DRUG RELATED PROBLEMS AMONG PATIENTS IN THE CRITICAL CARE UNIT OF KENYATTA NATIONAL HOSPITAL

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U56/88494/2016

A Dissertation Submitted in Partial Fulfilment for the Degree of Master of Pharmacy in Clinical pharmacy in the School of Pharmacy of the University of Nairobi

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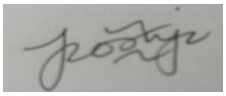
Signature……  ……. Date…19th November 2021

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ABBREVIATIONS AND ACRONYMS

ADE Adverse Drug Events

ADR Adverse Drug Reactions

ASHP American Society of Hospital Pharmacists

CKD Chronic Kidney Disease

DI Drug Interaction

DWI Drug Use Without Indication

DRP Drug Related Problem

DTP Drug Therapy Problem

ERC Ethical and Research Committee

FTD Failure to Receive Drug

HEALTH CARE PROVIDER Physician or Nurse

ICPS International Classification of Patient Safety

ICU Intensive Care Unit

IDS Improper Drug Selection

KNH Kenyatta National Hospital

MRP Medication Related Problem

NCC-MERP National Co-ordinating Councilfor Medication Error Reporting and Prevention.

OD Overdosage

Pi-Doc Problem intervention Document

PCNE Pharmaceutical Care Network Europe

STD Sub-therapeutic Drug Dosage

OPERATIONAL DEFINITION OF TERMS

Co-morbidities- Is the presence of an extra medical condition(s) concurrently with a primary disease and which require long-term treatment

Drug therapy problem- A drug therapy problem is any undesirable event in a patient that involves, or suspected to involve drug therapy and interferes with the health outcomes and requires a professional judgment to resolve. Also sometimes referred to as 'Drug related problem' or' Medication related problem' or also known as 'Medication Therapy problem'.

Pharmaceutical care: Is a practice in which a practitioner (clinical pharmacist) takes responsibility and accountability for a patient's drug-related needs.

Prevalence: The number of cases of a disease existing in a given population at a specific period of time (period prevalence) or at a particular moment in time (point prevalence).

Polypharmacy: Is the use of three or more medications on a patient. Has also been defined as use of at least five medications.

ABSTRACT

Background: Drugs are usually prescribed with the intention of achieving desirable therapeutic outcome(s), and alleviate patient suffering. However, the use of drugs more often than not may cause undesired outcomes, commonly known as drug/ medication related problem(s). Critically ill patients tend to be at risk of drug related problems due to a number of factors, such as the state of illness, polypharmacy, inability to participate in their care among others.

Study objective: This study aimed at characterizing drug therapy problems and their contributory factors in patients admitted in intensive care unit of Kenyatta National Hospital (KNH).

Study design and participants: A cross-sectional design study was conducted at the three critical care units of KNH and 87 participants were involved. Most of the data were abstracted from the patient records using a predesigned data collection tool. Simple random sampling with replacement was used to select the participants. The data were entered into Microsoft Excel 2010 and analyzed using STATA version 13.0. Descriptive and inferential analyses were conducted and results summarized in tables and charts. The p-value was set at 0.05.

Results: The prevalence of DRPs among patients admitted in the ICU of KNH was 59.77 Percent. The major different types of DRPs and causes identified in the study are high dosage (5.75%), adverse reactions (6.9%), needs additional drug therapy (16.1%), drug interactions (19.54%) and noncompliance (26.44%). There was a significant association of drug therapy problems with co-morbidities (p=0.013) and class of drugs (p=0.010), anticonvulsants (p=0.02), antimicrobials (p=0.010), polypharmacy (p=0.001), and multiple prescribers (p=0.01).

Conclusion: The prevalence of DRPs was high. Polypharmacy, multiple prescribers and renal problems were independent predictors of DRPs.

Recommendation: Compliance to medicines among patients in critical care unit should be enhanced. The causes of non-adherence should be investigated and addressed.

CHAPTER ONE: INTRODUCTION

1.1 Background

Drugs are usually prescribed with the intention of achieving therapeutic outcome (s), and alleviate patient suffering. The main objective of medication use is to optimize drug therapy with minimum safety problems/concerns with the framework of pharmaceutical care plan. Pharmaceutical care focuses on optimizing drug therapy within realistic costs and improves the patient's health related quality of life. However, the use of drugs more often than not may cause undesired outcomes, commonly known as drug/ medication related problem (s). A drug therapy problem (DTP) is any undesirable event experienced by a patient that involves, or is suspected to involve drug therapy, and that interferes with the desired goals of therapy and requires professional judgment to resolve the occurrence of DRPs .DTPs result from a patient's drug related needs that have not been fully met, and these forms the basis for pharmaceutical care practice. DTPs can be considered clinical problem that needs to be identified, treated or prevented. According to Hepler and Strand, there are eight categories of drug related problems namely: Untreated Indications(UI), Improper Drug Selection (IDS), Sub-therapeutic Dosage (STD), Failure to receive Drugs (FTD), Overdose (OD), Adverse Drug Reactions (ADR), Drug interactions (DI) and Drug Use Without Indication (DWI) (2) (3). Critically ill patients tend to have more drugs prescribed to them than the average patient.

Polypharmacy is a risk factor for drug related problems as it has been found to increase drug-drug interactions(4)(5). Due to their state of illness, these patients tend to require dose adjustments, which call for calculations that may result in arithmetic errors(6). The complexity of their treatment, coupled with their state of health and inability to participate in their treatment among the majority of these patients means that they are more vulnerable to DTPs than the average patient. Critically ill patients are a population at high risk for more frequent and more severe medication-related events. Critically ill patients receive twice the number of medications that non-critically ill, hospitalized patients receive, thus increasing the opportunity for adverse drug events to occur. ICU patients are more likely to have drug-drug interactions, drug accumulation due to failing organs, and a sensitivity to drug responses resulting from their labile

status. The complexity of the patients' treatment plans and the environment provide a risk for patient harm.

Critically ill patients are also more likely to develop drug-induced events such as acute kidney injury and coagulopathies. Even though healthcare professionals are very concerned about the patient safety, mistakes or errors unavoidably occur especially in a complex setting like the ICU(6). A study carried out in Saudi Arabia found that 3.6% of all admissions in the ICU were due to DRPs (7). In 2015, a similar study conducted in the ICU setting of a teaching hospital in Brazil found a drug related problem prevalence of 97.4% (8).

1.2 Problem statement

The treatment of critically ill patients involves many drugs that have the potential to cause serious harm(4)(5). The state of health of this group of patients, who are likely to have decreased renal and hepatic function makes them more susceptible to DTPs (6). There are several stages in the medication process, from the supply of drugs and their storage in the clinical area to drug prescription, preparation, administration and monitoring the response to treatment. The multiple risks in each of these stages have resulted in many reports of medication-related harm or potential harm to critically ill patients.

In the KNH ICU, there was a marked reduction in mortality over the last four years, from 42.9% to 35.2%. However, this mortality rate was still quite high compared to ICUs in more advanced countries. Statistics on morbidity are not available currently, since they have not been routinely done. Administration of drugs, as anticipated is done by the nursing staff, with infusions been prepared at bedside. A similar study carried out among patients with chronic kidney disease (CKD) in the same hospital found a high prevalence of DRPs (2 to 6) for every patient studied. CKD patients tend to have some similar traits as most of the critically ill patients, such as compromised drug excretory capacity as well as being put on multiple drugs for their complex medical needs. It was important to carry out a study on this critical patient population to determine whether DRPs have a bearing on the high mortality rates recorded, with the aim of improving on patient outcomes.

1.3 Purpose of the Study

There was limited information on the extent of drug related problems in critical care in Kenya and in Sub Saharan Africa in general. Considering the impact some of the DTPs can have on the patients, including but not limited to temporary harm, increased ICU stay, permanent damage or even death, it made it imperative to conduct a study on this area, to inform and improve on patient safety in our critical care setting.

1.4 Objectives

1.4.1 Broad objective:

To evaluate the drug related problems among critically ill patients in the intensive care unit of Kenyatta National Hospital.

1.4.2 Specific Objectives

The specific objectives were:

1. To determine the prevalence of DRPs among patients admitted in the ICU of KNH
2. To identify the different types of DRPs and their causes.
3. To investigate the risk factors associated with DRPs among patients admitted in ICU of KNH.

