POTENTIAL MEDICATION ERRORS AND THEIR PREDICTORS AMONG HOSPITALIZED PAEDIATRIC PATIENTS AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA

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Department of Clinical Pharmacy and Pharmacology

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By

Julphery Raphael Towo

A Dissertation Submitted in (Partial) Fulfilment of Requirement for the Degree of Master of Pharmacovigilance and Pharmacoepidemiology of

Muhimbili University of Health and Allied Sciences
October, 2024

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled**; "Potential medication errors and its predictors among hospitalized paediatric patients at Muhimbili National Hospital, Tanzania",** in (partial) fulfilment of the requirements for the degree of Master of Pharmacovigilance and Pharmacoepidemiology of Muhimbili University of Health and Allied Sciences.

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Dr. Ritah Mutagonda

(Co-supervisor)

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Date

DECLARATION AND COPYRIGHT

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

Signature…… **Date**……

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DEDICATION

“To my aunty and mother, Dr. Esther Naiman Towo, for being the cornerstone of my academic journey and everything I have achieved in life. Your inspiration and faith in my abilities have been my guiding light through the highs and lows of this pursuit. This dissertation is dedicated to you, with deepest gratitude and love.”

ABSTRACT

Background: Medication errors caused by human error or system flaws pose a significant risk to the safety of paediatric patients. These errors can lead to adverse drug reactions, decreased treatment effectiveness, and even death. However, there is a scarcity of data related to magnitude of medication errors in African countries including Tanzania.

Aim: This study aimed to determine the prevalence of potential medication errors and their predictors among paediatric patients admitted at Muhimbili National Hospital, Tanzania.

Methodology: This was a hospital-based cross-sectional study which was conducted from April to June 2024. A total of 365 participants were recruited consecutively during the study period. A structured questionnaire was used to collect data from participants below 18 years who provided an assent and their parents/guardian consented. Using SPSS version 27, data was entered and cleaned. Frequencies were run to obtain distributions. A univariable analysis was conducted and factors with a p-value <0.2 were considered fit for a multivariable analysis. In the multivariable analysis, factors with p-value <0.05 were statistically significant.

Results: This study revealed that 72.1% (263) of participants experienced medication errors, with duration errors 65.2% (238) and route errors 42.2% (154) being predominant. Commonly prescribed medications included vitamins/minerals (35.6%), bronchodilators (23.6%), and antibiotics (21.1%). Significant predictors of medication errors included shorter hospital stays (adjusted odds ratio [AOR]: 4.886, 95% CI: 2.702-8.835), absence of previous medication errors (AOR: 2.558, 95% CI: 1.393-4.697), and lack of medication error training for healthcare workers especially dispensers (AOR: 11.4, 95% CI: 4.945-26.348). Infrastructure factors, such as the absence of a dose reconciliation protocol, were also associated with increased odds of potential medication error (AOR: 2.097, 95% CI: 0.793-4.912).

Conclusion: This study found a high prevalence of potential medication error among paediatric patients. Significant predictors of medication errors identified include hospital stay of less than 5 days, lack of previous medication history, absence of medication error training for healthcare workers, and the absence of a dose reconciliation protocol. This study calls for further research

in Tanzania to enhance medication error training among healthcare workers, developing standardized reconciliation protocols, as well as improving hospital infrastructure with regard to medication prescription, dispensing and administration.

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ACRONYMS

ADE	Adverse Drug Event
ADRs	Adverse Drug Reaction
PME	Potential Medication Error
MNH	Muhimbili National Hospital
ICU	Intensive Care Unit
ME	Medication error(s)

DEFINITION OF TERMS

Adverse drug events (ADE):	any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment
Adverse drug reactions (ADRs):	a response to a medicinal product which is noxious and unintended
Potential medication error (PME):	is the recognition of circumstances that could lead to a medication error, and may or may not involve a patient
Medication error with harm:	is an error with an adverse drug reaction
Medication errors without harm:	is an error without an adverse drug reaction
Intercepted medication errors:	an error which indicates that an intervention caused a break in the chain of events in the treatment process before reaching the patient which would have resulted in a 'potential' ADR.
Acute sick looking	Patients who appear well and show no signs of acute illness
Critical	Patients whose condition is serious but not immediately life-threatening, requiring close monitoring
Severe	Patients who are in a life-threatening state, necessitating urgent medical intervention

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Medication errors (ME) can be caused by human error or system flaws. Any preventable incident in the prescription, transcribing, dispensing, administering, or monitoring process is considered a medication error, regardless of the actual or prospective risk of harm (1). In healthcare settings, the safety of paediatric patients is a paramount concern, and ensuring accurate medication administration is a crucial aspect of paediatric care. The availability of medications appropriate for children has not yet been resolved, despite recent advancements in pharmacological research in the paediatric population, and less than 50% of pharmaceuticals have been examined for paediatric use (2). The administration of adult-formulated drugs and the requirement to adjust original dosages are the most reported sources of errors in paediatrics. In addition to increasing the frequency and severity of adverse drug reactions (ADRs) and decreasing the effectiveness of the treatment, ME can have serious, even deadly consequences (3).

The following factors are significantly linked to medication administration errors: inadequate training, lack of guidelines for administering medications, interruptions during medication administration, poor communication when faced with issues, and disregard for the ten rights of medication administration. The ten rights of medicine administration are: right patient, right medication, right time, right dose, right route, right education/advice, right to refuse, right assessment, right evaluation/response, and documentation. Mistakes in any of these areas can lead to medication administration errors (4).

In healthcare facilities, it is important to foster a safety culture and raise provider knowledge of ME. A study conducted in France reported a decrease in ME following the implementation of routine paediatric nurse briefings on safe drug administration and appropriate training for recently hired nurses (5). Based on literature information, it is possible to eliminate ME by implementing consistent reporting methods and removing obstacles that prevent errors from

being reported, such as fear, a heavy workload, time limits, and unfavourable employee perceptions of error (6–8). A systematic review on ME in 2017, reported that there are no studies that particularly evaluated documentation errors, dispensing errors, and transcribing errors in African hospitals. This review also came up with recommendations that, future research must evaluate the clinical effects, preventability, and aetiology of ME when developing patient safety programs that specifically target these errors (9).

In Tanzania, a study assessing the extent of occurrence of ME by prescription conducted over a decade ago in a private tertiary in Dar es Salaam, reported occurrence of errors of omission and commission in prescription writing in which errors of commission accounted for 3.1% of all prescribed medicine (10). A recent study on the same matter was conducted in an outpatient pharmacy of a teaching hospital in Kilimanjaro and errors by omission was the leading cause of prescription errors (11). This calls in for further studies in ME to assess for other predictors especially in paediatric patients who are at greater risk of ME. Therefore, this study aimed to determine the prevalence of potential medication (PME) errors and their predictors among paediatric patients admitted at Muhimbili National Hospital (MNH), Tanzania.

1.2 Problem statement

In the world, ME are the most frequent medical errors, particularly in paediatrics (12). PME, including prescribing, dispensing, administering, and monitoring errors, have been identified as a critical issue affecting paediatric patients globally(13). These errors can lead to adverse drug events (ADEs), treatment complications, prolonged hospital stays, and even mortality (5,14–16). Ethiopia experiences a high rate of ME, as do many developing nations. Research from Jimma University Specialised Hospital and Tigray revealed that 89.9% and 62.7%, respectively, of paediatric inpatients had ME (17,18).

A systematic review on ME in 2017, reported that there are no studies that particularly evaluated documentation errors, dispensing errors, and transcribing errors in African hospitals (15). This is also true for Tanzania as reported in the two studies in Dar es Salaam and Kilimanjaro evaluating prescribing errors as source of ME (10,11). There is a serious risk to the safety and wellbeing of Tanzanian hospitalised paediatric patients due to the issue of possible ME. MNH serves as a major referral centre for paediatric care in Tanzania, catering to many hospitalized paediatric patients. However, the occurrence of PME in this setting is not known. This has raised concerns about patient safety and the need for effective preventive measures.

Addressing the problem of potential ME is crucial for improving the quality of paediatric care at MNH. By identifying the predictors of these errors, healthcare providers can implement targeted interventions, such as improved training, enhanced communication, and standardized protocols, to prevent ME and ensure the well-being of paediatric patients.

1.3 Rationale of the study

The occurrence of ME poses a significant concern for paediatric patient safety and quality of care. Because of their age, the need for weight-based dosage, and their developmental characteristics, paediatric patients are more susceptible to ME. ADEs, extended hospital stays, and other detrimental health consequences might result from ME in young patients. By examining PME and associated predictors, healthcare providers can work towards minimizing the prevalence of these errors and enhancing patient care. Understanding the factors contributing to these errors is crucial for developing effective interventions and improving medication management practices in paediatric healthcare settings in Tanzania.

1.4 Conceptual Framework

The conceptual framework below illustrates the relationships between the occurrence of PME (outcome variable) and various independent variables which include patient-related factors, healthcare professional-related factors, facility's infrastructure-related factors, and medication-related factors. This study will examine how these independent variables may influence the occurrence of PME among hospitalized paediatric patients. Moreover, analysis of the relationships between these variables, will identify potential predictors, and areas for intervention to mitigate ME.

