***Research Report***

# The Prevalence of Accidental Awareness during General Anaesthesia in Obstetric Patients Undergoing Caesarean Section in Pelonomi Tertiary Hospital

## A Cohort study in 2017

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## DECLARATION OF OWN WORK

I, Dr Sello Joseph Mofubelu, declare that the work done and put into this dissertation was carried out by me and in accordance with the requirements of the University of Free State's regulations and Code of Practice for Postgraduate Programme at the university and it has not been submitted for any other academic award. Except where indicated by specific reference in the text, this work is my own work. I have identified all material in this dissertation which is not my own work through appropriate referencing and acknowledgement. Where I have quoted from work of others, I have included the source on the references. Any views expressed in the dissertation are those of the author.

## ACKNOWLEDGEMENT AND DEDICATION

The Pelonomi maternity nursing staff, Department of Anaesthesiology Clinical Assisstants in Pelonomi hospital, as well as the Free State Government Department of Health in general.

## ABBREVIATIONS

a. DOH : Department Of Health
b. HOD : Head of Department
c. AAGA : Accidental Awareness during General Anaesthesia
d. DOA : Depth of Anaesthesia
e. C/S or C/section : Caesarean Section
f. ASA. : American Society of Anaesthesiologist
g. GA : General Anaesthesia
h. NAP-5 : National Audit Programme part 5
i. ANZCA : Australian and New Zealand College of Anaesthetists
j. HIV : Human Immuno-deficiency Virus
k. DVT : Deep Venous Thrombosis
l. IV : Intravenous
m. Pre-op : pre-operative
n. Post-op. : post-operative
o. Intra-op. : intra-operative
p. n : number

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## 1.INTRODUCTION

Accidental awareness is still one of the most common anaesthetic complications experienced around the world and yet one of the most avoidable of the complications. By consensus, Accidental Awareness under General Anaesthesia (AAGA) is defined or described as a state of being aware (with or without pain) while under general anaesthesia when expected to be unconscious.[1]

Previous studies showed the incidence of intraoperative awareness (synonymous with accidental awareness during anaesthesia) to be in the range of 0,13-7% while that of unpleasant dreams to be as high as 17%[23]. There has been a lot of new anaesthetic methods, addition of drugs and sophisticated but not necessarily completely accurate monitors developed to help curb the problem of AAGA. However, the incidence is still unacceptably high, though certainly reduced. Before 1970, anaesthesia used a mixture of Nitrous Oxide ($N_2O$): Oxygen ($O_2$) only in the ratio of 60-70% :40-30% for maintenance of anaesthesia after induction with Sodium Thiopentone 3-4mg/kg or a standard dose of 200-250mg for adults[4]. This anaesthetic technique had AAGA incidence of 4-7% associated with it. The addition of Halothane by Moir after 1970 substantially decreased the incidence to less than 2%.

Maintaining adequate depth of anaesthesia (DOA) has always been universally accepted as the sensitive and accurate way of preventing AAGA. Clinical signs and monitors are used intraoperatively to guide the adequacy of DOA, however several studies have suggested clinical signs to be inadequate and not very sensitive, which led to the development of many monitors to be mentioned later. Intraoperative movement, sweating, lacrimation, coughing, jerking are some of the signs used solely or in conjunction with patients saturation ($SpO_2$), dynamic haemodynamics such as blood pressure (BP) and electrocardiogram (ECG), end-tidal percentage of an inhalational agent used (eg ET Isoflurane) and more rare parameters in developing countries like electroencephalogram (EEG) and Bispectral Index monitor (BIS). The historical monitors/techniques which are still mentioned in the literature like, forehead galvanometry, isolated forearm technique, lower oesophageal motility assessment have since been replaced by the above-mentioned variables[5].

Detecting awareness is not simple. The review article by Ghoneim states that the Modified Brice protocol is still reliable and efficient in detecting intraoperative

awareness[6]. The Brice protocol was developed and introduced by Brice and collegues in 1970, and later modified by Lin and collegues in 1991

After reviewing the fifth National Audit Project (NAP-5) released by the Great Britain and Ireland Royal Colleges Association of Anaesthetists in 2015 and reading about the complications as well as risk factors associated with AAGA, we realized that this is a significant problem, especially in the Caesarean Section population and there is no study of such undertaken or published in Bloemfontein and the rest of South Africa after an extensive literature search of a similar or related studies in the country. Complications described are mostly psychological and can have medico-legal consequences as well. Insomnia, depression, anxiety, fear of future anaesthesia and surgery, and Post-Traumatic Stress Disorder (PTSD) are some of the well described complications of AAGA[7]. In fact, a study by Lennmarken and colleagues showed that 4 out of 9 patients who had experienced awareness developed severe symptoms of PTSD.

There was a study that showed that ASA (American Society of Anaesthesiologist) closed claims (successful) related to awareness was about 2% which was similar to myocardial infarctions and aspirations and had a median payment of about $18.000[8]. So there is also a huge financial loss associated with intraoperative awareness.

In 2015, NAP-5 released data from 329 hospitals around UK whereby there was spontaneous reporting of AAGA. The data was collected from June 1, 2012 and completed in May 31, 2013. This took into consideration (1) first time incidence reported to health care system (2) AAGA according to a definition given above (3) Spontaneous reporting.

The incidence during spontaneous reporting was found to be 1: 20 000 as compared to a 1: 600 (0, 17%) with Brice Questionairre. The most concerning which ended motivating us to undertake our study was, the incidence of AAGA from NAP-5 of overall obstetric patients was 1:1 200 (0,08%) and rising to 1:670 (0,15%) for caesarean sections. It is well known with Brice protocol that in Caesarian Sections the incidence of AAGA is 1:384 (0,23%) which is twice higher than the general population. What was further concerning with the NAP-5 data was the fact that obstetric cases only made up 0,8% of all General Anaesthesia cases of the survey but 10% of all

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reported cases of AAGA. This basically means the incidence of AAGA in obstetric patients is far higher than the general population. It is imperative that we find our own incidence so as we can develop or put means in place to deal with it. Below I will mention the reasons which make us believe that the incidence might be even higher in our population group of obstetric patients undergoing Caesarean Sections. The Australian and New Zealand College of Anaesthetist (ANZCA) recently found an incidence of 0,26%, but this survey used the small numbers[9]. A third of participants in that survey had Depth of Anaesthesia monitoring and this third had no AAGA.

The general identified risk factors for AAGA are very abundant in the South African healthcare practice, which puts us at a very high risk of actually having even a higher incidence of AAGA. The risk factors are divided into:
(1) Patient factors- Female, three times higher than in males, young patients, obesity, difficult airway, previous history of awareness (1,6% predisposal), children and ASA 3/4
(2) Organizational factors like junior anaesthetists, after hours surgery, emergency surgery and
(3) Technical factors such as Use of Thiopentone, rapid sequence induction, use of Neuromuscular blocking agents, drug errors and patients converted from spinal to general anaesthesia.
NAP-5 also emphasizes "mind-the-gap" which is a period between giving intravenous induction agents, intubating the patient and switching or opening the inhalational agent for maintenance of anaesthesia. This period, together with extraction of the baby has been associated with even increased risks of AAGA. The use of thiopentone deserves a special mention as it is associated with an increased risk of AAGA since it is no longer a popular drug amongst the anaesthetist, especially junior staff being less familiar with the drug and its dosages. A dose of 3-5mg/kg increases the risk of AAGA while 5-7mg/kg in Caesarean sections is considered to reduce AAGA from 1,3% to 0,4%. In the UK, 55% anaesthetists admit to hardly ever using or never using thiopentone and 87% admit to using it less than once a month.
From Jan 1, 2014 to Dec 31, 2014 thiopentone was only used on 2 occasions for a caesarian section in Pelonomi Academic hospital. On all but haemodynamic instability caesarian sections (C/S) propofol was the induction agent of choice with Etomidate being used in the former patients. The studies comparing propofol and thiopentone showed lighter planes on EEG of anaesthesia with propofol as compared to thiopentone. A further study suggested increased incidence of maternal awareness

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using propofol as compared to the thiopentone[10]. Propofol has a further disadvantage of long effect-site equilibration time, basically meaning a dose of no less than 2,5mg/kg is recommended in haemodynamically stable patients.
Furthermore, due to its undesirable side effects, even in obstetric patients, $N_2O$ is now out of favour in most surgeries, including C/S. Studies have shown that the use of an inhalational agent and $N_2O$ maintenance decreases the incidence of AAGA. $N_2O$ wasn't used at all in all the C/S on the above-mentioned period in Pelonomi Academic Hospital.

Between Jan 1, 2014 and Dec 31, 2014 there was 2648 C/S done by Pelonomi Academic Hospital which is one half and the biggest C/S centre of the Bloemfontein Academic Hospital, the other half of this being Universitas Academic hospital. Of this number, 381 (14,4%) of them were done under general anaesthesia (GA) with 79 (20,7%) of those being conversion from spinal anaesthesia (SA) to general anaesthesia for one reason or the other. Meaning, an average of 31,7 patients every month get C/Section under general anaesthesia in Pelonomi Hospital.

