# PREVALANCE OF INTRA-OPERATIVE HYPOTHERMIA AND ASSOCIATED FACTORS AMONG PEDIATRIC PATIENTS UNDERGOING SURGERY AT MUHIMBILI NATIONAL HOSPITAL

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# PREVALANCE OF INTRA-OPERATIVE HYPOTHERMIA AND ASSOCIATED FACTORS AMONG PEDIATRIC PATIENTS UNDERGOING SURGERY AT MUHIMBILI NATIONAL HOSPITAL.

**By**

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**A Dissertation submission in Partial fulfillment of the requirement for the degree of Master of Medicine in Anaesthesiology at**

**Muhimbili University of Health and Allied Sciences.**

**October, 2024**

## CERTIFICATION

The undersigned certify that they have read and hereby approve for examination by the Muhimbili University of Health and Allied Sciences a dissertation entitled ***"Prevalence of intra-operative hypothermia and associated factors among paediatric patients undergoing surgery at Muhimbili national hospital"*** in partial fulfilment of the requirements for the degree of Master of Medicine (Anaesthesiology) of Muhimbili University of Health and Allied Sciences.

_____

DR. ASHA ABDULLAH

**(Supervisor)**

Date: _____

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DR. RAYMOND OYUGI

**(Co- supervisor)**

Date: _____

## DECLARATION AND COPYRIGHT

I, **Ramadhani Shaban,** affirm that this dissertation is my original work that has not been or will not be presented to any other university for a similar or other degree award.

Signature……. Date ……

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## DEDICATIONS

I dedicate this research dissertation with boundless love and gratitude to the most important people in my life. To my beloved wife, Mwakombo, this dissertation stands as a testament to your unwavering love, support, and encouragement throughout this academic journey. Your presence in my life has been a constant source of strength, inspiration, and motivation.

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Lastly, I dedicate this research dissertation to my father, Shaban, your unwavering support and belief in my abilities will forever be cherished. This dedication is a tribute to your legacy and the lasting impact you have had on my life.

With all my love and gratitude,

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## ABBREVIATIONS

| | |
|---|---|
| ASA | American Society of Anaesthesiologists. |
| GA | General anaesthesia. |
| NICE | National Institute for health and Care Excellence |
| MNH | Muhimbili National Hospital |
| OR | Operating room |
| IV | Intravenous |
| SSI | Surgical site infection |
| MoH | Ministry of Health. |

## DEFINITION OF TERMS

**NORMOTHERMIA:** Is described as a core body temperature range of 36.5°Cto37.5°C(1,2)

**HYPOTHERMIA:** A core body in this study hypothermia will be defined according to this standard temperature of less than 36ºC Is referred to be a standard definition of hypothermia. (1,2)

**INTRA-OPERATIVE HYPOTHERMIA**: Occurs when a patient's temperature drops below 36 degrees for at least five minutes. (3)

**PEDIATRIC POPULATION:** Muhimbili National Hospital defines the ages of the paediatric population from infancy to the age of twelve in paediatric surgery department.

**ASA PHYSICAL STATUS CLASSIFICATION:** Is an evaluation and communication tool for a patient's pre-anaesthesia medical co-morbidities (4)

## ABSTRACT

**Background**: Hypothermia remains among the leading cause of morbidity and mortality worldwide. Paediatric patients are particularly vulnerable to hypothermia due to the lack of subcutaneous fat, an immature thermoregulatory centre and a higher surface area to volume ratio.

**Aim of the study**: To determine the prevalence of intra-operative hypothermia and associated factors among paediatric patients undergoing surgery at Muhimbili national Hospital.

**Methodology**: This was a hospital-based analytical cross-sectional study conducted among 327 paediatric patients at Muhimbili National Hospital. All patients who met the inclusion criteria were enrolled after obtained consent from their parents on the day of surgery. Patients were recruited using a consecutive sampling technique. Data was collected through a specifically designed questionnaire, intraoperative anaesthetic charts, and the patient medical records file,

The chi-square test, univariate and multi variate logistic regressions were utilised to determine the relationship between the independent variables and the dependent variable.

A p-value of <0.05 and a 95%CI were considered statistically significant.

**Results**: A total of 327 paediatric patients who underwent surgery at MNH were enrolled into the study. Among the enrolled participants, majority were aged between 2-5 years127 (38.84%). The majority of participants 177(54.13%) were male and more than three quarter 291(88.99%) had ASA physical status 1. The prevalence of intraoperative hypothermia was found to be 82.8%. This was affected by duration of surgery [AOR: 13.38, 95% CI: 5.47–32.71], and anaesthesia [AOR: 8.90, 95% CI: 3.05–25.92], ASAII [AOR: 7.88, 95% CI: 1.686–37.95], amount of fluid administered [AOR: 0.55, 95% CI: 0.34–0.90], fluid warmed [AOR: 3.74, 95% CI: 6.35-29.73], ], Forced air warming [AOR = 0.4, 95% CI: 0.26 - 1.04], Operating room temperature[AOR = 5.76, 95% CI: 3.38 - 8.97], and elective surgery [AOR: 2.65, 95% CI: 1.34-5.21] which were statistically significant.

**Conclusion and recommendation:** The paediatric population undergoing surgery at MNH developed intraoperative hypothermia by 82.8%. Factors which contributed to hypothermia were duration of surgery and anaesthesia, ASA status, amount of fluid administered, operating room temperature, forced air warming devices, and elective surgery. The study recommends the use of standard intravenous fluid protocol, short duration of surgery and anaesthesia, avoiding use of un-warmed IV fluid and continuous medical education (CME).

# CHAPTER ONE

## 1.0 INTRODUCTION

### 1.1 Background

Hypothermia is a core temperature below 36.0 °C. It is divided into three categories mild (core body temperature between 35°C and 35.9°C), moderate (between 34°C and 34.9°C), and severe (below 33°C). (1)

Paediatric patients who have general anaesthesia for surgery frequently encounter hypothermia due to their immature thermoregulatory centre, lack of subcutaneous fat and high surface area to volume ratio.(5,6)

Typically, heat loss during anaesthesia causes a triphasic form of hypothermia. Phase 1 (redistribution) results in the first rapid drop in temperature as warm blood from the core circulates to the peripheries, as well as cool blood from the peripheries, reaches the core circulation. The direct effect of anaesthetic drugs and the indirect effects of reduced vasoconstriction threshold both lead to vasodilation. Phase 2 is linear because heat loss is greater than the heat generated by metabolism. During general anaesthesia, the metabolic rate is lowered by 15%–40%. A negative heat balance, which results in hypothermia, is caused by a decrease in heat production and an increase in heat loss during anaesthesia. Phase 3 begins, when a state of balance is attained and thermoregulated vasoconstriction starts to work, when heat generation equals heat loss.(7,8)

Two types of temperature measurements are used to help in diagnosing intra operative hypothermia namely; near-core and core temperature. Among the near-core locations are the axilla, bladder, rectum, and tympanic membrane with an infra-red sensor. While the core sites include the distal part of the oesophagus, the nasopharynx, as well as the pulmonary artery and the tympanic membrane via a thermocouple..(9–11)

Axillary temperature can be accurately measured when the temperature measurement probe is positioned over the axillary artery and the patient's arm is kept tightly adducted at his or her side. This method can provide accurate core body temperature measurement by adding 0.4°C for children under general anaesthesia. (1)

Hypothermia can be managed by the following methods: Passive insulation, such as cotton blankets, plastic bags, reflective covers and surgical drapes, can reduce heat loss by around 30% by insulating the child from the environment. Active methods are the most widely utilized and effective active warming systems: forced-air warming devices which can raise the body's core temperature by roughly 0.75 degrees Celsius every hour (12).