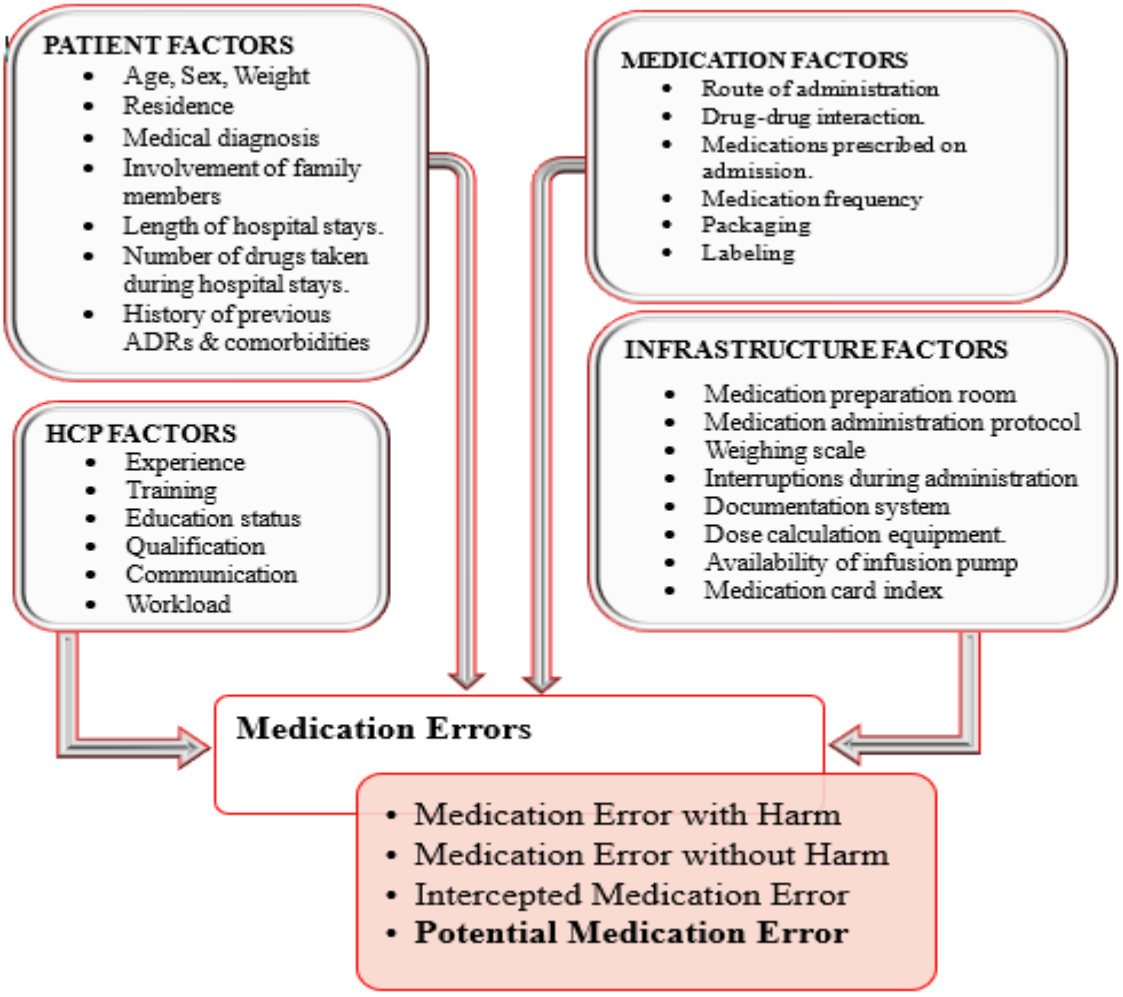


Figure 1: Conceptual framework on PME and its predictors

1.5 Research hypothesis

Patient-related factors (age, gender, and comorbidities), as well as healthcare-related factors (healthcare provider workload, number of medications and medication regimen complexity), are significant predictors of PME among hospitalized paediatric patients at MNH in Tanzania.

1.6 Research questions

1.6.1 Broad Research Question

What is the prevalence and types of potential ME and predictors among paediatric hospitalized patients at MNH, Tanzania?

1.6.2 Specific research questions

1. What is the prevalence of the PME among hospitalized paediatric patients at MNH in Tanzania?
2. What are the common types of PME identified among hospitalized paediatric patients at MNH in Tanzania?
3. What are the significant predictors of PME among hospitalized paediatric patients at MNH in Tanzania?

1.7 Objectives

1.7.1 Broad objective

To determine the prevalence and types of PME as well as predictors among paediatric hospitalized patients at MNH, Tanzania.

1.7.2 Specific objectives

1. To determine the prevalence of PME among hospitalized paediatric patients at MNH.
2. To describe the common types of PME identified among hospitalized paediatric patients at MNH in Tanzania.
3. To identify predictors of PME among hospitalized paediatric patients at MNH in Tanzania.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 PME among Hospitalized Paediatric Patients

Research has shown that different hospitalized paediatric patients had different rates for PME. An overall rate of 15.5 per 105 bed days was discovered in a study conducted in Canada by Burns et al 2023. Prescribing and administration stages were determined to be the main contributors of PME (19). A study aimed to examine if the technical and legal features of the package insert for medications used in paediatric intensive care units (ICUs) that use continuous infusion pumps support the guidelines provided by clinical protocols and applicable laws, revealed that hospitalized paediatric patients are three times more likely to experience ME with the potential to cause harm compared to adults (20).

Another important research focused on the medication error risk factors for epileptic paediatric patients at hospital admission. The study highlighted that the prevalence of PME among hospitalized paediatric patients is 63%, omissions during prescribing and medication history being the main contributors (21). Furthermore, a study conducted in Italy investigated the voluntary and anonymous reporting of ME in patients admitted to the department of paediatrics. The results indicated that the prevalence of PME among hospitalized paediatric patients is 41% (22).

Several studies have investigated the prevalence and types of PME among hospitalized patients. A study conducted in a university teaching hospital found that the overall prevalence of PME was 15.6% among paediatric inpatients. The most common types of errors were prescribing errors (8.7%), followed by administration errors (5.2%) and dispensing errors (1.7%) (11).

In addition, a study conducted in Ethiopia explored medication administration error and contributing factors among paediatric inpatient in public hospitals, the role of healthcare professionals' education and training in mitigating ME in paediatric patients was observed. Medication administration errors were more common when prescribed medications were given to patients younger than one month of age, by health professionals with a bachelor's degree, in

settings without a medication preparation room, and when patients had two or more prescriptions filled (18)

2.2 Predictors of PME

Inadequate training, lack of guidelines for administering medications, interruptions during medication administration, poor communication when faced with issues, and disregard for the ten rights of medication administration have been reported as factors that significantly contribute to ME. Mistakes in any of these areas can lead to medication administration errors (4).

According to a study conducted at public hospitals in Tigray, Northern Ethiopia, paediatric inpatients had a high rate of medication administration errors. Factors that were statistically significant in relation to the occurrence of drug administration errors were patient age, medication administrators' educational background, the number of medications given to a single patient, and the availability of a medication preparation room and guide (18).

A study conducted a decade ago in a private tertiary in Dar es Salaam, Tanzania, evaluated the prevalence of ME by prescription. The study found that errors of commission accounted for 3.1% of all prescribed medicine, while errors of omission occurred occasionally in prescription writing (10). A recent study (2019) on prevalence of ME by prescription was conducted in an outpatient pharmacy of a teaching hospital in Kilimanjaro and errors by omission was the leading cause of prescription errors (11).

D'Errico et al reported that, the most frequently source of ME in paediatric patients continue to be those related to dosage and administration, especially when it comes to off-label (18–64%) and unlicensed (7–10%) drug administration. Preparation of dilutions and opening capsules further increase the risk of errors in administration. Other factors include childhood obesity that may result to under dose, verbal prescriptions, frequent interruptions, and lack of clinical pharmacists in the care team(3).

Overall, the literature on PME and its predictors among hospitalized paediatric patients underscore the importance of continuous research, targeted interventions, and healthcare professionals' vigilance in ensuring the safe administration of medications to this vulnerable patient population. It is crucial to remember that while these studies concentrate on various ME, they could not fully represent the issue especially in Tanzania. To gain a thorough understanding of the prevalence of possible ME among paediatric hospital patients, more research is required.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a facility-based cross-sectional study.

3.2 Study site and duration

The study was conducted in paediatric wards at MNH in Dar es salaam, Tanzania which include MNH-Upanga and MNH-Mloganzila with 1500 and 608 bed capacity with various specialities, respectively. The study was conducted within three (3) months from 1st April to 30th June 2024.

3.3 Study population

All non-ICU paediatric patients admitted at MNH – Upanga and MNH-Mloganzila during the study period.

All healthcare workers serving study participants during the study period.

