A SURVEY OF PERIOPERATIVE MINIMUM MONITORING CAPACITY OF MAJOR REFERRAL HOSPITALS IN KENYA

DR. BRYAN ATANDI OGOTI

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University of Nairobi

A PROPOSAL FOR A DISSERTATION IN PART FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE IN ANAESTHESIA, UNIVERSITY OF NAIROBI.

Declaration by the Principal Investigator:

This proposal is my original work and has not been presented for degree award, publication, or scientific dissertation in any institution.

Dr. Ogoti Bryan Atandi, MB ChB.

Postgraduate student in Anaesthesiology, University of Nairobi.

Address: PO BOX 6810-00610 Nairobi, Kenya Email: bryanatandi@students.uonbi.ac.ke

Signature……. Date……..….

Declaration by the Supervisor:

This proposal has been submitted for examination for registration for the Masters of Medicine in Anaesthesiology degree with my approval as the university supervisor.

Dr. Thomas Muinga Chokwe, BSc, MB ChB, M.MED (Anaesth)

Senior Lecturer, Department of Anaesthesia, University of Nairobi

Address: PO BOX 2266, KNH-Nairobi-00202, Kenya Email: chokwe@uonbi.ac.ke

Signature……. Date…….

DEPARTMENTAL APPROVAL

This proposal has been approved by the Department of Anaesthesia, University of Nairobi, for submission to the KNH-UoN Ethics and Research Committee.

Chairman, Department of Anaesthesia, University of Nairobi.

Signature……. Date…….

LIST OF TABLES

LIST OF FIGURES

DEFINITION OF CONCEPTS AND ABBREVIATIONS

-AAGA: Accidental awareness during general anaesthesia

-AAGBI: Association of Anaesthetists of Great Britain and Ireland

-Anaesthesia provider: physician anaesthesiologists, clinical officer, and nurse anaesthetists.

-ASA: American Society of Anaesthesiologists

-ECG: Electrocardiogram

-KNH: Kenyatta National Hospital

-KSA: Kenya Society of Anaesthesiologists

-Major Referral Hospital: refers to the 7 regional referral hospitals, university teaching hospitals, and the two Level 6 largest mission hospitals in Kenya.

-Minimum monitoring devices: all devices in the standards set by the AAGBI, WFSA, ASA, and KSA for monitoring anesthetized or sedated persons.

-MTRH: Moi Teaching and Referral Hospital

-NAP4: The 4th national audit project of the United Kingdom

-NAP5: The 5th national audit project of the United Kingdom

-NIBP: Non-Invasive Blood Pressure

-REDCap: Research Electronic Data Capture

-Regional Referral Hospitals: largest referral hospitals serving multiple counties, formerly the provincial general hospitals.

-SPSS: Statistical Product and Service Solutions

-WFSA: World Federation of Societies of Anaesthesiologists

-WHO: World Health Organization

-UoN: University of Nairobi.

TABLE OF CONTENTS

TABLE OF CONTENTS

STRUCTURED ABSTRACT

Background

Monitoring in anaesthesia is checking the progress of patients over time. It is important to predict, prevent, and intervene in adverse outcomes, as has been demonstrated by various studies. Minimum monitoring is recommended by various organizations worldwide, including Kenya Society of Anaesthesiologists. This uniformly includes pulse oximetry, blood pressure, electrocardiogram, exhaled carbon dioxide, temperature, neuromuscular monitoring, and additional advanced monitoring.

Objective

The general objective of this study is to determine the capacity for recommended minimum monitoring in anaesthesia in major referral hospitals in Kenya. It aims to compare monitoring equipment availability with minimum standards.

Study Design and Sites

The study will be a cross-sectional, observational, descriptive study. It will be carried in areas sedation and anaesthesia is given at all the regional/provincial referral hospitals, university teaching hospitals, and the two largest mission hospitals; AIC Kijabe and Tenwek.

Materials and Methods.

In the areas anaesthesia is given, the study will count using a checklist questionnaire; the number of available monitoring devices for blood pressure, heart rate, oxygen and carbon dioxide concentration, temperature, and anaesthesia machines.

Data Management

The checklist questionnaire will be coded into the encrypted REDCap application for data entry. Data will be cleaned and exported to SPSS version 23.0 for analysis. Continuous data such as the number of devices will be summarized using measures of central tendency (mean), and measures of spread (standard deviation). Categorical data such as type of monitoring device will be summarized using frequency with corresponding percentages/histograms.

Variability from recommended numbers will be tested using a correlation coefficient. Data will be stored for 5 years before being deleted by hard format, and shredding of hard copies.

Expected Outcome.

The expected outcome of the study is to provide baseline information on available monitoring equipment, to allow for planning and improved practical utilisation of healthcare resources. This will be a basis for recommendations on policy to improve safety in anaesthesia.

CHAPTER 1

1.1 Introduction/Background of the Study

The Oxford Languages Dictionary defines monitoring, which is derived from the Latin word ‘monit’ that means ‘warned’. It defines monitoring as observing and checking the progress or quality of something over some time. Applied to perioperative anaesthesia, and believed to have been pioneered by Harvey Cushing, it implies vigilant awareness of various parameters to predict, prevent, and intervene any deviations from the normal physiologic states.

