SYSTEM AND PROCESS FACTORS THAT CONTRIBUTE TO INSULIN RELATED MEDICATION ERRORS IN PEDIATRIC AND ADOLESCENT PATIENTS IN KENYATTA NATIONAL HOSPITAL

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DEDICATION

I dedicate this work to my wife, Juliet Mwikali and children, Chelsy and Jayden.

ABSTRACT

Introduction

Insulin provides the greatest flexibility in the management of diabetes in hospital settings. It is categorized as a high risk medicine because of its low therapeutic index. Insulin medication errors can easily lead to patient harm and hence their prevalence in health care facilities should be established and suitable measures put into place to minimize their occurrence.

Objectives

The study aimed at determining the prevalence of insulin related medication errors among pediatric and adolescent patients in Kenyatta National Hospital and determination of the system and process factors that contributed to these problems.

Methods

The study was carried out in the pediatric and adolescent patients' wards and outpatient diabetic clinic of Kenyatta National Hospital. The study design comprised both quantitative and qualitative phases. The quantitative phase consisted of both cross-sectional and prospective aspects. The cross-sectional study entailed prescriptions, glucose recording logbooks and dispensing label reviews while the prospective aspect entailed the abstraction of data from patient files and treatment sheets to determine the prevalence of insulin prescribing, monitoring and dispensing errors. In the qualitative phase, interviews were carried out to explore gaps in patient safety systems that could contribute to insulin related medication problems. Descriptive data analysis was conducted using STATA version 13 software.

Results

There was at least one prescription error in most of the prescriptions (69%). In the outpatient department, 64 (70%) out of the 91 prescriptions reviewed had an error. In the inpatient department, 7 (58%) out of the total 12 treatment sheets reviewed had an error.

The most common prescription error was the use of dangerous abbreviations with a frequency of 54 (61%). The medication error rate was high at 14.2%. All the dispensing labels analyzed had at least one error, with the majority having 4 errors per label (72%). The most common dispensing error was failure to indicate the frequency of insulin use 96 (23%). Interviews identified lack of standard insulin use guidelines, an inpatient diabetic care management team and failure by

pharmacists to actively participate in the management of diabetes patients as some of the factors that contributed to insulin related medication problems.

Conclusion

There was at least one prescription error identified in 69% of records and all dispensing labels had at least one error. The hospital has inadequate patient safety systems in place to prevent occurrence of these errors. There is need for the hospital to put measures in place to minimize the occurrence of such errors.

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LIST OF ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reactions
ASHP	American Society of Health System Pharmacists
BGL	Blood Glucose Levels
DKA	Diabetic Ketoacidosis
DM	Diabetes Mellitus
HbA1c	Glycated Hemoglobin
HCWs	Health Care Workers
kgs	kilograms
KNH	Kenyatta National Hospital
MTC	Medicines and Therapeutics Committee
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NPH	Neutral Protamine Hagedorn (Isophane insulin)
RBS	Random Blood Sugar
SMBG	Self Monitoring of Blood Glucose
UoN	University of Nairobi

OPERATIONAL DEFINITIONS

Diabetes Ketoacidosis
A life threatening complication of diabetes occurring when high levels of ketones (blood acid) are generated in a diabetic patient.

Dispensing error
Inconsistencies or deviations from the prescription order such as dispensing the incorrect drug, dose, form and /or inappropriate labeling or use directions.

Hypoglycemia
Blood glucose levels of below 50 mg/dL or 4.0 mmols/ L

Medication error
Failure in the treatment process that leads to, or has the potential to lead to harm to the patient

Medication related problem
An event or situation involving medication therapy that actually or potentially interferes with the optimum outcome for a specific patient.

Monitoring error
Failure to perform and/ or communicate therapeutic drug monitoring results.

Pediatric and adolescent patient
Any patient aged 0 to 18 years

Prescription error
Failure in prescribing that results in wrong instructions about one or more of the normal features of a prescription. The normal features of a prescription include the identity of patient, drug name, formulation, dose, route, timing, frequency and duration of administration.

Therapeutic index
A measure used to assess the safety of a drug. It is the ratio of the median lethal dose to the median effective dose

Health care giver
An individual, such as family member or guardian who takes care of a diabetic pediatric or adolescent patient.

CHAPTER ONE: INTRODUCTION

1.1. Classification and Diagnosis of Diabetes Mellitus

There are four categories of diabetes mellitus. Type 1 diabetes arises due to the destruction of pancreatic β cells leading to absolute or partial deficiency of insulin. Diabetes type 2 can result from a number of factors like insulin resistance and progressive loss of insulin secretion. Gestational diabetes is usually diagnosed on the third trimester of pregnancy. Other forms of diabetes are specific to some causes like drug or chemical induced diabetes mellitus. Prolonged use of glucocorticoids is an example of a drug which can cause diabetes mellitus (1).

Classification of diabetes mellitus is important in determining the type of therapy. The traditional paradigms of type 2 diabetes mellitus occurring only in adults and type 1 occurring only in children are no longer accurate as both diseases occur in both age groups and hence it is not easy to categorize the types of diabetes. The onset of type 1 diabetes mellitus may be more variable in adults, and they may not present with classic symptoms observed in children (1). Diagnosis of diabetes mellitus is usually based on the plasma glucose levels (1,30).

Diabetes mellitus is believed to be on the rise in Kenya and in the world. Type 1 diabetes is the major type in the youth, accounting for over 85% of all types of the disease in patients aged 20 years and below worldwide (2). The incidence rate increases from birth, peaking at the ages 10 to 14 years (2). After age standardization, global diabetes prevalence is believed to have risen from a prevalence of 4.3% in 1980 to 9.0% in 2014 in men and from 5 to 7.9% in women (3). The number of adults living with diabetes mellitus in the world is estimated to have increased from 108 million in 1980 to 422 million in 2014 (3). People living with diabetes mellitus have a higher probability of being hospitalized and more likely to stay in hospital longer than the diabetes free people (4).

In the United States of America, it is estimated that 22% of all hospital inpatient days are incurred by diabetic patients and that about half of 174 billion US dollars goes to diabetic care (4,31). There are about 1.6 million annual new cases of diabetes mellitus in the US with an overall prevalence of about 23.6 million people. An additional 57 million American people are at risk of developing the disease (4). In Kenya, data on the prevalence of diabetes mellitus in pediatrics and adolescents is not available but it is estimated that in the general population, the

2010-2015 diabetic prevalence was about 3.3% with a projected rise to 4.5% in 2025 (33,34). This translates to about 1.8 million people with diabetes mellitus (5).

1.2. Insulin Use in Diabetes

Insulin provides the greatest flexibility to controlling blood glucose levels especially in the hospital setting (6). Medication errors associated with insulin use can be minimized by analysis of the setting, proper training, proper back ground checks and encouragement of health care workers to share key clinical information geared towards patient safety (6).

Despite the fact that it is a lifesaving drug, insulin has a narrow therapeutic index and if not used properly, it can be life threatening (6). In medical literature, the prevalence of insulin related errors is a high and a clinically important problem. Studies carried out in the United States of America show that approximately 33% of the medication errors that lead to mortality within 48 hours of admission can be attributed to insulin administration (6). In 2004, for a period of 9 months, 199 medication error incidents reported in 8 hospitals in Northern Ireland involved insulin (6).

1.3. Challenges in management of diabetic pediatric and adolescent patients

Management of diabetic pediatric and adolescent patients poses great challenges to both the healthcare workers and their care givers. This is due to normal growth and development, psychological characteristics, family dynamics (including social economic status and cultural considerations), and care outside of homes (7). These factors increase the intricacy of caring for pediatric and adolescent patients and addition of a chronic condition increases the complexity of their management.

Children are more prone to medication errors and harm due to a number of factors. Most drugs used in the care of pediatrics are usually formulated and packaged primarily for adults. These drugs must be prepared in different volumes or concentrations at the health facility before being administered to children (8). The need to alter the original medication dosage requires a series of calculations and tasks which increases the chances of errors. Most health care settings are usually built around the needs of adults. Many facilities lack trained staff oriented towards care of children(8). Children care protocols and guidelines may also not be easily available. Children are less able to physiologically tolerate medication errors because their renal, immune and

hepatic functions are not yet fully developed (8). Pediatrics may not be able to communicate effectively to care providers regarding any adverse effects that medications may cause (8).

1.4. Problem statement

Despite the fact that it is a life saving drug, insulin has a narrow therapeutic index and if not used properly, it can be life threatening (6). Medical literature identifies the prevalence of insulin errors as high and a clinically important problem. Studies carried out in the United States of America show that approximately 33% of the medication errors leading to mortality within 48 hours can be attributed to insulin administration (6). A study conducted in KNH found that insulin was prescribed to 60% of the adult diabetic patients discharged from the general medical wards (21). Insulin prescription error prevalence was found to be 98.5% and a medication error rate of 19.2% was determined (21). In-depth interviews identified lack of guidelines, failure to monitor prescriber practices, knowledge gap and limited pharmacist participation in clinical areas as some of the leading factors contributing to insulin prescription errors (21). The system and process factors put in place to minimize insulin prescription errors were found to be inadequate (21).

For pediatrics and adolescents, the need to alter the original medication dosage requires a series of calculations and tasks which significantly increase the possibility of errors. Children use very small doses and dilutions and this can easily lead to errors. There is an upsurge of diabetes mellitus in children and this requires that studies be conducted to highlight the prevalence of insulin related medication errors in this population. Currently there are no such studies available in KNH. The system and process factors in the hospital which contribute to insulin medication related errors in pediatric and adolescent patients need to be identified and the relevant recommendations made on how to minimize them.

1.5. Research questions

1. What is the prevalence of insulin use in the pediatric and adolescent patients in KNH?
2. What is the prevalence of insulin prescribing, dispensing and monitoring errors among pediatric and adolescent patients in KNH?
3. Does KNH have appropriate protocols and systems to promote rational use of insulin in pediatric and adolescent patients?

