ASSESSMENT OF EFFECTS AND CHALLENGES OF IMPLEMENTING INDIVIDUALISED DISPENSING ON MEDICATION RELATED PROBLEMS AT KENYATTA NATIONAL HOSPITAL

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

October 2014

DECLARATION

I hereby declare that this dissertation is my original work and has not been presented in any other academic institution.

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This dissertation has been submitted for evaluation and examination with our approval as university supervisors.

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DEDICATION

To my wife Jane for her unfailing support and encouragement and to my children Winnie, Rachael and Joshua for cheering me on.

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ABBREVIATIONS/ACRONYMS

ADR: Adverse drug reaction

ADD: Automated dose dispensing

KNH: Kenyatta National Hospital

MRP: Medication related problem

PCNE: Pharmaceutical care network Europe

WHO: world Health Organization

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OPERATIONAL DEFINITION OF TERMS

Medication related problem: also referred to as drug related problem, is an event or situation involving drug therapy that actually or has potential to interfere with desired health outcomes. Involves medication errors, non adherence, drug interactions and adverse drug events.

Individualised inpatient medication order: system of dispensing whereby medicines are supplied to a specific inpatient based on need as documented in the treatment chart.

Adherence: Extent to which a patient's medicine taking behavior matches the agreed recommendation from the prescriber.

Adverse drug reaction: An unintended noxious response occurring after the normal use of a drug, which is suspected to be associated with the drug.

Medication error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health professional or patient.

ABSTRACT

Background: Medication related problems are said to occur when the outcome of medicine use is not optimal resulting to a significant strain on the health delivery system and contributing to mortality, morbidity and escalation of healthcare costs. Potential and actual medication related problems can occur at any stage of the medicine use process.

Objectives: The objective of the study was to identify the challenges faced in the implementation of the individualized dispensing system at the medical wards of Kenyatta National Hospital. Further the effect of the change on medication related problems were determined.

Methods: A pre-post design was utilized to study effects. A systematic random sample of 236 patient files was picked for before study arm and 207 patient files for the after study arm. A cross section study was used for challenges faced study. A convenience sample of 25 that included nurses, pharmacists and pharmaceutical technologist were recruited and interviewed for the survey on challenges faced. Descriptive and inferential data analysis was performed.

Results: The main challenges faced during the implementation phase were inadequate medicine storage facilities, patient management software anomalies, delay in ordering patient medicines and increased workload. There was a high prevalence of medication related problem (97.5 % vs.95.7%) with prescribing errors (16.1 % vs. 15.8%), drug interaction (80.9 % vs. 69.9 %) and non adherence (80.9 % vs.91.3%) being most common. No robust mechanism for resolving medication related problems exist.

Conclusion: The study recommends the formation of multi-disciplinary teams involving pharmacists to identify and resolve medication related problems at the medical wards and to provide adequate resources for medicine storage facilities, requisite staff mix and effective patient management software.

CHAPTER ONE: INTRODUCTION

1.1 Study background

The use of medicines is as old as humanity, whether as concoctions from antiquity to the modern day pharmaceuticals, medicines play an important part in preventive and curative healthcare forming a huge cost of current spending. Since the days of Alexander Fleming with the discovery of penicillin, medicines have guaranteed an expansion of the life expectancy of man. This has enabled the current generation to reduce maternal mortality, child mortality and almost allowed the eradication of diseases such as polio and small pox which in ages gone were major causes of mortality.

The use of medicines is however sometimes associated with harmful effects such as the case of thalidomide in the 1960's that was found to be teratogenic after marketing authorisation had been granted. This therefore calls for judicious use of medicines with elaborate systems to ensure safety to patients[1]. Regulatory authorities constituted in various countries provide oversight in the research, discovery, development, marketing and use of medicines in their area of jurisdiction thus ensuring safety and effectiveness.

Medication related problems or drug therapy problems however do arise and are said to occur when the outcome of medicine use is not optimal. Medication related problems (MRPs) result into a significant strain on the health delivery system, contributing to mortality and morbidity, escalate cost of treatment and result in increased hospital stay. Helper and Strand (1990), proposed a classification system of identifying MRPs which includes untreated indication, treatment without indication, improper drug selection, too little drug, too much drug, non-compliance, adverse drug reaction and drug interaction[2,9]. However, majority of these medication related problems are preventable and strategies should be instituted to minimise them[3].

Medicine management in hospitals is a process that involves ways in which medicines are selected, procured and stored, prescribed, dispensed, administered and monitored to optimise patient health outcomes. Potential and actual medication related problems can occur at any stage

in the medicine use cycle [4]. At the Kenyatta National Hospital (KNH), medicine selection is a multidisciplinary process spearheaded by the medicines and therapeutics committee that has developed a hospital formulary that forms the basis of medicine procurement. The prescribing function is carried out by a composite of medical cadres ranging from clinical officers to consultant medical specialists while the dispensing role is fulfilled by a team of pharmacists and pharmaceutical technologists.

The hospital has been using a mixed system of bulk and individual medication order for inpatients till September 2013 when it shifted to a purely individualised inpatient medication order system. The individualised medication order system offers the pharmacy staff the opportunity to assess the patient medication order for a check on appropriateness of therapy with a view to minimising MRPs[4]. Drug administration is a function that is purely performed by nurses apart from specialist products such as oncology medicines that are administered by clinicians.

A study done by Nyakiba *et al*.(2012) showed a high prevalence of medication related problems at the medical wards of KNH[5]. As part of quality improvement process, the pharmacy department implemented a policy shift towards individualised medication orders to all inpatients commencing September 2013

1.2 Statement of the problem

In September 2013, KNH implemented a policy shift towards individualised dispensing system for inpatient medicine orders that allows pharmacy staff to access patient medication charts facilitating interventions to minimise medication related problems. Despite these changes, there seems to be a delay in initiating patient medication once prescribed. No formal system exists to monitor and document medication related problems at the medical wards. Since the introduction of these changes, no extensive study has been carried out to determine the effects on the frequency of medication related problems and the challenges faced in the implementation process.

1.3 Purpose of the study

The purpose of the study was to evaluate the influence of the change of dispensing system on medication related problems. Further, the challenges encountered in the implementation of the individualised dispensing system and methods used to resolve medication related problems at the medical wards of Kenyatta National Hospital were described.

1.4 Objective

To assess the effects and challenges of implementing individualised inpatient dispensing system on medication related problems.

1.5 The specific objectives

The specific objectives were;

1. To describe the challenges of implementation of an individualised dispensing system.

2. To compare the types of medication related problems before and after the introduction of individual dispensing system.

3. To compare the frequency of medication related problems before and after introduction of individual dispensing system.

4. To describe the mechanisms currently used to resolve medication related problems.

1.6 Research questions

The study sought to answer the following research questions;

1. What were the challenges encountered in the implementation of the individualised dispensing system?
2. Did individualised dispensing reduce medication problems compared to a mixed dispensing system?
3. How were medication related problems resolved?

