INCIDENCE OF AWARENESS WITH EXPLICIT RECALL IN PATIENTS UNDERGOING GENERAL ANAESTHESIA AT KENYATTA NATIONAL HOSPITAL

A dissertation submitted in part- fulfilment of the requirements for the award of the degree of Master of Medicine in Anaesthesiology of the University of Nairobi.

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DECLARATION

This dissertation is my original work and has not been presented for a degree or any other purposes in any institution.

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DEDICATION

To the men in my life,

My daddy, whom I love dearly, Eng. Tom Mbadi Olwero for his amazing sense of humour and for teaching me integrity through his life. To my father-in-law, Mr. Elly Owiti, a man I never met but I have admired even in death. May we meet on that resurrection morning. To my brothers, Phares, Elisha and Emmanuel, the boy child is not forgotten.

Finally to my Lenny, my best friend, husband and intercessor. Thank you for always mentioning my name to God. To an eternity of love and laughter witnessing each other’s lives.
ACKNOWLEDGEMENT

This is to thank God for His enabling in the completion of this work. We are because He is. I am indeed indebted to my supervisors Dr. Thomas Chokwe and Dr. Antony Gatheru for their expert guidance, selflessness and patience with me during this journey. Many thanks to the department of anaesthesia for their concern and support.

I sincerely appreciate the team that helped with data collection led by Mr. Martin Njenga and the patients who took their time to give us feedback that was the basis of this study.

I would also like to thank the Kenyatta National Hospital together with the Ethics and Review committee for giving me consent to conduct this study.

My sincere gratitude to my family for their love and support and for being a strong pillar in my life.

May God abundantly bless you
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<tr>
<td>AAGBI</td>
<td>Association of Anaesthetists of Great Britain and Ireland</td>
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<tr>
<td>ASA</td>
<td>American society of Anaesthesiologists</td>
</tr>
<tr>
<td>AWR</td>
<td>Awareness with recall</td>
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<tr>
<td>BIS</td>
<td>Bispectral Index</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CNS</td>
<td>Central Nervous System</td>
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<tr>
<td>EEG</td>
<td>Electroencephalogram</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>ENT</td>
<td>Ear, nose and throat</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GA</td>
<td>General Anaesthesia</td>
</tr>
<tr>
<td>IBM</td>
<td>International Business Machines</td>
</tr>
<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
</tr>
<tr>
<td>MAC</td>
<td>Minimum Alveolar Concentration</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health service</td>
</tr>
<tr>
<td>N2O</td>
<td>Nitrous oxide</td>
</tr>
<tr>
<td>PACU</td>
<td>Post Anaesthesia Care Unit</td>
</tr>
<tr>
<td>RCoA</td>
<td>Royal College of Anaesthetists</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical package for the Social sciences</td>
</tr>
<tr>
<td>TIVA</td>
<td>Total Intravenous Anaesthesia</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>UoN</td>
<td>University of Nairobi</td>
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OPERATIONAL DEFINITIONS

General anaesthesia can broadly be defined as a drug-induced reversible depression of the central nervous system (CNS) resulting in the loss of response to and perception of all external stimuli (1). Awareness with explicit recall is when the patient (spontaneously or at interview) states or remembers that he or she had been awake at a time when consciousness was not intended (2).
ABSTRACT

Background
Awareness with explicit recall during anaesthesia, also known as intraoperative awareness, is a rare but debilitating complication of general anaesthesia. It can be anaesthesia related, surgical related, patient related or multifactorial. It has short term and long term consequences. These may include but are not limited to insomnia, panic attacks, sensation of pain and post traumatic stress disorder. It is mostly detected using a structured interview done over time. This is because memory tends to evolve over time. The most commonly used tool is a modified Brice questionnaire (table 1).

Objectives

Broad objective
Determine the incidence, risk factors and groups at risk of awareness with recall (AWR) in patients undergoing general anaesthesia (GA) at Kenyatta National Hospital (KNH).

Specific objective
To determine the incidence of AWR in KNH
To identify groups at risk of AWR at KNH
To identify risk factors associated with AWR in KNH
To come up with recommendations on minimizing AWR in KNH

Methodology
This was a prospective observational study on all patients over 18 years undergoing general anaesthesia at Kenyatta national hospital theatres.

Evaluation of awareness was based upon three consecutive interviews. The patients were interviewed on the day of surgery (in PACU when fully awake) and then on the 3rd and 7th day post operatively. The interview was conducted using a modified Brice questionnaire (table 1).

The interviewers were blinded to both the anaesthetic procedure and the medication used. Suspension of an episode of AWR was registered together with its characteristics.

Patient, anaesthetic and surgical characteristics and the drugs used perioperatively was recorded in a separate form by the person administering the anaesthesia.

Results
Data was obtained from a total of 369 patients undergoing general anaesthesia in KNH. The mean age of the patients was 38.8 (± 14.5) years with an age range between 18 and 82 years.
Males were 186 (50.4%) and females 183 (49.6%) giving a male to female ratio of 1:1. Majority of patients were ASA I 230(63.5%). GA was administered by four anaesthesia provider cadres including consultants 108 (30.7%), graduate anaesthesia trainees 163 (46.3%), diploma anaesthesia trainees 32 (9.1%) and specialist anaesthesia registered clinical officers 49 (13.9%). Propofol 353(95.7%) and Fentanyl 319 (86.4%) were the most commonly used induction agents while maintenance was mostly done using Isoflurane 345 (93.5%) and nitrous oxide 272 (73.7%). The mean total gas flow 3.3 (SD ± 1.1) l/ min with a range between 1 and 7 l/ min. There were 6 (1.7%) patients with low total gas flow rates ( ≤1 l/min). The mean duration of anaesthesia and surgery were 2.7 (± 1.3) hrs and 2.4 (± 1.3) hours, respectively. Out of the 369 patients under GA, 2 had awareness with recall (AWR) giving a prevalence of 0.54%. The two patients with AWR were aged 23 years and 34 years, and both patients were male. There was no evidence of an association between patients age (p = 0.842) or sex (p = 0.16) and occurrence of AWR.

**Conclusion**

We were able to meet our primary objective which was incidence of AWR in patients undergoing GA at KNH. We got an incidence of 0.54% which is within the range (3). The two patients we got were both males and age range of 18-35 years. The statistical test done showed there was no association of gender and age with incidence of AWR. We were therefore unable to draw a conclusion on the risk factors and groups at risk of AWR. The study was not significantly powered to identify groups at risk and factors associated with AWR.
CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Awareness with recall during general anaesthesia is a rare but extremely feared complication of general anaesthesia. Its incidence varies between 0.1%-0.2% with certain specialities being more prone to awareness(3). AWR has been noted to be a problem preoperatively with several consequences ranging from insomnia, anxiety to post traumatic stress disorder(4)(5). This can and has led to fear of future surgery by affected patients and an increase in litigation for anaesthesia providers(6).