1.6. Main objective

This study sought to determine the prevalence of insulin related medication errors and their contributing factors among pediatric and adolescent patients in Kenyatta National Hospital.

1.7. Specific objectives

The specific objectives of this study were to:

1. Measure the prevalence of insulin use among pediatric and adolescent patients in Kenyatta National Hospital
2. Measure the prevalence of insulin prescription, monitoring and dispensing errors.
3**.** Determine the system and process factors that may contribute to the occurrence of insulin related medication errors.

1.8. Study justification

The prevalence of insulin related medication errors in pediatric and adolescent patients, and the factors that contributed to these errors in the hospital were unknown. This study aimed at identifying the prevalence of these errors and the gaps that needed to be addressed in order to improve the practice of insulin use. It is hoped that recommendations made on how best to address the identified system errors will minimize risk to patients.

CHAPTER TWO: LITERATURE REVIEW

2.1 Insulin prescription errors and their implications

Patient safety problems involving insulin are estimated to be frequent and can cause a lot of distress to patients living with diabetes, their family members and care givers. A prescription error is said to occur when a prescribing decision decreases the probability of the treatment being timely and effective, or increases the risk of harm as compared to generally accepted practice(10).

Insulin is designated as a high risk drug owing to the risk of harm that can occur in case of errors especially during the time of prescribing, transcribing and administration (4). The exact frequency of insulin related errors is unknown as most of the data available is dependent on spontaneous reporting (4). In most hospitals however, real time root cause analysis of the errors is not carried out (4). Among all the processes of insulin use (prescribing, transcribing, storage, dispensing, administration and monitoring), insulin errors are believed to occur most frequently during the prescribing and administration steps (11,32). Table 2.1 shows the types of errors which can occur during insulin use.

Table 2.1: Sources of insulin related medication errors

Source: American Journal of Health- System Pharmacy, Volume 70, 2013.

Phase	Error
Prescribing	Wrong dosages, insulin orders which are not rational and nomenclature related orders
Transcribing	Incorrect transcription of telephone or verbal insulin orders and or transcribing the wrong insulin dosages.
Storage and dispensing	Failure to double check before dispensing, containers which look alike. Non -segregated or unsecure storage of insulin in pharmacy and patient care areas. Failure to give dispensing instructions.
Administration	Improper use of insulin pens, wrong dosage administration and confusion of insulin names.
Monitoring	Failure to monitor insulin use and make appropriate dose adjustments.

2.2 Obstacles in safe use of insulin in hospitals

Although insulin can be a life saving drug, inappropriate use can also be life threatening. Optimizing control of blood glucose is usually a great challenge to patient safety (6). While some specific glycaemic targets are recommended, it is difficult to determine the level of blood glucose which is most ideal to achieve with few adverse events and the highest benefit (6).

For safe and effective use of insulin, there is need to analyze and redesign hospital systems to come up with a culture of safety that reduces insulin related medication errors and at the same time yield the best outcomes (6).

Patients without diabetes who develop hyperglycemia especially in acute illness may be mismanaged as the condition may be ignored or treated inappropriately (6). Poorly organized management plans, improper co-ordination of care, excessively high glycaemic targets and lack of therapeutic adjustments (6) are some of the factors contributing towards poor control of blood sugar. The fear of provoking hypoglycemia has hindered proper use of insulin(6).

There is need to put measures in place to address the procedures and pathways surrounding prescribing, dispensing, storage, administration and monitoring of insulin therapy in hospitals. In children, insulin poses a greater danger owing to their developing renal and hepatic systems, challenges in communication and the need for insulin dilution which may lead to medication errors (12). A failure mode effect analysis identified knowledge gap among nurses regarding children care as the leading factor in insulin related errors (12,13). Problems with dosages of insulin, omission, calculation and administration of diluted doses were all attributed to lack of a standardized educational process and infrequent treatment of children with diabetes (12).

2.3 Insulin dosing in pediatrics

Insulin is the main drug in the management of diabetes in pediatric and adolescent patients. The treatment regimen is dependent on a number of factors including the child's duration of diabetes, age, family lifestyle and socio economic status, patient and physician preferences (14,15). Regardless of the regimen, pediatric and adolescent patients should be treated to achieve the desired glycemic targets. The honeymoon period lasts up to two years after diabetes diagnosis. It is usually characterized by good glycemic control and low insulin dosage requirements (14). Afterwards, there is need for individualization of insulin therapy.

Doses of insulin should be based on the pattern of blood glucose levels. Pediatrics and adolescents should have access to rapidly acting or regular insulin for crisis management (5,16). The correct dose of insulin is that which achieves the best glycemic control in a pediatric with minimal or no obvious hypoglycemic incidents (15–17). During the partial remission phase, insulin dose is usually <0.5 international units/kg/day. In the pre pubertal phase, the dose may rise to 0.7-1.0 international units/kg/day. At puberty the daily insulin requirement may rise to above 1 and even up to 2 international units/kg/day (15–17). In diabetes ketoacidosis, insulin dose is 0.1 international units/kg/hour and 0.05 units/kg/hour in patients less than 5 years of age (17).

2.4 Insulin administration errors in pediatrics and adolescents

Administration errors during insulin use can arise from the use of incorrect equipment, wrong technique, poor timing and administration of improper dose. Wrong timing of subcutaneous insulin can lead to short or long term complications with hypoglycemia as a common outcome (18). Health care workers sometimes skip insulin administration in patients with hypoglycemia, if the patient is vomiting or is not eating well (18). Insulin should not be stopped even in severe illnesses unless there is prior consultation with a specialist diabetic professional. This helps to reduce the chances of patients developing diabetic ketoacidosis (18). Hospitals should have guidelines on the administration of insulin and HCWs involved in the administration of insulin should be properly trained to deliver insulin safely.

Children and their health care givers should be trained on body areas for self-injection (abdomen, thigh, arm and buttocks) at particular times of the day. They must however be cautioned to avoid injecting in the same spot for a long time to avoid lipohypertrophy (15). Insulin administration syringes should be calibrated to the concentration of insulin being used. There is need for proper pediatric training and reassessment on how to do self-injection. Syringes for use in insulin administration should not be shared to minimize the risks of acquiring blood borne infections. Guidelines on the administration of insulin should capture all the areas of insulin administration to reduce chances of medication errors. Health care workers involved in administration of insulin should be well trained in prescription interpretation, correct dose withdrawal, proper selection of injection sites and safe disposal of sharps immediately after use. Understanding the duration of action of insulin is important in determination of the frequency of administration. Table 2.2 shows the types of insulin and their average duration of action.

Table 2.2: Types of insulin and their properties (5,19).

Insulin preparation	Onset of action (minutes)	Duration of action (hours)	Injection s per day
Rapid acting analogues	10-20	3-5	Immediately before meals or with meals
Short acting(soluble)	30-60	6-8	30 minutes before meals
Intermediate acting(NPH)	60-120	13-18	Once or twice
Biphasic mixture 30/70	30	14-16	Twice
Long acting analogue	60-120	24	Once

2.5 Blood glucose monitoring during insulin use in pediatrics

Self-monitoring of blood glucose and HbA1c testing provides the best information on glycemic control (14). In pediatrics, the timing and frequency of glucose monitoring should be individualized based on the type of diabetes, the insulin regimen prescribed, the desire for information on blood glucose levels and the individual capacity to make use of the test results to adjust medications or change behavior (14). For type 1 diabetes, usually three tests daily are adequate (14). However, in resource limited settings, capillary blood glucose measurements can be carried out at least once or twice weekly depending on physician's discretion (16). It is believed that a Hb1Ac of <7% is acceptable if it can be attained without excessive hypoglycemia (5,16,20). Knowledge of the correct blood glucose levels is important in the monitoring of glycaemic levels. Table 2.3 shows the recommended reference ranges of blood glucose levels (BGL) in pediatrics.

Table 2.3: Blood glucose targets in pediatrics (16,29).

Age (years)	BGL before meals (mg/dL)	BGL at bedtime/ Overnight (mg/dL)	HbAIc (%)	Rationale
0-6	100-180	110-200	7.5-8.5	High risk and vulnerability to hypoglycemia
13-19	90-180	100-180	<8	Risk of hypoglycemia, development and psychological issues

*BGL – Blood glucose levels

2.6 Dispensing and storage of pediatric insulin

Insulin is temperature sensitive and improper storage can lead to decrease in its potency and hence affect its pharmacological action. Patients should be adequately educated on its storage. Insulin should never be frozen or used after its expiry date. Care should be taken to prevent direct exposure to heat or light and it should be well inspected before use. Insulin with some particles or which is cloudy should not be used (17). Vials which are not opened should be kept in a refrigerator between 2-8^{0}C. However, opened vials which are in use can be stored at room temperature. When storing pre-filled insulin syringes, one should ensure that the needle points up always (17). One should also record the date they have opened a vial. This is necessary as vials should be discarded three months after opening. This however may depend on the type of insulin and the storage conditions during use.

2.7 Studies on insulin use in Africa

Insulin use in African settings has not been widely studied. Some studies have been conducted focusing on medication related problems in African settings. A study conducted in a western Kenya referral hospital reported a medication error rate of 75.8% among the pediatric patients visiting the hospital (26). Medication errors were found to occur more frequently in male children less than one year old and in those admitted to the general pediatric wards (26). In KNH it is believed that the prevalence of prescribing errors could be as high as 15.8% (27). Many diabetic children in Kenya (72%) have poor glycemic control and hence there is need for more aggressive management and follow up (23). A study conducted in the KNH adult general wards

found that insulin was prescribed in 60% of the diabetic patients and a medication error rate of 19.2% was established (21). It has also been established that health related costs, age, duration of diabetes mellitus and insulin associated side effects are some of the factors which can have a negative impact on the adherence to insulin prescriptions (22). Weak patient safety systems like lack of guidelines, failure to monitor prescriber practices and knowledge gap among health care workers are believed to be some of the factors contributing to medication related problems in KNH (21).