The AAGBI standards of monitoring 2015 recommend minimum physiological monitoring devices for patients receiving general anaesthesia or sedation.[1] There is an emphasis that capnography should be present throughout the conduct of anaesthesia from induction to full recovery.

The ASA monitoring standards require that in addition to the availability of trained anaesthesia personnel; anaesthetized or sedated patient’s oxygenation, ventilation, circulation, and temperature be continuously monitored clinically and objectively using various devices.[2]

The WFSA standards of anaesthesia recommend clinical monitoring, continuous pulse oximetry, intermittent NIBP, and exhaled carbon dioxide for intubated patients.[3] Where resources allow, such as referral hospitals; disconnect alarms, electrocardiograms, temperature, and neuromuscular monitoring are suggested.

A set of mandatory monitoring equipment is recommended by KSA.[4] Similar to the AAGBI and ASA recommendations, it mandates the use of pulse oximetry, NIBP, ECG, exhaled carbon dioxide measurement, temperature, and neuromuscular monitoring. Oxygen analysers, breathing system disconnection alarms, and volatile agent concentration monitors are also recommended. There is emphasis that 5-lead ECG should be available in Level 5 and 6 hospitals as well as a variety of NIBP cuff sizes. Advanced monitoring equipment such as central venous pressure monitoring and electroencephalogram is recommended for referral hospitals, as specialized surgeries are performed here.

Monitoring in anaesthesia remains an area of research and new developments. Recommended minimum monitoring is important to predict, prevent, and intervene in any physiologic derangements.

It has been shown in various studies that perioperative events can be reduced by monitoring. Keenan RL, et al. were early to demonstrate a reduction in cardiac arrests due to monitoring of respiratory parameters.[5] This remains true to date. The ASA Closed Claims Project reported a significant decline over ten years, since the beginning of pulse oximetry and capnography, in serious perioperative events in which anaesthesiologists were liable.[6]

Part of the aims of the Global Oximetry Project was to identify the barriers to sustained oximetry use in low-income countries and develop appropriate solutions for low-income anaesthesia environments.[7] These aims could be achieved through data collection on monitoring capacity that will form a basis for recommendations on the appropriate solutions.

Capnography is a simple robust tool for making inferences about metabolism, perfusion, and ventilation during anaesthesia and sedation. Waveform analysis detects in real-time, multiple critical events such as missed esophageal intubation.[8,9] While capnography is more costly, waveform analysis cannot be achieved by capnometry. The indications for capnography in monitoring have been expanded recently by the AAGBI. However, no monitoring device has been shown to improve perioperative outcomes when used alone, and thus capnography cannot be considered alone.

The NAP5 report indicated that AAGA could occur due to deficient neuromuscular and end-tidal monitoring.[10] It was felt that more detailed guidance concerning minimal standards of monitoring should be provided.

Therefore, it emerges that minimum monitoring is important perioperatively, to reduce adverse outcomes. Inadequate monitoring can cause mortality.[11] Pre-operative and post-recovery monitoring are important. Pre-operative intermittent ambulatory NIBP monitoring may detect longstanding pre-operative hypertension, predicting surgical risks, or even serious comorbidity such as obstructive sleep apnea. Post-recovery monitoring may be used to determine surgical outcomes. However, the scope of pre-operative and post-recovery monitoring is complex, and beyond this study on monitoring during anaesthesia.

This study seeks to determine the current capacity for minimum monitoring devices, in major referral hospitals in Kenya; while comparing it with the standard minimums for safe anaesthesia. The types of available exhaled carbon dioxide measurement devices will be determined given the broad diagnostic information offered by capnography. The aim is to identify key strengths and pitfalls in the safe anaesthesia provision and possibly instigate desired changes in the allocation of healthcare resources.

1.2 Literature Review

1.2.1 Introduction

Safety in anaesthesia depends on several factors, including minimum monitoring standards defined by various relevant bodies. The AAGBI 2015 minimum standards include pulse oximetry, non-invasive blood pressure, electrocardiogram, inspired and expired oxygen, carbon dioxide, nitrous oxide, and volatile anaesthetic agents, airway pressure, peripheral nerve stimulator if neuromuscular blocking drugs are used, and temperature monitoring for procedures longer than 30 minutes. The majority of these devices are also recommended as minimums by the KSA, ASA, and WHO-WFSA. The capacity to adhere to these minimum monitoring standards has been evaluated in some fairly recent publications. However, the data available remains limited; both locally and in international regions.

1.2.2 Previous Studies

Blaise FNP, et al. in May 2020 published results of a survey of monitoring practices in the remote Democratic Republic of Congo.[14] It was found that 70% of the facilities failed to meet the WHO-WFSA monitoring standards and less than half of the anaesthesia providers used a multiple-parameter electronic monitor during anaesthesia. No health facility used waveform capnography or measured the fraction of inspired oxygen. ECG and pulse oximetry were not used all the time. It was further established that 20-39% of the instances of poor monitoring were due to lack of equipment or equipment parts. However, the study was limited geographically and included untrained anaesthesia providers as part of the respondents.

A Malawi survey by Jooste R, et al. in 2018 identified nearly complete unavailability of capnography equipment in theatres and intensive care units.[9] This study originated from the Global Oximetry Project, and in the few areas where capnography was available, there was compelling evidence for its role in recognition of critical incidents. About 80% of esophageal intubations and breathing circuit disconnections were recognized by capnography alone. The survey was limited to only the 10 largest hospitals in Malawi, and could not possibly reveal deficits in peripheral facilities.

