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School of Medicine

IMPACT OF SIMULATION TRAINING IN A CLINICAL EMERGENCY.

A simulation based randomized controlled trial on difficult airway management of a "can't intubate can't ventilate" case scenario at SIM Center Kigali Teaching Hospital, Rwanda.

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DECLARATION

I hereby declare that this dissertation: “Impact of simulation training in clinical emergency crisis: A simulation based randomized controlled trial on difficult airway management can’t intubate can’t ventilate case scenario at Simulation Center Kigali Teaching Hospital, Rwanda” is my own work. This study in whole or in part has neither been submitted for publication anywhere nor has it been submitted for the award of a degree in other university.

Signed

Date 31/8/2019

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I hereby declare that this dissertation has been submitted with my approval as the supervisor.

Signed

Date 31/8/2019

DEDICATION

I dedicate this dissertation to Almighty God without whose blessings and gifts of life and strength this study would not have been started.

This study is also dedicated to all family, friends and colleagues.

With love I dedicate this study to my beloved father Matthieu DIUR and my beloved mother KANYEKAMO Katherine for your unconditional support with my studies. I am honored to have you as my parents. Thank you for giving me a chance to prove and improve myself through my entire walks of life journey.

Special dedication to my mother KANYEKAMO Katherine for her resilience in insisting to educate me, you have successfully made me the person I am becoming, and you will always be remembered.

With the deepest gratitude and love that I dedicate this dissertation also to my brothers and sisters for all that they have sacrificed for me. Hoping that with this research I have proven to you that there is no mountain higher as long as God is our side. Hoping that you will walk again and be able to fulfill your dreams.

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Dr NGEBE KANYAMBO Eric

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ABSTRACT

Background: The effectiveness of simulation is rarely evaluated in Africa. The aim of this study was to assess the impact of a short training course on the ability of anesthesiology and emergency medicine residents, and non-physician anesthetists to comply with vortex approach tool for difficult airway management immediately after training.

Methods: Forty participants comprising anesthesiology and, emergency medicine residents, and non-physician anesthetist were assessed on simulation in a "can't intubate, can't ventilate" scenario after the training randomization into control group (use memory only) and intervention group (use cognitive aid). The scenario was built so that the participant was prompted to perform External Surgical Airway. Adherence with airway management guideline (grading checklist 0 to 14) and the External Surgical Airway' duration and Anesthesia Non-Technical Shills (0 to 4) were assessed as a checklist score.

Results: After training, all 40 participants (100%), the performance between control and intervention were good in the intervention group, the mean grading checklist score (0 to 14) was 10 (P 0.046) in the intervention group and 7 in the control group, the mean time to attempt ESA (0 to 8) was 165s in the intervention group and 183s in the control group, the mean score adherence to cognitive aid was 12.6 (90%) in the intervention group, in the control group was 6.3 (60%). The group with access to the cognitive aid had higher scores in all categories (Grading checklist and ANTS), there was a trend towards a higher proportion of the participants in the cognitive aid group being able to oxygenate within 3 min of entering the room.

Conclusion: The use of cognitive aid improved the participants' adherence to the protocol and their performance for time to attempt External Surgical Airway and Anesthesia Non-Technical Skills are improved when a cognitive aid is present during airway emergencies.

Keywords:
Simulation scenario, grading checklist, cricothyrotomy, anesthesia non-technical skills, difficult airway management.

List of tables:

Abbreviations:

ANTS: Anesthesia non-technical skills

ANOVA: Analysis of variants

CICV: Can't intubate can't ventilate

ASA: American society of anesthesiologist

BMV: Bag mask ventilation

CHUK: Centre Hospitalier de Kigali

CG: Control group

ESA: External surgical airway

ED: Emergence department

IG: Intervention group

IRB: Institutional review board

IRR: Inter-rater reliability

LMA: Laryngeal mask

NPA: Non physician anesthetist

PGY: Postgraduate year

RMH: Rwanda military hospital

SA: Standardized actor

SimMon: Simulation monitor

SimMan: Simulation Mannequin

WHO: World health federation

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Chapter I: GENERAL CONSIDERATION

I.1. Introduction

The past decades and especially the last 5 years have seen rapidly growing interest in using simulation for purposes of improving patient safety and patient care through a variety of applications[1]. Simulation technology has been advocated as a safer method for students to learn and practice skills in high-acuity scenarios without exposing real patients to the possibility of adverse events[2]. Teamwork training has made a fundamental impact on error reduction and human performance improvement in a number of commercial areas such as aviation and other major industries[2].

Simulation is firmly established within health care training but often focuses on training for technical tasks and can overlook crucial skills such as professionalism and physician-patient communication. By practicing repeatedly within a safe environment, technical skills, communication with patients and team members, decision making, and clinical judgment while preserving patient safety[3] can be enhanced. Medical simulation is fast becoming a standard of health care training throughout undergraduate and postgraduate education. The teaching tool emphasizes experiential learning and capitalizes on well-established principles of adult learning[4].

A majority of students do not have the ability to manage emergency situations properly while using memory recall alone. Even experts can fail to do the basics when stressed. In the critically ill, patient factors may preclude standard airway assessment. Urgency and reduced physiological reserve contribute dramatically to increased risks of profound peri-intubation hypoxemia, hypotension, arrhythmia, cardiac arrest, and death. Delays during tracheal intubation and multiple attempts at laryngoscopy are associated with increased morbidity and mortality. Critical illness and its management can make anatomically 'normal' airways 'physiologically difficult'[5].

In emergency situations, established clinical protocols are intended to help avoid fixation, facilitate teamwork and help ensure that time critical management options are not delayed or overlooked. Observations in both clinical and simulated settings, however, demonstrate that adherence to a guideline or protocol may be compromised in situations that are stressful and time pressured. This demonstrates the need for emergency guidelines to be as simple as possible so that they can be recalled and implemented effectively in a crisis situation. It is also crucial that all members of the team, to enable them to anticipate treatment priorities or to prompt the group if the performance of an individual becomes compromised, share knowledge of the appropriate protocol [6].

Many emergency procedures are performed rarely but are of vital importance when needed. Examples of such procedures include needle thoracocentesis,

cricothyroidotomy, and urgent thoracotomy for trauma. These complex procedural skills must be learned and retained for potentially long periods of time before they are needed. The duration between acquisition of skills and its eventual performance is referred to as the retention interval[7].

Failure to oxygenate a patient successfully is a rare and feared crisis of airway management. Rapid action is needed to create a passage by which oxygen can be delivered; otherwise, hypoxic brain injury and death will occur. Accordingly to established guidelines, when all other measures to provide oxygen fail, the final common step is the insertion of a surgical infraglottic airway[8].

Retention of procedural knowledge is an aspect of anesthesia training and simulation training in emergency crisis is proposed to be helpful. How does simulation training affect students' achievement during emergency crisis? What changes will students observe in their own clinical practice?

I.2. Review of literature

Despite the publication and dissemination of guidelines and algorithms in Europe and the United States, complications of difficult airway management occur and can have serious consequences. Airway management is essential for ensuring the safety of anesthetic practice in the operating theater, in intensive care units and in emergency departments. A recent study showed that 6.2 % of intubations in the operating room theater are difficult. Difficult intubation with difficult ventilation occurs in 1.5% of procedures, with impossible intubation and difficult ventilation in 0.3% of procedures, and a "can't intubate, can't ventilate" (CICV) situation in 0.07% of procedures [13].