1.7 Significance of the study

The results of this study will be used by the hospital to streamline the implementation process of the individualised dispensing system and to establish a system for documenting and reporting medication related problems. In addition, the results will be disseminated to help influence policy on individualised dispensing system for inpatients in public hospitals throughout the republic of Kenya.

1.8 Delimitation

The study covered records of patients admitted at the medical wards over a period of six months before (March to August 2013) and after the introduction of individualised dispensing system (November 2013 to April 2014). Nurses and pharmacists/pharmaceutical technologists at the medical wards were recruited and interviewed to indentify the challenges faced in the implementation process.

1.9 Limitations

Shortcomings encountered in this study were;

1. Non response for the survey on challenges of implementation.
2. Participants might not have provided truthful information due to reasons such as the desire to conceal potentially embarrassing information.
3. Incompleteness of records that were accessed including non capture of MRP'S.
4. Missing patient files.

1.10 Assumptions

This study was based on the following assumptions;

1. That medication related problems are random events that are evenly distributed throughout the study population and that the sample selected were representative of the target population.
2. That the respondents for the survey on challenges faced gave truthful and honest answers.

1.11 Conceptual Framework

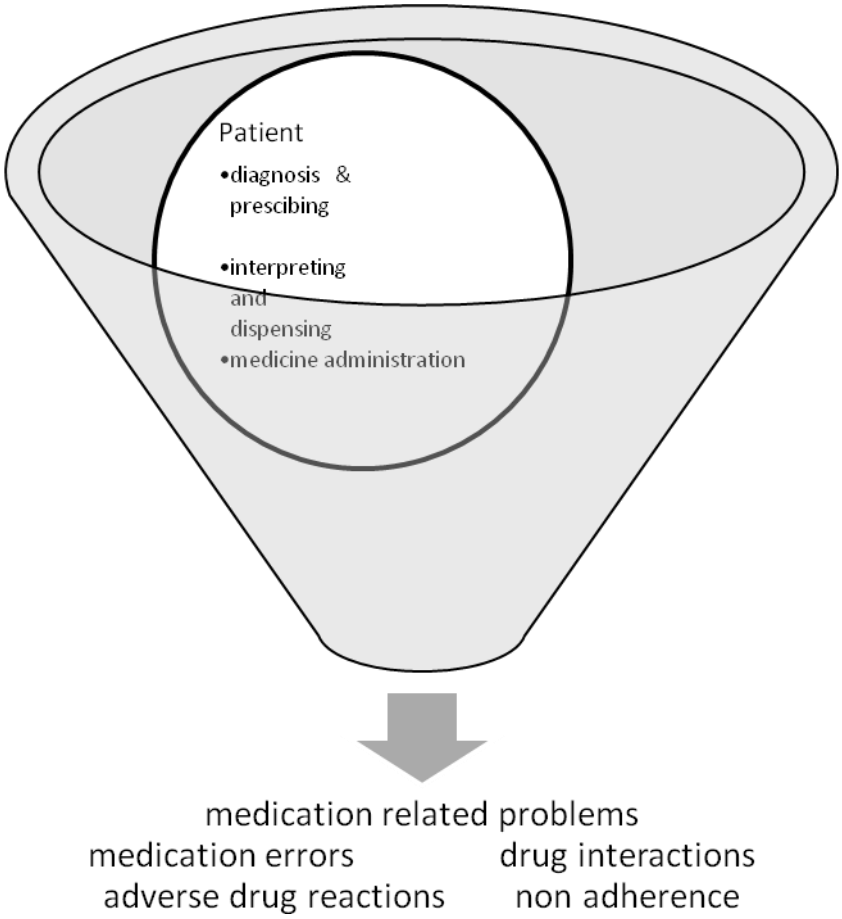


Figure 1: Conceptual framework of the medication use process and potential for medication related problems

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Systems used to prescribe, distribute and administer medicines in hospitals can have substantial influence on medication safety by minimising MRP's along the medication use process[6]. Studies in United Kingdom National health services (NHS) accredited hospitals report paper based prescribing at 87% with patient specific inpatient supplies at 50% among others, in the United States of America (USA), a national survey of pharmacy practice indicates use of a decentralised system with 89% of hospitals using automated dispensing system and 34% using computerised prescriber order entry[7]. Data from resource poor settings, including Africa is lacking. , Observation from Kenya indicate majority of public hospitals use bulk dispensing at inpatient settings.

At KNH, patient specific inpatient medicines supply was initiated in September 2013, with mostly paper based prescribing. Medication related problems are universal and are under-reported especially in developing countries where systems of care are beset with problems of resource limitations both human and material. The plethora of MRP's include, medication errors, adverse drug events, non adherence and drug-drug interactions. In USA, medication errors are estimated to occur at a rate of 2 % to 14 % of patients admitted in hospitals[8]. In England, adverse drug reactions are a cause of 6.5 % of hospital admissions with similar figures reported for USA[9].

In low resource settings, quality studies are few with a prospective observational study in India reporting a medication error rate of 11.5 % with administration and prescribing errors being the most common[10]. Another Egyptian study reported administration errors to be the most common[11] and a study in Ghana reported that 60.5 % of patients did not receive the actual quantity of medicines that they were supposed to get and prescribing errors were reported to be the most common[12].

In Kenya, the magnitude of medication related problems has not been established in well controlled studies but most of the studies have focused on adverse drug events where a National pharmacy-vigilance reporting system is operational and linked to the World Health organisation reporting centre at Upsalla Sweden. A study done at KNH reported a prevalence of 96.7 % with drug interactions, prescribing errors, non compliance and adverse drug reactions(30.5 %, 25.7 %, 21.9 % and 10.7 %, respectively) being the most common[5]. Another study on

potential drug-drug interactions reported a prevalence of 33.5 %[13] among a large Kenyan cohort involving antiretroviral drugs.

2.2 Dispensing

Drug dispensing has been the core responsibility of hospital pharmacy services. Medicines may be dispensed in bulk, as individual inpatient orders, as unit doses or where advances in technology allow in computerised dispensing machines. In bulk dispensing system, the pharmacy supplies wards with medications without regard to individual patient needs. The patient medication chart does not accompany the order and therefore no check on appropriateness is carried out by the pharmacy staff. Individual inpatient medication order facilitates assessment for medication related problems, billing of patients and results to a tighter inventory monitoring (4).

In much of the developed world, computerised dispensing systems are the norm and they do advance the safe use of medicines. However, these advanced dispensing systems require substantial investment in infrastructure in terms of repackaging equipment, medication cabinets, computerized dispensing machines and supporting bar coding technology[4]. A systematic comparative review by Sinnemaki *et al* (2013) on automated dose dispensing (ADD) demonstrated a reduction in discrepancies in the documentation of patients medication records compared to standard dispensing procedure thereby enhancing patient safety. There were fewer drug- drug interactions in the ADD group; however the patients using a standard dispensing procedure had less inappropriate drug use. [14]

Kenyatta National Hospital and other public hospitals in Kenya have been using the bulk distribution system with some measure of individual inpatient medication order for a narrow spectrum of medicine items. The private hospitals in Kenya embraced individual inpatient medication order system decades ago and a few of them are moving towards unit dose system of medicine distribution.