CHAPTER THREE: METHODS

The study was divided into two parts; quantitative and a qualitative components. The quantitative phase had both cross-sectional and prospective aspects. These studies were conducted to measure the prevalence of insulin prescribing, monitoring and dispensing errors. The qualitative aspect explored the gaps in the patient safety system and identified the required interventions to minimize insulin related medication problems.

3.1 QUANTITATIVE PHASE- DETERMINATION OF PREVALENCE OF INSULIN RELATED MEDICATION ERRORS.

3.1.1 Study design

Prospective study

A prospective cohort study was conducted over a period of three months until the target sample size was achieved. It involved daily reviewing of files and treatment sheets of admitted patients on insulin therapy from the day of admission to discharge.

Cross sectional study

Two cross sectional studies were conducted:

a) Review of dispensing labels from both outpatient and inpatient departments

b) Review of insulin prescriptions in the outpatient department as well as patient self monitoring procedures

3.1.2 Study site

The study was carried out in the pediatric and adolescent outpatient diabetic clinic and wards of Kenyatta National Hospital which is the largest public referral hospital in Kenya. According to KNH Health Management Information Systems 2016, the hospital has four general pediatric and adolescent wards (3A, 3B, 3C and 3D), five specialized pediatric wards (surgery, orthopedic surgery, oncology, ICU and renal unit which are located in 4A, 6B, 1E, Pediatric Intensive Care Unit, Pediatric Surgical and Renal Unit respectively). The general pediatric and adolescent wards have a bed capacity of 237 patients with an average bed occupancy of 133% and 174 admissions per month. The pediatric and adolescent oncology ward has 28 beds with an average occupancy of 87.6% and 10 admissions per month.

3.1.3 Target population

The target population for this phase was the patients admitted at the general pediatric and adolescent wards, Pediatric Intensive Care Unit, pediatric surgical unit and Pediatric Renal Unit. The study also made use of patient's prescriptions from the pediatric and adolescent outpatient diabetes clinic and dispensing labels from the pharmacy.

3.1.4 Inclusion and exclusion criteria

Any medication treatment sheet, files, prescription or dispensing label was included if the following criteria were met:

   a. Belonged to a diabetic patient who was aged 18 years and below.

   b. Contained any insulin formulation.

   c. Seen in KNH during the period of study (April-June 2017).

Treatment sheets, files, prescriptions or dispensing labels were excluded if the above criteria were not met. In addition insulin should have been indicated for diabetic patients.

3.1.5 Sample size

The outcomes of interest were insulin prescribing, monitoring and dispensing errors. A previous study in KNH general wards reported a medication error rate of 19.2% (21). This being a prospective study carried out to determine the prevalence of medication related problems, the Cochran formula (24, 28), was used to determine the sample size for patient files, treatment sheets, prescriptions and dispensing labels reviewed.

Equation 1: Cochran formula for sample size determination for descriptive studies

$$No = \frac{Z^2 *(p)\,(q)}{d^2}$$

Where:

Z = z statistic for 95% level of confidence which conventionally is 1.96

P = estimated medication error rate

q is 1-P.

d= level of precision used in the study set at 5%

Taking 19.2% as the estimated medication error rate, the sample size was calculated as shown below:

Because the study population was expected to be small, equation 2 for a finite population correction factor was applied.

Equation 2: Formula for finite population correction factor

$$na = \frac{nr}{1+\frac{nr-1}{N}}$$

Where na was the adjusted sample size, nr the original required sample size and N the assumed population of diabetic pediatrics who attended the hospital.

An assumption that the hospital admitted about 60 diabetic pediatric patients in a period of 3 months and that about 120 diabetic pediatric patients were attended to at the pediatric diabetes outpatient clinic in 3 months was made. The adjusted sample size calculation was as follows

$$Na = \frac{239}{1+\frac{239-1}{180}}$$

Na = 103.

As a result, 103 patient records were reviewed.

3.1.6 Sampling method

Because of the small number of diabetic patients attended to in the hospital, a universal sampling method was conducted to achieve the desired sample size. The inpatient files were accessed from the wards and perused daily. Since more patients were attended to at the outpatient compared to the inpatient department, the ratio of inpatient records to outpatient records was 1:8. Review of the files and treatment sheets was done in the afternoons to avoid disruption of ward rounds. For the outpatient department, prescriptions and glucose recording logbooks were reviewed in the diabetic clinic. Labels of dispensed items were accessed in the wards and pharmacy.

3.1.7 Data collection procedures

Cohort study

In the inpatient department, the patient files were obtained from the nursing station and perused to determine if they met the eligibility criteria. The files and treatment sheets that met the eligibility criteria were then assessed and scrutinized further in the doctor's room with the aid of the data collection tool in appendix A. Review of the treatment sheets and files was done daily from admission to discharge to detect any medication error or inconsistency which could have occurred during the period of hospitalization. The files were then returned to the nursing station as soon as data abstraction was completed. A list of all the reviewed patient files and treatment sheets was maintained to prevent double review.

Cross sectional study

In this phase, prescriptions and dispensing labels which met the eligibility criteria were assessed and scrutinized further with the aid of the data collection tool in appendix A. Dispensed items in the wards were reviewed against the insulin order sheets to determine if there were any discrepancies. Where there were discrepancies, the relevant staff was consulted.

In the outpatient department, prescriptions and glucose recording logbooks were reviewed immediately after patients left the doctors room. Patients were then requested to collect their insulin from the pharmacy and return them to the clinic for cross checking against their prescriptions to identify any dispensing discrepancies. Patients who opted not to return their dispensed items to the clinic were accompanied to the pharmacy and their dispensed items reviewed from there. A list of participant identifier was maintained to avoid double review.

3.2 QUALITATIVE PHASE- IDENTIFICATION OF SYSTEM AND PROCESS FACTORS THAT CONTRIBUTE TO INSULIN RELATED MEDICATION PROBLEMS.

3.2.1 Study design

This was a cross- sectional qualitative study involving key informant interviews. It was carried out to identify the gaps and challenges in the patient safety system that could contribute to insulin related medication problems.

3.2.2 Study site and population

The study was carried out in the pediatric and adolescent wards and in the pediatric outpatient diabetic clinic of Kenyatta National Hospital. The study population was the healthcare workers in the wards, pediatric outpatient diabetic clinic, Pediatric Intensive Care Unit, Pediatric Surgical and Renal Unit in KNH. These HCWs included the medical consultants, medical officers, Registrars, pharmacists and nurses.

3.2.3 Inclusion and exclusion criteria

Any HCW was included to participate in the study if they met the following criteria:
   a. voluntarily gave informed consent
   b. any cadre that provided prescribing, dispensing, nursing or nutritional services to diabetic pediatric patients.
   c. had worked in KNH for at least 6 months

Any health care worker who did not meet the above criteria was excluded. In addition, HCWs who were not directly involved in provision of diabetic care to pediatric patients were excluded.

3.2.4 Sample size

The recommended sample size for key informant interviews is 4. Participants were recruited and interviewed until a point of saturation was reached, which is a situation where there were no new emerging themes.

3.2.5 Participant recruitment

Snow balling method was used in the recruitment. The person in charge of each unit/section was approached in each study site and briefed on the study. They were then requested to participate or nominate competent participants to take part in the interview exercise. The nominated persons were approached after completion of ward rounds and informed about the study. They were then requested to select a convenient place and time for the interview to be conducted.

3.2.6 Data collection and consenting procedures

An interview guide (Appendix B), the data collection tool adapted from the ASHP Recommendations for the Safe Use of Insulin in hospitals (8) was used. It was pretested and the relevant adjustments made to improve on the quality of the data collected. Informed consent and

voluntary participation (Appendix C) was obtained from health care workers who met the inclusion criteria without coercion or incentives. The interviews were recorded by use of a digital audio device and manually using a pen and paper. The interview process lasted for about 20-30 minutes each. The responses were then transcribed within 48 hours into a Microsoft word document. The audio records were destroyed within 72 hours after transcribing.

3.3 Data management

The quantitative data was entered into an Epi Info Version 7 database. To ensure that data obtained remained confidential, serial numbers were used instead of names to identify patients. Data was also coded for privacy and confidentiality. The study made use of two research assistants, both final year Bachelor of Nursing students. They were trained on the methods of data collection and handling. Files were serialized to avoid erroneous repeat analysis. All information in soft copy was stored in password controlled files which were only accessible to the researcher. Data collection tools were piloted and the feedback obtained used to make the necessary adjustments.

3.4 Statistical analysis

Descriptive data analysis was done using STATA version 13 software. Normally distributed continuous variables were summarized using mean and standard deviations. Continuous variables that were not normally distributed were summarized using median and interquartile ranges. Categorical variables were summarized as percentages and 95% confidence interval
The prevalence of insulin medication related error such as prescription errors were calculated using equation3.

Equation 3:

Prevalence of prescription errors: $\underline{\text{Number of reviewed prescriptions with errors}}$ x 100
                                    Total number of patient prescriptions reviewed

Medication error rate (MER) was determined by calculating the percentage of errors. The numerator was the total number of errors while the denominator was the opportunity for errors which was the sum of errors that occurred plus errors that could possibly have occurred (23). The medication error rate was calculated using equation 4.

Equation 4:

Medication error rate: $\dfrac{\text{Total number of errors observed}}{\text{Opportunities for error}} \times 100$

A MER of 5% and above was an indication of facility systematic problems which required measures to be put in place to minimize the errors (25).

Analysis of qualitative data

Thematic analysis of qualitative data was carried out where words were classified into categories based on conceptual significance. Data was inspected to identify common issues that recurred. Transcripts were initially coded with key categories using the interview guide. Codes generated from the data were grouped into themes that summarized the views of the participants. The results were summarized into narratives supported by quotes from the interviewees.

3.5 Ethical considerations

Approval to carry out the study was sought and obtained from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (Approval number **P643/09/2016**). The approval letter from the ethics committee is attached in **Appendix D.** The study was registered in the hospital (Registration number **KNH/R &P/FORM/01**). The study registration certificate is attached in **Appendix E**. Authority to collect data from the hospital was obtained from Kenyatta National Hospital Management. Informed consent (**Appendix C**) was also obtained from the HCWs before they could participate in the study. Data collected was stored under lock and key. Electronic data was secured by use of passwords. The study made use of identity codes instead of names of participants and patients to ensure that patient confidentiality was observed.