1.4 Research Questions

The research questions for the study were:

1. What was the overall incidence of DRPs among patients in the ICU of KNH?
2. What were the different types of DRPs and their causes according to PCNE classification?
3. What risk factors were associated with the DRPs among patients admitted in the ICU of KNH?

1.5 Significance and anticipated outcome

The study assessed the prevalence and categories of DRPs among patients admitted in the ICU of KNH. It also sought to identify the risk factors and /or causes of the DRPs among that group of patients, and whether necessary interventions had been implemented to address the same.

The study findings guided in coming up with recommendations on how to reduce the frequency and impact of DRPs in critically ill patients in KNH, with the view of improving therapeutic outcomes.

1.6 Conceptual Framework.

Figure 1 below is adapted from the Conceptual Framework for the International Classification of Patient Safety (ICPS), 2009(9), with modifications to fit the scope of the study. It illustrates the inter-relationship between the various factors that come into play whenever a drug related problem occurs, the possible contributing/ risk factors.

These factors include patient socio-demographic characteristics, patient clinical characteristics, drug related factors and others. The factors are the predictor variables for the occurrence of DRPs and the dependent variables for the study. Drug related problems will be the outcome variable(s) (independent variable). Patient characteristics entails demographics, original reason for admission and the primary diagnosis (9). The possible contributing factors to the occurrence of the DRP either an error of omission or commission by any of the healthcare workers involved in the patient management: physician, pharmacist, nurse or nutritionist. Others are ineffective communication as well as external factors such as the work environment, and of course the patient specific characteristics such as age, state of illness, lifestyle among others.

Detection has to do with the capture of the occurrence of a DRP, which is then categorized and if need be necessary intervention undertaken. The intervention can entail discussing with the prescriber or nurse, which can lead to either withdrawal of the offending drug, change of regimen among others. Such interventions may play a role in influencing the impact of such DRPs on the patient. Outcomes could either be harmful or not; as well as increased length of hospital stay hence increased cost of care, both to the individual and the hospital. For the organization, if a DRP led to harm or increased hospital stay it means more resources going into managing the patient. There is also a risk of legal suits or negative media coverage. Actions entailed the steps taken to prevent future occurrences and improvement on the systems.

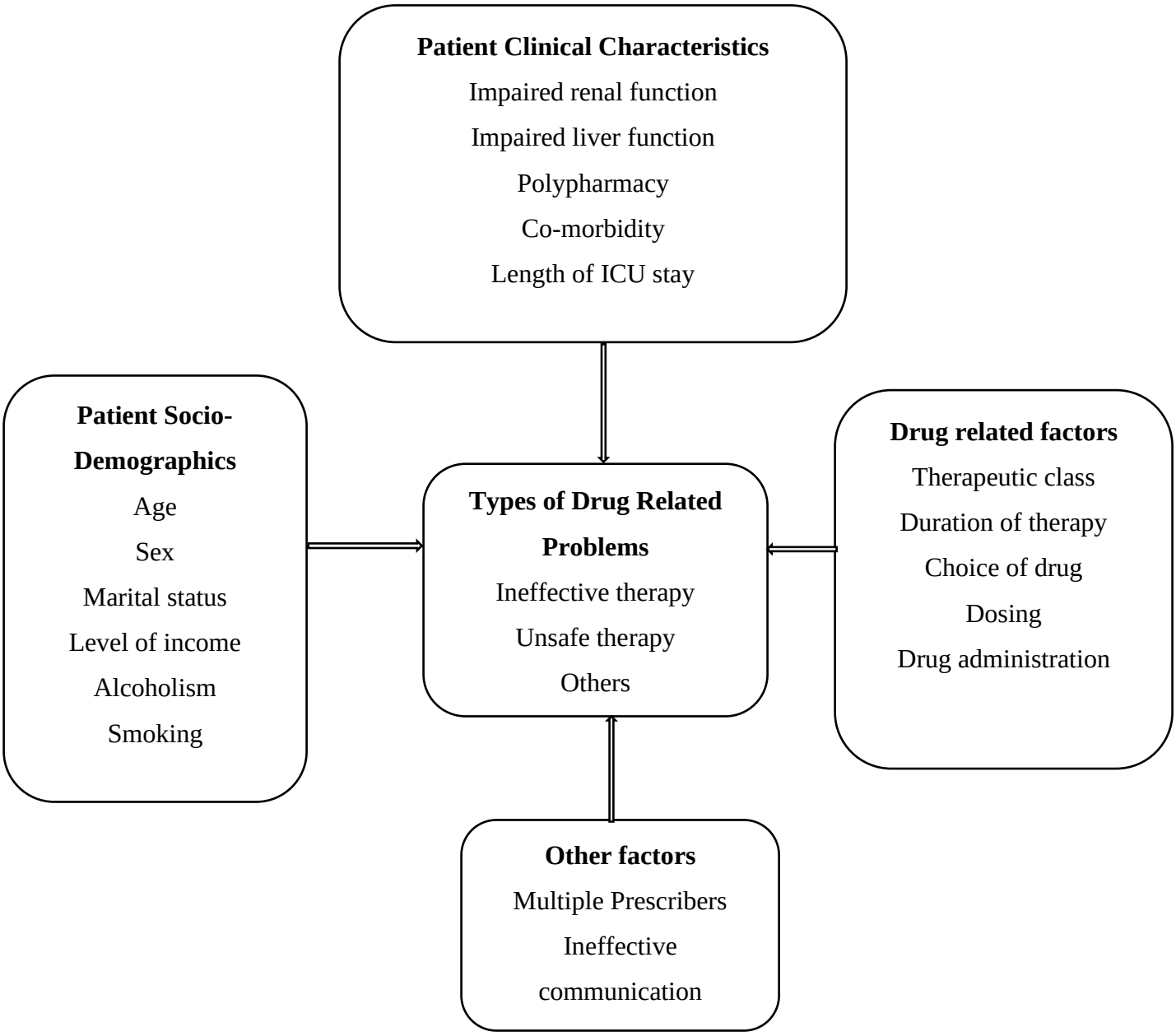

Figure 1: The Conceptual Framework

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

In this chapter is a summary of literature review on the prevalence of DRPs and their classification, the risk factors associated with the DRPs as well the impact/possible impact they have had on the studied patients.

2.2 Prevalence of Drug Related Problems

The prevalence of DRPs has been found to be quite high among different patient populations, both in inpatient and outpatient settings. A study carried out in a neonatal ICU setting found a high prevalence of real or potential DRPs at 33.6% (10). A DRP prevalence of 21% was found in another study done in a pediatric population (11). Another study identified adverse drug events (ADE) to account for 7.5% of all hospital admissions,28% of emergency department visits and 5% of all hospital deaths. (12). ADRs were identified as the reason for ICU admission in one study (13), while in another study 6.5% of all hospital admissions (14) were attributable to DRPs. Another study carried out in a pediatric population indicated a prevalence of 19.5% of DRPs(11). A similar study carried out in the same setting identified 271 DRPs among the study population, which was on average 4.5 DRPs per study participant, with each participant having at least one DRP, hence 100% prevalence (15). A cross –sectional study among patients with cervical cancer in the same institution found a DRP prevalence of 98.3%, with a mean of 2 DRPs per participant (16). Another prospective cohort study indicates a prevalence of DRPs at 21%, with at least one DRP for every study participant.

A study carried out in India among pediatrics to investigate the prevalence of ADRs found the prevalence to stand at 71% of the population (17). An interventional study carried out in an ICU setting found an average of 1.67 drug problem per prescription (18).

A study seeking to determine the impact of clinical pharmacy practice in an acute ward recorded a DRP prevalence of 85% (19). In 2015, a study carried out in the intensive care unit of a teaching hospital in Brazil identified a total of 2,869 incidences in a study population of 113, which was a prevalence of 97.4%. (8). The study sought to identify and categorize all DRPs in that patient population, whether they had caused harm or not.

In 2013, a study carried out in an acute ward of a Danish hospital estimated the prevalence of DRPs at 85%. It identified a total 538 DRPs, from 1724 prescriptions done for 188 patients during the period of the study.

Another study carried out in three departments of a Germany teaching hospital; urology, gastroenterology and neurology found an average of 2.3 DRPs per patient studied (20). This was indicative of how cross cutting this challenge is, and hence the need to devise ways of intervening to minimize the impact of DRPs on patients undergoing pharmaceutical care.