There is a common misconception that emergency manuals are not relevant in the management of time-sensitive acute events. Certainly, it can be harmful to consult a book or computerized device at the wrong time (e.g., when a pulseless patient needs chest compressions, or other acute physical actions, with insufficient clinicians present). However, with appropriate use, emergency manuals can be a helpful resource for important management priorities during many critical events, in addition to providing an accessible resource for more common needs of "Pre" crisis education and "Post" event debriefing [14].

Since the initial publication of the World Health Organization (WHO) surgical safety checklist in 2009, the potential for checklists and other cognitive aids to reduce errors during surgical procedures has been recognized worldwide. The impact of checklists in anesthesia has been investigated by a number of studies, and two recent editorials conclude that there is now "over- whelming evidence", as well as "sufficient justification to warrant widespread adoption" of perioperative crisis checklists "when well crafted" and when "clinicians are wisely prepared". Various institutions and professional anesthesia societies have begun to advocate for the use of such aids [15].

Despite improved patient outcomes resulting from using checklists in general, there is much more to learn about how to develop them, how to use them, and how to train clinicians to use them effectively for managing emergencies [16]. The ability to store, retain, and subsequently retrieve information is critical to every aspect of medical training and clinical practice. There is a general belief, based on subjective experience, that stress influences memory. Many clinicians anecdotally report that some experiences during their training or clinical practice seem as if they will be remembered for a lifetime, whereas other events seem to have been forgotten (or never encoded) because of the stress surrounding the event[17].

Perioperative teams are expected to be able to manage such emergency situations, but prior studies have shown that performance during simulations of perioperative emergencies is often suboptimal when patients are managed from memory alone. Furthermore, with limited exposure to these rare situations, appropriate care is less likely to be administered and the patient is more likely to experience an adverse outcome than during routine care [18].

Simulation training is in its infancy in the medical field and is most commonly focused on individual skills such as endotracheal intubation, central venous catheter placement, and endoscopy training; its use is likely to increase. Settings that are especially prone to errors are those that are high acuity or low frequency, and those that require teamwork[19]. Research by the National Aeronautics and Space Administration has concluded that the majority of commercial aviation accidents result not from technical or mechanical error, but from breakdowns in communication, leadership, and teamwork among flight crews[20].

Failure to effectively manage life-threatening complications in surgical patients has been recognized as the largest source of variation in surgical mortality among hospitals. Small-scale studies suggest that teams are commonly unable to properly manage crises. For example, studies of cases requiring advanced cardiac life support show poor adherence to appropriate practices, as well as substantial decay in retention of knowledge after training[21].

4th National Audit Project of the Royal College of Anesthetists and the Difficult Airway Society. Royal College of Anesthetists, London, 2011[22].

In Rwanda, could the use of cognitive aids provide a practical and safe means to manage an emergency crisis in anesthesia? Would such a modality enable safe practice with relatively brief training?
To do this, a randomized controlled trial, simulation study was designed. Posttest scores would elucidate any adherence and performance with the use of memory alone versus cognitive aid.

I.3. Research question and objectives

I.3.1. Research question and hypothesis

Can a cognitive aid help to translate best practices for patient care and retention of skills of residents during simulation training compare to the use of memory alone?
Hypothesis 1: The presence of a cognitive aid is associated with higher performance and adherence score (primary outcome).
Hypothesis 2: The presence of cognitive aid reduces the time to achieve External Surgical Airway (ESA).
Hypothesis 3: The presence of cognitive aid is associated with higher Anesthesia Non-Technical Skills (ANTS) scores.

I.3.2 General Objective

The purpose of this study is to determine how the use of cognitive aid in a simulated rare emergency anesthesia crisis, can improve timely and efficiency adherence to standard practice.

CHAPTER II. METHODOLOGY

II. 1. Study site:

We conducted our study at University Teaching Hospital of Kigali/CHUK in simulation center. The University Teaching Hospital/CHUK is the largest hospital located in District of Nyarugenge at KN 4 Ave, Kigali City. It is also the biggest referral of the country with a capacity of 519 beds. University Teaching Hospital of Kigali provides quality healthcare to the population, training, clinical research and technical support to district hospitals.

II. 2. Study population:

a. Inclusion criteria:

We have recruited residents from University of Rwanda in the department of Anesthesia and Emergency Medicine rotating in four referral hospitals (Kigali Teaching Hospital, Butare Teaching hospital, Rwanda Military Hospital, and King Faisal Hospital) and NPAs from Anesthesia department of the same referral hospitals.

b. Exclusion criteria:

- PGY1 considered having experience less than two years during residency training
- NPAs with experience less than two years' experience
- Refusal to participate in the study
- Participant who are not able to speak and to understand English

II. 3. Study procedure:

Ethical approval for this prospective, quantitative randomized control trial study was obtained from University of Rwanda Institutional Review Board (IRB). Participants were invited to volunteer via departmental email, and each provided written informed consent.
We enrolled 40 participants (female and male); the participants were members of anesthesia and emergency medicine teams from healthcare organizations (Kigali Teaching Hospital, Rwanda Military Hospital, Butare Teaching Hospital, and King Faisal Hospital).
Each study team of three consisted of a participant who plays the role of leader and primary airway manager (Anesthesia resident, Emergency Medicine resident, Non-Physician Anesthetist), and two assistants (junior anesthesia trainees who plays the role of anesthesia assistant).
The scenario were performed at one simulation center at University Teaching Hospital of Kigali during three days using the low-fidelity manikin as a patient, and with the SimMon on the ipad3 replacing the usual vital signs monitor. All the regular equipment: airway, medications, and intravenous fluid were available to the participants, and they were oriented to the location of the equipment and to the manikin for a period of 5 minutes before the scenarios.

Participants were randomized into two groups using a random envelope seal technique: Intervention group (cognitive aid) and Control group (memory alone).

Each participant was asked to manage a low-fidelity in situ simulation of Can't Intubate Can't Ventilate (CICV) event in the casualty. The crisis was constructed and programmed by a team of anesthesiologists with minimum of 3 years' experience in simulation education and research.

Participants in the intervention group were allowed to use cognitive aid while in the control group they were not allowed. According to the schedule outlined below:

1. Upon arrival to the Simulation Center all participants signed the consent and filled the pretest questionnaire.
2. Seminar was delivered via a video training produced by vortex approach team for difficult airway[33].
3. After the pretest questionnaire and the seminar, the participants were randomized for a post training assessment. The randomization was split accordingly to sealed envelopes ensured random allocation of participants (pair number for intervention group and impair number for control group), a number was given to each participant also as study number.
4. Before the start of the scenario, the participant was briefed on the emergency call, the materials provided and the assistance available locally.
5. Each participant was tested in a case scenario of 8 minutes on CICV as senior consultant who has been called for help at ED.
6. During the scenario each played the role of leader and airway manager with two assistants (emergency medicine resident and emergency medicine nurse).
7. After the scenario each participant filled a posttest questionnaire and debriefing was conducted about the scenario. It was focused on difficult airway management algorithms (vortex approach tool), decision-making times, technical skills, and non-technical skills for crisis resource management.