3.6 Study results dissemination plan

For this research to have an impact, efforts will be made to disseminate the findings to the relevant authorities in KNH. A policy brief will be prepared and availed to the hospital chief pharmacist who can then either invite the researcher to an MTC meeting to discuss the findings or directly discuss the report with the committee. There results will be published in a peer reviewed journal. Copies will be availed to the libraries in the College of Health Sciences.

CHAPTER FOUR: RESULTS

The results are presented in two parts: part one presents the findings of the quantitative phases (cross-sectional and prospective) aimed at identifying insulin prescribing, dispensing and monitoring errors. Part two are the findings of the qualitative study aimed at identifying system and process factors that contribute to insulin related medication problems.

4.1 Part 1: Insulin Prescribing, Monitoring and Dispensing errors.

4.1.1 Baseline characteristics of the pediatric patients on insulin

Approximately 103 pediatric diabetic patients were treated at the hospital during the three months study period from April to June 2017. The study had a target sample size of 103 and therefore a universal sampling was done. All the files, prescriptions and dispensing labels met the inclusion criteria and were evaluated for medication errors.

In the initial sample plan, we had hoped to sample 69 participants from the outpatient and 34 from the in-patient department. This target could however not be achieved because of the low population of diabetic pediatric in-patients. As a result 91(88%) out of the planned 103 participants were obtained from the outpatient department and the rest from the in-patient wards.

The median age of participants was 11 years with an interquartile range of 7 to 15 years. Most of the participants were aged 6 to 12 years (45, 44%), followed by 13 to 18 years (41, 40%) and 0 to 5 years (17, 16%). The median duration of illness was 36 months with an interquartile range of 12 to 60 months. Approximately 51% of the patients on insulin therapy were males.

All the patients had type1 diabetes as their primary diagnosis. Three percent had ketoacidosis. Most of the patients (90, 87%) were on insulin alone while 13% had insulin and additional drugs prescribed by the same clinician. The mean weight of the population studied was 37 kgs with a standard deviation of 16.3 kgs. The baseline characteristics are summarized in Table 4.1

Table 4.1: Baseline characteristics of pediatric patients with type 1 diabetes in KNH seen between April and June, 2017.

Variable	Frequency (percentage)
Department	n (%)
Outpatient	91 (88)
Inpatient	12 (12)
Sex	
Male	52 (51)
Female	51 (49)
Age category	
0-5 years	17 (16)
6-12 years	45 (44)
13-18years	41 (40)
Median age [IQR]	11 [7,15]
Weight in kgs	
Mean (SD)	37 (16.3)
Duration of illness in years	
Median [IQR]	3 [1, 5]
Primary diagnosis	
Type 1 diabetes	103 (100)
DKA	3 (3)
Medicines	
Had insulin only	90 (87)
Had insulin and other medicines	13 (13)
Cadre of prescriber	
Medical officers	2 (2)
Registrars	49 (48)
Medical consultants	52 (50)

4.1.2 Insulin formulations and types of administration devices

All the diabetic patients were on insulin which was administered subcutaneously. Most of them (65%) had a prescription of two types of insulin and the rest one type. Soluble insulin (Humulin R®) was the most commonly prescribed (33.5%). Most of the participants (98%) used one device for insulin administration while the rest used two injection devices at any one given time. The syringe was the most commonly used device with a prevalence of 89 (86%). Table 4.2 summarizes the insulin formulations prescribed and the injection devices used by the patients.

Table 4.2: Insulin formulations prescribed and injection devices

Department	Type of insulin	Generic name	Brand name	Frequency(percentage)
Out patient	Rapid acting	Insulin Lispro	Humalog®	14 (9)
		Insulin Aspart	NovoRapid®	3 (2)
	Short acting	Soluble insulin	Humulin R®	47 (31)
	Intermediate acting	Isophane/NPH	Humulin N®	28 (19)
	Long acting	Glargine	Lantus®	15 (10)
		Determir	Levemir®	6 (4)
	Premixed/Biphasic insulin	Biphasic isophane insulin	Mixtard 70/30®	38 (25)
Inpatient	Short acting	Soluble insulin	Humulin R®	10 (53)
	Long acting	Determir	Levemir®	2 (10)
	Premixed/Biphasic insulin	Biphasic isophane insulin	Mixtard 70/30®	7 (37)
Administration device	Syringe			89 (86)
	Pen			14 (14)

4.1.3 Prevalence of insulin prescribing errors

Because there were only 12 treatment sheets generated in the wards, the data obtained from the outpatient and inpatient departments were combined for assessment of prescribing errors. At least one error was found in a majority of the prescriptions/treatment sheets reviewed (69%). In the outpatient department, 64 (70%) out of the 91 prescriptions reviewed during the cross sectional study had an error. In the prospective study, 7 (58%) out of the total 12 treatment sheets reviewed in the inpatient department had an error. Figure 4.3 summarizes the episodes of insulin prescription errors identified per department.

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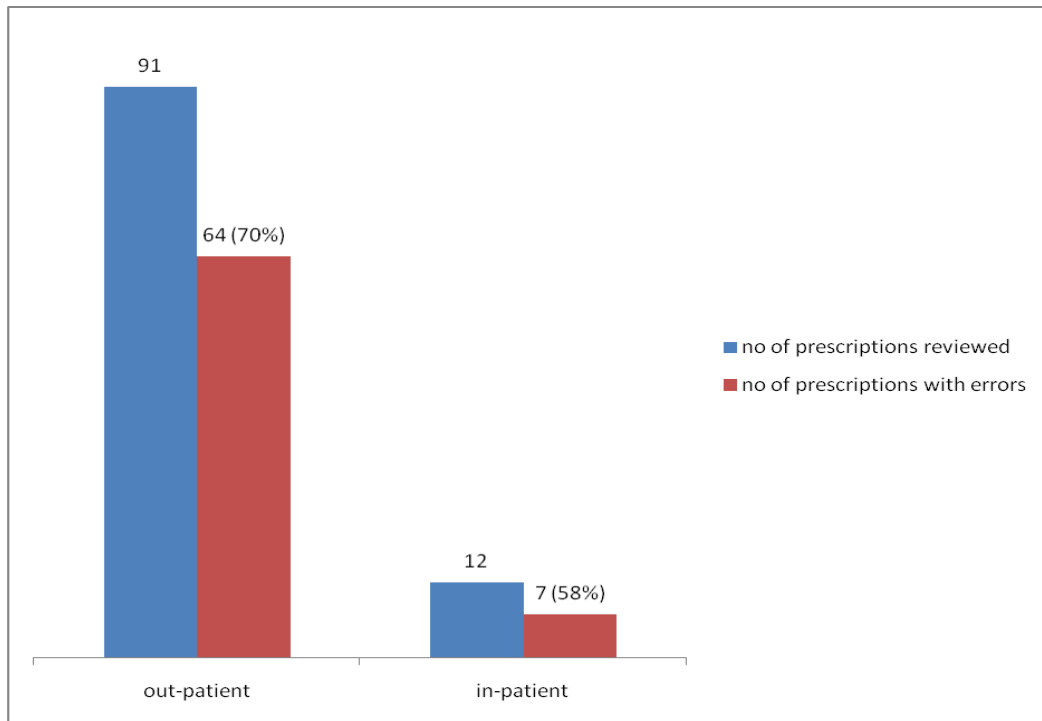
Figure 4.3: Proportion of prescriptions with errors per department

Use of dangerous abbreviations and route errors were the only prescribing errors identified during the prospective study. Where they existed, they were propagated throughout the period of the patient's admission. Most of the prescriptions/treatment sheets 57 (55%) had one error. Figure 4.4 summarizes the episodes of insulin treatment sheet/ prescription errors identified per patient record
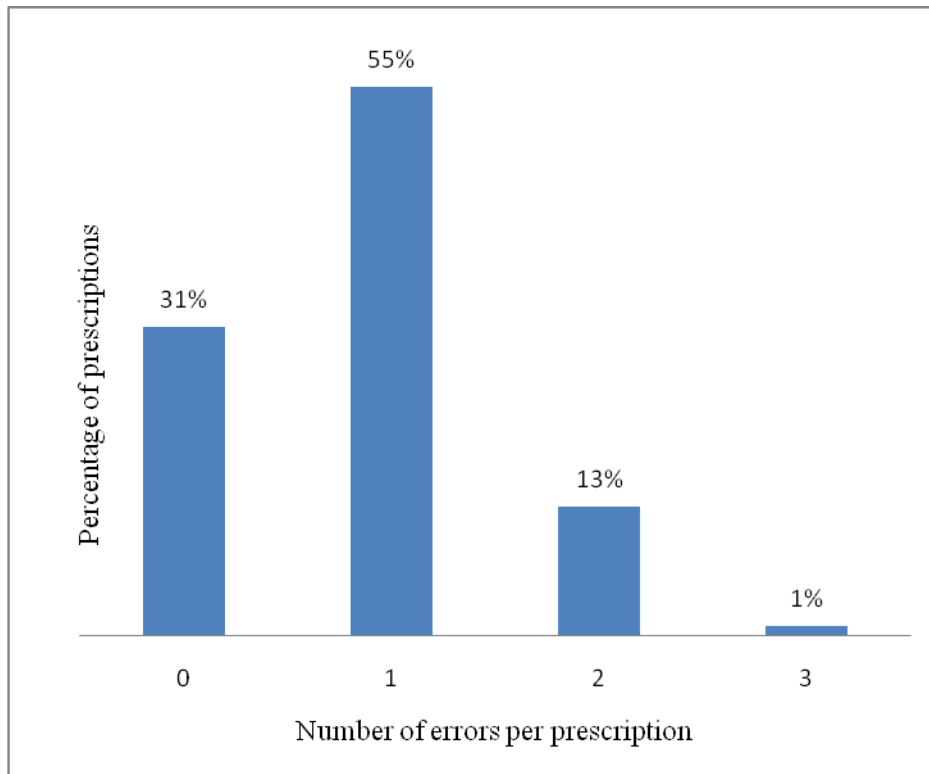
Figure 4.4: Frequency of errors per prescription