3.3.1 Study inclusion and exclusion criteria

Inclusion criteria

Paediatric patients aged < 18 years. Patients admitted to the paediatric non-ICU ward for at least 24 hours and had taken at least one medication on admission or as a continuation of the previous regimen who provided an assent or whose legal representatives, where willing to participate and provided informed consent for the study.

All healthcare workers serving at paediatric wards during the data collection period

Exclusion criteria

Paediatric patients with incomplete medical and medication records. Paediatric patients with known allergies to common medications.

3.3.2 Sample size and Sampling strategy

Sample size calculation.

The sample size was calculated based on a single population proportion formula: $n = [(z_{\infty/2})^2 p(1-p)]/ d^2$ with the assumption that Z = 1.96, the proportion of PME p =69.5% as reported in the study conducted in public hospitals of Gamo zone, Southern Ethiopia (23) and marginal error d= 5%. The study population from the study sites was estimated to be 365 paediatric patients with a non-response rate of 10%. All healthcare workers serving the sampled paediatric patients during the data collection period were enrolled.

Sampling strategy

Paediatric patients hospitalized at both MNH Upanga and Mloganzila for at least 24 hours were sampled just once during the study period using a non-probability consecutive sampling technique.

All healthcare workers serving the specific paediatric patients during the data collection period were enrolled for collecting data on qualification, experience, workload and ME training.

3.4 Data collection

A structured questionnaire (Appendix II) was used for data collection. Medical records were used to retrieve baseline data on patients, which include socio-demographic information (i.e., age, sex, weight, residence, and education status) and medical history as well as caretakers' education level and relationship to the patient. Any missing information was directly asked from the patients' caretakers who provided consent.

For detection of PME, a checklist assessing prescription, transcription, dispensing, and administration errors was used. From this, the prevalence and types of PME were captured. The patients' medical charts were used to collect data on medication information. Direct observation was done during the medication administration process and any errors that occurred were recorded.

A checklist was used to collect data on health care professional characteristics and facility infrastructure to evaluate predictors of PME.

Medications errors were classified based on the type of error (According to the good practice guide on recording, coding, reporting and assessment of ME as issued by the European Medicine Agency October 2015) and the error stage in the process of medication use (24).

3.5 Variables

3.5.1 Dependent variables

Prevalence of potential medication error is the primary outcome of the study, which is a composite variable derived from prescribing, dispensing, administration, and monitoring errors as defined in **Table 1.**

3.5.2 Independent variables

Socio-demographic

The next demographic characteristics were recorded: age (in days, months, and years), weight (in kilograms), sex (Male or Female), residence, involvement of family members/caregiver and length of hospital stay (number of days since admission).

Healthcare Professional characteristics

The following information about healthcare professional were recorded: experience, training, qualification, and workload.

Infrastructure factors

Medication preparation room, medication administration protocol, weighing scale, documentation system, and dose calculation equipment are information collected from nurses in-charge regarding infrastructure.

Medication related factors (Note: medications are categorized according to their anatomical and therapeutic actions and/or chemical classification)

The variables regarding medication related factors include type of medications prescribed during admission, dose, route and frequency as well as total number of medications administered per patient.

Table 1: Types of ME

Variable	Measurement
Prescribing Errors	These occur when the wrong medication is prescribed, the dosage is incorrect/inappropriate, or the instructions are unclear. This can happen due to misdiagnosis, incomplete patient information, or illegible handwriting
Dispensing Errors	These occur when the wrong medication is dispensed, the wrong dosage is given, or the medication is not labelled properly. This can happen due to miscommunication between the prescriber and the pharmacist, or due to errors in the pharmacy workflow.
Administration Errors	These occur when the medication is given to the wrong patient, at the wrong time, wrong dose, wrong frequency, wrong duration or by the wrong route. This can happen due to confusion about the patient's identity, or due to errors in the administration process.
Monitoring Errors	These occur when the patient's response to the medication is not monitored properly, or when side effects are not recognized or addressed. This can lead to serious complications, including death.

3.6 Data analysis

Data was analysed using SPSS statistics software version 27 where, findings were presented in tables, graphs, and charts. The descriptive statistics were used for socio-demographic characteristics of the study participants, medication history, prescribed medications, past medical condition, and current medical condition of the study participants.

The prevalence of PME among the paediatric patients was calculated. A univariable logistic regression analysis was performed to describe the collected data and discover pattern of each variable. Variables with p-value <0.2 were included in the multivariable logistic regression to identify the independent predictors of the PME. The results were expressed as Odds Ratio (OR)

accompanied by 95% Confidence Intervals (95% CI) and a p-value <0.05 were statistically significant.

The findings were presented based on patient socio-demographic features, participant diagnosis, participants medical history, prescribed medication, healthcare professional characteristics and classes of ME.

3.7 Ethical consideration

Before the study was conducted ethical clearance certificate with the number (MUHAS-REC-03-2024-2113) was obtained from the Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Review Board (IRB) before conducting the study (Appendix VI). Written data collection permission was granted by MNH Upanga and Mloganzila management (Appendix IV & V respectively). Assent from participants and consent from participants' caretakers were obtained for those who agreed to participate. (Appendices I to IV).

CHAPTER FOUR

4.0 RESULTS

Patients' socio-demographics characteristics.

A total of 365 paediatric patients were enrolled in this study, whereby about half of the study participants (47.7%) aged between one and seventeen years old. The majority of study participants (54.5%) were females. Majority of the participants (52.1%) weighed between one to ten kilograms. Most of them, (71.0%) resided in Dar es Salaam. The referral status indicated, that 38.4% were self-referrals. Other socio-demographic characteristics are summarized in **Table 2**.

Table 2: Patients' socio-demographics characteristics (n=365)

Variable	Frequency (n)	Percent (%)
Age (median=1.5)		
0-28 days	141	38.6
29 days-1 year	50	13.7
1-17 years	174	47.7
Sex		
Male	166	45.5
Female	199	54.5
Weight (kgs)		
Undefined	102	27.9
1-10	190	52.1
11-20	53	14.5
>21	20	5.5
Residence		
Dar es salaam	259	71.0
Outside Dar es salaam	94	25.8
Undefined	12	3.3
Referral status		
New admission	135	37.0
Self-referral	140	38.4
From other hospitals	90	24.7
Child's education status		
Literate	28	7.7
Primary school	23	6.3
Secondary school	13	3.6
Illiterate	301	82.5
Caretaker's education level		
No formal education	43	11.8
Primary school	113	31.0
Secondary school	119	32.6
College/university	90	24.7
Relationship with the patient		
Father	7	1.9
Mother	357	97.8
Grandmother	1	0.3

Patients' clinical characteristics

There were several diagnosis conditions among the 365 study participants however, sepsis was the most common diagnosis, affecting more than a quarter (27.1%) of the participants followed by respiratory distress syndrome (RDS) (21.6%). Regarding the severity of disease, more than half (51.5%) of participants were in critical condition. Pertaining diagnostic criteria, most of the participants (59.2%) were diagnosed using both empirical and laboratory findings, while laboratory findings alone accounted for 30.1% of diagnoses.

Table 3: Participants' clinical characteristics (n=365)

Variable	Frequency(n)	Percent (%)
Diagnosis		
Adenotonsilitis	22	6.0
Aplastic anaemia	20	5.5
Birth asphyxia	21	5.8
Burn	21	5.8
Bronchitis	45	12.3
Circumcision	3	0.8
Diarrhoea	41	11.2
Epilepsy	23	6.3
Intestinal obstruction	10	2.7
Malaria	2	0.5
Neonatal Jaundice	34	9.3
Other cancers	25	6.8
Oral candidiasis	17	4.7
Pneumonia	15	4.1
RDS	79	21.6
Scrotal hernia	7	1.9
Leukaemia	15	4.1
Sepsis	99	27.1
Umbilical hernia	15	4.1
Other diagnosis	85	23.3
Severity of the disease		
Acute sick looking	90	24.6
Severe	87	23.8
Critical	188	51.5
Diagnosis criteria		
Both empirical and laboratory findings	216	59.2
Empirical	39	10.7
Laboratory findings	110	30.1

Medication related information

The information about prescribed medication indicated that Vitamin and mineral supplements were the most frequently prescribed to more than a third (35.6%) of the participants. Bronchodilators were also commonly prescribed, accounting for 23.6% of total medication usage followed by antibiotics by 21.1%. On the other hand, the total number of prescribed medications varied, with 39.2% of participants receiving between 2 and 4 medications. [F**igure 2&3]**