2.3 Types of Drug Related Problems

Classification of DRPs is usually done for use in research into the nature, prevalence and or incidence of such DRPs among the patients being managed, as well to have defined process indicators for monitoring pharmaceutical care outcomes. It can also help healthcare professionals in documenting DRP-related information in the course of their day-to-day work in offering pharmaceutical care (21).

Various methods of DRP classification have been employed in various research work that have been published. Key among them includes: ABC of drug related problems, American Society of Hospital pharmacists(ASHP) classification, Cipolle/Morley/Strand classification, Hanlon Approach, Mackie classification, Hepler-Strand classification, Krska *et al* system, National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) taxonomy of medication errors, Problem–intervention documentation (PI-Doc), SHB-SEP classification**,** PAS coding system, Pharmaceutical Care Network Europe (PCNE) system (version 8.0) and the Westerlund system (2)**.**

Hepler-Strand classification has categorized DRPs into eight types namely: Untreated Indication(UI), Sub-therapeutic Dosage(STD), Failure to Receive Drug(FTD),Over Dosage(OD),Adverse Drug Reaction(ADR), Drug Interactions(DI) and Drug Use Without Indication(DWI). This classification defines a DRP as an event or circumstance involving a patient's drug use that actually or potentially interferes with the achievement of an optimal outcome (2).

The Pharmaceutical Care Network Europe Foundation (PCNE) classification, developed by the Pharmaceutical care Network Europe, has proven to be a very useful tool in the work of clinical pharmacists, when it comes to documenting DRPs. It categorizes drug related problems into three major groups; based on the effectiveness of the treatment given, how safe such treatment is and others. (1) With regard to the effectiveness, in some cases therapy may not achieve intended goal, may be suboptimal or necessary treatment may have been omitted altogether; if a condition that required to be treated is overlooked or omitted. Occurrence of adverse drug reactions is considered a stand-alone type of DRP, with regards to how safe the medication is to the patient. Patient parameters may come into play in this case, such as multiple organ failure, especially renal and hepatic, which are involved in the metabolism and elimination of most drugs.

DRPs attributable to other causes are lumped together. These include cases of the patient being put on therapy they did not require, as well as how effective the treatment is to them. PCNE classification lists the causes of DRPs ranging from the drug itself, with regards to its selection, form and dosage; duration of therapy, logistics in having it dispensed, right from prescription to the issuance from pharmacy; how the drug is administered to the patient, and finally the patient themselves, especially when the patient is independently taking the drugs. One interventional study carried out in an ICU setting found drug interactions as the most prevalent DRP at 78.2%, followed by correlation between drug therapy and medical problem at 7.4%. Others were inappropriate drug choice and regimen, adverse drug reactions and therapeutic duplication accounting for about 2% of all DRPs recorded (18).

Several researchers have used the PCNE classification in their work(4)(22)(10)(19)(22)(23). It enables one to classify the DRPs identified, their causes as well as all the interventions employed, together with their outcomes. It is a tool that is being reviewed and improved continuously annually(21). One study done in an acute ward setting found “ drug more costly than necessary” as the most common DRP, with suboptimal dug effect coming in second (19).

2.4 Risk factors Associated with Drug Related Problems

Pharmacotherapy is widely used in the critical care unit, and can be twice as common(18) compared to other hospital units. This is attributable to the complex environment that is the ICU, whose patients, the critically ill tend to have profiles and conditions that call for urgency in intervening(8), besides comorbidity, which is usually quite common among these patients(24).

A number of factors have been positively correlated to the occurrence of DRPs in the critically ill patients receiving care in the ICU. Among these factors include: anticonvulsant drugs, anti-arrhythmic drugs, the number of different therapeutic groups prescribed, surgery, Charlsons comorbidity index, length of hospital stay, and the number of drugs prescribed (25).

A study carried on pediatric renal patients in 2014 identified poly pharmacy as a risk factor of development of DRPs(26) this has been collaborated in other studies(4)(5)(27). Certain infectious and parasitic diseases, since these called for prescription of more drugs to the patients, with polypharmacy being defined as where a patient was on at least five different medications (22).

Studies carried out in The Netherlands to determine both the frequency and potential risk factors for DRPs found an association between DRPs and cognitive impairment, poor compliance to medications, impaired renal function and being dependent as patient related factors. The same study found polypharmacy, defined as being on 5 or more drugs as a drug related problem risk factor(28). In another study investing the prevalence of ADRs in a pediatric population found that anticonvulsants and antibiotics were associated with most of the ADRs, accounting for 25.96% and 22.11% respectively (17).

2.5 Literature Gap

From the literature review, it was evident that there is paucity of data on the extent of drug related problems among the critically ill patients receiving care in intensive care settings. The paucity of such data was even more for resource limited settings such as the country in which this study is carried out and other Sub- Saharan African settings. Given the complexity of the critically ill patients, and the many risk factors that make them more susceptible to drug related problems, this study sought to establish the extent of the problem in a developing country setting.

CHAPTER THREE: METHODOLOGY

The chapter presents the design that guided the study. The chapter also presents the study site description, study population, inclusion and exclusion criteria. In addition, the chapter presents the sample size and sampling method, data collection procedures, data management, data analyses techniques and ethical considerations.

3.1 Study design

This study was a cross-sectional survey for a period of two months and involved a direct observation of patients admitted in the critical care units of KNH and review of the medical records and medication charts, to check for real or potential DRPs at the point of contact.

3.2 Study site description

The study site was Kenyatta National Hospital, a teaching and referral hospital based in Nairobi, Kenya. It is currently the largest national referral, teaching and research hospital in the country, as well as in East Africa. The hospital has a staff capacity of 6000, bed capacity of 2000 with an average annual out-patient attendance of 600,000 and an average annual in-patient attendance of 90,000 patients. It receives patients on referral from other hospitals or institutions within or outside Kenya for specialized health care, as well as emergency care.

It also provides facilities for medical education for the University of Nairobi (UON) and Kenya Medical Training College (KMTC) and for research either directly by, or through other collaborating health institutions. The hospital has three critical care wards; main ICU, which has 21- bed capacity, Medical ICU which has a 5-bed capacity and the pediatric ICU (PICU) which is also 5-bed capacity.

3.3 Study population

The study subjects were obtained from among patients admitted in the three critical care units which admit 56 patients on average monthly. Out of these, 36 patients get discharged with the others being detained in the hospital.

3.4 Inclusion criteria

1. All patients admitted in the ICU who are on drug therapy, over a period of two months.

3.5 Exclusion criteria

1. Any patients admitted in the ICU who were not on any drug therapy or who died within 24 hours of admission.

3.6 Sampling method

Universal sampling was used, where all patients admitted into the ICU wards during the study period recruited into the study. The study was carried out in all the three ICU wards at Kenyatta National Hospital (KNH).

3.7 Sample size

The sample size was determined using the Fischer formula(29). Since no local studies have been carried out, the prevalence was assumed to be 50%. Hence;

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

Where: Z- z value for a certain confidence interval i.e. 1.96 for 95% confidence interval.

p- assumed prevalence for a certain outcome, in this case prevalence of DRPs in ICU.

d- level of significance (5% or 0.05).

n- sample size.

$$N = \frac{1.96^2 * 0.5(1-0.5)}{0.05^2} = 384$$

= 384 patients.

Data collection was done for 2 months.

Since the capacity of ICU facility per month is 56, the total for two months is 112. Using the reduction formula to determine the actual sample size:

$$n = \frac{N*n}{N+n} = \frac{384*112}{384+112} = 87$$

Eighty seven study participants were recruited.

3.8 Research instruments

3.8.1 Data collection tool

A well-structured and validated tool was used to extract data from patient inpatient files, treatment sheets and charts, laboratory reports, ward rounds, and consultation with attending physicians. Patient socio-demographic characteristics were retrieved from the inpatient patient files. These included age, sex, weight, and diagnosis at admission. The tool had two sections. Section one was used to capture the socio-demographic characteristics, admission diagnosis (primary diagnosis) and any secondary diagnosis the patient may have.

Section two had details relating to the occurrence of DRPs, the type of possible causes of the same, as well as any risk factor to which the DRP could be attributed to. Risk factors of interest were noted and the patient followed prospectively for the possible development of a DRP. MEDSCAPE clinical information software was used as a source of current clinical and drug information, which formed the basis of determining the presence or absence of drug related problem(15). The risk factors included extremes of age, polypharmacy – defined as being on five or more drugs concurrently -, impaired renal function, being on certain classes of drugs such as anticonvulsants or antiarrhythmic drugs, noncompliance and being dependent.