The risk factors for awareness include patient related, anaesthesia related, surgical related and multifactorial. Patient factors include genetic variation in pharamcokinetics based on gender. Women tend to wake up faster from anaesthesia compared to men(7). Younger people also emerge earlier compared to the elderly population. Patients with a previous history of drug abuse e.g. amphetamine, alcohol etc have a higher risk of awareness since they will need higher drug dosages to achieve an acceptable depth of anaesthesia. Patients who have a history of awareness have an increased risk of the same. Significant also is the ASA classification of the patient. The sicker the patient the higher their chance of awareness(8).

The type of surgery can put a patient at risk of awareness. Obstetric, trauma and cardiac surgery are known risk factors for intraoperative awareness(9)(10)(11). The duration of surgery too, with longer surgeries lasting more than 180 minutes and surgeries done at night being more at risk of awareness . The technique used during anaesthesia can predispose patient to AWR during GA. Significant is the use of neuromuscular blockers with studies showing higher incidence in patients to whom neuromuscular blockers were administered(12)(13). Light anaesthesia also with low MAC was shown to put patients at risk of AWR as well as low flow anaesthesia(14)(15).

Incidence of awareness with recall under general anaesthesia in patients undergoing general anaesthesia at KNH is limited. The studies done are only two and focus on subsets of patients and not the whole population hence this is a baseline survey of the incidence of AWR in our population. Advances in medical care, longevity and surgical advances have demanded more from anaesthesia with newly diagnosed terminal cases and very sick individuals presenting for anaesthesia for surgery or other interventional procedures.
Younger children are also involved in surgical interventions. Explicit recall may be difficult to assess but they may later present with cognitive dysfunction due to the same and it is of interest for them to be evaluated. Techniques in anesthesia have also advanced and we are now in the era of low flow anesthesia and we have become bolder in the use of total Intravenous anesthesia (TIVA). We are still challenged though, in that with these advances, we are yet to start anesthetic depth monitoring in our set up. We have various methods of monitoring depth of anesthesia. These methods have their advantages and disadvantages. These include use of:

1. Non EEG methods
   - Autonomic responses
   - Isolated forearm technique
2. EEG based methods
   - Evoked potentials
   - Lower esophageal contractility
   - Bispectral index

1.1.1 **Autonomic response**
Autonomic signs have been used to assess anesthetic depth. They include heart rate, lacrimation, blood pressure and sweating. The advantage is that there is no need for sophisticated equipment or training to be able to use autonomic responses to assess depth of anesthesia but they do have several limitations. First it is a very subjective method and can be affected by other factors e. g beta blockers can prevent tachycardia and atropine can cause tachycardia with papillary dilatation. It is also noted that a patient may exhibit signs of light anesthetic depth using clinical signs but not be aware. We however recognize that should an anesthetized patient have unexplained tachycardia and hypertension then the anesthetic agents must be reviewed. It therefore has limited use.

1.1.2 **Isolated forearm technique**
This is a technique that was introduced by Tunstall in 1977 to assess the processing of information during general anesthesia. It involves inflation of a tourniquet on the upper arm to pressures above systolic blood pressure before muscle relaxant is administered into the vein on the other arm and the tourniquet is released 15 to 20 minutes after administration of muscle relaxant. In case there is need to top up the tourniquet is re inflated. The patient can
then respond to command if the patient is awake. Studies have shown though that wakefulness did not necessarily translate to awareness and complex muscle movements may be involuntary and not necessarily due to wakefulness.

1.1.3 Evoked potentials
These measure electrical activity in certain parts of the brain in response to stimulation of specific nerve pathways. General anesthetics cause changes in amplitude and frequency of the waves but the changes are not consistent with all anesthetic agents making it not very reliable as a measure of depth of anesthesia.

1.1.4 Bispectral index
This is a complex statistically based parameter that integrates the electroencephalogram (EEG) and electromyography (EMG). It is presented in numerical form with 100 being awake and 0 being isoelectric EEG. The manufacturers recommend a BIS of 40-60 for adequate anesthetic depth. Several studies have been done on it. The B-AWARE trial concluded that it helped in reduction of awareness under general anesthesia with muscle relaxant but the cost was prohibitive (16). Another study by Duarte LT and Saraiva RA concluded that BIS can give false results in different clinical settings (17).

1.2 Justification
- All known methods of predicting AWR have shortcomings and therefore knowing the predisposing factors will help in mitigating AWR
- AWR is a global problem yet we don’t have baseline data to help us develop a protocol for managing a case of AWR
- No local studies to show us incidence of AWR despite high number of surgeries
- No explicit protocol to guide us on management of patients at risk

1.3 Objectives
1.3.1 General Objectives
Determine the incidence, risk factors and groups at risk of awareness with recall (AWR) in patients undergoing GA at Kenyatta National Hospital (KNH).
1.3.2 Specific objective
Determine the incidence of awareness with recall at Kenyatta national hospital.
Identify groups at risk of awareness with recall at Kenyatta national hospital.
Identify risk factors associated with awareness with recall at Kenyatta national hospital.
CHAPTER TWO

2.0 LITERATURE REVIEW

Awareness is the quality or state of being aware i.e. watchful, vigilant, informed, cognisant or conscious. Awareness during anaesthesia is as old as anaesthesia itself. In 1845 at Massachusetts General Hospital, Horrace Wells used nitrous oxide on a patient during dental extraction. The patient screamed in pain but had no recollection of doing so. A year later at the same hospital William Morton used ether to anesthetize a patient who later reported being aware of the surgery but he felt no pain. There are infrequent reports of awareness recorded but the problem of awareness with recall during general anaesthesia became more apparent with the introduction of muscle relaxants by Griffith and Johnson in 1942. This necessitated assessment of depth of anaesthesia since with muscle relaxation, patients were paralyzed even when conscious.

The assessment of depth of anaesthesia began way back in 1847 when John Snow described degrees of narcosis. This was followed years later by Guedel’s description of stages of anaesthesia in 1937. With the introduction of muscle relaxation in 1942, new ways of assessing depth of anaesthesia had to be employed. The use of MAC was introduced in 1965 as a measure of anaesthetic potency. The use of isolated forearm technique was introduced in 1977 by Tunstall to assess processing of information during anaesthesia.

