To my Friends and Relatives,

To my supervisors,

To my Patients

This piece of work is dedicated with great pleasure.

CHAPTER ONE: INTRODUCTION

1.1 Background

Emergency airway management constitute a crucial and fundamental part of emergency medicine care. One of the top priorities in management of a critically ill patients is protecting their airway. Airway management is a primary knowledge that must be mastered by every emergency physician.(1) Up to 1% of emergency patients may require intubation to treat conditions like respiratory failure, cardiac arrest and depressed mental status.(2)(3) Globally, there is an estimate of 50 million endotracheal intubations each year. A third of all documented intubations are performed in the United States. Among them 17% are classified as a difficult intubation.

Emergency medicine as a specialty is an emerging new department in healthcare systems located in sub-Saharan Africa, including Rwanda.(4) This has led to increasing number of intubations in emergency departments as patients in need are expected to be recognized earlier.

A study conducted by Gabin et al. at the emergency department of the University Teaching Hospital of Kigali explored the characteristics, physiology, and mortality of intubated patients. Results indicated that in one year, there were a total of 198 intubations performed, with the most experienced complication being hypoxia (27.0%) followed by aspiration of gastric content (6.7%) and cardiac arrest (3.6%).(4)

Rapid sequence intubation (RSI) is considered as one technique used to protect patients airway in the ED. Typically, RSI is performed in a chaotic and stressful environment which poses concerns about its safety compared to the intubations performed in other clinical areas like intensive care units (ICU) and operating rooms.(5)

Achieving patient safety requires multidisciplinary engagement throughout the health care system. The generation of new policies and procedures must be implemented in order to generate sustainable and transformative change for patient safety. New policies and practices will enhance the culture of accountability and transparency through reporting and documentation. This will, subsequently, help in

tackling gaps in the systems and establish policies to overcome those gaps. As such, the patient safety movement foundation has elaborated different Actionable Patient Safety Solutions (APSS) among which include Airway safety by establishing an airway pre-intubation checklist.(6)

It has been found that developing a comprehensive airway toolkit, initiation of using airway checklist and conducting team training can help in implementation of safer airway management and reduction of preventable airway adverse outcomes. Notably the checklist has been found to reduce multiple attempts, esophageal intubation, hypoxia, dental or soft tissue injury, and death.(7)(8)(9)

Unrecognized esophageal intubation, unplanned extubation, failure to secure endotracheal tube and multiple unsuccessful attempts, pulmonary aspiration, and hypoxia are major reported cause of preventable harm and death(10)(11). This results in extra expenses due to how costly it is for unnecessary payment repetition of what could have been earlier fixed.(12)

Risk factors of intubation related complications can be tackled in three ways: 1) patient related (indication of intubation, existing comorbidity and physiology), 2) operator related (experience, devices and pharmacology choices) and 3) setting resources (equipment, supplies and drug availability).(13)

Many strategies for patient airway safety improvement during endotracheal intubation have been attempted at EDs and ICUs worldwide and have yielded some improvements in different ways. In their study entitled "An intervention to decrease complications related to endotracheal intubation in the intensive care unit." researchers have found that using the developed intubation care bundle has revealed significant improvements on post intubation complications.(14)

1.2 Problem statement

There are many potential challenges to patient safety during endotracheal intubations. Yet, little is known about airway management in emergency departments located in Rwanda. Thus, far there has been no study conducted in addressing actionable solutions for airway management safety in Rwandan emergency settings.

Airway safety assurance and promotion are affected by the availability of equipment and drugs, trained staff, use of accredited policies and techniques; however, implementing a pre-intubation checklist in the emergency department could result in considerable improvements in airway management and patient care.

1.3 Research Objective

To evaluate the adherence to the APSS pre-intubation checklist among emergency medicine residents and its impact on post intubation complications during rapid sequence intubation.

1.4 Research question

Does the APSS pre-intubation checklist improve patient airway management and reduce related complications?

1.5 Rationale

This study will seek to evaluate the impact that the APSS pre-intubation checklist has on patient safety and outcomes (complication). Depending on the results of the study we will be able to recommend its use in Rwandan EDs to improve our airway management.

1.6 Hypothesis

Our hypothesis is that implementation of the APSS airway checklist will improve the safety of endotracheal intubations in emergency department at UTHK.

1.7 Structure of the study

This study seeks to assess the effect of the implementation of actionable patient safety solutions (APSS) in order to reduce airway complications in the emergency department of UTHK. This paper contains a title page, acknowledgements, dedication, abstract, and table of contents in the beginning, followed by six chapters: Introduction, Literature Review, Methodology, Results, Discussions, Conclusion and Recommendations.

CHAPTER TWO: LITERATURE REVIEW

2.1 Theoretical Literature

Endotracheal intubation refers to a technique by which an endotracheal tube (ET) is introduced into the trachea of the patient through the mouth or nose, aiming to protect the airway, give oxygen, medicine, anesthesia and support respiration in critically ill patients.

Types of endotracheal intubations

Endotracheal intubation can be:

- **Awake intubation**

Awake intubation refers to the introduction of an ET in a patient's airway without giving neuromuscular block to the patients. In this case, the patients' ability to breathe is maintained.(15)

Awake intubations are often performed when the patient has a known or suspected difficult airway or an antecedent of difficult intubation or ventilation, in whom catastrophic adverse events may follow loss of protective airway reflexes or frank apnea.

- **Rapid sequence intubation**

RSI is a definitive airway management technique that consists of providing sedative and muscular paralytic agents. It is the most common intubation used for the most effective way of protecting the emergency airway. There is no manual assist to the ventilation of the lungs after the onset of general anesthesia and apnea.

RSI is mostly used in the management of patient with an unimpaired gag reflex, a "full" stomach, and a serious injury or disease necessitating immediate airway protection such as patient without airway protection ability despite patency, hypoxia, hypoventilation, imminent obstruction (e.g., inhalation burn, penetrating neck trauma, long distance transfer, agitated patients, cervical spine injury (diaphragmatic paralysis).

Indications for intubation

A decision for endotracheal intubation should emerge from a careful patient evaluation with respect to three important criteria:(15)

(1) Inability to maintain or protect the airway.

(2) Inability to ventilate or oxygenate.

(3) Impending clinical course worsening.

Assessment for airway level of difficulty

It is very important to conduct and share a quick assessment for difficult intubation so that the treating team are aware and prepare for possible potential adverse events that can arise or follow the endo-tracheal intubation procedure.