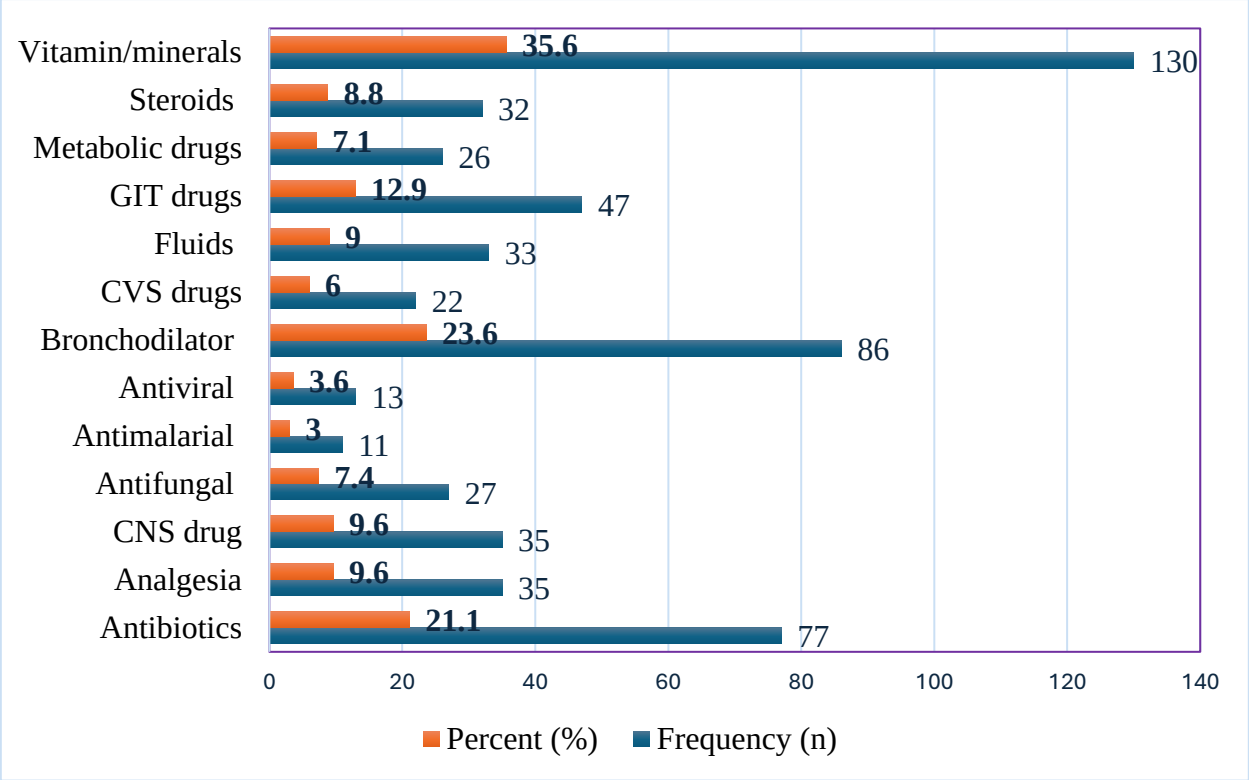


Figure 2: Classification of medications

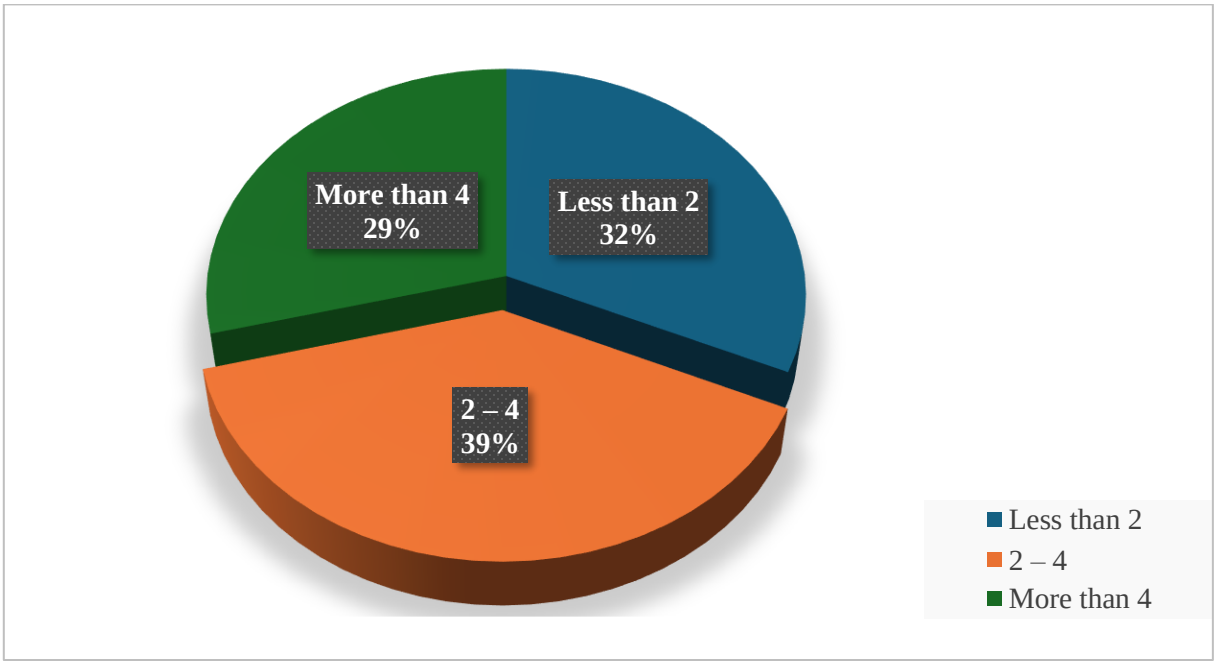


Figure 3: Total number of medications prescribed

Healthcare provider characteristics who served enrolled paediatric patients (n=365)

Regarding prescriber's qualification, it was revealed that, prescriptions to patients (39.2%) were largely written by medical interns. Meanwhile, majority of prescriptions (51%) were written by prescribers who had worked for less than one year. Considering workload, most prescriptions (83.6%) were written by prescribers who catered for more than 10 patients per day. Also, only 31 (8.5%) prescriptions were written by prescribers that had received training on ME.

The qualifications of dispensers that served paediatric patients showed that, 56.7% and 37% of prescriptions were dispensed by intern pharmacists and pharmacists respectively. Pertaining dispenser's work experience, it was observed that majority of paediatric prescriptions (57%) were served by dispensers with less than 1 year experience. Furthermore, at least a third (38.1%) of paediatric prescriptions were served by dispensers who had received training on ME. Moreover, all dispenser served more than 20 patients per day.

The credentials of the administrators who worked with paediatric patients revealed that nursing officers and assistant nursing officers administered an equal proportion (43.6%) of prescriptions. In terms of the experience of the administrators, it was found that most of the paediatric prescription (66.6%) were administered by those who had more than three years of experience. Considering workload, most prescriptions (91%) were administered by administrators who served more than 10 patients per day Moreover, administrators who had received training on ME administered at least one-third (15.9%) of the prescriptions for children. See **Table 4.**

Table 4: Healthcare provider characteristics who served 365 paediatric patients at MNH

Variable	Frequency (n)	Percent (%)
Prescriber's qualifications		
Medical intern	143	39.2
Registrar	86	23.6
Other	135	37.3
Prescriber's experience		
Less than a year	186	51.0
2 – 3 years	60	16.4
More than 3	119	32.6
Prescriber' workload		
1-5 patients	8	2.2
6-10 patients	52	14.2
More than 10	305	83.6
Prescriber's training on ME		
Yes	31	8.5
No	334	91.5
Dispenser's qualification		
Intern pharmacist	207	56.7
Pharmaceutical technician	23	6.3
Pharmacists	135	37.0
Dispenser's work experience		
<1 year	208	57.0
1-3 years	142	38.9
>3years	15	4.1
Dispenser's training on medication error		
Yes	139	38.1
No		

Variable	Frequency (n)	Percent (%)
Administrator's qualification		
Nursing officer	159	43.6
Assistant nursing officer	159	43.6
Intern nurse	47	12.9
Administrator's work experience		
<1 year	88	24.1
1-3 years	34	9.3
>3years	243	66.6
Administrator's workload		
1-5 patients	6	1.6
6-10 patients	27	7.4
>10 patients	332	91.0
Administrator's training on medication error	58	15.9
Yes		
No		

Prevalence and types of PME

The overall prevalence of PME were observed in 263 (72.1%) of the paediatric participants. Majority of the PME were characterised by duration errors (65.2%) followed by route error 154 (42.2%). See **[Figure 4&5]**

