INCIDENCE AND DETERMINANTS OF MEDICATION ERRORS AMONG PAEDIATRIC IN-PATIENTS AT KISII LEVEL 5 HOSPITAL.

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A Thesis submitted in partial fulfillment of the requirements for the award of the Degree of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance, School of Pharmacy, University of Nairobi.

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DECLARATION

I declare that this Thesis is my original work and has not been presented to any other academic institution for examination

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DEDICATION

I dedicate this thesis to my beloved son Chandler, niece Jasmine, and my entire family for their love, patience and unwavering support during my studies. I also dedicate this thesis to the Paediatric patients at Kisii level 5 Hospital.

LIST OF ABBREVIATIONS

ADEs	Adverse drug Events
AEs	Adverse Events
AIDS	Acquired Immunodeficiency Syndrome
CDSSs	Clinical Decision Support System
CPOE	Computerized Provider Order Entry
DRP s	Drug Related Problems
ED	Emergency Department
FGD	Focused Group Discussion
GPW	General Paediatric Ward
HWCs	Health Care Workers
IOM	Institute of Medicine
KL5H	Kisii Level 5 Hospital
ME	Medication Errors
MRPs	Medication Related Problems
MTC	Medicines and Therapeutic Committee
NCC MERP	National Coordinating Council for Medication Errors and Reporting
NBU	New Born Unit
PNCE	Pharmaceutical Care Network Europe
RCA	Route Cause Analysis
UK	United Kingdom
USA	United States of America
WHO	World Health Organization.

OPERATIONAL DEFINITION OF TERMS

Adverse Drug reaction: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function

Adverse Event: Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related

Caregivers: Parents or guardians of children admitted at the Kisii Level 5 Hospital during the period of study**.**

Iatrogenic injury: Injury that is caused by medical personnel or procedures or that develops through exposure to the environment of a health care facility

Medical error: Any preventable adverse outcome that results from improper medical management.

Medication error: unintentional errors in the prescribing, dispensing, administration or monitoring of a medicine while under the control of a healthcare professional, patient, or consumer

Patient Safety: Patient safety is the prevention of avoidable errors and adverse effects to patients associated with health care.

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ABSTRACT

Background: Medication errors are any error in prescribing, dispensing, administration, or monitoring of a drug and are an important cause of patient harm. They are also the single most preventable cause of patient harm yet when they occur in paediatrics patients, they have a much higher risk of death compared to adults. Literature suggests that children experience medication errors up to three times more than adults do. Some studies indicate up to tenfold higher rate of medication errors in children.

Objective of the study: The main objective of the study was to determine the incidence and factors associated with medication errors in paediatric patients admitted Kisii level 5 Hospital

Methodology: The study carried out between June and August 2014 was conducted in two parts; a descriptive cohort study that had a quantitative approach and a cross sectional survey that was qualitative in nature. The quantitative component entailed the prospective review of treatment sheets and files for medication related errors among children aged 0-5 years old admitted at the general paediatric ward and newborn unit at Kisii level 5 Hospital until discharge or up to a period of one month. The qualitative component included interviews of health care workers and caregivers alongside focused group discussions to identify the medication error types and causes. Descriptive statistics was used to determine frequency, incidences, means, and standard deviations. The relationships between predictor and outcome variables for dosing errors were computed using logistic regression (with significance set at p-value of 0.05 and 95% confidence interval). Key themes identified in the interviews and focus group discussions were explored for potential causes of medication errors.

Results: Out of 405 treatment sheets and files reviewed during the study, 307 contained errors yielding an overall medication error rate of 75.8% with the total number of medication errors observed being 1023. These errors were classified into various categories as documentation errors 756 (73.9%) which were more frequent, followed by dosing errors

(90, 8.8%), monitoring errors (88, 8.6%) and timing errors (58, 5.7%). The medication errors occurred more frequently in male children (164, 41.2%), children less than one year (186, 45.9%) and in those admitted to the general paediatric ward (196, 48.4%). Logistic regression of dosing errors revealed that children receiving more than five medicines were 6.4 times likely to experience dosing errors (OR 6.4; 95%CI: 2.7-15.1; P<0.001). Route of drug administration was a significant predictor of dosing errors with a 90% less risk of developing a dosing error for oral routes as compared to intravenous route (P <0.001). Various causes of medication error were identified and strategies to mitigate the occurrence of medication errors among the paediatric in-patients proposed.

Conclusion: The incidence of medication errors was significantly high with about 3.3 errors per prescription and larger studies would be appropriate to determine the extent of medication errors among children. Despite the fact that majority of errors observed were less likely to cause harm, some can be potentially fatal and therefore there is need for hospitals to have strategies of detecting and minimizing the errors.

CHAPTER ONE: INTRODUCTION

1.1 Background

A Medical error is any preventable adverse outcome that results from improper medical management (a mistake of commission) rather than from the progression of an illness resulting from lack of care (a mistake of omission) [1] . A medical error may or may not result in medical injury [1]. Medication errors are any errors in prescribing, dispensing, administration or monitoring of a drug irrespective of whether such errors lead to adverse consequences or not. They are also the single most preventable cause of patient harm [2].

Patient safety is the freedom from accidental injury due to medical care or from medical error. In its report to “Err is human”, the Institute of Medicine [3] estimated that medical errors in hospitals alone cause as many as 98,000 patient deaths and more than one million patient injuries at a cost of up to $ 29 billion each year. The report also details medical errors as a leading cause of death in the United States of America (USA) as compared to motor vehicle accidents, breast cancer or AIDS.

Medication errors (MEs) are significant types of medical errors and one of the most common and preventable causes of iatrogenic injuries [4]. Medication Errors contribute to the morbidity and mortality of hospitalized patients. According to Williams [2] in the USA, medication errors occur in 2 to 14 per cent of the in-patients with 1 to 2 per cent of them being harmed .Most of the errors are attributed to poor prescribing .The report further states that the medication errors are estimated to kill 7,000 patients per annum and account for nearly 1in 20 hospital admissions. Medication errors occur in 6.5 of 10 adult hospital admissions and 5 of 100 adult medication orders [4]. Approximately one third of adverse drug events (ADEs) are associated with medication errors thus preventable.

Paediatric patients have a much higher risk of dying than adults when exposed to medication errors [5] . Various factors that put children at a greater risk for medication errors these include; variations in age and weight, high intra-patient variability and rapid changes in the pharmacokinetic properties of drugs in children. Frequent use of "off-label" indications

predisposes them further to medication errors [4]. A systematic review by Miller and colleagues found that, the most common medication errors types in paediatric patients were administration 72-75%, documentation 17-21%, dispensing 5-58% and prescribing 3-37% [6].

1.2 Statement of the Problem

In the medication use cycle, creation of a prescription is the first step and this calls for critical review of the orders by pharmacists and nurses in order to detect and prevent medication errors. In paediatric patients most medication errors occur at the prescribing and ordering followed by the administration phases with majority being dosing errors. Medication errors, more so prescribing errors occur at a rate of 3 to 20% of all prescriptions in hospitalized paediatric patients and in 10.1% of children seen in emergency departments [7].

Medication use in children can pose great challenges when it comes to drug ordering and delivery process since most of their dosages must be calculated individually in some cases. . This leads to increased chances for medication errors with a relatively high risk of up to ten fold. The very young and critically ill children are more prone to ADEs than adults because they have less physiological reserves with which to buffer errors such as overdoses [8].

Among children, neonates are the most vulnerable to medication errors related to dosing and dispensing due to their rapidly changing body surface areas and weight. In addition, they have equally fast developing organ systems for drug metabolism. Their inability to communicate with the provider; further predisposes them to errors. Most of the drugs used in neonates are available in dosages and units for dispensing in children or adults. This needs a lot of calculation and has a higher potential for errors [8,9].

Children have less well developed communication skills than adults which limit feedback to healthcare workers about potential mistakes in medication use, however there is relatively little research that has addressed the problem of medication errors and ADEs in pediatric in-

patient settings. Reliable error detection requires intensive, comprehensive, and active ward-based data collection [10]

It is important that studies are carried out to identify medication errors within the Kenyan Health care setup. In a similar cross sectional study carried out in the general paediatric wards at Kenyatta National Hospital on children aged 0-5years,most (51.7%) of the 61 records sampled were for the age category 0-2 years and at least one medication prescribing error was noted in 59 (96.7%) of all records (n=61) sampled. The present study seeks to explore further on these findings.

1.3 Study Justification

The Constitution of Kenya 2010 under the Bill of rights stipulates that each citizen has a right to highest attainable health, goods and services of good quality, and information necessary for them to gain full benefits of the same. The constitution further ensures protection of health safety and economic benefits [11].

In ensuring medication safety, the Pharmacy and Poisons Board through the Ministry of Health launched a Pharmacovigilance System in 2009 [12]. This has mainly focused on adverse drug reaction reporting and issues of poor quality medicine, however up to date there is no clear system for the identification and reporting of medical errors. The few error reports available are either due to facility initiatives or what is reported in the media. It is against this that the study sets out to assess the prevalence and types of medication errors in paediatric in patients.

Identification of these errors is likely to lead to better modification of patient safety monitoring systems to improve medication use and safety among paediatric in- patients. The results will aid in the formulation of interventions that can help in the detection and prevention of medication errors

1.3 Research Question:

a) What is the incidence and types of MEs among pediatric in-patients at K L5H?
b) What are the potential risk factors for dosing errors occurring at the pediatric in-patient wards?
c) What are the potential causes of MEs

1.4 Broad Objective

To determine the incidence and determinants of medication errors in paediatric patients admitted in the general paediatric ward (GPW) and new born unit (NBU) at the KL5H

1.4.1 Specific Objectives:

The specific objectives of the of the study were to;

a) Determine the incidence and types of medication errors (MEs)
b) Determine potential risk factors for dosing errors in paediatric in-patients
c) Identify the potential causes of medication errors occurring in the in-patients.

CHAPTER TWO: LITERATURE REVIEW

2.1 What are Medication Errors

"A medication error (ME) is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer [13] . They could also be related to prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" [13]. A medication error is an avoidable event occurring at any phase of the medication use process, which may or may not harm the patient [14]. Damage due to medication errors can be characterized as an avoidable adverse drug event, defined as harm or injury, either temporary or permanent, occurring from inappropriate use, or lack, of the medication [15].

2.2 Classification of Errors

There are several classifications systems available for identifying and categorizing medication errors (MEs) and medication related problems (MRPs) in general. The systems include Hepler & Strand, Pharmaceutical Care Network Europe (PCNE), Psychological approach and the National Coordinating Council for Medication Errors &Reporting Programme (NCC MERP) classifications [16].

According to Hepler and Strand, [16] drugs are administered for the purpose of achieving definite outcomes that improve the patients' quality of life. The outcomes are either cure of a disease, reduction, or elimination of symptoms, arresting or slowing a disease process and preventing a disease or symptoms. However, there is always potential of outcomes that diminish the quality of life due to some drug related problem. The Hepler and Strand classification system consists of eight categories of drug related problems as shown in Figure 2.1

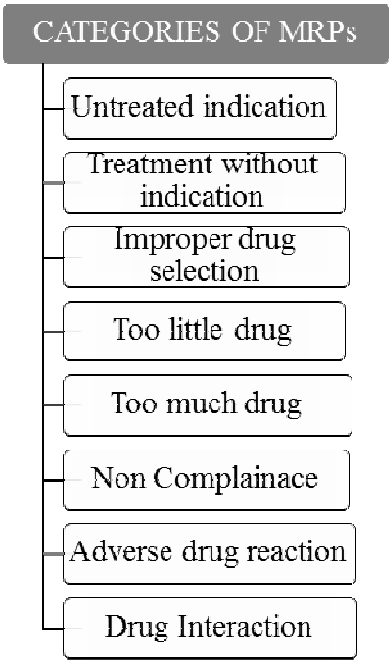


Figure 2.1: Hepler and Strand Categories of Medication Related Problems [16]

Untreated indication refers to an event where a patient with a medical condition requiring drug therapy is not given the drug. When a patient with a drug indication takes the wrong drug, it is referred to as improper drug selection. Sub therapeutic dosage is when a patient is getting too little of the drug. A patient with a medical condition that is being treated with too much drug (toxicity) constitutes to an Over dosage. Drug use without indications refers to a patient using a drug without a medically valid indication. Adverse Drug Reaction refers to a condition where the patient has experienced an adverse reaction upon use of drug. Drug interactions is when a patient has a medical condition that is a result of drug-dug, drug-food interactions,

The Pharmaceutical Care Network Europe (PCNE) Classification scheme for Drug Related Problems (DRP) separates real problems from its cause. Most often the problem is caused by certain types of errors such as prescribing, drug use or administration errors, though at times there may be no error. PCNE system has four sections consisting of problem, cause, intervention, and outcome. These sections are further divided into domains. The Problem section has 6 primary domains and 21 sub domains. The primary domains are classified as

adverse reaction, drug choice problem, dosing problem, interactions, and others. There are six primary and 33 sub domains for causes with the primary ones being categorized as drug or dose selection, drug use process, information, patient or psychological, pharmacy logistics and others. The intervention section consists of 5 primary domain and 17 sub domains. These sub domains can be regarded as explanatory for the principal domains. In 2003 a scale was added to indicate if or to what extend the problem has been solved [17]. The domains with problems and causes are illustrated in Table 2.1

Table 2.1: Pharmaceutical Care Network Europe Classification Scheme for Drug Related Problems

	Code V5.01	**Primary domains**
Problem	P1	**Adverse reaction(s):**Patient suffers from an adverse drug event
	P2	**Drug Choice Problem:** Patient gets or is going to get a wrong (or no drug) drug for his/her disease or condition.
	P3	**Dosing problem:** Patient gets more or less than the amount of drug he/she requires
	P4	**Drug usage Problem:** Wrong or no drug taken/administered
	P5	**Interactions:** There is a manifest or potential drug-drug or drug-food interaction Problems
	P6	**Other**
Causes	C1	**Drug/Dose Selection**: The cause of the DRP can be related to the selection of the drug and/or dosage schedule
	C2	**Drug Use Process :** The cause of the DRP can be related to the way the patient uses drugs.
	C3	**Information:** The cause of the DRP can be related to a lack or misinterpretation of information
	C4	**Patient/Psychological:** The cause of the DRP can be related to the personality or behaviour of the patient
	C5	**(Pharmacy) Logistics**: The cause of the DRP can be related to the logistics of the prescribing or dispensing mechanism
	C6	**Other**

The other commonly used system of classifications is the National Coordinating Council for Medication Error and Reporting Programme (NCC MERP). This classification provides a standard taxonomy of medication errors to be used in combination with systems analysis in recording and tracking of medication errors. The document is not all-inclusive, but can further be expanded as new issues arise. The purpose of this taxonomy is to provide a standard language and structure of medication error-related data for use in developing databases analyzing medication error reports [13,18]. This is illustrated in Table 2.2

Table 2. 2: National Coordinating Council for Medication Error Reporting and Error Category

Error Category	**Definition**
A	Circumstances or events that have the capacity to cause error
B	An error occurred, but the error did not reach the patient.
C	An error occurred that reached the patient but did not cause the Patient harm.
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
G	An error occurred that may have contributed to or resulted in the patient's permanent harm
H	An error occurred that required intervention necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient's death

2.2.1 Medication Errors, Adverse Drug Events, and Harm.

Medical errors need to be distinguished from adverse events, which are injuries caused by medical management rather than by underlying disease or condition of the patient. An adverse event results into harm to the patient; however, it is worth noting that not all medical errors result into adverse events [19].

An adverse drug event (ADE) is an injury due to a medication. ADEs are the most common type of adverse events (AEs) [3]. A preventable ADE is an ADE that based on the medical information known at the time and could have been avoided. An example is a patient who has a known allergy to macrolides being prescribed azithromycin and developing urticaria [19]. Non-preventable ADE is one, which could not have been fore seen based on the medical information known at the time for example development of a cefazolin-associated rash in a patient without a known cephalosporin allergy. An adverse drug reaction is synonymous with a non-preventable ADE. It is an event defined by the World Health Organization(WHO) as "noxious and unintended, and which occurs at doses used in man for prophylaxis, diagnosis or therapy" [19,20].