In the same period mentioned above, in Universitas hospital, the tertiary part of the Bloemfontein Academic Hospital Complex, there was a total of 297 C/Sections and 65 (22%) of them were done under GA with 4 (6%) of them being converted from Spinal anaesthesia to GA. 15,4% (10) of the GA patients were done using Sodium Thiopentone. As is seen, Universitas hospital relatively does more GA patients than Pelonomi but a few of them are actually converted from Spinal as compared to Pelonomi.

## 2.AIM

The aim of the study is to find the incidence of accidental awareness in obstetrics patients undergoing caesarean section under general anaesthesia in the Pelonomi Tertiary hospital

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# 3. METHODOLOGY

## 3.1 STUDY DESIGN

A descriptive observational study

## 3.2 SAMPLE/STUDY PARTICIPANTS

The study will include the first 100 general anaesthesia C/section patients in Pelonomi hospital that meet the inclusion criteria, with or without local/spinal/epidural anaesthesia and both elective and emergency C/sections between July and November 2016

### INCLUSION CRITERIA

Age≥18
ASA 1-3/E E=Emergency
Caesarean Sections (known viable pregnancy)
Informed Consent

### EXCLUSION CRITERIA

Refusal to Participate
ASA >3
Known Psychiatric illness
ICU admission and sedation post-operatively
<18yrs old

## 3.3 MEASUREMENTS

An informed consent will be attained from the viable candidates in the post-operative period through a verbal explanation of the procedure and also what the consent as well as the patient information sheet entails. Then, a patient will be asked to sign this informed consent. A questionnaire (Modified Brice Protocol/Questionnaire, see appendix) will be used to measure the possibility of intraoperative accidental awareness during a general anaesthesia. This will be done postoperatively within 24hrs in the post-natal care unit. The Modified Brice protocol (attached) which

basically has 6 questions as submitted by the Sprint National Anaesthesia Project-1 (SNAP-1) in the UK in their 2014 study will be the one used in our study to detect incidence of AAGA in our setting. This will be done in the form of an interview or self-filling depending on the results of our pilot study but the patient will also have a copy of the questionnaire in her hand should it be in the form of an interview. A pilot study to determine if patients understand how to answer the questionnaire on their own will be contacted.

Spontaneous reporting uncommon and patients might be afraid to report spontaneously with the fear of being described as insane, poor treatment because of complaining or it could just be patient's preference to forget the experience or even lack of information that it is not supposed to happen to be aware intraoperatively. Majority of the community in the Free State public hospitals are not very literate. It is often difficult to get patients' full attention postoperatively in the recovery room as their concentration is usually on more acute complications like pain, postoperative nausea and vomiting (PONV) or fatigue. It is suggested that only 50% of AAGA is usually detected in the post-operative care unit (Recovery room). We will contact our interview within 24hrs of post-operative period, only once before the patient is discharged. The anaesthesiology clinical assistant rotating at maternity theatre will be allowed to also do the interview, but I will collect data from the patients which they cannot get to.

I will ask all the obstetric anaesthesiology registrars to inform me of any general anaesthesia for C/sections that are done immediately after the procedure, whether an interview was done or not. I will also do daily checks of the patients' theatre registry book for any patients I was not informed about for different reasons.

## 3.4 ERRORS IN METHODOLOGY

### *Bias*

Even though we will be measuring an accidental awareness during general anaesthesia, there is always a possibility of inability to recall after anaesthesia. So a recall bias is a possibility in this study. Another possibility is refusal to participate.

### *Variation*

Since measurements will be conducted by multiple researchers, and inter-observer variation might influence the results.

This might be an issue with interpretation of results as well.

## 4. DATA ANALYSIS

The University of Free State Department of Biostatistics will help with analyzing data at the completion of the study. The Frequency Procedure will be the method used for analysis.

A panel of experts in the field of AAGA, namely Profs BJS Diedericks and G Lamacraft and Dr J Lemmer-Malherbe from the Department of Anaesthesiology will also take part in data analysis. They will review the questionnaires' answers and collectively identify possible and definite awareness cases.

## 5. IMPLEMENTATION/RECOMMENDATIONS

As mentioned in the introduction, AAGA can have devastating outcomes for the patients and the anaesthetists. Depending on the results, protocols on how to manage or prevent this can be developed and put into place, emphasis can be put on awareness for this problem, identification of high risk cases can be made easier and therefore better management of such patients.

This study will also be used as part of my MMed final report.

If appropriate, the results can be published and further studies in the country/continent can arise out of this.

## 6. Pilot Study

A pilot study of 5 patients will be contacted prior to the actual study to determine if the patients understand the questionnaire and can actually answer the questionnaire on their own without any guidance by the doctor. This will make data collection more practical if the patients can actually fill up the questionnaire on their own.

## 7. BUDGET

Stationery (questionnaires and informed Consent forms ) will be printed as required. No sponsors necessary. Estimated amount of R500 will be used for stationery

## 8. TIME SCHEDULE

Literature Review : June 2015- February 2016

Protocol writing : December 2015- March 2016

Ethics Committee submission : May 2016

Study Perfomance : July 2016- October 2016

Data Check : while data being collected

Analysis of Data : October 2016- November 2016

Writing Report : October 2016 – November 2016

Completion of Study : November/ DECEMBER 2016

## 9. ETHICAL ASPECTS

There will be an informed consent requested from the patients prior to their participation in the study. Participation will be on voluntary basis after explanation about the study. If the patient wishes not to be involved with the study or requests exclusion after giving informed consent and even partaking in the study, the request would be allowed and their results will not be included. Refusal to partake shall not influence further medical management and general treatment from and by the hospital and its clinical staff members. The technique of anaesthesia given to patients by individual clinicians will not be changed by the study and as a result no particular medication/drug will be recommended and used as part of this particular study.

The patients' rights to health will always be maintained throughout this study and violation of such will not be tolerated by the study team. We will not give out any identity of the patients involved in this study, we vow that it will remain confidential for as long as the study is concerned. Patient's wish to withdraw from the study at any given time will be granted without any threat to their health care.

The patients' interview will be done in private, without anyone else other than the concerned health workers presence. The records will be kept and locked away and would only be accessible by either the patient or the staff involved in this research for privacy purposes. Each patient will get a research specific identification number linked to their names. No names will be used during data interpretation, writing of a report or publication of the results.

Study will only be carried out after approval by the University of Free State Research Ethics Committee

The Free State Government Department of Health will be informed about the study and approval from them will also be necessary.

## 10. REFERENCES


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## APPENDIX A

## INFORMED CONSENT AND PATIENT INFORMATION

## APPENDIX A.1 (ENGLISH)

PRINCIPAL INVESTIGATOR : DR SJ MOFUBELU
STUDY LEADER : DR J LEMMER-MALHERBE

## PURPOSE AND PROCEDURES

The purpose of this study is to find out the incidence of accidental awareness during general anaesthesia within the patients that are undergoing Caesarian Section under general anaesthesia in Pelonomi Academic Hospital

## DURATION OF THE STUDY

July to October 2016, following Ethics committee approval

## RISKS AND BENEFITS

There are no risks related to this study, no drug or intervention will be used during the study. The benefits will be based on the outcomes of the study which will help us with awareness of the problem and better management of the studied problem. This awareness might bring about a change/alteration of our practice relating to the management of general anaesthesia during Caesarian Section, specifically relating to the prevention of accidental awareness in this group. Further studies might emerge from this study to help with prevention and management of the studied problem.

## COSTS AND COMPENSATION

We promise that there will not be any added costs to the patient for participating in this study and we also wish to inform the patient that there will not be any compensations or remunerations for partaking in this study.

## CONFIDENTIALITY

Throughout the whole study period, that is, during data collection, results analysis and publishing, if any, the patient's information will be kept strictly confidential. The patient's personal information will not be shown anywhere on the research sheets other than on this particular document (Consent Form) which will only have the patient's signature as proof of consent to participate in the study.
All records will be safely locked away and kept only for reference purposes.

## VOLUNTARY PARTICIPATION

The patient will voluntarily participate in the study and refusal to participate will be without any sort of penalty whatsoever, and also the patient can terminate participation at any point of the research for any reason without fear of exclusion from health access. All the entitled benefits to health care will stand regardless of the patient's decision regarding the study.

## SIDE EFFECTS

This study poses no side effects and the anaesthesia practice will be carried out the same way as prior to the start of research and will be essentially the same for participants and non-participants

## RESULTS

This study's results will be used in an MMED report of Dr SJ MOFUBELU as well as might be published in an appropriate journal. Also, the patient will be allowed access to their own as well as the study's results once the study is completed should they wish to.

## QUESTIONS

For any questions, complaints or concerns regarding the study, Dr SJ MOFUBELU can be contacted on 0748935255/jayjaysello@yahoo.com at the patient's convenience.