This was followed by investigation on the effects of anaesthesia on auditory evoked potentials by Thornton group. In 1987 Aspect medical systems company developed the bispectral index technology (BIS) which FDA approved in 1996 (18). Several studies on the subject have been conducted. One of the largest studies done was the 5th National Audit Project by the Royal College of Anesthetists (RCoA) and Association of Anesthetists of Great Britain and Ireland (AAGBI) that studied 3 million cases of general anaesthetics and 300 new reports of awareness. A nationwide network of local coordinators in the United Kingdom (UK) National Health Service (NHS) hospital and separately in Ireland anonymously reported incidences of awareness and its surrounding events including type of surgery, technique of anaesthesia and the attending sequelae to a central secure online database. This was later analysed by a multi-disciplinary team. The estimated incidence of patient reports of Accidental awareness during general anaesthesia was ~1:19,000.
anaesthetics. However, this incidence varied considerably in different settings. The incidence was ~1:8,000 when neuromuscular blockade was used and ~1:136,000 without it. Two high risk surgical specialties were cardiothoracic anaesthesia (1:8,600) and Caesarean section (~1:670)(19).

In the United States of America, a prospective, nonrandomized descriptive cohort study that was conducted at seven academic medical centres by P. S. Sebel et al between April 2001-December 2002 was carried out. Data from a total of 19,575 patients was presented after a structured interview in the postoperative room and 7th post operative day. A total of 25 cases of awareness were identified giving an incidence of 0.13% which is almost the same incidence worldwide. Logistical regression associated awareness with increased ASA status and type of surgery with the incidence being higher in cardiothoracic, ophthalmology and abdominal versus other surgeries(20).

A European study in Spain recorded an incidence of 1% with TIVA being a significant risk factor and caesarean sections done at night. This was a prospective observational investigation of AWR in patients undergoing general anaesthesia at Hospital General Universitario de Valencia. Blinded structured interviews were conducted in PACU, day 7 and day 30. Patient characteristics, perioperative and drug factors were also considered(21).

Nearer home, a prospective audit was conducted at University College Ibadan, Nigeria. This was a 10 month audit which used open ended questionnaires administered within 24-36 hours to patients who had had general anaesthesia. A total of 955 patients had general anaesthesia with 9 (7 females and 2 males) reporting intraoperative awareness with recall. This gave an incidence of 0.7%. Risk factors in the said patients included lack of amnesic premedication, suboptimal doses of hypnotic agents and failure to top up analgesics (15).

The problem with awareness is the consequences, which is feared by both patients and anaesthesia providers. The release of the American conspiracy thriller ‘awake’ in 2007, a movie about awareness during anaesthesia, increased public concern and awareness of the possibility of awareness with recall during general anaesthesia. This increased the possibility of litigation for the anaesthesia provider. In a closed claims analysis of awareness during anaesthesia, awareness accounted for 79 of 4,183 claims (1.9%) in the ASA Closed Claims Project database (22). Because the possibility of patient awareness has become better known in the
last decade, it should be easier for an attorney to argue that the anaesthesiologist should have been alert to the possibility of patient awareness. This expectation would, therefore, require the anaesthesiologist to routinely check for symptoms of light anaesthesia and continually abide by the newest guidelines and procedures (23).

Although majority of the patients who experience awareness with explicit recall during general anaesthesia do not experience pain, the proportion which do, report the pain as being severe most of the time (24). The feeling of being aware but paralysed brings about feelings of anxiety, fear of dying and later may lead to post traumatic stress disorder and even suicidal tendencies (25). Knowledge of the above possibilities may lead to fear by patients presenting for surgery (26)

In spite of the possibility of awareness with recall during general anaesthesia there are steps which can be taken to minimize the occurrence. The most important patient monitor is the anaesthesia provider. A vigilant anaesthesia provider, adequate premedication and benzodiazepine use, avoidance of unnecessary use of muscle relaxants and risk assessment of patients prone to AWR during general anaesthesia and provision of extra monitoring for such patients, avoidance of negative comments intraoperative are some of the ways to prevent AWR (25)

In a prospective, randomized, double-blind study conducted in the operating theatre of visceral surgery at Sahloul Teaching Hospital over a period of 4 months, they concluded that music therapy was a cost effective non-pharmacological way of reducing incidences if awareness (26)

In cases where a patient has AWR, a multidisciplinary management needs to be instituted. Dealing with cases of AWR may be beyond the scope of anaesthesiologists and may need to involve counselling psychologists or even psychiatrists. (25)

In Kenya we have a study on awareness that was been done by Dr. Salim S. E Noormohammed in 1995. Dr. Salim was comparing adults anaesthetized with ketamine and those anaesthetized with sodium thiopental. Dr. Mohammed found that ketamine was better at preventing awareness and memory during anaesthesia. In view of the limited literature we have on AWR in Kenya and the multiple horrific consequences of AWR, incidence of AWR in our setup is needed.
CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study design
The study was a prospective observational study on all adults over 18 years of age undergoing general anaesthesia at Kenyatta national hospital theatres. Evaluation of awareness was based upon three consecutive interviews. The patients were interviewed on day 0 (in PACU when fully awake), day 3 day and 7 post operatively. The interview was conducted using a modified Brice questionnaire.

<table>
<thead>
<tr>
<th>Table 1: Modified Brice questionnaire (27)</th>
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<tr>
<td>What is the last thing you remember before going to sleep?</td>
</tr>
<tr>
<td>First thing you remember after waking up?</td>
</tr>
<tr>
<td>Do you remember anything between going to sleep and waking up?</td>
</tr>
<tr>
<td>Did you dream during your procedure?</td>
</tr>
<tr>
<td>What was the worst thing about your operation?</td>
</tr>
</tbody>
</table>

The interviewers were blinded to both the anaesthetic procedure and drugs used. Patient, anaesthetic and surgical characteristics, and the drugs used were recorded in a separate form by the person administering the anaesthesia.

3.2 Study site
The study was carried out at Kenyatta national hospital (KNH).
KNH is the largest teaching and referral hospital in Kenya with a bed capacity of more than 1,800, 20 outpatient clinics, 24 operating theatres and 50 wards.
It also carries out specialized surgery which are not done in most public health facilities in Kenya e.g. neurosurgery, cardiothoracic surgery, paediatric surgery and plastic surgery. Approximately 60 patients receive general anaesthesia in a day hence its suitability as a study centre.