Epiu E, et al. in 2017 published results of a cross-sectional survey conducted at 5 main referral hospitals in East Africa, one of which was Kenyatta National Hospital.[15] Whereas the study did not entirely focus on minimal monitoring equipment, it noted that only 4% (3 of 85) of the anesthetists interviewed had access to electrocardiograms, continuous pulse oximetry,

blood pressure monitoring, capnography, and other variables such as access to suction equipment or critical care services. Conclusions on minimum monitoring devices in Kenya are impossible to make from this study since it was limited to the largest hospital in Kenya, and had broader objectives.

Hadler RA, et al. did a systematic review of documented anaesthesia capacity on key databases; PubMed, Cochrane Database of Systematic Reviews, and Google Scholar in 2016.[16] Whereas most of the reviewed studies revealed that large deficiencies exist in anaesthesia capacity in low- and middle-income countries, majority of the reporting was on availability of oxygen supply, electricity, airway devices and drugs used in anaesthesia. Functional pulse oximeters were present in 51 % of hospitals in 12 countries. It is important to note the limitation of the above reports; that is, pulse oximetry is only one of the minimum monitoring devices. None of these reports included data from Kenya.

In the United Kingdom, a survey led to the discovery that neuromuscular block monitoring was only done by less than 20 % of responding anaesthetists. Lack of resources for monitoring was an alluded contributing factor.[17]

Iddriss A, et al. did a survey of 65 hospitals in the Gambia in 2011, to assess the resources for essential and emergency surgical care in the Gambia.[18] It was found that functioning anaesthesia machines were available at only 70.6% of facilities. The term ‘functioning anaesthesia machine’ was not defined. Therefore, it would be impossible to discern what, if any of, or all minimum monitoring devices had to be present for it to be a ‘functioning anaesthesia machine’.

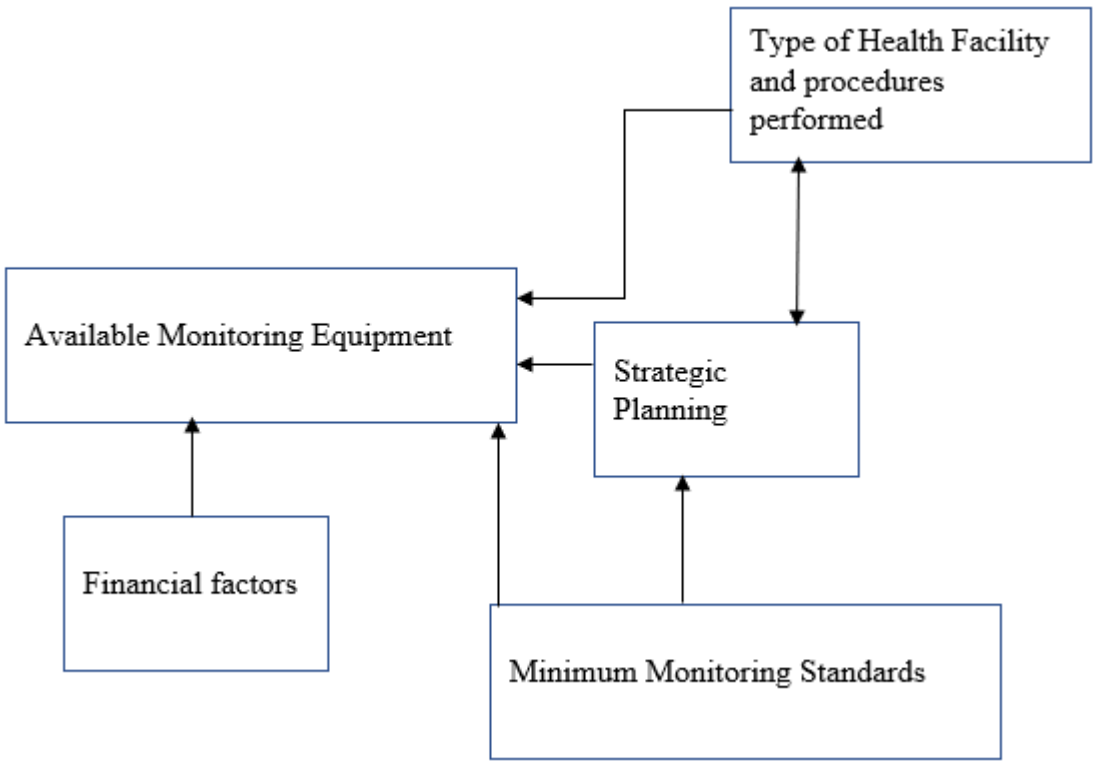
According to Funk LM, et al. in 2010, an analysis of data from WHO's safe surgery saves lives initiative, pulse oximetry data from 54 countries suggested that around 77 700 (19.2%) theatres worldwide were not equipped with pulse oximeters.[19] Although this analysis revealed inadequate equipment availability, it was generalized and no local data was provided.

A 2008-2009 prospective study done in Nigeria by Adudu P, indicated a scarcity of anaesthetic equipment available to paediatric anaesthesia providers in 30 hospitals in Nigeria.[20] In the survey it was noted that capnography was found in only 2 hospitals, 6.6% at the time of the study. The available anaesthetic equipment used largely failed to conform to standards at 98%. This study was limited to public facilities available for paediatric anaesthesia, and one of the included facilities had a large number of equipment. This may lead to a misinterpretation of the availability, and an assumption of equal distribution.