Potential ADE is a medication error that places a patient at significant risk of injury but does not actually result in harm .Potential ADEs are often referred to as "near misses." They can either be intercepted that is an error that is identified and corrected before it reaches the patient, or not intercepted such as an error that reaches the patient but, by pure coincidence, does not cause harm to the patient [18]. This relationship is illustrated in Figure 2.2

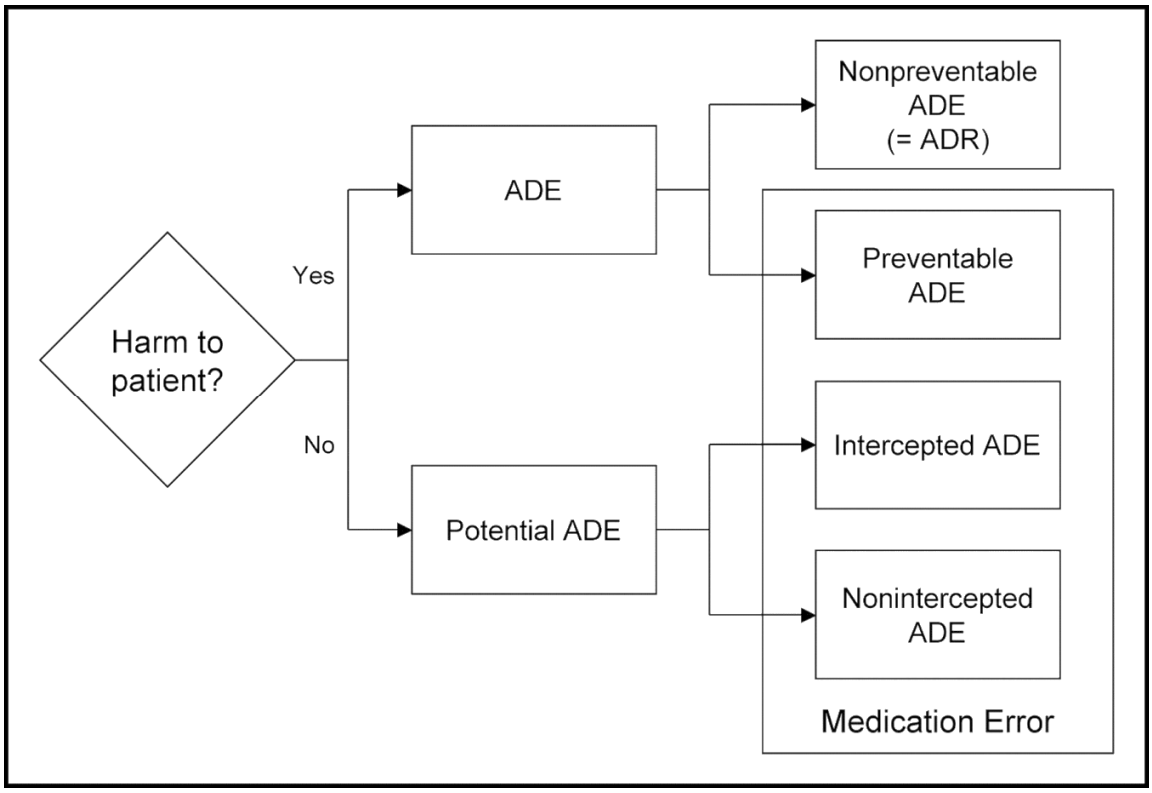


Figure 2.2: Relationship between medication errors, adverse events and harm [19].

2.3 Prevalence of Medication Errors

A review of existing literature shows varying statistics concerning the occurrence of medication errors. Medication error rates vary widely among clinical settings, patient populations, and studies. The reasons for this variation include different patient populations (illness severity, number, and type of prescriptions) clinical practice variation, lack of uniformity of definitions, the processes under investigation (e.g., prescription, transcription), methods of reporting, and the culture of the different centers reporting their data. Lack of standard definitions and reporting techniques make comparisons across organizations, regions or countries difficult [21].

The negative impact of preventable ADEs stimulated attempts to understand the nature and extent of medication errors. Research and review of literature show inconsistent pattern in the number, type and medication associated with medication errors. Single studies show

medication errors specifically prescribing errors in 0.4-15.4% of prescriptions written in the USA and 7.4-18.7% in the UK [22].

An analysis of medication errors in a stratified random sample of 36 institutions in the USA found that dosing errors were the most common type of medication errors with 19% of the doses) were in error. The most frequent errors by this category were wrong time (43%), omission (30%), wrong dose (17%), and unauthorized drug (4%). Seven percent of the errors were judged potential adverse drug events [23].

Barber et al [24], determined the prevalence, causes and potential harm of medication errors in care homes for older people in the United Kingdom(UK) and reported that two thirds of the residents were exposed to one or more medication errors. The residents recruited were taking a mean of 8.0 medicines with the mean number of medication errors per resident being 1.9 errors. Upon observing pharmacists [25] reviewing 17,320 medications ordered or administered to 6,471 patients in an emergency department in the USA, 504 errors were identified, or 7.8 per 100 patients and 2.9 per 100 medications. From the study, the most common medication classes associated with recovered medication errors were antimicrobial agents (32.1%), central nervous system agents (16.2%), and anticoagulant and thrombolytic agents (14.1%). The most common medication error types were dosing errors, drug omission, and wrong frequency errors. Potential severities of the recovered errors were most often serious (47.8%) or significant (36.2%).

A study to identify the frequency of medication administration errors and their potential risk factors in units using a computerized prescription order entry program; [26] reported that out of 2314 medication administered to 73 patients 509 (22.0%) errors were recorded. These were classified as 68 (13.4%) preparation and 441 (86.6%) administration errors.

In determining the incidence and nature of prescribing and medication administration errors in paediatric inpatients (27) a study was conducted across five hospitals in UK . An overall prescribing error rate of 13.2% with incomplete prescriptions as the most common form of

prescribing errors was reported. There was a 19.1% incidence of erroneous administrations with errors in drug preparation and incorrect intravenous administration being common.

Medication prescribing errors in a pediatric inpatient tertiary care setting in Saudi Arabia showed that out of an overall error rate of 56 per 100 medication orders ,dose errors were the most prevalent (22.1%) followed by route errors (12.0%), errors in clarity (11.4%) and frequency errors (5.4%). Other types of errors were incompatibility (1.9%), incorrect drug selection (1.7%) and duplicate therapy at 1% [4] .

2.3.1 Prevalence of Medication Errors in Africa

In a South African study to determine drug administration errors and near misses Anaesthetics in a paediatric tertiary teaching hospital [28] reported , 64 errors and 45 near misses. Most of the errors occurred during maintenance phase and more than half of the error (54%) were due to substitution. In the paediatric hospital incorrect dose was as frequent as error of substitution.

In assessing the incidence and type of Medication Errors in an Adult Emergency unit in a teaching hospital in Ethiopia[29] medication errors were reported in 154.84% of the total prescriptions with rate of 30.70 errors per patient. The most common type of medication errors were missing information on administration constituting 63.54% errors followed by prescribing errors at 32.11% and administration errors at 4.35%.

The risk of serious drug errors in anaesthesia may be higher than other specialities considering than an average anaesthetist may administer at least a quarter of a million drugs during their practice [30]. Prospective studies suggest that error rate in anaesthesia is around one in every 133 patients [31] . Intensive Care Unit (ICU) patients are at higher risk for ADEs because of the higher exposure to medicines compared with other patients. In a Moroccan Medical ICU [30] medication orders of 63 were reviewed and 492 MEs, whose incidence was 10 per 100 orders and 967 per 1000 patient –days recorded. There were 113 potential Adverse Drug Events (ADEs) and 8 ADEs that occurred in transcribing stage in 60% of the cases.

2.4 Risk factors for medication errors in children

Children are considered as a high-risk population for medication errors and ADEs. The risk for an ADE is estimated to be three times higher in hospitalized children than in adults [18]. More than one in six prescribing errors involved miscalculation of dose, wrong decimal point placement, incorrect expression of unit of measurement, or an incorrect medication administration rate. Calculation errors are more likely to occur in paediatric settings [32] . Children pose special challenges in the drug ordering and delivery process; for example, drug dosages often must be calculated individually, leading to increased opportunities for error with a relatively high risk of 10-fold errors as compared to adults [8].

Unlike adults, for whom dosing tends to be a single or with unlimited number of options, dosing for children usually is tailored to the patient based on his or her weight. Proper dosing requires that the prescriber have an accurate weight for the child as well as the proficiency to perform weight-based calculations., Most drugs are however packaged commercially for adult use hence the need for special compounding for pediatric usage, a task that requires a specific skill. This additional step in the medication delivery process introduces risk of error and, therefore, risk of harm [8,18,32]. Many over-the-counter medications for children are available in a variety of preparations and concentrations, which can contribute to confusion and subsequent dosing errors [18].

Children who experience extended lengths of stay, complex medication regimens, and higher severity of illness are at increased risk of ADEs [18]. Critically ill children , may be more prone to ADEs than adults because they have less physiologic reserve such as immature renal and hepatic systems to compensate medication errors with which to buffer errors such as overdoses [8,33]

Neonates and infants are at greater risk due to their immature hepatic, renal, and immune systems. ‘In settings such as the neonatal intensive care unit, where lengths of stay often are in months, patients can have significant changes in weight over the course of a hospitalization’ [18]. Neonates are also born at different gestational ages hence they

undergo rapid changes in their pharmacodynamics and pharmacokinetic parameters. This influences their ability to handle and tolerate medications and requires frequent adjustments to dosage and administration intervals [34]. This change requires vigilance to assure that medication-dosing regimens remain within safe and therapeutic ranges.

2.5 Factors contributing to the Occurrences of Medication errors

Formulating, prescribing, administering drugs, and monitoring their effects is not always straightforward. Medication errors, most of which are due to prescribing faults such as failures in the process of deciding which drug to use and how and prescription errors like failures in the prescription writing process that result in wrong instructions about one or more of the normal features of a prescription can arise in many ways [35].

Causes of medication errors include [36] over-load of work on health professionals, lack of expertise and training. Poor communication among professionals, lack of appropriate technologies such as computer aided diagnosis and prescription, and poor labeling. Formulation of the medication, illegibility of prescriber's handwriting and typographical errors, lack of systematic handing over procedures, and Lack of involvement of patients or their relatives in the care process is a contributor factor. Victimization of health care workers leading to non-reporting of identified errors [35, 34].

2.6 Impact of medication errors

Few studies provide the empirical evidence for the adverse effect of inappropriate medication use on health outcomes [37]. A substantial body of evidence from international literature points to the risks posed by medication errors and the resulting preventable adverse drug effects. In the USA, medication errors are estimated to harm at least 1.5 million patients per year, with about 400 000 preventable adverse events. In Australian hospitals, about 1% of all patients suffer an adverse event because of a medication error. In the UK, of 1000 consecutive claims reported to the Medical Protection Society from 1 July 1996, 193 were associated with prescribing and medications. About 1.5 million Prescriptions are written every day in general practice in the UK and 0.5 million in hospitals. In the period up to June 2008, >800 000 incidents were reported in England of these, about 71 000 were

related to medications [38]. Most studies of medication errors and ADEs are limited to adult patients and less is known about the epidemiology of medication errors and associated injury in pediatric patients [39].

2.7 Preventability of medication errors in Children

Medication errors are also costly to healthcare systems, to patients and their families, and to clinicians. Prevention of medication errors has therefore become a high priority worldwide [40].

Patient Safety can be framed within the public health model of prevention with medication errors being the disease being prevented. The primary goal of public health is the reduction of incidences or risk of diseases, for medication errors this would focus on the strategies that can be employed to prevent or minimize the errors.The Institute of Medicine recommends four strategic areas to improve patient safety: leadership and knowledge, identifying and learning from errors, setting performance standards and expectations for safety, and implementing safety systems in health-care organizations [19].

Institution based strategies play a major role in the prevention of the occurrence of medication errors. These strategies include Computerized Provider Order Entries (CPOE), clinical pharmacist's participation in ward rounds, improved provider communication, emergency dosage calculation tools, and training of all healthcare providers in appropriate medication prescribing, labeling, dispensing, monitoring, and administration. Other strategies include;, special procedures and written protocols for high alert drugs. Encouraging team environment for review of orders among nurses, pharmacists, prescribers and use of bar coding for medication administration among others can significantly reduce medication errors[68].

Computerized physician (or provider) order entry (CPOE**)** refers to a broad spectrum of electronic prescribing systems that have been shown to decrease medication errors and ADEs. CPOE can ascertain that required information is included in an order or prescription

using forced format screens and essentially can eliminate the issue of illegibility [8,19]). CPOE can be basic or in cooperated with Clinical Decision Support Systems (CDSSs), including checks of drug ordering with regard to drug factors such as dose, route, and frequency, and patient factors, including weight, allergies, renal function, age, and pregnancy status.

A prospective cohort study conducted by Fortescue et al [8] to classify the major types of medication errors in pediatric inpatients and to determine which strategies are most effective in preventing them showed that basic CPOE, which ensures legibility and completeness of orders but would not include decision support. It further has the potential to prevent 65.9% of all errors, whereas CPOE with decision support can prevent an additional 6.8% of all errors for a total error rate reduction from CPOE of 72.7%. Less than 10% of hospitals in the USA have CPOE systems available. CPOE systems are expensive, and successful implementation requires changes in the culture and processes of a hospital, a task requiring enormous investments in time, labor, and resources. For many Kenyan institutions, these factors are prohibitive for adopting such systems in the near future. Alternative methodologies to promote safe prescribing practices must, therefore, be sought and investigated [41].

Clinical pharmacist participation in inpatient rounds is shown as an effective means of primary prevention in various settings. The pharmacist plays a pivotal role in preventing medication misuse. The value of pharmacists' interventions to prevent medication errors that would have resulted from inappropriate prescribing has been documented [42]. Ideally, the pharmacist should collaborate with the prescriber in developing, implementing, and monitoring a therapeutic plan to produce defined therapeutic outcomes for the patient. It is important for the pharmacist to devote careful attention to dispensing processes to ensure that errors are not introduced at that point in the medication process.

In many pediatric hospitals, clinical pharmacists with specialized training in pediatrics intercept errors that occur during the medication use process, especially potentially harmful paediatric prescribing errors [39].

In assessing the rates of medication errors ,ADEs and Potential ADEs by comparison of reported adult rates, Kaushal et al [20] analyzed the major types of errors and evaluated the impact of prevention strategies. The prospective cohort study shows that ward based clinical pharmacists can potentially reduce the potential adverse drug event by 94%.The CPOE had the potential to reduce the errors by 93%. This study showed that to reduce the rate of potentially preventable ADEs in paediatrics; the most effect intervention can be the Computer Provider Order Entry with CDSSs and full–time ward-based clinical pharmacist.

A review of literature indicates that ineffective communication among health care professionals is one of the leading causes of medical errors of which medication errors are most common. Fortescue et al [7] have demonstrated that Improved Provider Communication is an effective prevention strategy in medication errors. In their study, improved communication between physicians and nurses prevented 17.4% of all errors and 29.2% of potentially harmful errors. Given the current structure of most inpatient pediatric medical settings, such interventions such can be relatively cost-effective and easy to implement.

2.8 Root Cause Analysis of Medication errors

Root cause analysis (RCA) is an analysis framework used in health care to determine the systemic causes and prevent recurrences of adverse events [43]. The RCA process is designed to answer three basic questions; *What happened? Why did it happen? What can be done to prevent it from happening again?*

It can also seek to explore if the risk of recurrence has actually been reduced [44]. In the area of medication errors, RCA can not only analyze the factors causing clinical errors but also facilitate development of policies on medication errors. Example of this is an online error-reporting system to enhance the efficiency of reporting medication errors and improve the procedures for medicine usage [45] .

RCA may employ various techniques, such as the Cause Effect (Fishbone /Ishikawa) diagram to identify many possible causes for an effect or problem. The problems are then sort into useful categories It can also employ the use of Pareto charts to demonstrate factors

that are more significant or the Scatter diagrams to help discern a pattern or relationship between two variables [46].

CHAPTER THREE: MATERIALS AND METHODS

The study consisted of two parts. The first part was a purely quantitative aspect that aimed at identifying the incidences, types, and risk factors for medication errors in paediatric children. The second involved structured interview with caregivers, in- depth interview and focused group discussions with health care workers to explore the possible causes of medication errors.

3.1 Determination of incidence, types, and risk factors for medication errors.

3.1.1 Study Site

The study was carried out at Kisii Level 5 Hospital General Paediatric Ward (GPW) and the New Born Unit (NBU). The hospital has a bed capacity of 450 with occupancy ranging from 90% to 150 % with average length of stay at 5 days. The staff establishment is 500 with 13 specialists one of which are a clinical pharmacist, 21 medical officers and interns, 6 pharmacists and pharmaceutical technologists and 245 nurses [47]. Data from the Health Information System (HIS) Department revealed that there is one general paediatric inpatient ward and one newborn unit. The General Ward has a bed capacity of 55 patients with an average 101.3% bed occupancy rate. The average number of admissions in the general wards is 227 patients per month. The New Born Unit has an average 137 admission per month with bed occupancy of 233%.