Instruction manuals were prepared outlining the preparation of the scenario (Appendix 1). All the simulations were video-recorded and rated on a blind basis; each video recording was anonymized through the attribution of a code number chosen by the participant and maintain throughout the study. The camera field of view was centered on the technical procedures. Each video recorded was viewed once and rated by the principal investigators. The principal noted the level of adherence and performance based on the algorithms of each grading checklist and awarded a checklist score for difficult airway algorithm modified from vortex approach tool (0-14) (Appendix 8-9) and anesthesia non-technical skills (Appendix 12), the duration of the cricothyrotomy (defined as the time between location of the cricothyroid membrane and the achievement of ventilation, through the cricothyrotomy cannula).

The scenario used lasted 8 minutes and through CICV (Appendix 1). The scenario consisted of code team personnel and roles, and patient as low fidelity mannequin (Appendix 2), the code consisted of three personnel, the participant acting as chief leader and airway manager, and two assistants (emergency

medicine resident and emergency medicine nurse), the nurse will combine two roles as a nurse and code chart reader (Appendix 3). One of the assistants was trained to be the standardized team, and he gave each participant a brief description of the situation per script.
There was a standard amount of information given to each participant scenario, and scripted responses were provided for questions that they might ask about the present condition and care of the simulated patient. During a scenario after help was called for, a standardized actor (SA) would arrive and, after 3 minutes, prompt the participant for a diagnosis. For the control group, the SA would simply ask, "Doctor, what do you think is going on with this patient?" For the intervention group, the SA would also act as a Reader and would ask the same question concerning the diagnosis of the patient condition. Then based on the answer from participant, the SA would find the paper cognitive aid in the room and offer to read the algorithm steps aloud during the course of the scenario. If the leader did not desire to have the cognitive aid read at that time, the SA would notify the leader that the algorithm was available in the room for their reference. During the scenario, if the leader did not use the cognitive aid for more than one minute, the SA would offer again to read the cognitive aid.
All sessions were performed in situ in the simulation center at University Teaching Hospital of Kigali using the SimMan mannequin. Patient monitors (SimMon), a code cart, and cricothyrotomy kit were used.
Audiovisual recordings were taken and saved for later analysis. Two independent observers evaluated the primary outcome of grading checklist and the secondary outcome of ANTS scores and, time to attempt ESA.
We chose 8 minutes as a point during which the diagnosis could be made and major initial and subsequent treatment steps undertaken as per the American Society of Anesthesiologist (ASA).
The participants did not know that they were going to manage a simulated CICV scenario. They knew that they had enrolled to participate in a study investigating simulated a clinical emergency management.

II. 4. Sample size:

In the fields of psychology and education, a Cohen's effect size greater than 0.4 is considered large and acceptable for a given teaching intervention[24]. Therefore, using ANOVA and assuming an effect size of 0.4 and power of 0.80, we calculated a total sample size of 40, which equals 20 participants per group (with 0.05 two-tailed) [25].

II.5. Statistical analysis

1. Primary outcome:
    - Grading checklist for CICV (Appendix 9). Allowed assessment of the adherence and performance between control group and intervention group with grading occurring in a fashion for each item (performed/performed poorly or at inappropriate time/not performed)
2. Secondary outcome:
    - Time to attempt ESA (= time interval between the start of the

scenario and the start of the attempt of a surgical airway)

- ANTS Scale (Appendix 10). The Anesthesia Non-Technical Skills was developed at the University of Aberdeen as a tool to assess those Skills considered germane to anesthetic practice.

Statistical analysis has been performed using SPSS (version 24, IBM, Armonk, NY). The inter-rater reliability of scores provided by the two observers was measured by correlation coefficient.

The primary outcome has been analyzed using one-way independent samples ANOVA to determine differences between the control and cognitive groups after normal distributions had been established. Proportions of participants attempted ESA within 3 min in each group and mean times to oxygenation were analyzed using Fisher's exact and Student's t-tests, respectively. Correlation between grading checklist scores and ANTS scores and ESA times were assessed using Spearman rank correlation and Pearson's coefficients, respectively. Inter-rater reliabilities were assessed using Cohen's Kappa analyses.

The secondary outcome has been analyzed similarly using design ANOVA for ANTS score

II. 6. Study procedure checklist

1. PREPARATION	`
a. Equipment/resources	
i. Audiovisual equipment:	
ii. Manikin	
iii. Other simulation equipment:	
iv. PowerPoint slides	
iv. Actors/confederates arranged	
v. Paperwork: Sign in sheet, Grading check list, ANTS grading score	

2. SUBJECT STUDY ID	

3. IMFORMED CONSENT	
a. Obtain informed consent from all subjects to participate in the study	
b. Obtain informed consent from all subjects to be video recorded, if required, if required by your study site.	
c. Obtain informed consent for debriefers if applicable	

5. PRE-TEST QUESTIONNAIRE and POST TEST QUESTIONNAIRE Ask each subject to fill out a pre-test and posttest questionnaire	

6. SCENARIOS	
a. Video recording:	
b. Scenario log	
c. Assigning scenarios	
d. Randomization of the scenario order:	

8. POST-TEST QUESTIONNAIRE Ask each subject to fill out a post-test questionnaire after every scenario	

II. 7. Ethical considerations

The research protocol was submitted for review and approval to IRB CMHS, no grant has been provided for this study. All participants signed a written informed consent and the video recorded was kept confidential using the agreement mentioned in appendix 13.

CHAPTER III. RESULTS

III.1. Description of sample

The study population comprised 40 participants in total, 25 second-third year- and fourth year anesthesia residents from University of Rwanda and 6 NPAs from CHUK and RMH in the department of anesthesia; 9 second-third-and fourth year emergency residents from University of Rwanda (28 men and 12 women; mean age: 33 years).

III. 2. Social demographic data

		Frequency	Percentage
Age group	<35 years	33	82%
	> 35 years	7	18%
Gender	Male	28	70%
	Female	12	30%
Level of education	NPA	6	15%
	PGY2	12	30%
	PGY3	12	30%
	PGY4	10	25%
Department	Anesthesia	31	77%
	Emergency	9	23%
Position	NPA	6	15%
	Resident	34	85%

Years of experience	1 year	12	30%
	2 years	12	30%
	3 years	10	25%
	4 years or more	6	15%
Total		40	100%

Among the study participants, 82% were aged below 35 years and the male to female ratio was 2.3. 15% were non-physician anesthetists and 85% were residents from anesthesia and emergency departments.

III. 3. Characteristics of course participants, pretest and posttest questionnaires with (Intervention) without (Control) cognitive aid

	Intervention (n=20)	**Control (n=20)**	**P value**
Clinical specialty			
Anesthesia resident	12 (60%)	14 (70%)	0.13
Emergency medicine resident	3 (15%)	5 (25%)	
NPAs	4 (20%)	2 (20%)	
Experience, years	12 (>3)	17 (>3)	0.06
Pretest			
Experience on difficult airway			
- Reviewed difficult airway algorithm airways	4 (20%)	6 (30%)	
- Difficult airway simulation	7 (35%)	3 (15%)	
- Team member in a difficult airway situation	8 (40%)	7 (35%)	
- Team leader in a difficult airway	5 (25%)	3 (15%)	
Training on difficult airway			
- Once	1 (5%)		
- Twice	3 (15%)	5 (25%)	
- Three times	5 (25%)	3 (15%)	
- Four times and more	9 (45%)	6 (30%)	
Comfortability on difficult airway			
- Somewhat disagree	2 (10%)	2 (10%)	
- Somewhat agree	6 (30%)	17 (85%)	
- Strongly agree	3 (15%)	10 (50%)	
Use of cognitive aids during difficult airway			
- Strongly disagree	7 (35%)	5 (25%)	
- Somewhat disagree	3 (15%)	3 (15%)	
- Somewhat agree	4 (20%)	10 (50%)	
- Strongly agree	4 (20%)	4 (20%)	
Posttest			

