

THE UNIVERSITY OF NAIROBI

KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVANCED TRAUMA LIFE SUPPORT PRINCIPLES AMONG HEALTH CARE WORKERS IN ACCIDENT AND EMERGENCY DEPARTMENTS IN NAIROBI, KENYA: A MULTI-CENTER STUDY

A RESEARCH DISSERTATION SUBMITTED AS PART OF FULFILLMENT FOR THE DEGREE OF MASTERS OF MEDICINE IN ORTHOPAEDIC AND TRAUMA SURGERY AT THE UNIVERSITY OF NAIROBI

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H58/11383/2018

DECLARATION

I declare that this study is my original work and has not been presented for the award of any degree at any other institution or university. Where I have used another person's work, I have acknowledged and referenced.

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TABLE OF CONTENTS

DECLARATION i
SUPERVISORSii
DEPARTMENTAL APPROVAL iv
TABLE OF CONTENTSv
LIST OF TABLES ix
LIST OF FIGURESx
ACRONYMS AND ABBREVIATIONS xi
DEFINITION OF OPERATIONAL TERMS xii
ABSTRACT xiii
CHAPTER ONE
1.0 INTRODUCTION1
1.1 Background1
CHAPTER TWO
2.0 LITERATURE REVIEW
2.1 Epidemiology of Trauma
2.2 Burden of Disease Due to Trauma4
2.3 Significance of ATLS in trauma outcomes
2.4 Effectiveness of ATLS principles in Trauma Management

2.5 Knowledge and Practice of ATLS Principles Among Practitioners
2.6 Gaps in Knowledge of ATLS Principles use in trauma management
2.7 Problem Statement10
2.8 Research Question
2.9 Study Objectives11
2.9.1 Broad Objective:
2.9.2 Specific Objectives11
CHAPTER THREE
3.0 METHODOLOGY
3.1 Study design
3.2 Study Site
3.3 Study population15
3.4 Inclusion and Exclusion Criteria15
3.4.1 Inclusion criteria15
3.4.2 Exclusion Criteria15
3.5 Sample Size Determination15
The appropriate sample size given the population size and specified combination of
precision, confidence and variability is 20916
3.5 Sampling Procedure
3.6 Variables

3.6.1 Dependent variables
3.6.2 Independent variable
3.7 Data Collection
3.8 Study Procedure
3.8.1 Consenting and Study Enrollment
3.8.2 Training Procedures
3.8.3 Quality Control
3.9 Ethical Consideration19
3.10 Data Management
3.11 Data Analysis
3.12 Data dissemination21
CHAPTER FOUR
4.0 RESULTS
4.1.1 Age22
4.1.2 Sex
4.1.3 Type of Training23
4.1.4 Cadres of doctors participating in study23
4.1.5 ATLS Self Rating24
4.2 Level of knowledge and their associations
4.3 Level of practice and its associations

4.4 Assessment of Attitudes	30
CHAPTER FIVE	32
5.0 DISCUSSION	32
5.1 The level of knowledge of ATLS principles among the respondents	32
5.2 The practice of ATLS principles among the respondents	32
5.3 Attitude towards ATLS principles among the respondents.	34
CONCLUSION	35
REFERENCES	37
List of Appendices	40
Appendix 1: QUESTIONNAIRE/ DATA TOOL	40

LIST OF TABLES

Table 1: Average number of patients presenting with trauma managed in Accident and
Emergency departments of the listed hospitals2
Table 2: Distribution of HCWs in the proposed study sites by their numbers
Table 3: Summary table for the characteristics of the study participants
Table 4: The table shows association of levels of knowledge on ALTS and their
determinants27
Table 5: The table below shows the association between the levels of practice on ATLS
and their determinants
Table 6: The table is a representation of the various attitude assessments
Table 6 cont.: assessment of importance of ATLS and participation in CMEs on ATLS

LIST OF FIGURES

Figure 1: Mortalities caused by trauma, infections, IHD and cancer in LMICs- 20163
Figure 2: ATLS Kenya Training sites and partnership report9
Figure 3. Conceptual framework
Figure 4: A histogram showing the distribution of the age of the participants22
Figure 6: A pie chart representing the distribution type of training of the participants23
Figure 7: A bar graph representing the Cadres of doctors participating in the study24
Figure 9: A pie chart representing the level of knowledge in ATLS of the participants .26
Figure 10: A pie chart representing the level of practice based of ATLS principles26
Figure 11: A graph showing the relationship between age and levels of knowledge28
Figure 12: A bar graph representing the level of knowledge by occupation28
Figure 13: A bar graph representing the Reason for failure to attend ATLS

ACRONYMS AND ABBREVIATIONS

- A&E- Accident and emergency department
- A.I.C- Africa Inland Church
- AMPATH- Academic Model Providing Access to Healthcare
- ANOVA Analysis of Variance
- ATLS Advanced Trauma and Life Support
- CME- Continuing Medical Education
- DLAYs- Disability-Adjusted Life Year(s)
- E.N.T- Ear, Nose and Throat
- ETC- Essential Trauma Care
- **GDP-** Gross Domestic Product
- HCW Health Care Workers
- IHD- ischemic heart disease
- KNH- Kenyatta National Hospital
- LMICs- Low- and Middle-Income Countries
- MTOS- Major Trauma Outcome Study
- MVAs- Motor Vehicle Accidents
- PTC- Primary Trauma Care
- **RTIs-** Road Traffic Injuries
- WHO- World Health Organisation

DEFINITION OF OPERATIONAL TERMS

ATLS Certification- certification attained after undertaking a course and sitting an exam in Advanced Trauma Life Support administered by the American College of Surgeons

Health Care Workers- Individual(s) who delivers care and services to the sick and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians, or even medical waste handlers.

Proficiency- high level of skill in a task; for the purposes of this study was assessed by the scores attained from both Exam type questions and open-ended questions included in the questionnaire.

Trauma- refers to physical injuries of sudden onset and severity which require immediate medical attention.

ABSTRACT

Background: According to the World Health Organization, traumatic injuries are among the leading contributors to death globally, with ninety percent of the injuries approximated to occur in LMICs. The Global Burden of Disease study in 2017 estimates a 26.0% upsurge in road and traffic-related incidences by the year 2030. As a country, we lack information on the practice of ATLS amongst health care workers, especially in the Accident and Emergency departments, where most injuries are noted to be present. Kenya has no standardized system of trauma care. It could be indicated that the high cost of ATLS training locally (USD 335) and limited training facilities (3 partner institutions) and faculty negatively impact ATLS teaching in LMICs such as Kenya.

Objectives: To determine the knowledge, attitude, and practice of ATLS principles among health care workers in accident and emergency departments of select Level 5 and 6 hospitals in Nairobi- Kenya

Methodology: Descriptive cross-sectional study was conducted at five urban centers within Nairobi, namely, Kenyatta National Hospital, Mbagathi Hospital, Aga Khan University Hospital, Mama Lucy Kibaki Hospital, Mater Misericordiae Hospital. Stratified proportionate sampling of 384 study participants from the proposed sites of study was carried out. The participants are nurses and doctors working at the Accident and Emergency units.