In usual practice, the main clinical way of assessing difficult airway is composed by evaluating the following elements:

1. Difficult laryngoscopy
2. Difficult bag mask ventilation
3. Difficult Extra Glottic Devices
4. Difficult cricothyrotomy

Each of these four elements require evaluation prior to any intubation. has. An example is a mnemonic that has been established to help during prompt recognition of adult patients with difficult laryngoscopy "LEMON".(15)

This mnemonic has been found to be useful in emergency departments to help in direct assessment of the level of difficult of airway before endotracheal intubation.(16)

- **L** – Look for features of potential difficulties notably facial dysmorphism or burns and neck masses
- **E** – Evaluate the mouth opening, thyromental distance and the distance between the mandible and the thyroid cartilage.
- **M** – Mallampati score
- **O** – Obstruction in the upper airway: signs include stridor, distant voice, and inability in handling secretions.
- **N** – Neck mobility: limited neck mobility which can be a result of congenital anomalies or cervical spine immobilization.

In addition to this, there are a series steps that are frequently adopted when carrying out endotracheal intubation commonly known as the "7Ps of endotracheal intubation" Preparation, Preoxygenation, Pretreatment, Paralysis with induction, Protection and positioning, Placement of the tube and Post intubation management.

2.2 Empirical Literature

Generally, there is a lack of studies on endotracheal intubation and pre-intubation check list use in the region and across Africa. A systemic review and meta-analysis conducted in South Africa on association of checklist use in endotracheal intubation with clinically important outcomes has revealed no association between survival and checklist use in patients undergoing ETI but checklist use was associated with a decrease in hypoxic events.(17) Another study done in the same country assessing checklist use during intubation of trauma patients showed that the use of a preprocedural checklist is associated with improved outcomes and may improve quality of care(18).

Formalized training in airway management, algorithms and cognitive aids have been proven to be part of strategies to reduce airway management related complications.(3) a study done by Caputo ND et all 2018 on application of gap analysis to develop a call out/call back airway checklist has revealed an improvement especially on aspiration from 3% (pre-checklist) to 1% (post checklist), and pulses losses from 2%(pre-checklist) to 1% (post checklist).(19) In their study: "impact of checklist on pre-intubation care in ED trauma patients" Conroy MJ et al found that the use of peri-intubation checklists resulted in higher rates of RSI in ED trauma but did not alter other measured metrics, therefore they suggest further evaluation on patients' outcome.(20) Smith et al in their study found that the use of a standardized preprocedural checklist is feasible when intubating severely injured trauma patients, and checklist implementation was associated with a reduction in immediate, intubation-related complications in a single academic ED. In their study, intubation-related complication was experienced by one (1.5%) patient in the post checklist period, compared to seven (9.2%) patients during the pre-checklist period, representing a 7.7% reduction.(21)

2.4 Critical Review and Research Gap identification

At present, there is limited data available regarding airway management in Rwandan emergency departments. There are currently no studies evaluating actionable solutions for airway management and safety in East Africa. In order to improve context specific patient care in the region. It is essential to evaluate current airway practices in the emergency department and look for solutions to improve outcomes for our patients.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This study sought to evaluate the impact of the implementation of actionable patient safety solutions (APSS) checklist to reduce airway complications in the emergency department of the UTHK. It required a robust research methodology to obtain accurate data. This chapter will give a detailed explanation of research design, population, sampling, ethical considerations, data collection, analysis and final data dissemination.

3.2 Study design

This study is a pre- and post-intervention study that implemented the apss intubation checklist (appendix 1) at the UTHK ED between 1st January 2021 and 9 May 2021.

3.3 Research approach

We used a pre- and post-intervention study design. The project consisted of three phases. The study was performed among senior residents in emergency department and patients who underwent rapid sequence intubations. At the start of the study, data was collected on how endotracheal intubation were being performed using a predesigned questionnaire. Next, residents were trained and mentored on the use of checklist before intubation and essential steps of intubation for 1 week. The checklist was also posted in patient intubation rooms and offices. Finally, data was then collected on how well residents complied with the checklist in their clinical practice. Data was collected by trained research staff at the UTHK ED who received an introduction to the study and training on how to fill in the data collection forms. The study took a period of 4 months and 1 week divided into 3 phases:

Phase I: Pre intervention.

For a period of two months, we observed routine practice on endotracheal intubations before the intervention was implemented. We recorded patients' demographic characteristics, the steps of intubation, number of attempts, time taken, medications used and procedural complications.

Phase II: Intervention.

Residents were trained and mentored on the use of the APSS pre-intervention checklist for 1 week. Large, printed duplicates of the pre-intubation checklist were attached on wall in each resuscitation room in the ED where it could be easily and clearly visualized. The APSS pre-intubation checklist has the following main items: preparation before intubation, during intubation and post intubation protection (Appendix 2). It was developed by patient safety movement foundation (PSMF) and was suggested to be used as one of actionable patient safety solutions for airway complication during intubation. (www.saferairway.org).

Phase III: Post intervention

During another two months period, residents were observed while using the checklist before intubation. Intubation checklist was completed after the decision to intubate had been made, preceding administration of induction drugs. The same information was recorded as in phase I. Each step of intubation and the time used for intubation, confirmation of tube placement and possible intubation related complications were recorded.

Important methodological definitions

***Rapid sequence intubation*:** Administration of rapid-onset induction agents and muscle relaxant without assist on breathing between induction and laryngoscopy

***endotracheal intubation attempt*:** each introduction of laryngoscopy in patient's mouth

***Duration of the intubation*:** Difference between time of tracheal intubation confirmation and decision of RSI.

Day time procedure: procedure performed from 7:00 am to 5:00 pm.

***Night time procedure**: procedure performed between 5:00 and 7:00 am.

***Aspiration*:** inhalation of gastric contents into the respiratory tract during intubation or within 1st hour after intubation based on clinical findings.

Esophageal intubation: accidental introduction of the endotracheal tube into the esophagus.

Hypotension: Persistent low blood pressure with systolic pressure less than 90mmhg in adult and less than 70+(2 X Age) in patients less than 8years.

Hypoxia: persistent hypoxia with SpO2 less than 88%.

Bradycardia: slow heart rate less than 60 beat per minute.

***Cardiac arrest*:** Pulses losses during or just after intubation.

3.4 Research setting

The APSS intubation checklist was piloted in a tertiary referral center, Kigali University Teaching Hospital (UTHK) Emergency department. UTHK is affiliated with the School of Medicine and Pharmacy at the University of Rwanda. UTHK has approximately 519 beds and is estimated to be a catchment area for more than 6,200,000 people (www.chuk.rw).

UTHK is located in the capital city, Kigali, and provides a wide range of services, including surgery, obstetrics/gynecology, internal medicine, pediatrics, radiology, ophthalmology, dermatology, and laboratory services. The emergency department at the UTHK has a total of 24 beds and conducts approximately 20,000 patient visits per year (www.chuk.rw). In the ED there are a total of 5 mechanical ventilators that can be used while managing patient's airways after endotracheal intubation.

At UTHK ED, intubations are primarily performed by emergency medicine and critical care residents under supervision of EMCC physicians. The emergency medicine and critical care residency program is 4 years in duration and during the first year, residents complete a full month rotation in anesthesiology to enhance knowledge and gain exposure of airway management.