Prior training on ANTS		
- Once	-	2 (10%)
- Twice	10 (50%)	7 (35%)
- Three times	2 (10%)	3 (13%)
- Four times or more	5 (25%)	2 (10%)
- Never	2 (10%)	7 (35%)
Prior training on ESA		
- Once	3 (15%)	5 (25%)
- Twice	3 (15%)	5 (25%)
- Three times	-	1 (5%)
- Four times or more	5 (25%)	2 (10%)
- Never	6 (30%)	10 (50%)
Cognitive aids are valuable too in medical practice		
- Somewhat agree	-	5 (25%)
- Strongly agree	20 (100%)	15 (75%)
Cognitive aids improve patient safety		
- Somewhat disagree	-	1 (5%)
- Somewhat agree	-	1 (5%)
- Strongly agree	20 (100%)	18 (90%)

All participants (N=40) had previous experience on difficult airway through difficult airway algorithm airways (20% in IG vs 30% in CG), difficult airway simulation (35% in IG vs 15% in CG), team members in a difficult airway situation (40% in IG vs 35% in CG), and team leader in a difficult airway (25% in IG vs 15% in CG). The majority (N=32) 80% stated they had experience in training on difficult airway.

Over half (57%) of participants stated they could comfortably manage a difficult airway, 33% strongly agree (15% in IG vs 50% in CG) and 10% somewhat disagree (30% in IG vs 85% in CG).

Frequently use cognitive aid during difficult airway, 20% of participants strongly agree (20% in IG vs 20% ib CG), 35% somewhat agree (20% in IG vs 50% in CG), 15% somewhat disagree (15% in IG vs 15% in CG), and 30% strongly disagree (35% in IG vs 225% in CG).

Previous training on ANTS, 77.5% stated they have been trained (85% in IG vs 70% in CG), and 22.5% never trained (10% in IG vs 35% in CG).

60 % of participants stated they have been trained once or more on ESA (55% in IG vs 65% in CG), and 40% never trained (30% in IG vs 50% in CG).

All participants stated cognitive aids are a valuable tool in medical practice, 87.5% strongly agree (100% in IG vs 75% in CG), and 12.5% somewhat agree (0% in IG vs 25% in CG).

95% of participants strongly agree that cognitive aids improve patient safety (100% in IG vs 90% in CG), 2.5 % somewhat agree (0% in IG vs 5% in CG) and, 2.5% somewhat disagree (0% in IG vs 5% in CG).

III. 4. Grading checklist, ANTS and time to attempt ESA, technical and non-technical performance of both groups

	CG (N=20)	IG (N=20)	IRR Cohen's K (p value)	(ANOVA test)	p value
Grading checklist					
Suction check	1.08 (0.75)	1.43 (0.63)	0.950 (<0.001)	7.56	0.005
Neuromuscular block	1.10 (0.88)	1.55 (0.55)	0.958 (<0.001)	7.81	0.005
Attempt oxygenation	1.08 (0.75)	1.43 (0.5)	0.949 (<0.001)	6.01	0.006
Attempt endotracheal Intubation	1.13 (0.85)	1.53 (0.59)	0.955 (<0.001)	7.26	0.005
Attempt BMV	1.10 (0.88)	1.48 (0.55)	0.952 (<0.001)	6.68	0.006
Attempt LMA	1.08 (0.0.75)	1.33 (0.69)	0.958 (<0.001)	7.68	0.005
ESA	1.13 (0.85)	1.53 (0.59)	0.952 (<0.001)	6.46	0.006
Total score	7.7 (5.71)	10.28 (4.1)			0.046
Time to attempt ESA; s	183.8 (65.0)	165.4 (64.4)	_	_	0.27
ANTS					
Team management	3.2 (0.8)	2.5 (0.8)	0.714 (< 0.001)	10.0	0.002
Team working	3.3 (0.7)	2.6 (0.9)	0.638 (< 0.001)	9.66	0.003
Situation awareness	3.5 (0.6)	2.6 (0.8)	0.608 (< 0.001)	18.4	<0.001
Decision making	3.4 (0.6)	2.7 (0.8)	0.713 (< 0.001)	13.9	<0.001
Total score	13.2 (2.4)	10.4 (3.1)	_	15.8	<0.001

Of the 20 participants provided with the cognitive aid, 18 (80%) were observed to read from it, hold it or place it on the patient's chest during the scenario. Only three of the participants in the control group asked for the cognitive aid but not allowed. There were significant differences between the groups with and without the cognitive aid. However, there was a trend towards a higher proportion of the participants in the cognitive aid group being able to oxygenate within 3 min of entering the room. Inter-rater reliability was good for all category scores: Grading checklist scores (K = 0.949 to K = 0.958), ANTS scores (K = 0.608 to K = 0.714). The group with access to the cognitive aid had higher scores in all categories (Grading checklist, ANTS) compared with the control group.

III. 5. Correlations between time to attempt ESA and performance of technical and non-technical skills

	Correlation coefficient (p)	p value
Grading checklist		
Suction check	0.246	0.014
Neuromuscular block	0.212	0.017
Attempt oxygenation	0.270	0.011
Attempt endotracheal Intubation	0.302	0.009
Attempt BMV	0.276	0.010
Attempt LMA	0.212	0.017
ESA	0.250	0.013
Total score	0.276	0.010
Time to attempt ESA	0.026	0.837
ANTS		
Team management	0.368	0.003
Team working	0.338	0.006
Situation awareness	0.383	0.002
Decision making	0.404	0.001
Total score	0.383	0.002

There were moderately strong positive correlations between the numbers of times the cognitive aid was used and the grading checklist scores ($p = 0.212$ to $p = 0.302$), ANTS scores ($p = 0.338$ to $p = 0.404$). There was no statistically significant correlation between the number of times the cognitive aid was used and the time to attempt the ESA.

III. 6. Adherence to cognitive aid

Group study		N	%	Mean	Min	Max
Group control	No adherence	12	60%			
	Poor adherence	8	40%			
	Total	*20*	*100%*	*6.3*	*5*	*9*
Intervention group	Poor adherence	2	10%			
	Good adherence	18	90%			
	Total	*20*	*100%*	*12.6*	*11*	*14*

The mean score in the intervention group was 12.6, which falls into a category of good adherence as opposed to the mean score of the control group of 6.3 graded as poor adherence. 90% of the intervention group had good adherence to the use of cognitive aid while 60% of the control group had no adherence to the cognitive aid.

Chapter IV. DISCUSSION

We tested the hypothesis that the implementation of a paper cognitive aid via a simulated scenario would improve adherence and performance to published guideline (Vortex approach algorithm) and safety of the patients in the management of an in situ simulation of CICV as compared with management from memory alone. Our results demonstrate that the employment of the paper cognitive aid by the team resulted in near-perfect adherence to published guidelines during an in situ simulation of CICV. Furthermore, our results emphasize the value of simulation for training in general and for the acquisition of algorithm and complex procedural skills in particular. The cricothyrotomy duration was shorter in the intervention group than in the control group but the difference was not significant. There were no significant differences in Non Technical Skills between the two groups but the intervention scored higher than control group but we noticed a significant difference in grading checklist in favor of intervention group compare to control group.