3.1.2 Study design

This was a descriptive cohort study entailed the prospective review of treatment sheets and files for medication related errors for until discharge or up to a period of one month after admission.

3.1.3 Target Population

The target population for was children aged 0-5 years admitted at the KL5H general paediatric ward (GPW) and newborn unit (NBU) during the period between June and August 2014.

3.1.4 Sampling Procedure

3.1.4.1 Sampling Plan

Samples were taken daily in the afternoon after completion ward rounds. The treatment sheets and patient files were picked from the nursing station and reviewed if they met the inclusion criteria for recruitment. Selection was based on age of the patient and those whose age fell in the 0-5 year category selected

3.1.4.2 Inclusion and Exclusion Criteria

Children aged 0-5years admitted to the KL5H paediatric wards during the study period (June to August 2014) were included in the study. Children who had been in the ward for more than 48hours this was to reduce chances of children who may have experienced errors that were already corrected. Any child treated as an outpatient case was also excluded.

3.1.4.3 Sample size determination and sampling method

Descriptive epidemiologic studies examine differences in disease rates among populations in relation to age, gender, race, and differences in temporal or environmental conditions [48]. This descriptive cohort study set out to determine the incidences of medication errors among children. Literature review of past studies show that the prevalence of medication errors in children is up to three times higher than in adults [19]. In a systematic review of epidemiology and an evaluation of evidence supporting reduction strategy recommendations on medication errors in paediatrics Miller et al [6] show that the overall frequency of errors is 5-27% .

The Cochran formula (48)was applied to determine the sample size as follows

$$n = \frac{Z^2 * p\,(1-p)}{d^2}$$

Where: Z- Level of significance (1.96%)

p- Prevalence of MEs

d- Precision Estimate around MEs (5% or 0.05).

n- Sample size.

Working on the assumption of 27% as the frequency of medication related problems among these patients; the sample size (n) was;

$$n = \frac{1.96^2 * 0.27 * (1-0.27)}{0.05^2} = 302.9$$

A total of 405 treatment sheets and files were sampled at the end of the study .Consecutive sampling was employed and every patient meeting the inclusion criteria included until the study period was over..

Pre testing of data collection form

The data collection tools were piloted by randomly selecting 10 prescriptions of patients admitted in the Paediatric general wards at Kenyatta National Hospital and also at the Kisii Level 5 Hospital. The data was the entered into the form to test its suitability in data collection. Revisions and adjustments were made as appropriate

3.1.4.3 Sampling of the Treatment sheets and files

Sampling was done on the day of admission or within 48 hours of admission. To avoid interrupting the normal activities of the wards, the treatment sheets were abstracted in the afternoons when the ward rounds were complete.

3.1.5 Data Collection and Materials

Pre-designed data collection tools with adaptations from the Institute for Safe Medication Practices (ISMP) [49] , by Avery et al [43] and Kwame [36] were used for to collect data on patient demographics , diagnosis and medication prescribed (Appendices C&D). For each medication, prescribed information on formulation, dosage, frequency, and duration of use was reviewed. Adequacy of the prescribed dosage, potential drug interactions, and adverse drug events were documented. The type of prescribing whether by generic or brand name or use of acronyms and abbreviation noted. Monitoring of high-risk medication reviewed and the cadre of the prescribers was noted. Review of drug for contraindications in the population or disease was done and errors noted were categorized according to National

Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors (Appendix H). Follow up was done by treatments sheet review on every two days from admission to discharge or for up to four weeks after admission by the trained research assistants..

3.1.6 Case Definitions

Medication errors are defined as any preventable event that may lead to inappropriate medication use or patient harm while in control of a health care provider, caregiver, or patient. They may be related to professional practice, medication, procedures of medication use or failure in systems [13]. The errors will be classified as selection, dosage, timing, documentation errors, omission or monitoring errors

Selection errors are defined as selecting the wrong drug for correct diagnosis, prescribing drugs that are contraindicated in a patient, drug duplications.

Dosage errors were errors occurring due to over dosage, under dosage, undecided dosages, wrong strength, and wrong dosage form or dose omission.

Frequency and duration errors entailed errors arising due to the medicines being given at the wrong time and intervals.

Documentation errors are defined as errors occurring due to; transcribing errors, use of brand names, illegibility, dangerous abbreviations, preceding zeroes, trailing zeroes and missing contact information of the prescribers.

Monitoring errors included errors due to lack of ordering monitoring parameters during use of a drug, or failure to follow up prescribed monitoring.

Omission errors are errors occurring where an action to be done is not performed. This included failure to administer a drug or complete failure to prescribe a drug.

Timing errors involved either use of wrong duration, wrong frequency, missing duration, or frequency.

3.1.7 Variables

The outcome variables were medication errors. The predictor variables included age, sex, and cadre of prescriber, disease condition, level of prescriber, number of medication per prescription, type of medication, route of administration , ward admitted in, average length of stay(ALOS), types and number of diagnosis.

3.2 Determination of Possible Factors Contributing to Medication Errors and Interventions

Structured interviews were carried out among caregivers in the paediatric wards. The objective was to their understanding on the children's medication use and any medication error occurrence. Information that may have been missing on the treatment sheets on possible adverse reactions and use of additional medication rather than the prescribed ones were explored. It further sought to find out if caregivers had been requested to purchase medication and if they actually bought.

In-depth interviews were carried out with Health Care Workers (HCWs). The objective was to identify possible factors that can contribute to occurrence of medication errors and proposed interventions that can mitigate the errors.

Focused Group Discussions involving the Health Care Workers were held in the paediatric ward and newborn unit. The main issues to be explored were awareness of medication errors and their experience with the occurrence of medication errors. Frequency of occurrence of errors, reporting of the errors and willingness to do so was discussed. Systems and interventions to mitigate the occurrence of medication errors we explored extensively

3.2.1 Study Site

The study site was the same as for the descriptive cohort study of the treatment sheets and files.

3.2.3 Study Population

Care givers and Health Care Workers (Medical Officers, Clinical officers, Pharmacists and Nurses) at the PGW and NBU of Kisii Level 5 hospital during the study period.

3.2.4 Sample size determination.

Purposeful sampling techniques were used in the determination of the sample sizes

Criterion sampling was employed in recruiting the caregivers. Caregivers whose children met the inclusion criteria were sampled until the sample size was reached. According to the recommended number for in-depth interviews of 10 -50 [50] a total of 19 HCWs were sampled and the exercise stopped when the point of theme saturation was reached. Homogeneous and snow balling sampling [51,52] was employed to come up with three focused groups representing prescribers, nurses, and pharmacists.

3.2.5 Sampling procedure

3.2.5.1 Sampling plan

Purposeful sampling techniques were employed so that at least each cadre was represented from the clinical setup. The sample included 7 clinical officers,6 nurses, 3 medical officers and 3 pharmacists for the in- depth interviews. Three FGD s were selected consisting of 6 HCWs each.

Interview for Caregivers

The questionnaire designed for the caregivers was based on the indicators for the concept of parents/guardians' participation their children is health care. The research instruments for the caregivers were all closed-ended and much straightforward to be translated to the caregivers for easy understanding. The instrument contained eleven items where patients responded YES and NO (Appendix E). The questionnaire translated by the researcher. The research assistants and the principal investigator conducted the interviews. Each participant was asked if they were willing to be interviewed and reassured that the information was

confidential and the study would in no way interfere with the care being accorded to their children.

Areas not covered or requiring further clarification were followed up later in the cause of the study.

In depth interviews for Health Care Workers

Potential participants for the interviews were contacted in the afternoons after the ward rounds and briefed about the purpose of the study and invited to participate at a mutually convenient time. . Before the interviews commenced, each participant was asked if they were willing to be audio – taped and reassured that any information given would be strictly confidential. The interviews were conducted by the principal investigator who collected data on the potential risk factors and causes of medication errors in their practice. These instruments were composed largely of both closed-ended and open-ended items to solicit the respondents' own ideas and gather more information on the subject. Questions included in the interview guide (Appendix F) were designed to generate information on the prescribers' work experience, workload and general understanding on what medication errors are. It also explored the frequency and types of medication errors that occur in their practice, the different causes attributed to occurrence of medication errors and how they handle errors. It further explored the interventions felt to be important in the mitigation of medication errors.

Focus Group Discussion

Three focus groups were arranged with the help of the pharmacist in charge. The interview guide for focus group discussion (Appendix G) explored the frequency of errors, the possible causes of medication errors and what safeguards could be put in place. The principal investigator having used training material from the National Patient Safety Agency (NPSA) website [53] a led the discussions while a research assistant kept note of inputs from the participants and conducted a Root Cause Analysis (RCA) of the occurrence of errors from the provided case studies . The discussions were audio –taped and later transcribed. The participants were encouraged to discuss freely and debated on raised issues. The following approach was employed:

Identification of the problem,: The researchers selected five treatment sheets that contained different types of medication errors .

Gathering information: A detailed review of the treatment sheets, interview with the health care workers in the focus group. This was followed by creating chronological narratives of the events that might have led to the errors.

Analysis of the information; The focus group discussion carried out a comprehensive review of the events leading to occurrence of the errors in order to identify the factors and root causes.

Proposal of interventions: The Focus Groups (FGs) were asked to propose ways in which similar errors can be prevented from occurring in the future and systems that can be put in place to mitigate the errors.

These were then documented and summarized into themes in line with the Root Cause Analysis framework .

3.2.5.2 Selection Criteria

Caregivers and health care workers at either the GPW OR NBU who consented were included. HCWs and caregivers who did not give consent or who were not directly involved in offering services during the study period were excluded.

3.2.6 Data collection and Material

Informed consent was obtained before the start of each interview. Care givers were approached at the end of ward rounds and interviews guided by the guide (Appendix) recorded manually. The Health Care Provider were allowed to select an interview date, time and venue that are convenient for them.. The interview s were recorded using a digital voice recorder and manually by pen and paper. The digital recording was then transcribed on to a Microsoft Access 2010 .Electronic data codebook was used to convert data codes for analysis All of the FGDs were audio-recorded and transcribed. The FGDs employed the Fish bone diagram technique and brainstorming approach to identify and explore all the possible causes of the problem. The brainstorming activity was based on four treatment

sheets with multiple errors picked from the general wards for this purpose. A question guide and fishbone diagram template aided this. The FGDs used the RCAs that focused on the conceptual framework illustrated in Figure 3.1

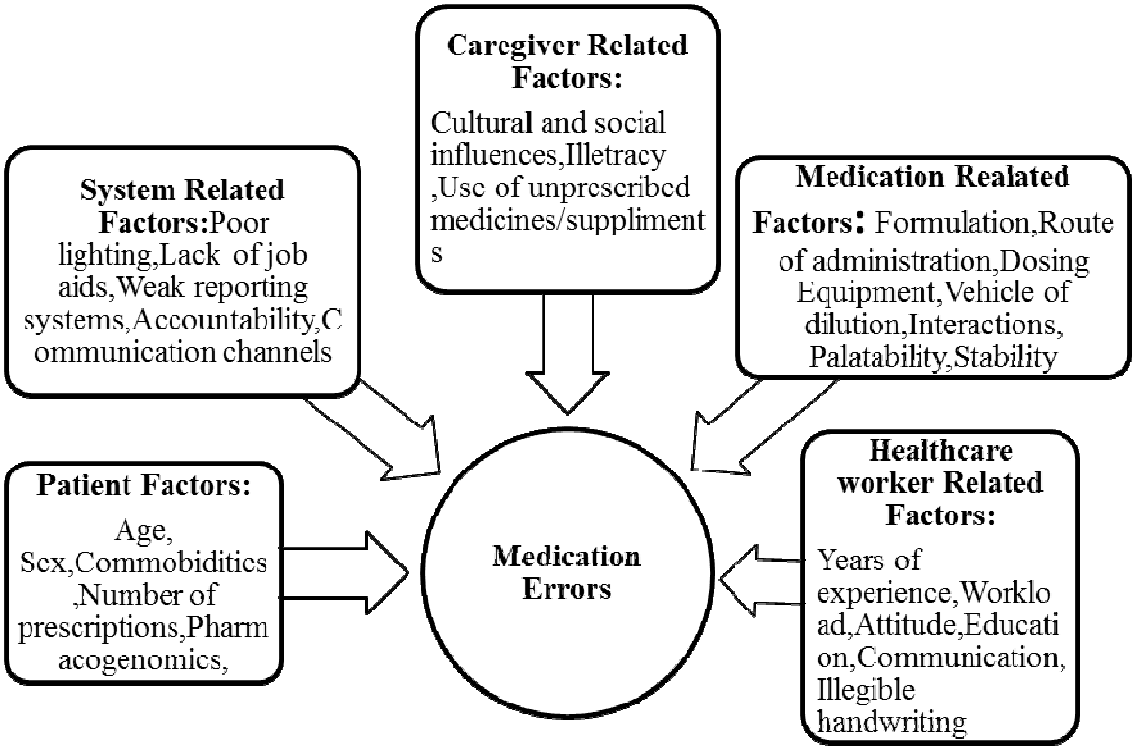


Figure 3.1: Conceptual Frame Work for Root Cause Analysis of Medication Errors

3.4 Quality Assurance and Data Management

Quality Assurance

The data collection forms and the interview guide were evaluated using a pilot study. The findings were used to modify the data collection instruments where needed. The research assistants were trained on how to collect data using an SOP. The training was considered sufficient if the inter data collection was agreeable. Four clinical officer interns were trained as research assistants and each reviewed the treatment sheets and patient files every two days. One research assistant and the principal investigator were in depth interviews and FGDs. One of the research assistants carried out the recording the proceedings of the interview, while the other conducted the interview. The hand written notes were compared to the transcribed version to check for any inconsistencies and find an agreeable end. Interviews were transcribed on the same day of the interview to capture all non-verbal and verbal interactions during the interview and to avoid loss of information. With the level of agreement between the two transcribers, the 2 transcribed copies were compared and any major inconsistencies were noted. A codebook was used to guide coding and identification of themes. The research progress was monitored every fortnight by the principal investigator.

Data Management

All data from the prescription abstraction and the in depth interviews were entered into a Microsoft Office-Access database 2010 and a Microsoft Office excel 2010 document respectively. Data cleaning and validation was performed and data exported into STATA version 12.0. Backing up of files to compact discs and flash sticks was done regularly to avoid loss. Confidentiality of the data was ensured by storing all data in password controlled files and directories, which were only accessible to the principal investigator.

3 6 Data Analysis

Descriptive data analysis of characteristics of children was done. All continuous variables were expressed as either the mean and range or median and inter-quartile range. Categorical variables were later presented as proportions using percentages with 95% confidence

intervals. The main outcome calculated was incidence of various types of medication errors as a percentage.

The risk factors for dosing errors were determined using logistic regression. Step-wise model building was performed to identify the most important risk factors for incorrect dosing. Medication error was modeled as the outcome and patient exposure as the covariate. Since a single child have several medication errors, hierarchical logistic regression models was run , with prescription episodes forming the level 1 observation and child variable forming the level 2 observation. Data was analyzed using STATA version 12.0 software. P-values of less than 0.05 were considered statistically significant. Qualitative data was analyzed using the Ground Theory approach. Key themes were identified and explored in depth. The root cause analysis was performed using the five selected treatment sheets and various RCAs and factors documented.

3.10 Ethical Considerations

Approval to carry out the study was sought and granted by the Kenyatta National Hospital/University of Nairobi Ethic Review Committee Ref: KNH-ERC/A/159 (Appendix A). The approval to collect data were also granted by Kisii Teaching and Referral Hospital Department of Research. Ref: KL5/DRE/14/23/Vol.1 (Appendix B).

Informed consent was obtained from the caregivers before being interviewed on the indicators for the concept of caregiver's participation on his/her child's care. Informed consent was also obtained from health care workers before they participated in the Focused group discussions and interviews. Care was undertaken to ensure maximum privacy and confidentiality of the information obtained from the study participants. The filled questionnaires and recorded information were stored in password-protected spreadsheets and under lock and key.