Impaired renal function was defined as acute kidney injury, which is a sudden onset of kidney failure or kidney damage which occurs within a few hours or a few days, and has been shown to be quite common in patients admitted in intensive care. Noncompliance occurs when the patient fails to receive their treatment regimen appropriately, in terms of dosage and duration of therapy. Almost all ICU patients are dependent on the care giver (healthcare provider) and hardly participate in their own management. Miscommunication or poor communication among the ICU team; doctors, nurses, pharmacists, nutritionists can also be a risk factor to the occurrence of DRPs.

3.8.2 Pre testing of the data collection tool

This was done through collection of data from a few patients and evaluated for probable analysis to obtain reliable and scientifically sound deductions.

3.9 Validity of the study

External validity was assured by having the same target population as the study population since all patients in the ICU at the time of data collection were recruited.
Internal validity was assured by defining all the dependent and independent variables adequately.

3.10 Data Collection

Data was collected for a period of one month. At point of contact, the patient demographics were captured, as well as the patient history, the treatment regimen, and any notable risk factor to a DRP as well as any DRP present, its cause and type. This data was collected from the inpatient files, treatment sheets, laboratory reports and any other relevant diagnostic test. This data was then entered into a Microsoft excel sheet that was password protected, and accessible to the principal investigator only.

The data was backed up in a flash disk that was under lock and key. All filled-in data collection tools were safely kept in a lockable locker during the period of the study. The data was collected by the principal investigator only. The same patients were followed up during their stay in ICU for an emerging DRPs for the period of the study, up to one month or upon discharge/death, whichever came earlier.

3.11 Data management

The data was analyzed using Stata version 13.0 software. Univariate analysis was done to determine the descriptive statistics of central tendency; mean, mode and median, as well as the measures of dispersion: range, variance, inter-quartile range and standard deviation. These univariate descriptive statistics were then presented as frequency distribution tables, bar charts, histograms and pie charts.

Bivariate analysis was done using Fischer's exact test of significance, to determine association between the categorical variables and the outcome of interest (occurrence of a drug related problem). Associations was deemed significant with a p-value of less than or equal to 0.05. Binary logistic regression analysis was done for the independent variables (risk factors for DRPs) and dependent variable (DRPs). At the end of the study, all soft copy files with patient information were deleted, and all hard copies shredded to assure confidentiality.

3.12 Ethical Considerations

3.12.1 Ethical approval

Ethical clearance was sought from the University of Nairobi and Kenyatta National Hospital-Ethics and research Committee (KNH UON-ERC) before carrying out the study. Upon approval, authorization to conduct the study was obtained from KNH administration. Participation in the study was voluntary and only after the participants consent to participate through signing a consent declaration form (Appendix 2B).

3.12.2 Informed Consent

All eligible patients (their care givers) were taken through the nature of the study and an explanation on filling the form (Appendix 1A). The patients or their caregivers were presented with a consent declaration form to sign (Appendix 1B). Patients were informed upfront that participation in the study was voluntary and they were free to withdraw from the study at any point without any repercussions. Adequate information on the nature of the study was provided. No incentives or coercion was used to influence participation in the study. Patients/caregivers were free to ask any questions about the study in the course of the encounter and were informed that if they had any concerns with regard to their rights, they were free to contact the KNH UoN-ERC.

3.12.3 Risks and benefits

The participants participated without any harm imposed to them. The results were to form a basis of recommendations to prevent and/or minimize future occurrence of similar drug related problems among the critically ill patients. Furthermore, the study was descriptive and did not involve any invasive procedures or involve taking additional medications.

3.12.4 Confidentiality

During the data collection and analysis process, study serial numbers were generated and used instead of patient names and contact details. The collected information was treated as confidential and restricted for access using password protected electronic medical record. Signed copies of the consent participation forms were kept in a locked office file cabinet. Only the principal investigator and assistant researcher were granted access to the documents.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter summarizes the findings of the research based on the study objectives. The results have been presented in form of frequency tables, normal tables, pie charts and bar graphs. The association between variables is also demonstrated.

4.2 Socio-demographic and Clinical profile information

4.2.1 Socio-demographic Characteristics of the Study participants

A total of 87 study participants were recruited into the study. Table 1 summarizes their socio-demographic characteristics.

Table 1: Socio-demographic characteristics

Variable	**n (%)**
Gender	
Males	55(63.22%)
Females	32(36.78%)
Age	
0-14years	11 (13.41%)
15-45 years	39 (47.56 %)
46-65years	25 (30.49%)
>65 years	7 (8.54%)
Not Indicated	5 (5.75%)
Marital status	
Married	43(49.43%)
Single	28(32.18%)
Not Indicated	16(18.39%)
Religion	
Christian	62(71.26%)
Muslim	3(3.45%)
Others	1(1.15%)
Not indicated	21(24.14%)
Education level	
None	10(11.49%)
Primary	13(14.94%)
Secondary	23(26.44%)
Tertiary	9(10.34%)
Not Indicated	32(36.78%)
Occupation	
Unemployed	40(45.98%)

Employed	22(25.29%)
Not Indicated	25(28.74%)
Smoking	
Yes	8 (9.20%)
No	46(52.87%)
Not Indicated	33(37.93%)
Alcohol	
Yes	14(16.09%)
No	41(47.13%)
Not Indicated	32(36.78%)

Majority of the participants (55, 63.22 percent) were males and 43(47.56%) were aged 15-45 years. It was also established that 43 (49.43%) participants were married. Christians comprised the majority (62, 71.26%) while 23 (26.44%) had attained secondary level of education. About forty six (45.98%) participants were unemployed. Eight (9.20%) and 14 (16.09%) had smoking history and drinking alcohol respectively.

4.2.2 Clinical characteristics

The study sought to investigate the clinical characteristics of patients undergoing intensive care (Figure 2).

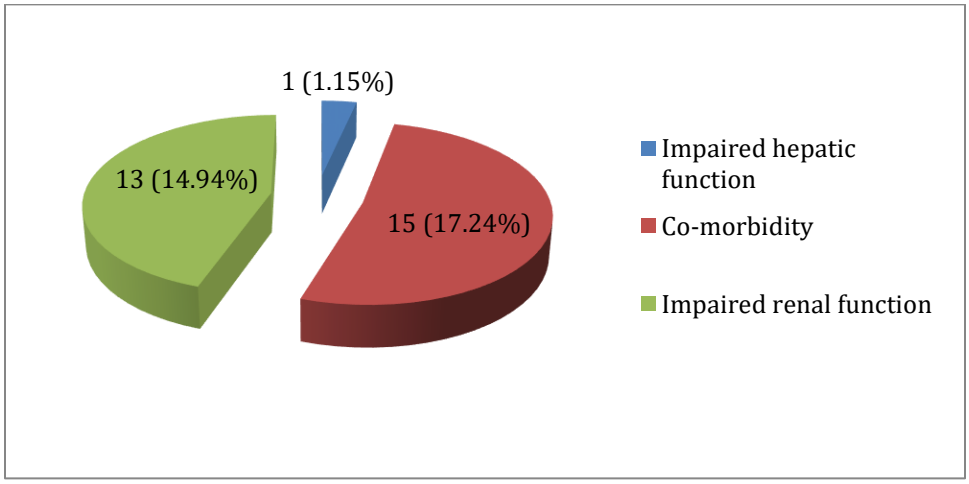

Figure 2: Clinical characteristics

The study found that most (15, 17.24%) participants had co-morbidities. It was also found that (13, 14.94%) had impaired renal function while only (1, 1.15%) had impaired hepatic function.

4.2.3 Therapeutic classification of drugs Prescribed

The therapeutic classification of drugs prescribed was investigated among the patients undergoing intensive care (Figure 3).