Hypothermia can lead to physiological disturbances and complications, such as impaired wound healing, increased bleeding and transfusion requirements, prolonged hospital stay, and decreased drug metabolism, and cardiac abnormality. Due to reduced oxygen supply to tissues as well as vasoconstriction, hypothermia has been associated with a higher risk of SSI, hypothermia results in thermo regulatory vasoconstriction, which lowers the oxygen concentration and slows the healing process (11,13).

Premature infants and neonates under cold stress may exhibit numerous physiological mechanisms, including a higher metabolism, catecholaminergic reactions, vasoconstriction, and reduced surfactant production. This could result in metabolic acidosis, hypertension, hypoxia of the tissues, hypotension, hypoperfusion of essential organs, and hypoglycaemia. The potential outcomes include apnoea, the requirement for artificial ventilation, and arrhythmias; an elevated risk for infections; and a long stay in hospital. (3,11,13)

## 1.2 Problem Statement

Hypothermia is a major problem and a leading cause of morbidity and mortality world-wide. with a prevalence as high as 52% in the developed world.(3) In sub-Saharan Africa, including Tanzania, intra operative hypothermia in paediatric patients undergoing surgery is a growing problem with prevalence 71.7%.(14)

Intraoperative hypothermia can be influenced by a number of factors, including anaesthetics, age, systemic disorders, operating room temperature, duration of surgery, and poor temperature management, such as a lack of intraoperative active and passive warming, a lack of an intraoperative patient temperature monitor, and a lack of prewarming IV fluids.

Data on intraoperative temperature management, the prevalence of hypothermia, and associated factors among paediatric patients undergoing surgery in our setting are scarce, leading to a significant challenge in managing and preventing complications in this group.

## 1.3 Conceptual Framework

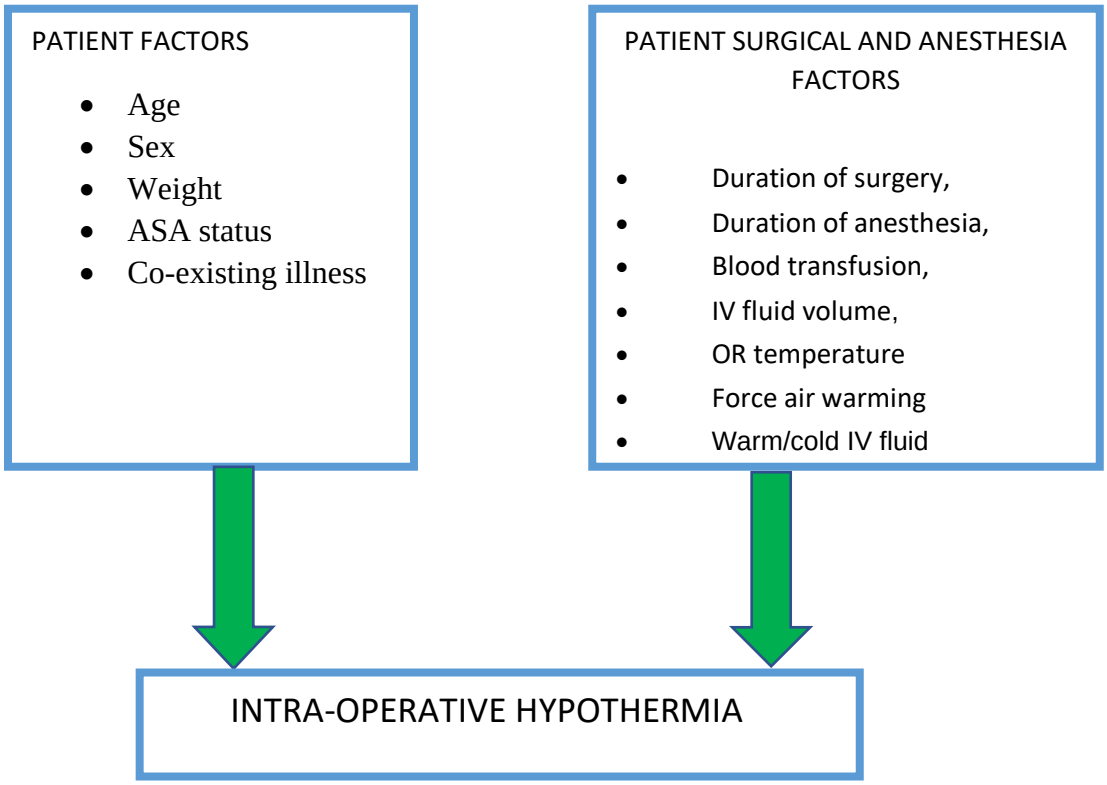



**Figure 1: conceptual frame work**

**Source: Conceptualized by author**

## 1.4 Rationale

The study findings would provide baseline information on hypothermia burden at our setting and the contributing factors which would help in planning strategies to improve intraoperative temperature management and hence decrease the incidence of hypothermia and the related complications in paediatric patients.

Additionally, this study would serve as a reference for future researchers in addressing the issues related to intraoperative temperature management in paediatric population that may not be covered in this study.

## 1.5 Research Questions

### 1.5.1 Broad research question

What is the prevalence of intra-operative hypothermia and associated factors among paediatric patients undergoing surgery at Muhimbili National Hospital?

### 1.5.2 Specific research question

1. What is the prevalence of intra-operative hypothermia among paediatric patients undergoing surgery at Muhimbili National Hospital?
2. What factors are associated with intraoperative hypothermia in paediatric patients undergoing surgery at Muhimbili National Hypothermia?

## 1.6 Objectives

### 1.6.1 Broad objective

To identify the prevalence of intra-operative hypothermia and factors associated among paediatric patients undergoing surgery at Muhimbili National Hospital.

### 1.6.2 Specific objectives

1. To identify the prevalence of intraoperative hypothermia among paediatric patients undergoing surgery at Muhimbili National Hospital from September to December 2023.
2. To determine the factors associated with intraoperative hypothermia among paediatric patients undergoing surgery at Muhimbili National Hospital from September to December 2023.

## 1.7 Research Hypothesis

### 1.7.1 Alternative hypothesis

There is an association between intraoperative hypothermia and age, sex, weight, ASA status, co-existing illnesses of the patient, the duration of surgery and anaesthesia**,** and temperature management practice.

### 1.7.2 Null hypothesis

There is no association between intraoperative hypothermia and age, sex, weight, ASA status, co-existing illnesses of the patient, the duration of surgery and anaesthesia**,** and temperature management practice.

# CHAPTER TWO

# 2.0 LITERATURE REVIEW

## 2.1 Prevalence of Intraoperative Hypothermia

Pediatrics are prone to intraoperative hypothermia despite the rewarming practices(15). This can be due to the effect of general anaesthesia, immature thermoregulatory centers, less subcutaneous fat and low body weight to surface ratio.

Paediatrics undergoing both elective and emergency surgeries under general anesthesia experience intraoperative hypothermia in both developed and developing countries. In developed countries prevalence range from 52% to 81.9% (3,15,16).

Whereas in developing countries, the prevalence ranges from 23.4% to 83.8% (14,17,18),with high prevalence being observed in neonates and infants, also increasing linearly with the duration of exposure to general anaesthesia and surgery.