3.5 Population

UTHK serves a population of approximately 6.2 million people. The patient demographic is made up of a mixture of rural and urban populations with a broad social demographic.

3.5.1 Selection of study population

a) Inclusion criteria:

- Being a senior resident registered in critical care and emergency medicine program and practicing at UTHK emergency department during the period of study.

- Patients who underwent Rapid sequence intubation.

b) Exclusion criteria:

- Patients who refused to sign the informed consent.
- Patients who were unable to give consent due to incapacitation by their injuries and had no family member or guardian present to provide consent.
- Any patient who did not undergo rapid sequence induction prior to intubation.

3.6 Sampling

Eligible patients to whom a rapid sequence intubation had been decided at UTHK ED during the study period were enrolled in the study. Eight nurses served as research assistants. After intubation decision is made, patients or caretaker were approached by the research assistant who was not involved in providing their medical care. The research assistant explained the study to the patient or caretaker (for pediatric patients and others unable to sign consent for themselves) and asked if the patient would like to participate. If accepted, the consent form was signed. The research assistant then completed a structured questionnaire. We requested consent waiver for residents in order to limit potential source of bias to this study.

3.6.1 Sample size calculation

The study aimed to include all patients who underwent RSI at the UTHK ED during the four-month study period. The total number of samples was determined by the number of rapid sequence intubations that was performed during the period of our study. In total seventy-seven (77) underwent of rapid sequence intubations, among those 40 patients were enrolled pre-intervention and 37 patients enrolled post intervention.

3.6.2 Sampling strategy

Study personnel were present 24/7 to enroll patients and gather data. All eligible patients who consented to participation were included in the study sample.

3.7 Validity and reliability of research instruments

A data collection form was developed using the relevant literature and the APSS safer airway checklist. The form was assessed by a consultant in anesthesiology and emergency medicine and critical care. Airway checklist used was developed by the Patient Safety Movement Foundation.

3.8 Data Collection

Data was collected using a predesigned data collection form. Data collection was performed by the principal investigator and research assistants (emergency nurses) for 24 hours a day, during the period of the study.

3.9 Data analysis

Data was entered into Excel and then further imported and analyzed using STATA Version 15.0 (Stata Corp; College Station, USA). Descriptive statistics of the study population was characterized using frequencies and percentages for categorical variables and continuous variables were described using median values with associated interquartile ranges (IQR). Cases were stratified by time periods of Phase One (pre-intervention) and Phase Three (post-intervention). Differences in characteristics were assessed using χ^2 or Fisher's exact tests for categorical variables and independent t-tests for continuous variables. A significance level of $p<0.05$ was utilized for all analyses.

3.10 Ethical consideration

This study was approved by the CMHS Institutional Review Board (IRB) No 304/CMHS IRB/ 2020 and the UTHK ethics committee EC/CHUK/123/2020.

3.11 Data management

All data sheets were kept in a secured locked location at the University Teaching Hospital of Kigali. Only study investigators had access to the data. No directly identifying information was collected in this study. For electronic copies, passwords were used to keep data secured.

3.12 Data Dissemination

The data will first be submitted as a thesis for the Master of Medicine in Emergency Medicine and Critical Care program and then to a peer-reviewed journal for publication.

3.13 Limitations and challenges

The limitations and challenges found will be analyzed in the discussion.

CHAPTER FOUR: RESULTS

4.1 Introduction

In total, there were seventy-seven (77) patients who underwent endotracheal intubation using rapid sequence intubation technique at the UTHK ED during the study period, of which all consented and were enrolled in the study. Of those enrolled, 40 (51.9%) patients were intubated during phase One (pre-intervention) and 37 (48.1%) patients intubated during phase Three (post-intervention phase).

4.2 Presentation of study findings

4.2.1 Sociodemographic information of patients intubated at UTHK ED

The majority of patients who were intubated and enrolled in the study were men (88.3%), had a median age of 39.25 (IQR: 25.5-59), weighed 70kg (IQR: 60-75), and were admitted for trauma (54.5%) (Table 1). In comparison of patient's sociodemographic information pre-intervention and post-intervention, there was a similarity between gender (p=0.731), age (p=0.316), weight (p=0.637) and reason for admission (p=0.412) (Table 1).

The majority of intubations were performed during the night, with 62.5% in Phase One and 70.3% in Phase Three (p=0.471) (Figure One). In both phases, the prime indicator for intubation was a low GCS followed by respiratory failure (p=0.850) (Table 1). The time required to place a tube from intubation decision was 15 minutes in the preintervention phase and 12 minutes in post-intervention (p=0.415). Senior resident performed all intubations in year three or year four of training. There was a statically significant difference in attending resident level of training in Phase One compared to Phase Three (p=0.0198). Year 4 residents performed 87.5% of intubations in phase One and 64.9% of intubations in phase Three. Overall, there was no significant statistical difference in patient vital signs between phases (Table 2).

Table 1. Sociodemographic information of patients intubated at UTHK ED

Characteristics	Pre-Intervention n (%) 40	Post-Intervention n (%) 37	P value
Gender			
Male	36 (90.0%)	32 (86.5%)	0.731
Female	4 (10.0%)	5 (13.5%)	
Age (Years)	36.5 (25.5-56.5)	42 (33- 59)	0.316
Estimated weight(kg)	70 (60-75)	70 (65-75)	0.637
Reason for Admission			
Trauma	24 (60.0%)	18 (48.7%)	0.412
Medical	15 (37.5%)	16 (43.2%)	
Intoxication	1 (2.50%)	3 (8.10%)	
Indication for intubations			
Low GCS	31 (77.5%)	28 (75.7%)	0.850
Respiratory failure	9 (22.5%)	9 (24.3%)	
Attending resident level of training			
PGYIII	5 (12.5%)	13 (35.1%)	0.0198
PGYIV	35 (87.5%)	24 (64.9%)	
Type of shift			
Day	15 (37.5%)	11 (29.7%)	0.471
Night	25 (62.5%)	26 (70.3%)	
Time used for intubation (min)	15 (11-20)	12 (10-20)	0.415