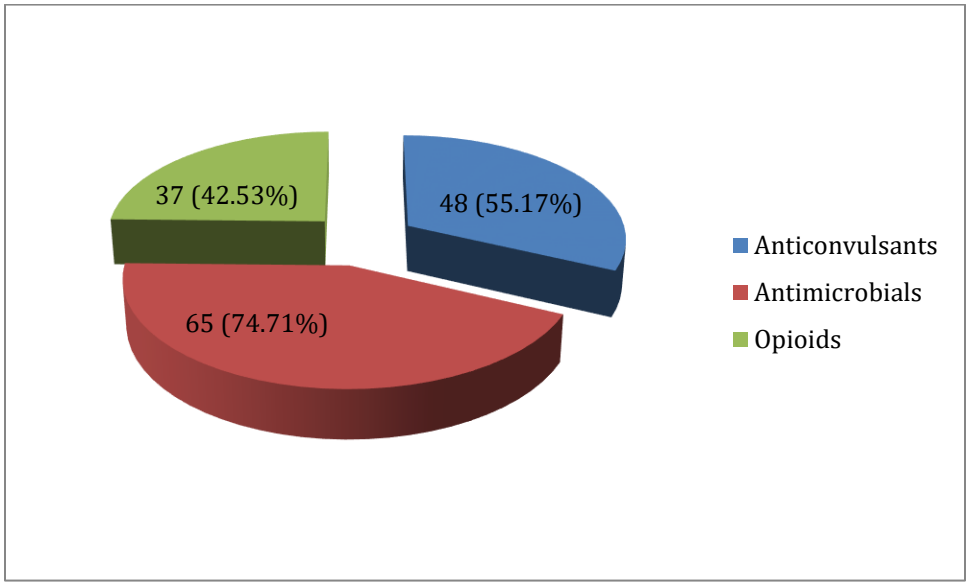

Figure 3: Therapeutic classification of drugs Prescribed

The majority (65, 74.71%) of the participants were on antimicrobials. The other main categories were anticonvulsants (48, 55.17%), and opioids analgesics (37, 42.53%).

4.2.4 Distribution of drug therapy problems by category

The study sought to investigate the distribution of drug therapy problems by category (Figure 4).

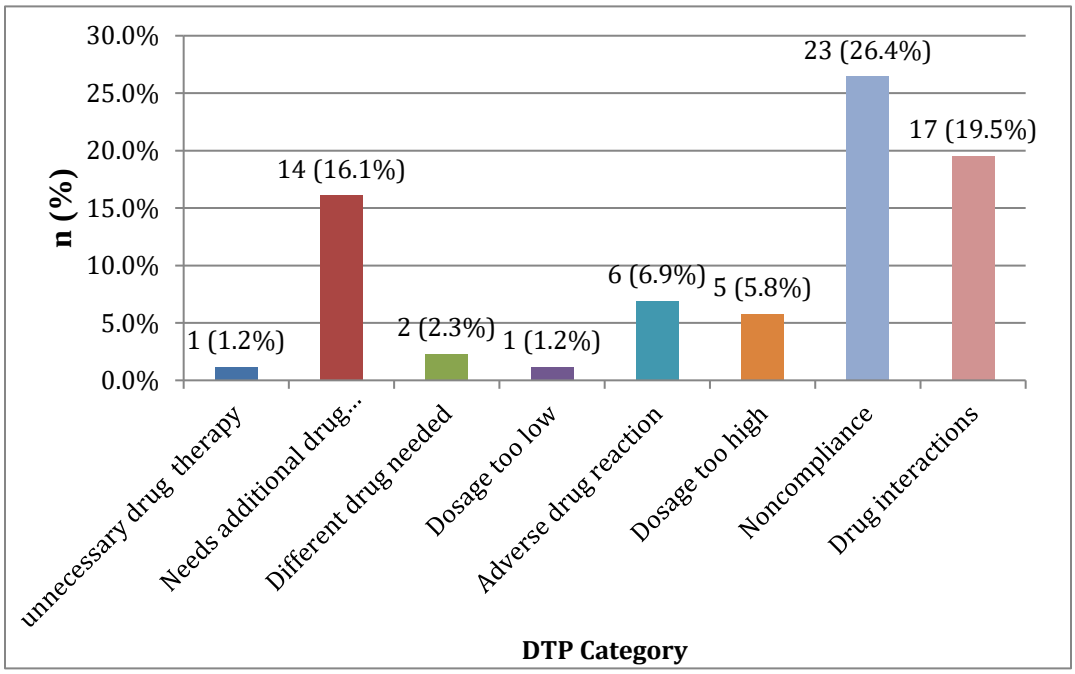

Figure 4: Distribution of drug therapy problems by category

Noncompliance (23, 26.4%) was the most common drug therapy problems followed by drug interactions (17, 19.5%) and needs additional drug therapy (14, 16.1%) as shown in Fig 4. The others were adverse drug reaction (6, 6.9%), dosage too high (5, 5.8%), different drug needed (2, 2.3%), unnecessary drug therapy (1, 1.2%) and dosage too low (1, 1.2%).

4.3 Prevalence of drug related problems

The study sought to investigate the prevalence of drug related problems at KNH (Figure 5). Fifty two (59.78%) participants were experiencing drug related problems.

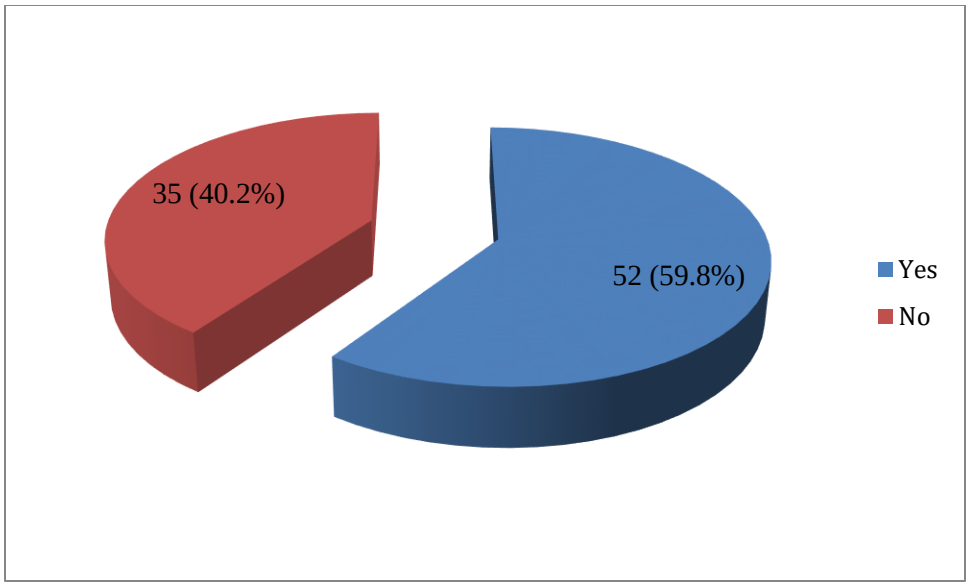

Figure 5: Prevalence of drug related problems

4.4 Association of drug therapy problems with socio-demographic characteristics

The study sought to determine the association of drug therapy problems against socio demographic characteristics. The socio-demographic characteristics under consideration are co-morbidity, age categories, gender and therapeutic class.

4.4.1 Association of drug therapy problems and co-morbidity

An association of drug therapy problems and co-morbidity was determined. Table 2 shows the results.

Table 2: Association of drug therapy problems and co-morbidity

DRPs	No Medical Condition	One Medical Condition	Two Medical conditions	Three Medical conditions	(At least) Four Medical conditions	Fischers exact	P value
Absent	1	3	9	11	11	11.117	0.013
present	0	1	8	9	34		

Cross tabulation results in Table 2 shows the association of drug therapy problems and co-morbidities. It was found that there is a significant association of drug therapy problems and co-morbidity.

4.4.2 Association between DRPs and age categories

An association of drug therapy problems and age categories was conducted (Table 3).

Table 3: Association between DRPs and age categories

	DRPs	Patients with 0-14years	Patients with 15-45 years	Patients with 46-65years	Patients with >65 years	Fischers exact	P value
	Absent	4	14	12	3	1.021	0.821
	Present	7	25	13	4		

Results in Table 3 show the association of drug therapy problems and age categories. It was found that there is no significant association.

4.3.4 Association between DRPs and gender

An association of drug therapy problems and gender of the patient was conducted (Table 4)

Table 4: Association between DRPs and gender

	DRPs	Male	Female	Fischer's exact	P value
	Absent	22	13	0.0033	0.954
	Present	33	19		

There was no significant association of drug therapy problems and gender of patient.