The study targeted six errors which could occur at the time of prescribing. They were listed as follows : dosing, frequency, drug ommission, route of administration, illegibility and use of dangerous abbreviation errors**.** The most common occurring error was the use of dangerous abbreviations (61%). There was widespread use of 'IU' instead of international units and 'U' instead of units during prescribing. The three types of insulin prescription errors identified were summarized in Figure 4.5.
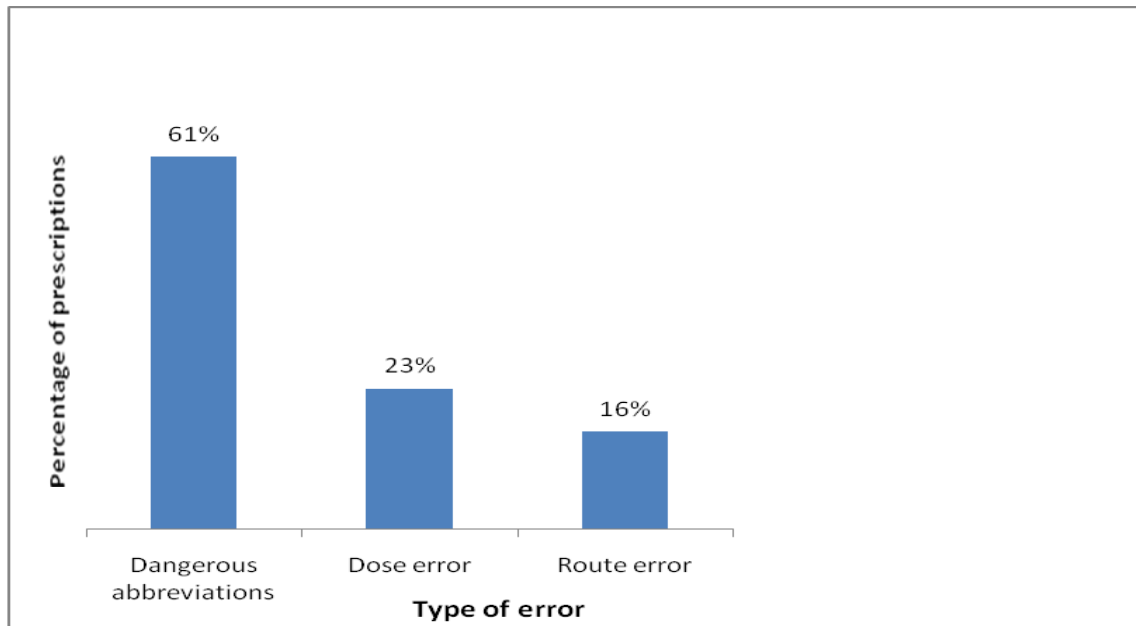
*Dose error referred to any dosage outside the range of 0.5 to 2 international units/kg/day. Route error referred to either a missing or wrong route of administration. Dangerous abbreviation referred to use of abbreviations like the "IU" to refer to international units.

Figure 4.5: Types of insulin prescription errors

A medication error rate was calculated based on the Roy *et al*, 2006 formula (25) and found to be relatively high at 14.2%.

4.1.4 Errors in the dispensing of insulin

Dispensed insulins were obtained and the labels analyzed to identify errors. Almost all the dispensing labels analyzed had at least one error (99%). Majority of the labels (72%) had 3 to 4 errors each. Most of the insulins dispensed from the pharmacy had only the name of the patient and the drug indicated on the label. The number of errors per patient is summarized in table 4.6.

Table 4.6: Number of insulin dispensing errors per label

No of errors per dispensing label	Frequency (percentage)
None	1 (1%)
1-2	6 (6%)
3-4	74 (72%)
5-6	21 (21%)

A total of 415 dispensing errors were identified. The most common error was the failure to indicate the frequency of insulin use 96 (23%). The dispensing error rate was computed from the total 918 opportunities for dispensing error and found to be 45.2%. The pie chart in figure 4.6 summarizes the various dispensing errors observed.
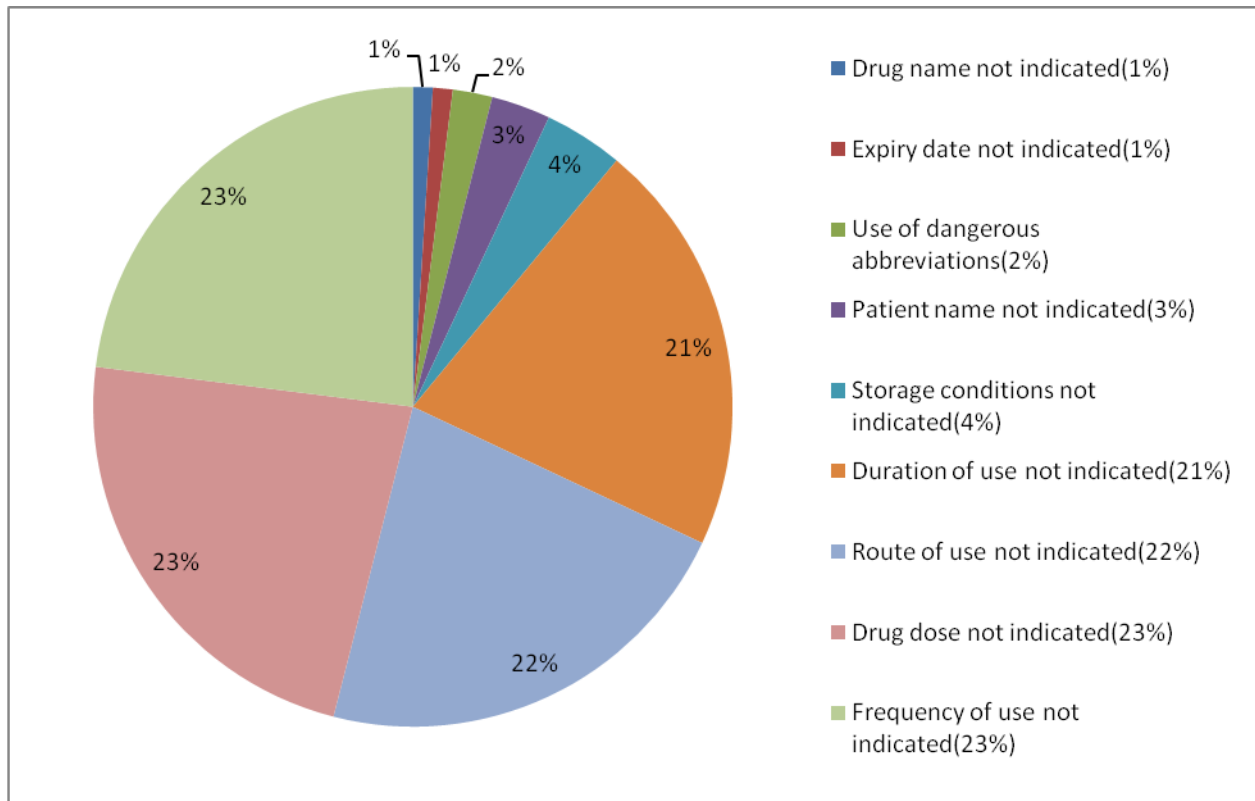
Figure 4.7: Proportion of dispensing errors identified

4.1.5 Monitoring of blood sugars

Inpatient department

The study monitored the patient's blood sugar level readings on daily basis from admission to discharge. In all the patients, regular blood sugar tests were requested and conducted within 24 hours. The least number of glucose level readings obtained from a single patient was 13 while the maximum number was 36. These patients were admitted for 5 and 12 days respectively.

The frequency of monitoring was 8 to 12 hourly. The lowest blood sugar level recorded was 2.1mmols/l and the maximum 41.4mmols/l. The mean blood sugar level at admission and discharge was 22.9mmols/l and 6.3mmol/l respectively. All the patients admitted experienced hyperglycemic episodes while hypoglycemic episodes were reported in only 2 (17%) of the

patients. HbA1C was requested for only 3 (25%) of the patients. It was however conducted for only one patient within the first week of request. The participants who were discharged during the study period had their blood sugar levels within the normal range of 4 to 7 mmols/L, an indication that proper sugar control was achieved during their hospital stay. The findings of blood glucose level monitoring are summarized in table 4.7.

Table 4.7: Blood glucose monitoring summary

Department	Variable	Frequency(percentage) n (%)
Inpatient		
	Number of patients	
	Admitted	12 (100%)
	Discharged	8 (67%)
	Duration of admission in days	
	Mean (SD)	9.1(2.8)
	BSL readings for a single patient	
	Maximum	36
	Minimum	13
	Overall blood sugar levels	
	Median [IQR]	10 [7,17]
	Admission BSL(mmol/l)	
	Mean(SD)	22.9 (5.6)
	Discharge BSL (mmol/l)	
	Mean(SD)	6.3 (0.4)
	BSL episodes	
	Hyperglycemia	12 (100%)
	Hypoglycemia	2 (17%)
	BSL normal days	
	At least one normal BSL day	8 (67%)
	No normal BSL day	4 (33%)
outpatient		
	Logbook	
	Present	72 (79%)
	Absent	19 (12%)
	Logbook status	
	Up to date	50 (69%)
	Not up to date	22 (31%)

*BSL- blood sugar levels

Outpatient department

In the outpatient department, patients were required to have blood sugar level recording log books. Blood sugar levels were supposed to be measured and recorded at home on daily basis. Most of the patients studied 72 (79%) had logbooks. However, the study established that only 69% of the logbook records were up to date.

4.2 Part 2: System and Process factors that contributed to insulin use medication related problems

To identify the system and process factors that could contribute to insulin use medication related problems, interviews were conducted with 15 health care workers. Majority of those interviewed had worked for at least 5 years in the institution. Table 4.7 summarizes the baseline characteristics of key informants.

