

EVALUATION OF THE EFFECT OF PARENTAL PRESENCE ON ANXIETY  
AMONG PAEDIATRIC PATIENTS DURING  
INDUCTION OF GENERAL ANAESTHESIA AT INTERMEDIATE HOSPITAL  
OSHAKATI:  
A CROSS-SECTIONAL QUASI EXPERIMENTAL TRIAL

A THESIS SUBMITTED IN PARTIAL FULFILMENT FOR THE  
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## **ABSTRACT**

**Introduction:** Parental presence reduces children's anxiety, improve the anaesthetic induction and has been shown to increase parental satisfaction This study investigated the impact of parental presence on preoperative anxiety and cooperation among paediatric patients undergoing general anaesthesia induction.

**Methodology:** A cross-sectional quasi-experimental trial was conducted at Intermediate Hospital Oshakati, involving 104 pediatric patients aged 2 to 10 years undergoing elective minor and major operations. Anxiety levels were assessed using the Modified YALE Preoperative Anxiety Score (mYPAS) in both the waiting area and theatre, while induction compliance was measured using the Induction Compliance Checklist (ICC). Statistical analysis included Welch's t-test and Chi-Square Test, with a critical significance level of 0.05.

**Results:** Results indicated that parental presence during induction significantly improved pediatric cooperation ( $p < 0.001$ ) and reduced anxiety levels in the theatre ( $p < 0.001$ ). Moreover, notable differences in anxiety levels and compliance were observed between different age groups. Younger children (2 to 5 years) displayed higher anxiety levels in the theatre compared to older children (6 to 10 years) with P-value 0.004. Interestingly, no significant differences in anxiety levels or compliance were found between patients undergoing minor and major surgeries.

**Conclusion:** The study underscores the significance of considering both parental presence and age when managing anxiety and promoting cooperation in pediatric patients undergoing inhalational induction. Age also plays a role, with younger children experiencing higher theatre anxiety.

**Recommendations:** The findings suggest promoting parental presence, developing age-specific strategies, and providing pre-operative education to alleviate anxiety and enhance cooperation among pediatric patients.

**Keywords:** Paediatric, preoperative anxiety, parental presence, anesthesia induction, age-specific strategies.

# TABLE OF CONTENT

|   |          |
|---|----------|
| <b>ABSTRACT</b>                                     | <b>i</b> |
| TABLE OF CONTENT                                    | ii       |
| LIST OF TABLES                                      | iv       |
| LIST OF ABBREVIATIONS AND ACRONYMS                  | v        |
| ACKNOWLEDGEMENTS                                    | vi       |
| DEDICATIONS   | vii      |
| DECLARATION   | viii     |
| <br>  |          |
| CHAPTER 1: Introduction                             | 1        |
| 1.1 Background of the study                         | 1        |
| 1.2 Statement of the problem                        | 2        |
| 1.3 Objectives of the study                         | 3        |
| 1.4 Hypothesis                                      | 3        |
| 1.5 Significance of the study                       | 4        |
| 1.6 Limitations of the study                        | 4        |
| 1.7 Summary   | 5        |
| CHAPTER 2: LITERATURE REVIEW                        | 6        |
| <br>  |          |
| 2.1 Physiological and psychological effects Anxiety | 6        |
| 2.2 Anxiety scoring scales                          | 7        |
| 2.3 Benefits of parental presence                   | 7        |
| CHAPTER 3: RESEARCH METHODOLOGY                     | 9        |
| <br>  |          |
| 3.1 Introduction                                    | 9        |
| 3.2 Study location                                  | 9        |
| 3.3 Study population                                | 9        |
| 3.4 Study design                                    | 10       |
| 3.5 Sampling technique                              | 10       |
| 3.6 Sample size determination                       | 10       |
| 3.7 Data collection and procedures                  | 11       |
| 3.8 Data analysis                                   | 13       |

|  |    |
|--|----|
| 3.9 Research ethics  | 14 |
| 3.10 Summary   | 15 |
| CHAPTER 4: RESULTS OF THE STUDY                                | 16 |
| CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS          | 23 |
| 5.1 DISCUSSION   | 23 |
| 5.2 CONCLUSION:  | 28 |
| 5.3 RECOMMENDATIONS:   | 28 |
| 5.4 LIMITATIONS  | 29 |
| REFERENCES   | 30 |
| APPENDIXES   | 34 |
| APPENDIX I QUESTIONNAIRE                                       | 34 |
| APPENDIX II Informed consent                                   | 41 |
| APPENDIX III Ethical Clearance Certificate                     | 46 |
| APPENDIX IV Permission to conduct research: Oshakati Hospital  | 47 |
| APPENDIX V Permission to conduct research : Ministry of Health | 48 |

## LIST OF TABLES

**Table 1:** Demographic characteristics of participants and parents (Age and gender)

**Table 2:** Relationship of parent with child to anxiety between the two groups

**Table 3:** Comparison of mean compliance scores of participants between parental presence and parental absence groups

**Table 4:** Comparison of mean anxiety scores of participants at reception and on induction between the two groups

**Table 5:** Comparison of the proportion of children aged 2 – 5 versus 6 – 10 years with anxiety between parental presence and parental absence groups

**Table 6:** Comparison of proportion of children with anxiety between PP and PA groups during minor and major operations.

## **LIST OF ABBREVIATIONS AND ACRONYMS**

**ANOVA**- Analysis of Variance

**ASA**-American Society of Anaesthesia

**CARS**- Clinical Anxiety Rating Scale

**EASI**- Emotionality, Activity, Sociability, Impulsivity

**ICC**- Induction Compliance Checklist

**IHO**- Intermediate Hospital Oshakati

**GA**- General Anaesthesia

**HR**- Heart Rate

**MYPAS**- Modified Yale Preoperative Score

**PA**- Parental Absence

**PP**-Parental Presence

**STAI**- State Trait Anxiety Inventory

**SPSS**- Statistical Package for the Social Sciences

**SD**- Standard Deviation

**VAS**- Visual Analogue Scale

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To all research participants, thank you for understanding and consenting to be part of this study. Your participation will change and improve our medical practice.

## **DEDICATIONS**

I would like to dedicate this thesis to my late father, Erastus Panduleni Iyambo (08/08/1957-05/07/2016).

Your hard work has always been my inspiration, thank you for being my guardian angel. May your soul continue to rest in peace.

## DECLARATION

I, Fenni Megameno Iyambo, hereby declare that this study is my own work and is a true reflection of my research, and that this work, or any part thereof has not been submitted for a degree at any other institution.