There are few data on the impact of simulation on the acquisition of airway management skills in general and cricothyrotomy in particular. A recent study by Boet et al. reported[26] that a single simulation cricothyrotomy training session improved the procedural skills of attending anesthesiologists and that this improvement was retained for at least a year. The same scenario was used in the study; the resident played the role of an anesthesiologist called on to help with an ongoing intubation attempt. On the simulated patient's arrival, the oxygen saturation was 92% and falling by 10% per minute. All intubation methods were destined to be unsuccessful, because the scenario was set up in the CICV. Hence, the scenario was designed to prompt the anesthesiologist to perform a cricothyrotomy.

The time needed to perform cricothyrotomy in Boet et al.'s study appears to be longer than that observed in this study and those reported elsewhere. Because the scenarios were set the same in the pretest and the posttests, one can reasonably suppose that in posttest, the anesthesiologists recognized the scenario that they had already acted out in the pretest and were therefore able to choose the right actions more rapidly. In contrast we used one scenario for the single test so that participants would not recognize the scenario. Hence, the participants could not presume that the scenarios would end in the same way (i.e., with identical SpO2 starting values and decreases).

Furthermore, our population of 40 participants was randomized for assessment in immediate post training period. Hence, each participant was assessed in the post-training period. This design avoided the training bias that would probably have been present if each participant had been assessed pretest, posttest, and retention test after training because each posttest scenario would have served as training for the next one. This choice of study design also prevented us from assessing the decision-making time, which is nevertheless an important parameter.

In the current study, the randomization was split by envelope seal technique to mitigate a potential source of bias related to hypothetical differences in the participants' respective knowledge and skills. With a view to limiting bias, no other training on difficult airway management was provided during the study period; the only way of being "trained" corresponded to the (rare) occurrence of

a difficult airway situation in the participants' clinical practice.
In view of the unavailability of a fiberscope and video laryngoscope in the scenario used here, the participants were ultimately prompted to perform a cricothyrotomy. This choice was justified because it enabled a complete exploration of difficult airway algorithm and allowed us to assess the associated steps and procedures. Furthermore, cricothyrotomy is the final option in all CICV airway management algorithms and is not easily available and usable under all circumstances.
Furthermore, we decided to avoid hypoxic cardiac arrest during the scenario by ensuring that the SpO2 remained above 40%. This choice avoided the involvement of cardiac arrest management, which was not an efficacy criterion in the current study. If the SpO2 reached 40%, the facilitator recommended a cricothyrotomy. It is clear that many hypoxic cardiac arrests would have been observed during the test and would have called on the participants' knowledge of cardiac arrest algorithms as well. No hypoxic cardiac arrests were recorded and the facilitator did not have to step in.
We acknowledge that [1] the use of memory alone is easier during elective case than during emergency crisis and [2] performance of a cricothyrotomy on a manikin is artificial and differs from real-life situations. However, controlled trials are difficult or even impossible to perform on humans because of the urgency and rarity of this procedure. Nevertheless, the literature seems to indicate that both non-technical and technical skills can indeed be transferred from simulators to patients, and places high value on simulations in medical education [31, 32]. Feedback is crucial to the learning process and we always performed debriefings. These debriefings were led by an expert in difficult airway management and an expert in simulation, the debriefing focused on the Vortex approach algorithm, decision-making times, and the duration of cricothyrotomy, and non-technical skills for crisis resource management. The participant, discussion of errors or points for improvement, and then constructive advice on how to perform better based them on self-assessment.
There are several limitations of our study that must be mentioned. First, as compared to real-life CICV events, this study presents data from a setting that was scripted and simulated. Although there are likely some real differences compared to an actual event, this study is the only feasible means to rigorously assess how to improve the delivery of care in such a rare event. Second, although our results accord with, and improve upon, those in recent studies, they do emerge from a single residency-training program. Third, in observing the performance of all participants, there is a clear variation in how participants used the decision tool and how they enforced implementation of the tool, and most of the participants seemed to have had difficult airway training before.
Finally, we have clearly shown one main point, that implementation of cognitive aid greatly improves adherence to published guidelines during in situ crisis simulations. These results are limited to this statement. Future research needs to investigate the form of the aid (paper vs electronic) makes as much of a difference as the method by which it is implemented (use of the designated Reader role). There is a large push to introduce checklists in medicine today under the banner of patient safety [27, 28, 29]. Great strides have been demonstrated in this domain, and we believe that our results indicate that implementation of a cognitive aid can lead to significant improvement in performance as compared to

management from memory alone. We also believe that caution is necessary before any cognitive aid, whether checklist (paper or electronic), is introduced into routine use. As noted by Neal [30] about the recent AURORA study, "it is seldom a single intervention that improves our patients' care, but rather using the entire toolbox." Proper orientation of the tool and proper implementation of it within the emergency team is likely as important as the tool itself. Although we agree that a checklist manifesto may be of use in the coming years of medical practice, carefully addressing the toolbox that accomplishes, the intended will require rigorous research as this field of implementation science progresses.

Chapter V. CONCLUSION AND RECOMMENDATIONS

V.1. Conclusion

Our seminar (based on simulation) was associated with an improvement in our participants' knowledge of difficult airway management algorithm. After training, all the participants complied with the algorithm and were able to perform this lifesaving procedure quickly and accurately in a CICV scenario. This inherently stressful situation did not prevent the participants from achieving good performance levels. The results testified to the participants' greater awareness and should, we hope, enable them to manage a true difficult airway situation with confidence in the future.

In summary, our results demonstrate that using a hand held cognitive aid through a designated scenario greatly improves performance and adherence to guidelines in an in situ simulation of CICV, as compare to management from memory alone. Possible benefits of cognitive aids are follows: They can direct clinicians to adhere to management guidelines and they can refer as secondary method of validating and double-checking clinical decisions. Such tools are promising in the future of patient care in anesthesiology, perioperative medicine, and acute care medicine. In light of this, although the best form of cognitive aid has not been determined, we have shown benefit of the one described in this study.

V.2. Recommendations

According to the findings of our research, we recommend:

1. To the Ministry of Health: to fund a multi-center randomized controlled trial in Rwanda to determine if the cognitive can improve patient safety.
2. To Anesthesia providers:

- To increase their knowledge of simulation practice through translation from simulated settings to the real world.
- To know the literature from the simulation laboratory, to understand the components of the toolbox, to do a local assessment, and discussion of these components with the clinical team

3. To all medical staff to bring those unique competences come together to really formulate a great treatment team through simulation training.

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33. Vortex approach. Org

Appendix 1: Can't intubate, can't ventilate scenario

SIMULATION SCENARIO

Topic	Can't intubate, can't ventilate scenario
Participants	N=40 resident in anesthesia and emergency medicine, and non-physician anesthetist

Scenario Summary

A 43-year old female has been admitted to the emergency department with a history of headaches and sudden loss of consciousness that is presumed to be a subarachnoid hemorrhage. She has a past history of cervical spine fusion 10 years ago following a road traffic accident.

You have been called to the emergency department to assist the junior emergency resident with intubation. He has called for help, as he is unable to ventilate or intubate the patient.