Some studies demonstrated intraoperative hypothermia prevalence in paediatrics of less than 50% which was achieved with improving the temperature management practice intraoperatively. Observational studies done by Kubra E et al in Turkey, Kioko P.M et al in Kenya and Mekete G et al in Ethiopia demonstrated 20.58%, 30% and 39.8% respectively as the prevalence of intraoperative hypothermia in paediatrics.(1,19,20)

## 2.2 Factors Associated with Intraoperative Hypothermia

### 2.2.1 Duration of Anaesthesia and Surgery

Prolonged duration of anaesthesia and surgery lead to intraoperative hypothermia due to increased time of contact between patient, operating bed and wet surgical drapes leading to heat loss via conduction. In open abdominal surgeries, prolonged time of surgery increases heat loss from visceral organs exposure to cold operating room environment. Also, prolonged exposure to anaesthetic drugs lead to vasodilation that cause redistribution of heat from the core to the periphery. An observational studies done in Europe and Asia found that duration of surgery and exposure to anaesthesia are significantly associated with intraoperative hypothermia with p value less than 0.001

and it was observed that when the time of surgery exceed more than 60 minutes, the strength of association increases linearly.(19,21,22)

### 2.2.2 Body Weight

Paediatric patients with low body weight have reduced weight-to-surface-area ratio, less subcutaneous fat, thin skin, and an immature thermoregulatory centre; this may lead them to lose heat more easily as compared to other populations. Extremely low birth weight neonates (1000g), have little ability to vasoconstrict in the presence of cold stress, because they depend on non-shivering thermo genesis to produce heat.

Studies done in Asia demonstrated that there was a significant association between low birth weight and intraoperative hypothermia with ($P<0.001$). In addition, it was observed that as you decrease the body weight, the risk of developing hypothermia also increases significantly. (21,23)

### 2.2.3 Age

Neonates have brown adipose tissue which can be doubled in infants, which is the main thermogenic organ in both infants and neonates. In efficient thermoregulation due to lower thermogenin levels may lead to intraoperative hypothermia because there is no peripheral vasoconstriction to preserve heat. A study done by LeeL et al in Malaysia and Hu Y *et al* found significant association between age and the development of intraoperative hypothermia and neonates were more affected compared to toddlers and older children(15,24). Older children have a tendency to experience intraoperative hypothermia due to relatively larger and cooler extremities, which cause redistribution of heat as study done by Pearce B *et al* demonstrated significant association. (3)

### 2.2.4 ASA Physical Status

Small and ill paediatric patients have a narrow thermo-neutral range and are prone to thermal instability as compared to normal-health paediatric patients with ASA grade 1. The higher the ASA grade, the greater the risk of developing intraoperative hypothermia, and this may happen to ASA grades 2 to 5. A study conducted by Jialian Z *et al*, Mekete G *et al* showed that higher ASA grade was associated with intraoperative hypothermia with a P value of less than 0.001. (1,25)

### 2.2.5 Temperature Management Practice.

Passive or active warming of the patients, such as using warm surgical drapes or cotton blankets or forcing air warming devices, warmed IV fluid administration, and patient temperature monitoring, are the means of preventing the occurrence of intraoperative hypothermia. Due to the fact that heat loss occurs during any surgical procedure and may occur through different mechanisms such as conduction, convection, and evaporation, and may significantly contribute to intraoperative hypothermia. Studies done in Europe and Asia , found that there was a strong association between intraoperative hypothermia and passive or active warming of the patients as well as temperature monitoring of the patient intraoperatively. (6,26,27)

### 2.2.6 Operating Room Temperature.

Operating room temperature is another factor that may lead to intraoperative hypothermia because as the ambient temperature decreases, the body loses heat through convection, especially in infants or neonates when they are in a cool operating room. Normally, room temperature of more than 23°C or 26°C is generally required to maintain normothermia in adults and infants respectively (1). Studies done in Ethiopia and Rwanda both demonstrated that when operating room temperature is between 22 - 24°C intraoperative hypothermia is six times higher than when temperature is above 24°C. (14,28)

# CHAPTER THREE

# 3.0 METHODOLOGY

## 3.1 Study design

Analytical hospital-based, cross-sectional study.

## 3.2 Study duration

The study was conducted from June to November, 2023

## 3.3 Study area

The study was conducted at Muhimbili National hospital which is situated in the Dar-es-Salaam region in the Upanga west administrative ward of the Ilala city council. Muhimbili National Hospital is a university teaching hospital with 1,500 beds and 295 paediatric beds, where about 1800 children receive medical care each month. It is the largest national tertiary health care centre in Tanzania. Referred patients from Tanzania's regional referral and zonal hospitals as well as those from the Dar-es-Salaam area are served by the hospital.

Muhimbili Paediatric Theatre has four operating rooms, two for general surgical conditions and each operating room has one operating bed. It typically handles 160 cases per month, or a total of 1920 cases per year. There are 24 nurses working in paediatric theatre, two of them are volunteers and the rest are permanent government employees, as well as 15 assistant nurse officers, two enrolled nurses, and eight health attendants, one of them is a volunteer as well as two anaesthesiologists and four nurse anaesthetists.

## 3.4 Study population

All paediatric patients less than 12 years old who underwent surgery at MNH within the specified time period.

## 3.5 Sampling technique

A consecutive sampling technique was used during this study in order to obtain the sample size. This is a non-probability sampling method where every subject meeting the criteria is selected until a predetermined sample size is reached. All paediatric

patients who met the inclusion criteria and happened to be available were enrolled in the study.

### 3.6 Sample size estimation

The sample size was calculated using Kish Leslie formula for cross sectional studies. In which case;

i) The allowed margin of error was 5%

P = 30%, represents the incidence and risk factors for intra-operative hypothermia among paediatric patients who underwent general anaesthesia at the Kenyatta National Hospital (20),

ii) Confidence interval was 95%,

iii) Z will be equal to 1.96,

$$n=\frac{z^2p(1-p)}{\varepsilon^2}$$

$$n=\frac{1.96x1.96x0.3(1-0.3)}{0.05^2}$$

n=322.6, approximately323

The minimum sample size for the proposed study included 323 patients. Our final sample size was 327, which was 4 people above the minimum. This can be justified by the fact that there is a higher flow of paediatric patients in our setting and an increased sample size allows a more precise estimate of the treatment effect.

### 3.7 Inclusion and Exclusion criteria

#### 3.7.1 Inclusion criteria

Paediatric patients who were less than 14 years old and whose parents consented for the study.

#### 3.7.2 Exclusion criteria

Patients who had a fever, patients with body temperature <36°C

Anaesthesia time <30minutes

Patients whose parents or guardians were not available or refused to sign the consent.

### 3.8 Study variables

#### 3.8.1 Dependent variables

Intraoperative hypothermia

### 3.9 Independent variables

PATIENTS FACTORS

Age

Sex

Weight

ASA status

Co-existing illness

PATIENT SURGICAL AND ANESTHESIA FACTORS

Surgical type

Duration of surgery

Duration of anaesthesia

Blood loss

Blood transfusion

Operating room temperature

IV fluid volume

Warmed/cold IV fluids

Use of active warming devices

### 3.10 Data collection method, tool and procedures

Data was collected through a specifically designed questionnaire adopted from previous similar studies done in Ethiopia (1), The first part of the questionnaire collected basic demographic and medical information; the second part collected specific information about intraoperative characteristics like OR temperature, anaesthetic agents, and the duration of surgery and anaesthesia. After obtaining consent from their parents on the day of surgery, the principal investigator or research assistant had to fill in the questionnaires with data such as patients' age, gender, ASA physical status, coexisting illnesses, patient medical records file, and other variables obtained from anaesthetic charts. The patient's temperature was measured upon arrival in the operating room, after induction of anaesthesia , and every 30 minutes until the procedure was completed and before extubating the patients by placing the anaesthetic machine's temperature measurement probe over the axillary artery and having the arm tightly adducted, with accuracy by adding 0.4°C-0.6°C as a compensation. Also, the room temperature was recorded using a digital room thermometer, after the patient arrived in the operating room, patients with a body temperature <36℃ were termed to have hypothermia. (1,29)

### 3.11 Data management and Statistical analyses

The data was cleaned for consistency, accuracy, completeness, and outlier detection. Pre coded responses to the questionnaire was entered into SPSS version 23.0. The categorical variables were summarised using frequency distribution tables and statistical diagrams. The chi-square test, univariate, and multivariate logistic regressions were utilised to determine the relationship between the independent variables and the dependent variable. A p-value of <0.05 and a 95% CI were considered statistically significant.