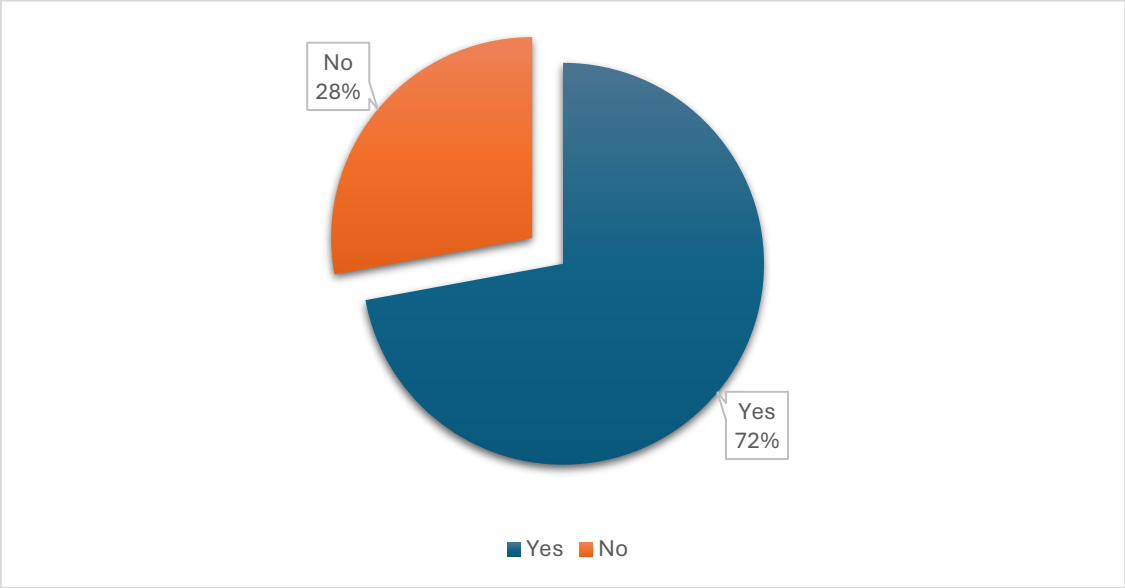


Figure 4: Proportion of PME among paediatric patients (n=365)

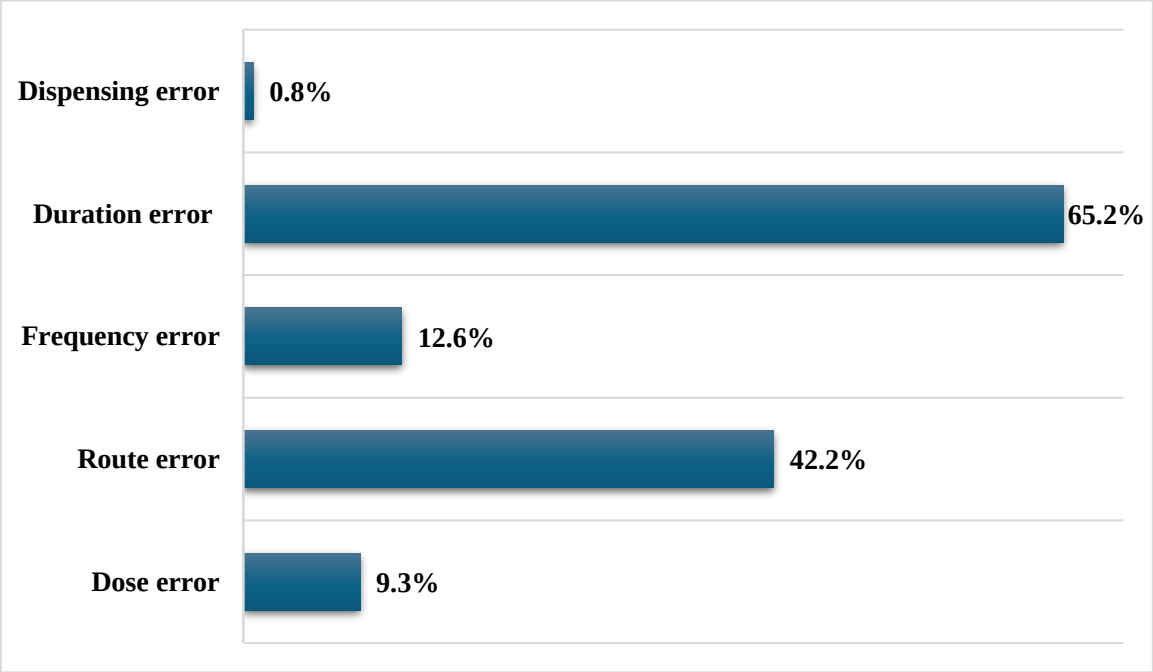


Figure 5: Types of PME (n=365)

Distribution of PME across patient and healthcare provider characteristics.

Regarding severity of the disease, significant proportion (75.9% and 75.5%) of paediatric patient with PME had critical and severe disease condition respectively.

Furthermore, majority of PME (78.3%) were observed in patients who used more than 4 medications. Pertaining hospital stays, those who stayed more than five days experienced most of the PME (88.8%). Additionally, those with previous medication history were observed to experience PME by 82.9%. See **Table 5**

Table 5: Distribution of PME Across Patient characteristics

Variable	PME		Total	p-value
	No (%)	Yes (%)		
Age				
0-28 days	33 (23.4)	108 (76.6)	141	
29 days-1 year	16 (32)	34 (68)	50	0.301
1-17 years	53 (30.5)	121 (69.5)	174	
Sex				
Male	51 (30.7)	115 (69.3)	166	0.280
Female	51 (25.6)	148 (74.4)	199	
Weight				
Undefined	24 (23.5)	78 (76.5)	102	
1-10	54 (28.4)	136 (71.6)	190	0.434
11-20	19 (35.8)	34 (64.2)	53	
>21	5 (25)	15 (75.0)	20	
Residence				
Dar es salaam	75 (29)	184 (71)	259	
Outside Dar es Salaam	25 (26.6)	69 (73.4)	94	0.614
Undefined	2 (16.7)	10 (83.3)	12	
Referral status				
New admission	38 (28.1)	97 (71.9)	135	
Self-referral	40 (28.6)	100 (71.4)	140	0.950
Form other Hospital	24 (26.7)	66 (73.3)	90	
Caretakers' education				
No formal education	24 (26.7)	66 (73.3)	90	
Primary education	29 (25.7)	84 (74.3)	113	0.813
Secondary education	37 (31.1)	82 (68.9)	119	
College/university	12 (27.9)	31 (72.1)	43	
Relationship with patient				
Father	0	7 (100)	7	
Mother	0	1 (100)	1	0.205
Other relatives	102 (28.6)	255 (71.4)	357	
Severity of disease				
Acute sick looking	35 (38.9)	55 (61.1)	90	
Severe	21 (24.1)	66 (75.9)	87	**0.029**
Critical	46 (24.5)	142 (75.5)	188	

Variable	PME		Total	p-value
	No (%)	Yes (%)		
Diagnosis criteria				
Both empirical and laboratory findings	69 (31.9)	147 (68.1)	216	
Empirical	11 (28.2)	28 (71.8)	39	0.076
Laboratory findings	22 (20)	88 (80)	110	
Total medication used				
Less than 2	44 (37.9)	72 (62.1)	116	
2-4	35 (24.5)	108 (75.5)	143	**0.013**
More than 4	23 (21.7)	83 (78.3)	106	
ADR experienced				
Yes	7 (16.7)	35 (83.3)	42	0.083
No	95 (29.4)	228 (70.6)	323	
Hospital stays				
Less than 5days	85 (39.9)	128 (60.1)	213	**<0.001**
More than 5days	17 (11.2)	135 (88.8)	152	
Previous medication history				
Yes	19 (17.1)	92 (82.9)	254	**0.002**
No	83 (32.7)	171 (67.3)	111	
Previous medical condition				
Yes	3 (17.6)	14 (82.4)	17	0.333
No	99 (28.4)	249 (71.6)	348	

Distribution of medication errors across healthcare provider characteristics.

Regarding prescriber's information, the study revealed that most of prescriptions written with prescribers with more than 3 years (86.5%) and with workload of one to five patients a day (87.5%), were associated with ME. Also, 90.3% of prescriptions written with prescribers who had not undergone ME training, had an association with ME.

The study also revealed that lack of ME training among prescriptions served by dispensers and administrators (95% and 87.9% respectively) were significantly associated with ME. See **Table 6.**

Table 6: Distribution of medication errors across healthcare provider characteristics.

Variable	Medication error		Total	p-value
	No (%)	Yes (%)		
Prescriber's education				
Medical intern	46 (32.2)	97 (67.8)	143	
Registrar	21 (24.4)	65 (75.6)	86	0.345
Other	35 (25.7)	101 (74.3)	136	
Prescriber's experience				
<3year	57 (30.6)	129 (69.4)	186	
1-3years	37 (31.1)	82 (68.9)	119	**0.022**
>3years	8 (13.3)	52 (86.7)	60	
Prescriber's workload				
1-5 patient	1 (12.5)	7 (87.5)	8	
6-10 patients	7 (13.5)	45 (86.5)	52	**0.022**
>10 patients	94 (30.8)	211 (69.2)	305	
Prescriber's medication error training				
Yes	3 (9.7)	28 (90.3)	31	**0.018**
No	99 (29.6)	235 (70.4)	334	
Dispenser's qualifications				
Intern pharmacist	64 (30.9)	143 (69.1)	207	
Pharmaceutical technician	6 (26.1)	19 (73.9)	23	0.341
Pharmacist	32 (23.7)	103 (76.3)	135	
Dispenser's work experience				
< 1year	64 (30.8)	144 (69.2)	208	
1-3years	1 (6.70	14 (93.3)	15	0.108
>3years	37 (26.1)	105 (73.9)	142	
Dispenser's medication error training				
Yes	7 (5)	132 (95)	139	**<0.001**
No	95 (42)	131 (58)	226	
Administrator's education level				
Nursing officer	48 (30.2)	111 (69.8)	159	
Assistant Nursing officer	42 (26.4)	117 (73.6)	159	0.698
Intern nurse	12 (25.5)	35 (74.5)	47	
Administrator's work experience				
<1year	28 (31.8)	60 (68.2)	88	
1-3years	9 (26.5)	25 (73.5)	34	0.649
>3years	65 (26.7)	178 (73.3)	243	
Administrator's training on medication error				
Yes	7 (12.1)	51 (87.9)	58	**0.003**
No	95 (30.9)	212 (69.1)	307	