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Fenni Megameno Iyambo

Name of student



Signature

April 2025

Date

## **CHAPTER 1: Introduction**

### **1.1 Background of the study**

The practice of parental presence has been shown to reduce children's anxiety, improve the anaesthetic induction and has been shown to increase parental satisfaction. This has also reduced the need for premedication by avoiding the distress of separation from parents just before induction.<sup>1,2</sup>

Preoperative anxiety can cause physiological and psychological derangement. It has been shown to stimulate sympathetic, parasympathetic and endocrine systems that consequently lead to an increase in heart rate, blood pressure and cardiac irritability that may lead to arrhythmias.

Furthermore, stressful anaesthetic inductions in children can have psychological impact and may lead to significant regressive behavioural disorders in the recovery period and for some time post surgery. Physiological changes that may occur due to long term anxiety include protein breakdown decreased wound healing and altered immune responses, with increased risk of infection and water-electrolyte imbalance.

Parental presence during induction of anaesthesia offers benefits to both the child and parent when planned and well negotiated with the health care team in a holistic manner.<sup>2-5</sup>

There are both pharmacological and non-pharmacological approaches used to alleviate pre-operative anxiety in children,<sup>6</sup> one widely practiced non pharmacological method is parental presence during induction of anaesthesia others include distraction methods with audio or visual aids, clown doctors or comic books.<sup>7,8</sup>

## **1.2 Statement of the problem**

Children who are extremely anxious and frightened during induction of anaesthesia are more likely to develop post operative delirium and greater pain issues as well as longer-term physiological and psychological problems of sleep disturbance, eating disorders and separation anxiety. Parental presence during induction of anaesthesia has been controversial however some studies have shown that it could diminish children's anxiety and increase their participation at induction. With parental presence, children are more comforted and relaxed at induction with less need for pharmacological interventions, better recovery time and higher parenteral satisfaction. Lastly, anxious and agitated paediatric patients during the preoperative period can lead to a difficult anaesthetic and cause distress to the theatre team.<sup>2,9,10</sup>

Preoperative intervention to reduce anxiety may either be pharmacological or behavioural. The current practice at the Intermediate Hospital Oshakati is that children are not premedicated. The reasons are multifactorial; poor availability of oral benzodiazepines such as midazolam, the additional cost of the medication, the need for additional nursing and observational bed in the holding bay due to excessive sedation, delayed discharge post operatively and lastly the delayed effect of behavioral sleep disorders. Children are therefore separated from their parents or guardians at the theatre reception resulting often in anxious and agitated patients just prior to induction of anaesthesia. The aim of this study is to introduce a culture change, and allow parents to be present in theatre with their child during anaesthesia induction; to assess the impact with an aim to reduce anxiety amongst this population and avoid the use of benzodiazepines and their side effects.

To the best of my knowledge, there are currently no studies done in Namibia that have looked into the impact of parental presence or absence during induction of anaesthesia as a method to alleviate preoperative anxiety amongst children presenting for elective surgery.

### **1.3 Objectives of the study**

#### **i) Main Objective**

To assess and compare the anxiety levels among paediatric patients presenting for elective surgery with and without parental presence during induction of general anaesthesia at IHO

#### **ii) Specific Objective**

- To assess the level of cooperation of paediatric patients among the two groups
- To assess the level of anxiety among the two groups.
- To compare the level of anxiety among the different age categories (2-5 and 6-10 years)
- To compare anxiety in children coming in for major and minor operations in each group.

### **1.4 Hypothesis**

#### **i) Null hypothesis**

There is no difference in the level of anxiety between children with or without parental presence during induction of general anaesthesia at IHO.

## **ii) Alternate hypothesis**

There is a difference in the level of anxiety amongst children with or without parental presence during induction general anaesthesia at Intermediate Hospital Oshakati.

### **1.5 Significance of the study**

If parental presence is shown to reduce anxiety in patients and improve compliance with anaesthesia then the policy change would be to allow parents to be present in theatre. There would need to be changes to preoperative information and preparation, which if included in a guideline, could be shared with other hospitals countrywide.

The results and evidence provided by this study could change the current pre-operative care amongst children presenting for elective surgery with the aim of reducing their anxiety levels and improving compliance during induction of anaesthesia.

If results show that behavioural intervention makes no difference, then there may be supporting evidence for an application to the hospital to obtain pharmacological methods i.e. source premedication).

### **1.6 Limitations of the study**

1. The more major the surgical operation, the greater may be the effect on anxiety that may contribute varying degrees.

2. A wide range in the participants age group with different behavioural issues.

**i) Delimitations of the study**

The study population was limited to Oshakati Intermediate hospital.

The data was collected over four (4) months, from August 2023 to November 2023.

**1.7 Summary**

This chapter highlights the significance of parenteral presence and absence on Anxiety amongst children that presented for elective major and minor operations at Intermediate Hospital Oshakati. The research objectives and hypothesis are discussed in this chapter. Furthermore, the significance of the study, limitations and delimitations are also presented.

## **CHAPTER 2: LITERATURE REVIEW**

### **2.1 Introduction**

Preoperative anxiety among children is distressing and can present many problems for the anaesthetist, healthcare staff and families, resulting in significant problems while caring for paediatric patients. Characteristically, preoperative anxiety is a subjective feeling of tension, apprehension, nervousness and worry that may be expressed in various forms. Parental presence may provide reassurance and comfort and so reduce anxiety levels of children during induction of anaesthesia before a surgical procedure, either with or without pharmacological intervention.<sup>2,11</sup>

### **2.2 Physiological and psychological effects Anxiety**

Paediatric perioperative anxiety has detrimental effects both physiologically and psychologically. It can lead to difficulties with patient compliance, anaesthesia induction, smooth airway control and intraoperative stability as well as postoperative emergence delirium, difficult pain management and recovery.

Physiological manifestations include activation of the human stress response which lead to increased serum cortisol, epinephrine and natural killer cell activity, causing delayed wound healing as a result of cortisol and catecholamine release.

Psychologically, preoperative anxiety is associated with postoperative negative behavioural changes such as new onset enuresis, withdrawal and sleep disturbance.<sup>1,11</sup>

### **2.3 Anxiety scoring scales**

Different behavioural and physiological assessment scales have been employed to measure anxiety levels in children, the most commonly used one being the modified Yale Preoperative Anxiety Scale (mYPAS) developed in 1995 and modified in 1997. The scale consists of five (5) items representing different domains of anxiety and observations are recorded at 4 time points during the preoperative phase. Other scales used include Emotionality, Activity, Sociability, Impulsivity (EASI), Clinical Anxiety Rating Scale (CARS), State Trait Anxiety Inventory (STAI) for measuring anxiety and compliance and finally Visual Analogue Scale (VAS), all of which can be implemented to objectively measure the level of anxiety.<sup>1,12,13</sup>

