

**ASSESSMENT OF KNOWLEDGE AND PRACTICE ON SEDATION
OUTSIDE THE OPERATING THEATERS AT MUHIMBILI NATIONAL
HOSPITAL, DAR ES SALAAM, TANZANIA, 2016**

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**MMed (Anesthesiology) Dissertation
Muhimbili University of Health and Allied Sciences
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**ASSESSMENT OF KNOWLEDGE AND PRACTICE ON SEDATION OUTSIDE THE
OPERATING THEATERS AT MUHIMBILI NATIONAL HOSPITAL,
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By,

Frederick Tembo, MD

**A dissertation Submitted in (Partial) fulfillment of the requirements for the Degree
of Masters of Medicine in Anesthesiology of
Muhimbili University of Health and Allied Science**

**Muhimbili University of Health and Allied Sciences
October, 2017**

CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: “*Assessment of knowledge and practice on sedation outside the operating theaters at Muhimbili National Hospital, Dar es Salaam, Tanzania*”, 2016 in (Partial) fulfillment of the requirement for the degree of Master of Medicine in Anesthesiology of Muhimbili University of Health and Allied Sciences.

Dr. Edwin R Lugazia

Supervisor

Date

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I, **Frederick Tembo**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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DEDICATIONS

I dedicate the results of this study to my beloved daughters, Faith and Fabiola, and to my lovely wife Herieth Stephen Mjuni. Thank you!

LIST OF ABBREVIATION

ASA	American Society of Anesthesiologists
BP	Blood Pressure
CPR	Cardio Pulmonary Resuscitation
CT	Computer Tomography
ECG	Electro Cardio Gram
ECHO	Echocardiogram
EEG	Electro Encephalo Gram
ETCO2	End Tidal Carbon dioxide
GA	General Anesthesia
ICP	Intra Cranial Pressure
IOP	Intra Ocular Pressure
IV	Intra Venous
MNH	Muhimbili National Hospital
MRI	Magnetic Resonance Imaging
MUHAS	Muhimbili University of Health and Allied Sciences
N2O	Nitrous Oxide
NIBP	Non-Invasive Blood Pressure
SPO2	Saturation partial Pressure of Oxygen
USA	United States of America

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DEFINITION OF TERMS

Medical personnel- Is a currently licensed practitioner of medicine, surgery or dentistry trained in the administration of medications used for procedural sedation and the management of complications associated with these medications.

Sedation practitioners- These are medical workers involved in giving the drugs for sedation.

ABSTRACT

Background: Sedation is the administration of sedatives to the patients planned for diagnostic and therapeutic procedures so as to reduce anxiety and fear. Most of the sedation providers are non-anesthesiologists. Sedation is supposed to be given by experienced and skilled personnel to avoid complications. Proper monitoring during the sedation procedure will make the practice efficiently, detect the complications and be able to manage the complications. Involvement of anesthesiologists and the use of trained non anesthesiologist doctors can lead into the better practice of sedation.

The aim of the study: The aim of the study was to assess providers' knowledge, and practice towards sedation outside the operating theater at MNH from May to July 2016.

Methodology: This was a hospital based descriptive cross sectional study which was done at MNH in the departments of Emergency medicine, Radiology (CT-scan and MRI), Psychiatry, Gastroenterology, Emergency department, and Dental unit. The study population was 110 sedation practitioners outside operating theaters. The information obtained was providers' age, sex, experience, duration of the practice, pre-sedation assessment form, completion of data monitoring form, use of protocol, monitoring during sedation, use of oxygen, use of assistant, use of resuscitation equipment, training in resuscitation, training in sedation, knowledge on pharmacology of drugs, type of the drugs used and route of administration and complications was obtained by an interview with eligible consented sedation providers using a modified standard questionnaire adopted by Fanning. Data were entered and analyzed using SPSS version 20.

Results: Nineteen percent of the study participants had high knowledge on pharmacology of the drugs. Approximately, 34.5% of the study participants used protocol for sedation, 18% did pre- sedation assessment of patients and 9.1% used monitoring data form during sedation. About thirty three percentage used oxygen during sedation while 35.5% had completed ACLS with only 31% of them had valid certificates. Fewer study participants (15.5%) underwent formal training prior to using sedation. Monitoring technique was poor and none used ETCO₂. Diazepam was found to be the most commonly used sedative. Intravenous route was used by most study participants (45.5%).

Conclusion: Despite providing sedation outside the operating theaters, majority of the sedation providers had poor knowledge and practice.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background information

Sedation outside the operating theater has been a common clinical practice in patients who are anxious, fear, suffering and those who are planned for undergoing diagnostic and therapeutic procedures outside the operating theaters; but a lot of problems can occur when giving sedation outside operating theater (1). The anesthesiologists, nurse anesthetists, anesthetic officers and trained medical personnel on sedation practice, are responsible for providing sedation (2).

The complications have been occurring during sedation practice such as laryngospasm, bronchospasm, nausea, vomiting, hypertension, hypotension, cardiac arrest and death (1–3).

The contributing factors to the above problems are lack of training, low skill and low knowledge of the sedation practitioners, inability to follow the sedation protocols, improper assessment and monitoring of the patients, and lack of team work (4).

Sedation practice is supposed to be done with proper monitoring and in presence of anesthesia supervision, but has not been so in the developing countries; as a results a lot of morbidity and mortality have occurred (5). Due to low number of anesthesiologists and anesthetists in these places, there is a need of training the other doctors and nurses so that they offer safe sedation outside operating theaters (6).

Administration of sedatives have reduced fear, anxiety and suffering to the patients who are planned for diagnostic and therapeutic procedures (7).

However there are three levels of sedation; 1.Minimal sedation which is the state induced by the drugs with the patient being alert and able to respond to normal verbal commands with maintained cardiovascular and respiratory functions but presenting with impairment of cognition and coordination (8), 2.Moderate sedation which is the depressed level of consciousness in a patient and he/she can respond to commands verbally, and there is no any

management needed to maintain respiration; the cardiovascular function remains unaffected (9), 3. Deep sedation which is the depressed consciousness induced by the drug where a patient cannot be arousable but can respond to pain; also the patient needs to be assisted in airway maintenance though cardiovascular system will be normal (10).

There is a need of monitoring the level of sedation in patients who are sedated outside the operating rooms; several sedation scales have been designed but the suggested scale most commonly used is Richmond Agitation Sedation Scale (11) which is elaborated below:

Sedation Assessment Scores Scale (Richmond Agitation Sedation Scale).

Score Term	Description
+4	Combative Overtly combative or violent, immediately danger to staff
+3	Severe agitated Pulls on or removes tubes or catheter or has behavior.
+2	Agitated frequently no purposeful movement
+1	Restless anxious or apprehensive
0	Calm or alert
-1	Drowsy Not fully alert
-2	Light sedation briefly awaken with eye contact to voice
-3	Moderate sedation any movements to voice
-4	Deep sedation No movement to voice but physical stimulus
-5	Unarousable No response to voice or physical stimulus (11)

Several indications are used in giving sedatives to the patients outside the operating theaters, and these include; patient with anxiety, severe gag reflex, prolonged and unpleasant

procedures, ASA class 1 and 2, avoidance of general anesthesia, provision of analgesia, prevention of secretion and for painless procedures such as MRI, Radiotherapy, CT scan, ECHO, and EEG (9,12).