### 3.12 Ethical consideration

Ethical approval for the study was sought from the Muhimbili University of Health and Allied Sciences (MUHAS) ethical committee. The approval to collect data was obtained from the Director of Research Services at MNH. Participation in the study was completely voluntary, and all study participants were assured of confidentiality throughout the study duration. The purpose of the study was explained, and both informed consent and assent were obtained from participants and their parents.

### 3.13 Dissemination research result

The final dissertation work will be made available for reference at the Muhimbili University of Health and Allied Science (MUHAS) repository. The study's findings will be presented at MUHAS scientific conferences, and a manuscript will be submitted for publication, with a copy given to Muhimbili National Hospital.

# CHAPTER FOUR

## 4.0 RESULT

### 4.1 Socio-demographic and clinical characteristics of paediatric patients.

Among 327 enrolled participants, majority were aged between 2-5 years, 127 (38.84%) and only 28 (8.56%) of participants were aged between 1 to 28 days. The smallest weight was 1.8kg and the highest was 31kg. More than half of the participants were below 13kg (52.91%). The majority of participants 177(54.13%) were male, more than three quarters 291(88.99%) had ASA physical status I. Those who had no co-existing illnesses were 293(89.6%), elective surgeries were 278(85.02%), with the majority being general surgery 158 (48.32%) (Table:1)

**Table 1: socio-demographic and clinical characteristics. Total (N) = 327**

| Variables | Category | Frequency | Percentage% |
|---|---|---|---|
| **Age** | | | |
| | 1-28days | 28 | 8.56 |
| | I-12months | 88 | 26.91 |
| | 2-5years | 127 | 38.84 |
| | 6-14years | 84 | 25.69 |
| **Gender** | | | |
| | Male | 177 | 54.13 |
| | Female | 150 | 45.87 |
| **Weight (Kg)** | | | |
| | 1.8-13 | 173 | 52.91 |
| | 13.1-31 | 154 | 47.09 |
| **ASA status** | | | |
| | I | 291 | 88.99 |
| | II | 21 | 6.42 |
| | III | 15 | 4.59 |
| **Any coexisting illness** | | | |
| | Yes | 34 | 10.4 |
| | No | 293 | 89.6 |
| **Specific illness** | | | |
| | Cardiomyopathy | 1 | 3.03 |
| | CHD | 24 | 69.7 |
| | CP | 4 | 12.12 |
| | Epilepsy | 3 | 9.09 |
| | Malnutrition | 2 | 6.06 |
| **Type of surgery** | | | |
| | Elective | 278 | 85.02 |
| | Emergency | 49 | 14.98 |
| **Surgical Procedure** | | | |
| | Burn surgery | 44 | 13.46 |
| | ENT | 20 | 6.12 |
| | General surgery | 158 | 48.32 |
| | Urology | 104 | 31.8 |
| | Others | 1 | 0.3 |

### 4.2 Intra-operative characteristics.

Among the 327 participants who had received surgical treatment, all had normal body temperatures on arrival at OR. The operating room (OR) temperatures varied from 23 – 27°C with 24°C being the most common OR temperature.

Body temperature after induction of anaesthesia shows both hypothermia (82.8%) and normothermia (17.13%). The body temperature was then measured after 30, 60, 90, 120, 180, 210 and 240 minutes of procedure. In the first 30 minutes, hypothermia was 56.88%. Between one hour and one hour and a half, hypothermia was less than 50%. For the paediatric patients whose procedures took between two hours and four hours, hypothermia was 65.47% at 120 minutes, 83.93% at 180 minutes, 92.86% at 210 minutes and 100% at 240 minutes. Among the induction agents, inhalation (99.39%) and fentanyl (97.86%) were the most commonly used and among muscle relaxants, 325 (99.39%) had used Atracurium. There was 99.08% and 93.88% use of paracetamol and fentanyl in analgesics respectively, while only 21.10% used morphine. Patients who used less than 500ml of IV fluids were 255(77.98%), and fluid was warmed in 241 (73.7%). Duration of surgery in the majority of the patients was between one to two hours (52.6%)

**On arrival**

i. The temperatures ranges from approximately 36°C to 37.5°C.
ii. The most frequent temperature appears to be around 36.7°C indicated by the tallest bar.

**After induction of anesthesia**

i. The temperatures range more broadly from 32°C to 37.5°C.
ii. The most frequent body temperature appears to be significantly lower, around 34°C indicated by tallest bar.

**Interpretation**

There is a notable drop in body temperature after the induction of anesthesia with many patient's temperatures clustering around 34°C

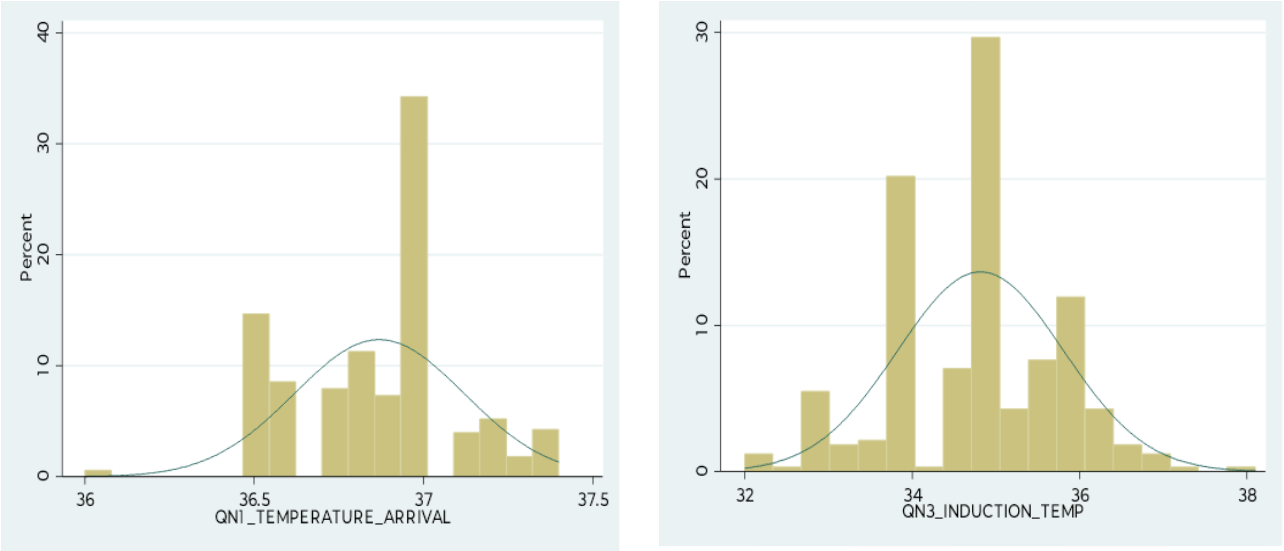



**Figure 2: Body temperature on arrival and after induction of anaesthesia**

### 4.3 Prevalence of intra-operative hypothermia

The finding of the study revealed the prevalence of intraoperative hypothermia after induction of anaesthesia was 82.87% among 327 paediatric patients who underwent surgery at MNH