### **2.4 Benefits of parental presence**

Parental presence at induction of anaesthesia has been studied extensively, with some studies acknowledging its benefits while others have found it to be controversial. According to a prospective study by Zuwala et.al, that involved eighty children randomized in two groups, children were more relaxed at induction of anaesthesia, with minimal need for medication both preoperatively and postoperatively as well as showing increased parental satisfaction. However an evidence based review on parental presence during anaesthesia induction and parent or child anxiety by Chundamala et al, reviewed 14 studies that included nine Randomized control study, four comparative prospective studies and one retrospective comparative study, concluded that parental presence had no effect on parent and child anxiety.<sup>14-16</sup>

In another meta-analysis of randomised controlled trials looking at the effect of parental presence at induction, Liang and colleagues, reviewed 15 articles with a

sample size of 1390 and recommended that parental presence could be used as a cost-free intervention for its effect on reduced incidence of restlessness at induction and emergence to children's surgery in hospitals.<sup>17</sup>

Sadenghi et al, looked at preoperative anxiety of both paediatric patients and their parents, using mYPAS scale for children and the STAI scale for parents. The study concluded that parental presence at induction of anaesthesia may reduce anxiety among children and improve quality of anaesthesia induction with higher parental satisfaction, however it showed no impact on parental state of anxiety.<sup>4</sup>

A randomised control study of 88 participants by Kain et al, comparing parenteral presence during induction of anaesthesia versus sedative premedication to determine which intervention was more effective, found that oral midazolam was more effective than parenteral presence.<sup>12</sup>

A recent study by Li et al, investigated the effect of parental presence during induction of anaesthesia in relieving preoperative anxiety in one hundred and sixty children undergoing tonsillectomy and adenoidectomy. The study used the mYPAS to score anxiety and Induction Compliance Checklist to assess the level of cooperation. Results of the study concluded that parental presence at induction of anaesthesia can significantly reduce preoperative anxiety and surgical physiological stress response in children undergoing tonsillectomy and adenoidectomy.<sup>27</sup>

## **CHAPTER 3: RESEARCH METHODOLOGY**

### **3.1 Introduction**

This chapter narrates on how the research was conducted. The details of the chapter provide information on the research design and methodology employed.

### **3.2 Study location**

The study was carried at the University of Namibia teaching hospital, Intermediate Hospital Oshakati. The department at the time consisted of three (3) anaesthesia specialists, 6 registrars and 1 medical officer. Surgical disciplines involved were mostly Ear, Nose and Throat, ophthalmology, orthopedics, pediatric general surgery, urology, plastic and maxillofacial surgery. Each of these departments covered by specialists, however some of the procedures were done by senior medical officers.

### **3.3 Study population**

The study population was made up of patients presenting for elective surgery aged between two (2) and ten (10) years with informed consent obtained from parents or guardians.

#### **a) Inclusion criteria**

Patients aged two (2) to ten (10) years presenting for elective surgery, classified under the American Society of Anaesthesiology as class I and II.

#### **b) Exclusion criteria**

Patients with previous exposure to theatre or surgery

Patients with developmental delay.

### **3.4 Study design**

This was a cross-sectional quasi experimental trial carried out over a period of four (4) months from August 2023 to November 2023. Patients recruited into the study were divided into two cohorts. The first cohort of pediatric patients presenting for surgery were not accompanied by parents while the second cohort consisted pediatric patients presenting for elective surgery accompanied by parents after obtaining written informed consent.

### **3.5 Sampling technique**

Eligible patients were grouped according to the time of presentation, starting with all presenting patients allocated to cohort one until the sample size was completed followed by allocation to cohort two thereafter.

### **3.6 Sample size determination**

The sample size was calculated based on a previous study by Kain et al.<sup>1</sup> Forty-two patients per group were needed to detect a difference of 12.3 in the mean anxiety score (using the modified Yale Preoperative Anxiety Scale (mYPAS scale)) between groups with 80% power, using the analysis of variance (ANOVA) and assuming an (two-sided) alpha of 0.05. An expected mean anxiety score was 61.8 (SD 21.8) in children with their parents absent, and an expected mean anxiety score of other two interventions was 49.5 (SD17.5).

Formula for a continuous outcome and equal sample sizes in both groups, assuming: alpha = 0.05 and power = 0.80 (beta = 0.20)

$$n = \frac{2(Z_{\alpha} + Z_{\beta-1})^2 \sigma^2}{(\mu_1 - \mu_2)^2}$$

n = the sample size in each of the groups

$\mu_1$  = population mean in the parental-presence group

$\mu_2$  = population mean in the control group

$\mu_1 - \mu_2$  = the difference the investigator wishes to detect

$\sigma^2$  = population variance (SD)= 18 score (Kain et al., 1998)

$Z_\alpha$  = conventional multiplier for alpha = 0.05

$Z_{\beta-1}$  = conventional multiplier for power = 0.80

$$n = \frac{2(1.96+0.84)^2 \times 18^2}{10^2}$$

$$10^2$$

$$= \frac{2(7.84) \times 324}{100}$$

$$100$$

$$= 51$$

Assuming attrition rate of 10%, n= 56

Sample size for each group is 56

### **3.7 Data collection and procedures**

Data was collected in the form of a questionnaire which was presented to the parent or guardian accompanying the eligible pediatric patient. Parents were prepared with information regarding the child's anaesthetic.<sup>18,19</sup> The questionnaire and consent were presented in English and Oshiwambo.

The participants were divided into two cohorts in time sequence rather than in parallel to avoid confusion among the health care workers. Data collected in the first half of the study was on those not accompanied by parents, cohort one, and in the second half of the study on those accompanied by parents, cohort two. A week break

was taken between the two cohorts to allow preparation and orientation of the health care workers for a change in practice.

An independent investigator was used to recruit the eligible patients for the study, distribute the information, and obtain informed and written consent; this was done the day before the operation. Parents were left with information explaining the conduct of anaesthesia which was also presented in English and Oshiwambo.<sup>18</sup> For the eligible patients that presented to theatre the next day, the same investigator was the outcome assessor in terms of scoring the anxiety. None of the patients were premedicated.

#### Anaesthesia and anxiety scoring

Anaesthesia induction was provided by medical officers, registrars and consultants in the theatres with pediatric patients, as was normal practice. With cohort one, children were brought into theatre from the waiting area by a nurse, whereas in cohort two, the children were accompanied into theatre by their parent or guardian. Upon arrival in theatre, younger children were induced immediately and monitors placed during process of induction while in older children, monitors were placed before induction as is normal practice in our unit. Most of the patients had intravenous access lines inserted in the ward and a few were inserted after induction, as was standard practice in our unit. Method of induction used was inhalational induction with sevoflurane.

The patient's anxiety was scored by the investigator using the modified Yale Preoperative Anxiety Scale (mYPAS) starting in the waiting area and continuing in

theatre. The compliance at induction was scored when the mask was applied on the patient.