2.3 Prevalence of medication related problems

Medication related problems can be described as " events or circumstances that interferes with desired health outcomes"[15]. Proper identification and resolution of medication related

problems has great impact on health outcomes resulting in reduction of hospital stay, morbidity and mortality. Several strategies have been advocated for proper identification of medication related problems. Manias 2013, proposed some of the best methods of detection as chart review, computer monitoring, direct care observation and prospective data collection, in that order. Risk factors cited for development of medication related problems include increasing age (>70years) and the number of drugs prescribed[16]. Evaluation for medication related problems should therefore focus on these high risk populations.

Reported prevalence of MRPS is imprecise, with several studies in the elderly from the West having reported varying figures ranging from 29 % to 87 %, this variation results from the methodology applied in detection. Studies from Africa are scarce, but a study among medical outpatient in Nigeria reported an overall prevalence rate of 58.6 % with non-adherence, potential drug-drug interactions and adverse events being most common [17].

2.4 Types of medication related problems

Several classifications for medication related problems exist, but none is universally accepted. The classification by Hepler and Strand and the pharmaceutical care network Europe (PCNE) have gained wider acceptance [9]. The PCNE is based on a model that includes, describing the problem, evaluating for the root cause and then suggesting an intervention to resolve the problem. The MRP can be classified as those related to lack of efficacy, potential lack of efficacy, adverse drug reaction, potential adverse drug effect and cost effectiveness[18]. Causes of the MRP can be categorized as those related to the known side effects of the drug(s), dose regimen problem, duplication of therapeutic classes, prescribing errors, errors in documentation of allergies and sub-optimal choice of drug formulation or interactions, unmanaged indications and non adherence.[9] Walleri *et al* affirms that medication related problems associated with dose are the most common (46.7 %[1]. Suggested interventions to avoid or prevent MRP's may include change of drug, substituting with a different drug formulation, documentation of allergies, dose alteration, patient monitoring, start/stop drug, therapeutic drug monitoring and change of timing of drug administration[19].

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter describes the components of methodology that were used to carry out the study. They include research design, variables, study area, target population, piloting, data collection instruments, data analysis technique as well as ethical and logistical considerations.

3.2 Research design

Cross section study design was employed to identify the challenges faced in implementing individualized dispensing approach. A pre-post study design was used to determine the prevalence of medication related problems before and after introduction of individualised dispensing at the medical wards. A questionnaire was constructed comprising both closed ended and open ended questions to elicit responses on challenges faced during the implementation phase. A data abstraction form was constructed to abstract data from sampled patient files.

3.3 Variables

The primary outcome/dependent variable were a medication related problem report with secondary outcomes including type of medication related problem, number of medicines per prescription and diagnosis. To capture information on challenges, the outcome variable were the identified challenges with the predictor/independent variables in both studies including introduction of individualised dispensing, age and gender.

3.4 Location of study

The study was carried out at the medical wards (7A-8D) of Kenyatta National Hospital, the largest referral medical facility in Kenya with a bed capacity of 1800. The Hospital serves as the teaching hospital for the University of Nairobi, College of health sciences and the Kenya Medical Training College that produces middle cadre health professionals. The hospital services are provided across its 50 wards, 22 outpatient clinics, accident & emergency centre and 24 theatres of which 16 are specialised. Admission to the medical wards is through the hospital clinics and the accident and emergency centre, patient management is mainly done by registrars with senior consultants and physicians attending major ward rounds twice weekly.

The medical wards were chosen because of the extensive use of medicines and the variety of medical conditions that are managed. The changes in the dispensing system would be expected to have a major influence in the medical wards.

3.5. Target population

The study population was composed of files of patients admitted at the medical wards during the study period (march- august 2013 and November 2013-April 2014). The medical wards at KNH have a bed capacity of four hundred and one. In 2013 a total of 9,783 patients were admitted at the medical wards representing a bed occupancy rate of 89.6 %[20]. During the study period March to August 2013 a total of 2,146 patients were admitted at the medical wards while a total of 2,878 patients were admitted from November to April 2014.

The study population for the challenges faced study arm was composed of nurses involved in patient care at the medical wards as well as pharmacist and pharmaceutical technologists attached to the Medical wards Pharmacy. On average, a medical ward is staffed with fifteen nurses, the medical wards pharmacy with five personnel (one pharmacist and four pharmaceutical technologists) bringing a target population of 125.

3.6 Sample size

Sample size for patient files was determined by applying the formula suggested by Marlies Noordzij *et al* (2010) for a binary outcome[21]

$$N = \frac{[(a+b)^2(p_1q_1+p_2q_2)]}{x^2}$$

Where;

N, is the desired sample size in each group,

a is the probability of making a type I error (α) by convention set at 5%,

b is the statistical power of the study set at 80%,

P1 is the proportion of patients with medication related problems in the before group (90%),

q_1 is the proportion of patients without medication related problems in the before group ($1-p_1$)

p_2 is the proportion of patients with medication related problems in the after group (60%)
q_2 is the proportion of patients without medication related problems in the after group ($1-p_2$)
x is the difference the investigator wishes to detect set at 10 %

Applying this formula,
Multiplier for a =1.96, for b =0.842,, relying on the Kenyan study(5), $p_1 = 0.9$, $q_1 = 0.1$, taking average of other studies, $p_2 = 0.6$, $q_2 = 0.4$

$$N = \frac{(1.96 + 0.842)^2 ([0.9*0.1] + [0.6* 0.4])}{(0.1)^2}$$

N= 259

The sample size was calculated as 259. An incidental sample of 40 was picked for the study on challenges faced during the implementation process.

3.7 Sampling Techniques

The sampling technique employed for the study on effects of individualised dispensing on medication related problems was stratified random sampling. A list of patients admitted at the medical wards during the study period was obtained from the health information department of KNH the list was arranged per ward in ascending order (7A to 8D). For the study period March to August 2013 every sixth patient on the list was selected, while for the period November 2013 to April 2014, every ninth patient was selected. 348 files were selected in the before group and 320 files for the after group, 236 files met the inclusion criteria for the before group while 207 files met the inclusion criteria for the after group.

Convenience sampling method was used for the survey on challenges faced during the introduction of individualised dispensing system.

3.8 Research instruments

A data extraction form was constructed to abstract data from patient files on medication related problems. The form captured the bio data, the type of medication related problem present and the diagnosis (appendix 1). Android applications of Mediscape, the KNH formulary [22] and the Clinical guidelines for level 4-6 hospitals[23] were used as reference information source. A questionnaire was constructed with both closed ended and open ended questions to determine the challenges faced in implementing individual inpatient medication order system (appendix 2). The tool was administered after consent to participate was given.

3.9 Pilot study

A pilot study was carried out between 23rd to 27th June 2014 at Kenyatta National Hospital to establish the validity and reliability of the research instruments; no modification of the research instruments was deemed necessary. .