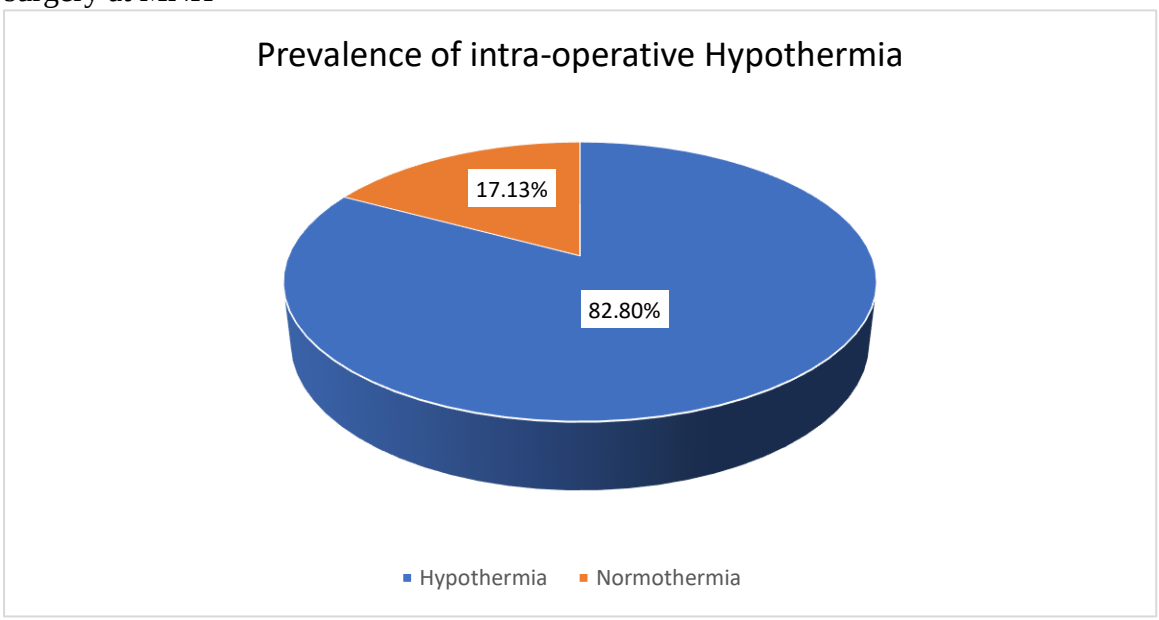



**Figure 3: Prevalence of intraoperative hypothermia**

### 4.4 Association between hypothermia and demographic, clinical and intra operative characteristics of paediatric patients who underwent surgery at MNH.

The study identified a statistically significant relationship between hypothermia among paediatric patients who underwent surgery and ASA status, type of surgery, surgical procedure, fluid warmed, force air warming, blood transfusion, surgery duration and anaesthesia duration. However, hypothermia did not show a statistical relationship with age groups, gender, weight, other muscle relaxants, analgesic use. (Table:2).

**Table 2: Relationship between hypothermia and demographic, clinical and intra-operative characteristics among paediatric patients who underwent surgery.**

| Variable | Categories | Hypothermia (N) | % | Chi2 | p value |
|---|---|---|---|---|---|
| Gender | Female | 85 | 56.6 | 0.5568 | 0.456 |
| | Male | 93 | 52.5 | | |
| Age | Children | 47 | 56 | 0.7048 | 0.872 |
| | Infants | 47 | 37 | | |
| | Neonates | 17 | 61 | | |
| | Toddlers | 67 | 76 | | |
| ASA status | I | 159 | 54.6 | 7.7274 | **0.02** |
| | II | 7 | 33.3 | | |
| | III | 12 | 80 | | |
| Specific illness | Cardiomyopathy | 0 | 0 | 9.065 | **0.05** |
| | CHD | 10 | 41.6 | | |
| | CP | 4 | 100 | | |
| | Epilepsy | 3 | 100 | | |
| | Malnutrition | 1 | 50 | | |
| Type of surgery | Elective | 142 | 51 | 8.4198 | **<0.01** |
| | Emergency | 36 | 73.4 | | |
| Surgical procedure | Burn | 30 | 68.1 | 12.561 | **0.01** |
| | ENT | 5 | 25 | | |
| | General surgery | 81 | 51.2 | | |
| | Urology | 61 | 58.6 | | |
| | Others | 1 | 100 | 61.86 | **<0.01** |
| Fluid warmed | Yes | 100 | 41.4 | | |
| | No | 78 | 90.6 | | |
| Force air warming | Yes | 4 | 2.7 | 276.82 | **<0.01** |
| | No | 174 | 95 | | |
| Blood transfusion | Yes | 30 | 68.1 | 9.545 | **<0.01** |
| | No | 0 | 0 | | |
| Surgery duration | 0 -60 | 34 | 34.3 | 40.84 | **<0.01** |
| | 61 - 120 | 95 | 55.2 | | |
| | 121 + | 49 | 87.5 | | |
| Anaesthesia duration | 0 - 60 | 12 | 40 | 54.06 | **<0.01** |
| | 61 - 120 | 59 | 37.3 | | |
| | 121 - 180 | 58 | 69.8 | | |
| | 181 - 240 | 45 | 86.5 | | |
| | 241+ | 4 | 100 | | |

### 4.5 Factors associated with hypothermia among paediatric patients who underwent surgery at MNH.

Several factors were associated with hypothermia among paediatric patients who have undergone surgery. These factors can be categorized into demographic characteristics, clinical and intra-operative related factors. The factors contributing to hypothermia and showed statistical significance have been discussed below.

On bivariate analysis, the existence of any co-existing illness [COR = 1.66, 95% CI: 0.53 – 2.155, $p$=0.01] was significantly associated with hypothermia. In addition, type of surgery [COR = 2.83, 95% CI: 1.36 – 5.16, $p$=0.01], surgery duration [COR = 14.83, 95% CI: 5.55 – 32.05, $p$=0.01], blood loss [COR = 3.31, 95% CI: 1 – 7.49, $p$=0.04], blood transfusion [COR = 0.801, 95% CI: 0.262 – 0.99, $p$=0.04] and force air warming [COR = 0.23, 95% CI: 0.196 – 0.53, $p$=0.01] were also significantly associated with hypothermia. After adjusting for confounding variables, the potential variables identified in the bivariate analysis was further examined using multivariate logistic regression. ASA II [AOR = 7.889996, 95% CI:1.686394 - 37.95076, $p$=<0.01], type of surgery [AOR = 2.652221, 95% CI: 1.34852 - 5.216292, $p$=<0.01]. Surgery duration between 61 – 120 minutes [AOR = 5.673684, 95% CI: 2.432169 - 13.23538, $p$=<0.01] was found to be associated with hypothermia.