The mYPAS has been used in >100 studies spanning diverse health fields, such as anesthesia, surgery, pediatrics, and dentistry. This measure uses 5 items, each representing a different domain of child anxiety, activity, vocalizations, emotional expressivity, state of apparent arousal, and use of parent. The child's behavior is rated from 1 to 4 or 1 to 6 (depending on the item), with higher numbers indicating the highest severity within that item. The Scoring was done by dividing each item rating by the highest possible rating (i.e., 6 for the 'vocalizations' item and 4 for all other items), add all of the produced values, divide by four, and multiply by 100 to get a percentage.

After induction, the accompanying parent or guardian was escorted out of theatre by the investigator and interviewed about their experience.

### **3.8 Data analysis**

The data was entered into a spreadsheet using Excel Microsoft office 2023 and data analysis was performed using SPSS.

Descriptive statistics were used to summarize the participant's socio-demographics, clinical characteristics and anxiety score. In addition to Chi-Square Test, the study employed the Fishers exact test to analyze the association or independence between categorical variables. This statistical tool is well-suited for assessing nominal or ordinal data, where variables are categorized rather than expressed numerically. A significance level of  $p < 0.05$  was employed to ascertain statistical significance in both types of analysis.

### **3.9 Research ethics**

Ethical clearance was obtained from the Institutional Ethics Committees of the University of Namibia and Ministry of Health and Social Services. Written informed consent was obtained from the participants, parents or guardians.

#### **a) Confidentiality of data**

The names recorded on the consent to participate for the study records will be stored with confidentiality however patient's numbers corresponding to the consent were used on the data collection tools.

Patients' personal information was handled with confidentiality and no patient identity will be revealed if the paper is to be published.

#### **b) Beneficence to participants**

This study aimed to reduce separation anxiety and enable a calm, smooth induction experience. Ethical guidelines of the Ministry of Health and Social Services and Health Professional Council of Namibia were implemented and practiced on all participants.

#### **c) Non-maleficence to participants**

This study was done at no extra cost to the participants. Due diligence was observed that participants were not exposed to extra risk. Equipment and emergency drugs were available to manage side effects and complications of general anaesthesia when they occur as is normal practice in our unit.

Right to Decline/Withdrawal from study without loss of benefits

Each patient had the right to refuse participation in the study or withdraw from the study at any point in time without any penalty or negative consequences on their management plan.

**d) Dissemination of results**

The results of the study will be presented locally to the Anaesthesia department, surgical disciplines dealing with paediatrics patients, hospital management and theatre nursing managers at Oshakati hospital. This can then be shared with anaesthetic departments across the country.

**3.10 Summary**

This chapter elaborated the research design, methods, study population and sampling methods.

The process of data collection, analysis and ethical aspects were also addressed in this chapter.

## **CHAPTER 4: RESULTS OF THE STUDY**

### **4.1 Introduction**

In this chapter, results obtained from the study are presented as texts and tables according to the study objectives and outcomes. Analysis of the results focused on demographic characteristics such children's age, gender, parent/guardian's gender, their relation to the child. Furthermore, results of the level of cooperation and anxiety between the two groups (children accompanied by parents/guardian and those unaccompanied). Comparison of anxiety between minor and major operations between the different age categories are also presented.

### **4.2 Participants distribution**

A total of one hundred and four patients (104) were recruited in this study. The participants were divided into two groups: cohort one with parental presence (PP) with 52 participants and cohort two with parental absence (PA) with 52 participants.

### **4.3 Demographic characteristics of the participants**

There was a total of 104 children recruited into this study with a mean age of  $5.2 \pm 2.5$  years.

Table 1 showed the demographic characteristics of the 2 groups of subjects: children < 6 years and > 6 years either accompanied or unaccompanied by parents.

The results showed that children with parental presence (PP) and parental absence (PA) were comparable with respect to age and gender. The differences were not statistically significant,  $p > 0.05$ .

**Table 1.1-1.3: Demographic characteristics of participants and parents**

| <b>Subject</b>  | <b>Variable</b>   | <b>PP</b><br>N=52(%) | <b>PA</b><br>N=52(%) | <b>Total</b> | <b>P- value</b> |
|-----------------|-------------------|----------------------|----------------------|--------------|-----------------|
| <b>Children</b> | <b>Age(years)</b> |                      |                      |              |                 |
|                 | 2-5               | 33(54.1)             | 28(45.9)             | 61           | 0.319           |
|                 | 6-10              | 19(44.2)             | 24(55.8)             | 43           |                 |
|                 | Mean age          | 5.29                 | 4.98                 |              | 0.525           |

**Table 1.2**

| <b>Subject</b>  | <b>Variable</b> | <b>PP</b><br>N=52(%) | <b>PA</b><br>N=52(%) | <b>Total</b> | <b>P- value</b> |
|-----------------|-----------------|----------------------|----------------------|--------------|-----------------|
| <b>Children</b> | <b>Gender</b>   |                      |                      |              |                 |
|                 | Female          | 24 (49.0)            | 25 (51.0)            | 49           | 0.844           |
|                 | Male            | 28 (50.9)            | 27 (49.1)            | 55           |                 |

**Table 1.3**

| <b>Subject</b> | <b>Variable</b> | <b>PP</b><br>N=52(%) | <b>PA</b><br>N=52(%) | <b>Total</b> | <b>P-value</b> |
|----------------|-----------------|----------------------|----------------------|--------------|----------------|
| <b>Parents</b> | <b>Gender</b>   |                      |                      |              |                |
|                | Female          | 48(52.2)             | 44(47.8)             | 92           | 0.220          |
|                | Male            | 4(33.3)              | 8(66.7)              | 12           |                |

**PP- Parental Presence, PA- Parental Absence**

Table 2 revealed that most children were accompanied by their mothers (78.9%) however in terms of anxiety between the two groups, there was no statistical significance in terms of relationship with the child ( $P > 0.05$ ).

**Table 2: Relationship of parent with child to anxiety between the two groups**

| <b>Variables</b>                   | <b>Anxiety<br/>(Induction)</b> | <b>No Anxiety<br/>(Induction)</b> | <b>p-<br/>Value</b> | <b>PP<br/>(N=52)</b> | <b>PA<br/>(N=52)</b> | <b>Total</b> | <b>P-<br/>Value</b> |
|------------------------------------|--------------------------------|-----------------------------------|---------------------|----------------------|----------------------|--------------|---------------------|
| <b>Relationship<br/>With Child</b> |                                |                                   |                     |                      |                      |              |                     |
| <b>Mother</b>                      | 60 (78.9)                      | 16(21.1)                          | 0.677               | 36(47.4)             | 40<br>(52.6)         | 76           | 0.141               |
| <b>Father</b>                      | 9(81.8)                        | 2(18.2)                           |                     | 4(36.4)              | 7(63.6)              | 11           |                     |
| <b>+Others</b>                     | 15(88.2)                       | 2(11.8)                           |                     | 12(70.6)             | 5(29.4)              | 17           |                     |

Others: Sister, Grandmother, Aunty

#### 4.4 Level of cooperation of the participants with and without parental presence

Table 3 showed that the compliance score in PP ( $0.65 \pm 1.28$ ) at induction of anaesthesia was significantly lower compared to PA group ( $3.06 \pm 2.95$ ) with a p-value of  $< 0.001$ . This indicated that parental presence was comforting for the accompanied children.