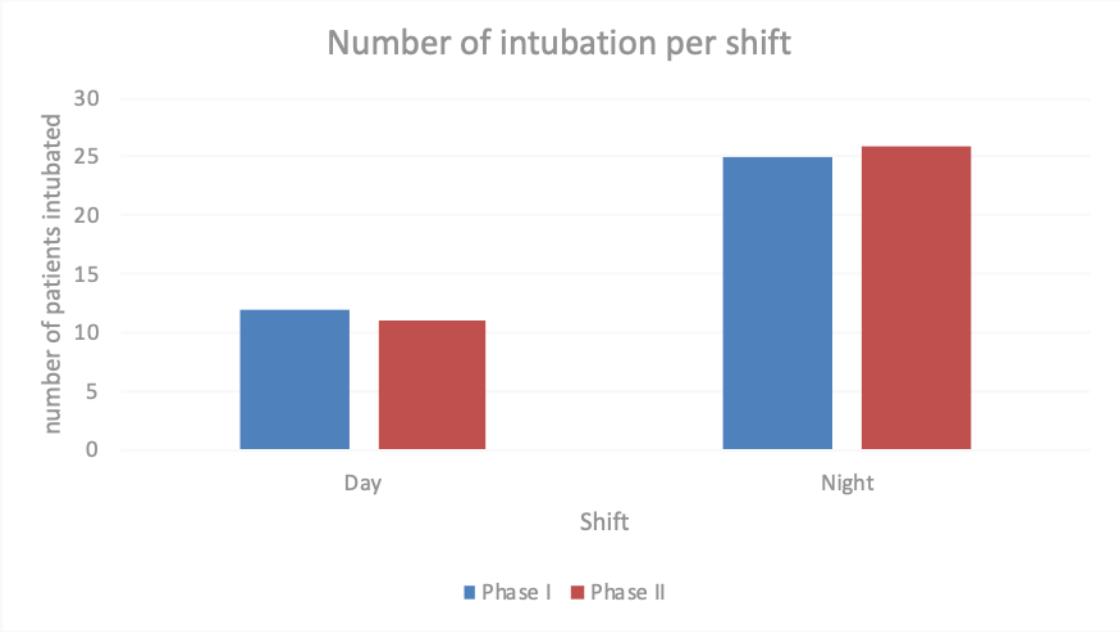

Figure 1. Number of intubations per shift

4.2.2 Compliance rate to the APSS pre-intubation checklist at UTHK ED.

For 35% of intubations preformed in phase one, the level of difficult was shared with the team. After implementation of the checklist, the sharing of the level of airway difficulty increased to 97.3%. Note that the level of difficulty was assessed based on the clinical condition of the patient and usual practice in emergency department.

Table 2. Compliance rate to all APSS pre-intubation checklist items

Characteristics	**Pre-intervention n (% 0r IQR)**	**Post-intervention n (% 0r IQR)**	**P value**
Level of airway difficult shared	14(35.0%)	36(97.3%)	0.000
Management plan preparation			
Plan A (DL or VL)	40(100%)	37(100%)	1.00

Plan B (LMA)	0(0.00%)	0(0.00%)	1.00
Plan c (Surgical airway kit)	38(97.4%)	37(100%)	0.327
Vital signs	40(100%)	37(100%)	1.00
Heart rate	99(86-118)	90(82-108)	0.372
Systolic Blood pressure	123(104-131)	131(118-142)	0.184
Oxygen saturation	92(79-97)	93(88-96)	0.290
Temperature	36.7(36.4-37)	36.5(36.1-37)	0.414
Respiratory rate	21(15-24)	20(18-24)	0.819
Positioning			
Yes	39(97.5%)	37(100%)	1.00
No	1(2.5%)	0(%)	
Preoxygenation			
Yes	40(100%)	37(100%)	1.00
No	0(0.00%)	0(0.00%)	
Equipment readiness			
Bag and mask suction setup			
Yes	40(100%)	37(100%)	1.00
No	0(0.00%)	0(0.00%)	
Airway cart glidescope setup			
Yes	10(25%)	37(100%)	0.001
No	30(75%)	0(0.00%)	
ETT/syringe			

Yes	39(97.5%)	37(100%)	1.00
No	1(2.50%)	0(0.00%)	
Intubation devices used			
Direct laryngoscopy & bougie	28(70.0%)	8(21.6)	
Video laryngoscopy& bougie	12(30.0%)	28(75.6)	0.000
LMA	0((0.00%)	1(2.70%)	
Premedication used			
Morphine	2(5.00%)	10(27.0)	
Fentanyl	2(5.00%)	3(8.11)	
Lidocaine	0(0.00%)	0(0.00%)	0.001
Other (atropine & adrenaline)	0(0%)	4(10.0%)	
None	36(90%)	20(54.0%)	
Induction medication			
ketamine	27(67.5%)	34(91.9%)	
propofol	3(7.50%)	1(2.70%)	0.036
diazepam	1(2.50%)	0(0.00%)	
midazolam	9(22.5%)	2(5.41%)	
Paralytics			
Succinylcholine	30(75.0%)	6(16.2%)	0.000
Vecuronium	9(22.5)	31(83.8)	
None	1(2.50%)	0(0.00%)	
Tube placement check up			

Auscultation	39(97.5%)	36(97.3%)	
Clinical	0(0.00%)	1(2.70%)	0.733
None	1(2.50%)	0(0.00%)	
Number of intubation attempts			
Once	28(70.0%)	29(78.3%)	
Twice	9(22.5%)	7(18.9%)	0.656
Three	3(7.50%)	1(2.70%)	
Above three	0(0.00%)	0(0.00%)	
Post intubation protection & care			
Head of bed elevation	40(100%)	37(100%)	1.00
NGT placement	36(90.0%)	26(70.3%)	0.043
Sedation orders	36(90.0%)	30(81.1)	0.336
Restrain patient	29(6.00%)	12(32.4%)	0.022
ABG in 10-15 minutes	1(2.50%)	11(29.7%)	0.001

Overall, there were no statical differences between Phase One and Phase Three for patient positioning (97.5% VS. 100%, p=1.00), pre-oxygenation (100% VS. 100%, p=1.00), or Bag and mask suction setup availability (100% VS. 100%, p=1.00) (Table 2). The majority of patients did not receive premedication in Phase One (90%) compared to in Phase Three, when only 54% did not receive premedication (p=0.001). Tube confirmation was done mainly by chest auscultation and clinical assessment. The study noticed one case (2.5%) where tube placement confirmation was not done in Phase One, and no case was found during post-intervention phase. In Phase One, 28 (70%) patients were intubated using directed laryngoscopy, while in Phase Three, 28 (75.6%) were intubated using a video laryngoscopy (p=0.000). However, this significant change to the intubation devices used may be linked to

the non-availability of functioning direct laryngoscope in the last week of phase One and almost first the two weeks of Phase Three.

Ketamine was the first induction choice medication for both phases, followed by midazolam and propofol. There was a significant difference in paralytic drugs used, where 30(75%) patients were paralyzed using succinylcholine in Phase One, and 31(83.8%) patients were given vecuronium in phase Three. Overall, residents adhered to the checklist steps for intubation and generally showed an increase in performance (Table 2).

4.2.3 Intubations related complications at UTHK ED.

The most common complication in Phase One was Hypoxia 8(20.0%) followed by hypotension 5(12.5%), aspiration of gastric content aspiration 3(7.50%) and lastly cardiac arrest 2(5.00%) (Table 3). While in phase Two hypotension was the more frequent complication 4(13.5%), followed by hypoxia 4(10.8%), bradycardia and cardiac arrest at 2.7% each. There was no aspiration noted in the second phase. In sum, there was a witnessed reduction of complications from 35% in Phase One to only 24.3% in Phase Three, however this was found to be not statically significant (p=0.306).