3.10 Validity

External validity was established by applying stratified random sampling thus ensuring that every admitted patient in the study period had an equal chance of being selected whereas internal validity was guaranteed by clear definition of outcomes.

3.11 Reliability

Reliability of the study was guaranteed by a concise description of methodology thus enabling reproducibility.

3.12 Data Collection Technique

Data was abstracted from patient's files using a data abstraction form (appendix 1), the treatment chart was assessed for medication related problems while the medical and nursing notes were evaluated for reports of adverse drug reactions, laboratory reports were then examined for evidence of normality of hepatic and renal function by use of child-pugh score and estimated glomerular filtration rate (eGFR) using the MDRD study equation respectively. The form was then reviewed for completeness and then coded and latter entered into an excel

spreadsheet. The form was stored under lock and key for the remainder of the study period. For the challenges, once consent was obtained, a questionnaire was administered by the researcher, and the information was latter entered into an excel spreadsheet, completed questionnaires were kept under lock and key.

3.13 Logistical and Ethical Considerations

A list files for patients admitted at the medical wards during the study period was collected from the central medical records of KNH; they were then sorted per ward and stratified random sampling was used to pick the required number of files for the study. No consent was required since there was no direct contact with the patients.

For the study on challenges, nursing and pharmacy staff were visited at their work place.

The researcher introduced himself to the participants and informed them about the title, purpose and potential benefits expected of the study. The researcher explained that participation was voluntary and that they could decline to participate or withdraw at any stage of the study without any consequences to them. He then asked for consent from subjects, when granted, a consent form was provided to the respondents who completed and signed, the researcher then signed on the space provided (Appendix 2). A questionnaire was then issued to the participant for completion (Appendix 3).Ethical approval was sought and granted by the KNH/UON research and ethics committee (appendix 4).

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter contains analyzed data according to objectives. Data analysis was performed using Statistical Package for social scientist (SPSS) version20 and descriptive and inferential statistics were used to organize the data into frequencies and proportions. Bivariate analysis was performed to exhibit relationship between age, gender, number of drugs per prescription and presence of medication related problem.

4.2. Challenges of implementing individualized dispensing system

A total of fifty questionnaires were distributed to recruited participants. Twenty five questionnaires were returned fully completed representing a response rate of 50% (Table 1). Thirty two percent of the respondents were males while 68 % were females. The average age of the respondents was 40.9 years and the nurses were the majority (88 %).

Table 1: Socio- demographic characteristics of healthcare workers

TRAIT	CATEGORY	Frequency	PERCENTAGE
Gender	Male	8	32%
	Female	17	68%
Age	20-29	3	12 %
	30-39	7	28 %
	40-49	11	44 %
	50-59	4	16 %
Designation	Nurse	22	88%
	Pharmaceutical technologist	2	8%
	pharmacist	1	4%

The major challenges faced in the implementation of individualized dispensing system according to the respondents are shown in table 2. They include inadequate storage space for the patient medicines (43.5 %), patient management software anomalies (37.5 %), delay in ordering patient medicine at admission (37.5 %) and increased workload (30.7 %). There were no individual

patient cabinets but there was improvisation with use of cupboards and small baskets to accommodate the patient medicines.

Table 2: type of challenges associated with individualised dispensing system

Challenge	Frequency	Percentage
Increased work load	7	30.4
Inadequate storage space	10	43.5
Shortage of dispensing materials	4	17.4
Lack of clear procedures	2	8.7
Software anomalies	3	37.5
Delay in ordering at admissions	3	37.5
Inadequate labeling of medicines	1	12.5
Patient unused medicines accumulating in the ward	1	12.5

4.3 Types of medication related problems

4.3.1 Socio demographic characteristics of patients

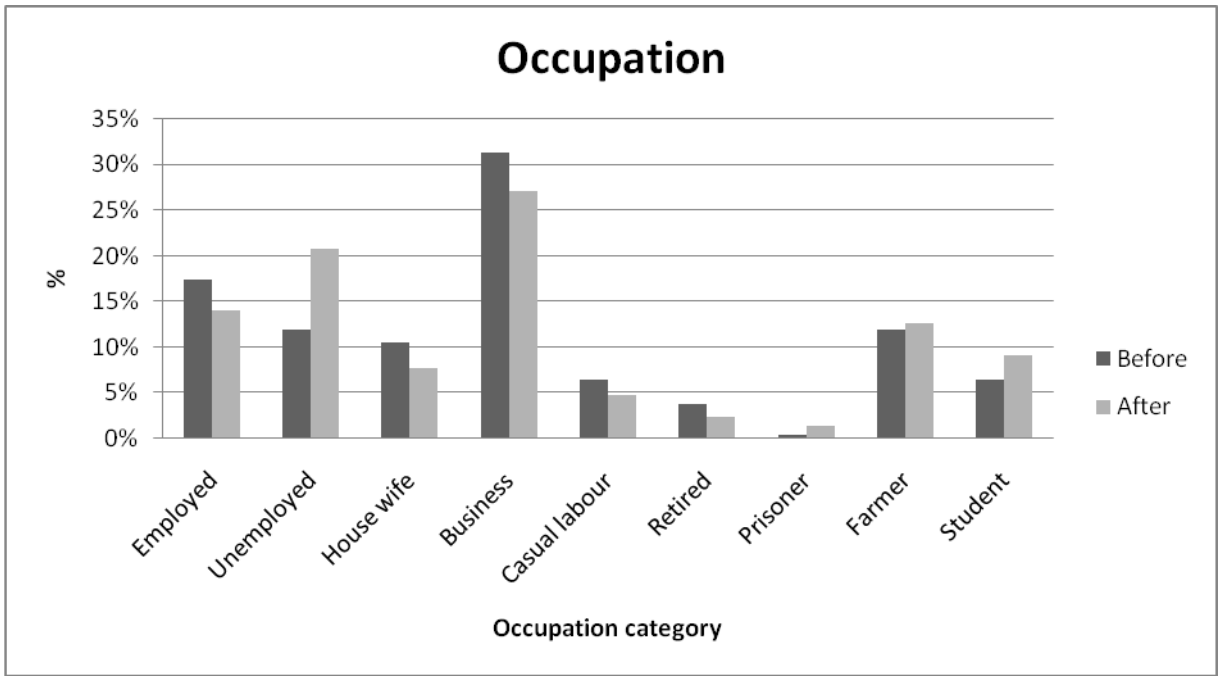
Six hundred and sixty eight patient files were sampled and four hundred and forty three met the inclusion criteria out of which 236 were before and 207 after implementation of the individualized dispensing system. Females comprised of 51.3 % and 52.7 % before and after study groups respectively. The average age for the before group was 31.4 years (range13 to 84 years) while the after group had an average age of 36.9 years (range13 to 102 years). Majority of the respondents in both groups had primary and secondary level of education while lowest category had no education as shown in table 3.