**Table 3: Comparison of mean compliance scores of participants between parental presence and parental absence groups**

| <b>Variable</b>                                  | <b>PP<br/>(N=52)</b> | <b>PA<br/>(N=52)</b> | <b>P-Value</b> |
|--|----------------------|----------------------|----------------|
| <b>Level of Cooperation/Induction compliance</b> | 0.65±1.3             | 3.06 ± 3.0           | < 0.001*       |

#### **4.5 Comparative analysis of the level of anxiety between parental presence and parental absence groups**

Table 4 results showed that parental presence impacted on the level of anxiety of the study participants both at reception and induction. There was a significant difference between the mean anxiety scores between the PP and PA groups at the reception,  $p = 0.029$ .

The mean anxiety score at induction for the PP patients ( $35.6 \pm 11.6$ ) was significantly lower compared to the PA group ( $59.8 \pm 29.4$ ),  $p < 0.001$ .

**Table 4: Comparison of mean anxiety scores of participants at reception and on induction between the two groups**

| <b>Variables</b>           | <b>PP (N= 52)</b> | <b>PA (N= 52)</b> | <b>P- value</b> |
|----------------------------|-------------------|-------------------|-----------------|
| <b>Anxiety (Reception)</b> | $23.4 \pm 0.7$    | $23.9 \pm 1.7$    | $0.029^*$       |
| <b>Anxiety (Induction)</b> | $35.6 \pm 11.6$   | $59.8 \pm 29.4$   | $< 0.001^*$     |

**PP- Parental Presence, PA-Parental Absence**

#### 4.6 Level of anxiety between the two age categories

The younger children < 6 years were more anxious when unaccompanied by parents than children aged 6 – 10 years as shown in Table 5. The difference was statistically significant,  $p = 0.002$ .

**Table 5: Comparison of the proportion of children aged 2 – 5 versus 6 – 10 years with anxiety between parental presence and parental absence groups**

| <b>Variable</b>              | <b>Anxiety</b> | <b>PP n (%)</b> | <b>PA n (%)</b> | <b>P value</b> |
|------------------------------|----------------|-----------------|-----------------|----------------|
| <b>Children 2 – 5 years</b>  | <b>No</b>      | 22 (66.7)       | 7 (24)          | 0.002          |
|                              | <b>Yes</b>     | 11 (33.3)       | 22 (76)         |                |
| <b>Children 6 – 10 years</b> | <b>No</b>      | 18 (94.7)       | 15 (65)         |                |
|                              | <b>Yes</b>     | 1 (5.3)         | 8 (35)          |                |

#### 4.7 Level of anxiety between the children that underwent minor and major operations

Table 7 indicated that most operations were minor (83 out of 104). The children in the PA group were more anxious during minor surgical procedures (58.2%). This difference was statistically significant between the PP and PA groups,  $p = 0.005$ .

**Table 6: Comparison of proportion of children with anxiety between PP and PA groups during minor and major operations.**

| Variables    | Anxiety    | PP N (%)  | PA N (%)  | Total | P-Value |
|--------------|------------|-----------|-----------|-------|---------|
| <b>Minor</b> | <b>Yes</b> | 28 (41.8) | 39 (8.2)  | 67    | 0.005*  |
|              | <b>No</b>  | 13 (81.2) | 3 (18.8)  | 16    |         |
| <b>Major</b> | <b>Yes</b> | 9 (52.9)  | 8. (47.1) | 17    | 0.669*  |
|              | <b>No</b>  | 2 (50.0)  | 2 (50.0)  | 4     |         |

## **CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS**

### **5.1 DISCUSSION**

#### **5.1.1 Introduction**

This chapter discusses the study findings which are further criticized based on previous similar studies. This chapter will draw a conclusion, formulate study recommendations and highlight study limitations in relation to the significance of the study.

#### **5.1.2 Demographics**

Although there were more patients in the younger age group, this study was the same in both cohorts and so the distribution was similar and showed no significant difference. Despite slightly more male patients in PP group again there was no significant difference.

#### **5.1.3 Level of cooperation of participants with or without parental presence**

This study was conducted to assess the level of cooperation of pediatrics patients among the two groups of PP (parental presence) and PA (parental absence).

Pediatrics patients with PP during induction were found to have a significantly lower mean induction compliance score ( $0.65 \pm 1.3$ ) compared to those with parental absence ( $3.06 \pm 3.0$ ). This suggests better cooperation with the anesthesiologist during induction when parents were present with a statistical significance ( $P < 0.001$ ).

These results would be supported by a study by Kain and colleagues<sup>12</sup> comparing the level of compliance using the ICC in 3 groups: of parental presence, parental absence, and sedative premedication which found that compliance was significantly higher in the parental presence group versus the control (PA) or midazolam group (25% vs 17% vs 0%, P = 0.013).

Another study by Sadeghi et al<sup>4</sup> found that more perfect scores were in the PP group (32) and poor scores (30) in the PA group.

The difference in ICC scores during induction of anaesthesia between PA and PP reached statistical significances (66% vs 6.3%; p<0.01).

Other studies have also been done to comparing different scales for evaluation of anxiety and compliance in children undergoing surgery as narrated by Garcia et al.<sup>20</sup>

#### **5.1.4 To assess the level of anxiety between the two groups**

Children with parental presence during induction had significantly lower mean anxiety scores in the theatre ( $35.6 \pm 11.6$ ) compared to those in the parental absence group ( $59.8 \pm 29.4$ ), suggesting the presence of a parent was a comfort to the child ( $p < 0.001$ ). Similarly, at the reception, children with parental presence exhibited slightly lower mean anxiety scores ( $23.4 \pm 0.7$ ) compared to those in the parental absence group ( $23.9 \pm 1.7$ ), which was also statistically significant ( $p = 0.029$ ). These findings in our study indicate that parental presence may contribute to a more calming environment for pediatric patients undergoing anesthesia induction, particularly in the theatre setting.

We accept there have been studies published that do not demonstrate a statistically significant difference in anxiety scores between parental presence or absence<sup>3,21</sup> but it is difficult to account for all the variables affecting children and the authors do however, emphasize the importance of parental presence during induction.

Jain and colleagues (22) compared parental presence with sedative premedication to reduce anxiety using MYPAS score on children aged 4-12 years and concluded that the midazolam group ( $31.30 \pm 12.04$ ) had a lower mean score than the parental presence group ( $63.19 \pm 25.31$ ) We acknowledge benzodiazepines are effective and have a role when used selectively but routine use has issues of availability, cost, staffing and side effects as discussed, and in our setting parental presence could be of benefit.