1.3 Conceptual framework

The response variable in this study will be the number and type of monitoring devices available in the selected operating theatres. The explanatory variable is multifactorial and could be financial factors, type of health facility, procedures performed, strategic planning, or inadequate awareness of the minimum monitoring standards.

Figure 1: Diagrammatic Representation of the Conceptual Framework



1.4 Justification of the study

Adherence to minimum monitoring standards has been shown to reduce and timely mitigate adverse perioperative events. Therefore, this study only seeks to determine the availability of recommended minimum monitoring devices for patients undergoing anaesthesia.

The study seeks to determine if locally available resources meet the standard. Although some studies have been done in other nations, there is no data on the available minimum monitoring devices in public hospitals in Kenya, and the capacity for minimum monitoring standards is largely unknown.

The absence of information on the availability of these minimum monitoring devices could cause a lack of the devices, due to the consequent poor planning or the cost of acquiring the devices. It was planned that better availability of medical equipment in remote counties could arise from the devolution of health. Similarly, the national managed equipment scheme that set out to support the devolution of healthcare planned to equip 2 hospitals in each county and the national referral hospitals with outsourced medical equipment, that included theatre equipment. Whereas there may have been improved access to medical equipment, a formal objective assessment has not been done.

By determining the available equipment and comparing it with the standard, the intent is to generate a basis for recommendations that will trigger planning and policy change on minimum monitoring devices to the health sector, particularly in the public hospitals.

This study will partly meet 2 of the 3 aims of the Global Oximetry Project and expand them to include other minimum monitoring devices, by data collection.

The particular emphasis on capnography by this study is meant to reiterate the diagnostic value of capnography and the recent expansion of the perioperative indications of capnography by the AAGBI minimum monitoring standards of 2015. This followed the findings of NAP4, where failure to use capnography was a factor in more than 70% of airway related deaths.[12]

The presence of a trained and vigilant anaesthesia provider who can clinically monitor, correctly interpret parameters, and intervene is recommended by all of the anaesthesia organizations. Therefore, an evaluation of monitoring capacity should include training capacity which would be complex, but part of training capacity lies in the availability of equipment.

Mission hospitals in Kenya form a bridge between private and public hospitals with a large service population, particularly those that have resident training programs due to specialized treatments they offer. For example, AIC Kijabe hospital performs about 10000 surgeries each year in 9 operating theatres.[13] Therefore, university teaching hospitals and the two largest mission hospitals have been included in the study, and the data that will be collected could influence the training of medical students and anaesthesia providers.

1.5 Research Question

What is the capacity for minimum monitoring devices for patients undergoing sedation and anaesthesia in major referral hospitals in Kenya?

1.6 Objectives of the Study

1.6.1 Broad objective:

To determine the capacity for recommended minimum monitoring in anaesthesia in major referral hospitals in Kenya.

1.6.2 Specific objectives:

1. To identify the number and distribution of available minimum monitoring devices in anaesthesia
2. To identify deficiencies and/or excesses in the distribution of minimum monitoring devices in anaesthesia
3. To determine specific exhaled carbon dioxide measurement and monitoring equipment available.

1.7 Research Hypothesis

Null Hypothesis

The available minimum monitoring devices in major referral hospitals in Kenya does not meet the 2015 AAGBI minimum standards.

CHAPTER 2: METHODOLOGY

2.1 Introduction

The study will use primary data collected by way of a checklist questionnaire.