By signing below, I give informed consent for participation in the study

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SIGNATURE OF PATIENT DATE

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If Applicable, signature of Parent, Guardian Or Legally Authorised Representative DATE

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SIGNATURE OF WITNESS DATE

---

SIGNATURE OF PERSON TAKING CONSENT DATE

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Signature of Translator (if necessary) DATE

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Signature of the Interviewer Date

APPENDIX A.2 (SOUTH SOTHO)

**TUMELLO KA KUTLWISISO ( Informed Consent)**

**Mmatlisisi - Dr SJ Mofubelu**

**Moetapele Wa Dipatlisiso – Dr J Lemmer-Malherbe**

**MAIKEMISETSO A PATLISISO ENA**

Maikemisetso a patlisiso ena ke ho fumana hore boteng ba Tlhokomelo ka Tshohanyetso (Accidental Awareness) nakong eo mokudi a rabaditsweng ka dithetefatsi bakeng sa opereishene ya hae ya ho pepa sepetleleng sa Pelonomi bo bokae.

**NAKO YA DIPATLISISO**

Phupu – Mphalane ( June to October) 2016

**DIKOTSI KAPA MENYETLA YA HO NKA KAROLO**

Ha ho na kotsi e amangwang le dipatlisiso tsena, ha ho dithetefatsi tse tla sebediswa ho mokudi nakong ya dipatlisiso tsena. Ho nka karolo ha hao ho tla thusa hore re thole le ho tseba ho hlokomela setla morao sena se sa tlamehang ho etsahala. Re ka kgona le hore re fetole mokgwa wa ho robatsa bakudi ba mmeleng ba pepang ebang ho hlokahahala ho ya ka dipheto tsa dipatlisiso tsena. Ho ka kgonahala le hore ho hlahelle dipatlisiso tse ding ho tswa ho ena eo o nkang karolo ho yona.

**MEPATALO**

Re o tshepisa hore ho nka karolo ha hao dipatlisisong tsena ha ho na eketsa seo o se lefang ebang o lefa kwano sepetlele. Ha ho na ba le tlhatso ya mahlo bakeng sa ho nka karolo dipatlisisong tsena. Mokudi ha a patale ebile ha a patallwe letho ho nka karolo mona.

**LEKUNUTU**

Nakong yohle ya dipatlisiso tsena, tsohle tse amanang le mokudi di tla behwa e le lekunutu. Ha ho na moo mabitso kapa dilemo, tsa lelapa le tse amanang le makunutu a mokudi di tla hlahiswa teng. Ho tekena ha hao pampiring ena ha ho bolele hore tsohle tsa hao di tla phatlallatswa. Tokomane ena ke yona feela e nang le tsa hao tsa boitsebiso. Tsohle tse amanang le dipatlisiso tsena di tla kwallwa phaposing e hlokomelehileng, di bolokwe komputeng mme di tla bulelwa feela batho ba tsamaisang dipatlisiso tsena, le wena ha o hloka.

**HO NKA KAROLO KA BOIKGETHELO**

Mokudi o nka karolo ka boikgethelo, ebang o sa batle ho nka karolo kapa o kgetha ho ikgula dipatlisisong tsena ka mora hore o dumele ho nka karolo, o tla dumellwa ho etsa jwalo nakong e nngwe le e nngwe eo o batlang ho etsa jwalo. Mokudi ha a na lahlehelwa ke ditokelo tsohle tseo e leng tsa hae tsa Bophelo Bo Botle. O tla tshwarwa le ho hlokomelwa ka ho tshwana le motho a sa nkeng karolo dipatlisisong tsena.

**DITLA MORAO**

Ha ho ditla morao tse tsamayang le dipatlisiso tsena. Tshebetso ka kamoreng ya opereishene e tla tshwana mahareng a batho ba nkang karolo le bao ba sa nkeng karolo.

**DIPHETHO**

Diphetho di tla sebediswa ho ngola lengolo la dipatlisiso tsa dithuto tse phahameng (MMed) tsa Dr SJ Mofubelu, le hore di phatlalatswe bukeng tsa dipatlisiso ebang ho dumelleha ebile ho kgonahala.

Bakudi ba ka thola diphetho tsa dipatlisiso tsena ebang ba batla ha ho se ho phethehile.

**DIPOTSO**

Lebisa dipotso tsa hao ho mophethi wa dipatlisiso, Dr SJ Mofubelu, nomorong ya 0748935255/jayjaysello@yahoo.com nakong e nngwe le e nngwe feela.

Ka ho tekena ka fatshe ka mona, o dumela ho nka karolo dipatlisisong tsena le hore o utlwisisa tse ka hodimo.

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Tekeno ka mokudi Letsatsi

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Tekeno ka Mohlokomedi Letsatsi

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Tekeno ka Paki Letsatsi

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Tekeno ka mmatlisisi/mmotsi Letsatsi

Ke lebohela ho nka karolo ha hao dipatlisisong tsena tsa rona.

APPENDIX B

## LETTER OF APPROVAL BY THE HEAD OF DEPARTMENT AND RELATIVE AUTHORITIES

## STUDY TOPIC

The incidence of Accidental Awareness during General anaesthesia in Obstetrics patients undergoing Caesarean Section in the Bloemfontein Academic Hospital Complex

## METHODOLOGY

Observational prospective descriptive study

## DURATION

July 2016 to October 2016

Principal Researcher : Dr SJ MOFUBELU ( jayjaysello@yahoo.com )
Study Leader : Dr J LEMMER-MALHERBE ( ja9malherbe@gmail.com )

| Anaesthesiology Department HOD | HOSPITAL CEO |
|---|---|
| Name ..... | Name ..... |
| Signature ..... | Signature..... |
| Date ..... | Date..... |

APPENDIX C

PROTOCOL SUMMARY

PRINCIPAL INVESTIGATOR : DR SJ MOFUBELU
STUDY LEADER : DR J LEMMER-MALHERBE

PURPOSE AND PROCEDURES

The purpose of this study is to find out the incidence of accidental awareness during general anaesthesia within the patients that are undergoing Caesarian Section under general anaesthesia in Pelonomi Academic Hospitals

DURATION OF THE STUDY

June to October 2016, following Ethics committee approval

STUDY TYPE

Descriptive prospective study

Methods

Questionnaire post-operatively, anytime between immediately post-Operatively and within 24hours of operation

POTENTIAL ADVANTAGES

Awareness regarding AAGA and possible change in practice to prevent it may be a call for more intraoperative monitors

PARTICIPATION

Totally voluntary and withdrawal allowed at any time of the study without loss of health care entitled benefits

CONFIDENTIALITY

Patient's information will be kept completely confidential during the whole study period

## PUBLICATION OF RESULTS

The research's results might be publish in an appropriate journal and will also be used for an MMED report for Dr MOFUBELU. The patient will be allowed access to the results of the research should the need them.

## COMPENSATION

No compensation or remuneration for the involved participants.

APPENDIX D.

D.1 ORIGINAL

## D.2 TRANSLATED QUESTIONNAIRE

### SOUTH SOTHO VERSION OF MODIFIED BRICE PROTOCOL (TRANSLATED)

**17. O ne o lebelletse hore o tla robatswa ( ka ho otlolloha) ha o thola oporeishene ya ena ?**

Tjhe ☐ Eya ☐

**18. Ntho ya ho qetela eo o e hopolang pele o robala ke e feng (Kgetha/tshwaya bokoso le le leng) ?**

- ke emetse ho kena ka kamoreng ya Oporeishene ☐ - ke bona kamore ya oporeishene ☐
- ke na le ba lelapa ☐ - ke utlwa mantswe ☐
- ke utlwa maske wa ho hema sefahlehong ☐ - monko wa kgase ☐
-ke utlwa motjheso ka mothapong o kentseng tiripi ☐ -ha e sebetse ☐
- enngwe: (ngola ka fatshe) ☐

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**19. Ntho ya pele eo o e hopolang ha o qeta ho tsoha (kgetha/tshwaya bokoso le leng)?**

-ke utlwa mantswe ☐ -ke utlwa peipi ya ho hema ☐
-ke utlwa maske wa ho hema sefahlehong ☐ -ke utlwa bohloko ☐
-ke bona kamore ya oporeishene ☐ -ke le kamoreng ya ho hlaphohelwa ☐
-Ke na le ba lelapa ☐ -ke le yuniting ya tlhokomelo e phahameng ☐
-letho ☐ -ha e sebetse ☐
-enngwe (ngola ka fatshe) ☐

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**20. Ho na le seo o se hopolang mahareng a ho robatswa le ha o tsoha (kgetha/tshwaya bokoso le le leng)?**