3.3 Study population
The study population was adults who seek healthcare at KNH.
3.4 Sample size estimation
Due to the finite number of patients undergoing surgery under GA at KNH, the Yamane Taro’s formula for determining the sample size was used (28)

\[ n = \frac{N}{1 + N \times (e)^2} \]

n = sample size
N = the population size
E = acceptable sample size
Substituting the following sample size assumption into the formula
N = 2100 (on average 700 adults are operated under GA in KNH per month and the data collection will be conducted over a 3-month period)
e = 0.05 (representing 95% level of confidence)
Taro Yamane’s formula assumes a prevalence of 50% for awareness and recall during GA.

\[ n = \frac{2100}{1 + 2100 \times (0.05)^2} \]

n = 336 patients
To compensate for numbers lost to follow-up or death among other factors, 10% of the sample size will be added to the sample size. The sample size will therefore be:

(336*0.1) + 336 = 370

3.5 Inclusion/exclusion criteria
3.5.1 Inclusion criteria
All consenting patients who were 18 years of age undergoing general anaesthesia at KNH

3.5.2 Exclusion criteria
Patients who did not or could not give consent
Patients who could not communicate
Patients under 18 years
Patients discharged before post operative visit and could not be reached through telephone calls.
In case of AWR patient was to be referred to patient support centre, which is a place where the department of psychiatry follows up its patients.

Consent was filled by the research assistants and they also did the interviews.

The questionnaire was filled by different cadres of anaesthesia providers. Questionnaire attached in Appendix 1

### 3.7 Study protocol and data collection

In theatre receiving area, consent was obtained from patients meeting the inclusion criteria. A questionnaire was then put in their files. This was filled by the person administering anaesthesia. Afterwards they were followed up in PACU and the modified Brice questionnaire administered to them. They were then be followed up day 3 and 7 postoperatively.
3.7.1 Outcomes
The primary end point was to get the incidence of AWR using the Brice questionnaire, in patients receiving general anaesthesia at Kenyatta National hospital. The secondary end point was to identify groups at risk and risk factors associated with AWR in Kenyatta National Hospital. Any incidence of awareness was to be referred to patient support centre for appropriate psychiatric management.

3.8 Data management and quality control
Quality control measures were implemented prior to data collection to reduce errors in data. This included training of research assistants on study procedures, interviewing and data recording on the study tools. Additional measures included developing standard operating procedures (SOPs) and data collection manual to guide data collection. The principal investigator also supervised all data collection.

Upon receiving the completed questionnaire form the principal investigator examined all questionnaires for completeness. This was done at every stage of data collection including initial contact in the recovery room, subsequent follow-ups on day 3 and day 7. All incomplete questionnaires were completed at by referring back to patient record and in cases where data was missing from records a code was assigned for missing values.

Data was entered into databases designed in MS Office Access (2007). The databases were customized using the study questionnaire structure with data stored in numeric coded format, and text for open ended questions. Range and consistency checks were built into the database as a quality assurance measure aimed at reducing data entry errors. Data was transferred from Access databases to SPSS for data cleaning and analysis. Data cleaning involved inspecting each variable in the database to check for invalid entries, and inconsistencies using SPSS procedure for summarizing variables. In cases where data entry errors were noted cleaning involved validating entries by referring back to the study questionnaire using the unique study identifier contained in each questionnaire. Any inconsistency between the questionnaire and data contained in the database was resolved by checking patient records and re-entering the data contained in the records.
3.9 Data analysis

Data was analyzed using SPSS (IBM version 21). Analysis was conducted in three stages, namely: univariable analysis, bivariable analysis and multivariable analysis. For the univariable analysis, each individual variable in the dataset was analyzed using descriptive statistics. During these stage continuous variables like age and duration of surgical procedure was analysed by calculating mean and standard deviation for normally distributed variables and median and ranges for skewed variables.

Categorical variables was analyzed using frequencies, and relative frequencies or percentages calculated using the relevant denominator values and presentation will be done using frequency distributions. The main objective related to determining incidence of awareness with explicit recall involved calculation of a percentage with the number of aware patients as numerator and the total number of study patients as denominator. The numerator included patients meeting the criteria of awareness comprising five questions contained in the modified Brice questionnaire.

Analysis of the factors associated with awareness involved calculating the percentages of patients with each of the factors namely: gender, age, ASA classification, type of surgery, TIVA or inhalational anaesthesia or both. Next, bivariate analysis was conducted by cross tabulating each factor with the dependent variable (explicit recall). Depending on how commonly explicit recall occurs then statistical tests were to be used to compare the prevalence of these factors in patient with and without explicit recall. For continuous factors for example age, mean age in patients with and without explicit recall was compared using Student’s t-test. Comparison of percentages across levels of categorical independent variables was done using Chi square test or Fisher’s exact test. Statistical significance was based on an alpha cut-off level of 0.05.

The final stage of analysis was a multivariable analysis conducted using logistic regress for binary outcomes represented by the percentage of patients with documentation for each dependent variable. The independent variables in the logistic regression included all variables showing significant association with quality of care in the bivariate analysis. Odds ratios and 95% confidence intervals were reported from the multivariable analysis.
3.10 Ethical considerations

All patients meeting the inclusion criteria were furnished with information concerning the study and an informed consent signed by them. A respondent who consented to participate confirmed such consent by appending her signature or thumb print on the availed Consent Form (Appendix iii). The subjects who developed awareness with explicit recall during the study were given appropriate treatment. Approval was sought from the KNH/UON-Ethics and Research Committee prior to carrying out the study.
CHAPTER FOUR

4.0 RESULTS

4.1 Patient characteristics

Data was obtained from a total of 369 patients undergoing general anaesthesia in KNH. The mean age of the patients was 38.8 (± 14.5) years with an age range between 18 and 82 years. The most common age group was 18-29 years (30.1%) followed by 30-39 years (28.7%), table 1. There were 186 (50.4%) males giving a male-to-female ratio of 1:1. Of the 369 patients 138 (42.3%) had primary level education and 133 (40.8%) had secondary education (table 1).