2.2 Study Design

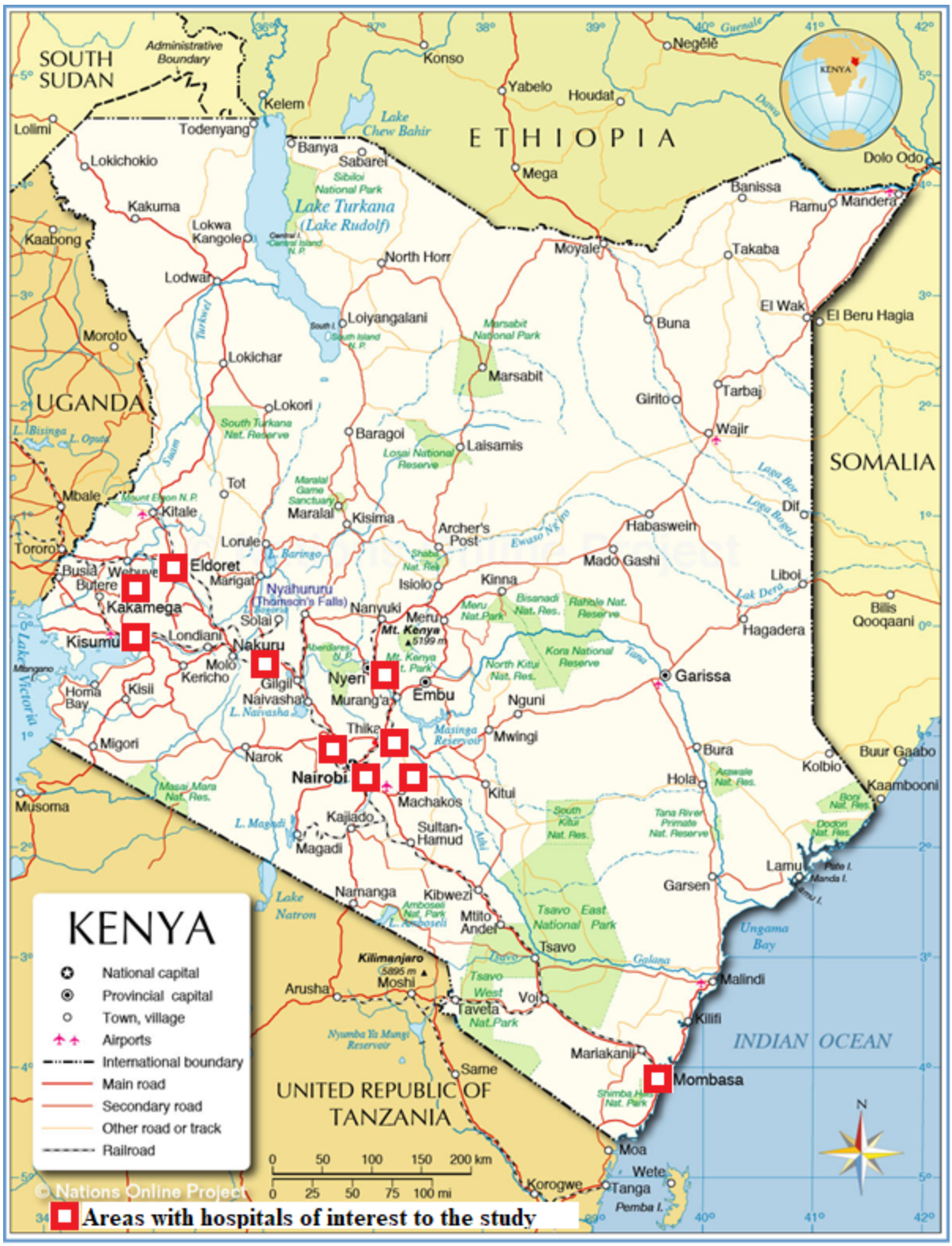
It will be a cross-sectional observational descriptive study, in which checklist questionnaires will be applied. The checklist questionnaire will be filled by the researchers rather than being self-administered to minimize response bias. Data collected will then be imported to SPSS for analysis.

2.3 Study Area

The study will be carried out at major referral hospitals in Kenya. Kenya is an independent republic in East Africa, organized into 47 counties. There are 13 major referral hospitals in Kenya. These are the regional referral hospitals, two level six mission hospitals and the university teaching hospitals. 7 major referral hospitals are the regional referral hospitals (former provincial general hospitals), namely; Jaramogi Oginga Odinga Teaching and Referral Hospital, Kakamega General Teaching and Referral Hospital, Nakuru Teaching and Referral Hospital, Coast General Provincial Hospital, Nyeri Teaching and Referral Hospital, Garissa Teaching and Referral Hospital, and Machakos Teaching and Referral Hospital. Kakamega General Teaching and Referral Hospital, and Jaramogi Oginga Odinga Teaching and Referral Hospitals also serve as university teaching hospitals. 2 major referral hospitals are the only Level 6 Mission Hospitals; Tenwek and AIC Kijabe, serving multiple counties. There are 4 separate university teaching hospitals. These are the Kenyatta University Teaching, and Referral Hospital, Kenyatta National Hospital, Moi Teaching, and Referral Hospital and Thika Level 5 Hospital.

It is assumed that the theatres and areas sedation is administered in these facilities will give a representative national picture of the regional availability of minimum monitoring devices. The image below shows a geographic map of Kenya, where the areas marked with a square indicate locations of the selected health facilities of interest to the study.

Figure 2: Geographical Map of Kenya[23]



Adapted from the Nations Online Project.

2.4 Study Population

The study population will be areas where patients are anaesthetized or sedated by anaesthesia providers in selected major referral hospitals in Kenya.

2.4.1 Inclusion criteria

All operating theatres in the selected hospitals being studied will be included. It will include areas in the selected hospitals where monitoring of anaesthesia is provided during sedation.

2.4.2 Exclusion criteria

It will exclude referral hospitals that are not regional referral hospitals. It will not include private hospitals, and will exclude Garissa Teaching and Referral hospital for geographic reasons.

2.5 Sample Size Determination

The sample size of the theatres and areas where patients are given anaesthesia or sedated in the selected hospitals, is obtained using the formula suggested by Cochran. This will help to determine inference about all theatres in Kenya. The formula suggested by Cochran for the sample size of a population, is shown below.[22]

$$n_0 = \frac{z^2 pq}{e^2}$$

where it is assumed that $\mathbf{n_0}$ is the size of the sample, **z** is the determined critical value, **p** is the estimated proportion of the population with the desired characteristic from the Institute for Health Metrics and Evaluation Report, q is equal to 1-p, **e** is the desired level of precision or statistical significance, and given that the total population of theatres and areas sedation is offered is is not known.

Thus, $n_0 = \frac{(1.96)^2 * 0.9 * 0.1}{0.05^2}$

n_0 = approximately 139 theatres and areas where patients are given anaesthesia or sedated.

Therefore, the study will aim to evaluate a minimum of 139 theatres and areas patients are given anaesthesia or sedated by anaesthesia providers.