4.3.5 Association between DRPs and therapeutic class

The study sought to investigate the association between DRPs and therapeutic class. The results of this investigation are shown in Table 5.

Table 5: Association between DRPs and therapeutic class

	DRPs	Antimicrobials (No)	Antimicrobials (Yes)	Fischer's exact	P value
	Absent	14	21	6.71	0.010
	Present	8	44		

Table 5 presents the results of the association of drug therapy problems and therapeutic class. It was found that there is significant association of drug therapy problems and therapeutic class. The deduction is supported by Fischers exact of 6.71 and p-value of 0.010<0.05. This is an implication that drug therapy problems are significantly associated with therapeutic class.

4.5 Association between medicine specific factors and the risk of DRP

The study sought to investigate the association between medicine specific factors and the risk of DRP. The results of the investigation are presented in Table 6.

Table 6: Association between medicine specific factors and the risk of DRP

Class of drugs	Drug therapy problems		P value
	Present	Absent	
Anticonvulsants	34	14	0.02*
Anticoagulants	32	20	0.682
Benzodiazepines	16	5	0.078
Cytotoxics	0	2	0.159
Antimicrobials	44	21	0.010*
Potassium	7	6	0.761
Opioid analgesics	24	13	0.508
Insulin	11	8	0.85
Diuretics	7	4	0.78

Statistically significant associations were found between anticonvulsants (p=0.02) and antimicrobials (p=0.010) and drug therapy problems.

4.6 Association between Drug therapy problems and risk factors

The study investigated the association between drug therapy problems and risk factors. The results are presented in Table 7.

Table 7: Association between Drug therapy problems and risk factors

Risk factor	Drug therapy problem		P value
	Present	Absent	
Renal impairment	5	8	0.089
Polypharmacy	30	5	**0.001***
Above 65 years of age	5	3	0.869
Polymorbidity	11	4	0.239
Multiple prescribers	19	4	**0.013***
Medicine specific factors	10	1	**0.04***
Multiple readmissions	1	1	0.776

*- *Statistically significant p values*

Polypharmacy (p=0.001), multiple prescribers (p=0.013) and medicine specific factors (p=0.04) had a statistically significant association with drug therapy problems.

4.6 Predictors of drug therapy problems

The predictors of drug therapy problems were investigated using both bivariate and multivariate logistic regression model (Table 8).

Table 8: Predictors of Drug therapy problems

Variable	Bivariable analysis		Multivariable analysis	
	COR (CI)	**P value**	**AOR (CI)**	**P- value**
Anticonvulsants	2.83 (1.17, 6.87)	**0.021***	2.81 (0.74, 10.7)	0.129
Benzodiazepines	2.67 (0.87, 8.13)	0.085	0.88 (0.18, 4.42)	0.879
Antimicrobials	3.67 (1.33,10.1)	**0.012***	4.48 (0.97, 20.62)	0.054
Polypharmacy	8.18 (2.74, 24.46)	**0.001***	13.26(1.49, 118.25)	**0.021***
Multiple prescribers	4.46(1.37, 14.49)	**0.013***	13.51 (1.65,110.71)	**0.015***
Medicine specific factors	8.10 (0.99, 66.42)	0.051	114.54 (3, 4359.02)	0.11
Renal impairment	0.36 (0.11, 1.21)	0.098	0.019 (0.001,2.75)	**0.004***

COR: Crude Odds Ratio, AOR: Adjusted Odds Ratio, CI: Confidence interval, *: $p<0.05$.

The results showed that Anticonvulsants (COR=2.83, 95% CI (1.17-6.87), p=0.021) and Antimicrobials (AOR=3.67, 95% CI (1.33-10.1), p=0.021) were significant predictors of drug therapy problems in the bivariate analysis. Those on anticonvulsants were 2.83 times likely to experience DTPs while those patients' using antimicrobials are 3.67 times likely to develop DTPs.

Polypharmacy was a predictor DTPs. Under bivariate method, participants on polypharmacy were 8.18 more likely to have a DTP (COR=8.18, 95% CI (2.74-24.46), p=0.001). In the multivariable analysis the odds increased to 13.26 (AOR=13.26, 95% CI (1.49, 118.25), p=0.021).

Multiple prescribers significantly predicted drug therapy problems in patients both in bivariate method (COR=4.46, 95% CI (11.37- 14.49), p=0.013) and multivariable analyses (AOR=13.51, 95% CI (1.65-110.71), p=0.015). Thus, participants who were attended by many prescribers were are 4.46 to 13.51 times likely to experience DTPs. Renal impairment had significant association with drug therapy problems in patients in the multivariable analysis results (AOR=0.019, 95% CI (0.001-2.75), p=0.004) an indication that participants having renal impairment were 0.019 times likely to experience DTPs probably because of the extra care the prescribers observed.

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter discusses the results obtained from the study and compares them to other studies done in different populations. It also includes the conclusions and recommendations.

5.2 Discussion

The study established that majority of the patients had drug related problems. Drugs that are used for the management of diseases may have an impact on the patients if used incorrectly. Drug-related problems can affect the treatment outcomes of patients and lead to increased morbidity and mortality. The effects of drugs are a result of their properties or their improper use is common among patients impacting desired health outcomes. This includes inappropriate dosage, adverse drug reaction, needs additional drug therapy, ineffectiveness, unnecessary drug therapy, and non-compliance. The prevalence of DRPs has been found to be quite high among different patient populations, both in inpatient and outpatient settings. Globally, DTP remains one of the public health problems, and about 10%–20% of inpatients will have at least one adverse drug reaction during their hospital stay (30). A study carried out in India among pediatrics to investigate the prevalence of ADRs found that it was 71%. In a study on drug-related problems among patients with infectious disease, found that the prevalence was 71.51% (31). Likewise, it was established DRP prevalence was high across medical specialties at 45.1%, in a population characterized by advanced age, polypharmacy and multimorbidity. It is evidently clear from results that DRPs prevalence remains higher across populations (32).

High dosage, adverse reactions, needs additional drug therapy, drug interactions and noncompliance were the main DRPs observed. DRPs are associated with many deleterious consequences. Some of these include emergency department visits, long term hospitalization, additional office visits, and long-term care admissions. The evaluation of pharmacotherapy after its initiation is vital to detect DRPs and optimize treatment outcomes. Adverse drug reactions occur almost daily in health care institutions and can adversely affect a patient’s quality of life, often causing considerable morbidity and mortality. Adverse drug reactions may cause patients to lose confidence in or have negative emotions toward their physicians and seek self-treatment options, which may consequently precipitate additional ADRs. Dosing problems result in

reduced efficacy or safety problems which leads patients to drug-related morbidity and mortality. The findings of the study concur with observations elsewhere (33). In line with this, several studies have also reported dosing problems to be the most frequently encountered DRPs in their settings (34). Shah, et al. (35) in a study on factors responsible for noncompliance to drug therapy in the elderly and the impact of patient education in India reported noncompliance to drug therapy was reported in 77.5 % of patients.

There is a significant association between drug therapy problems with co-morbidity and therapeutic class of drugs (36). Patients with more comorbidities were more likely to experience DTPs due to multiple medications. Hence, they could be reluctant to take their medications appropriately resulting to increased risk of drug-interactions and ADRs. The results are in line with on magnitude and determinants of drug therapy problems among type 2 diabetes mellitus patients with hypertension in Ethiopia and found that comorbidities is a significant determinants of drug therapy problems.

It was also established that anticonvulsants and antimicrobials were significantly associated with drug risk problems. Anticonvulsants are a significant predictor of drug therapy problems of patients. Treatment with anticonvulsant medication is usually initiated after a history of two seizures, when further seizures are likely and benefits of treatment outweigh the adverse effects of medication. The continuous use of anticonvulsant among patients may result to drug related problems. Antimicrobial are particularly important in critically ill patients due to their vulnerability. However, the antimicrobial drugs are often injudiciously used worldwide which often result to drug related problems. Anticoagulants, benzodiazepines, cytotoxics, potassium, opioid analgesics, insulin and diuretics did not have any significant effect on drug related problems. The occurrence of drug therapy problems in surgical ward and the role of clinical pharmacist has been documented (37).

Polypharmacy, multiple prescribers and medicine specific factors were predictors of DRPs. Polypharmacy may lead to poor-adherence, drug-interactions, and adverse drug events. The use of multiple medications has been shown to increase nursing home placement, difficulty with ambulation, admissions to the hospital, and mortality (38). Multiple prescribers present a challenge because of preferences as observed by (39), (40).