Study participants were interrogated through a semi-structured questionnaire on knowledge, attitude, and practices of ATLS as well as demographic and training levels. **Results:** In this study, 202 participants with a mean age of 30.8 and standard deviation of 2.8 were included, with 58.9% male and 41.1% female participants. There were more

xiii

62doctors (59%) than nurses (41%), and registrars were the majority among doctors. 84% of participants rated their ATLS knowledge as average. Younger participants and doctors were more knowledgeable about ATLS principles (p<0.001), while nurses and older practitioners were less proficient on ATLS principles and notably less adherent to these principles in practice (p<0.019 and p<0.001, respectively). Registrars were more knowledgeable about ATLS compared to MOs and interns (p=0.004). Most HCWs were welcoming to the idea of ATLS knowledge and practice. However, up to 62% of the respondents had not undertaken ATLS training citing unfavorable cost of the training and lack of time to undertake the training as the most common hinderances.

Conclusion: This study highlights the level of knowledge of ATLS principles as deficient amongst majority of the study participants and most notably amongst older participants and nurses. It was also noted that there's deficiency of practice of ATLS principles amongst majority of the study. Additionally, there's a positive attitude towards ATLS principles amongst the participants. The findings underscore cost of training as the most important limiting factor to training on ATLS. It was noted that there's a lack of CMEs on ATLS and on-site simulations on trauma management. **Recommendation:** As traumatic injuries are a significant contributor to global mortality rates, investing in ATLS training can reduce the burden of injuries locally, regionally as well as globally.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Trauma is a surgical disease and remains a significant contributor to inpatient and outpatient hospital visits and accounts for more than 5 million deaths globally on an annual basis (1). The injury burden is significantly higher in low and middle-income countries (LMIC), with approximately 90% of injury-related fatalities. Kenya, an emerging economy, has its fair burden of trauma cases. With the rise in urban population, i.e., 4.397 million persons according to the National census of 2019, the number of severe traumas requiring hospitalization has gradually increased (2, 3).

Advanced Trauma Life Support is a protocol for managing acute trauma, developed in 1976 by Dr. James Styner and formally adopted in 1980 by the American College of Surgeons Committee on Trauma (4). It's currently accepted globally as the protocol for assessing and managing patients in the emergent trauma setting. ATLS principles represent a systematic approach for assessment and management of severely injured patients and stipulate that the most serious risk to human life be addressed initially; the absence of a working diagnosis shouldn't hinder the use of an indicated management modality, and that precise history is not necessary to commence the assessment and management of patient(s) with acute injuries (5)

The level of knowledge, attitude, and practice of ATLS principles has not been adequately assessed amongst HCWs in Kenyan hospitals, especially in the urban setting. The choice of the facilities where the study is to be conducted is based on the number of patients presenting to the accident and emergency departments seeking medical attention for trauma. The first three hospitals (Kenyatta National Hospital, Mama Lucy Kibaki, and Mbagathi Hospitals) are major public hospitals. The other two (Aga Khan University Hospital and Mater Misericordiae Hospital) are the largest private, not-for-profit institutions attending to the most severely injured persons.

Table 1: Average number of patients presenting with trauma managed in Accident andEmergency departments of the listed hospitals

FACILITY	Average number of trauma		
	patients in A&E per day in 2021		
Kenyatta National Hospital	22		
Mbagathi Hospital	10		
Mama Lucy Kibaki Level 5 Hospital	16		
Aga Khan University Hospital	8		
Mater Misericordiae Hospital	6		

Source: Morbidity reports from Medical Records Departments of the above hospitals

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Epidemiology of Trauma

Traumatic injuries are one of the leading contributors to death worldwide, with ninety percent of the injuries approximated to occur in LMICs, according to WHO (1). Every year, more than 4 million persons succumb to injuries sustained from trauma. These fatalities are 59% higher than those caused by malaria, tuberculosis, and HIV put together and more so in LMICs, as shown in figure 1 (2).

Figure 1: Mortalities caused by trauma, infections, IHD and cancer in LMICs-2016





Motor vehicle accidents (MVAs) remain the commonest cause of trauma-associated morbidity and mortality. They cause more than a 1.3million deaths and 50 million injuries annually. The burden of MVAs is considerably higher in LMICs as they account for 93% of all motor vehicle related injuries and deaths worldwide (3). According to Mathers et al., MVAs constitute a leading cause of mortality and morbidity globally and are currently a significant public health issue (6). Notably, MVAs make up a substantial cause of severe injuries in the urban setting, with a prevalence of 63.6% (7). In Africa, a study in Botswana on Epidemiology of Traumatic Orthopedic Injuries at Princess Marina Hospital revealed that 73.5% of patients were admitted with traumatic orthopedic injuries (8). Countries in East Africa are equally affected. In 2017, Tanzania recorded 17,840 deaths due to MVAs, the 9th highest fatality rate from MVAs globally (9, 10).

According to a study by Botchey et al. (2017), conducted at four hospitals in Kenya, namely KNH, Machakos, Meru, and Thika level 5 hospitals, MVAs were the most prevalent cause of trauma accounting for 36.8% of trauma-related admissions. Moreover, of all the hospital trauma patients, which make up 40%, most trauma patients presenting to the hospitals were involved in MVAs (49.5%) (11).

2.2 Burden of Disease Due to Trauma

Reducing the burden of injuries is among the top public health challenges currently addressed globally. The World Health Organization is supporting countries and organizations in mitigating this problem. Specifically, the Department of Injuries and Violence Prevention (VIP) has led the initiative to increase the range of injury mitigation activities (10).

These include;

Improvement and standardization of injury surveillance systems.

Promotion of injury control policy initiatives against violence, traffic, and other trauma causes.

Promotion of sustainable programs of injury care in the pre-hospital and hospital-based setup.

The Global Burden of Disease 2017 study estimates a 26.0% increase in global MVAs related injuries by 2030 (12). Coupled with the tragic mortalities, MVAs also present a severe economic impact on people and governments in LMICs. The WHO reckons that RTIs cost countries 3% of their GDP globally (12). In South Africa, MVAs are estimated to cost the government approximately 8% of GDP (13). In Kenya, roughly 3,000 road deaths occur yearly, costing up to USD 2.63 Billion in lost productivity to the country, which accounts for 5% of her (GDP) (13, 14).