-ke utlwa mantswe ☐ -ke utlwa oporeishene e tswela pele ☐

-ke sa kgone ho tsitsinyeha kapa ho hema ☐ -ho tshoha/ngongoreha ☐

-ke utlwa bohloko ☐ -ke utlwa peipi ya ho hema ☐

-ke utlwa ke sewa ntle le ho utlwa bohloko ☐ -ha e sebetse ☐

-enngwe (ngola ka fatshe) ☐

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**21. O bile le ditoro ka nako ya oporeishene ya hao (kgetha/tshwaya bokoso le le leng)?**

-Tjhe ☐ -Eya ☐

Ka eng? (ngola ka fatshe)

---

**22. Ditoro tseo o bileng le tsona di ya o tshwenya (kgetha/tshwaya bokoso le le leng)?**

- Tjhe ☐ - Eya ☐

**23. Ntho e mpe ka ho fetisisa mabapi le oporeishene ya hao ke efeng (kgetha/tshwaya bokoso le le leng)?**

-ho tshwenyeha ☐ - ho utlwa bohloko ☐

-nako ya tlhaphohelo ☐ -ho se kgone ho phetha mesebetsi ya mehla ka tlwaelo ☐

-tlhokomelo(ho utlwa diketsahalo) nakong ya oporeishene ☐

-enngwe (ngola ka fatsh ☐

# *CHAPTER 2 : THE ARTICLE*

## a. ABSTRACT


### *INTRODUCTION*

The study investigated the prevalence of accidental awareness during general anaesthesia (AAGA) in obstetric patients undergoing Caesarean Section. The incidence for general surgical patients is known to be about 0,13-7%. Obstetric anaesthesia significantly increases the risk of accidental awareness. Depth of anaesthesia monitoring use is not readily available and has not been shown to completely eliminate AAGA.

### *METHODS*

It was a cohort study with a sample of 36 patients who had general anaesthesia for their Caesarean section. The Modified Brice Protocol/Questionnaire was used on all patients within 48hrs of the post-operative period. The Frequency procedure was used for analysis of data.

### *RESULTS*

The study showed that 11,1%, which is higher than what has been reported in other similar studies and is 4 of the 36 patients sampled, had experienced accidental awareness during their anaesthesia and operation. The feeling of an endotracheal tube, hearing events of surgery and feeling pain were the ones remembered the most during the anaesthesia.

### *CONCLUSION*

Obstetric anaesthesia increases the risk of accidental awareness during general anaesthesia. The incidence in Pelonomi hospital's obstetric patients undergoing Caesarean Section is at 11,1%.


## b. LITERATURE REVIEW

Accidental awareness is still one of the most common anaesthetic complications experienced around the world and yet one of the most avoidable of the complications. By consensus, Accidental Awareness under General Anaesthesia (AAGA) is defined or described as a state of being aware (with or without pain) while under general anaesthesia when expected to be unconscious.[1]

Previous studies showed the incidence of intraoperative awareness (synonymous with accidental awareness during anaesthesia) to be in the range of 0,13-7% while

that of unpleasant dreams to be as high as 17%[2,3]. There has been a lot of new anaesthetic methods, addition of drugs and sophisticated but not necessarily completely accurate monitors developed to help eliminate the problem of AAGA. However, the incidence is still unacceptably high, though certainly reduced. Before 1970, anaesthesia used a mixture of Nitrous Oxide ($N_2O$): Oxygen ($O_2$) only in the ratio of 60-70% :40-30% for maintenance of anaesthesia after induction with Sodium Thiopentone 3-4mg/kg or a standard dose of 200-250mg for adults[4]. This anaesthetic technique had AAGA incidence of 4-7% associated with it. The addition of Halothane by Moir after 1970 substantially decreased the incidence to less than 2%.

Maintaining adequate depth of anaesthesia (DOA) has always been universally accepted as the sensitive and accurate way of preventing AAGA. Clinical signs and monitors are used intraoperatively to guide the adequacy of DOA, however several studies have suggested clinical signs to be inadequate and not very sensitive, which led to the development of many monitors to be mentioned later. Intraoperative movement, sweating, lacrimation, coughing, jerkings are some of the signs used solely or in conjunction with patients' saturation ($SpO_2$), dynamic haemodynamics such as blood pressure (BP) and electrocardiogram (ECG), end-tidal percentage of an inhalational agent used (eg ET Isoflurane) and more rare variables in developing countries like electroencephalogram (EEG) and Bispectral Index monitor (BIS). The historical monitors/techniques which are still mentioned in the literature like, forehead galvanometry, isolated forearm technique, lower oesophageal motility assessment have since been replaced by the above-mentioned parameters[5].

Detecting awareness is not simple. The review article by Ghoneim states that the Modified Brice protocol is still reliable and efficient in detecting intraoperative awareness[6]. The Brice protocol was developed and introduced by Brice and colleagues in 1970, and later modified by Lin and colleagues in 1991

After reviewing the fifth National Audit Project (NAP-5) released by the Great Britain and Ireland Royal Colleges Association of Anaesthetists in 2015 and discovering that there is no study of such undertaken or published in Bloemfontein and the rest of South Africa after an extensive literature search of similar or related studies in the country. Complications described are mostly psychological and can have medico-legal consequences as well. Insomnia, depression, anxiety, fear of future anaesthesia and surgery, and Post-Traumatic Stress Disorder (PTSD) are some of the well described complications of AAGA[7]. In fact, a study by Lennmarken and colleagues showed that

4 out of 9 patients who had experienced awareness developed severe symptoms of PTSD.
There was a study that showed that ASA (American Society of Anaesthesiologist) closed claims (successful) related to awareness was about 2% which was similar to myocardial infarctions and aspirations and had a median payment of about $18.000[8]. So, there is also a huge financial loss associated with intraoperative awareness.

In 2015, NAP-5 released data from 329 hospitals around United Kingdom whereby there was spontaneous reporting of AAGA. The data was collected from June 1, 2012 and completed in May 31, 2013. This took into consideration (1) first time incidence reported to health care system (2) AAGA according to a definition given above (3) Spontaneous reporting.
The incidence during spontaneous reporting was found to be 1: 20 000 as compared to a 1: 600 (0, 17%) with Brice Questionnaire. The most concerning part that motivated us to undertake our study was, the incidence of AAGA from NAP-5 of overall obstetric patients was 1:1 200 (0,08%) and rising to 1:670 (0,15%) for caesarean sections. It is well known that with Brice protocol used in Caesarean Sections the incidence of AAGA is 1:384 (0,23%) which is twice higher than the general population[1,11]. What was further concerning with the NAP-5 data was the fact that obstetric cases only made up 0,8% of all General Anaesthesia cases of the survey but 10% of all reported cases of AAGA. This means the incidence of AAGA in obstetric patients is higher than in the general population. It is imperative that we find our own incidence so as we can develop or put means in place to deal with it. Below are the reasons which made us believe that the incidence might be higher in our population group of obstetric patients undergoing Caesarean Sections under general anaesthesia. The Australian and New Zealand College of Anaesthetist (ANZCA) recently found an incidence of 0,26%, but this survey used the small numbers[9]. A third of participants in that survey had Depth of Anaesthesia monitoring and this third had no AAGA, with this being said, monitoring depth of anaesthesia seems to be inadequate as a measure to eliminate AAGA.

The general identified risk factors for AAGA are very abundant in the South African healthcare practice, which puts us at a very high risk of actually having a higher incidence of AAGA. The risk factors are divided into:
(1) Patient factors- Female, three times higher than in males, young patients, obesity, difficult airway, previous history of awareness (1,6% predisposal), children and ASA 3/4

(2) Organizational factors like junior anaesthetists, after-hours surgery, emergency surgery and

(3) Technical factors such as Use of Thiopentone, rapid sequence induction, use of Neuromuscular blocking agents, drug errors and patients converted from spinal to general anaesthesia.

NAP-5 also emphasized "mind-the-gap" which is a period between giving intravenous induction agents, intubating the patient and switching or opening the inhalational agent for maintenance of anaesthesia. This period, together with extraction of the baby has been associated with even increased risks of AAGA. The use of thiopentone deserves a special mention as it is associated with an increased risk of AAGA since it is no longer a popular drug amongst the anaesthetist, especially junior staff being less familiar with the drug and its dosages. A dose of 3-5mg/kg increases the risk of AAGA while 5-7mg/kg in Caesarean sections is considered to reduce AAGA from 1,3% to 0,4%. In the United Kingdom, 55% anaesthetists admitted to hardly ever using or never using thiopentone and 87% admitted to using it less than once a month.

From Jan 1, 2014 to Dec 31, 2014 thiopentone was only used on 2 occasions for a caesarean section in Pelonomi Academic hospital. On all but haemodynamic instability caesarean sections (C/S or C/section) propofol was the induction agent of choice with Etomidate being used in the former patients. The studies comparing propofol and thiopentone showed lighter planes on EEG of anaesthesia with propofol as compared to thiopentone. A further study suggested increased incidence of maternal awareness using propofol as compared to the thiopentone[10]. Propofol has a further disadvantage of long effect-site equilibration time, basically meaning a dose of no less than 2,5mg/kg is recommended in haemodynamically stable patients.