Table 3: Socio-demographic characteristics of patients

Characteristic	Category	Frequency (%)	
		Before	After
Gender	Male	115(48.7 %)	98(47.3 %)
	Female	121(51.3 %)	109(52.7 %)
Education level	None	12(5.1 %)	31(15 %)
	Primary	73(30.9 %)	84(40.6 %)
	Secondary	61(25.8 %)	64(30.9 %)
	College	90(38.1 %)	28(13.53 %)

Most of the study participants in both groups were engaged in business (31.4% vs. 27.1%) followed by those in formal employment (17.4 % vs. 14 %) and farming (11.9 % vs. 12.6 %). A substantial proportion of participants in both groups were unemployed (11.9 % vs.20.8 %).

Figure 2: Types of patient's occupation



The least occupation categories were prisoners, retired and casual labour respectively as indicated in figure 2 above.

4.3.2 Type of diseases

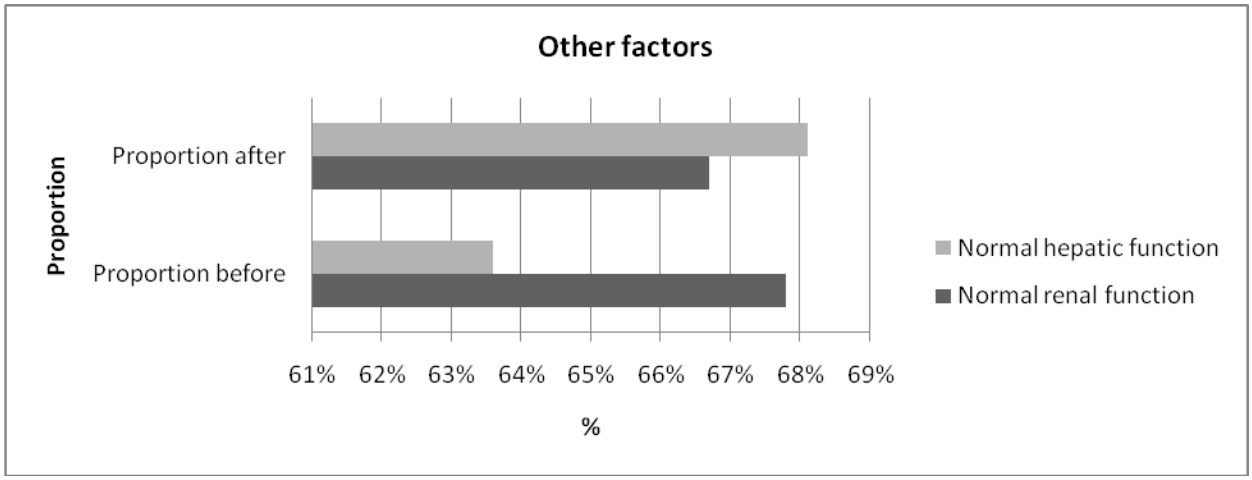
Out of 236 in the before group, the number ranged from one to six. There were more retroviral disease diagnosis (28 %) followed by neurological conditions, tuberculosis, gastrointestinal diseases among others as shown in table 4. The least common was Venous thromboembolism (3.4%).

Table 4: Type of diseases

Disease	**Before**	**After**
	Frequency (%)	**Frequency (%)**
Retroviral disease (RVD)	66 (28%)	51 (24.6%)
Kidney disease	61 (25.8%)	39 (18.8%)
Neurological conditions	49 (20.8%)	43 (20.8%)
Tuberculosis	36 (15.3%)	29 (14%)
Gastrointestinal diseases	34 (14.4%)	15 (7.2%)
Hypertension	31 (13.1%)	45 (21.7%)
Cancer	31 (13.1%)	27 (13%)
Diabetes Mellitus	22 (9.3%)	27 (13%)
Pneumonia	21 (8.9%)	22 (10.6%)
Other Respiratory diseases	20 (8.5%)	24 (11.6%)
Liver disease	19 (8.1%)	11 (5.3%)
Anaemia	18 (7.6%)	9 (4.3%)
Heart diseases	17 (13.1%)	25(12.1%)
Psychosis	11 (4.7%)	6 (2.9%)
Meningitis	10 (4.3%)	15 (7.3%)
Venous thromboembolism	8 (3.4%)	8 (3.9%)

Approximately 32 % of study participants in both study groups had a degree of renal impairment (eGFR<60ml/min/1.73m^2) while 36 % vs. 32 % (before and after) had some degree of hepatic dysfunction with a Child-pugh score of ≥7as shown in the figure below

Figure 3: Hepatic and renal function of patients



4.3.4 Classes of medicines prescribed

The most prescribed pharmacological class of medicines was anti-infectives, cardiovascular and alimentary agents as shown in the table below.

Table 5: pharmacological classes of medicines prescribed

		n	Proportion (%)	Mean	P value
Anti-infective	Before	329	20.64	1.39	
	After	322	21.13	1.56	0.784
Cardiovascular	Before	278	17.4	1.18	0.137
	After	244	16.0	1.18	
Alimentary	Before	181	11.9	0.77	0.715
	After	188	12.3	0.91	
Analgesic/anti-inflammatory Agents	Before	130	8.16	.55	0.504
	After	141	9.25	.68	
Anticoagulant/anti platelet	Before	139	8.72	.59	0.190
	After	118	7.74	.57	
Hormonal/metabolism	Before	88	5.52	.37	0.605

	After	95	6.23	.46	
Vitamins/supplements	Before	81	5.08	.34	0.811
	After	78	5.12	.38	
Fluid/electrolytes	Before	72	4.52	.31	0.55
	After	65	4.27	.31	
Blood forming	Before	60	3.8	.25	0.014
	After	36	2.4	.17	
Nervous system agents	Before	47	2.95	.2	0.149
	After	34	2.23	1.6	
Anti-tuberclosis agents	Before	33	2.07	.14	0.522
	After	28	1.84	.14	
Anti neoplastics	Before	22	1.38	.09	0.882
	After	23	1.51	.11	
Respiratory	Before	20	1.25	.08	0.456
	After	25	1.64	.12	
Dermatological	Before	9	0.31	.4	1
	After	9	0.59	.4	
Antiparasitic	Before	4	0.25	.02	0.366
	After	7	0.46	.03	
Various/others	Before	9	0.59	0.04	0.617
	After	7	0.46	0.03	

4.3.5 Type of medicines prescribed

The most prescribed medicines were ceftriaxone, heparin, omeprazole/esomeprazoe, paracetamol and furosemide.