2.3 Significance of ATLS in trauma outcomes

According to Maxwell et al., near-fatal albeit salvageable injuries in individuals have a six-fold more likelihood of resulting in mortality in the resource-limited setting (36% mortality) than in a high-income environment (6% mortality) (4, 16). These underscore the increasing necessity for Guidelines for Essential Trauma Care to mitigate such disproportions by locally initiating sustainable standards for injury care (15). ATLS is one of the most common trauma-oriented courses taught globally. In its Guidelines for ETC, the WHO recommends short, sustainable courses for providers working in LMICs (10). After ATLS training, physicians should have the ability to manage severe trauma victims adequately.

The course improves provider knowledge of trauma management, clinical skills, planning of trauma management, and a priority-based approach to the injured patient (17, 18).

Knowledge and skills acquired by ATLS participants deteriorate with time if these skills are not practiced, thus highlighting the importance of re-certification, acknowledging that trauma management is an evolving field based on new scientific evidence that leads to improvement of practice and guidelines. Teaching the ATLS course to health care workers who manage trauma patients in emergency departments is greatly recommended (19, 20).

2.4 Effectiveness of ATLS principles in Trauma Management

The primary endpoint of clinical educational activities is their significance in improving health care. ATLS has been noted to improve knowledge and practical skills in managing trauma patients. A judiciously implemented trauma system fully employing ATLS Principles can lower mortality rates of severe trauma patients by at least 15% (21). According to WHO, most of the recorded sub-acute deaths result from airway disruption, respiratory embarrassment, or uncontrolled bleeding. The three can be readily managed by prompt BTLS or ATLS measures such as

- i) the support of the airway and cervical spine,
- ii) oxygenation and blood pressure optimization through optimal wound and care of burns,
- iii) hemorrhage control,
- iv) appropriate immobilization of fractures and spine protection (22).

ATLS practice in the acute trauma setting may also prevent several delayed fatalities occurring in phase 3 and chronic complications and disability by optimizing the trauma patient and facilitating better outcomes from optimal hospital-based care (23). A systematic review on the benefits of PTC courses in LMICs concluded that departmental, institutional, and personal improvements had been noted to occur in clinical practice after formal PTC training of trauma team members in LMICs. In the review, most studies noted improvement in knowledge in injury management post- PTC course (p < 0.05) (24).

According to a study by Ger D.J Van Holden et al. (2004) on the clinical impact of ATLS, it was noted that the introduction of the ATLS program and subsequent implementation of ATLS Principles improved outcomes of trauma patients in the first hour of hospital admission (25). Furthermore, according to a study by Moore, Lynne, et al. 2018, a systematic review of the evidence of the impact of trauma system components that contribute to their effectiveness demonstrated judicious pre-hospital and hospital ATLS practice was associated with a significant reduction in hospital days for the injured patient (26).

ATLS courses, as indicated by Mohammad et al., 2014 established a level I evidence that ATLS markedly increases the knowledge of personnel managing trauma patients as regards clinical skills, organization, and prioritization in actual practice. However, there was also level II–1 evidence that knowledge and skills acquired through the ATLS course declined in 6 months, with a maximal decline in 2 years. However, organization and prioritization credentials are maintained up to 8 years after ATLS training.

Local studies have also indicated a significant impact of ATLS Principles and training. A study by Wanjiku et al., 2017 assessing the effects of an emergency trauma course for senior medical students in Kenya concluded that a novel student trauma course resulted in significant improvements in knowledge, skills, and confidence in trauma management for graduating students at a Kenyan medical school (19).

2.5 Knowledge and Practice of ATLS Principles Among Practitioners

ATLS course is currently taught in more than 80 countries globally, with more than 1 million physicians having been trained. This global audience has led to increased standardization of care in dealing with critically injured patients. Since 2009, in the USA, the American Board of Surgery has mandated ATLS certification for all general surgery residency graduates.

Extra training in ATLS programs is noted to adequately prepare paramedics and doctors to manage critically injured patients (27). It also improved the standards of care for trauma victims and was therefore advocated as a necessity for all HCWs managing acutely injured patients (28).

Of note, unnecessary delays in the provision of care by experienced and well-trained staff were observed to be a significant contributor to unsuitable trauma management, according to Baird C et al. (2004) in a comparative study done to investigate the influence of ATLS training on the performance of nurses in trauma care. Results from that study also concluded that the Advanced Trauma Course for Nurses had a crucial impact on performance of nurses in trauma settings. Competent staff who had undergone in-person ATLS training showed aptitude in assessing trauma situations leading to prompt and apt judgment (29).

An evaluation was done on the effect of the ATLS program on medical interns' performance in simulated trauma patient management; it concluded that the ATLS course played a crucial role in improving clinical know-how and skills of trauma care among the interns (30).

A study done in Africa on the level of knowledge of the Advanced Trauma Life Support protocol among non-specialist doctors involved in trauma care showed a deficiency in knowledge of ATLS among non-specialist doctors engaged in trauma care in Enugu, Nigeria. They recommended that ATLS training should be adopted by hospitals involved in doctors' training and ATLS certification ought to be a prerequisite to employing surgical residents (31).

Locally, Kenya Red Cross, AMPATH and Moi Teaching and Referral Hospital, and The Nairobi Hospital have partnered with the Surgical Society of Kenya to conduct in-person training ATLS course to train HCWs on the fundamentals of emergent assessment and management of trauma patients. This was aimed at improving knowledge of ATLS Principles among practitioners (19).

INSTITUTION: Kenya Red Cross Training School			
Partnership Start Date: 3 rd March 2015			
No. of Training sessions Conducted	21		
No. of participants trained	310		

Figure 2: ATLS	' Kenya	Training	sites and	partnership	report.
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INSTITUTION: Moi Teaching and Referral Hospital			
Partnership Start Date: 18th July 2018			
No. of Training sessions Conducted	4		
No. of participants trained	64		

INSTITUTION: The Nairobi Hospital			
Partnership Start Date: 27 th Feb 2020			
No. of Training sessions Conducted	6		
No. of participants trained	92		

SOURCE: Surgical Society of Kenya (SSK)

Other hospitals that have partnered with SSK by sponsoring and facilitating some of

their staff to be trained in ATLS include;

- Aga Khan University Hospital- Nairobi
- Mater Misericordiae Hospital
- Kenyatta National Hospital
- Moi Forces Memorial Hospital- Eldoret
- Tenwek Hospital
- A.I.C Kijabe Hospital

2.6 Gaps in Knowledge of ATLS Principles use in trauma management

Despite the increased number of trauma cases needing hospitalization, no standardized National trauma protocol has been adopted in Kenya.

The knowledge, attitude, and practice of ATLS Principles amongst health care workers in the Accident and Emergency departments have not been assessed in the Kenya urban setting, where most injuries are noted to occur as per the study by Botchey IM Jr et al., 2014 (5).