CHAPTER FOUR: RESULTS

Part One: Incidence and Risk Factors for Medication errors

4.1: Baseline Characteristics of paediatric study population

Between June and August 2014, 1613 paediatric children were admitted at Kisii Level 5 Hospital. Four hundred and five (405) treatment sheets and files from both General Paediatric Ward (GPW) and New Born Unit (NBU) at Kisii level 5 Hospital (KL5H) met the inclusion criteria and were evaluated for medication errors. The selection procedure is shown in Figure 4 below

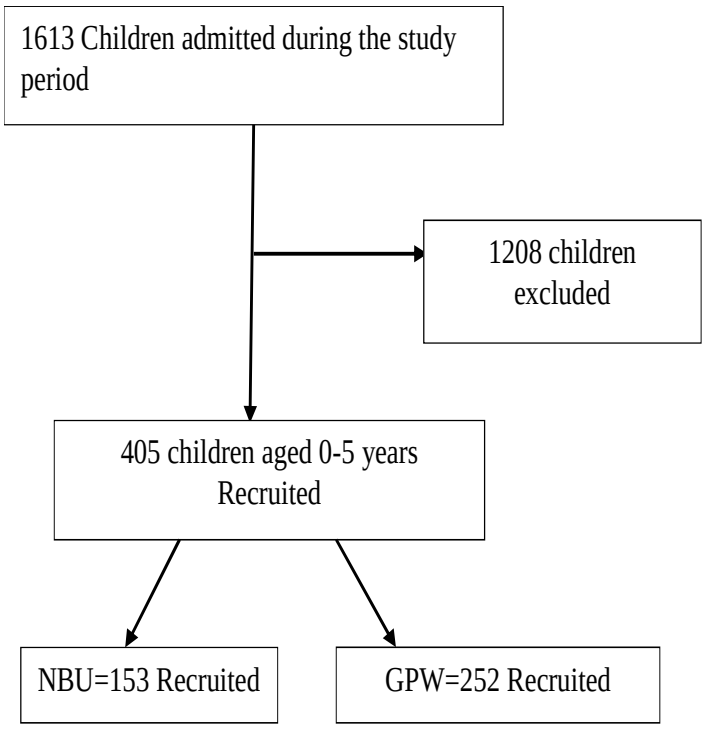


Figure 4.0:1: Consort diagram for recruitment of children

Among these, 252 were from the GPW and 153 from the NBU. Slightly more than half (164, 53.4%) admitted at the time of the study were male, with 123(60.9%) being admitted

at the GPW. The median age at admission was 16.8 months and ranged from 1 day to 60 months; 168(41.2%) were aged less than one month. Most of the children (192, 47.4%) presented with fever as the major complaint, followed with vomiting (82, 20.3%). The other common complaints included cough (68, 16.8%), convulsions (61, 15.1%), difficulty in breathing (50,12.4%) and diarrhoea (45, 11.1%). Most children presented with more than one complaint.

The most common diagnosis was malaria (183, 45.2 %) of which 179 (97.8 %) were in the GPW followed by asphyxias/respiratory distress (71, 17.5%), pneumonia (54, 13.3%), anaemia (50, 12.4%), and meningitis (39, 9. 6%). The leading reason for NBU admission was birth asphyxia, followed by prematurity 26 (6.4%) and neonatal sepsis 19(4.7%).
Most of the paediatric in-patients only had one diagnosis (62.0%) while 27.2% accounted for children with two diagnoses. Only a small fraction 1.5% had3 or more diagnoses. 9.4% of the total population sampled had no diagnosis documented. These statistics are presented in Table 4.1

Table 4.1: Baseline Characteristics of the Paediatric Patients

	Ward		
	GPW	**NBU**	**Total**
	n (%)	**n (%)**	**n (%)**
Sex			
Female	124(66.7)	62(33.3)	186(100)
Male	123(60.9)	79(39.1)	202(100)
Missing	5 (29.4)	12(70.6)	17 (100)
Age			
<1 month	15(8.9)	153(91.1)	168(100)
1-12 months	69(100)	0(0)	69(100)
13-35 months	76(100)	0(0)	76(100)
36-59 months	92(100)	0(0)	92(100)
Presenting complaints			
Fever	182(94.8)	10(5.2)	192(47.4)
Vomiting	79(96.3)	3(3.7)	82(20.3)
Cough	68(100)	(0)	68(16.8)
Convulsion	57(93.4)	4(6.6)	61(15.1)
Difficulty in breathing	34(68)	16(32)	50(12.4)
Diarrhoea/ dehydration	43(95.6)	2(4.4)	45(11.1)
Diagnosis			
Malaria	179(97.8)	4(2.2)	183(45.2)
Pneumonia	54(100)	(0)	54(13.3)
Asphyxia	(0)	71(100)	71(17.5)
Anaemia	49(98)	1(2)	50(12.3)
Meningitis	37(94.9)	2(5.1)	39(9.6)
Prematurity	(0)	26(100)	26(6.4)
Sepsis	1(5.3)	18(94.7)	19(4.7)
Others	33(46.5)	38(53.5)	71(17.5)
Number of diagnosis per child			
None	3(7.9)	35(92.1)	38(9.4)
1	148(59)	103(41)	251(62)
2	96(87.3)	14(12.7)	110(27.2)
3 or more	5(83.3)	1(16.7)	6(1.5)

4.2 Prescriber Characteristics and Prescribing Patterns

The characteristics of prescribers responsible for medicine prescriptions for the paediatric patients is shown in Table 4.2

Table 4.2: Prescriber Characteristics and Prescribing patterns

	WARD				
	GPW n(%)		**NBUn(%)**		**Total**
Prescriber					
Medical Officer	74	(80.4)	18	(19.6)	92(22.7)
Clinical Officer	167	(57)	126	(43)	293(72.3)
Medicines prescribed					
Antimicrobials	296	(51.4)	280	(48.6)	576
Antipyretics	189	(92.6)	15	(7.4)	204
Antimalarials	189	(97.4)	5	(2.6)	194
Bronchodilators	2	(4.9)	39	(95.1)	41
Anticonvulsants	16	(64)	9	(36)	25
Antidiarrhoerals	55	(100)	0	0	55
Supplements	13	(12)	95	(88)	108
Other drugs	29	(80.6)	7	(19.4)	36
Number of medicines prescribed per child					
None	7	(50)	7	(50)	14 (3.5)
1 to 2	83	(73.5)	30	(26.5)	113(27.9)
3 to 5	128	(59.3)	88	(40.7)	216(53.3)
5 and above	34	(54.8)	28	(45.2)	62 (15.3)

Clinical officers interns generated most of the prescriptions both in the GPW and NBU accounting for 293(72.3%) of the total prescriptions. This could be attributed to the fact that majority of the prescribers are the clinical officers and clinical officer interns.

The commonly prescribed class of medicines was antimicrobials with 576 instances of antimicrobial prescribing among the study cohort. In many cases, patients would be prescribed more than one antimicrobial. The commonly prescribed antimicrobials were benzyl penicillin and gentamicin. The second and third most commonly prescribed drugs were antipyretics at 204 and antimalarials at 194 prescribing instances. The commonly prescribed anti-malarials and antipyretics were artesunate and paracetamol, respectively. Most of the children (216, 53.3%) had between three and five medicines prescribed to them; 128 (59.3%) of these children were from the GPW.

4.3 Incidence and Distribution of Medication Errors

A high proportion of the children experienced errors in their prescriptions. Medication errors were observed in 307 out of the 405 Paediatric admissions yielding a prevalence of 75.8%. The occurrence of medication errors was significantly lower among female patients (133, 71.5%) than among male patients (164, 81.2%), yielding a prevalence ratio of 0.9 (95% CI; 0.8-0.99 p= 0.03)

Children aged 1 -12 months were 1.2 times likely to have experienced medication errors compared to those less than one month old (95% CI 1.1-1.4) p= 0.001. There did not appear to be a significant difference between the proportions of medication errors observed among the other age groups.

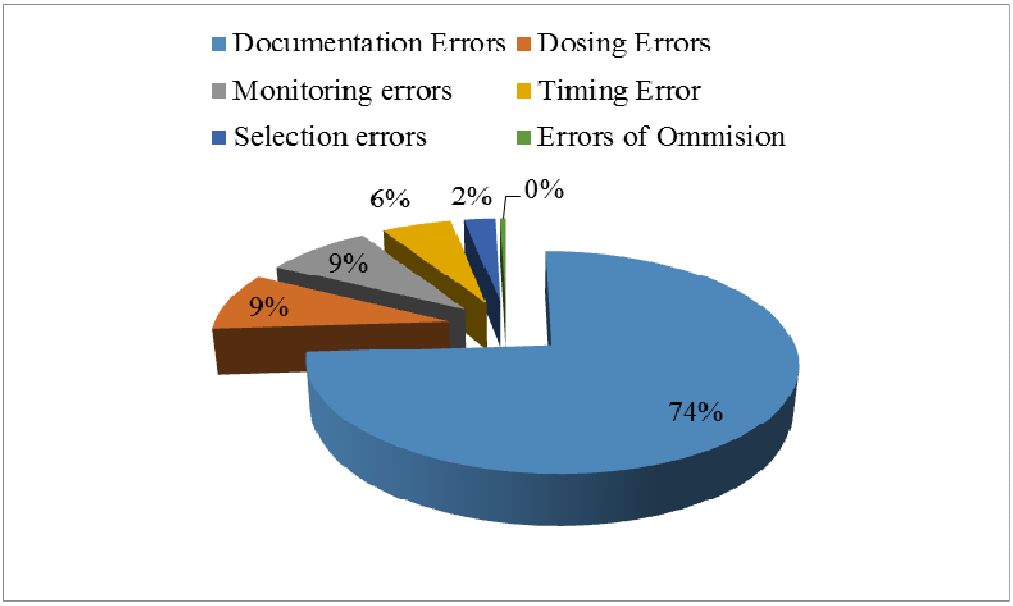
Though paediatric patients at NBU appeared to be less likely to experience medication errors compared to those in GPW, there was no evidence that this reduction in occurrence of medication errors was significant (prevalence ratio 0.9 (95% CI; 0.9-1.0) p=0.25. The prevalence of medication errors is shown in Table 4.3

Table 43: Incidence of Medication Errors in Paediatric Admissions

	Medication error				
	Yes n (%)	**No n (%)**	**Total n (%)**	**PR(95% CI)**	**P value**
Sex					
Male	164(81.2)	38(18.8)	202(100)	1.0	
Female	133(71.5)	53(28.5)	186(100)	0.9(0.8-0.99)	**0.03**
Missing	10(58.8)	7(41.2)	17(100)	-	-
Age months)					
<1 month	124(73.8)	44(26.2)	168(100)	1.0	
1-12 months	62(89.8)	7(10.1)	69(100)	1.2(1.1-1.4)	**0.001**
13-35 months	60(79)	16(21)	76(100)	1.1(0.9-1.2)	0.37
36-59 months	61(66.3)	31(33.7)	92(100)	0.9(0.8-1.1)	0.22
Admission ward					
Paediatric ward	196(77.8)	56(22.2)	252(100)	1.0	
NBU	111(72.6)	42(27.4)	153(100)	0.9(0.8-1.0)	0.25

4.4 Types of Medication Errors Reported

Various types of medication errors were identified. Of the 405 treatment sheets and files reviewed, 1023 medication errors were observed on 307 treatment sheets. These errors were classified into various categories as documentation, dosage, frequency and duration, monitoring and selection errors as shown in Figure 4.2



.Figure 4.2: Type of medication errors

Documentation errors were the leading type of medication error accounting for 756 (73.9%). Regarding this type of errors, the incidence of use of abbreviations was the highest (408, 39.88%), followed by missing information (234, 22.87%), and use of brand name (114, 11.14%). The incidences of abbreviations included xpen instead of benzyl penicillin, CAF instead of chloramphenicol, Genta instead of gentamycin and RL instead of ringers lactate among others. Brand name use included Gacet for paracetamol suppositories, Septrin for cotrimoxazole and Rocephine for ceftriaxone.

Dosing errors were the second leading type of error at 90 (8.8%) with no dosage indicated as main type of dosing error 38 (3.71%), followed by wrong strength 18 (1.71%), overdosing

16 (1.56%), under dosing 4 (0.39%), wrong dosage form 10 (0.98%) and dose omission 4 (0.39%).

Monitoring errors were classified as either monitoring not requested, or requested but not done. Examples where monitoring was to be done but not requested was on drugs like gentamicin, atropine, and anti convulsants. Incidences of monitoring requested but not done was noted for atropine and aminophylline which occurred at a rate of 88 (8.6%) of the total number of errors that were observed.

Timing errors occurred at a rate of 5.67% of all errors. These included incidences of frequency not indicated (40, 3.91%) missing durations (13, 1.27%), wrong frequency of administration (5, 0.49%) and wrong duration of administration (4, 0.39%). Incidences of wrong frequency of administration occurred in folic acid indicated as three times instead of once daily. A case of wrong duration of administration occurred in artemether injection where the medicine was administered for seven days instead of three days as indicated by prescriber. These categories and types of errors are presented in the Table4.4.

Table 4.4: Types of Medication Errors Observed at the Paediatric Wards

Type of Error	Number of errors(n)	Percentage (%)
Documentation		
Use of brand name	114	11.14
Abbreviations	408	39.88
Missing information/ Transcribing errors	234	22.87
	756	**73.9**
Dosage errors		
No dosage indicated	38	3.71
Wrong strength	18	1.76
Overdose	16	1.56
Under dose	4	0.39
Wrong dosage form	10	0.98
Dose omission	4	0.39
	90	**8.80**
Monitoring Errors		
Not requested	3	0.29
Requested not done	85	8.31
	88	**8.60**
Timing Errors		
Wrong frequency	5	0.49
Wrong duration of administration	4	0.39
Frequency not indicated	36	3.52
Duration not indicated	13	1.27
	58	**5.67**
Selection		
Unnecessary drug	7	0.68
Contraindicated drugs	3	0.29
Drug duplication errors	1	0.1
Formulation errors	15	1.47
	26	**2.54**
Omission errors		
Failure to prescribe Medication	2	0.2
Failure to administer Medication	3	0.29
	5	**0.49**
Total	**1023**	**100%**

Selection errors were 26 (2.54%) of the total prescription of errors with incidences of formulation errors being highest at 15 (1.47%). Other selection errors included, unnecessary drug 7(0.68%) a case where a child was prescribed antibiotics yet the diagnosis was malaria. Contraindication occurred at 3 (0.29%) and constituted cases where a child was prescribed for medicines that they had previously developed an allergic reaction. Drug duplication error occurred when a child got paracetamol suppositories at the same time ibuprofen prescribed

Omission errors were the least category of medication errors and constituted 5 (0.49%) of the total errors. They included failure to prescribe medication 2(0.2%) where a child with diarrhoea had no zinc sulphate prescribed and failure to administer medication 3(0.49%) a case involving lack of administration of an intravenous antimalarial for four days because there was no line.

Number of medication errors per Paediatric admission

The number of medication errors per Paediatric admission ranged from zero to more than seven errors. About 75% of the treatment sheets and files had at least one error. Children with only one error were 93(23%), while 44(10.9%) of children experienced seven or more medication errors. In general 1023 errors were observed among the 405 children with GPW contributing a more than half the errors 670(65.49%). This is shown in Figure 4.3.