### **5.1.5 Anxiety between different age categories**

The analysis revealed notable differences in anxiety levels between different age groups during anaesthesia induction and between the PP and PA groups. When a comparison in anxiety was done between the two age categories, it revealed that children of the age 2-5 years had higher anxiety levels than those that are 6-10 years with a statistical significance of  $P=0.002$ . This suggests that younger children may experience higher levels of anxiety during anesthesia induction, particularly in the theatre setting.

Comparison of gender of participants and anxiety between the two groups revealed that there was no significant difference  $P > 0.05$ .

Talabi and others,<sup>23</sup> also compared anxiety levels amongst different age categories and concluded that there was a correlation between the age of all participating children and their anxiety scores at induction of anaesthesia.

As the age increases, the anxiety state of the children reduces,  $T = -0.398$ ,  $P < 0.001$ . In addition, there was a statistically significant difference between age groups (preschool versus older children) and anxiety (mYPAS > 30),

$P = 0.025$ , and not with the sex of the patients,  $p = 0.189$ . A randomized trial by Hussain and Khan<sup>24</sup> yielded the same results in terms of age categories.

Overall, these findings highlight the importance of considering age as a factor when assessing anxiety levels and compliance in pediatric patients undergoing anesthesia induction. Healthcare providers should be aware of the potential differences in anxiety and cooperation among different age groups and tailor their approach accordingly to provide optimal care and support during this critical phase of medical treatment.<sup>25,26</sup>

#### **5.1.6 Level of anxiety between the children that underwent minor and major operations.**

When comparing anxiety levels between different children undergoing minor and major surgeries, numbers presenting for minor operations were predominantly higher in both groups as compared to major operations. When anxiety was compared between the two groups in the minor operations, the study found that there was a statistical significance between the two groups  $P=0.005$  but none with major operation  $P > 0.05$ . This statistical analysis could be explained by the discrepancy in numbers between the two groups. Talabi et al,<sup>23</sup> was unable in their study to

demonstrate a significant difference in anxiety scores in children for minor elective day case operations ( $P=0.448$ ).

Overall, these findings suggest that while the type of surgery does not significantly affect anxiety levels or compliance during induction, other factors may play a more significant role in pediatric patients' experiences and behaviors during this critical phase of medical care.

## **5.2 CONCLUSION:**

The study suggests that parental presence during induction can significantly improve a child's cooperation and reduce anxiety, especially in the more stressful theatre setting. Age also plays a role, with younger children experiencing higher theatre anxiety (< 6 years) hence parental presence will be more effective in this age group. The type of operation had no impact on children anxiety in this study.

These findings highlight the importance of considering both parental presence and age when creating a supportive environment for children undergoing anesthesia induction.

## **5.3 RECOMMENDATIONS:**

**Promote Parental Presence:** Encourage and facilitate parental presence during all stages of anesthesia induction, whenever possible. This can significantly improve a child's cooperation and reduce anxiety, especially in the theatre setting.

**Age-Appropriate Strategies:** Develop age-specific approaches for managing anxiety and promoting cooperation. Younger children may require more distraction and calming techniques, while older children might benefit from clear explanations and participation opportunities.

**Pre-Operative Education:** Provide age-appropriate education and preparation for children and their families before surgery. This can help alleviate anxiety and create a sense of control.

## **5.4 LIMITATIONS**

The participants age range was broad and there are no scales to measure anxiety in different age categories.

The anesthetic was given by different anesthetists, and they might have difference in their approach to anaesthetizing pediatrics patients.

Some children were not accompanied by close parent but by relatives such as uncles, cousins and aunties that might contribute to their anxiety.

Some surgeries were done later during the day therefore prolonging the fasting period and increasing levels of agitation and anxiety.

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APPENDIXES

**APPENDIX I QUESTIONNAIRE**

**Evaluation of the effect of parental presence or absence on anxiety among  
paediatric patients during induction of general anaesthesia at Intermediate  
Hospital Oshakati**

**PREOPERATIVE QUESTIONNAIRE**

**Part 1: Demographics details**

Hospital reference number:

Age:

Gender:

Diagnosis:

ASA classification:

Name of proposed operation:

Fasting period in hours:

Baseline pulse rate:

**Part 2: Parent/ guardians demographics details**

Gender:

Relationship with patient:

Prior Knowledge or idea on induction of anaesthesia: Yes

No



Poor      Satisfactory      Good      Excellent

Do you think you information could be communicated better? If yes, how

**MODIFIED YALE PREOPERATIVE ANXIETY SCALE**

| ACTIVITIES   | Score | Patient's score<br>(tick) |
|--|-------|---------------------------|
| The child looks around, is curious, plays with toys, reads (or other behaviour appropriate for the age group); moves around the preanesthetic/treatment room to get toys or seeks family members; might move toward the equipment in the surgery room. | 1     |                           |
| The child does not explore or play, may look down, plays with own hands or sucks its thumb (blanket); may sit close to family members while it is playing or may show a manic quality while playing.   | 2     |                           |
| The child moves without concentration from the toy to family members, movements are not connected to the activity; movements or play are frantic/agitated; twisting, moving on the table; may push the mask or grab family members.                    | 3     |                           |

|  |   |  |
|--|---|--|
| Tries to escape, pushes with feet and arms, may move its entire body; in the waiting room, runs around without purpose, does not look at the toys, does not want to be apart from family members, clings on desperately.                       | 4 |  |
| <b>Total score divided by all items</b>  |   |  |
| <b>VOCALIZATION</b>  |   |  |
| Reads (vocalization not adequate for the activity), ask questions, makes comments, stutters, laughs, answers questions promptly, but is usually quiet; child is too young to speak in social situations or too absorbed in the play to answer. | 1 |  |
| Answers to adults but whispers, “baby talk”, only shakes its head  | 2 |  |
| Quiet, no sound, or does not answer to adults  | 3 |  |
| Weeping, moaning, grunting, silent cry   | 4 |  |
| Child is crying or might yell no.  | 5 |  |
| Crying high pitched and sustained cry  | 6 |  |
| <b>Total score divided by all items</b>  |   |  |
| <b>EXPRESSING EMOTIONS</b>   |   |  |
| Happy, smiling, or concentrated on the play  | 1 |  |
| Neutral, no discernible face expression  | 2 |  |

|   |   |  |
|---|---|--|
| From worried (sad) to frightened, sad, worried, or teary eyed   | 3 |  |
| Distressed, crying, uncontrolled, eyes might be wide opened   | 4 |  |
| <b>Total score divided by all items</b>   |   |  |
| <b>STATE OF AROUSAL</b>   |   |  |
| Alert, looks around occasionally, notices, or follows anesthesiologist's action (might be relaxed)  | 1 |  |
| Withdrawn, calm, and silent, might suck its thumb, or its face might be like an adult's face  | 2 |  |
| Attentive, looks around quickly, might be startled by noises, eyes wide opened, body is tense   | 3 |  |
| Whines in panic, might cry or shun others and turn body around  | 4 |  |
| <b>Total score divided by all items</b>   |   |  |
| <b>USE OF PARENTS</b>   |   |  |
| Busy playing, sitting idle, or engaged in age- appropriate behavior and does not need parent; may interact with parent if parent initiates the interaction. | 1 |  |

|   |   |  |
|---|---|--|
| Reaches out to parent (approaches parent and speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent.              | 2 |  |
| Looks to parents quietly, apparently watches actions, does not seek contact or comfort, accepts it if offered or clings to parent.                | 3 |  |
| Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and will not let parent go. | 4 |  |
| <b>Total score divided by all items</b>   |   |  |
| <b>Overall percentage score</b>   |   |  |