Meanwhile, contraindications to sedation are: known allergic reactions to drugs, pregnancy, patients treated for depression and bipolar disorders, cardiac and respiratory failure, neuromuscular diseases, children less than 1 year, and higher Intracranial pressure (ICP) (13).

The person who is fit to give sedation outside the operating theaters, is supposed to be a health care provider with the knowledge of anesthetic training, or any medical personnel who is trained to provide sedation with the certificate of sedation and analgesia; be able to give drugs, assessing the pre-sedation patient and able to do CPR in case of cardiopulmonary failure (14,15,16).

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Provider's knowledge on sedation outside operating theaters.

Several studies have been done on sedation outside the operating theaters on assessment of the knowledge of sedation providers.

The study done in Dublin, Ireland on patient's monitoring during sedation on assessment of knowledge of the providers on understanding the pharmacology of sedative drugs by Fanning RM, 2008, showed that majority of them had low knowledge (1). Another study done by Landham PR et al in Wales, 2011 to see if there is safe practice in sedation performed by doctors who are not anesthesiologists, showed that more than half of the practitioners had higher knowledge on the drugs used for sedation (19). Scally KJ et al, 2015, at Newcastle school of Dental Sciences did a study on assessment of clinical knowledge acquisition and experiences in conscious sedation of dental students; the pre-attachment test showed that 71% of them, passed the test and then they were attached for in conscious sedation, the post-attachment test showed that 92% of them passed the test (34). The improvement in performance in post-attachment test was due to being taught on sedation. The study done at Witwatersrand University in Johannesburg in South Africa by Israel K.A.B to compare knowledge between community doctors and interns, registrars and consultants, the results were 77%, 70% and 67% respectively (36).

2.3 Sedation practices

Monitoring equipment and monitoring in sedation practice outside operating theaters are very important. Study done in Ireland by Fanning RM, 2008 looking at the practice of non-anesthesia doctors, showed that 82% of those who responded to the study, used pulse oximetry in monitoring of saturation, 80% used non-invasive BP, 53% used ECG and no one used capnography (1). Study on anesthesia care beyond operating rooms by Ramkumar P, suggested that monitoring of sedated patients could be more effective when anesthesiologists and anesthesiologists are involved; the study also recommended the use of thermometers, pulse

oximetry, ventilation, ETCO₂, NIBP invasive BP, low oxygen concentration alarm and observing the patients in monitoring (21). The study done by Kodali BS, 2013, on capnography outside the operating rooms recommended on the use of capnography, pulse oximetry and visual inspection of the chest to detect easily respiratory depression (26). The study done by Eichhorn V et al, 2010 in Canada described that monitoring of hemodynamic and respiratory function is essential in sedation practice outside operating theaters, and the study further stressed on the use of pulse oximetry and ETCO₂ in monitoring (27). The study done in Ireland by Fanning RM, 2008 on monitoring on sedation offered by those who are not anesthesiologists, showed that more 70% of the participants used observation charts and also protocol was required for discharging the patients, use of assistants during sedation was 88% of the study participants, pulse oximetry, 82% of the participants, NIBP used by about 80% of them, ECG used by 53%, no one used capnography in monitoring of patients; those with the training of adult cardiac life support were 29% of them and 22% of them had complications (1). The systematic review study done by McCoy S. et al, to find out if both anesthesiologists and non-anesthesiologists were using the protocol when giving sedatives revealed that; if the protocol is followed in giving drugs, patients' outcome would be improved (28). The study done in Great Britain by Landham PR et al, 2011 to see the practice of registrars of orthopedic department on sedation showed that 45% of them used sedation protocol, 21% of them used monitoring data form during procedure, 23% used data monitoring form after procedure, 98% used assistants during sedation, 89% cross checked drugs with other healthcare workers, all participants used oxygen to the patients when needed, 98.1% made sure that resuscitation equipments were available, around 89% underwent advanced life support training and 68% of these participants had a 3 year valid certificates, 30% did formal sedation training, on the use of monitoring, 53% used pulse oximetry, ECG 26% and NIBP 53% (19). The study done by Lightdale et al, 2007, in Philadelphia on methods of sedation in pediatric endoscopy revealed that 77% of study participants used oxygen in provision of sedation (10). The study done by Beeton A, in Johannesburg in South Africa in 2006 on Sedation whether it is getting easier in Private practice, found that above 50% of gastro-enterologists and surgeons provided sedation without the use of Oxygen and about 60% of gastro-enterologists were using monitors (31).

Another African study done by Omisore AD et al in Nigeria in 2016 in 5 teaching university hospitals among Nigerian radiology residents, found that 76.3% of them did not have formal sedation training, 22% used protocol, 16.1% underwent formal resuscitation training,; 89.8% used SPO2, 82% BP, , 84.2% had resuscitation equipments during sedation (32).

2.4 Drugs and routes used in sedation

The systematic review study done in USA, 2009 by Hitchcock D et al, showed that Ketamine, dexmedetomidine, and midazolam were used; the use of dexmedetomidine was high due to less side effects (20). Another study done by Ramkumar P on anesthesia care beyond operating rooms showed that midazolam, fentanyl, propofol and ketamine were the frequently used drugs (21).

The study done by Pramira P, 2007 insisted on the use of remifentanyl, midazolam, propofol, and sevoflurane; furthermore, propofol use needed close monitoring (22). The study done in Philadelphia, 2007 by Lightdale JR et al on methods of sedation in pediatric sedation to those sedation practitioners, showed that 10% reported using GA in all the sedation, 23% had never used GA, 82% reported to do procedures in-hospital operating theaters, 60% reported to be using occasionally anesthesiologist-IV propofol sedation and 9% only used propofol for sedation practices (10). The study done by Cravero JP, 2009, to see drugs used for sedation in addition to propofol, showed that Ativan, Chloral hydrate, Dexmedetomidine, Etomidate, Ketamine, Methohexital, Midazolam, all types of opioids, Pentobarbital , Pentothal and Valium were used; of all these drugs, Opioids found to be used much more followed by Midazolam (23). Study done in Thailand, by Amornyotin S, 2011, showed that Fentanyl was found to be a good drug because of its fast onset of action, short duration of action, without direct cardiac function to be depressed, no releasing of histamine and easily titrated; the study also recommended on the use of Ketamine in combination of Midazolam and Fentanyl (24). The study done in Chicago, 2011, by Couloures KG et al on Pediatric procedural sedation complication rates; showed that hypoxia was 40%; Ketamine related depressed respiratory function was 3.9% and oxygen desaturation (17). Review done in USA, 2010 by Metzner J et al, showed that most of complications were respiratory depression, desaturation, and