Table 1: Characteristics of patients undergoing general anaesthesia at KNH

<table>
<thead>
<tr>
<th></th>
<th>Frequency (n)</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29 years</td>
<td>111</td>
<td>30.1</td>
</tr>
<tr>
<td>30-39 years</td>
<td>106</td>
<td>28.7</td>
</tr>
<tr>
<td>40-49 years</td>
<td>77</td>
<td>20.9</td>
</tr>
<tr>
<td>50-59 years</td>
<td>37</td>
<td>10</td>
</tr>
<tr>
<td>60 years and above</td>
<td>38</td>
<td>10.3</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>186</td>
<td>50.4</td>
</tr>
<tr>
<td>Female</td>
<td>183</td>
<td>49.6</td>
</tr>
<tr>
<td><strong>Level of education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal education</td>
<td>16</td>
<td>4.9</td>
</tr>
<tr>
<td>Primary</td>
<td>138</td>
<td>42.3</td>
</tr>
<tr>
<td>Secondary</td>
<td>133</td>
<td>40.8</td>
</tr>
<tr>
<td>University/ college</td>
<td>39</td>
<td>12</td>
</tr>
</tbody>
</table>
4.2 ASA Classification

Figure 1 shows the physical status of patients prior to surgery. Majority of patients had no systematic disturbance with 230 (63.5%) having ASA I classification. There were 110 (30.4%) patients who had moderate but definite systematic disturbance representing ASA II.

Figure 1: ASA physical status classification of patients undergoing GA
4.3 Types of Surgery

A total of 123 (33.3%) patients undergoing GA in KNH had general surgeries (Figure 2). There were 68 (18.4%) patients undergoing orthopaedic surgery and 63 (17.1%) who underwent ENT surgery.

**Figure 2: Types of surgery conducted in patients in KNH**
4.4 Incidence of awareness with recall

Out of the 369 patients under GA, 2 had awareness with recall (AWR) on day 1, 3 and 7 (table 2) giving a prevalence of 0.54%. Thus, the incidence for AWR under general anaesthesia was 5.4 cases per 1,000 patients. Intraoperative dreaming was reported by 45 (12.2%) patients and none of these reported that the dreams were disturbing.

Table 2: Incidence of AWR based on modified Brice questionnaire

<table>
<thead>
<tr>
<th></th>
<th>Number of AWR patients (n = 369)</th>
<th>Intraoperative dreaming (n = 369)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>2 (0.54%)</td>
<td>42 (11.4%)</td>
</tr>
<tr>
<td>Day 3</td>
<td>2 (0.54%)</td>
<td>18 (4.9%)</td>
</tr>
<tr>
<td>Day 7</td>
<td>2 (0.54%)</td>
<td>17 (4.6%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2 (0.54%)</strong></td>
<td><strong>45 (12.2%)</strong></td>
</tr>
</tbody>
</table>
4.4 Patient demographics and AWR

Table 3 shows that the two patients with AWR were aged 23 years and 34 years, and both patients were male. There was no evidence of an association between patients age (p = 0.842) or sex (p = 0.16) and occurrence of AWR.

**Table 3: Patient demographics and occurrence of AWR**

<table>
<thead>
<tr>
<th>Age</th>
<th>AWR n (%)</th>
<th>No AWR n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29 years</td>
<td>1(1)</td>
<td>110(99)</td>
<td>0.842</td>
</tr>
<tr>
<td>30-39 years</td>
<td>1(1)</td>
<td>105(99)</td>
<td></td>
</tr>
<tr>
<td>40-49 years</td>
<td>0(0)</td>
<td>77(100)</td>
<td></td>
</tr>
<tr>
<td>50-59 years</td>
<td>0(0)</td>
<td>37(100)</td>
<td></td>
</tr>
<tr>
<td>60 years and above</td>
<td>0(0)</td>
<td>38(100)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex</th>
<th>AWR n (%)</th>
<th>No AWR n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>2(1)</td>
<td>184(99)</td>
<td>0.16</td>
</tr>
<tr>
<td>Female</td>
<td>0(0)</td>
<td>183(100)</td>
<td></td>
</tr>
</tbody>
</table>
4.5 Anaesthesia provider and AWR

GA was administered by four health provider cadres including consultants 108 (30.7%), anaesthesia trainees at graduate 163 (46.3%) and diploma 32 (9.1%) levels and specialist anaesthesia registered clinical officers 49 (13.9%). As shown in table 4, AWR occurred in a single patient in the group administered GA by consultant anaesthetist and in one patient administered GA by graduate anaesthesia trainee.

Table 4: Anaesthesia provider cadre and occurrence of AWR

<table>
<thead>
<tr>
<th>Health provider cadre</th>
<th>AWR n (%)</th>
<th>No AWR n (%)</th>
<th>Total n = 369</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant</td>
<td>1(1)</td>
<td>107(99)</td>
<td>108(30.7)</td>
</tr>
<tr>
<td>Graduate anaesthesia trainee</td>
<td>1(1)</td>
<td>162(99)</td>
<td>163(46.3)</td>
</tr>
<tr>
<td>Diploma anaesthesia trainee</td>
<td>0(0)</td>
<td>32(100)</td>
<td>32(9.1)</td>
</tr>
<tr>
<td>Registered clinical officer anaesthetist</td>
<td>0(0)</td>
<td>49(100)</td>
<td>49(13.9)</td>
</tr>
</tbody>
</table>
4.6 Induction agents

Table 5 presents the rate of awareness for different induction agents. Overall, propofol (95.7%), and fentanyl (86.4%) were the most commonly used induction agents. Both patients who had AWR received propofol and one of the two cases reporting awareness also received fentanyl. The two patients with AWR did not have any of the other induction agents administered namely isoflurane, halothane, remifentanil, morphine, ketamine or midazolam (table 5). These induction agents were administered in between 1.6 and 4.6% of the patients who did not report AWR.

Table 5: GA induction agents used in patients with and without AWR

<table>
<thead>
<tr>
<th>Induction agent</th>
<th>AWR n (%)</th>
<th>No AWR n (%)</th>
<th>Total n = 369</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflurane</td>
<td>0(0.0)</td>
<td>13(3.5)</td>
<td>13(3.5)</td>
</tr>
<tr>
<td>Halothane</td>
<td>0(0.0)</td>
<td>6(1.6)</td>
<td>6(1.6)</td>
</tr>
<tr>
<td>Propofol</td>
<td>2(100.0)</td>
<td>351(95.6)</td>
<td>353(95.7)</td>
</tr>
<tr>
<td>Remifentanil</td>
<td>0(0.0)</td>
<td>7(1.9)</td>
<td>7(1.9)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1(50.0)</td>
<td>318(86.6)</td>
<td>319(86.4)</td>
</tr>
<tr>
<td>Morphine</td>
<td>0(0.0)</td>
<td>8(2.2)</td>
<td>8(2.2)</td>
</tr>
<tr>
<td>Ketamine</td>
<td>0(0.0)</td>
<td>17(4.6)</td>
<td>17(4.6)</td>
</tr>
<tr>
<td>Midazolam</td>
<td>0(0.0)</td>
<td>14(3.8)</td>
<td>14(3.8)</td>
</tr>
<tr>
<td>Other induction agent</td>
<td>0(0.0)</td>
<td>11(3.0)</td>
<td>11(3.0)</td>
</tr>
</tbody>
</table>
4.7 Maintenance agents

The most frequently administered maintenance agents were isoflurane (93.5%), nitrous oxide (73.7%) and morphine (58.8%), table 6. The two patients with AWR both received isoflurane and one of these patients also received nitrous oxide in addition to isoflurane. Each of the remaining maintenance agents were each administered in less than 5% of patients with none of the patients with AWR receiving these agents.