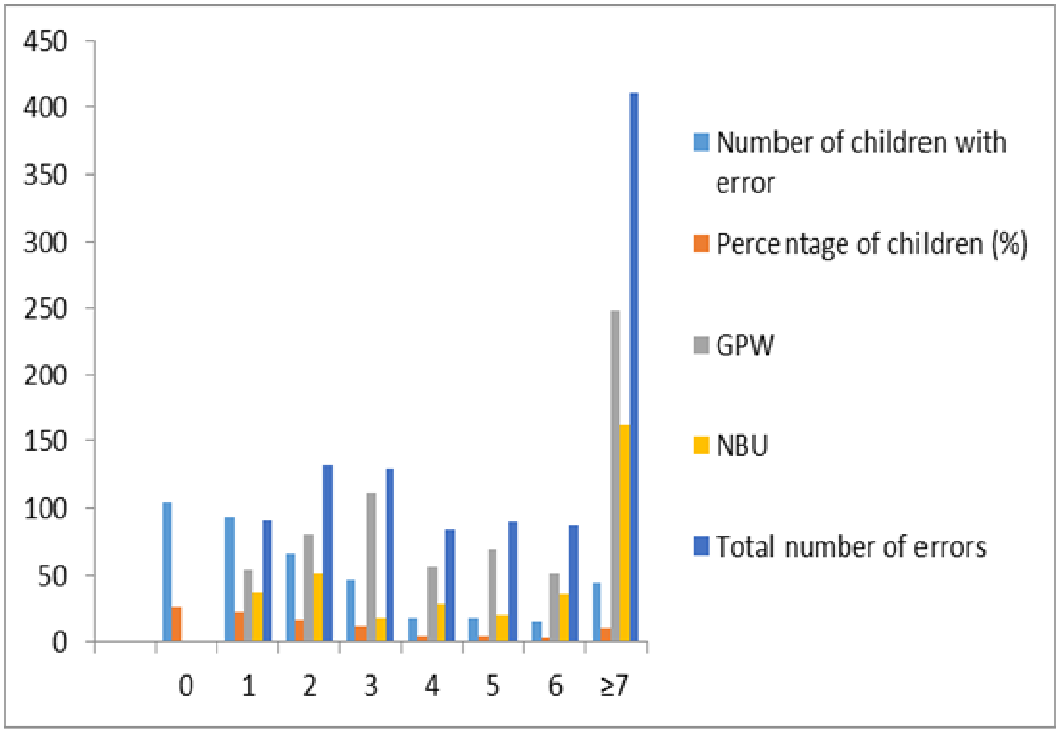


Figure 4.3: Number of medication errors per admission

Distribution of medication errors between drug classes

Antimicrobials contributed to the highest observed number of medication errors accounting for 40.2% of the total observed errors. This class further contributed to majority of errors in the monitoring category 78.41%, use of abbreviation 60.29%, error of omission drug leading to a drug not being administered 100%, contraindication 66.7% and unnecessary drug 71.43%.

Analgesics/Antipyretics were the second most commonly class with medication errors 18.7%. They accounted for 39.47% of the brand name errors, 27.78% dosing errors, 22.41% timing errors, 20.59% abbreviation, and 6.67 formulation. Bronchodilators contributed to the least number of medication errors 2.9%. This class contributed 5.6% of monitoring errors, 4.7% missing information, 1.72%timing errors and 1.11% dosing errors. As shown in Figure 4.4

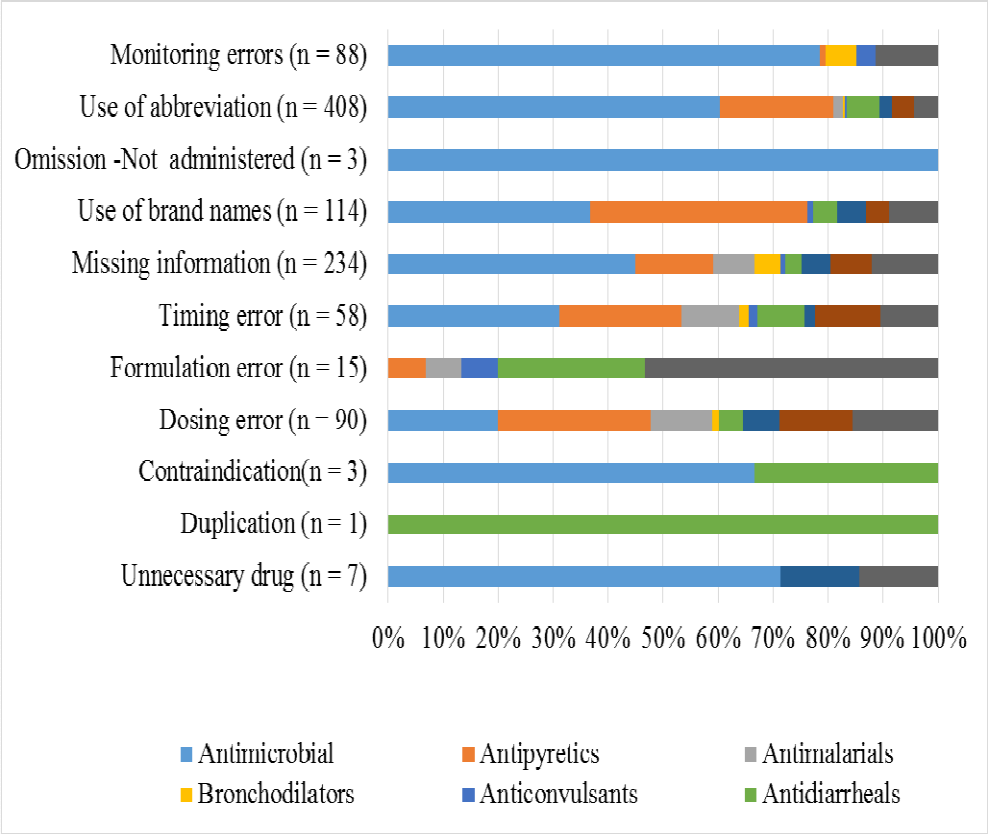


Figure 4.4: Distribution of medication errors across drug categories

Distribution of medication errors by diagnosis

Malaria was the leading diagnosis 183(45.2%) for admission with GPW having the highest number during the study period. It contributed to 48.28% of timing errors, 48.28% formulation error, 44.74% use of brand name, 34.8% abbreviation error, 33.61% missing information, 33.33% contraindication, 32.3% dosing and 10.23% monitoring errors. This is shown in Figure 4.5

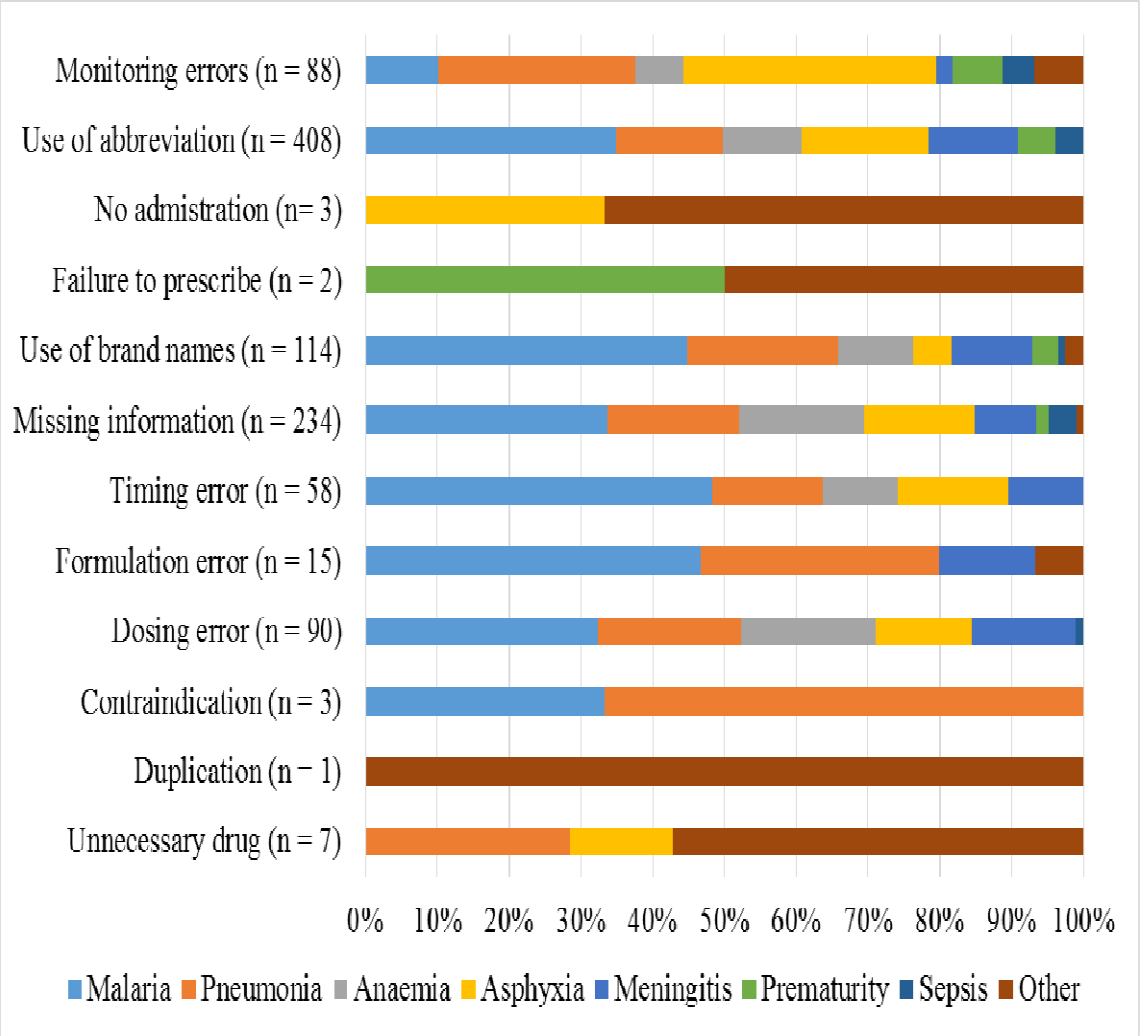


Figure 4.0:5: Distribution of Medication errors across diagnosis

Asphyxia was the leading diagnosis in the NBU and fourth among all recorded diagnosis 50(12.3%). This diagnosis had 35.23% of monitoring errors, 33.3% of errors of omission,17.65% use of abbreviations,15.52% timing,15.38% missing information,14.29% unnecessary drug,13.3%dosing errors and 5.26% use of brand names.

4.5 Risk Factors for Dosing Errors

A review of literature reveals that dosing errors are the most common type of medication errors [25,23,10]. When dosing errors occur children are likely to get harm due to their less developed organ systems. Bivariate analysis was undertaken to identify the risk factors associated with dosing errors in this particular study.

The baseline characteristics of patients with or without dosing errors were compared and summarized in Table 4.5

On comparison of the distribution of variables across those who experienced dosing errors and those who did not, there was a statistically significant difference for the number of drugs, diagnosis, and route of administration. There were no statistical significant association between sex, age, ward, prescriber, number of diagnosis, average length of stay and drug categories with dosing errors.

Table 4.5: Characteristics for patients with or without dosing errors

Predictor Variable	No dosing error	Dosing error	P value
Sex			
Missing	13(76.5)	4(23.5)	0.145
F	165(88.7)	21(11.3)	
M	167(82.7)	35(17.3)	
Age			
<1 month	148(88.1)	20(11.9)	0.394
1-12 months	57(82.6)	12(17.4)	
13-35 months	61(80.3)	15(19.7)	
36-59 months	79(85.9)	13(14.1)	
Ward			
GPW	209(82.9)	43(17.1)	0.102
NBU	136(88.9)	17(11.1)	
Number of drugs			
1	103(91.2)	10(8.8)	**<0.001**
3	186(86.1)	30(13.9)	
5	42(67.7)	20(32.3)	
0	14(100)	0(0)	
Prescriber			
MO	76(82.6)	16(17.4)	0.137
CO	249(85)	44(15)	
0	20(100)	0(0)	
Number of diagnosis			
0	35(92.1)	3(7.9)	0.056
1	217(86.5)	34(13.5)	
2	89(80.9)	21(19.1)	
3	4(80)	1(20)	
4	0(0)	1(100)	
Malaria	152(83.1)	31(16.9)	0.274
Pneumonia	41(75.9)	13(24.1)	**0.04**
Asphyxia	60(84.5)	11(15.5)	0.859
Prematurity	26(100)	0(0)	**0.028**
Sepsis	18(94.7)	1(5.3)	0.23
Anemia	42(84)	8(16)	0.8
Meningitis	31(79.5)	8(20.5)	0.292
Route			
Intravenous	242(69.9)	16(26.7)	**<0.001**
Intramuscular	52(15)	11(18.3)	
Topical	35(10.1)	10(16.7)	
Oral	17(4.9)	23(38.3)	
Average LOS	5.0(SD 4.6)	5.2 (SD 5.1)	0.8
Drugs categories			
Antimicrobial	215(93.1)	16(6.9)	0.64
Antimalarial	17(63)	10(37)	0.21
Antipyretic	102(81.6)	23(18.4)	0.38
Bronchodilator	11(91.7)	1(8.3)	0.93
Anticonvulsant	6(100)	0(0)	NA
Antidiarrheal	25(86.2)	4(13.8)	0.09
Supplements	22(78.6)	6(21.4)	0.91
Topical	18(62.1)	11(37.9)	0.48

**Chi square measure of association was employed to assess whether there was significant association between the various predictor variables and occurrence of dosing errors.*

More males experienced dosing errors as compared to female, though this difference was not statistically significant (p = 0.145). The age of the children did not have any significant influence on occurrence of dosing errors (p=0.394). The ward setting also did not have any significant effect on dosing errors.

Children receiving one drug were less likely to experience a dosing error (10, 8.8%) as compared to those with three drugs (30, 13.9%) and five drugs (20, 32.3%). This shows that number of drugs prescribed was a significant predictor (p=<0.001) of the occurrence of dosing errors.

Clinical officers were more likely to generate dosing errors (44, 15%) as compared to medical officers (16, 17.4%); however, this difference was not statistically significant (p=0.137). As much as children were likely to develop dosing errors with increase in the number of diagnosis it was not a statistically significant factor (p=0.06). Being diagnosed with pneumonia (13, 24.1%) was likely to lead to dosing errors (p=0.04), while there was a significantly reduced chance of developing dosing errors when diagnosed with prematurity (p=0.03) as compared to others.

Dosing errors were more likely to occur with intravenous (16, 26.7%) and oral (23, 38.3%) routes as compared to intramuscular and topical routes. Route of administration was a statistically significant predictor (p=<0.001) of the occurrence of dosing errors. Average length of stay (ALOS) showed no statistically significant effect on the occurrence of dosing errors. There was no statistical significance linking categories of drugs to dosing errors.

Multivariable analysis- Risk Factors for dosing errors

Logistic regression was done to identify the independent variables predictive of dosing errors. All variables with a p-value of ≤ 0.20 at bivariate analysis were included in multiple analysis models. The statistical analysis is as presented on table 4.6

Table 4.5: Risk factors for dosing errors

	Crude OR (95% CI)	**P value**	**Adjusted OR (95% CI)**	**P value**
Sex				
Female	1.0 Ref		-	
Male	0.6(0.3-1.1)	0.09	-	
Age in months				
<1 month	1.0 Ref			
1-12 months	1.6(0.7-3.4)	0.26	-	
13-35 months	1.8(0.9-3.8)	0.11	-	
36-59 months	1.2(0.6-2.6)	0.61	-	
Ward				
NBU	0.6(0.3-1.1)	0.1	-	
Number of drugs				
1	1.0 Ref		1.0 Ref	
3	1.7(0.8-3.5)	0.19	1.7(0.8-3.7)	0.15
5	4.9(2.1-11.4)	<0.001	6.4(2.7-15.1)	**<0.001**
Prescriber				
MO	1.0 Ref			
CO	0.8(0.4-1.6)	0.58	-	
Number of diagnosis				
0				
1	1.8(0.5-6.3)	0.34	-	
2	2.8(0.8-9.8)	0.12	-	
3	2.9(0.2-35)	0.4	-	
4	NA	NA		
Diagnosis				
Malaria	1.4(0.8-2.4)	0.274	-	
Pneumonia	2.1(1.02-4.1)	0.04	1.8(0.9-3.8)	0.12
Asphyxia	1.1(0.5-2.2)	0.859	-	
Prematurity	NA	0.028	-	
Sepsis	0.3(0.04-2.4)	0.23	-	
Anemia	1.1(0.5-2.5)	0.8	-	
Meningitis	1.6(0.7-3.6)	0.292	-	
Route				
Intravenous	1.0(Ref)		1.0(Ref)	
Intramuscular	0.3(0.1-0.8)	0.004	0.4(0.2-0.7)	**<0.001**
Topical	0.2(0.1-0.6)	<0.001	0.2(0.1-0.5)	**<0.001**
Oral	0.1(0.03-0.2)	<0.001	0.1(0.08-0.3)	**<0.001**

On bivariable analysis important predicator variables which had p values of less than 0.2 included sex, age in months, clinical setting, number of drugs, number of diagnosis, type of diagnosis and route of administration. In the multivariable analysis, two predictor variables found to be significantly associated with dosing errors were number of drugs and routes of administration.

On multivariable analysis of factors leading to occurrence of dosing errors, it was noted that children receiving more than five medicines were 6.4 times likely to experience dosing error (OR 6.4 95%CI: 2.7-15.1,P=<0.001), as compared to those with either one.

Route of drug administration was a statistically significant factor in dosing errors. This was reflected by the fact that there was a 60% reduced risk of developing a dosing error on intramuscular 80% , topical and 90% oral routes as compared to intravenous route (P= <0.001).