2.6 Sampling Criteria

In this study the sampling procedure is purposive. The study is being carried out in the hospitals known to be major referral hospitals. This study will be carried out in all of these hospitals. In these facilities, all theatres and areas where sedation and anaesthesia are administered by anaesthesia providers will be studied.

2.7 Analysis of Data

The checklist questionnaire will be coded into the REDCap application where the data will be entered. The access to the REDCap page will be encrypted. It will require a unique confidential login username and password that will be used by the principal investigator and research assistant for access. The data will be cleaned and then exported to SPSS version 23.0 where statistical analysis will be done. The data forms will be continuously checked for completeness and accuracy of the input information.

Continuous data such as the number of theatres or monitoring devices will be summarized using measures of central tendency such as mean and mode, and measures of spread such as standard deviation and inter-quartile range. The categorical data such as type of monitoring device will be summarized using frequency with the corresponding percentages and histograms. The monitoring devices and their numbers will be tabulated and presented as frequencies and proportions. The degree of how the number of available monitoring devices vary from the minimum recommended numbers will be tested using a correlation coefficient. Statistical significance will be considered at p less 0.05.

At the end of the study, the raw data from the REDCap application will be stored for 5 years before being deleted. All softcopies from computers and any storage devices deleted by hard format, and any hard copy documents will be shredded and burnt down.

2.8 Limitations of the Study

The study would have some limitations:

-Exclusion of private hospitals, which may also lack the capacity for minimum monitoring standards. However, data from referral public hospitals could trigger future studies in private hospitals.

-It will not assess the practice and knowledge of use and interventions that might be triggered by monitored parameters. The part assessment of training capacity could create recommendations that will improve practice and knowledge.

-Inclusion of the largest referral hospital in Kenya, which proportionately has more operating theatres, may skew the national data. Each health facility will receive its data, and this can be used for regional planning.

2.9 Ethical Considerations.

The clearance of the survey protocols will be sought from by the KNH-UoN Ethics and Research Committee. The survey will collect information on available healthcare equipment in the selected health facilities. It will neither collect, nor disseminate any information about patients in any of the involved health facilities. Authorization to conduct the study will be sought from the relevant administration of the all facilities involved in the study before collecting the data. It will follow all ethical standards without any direct contact with human and/or animal subjects. The names of participating facilities will not be revealed in any future publications that arise from the study.

2.10 Dissemination and Application of the Study Results

The data collected and analyzed will be shared with the Ministry of Health, all the participating hospitals, and the local county governments, through their representative council.

It is believed that this will enable them to determine their capacity for minimum monitoring devices, and identify areas that may need improvement in terms of resource allocation.

The results will be shared with the KNH-UoN Ethics and Research Committee, the University of Nairobi Library, and the University of Nairobi Online Repository.

A publication of the results will be done on a peer-reviewed scientific journal.

CHAPTER 3. STUDY BUDGET, WORK PLAN AND CLOSURE PROTOCOL.

3.1 Study Timeline/Workplan

Date **Activity**	March to November 2020	November to January 2020	January 2021 to December 2021	January to July 2022
Proposal Development				
Departmental Approval				
Institutional Ethics Clearance				
Data Collection				
Data cleaning and analysis				
Thesis Compilation				
Thesis Presentation and Corrections				
Journal Publication				

3.2 Study Budget.

The study will be sponsored by the principal investigator's savings, with the following budget.

Item	Cost per Unit	Quantity	Total
Travel Costs			20000
Accommodation Costs	3000	4	12000
Research Assistant	40000	1	40000
Statistician	40000	1	40000
Stationary	2400	5	12000
Pen Drive	2000	1	2000
Total			126000

3.2.1 Justification of the Budget.

The budget is an estimate. When traveling from Nairobi to Kisumu, Mombasa, Eldoret and Kakamega the researcher will need a night accommodation given the long-distance of the travel. The average travelling cost to and from the areas of interest is 1000 to 3000 kenya shillings, thus an estimate of 20000 kenya shillings for the travel costs. An extra 20000 kenya shillings will be allocated for excesses beyond the total.

3.3 Study Closure Plan

Should challenges arise in the course of planning or executing the study, the principal investigator shall write the study closure report to the KNH-UoN ERC with clear information on the decision to close the study. Information on whether the study will be reopened or entirely forfeited shall be communicated. In the event of insurmountable limitations as listed above, the need for study closure shall be communicated. Research Data and Document Archiving plans shall be communicated as well. Upon completion of the study, the principal investigator shall inform the KNH-UoN ERC in writing. The Principal Investigator shall ensure the safety and storage of all original records that is questionnaires, research authorisation documents for anonymity and completion.

The final database, on which data analysis and publication is based, shall be properly labelled ready for archiving. ThePrincipal Investigator shall be responsible for the final reporting procedures including reporting to KNH-UoN ERC at the end of the research project including publications and results dissemination plan. If the KNH-UoN ERC closes the study due to technical issues, the investigators will comply with its decision.

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APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

A: Demographic characteristics:

Facility:

1. Facility Name:
2. Type: (tick one)

-University Teaching Hospital	
-Mission Hospital	
-Referral Hospital	

3. Number of Operating theatres:
4. Is the facility undertaking specialized surgeries such as cardiac and vascular operations?