Furthermore, due to its undesirable side effects, even in obstetric patients, $N_2O$ is now out of favour in most surgeries, including Caesarean Sections. Studies have shown that the use of an inhalational agent and $N_2O$ maintenance decreases the incidence of AAGA. $N_2O$ was not used at all in all the Caesarean Section on the above-mentioned period in Pelonomi Academic Hospital.

Between Jan 1, 2014 and Dec 31, 2014 there were 2648 Caesarean Sections performed at Pelonomi Academic Hospital which is part of and the biggest Caesarean Sections centre of the Bloemfontein Academic Hospital, the other part of this being Universitas Academic hospital. Of this number, 381 (14,4%) of them were done under general anaesthesia (GA) with 79 (20,7%) of those being conversion from spinal anaesthesia (SA) to general anaesthesia. Meaning, an average of 31,7 patients every month got Caesarean Sections under general anaesthesia in Pelonomi Hospital in that year.

In the same period mentioned above, in Universitas hospital, the tertiary part of the Bloemfontein Academic Hospital Complex, there was a total of 297 Caesarean Sections and 65 (22%) of them were done under GA with 4 (6%) of them being converted from Spinal anaesthesia to GA. About 10 patiets, 15,4% of the GA patients were done using Sodium Thiopentone. As is seen, Universitas hospital relatively does more GA patients than Pelonomi but a fewer of them are actually converted from Spinal anaesthesia as compared to Pelonomi hospital.

## c. AIM

The aim of this study was to find the incidence of accidental awareness in obstetrics patients undergoing caesarean section under general anaesthesia in the Pelonomi Tertiary hospital

## d. METHODS

This was a cohort study. The study included 36 patients who had C/section under general anaesthesia in Pelonomi hospital who met the inclusion criteria, with or without local/spinal/epidural anaesthesia and both elective and emergency C/sections between February 2017 and May 2017. All patients were aged ≥18yrs, ASA 1-3/E E=Emergency, Caesarean Sections (known viable pregnancy) were done and Informed Consent was attained on all of them. No patient was excluded according to the criteria, there was however, 1 patient who could not be found for an interview after her operation, it was later discovered that the patient was sent over to Universitas hospital after her operation for high care post-operative management, so this patient was recorded as missed.

A questionnaire, Brice Protocol/Questionnaire (attached) was used to measure the possibility of intraoperative accidental awareness after a general anaesthesia. This was done postoperatively within 48hrs in the post-natal care unit. All the interviews were done by the primary researcher.

Data analysis and statistics was done by University of Free State's Department of Biostatistics. Data was entered manually and verified. Double data entries of questionnaires were done. The Frequency Procedure (Freq Proc) was used to create data tables with statistics and results. The study was only carried out after approval by the University of Free State Research Ethics Committee, as well as approval by the Free State Government Ethics committee.

## e. RESULTS

*Table 1. Patient Demographics and Clinical Data*

| **Race** | | n (36) |
|---|---|---|
| Black | 97,2% | (35) |
| Coloured | 2,8% | (1) |
| **Occupation** | | |
| Unemployed | 50% | (18) |
| **Highest Qualification** | | |
| Matric | 60% | (21) |
| Others | 40% | (14) |
| **Marital status** | | |
| Unmarried | 52,8% | (19) |
| Married | 13,9% | (5) |
| Living Together | 33,3% | (12) |
| **Mean Age (yrs)** | 28 | (36) |
| Weight (kg) | 84,8 | (35) |
| Height (m) | 1,6 | (35) |
| **Chronic illnesses** | | |
| Hypertension | 8,3% | (3) |
| HIV | 8.3% | (3) |
| Meningitis | 2,8 % | (1) |
| DVT | 2,8% | (1) |

*Table 1 abbreviations*

DVT= Deep Venous Thrombosis HIV= Human Immuno-Deficiency Virus

Yrs= years kg= kilogram m= meter

Table 1 shows the patients' demographics and clinical data. There was a total of 36 patients enrolled with one patient missed throughout the study period. About 97% of the patients were black with the rest being coloured, no any other race was seen in this study. Most patients had completed matric (60%), while the other percentage was made up of either education beyond high school or non-matriculants with half of the study sample

HOSPITAL NUMBER.....

CASE NUMBER.....

**Mark the appropriate block with a X or write your answer on the space provided.**

For Office Use

1-3

1.1 Dat of surgery dd/mm/yy).../...../..... 4-9

1.2 Date questionnaire done dd/mm/yy).../...../..... 10-15

d d m m y y

2. what is your race

| black(1) | white(2) | asian (3) | coloured(4) | others (5) |
|---|---|---|---|---|

16

3. What is your age?

.....year 17-18

4. What is your occupation? ..... 19-20

5. What is your highest qualification?..... 21-22

6. What is your birthdate?(dd/mm/yy)...../...../..... 22-28

d d m m y y

7. What is your marital status?

| | |
|---|---|
| 1 | Unmarried |
| 2 | Married/Traditional marriage |
| 3 | Divorced/Separated |
| 4 | Widow/Widower |
| 5 | Living together |

29

8. What is your home language?

| | |
|---|---|
| 1 | Afrikaans |
| 2 | English |
| 3 | Sotho |
| 4 | Tswana |
| 5 | Xhosa |
| 6 | Zulu |
| 7 | Other, specify..... |

30

9. What is your weight? .....Kg 31-35

10. What is your length? .....cm 36-38

11. Existing illnesses

..... 39-40

..... 41-42

..... 43-44

..... 45-46

12. What chronic medication are you taking

..... 47-48

..... 49-50

..... 51-52

14 How many weeks were you pregnant before delivery? 54

..... Weeks

How many children do you have?

.....

Any previous operations before this one?

YES

NO

E QUESTIONS ON THE NEXT PAGE RELATE TO THE
RGERY YOU JUST HAD
QUESTIONS 17-23

.....

☐ 55

☐ 56.

# MODIFIED BRICE QUESTIONNAIRE

**17. Were you expecting to have a general anaesthetic (be completely asleep) for this operation?** No ☐ Yes ☐

**18. What is the last thing you remember before going to sleep (please tick one box)?**

-Being in the pre-operative area ☐ -Seeing the operating room ☐
-Being with family ☐ -Hearing voices ☐
-Feeling mask on face ☐ -Smell of gas ☐
-Burning or stinging in the IV line ☐ -Not applicable ☐
-Other [Please write below]:

---

**19. 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 the intensive care unit ☐
-Nothing ☐ -Not applicable ☐
-Other [Please write below]:

---

**20. 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 ☐ -Not applicable ☐
-Other [Please write below]

---

**21. Did you dream during your procedure (please tick box)?**

-No ☐ -Yes ☐
-What about [Please write below]:

---

**22. Were your dreams disturbing to you (please tick box)?**

-No ☐ -Yes ☐

**23. 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]:

---

unemployed. Just above half of the patients were unmarried with 14% married. The mean age was 28yrs old with a range of 18yrs to 39yrs of age. Hypertension and HIV were the most common chronic illnesses, as expected in this category, both at 8,3%. The other relevant diseases were meningitis and DVT, one being in 2 of the other patients. One of the HIV positive patients was the one with Meningitis. There were not any post-dates parturients in the study but a couple of preterm patients, close to 10% had not completed 37 weeks of gestation. In this group, 41,7% of the patients were primigravidae, with 36% on their second pregnancy. Of the 36 patients, 44,4% had previous operations before, being a Caesarean Section or another operation.

All 36 patients reported that they had expected to be completely asleep during their operation as informed by the anaesthetist responsible.

We used the Modified Brice Questionnaire. Table 2.1 to 2.6 show results of answers to a Modified Brice questionnaire(attached).

TABLE 2.1 Last thing remembered before going to sleep

| ***Question*** | ***Frequency (n)*** | ***Percent %*** | ***Cumulative Frequency (n)*** | ***Cumulative Percent %*** |
|---|---|---|---|---|
| 1.Being in the preoperative area | 3 | 8,33 | 3 | 8,33 |
| 2.being with family | 0 | 0 | | |
| 3.feeling mask on face | 7 | 19,44 | 10 | 27,78 |
| 4.burning or stinging in the IV line | 4 | 11,11 | 14 | 38,89 |
| 5.nothing | 3 | 8,33 | 17 | 47,22 |
| 6.seeing the operating room | 1 | 2,78 | 18 | 50 |
| 7.hearing voices | 9 | 25 | 27 | 75 |
| 8.smell of gas | 9 | 25 | 36 | 75 |
| 9.other | 0 | 0 | | |

From the above table (table2.1), Hearing voices and the smell of gas were the two most common things remembered about pre-anaesthesia, each contributing 25% of the things remembered before anaesthesia. None of the patients reported remembering being with

the family. Feeling the mask on the face and burning in the intravenous line were next common things, with the latter having 11,1% and former having 19,4%.

TABLE 2.2 First thing remembered after waking up

| ***Question*** | ***Frequency(n)*** | ***Percent %*** | ***Cumulative frequency (n)*** | ***Cumulative percent %*** |
|---|---|---|---|---|
| 1.hearing voices | 2 | 5.56 | 2 | 5.56 |
| 2.feeling mask on face | 4 | 11.11 | 6 | 16.67 |
| 3.seeing the operative room | 1 | 2.78 | 7 | 19.44 |
| 4.being with family | 0 | 0 | | |
| 5.nothing | 23 | 63.89 | 30 | 83.33 |
| 6.feeling breathing tube | 1 | 2.78 | 31 | 86.11 |
| 7.feeling pain | 2 | 5.56 | 33 | 91.67 |
| 8.being in the recovery room | 3 | 8.33 | 36 | 100 |
| 9.being in ICU | 0 | 0 | | |
| 10.other | 0 | 0 | | |

From table 2.2, about the first thing they remembered after waking up, most patients (63,9%) reported to have remembered nothing immediately after waking up. Those that remembered something, most common thing remembered was feeling a mask on the face, which was 11% of them, followed by remembering having been in the recovery room with 8,33% and both hearing voices and feeling pain at 5,56% each. There is a patient that remembered having a breathing tube and one who remembered seeing the operative room, each at 2,78%.

TABLE 2.3 Remembering anything between going to sleep and waking up.

| | ***FREQUENCY(n)*** | ***PERCENT %*** | ***CUMULATIVE FREQUENCY (n)*** | ***CUMULATIVE PERCENT %*** |
|---|---|---|---|---|
| NO | 32 | 88.89 | 32 | 88.89 |
| YES | 4 | 11.11 | 4 | 11.11 |

TABLE 2.3.1 What was remembered

| ***WHAT DO YOU REMEMBER?*** | ***FREQUENCY (n)*** | ***PERCENT %*** | ***CUMULATIVE FREQUENCY (n)*** | ***CUMULATIVE PERCENT %*** |
|---|---|---|---|---|
| 1.hearing voices | 1 | 25 | 4 | 100 |
| 2.unable to move or breathe | 0 | 0 | 0 | 0 |
| 3.feeling pain | 1 | 25 | 4 | 100 |
| 4.feeling surgery without pain | 1 | 25 | 4 | 100 |
| 5.hearing events of surgery | 1 | 25 | 4 | 100 |
| 6.anxiety/stress | 1 | 25 | 4 | 100 |
| 7.sensation of breathing tube | 2 | 50 | 4 | 100 |
| 8.other | 0 | 0 | | |

TABLE 2.4. Dreams during the procedure

| ***DID YOU DREAM*** | ***FREQUENCY (n)*** | ***PERCENTAGE %*** |
|---|---|---|
| No | 36 | 100 |
| Yes | 0 | 0 |

TABLE 2.5 Worst thing about the operation

| | FREQUENCY (n) | PERCENT % | CUMULATIVE FREQUNCY (n) | CUMULATIVE PERCENT % |
|---|---|---|---|---|
| 1.anxiety | 11 | 30.56 | 11 | 30.56 |
| 2.recovery process | 4 | 11.11 | 15 | 41.67 |
| 3.awareness | 3 | 8.33 | 18 | 50 |
| 4.pain | 12 | 33.33 | 30 | 83.33 |
| 5.unable to carry out usual activities | 6 | 16.67 | 36 | 100 |
| 6.other | 0 | 0 | | |

With the main question at hand, table 2.3 shows that 4 of the 36 patients (11,1%) reported to remember something regarding the events of the operation and/or

anaesthesia between going to sleep and waking up. Of the 4 patients, 2 remembered the sensation of a breathing tube (50%), while a patient having a sensation of being unable to move or breathe was the only thing not mentioned by either of the 4 patients (TABLE 2.3.1). However, none of these particular patients reported any dreams during the operation (TABLE 2.4). Post-operative pain (33.3%) and pre-operative anxiety (30.5%) were reported as the leading worst things about the operation, and 3 patients (8,3%) reported Awareness as the worst thing about their operations (TABLE 2.5). This was 3 of the 4 patients (75%) that had intraoperative awareness, while the other patient's worst thing about the operation was pain, like most of the study patients. The recovery process as the worst thing about the operation made up 11,1%, which was 4 of the patients while inability to carry out activities was in 16,6% of the patients.

## f. DISCUSSION

First and foremost, due to delay in acquiring permission from DOH Ethics committee, the study's time frame changed to only after approval by the DOH which was in January of 2017. Study commenced the following month after that till four months later (May 2017). No pilot study done due to time constraints and only one interviewer did the questioning so no risk of inter-observer bias as it was initially mentioned during the protocol.

The obstetrics department in Pelonomi Hospital is intended mostly for moderate and some of the high-risk obstetrics patients, e.g PreEclampsia and Eclampsia, Previous C/section, Teenage pregnancy, class 3 obesity pregnant patients, advanced maternal age and others. They sometimes also see high risk patients, e.g HELLP Syndrome, Gestational Diabetes amongst others. Walk ins and unbooked patients are also very common in this hospital. Usually, majority of the patients seen are the economically disadvantaged patients. As seen in Table 1 above, patients are predominantly black and unemployed, with only a few married. These are some of the issues which were taken into consideration when consenting and doing the interview on these patients.
Pregnancy-induced hypertension (as seen from the doctor's notes as well as informed by the patient) and HIV (verbal confirmation by the patient) were the two common diseases and this was not a surprise since it is a known trend amongst the pregnant patients. Sub-Saharan Africa has 35% prevalence of teenage pregnancy and a HAST (HIV/AIDS, STI and TB) study by G Mchunu et.al on Adolescent pregnancy and Associated factors in South African Teenagers showed a 7,4% HIV prevalence[13], while our study showed an 8,3% prevalence, even though it was not only looking at pregnant teenagers. Both these diseases can influence the choice of anaesthesia, as well as the timing of delivery if the patients have to deliver by operation. Those patients that had both these diseases were

on treatment for them. The patient that had meningitis was on treatment for it, and there was no history of depreciation in mental status, confirmed during interview, that is for example confusion, drowsiness, disorientation and others prior to delivery, immediately after delivery or when seen for questionnaire, so was included in the study.
None of the 44,4% patients with previous operations voluntarily reported anaesthetic awareness on their earlier operations.
From the Modified Brice questionnaire, the first question to ask is if a patient expected to be completely asleep during their operation. All the patients (100%) answered positively to this question, mentioning that once the anaesthetist chose GA as a mode of anaesthesia, they understood that they would be completely unaware of the proceedings, and a consent was signed as such. From table 2.1, it seems a majority of patients remembered some of the last things done to them prior to Guedel's stage 2 of anaesthesia, that is, the smell of gas, hearing voices and burning or stinging in the IV line. This is possibly because obstetrics patients are all pre-oxygenated with 80-100% oxygen for 3 minutes before IV administration of anaesthetics, hence the smell. Stinging or burning in the IV line is a result of Propofol, which is known to burn in the vein on administration. The usual rule of theatres that states that there should be SILENCE IN THEATRE might have been breached in our patients, and possibly with any other patient who goes to theatre because most of them heard voices before going to sleep, meaning silence was not maintained. A speculative reason for none of the patients remembering having been with the family is based on the observation made that families are usual not present shortly before the patient is taken into theatre. This is an observation made about this particular hospital.
Majority of the patients (63,9%) had amnesia about the perioperative events, which is not a surprise as balanced anaesthesia seeks to achieve this, together with muscle relaxation, hypnosis, analgesia and anxyolysis. A feeling of a mask on the face was the most remembered first thing after waking up, at 11,1%. This was closely followed by remembering having been in the recovery room as well as having post-operative pain. There are 2 patients who also mentioned hearing voices as the first thing they remembered after waking up. However, the Questionnaire does not specify if it should be pre-operative, intra-operative or post-operative event but all the questions allowed answers from any of those anaesthetic periods.

This study revealed a significantly high incidence of AAGA in pregnant patients having C/section as 11,1% of the patients reported some awareness. The 2 different patients reported a feeling of the endotracheal tube, hearing events of the surgery, feeling surgery without pain, feeling pain and hearing voices as other things they remember between

going to sleep and waking up. No patient had a feeling of being unable to breathe or to move. This shows a dominant muscle relaxant over inadequate hypnosis did not play a major part in these patients, which could be a devastating complication. A patient was allowed to give more than one answer in this category. This is the most important part of the questionnaire as it is the one actually answering our question and any positive answer on this one is taken as significant and influential on the statistics.