People required for scenario

	Role in scenario
Participants	Anesthesia residents, Emergency residents and Non physician anesthetists play the role as Seignior anesthetist
Two confederates	Emergency resident and emergency nurse will be play by PGY4 anesthesia resident
Four instructors	Facilitators

Equipment required for scenario

	Adult low fidelity manikin adjusted to obese patient		SimMon software (iPads)
	Emergency trolley		Cognitive aid depending on randomization
	Adult intubation kit nearby, various laryngoscopes / ET Tubes / oral airways		Video cameras recording
	Cricothyroid needles		Timekeeper
	Drapes		

Time required for simulation

Event	**Duration (min)**
Pre-briefing/Orientation	2 min for each participant
Scenario	8 min for each participant
Debriefing and Training on Vortex approach	1h30 min for all participants

Baseline Vitals and Patient Status

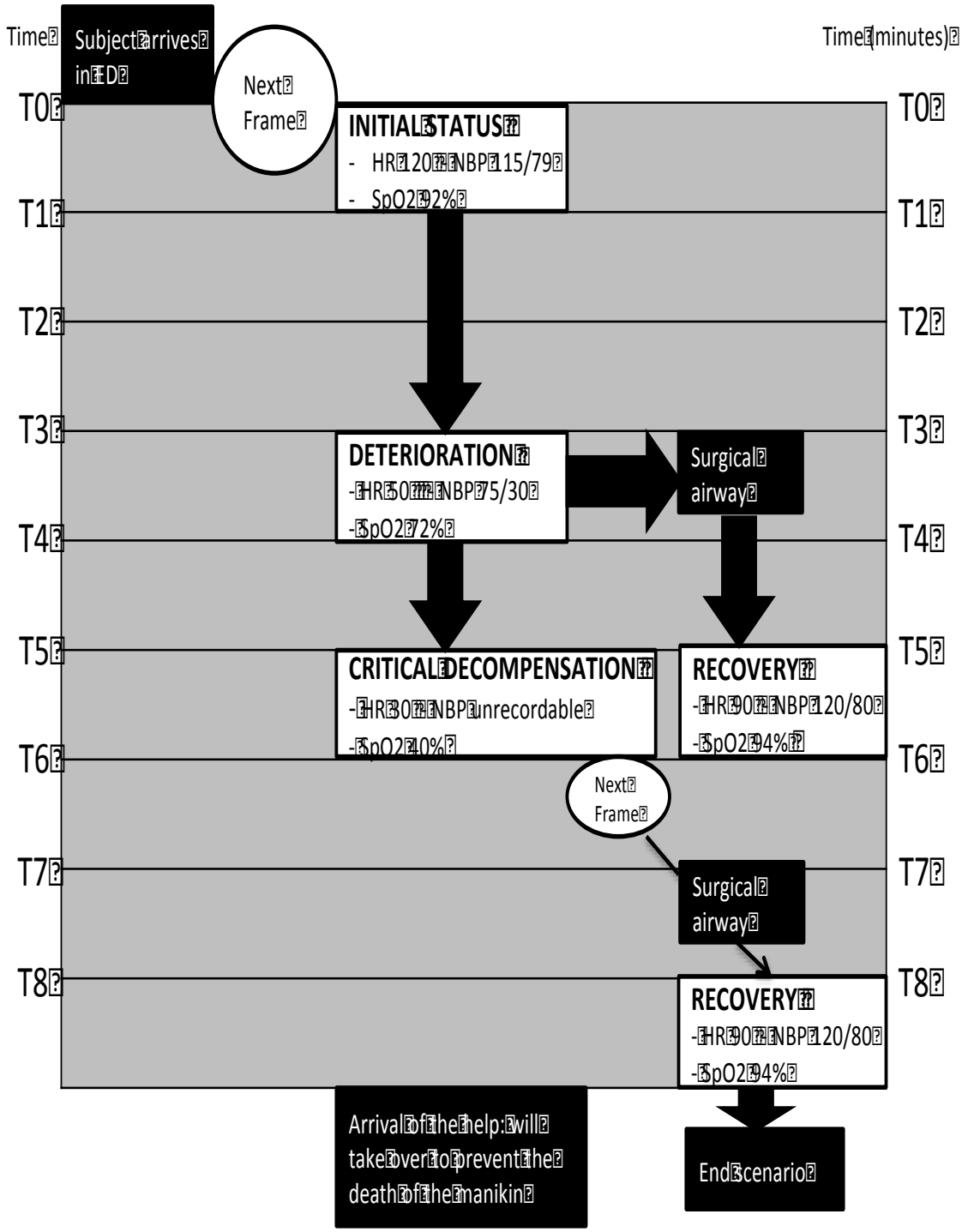
BP: 115/79	**HR:** 120	**SaO2:** 92%	**RR:** No breath
Temp: N/A			

Neurologic Status	Paralyzed, no response
Cardiovascular	Slightly tachycardia
Respiratory	No breath
Genitourinary	N/A
Other	N/A

Information for participants

	Initial information provided to participants
Participants	Junior emergency resident not able to manage airway effectively, as self-inflating bag and mask on and guedel airway in situ. States on arrival of participant "This is a can't intubate, can't ventilate through a facemask or LMA and this lady is a grade 4 laryngoscopy". Emergency staff able to assist with airway material.

Appendix 2: Scenario timeline and time to attempt ESA

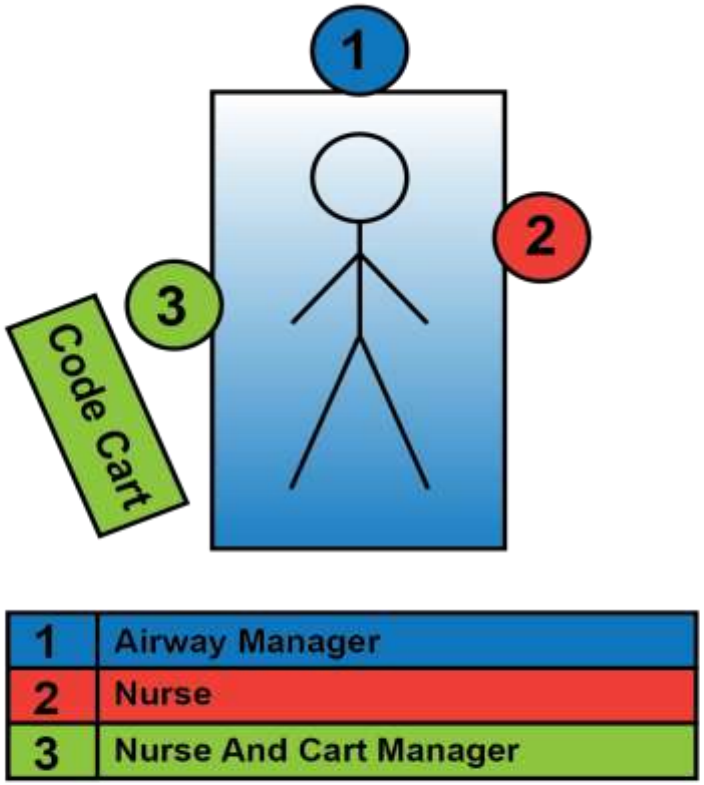


	Baseline	**Stage 1**	**Stage 2**	**Stage 3**
Name of state	Initial status	Deterioration	Critical decompensation	Recovery
Rhythm	SR	SB	SB	SR
SpO2	92	72	40	94
HR	120	50	40	90
BP	115/79	75/30	Unrecordable	120/80
Air Entry	Bilateral	None	None	Bilateral