B. Availability of Monitoring Devices:

AVAILABLE MONITORING DEVICES	**OPERATING THEATRE**									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
a) NIBP available										
-Number of neonate cuffs										
-Number of paediatric cuffs										
-Number of Adult cuffs (indicate if in various sizes)										
b) ECG available										
-3 lead available										

-5 lead available										
-Various electrode sizes present										
c) Continuous pulse oximetry available										
-Age-appropriate probes available:										
d) Skin temperature probe available										
e) Type of Exhaled carbon dioxide measurement available:										
-Capnometry										
-Waveform capnography										
f) Nerve stimulator available (when muscle relaxants are used)										
g) Anaesthesia work station measures and displays:										
-Airway pressure										
-Volatile agent concentration										
-Inhaled oxygen concentration										
h) Functioning patient monitor available*										
i) Maintenance personnel constantly available										

*The monitor has a continuous display, alarms with modifiable limits, and keeps a record of monitored parameters.

5. Devices available in satellite areas, if any, where sedation is offered.

	Location:									
Device	1	2	3	4	5	6	7	8	9	10
NIBP										
ECG										
Pulse oximetry										
Capnography										
Temperature										

6. Devices available for continuous monitoring for each patient bed in recovery areas

Device	**Recovery Bed:**									
	1	2	3	4	5	6	7	8	9	10
NIBP										
ECG										
Pulse oximetry										
Capnography										
Temperature										

7. Portable monitoring devices used during the transfer of patients within the hospital

Device	**Number Available**
NIBP	
ECG	
Pulse oximetry	

8. Is there access, within the facility, to additional monitoring such as invasive arterial blood pressure when needed for specialized surgeries?

Device	**Available**
Central Venous Pressure	
Invasive Arterial Blood Pressure	
Electroencephalogram	

APPENDIX 2: CONSENT FOR ENROLLMENT INTO THE STUDY

Title of Study: A Survey of the Perioperative Minimum Monitoring Capacity of Major Referral Hospitals in Kenya

Principal Investigator\and institutional affiliation: Dr. Bryan Atandi Ogoti, University of Nairobi

Co-Investigators and institutional affiliation: None

Introduction: I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect any interactions between you and the researchers. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?

The researchers listed above are surveying theatres and areas sedation is administered. The purpose of the interview is to find out if there are recommended equipment for monitoring of patients that are treated in these areas. The survey will check for presence of monitoring equipment such as blood pressure machines and heart monitors. There will be approximately 139 participating areas in this study. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 10 minutes. The interview will cover topics such as the types of surgeries done and the number of theatres in the facility. After the interview has finished, the interviewer will count the number of monitoring devices available in the theatre or area sedation is administered. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: to update you on study results or to get clarification of details if needed.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify the area in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about your area. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving a free report of the available monitoring equipment, and if the standard recommendation is being met by your area. Also, the information you provide will help us better understand the status of availability of monitoring devices in Kenya. This information is a contribution to science and planning of healthcare resources.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

You will not be required to pay for anything when participating in this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

You will not be paid for participating in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: **Yes** **No**

I agree to provide contact information for follow-up: **Yes** **No**

Participant printed name:

_____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____

Date: _____ Signature_____

Role in the study: _____

For more information contact _____ at _____ from _____ to _____

Witness Name_____

Contact information _____ Signature /Thumb stamp: _____ Date; _____

APPENDIX 3: SWAHILI TRANSLATION OF CONSENT FOR ENROLLMENT AND CONSENT FORM

RIDHAI YA KUJIANDIKISHA KWENYE MAFUNZO

Kichwa cha Utafiti: Utafiti wa Uwezo wa Kiwango cha chini cha Ufuatiliaji wa Wafanyakazi wa Hospitali Kuu za Rufaa nchini Kenya

Mchunguzi Mkuu \ na ushirika wa kitaasisi: Dk. Bryan Atandi Ogoti, Chuo Kikuu cha Nairobi

Wachunguzi-wenza na ushirika wa kitaasisi: Hakuna

Utangulizi

Ningependa kukuambia juu ya utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari utakayohitaji kukusaidia kuamua ikiwa ni mshiriki wa utafiti huo au la. Jisikie huru kuuliza maswali yoyote juu ya madhumuni ya utafiti, nini kinatokea ikiwa unashiriki katika utafiti, hatari na faida zinazowezekana, haki zako kama kujitolea, na chochote kingine juu ya utafiti au fomu hii ambayo haijulikani wazi. Wakati tumejibu maswali yako yote kukuridhisha, unaweza kuamua kuwa kwenye somo au la. Utaratibu huu unaitwa 'ridhaa inayofahamishwa'. Mara tu utakapoelewa na kukubali kuwa kwenye utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni wa hiari kabisa ii) Unaweza kujiondoa kutoka kwa utafiti wakati wowote bila kutoa sababu ya kujitoa kwako iii) Kukataa kushiriki utafiti hautaathiri mwingiliano wowote kati yako na watafiti. Tutakupa nakala ya fomu hii kwa kumbukumbu zako.

Naweza kuendelea? NDIO LA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi.

UTAFITI HUU UNAHUSU NINI?