Renal impairment had significant association with drug therapy problems in patients in the multivariable analysis results. The treatment of renal complications requires multiple medications. The manifestations of other medical disorders in patient during renal treatment attract the use of other medication resulting to drug therapy problems. A study on evaluation of drug therapy problems among renal patients receiving care in some tertiary hospitals in Nigeria found that drug therapy problems among renal patients were high (40).

5.3 Conclusions

The prevalence of DRPs was high. The most common were non-compliance, drug interactions and needs additional drug therapy. Polypharmacy, multiple prescribers and renal impairment were independent predictors of DRPs.

5.4 Recommendations

5.4.1 Recommendations for policy and practice

1. The number of prescribers per patient should be minimized. This will limit frequent and diverse change of the prescriptions, as multiple prescribers were a predictor of drug related problems.
2. Compliance to medicines among patients in critical care unit should be enhanced. The causes of non-adherence should be investigated and addressed.
3. A holistic approach to care should be encouraged. This is because need for additional therapy was a common DRP suggesting that some of the problems the patients had were not being treated.

5.4.2 Recommendations for further research

Further research should be done on the causes of DTPs from the prescriber perspective. The gaps that may be identified regarding prescribing competence should be addressed.

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APPENDICES

APPENDIX 1A: PARTICIPANT/CAREGIVER INFORMATION FORM

DRUG RELATED PROBLEMS AMONG PATIENTS ADMITTED IN THE CRITICAL CARE UNIT OF KENYATTA NATIONAL HOSPITAL

Principal Investigator

Dr. Mule Philip Kyalo- Master of Pharmacy (Clinical Pharmacy) Second-year student at the University of Nairobi

Supervisors: Dr. Karimi P.N-Lecturer, UoN; Dr. Kinuthia R.K – Clinical Pharmacist, KNH

Introduction

I, Philip Kyalo Mule, a postgraduate student at the University of Nairobi, school of pharmacy, would like to tell you about a study being conducted by the above-listed researchers. The

purpose of this consent form is to give you the information you will need to help you decide whether or not to participate in the study. Feel free to ask any questions about the purpose of the research, what happens if you choose to participate or not participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? **YES** **NO**

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No.: _____

What is this study about?

Most critically ill patients tend to be prone to drug related problems due to a number of factors. These patients tend to have more than one conditions at any given time that require drug therapy, and will end up being on many drugs, posing a challenge of drug interactions. They also tend to have their kidneys and the liver compromised, and these two organs are critical for handling drugs in the body. They have drug therapy problems simply due to the severity of their conditions and multi-medications. In this study, we will seek to observe any problems that may arise from the use of medications. Our purpose is to find out whether the medications you are prescribed are working for you or causing any trouble, to find out whether they are safe and effective, to find out which drugs the patient is using and identify things the patient is doing or not doing that may be significantly increasing occurrences of Drug Therapy Problems. There will

be 87 participants in this study randomly selected. We are asking for your consent to consider participating in this study.

What will happen if you decide to be in this research study?

If you agree to participate in this study, the principal investigator will have access to your medical records, as well as observe you for any adverse drug reactions that may occur during therapy.

Are there any risks, harms /discomforts associated with this study?

Psychological, emotional, social and physical factors are risks introduced by a medical research. However, a concerted effort must be put in place to mitigate the risk. One of the risk that you may encounter is lack of privacy. Your information will be treated confidentially and will use a code number to identify you in a password protected computer database restricted for access using password protected electronically. Signed copies of your consent participation forms will be kept in a locked office file cabinet. Only the principal investigator and assistant researcher will access the documents. Furthermore, this study does not involve any invasive procedures or taking additional medications and therefore no harm to the participants.

Are there any benefits?

The study findings will help us improve health outcomes among the critically ill patients being treated in this intensive care unit. It will help develop guidelines and protocols that will prevent drug therapy issues from occurring. To any drug therapy problem occurring during your stay, and for which intervention is possible, the Principal investigator will initiate such intervention to ensure that the problem is ameliorated.

Will being in this study cost you anything?

This study will not have any financial cost to you.

Are there any reimbursements?

There will be no payments inform of fiscal, gifts or incentives as a result of participation in the study.

What if you have questions in future?

If you have further questions or concerns about participating in this study, you are free to call or send a text message to the Principal Investigator before, during, and after the study. For more information about your rights as a research participant you may contact the Principal Investigator on Email: philkmule@gmail.com, and Telephone Number 0724275473.

In addition, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No.: **2726300** Ext: **44102** Email:*uonknh_erc@uonbi.ac.ke.*

What are your other choices?

Your decision to participate in research is voluntary. You are free to decline participation in this study and you can withdraw from the study at any time without injustice or loss of any benefits.

APPENDIX 1B: CONSENT DECLARATION FORM

PATIENT [ ]

CAREGIVER [] RELATIONSHIPTO PATIENT.....

I have read this consent form or had the information read /explained to me. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw anytime. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**YES**	**NO**
I agree to provide contact information for follow-up:	**YES**	**NO**

Participant printed name:

_____

Participant signature / Thumb stamp _____

Date _____

Witness_____Date_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above. The participant has understood and has freely given his/her consent.

Researcher's Name: _____ **Signature** _____

Date: _____

APPENDIX 2A: MAELEZO KUHUSU KUSHIRIKI KATIKA UTAFITI

Kichwa cha Uchunguzi

KUCHUGUZA MATATIZO YA DAWA ZA TIBA KWA WAGONJWA AMBAO WANAPOKEA MATIBABU KATIKA CHUMBA CHA WAGONJWA WALIO HALI MAUTUTI ,KWENYE HOSPITALI KUU YA KENYATTA.

Mchunguzimkuu

Dkt Philip Kyalo Mule-mwanafunzi wa mwaka wa pili akiwa ni mwanafunziwa chuo kikuu cha Nairobi.

Wasimamizi: Dkt. Karimi P.N, Mhadhiri, Chuo Kikuu cha Nairobi, Dkt. Kinuthia R.N, Idara ya Pharmasia, Hospitalikuuya Kenyatta

Utangulizi

Mimi ni Philip Kyalo Mule, mwanachuo katika chuo kikuu cha Nairobi, kitengo cha shule ya pharmacia.

Nafanya uchunguzi wa matatizo ya dawa kwa wagonjwa ambao wanapokea matibabu katika chumba cha wagonjwa walio hali maututi kwenye hospitali ya kitaifaya Kenyatta.

UMUHIMU WA MAFUNZO

Wagonjwa wengi wanajulikana kama wameathirika na magonjwa endapo wana matatizo ya kiafya na matibabu ya magonjwa mbalimbali, pamoja na matatizo ya dawa ya tiba kutokana na hali zao mbaya. Katika mafunzo haya tutazungumzia utumiaji dawa na mambo unayo pata unapotumia dawa.

Lengo letu ni kujua na kuelewa matatizo au changamotowagonjwawaliohalimaututihupitiawakatiwanapokuwawakipokeamatibabu.

Tutafuata utaratibu ambapo unaweza ukakubali kushiriki kwenyeu chunguzi huu.

Taarifa zote zitakazokusanywa na mchunguzi mkuu na mtafiti msaidizi zitakuwa ni za siri.

USHIRIKI WA KUJITOLEA

Katikamafunzohaya,
kuchaguakushirikinikujitoleanaunaoneshauhuruwakobaadayakukubalikushiriki.
Unawezakujiondoakwenyeuchunguzihuuwakatiwote,
nakwakufanyahivyohautahadhirikakwavyovyote.

HATARI NA MADHARA

Kisaikolojia, kihisia, kijamiinakimwilihizinihatarizilizondaniyautafiti. Vilevilejuhudihalisizitakuwepokupelekeakupunguzahatari,
mojawapounayowezakukutananayoniukosefuwausiri.
Taarifainayokusanywaitakuwaniyasirinaitalindwakwakutumianywilainayolindwanaumemewamfumowataarifayamadawa.
Nakalazakozilizosahiniwazenyemawazoyakozaushirikiwakozitafungiwakwenyekaratasi la kuhifadhinyalakayakiofisi.
Mchunguzimkuunamtafitimsaidizipekeehaondiowatakaofanyiakazitaarifayako.
Kwakuongezea, wakatiwaufanyajiwadodoso, mafunzoyatachukuamudawakobinafsi, tunaahidikuangaliamudakuondoamwingilianoukiwakamamshirikiwamafunzo,
zaidimafunzohayahayatahusisha au kutumiamadawa

TAREJESHEWA PESA ZAKO?