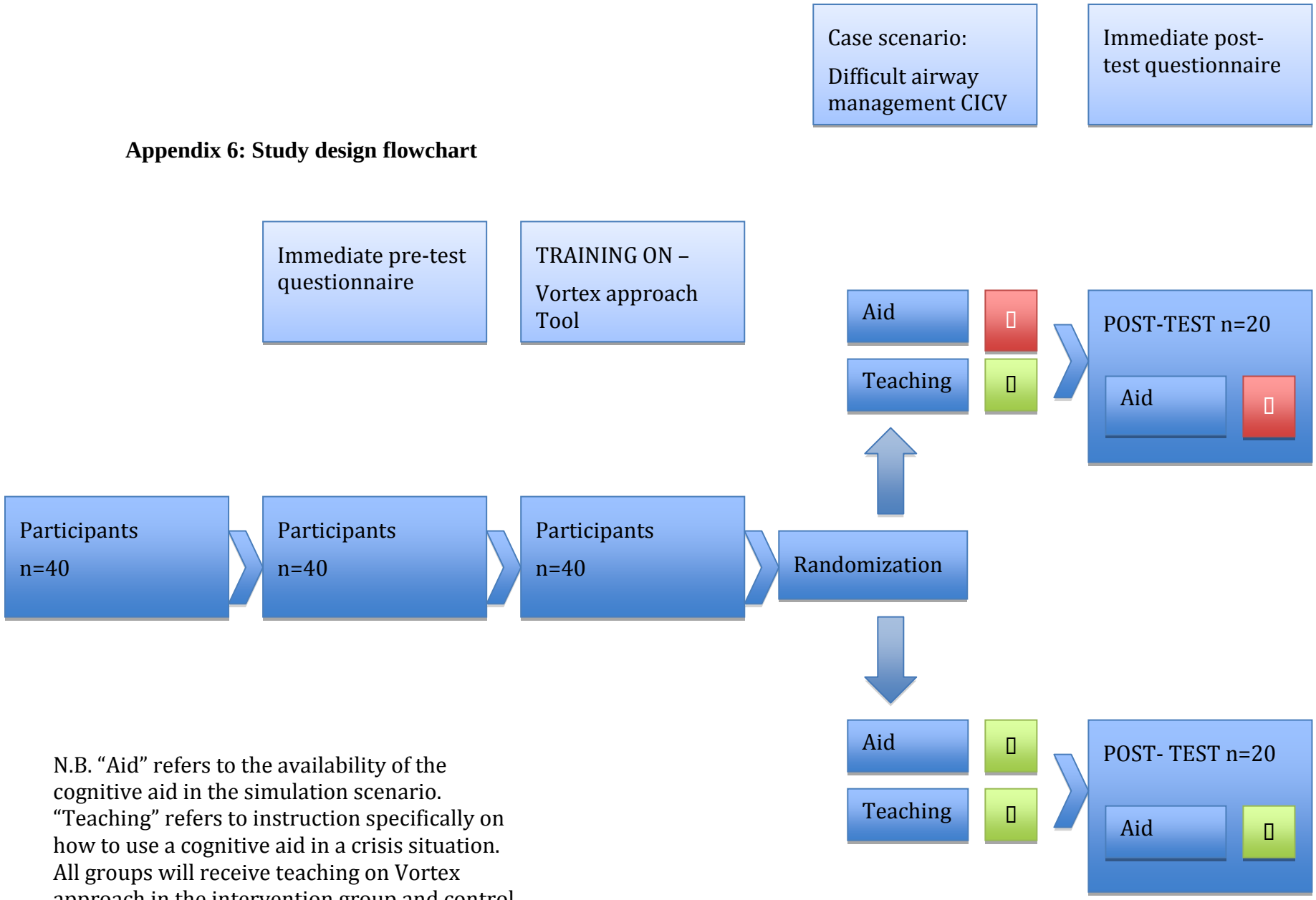
Appendix 3: Low fidelity manikin

Appendix 4: Sony Alpha a7ii with tripod and microphone

Appendix 5: Code team personnel and roles



Appendix 6: Study design flowchart



N.B. "Aid" refers to the availability of the cognitive aid in the simulation scenario. "Teaching" refers to instruction specifically on how to use a cognitive aid in a crisis situation. All groups will receive teaching on Vortex approach in the intervention group and control group.

Appendix 7: Proposed research timeline

2018-2019												
	J	J	A	S	O	N	D	J	F	M	A	M
	6	7	8		5	6	7	8	9	10	11	12
REB application												
Recruiting & training of raters												
Data collection												
Rating of videos												
Data Analysis												
Write manuscript												
Submit & peer review												

Appendix 8: Immediate Pre-test questionnaire on difficult airway management

Study number: (do not fill in, assigned by researcher)

Age: Sex: M F Department:

PGY level: 2 3 4

NPAs year of experience: 2 3 4+

I. What experience have you had on difficult airway? Please circle all that apply

1. Review of difficult airway algorithm (e.g. American Society of Anesthesiologist algorithm or others)
2. Difficult airway simulation
3. Team member in a difficult airway
4. Team leader in a difficult airway

II. If you circled 3 and or 4 above, please indicate number of times.

1 2 3 4+

On scale of 1-4: 1-Strongly disagree; 2-Somewhat disagree; 3-Somewhat agree; 4-Strongly agree. Please answer the following questions:

III. I can comfortably manage a difficult airway

1 2 3 4+

IV. I frequently use cognitive aid during difficult airway management

1 2 3 4+

Appendix 9: Immediate Post test questionnaire on difficult airway management

Study Number:_____(do not fill in, assigned by researcher)

Age: Sex: M F Department:

PGY level: 2 3 4

NPAs year of experience: 2 3 4+

I. Have you previously attended training on Anesthesia Non Technical Skills (ANTS)? Please estimate the number of training you have attended

Yes No 1 2 3 4+

II. Have you ever done an External Surgical Airway or training on it? Please estimate the number of External Surgical Airway you have done or training.