The type of diagnosis had a significant association with the occurrence of dosing errors in the bivariate analysis as depicted by pneumonia (OR2.1 95%CI 1.02-4.1, P=0.04) however on multivariate analysis it was no longer statistically significant (OR1.8 95%CI0.9-3.8, P=0.12)

Part two: Knowledge ,Causes and Mitigation Factors for Medication Errors

4.6 Care givers Understanding of their Children's Medication Use:

A total of 405caregivers were interviewed to explore their understanding of the medication use of the children under their care. Information was sought from them to find out if their children were newly admitted or had been transferred from other facilities. Three hundred and forty three 343 (84.1 %) had patients who had been newly admitted in KL5H.

Probing of medication use before admission and if the medicine had been presented at admission was done. Of all the caregivers interviewed only 30 (46.2%) presented a previous prescription to the clinicians. Some caregivers reported that no one had asked them about the previous prescription or did not carry the medicine.

''*…yes, the child has been on medication but no one asked for them.*'' (Caregiver 356)
"*….I carried but was not asked about them.*'' (Care giver 358).
"*….yes the child was using medication but I did not carry them along*." (Caregiver 368).

Out of all caregivers interviewed only 10(2.5%) had correct knowledge regarding to the medication their child was receiving. 102(25.2%) were aware of the correct frequency with which their children should receive their medication and only 8 (2.0%) reported correct knowledge of dosage of drug administration. However, only five (1.2%) said their children received medication on time, with 256 reporting that there were time inconsistencies in the issuing of medicines.

''*.. time is inconsistent, and the child has missed medication since last night because the line blocked*.'' (Care giver 366)
"*...it is only the medication I came with from home that the child takes on time the rest times keep varying*." (Caregiver 374)

5,1.2% care givers reported that their children had develop a suspected adverse reaction and only 4 (1.0%) had reported this to the health care providers.

Only twelve of the fourteen caregivers asked to buy medicines to for administration to their children when admitted at the hospital complied. Analysis on caregivers understanding of medication is shown on table 4.6

Table 4. 6: Caregivers understanding of children medication

	Frequency	**Per cent**
Newly admitted	340	83.9
Referral	65	15.9
Presented previous prescription (n = 65)	30	46.2
Caregiver reported understanding of:		
Type of drugs being given to child	10	2.5
Frequency of drug administration to child	102	25.2
Dosage of drug administration	8	2.0
Caregiver reporting that:		
Child receives drug on time	5	1.2
Child has experienced reaction to medication	5	1.2
Reported drug reaction to health worker	4	1.0
Was asked to buy medication	14	3.5
Bought medication	12	3.0

4.7 Causes and Possible Interventions for medication Errors

Factors associated with potential occurrence of medication errors were determined using in-depth interviews and Focused Group Discussion (FGDs).

4.7.1 In-depth Interview with Health Care Providers

A total of 19 interviews were carried out during the month of July and the interviews coded as represented in figure 4.6.

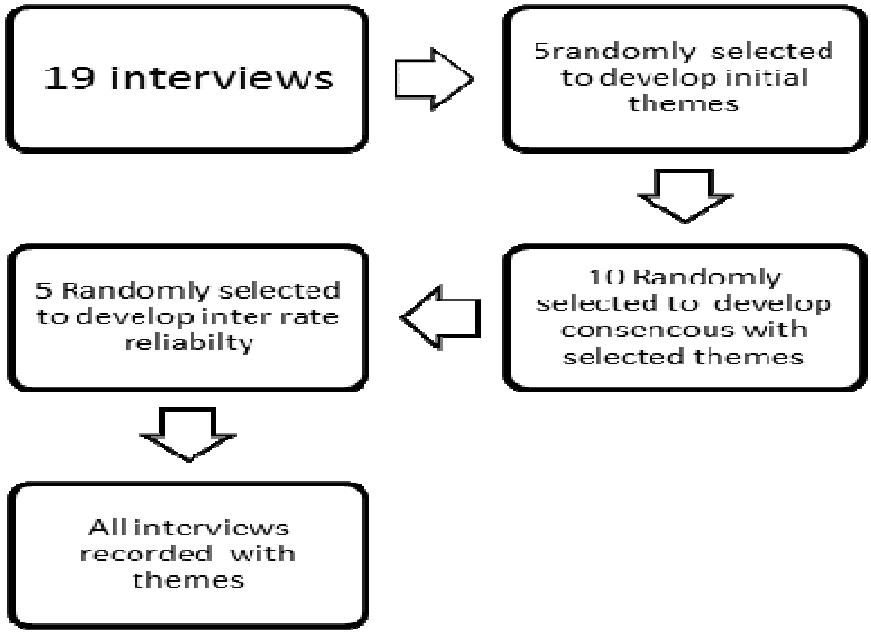


Figure 4:6: Coding for Health Care Workers Interview

The participant identification code was formatted in such a manner that allows identification of the cadre of the interviewee. Different abbreviations were used to denoted the interviewee per cadre for example P1-CO1 represents participant number one in the particular cadre. The codes represented the following:

P1-CO - Clinical officers

P2- NO- Nurses

P3-MO – Medical Officers

P4-PC- Pharmacists

A summary of the characteristics of the interviewees are represented in the table 4.7 below.

Table 4.7: Characteristics of Health Care Workers Interviewed.

Interview code	Sex	Age (yrs.)	Working Hours	Average Patients Seen per day	Work Period in yrs.	Role in Paediatric care
P1-CO1	M		8	50-70	1-3	Clinical Officer
P1-CO2	F		10	50-80	4-6	Clinical Officer
P1-CO3	F	24	12	30	1-3	Clinical Officer
P1-CO4	M	23	10	40	1-3	Clinical Officer
P1-C05	F	25	10	≥30	1-3	Clinical Officer
P1-CO6	F	24	9	5	1-3	Clinical Officer
P1-CO7	F	26	11	20	1-3	Clinical Officer
P2-NO1	F	48	10	≥50	≥13	Nurse
P2-NO2	F	40	≥8	≥40	≥13	Nurse
P2-NO3	F	32	8	10	4-6	Nurse
P2-NO4	F	26	11	20	1-3	Nurse
P2-N05	F	22	8	10-12	≤1	Nurse
P2-NO6	F	22	10	20	1-3	Nurse
P3-MO1	F	26	12	70	1-3	Medical officer
P3-M02	F		12	30-50	1-3	Medical officer
P3-M03	F	26	12	40	1-3	Medical officer
P4-PC1	M	30	9	100	1-3	Pharmacist
P4-PC2	M	31	8	30-50	7-9	Pharmacist
P4-PC3	M	30	12	20-40	1-3	Pharmacist

A total of 19 health workers at KL5H comprising of seven clinical officers, three medical officers, three pharmacists and six nursing officers participated in the in depth interviews(table 4.8 above). The mean age of participants was 28.4 years, with a range from 22 to 48 years. There were 14 (73.7%) female and 5(26.3%) males included. Most (13,68.4%) of the health workers interviewed had been employed for periods of between 1 and 3 years and worked in a typical shift at the hospital lasting 8 hours. The health care workers attended to at least 10 in-patients and 40 to 80 outpatients per day

Health worker perception of medication errors

All 19 interviewees reported that they were familiar with the term medication errors and had indeed encountered medication errors in practice. However, there were variations in reported frequency of medication errors in clinical practice with most interviewees (11, 57.9%) describing the errors as occasional and some reporting that the errors occurred *'very often'*. It was notable that nurses reported that medication errors occurred frequently compared to other health care worker cadres.

Health workers identified periodic fluctuations in medication errors. Specific reference was made to clinical rotation of medical interns as a cause of these periodic variations in frequency of errors.

> *"...errors occur once in a while, especially during new rotation of interns." [Health worker 7]*

The most common responses from health workers when asked about types of medication errors encountered in the hospital ranged from dosage errors, incomplete prescriptions, use of abbreviation and brand names, incorrect frequencies and unnecessary drugs. Certain types of medication errors were associated with specific drugs. For example, dosing errors were reported for drugs that have complicated dosing regimens, and inappropriate route of administration for some frequently prescribed anticonvulsants like diazepam:

> *"Yes... we commonly encounter dosing errors, for example phenobarbitone loading and maintenance dose are often confused, and accurate weighing during admission is not done leading to wrong dosages. Most prescribers are not sure when to use intramuscular or intravenous routes especially when it comes to diazepam." [Health worker 2]*

Handling medication errors in clinical practice

Most of the health workers readily admitted to having noted medication errors that occurred under their care. The most common interview responses were taking direct corrective action or in the cases of nurses bringing the error to the attention of the prescriber. In instances that nurse contacted prescribers, regarding medication errors the nurses indicated that the clinicians were receptive and corrected the prescription errors.

"…I contacted the prescriber who rectified the error." (Health Care Worker 18)

With exception of a single interviewee, not all the participating health care providers were aware of any formal system for reporting medication errors within the hospital. In the view of the health care provider who considered that the hospital had a system for reporting medication errors, Continuous Medical Education (CME) meetings provided an ideal forum for medication error reporting. Following on the responses health workers indicated that there were no tools or job aides in the clinical setting to help in identification and reporting of medication errors.

Causes of medication errors

In general, health care providers agreed that the causes of medication errors were multiple and spanned the entire spectrum of patient management from admission management to drug prescription and administration. During analysis, the findings related to causes of medication errors were broadly categorized into systemic or hospital level factors and health worker factors.

Systemic factors identified as common causes of errors

Health workers singled out issues with the hospital staffing and drugs systems that they thought contributed to medication errors. Particular problems seemed to be with understaffing and the large workload, absence of a standard hospital drug formulary and system for detecting and reporting errors. There were also concerns with the organization of care, orientation of new staff and level of support supervision during the actual patient care process.

Among the health provider causes of medication errors were: non-adherence to clinical protocols, lack of regular updates of clinical knowledge, and non-completion of clinical tasks related to prescription of drugs for example documentation of age and weight of admissions.

Proposed Solutions for Medication Errors

Health care providers recommended that hospitals should deal with human resource problems through recruitment of more staff, adequate orientation of new staff and providing adequate support supervision in the clinical areas. Specific reference was made to strengthening of clinical pharmacy practice in the hospital:

> *"There should be routine prescription checks by pharmacists in the clinical areas and the hospital should employ more personnel" [Health worker 6]*

Other recommendations included CMEs that are more regular and specific attempts to update staff especially nurses on drugs, development of a standardized hospital formulary and a hospital system for identifying and reporting errors.

4.7.2 Focused Group Discussions

Focused group discussions (FGDs) were held with a group comprising of Nurses, Pharmacists, Clinical Officers, and Medical Officers and in total three FGDs were held and the representation is shown in table 4.8

Table 4.8: Focused Group Discussions Representation

Focus group Number	**No of participants**	**No.Medical officers**	**No. of Clinical Officers**	**No. of Pharmacists**	**No. of Nurses**
FG1	6	3	3	0	0
FG2	6	0	0	0	6
FG3	5	0	0	5	0
Total	**17**	**3**	**3**	**5**	**6**

The Focus Groups (FGs) employed the brainstorming techniques to try to identify which factors contributed to the occurrences of medication errors in their practice. A total of five main error-producing conditions perceived to contribute to an increased risk of medication errors, these were described and explored in-depth. With the help of a Fish Bone diagram the goal of identifying and grouping the causes (factors contributing to medication errors) which generate an effect (Medication Errors). Five (5**)** main factors (**Medicine, Patient, Caregivers, Health care workers** and **System-related factors**) and thirty six (36) secondary factors contributing to medication were identified and are characterized by Figure 4.7 below

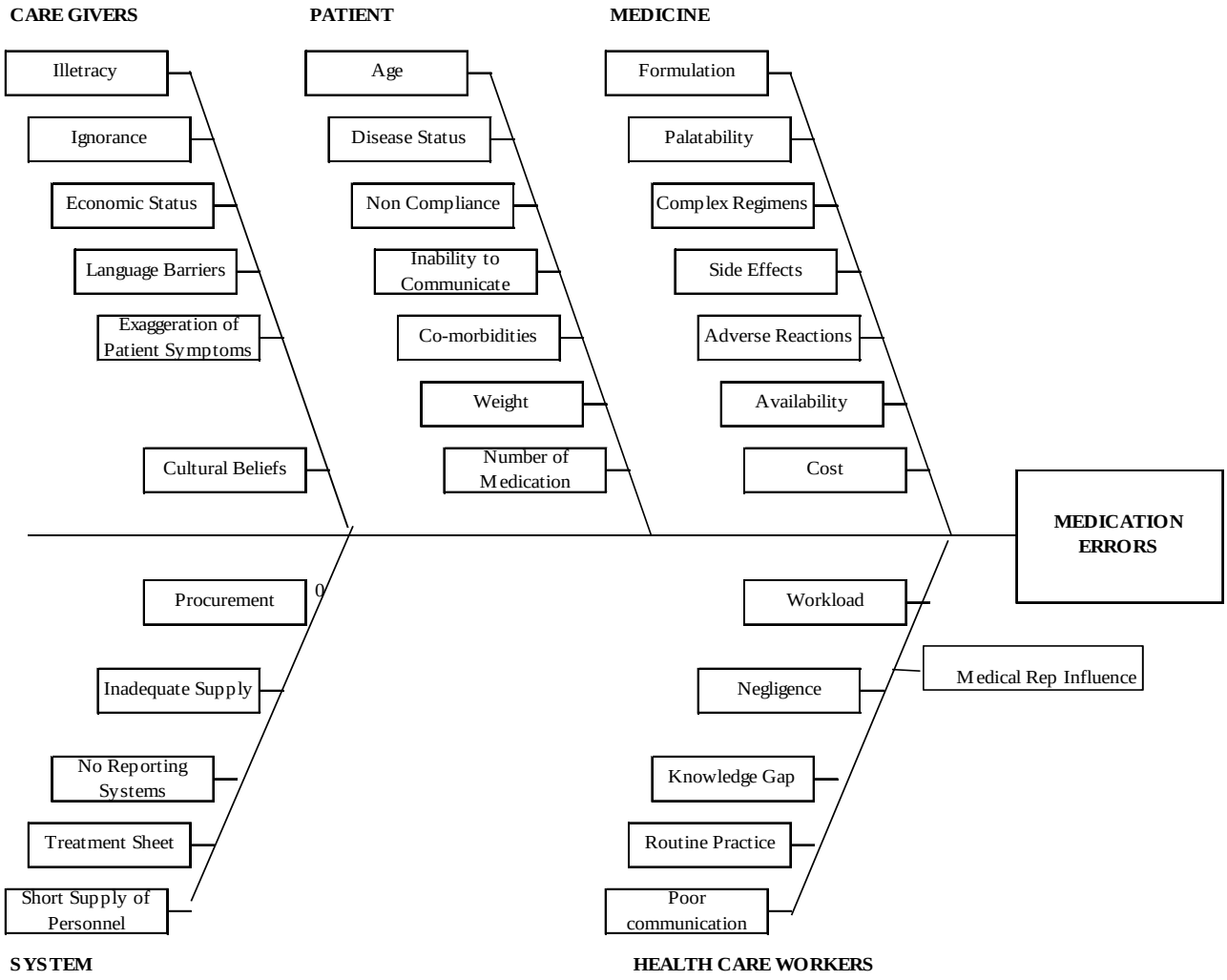


Figure 4:7 Fishbone diagram for causes of medication errors

The main findings presented in the fish bone diagram were explored extensively and presented as follow.

Medication – seven conditions considered to affect medicine namely their *formulations, palatability, complexity of regimen, side effects, adverse reactions, availability, and cost* were discussed extensively. In all the FGDs, the healthcare workers appeared to agree that formulation of medicines was the major contributor of medication errors, followed by availability and cost. It was felt that in availability of formulations specifically meant for use in children such as intravenous medicines was likely to predispose children to high occurrence of medication errors especially dosing errors.

‘‘… *most of the formulations we have are for adults hence it becomes very difficult to calculated the appropriate dose for children especially in cases of fixed dose combinations while lead to wrong dosage errors.’’* (FGDs)

"*…fixed dose pose a challenge of administration to children, especially where a tablet is to be split into two. One can never be sure of the actual distribution of the active pharmaceutical ingredient leading to a risk of suboptimal dosages."* (FGD3)

‘‘*...some medicines are not very palatable and may lead to spitting or complete refusal by the child to take the medicines hence leading to causes of incorrect dosages.*" (FGD1)

Patient - patient characteristics including *age, weight* and the *complexity of the individual case disease status, noncompliance, inability to communicate and the number of medication prescribed*, were found discussed as a major contributor to medication errors. Due to their rapid change in weight, it proves difficult keeping up with calculation of their dosages, which can easily lead to under, or over dosing. Having co-morbidities was generally agreed amongst the three FGDs as a likely cause of medication errors among children due to increased changes of drug interactions, contraindications, and poor compliance.