Table 6: GA maintenance agents used in patients with and without AWR

<table>
<thead>
<tr>
<th>Maintenance agent</th>
<th>AWR n (%)</th>
<th>No AWR n (%)</th>
<th>Total n = 369</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflurane</td>
<td>2(100.0)</td>
<td>343(93.5)</td>
<td>345(93.5)</td>
</tr>
<tr>
<td>Halothane</td>
<td>0(0.0)</td>
<td>7(1.9)</td>
<td>7(1.9)</td>
</tr>
<tr>
<td>Propofol</td>
<td>0(0.0)</td>
<td>1(0.3)</td>
<td>1(0.3)</td>
</tr>
<tr>
<td>Remifentanly</td>
<td>0(0.0)</td>
<td>14(3.8)</td>
<td>14(3.8)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>0(0.0)</td>
<td>8(2.2)</td>
<td>8(2.2)</td>
</tr>
<tr>
<td>Morphine</td>
<td>0(0.0)</td>
<td>217(59.1)</td>
<td>217(58.8)</td>
</tr>
<tr>
<td>Pethidine</td>
<td>0(0.0)</td>
<td>1(0.3)</td>
<td>1(0.3)</td>
</tr>
<tr>
<td>Ketamine</td>
<td>0(0.0)</td>
<td>4(1.1)</td>
<td>4(1.1)</td>
</tr>
<tr>
<td>Midazolam</td>
<td>0(0.0)</td>
<td>3(0.8)</td>
<td>3(0.8)</td>
</tr>
<tr>
<td>Other maintenance agent</td>
<td>1(50.0)</td>
<td>15(4.1)</td>
<td>16(4.3)</td>
</tr>
<tr>
<td>Nitrous oxide</td>
<td>1(50.0)</td>
<td>271(73.8)</td>
<td>272(73.7)</td>
</tr>
</tbody>
</table>

4.8 Total gas flow

The mean total gas flow 3.3 (SD ± 1.1) l/ min with a range between 1 and 7 l/ min. There were 6 (1.7%) patients with low total gas flow rates (≤1 l/min). The two patients with AWR had total gas flow rates of 4 l/min and 5 l/min.

4.9 Duration of surgery and anaesthesia

The mean duration of anaesthesia and surgery were 2.7 (± 1.3) hrs and 2.4 (± 1.3) hours, respectively. The two patients with AWR had durations of anaesthesia of 1 hour and 2 hours.

21
The corresponding duration of surgery for these patients with AWR was 45 minutes and 1 hour 50 minutes, respectively. The ranges for duration of surgery and anaesthesia in the study were 20 minutes to 8 hours and 20 minutes to 8.5 hours.

**Table 7: Duration of anaesthesia and surgery in patients undergoing GA in KNH**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of surgery</td>
<td>2.4 hrs</td>
<td>1.3</td>
<td>20 min - 8 hrs</td>
</tr>
<tr>
<td>Duration of anaesthesia</td>
<td>2.7 hrs</td>
<td>1.3</td>
<td>20 min - 8.5 hrs</td>
</tr>
</tbody>
</table>
CHAPTER FIVE

5.0 DISCUSSION, RECOMMENDATION AND CONCLUSION

5.1 Discussion

Awareness with explicit recall is a rare but dreaded, by both patients and anaesthesiologists, complication of general anaesthesia. The implications of AWR include but is not limited to insomnia, anxiety disorders, depression and suicidal tendencies (4)(5)(6). It is also a major medicolegal issue. In this era of balanced anaesthesia and increased monitoring, it can be argued that the anaesthesia provider should have suspected signs of light anaesthesia (23).

Since AWR is based on patient’s recollection of the event, the gold standard tool for inquiring about explicit recall is the Brice questionnaire. This tool has been modified over the years but the core questions remain the same. The time of administration has also been varied among the different researchers given that memory evolves. It has ranged from day 1 in PACU to 30 days post surgery. In our case, we conducted three consecutive interviews on day 1, day 3 and day 7 using the modified Brice questionnaire.

We note that majority of our patients were between 18-50 years with the highest percentage being 18-29 years. The male to female ratio was almost 1:1 as shown in table 1. Figure 1 shows us the ASA status of the patients. This was based on what the anaesthesia provider documented in the questionnaire. Of note is that a majority of the patients are in ASA I, 63.5%, which would be more likely in a paediatric or adolescent population as opposed to our age group. This is because smoking, alcohol consumption and pregnancy places one in ASA II. The majority of our patients 79.7% are between the ages of 18-50 years and there is high likelihood of use of alcohol and tobacco in this population as well as it is the reproductive age of most women. This brought to question the possibility of there being a knowledge gap that needs to be filled regarding ASA classification. Both patients with AWR were documented as ASA II. With regard to patient characteristics which puts patient at risk of AWR and in particular ASA classification, studies report more incidence of AWR with ASA III and IV patients more than ASA I and II (8).

Concerning the types of surgeries done in KNH, most of the cases were general surgical cases and these included mastectomies, thyroidectomise explorative laparatomies for different gastrointestinal pathologies, excisions and biopsies. This was followed by orthopaedic
procedures. While in most setups most orthopaedic procedures are done under regional anaesthesia, in our setup it was noted that regional techniques was mostly used for lower limb surgeries with orthopaedic surgery in another anatomical region other than lower limbs was an indication for general anaesthesia in most cases. There is need for education in regional anaesthesia techniques to fully benefit our population of that essential and safe mode of anaesthesia. On the other hand, for obstetric anaesthesia, regional technique is what is mostly used hence we had very few obstetric patients under general anaesthesia.

While we do a lot of otolaryngeal procedures in KNH, majority of the patients fall in the paediatric age group who were excluded in our study. Significant also is that during the study period, there was no open heart surgery going on in the hospital and so were not able to sample those patients. This is significant in that cardiac surgery is one of the high risk factor for AWR. Most neurosurgical patients were taken to ICU post operative and were therefore unable to communicate which was one of our exclusion criteria.