Yes No 1 2 3 4+

Please rate the following statement on scale

1. Strongly disagree
2. Somewhat disagree
3. Somewhat agree
4. Strongly agree

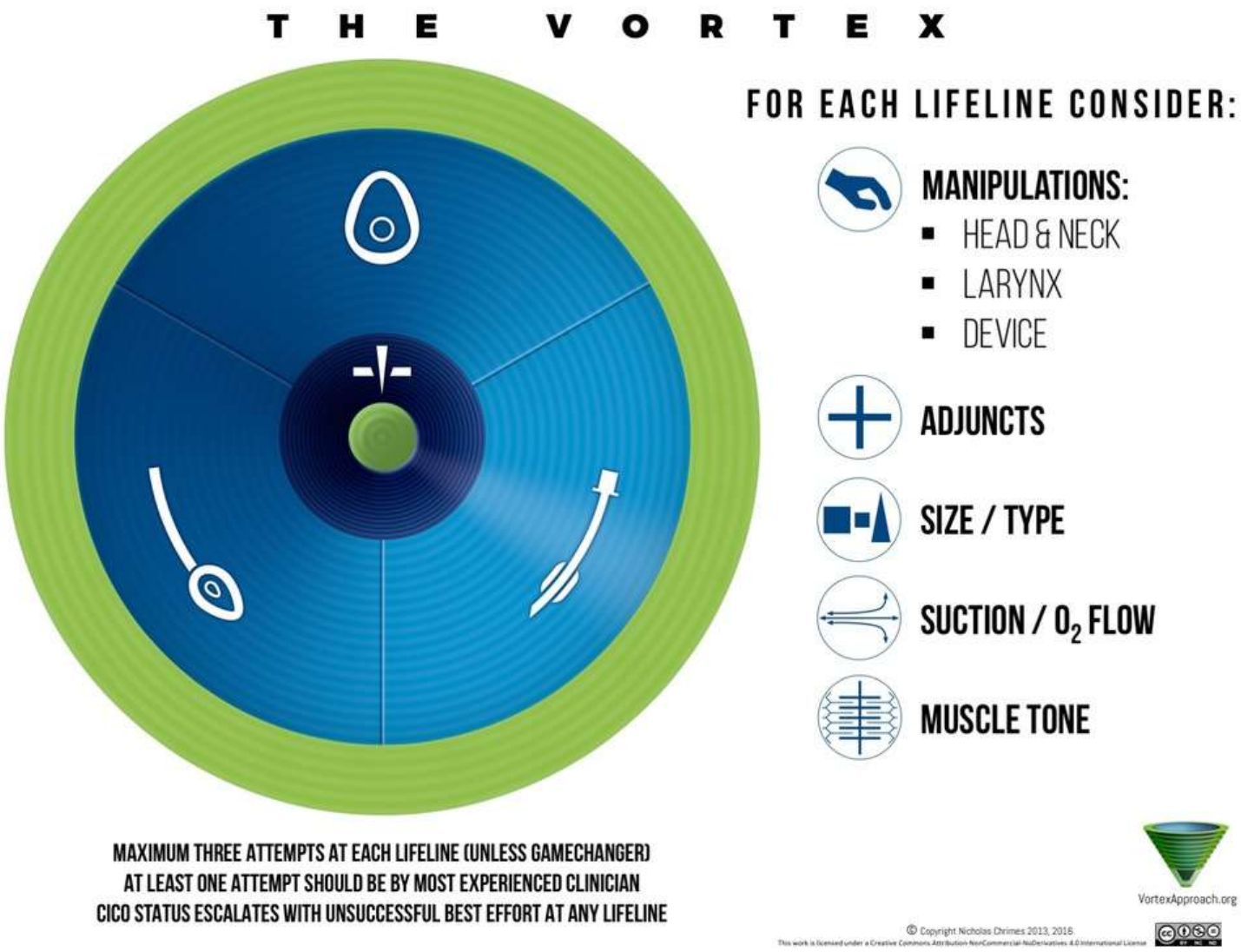
III. Cognitive aids are valuable tool in medical practice

1 2 3 4

IV. Cognitive aids improve patient safety

1 2 3 4

Appendix 10: Vortex approach cognitive aid tool



Appendix 11: Grading checklist for can't intubate can't ventilate. **Study number:**

Intervention	Performed well (2)	Performed poorly or at inappropriate time (1)	Not performed (0)
SUCTION check			
NEUROMUSCULAR BLOCK administered			
Attempts to maintain **OXYGENATION** throughout including apneic oxygenation			
Attempted **ENDOTRACHEAL INTUBATION (**including all appropriate manipulations/positioning and adjuncts)			
Attempted **BMV** (including all appropriate manipulations/positioning and adjuncts)			
Attempted **LMA** (including all appropriate manipulations/positioning and adjuncts)			
ESA with appropriate use of positioning and adjuncts			
TOTALS			

Appendix 12: Anesthesia nontechnical skills rating scale

Categories	*Elements*	*Observations*	*Element Rating*	*Debriefing notes and category rating*
Task Management	Planning & preparing			
	Prioritising			
	Providing & maintaining standards			
	Identifying and utilising resources			
Team Working	Co-ordinating activities with team			
	Exchanging information			
	Using authority & assertiveness			
	Assessing capabilities			
	Supporting others			
Situation Awareness	Gathering information			
	Recognising & understanding			
	Anticipating			
Decision Making	Identifying options			
	Balancing risks & selecting options			
	Re-evaluating			

System rating. **Study number:**

Rating Label	**Description**
4 - Highly effective	Performance was of a consistently high enhancing patient safety; it could be used as a positive example for others.
3 - Effective	Performance was of a satisfactory standard but could be improved.
2 - Ineffective	Performance indicated a cause for concern, considerable improvement is needed.
1 - Highly Ineffective	Performance endangered or potentially endangered patient safety, serious remediation is required.
N/A - Not applicable	Skills was not required or relevan**t**

Appendix 13: Consent Form for Participant Subjects. Study number:

Does Instruction on Cognitive Aids Improve Performance and Retention of Skills? A Randomized Controlled Trial.

Investigators:

At the University of Rwanda Skills and Simulation Centre.

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Purpose of the Research:

Crises are commonly encountered in many areas of medical practice. It is well documented that the knowledge and skills attained by completion of emergency crisis deteriorate rapidly. The purpose is to study training in cognitive aid use and to see of using a cognitive aid is helpful in emergency difficult airway management.

Description of the Research:

- You will have the study explained to you in person and given an opportunity to ask questions before consenting to take part
- This study will involve you participating in simulation-based learning for scenarios involving difficult airway management.
- You will be asked to fill out a questionnaire asking demographic details
- You will have a total of two simulation sessions (pre-test and immediate post-test) involving an acute medical crisis and the third one will be in few month later as an extension of this study. You will be playing the role of team leader and airway manager in all of the scenarios.
- All simulation sessions will be recorded for later analysis.
- Video data will be encrypted and stored in a secure location. The video data will only be seen by the principle investigators and by raters who are qualified instructors. All participants including raters will be required to sign a confidentiality agreement.
- The video data collected may be used for directly related research with the same objective as this study.
- At your request, you can receive a copy of the study results at the end of the study.
- The project does not involve quality assurance/improvement, and as such, participation is entirely voluntary and not work-related.
- The decision to participate or not will in no way be shared with others.

Potential Harms:

We know of no harm that taking part in this could cause you. Neither your performance nor your non-participation will be used towards your program evaluation in any way. You are free to withdraw from the study at any time. We will inform you of any new information that might influence your decision to continue to participate in this research project.

Potential Discomforts or Inconvenience:

The simulation session for this study may be undertaken outside your usual working time.

Potential Benefits:

To individual subjects: These data are being collected for the purposes of this study, if you do not wish to take part in this study this will not affect your training in any way. Involvement in this study will be of no direct benefit to you except for the potential educational experience gained from additional time in simulation and reflection in the debriefing.
The research results will be made available to you at the end of the study.

To society: If this study shows an alternative technique for the retention of essentials skills then this has broad implications for medical education and patient care.

Alternatives to participation:

You are not obliged to participate in this study. As a resident or fellow, refusal to participate will in no way affect your training or evaluation at the University of Rwanda.

Confidentiality:

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law.
The data produced from this study will be stored in a secure, locked location. Electronic data will be securely encrypted. Only members of the research team (and may be those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by The Kigali Teaching Hospital policy. Published study results will not reveal your identity.

A copy of this consent form was given to the participant.

Reimbursement:

There will be no out of pocket expenses for being in this study.

Participation:

It is your choice to take part in this study. If you choose to take part in this study you can take yourself out of the study at any time.

Sponsorship:

There is currently no sponsorship for this study.

Conflict of Interest:

Drs Ngebe, Banguti, Bould and the other members of the research team have no conflicts of interest to declare for this study.

Participant signature: