PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

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2016

DECLARATION

I, Elizabeth Kemunto Okerosi, do hereby declare that this thesis is my original work and that this work has not been presented for the award of any other degree or to any other university.

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Elizabeth Kemunto Okerosi, BPharm

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Title of the work: Prevalence and risk factors for Medication Discrepancies on admission of elderly diabetics at Kenyatta National Hospital

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ABSTRACT

Background

Medication discrepancies are defined as the variations in drug regimens during transition from one health care worker or hospital to another. These medication discrepancies are either intentional or unintentional and can lead to errors which can be detrimental to patients and in the long term result in Medication Related Problems (MRPs). The unintentional discrepancies can result in poor management of acute and chronic diseases, hospital readmission, and death. Elderly diabetic patients are at high risk of medication discrepancies due to their multiple chronic diseases resulting in different medication from the many healthcare providers they are likely to see. The fact that they are elderly and undergoing normal age related changes also puts them at high risk. Medication Reconciliation is therefore needed to identify and rectify these discrepancies to promote patient safety.

Objectives

The main objective of the study was to measure the prevalence and identify risk factors for medication discrepancies at admission in inpatient elderly diabetics at Kenyatta National Hospital (KNH).

Methodology

A cross sectional study was carried out involving elderly diabetic patients aged 60 years and above admitted to the medical wards at Kenyatta National Hospital (KNH) in 2016. Convenient sampling was done to select the participants who met the inclusion criteria. The participants who gave consent were recruited 24 hours after admission.

Data was abstracted from patient medical files, patient/caregiver interviews, clinical discharge summaries and a physical check of drugs in use. A comparison of the medication used before and after admission was done to determine the number of discrepancies. The discrepancy types identified were classified into intentional, undocumented intentional and unintentional discrepancies. Linear regression was done to identify risk factors for medication discrepancies.

Results

Among the 163 patients recruited, 1089 medication discrepancies were identified. On classification, 849 (78%) were intentional and 240 (22%) were unintentional. Among the unintentional, 225 (94%) had the potential for harm with a prevalence rate of 1.4 per patient. The most common discrepancy type is omissions 236 (98.3%). Only 94 (42%) of the 225 unintended discrepancies were resolved. Exactly, 63.2% of the patients had at least one unintentional discrepancy (medication error).

Independent risk factors for number of discrepancies were the number of medications prior to admission (adjusted β coefficient 1.377 (95% CI: 0.767, 1.987)), hypertension (β 0.992 (95% CI: 0.094, 1.890)) and those with discharge forms from previous facilities (β 0.701 (95% CI: 0.010, 1.392)). Age had a negative association with medication discrepancies (β -0.755 (95% CI: -1.284, -0.226)).

Conclusion

Medication discrepancies are common on admission. Our results support the importance of a comprehensive medication history at hospital admission and putting in place a medication reconciliation program, as demonstrated throughout the literature.

DEDICATION

I would like to dedicate this thesis to my supportive husband and friend Ham Wesonga Sikhila, for his support and my little angel daughter, Aria Tandi Wesonga, for putting up with mum's absence.

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LIST OF ABBREVATIONS AND ACRONYMS

ACCORD	Action to Control Cardiovascular Risk in Diabetes
ADE	Adverse Drug Events
ADR	Adverse Drug Reactions
AMOs	Admission Medication Orders
BMI	Body Mass Index
BPMH	Best Possible Medication History
DM	Diabetes Mellitus
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KNH	Kenyatta National Hospital
MRPs	Medication Related Problems
T2DM	Type 2 Diabetes Mellitus
UoN	University of Nairobi
WHO	World Health Organization

DEFINITIONS OF OPERATIONAL TERMS

Admission Medication Orders (AMOs): Prescriber-recorded admission medication orders documented within 24 hours from the time of admission to healthcare facility.

Adverse Drug Event (ADE): An injury from a medicine or lack of an intended medicine and includes adverse drug reactions and harm from medication incidents.

Best Possible Medication History (BPMH): is a history created using a systematic process of interviewing the patient/family and a review of at least one other reliable source of information to obtain and verify all of a patient's medication use (prescribed and non-prescribed)

Elderly Diabetic Patients: Patients 60 years of age and older. They can be categorized as follows: The "Young Old" those entering old age- 60-74years. These are patients who are independent and healthy and are still able to do a lot on their own. The "Old" are aged 74-84 years. These patients are slowly sliding into frail old people. Lastly the "Oldest-Old" are aged 85yrs and older. These patients have increasing medical and social care needs. They are commonly living with a relative for support or are in assisted care facilities or nursing homes.**(1)**

Intentional Discrepancies: An intentional choice by a prescriber to add, change or discontinue a medication based on a clinical rational and the choice is clearly documented.

Medication Discrepancies: Any difference, intended or unintended, between the diabetes-related medication list in the patient's file, and the diabetes-related medications reported by the patient during the medication use interview.

Medication Errors: The unintentional discrepancies for which there is no clinical rational.

Medication Reconciliation: A formal process that requires a systematic and comprehensive review of all the medications a patient is taking to ensure that medications being added, changed or discontinued are carefully evaluated. It is a component of medication management and will inform and enable prescribers to make the most appropriate prescribing decisions for the patient.

Polypharmacy: refers to the use of multiple medications, typically five or more. (4) Recently, it has been used to describe the use of inappropriate medications, or more medications than clinically indicated.

Transitions of Care: refers to movement of patients at different points of care within the hospital from admission, transfer within units in the hospital and discharge or can be different health care practitioners as their condition and care needs change.

Unintentional Discrepancies: Un-intentional changes made by a prescriber to medication the patient has been taking prior to admission and are potential medication errors than can lead to Adverse Drug Events.

1.0 CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Medication discrepancies are defined as unexplained differences among drug regimens such as dose, route and frequency of administration during transition from one health care worker or hospital to another. (**2**) Medication discrepancies also occur at transitions during hospitalization such as hospital admission, transfer between units and discharge. These are defined as transitions of care or interfaces of care. (**3**) These medication discrepancies are either intentional or unintentional and can lead to reconciliation errors which can be detrimental to patients. (**2**)

Intentional discrepancies are not errors but deliberate changes in a patient's medication regimen made by a provider, unintentional discrepancies however, are caused by accidental medication prescribing and are medication errors. They can result in adverse drug events (ADEs) if actual harm is caused or (potential ADEs) that are near misses and have the potential to cause harm. (**4**) The unintentional discrepancies can result in poor management of acute and chronic diseases, hospital readmission, and death.(**4**) The prevalence of unintentional discrepancies that have the potential for harm range from 11-59% of all discrepancies.(**5**)

The factors that contribute to medication error include: older age, people with serious and multiple health conditions, those taking multiple medications and those using high risk medicines.(**6**)

1.1.1 Risk of Medication Errors in Elderly Diabetic Patients

The elderly are at increased risk of medication errors due to the following factors: normal ageing changes that can result in the individual not taking medication correctly, multiple/chronic illnesses, poly-pharmacy, medical conditions that need new or additional medications therapy, patients taking unnecessary medication through self-medication, wrong medication for the individual's medical condition, and inappropriate dose. (**7**)

Geriatrics who are diabetics with multiple chronic illnesses are likely to receive care from several healthcare providers, each of whom may prescribe a different medication to treat similar symptoms.(**7**) The result is poly-pharmacy and can put the patients at risk of medication errors that predisposes them to ADEs. (**7**) There is a tendency of elderly people to

keep medications that were prescribed years ago as well as medications that were changed after a hospitalization. (**4**)

Physiological changes associated with age affect body systems, resulting in changes to the pharmacokinetics/pharmacodynamics which may potentiate or affect a drug's effects. (**7**) This greatly increases the risk of medication-related problems and adverse events in these patients. The sensory system undergoes changes related to age which may adversely affect the ability to perform day to day activities such as self-care and taking of medications. These sensory changes include: reduction in tympanic membrane flexibility, deterioration of the vestibular apparatus, and, stiffer ossicles which can result in loss of hearing and balance issues. Consequently, the elderly have difficulty hearing instructions given by health care workers correctly with regard to medication use leading to medication errors. (**7**) Poor cognition also occurs in the elderly and is associated with both over and under adherence of prescribed medication regimens. (**7**)

1.2 STATEMENT OF THE PROBLEM

Medication discrepancies commonly occur at the time of admission due to inaccurate medication history taking. These discrepancies can lead to medication errors and eventually Medication Related Problems (MRPs) such as Adverse Drug Reactions (ADRs), non-adherence among others if left unidentified and corrected. In a study by Nyakiba (2012) done in medical wards at Kenyatta National Hospital (KNH), the prevalence of Medication Related Problems (MRPs) was found to be 96.7%.(**8**) This is a clear indication that discrepancies occur in medications used by patients in the medical wards.

The high incidence of Medication Related Problems in KNH can be attributed to inaccurate history taking. There is however no data on MRPs in diabetics especially the elderly. The study explored medication discrepancies and the need for medication reconciliation to identify and correct them. There is no data on this locally.

Issues with regard to management of medication in the treatment of diabetes have been well documented, however less is known about the prevalence and predicting factors that contribute to medication discrepancies associated with diabetic patients 60 years of age and older at admission in hospitals in Kenya.

1.3 RESEARCH QUESTIONS

The study sought to answer the following research questions:-

1. What types of medication discrepancies occur at admission of elderly diabetic patients?
2. What is the prevalence of these discrepancies?
3. What are the risk factors of these discrepancies?

1.4 OBJECTIVES

1.4.1 Main Objective

To determine the prevalence and risk factors for medication discrepancies at admission in inpatient elderly diabetics at Kenyatta national Hospital (KNH).

1.4.2 Specific Objectives

The specific objectives were to:-

- To measure the prevalence of medication discrepancies identified during medication reconciliation at admission.
- To classify reconciliation errors/discrepancies.
- To identify the predictors/risk factors of medication discrepancies at admission.

1.5 JUSTIFICATION OF THE STUDY

This study was expected to show high prevalence of medication discrepancies and their potential for harm. Findings of this study would be used to lobby for establishment of a formal medication reconciliation system in a teaching and referral hospital as well as other hospitals in Kenya. According to Bookvar, medication reconciliation was associated with lower chances of medication discrepancy-related adverse drug events. (**9**) "A combined intervention of pharmacists and physicians in a collaborative medication reconciliation process has a high potential to reduce clinically relevant errors at hospital admission among elderly patients."(**10**)

By identifying risk factors for medication discrepancies, targeted interventions are put in place that addresses these risk factors so as to improve disease management in elderly diabetics. Risk factors can be used to target intervention towards patients, particularly those at risk for discrepancies especially at admission.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 MEDICATION RECONCILIATION

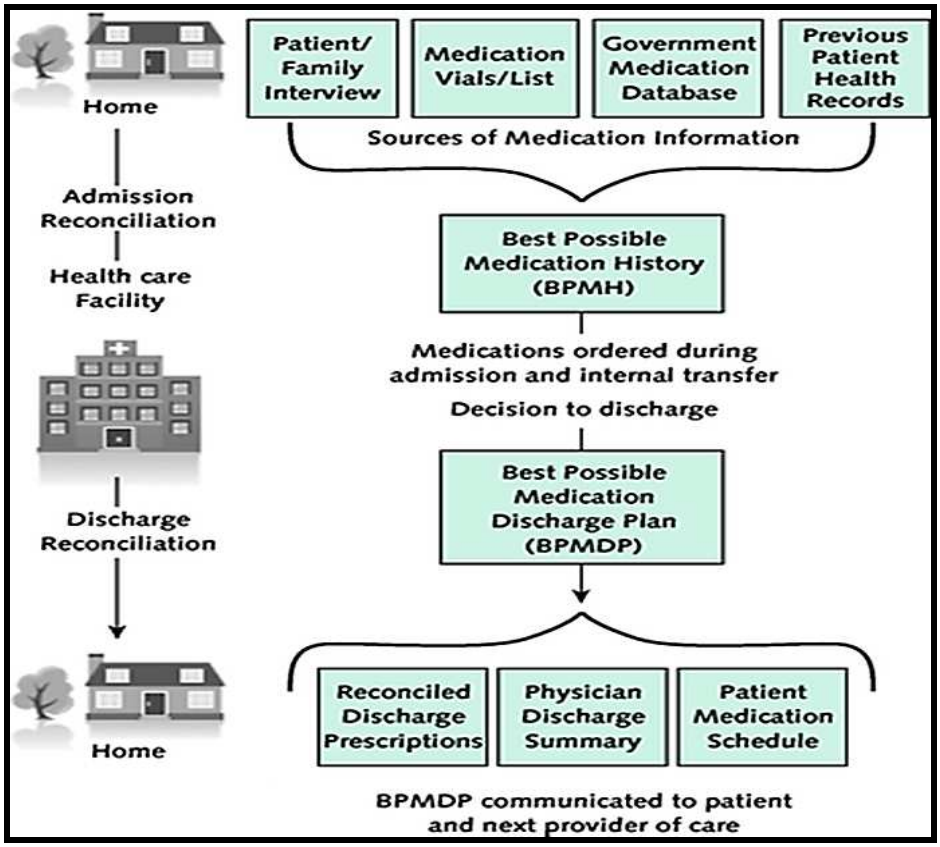
Medication reconciliation is a process of coming up with a list of a patient's current medications that is as complete and accurate as possible then comparing the medications with those in the provider medication orders within the patient's medical record and should be conducted during transitions of care. (**7**) "The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) defines medication reconciliation as process of comparing patient's medication orders to all of the medications that the patient has been taking." The aim of medication reconciliation is to foster patient safety by identification of errors of omission, duplication, incorrect doses or timing, and the potential for ADEs. (**12**)

As part of medication reconciliation, medications that are duplication, or "that contain the same active ingredient but were prescribed as a different formulation or as part of a combination drug" should be discontinued. (**4**)

2.1.1 The process of Medication Reconciliation

Medication reconciliation should be carried out at every point of care such as changes in clinical setting, practitioner or level of care in which new medications are ordered or existing orders are rewritten.

This is a five step process comprising of: development of a list of current medications, development of a list of medications to be prescribed, comparisons of the medications on the two lists made; clinical decision making based on the comparison, and communication of the new list to appropriate caregivers and to the patient. This process is summarized in Figure 1.



Adapted from Fernandes, Medication Reconciliation. Primary Practice 2009; 25:26.

Figure 1: Overview of medication reconciliation- what, where, when and how (5)

2.1.2 Medication Reconciliation at Admission

The Best Possible Medication History (BPMH) is obtained from various sources: patient/caregiver, patient files and physical examination of medications being used. A comparison is made with the Admission Medication Orders (AMOs) and discrepancies identified. Reconciliation is made by finding out if the discrepancy is intentional or not. Documentation is done for intentional discrepancies, while corrections made for unintentional discrepancies. This is illustrated in Figure 2.

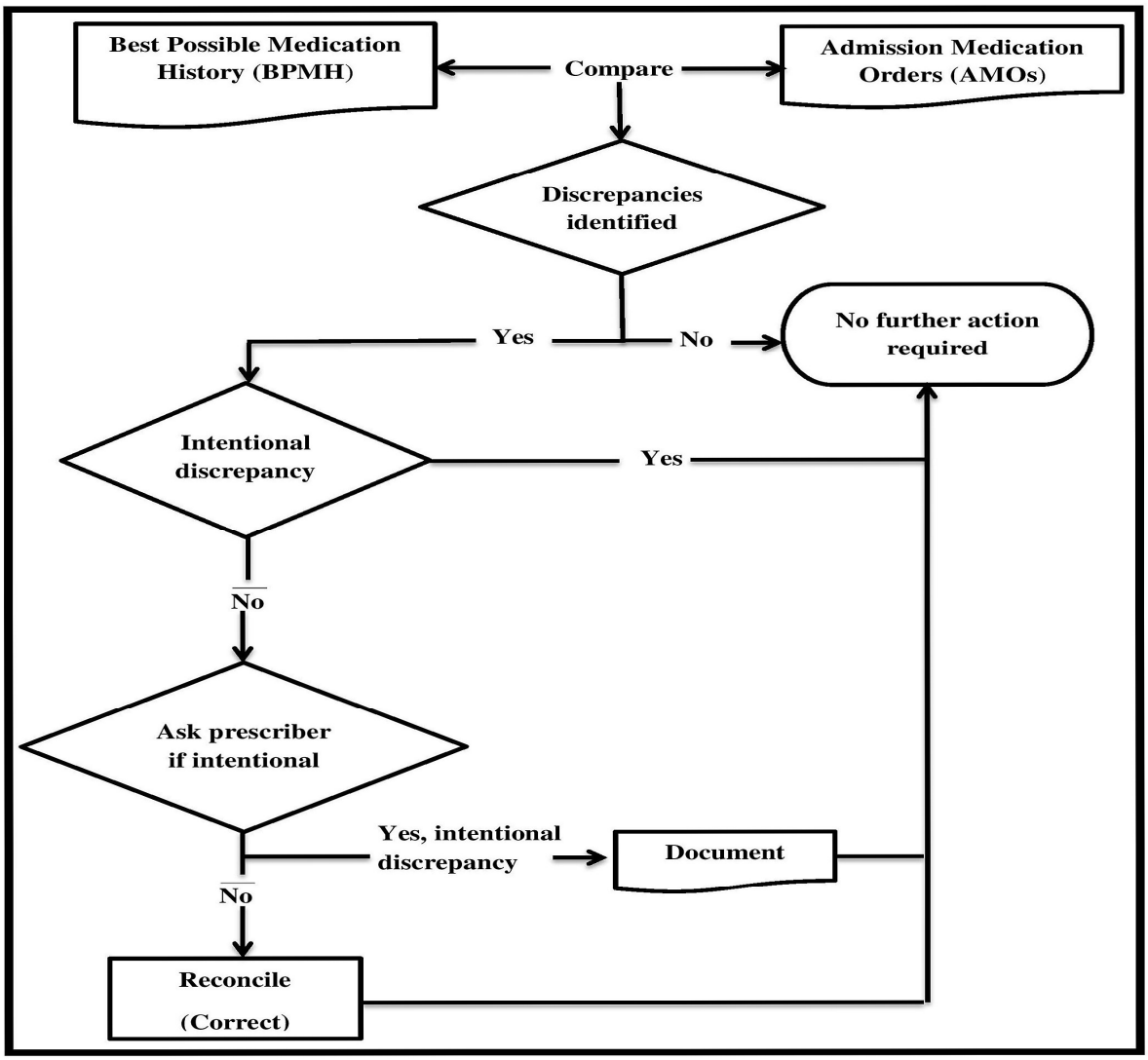


Figure 2 Medication Reconciliation Process Flow Chart: Admission to a Healthcare Facility

2.1.3 Provider Knowledge of Medication Reconciliation

According to a paper by Barnsteiner (2005), nurses were noted to spend more than an hour per patient during admission or transfer in an effort to accurately identify medications a patient has been receiving. (**11**)

When patients are hospitalized, it is usually for a specific procedure, for example surgery, or for on an urgent issue therefore, specialists will tend to focus on the area of care related to the specific encounter and are not likely to holistically view other aspects of the patients' health care needs and practices, there is therefore a high chance of giving new medications that may cause an adverse event when combined with a patient's existing medications and this can easily be overlooked. (**11**) Pharmacists play a crucial role in a patient's health team during a transition when carrying out medication reconciliation as they have expertise knowledge of a

patient's drug therapy and can improve safety by identification of drug-to-drug interactions and duplication in medication regime.(**13**)

Medication reconciliation is a complex process and for it to work, it requires designing and testing streamlined processes that will work across the continuum of care with involvement of all stakeholders.(**11**) These stakeholders include patients and their caregivers, physicians and nurses as well as the management to ensure the process of reconciliation runs smoothly.

The challenge with implementing medication reconciliation is developing effective programs at the various sites of care, standardizing the process, and including the patient in the process. Another is amassing leadership and support, getting health providers to understand the need for medication reconciliation as well as to participate in the design and implementation of programs. This is a greater challenge in organizations where the providers already feel burdened.(**11**)

At the onset of this study, the relevant stakeholders (prescribers and patients) were made aware of what medication reconciliation was all about and the benefits to the patients' health in the long run.

2.1.4 The Impact of Medication Reconciliation

The process of reconciliation has been shown to be a powerful program to reduce ADEs as participants transition from one level of care to another. Studies show that medication reconciliation at admission led to a significant reduction in actual ADEs caused by errors in admission orders. (**14**) Medication errors rate were successfully decreased by 70% and ADEs reduced by over 15% through a series of interventions, including medication reconciliation, introduced over a seven-month period.(**15**) There was a reduction in potential ADEs within three months of implementation when pharmacy technicians were used to initiate the process of reconciliation by obtaining medication histories for a scheduled surgical population. (**16**)

A Canadian study done in 2006 found that 60% of patients had at least one unintended discrepancy at the time of admission and 18% had at least one that was clinically significant. None of the discrepancies had been detected by usual clinical practice before process of reconciliation was conducted. A medication reconciliation process intercepted about 75% of the 20 clinically significant discrepancies before patients were harmed. (**17**)
Literature shows evidence that successful medication reconciliation processes reduces work and rework that is often accompanied with the management of medication orders. A

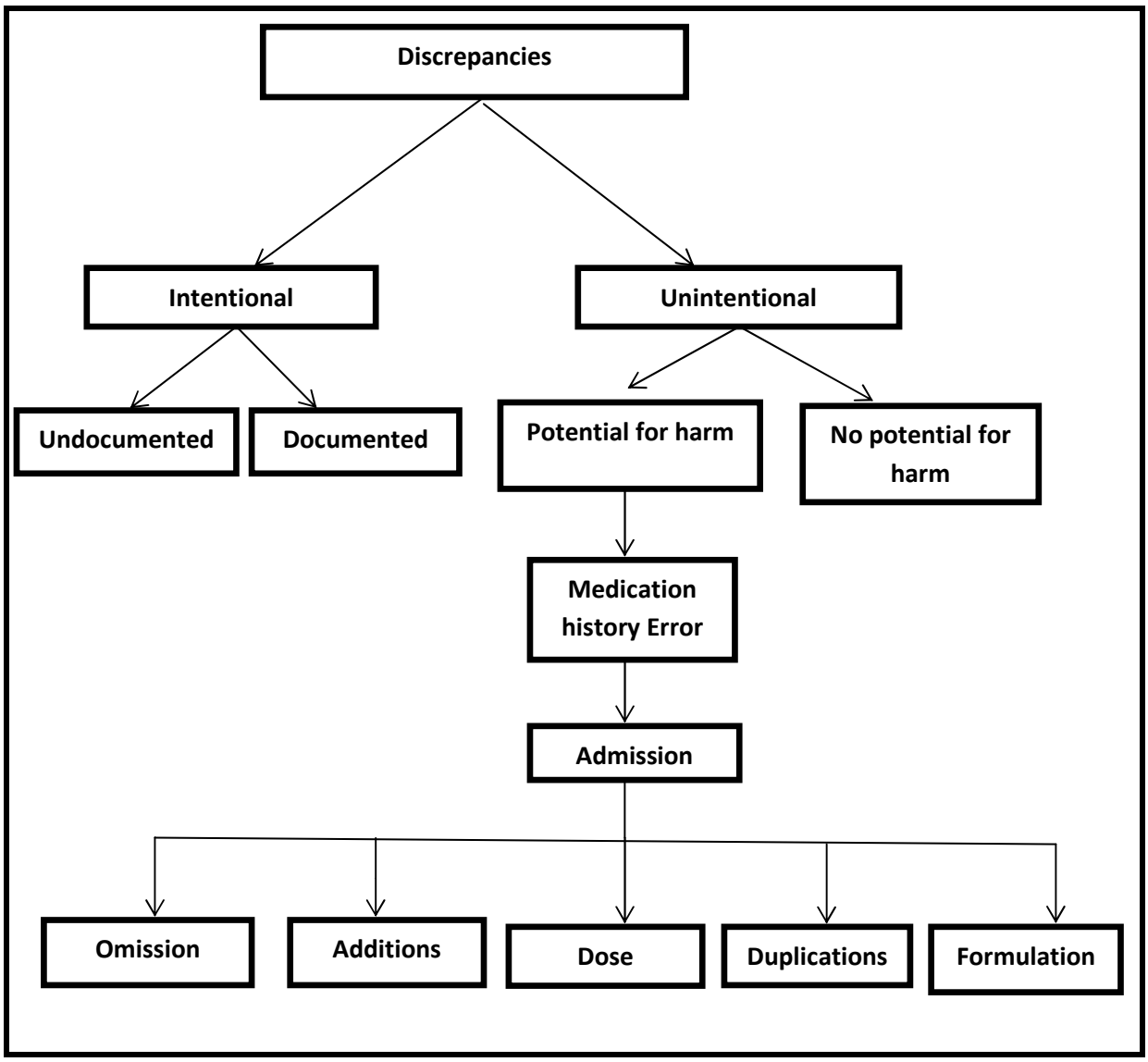
reduction in nursing time at admission by over 20 minutes per patient was observed as well as reduction in the amount of time pharmacists were involved in discharge by over 40 minutes. (**11**)

2.1.5 Systems and Tools for Medication Reconciliation

It is important to identify predictors of medication discrepancies in old diabetics as this improves medication reconciliation. (**6**) The Agency for Healthcare Research and Quality (AHRQ) funded an initiative that comprised of a multidisciplinary team to promote medication reconciliation. The team consisted of two universities and The Joint Commission. The team came up with a toolkit that comprised of guidelines on how to assemble a team to conduct medication reconciliation and provide educational and training materials. The tool also included guides for designing and implementation of medication reconciliation. Resources were availed for patients to promote this exercise. (**18**) Seton Home Health Care came up with an interdisciplinary Care Transitions Readmission Committee with representation from the various departments and held team meetings monthly in order to identify and improve on communication and care coordination gaps. In the system by Seton Home, the admitting nurse would complete a list of medications the patient was taking prior to admission and enter the information into an electronic database managed by the pharmacy.(**18**)

2.2 CLASSIFICATION OF MEDICATION DISCREPANCIES

Discrepancies between Admission Medication Orders and the Best Possible Medication History can be divided into three main categories: documented intentional, undocumented intentional or unintentional. According to a study in 2008, medication discrepancies were classified as shown in figure 3. Results from the study showed that the highest prevalence of discrepancies was that of omissions at 60% followed by dose changes at 53%. (**19**) Unintentional discrepancies rates of 30–70% between the medicines patients were taking before admission and their prescriptions on admission have been reported in literature reviews.(**20**)



Adapted from a study by Pippins. (**19**)

Figure 3: Classification of medication discrepancies

2.3 RISK FACTORS FOR MEDICATION DISCREPANCIES AT TRANSITIONS OF CARE.

Several predictors of harmful or potentially harmful medication discrepancies have been identified. A study done in 2005, showed that "increasing number of prescription medications, poor patient understanding of preadmission medications, and numerous medication changes were significant predictors for unintended medication discrepancies".(**11**)

2.3.1 Polypharmacy and Advanced age

As people get older, the development of chronic conditions is inevitable, this result in more medications prescribed. Data from the Canadian Institute for Health Information showed that

23% of those 65 years of age and older and 30% of those 85 years of age and older had claims for 10 or more drug classes in 2009. (**7**) There is an increased risk of prescribing cascades due to prescribers' reluctance to change drug regimens other prescribers' started this results in prescribers not being able to recognize medication side effects. (**7**)

A prospective cohort study of 400 patients discharged from hospital found that increased risk of a medication error was associated with increasing numbers of medication prescribed at discharge. (**4**) Good (2002) found that about 40% of elderly patients admitted to a facility were taking five or more medications. Another study of the elderly in Sweden also found that approximately 39% were taking five or more drugs concomitantly.(**21**) Polypharmacy makes elderly patients susceptible to adverse drug events (ADE). For elderly diabetics specifically, it puts them at increased risk of drug interactions, non-compliance and unwanted geriatric syndromes.(**21**)

Advancing age leads to progressive functional decline in organ systems leading to changes in the way medications are managed and presented due to pharmacokinetic and pharmacodynamics changes in the body. (**7**) The elderly are particularly at high risk for medication discrepancies given the prevalence of poly-pharmacy in this population. (**13**)

2.3.2 Patient Education Levels

Elderly patients with low levels of education may be unable to read instructions and understand on how to take their medication. (**3**) About 44% of the 147 elderly diabetic patients involved in the study were not educated. Those diabetic patients who have low literacy and knowledge might be facing troubles in learning self-care skills for glycaemic control made worse by cognition impairment, decreasing vision and hearing loss as a result of aging process.

In a study done in Malaysia involving 147 elderly type 2 diabetes mellitus in medical wards in a tertiary healthcare facility, it was found that only 15% of them could provide correct names to their medication and 76% of them demonstrated good knowledge of the reasons for taking their medication.

2.3.3 Poor Communication at Care Interfaces

As patients transition from one point of health care to another, changes to their medication regimen often occurs. The changes may include withholding, addition of new medications or changes to chronic medications. When there is lack of precise documentation and/or

communication of information from one point of care to another, medication discrepancies between medication lists may occur. This has a clinical impact on the safety of patients as literature shows that approximately 30% of discrepancies have the potential to cause patient harm. (**2**)

Healthcare providers should ideally communicate and work together on the treatment plan, but more often than not, this does not occur and crucial information is lost. Due to poor communication among health care providers, 50% of medication errors and 20% of harmful adverse drug events occur at transition points.(**5**)

A study done in 2012 showed that approximately 27% of unintentional discrepancies were due to incomplete or inaccurate information in primary care medicines lists including referrals by the general practitioner and print outs of medicines.(**20**)

2.3.4 Medication Use History taken at Admission

An accurate medication history at the time of hospital admission is important and better methods are needed to adequately carry this out. Accuracy of the medication history is vital because, medication errors at hospital admission are common, and some have the potential to cause harm. (**10**)

Several studies show that inaccurate history taking result in medication discrepancies. Bayley identified that omission of medication, altered doses and incomplete allergy histories as the most common discrepancies in medication history from ambulatory to inpatient care. A study by Gleason discovered that “more than half of the patients they studied had discrepancies in medication histories or admission medication orders”.(**11**)

2.4 WHY ELDERLY DIABETICS?

Elderly diabetics are a heterogeneous group of patients. Some could be living alone, others with care givers while others could be in assisted care living. They require multiple drugs for their diabetes (DM) and their associated comorbidities. (**12**) Management of type 2 diabetes in the elderly population is difficult because of complex comorbidities and the difficulties they generally encounter in performing normal daily activities.(**22**) Geriatric syndromes such as cognitive dysfunction, functional impairment resulting in limited physical activity and vision and hearing impairment occur more often in the elderly with diabetes and may affect self-care abilities and health outcomes(**23**) and serve to make management of diabetes more difficult.

2.4.1 Management of Diabetes in the Elderly

Glycaemic control in the elderly is tricky due to the risk of hypoglycaemia. In an ACCORD trial, older participants had approximately 50% higher rates of severe hypoglycaemia than participants under the age 65 years.(**23**) Glycaemic control is achieved through use of insulin and oral hypoglycaemic agents. Metformin is often used as the first-line of therapy in type 2 diabetes. It may be beneficial in older adults due to its low risk for hypoglycaemia, however the gastrointestinal intolerance and weight loss from the drug may be harmful in frail patients.(**23**) Sulfonylureas, although less costly, put older patients at risk of hypoglycaemia; for example glyburide which should not be prescribed for older adults. Insulin therapy can be used to achieve glycaemic control in selected older adults with type 2-diabetes. However, given the heterogeneity of this cohort, the risk of hypoglycaemia must be carefully examined before using an insulin regimen for hyperglycaemic control. (**23**) Manual dexterity is also an issue for the elderly and brings problems especially in insulin administration

The risk of complications has to be reduced through use of lipid lowering agents such as the statins and aspirin. These reduce the risk of cardiovascular events since the elderly are at higher risk. Trials show consistent evidence that the cardiovascular risk is reduced in geriatrics with diabetes by lowering blood pressure from very high levels to moderate targets (SBP 150 mmHg). (**23**)

It is clear that multiple drugs are needed to manage diabetes; therefore in treating patients with type 2 diabetes, a challenge is that polypharmacy may be inevitable and necessary to control related comorbidities and reduce the risk of diabetes complications. Medication reconciliation is therefore needed at each point of care. (**23**)

2.4.2 Comorbidities of Diabetes

In the elderly, diabetes is often associated with increased risk of multiple chronic illnesses that coexist with the diabetes.(**23**) These comorbidities include: dyslipidaemia, obesity, hypertension, chronic kidney disease. The risk of muscle atrophy, postural instability and problems with balance increases due to peripheral neuropathy that occurs in about 50–70% of geriatrics with diabetes.(**23**)

2.4.3 Types of Medication errors occurring in diabetic patients

Omission or addition of a medication to the patient's medical record are the most frequent types of medication discrepancies and are common to all three points of care, admission, transfers within hospital units and discharge. Research has shown at least one omission error

contained in about “10 -61% of medication histories taken on hospital admission and 13–22% had at least one addition of a drug not used before admission.”(**3**)

Insulin dosing errors happen in the elderly due to polypharmacy and the higher prevalence of poor vision, arthritis, and other geriatric syndromes and this increases the risks of hypoglycaemia. In an article in Women’s health, the U.S pharmacopoeia gave an annual report stating that 55% of fatal hospital medication errors reported involved the elderly; 35% of the medical errors are not caught before they reach the elderly patients, 4.2% of errors involved giving the wrong patient a medication, 43% of errors involved omission of a patient’s prescribed medications, 18% related to dosage or quantity changes and 11% involved giving unauthorized drugs to patients.(**24**)

In an audit done in Australia on medication variances, more than 80% of referral letters contained at least one discrepancy when transferring diabetic patients from primary to tertiary care and about 59% of these were omissions. Most notable from this study was the high discrepancy rate for all insulins with a 43% prevalence rate for omissions. (**3**)

2.4.4 Reasons for Admission of Diabetic Patients

According to a 2006 article, from the 310 DM patients admitted, about 11% of participants were admitted for regular check-up, approximately 29% for adjusting the dose of insulin, and about 36% for investigations and treatment of complications.(**25**)

In an article, Good found that more than 10% of the visits by geriatrics to the emergency room in Canada were due to adverse drug-related events.(**21**)

3.0 CHAPTER THREE: METHODOLOGY

3.1 STUDY DESIGN, SITE AND POPULATION

The study was a cross sectional study involving elderly diabetic patients hospitalized at Kenyatta National Hospital from January to May 2016.

Data was collected on elderly diabetics admitted to medical wards 7A, 7B, 7C, 7D and 8A, 8B, 8C, 8D at KNH located in Nairobi, Kenya. The medical wards are for patients with chronic illnesses. Ward 7C admits cancer patients and ward 8C for those with skin disorders.

Kenyatta National Hospital is the largest National Teaching and Referral in Kenya. From the statistics department at KNH, there were a total of 422 elderly diabetic participants admitted to the wards in the year 2014. From January to June 2015, 238 elderly diabetics have so far been admitted. The number of diabetic participants attending clinic at KNH diabetes clinic in the year 2014 was 2763. The number attending clinic from January to June 2015 was 1867.

The study population was elderly diabetic participants aged 60 years and older who were admitted to the medical wards at KNH in 2016. The clinicians were also respondents in the study.

3.2 ELIGIBILITY CRITERIA

Participants were included in the study if they were diabetics of both sex, and aged 60 years and older. The patients had to be admitted to the KNH medical wards in 2016. Voluntary informed consent was required from the participants or proxy consent if participant was too ill, had no knowledge of their medications and there was a language barrier. Participants who declined to give consent or were comatose were excluded from the study.

3.3 SAMPLE SIZE DETERMINATION

The sample size was based on the estimates of the prevalence of medication discrepancies for participants on admission to hospital. According to Cornish 2005, 60% of patients had at least 1 discrepancy in their admission medication history when admitted to the hospital. In another study, 122 older inpatients were interviewed and a 60% discrepancy rate was found.(**26**) The prevalence of 60% was used in calculation of sample size using the Hulley formula (**27**):

$$\mathbf{N=4Z_{\alpha}^{2}p(1-p)\div w^{2}}$$

Where

N is the total sample required for the study

Z_α is the standard normal deviate for a two sided α (95% confidence level Z_α=1.96)

p is the expected proportion for the study which is 60%

w is the width of the confidence interval that is 5%

The calculated minimal size was approximately 148 patients. This figure was inflated by 10% to cover poor response during data collection giving a final sample size of 163 patients.

3.4 SAMPLING METHOD AND PARTICIPANT RECRUITMENT

Convenient sampling was used to recruit every patient who met the inclusion criteria. Participants were recruited a day after admission in order to allow for standard care to take place. Participants, who had a history of diabetes and were admitted, were identified from the admission register on the date of recruitment. Files of these patients were perused to identify patients who met the inclusion criteria. Patients were recruited in the afternoons and after ward rounds when there was reduced work in the wards. For patients who were too ill or only spoke their mother tongue, the next of kin were interviewed during visiting hours. Patients and caregivers were informed that they were free to leave the study at any time without any explanation.

3.5 CASE DEFINITION

Elderly diabetic patients were defined as patients that were 60 years of age and older who were on insulin or oral hypoglycaemic drugs, had comorbidities and were on medication for the comorbidities they suffer.

Omissions were defined as the absence of commonly used diabetic medication of patients from the admission mediation orders.

Medication discrepancies were any differences that were intentional or unintentional, between the diabetes-related medication list in the patient's file, and the diabetes-related medications reported by the patient during the medication use interview.

3.6 DATA COLLECTION

The list of the participants who accepted to take part in the study and who met the inclusion criteria was obtained. The files were retrieved and the following information obtained: the sex, age, weight, admission day, admission time, admission diagnoses, medication history of drugs used, BMI, pre-existing comorbidities and medication list on admission from the treatment sheet. Data was abstracted in the appended form. (Appendix 1)

The investigator interviewed the participants at an hour that was not too busy for them which was mostly the afternoon. A comprehensive medication history was carried out by use of a questionnaire. A list of medications used at home prior to admission was obtained. The patient was then requested to ask his caregivers to bring his home medications in the next visit if he did not have them with him at the time of the interview. For participants with poor knowledge of drugs or those who could not speak English or Kiswahili, the research pharmacist then interviewed the caregivers during visiting hours. (Appendix 2) Best Possible Medication Histories (BPMH) was obtained using the aid of appended questionnaires (Appendices 1 and 2). Multiple methods were used because it was anticipated that participants would have poor knowledge of their medications.

Specific questions were asked about the use of analgesics, cardiovascular disease medications, gastrointestinal disease medications, sleeping pills, anti-diabetics, antihypertensive medication, antibiotics, medication for other comorbidities, inhalation drugs, eye/ear drops, over-the-counter drugs, herbal drugs, among others in order to increase the probability of including all the participant's medications.

The total number, name /brand and doses of drugs the patient was taking prior to admission were obtained by carrying out a physical examination of medications the patient had brought to hospital. The caregiver was asked to bring to the hospital medications used by the participant at home in the next visit. (Appendix 2)

3.6.1 Reconciliation of medications

After obtaining a list of medications used by the participants prior to admission, a comparison was made between that list of drugs and that of the admission list in the participant’s file. Each participant’s pre admission and admission medications were studied for discrepancies and categorized by the investigator with the help of clinicians who agreed to take part in the study; an attempt made to do corrections/rectifications as soon as possible. Any additions,

omissions and dose changes of drugs in the hospital admission medication list were considered medication discrepancies. (Appendix 3)

3.6.2 Clinician Interview on identified Medication Discrepancies and Classification of the Discrepancies

The prescribers' names and contacts were obtained from patient files and the ward in charge of the various wards. Consent was obtained from prescribers prior to interview. Five clinicians agreed to take part in the study and were made aware of the discrepancies identified by the investigator. An interview was then set up with each of the clinicians so as to determine if the discrepancies were intentional or not. (Appendix 4) The discrepancies were categorized as intentional, undocumented intentional and unintentional. (Figure 3) These discrepancies were further sub classified according to the scheme presented in figure 2. Two postgraduate clinical pharmacy students were included in the study as well to help with the classification of the medication discrepancies. Medication discrepancies for which there was no clinical rationale (unintentional changes) were concluded to be medication errors.

3.7 VARIABLES

The main outcome variable and dependent variable was the number of discrepancies between preadmission and admission medications. The independent variables were: age, sex, ward, marital status, job status, poly-pharmacy, comorbidities, cadre of admitting clinician, education level, time of admission, discharge forms from previous facility, and management of own medication.

3.8 DATA MANAGEMENT

To ensure confidentiality unique patient numbers rather than patient names or outpatient numbers were used for forms used to retrieve the data from the files. The patient files were retrieved and the data extracted within the medical wards. Any document linking the collected data to the patient files including the raw data was kept under lock and key and only accessible by the principal investigator or on request by regulatory teams like the Ethics committee.

Data obtained was entered into Epi Info version 7 (2007-2010) and a database created. Back up was done on a weekly basis. Data cleaning was also carried out weekly. Data was stored on a Compact Disc (CD) and a flash disc.

3.9 QUALITY ASSURANCE

All data obtained from patient files was double checked by the investigator during data entry. The final report was subjected to inspection and quality audit as per the Good Clinical Practice (GCP) standards and protocols outlined by the ICH (2010). A Pre-test was carried out for feasibility. The data collection tools were modified based on the pre-test.

The data collector had medical knowledge and was a nurse in training who was doing his attachment at the medical wards. The data collector was trained prior to data collection. Training included how to carry out a medication use history, and how to fill out the questionnaires. Any deviation from the standards and protocols were recorded and reviewed. For those that were to affect the validity of the study; they were documented in the final report.

3.10 STATISTICAL ANALYSIS

Continuous data was summarized in form of means, standard deviations, medians and interquartile ranges (IQR). Categorical data was summarized as counts and percentages.

A bi-variable analysis of the total number of discrepancies was regressed against its covariates and those variables whose p value was less than 0.05 and also those with high clinical impact were considered for multivariable linear regression analysis with robust estimation. This was used to adjust for confounding as well. Linear regression analysis was carried out using version 21 IBM SPSS statistics. The dependent variable was the total number of discrepancies that was regressed against the potential predictor variables age, sex, ward, marital status, job status, poly-pharmacy, comorbidities, cadre of admitting clinician, education level, time of admission, discharge forms from previous facility, and management of own medication. Backward stepwise model building was done to come up with a parsimonious model.

3.11 ETHICAL CONSIDERATIONS

Approval to carry out the study was obtained from the KNH/ UoN Research and Ethics Committee in November 2015 prior to commencement of the study. (Appended approval letter Ref No. KNH-ERC/A/470)

Informed consent was obtained from participants and proxy consent obtained from caregivers of patients who were too ill, had no knowledge of their medications and could not communicate in English or Kiswahili. This was done by having the participants and

caregivers sign the consent forms prior to interview. (Appendix 5) Consent from some of the admitting clinicians was also obtained. (Appendix 6)

Participants were assured of minimal risk to them as there were no invasive procedures being done to them. Data collected from them was safely secured and there was low risk of their personal information being made public. Confidentiality of the patient was maintained. The benefits to the patients were immense because serious errors were identified and communicated to the physician resulting in better patient outcomes. There was no coercion and the quality of care improved.

4.0 CHAPTER FOUR: RESULTS

4.1 Participant Recruitment

During the three and a half month study, 183 T2DM elderly patients were screened for eligibility, of these, 163 met the inclusion criteria. Twenty patients were excluded for the following reasons: 3 were discharged home before an interview could be carried out; 5 declined consent; 8 died before a medication use interview; and 4 were not on any antidiabetic medication (**Figure 4).**

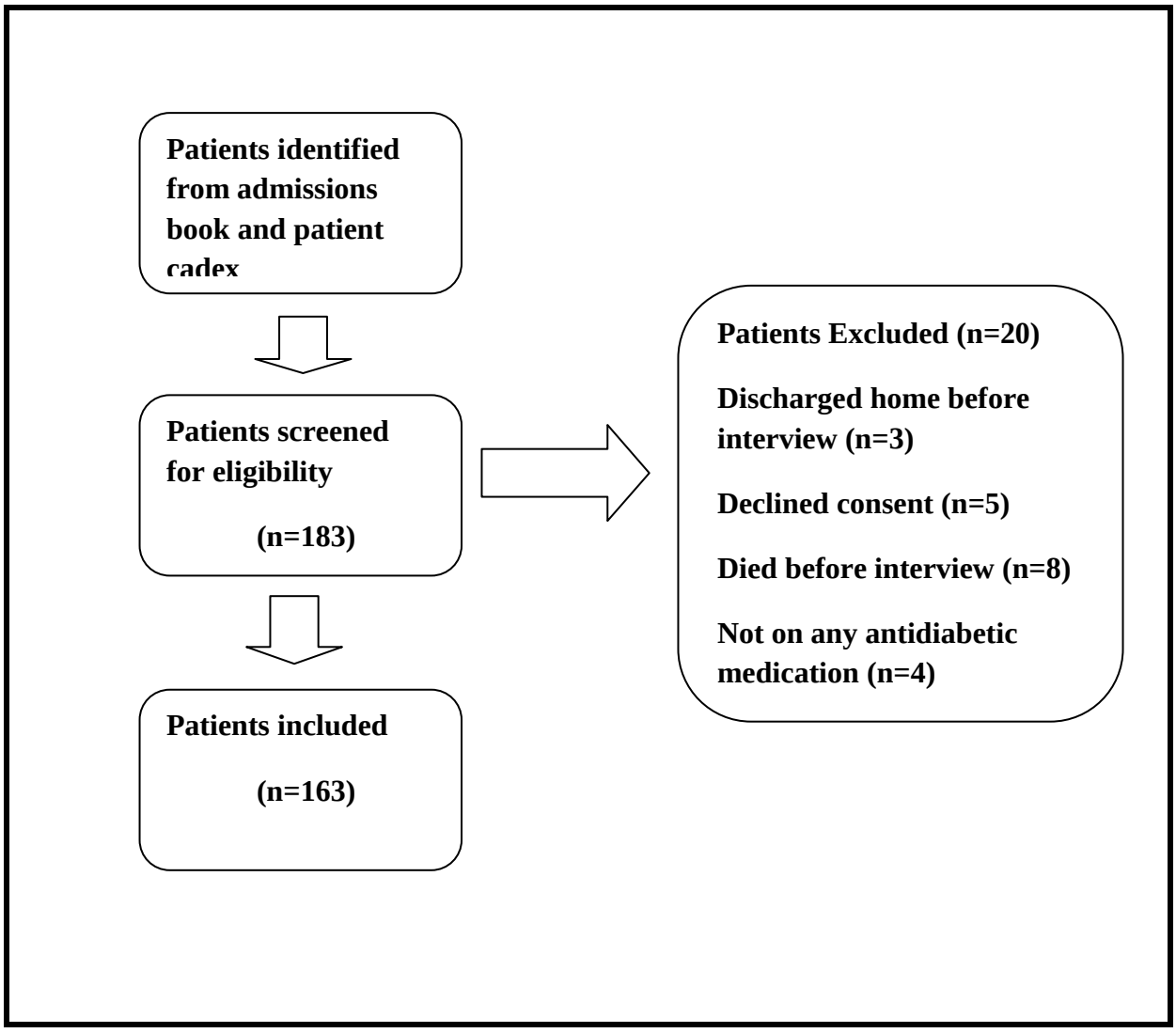


Figure 4: Consort diagram of participants included in the study

4.2 Sociodemographic characteristics of the study participants

The characteristics of the 163 participants in the study population are summarized in **Table 1.**

Table 1: Baseline characteristics of the study participants

Characteristic		n(%)
Age	60-64	60 (36.8)
	65-69	41 (25.2)
	70-74	28 (17.2)
	75-79	20 (12.3)
	80-84	5 (3.1)
	>84	9 (5.5)
Sex	Male	82 (50.3)
	Female	81 (49.7)
Wards	7A	31(19.0)
	7B	20 (12.3
	7D	26(16.0)
	8A	31(19.0)
	8B	28(17.2)
	8D	25(15.3)
Marital status	Single	16 (9.9)
	Married	122 (75.3)
	Divorced	6 (3.7)
	Widowed	18 (11.1)
Education level	Primary	119 (73.0)
	Secondary	38 (23.3)
	Certificate	1(0.6)
	Diploma	3 (1.8)
	Degree	2 (1.2)
Job status	Employed	12 (7.5)
	Self-employed	80 (49.1)
	Retired	22 (13.5)
	Other	5 (3.1)
	Unemployed	44 (27.0)

**Wards 7C and 8C had only one participant each.*

Most of the participants were aged between 60 and 64 years (36.8%, n=60). As age increased, the number of participants declined. The median age was 67 [62-73]. Nearly half, (50.3%) of the participants were male. Majority of the participants were recruited from wards 7A and 8A and only one each from wards 7C and 8C. About three quarters (75.3%) of the participants were married. Most (73%) had attained primary level education and 49.1% were self-employed in farming.

4.2.1 Participant Medical Information

A large number of the participants were admitted at night from 8 p.m to midnight (30.1%, n=49) followed by midnight to 6 a.m (23.9%, n=39). Senior health officers/ registrars were the most common admitting clinician (66.3%, n=108). About half (50.9%) of the patients were admitted from home and the most common diagnosis at admission was diabetic foot injury (12.9%, n=21**)** (NB: Not all the diagnoses were indicated in the table, just the most common) **(Table 2).**

Table 2: Participants' Admission Information

Admission Information	**n**	**%**
Cadre of Admitting Clinician		
Medical officer	26	15.9
Senior health officer	108	66.3
Cadre not indicated	29	17.8
Admission from		
Home	83	50.9
Kenyatta hospital clinic	8	4.9
Nursing home	1	.6
Other hospital / referral	71	43.6
Time of Admission		
Early morning (00.00 - 5.59 a.m)	39	23.9
Morning (6.00-11.59 a.m)	32	19.6
Afternoon (12.00-3.59 p.m)	20	12.3
Evening (4.00 -7.59 p.m)	23	14.1
Night (8.00 - 23.59p.m)	49	30.1
Diagnoses at Admission		
Diabetic foot	21	12.9
Heart disorders	17	10.4
End organ damage	11	6.7
Respiratory infections	11	6.7
Sepsis	10	6.1

Table 3: Comorbidities and Medical History of Elderly participants with Type 2 diabetes at Kenyatta National Hospital

Comorbidities		**n**	**%**
Hypertension		131	80.4
Cardiovascular		26	16.0
End Stage Renal Disease		22	13.5
Chronic Renal Disease		20	12.3
Cancer		12	7.4
Retroviral Disease		5	3.1
Epilepsy		3	1.8
Asthma		3	1.8
Liver Disease		2	1.2
Parkinsonism		2	1.2
Arthritis		1	0.6
Medical history			
Years since diagnosed	1-5 years	44	27.2
	5-10 years	36	22.2
	10-15 years	42	25.9
	>15 years	40	24.7
Attendance of clinic	Monthly	99	60.7
	Every 3 months	39	23.9
	Never	19	11.7
	Other	6	3.7
	-Every 2 weeks	5	3.1
	-Yearly	1	.6
Attendance of clinic for comorbidities	Yes	122	74.8
	No	22	13.5
	No comorbidities	19	11.7
Drug Allergies			
Has allergies	Known	97	59.5
Drug allergy to	Aspirin	1	.6
	None	87	53.4
	Not sure of meds	1	.6
	Sulphur based drugs	8	4.9
Management of own medication	Yes	134	82.7

Nearly 80%, (131) had hypertension. Only one participant had arthritis. Other comorbidities are as shown in **Table 3**. From the past medical history taken, 27.2% of the patients were diagnosed 1-5 years ago and a large proportion were attending clinic for diabetes (60.7%) and other comorbidities (74.8%). Eight participants were allergic to Sulphur based drugs. Majority of the participants (82.7%) managed their own medication. The rest had a family member manage their medication intake and storage (**Table 3).**

4.2.2 Patterns of Medicine use among the Participants

A total of 112 (68.7%) participants were on metformin prior to admission; 68 (41.7%) were on insulin 70/30 and 54 (33.1%) were using glibenclamide. The use of glibenclamide is a medication error as it is discouraged in elderly persons. About 35% of the participants were put on soluble insulin on admission. Only six were put on Insulin 70/30 upon admission.

Table 4: Patterns of Medicine use among the Elderly Participants

Drug Classes	Medication used at home	Number of participants n (%)	Medication added on admission	Number of participants n (%)
Hypoglycemic Agents	Insulin 70/30 Metformin Glibenclamide Glimepride Gliclazide Saxagliptin Chlorpropramide	68(41.7) 112 (68.7) 54 (33.1) 2 (1.2) 5 (3.1) 2 (1.2) 1(0.6)	Soluble insulin Insulin 70/30 Metformin	57 (35.0) 6 (3.7) 1 (0.6)
Antihypertensive Drugs				
ACE inhibitors	Enalapril	44 (27.0)	Enalapril	15 (9.2)
Calcium Channel blockers	Nifedipine Amlodipine	33 (20.2) 30 (18.4)	Amlodipine Nifedipine Nimodipine	7 (4.3) 12 (7.4) 1 (0.6)
Beta blockers	Atenolol Propranolol Metoprolol Nebivolol	13 (8.0) 2 (1.2) 2 (1.2) 3 (1.8)	Atenolol	2 (1.2)
Alpha and Beta blocker	Carvedilol	20 (12.3)	Carvedilol	6 (3.7)
Alpha 2 adrenergic receptor antagonists	Methyldopa	4 (2.5)	Methyldopa	1 (0.6)
Angiotensin II receptor antagonists	Losartan Losartan/ Hydrochlorothiazide Telimisartan/ Hydroclorothiazide	16 (9.8) 21 (12.9) 2 (1.2)	Losartan Losartan/ Hydrochlorothiazide Telmisartan	7 (4.3) 4 (2.5) 1 (0.6)
Vasodilators	Hydralazine	2 (1.2)	Hydralazine	5 (3.1)

For participants with hypertension as comorbidity, enalapril (27%, n=44) was the most commonly used drug prior to admission followed by nifedipine (20.2%, n=33) and lastly amlodipine (18.4%, n=30) (**Table 4).** On admission, enalapril was also the most commonly prescribed drug; 15 patients were put on this drug. Twelve participants were prescribed nifedipine. Participants with other comorbidities had an additional 215 medications in total prior to admission. On admission, an additional 422 medications were given to participants for various medical reasons.

4.3 The Medication Reconciliation process and Prevalence of Medication Discrepancies

The Best Possible Medication History (BPMH) was obtained from various sources, and from this, a pre-admission medication list was generated. The most common source was patient/caregiver interview (100%, n=163) (**Table 5).**

Table 5: Sources of the Pre-admission Medication information and time from admission to reconciliation

	n	%
Sources of pre-admission medication		
Patient/Caregiver interview	163	100
Medication history by provider on admission	159	97.5
Discharge forms from previous facility	71	43.6
Physical observation of medicines	25	15.3
Duration between admission and reconciliation		
0-1 days	78	47.9
2-3 days	69	42.3
4-12 days	16	9.8

This was followed by the medication history in the participants' files written by the provider (97.5%, n=159). Only 15.3% had their medication with them for reconciliation. The duration between admission and reconciliation are summarized in **Table 5**. Most medications were reconciled 24 hours after admission.

On reconciliation of the 163 patients' medication, 1089 medication discrepancies were identified. The mean number of discrepancies per participant was 6.68 ± 2.4. Only one patient had no medication discrepancy.

The distribution of medication discrepancies per patient is represented in (**Figure 5).**

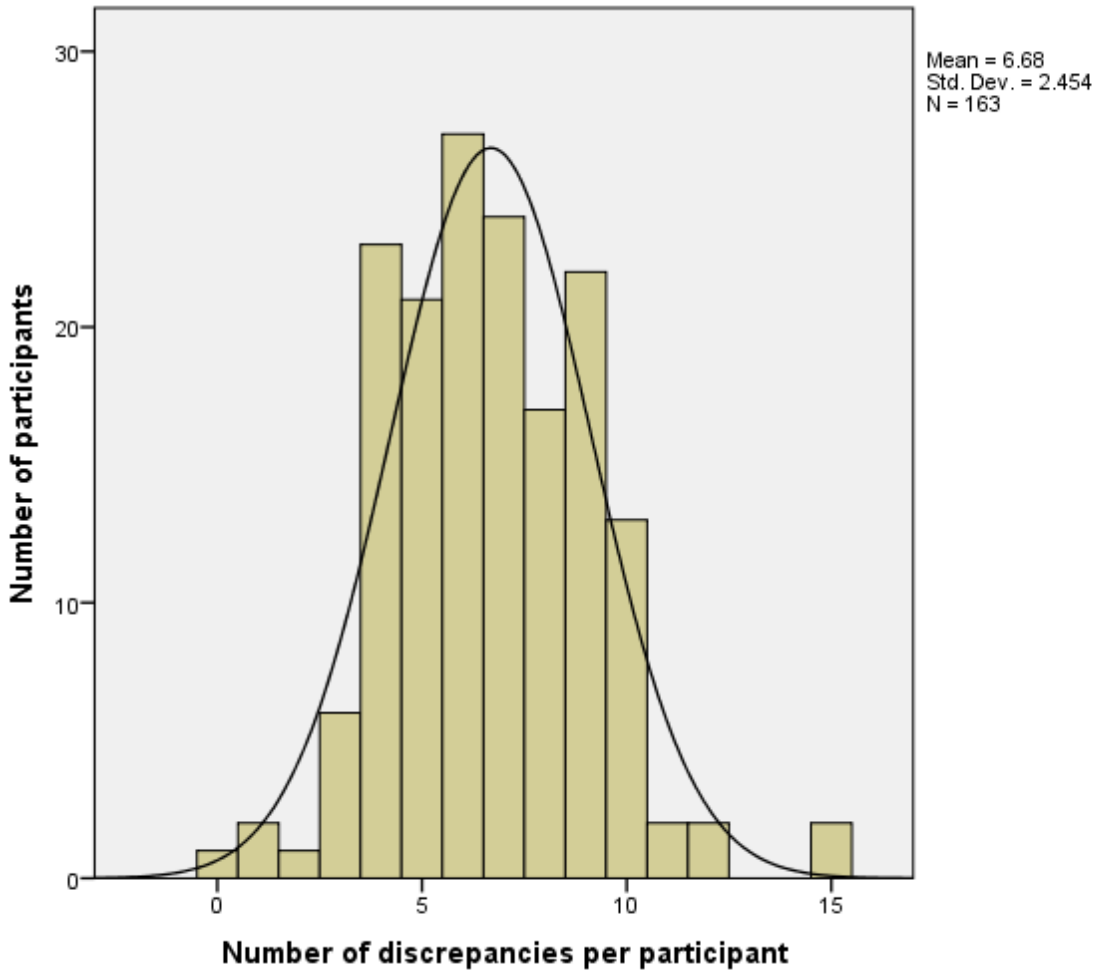


Figure 5: The number of discrepancies per participant

Approximately 16% (n=27) of the participants had 6 medication discrepancies each. Two participants had the highest number of discrepancies (n=15). The median number of discrepancies was 7 (IQR [5-9]). The most common class of drugs with discrepancies was antidiabetic drugs (37.9%, n=91). Others included antihypertensive drugs, diuretics, lipid lowering drugs like atorvastatin, cardiac glycosides like digoxin and anti-platelets, among others.

4.3.1 Classification of Medication Discrepancies

Classification of medication discrepancies is presented in **Figure 6.** Classification was done in accordance to a method used in a study done by Pippins et al (2008).

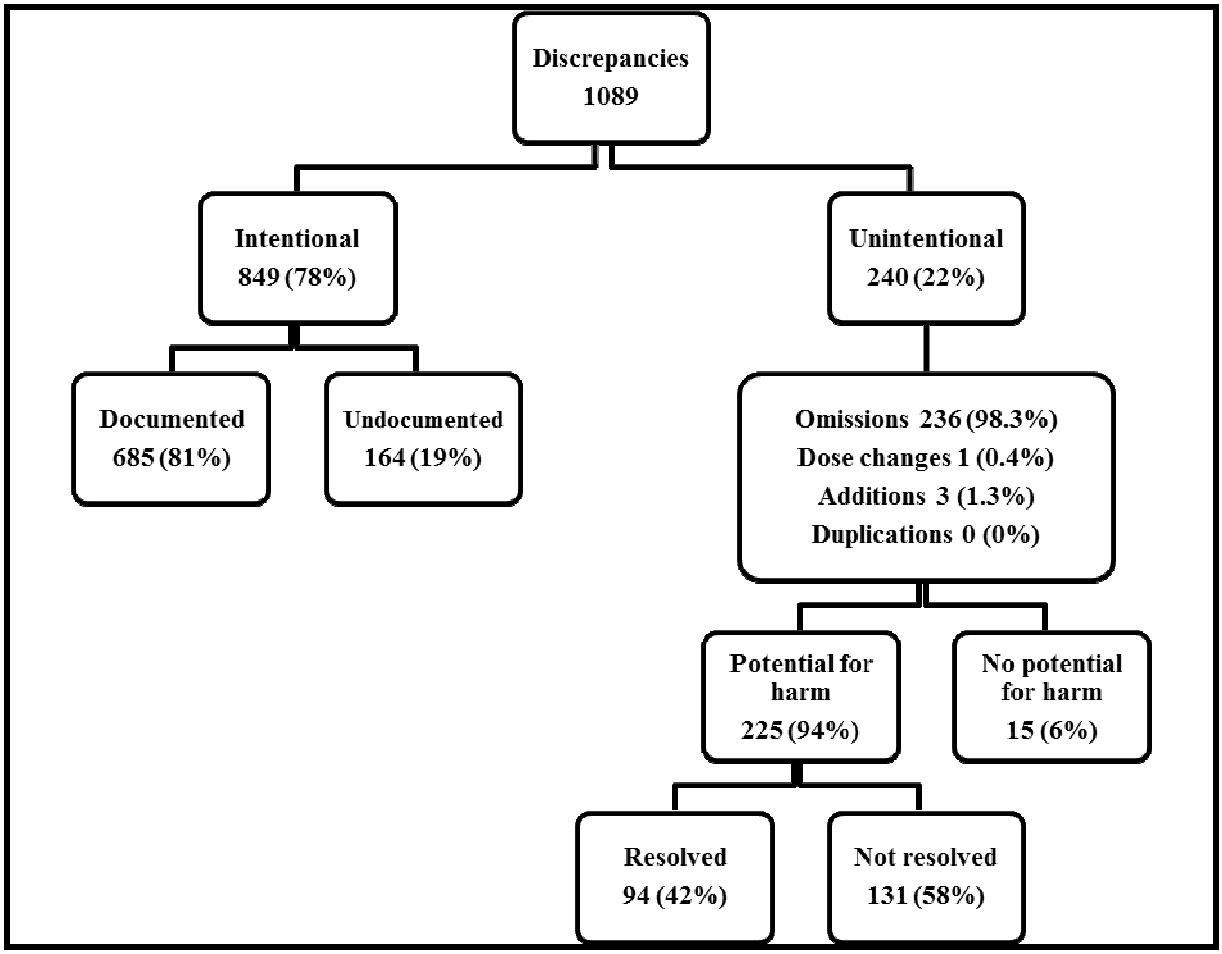


Figure 6: Classification of medication discrepancies detected

Of the medication discrepancies, 849 were intentional and 19% of them were undocumented; an average of one undocumented discrepancy per participant. The remaining discrepancies (22%, n=240) were unintentional discrepancies. Omissions were the most common unintentional discrepancies (98.3%, n=236), while 0.4% were dose changes (n=1) and 1.3% were additions (n=3). The unintentional discrepancy rate per participant was 1.5. Approximately every participant had one unintentional discrepancy. There were no duplications.

Among the unintentional discrepancies, 94% were judged to have potential for harm (n=225). Only 42% were resolved. An example of a discrepancy with a potential for harm was the omission of metformin, insulin 70/30 among others from the admission orders with no

clinical rationale **(Table 6)**. The most common drug classes of medications involved in unintentional discrepancies were antidiabetic (37.9%, n=91), antihypertensive (24.2%, n=58) and diuretic drugs (8.3%, n=20). All these are Class A drugs that are essential; their omission can potentially be harmful.

One hundred and three patients (63.2%; 95% CI, 55.6%-70.3%) had at least one unintentional discrepancy. Of the 103, 35.9% had only one unintentional discrepancy (n=37). Majority (55.3%, n=57) had 2-4 discrepancies; nine (8.7%) had more than 4 discrepancies as summarized in **Figure 7.**

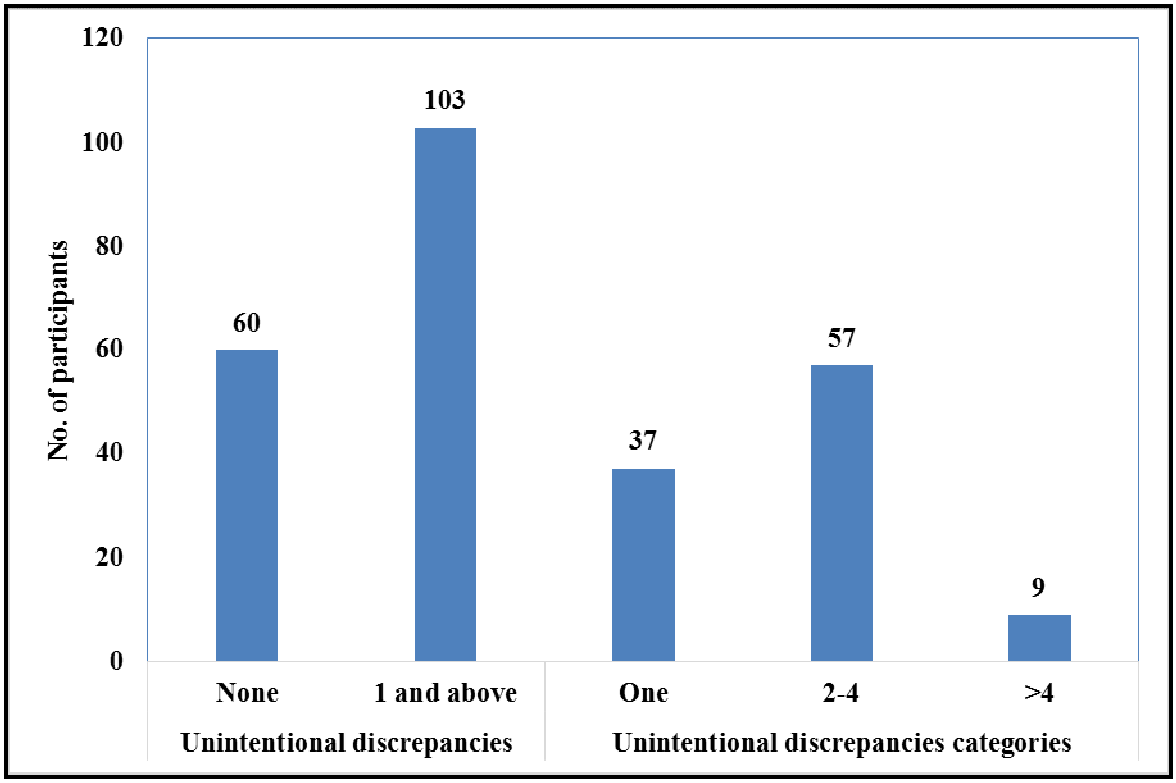


Figure 7: Frequency and categories of Unintentional discrepancies

4.3.2 Resolution of the Unintentional Discrepancies/Errors

As shown earlier in Figure 6, only 42% of the 225 unintentional discrepancies with potential for harm were resolved. Recommendations were made to resolve some of them (79.8%, n=75), while others were resolved 24 hours from the time of admission without the intervention of the investigator (20.2%, n=19) (**Figure 8).**

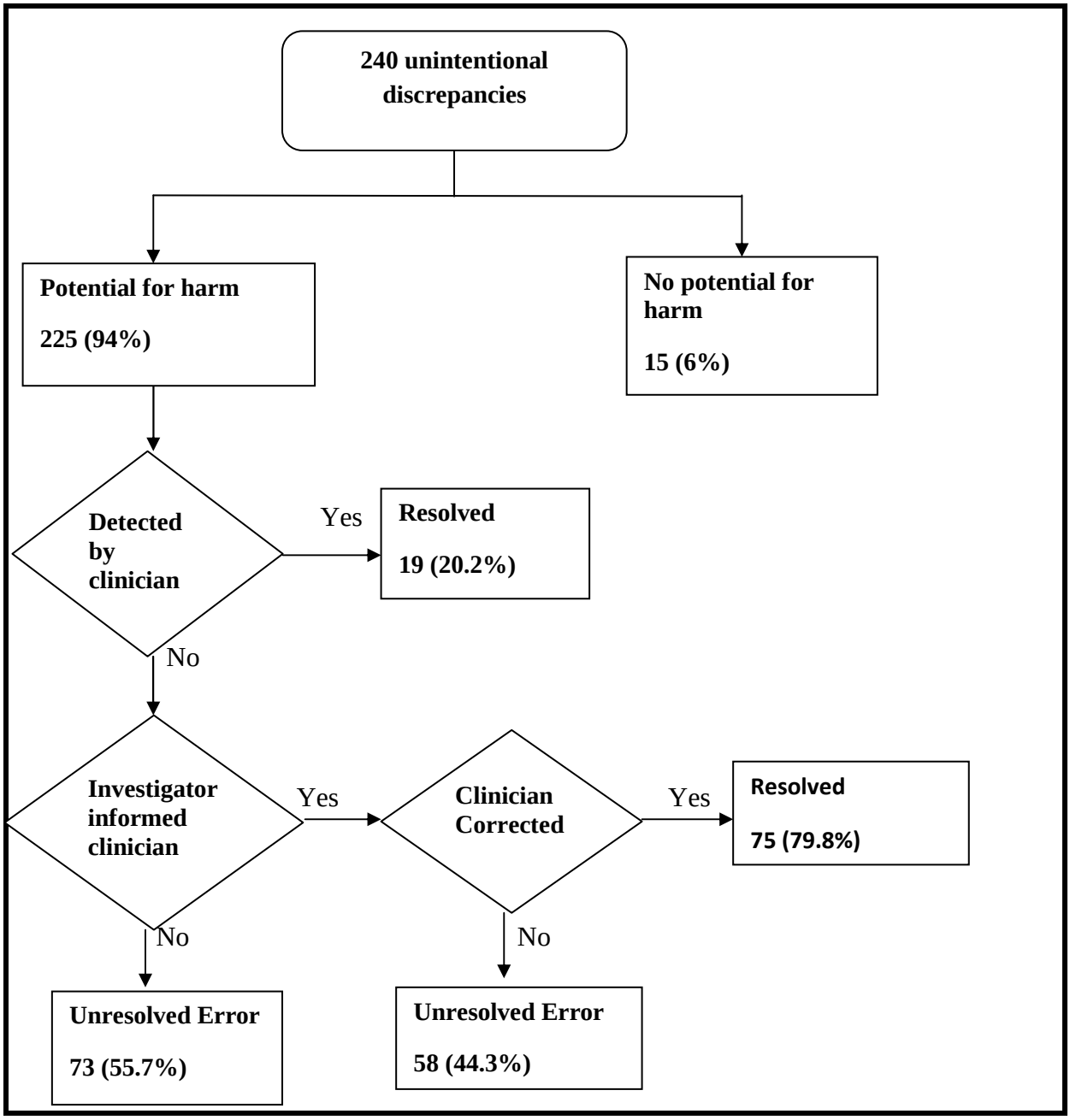


Figure 8: Resolution Process of unintentional discrepancies

Of the unresolved errors, 55.7% were due to the investigator not informing the clinician due to time constraints and limited man power. Omission of antidiabetic drugs like metformin, Insulin 70/30 and glibenclamide occurred severally. The errors of omission were corrected in several ways: by inclusion in the treatment sheet about 48 hrs from admission by the clinician after being informed by the investigator, prompting by the investigator that the participant had been taking the medication without the knowledge of the clinician; the drug was then included in the treatment sheet, clinicians themselves noted the error without being prompted by the investigator and the investigator detected the error and it was corrected immediately as

clinician was writing notes on the patient file after a ward round. Omission of Insulin 70/30 was corrected by a different clinician about 24hours from admission and indicated in the treatment sheet. Glibenclamide on the other hand was corrected 24 hrs after admission on intervention by the investigator. The drug was included in the treatment sheet by the clinician. The drug was accidentally omitted from the treatment sheet but noted in the file that it should be given. A clinician was informed of this and the drug included in the treatment sheet the following day. The number of errors resolved and drugs involved are summarized in **Table 6**.

Table 6: Errors with Potential for Harm that were Resolved

Type of Error	**Drug with Error**	**Number Resolved**
Omission		
Antidiabetic drugs	Metformin	18
	Insulin 70/30	7
	Glibenclamide	8
Antihypertensives	Atenolol	5
	Losartan	2
	Losartan/ Hydrochlorothiazide	1
	Amlodipine	4
	Enalapril	5
	Nifedipine	4
	Hydrochlorothiazide	2
	Aldactone	1
Others	Digoxin	2
	Atorvastatin	2
	Pregabalin	1
	Ranferon	2
	Acetazolamide	1
	Tramadol	1
	Other medication	23
Wrong dose		
	Metformin	1
	Enalapril	1
	Other medication	3

Other key drugs omitted and resolved are Acetazolamide (Diamox) that was omitted from the treatment sheet and corrected the next day by clinicians by including the drug in the treatment sheet. Drugs used in management of asthma such as tiotropium and budesonide among others were omitted from the treatment sheet. The patient had been taking them even though they were not included in the treatment sheet. Clinician was made aware of this.

A dosing error of metformin occurred once. It was noted by the investigator and corrected 24 hrs after reconciliation. Others included wrong dose of antihypertensive drug that was corrected 24 hrs from admission after the investigator prompted the clinician. Low dose of atorvastatin was being given to a patient. Clinician was informed of this by the investigator and the dose corrected in the treatment sheet. Unfortunately many were not able to be corrected due to time constraints and not enough personnel to follow up on the errors for each patient. Other medications with errors were diuretics, anticoagulants such as warfarin and many more.

4.3.3 Risk factors for Medication Discrepancies

4.3.3.1 Comparison of the number of medication discrepancies per patient across variables

Bi-variable inferential analysis was carried out to compare the total medication discrepancies with the various categorical variables as shown in **Table 7**. From the analysis, wards 7A, 7D and 8B had the highest number of discrepancies most likely due to the high number of participants from each of these wards. Participants with 3 comorbidities had the most medication discrepancies. Another observation of interest is that most discrepancies occurred in the morning. Those who had more than 10 medications prior to admission also had the highest number of medication discrepancies.

Table 7: Comparison of the number of medication discrepancies per participant with various categorical variables at admission

Variables		Total discrepancies		
		Mean	Standard Deviation	p value
Age groups	60-69	7	3	**0.046**
	70-79	7	2	
	80 and above	5	2	
Ward	7A	8	3	0.081
	7B	6	2	
	7C	6	2	
	7D	7	2	
	8A	6	3	
	8B	7	2	
	8C	5	1	
	8D	6	2	
Sex	Male	7	3	0.743
	Female	7	2	
Marital status	Single	7	3	0.981
	Married	7	2	
	Divorced	6	3	
	Widowed	7	2	
Job status	Employed	7	2	0.877
	Self-employed	7	2	
	Retired	7	2	
	Other	7	2	
	Unemployed	6	3	
Cadre of clinician	Medical officer	7	3	0.578
	Senior health officer	7	3	
Education level	Primary	7	2	0.059
	Secondary	6	3	
	Certificate	5		
	Diploma	7	1	
	Degree	7	1	
Number of comorbidities	0	6	2	**0.029**
	1	6	2	
	2	7	3	
	3	8	2	
Hypertension	No	6	2	**0.002**
	Yes	7	2	
Cardiovascular	No	7	2	0.526

Table 7 continues from the previous page

	Yes	7	3	
Chronic Renal Disease	No	7	2	0.521
	Yes	6	2	
End Stage Renal Disease	No	6	2	**0.002**
	Yes	8	3	
Retroviral Disease	No	7	2	**0.05**
	Yes	9	2	
Cancer	No	7	2	**0.048**
	Yes	5	3	
Liver Disease	No	7	2	0.854
	Yes	7	1	
Epilepsy	No	7	2	0.629
	Yes	6	3	
Arthritis	No	7	2	0.494
	Yes	5		
Asthma	No	7	2	0.24
	Yes	8	6	
Parkinsonism	No	7	2	0.854
	Yes	7	1	
Person interviewed	Patient	7	3	0.668
	Caregiver	7	2	
Patient/Caregiver interview	No	8	6	0.24
	Yes	7	2	
Physical observation	No	7	2	0.928
	Yes	7	3	
Discharge forms from previous facility	No	6	3	0.113
	Yes	7	2	
Medication history by provider on admission	No	8	3	0.501
	Yes	7	2	
Number of previous medications	1-4	6	2	**<0.0001**
	5-9	8	2	
	10 and above	9	3	
Handling own medication	No	6	2	0.162
	Yes	7	2	
Time of admission	Early morning	5.97	2.112	0.055
	Morning	7.69	3.063	
	Afternoon	6.6	2.234	
	Evening	6.35	2.516	
	Night	6.65	2.057	

Patients with hypertension, cancer, retroviral disease and end stage renal disease as comorbidity had the most discrepancies. The following variables were considered for multivariable regression analysis: Age, ward, education level, number of comorbidities, hypertension, end stage renal disease, retroviral disease, cancer asthma, discharge forms from previous facilities, number of medication previous medication management of own medication and the time of admission. The analysis was also done to adjust for confounding.

A bi-variable regression analysis was carried out by regressing of the number of medication discrepancies against each of the covariates as shown in **Table 8**. On multivariable linear regression analysis, the number of medications prior to admission, and having hypertension as comorbidity were significant predictors for medication discrepancies at admission. Backward stepwise model building was carried out to come up with a parsimonious model. **Table 8** There was a negative association between increasing age and medication discrepancies; participants who were younger were in this case found to be more likely to have medication discrepancies (adjusted β coefficient -0.755 (95% CI: -1.284, -0.226)) this was significant (p=0.005). Participants with hypertension were more likely to have medication discrepancies than those without hypertension (adjusted β coefficient 0.992 (95% CI: 0.094, 1.890)) and this was statistically significant (p=0.031).There was a linear relationship between the number of medication discrepancies and the number of medications prior to admission. For every unit increase in the number of medication given before admission, there is an increase in medication discrepancies at admission. Those with many medications prior to admission were more likely to have medication discrepancies than those with less medication on admission (adjusted β coefficient 1.377 (95% CI: 0.767, 1.987)) statistical significance of (p=<0.0001). Age in this case was a confounder because it is independently associated with medication discrepancies and is also associated with diabetes. Those with information on their drug usage from discharge forms from previous facilities interestingly showed a positive relationship with the number of medication discrepancies (adjusted β coefficient 0.701 (95% CI: 0.010, 1.392)). Participants with medication information in their discharge forms were more likely to have medication discrepancies than those with no discharge forms. Therefore the number of previous medication, hypertension and those with discharge forms from previous facilities were significant predictors of medication discrepancies. **Table 8**

Table 8: Regression analysis for determination of possible predictors to medication discrepancies

Variables	Bi-variable Regression Analysis		Parsimonious Model on Multivariable Regression Analysis	
	Crude β coefficients		Adjusted β coefficients	
	β (95% CI)	P value	β (95% CI)	P value
Age group	-0.667 (-1.245, -0.0896)	**0.024**	**-0.755(-1.284, -0.226)**	**0.005**
Ward	-0.112 (-0.274, 0.049	0.173	-	-
Education Level	-0.220 (-0.759, 0.319)	0.422	-	-
Number of comorbidities	0.665 (0.197, 1.133)	**0.006**	-	-
Hypertension	1.469 (0.539, 2.400)	**0.002**	**0.992 (0.094, 1.890)**	**0.031**
End stage renal disease	1.735 (0.654, 2.816)	**0.002**	-	-
Retroviral disease	2.186 (0.005, 4.368	**0.05**	-	-
Cancer	-1.455 (-2.894, -0.015)	**0.048**	-	-
Asthma	1.683 (-1.137, 4.504)	0.24	-	-
Discharge forms from previous facility	0.615 (-0.147, 1.377)	0.113	**0.701 (0.010, 1.392)**	**0.047**
Number of previous medication	1.488 (0 .880, 2.096)	**<0.0001**	**1.377 (0.767, 1.987)**	**<0.0001**
Management of own medication	-0.712(-1.713, 0.289)	0.162	-	-
Time of admission	0.029(-0.211, 0.268)	0.813	-	-

5.0 CHAPTER FIVE: DISCUSSION

In the study population of elderly diabetics, all but one of the patients had medication discrepancies following medication reconciliation. On classification of the discrepancies, 63.2% of the patients (95% CI 55.6-70.3) experienced at least one unintentional discrepancy. The findings were similar to other studies despite different definitions, methods and conceptualization. A study done in 2006 corroborates that at least about 60% had at least one unintentional discrepancy. (**14**) However there were studies opposing these findings. Other studies found about half of participants had at least one unintentional discrepancy.(**26**, **28**)

The most common unintentional discrepancy/error was an omission of a medication the participant reported taking before admission (n=236, 98.3%). This was consistent with other studies that also showed that omissions were the most common unintended discrepancy. **(10**, **26**, **28**)

About 94% of the unintentional discrepancies had the potential for harm. Only 42% of these were corrected before harm could occur. These results were different from a study that found fewer discrepancies with potential for harm.(**10**) The low resolution rate could have been due to understaffing at the hospital and limited man power. This study reported a prevalence of unintentional medication discrepancies with potential for harm of 1.4 per participant similar to a study that also reported an average of 1.4 per patient.(**19**). It is important to note that some studies use medication discrepancies to mean the same as medication errors, however in this study the two are different. Unintentional discrepancies in this study are the errors and specifically reconciliation errors.

The most common drug classes involved in unintentional discrepancies were antidiabetic (37.9%, n=91), antihypertensive (24.2%, n=58) and diuretic drugs (8.3%, n=20). This has a clinical impact on management of diabetic patients more so those with hypertension. This finding is in contrast to a study that identified nervous system (22.0%), gastrointestinal (20.0%) and cardiovascular (18.0%) medications as the most common drugs involved however the study was not specific to elderly diabetics.(**10**)

The results showed, wards with high density of medical cases had higher number of discrepancies. Those admitted in the morning between 6.00 am and 11.59a.m had the most discrepancies. The probable reason why most discrepancies occurred at this time could be because this is a busy time when ward rounds are being conducted and the quality of care

may decline. The higher the number of comorbidities a patient had, the higher the number of discrepancies.

Risk factors for the occurrence of medication discrepancies included an increased number of preadmission drugs and hypertension as comorbidity. There was a positive linear relationship between the number of medications prior to admission and the number of discrepancies ($P < 0.0001$) similar to studies done 2011 and 2012.(**28**, **29**) This relationship is not surprising and was expected. A study in 2008 contradicted this finding. (**19**)

Older age however showed a negative correlation with medication discrepancies; the younger age was associated with medication discrepancies. A study in 2011 showed no association between age and the number of medication discrepancies ($p=0.279$) compared to this study that showed a negative association. **(29**) This finding contrasted another that found that older age as a significant predictor to medication discrepancies. This again could be due to the different definitions and use of medication discrepancies and medication errors. The differences noted in general could be due to fewer ward pharmacists in Kenya compared to the west.

A positive association was found between hypertension and medication discrepancies. There was however no studies that showed this association. This could be the first. The variables, end stage renal disease (ESRD), retroviral disease (RD) and cancer, may not have shown a statistical significance association but showed clinical significance in that, participants with these comorbidities had more medication discrepancies. It is of clinical importance to note that these participants are more likely to have medication discrepancies compared to those without these comorbidities. There are however no studies supporting this observation. This could be the first.

The study showed that those with discharge forms from previous facilities were also more likely to have medication discrepancies. This not only showed statistical significance but is of clinical significance. This could be an indication of the lack of accurate discharge summaries and not just inaccurate medication histories. Several studies have been done that show a high discrepancy rate at discharge(**30**, **31**, **32**). There is however no studies to support this as risk factor to medication discrepancies at admission.

5.1 Strengths and Limitations

There are no other studies in Kenya and Africa on medication discrepancies. This is the first and could provide baseline data for future study in this area. The strength of this study is that it also highlighted the critical role a pharmacist can play in preventing patient medication errors through medication reconciliation.

There are several limitations of this descriptive study. First, it was conducted only in the internal medicine wards of a single hospital limiting its generalizability. Secondly, due to logistical issues it was not possible to sample patients as they were admitted; therefore patients sampled were those admitted after 24 hours. Thirdly, there is currently no gold standard for the identification of medication use at home. Therefore an assumption was made that the drugs the patient or caregiver gave as drugs used prior to admission were the accurate drugs being used. This limitation was mitigated by using various sources to obtain medication history. Fourthly, the classification of the discrepancies into intentional, undocumented intentional and unintentional partly relies on subjective judgement and is therefore subject to bias. One could argue that undocumented intentional medication discrepancies represent "latent" medication errors that could lead to harm. The researcher enlisted the help of clinical pharmacy students to come up with an accurate classification as far as possible. Lastly there was a likelihood of Hawthorne bias that resulted from clinicians being aware of the researcher's presence in the wards. This was managed best by using the research assistant to collect data and collection of data randomly across the wards and at different times. There was non-response bias from prescribers as anticipated. A total of 20 clinicians working at the medical wards were approached. Only 5 clinicians agreed to take part in the study to the end. Four clinicians withdrew from the study citing that they were very busy and would take up too much of their time, while 11 clinicians were not interested in taking part in the study. To mitigate this, clinical pharmacy students who were rotating in the medical wards were recruited into the study.

6.0 CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The objectives of the study were met. A total of 1089 medication discrepancies were identified and classified into intentional and unintentional discrepancies. Omissions were the most commonly occurring type of discrepancies. A high number of these discrepancies had the potential to cause harm and only 42% were resolved. Hypertension, increased number of medication prior to admission, and discharge summaries from previous facilities were significant predictors of medication discrepancies.

Medication discrepancies are common on admission. Our results support the importance of a comprehensive medication history at hospital admission and putting in place a medication reconciliation program, as demonstrated throughout the literature.

6.2 Recommendations.

Based on the results, an accurate medication history is vital in obtaining an accurate and complete list of a patients' current medication. As a starting point I would recommend to the hospital to begin with patients with high number of drugs prior to admission and those diabetics with hypertension since results showed these as key predictors of medication discrepancies. Pharmacists, physicians, nurses, and patients play a key role in this process. Pharmacists especially are central to medication reconciliation and are responsible for identification and resolving errors with collaboration from the physicians, nurses and the patients themselves. Therefore systems of medication reconciliation should be set up and training carried out.

Studies need to be done on the clinical impact of unintentional discrepancies more so those with the potential for harm. Future studies can include nurses and not just prescribers. Medication reconciliation can be carried out at other points of care such as transfers within the hospital and discharge. The findings showed that those with discharge summaries were at risk of medication discrepancies, reconciliation therefore can be done at discharge. Studies also to be done that look into factors about the patients that can contribute to medication discrepancies such as compliance, no knowledge of medication. Impact reconciliation had on reduction of errors identified can be further looked into.

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APPENDICES

APPENDIX I: ELIGIBILITY CHECKLIST

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

All participants recruited must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application approved by the KNH/ UoN Research and Ethics Committee.

I. Study Information

Study Title:		
Principal Investigator name:		Signature: _____
Date of Recruitment:		

II. Patient Information

Patient Code:	
Sex:	Male □ Female□

III. Inclusion/Exclusion criteria(Tick where appropriate)

Inclusion Criteria (list each criteria)	**Yes**	**No**
1. Diabetic patients either male or female		
2.Admitted to the KNH medical wards in 2016		
3.Aged 60 years and older		
4. Voluntary informed consent/Proxy consent given		
Exclusion Criteria (list each criteria)	**Yes**	**No**
1. Declined to give informed consent		
2. Patients younger than 60 years of age.		
3. Patients who are comatose		

APPENDIX II: DATA EXTRACTION FORM.

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Serial Number_____ Date of Collection_____ Version: 1

Name of Data Collector_____

A. BIODATA

1. Patient code:_____
2. Age:_____
3. Gender: Male □ Female □
4. Marital status: Married □ Single □ Widowed □ Divorced □ Not Indicated □
5. Employment:_____
6. Ward:_____
7. Bed No.:_____

B. PRESCRIBER INFORMATION AT ADMISSION

8. Cadre of admitting clinician:
   Consultant □
   Senior Health Officer/Registrar□
   Medical Officer □
   Medical Officer Intern □
   Registered Clinical Officer □
   Clinical Officer Intern □
   Not Indicated □

C. PATIENT MEDICAL RECORD ON ADMISSION

9. Date of Admission:_____

10. Time of Admission: _____

11. Admission Diagnosis:_____

12. Drugs used at home from the Medication History in the file:

NAME OF DRUG		DOSE	ROUTE	FREQUENCY
GENERIC NAME	BRAND NAME			
Antidiabetic drugs				
Antihypertensive drugs/ Diuretics				
Lipid lowering drugs				
Over-the-counter medication e.g cold preparations, ointments, antibiotics				
Herbals, Vitamins, Minerals				

13. Medication list of drugs prescribed/ordered on admission:

NAME OF DRUG		DOSE	ROUTE	FREQUENCY
GENERIC NAME	BRAND NAME			
Antidiabetic drugs				
Antihypertensives/Diuretics				
Lipid lowering drugs				
Over-the-counter medication e.g cold preparations, ointments, antibiotics				
Herbals, Vitamins, Minerals				

D. PRE EXISTING COMORBIDITIES

14. Hypertension □
15. Cardiovascular Disease □
16. Chronic Renal Disease □
17. End Stage Renal Disease □
18. Liver Disease □
19. Depression □
20. Dyslipidemia □
21. Cancer □
22. Retroviral Disease
23. Epilepsy
24. None
25. Other _____

APPENDIX III: MEDICATION USE QUESTIONNAIRE

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Ward: **Bed:** **Date of Interview:** **Serial number:**

Patient Code: **Version No.: 1**

Gender: M □ F □ Age:

Person interviewed:

Patient □

Caregiver □

Relationship with the Patient_____

Caregiver Contacts_____

Part 1: BIODATA

Bio data given will be that of the patient.

1. When were you admitted to the hospital?_____

2. Who brought you to the hospital? _____

3. From where were you admitted?

Home □

Kenyatta Hospital clinic □

Other Hospital/Referral □

What is the name of the hospital?_____

Hospice □

What is the name of the hospice?_____

Nursing home □

What is the name of the Nursing home? _____

4. What is the reason that brought you to hospital?_____

5. What is your marital status?

Married □ Single □ Widowed □ Divorced □ Other □_____

6. Do you have children?

Yes □ No □

7. If yes how many children? _____

8. What is your education level?

Masters/PhD □ Degree □ Diploma □ Certificate □ Secondary □ Primary □

9. What is your current job status?

Employed □ Self Employed □ Unemployed □ Retired □ Other □_____

Part 2: PAST MEDICAL HISTORY

10. When were you diagnosed with diabetes?

1-5 years ago □ 5-10 years ago □ 10-15 years ago □

More than 15 years ago □

11. Where do you go for clinic?_____

12. How often do you attend clinic?

Monthly □ Every 3 months □ Every 6 months □ Never □ Other□____

13. What other chronic illnesses do you suffer from?

Hypertension □

Depression □

Other □ _____

14. Do you see specialists for the other illnesses you have at the same clinic?_____

15. If no, which facility/hospital do you go to see specialists for the other illnesses?

_____

16. What medicines are you allergic to? _____

Part 3: MEDICATION HISTORY TARGETING DRUGS USED AT HOME

17. What drugs have you been using while at home?

NAME OF DRUG		DOSE	ROUTE	FREQUENCY
GENERIC NAME	BRAND NAME			
Antidiabetic drugs				
Antihypertensives/Diuretics				
Lipid lowering drugs				
Over-the-counter medication e.g cold preparations, ointments, antibiotics				
Herbals, Vitamins, Minerals				

18. Do you handle your own medication? Yes □ No □

19. If no, who handles them? _____

PART 4: PHYSICAL EXAMINATION OF DRUGS BROUGHT TO THE HOSPITAL

A physical examination of the drugs the patient has been using will be done.

NAME OF DRUG		DOSE	ROUTE	FREQUENCY
GENERIC NAME	BRAND NAME			
Antidiabetic drugs				
Antihypertensive drugs/Diuretics				
Lipid lowering drugs				
Over-the-counter medication e.g cold preparations, ointments, antibiotics				
Herbals, Vitamins, Minerals				

APPENDIX IV: MEDICATION RECONCILIATION FORM

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Version No: 1

I. Patient Information

Ward:	Date of Reconciliation:	Serial number:
Patient Code:	Gender: M □ F □ Allergies: Unknown □ Age: Known □ _____	

II. Medication Information

Best Possible Medication History (BPMH):(prescription, OTC, vitamins herbals etc..)

Sources of Medication List: Patient/Caregiver interview □ Physical Observation □ Discharge forms from previous facility □ Medication History by provider on admission □

Instructions:

- Compare the BPMH to the Admission Medication orders (AMOs) for this patient.
- To complete the reconciliation section, check the appropriate box with an (×) for each medication and indicate with a (√) if the discrepancy was resolved in the "Resolved" column.

HOME MEDICATION HISTORY	**RECONCILIATION WITH ADMISSION ORDERS (Discrepancy types)**						**CLINICIAN CONTACTED**
(Drug, Dose, Route, Frequency)	No discrepancies	Omissions	Dose Changes	Duplications	Additions	Resolved(Tick)	Reason for Change/ Clinical Rationale for the discrepancies.(if not rational give reason)
	0	1	2	3	4		

Total number Discrepancies							

Additional Comments

Classification of discrepancies on consultation with admitting clinicians		**Total number**
Intentional discrepancies		
Undocumented Intentional discrepancies		
Unintentional discrepancies		

Intentional discrepancy: a prescriber makes a deliberate choice to add, change or discontinue a medication and is clearly documented.

Undocumented intentional discrepancy: a prescriber makes a deliberate choice to add, change or discontinue a medication but this choice has not been clearly documented.

Unintentional discrepancy: a prescriber accidentally changed, added or omitted a medication the patient was using prior to admission.

APPENDIX V: CLINICIAN INTERVIEW

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Clinician Code _____ Gender_____

Cadre of Clinician _____ Serial No_____

Date of Interview_____ Interview done by _____

SECTION A

1. Are you an employee of Kenyatta National Hospital (KNH)?

Yes □ No □

2. If No, what is your role at KNH? _____

3. How long have you worked at the medical wards at KNH? _____

4. Where were you working before you came to KNH? _____

5. Is this the first time dealing with diabetic patients?

Yes□No□

6. If no how long have you handled diabetic patients? _____

SECTION B:

7. Kindly fill out the following table on medications discrepancies found after medication reconciliation was done.

Medication			**Reasons for discrepancy**			
Name	Dose	Frequency	Omission	Addition	Duplication	Dose changes

APPENDIX VI: VOLUNTEER INFORMATION AND CONSENT FORM.

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Consenting process

This document is a consent form; it has information about the study and will be discussed with you by the investigators. Please study it carefully and feel free to seek any clarification especially concerning terminologies or procedures that may not be clear to you. Once you understand and agree to take part, I will request you to sign your name on this form. You should understand the following general principles which apply to all participants in a medical research.

i. Your agreement to participate in this study is voluntary

ii. You may leave 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 that you are entitled to receive in this Clinic.

Introduction to the study

Medication discrepancies are common during movement from one care point to another when a patient is hospitalized or from one physician to another. These discrepancies are more common during admission when medication history taking is being done. Elderly diabetic patients are at greater risk of discrepancies due to the multiple medications they take and multiple prescribers they have to see. Medication discrepancies can result in medication errors and adverse drug events if not identified and corrected.

Elderly diabetic patients should have their medication reconciled at every point of care through a process of medication reconciliation to ensure that at any given time a patient's medication list is complete and accurate.

In this study I am identifying the discrepancies of your medication at admission and assessing the factors that are contributing tothe discrepancies. Permission is requested from you to enrol in this medical research study.

Purpose of the study

The primary objective of this study is to measure the frequency of occurrence of medication discrepancies at admission in elderly diabetic patients. The second objective is to determine the risk factors for the medication discrepancies.

Procedures to be followed

With your permission we will go through your medical records to obtain information on the medication history taken upon your admission and the admission medication orders (AMOs). You will be asked a few questions about your diabetes medication that you use at home, if you are using any other drugs (prescription or over the counter) or herbal products, whether you attend clinic regularly, how regularly you take medication, if you know the medication you are using and whether you handle your own medication.

Selection criteria

You will be selected to take part in this study if you meet the following criteria:

1. Are a diabetic patient male or female
2. Admitted to the KNH medical wards in 2016
3. Aged 60 years and older
4. If you give voluntary informed consent
5. Proxy consent is given by a primary caregiver.

Acceptance of participation into the study

I will interview you at a time that is not inconveniencing to you and obtain personal and medical information from you. Even after acceptance into the study, you are free to leave if you so wish.

Risks or/and discomfort.

The study will have a few risks but all will be done to minimize harm to you in any way psychologically, socially, emotionally and physically.

Rights and safety

To safeguard your rights and safety as a participant taking part in this study, the Kenyatta National Hospital/University of Nairobi Research and Ethics Committee will review the study protocol and the informed consent process before commencing the research.

Benefits

The study may be of benefit to you and other diabetic patients in that it will hopefully be used by KNH as soon as the study is done to enhance detection of discrepancies at admission. It may also inform policy makers on the need to for medication reconciliation at admission for elderly diabetics.

Payments/Re-Imbursements

There will be transport re-imbursement only for the caregivers whom I will send back to bring patients medications. There will be no other payments made to the participants.

Assurance on confidentiality

Utmost care will be taken to keep your participation in this study confidential. All information obtained from your file and laboratory investigation will be kept confidential and used for the purpose of this study only. Your name will not be used during data handling or in any resulting publications, codes will be used instead. Your medical records will be kept under lock and key and information will be accessible to the investigator, data collector and the supervisors of the study.

Contacts

For any further information about this study you may contact me, my academic department or the Kenyatta National Hospital/University of Nairobi Ethics and research Committee using the contacts provided below:

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Prof. Mark Chindia -The Secretary,
The Kenyatta National Hospital/University of Nairobi Research and Ethics Committee,
P.O Box, 19676- Nairobi. Tel: 020-2726300 Ext 44102

STATEMENT OF CONSENT (Tick where appropriate)

PATIENT □

CAREGIVER □ RELATION TO PATENT _____

I have understood the information on the consent form. I have had a chance of discussing the research study with the investigator and I have had my concerns addressed. 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 leave 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 a research study.

I have read the consent form, or have had it read to me YES/NO

I agree to participate in this research study YES/NO

I agree to have my medical records used in this study YES/NO

Participant signature _____ Date _____

I confirm that I have explained the nature and effect of the study to the participant named above and believe that the participant has understood and has willingly given his/her consent.

Printed name _____ Date _____

Signature _____ Role in the study _____

KIBALI CHA UTAFITI

Mimi, Bi/Bwana

……..……..……nimekubalikushirikikatikautafitihuu baadayakuelezwanadaktari……

Sahihiyangunithibitishoyakwambanimeelewaumuhimuwautafitihuunakwambahabari

yoyotenitakayotoaitawekwasiri.

Pia nathibitishayakwambasijapewa au kuahadiwapesa au chochotekile, kukubaliKushirikikwenyeutafitihuu.

Sahihi …….…….

Tarehe …….

Sahihiyamtafiti ……. Tarehe ……

APPENDIX VII: CLINICIAN CONSENT FORM

STUDY TITLE: PREVALENCE AND RISK FACTORS FOR MEDICATION DISCREPANCIES ON ADMISSION OF ELDERLY DIABETICS AT KENYATTA NATIONAL HOSPITAL, KENYA

Consenting process

You are being invited to participate in a study that seeks to find out the medication discrepancies that occur at admission among elderly diabetic patients in medical wards at Kenyatta National Hospital. Before you make the decision whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask for more information, especially if there is anything that you do not understand.

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

1) Your agreement to participate in this study is voluntary.
2) You may withdraw from the study at any time without necessarily giving a reason for you withdrawal.
3) After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Introduction to the study

Medication discrepancies are common during movement from one care point to another when a patient is hospitalized or from one physician to another. These discrepancies are more common during admission when medication history taking is being done. Elderly diabetic patients are at greater risk of discrepancies due to the multiple medications they take and multiple prescribers they have to see. Medication discrepancies can result in medication errors and adverse drug events if not identified and corrected.

Elderly diabetic patients should have their medication reconciled at every point of care through a process of medication reconciliation to ensure that at any given time a patient's medication list is complete and accurate.

In this study I will be making comparisons of elderly diabetic patients' pre admission medication list obtained from various sources to the admission orders to determine if there are any discrepancies and how many. The aim is to establish a complete and accurate list of a patient's current medications and will not a punitive exercise.

Title of the study: Prevalence and risk factors for medication discrepancies at admission of elderly diabetics at Kenyatta National Hospital.

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

Investigator: Elizabeth Kemunto Okerosi P.O Box, 19676- Nairobi. Tel: 0720-813996

Supervisors: Dr Sylvia Opanga, Department of Pharmaceutics and Pharmacy Practice

Dr Faith A. Okalebo Department of Pharmacology and Pharmacognosy

Prof. Anastasia Guantai Department of Pharmacology and Pharmacognosy

Ethical Approval: Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, P.O BOX 20723-00100, Nairobi Tel: 2726300/2716450 Ext. 44102. Approval Ref No.KNH-ERC/A/470

Purpose of the study: The primary objective of this study is to measure the frequency of occurrence of medication discrepancies at admission in elderly diabetic patients. The second objective is to determine the risk factors for the medication discrepancies.

Procedure to be followed: With your permission, I will you to clarify any discrepancies noted during the reconciliation process. This will be done at a time that is convenient to you and will not interrupt your work schedule.

Risks: There will be minimal risks involved in this study.

Benefits: There will be no direct benefits to you but findings of this study will be useful in improving management of elderly diabetic patients at admission at Kenyatta National Hospital and ensuring the patients are given their correct drugs.

Confidentiality: Utmost confidentiality will be ensured. Your name will not be mentioned or used during data handling or in any resulting publications. Study numbers/codes will be used instead.

Contacts: Please feel free to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee for any clarifications or concerns. Use the contacts provided above.

STATEMENT OF CONSENT

I confirm that I have read and understood the information given above for the study. I have had the opportunity to consider the information, asked questions and have had these answered satisfactorily. I understand that my participation is voluntary and I am free to leave at any time without giving any reason, without infringement of my rights. I agree to take part in the above study.

Clinician:

Name……Signature……Date……

Investigator:

Name…….Signature…….Date……

APPENDIX VIII: KNH-UoN ETHICS AND RESEARCH COMMITTEE APPROVAL LETTER

UNIVERSITY OF NAIROBI
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KNH-UON ERC
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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
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Fax: 725272
Telegrams: MEDSUP, Nairobi

16 NOV 2015

Ref: KNH-ERC/A/470

16th November 2015

Elizabeth Kemunto Okerosi
U51/74447/2014
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Elizabeth

Research proposal: Prevalence and risk factors for medication discrepancies on admission of elderly diabetics at Kenyatta National Hospital, Kenya (P652/10/2015)

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 16th November 2015 – 15th November 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-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.

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APPENDIX IX: KNH-UoN ETHICS AND RESEARCH COMMITTEE APPROVAL OF MODIFICATIONS

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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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Tel: 725300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/ Mod&SAE/130

20th April, 2016

Elizabeth K.Okerosi
U51/74447/2014
Dept.of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Elizabeth

Re: Approval of modifications – Prevalence and risk factors for medication discrepancies on admission of elderly diabetics at Kenyatta National Hospital" (P652/10/2015)

Your communication of April 14 2016 refers.

Upon review of your request, the KNH- UoN Ethics and Research has reviewed and approved the following -

1. Age of inclusion of patients to the study from 65 and above to 60 and above.
2. Addition of another cadre of clinicians in the tools and increase the options of pre-existing comorbidities in the tools.

These changes have been reflected in the revised proposal.

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 Chair, KNH- UoN ERC
The Dean, School of Pharmacy,UoN
Supervisors: Dr.Sylvia Opanga, Dr.Faith A. Okalebo, Prof.A.N.Guantai

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