Literature search had not showed a study with AAGA, even in pregnant patients, with an incidence this high. The incidence is reported to be between 0,13-7%. The latest on this study, NAP5 in UK, showed an incidence of 0,15%, but this was done on spontaneous reporting. It is known that with the use of Modified Brice questionnaire, the incidence in obstetric patients rises to 0,23%. ANZCA in Australia and New Zealand also recently found the incidence to be 0,26%, still lower than ours. We looked at a few possible explanations for these significant discrepancies in our patients and their patients. As mentioned during the introduction, we expected our incidence to be slightly higher due to possession of a majority of risk factors for AAGA in our setting. On top of the risk factor list is the junior staff. Pelonomi hospital anaesthetic department is mostly operated on by the most junior staff in the Bloemfontein's Anaesthetic Academic side. Any medical officer and first year registrars rotate in Pelonomi, as well as do calls here for most part of the first academic year. Conversion rate of spinal anaesthesia to general anaesthesia in C/section patients is high amongst juniors, experience of difficult airway in these particular patients is also a common issue and all these patients needs to have rapid sequence induction if they get general anaesthesia. All these factors increase the possibility of accidental awareness significantly, especially in combination. The study was not designed to look if these factors were existent in each of the patients. The study was done during the time when the anaesthesiology department was experiencing a great shortage of consultants, especially senior consultants, so the supervision of the junior staff was very compromised, and this could have also played a role in the quality anaesthesia administered. The other big issue is the occurrence of emergency operations, especially in the after-hour period, which is an independent risk factor for accidental awareness but also increases the risk even more because the junior staff are on their own at these hours. The fact that Thiopentone is not used anymore in this setting and that with most, if not all general anaesthetics for Caesarean section there is a use of muscle relaxants, could have also played a role. Unfortunately, the study was not designed to look at all these factors, so further studies are recommended to determine the most relevant of the risk factors. When a questionnaire was done, the patients who gave a positive answer regarding remembering something between going to sleep and waking were not given the options right from the beginning, they first had to say if there was something specifically they remembered. All the four patients gave what they remembered before the options were given to them.

Even though the consents and questionnaires were in two languages (South Sotho and English), the interviews were done in South Sotho as all the black patients preferred that, and the other patients were questioned in English. This was done to eliminate possible errors and misunderstandings, with resultant wrong answers. With this being said, enough was done to make sure patients understood the questions. Each question was asked two times and no single patient showed inconsistency.
Also, there was only a single interviewer, with the hope to eliminate interviewer or interpreter bias. This guaranteed that a questionnaire was carried out as consistent as it could possibly happen.
What also worth mentioning is that previous studies have shown 17% of the patients to have unpleasant dreams with general anaesthesia, but our study did not discover any patients with unpleasant dreams.
Since Lennmarken and Collegues showed a high rate of Post-Traumatic Stress Disorder in patients who had experienced awareness[7], perhaps appropriate help must be immediately organized for identified patients instead of waiting for the symptoms and signs to surface.

Post-operative pain and pre-operative anxiety were regarded, by patients, as the worst things about the operation, table 2.5. This signifies that the time spent with a patient for premedication was either not adequate in terms of either quantity or quality, hence the anxiety. Another possibility is the fact that most of these patients were emergency surgeries, with very limited preoperative consultation time available. Anxiety reduces these patients' threshold for pain. Analgesic approach for these patients is also a challenge. A few analgesics are either absolutely and/or relatively contraindicated in patients of this profile, either pre-delivery, intra-operative or post-operative in those lactating and breastfeeding. The unpleasant recovery process and inability to perform normal chores were next after anxiety and pain, in almost half of the patients if compared with the latter. Only 3 patients regarded worst thing about their operation as awareness and these, not surprisingly, were 3 of the 4 patients who had had AAGA

## g. CONCLUSION AND LIMITATIONS

From our study, we conclude that the prevalence of Accidental Awareness during General Anaesthesia in obstetric patients in Pelonomi Academic Hospital is 11,1% and is higher than what has been reported in the literature (0,13-7%).

Obstetric anaesthesia is a huge risk factor for AAGA. Beside General anaesthesia for obstetric patients being an independent risk factor for AAGA, it also carries with it other

high-risk factors, for example, Rapid Sequence Induction, emergency surgery, incorrect and/or inadequate dosing of anaesthetic drugs, omission of opiods with induction until extraction of fetus, after-hour anaesthesia, little time between induction and start of surgery, the use of muscle relaxant, obesity and difficult airway amongst others. This, getting a great contribution of junior staff administering anaesthesia as another major risk factor in our setting.

## LIMITATIONS

The most notable limitation of our study is the sample, a bigger sample is needed to actually make this study comparable to previous similar studies. Initially a sample of 100 patients was targeted but the number of patients with general anaesthetics during C/section done per month massively decreased since literature review. This could be due to a lot of reasons, including preference by new clinical assistants, lack of monitoring, patient's choice of anaesthesia, increase in Vaginal births after Caesarean section and others.

Another limitation is the timing, in terms of conducting questionnaires. Allowing a longer time for post-operative recovery before conducting an interview might have brought with different answers. A longer time for the study and including spontaneous reporting might have also showed some difference.

Allowing different interviewers to do questionnaires might also improve the quality of answers.

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# *CHAPTER 3 :*

## RECOMMEMDATIONS FOR FURTHER RESEARCH

Larger population study needed to cement or dispute this, more studies to determine the specific important risk factors in our setting, the use of depth of anaesthesia monitoring even though studies have not shown total elimination of awareness with the monitoring, are all recommended.

Brice protocol should be applied on all Caesarean section patients, for early detection of AAGA, identification of the patients at risk and appropriate management. There should be protocols in place for stepwise prophylaxis and/or treatment of these particular patients. Psychological therapy must be immediately available for those identified to have AAGA

Anaesthetic informed consent forms must clearly include the possibility of AAGA so that patients are aware of it as a common complication.

The Modified Brice Questionnaire could be modified further to accommodate our public health system patients and some of the questions are not really specific about the perioperative time.

## DECLARATION OF INTEREST

The researchers declare no financial interest whatsoever in the topic being covered

# ***APPENDICES***

## APPENDIX A – INFORMED CONSENT

### INFORMED CONSENT AND PATIENT INFORMATION

PRINCIPAL INVESTIGATOR : DR SJ MOFUBELU
STUDY LEADER : DR J LEMMER-MALHERBE

PURPOSE AND PROCEDURES

The purpose of this study is to find out the incidence of accidental awareness during general anaesthesia within the patients that are undergoing Caesarian Section under general anaesthesia in Pelonomi Academic Hospital

DURATION OF THE STUDY

July to October 2016, following Ethics committee approval

RISKS AND BENEFITS

There are no risks related to this study, no drug or intervention will be used during the study. The benefits will be based on the outcomes of the study which will help us with awareness of the problem and better management of the studied problem. This awareness might bring about a change/alteration of our practice relating to the management of general anaesthesia during Caesarian Section, specifically relating to the prevention of accidental awareness in this group. Further studies might emerge from this study to help with management of the studied problem.

COSTS AND COMPENSATION

We promise that there will not be any added costs to the patient for participating in this study and we also wish to inform the patient that there will not be any compensations or remunerations for partaking in this study.

CONFIDENTIALITY

Throughout the whole study period, that is, during data collection, results analysis and publishing, if any, the patients information will be kept strictly confidential. The patient's personal information will not be shown anywhere on the research sheets other than on this particular document ( Consent Form) which will only have the patient's signature as proof of consent to participate in the study.
All records will be safely locked away and kept only for reference purposes.

VOLUNTARY PARTICIPATION

The patient will voluntarily participate in the study and refusal to participate will be without any sort of penalty whatsoever, and also the patient can terminate participation at any point of the research for any reason without fear of exclusion from health access. All the entitled benefits to health care will stand regardless of the patient's decision regarding the study.

SIDE EFFECTS

This study poses no side effects and the anaesthesia practice will be carried out the same way as prior to the start of research and will be essentially the same for participants and non-participants

RESULTS

This study's results will be used in an MMED report of Dr SJ MOFUBELU as well as might be published in an appropriate journal. Also, the patient will be allowed access to their own as well as the study's results once the study is completed should they wish to.

QUESTIONS

For any questions, complaints of concerns regarding the study, Dr SJ MOFUBELU can be contacted on 0748935255/jayjaysello@yahoo.com at the patient's convenience.

By signing below, I give consent for participation in the study

---------- ----------

SIGNATURE OF PATIENT DATE

---------- ----------

If Applicable, signature of Parent, Guardian DATE
Or Legally Authorised Representative

---------- ----------

SIGNATURE OF WITNESS DATE

---------- ----------

SIGNATURE OF PERSON TAKING CONSENT DATE

---------- ----------

Signature of Translator (if necessary) DATE

---------- ----------

Signature of the Interviewer Date

**SOUTH SOTHO VERSION**

**TUMELLO KA KUTLWISISO (Informed Consent)**

**Mmatlisisi - Dr SJ Mofubelu**

**Moetapele Wa Dipatlisiso – Dr J Lemmer-Malherbe**

**MAIKEMISETSO A PATLISISO ENA**

Maikemisetso a patlisiso ena ke ho fumana hore boteng ba Tlhokomelo ka Tshohanyetso (Accidental Awareness) nakong eo mokudi a rabaditsweng ka dithetefatsi bakeng sa opereishene ya hae ya ho pepa sepetleleng sa Pelonomi bo bokae.