Table 6: Types of medicines prescribed

Type of medicine	Proportion before		Proportion after	
	frequency	%	Frequency	%
Ceftriaxone	88	37.3	85	41.1
Heparin	81	34.3	51	24.6
Omeprazole/esomprazolee	78	33.1	62	30
Paracetamol	69	29.2	74	35.7
Furosemide	66	28	48	23.2
Nsaline	44	18.6	44	21.3
Enalapril	39	16.5	26	12.6
Metronidazole	34	14.4	35	16.9
Coamoxiclav	32	13.6	29	14
Spironolactone	31	13	24	11.6
Insulin	29	12.3	30	14.5
Rhze	28	11.9	24	11.6
Atorvastatin	27	11.4	30	14.5
Clarithromycin	25	10.6	31	15
Carvedilol	24	10.2	17	8.2
Warfarin	23	9.7	19	7.7
Aspirin75	22	9.3	27	13
Nifedipine	22	9.3	26	12.6
Ciprofloxacin	17	7.2	12	5.8
Digoxin	14	5.9	12	5.8
Flucloxacillin	10	4.2	8	3.9
Losartan	9	3.8	14	6.8
Diclofenac	6	2.5	7	3.4
Propranolol	6	2.5	1	0.5
Mannitol	6	2.5	10	4.8
Metolazone	4	1.7	2	1
Allopurinol	3	1.3	2	1
Ceftazidime	3	1.3	13	6.3
Sildenafil	3	1.3	1	0.5
Metformin	2	0.8	9	4.3
Pregabalin	1	0.4	2	1

4.4 Types of medication utilization errors

Prescribing errors were quite common with drug-drug interactions most frequent in both study groups, followed by dosage regimen where most of the patients had no duration indicated (Table 7). Almost all patients had frequency and route of medication correctly indicated and approximately 10 % of patients requiring dose adjustment for renal and hepatic impairment did not have their medication dosage adjusted appropriately and the difference in the two study groups was not statistically significant. However there were statistically significant differences for some traits

Table 7 : Types of medication utilization errors

Trait	Categories	Frequency before	Frequency after	P value
Dose	High	3(1.3%)	2(1%)	0.423
	Low	0	2(1%)	
	Correct	207(88.1%)	177(85.5%)	
	Adjustment	25(10.6%)	26(12.6%)	
Route	Wrong	0	1(.5%)	0.152
	Missing	2(0.8%)	0	
	Correct	234(99.2%)	206(99.5%)	
Frequency	Wrong	7(3%)	5(2.4%)	0.74
	Missing	1(.4%)	2(1%)	
	Correct	228(96.6%)	200(96.6%)	
Duration	Wrong	0	0	0.000
	Missing	195(83%)	149(72%)	
	Indicated	41(17%)	58(28%)	
Drug–drug interaction	Yes	191(80.9%)	165(69.9%)	0.825
	No	45(19.1%)	41(17.4%)	
	Contraindication	5(3.5%)	5(4.5%)	0.689
	Serious	48(33.3%)	42(37.5%)	
	Minor	91(63.2%)	65(58%)	
Adverse drug reaction	Yes	26(11%)	18(8.7%)	0.017
	No	210(89%)	189(91.3%)	
Adherence	Yes	45(19.1%)	18(8.7%)	0.002
	No	191(80.9%)	189(91.3%)	

namely; indicated treatment duration, non adherence and adverse drug reactions. Non adherence was reported in majority of patients with 80.9 % in the before group and 91.3 % in the after group [p =0.002] and adverse drug reactions were reported in a minority of patients.

4.5 Prevalence of medication related problems

Prevalence of medication related problems was 230(97.5%) before and 198(95.7%) after introduction of individualized dispensing system.

4.51 Non-adherence

Non-adherence had a prevalence of 80.9 % before and 91.3 % in the after study group [p= 0.002] as shown in table 7. The main reasons for non-adherence were non availability, delay in ordering medication after admission, no apparent explanation for non-adherence, lack of intravenous access and patient factors as shown in table 8 below. No apparent explanation for non-adherence reason was statistically significant (p= 0.0001) between the two study groups.

Table 8: Reason for non-adherence

Reason	Frequency before	Frequency after	P value
Non availability	120(50.8%)	110(53.1%)	0.63
Delay in administration	75(31.8%)	82(39.6%)	0.086
Patient factors	20(8.5%)	16(7.8%)	0.786
No IV access	19(8.1%)	30(14.6%)	0.03
Non apparent	45(19.1%)	93(44.9%)	0.000

4.5.2 Potential Drug interactions

Potential drug on drug interactions had a prevalence of 80.9 % in the before group with 69.9 % in the after group but there was not statistically significant difference between the two groups [p= 0.825]. Minority of the interactions were categorized as contra-indication while the majority were serious and minor as shown in the table 9 below.

Table 9: Drug- drug interactions

Patient category	Category of interaction		
	Contraindication	Serious	Minor
Before	3.5%	33.3%	63.2%
After	4.5%	37.5%	58%

The average number of drug interactions in the before group was 5.82 while the after group had an average of 5.94 interactions per patient and the difference was statistically significant [p= 0.005]. The most common drug pairs involved in the interactions were ceftriaxone/anticoagulants, sulfamethoxazole/anticoagulants, heparin/warfarin and maclorides/anticoagulants while the contra-indications reported in both study groups involved ceftriaxone and calcium salts.

Table 10: The most common interacting drugs

Drug pair	Frequency before	Frequency after
Ceftriaxone/Anticoagulants	39 (16.5%)	31 (15%)
Sulfamethoxazole/Anticoagulants	19 (8.1%)	17 (8.2%)
Heparin/Warfarin	12 (5.1%)	9 (4.3%
Macrolides/Anticogulant	8 (3.4%)	15 (7.2%)
Ceftriaxone/calcium	5 (2.1%)	4 (1.9%)
Isoniazid/Omeprazole	4 (1.7%)	1 (0.5%)
Clarithromycin/Atorvastatin	2 (0.8%)	1 (0.5%)
Rifampicin/Warfarin	2 (0.8%)	3 (1.4%)
Rifampicin/Warfarin	2 (0.8%)	0
Levothyroxine/Heparin	2 (0.8%)	0
Isoniazid/Carbamazepine	2 (0.8%)	0
Clarithromycin/Sildenafil	1 (0.4%)	0
Calcium carbonate/Digoxin	1 (0.4%)	3 (1.4%)
Metronidazole/Warfarin	1 (0.4%)	0

4.5. 3 Prevalence of adverse drug reactions

The patients with documented adverse drug reaction were 11 % before and 8.7 % after introduction of individualized dispensing system. There was a statistically significant difference between the two study groups [p= 0.017], the most common adverse drug reactions reported were hyperkalemia, hepatotoxicity and nephrotoxicity as shown in the table 11 below.