**Scoring: Divide each item rating by the highest possible rating (i.e., 6 for the ‘vocalizations’ item and 4 for all other items), add all of the produced values, divide by five, and multiply by 100.**

## Induction Compliance Checklist

### Checklist Score

|   |  |
|---|--|
| Perfect induction(does not exhibit negative behaviours, fear or anxiety)    |  |
| Crying, tears in eyes   |  |
| Turns head away from mask   |  |
| Verbal refusal, says 'no'   |  |
| Verbalization indicating fear or worry, 'where's mommy?' or 'will it hurt?' |  |
| Pushes mask away with hands, pushes nurse/anaesthetist with hands/feet      |  |
| Covers mouth/nose with hands/arms or buries face                            |  |
| Hysterical crying, may scream   |  |
| Kicks/flails legs/arms, arches back, and/or general struggling              |  |
| Requires physical restraint   |  |
| Complete passivity, either rigid or limp                                    |  |
| Total score   |  |

**Total score =the number of categories checked ( perfect score=0)**

## **APPENDIX II Informed consent**

### **Evaluation of the effect of parental presence on anxiety among paediatric**

### **patients during induction of general anaesthesia at Intermediate Hospital**

### **Oshakati: A cross-sectional quasi experimental trial.**

|  |  |   |
|--|--|---|
| <b>Title:</b>  | <b>Dr.</b>   | <b>Initials: F.M</b>                            |
| <b>Surname</b>   | <b>Iyambo</b>  |   |
| <b>Name/s:</b>   | <b>Fenni Megameno</b>  |   |
| <b>Academic or equivalent Institutions to which affiliated</b>   | <b>Past: University of Namibia</b>   | <b>Present: University of Namibia</b>           |
| <b>Present Academic Rank</b>   | <b>Anaesthesia Registrar</b>   |   |
| <b>Work and employment Experiences</b>   | <b>Past: Oshakati Intermediate Hospital</b>  | <b>Present: Oshakati Intermediate Hospitals</b> |
| <b>Physical Contact Details {Courier Delivery }:</b>   | <b>Erf 1504, Ekuku, Oshakati</b>   |   |
| <b>Telephone numbers1:</b>   | <b>Office: 065 2233000</b>   | <b>Cell: 081 3770450</b>                        |
| <b>Email address:</b>  | <b><a href="mailto:fmiyambo@gmail.com">fmiyambo@gmail.com</a></b>                        |   |
| <b>Academic qualifications and Year obtained/institution</b>   | <b>MBCbB 2015 University of Namibia<br/>DA 2021 Colleges of Medicine of South Africa</b> |   |
| <b>Area/s of Expertise/Specialisation</b>  | <b>Primary<br/>Anaesthesia</b>   | <b>Secondary</b>                                |
| <b>Record of publications in the last 10 years</b>   |  |   |
| <b>ARTICLES IN PEERED REVIEWED JOURNALS/PROCEEDINGS</b>  |  |   |
| <b>NONE</b>  |  |   |
| <b>NATIONAL AND INTERNATIONAL CONFERENCES</b>  |  |   |
| <b>NONE</b>  |  |   |
| <b>CONTRIBUTION IN BOOKS, CHAPTERS IN BOOKS ECT</b>  |  |   |
| <b>NONE</b>  |  | <b>NONE</b>                                     |
| <b>List of key research projects undertaken or coordinated for the last 10 years, starting with the most recent:</b> |  |   |
| <b>NONE</b>  |  |   |
| <b>Record of postgraduate student supervision for the last 10 years, starting with the most recent:</b>              |  |   |
| <b>NONE</b>  |  |   |

**Principal investigator: Fenni M Iyambo**

**Phone numbers: 08137770450**

**Research approval number: SOM/03/2023**

**Purpose of the research:**

This research will compare the effects of parental presence or absence on anxiety among paediatric patients during induction of general anaesthesia and assess the level of cooperation among these patients at induction,

**Procedure of the research:**

You are being selected to participate in the study because you meet the following inclusion criteria: your child is within the age of 2-10 years, coming in for an elective surgery. If you agree to take part in this study, detailed explanation including visual aids of the process will be explained and demonstrated to you during pre-operative assessment.

If you agree to participate after reading this consent form, and selected for the parental presence group, you will accompany the child until the induction of anaesthesia is done and in the parental absence group, the child will be accompanied by the nurse.

The scoring for both groups will be done using an anxiety scale which includes scores for activities, vocalization, how they express their emotions, state of arousal and their interaction with parents for those accompanied by parents at the holding area, upon entrance of the theatre and upon introduction of the facemask.

A checklist to see how compliant the children are will be done upon introduction of the facemask. The scoring will be done by a trained medical personnel. This will not be an experimental study, all drugs administered (doses and routes) will be done according to the usual procedures. After the operation, you will be asked questions about your experience if you are selected for the parental presence group.

**Potential risks:**

There are no potential risks for the participating child. There is a potential that parents or guardians accompanying children in the theatre might experience anxiety due to unfamiliarity of the environment and as they see the child falling asleep from the anaesthetic. This will be mitigated by demonstrations to the parents during pre-anaesthetic evaluation. Please note that the University of Namibia or hospital management will not be responsible in such events and there will be no liability on the University or the hospital management

**Potential benefits:**

The results of this study could be used to change the practice at the hospital with the aim of reducing anxiety amongst children presenting for surgery.

**Financial implication for joining the research:**

Participation in this research will not cost you anything except the usual hospital charges for medical services rendered. There will be no payment for participating in this research.

**Confidentiality:**

The names will only be recorded on the consent to participate for the study records which will be stored confidentially however patient's numbers corresponding to the consent will be used on the data collection tools.

Patients' personal information will be handled with confidentiality and no patient identity will be revealed if the paper is to be published. The principal investigator

will store the data captured in a computer system with a password only known by her.

**Voluntariness:**

Participation in this study is entirely voluntary. We will appreciate your willingness to participate however you are free to decline participation in this study and you may choose to be invited to attend with your child or not.