Table 3.Difference in complication before and after implementation of APSS pre-intubation airway checklist.

Complication noted after intubation	*Pre-intervention n (%)*	*Post-intervention n (%)*	*P value*
Hypoxia	8(20.0%)	4(10.8%)	0.352
Bradycardia	0(0.00%)	1(2.70%)	0.481
Hypotension	5(12.5)	5(13.5%)	1.00
Cardiac arrest	2(5.00%)	1(2.70)	1.00
Aspiration	3(7.50%)	0(0.00)	0.241
None	26(65%)	28(75.68%)	0.306

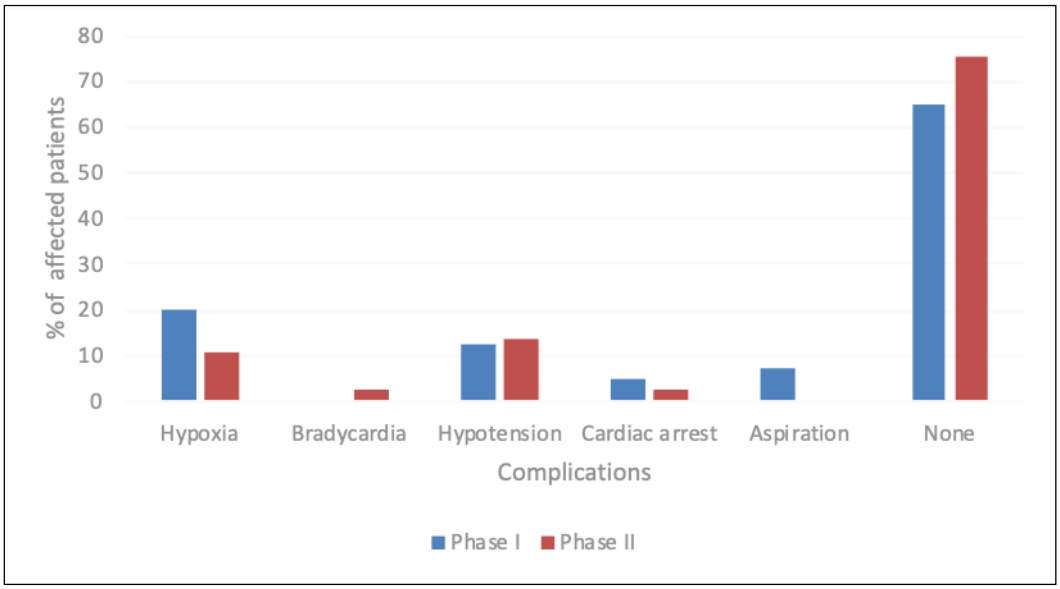

Figure 2 Complication post intubation

CHAPTER FIVE: DISCUSSION

This study sought to evaluate the impact of implementing the Actionable Patient Safety Solutions (APSS) checklist to reduce airway complications in the emergency department of the UTHK. In this pre-and post-intervention cross-sectional study, between 1 January 2021 and 9 May 2021, enrolled a total of 77 endotracheal intubations in the ED of UTHK. Residents were found to be compliant in completing the checklist, and overall, there was an increase in safety procedures performed. Notably, there was an increased adherence on steps of intubation among emergency residents and an overall reduction among patient complications; however, it did not reach a statistical difference.

During Phase One, 40 patients were enrolled, while in Phase Three, 37 patients were included. The sample size shows similarity if compared with another study performed in the same department on intubation which found 176 intubations in an entire year(4). Observations in gender, age, patient weight, and reason for ED admission were similar between the two phases. Males were more likely to be intubated compared to females in both phases. This finding may be linked with a high number of trauma patients enrolled in the study. Previous studies have shown that males are more exposed to trauma than females at UTHK ED (22)(4).

This study has revealed a decrease in the number of intubations attempts and time used for intubations during the use of APSS pre-intubation checklist (Phase Three). It also demonstrates a decrease in hypoxic events. This finding is consistent with other studies that have shown that a decrease in the number of intubation attempts was associated with the reduction of hypoxic events in emergency and trauma center department in Addis Ababa, Ethiopia (1) and in an ED in Arizona, USA (7)(23). This may be a result of timely availability of drugs and equipment on bedside during preparation before endotracheal intubation as recommended by the APSS pre- intubation checklist used. Another significant finding of the study is the fact that the majority of the intubations carried out during the first phase were done using direct laryngoscopy compared to VL in phase Three (Table 2). Perhaps this also played a role in reducing the number of attempts and complications as well.

The resident's pharmacological choices were associated with significant statistical differences for both induction and paralytic agents used between the two phases. Pretreatment medication was given only in 4(10.0%) patients in phase One, while 17(46%) received premedication in phase Three. Morphine was the medication used most for premedication, followed by fentanyl. Succinylcholine was the most paralytic drug used in phase one (75.0%), and vecuronium (83.8%) mainly being used in phase Three. These medication preference changes resulted from intermittent pharmacy stock out experienced in ED during the time of the study, which has influenced the choice of medication for residents during intubation. However, the post-intervention phase was associated with good outcomes in terms of complication. We can't be sure if this results from an increase in pretreatment or vecuronium use in phase Three meanwhile, suxamethonium is encouraged by many studies as a paralytic drug of choice during RSI for its faster onset of action over vecuronium but also feared for its complications notably hyperkalemia which can cause arrythmia and cardiac arrest after intubation.(24) Another recent study has found suxamethonium to be associated with low all-cause mortality rate comparing to vecuronium and rocuronium.(25)

Pretreatment was improved during APSS pre-intubation airway checklist use because 10.0% of patients in phase One received pretreatment medication compared to 46.0% in the post-intervention phase. It is difficult to know whether a patient's clinical conditions raised the number of those who received pretreatment before intubation or if it was just an impact of the APSS pre-intubation checklist use. Notably, there was no significant difference in patients' vital signs between pre- and post- intervention phases. Generally, it is believed that pretreatment of unstable patients before rapid sequence intubation can significantly impact their eventual outcome, but limited studies are supporting its benefits. On the other hand, a clinical review conducted to evaluate the importance of pretreatment during rapid sequence intubation has found supporting literature to this practice.(26)

Adherence to essential steps of intubation increased considerably from Phase One to Phase Three. This result may be from training and mentorship provided to residents during Phase Two of the study. The use of a checklist was associated with

increased adherence to essential steps of intubation among emergency residents. This was similar to other studies, which showed an increase in adherence to safety measures during the implementation of the pre-intubation checklist in trauma patients in ED and ICU settings.(21)(27) The reason for this increased adherence could be that adopting the APSS checklist helped emergency residents and intubating teams recognize whether any essential components of the procedure or equipment was missing prior to commencing.