The other factors with significant association with hypothermia was duration of anaesthesia between 61 – 120 minutes [AOR = 10.97291, 95% CI: 4.644451 - 25.92441, $p$=<0.01], 121 – 180 minutes [AOR = 2.770936, 95% CI: 1.099708 - 6.981933, $p$=0.031], 181 – 240 minutes [AOR = .1555556, 95% CI: 0.0701524 - 0.3449279, $p$=<0.01], fluid warming [AOR = 13.7475, 95% CI: 6.356232 - 29.73362, $p$=<0.01], Forced air warming [AOR = 0.4, 95% CI: 0.26 - 1.04, $p$=<0.02], Operating room temperature[AOR = 5.76, 95% CI: 3.38 - 8.97, $p$=<0.01], and IV fluids 501 – 1000 ml [AOR = .5555556, 95% CI: 0.3407223 - .9058462, $p$=0.018], had statistical significance association with hypothermia among paediatric patient. (Table:3)

**Table 3: Factors associated with hypothermia among paediatric patients.**

| Variable | Categories | COR 95%CI; p-value | AOR 95%CI; p-value |
|---|---|---|---|
| **Age group** | Children(6-14years) | 1.078019(.506- | .879(.505-1.529):0.648 |
| | Infants(1-12months) | 1.526):0.648 | .974(.564-1.679):0.925 |
| | Neonates(1-28days) | 1.345(.566-1.676):0.924 | .722(.313-1.664):0.445 |
| | Toddlers(2-5years) | .722(.318-1.643):0.444 | **Ref** |
| | | **Ref** | |
| **Gender** | Male | 1.009(.78-1.868):0.39 | 1.20(.78-1.87):0.397 |
| | Female | **Ref** | **Ref** |
| **ASA status** | I | 3.1(.982-11.17):**0.05** | 3.32(.917-12.01):0.06 |
| | II | 8(1.76-35.443) **:<0.01** | 7.889(1.686- |
| | III | **Ref** | 37.95) :<**0.01** |
| | | | **Ref** |
| **Weight(kg)** | 13+ | 0.894(.475-1.139):0.169 | 0.736(.475-1.14):0.17 |
| | < 13.0 | **Ref** | **Ref** |
| **Any coexisting illness** | Yes | 1.633(0.53-2.155);**0.003** | 1.06(.524-2.17);**0.005** |
| | No | Ref | **Ref** |
| **Type of surgery** | Elective | 2.83(1.36-5.16)**0.003** | 2.652(1.34-5.21);**0.005** |
| | Emergency | Ref | Ref |
| **Surgery duration in minutes** | ≤ 60 | 14.83(5.55-32.05) :<**0.17** | 13.38(5.47-32.71) :<**0.42** |
| | 61 – 120 | 5.94(2.47-12.96): **<0.01** | 5.67(2.43-13.23) :<**0.01** |
| | 121+ | Ref | **Ref** |
| | | . | |
| **Anesthesia duration in mins** | ≤ 60 | (1.27-.):0.02 | 8.9(3.0-25.9) :<**0.01** |
| | 61 – 120 | .(1.67-.):0.01 | 10.9(4.64-25.9) :<**0.01** |
| | 121 – 180 | .(.432-.):0.18 | 2.77(1.09-6.98):**0.03** |
| | 181 – 240 | .(.14-.):0.43 | .155(.07-.344): **0.05** |
| | 241 + | Ref | **Ref** |
| **Blood loss(ml)** | 0 | 2.53(.73-6.477):0.15 | 2.25(.718-7.05):0.16 |
| | ≤ 50 | 3.31(1-7.49): **0.0490** | 2.7(.96-7.79):**0.057** |
| | 51 + | Ref | Ref |
| **Blood transfusion** | Yes | .801(.262-.99):**0.04** | .51(.26-1):**0.052** |
| | No | Ref | **Ref** |
| **Fluid warmed** | Yes | 16.2(6.44-29.25**) :<0.01** | 13.73(6.35-29.73) :<**0.01** |
| | No | Ref | **Ref** |
| **IV fluids(ml)** | ≤ 500 | (.486- .): 0.17 | 1.7(.98-2.94):**0.056** |
| | 501 – 1000 | (.274 -.):0.29 | .55(.34-.90):**0.018** |
| | 1001+ | Ref | **Ref** |
| **Forced air warming** | Yes | 0.23(.196-0.53):**0.02** | 0.4(0.26-1.04):**0.02** |
| | No | Ref | **Ref** |
| **OR temperature** | <25°C | 5.43(3.74-8.87): **<0.01** | 5.76(3.38-8.97); **<0.01** |
| | ≥25°C | Ref | Ref |

# CHAPTER FIVE

# 5.0 DISCUSSION

## 5.1 Discussion

### 5.1.1 The proportion of paediatric patients with hypothermia

The finding of the study revealed the proportion of hypothermia after induction of anaesthesia was 82.87% among paediatric patients who underwent surgery at MNH. The difference in temperature could be attributed to different factors such as operating room temperature, induction agent, muscle relaxants, analgesics, which play a role in the proportions of hypothermia. Similar results were seen in a study done in China where the incidence of intraoperative hypothermia was 82.83% however it was in neonates (25). These findings were found to be higher than studies conducted in the United States of America (USA) 52% (3) and 65.45% (30), China (24). In similar African settings, a clinical trial conducted in Malawi with intraoperative air warming methods experienced incidence of hypothermia of 59% and 60.5% respectively in both its arms (31). Another study that was conducted in Ethiopia reported a prevalence of 39.8% (1), 30% in Kenya (20) and in Rwanda there was incidences of preoperative, intraoperative and postoperative hypothermia were 67%, 71.7% and 67.7%, respectively (14).

### 5.1.2 Factors associated with intra-operative hypothermia

Although various studies have documented that hypothermia can be influenced by several factors, our study documented the following factors influenced intraoperative hypothermia among paediatric patients who underwent surgery at MNH.

**Age group**

In our study, all age groups; neonates, infants and toddlers have been shown to have no significant association with intraoperative hypothermia [AOR =0.722, 95% CI: 0.313–1.664, p=0.445], [AOR = 0.974, 95% CI: 0.564–1.679, p=0.925], [AOR = 0.879, 95% CI: 0.505–1.529, p=0.648] respectively. This finding is not consistent with similar studies done in Ethiopia and Malaysia, which found a statistically significant

association between neonates and infants with hypothermia [AOR =15, 95% CI: 2.256,101.8, p = 0.05], [ AOR = 8.4 95% CI: 1.548,45.86,p = 0.014],and [p = 0.05] respectively (1,15). This could be due to the small sample size of this age group used in our study. However, physiologically this age group lack of subcutaneous fat or have an immature thermoregulatory mechanism, making them prone to intraoperative hypothermia.

**Body weight**

The study found no statistically significant association between body weight and intra-operative hypothermia [AOR = 0.736, 95% CI: 0.475–1.14, p = 0.17]. This finding was contrary to studies conducted by Qing M. et al. in China and Maho et al in Japan, where they found a statistically significant association between body weight and intra-operative hypothermia (p = 0.0001 and p = <0.001, respectively (21,23). This could be possibly explained by difference in races or physique of our study population.

**ASA status**

According to our findings, paediatric patients with ASA physical II were statistically significantly associated with intraoperative hypothermia [AOR = 7.889996, 95% CI:1.686394 - 37.95076, p = <0.01]. This might be due to narrow thermo-neutral range of small and ill paediatric patients as compared to normal-health paediatric patients with ASA grade I, so the higher the grade, the greater the risk of developing intraoperative hypothermia.

This finding was contrary to a study conducted in Ethiopia, which documented that there was no association between ASA physical status and developing intraoperative hypothermia(1).

**Operating Room Temperature**

According to this study, an operating room temperature of less than 25°C was statistically significantly associated with intraoperative hypothermia compared to a higher operating room temperature [AOR = 5.76, 95% CI: 3.84–3.97, P = <0.01]. The findings of this study are in line with findings from studies done in Ethiopia, Rwanda, and Turkey (p = <0.001) respectively (1,14,28,32). The likely reasons might be that, as the operating room temperature drops, the body tends to lose heat through convection thus contributing hypothermia.