Table 4.8: Baseline characteristics of interview participants

Characteristic	Frequency (percentage) n=15
Sex	
Male	7 (47)
Female	8 (53)
Cadre	
Medical doctor	4 (27)
Pharmacist	5 (33)
Nurse	6 (40)
Number of years worked in KNH	
0-5	7 (47)
6-10	6 (40)
11-15	1 (7)
16-20	1 (7)

Participants identified the gaps and the areas of improvement to minimize or eliminate insulin related medication errors. Seven themes emerged from the interviews.

4.2.1 Lack of standard insulin use guidelines

Majority of the interviewed staff reported that there were no standard insulin use guidelines within the hospital. There was generally a lack of awareness of any set of guidelines for use among the health care workers and where the guidelines were reported, their use was not evident.

"I can't remember the name but there is a blue book that we were given during a two day induction. I think that book should be a form of standard operating procedures". "It's a big book on management of diabetes and its complication."[**Interviewee1, medical doctor**]

"We use the ISPAD (International Society for Peadiatrics and Adolescent Diabetes) guidelines. These are the guidelines we routinely refer to" [**Interviewee 2, medical doctor**]

"I have not seen any guidelines. I don't really refer to any guidelines. I deal mostly with the aseptic technique of handling insulin."[**Interviewee 4, Nurse**].

"*What guidelines? I don't think so; there are no insulin use guidelines in Kenyatta apart from the usual dispensing guidelines which apply to all medicines. What we normally use are the international booklets like the British National Formulary for the dosing. There are no guidelines."* [**Interviewee 9, Pharmacist**]

The guidelines reportedly used by the clinicians were not the same across the facility. Some staff members reported that they used reference materials such as the British National Formulary.

4.2.2 Lack of an inpatient diabetic care management team

Most of the staff members interviewed reported that there is diabetic care management team in the hospital outpatient department. The team is said to be composed of nurses and clinicians. It was highlighted that pharmacists were not members of the team. The in-patient department did not have a diabetic care management team.

"In the wards, I don't know about any other patient care team. I think our patients come to the wards, we treat them and they go home. We do not know whether there is any other team which is interested in the patients. May be there is a team. For us we are a silent team. I don't know whether there is another team." [**Interviewee 12, medical doctor**]

"There is a team, which is facilitated by those dealing with diabetes type 2 in outpatient Clinic number 17. The members are endocrinologists and nurses. The pharmacists are missing in the team. I have never seen a pharmacist there and I do not know the reason. May be they should be part of the team. I think there should be an inpatient team too."[**Interviewee 4, Nurse**]

"There is an outpatient team composed of nurses and endocrinologist doctors. I only know of those two. The doctors review the patients and nurses do the counseling. The nurses talk to the parents and teach them on the food, how to administer insulin, storage and where to get glucometers."[**Interviewee 5, Nurse**]

"*There is a team of consultants and nurses. The members are from the outpatient clinic. Their roles, I think they should know better. But if you call them, they come to manage the patient in the wards. They show them how to administer insulin, issues of diet and where to get glucometers. But sometimes you call them and they are not available. We need an in-patient team which will always be available even at night and over the weekends."* [**Interviewee 6, Nurse**]

"Yes, there is a team based in clinic 23. I have talked to the people there and we have purposed to have a meeting to know how we can face the challenges of diabetics in the in-patient department but we have not sat down to discuss the issue. The team has doctors (consultants) and nurses specialized in diabetes care. There is a team of about 7 and they say that a pharmacist should be involved. We are still on the talks especially for the inpatients." [**Interviewee 8, Pharmacist**]

There was no inpatient care team to handle the patients in the wards instead of relying on those in the outpatient who were not always available especially at night and over the weekends.

4.2.3 Shortage of resources within the hospital

Some participants acknowledged that the technical evaluation committee had made efforts to procure a wide range of insulins. Insulin pens and cartridges were available in the hospital. However, the shortage of some devices like glucometers and insulin pumps was highlighted as a challenge in the management of pediatric diabetes patients. This was attributed to funding

constrains experienced by the public health facility. Some participants felt that insulin pens and cartridges should replace the needles and vials.

"*For the glucometers, we have challenges but the strips should be readily available. We have a good range of insulins however sometimes they go out of stock. I know pumps exist but I haven't seen them. How expensive they are, I don't know. Am thinking that, for us to stock them we have to consider the monetary factors. Our patients are quite needy and stocking expensive items may be a challenge.*" [**Interviewee 10, Pharmacist**]

"*During our formulary review, quite a number of the insulins were added. I think we almost have all the insulins we need. We are okay, the only problem is that at some point we get stock outs. Even the devices, we have the pens, the vials and the cartridges, they are there. But for pumps, I don't think so; the hospital may need to allocate more finances for that.*" [**Interviewee 9, Pharmacist.**]

If it were possible all the available insulins and devices in the market should be stocked. But given this is a public hospital, it's a bit difficult, there is always the challenge of inadequate resources. There is a technical evaluation committee that decides the drugs to be stocked. Pens are available. Am not aware of the availability of pumps, the hospital should procure some so that we can see how useful they are". [**Interviewee 7, Pharmacist**]

"*I think pens and cartridges instead of needles and vials should always be availed. They are more safe, efficient and more friendly. Instead of going around with needles and vials, it's challenging and these are school going children. The hospital should provide enough resources to ensure that these items are always available.*" [**Interviewee 2, medical doctor**]

"*Insulin pumps are required and I am not sure but I think that they are only in the ICU (intensive care unit). We do have the pens. We order from the pharmacy. Sometimes however, the pharmacy does not stock all the insulins prescribed.*" [**Interviewee 15, Nurse**]

Lack of continuous training of health care workers

Most of the interviewees expressed the need for further training and job aids to build their knowledge on the management of diabetic patients and the use of insulin. Some said that the knowledge obtained at tertiary level alone was not enough and that there was need for

continuous training on the available insulin products in the market, the devices and how to use them. The training needs to include dosing, handling of insulin, dose titrations, transitioning from one insulin to another, prescription screening and interpretation of sugar levels.

"We need a lot of training as majority of the staff have challenges in handling insulin. There should be charts. An observation chart to show how to handle the sugars should be availed. Training on diabetes management should be done to all nurses. I don't know why they choose to train specific people. All of us need training."[**Interviewee 6, Nurse**]

"*We need training, training on dosing. Dosing is a challenge especially during insulin initiation, Titrating and the transitioning from one insulin to another. It's a big challenge. This things need to be written down in a protocol and then training of the staff be done well. There should a trained person to keep screening the prescriptions; I think there is no one specifically looking at the dosing."* [**Interviewee10, Pharmacist**]

"I think staff in this hospital especially in the pharmacy need a lot of training on how to handle insulin. We need to be given the opportunity to train some cadres especially in the Pharmacy. Sometimes you make an error in the prescription and realize when the patient has already left. The pharmacy will not call you to clarify the issue. Lucky enough majority of our patients are enlightened and mostly know their insulin and the dosages well." [**Interviewee11, medical doctor**]

4.2.5 Lack of proper dissemination of standardized error reporting system

There was poor dissemination of the standard medication error reporting system within the facility. The pharmacists reported to be aware of the reporting procedures while the nurses seemed to be unaware. Some said they call the doctor involved directly; others record at the back of the prescription while some said that after correction of the errors they saw no need to record the errors.

Errors are there, if for example you come across a prescribing error, you correct with the prescriber. There are no books for recording, they are very rare. And even if they are there, I have never recorded anything on them. [**Interviewee 4, Nurse.**]

"There are errors sometimes, if the one prescribing does not know what to do, you may find a child given an under dose or overdose. Sometimes you find someone has prescribed once daily. What we do is this, if you don't know the doctor or the consultant, we consult the seniors, the specialist. We have the communication book where we can also record. Sometimes we communicate directly to the doctor involved or we just discuss amongst ourselves and make the corrections. We need a standard way of doing things" [**Interviewee 5, Nurse**]

"Yes, we experience quite a number of medication errors and we normally record. We encounter a lot of errors. Like yesterday we had one where the doctor had written insulin; he had not specified the brand, he had just written humulin. That was actually for a pediatric patient. I think we documented the error. There is a format for reporting medication errors, not in a book. There is a form for recording. Once filled, the form goes centrally; there is a medication error team. Dr A. is in charge of that. We send them to her for further analysis." [**Interviewee 13, Pharmacist**]

"Yes, we see some insulin related errors. There is an intervention book for recording errors. On our side we control the treatment sheet. When we are dispensing we look at the dose and if there is a query we go to the internet to confirm. We can write a note to the doctor due to the workload or we can call and see the way forward. It would have been much better if we had clinical pharmacists going around looking for such errors because that would have been their work. Shortage of staff is real."[**Interviewee 7, Pharmacist**]

The hospital had books and forms for recording medication errors. It seemed that there was need to educate the staff on the importance of recording the errors. There was also need for the hospital to actively act on reported errors.

4.2.6 Lack of special education for the caretakers, parents and teachers

Majority of the interviewees especially the medical doctors and the nurses reported that the hospital had a role to play in educating the caretakers, parents and teachers of the children. Staff members reported that the biggest challenge they faced in ensuring proper use of insulin and management of diabetic pediatrics was lack of adequate information for the caretakers. Some of the errors committed by care takers were: inaccurate recording of sugar levels and the failure to follow dietary instructions.