**Alternatives to participation:**

Your treatment in the hospital will not be affected by your refusal to participate in this research. You have a right to withdraw from the research at any given time, if you choose to.

**Consequences of participants' decision to withdraw from the research and procedure for orderly termination of participation:**

As a participant you are free to withdraw from the research at any point in time. You must note that information gathered about you before this withdrawal may have been analysed and used in reports and publications. These cannot be withdrawn anymore. However, we promise to comply with your wishes as much as possible.

**What happens to participants at the termination of the research?**

The outcome of this research will be made available to the University of Namibia as well as the Ministry of Health and Social Services. As a participant of this research you will be notified if any further information is required or any further participation.

**AUTHORIZATION**

I, \_\_\_\_\_ GIVE CONSENT  
TO BE PART OF THIS STUDY THAT HAS CLEARLY BEING OUTLINED TO  
ME. MY SIGNATURE INDICATES THAT I HAVE READ AND UNDERSTOOD  
THE INFORMATION PROVIDED ABOVE. I HAVE HAD ALL MY QUESTIONS  
ANSWERED AND HAVE DECIDED TO VOLUNTARILY PARTICIPATE.

RESEARCH PARTICIPANT:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

STAFF OBTAINING CONSENT:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**A COPY OF THIS CONSENT FORM WILL BE PROVIDED TO YOU.**

## APPENDIX III: Ethical Clearance Certificate (UNAM)



### ETHICAL CLEARANCE CERTIFICATE

**Ethical Clearance Reference Number: SOM03/2023 Date: 3/03/2023**

This Ethical Clearance Certificate is issued by the University of Namibia Ethics Committee (REC) in accordance with the University of Namibia's Research Ethics Policy and Guidelines. Ethical approval is given in respect of undertakings contained in the Research Project outlined below. This Certificate is issued on the recommendations of the ethical evaluation done by the ethics committee.

**Title of Project:** Comparison of the effect of parental presence on anxiety among paediatric patients during induction of general anaesthesia at Intermediate Hospital, Oshakati: a cross-sectional quasi experimental trial

**Student:** Iyambo, F.M.

**Student Number:** 201020203

**Supervisor(s):** Dr Judith Morgan

**Centre for Research Services**

Take note of the following:

1. Any significant changes in the conditions or undertakings outlined in the approved Proposal must be communicated to the ethics committee. An application to make amendments may be necessary.
2. Any breaches of ethical undertakings or practices that have an impact on ethical conduct of the research must be reported to the ethics committee
3. The Principal Researcher must report issues of ethical compliance to the ethics committee (through the Chairperson) at the end of the Project or as may be requested by the ethics committee
4. The ethics committee retains the right to:
  - i) Withdraw or amend this Ethical Clearance if any unethical practices (as outlined in the Research Ethics Policy) have been detected or suspected,
  - ii) Request for an ethical compliance report at any point during the course of the research.

The ethics committee wishes you the best in your research.

*Mareli Claassens*

A/Prof Mareli Claassens (Chairperson Ethics Committee)

*Prof. Davis Mumbengegwi*

Prof. Davis Mumbengegwi (Head, Multidisciplinary Research)

## APPENDIX IV: Permission to conduct research; Intermediate Hospital Oshakati



9 - 0/0001

### REPUBLIC OF NAMIBIA

#### Ministry of Health and Social Services

Private Bag 5501

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OSHAKATI

INTERMEDIATE HOSPITAL OSHAKATI

Fax: + 264 65 224564

Enquiry: Ms Selma P. Mwandingi

11/ 10/2023

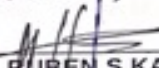
Ms.Fenny M.Iyambo  
Po.box 1817  
Ondangwa

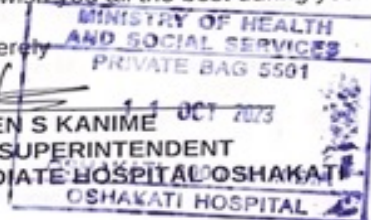
Dear Ms.Iyambo

#### PERMISSION TO CONDUCT A RESEARCH STUDY


1. Your letter dated 11/10/ 2023 has reference
2. This is to inform you that your request to conduct a research study in Oshakati Intermediate Hospital on "Comparison OF THE EFFECT OF PARENTAL presence on anxiety among paediatrics patients during induction of general anaesthesia at Intermediate Hospital Oshakati" has been approved.
3. Take note that this approval is subject to all the conditions outlined in a letter dated \11\07\2023 from the MOHSS.
4. Kindly be informed that confidentiality of the patient information seen during your research must be observed. In case of breach of confidentiality, you will be charged by the Nursing Act (Act No.8 of 2004).
5. In addition, the hospital requires a copy of your dissertation for our archive when you have completed your study.
6. We wish you all the best during your research.

Yours sincerely

  
DR. RUBEN S KANIME  
MEDICAL SUPERINTENDENT  
INTERMEDIATE HOSPITAL OSHAKATI  
OSHAKATI HOSPITAL



**APPENDIX V : Permission to conduct research: Ministry of Health and Social Services**

  
REPUBLIC OF NAMIBIA

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**MINISTRY OF HEALTH AND SOCIAL SERVICES**  
**OFFICE OF THE EXECUTIVE DIRECTOR**

Ministerial Building  
Harvey Street  
Private Bag 13198, Windhoek

Tel: No: 061 -203 2507  
Fax No: 061-222 558  
Andreas.Shipanga@mhs.gov.na

Ref: 22/4/2/3  
Enquiries: Mr. A. Shipanga

Date: 11 July 2023

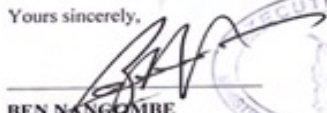
Ms. Fenni M. Iyambo  
PO Box 1817  
Ondangwa  
Namibia


Dear Ms. Iyambo

**Re: Comparison of the effect of parental presence on anxiety among paediatric patients during induction of general anaesthesia at Intermediate Hospital, Oshakati.**


1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
  - 3.1 The data to be collected must only be used for academic purpose;
  - 3.2 No other data should be collected other than the data stated in the proposal;
  - 3.3 Stipulated ethical considerations in the protocol related to the protection of Human Subjects should be observed and adhered to, any violation thereof will lead to termination of the study at any stage;
  - 3.4 A quarterly report to be submitted to the Ministry's Research Unit;
  - 3.5 Preliminary findings to be submitted upon completion of the study;
  - 3.6 Final report to be submitted upon completion of the study;
  - 3.7 Separate permission should be sought from the Ministry for the publication of the findings.
4. All the cost implications that will result from this study will be the responsibility of the applicant and **not** of the MoHSS.

Yours sincerely,

  
BEN NANGOMBE  
EXECUTIVE DIRECTOR



All official correspondence must be addressed to the Executive Director

  
10.23.2023