2.7 Problem Statement

Traumatic injuries are one of the leading contributors to death worldwide, with ninety percent of the injuries approximated to occur in LMICs, according to the WHO (1). As a country, we lack information on the knowledge, attitude, and practice of ATLS

Principles among health care workers, especially in the Accident and Emergency departments, where most injuries present. Kenya has no standardized system of trauma care. Notably, the high cost of ATLS training, insistence on 'North America Principles,' recognized shortcomings in equipment and diagnostic imaging, and the organization's rigidity to change has led to a declining uptake of ATLS training.

2.8 Research Question

- What are the knowledge, attitude, and practice of ATLS principles among health care workers in accident and emergency departments at five hospitals in Nairobi, Kenya?
- 2. What are the determinants of knowledge, attitude, and practice of ATLS among healthcare workers in urban hospitals in Kenya?

2.9 Study Objectives

2.9.1 Broad Objective:

To determine the knowledge, attitude, and practice of ATLS principles among health care workers in accident and emergency departments of KNH, Mama Lucy Kibaki Level 5 Hospital, Mbagathi Hospital, Aga-Khan University Hospital- Nairobi, and Mater Misericordiae Hospital.

2.9.2 Specific Objectives

- 1. To evaluate the level of knowledge of ATLS principles among the respondents.
- 2. To assess the practice of ATLS principles among the respondents
- 3. To assess the attitude towards ATLS principles among the respondents.

CONCEPTUAL FRAMEWORK



Figure 3. Conceptual framework.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

The study is a descriptive cross-sectional study. The study participants are health professionals working in trauma units. They were interrogated to determine their level of knowledge, attitudes, and practice of ATLS Principles.

3.2 Study Site

The proposed sites of study included the Accident and Emergency departments of the following collaborating institutions. These are Kenyatta National Hospital, Mbagathi Hospital, Mama Lucy Kibaki level 5 Hospital, Aga khan University Hospital and Mater Misericordiae Hospital.

Kenyatta National Hospital:

Established in 1901 with a bed capacity of 40, KNH became a State Corporation in 1987 with a Board of Management and is at the apex of the referral system in the Health Sector in Kenya. It is located along Hospital Road in Nairobi's Upper hill area. The KNH complex contains the College of Health Sciences (University of Nairobi), the Kenya Medical Training College, Kenya Medical Research Institute, and the National Laboratory Service (Ministry of Health). The total bed capacity is 1800. It has 50 wards, 22 outpatient clinics, 24 theaters, and Accident & Emergency Department. *Mbagathi Hospital:*

Initially known as Infectious Diseases Hospital (IDH) under the then King George VI Hospital, currently Kenyatta National Hospital. The hospital was built in the 1950s to cater to infectious diseases which required isolation, such as Tuberculosis, Measles, Meningitis, and Leprosy. In 1995, IDH was curved from Kenyatta National Hospital and transformed into an autonomous District Hospital for Nairobi City. The main hospital facility is located along Raila Odinga Way in the Dagoretti Division of Nairobi West District

Mama Lucy Kibaki Level 5 Hospital:

A level-5 Hospital located in the populous Embakasi Constituency of Nairobi County. It was established in 2011 but officially opened in 2013. It's located at the junction of Kangundo road and Kayole Spine road. The hospital has a bed capacity of 112, offering specialized services for both outpatient and inpatient cases

Aga-Khan University Hospital- Nairobi:

It was established in 1958 as a private, not-for-profit institution that provides tertiary and secondary level health care services. The main hospital campus is a 300-bed facility located along 3rd Parklands Avenue in Nairobi, Kenya. In addition, there are 50 Medical and Diagnostic Centres throughout East Africa providing emergency, primary and specialized care and various diagnostic tests.

Mater Misericordiae Hospital:

It was opened in 1962 by the sisters of Mercy, a Catholic Order of Nuns originating from Ireland. The hospital is located along Mariakani road, Nairobi- Kenya. It is a 176bed capacity hospital that serves as a tertiary and secondary health care institution offering outpatient, inpatient, and emergency care and serving as a teaching hospital.

3.3 Study population

Health care workers who are primarily involved in care of trauma patients at the Accident and Emergency department.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion criteria

- I. Health care workers in the accident and emergency departments of the 5 listed Health facilities i.e., Surgeons, Surgical Residents, Medical Officers. Medical Officer- Interns and Nurses
- II. Health care workers consenting to participate in this study

3.4.2 Exclusion Criteria

I. Health care workers not primarily involved in patient care at the accident and emergency departments of the 5 listed Health facilities.

3.5 Sample Size Determination

Calculation done using the Cochran's Formula:

$$n_0 = \frac{Z^2 p q}{e^2}$$

Where:

 n_{o} = desired sample size

Z=95% confidence interval (1.96)

e = Margin of error (0.05)

P=The estimated proportion of population of health care workers without knowledge of ATLS was estimated to be 50% since there are no studies that have documented the proportion in the regions.

q= 1-P

The total population of trained healthcare workers working in the proposed hospitals and dealing with trauma patients at first encounter are 453.

Thus, sample size: 384 health care workers.

Adjusting sample size for desired population

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

The appropriate sample size given the population size and specified combination of precision, confidence and variability is 209.

3.5 Sampling Procedure

Stratified proportionate random sampling approach was used. This sampling approach allowed proportionate distribution of study participants in the sample as based on their numbers in respective facilities.

Facility	Surgeons	Residents*	Medical officers	Medical Officer interns	Nurses	Total
Kenyatta National Hospital	4	201	20	0	70	295
Mbagathi Hospital	2	0	4	4	14	24
Mama Lucy Kibaki Hospital	2	0	5	2	12	21
Aga Khan University Hospital	6	10	26	0	28	70
Mater Misericordiae Hospital	4	8	10	0	21	43
Total	18	219	65	6	145	453

Table 2: Distribution of HCWs in the proposed study sites by their numbers

*Residents- Includes Registrars in training under the department of Surgery in The University of Nairobi, and The Aga Khan university Hospital as well as COSECSA Surgical Residents at the Mater Misericordiae Hospital. These include the following disciplines: General Surgery, Neurosurgery, Urology Surgery, Thoracic and Cardiovascular Surgery, Plastics and Reconstructive Surgery, Oral and Maxillofacial Surgery, ENT surgery and Orthopaedic Surgery.

To execute this sampling strategy, the following steps was followed.

1. Calculate the proportion of study participants to be recruited from each facility.

- 2. Calculate the total number of study participants required from the desired sample size from the proportion derived in step (1) required from each facility.
- 3. Convenience sampling of study participants from each facility till the desired sample size is arrived at.

Thus, this amounted to:

i.	Kenyatta National Hospital –	65.12% * 209 = 136
ii.	Mbagathi Hospital –	5.2% * 209 = 11
iii.	Aga Khan University Hospital –	15% * 209 = 30
iv.	Mama Lucy Hospital –	4.6% * 209 = 9
v.	Mater Hospital –	9.1% * 209 = 19

3.6 Variables

3.6.1 Dependent variables

- level of knowledge of ATLS Principles
- Practice on handling different scenarios
- Attitude on ATLS principles

3.6.2 Independent variable

- Age
- Gender
- level of training
- level of experience
- Access to emergency equipment

3.7 Data Collection

A semi-structured questionnaire covering different stages of ATLS and the components

of primary survey was designed and administered to the respondents who then

completed it in writing. The questionnaire was then marked and scored against the

developed marking scheme by the principal investigator.