Predictors of PME

Univariable and multivariable analysis of the predictors of PME are presented in **Table 7.** In the univariable analysis predictors that were significantly associated with PME included age, hospital stays, previous medication history, number of medications, prescriber's experience, prescriber workload, prescriber training on MEs, administrator's training on ME, dispenser's qualification, dispenser's work experience, dispenser's MEs training, dose reconciliation protocol and medication preparation room. Upon adjusting for confounders in multivariable analysis, age, hospital stays, previous medication history, number of medications, prescriber experience, prescriber workload, prescriber training on MEs, administrator's training on ME, dispensers' qualification, dispenser work experience, dispenser MEs training, dose reconciliation protocol and medication preparation room were found to have significant association with PME. See **Table 7**

Table 7: Regression Analysis for Factors Associated with PME

Variable	COR (95% C.I)	p-value	AOR (95% C.I)	p-value
Age				
0-28 days	1.434(0.864-2.378)	0.163	0.658(0.381-1.137)	0.134
29 days- 12months	0.931(0.473-1.830)	0.835	0.990(0.457-2.097)	0.978
1-17 years	Ref			
Sex				
Female	0.777(0.491-1.229)	0.281		
Male	Ref			
Weight group				
Less than 10kg	1.083(0.357-3.290)	0.888		
11-20kg	0.840(0.291-2.423)	0.746		
More than 20kg	Ref			
Residence				
Dar es Salaam	0.491(0.105-2.293)	0.365		
Other regions	0.552(0.113-2.695)	0.463		
Undefined	Ref			
Referral status				
New admission	0.928(0.51-1.690)	0.808		
Self-referral	0.909(0.502-1.646)	0.753		
Referral from other hospital	Ref			
Hospital stays				
Less than 5 days	0.190(0.107-0.337)	<0.001	4.886(2.702-8.835)	**<0.001**
More than 5 days	Ref			
Previous medication history				
No	0.425(0.243-0.744)	0.003	2.558(1.393-4.697)	**0.002**
Yes	Ref			
Previous medical condition				
No	0.539(0.152-1.916)	0.340		
Yes	Ref			
Number of medications				
Less than 2	0.453(0.250-0.822)	0.009	1.906(0.986-3.681)	0.055
2- 4	0.855(0.470-1.556)	0.608	0.926(0.484-1.773)	0.818
More than 4	Ref			

Variable	COR (95% C.I)	p-value	AOR (95% C.I)	p-value
Prescriber's education				
Medical intern	0.731(0.434-1.230)	0.731		
Medical registrar	1.073(0.574-2.003)	0.826		
Registrar	Ref			
Prescriber's experience				
Less than a year	1.021(0.621-1.680)	0.934	1.332(0.749-2.369)	0.330
More than 3 years	2.933(1.267-6.790)	0.012	0.381(0.153-0.947)	**0.038**
1-3 years	Ref			
Prescriber's workload				
1 – 5	3.118(0.378-25.705)	0.291	0.534(0.052-5.435)	0.596
6 – 10	2.864(1.246-6.585)	0.013	0.330(0.133-0.818)	**0.017**
More than 10	Ref			
Prescriber's training on MEs				
No	0.254(0.076-0.856)	0.027	0.873(0.165-4.625)	0.873
Yes	Ref			
Administrator's education				
Nursing officer	0.793(0.379-1.658)	0.538		
Assistant nursing officer	0.955(0.454-2.011)	0.904		
Intern nurse	Ref			
Administrator's training on ME				
No	0.306(0.134-0.700)	0.005	2.21690.710-6.913)	0.171
Yes	Ref			
Administrator's work experience				
Less than 3 years	0.771(0.319-1.868)	0.565		
More than 3 years	0.986(0.437-2.223	0.973		
1 – 3 years	Ref			
Dispensers' qualification				
Intern pharmacist	0694(0.423-1.138)	0.148	0.735(0.333-1.754)	0.912
Pharmaceutical technician	0.880(0.320-2.421)	0.805	0.928(0.297-2.897)	0.898
Pharmacist	Ref			
Dispenser's work experience				
Less than 3 years	0.161(0.021-1.248)	0.080	0.818(0.250-3.124)	0.467
More than 3 years	0.203(0.260-1.595)	0.129	0.495(0.450-2.409)	0.144
1 – 3 years	Ref			

Variable	COR (95% C.I)	p-value	AOR (95% C.I)	p-value
Dispenser's MEs training				
No	0.073(0.033-0.164)	<0.001	11.4(4.945-26.348)	**<0.001**
Yes	Ref			
Documentation of treatment duration				
No	1.121(0.704-1.784)	0.631		
Yes	Ref			
Documentation of drug interaction				
No	1.957(0.226-16.961)	0.542		
Yes	Ref			
Dose reconciliation protocol				
No	3.127(1.288-7.594)	0.012	2.097(0.793-4.912)	**0.05**
Yes	Ref			
Medication preparation room				
No	2.122(0.568-3.912)	0.02	0.135(0.122-0.983)	0.612
Yes	Ref			

CHAPTER FIVE

5.0 DISCUSSION

This study aimed to investigate PME and their predictors among hospitalized paediatric patients at MNH, Tanzania. The findings indicate that most patients were between 1 and 17 years old, with a slight predominance of female patients (54.5%). The most common diagnoses were sepsis and respiratory distress syndrome, and the medications most frequently prescribed included vitamins/minerals, bronchodilators, and antibiotics. Significantly, 72.1% of the participants experienced at least one potential medication error, with duration errors being the most prevalent. These results underscore the critical need for improved medication safety protocols in paediatric care at MNH.

The study found a high prevalence (72.1%) of PME, consistent with global studies reporting similar trends in paediatric hospitals. Research shows that the prevalence of PME among hospitalized paediatric patients can vary widely; one study reported a prevalence of 63%, with omissions during prescribing and medication history being the main contributors (21). Additionally, a study conducted in Ethiopia found that medication administration errors were more common among paediatric patients, especially those younger than one month of age (18). The higher prevalence of PME in our study compared to the global average suggests that regional factors such as healthcare infrastructure, training, and protocols may significantly influence error rates.

The data revealed that duration errors were the most frequent, followed by route errors. These findings align with previous research indicating that paediatric patients are particularly vulnerable to ME due to the complexity of dosing calculations and the need for individualized medication regimens. For instance, a study found an overall rate of 15.5 PME per 105 bed days, with prescribing and administration stages being the main contributors (19). Another study revealed that hospitalized paediatric patients are three times more likely to experience ME compared to adults (20). Furthermore, one study reported a 41% prevalence of duration errors among paediatric patients, highlighting the significant risk within this population (22).

Shorter hospital stays and the absence of previous medication history were linked to higher odds of ME. This result is suggesting that shorter hospital stays may increase the risk of errors because of insufficient medication reconciliation during hospital stay which may be contributed by workload hence insufficient time for patients monitoring. This finding contrasts with some studies that suggest longer hospital stays are associated with higher error rates due to increased medication exposure (25).

Patients with no previous medication history were reported to have a higher risk of PMEs. This finding is opposed to some research suggesting that individuals with long medication histories are frequently more vulnerable because of the complex nature of their treatment plans (26). However, it highlights the need for thorough medication reviews for all patients, regardless of their history.

Greater prescriber experience was associated with lower odds of errors. This shows that more experienced prescribers are less prone to make errors and have greater ability to manage complex drug regimens. Less experienced prescribers, on the other hand, might not have the knowledge or abilities needed to avoid common medication management errors. These findings align with findings from a study in Northern Ethiopia indicating that factors such as healthcare professionals' educational background and experience play crucial roles in mitigating ME (18).

Prescribers who work with six to ten patients have an AOR of 0.330 ($p = 0.017$), which is significantly lower than the risk of MEs for prescribers who work with more than ten patients. This indicates that heavy workloads might cause burnout and higher error rates among healthcare personnel. Two studies conducted in India reported similar results (26,27).

Additionally, the lack of ME training for dispensers was a significant predictor of ME, emphasizing the critical need for continuous professional development among dispensers and other healthcare workers.

The study also found that the absence of a dose reconciliation protocol significantly increased the odds of ME. This finding is crucial as it highlights an actionable area for intervention. Dose

reconciliation protocols have been shown to reduce ME significantly in various settings by ensuring accurate medication records throughout patient care transitions (3). The significant impact of this factor on ME at MNH suggests that implementing such protocols could substantially improve patient safety.