"The biggest challenge we face is that the children don't understand. You have to explain to the mother. But even after explaining to the mother, there is the teacher in school. It's difficult to reach these teachers and tell them how they should handle the children, how to inject and what to do in cases of emergency. I think the hospital can have an open day and ask the parents to inform their teachers to attend. Or at least we should have the numbers of the teachers so that sometimes we can be able to talk to them." [**Interviewee 1, Medical doctor**]

"We face a lot of challenges; the children don't want to be injected. Recordings of regular blood sugars in their booklets are not always very accurate. Diet, they don't want to follow the required diet. I think maybe we need to increase and review how the hospital does the counseling of the parents." [**Interviewee 2, Medical doctor**]

"These patients, some of them don't take the measurements of their blood sugars from home. Some have no strips; they have machines but no strips. Financial crisis, patients have no money for review and there are no mechanisms for waiving bills at the outpatient department. Children are told to go home because they have no money for review. I have just sent someone home because they have no money. They could not afford Kshs600 only. The hospital must come up with a mechanism of ensuring that the parents are educated well on their obligations and duties in the management of the children." [**Interviewee 14, Nurse.**]

"The biggest challenge is the parents, you educate them on what to give the child but they give them juices and the sugars go up. I believe as a hospital we need may be to review how we counsel the parents, or maybe increase their training." [**Interviewee 5, Nurse**]

4.2.7 Failure by pharmacists to actively participate in the management of patients on insulin in the hospital

During the interviews, it emerged that the input of pharmacists within the hospital in the management of pediatrics on insulin was minimal. Majority of the participants said that the pharmacists needed to be actively involved in the management of the patients and that their input was greatly needed. This was supported by statements such as:

"For all medication units, there should be a label printer to help print the instructions for patients. Pharmacists should be given a room in every ward for patients to be able to consult properly; I also believe that pharmacists should be stationed next to clinicians for advice where

necessary. Currently I think that as pharmacists, there is still a lot we do not do." **[Interviewee 10, Pharmacist]**

"*Because we don't usually inject the children, we do not know whether they measure the right amount. In pharmacy, the patient needs to come and we talk to them, they show you how they inject, and you see whether they know or not. We need to start that. The pharmacy staff must begin to interact with these patients more than we currently do.*"**[Interviewee 9, Pharmacist]**.

"*Instead of us calling the team from elsewhere every time there is a patient using insulin, we need to start doing it ourselves. The pharmacy should be involved. There should be clinical pharmacists assisting.*" **[Interviewee 7, Pharmacist]**

"*The pharmacists are missing in the management of these patients. They need to come out and assist where necessary.*" [**Participant 3, Nurse**]

CHAPTER FIVE: DISCUSSION

The aim of the study was to determine the prevalence of insulin prescription, monitoring, storage and dispensing errors. It also attempted to identify the factors that contributed to the occurrence of the errors and the prevalence of insulin use in the study population.

The frame work that summarizes the factors that could contribute to insulin related medication problems is presented in Figure 4.9 (9).

System factors	Process factors	Outcomes
Proper hospital governance Availability of updated guidelines, standard operating procedures and protocols Availability of resources for insulin purchase Availability of qualified and motivated staff Proper nutritional counseling services	Proper insulin use monitoring Proper blood glucose monitoring Proper pediatric patient care Proper prescribing and dispensing culture Proper child nutrition	Reduction in medication errors Improved blood glucose control

Figure 4.9: Conceptual frame work for system and process factors contributing to insulin medication related problems.

All the patients studied used insulin as the only anti-diabetic drug. This is not unique since they all had type 1 diabetes as the primary diagnosis which requires lifelong insulin therapy (36). Soluble insulin (Humulin R®) was the most commonly prescribed insulin (33.5%). This is in line with the international guidelines which requires that type 1 diabetic children and adolescents should have access to adequate amounts of at least regular and NPH insulin (36).

Diabetes ketoacidosis occurred in 3% of the population. This was relatively high compared to 1.7% established in a study carried out in Sweden (37). All the in-patients had their blood sugar levels monitored at a frequency of 8 to 12 hourly. This was an important finding since for type 1 diabetes, usually three tests daily are adequate (14). However, in resource limited settings, capillary blood glucose measurements can be carried out at least once or twice weekly depending

on physician's discretion (16). In the outpatient department, patients used logbooks to record their blood sugar levels. This was an important finding since the national guidelines recommends that blood sugar readings be recorded in logbooks (38). It helps the clinicians to know how to adjust the insulin dosages for the patients. However, lack of standard insulin use guidelines could explain why despite consistent measurements, the blood sugar levels remained high with a median of 10 mmols/L. HbA1c was requested for only 25% of the inpatients and carried out only in one patient. This could be due to the fact that this is a public facility and majority of the patients could be needy. The socio economic status of the patients could not be established but it is believed that physicians may not request for these tests as caregivers cannot afford the cost.

Majority of the prescribers were medical consultants (50%). This is a positive finding since a study by Eran et al (2006) found that the risk of an error was higher when the order was given by a trainee staff than when issued by a staff physician (39). At least one error was found in most of the prescriptions reviewed (69%). This is relatively high and consistent with a study carried out in the adult population within the hospital which found an error in almost all the records reviewed (21). The prevalence of medication errors was higher in the outpatient (64%) compared to the inpatient department (58%). This could be attributed to the high patient numbers in the outpatient department. Working hours may have a negative effect on physician's performance. Staff who work for fewer hours commit fewer unintentional failures (39). Lack of standard treatment guidelines and continuous staff training on insulin use could also have contributed to the high number of prescription errors found.

Use of dangerous abbreviations during prescribing was the most common occurring error with a prevalence of 61%. This could be attributed to lack of job aids like the list of dangerous abbreviations to be avoided. Use of abbreviations is a potent source of errors and can lead to serious harm if the error reaches the patient (39). The medication error rate was to be 14.2%. This is relatively high and compares with an error rate of 19.2% established in the adult population in a previous study carried out in the same hospital (21). A medication error rate greater than 5% is suggestive of a system problem and requires that measures be put in place to minimize or eliminate the errors (25).

The incidence of dispensing errors was very high at 99%. Most of the dispensed insulins (72%) had four errors per label. It was however difficult to find a local study on insulin dispensing

errors for comparison. This could be attributed to the fact that in the Kenyan context, dispensing errors are rarely evaluated. This study could be the first in the African region that evaluates errors in the dispensing system. Incidences of dispensing errors vary depending on the dispensing system adopted by an institution (40). A dispensing error rate of 45.2% was computed. Most of the dispensing labels reviewed had only the name of the patient and the drug. The high error rate of above 5% established could be an indication of a system problem which needed to be addressed. Lack of standard insulin use guidelines could have contributed to the high error rate found. The dispensing pharmacy personnel could also have failed to embrace the expanded role of pharmacists in provision of care as opposed to simply being sellers of drugs.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The prevalence of insulin prescription errors was high at 69% while all the dispensed insulins had at least one error per label. The hospital was found to have inadequate patient safety systems in place prevent these errors. There is hence need for the hospital to put measures in place to minimize the occurrence of such errors.

6.2 Study limitations

The study could not achieve the target sample size for the in-patients. This was due to the small number of hospitalized pediatric patients. Universal sampling was done in both outpatient and inpatient departments in an attempt to achieve the desired sample size. The prevalence of prescription errors in the inpatients may not be representative due to the small sample size studied. It was also difficult to measure some parameters like the duration of insulin use and co morbidities because of poor recording by clinicians.

Some of the factors such as the age, gender and years of experience of prescribers which may have contributed to prescription errors could not be obtained. It was also not possible to link specific system and process factors to errors as data on these variables was missing. It was difficult to analyze monitoring parameters in the outpatient department because care givers use logbooks to record their blood sugar levels at home and some of them lacked consistency in recordings while others failed to bring their logbooks during their clinic visits. The study could also not appraise all the prescribed items for dispensing errors as some patients opted not to buy from the hospital pharmacy. It was also not possible to identify the cadre of those who dispensed in the pharmacy a factor which could have contributed to errors. There was a risk of bias arising from the selection of HCWs during the study. This was minimized by comparing the information provided by the participants to what was documented or available in the hospital.

6.2 Recommendations for policy and practice

There is need for the hospital to put measures in place to minimize these errors and improve on patient safety. The following recommendations are made to the hospital management based on the findings of the study.

1. The hospital should develop standard insulin use guidelines and disseminate the same to ensure that all health care workers are aware of these guidelines and can routinely refer to them where necessary.

2. Hold regular continuous medical education sessions for health care workers to build their knowledge on the management of diabetic patients and the use of insulin.

3. Form an all inclusive inpatient diabetic management care team with clear roles to manage diabetic inpatients.

4. Have ward based pharmacists who can help identify and intercept prescribing errors to enhance patient safety.

5. That the hospital develops systems and tools for error reporting and disseminates the same to health care workers to aid in identification, reporting and minimization of medication errors.

6. That the hospital allocates enough resources to ensure adequate supply of pharmaceuticals, non pharmaceuticals and that insulin pens and cartridges replace the needles and vials.

7. Computerized generation of prescriptions should be tested and used throughout the hospital as a means of safe prescribing, error tracking and reduction

6.3 Recommendations for future research

Large prospective researches carried out over a longer duration of time to determine the incidence, prevalence and outcomes of medication errors among pediatric patients using insulin across the country would be important. These researches should be designed in a manner that they are able to determine whether insulin related medication errors could have led to mortalities. The studies should also be carried out in other public hospitals in the country where there are proper measures in place to prevent occurrence of errors. This will make it possible for comparisons to be done between the public and private facilities where there are improved patient safety systems. It would also be important in identifying the association between system, process factors and the medication related problems.

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APPENDICES:

APPENDIX A :MEDICATION ERROR DATA COLLECTION TOOL

STUDY TITLE: SYSTEM AND PROCESS FACTORS THAT CONTRIBUTE TO MEDICATION RELATED PROBLEMS IN PEDIATRIC PATIENTS ON INSULIN IN KENYATTA NATIONAL HOSPITAL

A) Records eligibility check list, (Tick as appropriate).   Date……………………..

	Y	**N**
1. Belongs to diabetic patient aged 18yrs and below		
2. Contains any insulin formulation		
3. Seen in KNH between April-June 2017		

B) Exclusion criteria (tick as appropriate)

	Y	N
1. Does not meet the eligibility criteria		
2. Insulin is prescribed to a non diabetic patient		

C) Patient details (from patient records).