Watafiti walioorodheshwa hapo juu wanachunguza sinema na maeneo ya sedation yanasimamiwa. Kusudi la mahojiano ni kujua ikiwa kuna vifaa vilivyopendekezwa vya ufuatiliaji wa wagonjwa wanaotibiwa katika maeneo haya. Utafiti utaangalia uwepo wa vifaa vya ufuatiliaji kama mashine za shinikizo la damu na wachunguzi wa moyo. Kutakuwa na

takriban maeneo 139 yanayoshiriki katika utafiti huu. Tunaomba idhini yako kuzingatia kushiriki katika utafiti huu.

NINI KITATOKEA UKIAMUA KUWA KWENYE UTAFITI?

Ikiwa unakubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea: Utahojiwa na mhojiwa aliyefundishwa katika eneo la kibinafsi ambapo unahisi raha kujibu maswali. Mahojiano hayo yatachukua takriban dakika kumi. Mahojiano yatashughulikia mada kama aina ya upasuaji uliofanywa na idadi ya sinema katika kituo hicho. Baada ya mahojiano kumaliza, mhojiwa atahesabu idadi ya vifaa vya ufuatiliaji vinavyopatikana kwenye ukumbi wa michezo au sedation ya eneo inasimamiwa. Tutauliza nambari ya simu ambapo tunaweza kuwasiliana nawe ikiwa ni lazima. Ikiwa unakubali kutoa habari yako ya mawasiliano, itatumika tu na watu wanaofanya kazi kwa utafiti huu na hawatashirikiwa na wengine kamwe. Sababu ambazo tunaweza kuhitaji kuwasiliana na wewe ni pamoja na: kukusasisha juu ya matokeo ya utafiti au kupata ufafanuzi wa maelezo ikiwa inahitajika.

KUNA ATHARI ZOZOTE, ZINAZIDHARAU HASARA ZINAZOHUSIANA NA UTAFITI HUU?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Jitihada inapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unatuambia kama siri iwezekanavyo. Tutatumia nambari ya nambari kutambua eneo hilo kwenye hifadhidata ya kompyuta inayolindwa na nywila na tutaweka rekodi zetu zote za karatasi kwenye baraza la mawaziri la faili lililofungwa. Walakini, hakuna mfumo wowote wa kulinda usiri wako ambao unaweza kuwa salama kabisa, kwa hivyo bado inawezekana kwamba mtu anaweza kujua kuwa ulikuwa kwenye utafiti huu na angeweza kupata habari kuhusu eneo lako. Pia, kujibu maswali kwenye mahojiano inaweza kuwa mbaya kwako. Ikiwa kuna maswali ambayo hautaki kujibu, unaweza kuyaruka. Una haki ya kukataa mahojiano au maswali yoyote yanayoulizwa wakati wa mahojiano.

KUNA FAIDA ZOZOTE ZINAKUWA KATIKA UTAFITI HUU?

Unaweza kufaidika kwa kupokea ripoti ya bure ya vifaa vya ufuatiliaji vinavyopatikana, na ikiwa pendekezo la kawaida linapatikana katika eneo lako. Pia, habari unayotoa itatusaidia kuelewa vyema hali ya upatikanaji wa vifaa vya ufuatiliaji nchini Kenya. Habari hii ni mchango kwa sayansi na upangaji wa rasilimali za huduma ya afya.

JE, KUWA KWENYE UTAFITI HUU KUTAKUGHARAMIA CHOCHOTE?

Hautalazimika kulipia chochote wakati unashiriki katika utafiti huu.

JE, UTALIPWA PESA YOYOTE KATIKA UTAFITI HUU?

Hautalipwa kwa kushiriki katika utafiti huu.

NINI KAMA UNA MASWALI BAADAYE?

Ikiwa una maswali zaidi au wasiwasi juu ya kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi kwa wafanyikazi wa utafiti kwa nambari iliyotolewa chini ya ukurasa huu. Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Maadili na Kamati ya Utafiti ya Nairobi Nambari ya simu 2726300 Ext. Barua pepe 44102 uonknh_erc@uonbi.ac.ke. Wafanyakazi wa utafiti watakulipa malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na utafiti.

CHAGUO ZAKO ZINGINE NI NINI?

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Uko huru kukataa kushiriki katika utafiti na unaweza kujiondoa kutoka kwa utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

FOMU YA MAJALIZO (TAARIFA YA MAJIBU)

Taarifa ya Mshiriki

Nimesoma fomu hii ya idhini au habari hiyo imesomwa kwangu. Nimekuwa na nafasi ya kujadili utafiti huu wa utafiti na mshauri wa utafiti. Nimejibiwa maswali yangu kwa lugha ambayo ninaelewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu wa utafiti. Ninaelewa kuwa juhudi zote zitafanywa kutunza habari kuhusu kitambulisho changu binafsi kuwa siri. Kwa kusaini fomu hii ya idhini, sijatoa haki yoyote ya kisheria ambayo ninayo kama mshiriki katika utafiti wa utafiti.

Ninakubali kushiriki katika utafiti huu: **Ndio Hapana**

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio Hapana

Jina la mshiriki aliyechapishwa:

_____

Saini ya mshiriki / Stempu ya kidole gumba _____ Tarehe _____

Kauli ya Mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki ameelewa na kwa hiari na kwa hiari ametoa idhini yake.

Jina la Mtafiti: _____

Tarehe: _____ Saini_____

Jukumu katika utafiti: _____

Kwa habari zaidi wasiliana na _____ saa _____ kutoka _____ hadi _____

Jina la Shahidi_____

Habari ya mawasiliano _____ Saini / Kidole