''…having comorbid conditions puts the children to a higher risk of medication errors. The incidences of drug-drug interactions and adverse events are likely to be on the increase. It further becomes difficult to know whether the worsening of a condition is due to a medication errors or disease state." (FGDs).

"….previous cases of allergies may predispose a child to medication errors, more so because they are unable to communicate this to the care health care workers." (FGD3)

Caregiver may likely to contribute to occurrence of medication errors to various factors such as *illiteracy, ignorance, economic status, language barriers, cultural beliefs, and exaggeration of patients' symptoms.* The FGDs felt that care givers can at times be a barrier to children getting quality health care by contributing to the occurrences of medication errors through exaggeration of medical conditions of their hospitalized children in order to seek sympathy and undivided attention form health care .This can lead to chances of overdose and toxicity dues to unnecessary prescribing. Cultural belief among care givers were discussed a s a potential cause of medication errors in children;

"….in Kisii region most parents believe in giving their children especially infant's herbal concoctions to protect them from the evil eye, this can easily lead to cases of drug-herb interactions leading to increased toxicity or worsening of disease condition." (FGD2)

The economic status of caregivers can be a hindrance to children receiving all prescribed medications:

"…at times the hospital may not have certain medication in stock so the health care givers are requested to purchase. We have seen case where the child has missed up to several scheduled doses of a medicine because the caregiver has no money to purchase the same. Some may also prefer to purchase certain medication and leave out others because of financial constraints. All this leads to missed doses and thus suboptimal treatments." (FGDs)

Health Care Workers; conditions found to affect HCWs, were, *knowledge gaps medical representative influences, routine practice/experience, workloads, perception of risk,*

negligence, and communication. HCWs were likely to contribute to errors due to huge workloads that result from inadequate supple of personnel. Routine practice was cited as a major contributor of errors where HCWs prescribe based on practices found there whether right or wrong. Knowledge gaps on the therapeutic management of drugs especially new molecules was cited a contributor to occurrence of medication errors.

"*…the use of abbreviations and brand names is rampant because it is the routine practice that is passed down to new prescribers. This is also most of the time due to influence from medical representatives*." (FGD3)

"…poor communication channels between the prescribers, dispensers, and administrators can at times lead to miscommunication and errors. In some instances a medication that is prescribed is out of stock, yet the prescriber is not aware hence the child ends up with missed doses." (FGD1)

System: System failures were also discussed in all the three groups as a major contributor to occurrence of medication errors. These were listed as inadequate *supply, short supply of personnel, lack of reporting systems, unfavorable treatment sheets.* FGDs felt that there were no proper support systems in place to help track and prevent medication errors. The groups felt that bureaucracy especially in the policies contributed to occurrence of medication errors due the fact that most formulations available are not paediatric friendly yet the hospital could not procure paediatric specific ones. The available treatment sheets are not adequate in capturing all the needed information. Hence keeping track of a patient's medication use was almost

4.7.3 Root Cause Analysis of Errors

Using cases studies identified from the review of treatment sheets, the FGDs identified the potential root causes of the errors and the principal investigator documented the RCAs considering them in the light of the findings from the analysis of interviews and focus groups.

Out of the five randomly selected treatment sheets with errors six root cause analyses were undertaken. The RCAs were coded and briefly described as shown in table 4.9

Table 4. 9 : Root cause analyses

RCA Code	Type of Error	Description of errors
RCA1	Dosing Error	A One day old child prescribed for vitamin k as 1gm, this is an over dose is supposed to be 1mg stat
RCA2	Dosing Error	5yr old weighing 18kgs prescribed for IV.Artesunate 14mg@ 0, 12, 24 then OD x3/7. This is an under dose as it is supposed to be 2.4mg/kg body weight
RCA3	Documentation errors-Missing information	Neonate prescribed for Benzylpencillin 150,000iu b BD*7/7, Gentamycin 15mg OD*7/7, TEO. Present on the file but not on the treatment sheet.
RCA4	Monitoring error – ordered but not done	Atropine for poisoning. Treatment sheet indicated that monitoring every hour but not done.
RCA5	Documentation error-use of abbreviations and brand names	Three of the prescriptions have Gentamycin written as Genta, Benzylpencillin as X-pen and Paracetamol Suppositories prescribed as Gacet
RCA6	Omission error – failure to administer medication to a child	4 year old started on treatment of malaria only got first two dose and missed other doses because an iv line had not been put up

These were linked to the error causing factors identified in the focused group discussion and key factors that could have let to this specify errors described as follows:

Health Care Worker related factors

Factors relating to the HCW thought to contribute to errors including failure carefully check dosages can be seen RCA 1and RCA2. Routine practice of using abbreviations or influence by medical representatives is seen in RCA5. Huge workload and negligence can be a contributor to RCA 3 and RCA 4 and RCA6.

Patient factors

In RCA 6 there may be a possibility that due to the illness of the child, the veins may have collapse hence difficulty in finding an Iv line for drug administration. Inability of the child

to articulate issues can also lead to continued missing of the drugs, unlike an adult who can lodge complaints.

System Factors

Lack of guidelines and protocols could be a contributory factor to RCA3, RCA4 and RCA6. If there were standard SOPs on how to transfer information from file to treatment sheet then RCA3 may not have arisen. Since there are no guidelines on how to prescribe medication the prescribers use the practice on the ground hence RCA5 occurring. Lack of proper communication channels could also have led to occurrence of RCA 6.

4.7.4 Mitigation strategies proposed

From the In-depth interviews and Focused group discussions various strategies for medication error reduction were proposed and are represented in table 4.10

Table 4.10: Mitigation strategies for medication errors

	Potential Causes Of Errors	Safeguards Proposed
1	**System Related**	
	Shortage of Personnel	Redistribution of personnel, include a pharmacist to monitor medication use, and participate in ward rounds to ease burden of the prescribers and nurses.
	Unfavorable Treatment sheets	Pharmacists and Pediatricians to review the treatment sheets to include trigger tools for medication errors monitoring
	Procurement policy	Carry out Drug utilization research among paediatric patients and review the procured formulations
	Influence by medical reps	MTC to formulate a hospital formulary or use the Paediatric protocol available and promote the use of generic rather than brand names
	Lack of reporting systems	MTC to formulate Standard operating procedure on how to identify, report an prevent medication errors
2	**Health Care Worker Related**	
	Knowledge gap	Continuous CMEs and updates on paediatric medication use and monitoring
	Poor Channels Of Communication and Improper Handing Over	Standard operating procedures of handing over, and communication wherever there is a concern on children medication.
	Assumptions and routine practice	Proper orientation of interns and new personnel on standard prescribing practices and continuously update older staff
3	**Patient Related**	
	Variability in age , weight	Avail neonatal formulations where possible. Have a ward based pharmacist to review medication prescriptions and provide guidance on use

CHAPTER 5: DISCUSSION

5.1 Type of Medication Errors and Risk Factors

The most common diagnosis in this population was malaria accounting for 45.2% of all admission. This was consistent with a study on Impact of Malaria Control on Infant Mortality in Kenya [54] which showed that Malaria was the leading cause of mortality and accounted for about 20% of all in-patient admissions

A study on assessment of neonatal care in clinical training facilities in Kenya [55] showed that the three most common disease conditions at admission were birth asphyxia , neonatal sepsis and prematurity. The present study demonstrated this with birth asphyxia at (71,17.5%) being the leading cause of neonatal admission in KL5H.

Medication errors occur during either prescription or administration of medicines and can be serious or potentially harmful. When they occur paediatric patients have a much higher risk as compared to adults [4]. Medication errors occur possibly in as many as 5% to 10% of all pediatric in-patients [56]. In the present study evaluating 405 paediatric inpatient treatment sheet and files, 307(75.8%) and were found to contain errors , this figure is much higher than those recorded by Al –Jeraisy et al [4] 56% and Kaushal et al [10] that recorded 5.7% medication errors.. This difference could be attributable to the fact that our sample size was smaller than the 2,380 medication orders with 1,333 medication errors in the and 10,778 medication orders with 616 medication errors respectively in the previous study.

Documentation Errors

The use of abbreviations in prescribing medication has recently received much attention and has become an international concern as one of the major causes of medication errors. Al-Jeraisy et al [57] found that abbreviations were used in 82% of all orders. In the present study, 408 (39.9%) of medication errors were due to abbreviations . Although it saves time and space, using abbreviations may sometimes turn out to be very expensive, as they may be misinterpreted, have double meanings, be confusing and give rise to errors [58].

According to the National Coordinating Council for Medication Error Reporting and Prevention [13] all prescriptions should clearly include important information such as the dosage form, dose and route of administration, age and, when appropriate, weight and height of the patient on the prescription or medication order. When prescriptions are not complete, it may cause serious risks to patient safety. In this study, few prescriptions analyzed contained the correct and complete specifications, which are paramount to treatment success [58]. In the present study 234 (22.8%) of the treatment, sheet and files had missing information. The figure was slightly lower than that of Zeleke et al [33] which was 121(54.26%), our sample size was however larger than for the previous study. The missing information included sex, height, frequency, duration of administration, the prescriber, the weight of the patient, and route of administration. Use of brand names can lead to a series of errors especially in the lookalike sound alike drugs. Commercial brands are expensive and can lead to error of omission and can be a limiting factor for treatment adherence [58] . In the present study 114(11%) of the prescriptions had use of brand name.

Dosing Errors

A systematic review by Wong et al [59] demonstrates the dosing errors are the most common type of medication errors. It further observed that dosing error rate ranges from 0.03 per 100 admissions in the UK to 2 per 100 admissions in the US, giving an incidence of about 50 ,000 paediatric dosing errors per year in England. In general most studies show that dosing errors are the most common type of medication errors in children with over dosage outnumbering under dosage [57]. In this study medication, dosing errors were the second most common types of errors 90 (8.7%). This constituted; no dosage indicated at 38(5.4%), wrong strength (18,2.5%), over dosage (16,1.67%),under dose (4,0.39%).The dosing errors in this study were significantly lower compared to studies by Al- Jeraisy et al 22% and Hoyle Jr et al 34.7 % [57,60]. It was also lower than Lan et al ‘s study [61] 61.0% dosing errors. This could be because all the prescribers had a paediatric protocol that they referred to while creating their medication orders.

Paediatric patients aged less than 2years have been reported to experience the greatest proportion of errant medication prescriptions [57]. Zeleke et al [33] report shows that

children less than one year contributed largest proportion of errors (22%) with the rate of medication error was twice in the age group 29 day – 1 year as compared to those patients who were 28 days old or younger . This shows consistency with our present with children aged one year and below (188, 46.4%) experiencing majority of the medication errors with children aged 1-12months having more errors compared to the ones aged less than a month.

5.2 Causes and Mitigation Factors for Medication Errors

Studies show that treatment adherence in pediatric care has been less extensively studied yet influences appear even more complex than in the care of adults. For example, the burden of treatment generally lies with caregivers rather than with the patients themselves whereas in adults the therapeutic relationship is between the medical team and the patient. In pediatric care there is a 'therapeutic triad' with communicative interactions between parent - professionals; child - professionals and parent –child [62]. This is likely to lead to occurrence of medication errors due to factors related to both caregiver and child. For example, economic status of caregiver can lead to dose omissions as they may not be in a position to purchase medication, or palatability of medication can make a child miss medication and the caregiver may not be in a position to rectify this.

From the data presented from the caregiver's interview in the present study one c, draw conclusions about the correlation between caregiver's knowledge of children medication use and occurrence of medication errors. It is however evident that most caregivers have limited knowledge on what type of treatment their children receive especially when admitted to hospital. It was also evident that gaps due to lack of communication between caregivers and health care workers could lead to errors. Caregivers said they were not asked about previous medication and this could lead to chances of over doses and contraindications. The aspect of delayed drug administration was noted in the caregiver responses, which can lead to suboptimal therapy, it could also be due to negligence of health care workers or huge workloads.

A study on the frequency, types, causes, and consequences of voluntarily reported emergency department medication errors by Pham et al [63] showed that the leading causes

were noncompliance to procedure/protocol (17%), and poor communication (11%), whereas contributing factors were distractions (7.5%), emergency situations (4.1%), and high workload (3.4%). Computerized provider order entry caused 2.5% of errors.

Various factors predispose paediatric patients to medication errors are compared to others. Lacy et al [5] reported that heavy workload among nurses was likely to contribute to dosing errors in paediatric patients. Kaushal et al [10] attributed increases incidences of medication errors in children to formulations not suitable for neonate dosing. Rood et al [64] reported considerable degree of variation in current oral pediatric liquid formulations posing a risk of dosing errors.

In the present study the in depth interview with health care workers gave the following points as the major contributors to occurrences of medication errors; medication formulations, understaffing, non-adherence to protocols, lack of regular updates on clinical knowledge, absence of a hospital formulary and systems for detecting and reporting medication errors.

A number of error producing conditions were identified from focus discussion groups. These have been classified into five main level categories: 'health care worker', 'the patient', 'the caregivers', 'the medicine,' and 'the system'. This is almost similar to a study by Avery et al [43] that had prescriber, patient, team, communication, work environment and task factors as producing conditions for medication errors.

Strengths and Limitations

The main strength of this study is that being a prospective cohort study data was collected in real time.

Limitations included costs and time. Subjectivity in assessing the extent of medication errors may also have persisted as a limitation despite various measures to minimize it. Incomplete medical records posed a challenge despite the measures in data collection to ensure a near complete data set as possible.

The respondents may not have given a true response to some of the items that seeks to identify valuable information such as responsibility for a medication error and reporting of incidents to protect their professional integrity.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

Conclusion

The prevalence of medication errors was significantly high (75.8%) .and a larger follow up study would be appropriate to determine the extent of medication errors among children in Kenyan hospitals. . Despite the fact that majority of errors observed were less likely to cause harm, some can be potentially fatal and therefore there is need for hospitals to have strategies of detecting and minimizing the errors.

The risk factors identified in this study for dosing errors include number of drugs, age, route of administration, number of diagnoses and type of diagnosis. Even though age, type of diagnosis and number of diagnoses were not statistically significant, they can help clinicians be more vigilant when handling medication in children.

Recommendations

It is very important for the hospital to recognize the possibility of medication errors occurring in the treatment of paediatric patients. Therefore there is a need to have measures put in place to help minimize the incidence of occurrence of the errors or avoid them in general. The following recommendations are given based on the findings of our study**.**

1. The hospital should have protocols and trigger tools in place that can help detect medication errors occurring in this study population.
2. Have a ward-based pharmacist that can help capture and intercept medication-prescribing errors.
3. The MTC should develop systems and tools to aid the identification, reporting and mitigation of errors.
4. Health Care Workers should be encouraged to write medication names in full or if they have to use abbreviations then it has to be standardized by the hospital or internationally approved abbreviations and acronyms.

5. Continuous professional development for health care workers should be carried out by the hospital training committees through seminars, talks or distance learning programmes.

Future Recommendations.

1. Larger prospective studies are recommended to determine the incidence ,prevalence and outcomes of medication errors in among paediatric patients across Kenyan hospitals

2. Pharmacists and pediatrician should develop effective programs to safely provide medications, and report medication errors

3. Pharmacy and Poisons Board -Pharmacovigilance Department being the institution with ensuring patient safety , should set up systems for identification , reporting, analysing and minimizing medication errors.

4. The Ministry should endeavor to; eliminate barriers to reporting medication errors by encouraging voluntary reporting of errors whenever they occur.