**NAKO YA DIPATLISISO**

Phupu – Mphalane ( June to October) 2016

**DIKOTSI KAPA MENYETLA YA HO NKA KAROLO**

Ha ho na kotsi e amangwang le dipatlisiso tsena, ha ho dithetefatsi tse tla sebediswa ho mokudi nakong ya dipatlisiso tsena. Ho nka karolo ha hao ho tla thusa hore re thole le ho tseba ho hlokomela setla morao sena se sa tlamehang ho etsahala. Re ka kgona le hore re fetole mokgwa wa ho robatsa bakudi ba mmeleng ba pepang ebang ho hlokahahala ho ya ka dipheto tsa dipatlisiso tsena. Ho ka kgonahala le hore ho hlahelle dipatlisiso tse ding ho tswa ho ena eo o nkang karolo ho yona.

**MEPATALO**

Re o tshepisa hore ho nka karolo ha hao dipatlisisong tsena ha ho na eketsa seo o se lefang ebang o lefa kwano sepetlele. Ha ho na ba le tlhatso ya mahlo bakeng sa ho nka karolo dipatlisisong tsena. Mokudi ha a patale ebile ha a patallwe letho ho nka karolo mona.

**LEKUNUTU**

Nakong yohle ya dipatlisiso tsena, tsohle tse amanang le mokudi di tla behwa e le lekunutu. Ha ho na moo mabitso kapa dilemo, tsa lelapa le tse amanang le makunutu a mokudi di tla hlahiswa teng. Ho tekena ha hao pampiring ena ha ho bolele hore tsohle tsa hao di tla phatlhallatswa. Tokomane ena ke yona feela e nang le tsa hao tsa boitsebiso. Tsohle tse amanang le dipatlisiso tsena di tla kwallwa phaposing e hlokomelehileng, di bolokwe komputeng mme di tla bulelwa feela batho ba tsamaisang dipatlisiso tsena, le wena ha o hloka.

**HO NKA KAROLO KA BOIKGETHELO**

Mokudi o nka karolo ka boikgethelo, ebang o sa batle ho nka karolo kapa o kgetha ho ikgula dipatlisisong tsena ka mora hore o dumele ho nka karolo, o tla dumellwa ho etsa jwalo nakong e nngwe le e nngwe eo o batlang ho etsa jwalo. Mokudi ha a na lahlehelwa ke ditokelo tsohle tseo e leng tsa hae tsa Bophelo Bo Botle. O tla tshwarwa le ho hlokomelwa ka ho tshwana le motho a sa nkeng karolo dipatlisisong tsena.

**DITLA MORAO**

Ha ho ditla morao tse tsamayang le dipatlisiso tsena. Tshebetso ka kamoreng ya opereishene e tla tshwana mahareng a batho ba nkang karolo le bao ba sa nkeng karolo.

**DIPHETHO**

Diphetho di tla sebediswa ho ngola lengolo la dipatlisiso tsa dithuto tse phahameng (MMed) tsa Dr SJ Mofubelu, le hore di phatlalatswe bukeng tsa dipatlisiso ebang ho dumelleha ebile ho kgonahala.

Bakudi ba ka thola diphetho tsa dipatlisiso tsena ebang ba batla ha ho se ho phethehile.

**DIPOTSO**

Lebisa dipotso tsa hao ho mophethi wa dipatlisiso, Dr SJ Mofubelu, nomorong ya 0748935255/jayjaysello@yahoo.com nakong e nngwe le e nngwe feela.

Ka ho tekena ka fatshe ka mona, o dumela ho nka karolo dipatlisisong tsena le hore o utlwisisa tse ka hodimo.

---------- ----------

Tekeno ka mokudi Letsatsi

---------- ----------

Tekeno ka Mohlokomedi Letsatsi

---------- ----------

Tekeno ka Paki Letsatsi

---------- ----------

Tekeno ka mmatlisisi/mmotsi Letsatsi

Ke lebohela ho nka karolo ha hao dipatlisisong tsena tsa rona.

APPENDIX B- FORMS FOR COLLECTING DATA

APPENDIX C- MODIFIED BRICE PROTOCOL

APPENDIX D- ETHICS APPROVAL LETTER

APPENDIX E- PERMISSION FROM DOH

# APPENDIX B

HOSPITAL NUMBER.....
CASE NUMBER.....

**Mark the appropriate block with a X or write your answer on the space provided.**

1.1 Dat of surgery dd/mm/yy)..../...../.....
1.2 Date questionnaire done dd/mm/yy)..../...../.....

2. what is your race

| black(1) | white(2) | asian (3) | coloured(4) | others (5) |
|---|---|---|---|---|

3. What is your age?

.....year

4. What is your occupation? .....

5. What is your highest qualification?.....

6. What is your birthdate?(dd/mm/yy)...../...../.....

7. What is your marital status?

| | |
|---|---|
| 1 | Unmarried |
| 2 | Married/Traditional marriage |
| 3 | Divorced/Separated |
| 4 | Widow/Widower |
| 5 | Living together |

8. What is your home language?

| | |
|---|---|
| 1 | Afrikaans |
| 2 | English |
| 3 | Sotho |
| 4 | Tswana |
| 5 | Xhosa |
| 6 | Zulu |
| 7 | Other, specify..... |

9. What is your weight? ..... Kg

10. What is your length? ..... cm

11. Existing illnesses

.....
.....
.....
.....

12. What chronic medication are you taking

.....
.....
.....

14 How many weeks were you pregnant before delivery?
..... Weeks

For Office Use

| | |
|---|---|
| | 1-3 |
| | 4-9 |
| | 10-15 |
| d d m m y y | |
| | 16 |
| | 17-18 |
| | 19-20 |
| | 21-22 |
| | 22-28 |
| d d m m y y | |
| | 29 |
| | 30 |
| . | 31-35 |
| | 36-38 |
| | 39-40 |
| | 41-42 |
| | 43-44 |
| | 45-46 |
| | 47-48 |
| | 49-50 |
| | 51-52 |
| | 54 |

15. How many children do you have?

.....

16. Any previous operations before this one?

YES

NO

THE QUESTIONS ON THE NEXT PAGE RELATE TO THE SURGERY YOU JUST HAD

QUESTIONS 17-23

.....

55

56

APPENDIX C

# MODIFIED BRICE QUESTIONNAIRE

**17. Were you expecting to have a general anaesthetic (be completely asleep) for this operation?** No ☐ Yes ☐

**18. What is the last thing you remember before going to sleep (please tick one box)?**

-Being in the pre-operative area ☐ -Seeing the operating room ☐
-Being with family ☐ -Hearing voices ☐
-Feeling mask on face ☐ -Smell of gas ☐
-Burning or stinging in the IV line ☐ -Not applicable ☐
-Other [Please write below]:

---

**19. 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 the intensive care unit ☐
-Nothing ☐ -Not applicable ☐
-Other [Please write below]:

---

**20. 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 ☐ -Not applicable ☐
-Other [Please write below]

---

**21. Did you dream during your procedure (please tick box)?**

-No ☐ -Yes ☐
-What about [Please write below]:

---

**22. Were your dreams disturbing to you (please tick box)?**

-No ☐ -Yes ☐

**23. 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]:

---

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

17 January 2017

DR SJ MOFUBELU
DEPT ANAESTHESIOLOGY
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr SJ Mofubelu

**HSREC 89/2016**
**PROJECT TITLE: THE INCIDENCE OF ACCIDENTAL AWARENESS DURING GENERAL ANAESTHESIA IN OBSTETRIC PATIENTS UNDERGOING CAESARIAN SECTION IN PELONOMI TERTIARY HOSPITAL**

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met. This decision will be ratified at the next meeting to be held on 31 January 2017.

2. The Committee must be informed of any serious adverse event and/or termination of the study.

3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.

4. A progress report should be submitted within one year of approval and annually for long term studies.

5. A final report should be submitted at the completion of the study.

6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.

7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
PROF WJ STEINBERG
FOR CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

health

Department of
Health
FREE STATE PROVINCE

**30 November 2016**

**Dr SJ Mofubelu**
**Dept. of Anaesthesiology**
**Faculty of Health Science**
**UFS**

**Dear Dr SJ Mofubelu**

**Subject: The incidence of accidental awareness during general anaesthesia in obstetric patients undergoing caesarian section in Pelonomi Tertiary hospital.**

- Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent by each participants must be obtained
- Serious adverse events to be reported and/or termination of the study.
- Ascertain that your data collection exercise neither interferes with the day to day running of Pelonomi Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and no names will be used.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** khuseng@fshealth.gov.za **or** sebeelats@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution managers/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see http://nhrd.hst.org.za

I trust you find the above in order.

Kind Regards

**Dr D Motau**
**HEAD: HEALTH**
**Date:** 29/12/2016