Overall, the results of this study showed a reduction in the number of intubation complications, although this failed to reach statistical significance. The most common intubation-related complications were hypoxia (20%) and hypotension (12.5%) in Phase One and hypoxia (10.8%) and hypotension 13.5% in Phase Three (Figure 2). These listed complications are comparable to other studies performed on intubations conducted in the same setting at UTHK in Rwanda(4) and other studies completed in South Africa (18) and the USA (20). While a sizeable but non-statistically significant decrease in ED patient complication occurred, we believe that an increase in sample size could highlight the findings.

Limitations

There are limitations to this study. Firstly, this study was conducted in a single center and with a small sample size over a short period of time. Further research should focus on enrolling a large number of patients and include different emergency centers in the country or in the region in order to increase the generalizability of findings. Another limitation was the availability of drugs and devices used during the study period. As this study was conducted in a recourse constraint hospital, a common challenge is frequently experiencing temporary or intermittent pharmacy stock out and broken devices. This may have affected emergent residents' choices during endotracheal intubation practice. Meanwhile, an ongoing study is looking at the causes of essential ED medications and supplies stock out; as such there is an ongoing study intended to offer solutions to this challenge. Lastly, we couldn't evaluate all components of post-intubation care on the checklist due to the lack of essential equipment in the settings. Notably, the ED

is currently missing a waveform capnography, portable x-ray machine and intermittently nonfunctioning ABG machine during the period of our study. Further research is encouraged to continue to evaluate the impact of the APSS pre-intubation checklist.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

In UTHK ED, APSS pre-intubation checklist during rapid sequence intubations was associated with reducing intubation-related complications, although this reduction was not statistically significant. An increase in adherence to essential steps of intubation among emergency residents was also noted. APSS pre-intubation checklist use was also associated with raised number of first attempt passes and a reduction in time required to intubate the patient once the decision to intubate was made by the clinician.

6.2 Recommendations

Based on the results of this study, we recommend the university teaching hospital of Kigali to initiate pre-intubation checklist use in the emergency department and conduct regular training and mentorship for ED staff on the use of pre-intubation checklist and endotracheal intubation procedures in general.

We would also recommend using this APSS pre-intubation checklist in emergency departments within the country to reduce post-intubation complications and increase patient airway safety. However, for the non-availability of supplies and equipment in some emergency settings, the author of the checklist template encourages its customization to make it more comprehensive and meet local practice.

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APPENDICES

1. Data collection form(Data sheet was made using APSS airway checklist and the study done by Janz et al.(28)

Patient ID: _____

Age: _____

Sex: Male ☐ Female ☐

Estimated patient weight: _____

Attending resident year of training: PGYI ☐ PGYII ☐ PGYIII ☐ PGYIV ☐

Indication: _____

Comorbidities: _____

Intubation procedure: _____

Start time: _____ End time: _____

Run Checklist:

1. **Preparation before intubation:**
    a. **Airway assessment and a plan shared**
        i. Level of difficulty (circle if doctor mentions):
            1. Low Moderate High Very High Did not say
        ii. Plan ABC and Medication needed (Check all plans that doctor has prepared for)
            1. Plan A- "Primary"- DL/VL Bougie ☐
            2. Plan B- "Backup"- SGA (LMA) Size ☐
            3. Plan C- "Cricothyrotomy" ☐
    b. **Patient Ready?**
        i. Monitoring vital signs- Did the doctor check each vital sign? (Circle yes or no)
            1. HR: _____ YES NO

2. BP: _____ YES NO
3. SPO2: _____ YES NO
4. EtCO2: _____ YES NO
5. Temp: _____ YES NO
6. RR: _____ YES NO

ii. Positioning: Did the doctor position the patient? YES NO

iii. Pre-Oxygenation: Did the doctor Pre-Oxygenate the patient? YES NO

c. **Equipment Readiness (Check the box if the doctor has set up the all of the equipment)**

i. Bag and mask & suction setup ☐
ii. Airway Cart & glideslope setup ☐
iii. ETT/syringe SGA on bedside ☐

d. **Intubation devices actually used:**

i. Direct laryngoscopy ☐
ii. Video laryngoscopy ☐
iii. Bougie ☐
iv. LMA ☐
v. Surgical airway ☐

e. **Medication ready?**

i. Pretreatment:
1. None: ☐
2. Fentanyl: ☐
3. Lidocaine: ☐
4. Morphine: ☐
5. Other: _____

ii. Induction:
1. Ketamine: ☐

2. Propofol: ☐
3. Midazolam: ☐
4. Diazepam: ☐
5. Thiopental: ☐
6. Other: _____

iii. Paralytic:

1. None ☐
2. Succinylcholine ☐
3. Vecuronium ☐
4. Other: _____

2. <u>During Intubation:</u>

a. Intubation (Check the box if the doctor performed these tasks):

i. Timeout- "Everyone ready?" ☐
ii. Announce: "Beginning Intubation" (Give RSI Medication) ☐
iii. Maintain Nasal Cannula at 15+ LPM ☐
iv. Confirm Tube Placement: ☐