CHAPTER SIX

6.0 LIMITATION, CONCLUSION AND RECOMMENDATIONS

6.1 Study limitation and mitigation

The study's limitations include single-centre design, which may limit generalizability to broader healthcare contexts. Residence of study participants captured during data collection reflect representation of people all over the country. Language barriers from few participants made communication difficult. In such cases, the researcher retrieved most information from the patients' files.

6.2 Conclusion

The findings from this study indicate that the prevalence of ME among paediatric children is high, with majority (72.1%) experiencing PME. The most common types of errors were duration errors, route errors, and frequency errors. Significant predictors of PME identified in this study include a hospital stay of less than 5 days, lack of previous medication history, prescriber experience of more than 3 years, prescriber workload of 6-10 patients per day, absence of medication error training for healthcare workers, and the absence of a dose reconciliation protocol. These findings highlight critical areas for intervention to improve medication safety in healthcare settings.

6.3 Recommendations

To address the predictors of PME identified in this study, it is recommended to implement comprehensive training programs for healthcare workers, establish and enforce standardized dose reconciliation protocols, and optimize prescriber workloads to manageable levels. Additionally, encouraging the retention and continuous education of experienced prescribers, considering extended hospital stays for high-risk patients, and developing a system for tracking and sharing information on previous ME among healthcare providers are crucial steps. These strategies aim to reduce ME, improve patient outcomes, and enhance overall care quality.

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APPENDICES

Appendix I: Informed Consent Forms

Consent to participate in PME and its predictors among hospitalized paediatric patients at MNH.

Dear Sir/Madam

My name is Julphery Raphael Towo, a postgraduate student pursuing Master of Pharmacovigilance and Pharmacoepidemiology resident pharmacist in the department of clinical pharmacy and pharmacology at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research study on PME and its predictors among hospitalized paediatric patients at MNH (MNH).

I now request your participation

Purpose of the study: This study aims to assess PME and its predictors among paediatric patients admitted at MNH.

How to participate: Parents of patients or healthcare profession willing to participate in this study will have to sign a consent form. Other information will be obtained from patients' files and database at the MNH paediatric wards.

Confidentiality: Information obtained from you will be kept confidential and will be very helpful in this study and promote better health outcomes of paediatric patients on preventing PME.

Cost: You will not be required to pay any funds to participate in this study.

Voluntary participation and the right to withdraw from the study:

Your participation is voluntary, and you have the right to withdraw from participating in this study. Whatever your decision may be, it will not affect your rights to care and treatment.

Risks: There are no risks involved.

Benefits: Your participation in this study will help you know how to prevent potential medication errors.

I hope that this research information will help improve the quality of your care at MNH.

Contact person:

If you have any inquiries about this study, please do not hesitate to contact:

JULPHERY RAPHAEL TOWO
Principal investigator
The Muhimbili University of Health and Allied Sciences,
Department of Clinical Pharmacy and Pharmacology,
P.O.BOX 65013,
Dar es salaam.
TEL: 0652502963

In case of any information about your rights as a participant in this study, please contact;

The chairperson of the Research and Ethical Committee

Muhimbili University of Health and Allied Sciences (MUHAS),
PO BOX 65001,
Dar es Salaam.
Tel.022-2152489

I will be grateful if you willingly agree to participate in this study.

I have understood that the investigator has answered the above information and my questions to my satisfaction. I willingly agree to take part in this research.

Name of the participant ……

Signature of the participant …….. Date ……

Signature of investigator …… Date ……

Appendix II: Fomu ya ridhaa kwa Kiswahili

Ridhaa ya kushiriki katika utafiti wa tathmini ya makosa yanayoweza kutokana na dawa pamoja na visababishi kwa Watoto waliolazwa hospitali ya taifa ya Muhimbili.

Jina langu ni Julphery Raphael Towo mwananfunzi wa shahada ya uzamili katika usalama wa dawa na famakoepidemiolojia kutoka idara ya Famasi tiba na famakolojia ya chuo kikuu cha afya na sayansi shirikishi cha Muhimbili. Ninafanya tathmini ya makosa yanayoweza kutokana na dawa na visababishi vyake kwa Watoto waliolazwa katika hospitali ya taifa Muhimbili.

Namna ya kushiriki: Kwa wagonjwa au watoa huduma watakaoridhia kushiriki katika utafiti huu watajaza na kusaini fomu ya ridhaa.

Usiri: Taarifa zote zitakazopatikana kutoka kwako zitatunzwa kwa usiri wa hali ya juu na zitatumika kwa ajili ya utafiti huu na pia kuboresha hali ya kutoa huduma kwa wagonjwa.

Gharama: Hakuna gharama yoyote katika kushiriki kwenye utafiti huu. Ni hiyari kushiriki na kujitoa ushiriki katika utafiti huu muda wowote unapohisi kufanya hivyo.

Maamuzi yako ya kuamua kutoshiriki au kujitoa.

Maamuzi yako katika utafiti huu ni ya hiari na hayataathiri haki yako ya kupata huduma na matibabu.

Madhara ya kushiriki utafiti: Hakuna madhara yeyote yatakayompata mshiriki wa utafiti huu.

Manufaa ya kushiriki utafiti: Ushiriki wako katika utafiti huu utakuwa na faida kwako kwa kuweza kujua namna ya kuepuka makosa yanayotokana ma dawa. Pia, matokeo ya utafiti huu utakuwa yatasaidia kushauri katika matibabu sahihi kwa wagonjwa na kuwaepusha na makosa yanayotokana na dawa.

Nitashukuru sana kama kwa hiyari yako utaamua kushiriki katika utafiti huu.

Kauli ya Mtafiti: Mimi Julphery Raphael Towo mtafiti, nakiri nimemuelewesha mshiriki wa utafiti huu kuhusu huu utafiti. Sahihi……. Tarehe…….

Mawasiliano Kwa wahusika: Kwa maswali au maoni kuhusiana na utafiti huu tafadhali wasiliana na wafuatao:

JULPHERY RAPHAEL TOWO
Mtafiti mkuu Chuo kikuu cha afya na tiba shirikishi Muhimbili
Idara ya Famasi tiba na famakologia
S.L.P 65013
Dar-es-salaam
Nambari ya simu: 0652502963

AU

Kwa mawasiliano zaidi kuhusiana na haki zako kwenye utafiti huu kama mshiriki, tafadhali wasiliana na:
Mwenyekiti wa tume ya tafiti na uchapishaji wa tafiti.
Chuo kikuu cha afya na tiba shirikishi Muhimbili
S.L.P 65001
Dar-es-salaam
Nambari ya simu.022-2152489

Kauli ya Mshiriki: Natoa idhini mwenyewe bila aina yeyote ya kushurutishwa au kulazimishwa kushiriki katika utafiti uliotajwa.

Nafanya hivi baada ya kuelewa taarifa zote nilizoelezwa na Julphery Raphael Towo na pia amenijibu na kunielewesha zaidi maswali niliyomuuliza.

Nimeelewa kikamilifu kuhusu madhumuni ya tafiti yake na naelewa kuwa nitaulizwa maswali.

Pia naelewa naweza kujiondoa kwenye utafiti wakati wowote iwapo nitabadilisha mawazo

Jina la mshiriki ……. Sahihi ya mshiriki …… Sahihi ya mtafiti ……. Tarehe ……

Appendix III: Assent Form for Children (7-17 years)

To be completed by the child, in the presence of their parent / guardian

I have been told that my parents (mom or dad/caretaker) have said it's okay for me to

participate, if I want to, in a project about "Potential medication errors and its predictors among hospitalized paediatric patients at Muhimbili National Hospital, Tanzania."

I know that I can stop at any time I want to, and it will be okay.

Please write your name and today's date if you want to take part.

Your name:	
Today's date:	

Your [parent / mom or dad / legal guardian] must also sign this form:

Parent / guardian full name:	
Parent / guardian signature:	

Today's date:	

The researcher who explained the study to you must also sign this form:

Researcher's Name:	
Researcher's signature:	
Today's date:	

The following people are happy to hear from you about questions or concerns that you may have:

About the research study:

Principal investigator

The Muhimbili University of Health and Allied Sciences,

Department of Clinical Pharmacy and Pharmacology,

P.O.BOX 65013,

Dar es salaam.

TEL: 0652502963

About data protection:

The chairperson of the Research and Ethical Committee

Muhimbili University of Health and Allied Sciences (MUHAS),

PO BOX 65001,

Dar es Salaam.

Tel.022-2152489

Appendix IV: Fomu ya Ushiriki wa Tafiti kwa Watoto (miaka 7-17)

Inatakiwa kukamilishwa na mtoto, mbele ya mzazi/mlezi wake

Nimeambiwa kwamba wazazi wangu (mama au baba/mlezi) wamesema ni sawa kwangu kufanya hivyo, kushiriki, kama ninataka, katika mradi unaohusu "Makosa ya dawa na vitabiri vyake miongoni mwa wagonjwa watoto waliolazwa katika Hospitali ya Taifa ya Muhimbili, Tanzania"

Najua kwamba ninaweza kuacha wakati wowote ninaotaka, na itakuwa sawa

Tafadhali andika jina lako na tarehe ya leo ikiwa unataka kushiriki.