In our conduct of anaesthesia, during induction, 95.7% of patients received propofol, 86.4% received fentanyl, a few also used midazolam, morphine and ketamine as shown in Table 5. We had very little inhalational induction in adults 1.6% that is 6 patients and this was using halothane since the cost of sevoflurane is still prohibitive. This was mainly used with difficult airways. Therefore most of our induction combination of propofol and fentanyl was used. 93.5% of patients were maintained on isoflurane with only 1.9% that is 7 patients being maintained on halothane. Nitrous oxide was used in 73.8% of patients making oxygen, nitrous oxide and isoflurane being the maintenance technique mostly used. On use of neuromuscular blockade, 95.9 patients receive neuromuscular blockade with cisatracurium being the mostly used, 59.9% Table 7.

We had two patients out of the 369 patients who had explicit awareness with recall Table 2. This was revealed in the first interview in PACU and the subsequent interviews on day 3 and 7. Their files were retrieved and their preoperative records viewed, the anaesthetic chart was examined and they were further questioned. They were followed up but they declined any psychological disturbance and were not willing to be seen by a psychiatrist. A total of 12.2% had dreams. They were further interviewed as to the nature of their dreams in case they had AWR thinking they dreamt. On further evaluation, the dreams were unrelated to the surgical
and anaesthetic procedure and they mostly revolved around their social life and were not disturbing to them. We were not able to identify groups at risk and risk factors for AWR given the methodology used and the rarity of the event. We got two patients who were both male in the same age group. We were therefore unable to draw a statistically sensible conclusion from the result.

Noteworthy is that the last question in our modified Brice questionnaire was what was their worst experience, most respondents, 62.4%, complained of pain in PACU. This was promptly relieved in PACU. We did not use a visual analogue scale since pain was not what we were investigating but it was a significant finding and further study could be considered so that we may improve our patient satisfaction with perioperative care.

**CASE 1**

23 year old male with a BMI of 25 came for elective tonsillectomy for recurrent tonsillitis. The anaesthesia provider who reviewed him classified him as ASA I. He had no history of smoking or alcohol use. No previous history of AWR. He was induced at 12.15 pm with propofol 200mg, fentanyl 100mcg and atracurium 30mg. He was intubated with an orotracheal tube 7.5 mm internal diameter depth of 23 cm. Tube was cuffed. Anaesthesia was maintained on isoflurane 1%-2%, oxygen 2.5L/min and nitrous oxide 2.5L/min. Total gas flow was 5L/min. End tidal carbon dioxide ranged from 36-40mmHg. Vital signs ranged from heart rate of 70-110, SpO2 99-100% and blood pressure 115/65-178/102mmHg. The high blood pressure readings were at induction. Emergence was at 2pm. He was taken to PACU awake.

He got left tonsillar bed bleed and was taken back to theatre same day at 4.30 pm. He was induced with ketamine 75 mg and fentanyl 100mcg. He was intubated with a size 6.5 endotracheal tube to a depth of 22 cm. He was maintained on halothane 2%, nitrous oxide 3L/min and oxygen 3L/min. End tidal carbon dioxide ranged from 40-45 mmHg. Vital signs ranged from heart rate of 90-115, blood pressure 65/38-145/85mmHg and SpO2 98-100%. Emergence was at 6pm and patient was taken to PACU.

Same day a little past midnight, patient was taken back to theatre for left tonsillar bed bleed. He was induced at 12.45 am the following day with propofol 50mg, ketamine 50mg and suxamethonium 100mg. He was intubated with size 7.0 endotracheal tube to a depth of 22
cm. He was maintained on isoflurane 0.8%, oxygen 2L/min and nitrous 2.3L/min. He was paralysed with cisatracurium. Blood pressure ranged from 88/38-148/68. Intraoperative, he got 4 litres of crystalloids and 1 unit of blood. Estimated blood loss was 1100 mls. Emergence was at 4 am and he was taken to PACU awake.

48 hours later he went back to theatre and the pack was removed. Haemostasis had been achieved. In the course of our interview, he reported being unable to move but could hear could hear staff in theatre talking and asking for instruments then he says he fell asleep. He reports this occurred with the surgery done at night. Initially he reports being a bit anxious but he woke up and he says it is part of anaesthesia. He is not distressed about it. No pain was reported though. In his case we relied on the documentation of the anaesthesia provider. There is a possibility suxamethonium took effect before the induction drugs. And also due to the haemorrhage, anaesthesia was kept light

CASE 2
34 year old male who presented with renal calculus for open pyeloplasty. He had no history of previous exposure to anaesthesia and did not use alcohol or cigarette. He was induced at 11.25 am with fentanyl 100mcg, cisatracurium 14mg and propofol 160mg. He was intubated with an endotracheal tube size 7.5 mm to a depth of 22 cm. He was maintained on isoflurane 0.6-1.5%, oxygen 2l/min and nitrous 2L/min. Vitals signs were within normal throughout the procedure. Heart rate ranged from 68-80 beats/minute, blood pressure ranged from 85/58-138/78 and SpO2 98-100%. End tidal carbon dioxide ranged from 33-36mmHg. Emergence was at 1pm and he was taken to PACU. He reports feeling pain and hearing people talking. He was unable to move.

We could not elicit a reason for awareness unless he was light at the time when Isoflurane was reduced to 0.6%. We talked and he said the event did not distress him since he was now well. He was reluctant for psychiatric follow-up.

Strengths
This study is believable because we got an efficiently large enough sample to estimate the prevalence of AWR in KNH during the study period with adequate precision.
The tool used which is the Brice questionnaire, is the gold standard for studies on AWR because it is based on recall and the questions are objective.

The sample was a good representation of the patients who present in KNH for surgical care.

**Limitation**

We were limited in that the methodology used is not ideal for a rare event such as AWR. The work was therefore very involving and costly. A better design would have been a case control with the cases being defined by occurrence of AWR. The challenge currently with case control studies is that there needs to be a robust and electronic patient data system which is still not there so a lot of information tends to be missing from patients files.

A group at significant risk of AWR was not present that is the open heart patients.

In conclusion, the overall risk of AWR ranges from 0.1-0.8% depending on a number of factors. In our case...

5.2 Conclusion

- The incidence of AWR in KNH is 0.54%
- There was no specific group of patients that were identified as being at risk for AWR.
- There were no major risk factors for AWR which were identified in this study.
- Of the two patients who had AWR, one had clinical attributes which would predispose him to AWR; successive repeated anaesthesia for resuscitative surgery.