Patient code_____

Department	Outpatient ☐		
	Inpatient ☐	Date of admission	Date of discharge
Age	Sex	Weight	
	Male ☐	Female ☐	
Diagnosis			
Year diagnosed with diabetes		Duration since diagnosis with diabetes (months)	

C. Details of insulin	

Brand name	A(Name)	
	B(name)	
	C(name)	
	Other(specify)	
Route of administration	Subcutaneous	☐
	Intravenous	☐
Device used for administration	Pen	☐
	Syringe	☐

D. Co-prescribed medications				
No.	Name	Dosage	Frequency	Duration

Cadre of prescriber	Clinical officer intern	☐
	Clinical officer	☐
	Medical officer intern	☐
	Medical officer	☐
	Registrar	☐
	Consultant/Specialist	☐
Is the above prescriber the same as that who prescribed insulin?	Yes	☐
	No	☐

F) Prescribing error:

Calculation of insulin dose: insulin dosage varies from patient to patient. For purposes of this study, the following range will be used.

Weight in Kgs………

Lower limit daily dose = (0.5 x weight in Kgs) international units

Upper limit daily dose = (2 x weight in Kgs) international units

Calculated range …………

Actual prescribed dose………….

Does the prescribed dose lie within the calculated range Yes ☐   No ☐

Indicate Yes (Y) if error is present or No (N) if no error.

Error code	Error description	Y	N
1.	Frequency error (wrong frequency/ frequency not indicated)		
2.	Omission error (drug not prescribed).		
3.	Route error(route missing/ wrong route)		
4.	Illegibility of prescription(illegible prescription)		
5.	Use of dangerous abbreviations(use of U or IU)		

Briefly describe the error (s) observed………………………….

G) Monitoring error

Random blood sugar

a) Has random blood sugar (RBS) test been requested?   Yes ☐ No ☐

b) Has the RBS test been done within 24hrs after the request? Yes ☐ No ☐

c) What is the frequency of RBS test? (Tick one from below)

Hourly   ☐   4-6hrs   ☐   8-12hrs   ☐   24hrs   ☐

Weekly   ☐   twice weekly   monthly   Others

HbA1c (glycated hemoglobin) test

a) Is there evidence of HbA1c test request? Yes ☐   No ☐

b) Has the requested HbA1c test been carried out in the last 1 week? Yes ☐   No ☐

c) What is the frequency of the HbAIc…………………..

Fill the readings of the RBS and the HbAIc in the table below

	Day 1	Day 2	Day 3	Day 4	Day 5
RBS levels					
HbAIc levels					

H) Dispensing errors (use the label for dispensed items)

Error code	Error description	Y	N
1.	Is the correct name of the drug clearly indicated?		
2.	Is the name of the patient indicated?		
3.	Is the right dosage clearly indicated?		
4.	Is there use of dangerous abbreviations (U or IU)?		
5.	Is the right frequency indicated?		
6.	Is the right route of administration indicated?		
7.	Is the right duration of use indicated?		
8.	Are the correct storage conditions indicated?		
9.	Is the expiry date indicated?		

Frequency of insulin use

Frequency of insulin use varies due to a number of factors. For purposes of this study, the right frequency will be determined using the table below.

Insulin preparation	Duration of action	Injections per day
Short acting(soluble)	6-8hrs	30 minutes before meals
Biphasic mixture 30/70	14-16hrs	Twice

APPENDIX B. INTERVIEW GUIDE

STUDY TITLE: SYSTEM AND PROCESS FACTORS THAT CONTRIBUTE TO MEDICATION RELATED PROBLEMS IN PEDIATRIC PATIENTS ON INSULIN IN KENYATTA NATIONAL HOSPITAL

Serial No_____   **Version 01   June 2017**

Introduction: My name is Dr Kimaile Benjamin and I am carrying out a study titled "System and Process factors that contribute to medication related problems in pediatric patients on insulin in Kenyatta National Hospital."

I would appreciate your contribution in the study by responding to various questions during the interview.

Purpose of the interview: I would like to identify the factors that may contribute to insulin related medication problems among pediatric patients in Kenyatta National Hospital. I would therefore wish to obtain your views on system and process factors that may contribute to insulin related medication problems in this population.

General Background:

1. Cadre   gender

2. Kindly tell me the position you hold in the unit and for how long you have worked in the hospital.

3. Do you directly deal with diabetic pediatric patients?

Interview topics:

 System factors

1. What guidelines or standard operating procedures do you use in management of Paediatric diabetic patients?
2. Do you routinely refer to the guidelines or SOPs?

3. What documents, policies or job aids on dosing or use of insulin do you have that facilitate its safe use?

4. Is there a diabetic care management team?

   Probe: if yes please give me information on its composition, roles and functions?

Process factors

1. How do you monitor insulin therapy?

2. Have you encountered any medication errors in the course of your work?

   Probe: a) If so, how did you document or report?

   b) Any errors involving insulin?

   c) Any safety measures in place to avoid errors?

3. What insulin products and/or devices do you think should be stocked within the hospital?

4. What problems do you encounter in the management of diabetic pediatric children?

5. What suggestions do you have that can aid to improve care and encourage safe handling of insulin?

Wrap up

Thank you for participating in the study. Do you think there is an area that was not well covered and you would wish to commend on?

APPENDIX C: Consent form for the interviews of health care workers.

Title of the study: system and process factors that contribute to medication related problems in pediatrics on insulin in Kenyatta National Hospital**.**

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

Principal investigator: Dr Kimaile Benjamin Muisyo, P.O. BOX, 30197-00400, Nairobi.

Supervisors: Prof. Faith Okalebo- Department of Pharmacology and Pharmacognosy , UoN.

                 Dr. Margaret Oluka- Department of Pharmacology and Pharmacognosy , UoN.

Ethical approval: Kenyatta National Hospital- University of Nairobi Ethical 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 research is voluntary

   ii.   You may withdraw from the study at any time without necessarily giving a reason for you withdrawal.

 iii.   After you have read the explanations, please feel free to ask any question that will enable you to understand clearly the nature of the study.

  iv.   The exercise will take about 20-30 minutes.

Study introduction: in this study, I am going to assess the prevalence of insulin use, prevalence of insulin medication related problems and factors which may lead to the occurrence of these problems in the pediatric wards and the diabetic outpatient clinic of KNH.

Purpose of the study: the purpose of the study is to determine the system and process factors that contribute to insulin related medication problems in KNH pediatric population.

Study procedures and role of participants: With your permission, I will engage you in a discussion about your perception on the hospital's pediatric patient safety environment with the intention of highlighting the factors contributing to insulin related medication errors. I will take notes of our discussion by pen and paper and if you are willing I will record using a digital voice recorder. Your voice shall be masked during the recording which will subsequently be destroyed within 72 hours. All information will be handled with confidentiality.

Benefits: Your participation in the study will not attract any direct financial benefits. It's however worth to note that your input may be of great importance in improving the quality of health care of pediatrics within the hospital.

Risks and discomforts: This is a minimal risk study. There will be no physical harm to the research participants. However, there could be some psychological risk attributed to information disclosure by the participant during the interview. This will be minimized or eradicated completely by effective confidentiality strategies. Only the principal investigator will handle the primary data that could have some elements of identifiers in it. Any other research assistants involved in data entry and analysis will handle the secondary data that will be delinked from the primary data.

Confidentiality: all information obtained from you will be kept highly confidential. Your name will not be indicated anywhere but rather codes will be used where necessary in any subsequent publications.

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

STATEMENT OF CONSENT

I……………………………………………………give consent to the investigator to interview me and use the information obtained from me in his study. Dr Kimaile Benjamin has explained the nature of the study to me.

Signature……………………………………Date……………………………….

I……………………………………………. confirm that I have explained to the participant the nature and effects of the study.

Signature…………………………………..Date……………………………….

APPENDIX D: Ethical approval letter

APPENDIX D:KNH/UON- Ethical approval letter

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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/452

16ᵗʰ November 2016

Kimaile Benjamin Muisyo
Reg. No.U51/81800/2015
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Benjamin

REVISED RESEARCH PROPOSAL- SYSTEM AND PROCESS FACTORS THAT CONTRIBUTE TO MEDICATION RELATED PROBLEMS IN PEDIATIC PATIENTS ON INSULIN IN KENYATTA NATIONAL HOSPITAL (P643/09/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 16ᵗʰ November 2016- 15ᵗʰ November 2017.

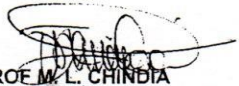This approval is subject to compliance with the following requirements:

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 serious 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 ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study.

Protect to discover

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 **http://www.erc.uonbi.ac.ke**

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 Chair, Dept. of Pharmacology and Pharmacognosy,UoN
         Supervisors: Dr.Faith Okalebo(UON), Dr.Aywak Dorothy Atieno (KNH), Dr. Monica Karara(JKUAT)

Protect to discover

APPENDIX E: Study registration certificate

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR KIMAILE BENJAMIN MUISYO

2. Email address: kimailemuisyo@gmail.com   Tel No. 0720668026

3. Contact person (if different from PI)..

4. Email address: ....   Tel No. ....

5. Study Title
   System and process factors that contribute to Medication related problems in pediatrics patients on Insulin in Kenyatta National hospital.

6. Department where the study will be conducted ...... Pediatric department
   (Please attach copy of Abstract)

7. Endorsed by Research Coordinator of the Department where the study will be conducted.

   Name: .... Signature .... Date ....

8. Endorsed by Head of Department where study will be conducted.

   Name: ...Dr. Irimu... Signature .... Date 3.o.l.u.l.6

9. KNH UoN Ethics Research Committee approved study number P6+F3|09|2016
   (Please attach copy of ERC approval)

10. I Kimaile Benjamin Muisyo _____ commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.

    Signature........................... Date 30|11|2016

11. Study Registration number (Dept/Number/Year)_____ Paedratrics / 79 / 2016
    (To be completed by Research and Programs Department)

12. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital **must** be **registered** with the Department of Research and Programs and investigators **must commit** to share results with the hospital.

Version 2: August, 2014

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