1. Auscultation ☐
2. EtCO2 ☐
3. Clinical ☐
4. Other: _____

b. Number of Intubation attempts: _____

3. <u>Post Intubation Protection:</u>

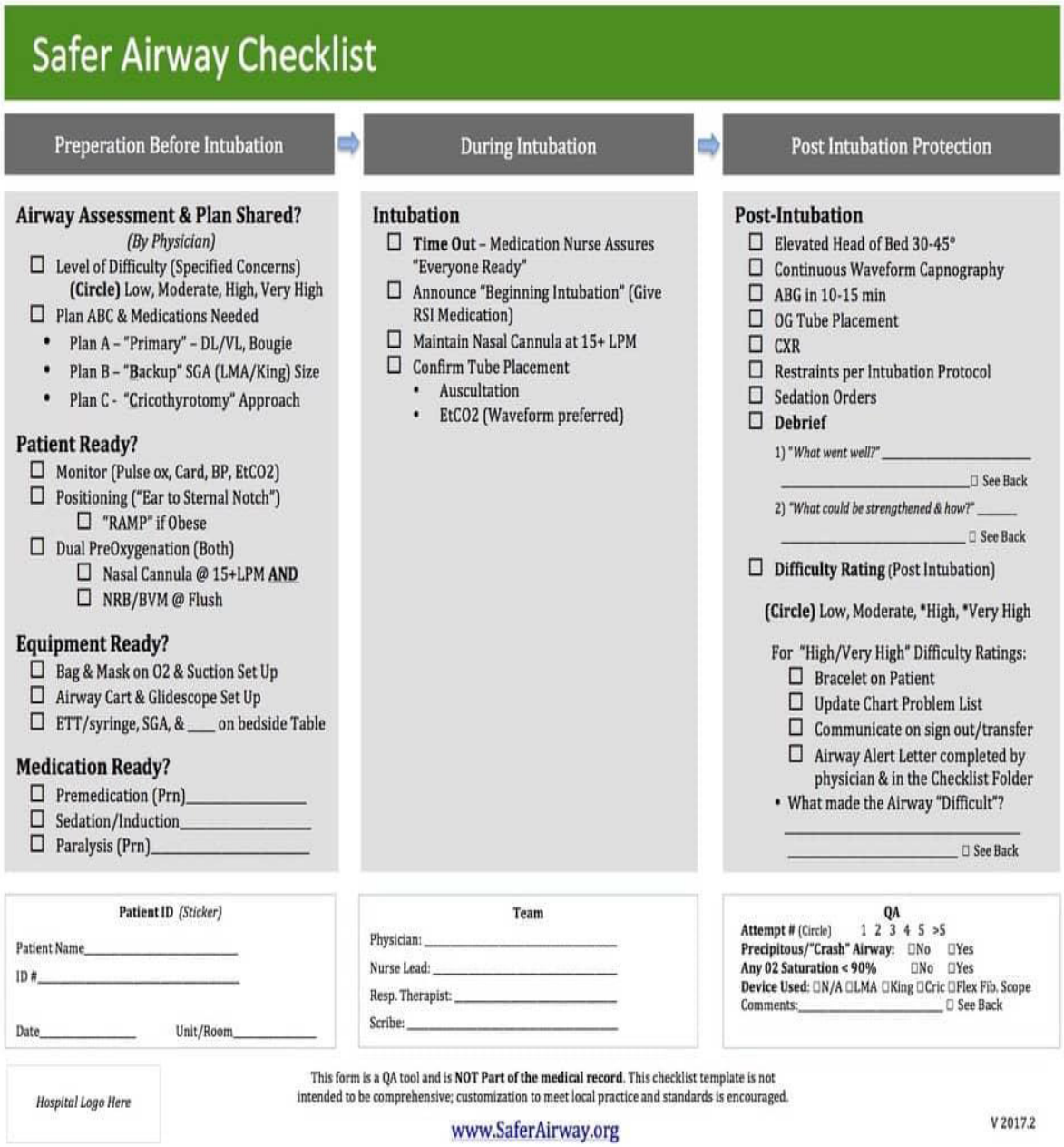
a. Post Intubation (Check the box if the doctor performed these tasks):

i. Elevated head of bed 30-45 ☐
ii. Continuous waveform capnography ☐
iii. ABG in 10-15 min ☐
iv. OG Tube Placement ☐
v. Restraints per Intubation Protocol ☐
vi. Sedation Orders ☐

b. Complication noted after intubation:
    i. None ☐
    ii. Hypoxia ☐
    iii. Bradycardia ☐
    iv. Cardiac arrest ☐
    v. Aspiration ☐
    vi. Hypotension ☐
    vii. Esophageal intubation ☐
    viii. Other: _____

c. Doctors Thoughts About Intubation:
    i. How would the doctor now rate the Intubation?
        1. Low Moderate High Very High
        Did not say

2. Checklist used.



Safer Airway Checklist

Preperation Before Intubation

Airway Assessment & Plan Shared?
(By Physician)

- ☐ Level of Difficulty (Specified Concerns) **(Circle)** Low, Moderate, High, Very High
- ☐ Plan ABC & Medications Needed
  - Plan A – "Primary" – DL/VL, Bougie
  - Plan B – "Backup" SGA (LMA/King) Size
  - Plan C - "Cricothyrotomy" Approach

Patient Ready?

- ☐ Monitor (Pulse ox, Card, BP, EtCO2)
- ☐ Positioning ("Ear to Sternal Notch")
  - ☐ "RAMP" if Obese
- ☐ Dual PreOxygenation (Both)
  - ☐ Nasal Cannula @ 15+LPM **AND**
  - ☐ NRB/BVM @ Flush

Equipment Ready?

- ☐ Bag & Mask on O2 & Suction Set Up
- ☐ Airway Cart & Glidescope Set Up
- ☐ ETT/syringe, SGA, & ____ on bedside Table

Medication Ready?

- ☐ Premedication (Prn)_____
- ☐ Sedation/Induction_____
- ☐ Paralysis (Prn)_____

During Intubation

Intubation

- ☐ **Time Out** – Medication Nurse Assures "Everyone Ready"
- ☐ Announce "Beginning Intubation" (Give RSI Medication)
- ☐ Maintain Nasal Cannula at 15+ LPM
- ☐ Confirm Tube Placement
  - Auscultation
  - EtCO2 (Waveform preferred)

Post Intubation Protection

Post-Intubation

- ☐ Elevated Head of Bed 30-45°
- ☐ Continuous Waveform Capnography
- ☐ ABG in 10-15 min
- ☐ OG Tube Placement
- ☐ CXR
- ☐ Restraints per Intubation Protocol
- ☐ Sedation Orders
- ☐ **Debrief**

1) *"What went well?"* _____
_____ ☐ See Back

2) *"What could be strengthened & how?"* _____
_____ ☐ See Back

- ☐ **Difficulty Rating** (Post Intubation)

(Circle) Low, Moderate, *High, *Very High

For "High/Very High" Difficulty Ratings:

- ☐ Bracelet on Patient
- ☐ Update Chart Problem List
- ☐ Communicate on sign out/transfer
- ☐ Airway Alert Letter completed by physician & in the Checklist Folder
- What made the Airway "Difficult"?
_____
_____ ☐ See Back

Patient ID *(Sticker)*

Patient Name_____

ID #_____

Date_____ Unit/Room_____

Team

Physician: _____

Nurse Lead: _____

Resp. Therapist: _____

Scribe: _____

QA

Attempt # (Circle) 1 2 3 4 5 >5
Precipitous/"Crash" Airway: ☐No ☐Yes
Any 02 Saturation < 90% ☐No ☐Yes
Device Used: ☐N/A ☐LMA ☐King ☐Cric ☐Flex Fib. Scope
Comments:_____ ☐ See Back

Hospital Logo Here

This form is a QA tool and is **NOT Part of the medical record**. This checklist template is not intended to be comprehensive; customization to meet local practice and standards is encouraged.

www.SaferAirway.org

V 2017.2

3. Informed Consent Form /English

Introduction:

Hello, my name is **BIRAMAHIRE Joseph**, I am an Emergency Medicine and Critical Care doctor in training at University of Rwanda/College of Medicine and Health Science studying "***IMPLEMENTING THE ACTIONABLE PATIENT SAFETY SOLUTION (APSS) PRE-INTUBATION CHECKLIST IN THE EMERGENCY DEPARTMENT OF THE UNIVERSITY TEACHING HOSPITAL OF KIGALI***". I request your participation in our study and wish to share with your important information about the project so that you may understand if there is a question you are free to ask.