3.8 Study Procedure

3.8.1 Consenting and Study Enrollment

Oral explanation of the objective of the study and signed informed consent was given by the participants. There was no coercion. Participation in this research was on a voluntary basis.

3.8.2 Training Procedures

Suitable research assistants with knowledge in data collection were sought and trained on the use of the tools. These included students of health science programs including medicine, clinical medicine and surgery.

3.8.3 Quality Control

To check on reliability and validity, pretesting of the tool was done on 10% of the sample size. The tools were analyzed to check on whether they were able to provide the required information. The tools were amended if need arose to ensure reliability. The Questionnaire was reviewed by 3 ATLS instructors for relevance and comprehensiveness and was deemed to capture the necessary testable concepts of ATLS.

3.9 Ethical Consideration

Permits: Ethical approval and licensure to conduct the study was sought from the;

- Kenyatta National Hospital/University of Nairobi Ethical, Research and Standards review committee. (KNH/UON ERC)
- The Aga Khan University, Institutional Scientific and Ethics Review Committee (AKU- ISERC)
- National Commission for Science Technology and Innovation.

The study was conducted in compliance with the law and respect for the participants Confidentiality. The information collected during the research was treated with the utmost confidentiality. Information about the participants that was collected during the research was held in confidentiality and used only for the purpose for which this study is intended. Any information about the participants had a unique number assigned to it instead of the respondent's name. All the information stored in soft copy was kept secured using a password.

Appropriate personal protective equipment was worn by both the research team and the respondents during the interview process in line with the guidelines issued by the Ministry of Health in curbing the spread of COVID19.

3.10 Data Management

Data was entered into password protected Ms. Access. Only the principal investigator and the authorized personnel was allowed to access the data.

Structured data collection tools were stored in a safe and secure location after data entry.

3.11 Data Analysis

Stata 16.0 was used for data analysis. Descriptive statistics such as means and medians was used to analyze quantitative data to characteristics of the study participants.Categorical variables were reported in proportions and percentages.Proportion of study participants with adequate level of knowledge on ATLS was determined by calculating the proportion of the total who score above average in the

exam type questions included in the questionnaire to determine the proficiency in knowledge and practice.

For hypothesis testing, to assess the association between various study participants characteristics e.g., cadre, level of experience, type of training and the ATLS knowledge score among various study participants, Student's T test was used for Analysis of Variance (ANOVA) in variables with more than 2 categories.

A p-value of <0.05 was considered statistically significant.

Attitudes was assessed in Likerts scale to allow for adequate analysis.

Data was presented in frequency tables, histograms, bar charts, pie charts, and written reports.

3.12 Data dissemination

Once data is analyzed and manuscript developed, study findings will be disseminated in conferences, and professional meetings as well as the management of the institutions collaborating in the study. The manuscript shall also be published in a peer reviewed medical journal.

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic characteristics

4.1.1 Age

The mean Age of study participants was 30.8 with a standard deviation of 2.8 and a median of 31 with in a range of 24 to 46 (Figure 4).



Figure 4: A histogram showing the distribution of the age of the participants

4.1.2 Sex

There were more male 119(58.9%) participants in the study than the females 83(41.1%) (Figure 5).



Figure 5: A pie chart showing the distribution of the sex of the participants

4.1.3 Type of Training

Many doctors 121(59%) participated in the study while 84(41%) nurses participated in the study (Figure 6).



Figure 6: A pie chart representing the distribution type of training of the participants

4.1.4 Cadres of doctors participating in study

Majority of the participants were Registrars 76(63.3%) (Figure 7).



Figure 7: A bar graph representing the Cadres of doctors participating in the study

4.1.5 ATLS Self Rating

Most of the participants 84% had an ALTS self-rating score of 'average' (Figure 8).



Various demographic characteristics of study participants are shown in Table 3.

Variable	Categories	Frequency
		(Percent)
Age	18 - 35	172 (96.6%)
	36 - 50	6 (3.4%))
	51 - 60	0
Sex	Male	119 (58.9%)
	Female	83 (41.01%)
Type of training	Doctor	121 (59%)
	Nurses	84 (41%)
Cadre of doctors	Surgeons	0
	Registrar	76 (63.3%)
	Medical Officer	39 (32.5%)
	Medical Officer intern	5 (4.1%)
Level of experience	0-3 years	74 (67.9%)
(working in A&E)	4-7 years	33 (30.3%)
	>8yrs	2 (1.8%)
Level of knowledge in	< 50%	102 (49.8%)
ATLS	50 - 75%	73 (35.6%)
	>76%	30 (14.6%)
Practice based on ATLS	< 50%	128 (62.4%)
principles.	50 - 75%	70 (34.1%)
	>76%	7 (3.4%)

 Table 3: Summary table for the characteristics of the study participants



Approximately half of participants have a knowledge level of less than 50% (Figure 9)

Figure 9: A pie chart representing the level of knowledge in ATLS of the participants In terms of practicing ATLS protocols, majority of participants scored less than 50% (Figure 10).



Figure 10: A pie chart representing the level of practice based of ATLS principles

4.2 Level of knowledge and their associations

There are various factors influencing the knowledge levels of ATLS. The most important factor was age of study participant where younger persons were more versed on ATLS principles (Figure 11) and the type of training where doctors were noted to be more versed on ATLS principles as compared nurses (Table 4).

 Table 4: The table shows association of levels of knowledge on ALTS and their
 determinants

Variable	Categories	Mean level of knowledge based on ATLS exam	Student T test / ANOVA p value
Age	18 - 35 36 - 50	59.9 36.7	0.0047
Sex	Male Female	57.2 51.9	0.045
Type of training	Doctor Nurses	64.1 42.2	P<0.001
Cadre of doctors	Surgeons Registrar Medical Officer Medical Officer intern	0 64.5 57 64.8	0.6101
Level of experience	0 – 3 years 4 – 7 years >8yrs	65.1 65.6 40	0.1101

Younger study participants were more likely to have knowledge of ATLS principles compared to older study participants (Figure 11).