**Type of surgery**

This study found that paediatric patients who underwent elective surgery were significantly associated with intra operative hypothermia as compared to emergency surgery (p= <0.01). This would be probably due to more cases in our study being elective. However, similar findings were seen in two different studies by Lee et al and Engorn et al where hypothermia occurred less frequently with emergency compared to elective procedures [AOR 0.43, CI: 0.21–0.91; P = 0.026) and [AOR: 17.77; 95% CI: 2.07–125.7; P = 0.003] respectively (5,33). Contrary to our findings, a study conducted by Hanna et al., revealed that hypothermia was significantly associated with neonates requiring emergency procedures though the cases were also premature infants, who are naturally at high risk of heat loss (p=0.007) (34).

**Warmed Fluids**

Patients who received warmed IV fluids were significantly associated with prevention of intraoperative hypothermia [AOR=13.73, 95% CI: 6.35-29.73; p=<0.01**]**, The findings are consistent with those from other studies done by Getachew et al in Ethiopia and Lee et al in Singapore which reported that use of warmed fluids during surgery were significant associated with prevention of intraoperative hypothermia [p=<0.01] and [p=0.006] respectively (1,5). This could be related to the fact that use of warmed fluids reduces the effects of heat loss and low body temperature.

**Amount of Fluid administered**

Administration of less than 1 liter of fluid was significantly associated with the prevention of the occurrence of intraoperative hypothermia [AOR=0 .55,95% CI: 0.34-0.90; p = 0.018]. Similarly to a study done in Ethiopia that documented a protective effect of not developing intraoperative hypothermia among patients who were given lee than 1 liter of fluid (p = 0.001) (1). This is because when a large volume of fluid is used, a shift of a large volume of fluid into the body system occurs resulting in a drop-in body temperature.

**Blood loss and blood transfusion**

The study found no statistically significant association between the amount of blood loss and transfusion with intraoperative hypothermia [AOR=2.27, 95%CI:0.96-7.79, P=0.057] and [AOR=0.51, 95%CI:0.26-1,P=0.051] respectively. This might be due to the fact that it was warmed prior to administration, but also because the amount of loss was minimal. This finding was similar to study done by Getachew et al. in Ethiopia that found no significant association between amount of blood loss and blood transfusion with occurrence of intraoperative hypothermia [AOR= 0.87,95%CI: 0.38-1.99, p = 0.73] (1).

**Forced air warming**

In our study, those who were exposed to forced air warming intraoperatively were prevented from developing hypothermia [AOR=0.4, 95% CI: 0.26-1.04, p = 0.02]. This finding was similar to the study done in Singapore, where the intraoperative use of forced air warming was found to be protective against intraoperative hypothermia (p=0.08). The possible reasons might be the constant transfer of heat to the patient, which compensates for heat loss(5).

**Surgery and Anaesthesia duration.**

Our study found that both duration of surgery and anaesthesia of more than an hour respectively, was significantly associated with intraoperative hypothermia [AOR = 5.67, 95% CI: 2.43 - 13.23 p=<0.01]and [AOR =10.9, 95% CI: 4.64 - 25.9, p=<0.01]. Our finding concurs with those of studies carried out by Getachew et al in Ethiopia, and Zhao et al with [AOR = 3.37, 95% CI: 1.29-8.79;p=<0.01 **]** and [p=0.006] respectively, This might be due to increased time of contact between patient, operating bed, and wet surgical drapes, leading to heat loss via conduction and also suppression of the thermoregulatory centre by anaesthetic agents (1,25).

## 5.2 Study strengths and limitation

### 5.2.1 Study Strengths.

i. There was an adequate sample size that increased the power of the study, which is evident from the findings (significant p values and confidence intervals)

ii. Several areas for improvement have also been identified, including improved use of warming techniques and consistent reassessment of temperature during operation.

### 5.2.2 Study limitations

i. The use of a digital axillary thermometer as a measurement of core body temperature may lead to measurement errors.

ii. This was a cross-sectional study hence causal effect relationship cannot be well established

# CHAPTER SIX

# 6.0 CONCLUSION AND RECOMMENDATIONS

## 6.1 Conclusion

The majority of paediatric population (82.8%) undergoing surgery at MNH developed intraoperative hypothermia. Several factors were identified being associated with hypothermia in this patient population. These factors leading to hypothermia were ASA status, type of surgery, surgical procedure, use of warmed IV fluid, forced air warming, operating room temperature, surgery duration and anaesthesia duration.

## 6.2 Recommendation.

**Recommendation for anaesthesia provider**

i. Provide continuous education on the factors associated with hypothermia such as use of unwarm IV fluid, long duration of surgery and anaesthesia, and ASÁ physical status, so that they can comprehend and provide better management.
ii. To strengthen and provide routine intra-operative hypothermia assessment and its management.

**Recommendation for hospital management**

i. To provide equipment for temperature assessment and making sure means of hypothermia management are readily accessible during surgery.

**Recommendation for further studies.**

i. To conduct multi centre studies for comparison of proportions and factors that are associated with hypothermia in various facility settings from the national level to the lowest level where procedures are carried out.

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# APPENDICES

## Appendix 1. Questionnaire

**Instruction:** For each of the questions below, please circle or tick (✓) the number of alternative(s) that corresponded to the response or fill in the blanks.

Part I: Socio-demographic data about the patient & pre-operative anaesthetic evaluation:

| S/ No | Variable | Response | If no, go to |
|---|---|---|---|
| 1 | Age of the patient | ---------- | |
| 2 | Gender of the patient | 1.Male---------<br>2.Female------ | |
| 3 | Weight in kilograms | ---------Kg | |
| 4 | ASA physical status | 1.ASA I------<br>2.ASA II------<br>3.ASA III-----<br>4.ASA IV----- | |
| | Any coexisting illness | 1.Yes----<br>2.No----- | |
| | If yes; specify the disease | | |
| | Type of surgery | 1.Elective------<br>2.Emergency--- | |
| | Surgical procedure | ---------- | |

Part II Questions about intraoperative features of patient

| S/ No | Variable | Response | If no, go to |
|---|---|---|---|
| 1 | Body temperature on arrival to OR | ------0C | |
| 2 | OR temperature | --------0C | |
| 3 | Body temperature After induction of anesthesia | --------0C | |
| 4 | Body temperature after 30 minutes of procedure | ----------0C | |
| 5 | Body temperature after 60 minutes of procedure | ----------0C | |
| 6 | Body temperature after 90 minutes of procedure | ----------0C | |
| 7 | Body temperature after 120 minutes of procedure | ----------0C | |
| 8 | Body temperature after 180 minutes of procedure | ----------0C | |
| 9 | Body temperature after 210 minutes of procedure | ----------0C | |
| 10 | Body temperature after 240 minutes of procedure | ----------0C | |
| 11 | Induction Agent | 1.Ketamine<br>2.Thiopental<br>3.Propofol<br>4.Inhalational-----<br>5.fentanyl | |
| 12 | Muscle relaxant | 1.Suxamethonium<br>2.Atracurarium<br>3.Vecuronium<br>4.Pancuronium | |

| | | | |
|---|---|---|---|
| 13 | Analgesics | ---------- | |
| 14 | Spinal anesthesia | 1.Bupivacaine----<br>2.Lidocaine------- | |
| 15 | Name of block if any | ---------- | |
| 16 | Volume of LA for block | ----------ml | |
| 17 | Total IV fluids administered | --------ml | |
| 18 | Is fluid warmed? | 1.Yes2.No | |
| 19 | Is there use of Forced air warming? | 1.Yes 2. No | |
| 20 | Intra-operative blood loss | ----------ml | |
| 21 | Blood Transfusion | 1.Yes----<br>2.No----- | |
| 22 | Amount of blood transfused in ml | ----------ml | |
| 23 | Duration of surgery in minute | ----------minutes | |
| 24 | Duration of anesthesia in minute | ----------minutes | |

**Appendix 2. Consent Form**

**Introduction:** My name is Dr. Ramadhani Shaban, a second-year resident studying MMed anaesthesiology at Muhimbili University of Health and Allied Sciences (MUHAS).
Currently, I am researching the topic of, **"Prevalence of Intraoperative Hypothermia, and Associated Factors Among Paediatric Patients Undergoing Surgery at Muhimbili National Hospital from September 2023 to December 2023".**

**Participation in the research;** This study won't have an impact on how you manage or conduct your daily duties. You won't be harmed in any way by this study, you have the right to accept or reject research participation and to leave the study whenever you like.