Purpose of Study:

The purpose of this study is to assess the impact of implementation of actionable patient safety solutions for airway complication and therefore to improve patient's airway safety in emergency department. This study is will be conducted in emergency department at CHUK.

Type of Research Intervention:

There will be no intervention on your body we will be observing what is happening during airway management and we will record how the procedure happened.

Confidentiality:

All information collected will be kept confidential and viewed only by members of the research team. No identifiable information will be collected and information will be randomized with confidentiality. All data will be used for research purposes only and disposed of following completion of the study.

Risks and Benefits:

There are minimal risks of participation in the study. Data will be shared only with members of the research team and for research purposes with disposal following the study. Careful attention will be paid to protect information recorded. No information will be shared with outside parties.

The benefit of participating in the study is helping our team better understand the impact of the use of pre-intubation checklist on airway complications and help on improvement of patient's safety while managing airways.

Compensation:

They will be no compensation for participation to this study.

Right to Refuse or Withdraw from the Study:

Participants are permitted to refuse or withdraw from the study at any time without any adverse consequences.

Contact Details:

For further information or if you have any questions, concerns, or wish to withdraw from the study you may contact:

-**Dr Biramahire Joseph**: Tel: +250785639579 Email: jobamahire2@gmail.com

- **Dr Stefan Jansen**, chair IRB CMHS/UR: Tel: +250784575900

-**Dr RUSINGIZA Kamanzi Emmanuel**, Chairperson of Ethic committee, CHUK Tel: +250785466254 Email: erkamanzi@gmail.com

Certificate of Consent:

I (patient/next of kin) have been explained the foregoing information. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant/next of kin

……

Signature of Participant/ next of

kin…….

Date ……. /……/……

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands his participation to this study.

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

Print Name of Researcher/person taking the consent……

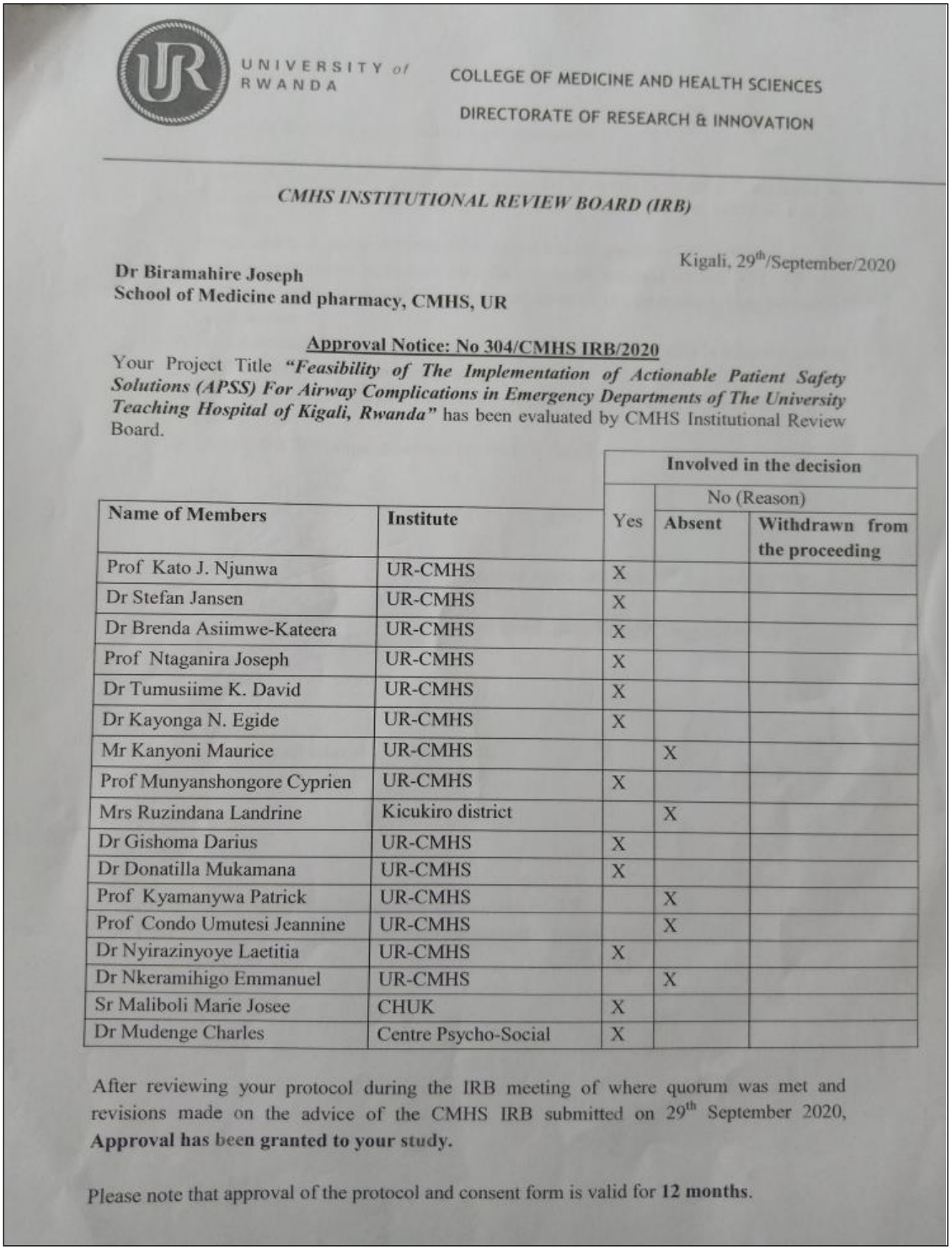
Signature of Researcher /person taking the consent

…….

Date ……...../……. /……..

Day/month/year.

4.CMHS/IRB/Approval



UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 29th/September/2020

Dr Biramahire Joseph
School of Medicine and pharmacy, CMHS, UR

Approval Notice: No 304/CMHS IRB/2020

Your Project Title ***"Feasibility of The Implementation of Actionable Patient Safety Solutions (APSS) For Airway Complications in Emergency Departments of The University Teaching Hospital of Kigali, Rwanda"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Dr Stefan Jansen	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 29th September 2020, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 29th September 2020

Expiration date: The 29th September 2021

Dr Stefan Jansen
Ag. Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

5. KUTH/Ethic committee approval

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care Training & Research

Ethics Committee / Comité d'éthique

30,Dec,2020 *Ref.:EC/CHUK/123/2020*

Review Approval Notice

Dear Joseph Biramahire,

Your research project: ***"Feasibility of the implementation of actionable patient safety solutions (APSS) for airway complications in emergency departments of one teaching hospital in Rwanda "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 30,Dec,2020 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=197&&chuk.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali

ETHICS COMMITTEE
CHUK

Scan code to verify

" University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations "

B.P. :655 Kigali- RWANDA www.chuk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw