PATTERN AND FACTORS ASSOCIATED WITH POTENTIALLY INAPPROPRIATE MEDICATIONS TO ELDERLY PATIENTS PRESENTING AT MUHIMBILI NATIONAL HOSPITAL EMERGENCY DEPARTMENT

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PATTERN AND FACTORS ASSOCIATED WITH POTENTIALLY INAPPROPRIATE MEDICATIONS TO ELDERY PATIENTS PRESENTING TO MUHIMBILI NATIONAL HOSPITAL-EMERGENCY DEPARTMENT

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"A dissertation research proposal submitted in partial fulfillment of the requirement for degree award of Mmed Emergency Medicine of Muhimbili University of Health and Allied Science"

October, 2024

CERTIFICATION

The undersigned certify that they have read and herby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation titled "Patterns and factors associated with potentially inappropriate medication to elderly patients presenting to Muhimbili National Hospital – Emergency Department" in (partial) fulfilment of the requirements for the degree of Masters of Medicine in Emergency Medicine of the Muhimbili University of Health and Allied Sciences.

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DECLARATION OF COPYRIGHT

I, **Patrick Venance Lumato,** declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature…… Date……

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DEDICATION:

I dedicate this research to my beloved grandparents.

ABSTRACT.

Background: Older adults in Emergency Departments (EDs) often have complex medical demand due to the presence of multiple chronic illnesses, this has led to the use of multiple medication (polypharmacy), causing them to be vulnerable to Potentially Inappropriate Medications, hospitalization, multiple emergency department visits and adverse events.

Objectives: To determine the pattern and factors associated with potentially inappropriate medication given to older patients aged 65 years and above who present to Muhimbili National Hospital Emergency Department.

Methods: This was a retrospective cross sectional study which obtained data of patients aged ≥65 years who presented from January 2024 to June 2024. Data was extracted from the Wellsoft Electronic Health Record System (EHRS) to Case Report Form (CRF) in Redcap on demographic and clinical data, medication data. Potentially Inappropriate Medications (PIMs) were identified by using Screening Tool of Older Persons Potentially Inappropriate Prescription/ Screening Tool to Alert to Right Treatment (STOPP/START) criteria**.** Data was then represented by frequencies and mean. Univariate analysis to find association between patient characteristics and PIMs was done. Multivariate analysis to identify independent predictors of PIMs employed by importing all variables with P value less than 0.05 considered significant.

Results: A total of 467 elderly patients aged ≥65 years participated in this study, with the mean age of 73.5 years, of which 278 (59.5%) were males. The proportion of PIM use according to STOPP/START criteria version three was 51.6%. Most common PIM pattern were analgesics, the Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) 13.5%, and the gastrointestinal medications Proton Pump Inhibitors (PPIs) 11.5% as identified by STOPP/START criteria. The factors which were independently associated with PIMs after multivariate analysis were night shifts attending doctor, specialist and registrar, The increase in number of complain above 2 and large number of diagnoses which were statistically significant.

Conclusion: The study highlights the high proportion of potentially inappropriate medications in elderly patients at emergency departments, with night shift, specialist and registrar, increasing in number of complain and diagnosis being the main factors associated with PIMs. Therefore, emphasizing the need for improved prescribing practices, including electronic prescription systems and regular medication review.

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LIST OF ABBREVIATIONS

ADRS	Adverse Drug Reactions
DRTC	Director of Research, Training and Consultancy
DUR	Drug Utilization Review
ED	Emergency Department
HICs	High income countries
LICs	Lower income country
MNH	Muhimbili National Hospital
MRAE	Medication Related Adverse Events
OADR	Older Adults Drug Regimen
PIMs	Potentially Inappropriate Medications
PIPs	Potentially Inappropriate Prescriptions
START	Screening Tool to Alert to Right Treatment
STOPP	Screening Tool of Older Persons Potentially Inappropriate Prescription

DEFINITION OF KEY TERMS

1. **Adverse Drug Events** a response to a drug that is noxious and unintended and that occurs to a dose normally required for therapeutic use.

2. **Critical patient:** A critically ill or injured patient is defined as one who has an illness or injury impairing one or more vital organ systems such that there is a high probability of imminent or life-threatening deterioration in the patient's condition".

3. **Drug Utilization Review:** is an authorized and structured ongoing review of practitioner prescribing, pharmacist dispensing and patient use of medications. The purpose of DUR is to ensure drugs are used appropriately, safely and effectively to improve patient health status

4. **Elderly: individual aged 65 years.** This age group is used in geriatric medicine to define the elderly population due to age-related physiological changes, altered pharmacodynamics and pharmacokinetics of medication of this age together with increased prevalence of chronic conditions.

5. **Medication-Related Adverse Events:** Unintended and harmful events or outcomes resulting from medication use, such as side effects, drug interactions, or anaphylactic reactions.

6. **Older Adults Drug Regimen:** The specific medications and dosages prescribed to older adults as part of their medical treatment plan.

7. **Polypharmacy:** The practice of a patient taking many medications, which is frequently linked to a higher risk of adverse events and drug interactions, particularly in older persons. denotes the use of five or more drugs in accordance with an analysis of recent data. Because of the physiological and pathological changes that come with aging, people are more likely to be prescribed many drugs and are at risk of multi-morbidity, which is the coexistence of two or more chronic health disorders

8. **Potentially Inappropriate Medications:** these are Medications that have a higher risk of causing harm or adverse effects when prescribed to older adults due to factors such as age-related physiological changes.
9. **Potentially Inappropriate Prescription:** an act of prescribing of medications that may cause more risks than health benefits for a patient, especially when it comes to older adults, due to factors like age related changes, chronic illnesses, or polypharmacy.
10. **Screening Tool of Older Persons' Potentially Inappropriate Prescriptions:** A set of standards used to alert medical staff to possibly improper prescriptions in older individuals who are sick in an effort to maximize medication safety and high-quality patient care
11. **Screening Tool to Alert to Right Treatment:** A set of criteria used to notify healthcare personnel on the potentially appropriate medications that may be underutilized to older adults, with the goal of improving their healthcare outcomes.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Population aging is a natural outcome of longer life spans and lower fertility; aging and negative population growth are processes that reinforce one another(1). The population 65 years of age or older was projected to reach 727 million in 2020; by 2050, this figure is projected to rise to 1.5 billion(2). With the continuous increase in the number and proportion of the older population, the degree of aging in the world will continue to increase. In Tanzania currently elderly patients are at 3.8% of the population and is expected to double by 2050(3).

In addition to being a social concern, population aging is a significant health concern for this era. Elderly people undergo multiple physiological changes such as declines of renal excretion metabolism functions and body immunity predispose elderly people to comorbidities, particularly chronic conditions and polypharmacy

The use of medications in the elderly is a critical aspect of healthcare, given the complex interplay of comorbidities, polypharmacy and physiological changes associated with aging. Potentially Inappropriate Medications (PIMs) pose significant risks to this vulnerable population, leading to adverse drug reactions, hospitalization, and increased mortality. Identifying patterns and factors associated with PIM use among elderly patients is essential for improving medication safety and healthcare outcomes.

At the moment, the focus of treatment for older people with chronic illnesses is typically on one illness(4). Older people frequently require concurrent use of many drugs due to the rise in compounded chronic conditions. Polypharmacy is the term used to describe the concurrent use of five or more medications by a patient. While inappropriate prescribing includes the use of medication that are not indicated, are ineffective or pose higher risk than benefit. It also includes omission of potentially beneficial medications(5).

Some medications used by elderly individuals may have more potential side effects than advantages; these medications are known as potentially inappropriate medications (PIMs). The American Geriatrics Society, working with a panel of experts located in the US, has taken on the responsibility of regularly reviewing and revising the Beers criteria, which are currently in their sixth iteration. The Beers criteria were the first expert agreement on PIMs in the older population (6). Using the Delphi technique, University College Cork brought together specialists from many disciplines to develop the Screening Tool of Older People's Prescriptions/Screening Tool to Alert to Right Treatment (STOPP/START) criteria. The second edition of the tool was revised in 2014(6). Worldwide, a lot of people employ these two standard criteria.

Previous researches have shown a strong correlation between elderly patients' usage of PIM and an increased risk of adverse drug events (ADEs) and Emergency Department visits(7). In the meantime, patients' health-related quality of life is lower than that of patients who do not utilize Potentially Inappropriate Mediation (PIM).

Muhimbili National Hospital (MNH) Upanga and Mloganzila campus are the tertiary healthcare facilities in Tanzania serves a large number patient population, including a significant number of elderly patients aged 65 years and above. The Emergency Department at MNH frequently encounters elderly patients presenting with multiple acute conditions such as pain, difficulty in breathing, alteration of mental status and other more, making it crucial point of care for assessing medication appropriateness which are to be given to this population based on their comorbidities or other types of medications they are on, so as to prevent adverse drug events, drug-drug interaction, or even mortality.

This study aims at investigating the proportion, patterns and factors associated with potentially inappropriate medication to elderly patients presenting to the Muhimbili National Hospital Emergency Medicine Department. By understanding the scope and determinants of PIMs use will ultimately enhance the quality of care for elderly patients at the Emergency Department.

1.2 Problem statement:

The elderly population is particularly vulnerable to the adverse effects of potentially inappropriate medications, which can lead to significant health complications, including adverse reactions, hospitalization and high mortality. Despite of the known risks associated with PIM use, these medications continue to be prescribed, often exacerbated by factors such as multiple comorbidities, polypharmacy, and the complexes of age related physiological changes in this population(8).

The emergency department of Muhimbili National Hospital being the port of entry for most of these elderly patients requiring urgent medical attention.

There is limited data on the patterns and factors associated with PIMs in older patients presenting to the Emergency Department (ED) of tertiary hospital in Tanzania which hampers efforts to improve medication safety and optimize patient outcomes. This study aims to fill this gap by investigating the proportional, pattern and determinants of potentially inappropriate prescriptions in the ED.

1.3 Conceptual Framework:

The figure below shows the relationship between variables and outcome of interest of this study. The outcome of older patients at ED on pattern and factors associated with inappropriate prescription and medication depends on a number of factors like age, sex, comorbidities, polypharmacy, chronic illnesses, lack of geriatric pharmacological knowledge. However, it may also be affected indirectly by financial constrain or disease severity figure 1 below

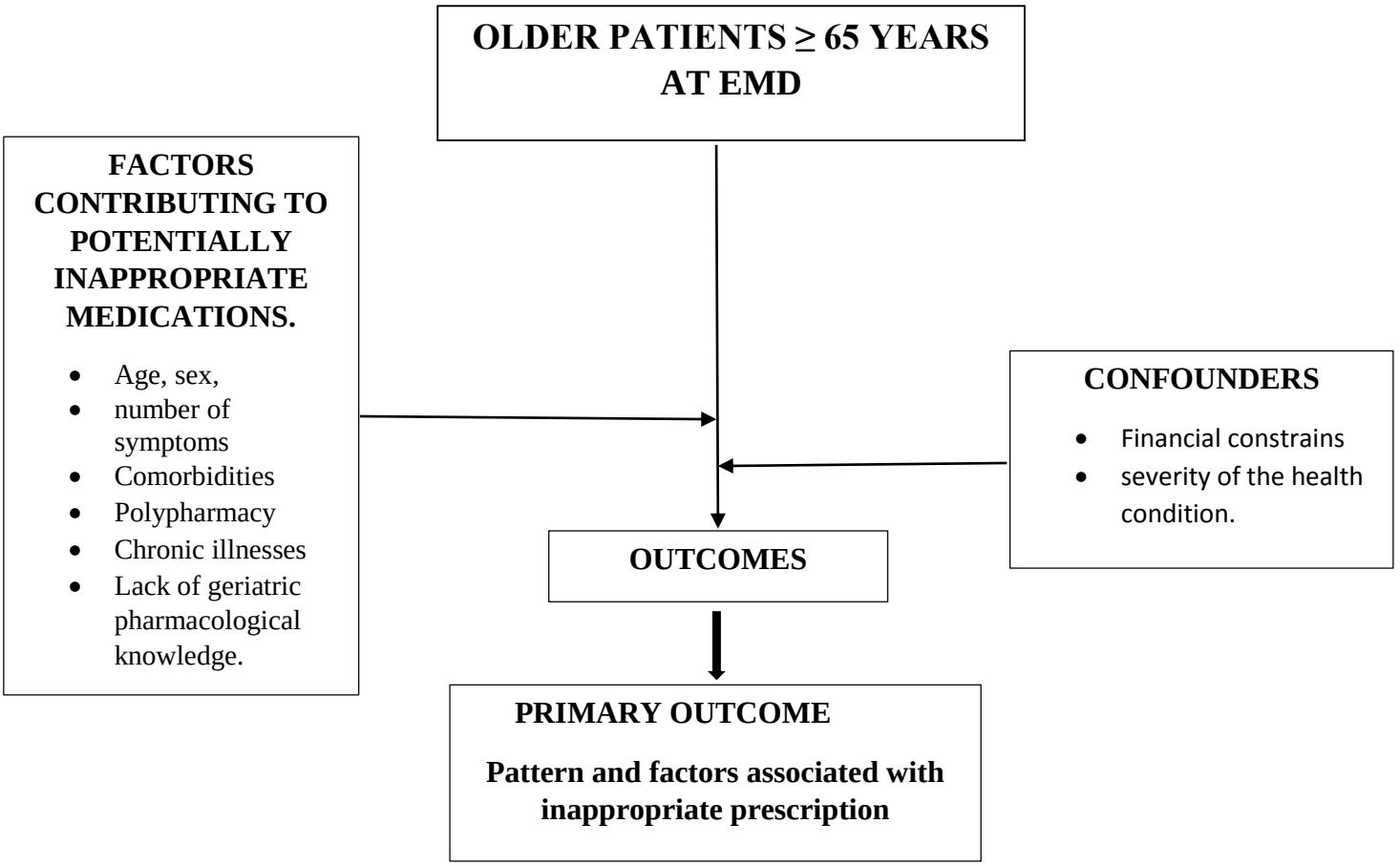


Figure 1. Flow chart of conceptual frame work.

1.4 Rationale of the study:

Older patients frequently present to EDs with complex medical conditions which often leading to prescription of multiple medications. Despite the known risks, PIMs continue to be prescribed at alarming rates, particularly in high-pressure environments like the EDs. The findings of this study will help in identifying pattern and factors associated with PIPs which is essential in developing targeted interventions to reduce the use of inappropriate medications and enhance the quality of care for older patients in the emergency department.

1.5 Broad Research Question:

In elderly patients aged 65 years and above presenting to Muhimbili National Hospital's Emergency Department what are the patterns and factors associated with Potentially Inappropriate medication (PIMs) prescription?

1.5.1 Specific research questions

1. Among the elderly patients presenting to the MNH, what is the proportion of PIM at ED?
2. In the elderly patients with potentially inappropriate medication presenting to MNH-ED what are their demographic and clinical characteristics?
3. Elderly patients presenting to MNH-ED are prone to what patterns of PIMs.
4. In the elderly patients presenting to MNH, what are the factors associated with PIMs at the ED?

1.6 Hypothesis:

Elderly patients presenting at Muhimbili National Hospital Emergency Department are at higher risk of receiving potentially inappropriate medications/prescriptions due to factors such as polypharmacy, multiple comorbidities, cognitive impairment, time constrains in the Emergency Department and may be due to lack of comprehensive patient medical records.

1.7 Broad Objective:

To determine the pattern and factors associated with PIMs among older patient presenting at Muhimbili National Hospital's Emergency Department.

1.7.1 Specific Objectives:

1. To determine the proportion of elderly patients with PIMs presenting to the ED-MNH in the past 6 months of 2024.
2. To determine the demographic and clinical profile of elderly patients in the last 6 months with PIMs presenting to ED-MNH
3. To describe patterns of PIMs which were given older patients who presented in the last 6 months to ED-MNH.

4. To determine the factors associated with PIMs among older patients presenting to ED- MNH in the past 6 months of year 2024.

CHAPTER TWO

2.0 LITERATURE REVIEW

Potentially inappropriate medication is a great concern when it comes in affecting the qualities of life in elderly patients who are 65 years and above. As the population ages, multimorbidity and polypharmacy becomes prevalent. This increases the risks of adverse drug events, increased healthcare utilization, hospitalization, increased risks of fall, drug-drug interactions and poor health outcomes. Potential Inappropriate Medications are defined as medications that causes more risks than benefits.

The elderly patients are vulnerable due to age related physiological changes including reduced renal and hepatic functions which alter drug metabolism and excretion. Guidelines such as Beers Criteria and STOPP/START Criteria have been established to identify and reduce PIMs, but despite these efforts, inappropriate prescribing of medications remain a global problem.

The most widely used tools for identifying PIMs STOPP (Screening Tool of Older People's Prescription) and START (Screening Tool to Alert doctors to Right Treatment) Criteria are validated tools which were developed in Europe as complementary tool to Beers Criteria. STOPP identifies potentially Inappropriate medications, while START highlights medications that should be prescribed to avoid under-treatment of common conditions in the elderly. Apart from using these tools STOPP/START and Beers Criteria, there other several interventions to reduce PIMS such as medication reviews by pharmacists or geriatricians, clinical decision support systems such that Electronic Health Records (EHRs) are equipped with decision-support system that alert prescribers when PIM is being prescribe, together with education and training about the risks of PIMs and the use of prescribing guidelines such as STOPP/START and Beers Criteria.

2.1 The proportion of elderly patients with PIMs

Due to various age-related factors, providing medications appropriately in elderly patients is difficult and complex. Among these factors are age related physiological changes that

influence the pharmacodynamics and pharmacokinetic profile of medication hence increasing the PIPs and PIMs prevalence(9). In a study by Smith et al 2018 on assessment of elderly patients who visit ED with PIPs, indicated that there was a prevalence of 30% based on the STOPP criteria(10). Another study by Rancourt et al 2004, in Quebec City indicated that a total prevalence of PIPs among the population under study was 51.5%(11). Tian et al 2023 in their systemic review showed that the prevalence of PIMs was 36.7%. Also the study by Gallagher et al 2007 indicated that there was high prevalence of PIPs among elderly patients treated with acute illnesses in United States and Europe(12). Furthermore, a study by Lai et al, 2009 in Taiwan found that PIMs were prevalently higher and was associated with emergency department revisits(13). In Africa a study done by Bhagavanthula et al 2021 in Ethiopia indicated that proportional of PIMs was 47.2%(10). However, in South Africa a study by Rangini and Andrew in 2004 documented a low prevalence of PIPs being 30%. And most of these studies in Higher Income Countries (HICs) and Lower Income Countries (LICS) have estimated the prevalence of PIPs and PIMs outside emergency departments(14). In Tanzania there are limited reports from literatures about PIPs and PIMs in older patients and most of the manufacturers of medicine does not include elderly patients in their trials, making it difficult to estimate their prevalence.

2.2 The clinical profile of elderly patients with Potentially Inappropriate medications**.**

Elderly patients have complex nature of illnesses which pose them into risk of having inappropriate prescription with inappropriate medication being high in the list. Jhaveri et al. 2014 in their study indicated that, about 52% of patients were females, having 72 years of age, most of them had heart and renal failure(15). However, a study by Perez et al. 2018, showed that males were only 43%, and having history of previous single admission with multi-morbidity(16). Motappa et al. 2022 indicated that, study population's most prevalent illness was arthritis, which affected most of the elderly, followed by hypertension(17). Diabetic mellitus, arthritis, hypertension and atrial fibrillation were also identified by Van Heerden et al. 2016 in a study done in South Africa in most of the females with 74years of age(14). The same findings were observed in Nigeria by Akande-sholabi et al. 2020 with

only small difference in age group of which the study population had 69years of age(18). In Ethiopia a study by Lemma et al. 2020 indicated that most of the study participants were males, prescriptions with an antibiotic injection was prevalent, and more than 5 drugs were prescribed only to 10.8 % of elderly patients. Cardiovascular drugs constituted about a quarter of the prescribed medications others were analgesics, anti-inflammatory, anti-infective, endocrine drugs, gastrointestinal drugs(19). In Tanzania and East Africa there are limited such studies making this study to be of paramount to this age group.

2.3 Patterns of Potentially Inappropriate medication among elderly patients**.**

Elderly patients frequently receive inappropriate prescriptions, which are linked to poor health outcomes. It is unclear how various PIPs patterns fit into clinical practice. However, Zuleta et al 2024 in Barcelona described four patterns of PIPs identified as extreme polypharmacy (10 or more drugs), potentially inappropriate medications (PIMs), potential prescribing omissions (PPOs) and anticholinergic burden(20). Another study from Nigeria by Fadare et al, 2013 identified that non-steroid anti-inflammatory drugs, antihistamine and amitriptyline were the commonest group of drugs to PIPs in elderly patients(21). Albarqouni et al. 2022 in their systemic review article indicated that Proton pump inhibitors, antihypertensive medications, antimicrobials, and psychiatric medicines were among the frequently overused drug category. Abdulah et al, 2018 in their study indicated that Chlorpheniramine, metoclopramide, mefenamic acid, ibuprofen, and nifedipine were the most commonly prescribed PIM, however most of the data are from non EDs(22). Jhaveri et al. 2014 found that Metoclopramide, alprazolam, diazepam, digoxin > 0.125 mg/day, and diclofenac were the commonly used inappropriate medications and Use of nonsteroidal anti-inflammatory drugs (NSAIDs) was common in patients with positive history of gastric or duodenal ulcer heart and renal failure. There are limited information from sub-Saharan Africa regarding pattern of PIPs and PIMs among elderly patients presenting to EDs.

2.4 Factors associated with Potentially Inappropriate medication among older patients

Several factors have been linked to PIPs and PIMs worldwide. These factors are either demographic, clinical profiled, health facility utilization or prescribers' knowledge.

Literature from Rochon et al. 2021, have shown that sex (biological) and gender (sociocultural) factors are important considerations in safe drug prescribing(23). Age is not found to be a predictor of inappropriate prescribing(14). An association is found between sex and inappropriate prescribing, with female sex being associated with a greater degree of potentially inappropriate prescribing. A higher number of comorbidities, both physical and mental, were found to be patient-related clinical risk factors for PIPs, and a bigger number of drugs were found to be positively correlated with PIPs(16). Furthermore, environmental factors (e.g., lack of integrated care, insufficient investment, time constraints), patients (e.g., limited understanding, patient non-adherence, drug dependency), prescriber (e.g., inadequate knowledge, concerns of adverse consequences, clinical inertia, lack of communication), and technology (e.g., complexity of implementation and inapplicable guidance) were also associated with PIPs and omission. Tampaki et al. 2023 have shown that age, sex, frailty, comorbidities, and total medication number were the independent risk factors of PIPs and PIMs(24). Using psychiatric drugs, musculoskeletal pharmaceuticals, alimentary tract medications, self-medication, high risk of clinical-functional vulnerability and other characteristics were linked to high prevalence of PIPs and PIMs(25). Those who were elders and took potentially improper drugs had different features from those who did not: higher education, private employment, income up to three minimum salaries, multi-morbidity, hypertension, cardiovascular disease, chronic renal disease, depression, adverse events, and polypharmacy(26). Another study from Eastern Ethiopia by Nigussie et al. 2024, identified Male sex, diabetes mellitus, and chronic kidney disease to be the decisive variables for PIM usage based on the 2023 AGS Beers Criteria and According to STOPP/START version 2 criteria, deep vein thrombosis, diabetes mellitus, hypertension, and advanced age were important factors in the use of PIMs(10). There are limited studies in Tanzania which have explored the factors associated with PIPs and PIMs.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was a retrospective cross sectional study among elderly patients aged 65 years and above presenting to the Emergency Department of MNH Upanga and Mloganzila campus. Data were extracted from electronic health medical records Wellsoft in the past 6 months from January 2024 to June 2024.

3.2 Study Setting:

The EMD-MNH Upanga and Mloganzila in Ilala and Ubungo districts respectively, Dar Es Salaam, Tanzania, were the sites chosen for this project. MNH-Upanga has been in operation for the past 14 years, this Emergency Department is the first with a full capacity in the nation. Located in the largest commercial city in Tanzania, it serves more than 60,000 patients annually on average. It offers care for critically ill patients with potentially fatal conditions by stabilizing and managing them for 24 hours including weekends and holidays before transferring them to an inpatient unit, intensive care unit, outpatient clinic, or, if necessary, a medical evacuation for additional diagnostic testing and treatment.

EMD-Mloganzila was opened in September 2017; it is among the few emergency departments in Tanzania that operate 24 hours every day including weekends and holidays. It has the capacity to care for 35-40 patients per day which is equivalent to 1200 patients per month and 14000 per year. It is staffed by EMD Physicians and equipped with advanced life support machines and point-of-care that help to provide specialized and quality emergency interventions to all investigation's patients, adult and pediatric presenting with different surgical, medical, and traumatic illnesses at different levels of acuity. **Organization:** EMD -Mloganzila is divided into 6 sections to provide organized high-quality care, these include the Triage area, Resuscitation area (wing A), Adult treatment area (wing B), Pediatric treatment area (wing C), Isolation (2negative pressure rooms), Emergency pharmacy. In all these Emergency Department, there has been a rise in a

significant number of elderly patients attending the at the department seeking for emergency services care.

3.3 Target population

All elderly patients 65 years and above who presented to the acute care settings in Tanzania

3.4 Accessible population

All elderly patients who presented to the EMD-MNH Upanga and Mloganzila campus

3.5 Study population

All elderly patients 65 years and above who presented to the EMD-MNH Upanga and Mloganzila who met the inclusion criteria to be involved in study within a specified time of study.

3.6 Sampling design

Convenient sampling of older patients 65 years and above who presented to EMD of MNH Upanga and Mloganzila was applied during the period of study with complete medical information in the Wellsoft will be enrolled.

3.7 Study Subject

3.7.1 Inclusion criteria:

All the participants who met the following inclusion criteria were enrolled in the study

- Age $\geq$ 65 years
- Older patient who received at least one medication at ED
- Having a complete medical record

3.7.2 Exclusion criteria

Elderly patients with the following criteria were excluded in the study

- Discharge against medical advice
- Missing data

- Patients with medications that are not identified by the STOPP/START criteria version III such as antibiotics and supplements.

3.8 Variables of interest:

3.8.1 Independent variables

1. Demographic Variables:
    - Age in years
    - Sex (male / female)
    - referral status (referred or self-referral)
    - insurance status (insured / non-insured)
2. Clinical data;
    - Comorbidities per systems:
    - Number of chief complains
    - ED diagnosis number and types
3. Medication-Related Variables:
    - Number of medication that the patient is current using and its type
    - Number of medications prescribed at ED.
    - Type of medications prescribed
4. Disposition plan
    - Hospitalized
    - Discharged home,
5. Healthcare care utilization status;
    - frequency of ED visits and hospitalization

3.8.2 Outcome variables;

- Potentially Inappropriate Prescription
- Pattern of Inappropriate Prescription

- Potentially Inappropriate Medication

3.9 Sample Size Estimate.

A study which was conducted by Fangyuan Tian et al. and published in JAMA Network Open in 2023, which included about 273.1 million adult patients found an overall prevalence of Potentially Inappropriate Medications in African countries is 47.0%; 95% CI, (34.7% - 59.4%).

By using the expected prevalence between of 47% (9), the minimum sample size of study participant by the Kish-Leslie formula

$$n = Z^2P (1-P) /d^2$$

Whereby;

n = minimal sample size

Z= Z statistic for a level of confidence

P= expected prevalence or proportion

(if the expected prevalence is 47%, then P=0.47) and

d = Precision (If the precision is 5%, then d = 0.05).