**Confidentiality:** Your name will not be part of the study, and the data you provide will only be used for research.

**Participation-related risk:** There are no potential dangers or negative effects from taking part in this study.

**Benefits:** The study will provide information and understanding of the prevalence of intraoperative hypothermia, and associated factors among paediatric patients undergoing surgery at Muhimbili National Hospital.

**Contact person:** If you have any queries or issues regarding this study, please get in touch with:

**Principal Investigator**
Dr. Ramadhani Shaban
Phone:0754086957
Email: shabanramadhani045@gmail.com
P.O. Box 65001, Dar-es-Salaam.
Tel.no 2150302-6.

Signing consent

If you are willing to take part in the study, please sign below.

I(initials)……have read and comprehended all information. My questions have been addressed, and I have received a satisfactory explanation. Therefore, I give my permission to take part in the study.

Signature of Participant…….

Date consent signed…….

**Appendix 3: Consent Form – Swahili version**

**Utangulizi:**

Mimi Ramadhani Shaban mwanafunzi wa mwaka wa pili wauzamili katika taaluma ya udaktari wa dawa za ganzi na usingizi kutoka chuo kikuu cha afya ya sayansi shirikishi, Muhimbili. Nafanya utafiti unaohusu, kuenea kwa upungufu wa joto la mwili na mambo yanayohusiana kwa Watoto wadogo wanaofanyiwa upasuaji kuanzia mwezi wa tisa 2023 mpaka mwezi wa kumi na mbili 2023.

**Kushiriki kwenye utafiti:**

Umuhimu wakushiriki katika tafiti hii utasaidia kufahamu namna ya kuenea kwa upungufu wa joto la mwili na mambo yanayohusiana kwa Watoto wadogo wanaofanyiwa upasuaji.
Ukikubali kushiriki katika tafiti hii, utaulizwa maswali yaliyomo katika dodoso, pia utajaza form ya ridhaa ya kushiri.

**Usiri wa taarifa zako:**

Taarifa zote zitatumika kwa dhumuni la tafiti nasi vinginevyo. Pia una uhuru wakujitoa katika tafiti hii wakati wowote tafiti hii haina madhara yoyote kwako.

**Mawasiliano:**

Kwa maswali au taarifa yoyote kuhusu utafiti huu wasiliana na mtafiti:

Namba ya simu 0754086957,

Anuani, S.L. P 65001,

Dar es Salaam,

**AU**

Dr. Edwin Lugazia,

Msimamizi +255754283900

**AU**

Mkurugenzi wa utafiti na uchapishaji,

Dr. Nahya Salim (MUHAS),

S.L. P 65001, Dar-es-Salaam,

Sim. no 2150302-6.

**Kukubali kushiriki:**

Tafadhali thibitisha endapo umekubali kushiriki kwenye utafiti huu

Mimi…..... nimesoma na kuelewa yote yaliyoelezwa katika fomu hii. Hivyo naridhia kushiriki katika utafiti huu.

Sahihi ya mshiriki……, tarehe…….

Sahihi ya mtafiti…....., tarehe……

## Appendix 4: Ethical clearance

**UNITED REPUBLIC OF TANZANIA**

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

**OFFICE OF THE DIRECTOR – RESEARCH, INNOVATION AND PUBLICATIONS**

In reply quote;
Ref. No.DA.282/298/01.C/1618 Date: 11/04/2023

**MUHAS-REC-04-2023-1618**

Ramadhani Shaban
College of Medicine
MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE OF INTRA- OPERATIVE HYPOTHERMIA AND ASSOCIATED FACTORS AMONG PEDIATRIC PATIENTS UNDERGOING GENERAL SURGERY AT MUHIMBILI NATIONAL**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 11/04/2023
EXPIRATION DATE OF APPROVAL: 10/04/2024

**STUDY DESCRIPTION:**
**Purpose:**
The purpose of this observational cross sectional study is to determine the prevalence of intra operative hypothermia and associated factors among pediatric patients undergoing general surgery at Muhimbili National Hospital.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014241.pdf and in the MUHAS archives.

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

**The PI is required to:**

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr Kasusu Nyamuryekung'e
**Chairman, MUHAS Research and Ethics Committee**

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

cc; **Director of Postgraduate Studies**
**MUHAS**

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

**Appendix 5: Introduction letter**

**UNITED REPUBLIC OF TANZANIA**
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
**OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES**

In reply quote;
Ref. No. HD/MUH/T.10/2021

17th April, 2023

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
**DAR ES SALAAM**

**RE: INTRODUCTION LETTER OF RAMADHANI SHABAN**

We would like to inform you that the bearer of this letter is Ramadhani Shaban with Reg. No. HD/MUH/T.10/2021 is a student at College of Medicine in the Muhimbili University of Health and Allied Sciences (MUHAS) " pursuing MMed Anaesthesiology.

As part of his studies, he will be doing an elective research titled: "***Prevalence of Intra-Operative Hypothermia and Associated Factors among Paediatric Patients undergoing General Surgery at Muhimbili National Hospital (MNH).***" He is being supervised by Dr. Asha Abdullla (main supervisor) from MUHAS Department of Anesthesiology and Dr. Raymond Samueli Oyugi from Department of Anesthesiology at MNH

The Ethical Clearance for doing the said research has been given by the university.

Kindly request your necessary assistance and coorperation to our student.

Yours Sincerely,

Mr. Sebe Mohamed Yusuf
**FOR DIRECTOR, POSTGRADUATE STUDIES**

Cc: Ramadhani Shaban

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

## Appendix 6: Permission letter

THE UNITED REPUBLIC OF TANZANIA

*MINISTRY OF HEALTH*

***MUHIMBILI NATIONAL HOSPITAL***

***In reply please quote:***

Ref. No.: MNH/CRTCU/Perm/2023/384 Date: 02nd June, 2023

Head of Department,
Surgery,
**Muhimbili National Hospital**

**RE: PERMISSION TO COLLECT DATA AT MNH.**

| | |
|---|---|
| Name of student | **Ramadhan Shaban** |
| Title | **"Prevalence of Intra-Operative Hypothermia and Associated Factors among Paediatric Patients Undergoing General Surgery at MNH".** |
| Institution | Muhimbili University of Health and Allied Sciences |
| Supervisor | Dr. Asha Abdulla (MUHAS) |
| Co - supervisor | Dr. Raymond Samueli Oyugi (MNH) |
| Period | 02nd June, 2023 to 30th July, 2023 |

Approval has been granted to the above principal investigators to collect data at MNH. Dissemination of study findings at MNH shall be overseen by **Dr. Raymond Samueli Oyugi** (MNH) Co - supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Sincerely,

HEAD TEACHING, RESEARCH & CONSULTANCY UNIT
P. O. Box 65000
DAR-ES-SALAAM
MUHIMBILI NATIONAL HOSPITAL

**Dr. Charles K. Pallangyo**
**For: Head of Clinical Research, Training and Consultancy Unit**

c.c DSS
**c.c Ramadhan Shaban**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2