obstruction of the airway which led to hypoxemia and hypoventilation (25). Cravero JP et al, 2009, found that, the side effects of sedation using propofol were obstruction of airway, light anesthesia, drug allergic reaction, aspiration, cardiac arrest, low saturation, laryngospasm, and wheezing (23). However the study by Fanning RM, 2008, showed midazolam was used by many providers (98.2%), which was followed by opioids (morphine and pethidine), but propofol, diazepam and fentanyl not used by any of the study participants, hypoxia was more than any other complications, followed by respiratory depression and prolonged sedation, 1.8% of participants required the help from anesthesia staff, 96.4% participants gave drugs were in bolus form rather than dose per kilogram (1). The study done by Landham PR. et al noted that morphine and other opioids were used by 83% of participants, followed by midazolam 66%, and propofol 28%, 66% of study participants gave sedative drugs in form of boluses but not dose per kilogram, 80% of the participants had sedation complications led by hypoxia 37.7%, hypotension 26.4%, nausea and vomiting 26.4%, respiratory depression 24.5%, prolonged sedation 24.5% and loss of consciousness 13.2%, and about 55% of study participants sought for help from anesthetists (19). The study done in Thailand, 2010, by Amornyotin S, showed propofol to be used the most followed by midazolam and fentanyl, also the most encountered complication was hypotension followed by hypoxia and also the study revealed Intravenous route of sedation was used more than any other route of administration, 80.7% of cases (5). African study done by Omisore AD et al in Nigeria in 2016 in 5 teaching university hospitals among Nigerian radiology residents, found that vomiting was the most frequent complication (54.2%), followed by airway obstruction (29.2%) and aspiration, 99.2% gave sedatives by using intravenous route, and Diazepam was the most commonly used drug (32). Tan S. et al in Philippine in 2014 in University of Philippines general hospital did a survey study of knowledge, attitude and practice of sedation and analgesia among medical residents and pulmonary fellows found that midazolam was the more preferred sedative and morphine was also the most commonly used analgesia (33).

2.5 PROBLEM STATEMENT

A lot of complications have occurred due to sedation practice, which can be hypotension, nausea, vomiting, prolonged sedation, cardiac arrest and death; contributing factors are lack of training, protocol and monitoring of patients (1).

In order to ensure safety to the patients, sedation practice outside the operating theater is performed under the protocols which are set to make sure that the patients are well evaluated, properly monitored during and after the procedure so that the sedation-related complications cannot occur to the patients. The providers are supposed to have good training on how to give proper drugs to the patients and be able to manage the complications(15,29).

Very little if any is known on sedation practices outside of operating theater at MNH and in Tanzania at large; so this remains as a gap in our setting.

Hence there was a need to document clearly the knowledge, and practice on sedation outside operating theaters at MNH as one of the way forward to set the common standard protocol to regulate sedation outside the operating theaters in Tanzania.

2.6 RATIONALE

In both developed and developing countries, including Tanzania, procedural sedation outside the operating theater has been done by different specialties including radiology, ophthalmology, anesthesiology, psychiatry and surgery.

This practice needed to be done by the practitioner who has been trained well in providing sedation to the patients outside our operating theaters. So there was a need of doing this study to our setting so as to know if we follow the standard procedures and be able to set the protocols.

This study seeks to assess providers' knowledge and practice outside the operating theaters at MNH.

This study is also a part of partial fulfillment of my course of MMED of anesthesiology.

The study also documented how handling of sedative drugs, pre-sedation assessment, detection of complications, and management of complications was done. The study furthermore found out who are supposed to practice sedation outside the operating theaters at MNH.

2.7 RESEARCH QUESTION

What are the knowledge and practice of sedation outside the operating theaters at MNH?

2.8 OBJECTIVES

2.8.1 BROAD OBJECTIVE

To assess providers' knowledge and practice towards sedation outside the operating theaters at MNH from May-July 2016.

2.8.2 SPECIFIC OBJECTIVES

1. To assess the knowledge of providers on sedation outside operating theater at MNH from May-July2016.
2. To assess the sedation practice at MNH from May-July 2016.
3. To determine the type of the drug used and route of sedation that is practiced outside operating theater at MNH from May to July 2016.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design and period:

This study was a hospital based descriptive cross-sectional study, conducted for 3 months (From May to July 2016).

3.2 Study setting

This study was conducted at Muhimbili National Hospital (MNH) in the radiology, psychiatry, dental, emergency medicine and gastroenterology departments. MNH is geographically located in Dar Es Salaam, Tanzania. MNH is the largest hospital in Tanzania with capacity of beds of 1400. The daily outpatients' number is about 1000-1200 and caters for more than 4 million people living in Dar es Salaam. MNH receives referrals from regional hospitals such as Amana, Temeke and Mwananyamala which are located in three municipalities of Dar es Salaam and from other parts of Tanzania. The study was conducted in Radiology, Psychiatry, Emergency Medicine, Gastroenterology and Dental departments.

3.3 Study population:

The population involved all sedation practitioners performing procedural sedation outside the operating theater at the Radiology (CT scan and MRI), Gastroenterology, Psychiatric, Emergency medicine and Dental departments.

3.4 Inclusion criteria

All sedation practitioners outside the operating theaters

3.5 Exclusion criteria

All sedation practitioners who did not consent participate in the study.

3.6 SELECTION OF STUDY PARTICIPANTS

All sedation providers who were giving sedation in their sedation sites and who fulfilled the eligibility criteria and consented were enrolled into the study.

3.7 Sample size calculation

Sample size:

$$n = \frac{z^2 p (1-p)}{\epsilon^2} \quad \text{or} \quad n = \frac{z^2 p (100-p)}{\epsilon^2}$$

$$\epsilon^2$$

$$\epsilon^2$$

P = 7.7%, which was the prevalence of the respondents who were giving propofol without an anesthesiologist or a nurse anesthetist (Sedation and anesthesia in GI endoscopy(30)).

Z = 1.96 (assuming 95% confidence interval)

ε = 5% (maximum error allowed).

$$n=109.2$$

Hence sample size was 110 sedation practitioners.

3.8 DATA COLLECTION PROCEDURE

The data was collected by the principle researcher and 2 trained research assistants. The data collection tool used was standardized questionnaire adopted from Fanning (Appendix 1). The data sources were from face to face interview using a questionnaire filled by the principle researcher and the research assistants. The recorded information was experience of the practitioners, age and sex of the practitioners, qualification of the performer, use of protocol, pre-sedation assessment form, completion of data monitoring form, monitoring of patients, use of assistant, checking of sedatives with someone else, use of resuscitation equipment, training in advanced cardiac life support, validity of advanced cardiac life support, training in sedation

and training in sedation, knowledge of sedation providers on pharmacology of the drugs, drugs used for sedation, route of administration, and complications.

There were 6 questions which were used to assess knowledge of pharmacology of drugs.

These questions were as follows: 1. Midazolam affects neuromuscular transmission, 2. Diazepam has greater amnesic effect than Midazolam, 3. Fentanyl- induced respiratory depression is dose dependent, 4. Morphine does not possess active metabolites, 5. Pethidine is metabolized mainly in the kidney, and 6. Midazolam has longer duration of action than diazepam. The response to each question was either YES or No. Those who got 5-6 scores, were graded to have high knowledge, 3-4 scores, were graded to have moderate knowledge and 0-2 scores, graded to have low knowledge.

3.9 DATA QUALITY AND MANAGEMENT

Principal investigator was assisted by two trained research assistants, trained on how to administer the questionnaire and how to use the data extraction tool. All filled questionnaires and data extraction tool were rechecked on a daily basis to ensure quality filling of the information. Data were kept in a password secured computer to ensure confidentiality. All filled questionnaires were by the principal investigator to ensure confidentiality until time of destruction of the said documents.

3.10 STUDY VARIABLES

The study variables were as follows: use of protocol, monitoring data form, monitoring during and after sedation, monitoring of patients, training on sedation and adult cardiac life support, drug used, routes of administration and complications, and knowledge of study participants on pharmacology of sedative drugs.

3.11 DATA ENTRY AND ANALYSIS

Data were entered into a spreadsheet of a password secured computer and analyzed using statistical package for social sciences (SPSS) version 20 according to specific objectives. Descriptive analysis was undertaken and results were presented as frequency tables.

3.12 Dissemination plan

The study findings will be disseminated to MNH authorities for suggested considered corrective measure for establishing sedation protocol, to MUHAS library as reference material and for further studies in the study area.

3.13 Ethical considerations

The ethical clearance was sought from Muhimbili University of Health and Allied Sciences (MUHAS) ethical review board. The permission to do the study was sought from the Director of MNH. Benefits and any potential risks were explained to the participants. Confidentiality of the participants' information was maintained throughout the study by principal investigator.

3.14 Study limitations

The findings from this study are derived from tertiary super specialty facility allowing unique interaction of experts in work which directly or indirectly affects respondent's knowledge, and skills towards sedation outside operating theaters, therefore their generalization requires special considerations.

3.15 Mitigation

The use of adopted standardized questionnaire in data collection tool to respondents in all departments involved ensured uniformity of the concepts to be revealed by the study.

CHAPTER FOUR

RESULTS

This chapter presents study results which are organized around the objectives that the study sought to answer. As such, it has four main sections:

4.1: Socio-demographic characteristics of the study participants (N=110)

The **table 1** below shows that the majority of the sedation providers were aged between 31-40 years. The mean age of the study population was 37.72 years (± 5.79 SD). Males represented the majority and accounted for 53.6% of the total study sample. The majority of the study participants had practiced for the duration between 2-5 years. The mean duration of practice was 2.47 years (± 0.66 SD). Majority of the study participants were nurses, 41 (37.3%).

Table 1: Socio-demographic characteristics of the participants (N=110)

Characteristics		N (%)
Age in years	21-30	13 (11.8)
	31-40	68 (61.8)
	41-50	27 (24.5)
	51-60	2 (1.8)
Sex	Male	59 (53.6)
	Female	51 (46.4)
Duration of practice in years	≤ 1	4 (3.6)
	2-5	56 (50.9)
	6-10	44 (40)
	>11	6 (5.5)
Profession	Radiographer	21 (19.1)
	Specialist	25 (22.7)
	Anesthetist	1 (0.9)
	Nurse	41 (37.3)
	Registrar	5 (4.5)
	Resident	17 (15.5)

4.2: Knowledge of providers on sedation outside operating theaters

Majority of the sedation providers 61 (55.5%), had moderate knowledge on sedation outside operating theaters based on the questions asked. (**Table 2 below**)

Table 2: Knowledge of providers on sedation outside operating theaters

Profession	Knowledge		
	High	Moderate	Low
Specialist	5	14	6
Radiographer	3	8	10
Anesthetist	0	1	0
Nurse	8	24	9
Registrar	2	3	0
Resident	3	11	3
Total	21 (19.1%)	61 (55.5%)	28 (25.5%)

4.3: Provider's sedation practice

According to the results shown in **table 3 below**, only thirty eight (34.5%) study participants used protocol when administering sedation. Twenty (18.2%) completed pre-sedation assessment forms and only ten (9.1%) completed the monitoring data forms during and after sedation. Seventy (63.6%) gave advice to the patients on discharging. Seventy six (69.1%) sedation providers used assistants when giving sedation. Eighty three (75.5%) checked sedative drugs with other fellow health care workers. Thirty six (32.7%) said that they use oxygen whenever needed during sedation. Thirty nine (35.5%) said that they had undergone adult cardiac life support and only 31.8% of them had valid qualification of this training. 17 (15.5%) had received formal training prior to using sedation. On monitoring part, forty seven (42.7%) used NIBP, 34 (30.9%) used SPO2, four (3.6%) used ECG, two (1.8%) used temperature probe, eighty (72.7%) used visual observation while none of them used ETCO2.

Table 3: provider's sedation practice

Practice and complications	Frequency, N (%)	
	Yes	No
Sedation protocol	38 (34.5)	72 (65.5)
Completion of pre-sedation assessment form	20 (18.2)	90 (81.8)
Completion of monitoring data form	10 (9.1)	100 (90.9)
Giving discharging advice	70 (63.6)	40 (36.4)
Use of assistant during sedation	76(69.1)	34 (30.9)
Checking of sedatives with someone	83 (75.5)	27 (24.5)
The use of oxygen during sedation	36 (32.7)	74 (67.3)
Completion of advanced cardiac life support	39 (35.5)	71 (64.5)
Validity of certificate for advanced cardiac life support	35 (31.8)	75 (68.2)
The use of resuscitation equipment	49 (44.5)	61 (55.5)
Received formal training prior to using sedation	17 (15.5)	93 (84.5)
Monitoring during sedation		
NIBP	47 (42.7)	63 (57.3)
SPO2	34 (30.9)	76 (69.1)
Visual observation	80 (72.7)	30 (27.3)
End tidal carbon dioxide	0 (0)	110 (100)
ECG	4 (3.6)	106 (96.4)
Temperature	2 (1.8)	108 (98.2)

4.4 Status of resuscitation equipment, drugs, route of sedation being practiced and complications encountered.

This study assessed availability of resuscitation equipment in the sedation sites.

4.4.1 Availability of resuscitation equipment:

The **table 4** below shows the extent availability of resuscitation equipments. Only two sedation sites (Emergency department and gastroenterology) had all the required resuscitation equipments. Dental unit had few types of equipments but both psychiatry and radiology units did not have any of the resuscitation equipments.

Table 4: Availability of resuscitation equipment in the sedation sites

Sedation sites	Available equipments
Dental unit	Ambu bag Suction machine Suction catheter Suction tube Face mask
Radiology	None
Psychiatry	None
Emergency department	Resuscitation drugs Suction machine Suction tube Suction catheter Ambu bag Endotracheal tube Defibrillator Laryngoscope handle, blades and extra battery Cannulae Oropharyngeal airway Nasopharyngeal airway Laryngo mask airway Intravenous catheter

	Intravenous fluid
	Oxygen cylinder + tubing
	Magill forceps
	Nasogastric tube
	Ventilator
Gastroenterology	Resuscitation drugs
	Suction machine
	Suction tube
	Suction catheter
	Ambu bag
	Endotracheal tube
	Defibrillator
	Laryngoscope handle, blades and extra battery
	Cannulae
	Oropharyngeal airway
	Nasopharyngeal airway
	Laryngo mask airway
	Intravenous catheter
	Intravenous fluid
	Oxygen cylinder + tubing
	Magill forceps
	Nasogastric tube

4.4.2 The type of drug used outside operating theaters

As indicated in **table 5** below, Diazepam was used by most of the sedation providers, 76 (69.1%), followed by ketamine 40 (36.4%), chlorohydrate 35 (31.8%), and Midazolam, while Fentanyl was not reported to be used by any of the sedation providers.

Table 5: The types of drug used outside operating theaters

Type of drug used	Frequency, N (%)	
	Yes	No
Diazepam	76 (69.1%)	34 (30.9%)
Pethidine	28 (25.5%)	82 (74.5%)
Midazolam	31 (28.2%)	79 (71.8%)
Propofol	8 (7.3%)	102 (92.7%)
Fentanyl	0 (0%)	110 (100%)
Morphine	25 (22.7%)	85 (77.3%)
Ketamine	40 (36.4%)	70 (63.6%)
Chlorohydrate	35 (31.8%)	75 (68.2%)

4.4.3 Route of sedation

Most of the sedation providers 50 (45.5%), reported to use intravenous route (**Table 6** below).

Table 6: Route of sedation practiced.

Route	Frequency
IV	50 (45.5%)
IV and IM	25 (22.7%)
IV and Oral	6 (5.5%)
Oral	29 (26.4%)

4.4.4 Type of administration of medication

Most of study participants administered drugs in form of dose per kilogram (60%) (**Table7**).

Table 7: Type of administration of medication

Type of administering drugs	Frequency, N 9%)
Uncalculated dose	44 (40%)
Dose per kilogram	66 (60%)

4.4.5 Complications

The most common complication noted by most of sedation providers, in **table 8** below, shows that eighty (72.7%) was nausea followed by prolonged sedation, seventy nine (71.8%).

Table 8: Complications encountered.

Complications	Frequency	
	Yes	No
Hypoxia	29 (26.4%)	81 (73.6%)
Respiratory depression	57 (51.8%)	53 (48.2%)
Death	16 (14.5%)	94 (85.5%)
Loss of consciousness	43 (39.1%)	67 (60.9%)
Prolonged sedation	79 (71.8%)	31 (28.2%)
Hypotension	20 (18.2%)	90 (81.8%)
Nausea	80 (72.7%)	30 (27.3%)
Cardiovascular collapse	14 (12.7%)	96 (87.3%)

4.4.6 Contact of anesthesia department and sedation complications

Table 9 below shows that, only five (4.5%) sedation providers contacted anesthesia department when complications occurred, two participants contacted due to nausea and prolonged sedation.

Table 9: Contact of anesthesia department and sedation complications

Contact anesthesia department after complications	Sedation complications					Total
	No	Nausea+ prolonged sedation	Respiratory depression+ Prolonged sedation + nausea	Prolonged sedation	Respiratory depression + death + loss of consciousness + prolonged sedation + nausea	
Yes	0	2	1	1	1	5
No	105	0	0	0	0	105
Total	105	2	1	1	1	110

4.4.7 Sedation sites and complications

Table 10 below shows that, hypoxia, hypotension, and cardiovascular collapse were encountered by most Emergency department providers. Death was reported more by psychiatric unit, while, loss of consciousness, prolonged sedation and nausea and respiratory depression were more noted by radiology providers.

Table 10: Sedation sites and complications

Sedation sites	Complications							
	Hypoxia	Respiratory depression	Death	Loss of consciousness	Prolonged Sedation	Hypotension	Nausea	Cardiovascular collapse
Emergency Department	23	18	1	11	18	16	18	7
Psychiatry	0	3	5	1	5	1	4	2
Radiology	0	19	4	14	31	0	27	2
Gastroenterology	6	6	2	6	3	3	5	0
Dental unit	0	11	4	11	22	0	26	3

CHAPTER FIVE

5.0: DISCUSSION

This study was conducted at MNH involving 110 sedation providers outside operating theaters in 5 sedation sites (radiology, gastroenterology, psychiatry, Emergency medicine and dental unit), so as to assess their knowledge and practice on sedation. Majority of the respondents aged between 31-40 years. About 51% had delivered sedation for 2-5 years. Professional wise, majority of the sedation providers outside operating rooms at MNH were nurses.

5.1: Knowledge on sedation

Sedation providers outside the operating theaters need to have knowledge on pharmacology of sedatives; as a result can reduce unnecessary complications. This study showed that, 19.1% of sedation providers had high knowledge. This finding indicates that generally there is poor knowledge among sedation providers outside operating theater on pharmacology of sedatives. This poor knowledge on pharmacology of sedatives of the study participants can be explained by the result of those who underwent formal training prior to using sedation, which showed that only about 15% of the sedation providers trained on sedation. There is a need of teaching these participants on the pharmacology of the sedatives. Similarly, a study done by Mayson K, in Canada in 2006 among Canadian residents on their knowledge on onset of action and duration of sedatives which were used most commonly, they found that, majority of them had poor knowledge (35). Fanning RM in Dublin, Ireland in 2008 did a study at different teaching university hospitals among surgeons and physicians who were giving sedation and analgesia; showed that their knowledge was poor (1). Also, Omisore AD et al, in Nigeria in 2016 did a study at university teaching hospitals on sedation practice among radiology residents, showed that less than 50% of them, had good knowledge (32). Their studies' findings are similar to ours may be due to all studies involved almost all of the study participants who were none anesthesiologists, hence had no enough knowledge on pharmacology of the drugs used.

In contrast, a study done by Landham PR et al in Wales in 2011 did a study among Orthopedic and trauma registrars, on whether the safety of the patients being compromised by non-anesthetists showed that over 50% of the respondents had good knowledge (19). Their findings have been more than half of sedation providers had good knowledge compared to our findings. This may be due to different in study population and different types of medical practitioners, they used orthopedic and trauma registrars while we used different types of types of sedation providers containing nurses, specialists, radiographers, registrars and residents from different specialties and anesthetists. Scally KJ et al in Britain in 2015 at Newcastle school of Dental Sciences on assessment of clinical knowledge acquisition and experiences in conscious sedation of dental students, showed that in pre-attachment test, about 71% of them passed likewise when they did post-attachment, 92% of them passed the test (34). These results are high especially in post-attachment, may be they were taught so that they passed well. Israel K.A.B, in South Africa in 2014 at Witwatersrand University in Johannesburg, did comparative study between three groups on knowledge, showed that knowledge of community doctors and interns was 77%, registrars 70% and consultants was 67% (36). Their results show that the interns and community doctors had high knowledge may be due to interns were fresh from school so they could remember the questions on knowledge asked but their results were different to our results may be due to different study population.

5.2: Sedation practices

Sedation protocol is very important sedation practice as it guides the sedation providers when giving sedation. Our study has shown that, few sedation providers used protocol (34.5%). The result is very low, as far as sedation practice is concerned; sedation protocol should be followed as a result will improve the practice. This low number of those who used protocol, can be explained by few providers had trained on sedation. This finding can be comparable with the Nigerian study done by Omisore et al in Nigeria in 2016 among radiology residents which showed that about 40% used protocol during sedation (32) and also with study done in Wales by Landham PR et al in 2011 among orthopedics and trauma registrars which showed

45% of them used sedation protocol (19). The use of protocol has been limited hence there is a need of using it in every day practice.

The pre-sedation assessment form prior to administration of sedation is the standard practice before doing sedation; this will show the physical status of the patient before giving sedation as well as if the patient has any chronic medical condition. Our study has shown that only about 18% of study participants completed the pre-sedation form. This number is low thus there is a need of following the sedation guideline. Our finding was comparable with the study done by Landham PR et al in Wales in 2011 which had shown that less than 25% of study participants used it in sedation (19).

Using assistants in sedation practice has been one of the important components of the sedation guideline, the assistants are fellow medical personnel whose duty is to help in giving sedation and also checking the drugs, monitoring of patients during sedation and doing resuscitation whenever needed. This study of ours has shown that 69% of the sedation providers who were involved in this study used assistants. This finding was comparable with the study done by Fanning RM in Ireland in 2008 which showed 88% used assistants (1) and also with the study done by Landham PR et al in Wales in 2011 which showed 98% used assistants (19). Though the Landham PR et al study showed almost all the participants used assistants.

When the patients are given sedation, they can get hypoxia which will require giving them oxygen. So oxygen is very important to be at the sedation site. Our study has shown that about 32% of the sedation providers used oxygen and had oxygen available. There is a need of making sure that oxygen is available in all the sedation sites outside operating rooms so that in case of hypoxia, it can be used. The African study done in Nigeria in 2016 by Omisore et al among radiology residents showed 56% of participants used oxygen (32). Study done by Landham PR et al in Wales showed that all the participants (100%) used oxygen (19). Laghtdale JR et al in Philadelphia in 2007 showed that 77% used oxygen (10). Our finding on use of oxygen has been lower in comparison to other studies due to poor resource and lack of use of sedation guidelines in our country.

The sedation providers are required to have advanced life support training with valid certificates and skills so that when resuscitation is required, it can be done easily to rescue the patients' life. 35.5% of our study participants had advanced cardiac life support training, of which only 32% of them had within 3 years valid certificates. This result is very low, and majority cannot be able to do cardiopulmonary resuscitation when cardiac arrest occurs as a complication. This study finding was comparable with the findings from 2 different studies: Omisore et al 2016 Nigerian study showed that 16% of the radiology residents underwent formal resuscitation training (32) and the study done by Fanning RM in Ireland in 2008 which showed 29% of the study participants did adult cardiac life support. In contrast to our study, Landham PR et al in Wales showed that 89% of participants underwent adult life support training and 68% of them had 3 year valid certificates (19). Israel KA in Johannesburg, in 2014 study on awareness of procedural sedation and analgesia among non-anesthesiologists had the findings which showed that about 70% respondents completed basic life support training and 60% had adult cardiac life support training (36). So most of our participants and those of Nigeria did not do such training may be due to both studies were in the low resource countries hence the emphasis of training was not put.

Both anesthesiologists and non-anesthesiologists are called to have undergone formal training on sedation practice before doing sedation; this training will improve sedation practice and reduce morbidity and mortality which can be brought up by sedation. Only minority (15.5%) of our sedation providers received formal training on sedation. This number is not satisfactory as far as sedation practice outside operating rooms is concerned. All sedation providers need to be trained in sedation practice and this will reduce unnecessary complications. Mayson K et al in Canada in 2006 did a study among residents of radiology department; found that only 35% of residents underwent formal training in sedation administration (35). Landham PR et al found that 30% of participants had formal sedation training (19) while Fanning RM found that 38% of study participants had formal training in sedation administration (1). Our findings and theirs are low; the anesthesiologists are needed to prepare sedation trainings to non-anesthesiologists.

Monitoring during sedation practice has led to the good outcome of the patients who are given sedatives. Our study found that monitoring was very poor, except visual observation which was practiced by about 72% of the study participants. But visual observation alone cannot be the standard monitoring technique. This study has found that none of the participants used end tidal carbon dioxide; this finding was not comparable to the study done by Fanning RM in Ireland in 2008 which showed that no any study participants monitored end tidal carbon dioxide, 53% ECG, pulse oximetry 82% , None invasive blood pressure 80%(1). Study by Landham et al showed that 68% used pulse oximetry, 26% ECG, None invasive blood pressure 53%, and the use of end tidal carbon dioxide was not stated (19). Omisore AD et al found that 82.2% used none invasive blood pressure, and 55% used pulse oximetry (32). The use of end tidal carbon dioxide has been very important in assessing ventilator function during deep sedation. Their studies have shown high findings as compared to our study may be due to availability of monitors and also the use of sedation guidelines is higher to them as compared to us here.

The availability of resuscitation equipments has been one of the demands in the sedation sites so as to handle sedation complications. Our study has found that 44.5% of the study participants had available resuscitation equipments in their sedation sites. This study has also found that in only two sedation sites (gastroenterology and Emergency department) had almost all resuscitation equipments available, dental unit had few resuscitation equipments but radiology and psychiatric sedation sites did not have any resuscitation equipments. Omisore AD et al found that 85% of study participants had resuscitation equipments available at their sedation sites (32). Fanning RM found that 92% had resuscitation equipments available (1). Landham PR eta al found that 98% had available resuscitation equipments (19). Our findings are not comparable to their finding may be due to different study settings, and poverty.

5.3: The drugs used during sedation and route of sedation practiced.

Our study showed that diazepam was used by most of the sedation providers (69.1%) followed by ketamine (36.4%) and chlorohydrate (31.8%). Fentanyl has not been used in this study may be due to its absence in most of our sedation sites. The use of diazepam is not the first line in the sedation practice, diazepam has been shown to be used more than other sedatives in this study, may be due to being readily available as compared to other drugs, poor knowledge of study participants on the use of other sedatives and lack of some of the equipments which are currently used to give some sedatives such as infusion pumps. Study done by Omisore AD in Nigeria in 2016 among radiology residents showed that Diazepam was the most commonly used sedative, 80% of the radiology residents (32). Our finding was similar to the Nigerian study finding. Study done by Hodkinson PW et al in Cape Town, South Africa in 2008, showed that, Midazolam was more used (91 %,) than any other sedatives (37). Study done by Landham PR et al found that Morphine and other opioids were used more than other sedatives (83%), followed by Midazolam (66%) and Diazepam (58%) (19). The study done by Fanning RM showed that Midazolam was used by most of study participants (98.2%), followed opioids (33%), and none of the participants used Diazepam, propofol and fentanyl (1).

Our study showed that intravenous route alone was the most commonly used route (45.5%), 60% of drugs were given in dose per kilogram and nausea was the most common complication (72.7%), Sixteen study participants (14.5%), encountered death; Psychiatry unit being the most department to have higher number of death (5 participants). This may be due to lack of resuscitation equipment in the psychiatry unit. Five sedation providers (4.5%) contacted anesthesia department due to complication 2 of the 5 participants contacted due to nausea and prolonged sedation. Intravenous route has been the most commonly used in our study may be it is the easiest method of giving drugs. The most common complication in our study has been found to be nausea, followed by prolonged sedation (71.8%). Our study has also shown that only 4.5% of the study participants contacted anesthesia department following complication, this shows that most of these participants did not see the importance of the other medical staff that might be better than them in this area of sedation. The study by Omisore AD et al in Nigeria among the radiology residents showed that vomiting was noted more than other

complication (54.2%), followed by airway obstruction (29.2%), 99.2% of the participants gave drugs by using intravenous route (32). The Nigerian study also did not have proper monitoring and that is why other complications were not noted. The study done by Fanning RM in Ireland showed that most common complication found was hypoxia, and 96.4% of the study participants gave drugs in form of boluses (1); the study showed that pulse oximetry was used by 82% of the study participants and thus hypoxia was seen easily. Landham PR et al study showed that hypoxia was the most common complication (80%), 66% of the study participants gave drugs in boluses and 55% contacted anesthesia department for further help when they had complication (19). The study had also good monitoring using pulse oximetry and it led to detection of hypoxia, the study participants also saw the important of anesthesia as more than 50% of participants contacted anesthesia department for help. However, the study done in Thailand in 2010 in Siriraj hospital found that 80.7% of participants used intravenous route (5).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1: CONCLUSION

Sedation is most commonly practiced outside the operating rooms and can be performed in different sedation sites by nurses, specialists, radiographers, residents and registrars. In order for patients to be sedated well, the sedation providers should have good knowledge on sedation, and practice which includes skills and training in sedation and resuscitation and use of sedation protocol and guidelines. This study has involved 110 sedation providers from different hospital departments such as radiology, Emergency medicine, psychiatry, dental unit and gastroenterology. Majority of sedation providers have moderate knowledge but have poor practice and not having sufficient training in sedation. The findings in this study revealed critical insufficient knowledge on the pharmacology of sedative medication among some sedation providers. This is a very bad situation to our sedation providers hence they need to train in sedation, use standard guidelines and common protocol.

6.2: RECOMMENDATION

Basing on the findings of this study, It is recommended that:

- 1: The sedation providers should have a common protocol which can be used in all departments within the hospital and be familiarized by all sedation providers within and outside the operating rooms.
2. The training should be conducted to all sedation providers on adult life support and provision of sedation. This should be organized by anesthesiologists.
- 3: The basic facilities such as monitors, resuscitation equipments and drugs should be provided and be available in all the areas which practice sedation within the hospital.

4: The anaesthesiologists should be involved in the sedation practice and supposed to take the overall supervision of the practice, conducting some training and be available whenever needed by the sedation providers.

5: The standard sedation protocol (Academy of Medical Royal College Standard guidance 2013) should be used as standard guideline by sedation providers at MNH.

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APPENDIX 1: A QUESTIONNEIRE ON ASSESSMENT OF SEDATION PRACTICES OUTSIDE THE OPERATING THEATER

- 1. **Serial number**.....
- 2. Age.....
- 3. Sex.....
- 4. Experience on sedation practice in years.....

5. Profession

- a) Radiologist
- b) Radiographer
- c) Dentist
- d) Surgeon
- e) Anaesthesiologist
- f) Anaesthetist
- g) Nurse
- h) Psychiatrist

Procedure

What procedure do you use sedation for?

Protocol and Practice

- 1. Do you have sedation protocol in your department?
 - a) Yes
 - b) No

2. Do you complete pre-sedation assessment form prior to administering sedation?

a) Yes

b) No

3. Do you or an assistant complete a monitoring data form:

a) During the procedure?

b) After the procedure?

4. Do you or an assistant advice the patient on discharging case?

a) Yes

b) No

Safety and training

1. What monitoring do you use during sedation?

2. Do you use an assistant during sedation? (Nurse/Doctor/Healthcare professional)

3. Do you check your drugs with someone?

a) Yes

b) No

4. Do you give patients oxygen?

a) Yes

b) No

5. Have you completed adult Life Support training?

a) Yes

b) No

6. Is your Adult Life Support still valid?

7. Do you have resuscitation equipments available?

a) Yes

b) No

8. Have you received formal training prior to using sedation?

a) Yes

b) No

Medications (Which medications do you use?)

Diazepam, Pethidine, Midazolam, Propofol, Fentanyl, Morphine, Opiates in conjunction with sedation, local anaesthesia in conjunction with sedation

Pharmacology

1. When administering medications, do you tend to administer medications in uncalculated dose or dose per kilograms?

2. Which routes do you use to administer drugs?

3. Midazolam affects neuromuscular transmission

a) Yes

b) No

4. Diazepam has greater amnesic effect than Midazolam

a) Yes

b) No

5. Fentanyl-induced respiratory depression is dose dependent

a) Yes

b) No

6. Morphine does not possess active metabolites

a) Yes

b) No

7. Pethidine is metabolized mainly in the kidney

a) Yes

b) No

8. Midazolam has longer duration of action than diazepam

a) Yes

b) No

Adverse events

1. Has a patient of yours experienced an adverse event? (Circle please)

a) Hypoxia

b) Respiratory depression

c) Death

d) Loss of consciousness

e) Prolonged sedation

f) Hypotension

g) Nausea/Vomiting

h) Cardiovascular collapse or arrest

2. If your patient suffered adverse events, did you contact the anaesthetic department?

a) Yes

b) No

APPENDIX 2: Consent Form English Version

Introduction

I am Dr. Frederick Tembo, a researcher from Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a study titled ‘**Assessment of sedation practices outside the operating theater at Muhimbili National Hospital, Dar Es salaam, Tanzania**’. The aim of this research is ‘**to determine the sedation practices among the practitioners outside the operating theater at Muhimbili National Hospital Dar Es salaam, Tanzania**’.

Participation in the study

You are kindly requested to participate in this study. If you accept to participate in this study your particulars/information will be taken and used for the purpose of this research and this will certainly not bother you or cause any discomfort to you. Your participation in this study will involve the following: Interviewing you about how you do sedation practices, look at the monitoring equipments you are using and observing how you do sedation practices.

Confidentiality

You are strongly assured of the confidentiality of the information obtained that will only be used for the purpose of this research and anonymity will highly be observed when collecting data and compiling report. To assure you, even your name will not be required to appear in the questionnaire.

Risk to participant

No anticipated risk or harm that may result from participating in this study. Your participation is absolutely voluntary and there is no penalty for refusing to participate. You are free to ask any question and you may stop to participate in this study any time.

Contact Person

The principal investigator, Dr. Frederick Tembo (0718951064) is a key contact person with regard to any queries about this study. If you have any questions/concerns about your rights as a participant you may contact Professor Said Aboud, the chairman of the university senate research and publications, MUHAS P.O.BOX 65001, Dar es Salaam. Telephone; 2150302-6

Signing of the consent

If you agree to participate in this study please sign in this consent form.

I (initials)..... have read and understood the contents of this form and I have been given satisfactory explanation with all my questions answered. I therefore consent to participate in this study.

Signature of intervieweeDate.....

Signature of interviewerDate9.3 Consent

form Kiswahili version

APPENDIX 3: FOMU YA RIDHAA KUSHIRIKI KATIKA UTAFITI YA KISWAHILI

Utangulizi

Mimi naitwa Dkt. Frederick Tembo, mtafiti kutoka Chuo Kikuu cha Sayansi ya Tiba Muhimbili. Ninafanya utafiti kuhusiana na ‘Matumizi ya dawa zinazoleta usingizi nnje ya chumba cha upasuaji katika Hospitali ya Taifa Muhimbili, Dar Es Salaam, Tanzania’. Lengo la utafiti huu ni kubaini namna dawa zinazoleta usingizi zinavyotumika nnje ya chumba cha upasuaji katika hospitali ya Taifa Muhimbili, Dar Es Salaam, Tanzania.

Kushiriki katika utafiti huu

Tafadhali unaombwa kushiriki katika utafiti huu, na mara tu utakaporidhia, unahakikishiwa kuwa habari zako na maelezo utakayotoa yatatumika kwa makusudio na malengo ya utafiti huu tu na kuwa hii haitakuletea usumbufu wowote.

Usiri wa taarifa za mshiriki

Unahakikishiwa tena kuwa taarifa zozote zitakazopatikana kutoka kwako wakati wa utafiti huu zitapewa usiri mkubwa sana na hazitatumika kwa malengo mengine yoyote tofauti na utafiti husika. Kuhakikisha hilo, dodoso litakalohusika, halitakuwa na jina lako wakati wote wa utafiti na hata baada ya utafiti.

Athari za utafiti huu kwa mshiriki

Hakuna athari au madhara yoyote yatakayokupata kutokana na kushiriki katika utafiti huu.

Haki ya kushiriki au kutoshiriki katika utafiti huu

Ushiriki wako katika utafiti huu ni wa hiari kabisa. Unayo haki ya kushiriki au kutoshiriki bila kulazimika. Pia unayo haki ya kukataa kuendelea kushiriki/kuacha kujibu maswali wakati wowote utakapojisikia kufanya hivyo na hakutakuwa na hatua yoyote itakayochukuliwa dhidi yako au kulaumiwa kwa kufanya hivyo.

Mawasiliano

Wasiliana na mtafiti mkuu, Dkt. Frederick Tembo, kwa simu namba 0718951064 wakati wowote utakapokuwa na maswali au jambo lolote lenye kuhitaji ufafanuzi kuhusu utafiti huu. Hata hivyo endapo utakuwa na maswali kuhusu haki yako kama mshiriki unaweza pia kuwasiliana na Prof. Said Aboud, Mwenyekiti wa Baraza la Utafiti na Uchapishaji wa Chuo Kikuu cha Sayansi ya Tiba Muhimbili. S.L.P. 65001, Dar EsSalaam. Simu namba 2150302-6

Kukubali kushiriki

Ukikubali kushiriki tafadhali thibitisha kwa kujaza na kusaini sehemu ya fomu hii hapa chini.

Miminimesomewa na kuelewa yaliyomo kwenye form hii na maswali yangu yote yamejibiwa vizuri. Hivyo ninakubali mwenyewe kwa hiari yangu bila kushurutishwa au kushawishiwa kushiriki katika utafiti huu.

Sahihi ya mhojiwa..... Tarehe.....

Sahihi ya mhoji.Tarehe

APPENDIX 4: STANDARD SEDATION PROTOCOL (ACADEMY OF MEDICAL ROYAL COLLEGE STANDARD GUIDANCE 2013).

1: Pre-assessment.

- Pre-assessment should whenever possible, include previous patient's records.
- All patients should be pre-assessed to avoid unnecessary complications.

2: Information and consent.

- Valid consent is an essential preliminary to sedation.
- Information which includes risks and benefits of sedation, alternative to sedation, should be addressed to the patients.
- This should be a discussion with the patients and they should be allowed to ask questions. For those patients with psychiatric conditions or children, the carers must be involved.

3: Fasting.

- Before sedation, fasting is important and the fasting guidelines should be followed based on age and type of food taken.

4: Titration to effects.

- It is important to titrate the dose especially for conscious sedation, and the dose must have full effect before any additional dose is given.
- The use of fixed doses or boluses is unacceptable.

5: Multiple drugs and anaesthetic drugs/Infusion.

- Should only be considered where there is clear clinical justification, having excluded simple techniques. Due to the synergistic effects, there can be adverse events.

6: Use of antagonists.

- Use of flumazenil and naloxone for emergency use is acceptable.

-Recommendations have been made that the use of flumazenil should be regularly audited as a marker of excessive dosage of benzodiazepines.

7: Extremes of age.

-Young patients are more sensitive to sedatives and opioids than adolescent and adult patients due to their physiological and anatomical considerations that demand supplementary knowledge and skills, hence special training is required.

-Elderly are more sensitive to many drugs than young patients, hence dose should be reduced or titrated.

8: Monitoring and the use of supplementary oxygen.

-All the patients under sedation should be monitored ECG, NIBP, Capnography, and pulse oximetry.

-Eye monitoring of the patient is very important.

-Oxygen should be available in case of respiratory depression.

9: Team and the role of the operator-sedationists.

-A provider should not both administer sedation and perform the required procedure. He/she should have a trained person to assist.

-Team work is very important.

10: Discharge.

-Before discharged, the patient should be assessed; the vital signs should be stable, no pain, presence of someone to escort the patient, written instructions, and informing ICU if ICU care needed.

11: Record keeping.

-Patient evaluation, consent, data from monitoring during and after sedation should be documented and stored.

12: Audit and quality assurance.

-All clinical incidences should be reported including auditing outcomes, mortality within 30 days, use of flumazenil and naloxone, need for ventilation and sustained oxygen saturation < 90%.

13: Sedation within an institution: The sedation Committee.

-To ensure appropriate governance of sedation within an institution, a sedation committee should be established to lead and support implementation and recommendations at the hospital level.

This should include representatives from clinical team using procedural sedation and anaesthesiologists/anaesthetists.

-Suggested duties include development and review of local guidelines, drugs used for sedation, review the reported clinical incidences, annual auditing of number of sedation cases done by each provider, conducting training to staff. This will improve clinical standards.

14: Educational and training standards.

-Irrespective of educational background, the competencies are required for safe sedation and rescue any adverse events. There must be standards for all.

-Successive publications have highlighted a lack of formal training contribute to sedation-related adverse events.

-Sedation committee must be responsible to make sure that their trainee receives accredited training in sedation so as to maintain appropriate level of performing.

15: Supplementary doses of opioids.

-Must be required in prolonged uncomfortable procedures such as colonoscopy for which local anaesthesia is not appropriate.

16: Setting.

-It is important to recognize the limitations in working in relative isolation of non-theatre or non-hospital setting.

-The management of sedation-related complications and medical emergencies should be regularly rehearsed as a team.