Utafitihuuhautakugharimupesa.

NA KAMA UTAKUWA NA MASWALI BAADAYE?

Kama unamaswalizaidi au loloteambalohulielewikuhusuutafitihuu, tafadhaliusisite kuwasilianasikupitianambariambazozimeandikwahapachini.

Kwamaelezozaidikuhusuhakizamshirikikatikautafiti, wasilianaMtafitiMkuu Tovuti:philkmule@gmail.comSimu: 0724275473

auKabitu/MwenyekitiSimu.: **2726300**ongezo: **44102** Tovuti: *uonknh_erc@uonbi.ac.ke.* Utarudishiwaadayamazungumzokupitialainihizikamamazungumzoyenyeweyanahusuutafitihuu.

RIDHAA (KUKUBALI KUSHIRIKI)

TaarifayaMshiriki

Nimesoma au nimesomewanakalahili. Nimepatakuzungumzakuhusuutafitihuunamtafitimwenyewe.

Maswaliyanguyamejibiwakwalughaninayoielewavizuri. Madharanamanufaayameelezwawazi.

Ninaelewakushirikikwangunikwahiarinakwambaninaouhuruwakutoshirikiwakatiwowote.

Ninakubalibilakushurutishwakushirikikatikautafitihuu.

Ninaelewakwambabidiiitatiwakuhakikishahabarizanguzimewekwasiri.

Kwakutiasahihikwadaftarihili,

sijapeanahakizanguzakisheriaambazoninazokamamshirikikatikautafitihuu.

Nimekubalikushirikikatikautafitihuu: NDIO ☐ **LA** ☐

Nimekubalikupeananambariyamawasilianaobaadaye: **NDIO** ☐ **LA** ☐

Jina la Mshiriki: _____

Sahihi / Kidole_____

Tarehe_____

TaarifayaMtafiti

Mimi, ninayetiasahihihapochini, nimeelezeamaswalamuhimuyautafitihuukwamshirikialiyetajahapojuunaninaaminiyakwambaame yaelewavilivyonakwambaameamuabilakushurutishwakukubalikushiriki.

Jina la Mtafiti: _____**Sahihi** _____

Tarehe: _____

Kaziyangukwautafitihuu: _____

APPENDIX 3: DATA COLLECTION FORM

Study number…… Date……

I. PATIENT BIODATA

1. Age…….
2. Weight……Kg
3. Sex……Male (0) Female (1)
4. Marital status : Married (0) Single (1)

5. Occupation: Unemployed (0) Self-employed (1) Employed (2) Retired (4)

6. Level of Education:

Primary (0) Secondary (1) Tertiary (2)

II. HOSPITALIZATION

Admission Details

Date of Admission to the Hospital……..Date of admission to ICU……..

Date of referral……..

Date of Discharge from ICU/ Death…….

7. Length of ICU stay…….Days

Diagnosis at admission to ICU

8. Category of the illness
   i. Medical [0]
   ii. Surgical [1]
   iii. Trauma [2]
   iv. Other (specify (3)…….

9. Primary Diagnosis…….

S/No	Disease/ condition	Present	Absent
9a	Diabetes mellitus	1	0
9b	Hypertension	1	0
9c	Severe head injury	1	0
9d	Diabetic ketoacidosis	1	0
9e	Sepsis	1	0
9f	Shock	1	0
9g	Stroke	1	0
9h	Ruptured brain aneurysm	1	0
9i	Trauma	1	0
9j	Post-operative intensive care	1	0
9k	Heart failure	1	0
9l	Cancer related intensive care	1	0
9m	Respiratory failure	1	0
9n	Poisoning	1	0
9o	Sub arachnoid hemorrhge	1	0
9p	Sud-dural hematoma	1	0
9q	Others	1	0

10 Secondary Diagnosis

S/No.	Disease/Condition	Present	Absent
10a	Diabetes Melitus	1	0
10b	Hypertension	1	0
10c	Chronic kidney disease	1	0
10d	Chronic liver disease	1	0
10e	Pneumonia	1	0
10f	Acute kidney injury	1	0
10g	Asthma	1	0
10h	Sub-dural hematoma	1	0
10 i	Others	1	0

11. Type of drugs prescribed

S/No	Class of drug	Present	Absent
11a	Anticonvulsant	1	0
11b	Anticoagulants	1	0
11c	Benzodiazepines	1	0
11d	Anticholinergics	1	0
11e	Cytotoxic chemotherapy	1	0
11f	Antimicrobials	1	0
11g	Intravenous potassium	1	0

11h	Opiod analgesics	1	0
11i	Insulins	1	0
11j	diuretics	1	0
11k	Immune suppressing therapy	1	0
11L	Others. Specify-------		

`12.Drug related problem present: Yes (1) No (0)

III. 14.Risk factors for Drug Related problems

S/No	Risk factor	Present	Absent
14a	Renal impairment	1	0
14b	Hepatic impairment	1	0
14c	Polypharmacy	1	0
14d	Aged 65years or older	1	0
14e	Polymorbidity	1	0
14f	Multiple prescribers	1	0
14g	Medicine specific risk factors	1	0
14h	Frailty	1	0
14i	Multiple readmissions to hospital	1	0
14j	Others: Specify…….	1	0

IV. 15. What are the different types of Drug Related Problems

S/No.	Type of DRP	Present	Absent
15a	Unnecessary drug therapy	1	0
15b	Needs additional drug therapy	1	0
15c	Different drug needed	1	0
15d	Dosage too low	1	0
15e	ADR	1	0
15f	Dosage too high	1	0
15g	Non-compliance	1	0

V 16. What are the specific causes of the different types of DRPs?

DRP	CODE	CAUSES	CODE
16a.Unnecessary drug therapy	A	No valid medical indication	1
		Duplicate therapy	2
		Nondrug therapy indicated	3
		Treating avoidable ADR	4
		Addictive /recreational	5
16b.Needs additional drug therapy	B	Untreated condition	1
		Preventive	2
		Synergistic/potentiating	3
16c.Different drug needed	C	More effective drug available	1
		Dosage form inappropriate	2
		Condition refractory to the	3

		drug	
		Contraindication present	4
		Drug effective for the condition	5
16d.Dosage too low	D	Ineffective dose	1
		Needs additional monitoring	2
		Frequency inappropriate	3
		Drug interaction reduces amount of active drug	4
		Duration inappropriate	5
16e.ADR	E	Undesirable effect	1
		Unsafe drug for patient	2
		Dosage administered or changed too rapidly	3
		Drug interaction causes undesirable reaction that is not dose-related	4
		Allergic reaction	5
		Contraindications present	6
16f. Dosage too high	F	Dose higher than indicated	1
		Needs additional monitoring	2
		Frequency too short	3
		Duration too long	4
16g.Noncompliance	G	Cannot afford drug product	1
		Drug product not available	2
		Missed dose(s)	3

APPENDIX 4: LETTER OF ETHICAL APPROVAL

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COLLEGE OF HEALTH SCIENCES
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Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

Ref: KNH-ERC/A/443

19th December 2018

Dr. Philip Kyalo Mule
Reg. No. U56/ 88494/2016
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Dr. Kyalo

RESEARCH PROPOSAL – DRUG RELATED PROBLEMS AMONG PATIENTS ADMITTED IN THE CRITICAL CARE UNIT OF KENYATTA NATIONAL HOSPITAL (P641/09/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 19th December 2018 – 18th December 2019.

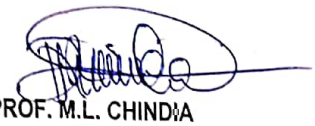
This approval is subject to compliance with the following requirements:

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) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) 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*).
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 **http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,



PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmaceutics and Pharmacy Practice, UoN
Supervisors: Dr. Peter Ndirangu Karimi, Dr. Rosaline Njoki Kinuthia

APPENDIX 5: PLAGIALISM CERTIFICATE **19/11/2021**

DRUG RELATED PROBLEMS AMONG PATIENTS IN THE CRITICAL CARE UNIT OF KENYATTA NATIONAL HOSPITAL

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