5. Computerized generation of prescriptions should be looked at as a means of error tracking and reduction.

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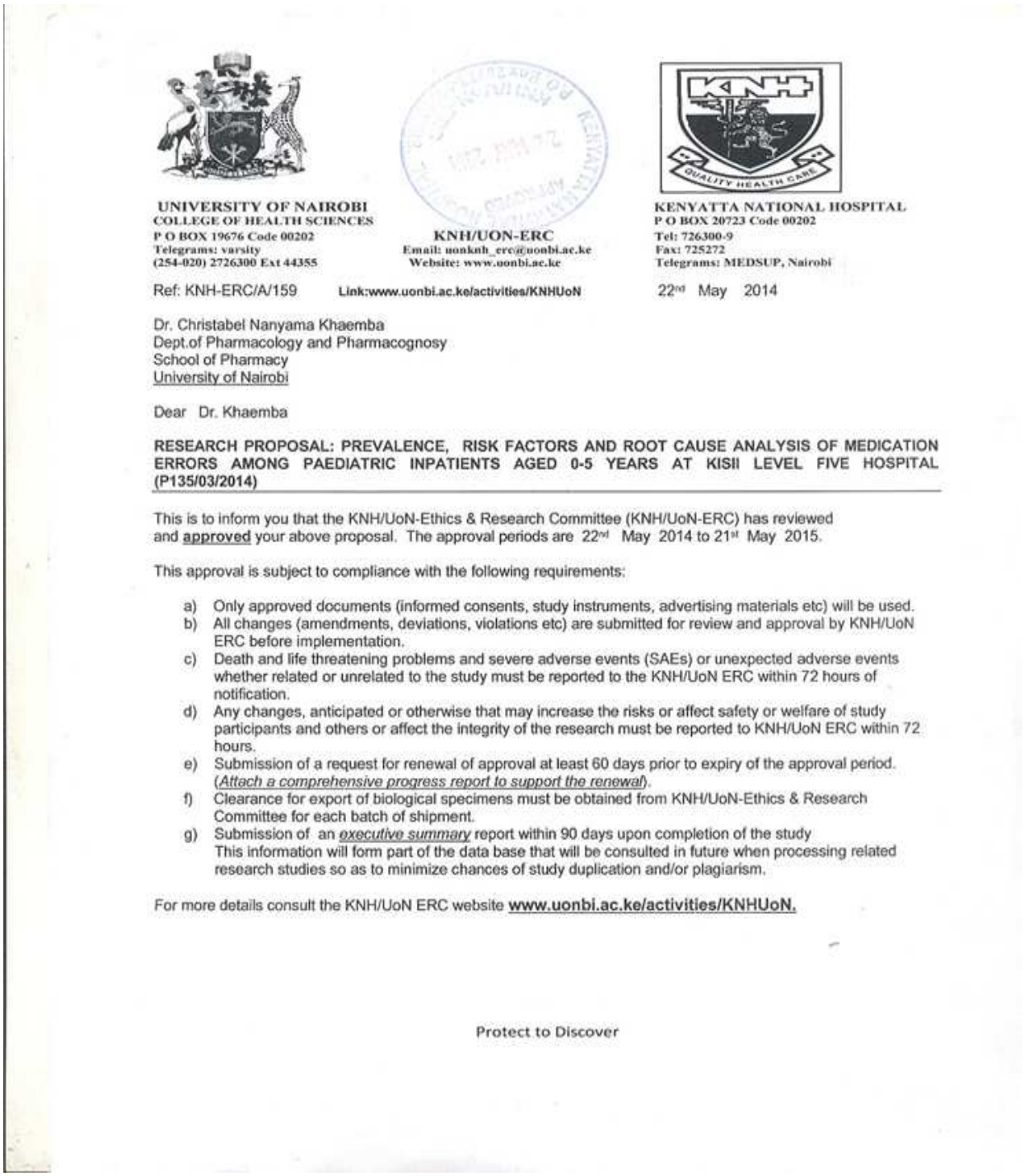
APPENDICES

Appendix A: Kenyatta National Hospital ERC Approval



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Ref: KNH-ERC/A/159 Link:www.uonbi.ac.ke/activities/KNHUoN 22nd May 2014

Dr. Christabel Nanyama Khaemba
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Dr. Khaemba

RESEARCH PROPOSAL: PREVALENCE, RISK FACTORS AND ROOT CAUSE ANALYSIS OF MEDICATION ERRORS AMONG PAEDIATRIC INPATIENTS AGED 0-5 YEARS AT KISII LEVEL FIVE HOSPITAL (P135/03/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 22nd May 2014 to 21st May 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chairman, Dept. of Pharmacology and Pharmacognosy, UoN
Supervisors: Dr. Margaret O. Oluka, Dr. Eric M. Guantai

Appendix B: Kisii Level 5 Hospital Approval

REPUBLIC OF KENYA

MINISTRY OF HEALTH
KISII TEACHING AND REFERRAL HOSPITAL

Telegrams:
Telephone:
E mail: kisiihospitall@gmail.com
Ref: KL5/DRE/14/23/Vol.1
Date: 24th June 5 2014

DEPARTMENT OF RESEARCH
KISII LEVEL 5 HOSPITAL
P.O. BOX 92-40200
KISII

Christabel Nanyama Khaemba

RE: Data a Collection at Kisii Level 5 Hospital

This is to inform you that the department of research at Kisii Level 5 Hospital has reviewed your proposal titled: **Prevalence,Risk Factors and root cause analysis of medication errors among paediatric inpatients aged 0-5 years at KL5H.**The following are our comments:

You are authorized to proceed with data collection upon payment of **Kshs.2,000/= (Two Thousand Shillings Only)**

Please ensure a copy of final Study report is sent to us for retention, information and use

MEDICAL SUPERINTENDENT
KISII LEVEL 5 HOSPITAL
P.O. BOX 92, KISII.

Dr. Jeremiah Okatch
Department of Research

CC: 1.Medical Superintendent-Kisii Level 5;

1

Appendix C Form for collecting patient demographic and medication data

Form 1: Prescription information

Fill one sheet per patient (use extra if the medications are more than 10)

What is the patient's Biodata? Please fill in these details in the spaces below.

Study no:	Age:	Weight:
Ward/bed number:	Sex:	Height:
Inpatient number:	Date of Admission: Date of Discharge:	BSA (m^2):
Initials of Reviewer		

What is the patient's chief complaint? Briefly state it in the space below.

……

……

……

…….

Final Diagnosis

……

…….

Medications History.

If this patient has no prescribed medicine move to the next one. In the table below record data on the medication for the patient is currently on and has been on in the last 3 months

Rx no	Drug name dosage, form and strength	Is the drug on the monitoring list Y/N	New(N) or Repeat(R)	Type of prescriber Co/CoI/MoI/MO/R/CT	No of Possible Error	No of Prescribing Monitoring error
1						
2						
3						
4						
5						
6						
7						
8						
Review Number:						
Review Number:						
Review Number:						

Key: Record drug information as it appears on the treatment sheet/patient file. Rx= Prescription Number, Co=Clinical Officer, Co I= Clinical Officer Intern, MO=Medical Officer, MoI= Medical Officer Intern, R= Registrar, CT=Consultant /Specialist.

Medication errors from the records review:

Does the patient have any errors with his/her medication? YES ☐ NO ☐

If yes fill form 2

Appendix D: Form used for collecting detailed information on potential medication errors.

Form 2: Details of Possible Medication Errors

Study no:	Age:	Weight:
Ward/bed number:	Sex:	Height:
Inpatient number:	Date of Admission: Date of Discharge:	BSA (m^2):
Initials of Reviewer		

For all possible error identified in form one fill in the table below. The treatments sheets will be reviewed during the follow up and form 2 filled for any potential identified errors.

Rx No from form 1	**Drug Name and formulation**	**Dosage Strength**	**Dosage Instructions**	**Number of Medication Errors**	**Error Code/s**

Key: Please use the appropriate prescription number from form1, enter drug name as it appears on the treatment sheet. Use the following error codes

Prescribing and Administration Errors		**Monitoring Errors**
1. Unnecessary drug	8.Formulation Error	15.Monitoring not Requested
2. Incorrect drug	9.Timing Error(Wrong frequency, administering beyond scheduled frequency)	16.Requested not done
3. Duplication(Use of two medicines or more with same spectrum)	10. Missing information (No identifiable prescriber, missing weight, no height, no duration, no dosage indicated, no indication provided etc.)	17.Results not available
4. Allergy error(Giving a medicine that the patient already had allergic reaction to)	11.Generic/Brand name Error(Use of Brand names instead of Generic names	18.Results not acted upon
5. Contraindication	12.Ommission Error relating to failure to prescribe a medicine	
6. Interaction	13. Omission Error relating to failure to administer a medicine	
7. Dose/Strength Error (No dosage indicated, under or over dose, using the concentration instead of mgs/gms/iu etc.)	14.Use of Abbreviations	

After filling in the tables complete the following information on the potential errors in below.

1. Describe the Potential Error

Rx No:

……

……

……

Rx No:

……

……

……

Rx No:

……

……

……

Rx No:

……

……

.....

....

Rx No:

……

……

.....

....

Rx No:

……

……

.....

Rx No:

……
……
.....

2. Was this a single event? YES/NO(Circle appropriately) .If YES go to 4 if NO to 3

3. If it is a repeat error, how long has it been repeated

Rx No:

……
……
.....

Rx No:

……
……
.....

Rx No:

……
……
.....

Rx No:

……
……
.....

4. Why do you think the error occurred? What could have happened to lead to the error?

……
……

……
……
……

5. Has there been any adverse event associated with the error? YES/NO (Circle appropriately. If YES go to 6 if NO go to 7

6. If you think the adverse event may be associated with the error, please describe below……
……
……
……
……

7. What category of error was this? Use the NCC MERP Scale to categorize
……
……
……
……
……
……
……

Appendix E: Interview guide for caregivers

NO	ITEM	YES	NO	COMMENTS
1	Was your child transferred from another facility?			
2	Do you know the types of medication/ drugs that are being given to your child in this hospital?			
3	Was the child on a previous prescription before admission to hospital?			
4	If so did you present the previous prescription to this hospital?			
5	Do you know the number of times your child should take his/her drugs?			
6	Do you know the dosage that he/she should take?			
7	Is he/ she receiving it on time?			
8	Has your child experience any reaction to any medication since you came on admission?			
9	Have you reported the reaction to the Health Care Workers?			
10	Have you been asked to buy any medicines?			
11	Have you bought?			

Appendix F: Interview Guide for HealthCare Workers

These items are designed to find out the possible causes of medication errors in the health care system in this hospital. I would appreciate your contribution to this study if you could take a short time (5-10 minutes) to fill in your response to the items below.

1. Biography

Gender Male ☐ Female ☐ Age ☐

2. How long have you been working?

1-3yrs 4-6yrs, ☐ 7-9yrs ☐, 10-12yrs, ☐ 13 and above ☐

3. How many hours on average do you work in a day?

……

……

4. On average how many patients are you supposed to see in day...

How many do you actually see? .....

5. Are you familiar with the term medication errors? ….....

6. Have you come across medication errors during your time of practice? .....

   How frequently do they occur? .....

   ……

7. Do you recall some of the most common errors that have occurred or you have come across? Briefly elaborate.

   ……

   ……

   ……

8. Has an error occurred under your care? What action did you take?.....

.....

.....

9. Does the hospital have a system for reporting medication errors? What does it do?.....

   .....

10. Do you have a tool for reporting or job aids to help in identification and reporting of errors?

    ……

    ……

11. In your opinion what do you think are some of the factors that lead to occurrence of medication errors?

    .....

    .....

12. What solutions can you propose?

    .....

    .....

13. How willing would you be to report a medication error that occurs under your care?

    ……

Appendix G: Focused Group Discussion Questions

The purpose of this group is to discuss your experiences/ opinions on medication errors, identify the risk factors, cause, and offer solutions that can mitigate the problem. The FGD is expected to last between 20-30 minutes

1. What are medication errors, how frequently do they occur in your practice?
2. What factors do you think contribute to medication errors?
    - Patient related factors
    - Medicine related factors
    - Health provider related factors
    - System related factors
3. What systems if any exist for reporting errors and learning from them?
4. Are there any safeguards in place whether formal or informal to prevent errors?
5. What systems or practices can we adopt in order to prevent or minimize errors?
6. Reviewing the case studies provided kindly help identify the factors that could have led to occurrence of the errors.

Appendix H: Medication Error Categories

Error Category	Definition
A	Circumstances or events that have the capacity to cause error
B	An error occurred, but the error did not reach the patient.
C	An error occurred that reached the patient but did not cause the Patient harm.
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.
G	An error occurred that may have contributed to or resulted in the patient's permanent disability
H	An error occurred that required intervention necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient's death

Appendix I : Consent form for interview with workers

To be read in a language that the respondent in fluent in.

Title of the study: Prevalence, risk factors and root cause analysis of medication errors among paediatric inpatients aged 0-5years at Kisii level 5 Hospital

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr Christabel N.Khaemba, P.O BOX, 30197-00400, Nairobi.

Supervisors: Dr.K.A.Sinei,Dr.M.O.Oluka, and Dr.E.M.Guantai - Department of Pharmacology and Pharmacognosy;

Ethical Approval: Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee, P.O BOX 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Permission is requested from you to enroll in this medical research study. You should understand the following general principles, which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary.
ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
iii. After you have read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of the study.
iv. The interview is anticipated to last 15-30 minutes

Introduction: In this study, I am assessing medication errors in children under five years old.

Purpose of the study: The purpose of this study is to determine the prevalence, types, and cause of medication errors among paediatric in patients

Procedure: With your permission, I will engage in a discussion about medication errors in children that I will record using a voice recorder. I will also take some notes on pen and paper where necessary. All information obtained will be handled with confidentiality.

Risks: There will be no risks involved in this study,

Benefits: There will be no direct benefits to you but the findings will be useful in improving the quality care among children less than 5 years, through identification and mitigation of medication errors that may occur during practice.

Assurance of confidentiality: All information obtained from you will be kept in confidence. At no point will your name be mentioned or used during data handling or in any resulting publications. Codes will be used instead.

Contacts: In case you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to use the contacts provided above.

STATEMENT OF CONSENT

I----------give consent to the investigator to interview me and use the information obtained in her study. Dr Christabel Khaemba has explained the nature of the study to me

Signature---------- Date----------

I confirm that I have explained the nature and effect of the study.

Signature---------- Date----------

Appendix J : Consent form for care givers

To be read in a language that the respondent in fluent in.

Title of the study: Prevalence, risk factors and root cause analysis of medication errors among paediatric inpatients aged 0-5years at Kisii level 5 Hospital

Institution: Department of Pharmacology and Pharmacognosy, School of Pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr Christabel N.Khaemba, P.O BOX, 30197-00400, Nairobi.

Supervisors: Dr.K.A.Sinei, Dr.M.O.Oluka, and Dr.E.M.Guantai - Department of Pharmacology and Pharmacognosy;

Ethical Approval: Kenyatta National Hospital / University of Nairobi Ethical and Research Committee, P.O BOX 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Permission is requested from you to enroll in this medical research study.

Preamble: We are requesting you to volunteer freely in this study. Before you decide to join, we would like to provide you with information about the study. This document is a consent form; it has information about the study and will be discussed with you by the investigators. Please, study it carefully and feel free to seek any clarification especially concerning terminologies or procedures that may not be clear to you. If you agree to join this study, you will be asked to sign this consent form and a copy will be given to you.

Purpose of the study: The purpose of this study is to determine the prevalence, types, and cause of medication errors among paediatric in patients who are under five years old.

Procedure: Information will be obtained from you by patient interview using a questionnaire. A medical history of your child will be taken from you to determine the chief complaint, past medical history, medication history, allergy status, adherence, and adverse effects among others. Please be as truthful as possible during this process. In addition, we will review your child's treatment sheets such that information on the medical history, diagnosis, and treatment will be obtained. The Doctor in the ward will also be consulted as need arises. Your child will be followed up from admission to discharge or for a period of up to 4 weeks after admission.

Risks: There will be no risks involved in this study. The study staff will take utmost care to keep your participation in this study confidential. Information on your child's health will

be identified only by a coded number. Information from this study may be used in reports, published papers or presented in public but your child's name will never be used. It is only the principal investigators who know the name of the child and your name.

This study does not in any way introduce a new intervention or treatment to your child's care plan. The care offered to you will be as per the KL5H protocols. We will only ask questions and observe your treatment.

Benefits: study may be of benefit to your child in that your child will be evaluated during the study and any problems with his/her medication addressed or communicated to the attending doctor. The findings of this study will primarily be of benefit to the Kenyan health system in terms of improved safety of medicines and quality of care and therefore improved performance.

Questions: You are free to ask any questions at any time about the study and regarding your rights as a research volunteer. You will not be giving up any of your legal rights by signing this consent form.

Contacts: In case you need to contact me, my academic department or the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee concerning this study please feel free to use the contacts provided above.

STATEMENT OF CONSENT

I----------give consent to the investigator to interview me and use the information obtained in her study. Dr Christabel Khaemba has explained the nature of the study to me

Signature---------- Date----------

I confirm that I have explained the nature and effect of the study.

Signature---------- Date----------