Jina lako:	
Tarehe ya leo:	

Mzazi / mama au baba / mlezi wako wa kisheria] lazima pia atie sahihi kwenye fomu hii:

Jina kamili la mzazi/mlezi :	
Sahihi ya mzazi/mlezi:	

Tarehe ya leo:	

Mtafiti aliyekueleza utafiti lazima pia atie sahihi kwenye fomu hii:

Jina la Mtafiti:	
Saini ya mtafiti:	
Tarehe ya leo:	

Watu wafuatao wanafurahi kusikia kutoka kwako kuhusu maswali au mashaka ambayo unaweza kuwa nayo:

Kuhusu utafiti:

Julphery Raphael Towo,

Mtafiti mkuu,

Chuo kikuu cha afya na tiba shirikishi Muhimbili,

Idara ya Famasi tiba na famakologia

S.L.P 65013

Dar-es-salaam

Nambari ya simu: 0652502963

Kuhusu ulinzi wa taarifa:

Mwenyekiti wa tume ya tafiti na uchapishaji wa tafiti.

Chuo kikuu cha afya na tiba shirikishi Muhimbili

S.L.P 65001

Dar-es-salaam

Nambari ya simu.022-2152489

Appendix V: Data Collection Tool

Date of the interview (date/month/year): _____			
Name of the health Institution: _____			
Interviewer's name & signature:	Name: _____	Signature_____	
S/N	**Question**	**Response**	**Skip**
Part I: Socio-demographic Characteristics			
101.	Medical registration number (MRN)		
102.	Child information (age in years & weight in Kg.)	Age ☐ Sex ☐ Weight ☐	
103.	Residence of the child's family?	1. Urban 2. Rural	
104.	Education status	1. Unable to read and write. 2. Able to read and write 3. Primary (1-8) 4. Secondary (9-12) 5. College and above	
105.	Are family members involved in their childcare? (decision making)	1. Yes 2. No	
Part II: Healthcare Providers Characteristics			
201.	What is the qualification of the healthcare provider that order the medication for the child?	1. Physician 2. Medical intern 3. Registrar	

		4. Other (specify)_____	
202.	Does the medication prescription paper include the following components (must be filled by observing the prescription form given for the parents)		
	1. Name of the prescriber	1. Yes 2. No	
	2. Signature of the prescriber	1. Yes 2. No	
	3. Date of prescription	1. Yes 2. No	
	4. Patient full name	1. Yes 2. No	
	5. Patient address	1. Yes 2. No	
	6. Age of the patient/date of birth	1. Yes 2. No	
	7. Medical diagnosis	1. Yes 2. No	
	8. Name of medicine	1. Yes 2. No	
	9. Dose	1. Yes 2. No	
	10. Frequency	1. Yes 2. No	
	11. Duration	1. Yes 2. No	
	12. Route administration	1. Yes 2. No	
	13. Legible handwriting	1. Yes 2. No	
	14. Unstandardized abbreviations	1. Yes 2. No	
	15. Weight of the child	1. Yes 2. No	
	16. Medical registration number?	1. Yes 2. No	
	17. Other (specify)_____		
203.	Work experience of the medication prescriber.	Months ____, Years_____	
204.	Educational level of medication administrator?	1. Diploma nurse/midwife 2. BSC nurse/midwife 3. Nurse intern	

		4. Other (specify)_____	
205.	The experience of the medication administrator in the unit?	Months ____, Years_____	
206.	Does the medication administrator have an additional workload?	1. Yes 2. No	
	How many patients do you give care to per day? _____		
207.	Is the working environment suitable for medication preparation and administration?	1. Yes 2. No	
Part III: Medical Conditions of the Child			
301.	Child's level of consciousness?	1. Conscious 2. Unconscious	
302.	What is the reason for admission? More than one answer is possible.	1. Diarrhea 2. Pneumonia 3. Malaria 4. Sepsis 5. Asphyxia 6. Meconium aspiration 7. Leukemia 8. Retinoblastoma 9. Epilepsy 10. Other (specify)_____	
303.	Severity of the disease (what was the condition of the child?)	1. Acute sick looking 2. Severe 3. Critical 4. Other (specify)_____	

304.	Does the child have a previous medical condition?	1. Yes 2. No	
305.	If yes for QNo. 304 would you list it?	_____	
306.	Does the child have previous admissions? How many?	1. Yes 2. No	
307.	Does the child have previous medication history	1. Yes 2. No	
308.	By what diagnosis criteria the child is treated for the current problem?	1. Empirical diagnosis 2. Laboratory investigation 3. Both empirical and laboratory investigation	

Part V: Medication order data

401. **Ordered medication:** Type with prescribed dose, frequency, route and duration from a card or prescription with single dose amount to be administered medication *(should be filled from child's card and medication availability from the pharmacy/parents)*

s/n	Medicine	Dose	Route	Frequency	Duration	Availability in the hospital
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Part V: Medication Administration Data			
Medical registration number (MRN) ☐			
Medication administration: The questions below must be filled by serious observation of the provider while he/she prepares and administer the medications and should be crosschecked with the ordered medications in QNO. 401.			
402.	Which types of medication to be administered from a list of ordered medication type in QNo 401? _____ _____ _____ _____		
403.	Time of drug administration? Recorded the exact time	1. Day _____ 2. Night_____	
404.	Is the selected drug to be administered like the prescribed drug?	1 Yes 2 No	
405.	Does the nurse reconcile the dose? (observe and check with the order dose)	1. Yes 2. No → **407**	
406.	If the answer for QNo. 405 is 'Yes'; Is the calculated dose similar to the ordered single dose to be administered in QNo. 401?	1. Yes 2. No	
	The calculated single dose to be administered is _____		
407.	Does the nurse reconstitute and draw the right amount of dose?	1. Yes 2. No	
408.	Does the medication administrator identify the right route?	1. Yes → **409**	

		2. No	
409.	If the answer for QNo. 408 is No; explain the error committed? _____ _____ _____		
410.	Does the nurse give the medication at the right time?	1. Yes 2. No	→ **411**
411.	If the answer for QNo. 410 is No; what types of error committed _____		
412.	Is there any missed medication that is not given to the patient at the required time?	1. Yes 2. No	→ **413**
413.	If the answer for QNo. 412 is Yes, which medication is missed_____		
414.	Is there any un-prescribe drug given to the patient?	1. Yes 2. No	→ **415**
415.	If the answer for QNo. 414 is Yes; what type of medication? _____		
416.	Does the medication administrator identify the right child?	1. Yes 2. No	→ **417**
417.	If the answer for QNo. 416 is No; what type of medication? What type of error committed? _____		

Appendix VI: Approval for ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/2113 Date: 25/03/2024

MUHAS-REC-03-2024-2113
JULPHERY RAPHAEL TOWO
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: POTENTIAL MEDICATION ERRORS AND ITS PREDICTORS AMONG HOSPITALIZED PAEDIATRIC PATIENTS AT MUHIMBILI NATIONAL HOSPITAL, TANZANIA.

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: 25/03/2024
EXPIRATION DATE OF APPROVAL: 25/03/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this prospective observational cohort study is to determine the incidence of potential medication errors and its predictors among paediatric hospitalized patients at Muhimbili National Hospital, Tanzania.

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-%2014554.pdf and in the MUHAS archives.

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. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. 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)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. 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. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee

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

Appendix VII: Permission to collect data MNH Upanga

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2024/154 Date: 27th March, 2024

Head of Department,
Paediatrics and Child Health
Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name Student	**Julphery Raphael Towo**
Title	**"Potential Medication Errors and Its Predictors Among Hospitalized Paediatric Patients at Muhimbili National Hospital".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Alphonce Marealle (MUHAS)
Co - Supervisor	Dr. Richard Christopher (MNH)
Period	27th March, 2024 to 30th June, 2024

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. Richard Christopher** (MNH) supervisor.

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

Sincerely,

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

c.c DMS,
c.c Dr. Richard Christopher
c.c Julphery Raphael Towo

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
Email: info@mnh.or.tz, Website: www.mnh.or.tz

Appendix VIII: Permission to collect data MNH Mloganzila

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL
MLOGANZILA

In reply please quote
Ref. No.: JA.294/428/01B/166

02/04/2024

Head of Department,
Paediatric and Child health
Muhimbili National Hospital-Mloganzila

RE: PERMISSION TO COLLECT DATA AT MNH - MLOGANZILA

Name of Principal Investigator	**Julphery Raphael Towo**
Title	**"Potential Medication Errors and its Predictors Among Hospitalized Paediatric Patients at Muhimbili Hospital".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisors	Dr. Alphonce Marealle Dr. Mwanaidi Msuya
Period	02nd April 2024-30th June 2024

Approval has been granted to the above principal investigator to collect data at MNH-Mloganzila. Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Ng'amilo Mbwalila
For: Executive Director
Muhimbili National Hospital-Mloganzila

c.c. DMS
cc. Julphery Raphael Towo

Mloganzila, Kibamba – Ubungo, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-222215715, Telephone: +255-22-2215701,
Email: info@Mloganzila.or.tz, Website: www.mloganzila.or.tz