5.3 Recommendations

- A larger study needs to be done to involve as many patients as possible.
- Clear guidelines of prevention of AWR in patients presenting for acute interventions need to be developed
REFERENCES


APPENDIX I: RESEARCH QUESTIONNAIRE

Serial No. ...........................

To be filled by the research assistant

Patient:

1. AGE    Years ..................... Months......................
2. GENDER .............. 1=Male 2= Female
3. Height ..............................cm  Weight ..............................Kgs
4. RESIDENCE □
5. HIGHEST LEVEL OF EDUCATION ........ 1= no formal education 2= Primary 3= Secondary 4= University/ College
6. TELEPHONE CONTACT □
7. TIME BETWEEN LAST MEAL AND ANAESTHESIA ....... 1= >6 HOURS 2= <6 HOURS

SCHEDULED SURGERY ........................................

SITE OF SURGERY .............................................

ANAESTHESIA

Cadre of anaesthesia provider  Consultant □
               Graduate anaesthesia trainee □
               Diploma anaesthesia trainee □

ASA  1  □  2  □  3  □  4  □

TIME OF INDUCTION:  AM □
                      PM □

INDUCTION AGENTS:  Isoflurane □  Halothane □  Propofol □
                     Remifentanil □  Fentanyl □  Morphine □
                     Pethidine □  Ketamine □  Midazolam □
STP □ Others □

MAINTAINANCE AGENTS: Isoflurane □ Halothane □ Propofol □
Remifentanil □ Fentanyl □ Morphine □
Pethidine □ Ketamine □ Midazolam □
Others □ Nitrous Oxide □

TOTAL GAS FLOWS .......L/MIN.

NEUROMUSCULAR BLOCKER None □ Suxamethonium □

Atracurium □ Cisatracurium □
Others □

TIME OF EMERGENCE ........................................
DURATION OF SURGERY ......................................
DURATION OF ANAESTHESIA .................................
Questionnaire II

Modified Brice Questionnaire

Were you expecting to be completely asleep for this operation (please circle)? YES / NO

1. What is the last thing you remember before going to sleep (please tick one box)?
- Being in the pre-op area
- Seeing the operating room
- Being with family
- Hearing voices
- Feeling mask on face
- Smell of gas
- Burning or stinging in the IV line
- Other [Please write below]:

2. What is the first thing you remember after waking up (please tick one box)?
- Hearing voices
- Feeling breathing tube
- Feeling mask on face
- Feeling pain
- Seeing the operating room
- Being in the recovery room
- Being with family
- Being in ICU
- Nothing
- Other [Please write below]:

3. Do you remember anything between going to sleep and waking up (please tick box)?
- No
- Yes: - Hearing voices
- Hearing events of the surgery
- Unable to move or breathe
- Anxiety/stress
- Feeling pain
- Sensation of breathing tube
- Feeling surgery without pain
- Other [Please write below]:

4. Did you dream during your procedure (please tick box)?
- No
- Yes
- What about [Please write below]:

5. Were your dreams disturbing to you (please tick box)?
- No
- Yes

6. What was the worst thing about your operation (please tick box)?
- Anxiety
- Pain
- Recovery process
- Unable to carry out usual activities
- Awareness
- Other [Please write below]:

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APPENDIX II: CONSENT FOR PARTICIPATION IN RESEARCH

Serial No.………..
Consent explanation.
My name is Dr. Ruth Mbadi. I am doing my postgraduate study in Anesthesia at the University of Nairobi. As part of my course work I am required to perform clinical research and my study is on INCIDENCE OF AWARENESS WITH EXPLICIT RECALL IN PATIENTS UNDERGOING GENERAL ANAESTHESIA AT KENYATTA NATIONAL HOSPITAL.

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 the services you are entitled to in this health facility or other facilities.

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. ____________________________

I will be interviewing individuals who are 18 years and above and have undergone general anaesthesia in Kenyatta national theatres. The purpose of the interview is to find out those who are able to remember anything that happened when they were under anaesthesia. Participants in this research study will be asked questions about the last thing they remember before going to sleep and the first thing they will remember on waking up, if they remember anything in between going to sleep and waking up, any dreams that they had during the procedure and their worst experience about the operation.

There will be approximately 370 participants in this study. We are asking for your consent to consider participating in this study.

If you agree to participate in this study, the following things will happen: You will answer a few questions when fully awake in recovery room and similar questions on day 3 and 7 in the ward. If you will have been discharged by day 3 or 7, we shall conduct the day 7 interview via phone call. The interview will last approximately 5 minutes.

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.

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 you 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 you. 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. It may be embarrassing for you to have to answer questions in public but we will do everything we can to ensure that this is done in a confidential manner. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, recall of unpleasant events may be stressful. In case of complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will handle the situation or refer you when necessary.

The information you provide will help us better understand awareness and anaesthesia and how to prevent this distressing outcome to both patients and anaesthesia providers. This information is a contribution to science and in particular the medical practice. Participating in this study does not have financial implications to you.

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.

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 heard the information read to me. 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** ........................................ ............................................................

**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:** Dr. Ruth Mbadi **Date** ..............................................

**Signature** ..............................................................

For more information contact:
Secretary KNH-ERC, Kenyatta National Hospital, P.O. BOX 20723, Nairobi
Tel : 2726300 Ext. 44102.
Dr. Chokwe 0722 528237
Dr. Gatheru 0721 654 806
Dr. Mbadi 0721 272777
Incidence of Awareness with Explicit Recall in Patients Undergoing General Anaesthesia at Kenyatta National Hospital


Utafiti huu umeidhinishwa na The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. ____________________________

Kwa idhini yako kuna maswali utaulizwa siku ya kwanza, ya tatu na ya saba baada ya operesheni. Ikiwa utapewa ruhusa ya kwenda nyumbani kabla ya kuulizwa maswali za siku zinazofuata utapigiwa simu huko nyumbani. Tunaomba kwa simu huu kuwa utapewa ruhusa ya kwenda kwenda kabla ya kuulizwa maswali za siku zinazofuata. Tunaomba kwa simu huu kuwa utapewa ruhusa ya kwenda kwenda kabla ya kuulizwa maswali za siku zinazofuata.


If you have any questions, please feel free to ask. If you are satisfied with the service you have received, please let us know. If you have any other concerns, please contact us.


If you have any questions, please feel free to ask. If you are satisfied with the service you have received, please let us know. If you have any other concerns, please contact us.


If you have any questions, please feel free to ask. If you are satisfied with the service you have received, please let us know. If you have any other concerns, please contact us.