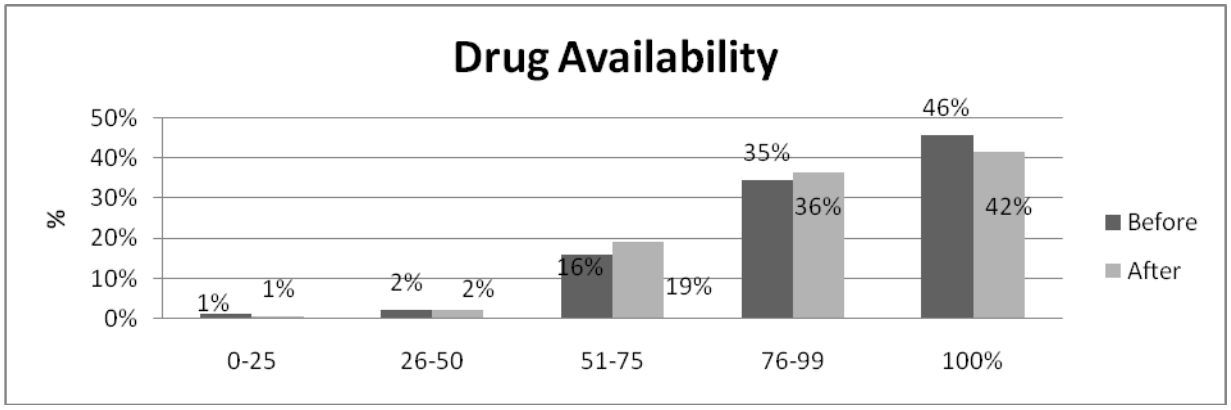
Table 11: Types of adverse drug reactions

Adverse event	**Frequency before**	**Frequency after**
Hyperkalemia	5 (2.1%)	3 (1.4%)
Hepatoxicity	5 (2.1%)	5 (2.4%)
Nephrotoxicity	5 (2.1%)	1 (0.5%)
Skin rash	3 (1.3%)	1 (0.5%)
Haemorrhage	3 (1.3%)	1 (0.5%)
Constipation	3 (1.3%)	2 (1 %)
Diarrhoea	1 (0.4%)	1 (0.4%)
Epigastric pain	1 (0.4%)	-
Cushingoid/moonface	-	1 (0.7%)
Vomiting	-	1 (0.2%)
Hypokalemia	-	1 (0.2%)

4.5.4 Drug Availability

The mean drug availability was 87. 5 % (before) and 86.92 % (after) and there was no significant statistical difference between the two study groups [p= 0.746]. Majority of the patients received all the drugs that were prescribed(46 % vs.42 %) while 3 % of patients in both study arms received less than half of the prescribed drugs as shown in the figure 5 below.

Figure 4: Drug availability



4.5.5 Bivariate analysis

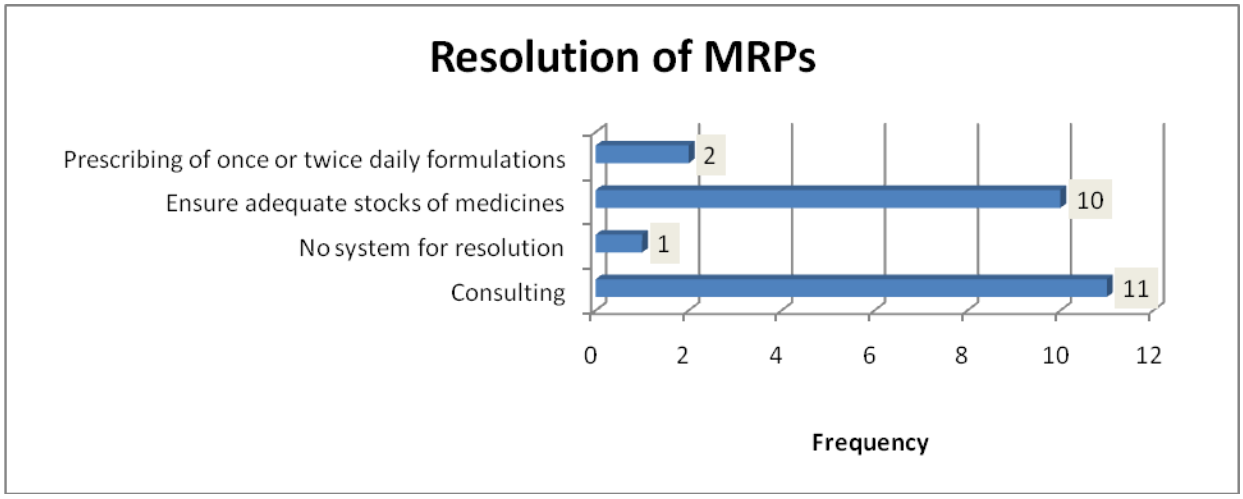
There was an association between age with presence of a medication related problem with young age(<20 to 30-39 years) least affected, then peaking at age 40-49 years and lowest at age 50-59 years. The male female ratio for prevalence of medication related problems in this cohort of patients was 1:1.24[p, 0.084].

The number of drugs per prescription had an effect on the prevalence of medication related problem with 1-3 drug category per prescription having the lowest prevalence while the 8-11 category had the highest prevalence of medication related problems[p<0.001]. The number of diagnosis had an association with presence of medication related problem with patients who had more than two diagnosis having a higher prevalence.

4.6 Mechanism currently used to resolve medication related problems

Mechanisms currently in use to resolve medication related problems were consultations with other members of the healthcare team (45.8%), ensuring adequate stocks of medicines(41.7 %) and prescribing of once or twice daily formulations(8.3%) as shown in figure 6 below.

Figure 5: Mechanisms of resolving MRP'S



CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter compares the findings with similar studies carried by other researchers. It also highlights the conclusions and recommendations.

5.2 Discussion

The medication related problems evaluated were found to be prescribing errors, drug interactions, non-adherence and frequency of adverse drug reactions. The study demonstrates a high prevalence of medication related problems both before and after change of medicine distribution system towards a patient centered individualized dispensing system which was similar to a study conducted in the same institution in 2012 which characterized the extent of medication related problems[5]. Key challenges encountered during the change were inadequate medicine storage facilities, patient management software anomalies, delay in ordering medicines after patient admission and increased workload.

The operationalisation of individualized dispensing system from a mixed system drug distribution system is faced with challenges that hinder complete realization of individual medication order benefits. Provision of resources is vital to successful implementation of change in hospital medicine distribution system and was evident in the study results that cited inadequate medicine storage facility and patient management software as some of the main challenges. Of importance is the critical role of human resource mix of adequate numbers and skills, at a ratio of 1 and 3 pharmacist/ pharmaceutical technologists per 100 hospital beds, respectively. This constraint was highlighted by the number of respondents who reported increased workload and delay in ordering medicines as main challenges. Comparative staffing levels for USA are high [7, 24].

The study did not show a statistically significant difference in the frequency of medication related problems in the two study groups, however there was a significant increase in the number of treatment charts with an indication of treatment duration and a reduction in reported frequencies of adverse drug reactions in the after study group. A check on appropriateness of prescribed medication would be expected to result to a reduction in medication error

rate[4].There was no significant difference in dose and medication frequency errors comparable to findings in India[10].

Potential drug-drug interactions were reported by majority of study participants with an average of 5.82 drug interactions in the before group while the after group had an average of 5.94 interactions per patient, there was no statistically significant difference between the two study groups with prevalence at 80.9 % before and 69.9 % after was higher than that reported in other studies in Kenya and Pakistani[13,24]. Adoption of simple technology such as the android mobile phone with free drug interaction checker and prescriber education can lessen the burden of the potential drug-drug interaction reported in this study. Common drug interaction pairs reported in this study were cefttriaxone/anticoagulants, sulfamethoxazole/anticoagulants, heparin/warfarin, macrolides/anticoagulants and ceftriaxone/calcium salts and therefore assessment of prescriptions for potential drug-drug interactions should focus on the common drugs indentified in this study.