Figure 11: A graph showing the relationship between age and levels of knowledge Doctors were more likely to be knowledgeable on ATLS as compared to nurses (p <0.001) (Figure 12)



Figure 12: A bar graph representing the level of knowledge by occupation

4.3 Level of practice and its associations

Younger practitioners are more likely to be versed on practice of ATLS compared to older practitioners (p<0.019). Doctors were more likely to implement their practices based on ATLS as compared to nurses (p<0.001). Medical Officers were more versed on practice of ATLS compared to Registrars and MO-interns (p = 0.04) (Table 5)

Table 5: The table below shows the association between the levels of practice on ATLSand their determinants

Variable	Categories	Mean level of practice based	Student T test / ANOVA p value
		on ATLS exam	
Age	18 - 35	43.2	0.019
	36 - 50	21.3	
	51 - 60		
Sex	Male	39.1	0.351
	Female	41.2	
Type of training	Doctor	48	P<0.001
	Nurse	41	
Cadre of doctors	Surgeons	0	0.004
	Registrar	41.4	
	Medical Officer	56	
	Medical Officer intern	48.5	
Level of experience	0-3 years	45.1	0.819
	4-7 years	47.4	
	>8yrs	38.8	

4.4 Assessment of Attitudes

In assessment of attitude towards ATLS knowledge and practice, the findings are

demonstrated in Table 6.

Table 6: The table is a representation of the various attitude assessments

No.	Question	Strongly Agree	Agree	Disagree	Unsure	Total Respondents
1	ATLS knowledge is important to effectively manage a trauma patient?	149 (78.4%)	41 (21.6%)	0	0	190
2	ATLS certification status determines effectiveness of patient care in the trauma setting?	109 (57.4%)	68 (35.8%)	10 (5.3%)	3 (1.6%)	190
3	ATLS certification should be made a requirement amongst HCWs in the Accident and Emergency department?	124 (65.6%)	62 (32.8%)	3 (1.6%)	0	190
4	CMEs on Trauma and/or simulations on mass injury scenarios should be held regularly at your workplace?	129 (68.6%)	58 (30.9%)	1 (0.5%)	0	190
5	ATLS knowledge adequately prepares HCWs working in the Trauma setting to work effectively as a team?	131 (69.7%)	56 (29.8%)		1 (0.5%)	188

Table 6 cont.: asse.	ssment of importance	of ATLS and	participation in	CMEs on ATLS
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No.	Question	Yes	No	Unsure	Total Respondents
6	Have you at any time felt that your knowledge in ATLS was beneficial to patient care in the trauma setting?	166 (89.7%)	4 (2.2%)	15 (8.1%)	185
7	Have you participated in a CME (continuing medical education) on ATLS in the past 6-12 months?	66 (36.5%)	115 (63.5%)	0	181

4.4.1 ATLS course attendance

62% of study participants had not undertaken the formal ATLS course and the most common reasons for failure to undertake ATLS training was reported as unfavorable cost of the training and lack of time to undertake the training (Figure 13).

If you have not attended an ATLS course, what was the greatest limiting factor to do so?



Figure 13: A bar graph representing the Reason for failure to attend ATLS

CHAPTER FIVE

5.0 DISCUSSION

5.1 The level of knowledge of ATLS principles among the respondents

The study found that almost half of the participants 102 (49.8%) had a low knowledge of ATLS, which is consistent with findings of previous studies by Mohammed A et al 2014 (17) and Amaraegbulam et al 2013 (31).

The level of knowledge was found to be inversely related to the age of the participants. Additionally, healthcare workers who have undergone ATLS training have been reported to have higher confidence levels than those who have not (17, 18, 19, 20). In the study, majority of the respondents reported to have an ATLS self-rating score of above average. Studies have shown that knowledge and skills acquired through ATLS training decline within six months and offer a maximal decrease within two years (20). This decline may be why there was an inverse association between age and the level of knowledge in ATLS.

5.2 The practice of ATLS principles among the respondents

The study found that most participants (62.4%) did not practice ATLS protocols in trauma management due to a lack of knowledge and a proper structure to train healthcare workers on ATLS protocols in the country, this is similar to the findings by Jana et al. 2019 (18) and Abu-Zidan. 2016 (20).

Younger practitioners were more likely to be familiar with ATLS protocols than older ones. It has been observed in many studies that the competencies learned in ATLS training tend to diminish over time, explaining why more senior practitioners may need to practice ATLS protocols more often since they may have undertaken the training a while back (19, 20). Refresher courses and recertification on ATLS protocols have been suggested to help mitigate the loss of competencies over time and to keep up with current trends (29).

The study also found that Medical Officers were more familiar with practice of ATLS principles than Registrars and MO-interns, this goes contrary to a survey by Baird et al. (2004) that found that a healthcare worker's experience level influenced their practice on ATLS protocols (29) where more experienced providers demonstrated higher competencies compared with their counterparts.

The type of training also influenced the practice of ATLS principles among the respondents. Doctors were more likely to implement their practices based on ATLS protocols than nurses. These findings shed light on the level of training and awareness of ATLS protocols among different cadres of healthcare workers in the country. Through partnerships with Kenya Red Cross, AMPATH, the Moi Teaching and Referral Hospital, and the Nairobi Hospital, Kenya's surgical society should incorporate other healthcare workers into the ATLS training. These findings were consistent with a Nigerian study that found a deficiency in the knowledge of ATLS among non- specialist doctors engaged in trauma care in Enugu (31).

5.3 Attitude towards ATLS principles among the respondents.

The study found that most healthcare workers were receptive to the knowledge and competencies taught in ATLS training. Most respondents believed that ATLS training was crucial in managing trauma patients and improved the effectiveness of trauma care. Furthermore, respondents felt ATLS training and certification should be mandatory for HCWs in the Accident and Emergency departments. Regular CMEs on trauma and mass injury were also suggested as necessary. Baird et al., 2004 also reported similar findings, where 98% of respondents considered ATLS training essential or very important (29). Non- specialist doctors in Enugu, Nigeria, were also of the same opinion as they felt that ATLS training should be adopted by the hospitals involved in doctors' training and recommended that ATLS certification should be a prerequisite for employing surgery residents. Interestingly, despite the positive attitudes towards ATLS training, most of the participants in this study, 126 (62%) had not received formal ATLS training and 129(68%) had not participated in a CME on ATLS or an on-site trauma simulation in the preceding 6-12 months of the study period. The most common reasons for lack of formal training in ATLS were reported to be the unfavorable cost of training and the lack of time to undertake the training. Similar obstacles were identified in a study by Wanjiku et al. (2017), which assessed the effects of an emergency trauma course for senior medical students in Kenya (19).

CONCLUSION

This study indicated a variability of the understanding of ATLS principles among participants with lower levels noted among the nurses and older respondents. The study also noted that there was a deficiency in practice of ATLS principles amongst majority of the study participants with age and cadre of training being the most important determinants of this.

Additionally, the study highlights a positive attitude towards ATLS principles amongst the participants and emphasizes cost of training as the most significant barrier to formal training on ATLS.

Moreover, the study noted that there was a lack of CMEs and on-site simulations on trauma management an essential component in knowledge retention and confidence building of staff as appertains ATLS principles

The discrepancy underscores need to have more staff undertake comprehensive ATLS training to ensure the participants attain high levels of proficiency.

RECOMMENDATIONS

- The results underscore the critical need for ATLS training as it enhances healthcare workers' knowledge and practices in trauma management.
- As traumatic injuries continue to be a major public health issue, investing in ATLS training for healthcare workers can significantly reduce the burden of injuries globally.
- There's need for on-site CMEs and simulations on trauma to enhance staff knowledge and boost confidence in care of trauma patients, these should be done regularly and should be audited for effectiveness.
- There's need for development of a cost-effective option to the costly ATLS program or enhancement of institutional sponsorships for staff willing to undertake ATLS training
- ATLS certification ought to be a prerequisite for staff working in the accident and emergency departments to enhance and improve patient care in the trauma setting.

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List of Appendices

Appendix 1: QUESTIONNAIRE/ DATA TOOL

I: Demographics and training

- 1. Form Number: _____
- 2. Facility:_____
- 3. Age: _____
 - i Sex: Male _____ Female_____
 - ii Type of training: Doctor_____ Nurse____
 - iii If doctor, cadre: Medical Officer intern___ Medical Officer___ Registrar__

Specialist____

- iv Level of experience: (post internship- MOs / Year of Study- Registrars) _____year(s)
- v Duration of ATLS training: ____weeks
- vi How would you rate your proficiency in ATLS? (Tick one)
 - Excellent___
 - Average____
 - Poor____
 - Not sure_____

II: Knowledge of ATLS: The following are twenty (20) ATLS standard pretest questions

covering the various aspects of ATLS primary survey. Choose ONE ANSWER amongst

the choices provided

- 1. A 22-year-old man is hypotensive and tachycardic after a gunshot wound to the left shoulder. His blood pressure normalizes after initial IV fluid resuscitation, a closed tube thoracostomy is performed for decreased left breath sounds. What is the best next step in his management?
 - a) Re-examine the chest
 - b) perform an aortogram
 - c) obtain a CT scan of the chest

- d) obtain arterial blood gas analyses
- e) perform trans-esophageal echocardiography
- 2. A construction worker falls two stories from a building and sustains bilateral calcanealfractures. In the emergency department, he is alert, vital signs are normal, and he is complaining of severe pain in both heels and his lower back. Lower extremity pulses are strong and there is no other deformity. The suspected diagnosis is most likely to be confirmedby?
 - a) angiography
 - b) compartment pressures
 - c) retrograde urethrogram
 - d) Doppler-ultrasound studies
 - e) complete spine x-ray series
- 3. In managing the head injured patient, the most important initial step is to
 - a) secure the airway
 - b) obtain c-spine film
 - c) support circulation
 - d) control scalp hemorrhage
 - e) determine the GCS score
- 4. A previously healthy, 70kg man suffers an estimated acute blood loss of 2 liters. Which one of the following statements applies to this patient?
 - a) his pulse pressure was widened
 - b) his urinary output was at the lower limits of normal
 - c) he will have tachycardia, but no change in his systolic blood pressure
 - d) his systolic blood pressure was decreased with a narrowed pulse pressure
 - e) his systolic blood pressure was maintained with an elevated diastolic pressure
- 5. Establishing a diagnosis of shock must include
 - a) hypoxemia
 - b) acidosis
 - c) hypotension
 - d) increased vascular resistance
 - e) evidence of inadequate organ perfusion
- 6. The best guide for adequate fluid resuscitation of the burn patient is
 - a) adequate urinary output
 - b) reversal of systemic acidosis
 - c) normalization of the heart rate
 - d) a normal central venous pressure
 - e) 4mL/kg/percent body burn/24 hours

- 7. A 7-year-old boy is brought to the emergency department by his parents several minutes after he fell through a window. He is bleeding profusely from a 6-cm wound of his medial right thigh. Immediate management of the wound should consist of
 - a) application of a tourniquet
 - b) direct pressure on the wound
 - c) packing the wound with gauze
 - d) direct pressure on the femoral artery at the groin
 - e) debridement of devitalized tissue
- 8. For the patient with severe traumatic brain injury, profound hypocarbia should be avoided to prevent
 - a) respiratory alkalosis
 - b) metabolic acidosis
 - c) cerebral vasoconstriction with diminished perfusion
 - d) neurogenic pulmonary edema
 - e) shift of the oxyhemoglobin dissociation curve
- 9. A 25-year-old man is brought to a hospital with a general surgeon after being involved in a motor vehicle crash. He has a GCS of 13 and complains of abdominal pain. His blood pressure was 80 mm Hg systolic by palpation on arrival at the hospital, but increases to 110/70 mm Hg with the administration of 2 liters of intravenous fluid. His heart rate remains 120 beats per minute. Computed tomography shows an aortic injury and splenic laceration with free abdominal fluid. His blood pressure falls to 70 mm Hg after CT. The next step is
 - a) contrast angiography
 - b) transfer to higher level trauma center
 - c) exploratory laparotomy
 - d) transfuse packed red blood cells
 - e) transesophageal echocardiography
- 10. The first maneuver to improve oxygenation after chest injury is
 - a) intubate the patient
 - b) assess arterial blood gases
 - c) administer supplemental oxygen
 - d) ascertain the need for a chest tube
 - e) obtain a chest x-ray
- 11. A 25-year-old man, injured in a motor vehicular crash, is admitted to the emergency department. His pupils react sluggishly and his eyes open to painful stimuli. He does not follow commands, but he does moan periodically. His right arm is deformed and does not respond to painful stimulus; however, his left hand reaches purposefully toward the painful stimulus. Both legs are stiffly extended. His GCS Score is
 - a) 2
 - b) 4
 - c) 6

- d) 9
- e) 12
- 12. A 20-year-old woman, is stabbed in the upper right chest. In the emergency department, her blood pressure is 80/60 mm Hg. She is gasping for breath, extremely anxious, and yelling for help. Breath sounds are diminished in the right chest. The most appropriate first step is to
 - a) perform tracheal intubation
 - b) insert an oropharyngeal airway
 - c) perform needle decompression of the right chest
 - d) manually displace the gravid uterus to the left side of the abdomen
 - e) initiate 2, large-caliber peripheral IV lines and crystalloid infusion
- 13. Which one of the following findings in an adult should prompt immediate management during the primary survey?
 - a) distended abdomen
 - b) Glasgow coma scale score of 11
 - c) temperature of 36.5C (97.8F)
 - d) heart rate of 120 beats per minute
 - e) respiratory rate of 40 breaths per minute
- 14. The most important, immediate step in the management of an open pneumothorax is
 - a) endotracheal intubation
 - b) operation to close the wound
 - c) placing a chest tube through the chest wound
 - d) placement of an occlusive dressing over the wound
 - e) initiation of 2, large-caliber IVs with crystalloid solution
- 15. The following are contraindications for tetanus toxoid administration
 - a) history of neurological reaction or severe hypersensitivity to the product
 - b) local side effects
 - c) muscular spasms
 - d) pregnancy
 - e) all of the above
- 16. A 56-year-old man is thrown violently against the steering wheel of his truck during a motor vehicle crash. On arrival in the emergency department, he is diaphoretic and complaining of chest pain. His blood pressure is 60/40 mm Hg and his respiratory rate is 40 breaths per minute. Which of the following best differentiates cardiac tamponade from tensionpneumothorax as the cause of his hypotension?
 - a) tachycardia
 - b) pulse volume
 - c) breath sounds
 - d) pulse pressure
 - e) jugular venous pressure

- 17. Bronchial intubation of the right or left mainstem bronchus can easily occur during infant endotracheal intubation because
 - a) the trachea is relatively short
 - b) the distance from the lips to the larynx is relatively short
 - c) the use of tubes without cuffs allows the tube to slip distally
 - d) the mainstem bronchi are less angulated in their relation to the trachea
 - e) little friction between the endotracheal tube and the wall of the trachea
- 18. A 39-year-old man is admitted to the emergency department after an automobile collision. Heis cyanotic, has insufficient respiratory effort, and has a GCS score of 6. His full beard makesit difficult to fit the oxygen facemask to his face. The most appropriate next step is to
- a) perform a surgical cricothyroidotomy
- b) attempt nasotracheal intubation
- b) attempt nasotracheal intubation
- c) ventilate him with a bag-mask device until c-spine injury can be excluded
- d) attempt orotracheal intubation using 2 people and inline stabilization of the cervical spine.
- e) ventilate the patient with a bag-mask device until his beard is shaved for better maskfit.
 - 19. A patient is brought to the emergency department 20 minutes after a motor vehicle crash. He is conscious and there is no obvious external trauma. He arrives at the hospital completely immobilized on a long spine board. His blood pressure is 60/40 mmHg and his heart rate is70 beats per minute. His skin is warm. Which one of the following statements is true?
 - a) vasoactive medications have no role in the patient's management
 - b) the hypotension should be managed with volume resuscitation alone
 - c) flexion and extension views of the c-spine should be performed early
 - d) occult abdominal visceral injuries can be excluded as a cause of hypotension
 - e) flaccidity of the lower extremities and loss of deep tendon reflexes are expected
 - 20. A patient arrives in the emergency department after being beaten about the head and face with a wooden club. He is comatose and has a palpable depressed skull fracture. His face is swollen and ecchymotic. He has gurgling respirations and vomitus on his face and clothing. The most appropriate step after clothing. The most appropriate step after providing supplemental oxygen and elevating his jaw is to
 - a) requires a CT scan
 - b) insert a gastric tube
 - c) suction the oropharynx
 - d) obtain a lateral cervical spine x-ray
 - e) ventilate the patient with a bag-mask

III: Practice of ATLS

1.	what is the critical step to observe as you secure the airway?	
2.	what are the danger signs to watch for in a patient with a suspected blunt chest inju	ıry?
3.	What do you do if a patient has an open bleeding wound?	-
4.	How do you asses the patient's consciousness level?	
5.	How many team members do you need to effectively perform a log-roll maneuver exam and where do you position them for optimum results?	to conduct a spine
6.	After completion of disability assessment? What is the next best step?	
7.	How do you effectively reduce a suspected pelvic fracture in a patient with hemod	ynamic instability?
8.	How many team members do you need to effectively reduce a suspected pelvic fra roles during the reduction process?	cture what are their
9.	How do you temporarily reduce and stabilize long bone fractures in the A&E depa	rtment?
10	. What critical information should be included when consulting with a colleague or patient to a dedicated trauma center?	when transferring a

Answer them to the best of your ability.

1. ATLS knowledge is important to effectively manage a trauma patient?

STRONGLY AGREE	
AGREE	
DISAGREE	
UNSURE	

2. ATLS certification status determines effectiveness of patient care in the trauma setting?

STRONGLY AGREE	
AGREE	
DISAGREE	
UNSURE	

3. If you have not attended an ATLS course, what do you think is the greatest limiting factor to you

doing so? _____

4. Have you at any time felt that your knowledge in ATLS was beneficial to patient care in the trauma

setting?

YES	
NO	
UNSURE	

5. ATLS certification should be made a requirement amongst HCWs in the Accident and Emergency

department?

STRONGLY AGREE	
AGREE	
DISAGREE	
UNSURE	

6. Have you participated in a CME (continuing medical education) on ATLS in the past 6-12 months?

YES	
NO	

7. CMEs on Trauma and/or simulations on mass injury scenarios should be held regularly at your

workplace?

STRONGLY AGREE	
AGREE	
DISAGREE	
UNSURE	

8. ATLS knowledge adequately prepares HCWs working in the Trauma setting to work effectively as a

team?

STRONGLY AGREE	
AGREE	
DISAGREE	
UNSURE	



UNIVERSITY OF NAIROBI FACULTY OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity Tel:(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/206

Dr. Nicholas Koome Guantai Reg. No. H58/11383/2018 Dept. of O-Ihopaedic Surgery Faculty of Health Sciences University of Nairobi

NATIONAL PPROVEL 00202

KNH-UON ERC

Email: uonknh_erc@uonbi.ac.ke

Website: http://www.erc.uonbl.ac.ke Facebook: https://www.facebook.com/uonknh.erc Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

27th May, 2022

Dear Dr. Guantai,

RESEARCH PROPOSAL: KNOWLEDGE, ATTITUDE AND PRACTICE OF ADVANCED TRAUMA LIFE SUPPORT PRINCIPLES AMONG HEALTH CARE WORKERS IN ACCIDENT AND EMERGENCY DEPARTMENTS IN NAIROBI, KENYA; A MULTI-CENTER STUDY (P140/02/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is P140/02/2022. The approval period is 27th May 2022- 26th May 2023.

This approval is subject to compliance with the following requirements;

- Only approved documents including (informed consents, study instruments, MTA) will be used. i.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of iv. study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- Clearance for export of biological specimens must be obtained from relevant institutions. ٧.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval vi. period. Attach a comprehensive progress report to support the renewal.
- Submission of an executive summary report within 90 days upon completion of the study to KNHvii. **UoN ERC.**

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Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <u>https://research-portal.nacosti.go.ke</u> and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE SECRETARY, KNH-UON ERC

C.C.

The Dean, Faculty of Health Sciences, UoN The Senior Director, CS, KNH The Chairperson, KNH- UoN ERC The Assistant Director, Health Information, KNH The Chair, Dept. of Orthopaedic Surgery, UoN Supervisors: Dr. Edward Gakuya, Dept. of Orthopaedic Surgery, UoN Dr. Tom S. Mogire, Dept. of Orthopaedic Surgery, UoN Dr. Parmenas Oroko, Consultant Orthopaedic Surgeon, Aga Khan University Hospital, Nairobi

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THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research

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