Majority of patients reported non-adherence to the prescribed medication and this was an interesting observation given the study patients were hospital inpatients. It differs markedly with the 2012 study where 20.9 % of the patients were non-compliant [5].The main reasons for non-adherence were non availability, delay in ordering medication after admission, none apparent, lack of intravenous access and patient factors.

The proportion of respondents with documented adverse drug reaction was 11 % before and 8.7 %, showing a statistical difference between the two study groups. The most common adverse drug reactions reported were hyperkalemia, hepatotoxicity and nephrotoxicity. This prevalence was comparable to Kenyan and Nigerian studies carried out among medical outpatients[5,17].

Majority of the patients received all the drugs that were prescribed while 3 % of patients in both study arms received less than half of the prescribed drugs. Drug shortage still continues to plague the public health sector and strict adherence to the hospital formulary system coupled with higher resource allocation could ameliorate this situation. Mechanisms currently in use to

resolve medication related problems were consultations with other members of the healthcare team, ensuring adequate stocks of medicines and prescribing of once or twice daily formulations.

Studies elsewhere have reported robust methods with wide acceptance for identifying and resolving medication related problems that involve multidisciplinary teams including pharmacists[2,25]. The use of electronic aids has been shown to improve detection of drug related problems.

5.3 Conclusion

The study has indicated the challenges faced in the implementation of the individualised inpatient dispensing system and the high prevalence of medication related problems both before and after implementation of the individualized inpatient dispending system. Robust multi-disciplinary systems of identifying and resolving medication related problems that improve medication safety are however lacking.

5.4 Recommendations for Policy and Practice

The study recommends;

1. The formation of multi-disciplinary teams involving pharmacists to identify and resolve medication related problems at the medical wards.

2. Adequate resources to be provided for medicine storage facilities, requisite staff mix and acquisition of effective patient management software.

5.5 Recommendations for Further Research

This study did not assess dispensing and administration errors that contribute to medication related problems, further research is warranted. The factors contributing to the apparent high prevalence of non-adherence among inpatients should be investigated.

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APPENDICES

APPENDIX 1: DATA ABSTRATION FORM FOR PREVALENCE OF MEDICATION RELATED PROBLEMS

Code.....

1 Age..... Sex.....

DOA.....WD .....DOD.....

2 Occupation..... Education Level.....

3 Diagnosis.....

.....

4 Number of medicines on treatment chart

Regular.....

Stat / PRN.....

Type of medicine.....

5 Is medication related problem present? Yes..... No..... Number-------.

6 Type of medication related problem if answer to 5 is yes.

Dose; high..... Low..... Adjustment.....

Route; correct ..... wrong..... missing.....

Frequency; wrong.....missing.....

Duration; wrong.....missing.....

Drug interaction; contraindication.....serious.....minor.....

Drug – disease interaction present? Yes..... .. No.....

Adverse drug reaction; Yes..... No.....

If yes which one? .....

Drug availability; number.....out of.....

7 Renal function; normal Yes..... NO.....

If no, Serum creatinine..... Estimated CLcr.....

8 Hepatic function; normal Yes.....NO

9 Adherence: Yes..... NO..... Reason(s).....

APPENDIX 2: QUESTIONNAIRE ON CHALLENGES FACED IN IMPLEMENTING INDIVIDUALISED INPATIENT MEDICATION ORDER SYSTEM

Kindly answer the following questions as accurately and truthfully as possible. Information provided will be kept confidential.

1 Gender

☐ Male

☐ Female

2 Age..... in years

3 Cadres

☐ Nurse

☐ Pharmaceutical technologist

☐ Pharmacist

4 What challenges have you faced in implementing individualised medication orders?

☐ Increased workload ☐ inadequate storage space

☐ Shortage of dispensing materials ☐ lack of clear procedures

Others specify.....

.....

5 suggest ways of improvement

.....

.....

6 What type of medications related problems do you encounter?

.....

7 How do you resolve medication related problems?

.....

.....

.....

.....

APPENDIX 3: INFORMED CONSENT FORM

TITLE OF THE STUDY: Assessment of the uptake of inpatient individualised dispensing system at Kenyatta national hospital**.**

INVESTIGATOR: DR ALFRED BIRICHI RUGENDO.

.

SUPERVISORS: DR PETER KARIMI, DR BEATRICE AMUGUNE.

COLLABORATING INSTITUTION: KENYATTA NATIONAL HOSPITAL

P.O.BOX 20723-00202, KNH, NAIROBI.

STUDY SITE: MEDICAL WARDS AT KENYATTA NATIONAL HOSPITAL, NAIROBI.

PREAMBLE

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

PURPOSE OF THE STUDY: The purpose of the study is to identify the challenges encountered in the implementation of the individualised dispensing system at the medical wards of Kenyatta National Hospital. Further the effect of the change on medication related problems will be determined.

STUDY PROCEDURES

Should you agree to participate in this study, you will be required to sign a consent form.

You will then be given a questionnaire to fill that will at most take ten minutes.

Risks and Discomforts

Participating in this study may be associated with no or minimum risk and discomfort during the interview. Filling of the questionnaire may take at most ten minutes.

Benefits

The results of this study will be used to refine the individualised inpatient dispensing system. It will also be used to enhance medication safety by implementing recommended strategies for minimising medication related problems.

Voluntary participation/withdrawal from study

The decision to take part in this research study is your choice. You may choose not to take part or to stop participating at any time without any consequences.

Questions

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

Further Information

Further information regarding your rights as a study participant can be obtained from the Secretary KNH/UON research and ethics committee at uonknh_erc@uonbi.ac.ke,

P.O Box 20723-00202 Nairobi, Tel. 2726300 Ext. 44102

Study title	Assessment of the uptake of inpatient individualized dispensing system at Kenyatta National Hospital.		
Version	01	Date	28th May 2014

STATEMENT OF CONSENT

I have read and I have had the chance of discussing this research study with the investigator where my questions have been answered in a language I understand. The risks and benefits have been explained to me and I do understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in the research study.

- I have read YES/NO
- I agree to participate in this research study YES/NO

Participant's signature: _____Date: _____

I, the undersigned have fully explained the relevant details of this research study to the participant named above and believed that the participant has understood and has knowingly given his consent.

Name: _____Date: _____

Signature: _____

Role in this study: _____

Appendix 4: Ethical approval from KNH/UON research and ethic committee

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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/171 Link:www.uonbi.ac.ke/activities/KNHUoN 5th June 2014

Dr. Alfred Birichi Rugendo
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
University of Nairobi

Dear Dr.Rugendo

Research proposal: Assessment of the uptake of inpatient individualized Dispensing system at Kenyatta National Hospital (P228/04/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 5th June 2014 to 4th June 2015.

This approval is subject to compliance with the following requirements:

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

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

Protect to Discover

Yours sincerely

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

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
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