Z=1.96, P=47%, d=0.05

Then, $n = 1.96^2 x 0.47 (1-0.47)/ 0.05^2$

n = 352

However, in this retrospective study we don't expect to get drop out study participants therefore, sample size for this study was expected not to be less than 352 participants.

3.10 Patient Recruitment and Data Management

3.10.1 Identification:

By using the Hospital Information System (HIS), the principal investigator and the six research assistants were actively participating in the initial identification of all elderly patients who are admitted through the EDs of MNH Upanga and Mloganzila campus

through Electronic Health System (EHS). The system was queried to generate a list of all elderly patients who were ≥ 65 years who presented between January 2024 and June 2024 patients were identified based on their date of birth and Medical Record Number (MRN). The inclusion criteria ensured that all selected patients had complete medical record and were given at least one medication at ED.

3.10.2 Screening and enrollment:

The principal investigator always counterchecked the patients screening and enrollment process to ensure that all eligible patients were included in the study. To avoid bias and maintain accuracy a systematic sampling was applied, research assistants were instructed to select 3rd patient on the list who met inclusion criteria and enroll. Each research assistant was instructed to collect at least one hundred Patients for the period of four days consecutive. Those who meet the inclusion criteria their demographic information filled into RedCap Case Report Form (CRF).

3.11 Data management

The trained research assistances extracted data from the Wellsoft Software from the selected patient records to capture the variables such as demographics and clinical information (age, gender, comorbid conditions, diagnosis at admission and type of medication given at ED. PIMs were then identified by STOPP/START criteria version 3.

The collected data were entered into a secure, password-protected, and each patient data was identified by a specific MRN. After data entry, the data were checked for any errors such as double entry. Data were encrypted to drives to prevent data loss. Data confidentiality was ensured.

3.12 Collection of Data

3.12.1 Standardized data collection tool.

For all patients aged over 65 years old, demographic information (age and gender), clinical history comorbidities and diseases,) and medication prescriptions history as identified by the updated STOPP/START criteria version three for identification of PIMs were filled in a Case Report Form (CRF) to collect information from the electronic medical record

(Wellsoft) retrospectively. Redcap Version 6.0.1 from Vanderbilt University, Tennessee, USA was used.

3.12.2 Pre-testing of the tool

The six research assistants were given a Case Report Form that was transformed into online Redcap, which was used to collect data. After the research assistants successfully finished the training and understood how to utilize the data collection tool, the data collection form was pre-tested to gather information from the patients records who fits the study at the ED which was around 35 patients 10% of the sample size. This helped in locating and resolving issues that raised prior we started data collection process.

3.13 Statistical Data analysis

The data was exported using RedCap (Version 6.0.1, Vanderbilt University, Tennessee, USA) data was transferred into an Excel file (Microsoft Corporation, Redmond, WA, USA), which was subsequently imported and subjected to statistical analysis tool IBM SPSS 26 Verson. The aforementioned program examined the data after it was put into a computer. Proportions and frequency was used to describe categorical data and mean (SD) or median (IQR) was used to examine continuous data as needed. A statistically significant P value was one that was less than 0.05.

First objective; To determine the proportion of elderly patients with PIMs among elderly patients presenting to the ED-MNH, has been represented as proportion by calculating elderly patients with PIMS and the total number of elderly patients attended during the period of study. The frequency distribution table has been tabulated to summarize the findings.

Second objective; To identify demographic and clinical characteristics of the elderly patients presenting to the ED- MNH. the frequency distribution table has been tabulated to summarize them.

The third object; To identify patterns or types of PIMs prescribed to elderly patients in the ED-MNH, a bar chart has been used to summarize the findings.

Fourth objective; To identify factors associated with PIMs in elderly patients presenting to ED-MNH. The logistic regression and multivariate analyses were performed to determine the factors associated with PIMs in our study population.

3.14 Ethical Clearance

The MUHAS Senate of Research and Publication Committee was contacted to obtain this project ethical approval from IRB. DRTC- MNH personnel was asked for permission access for data collection from hospital information the system. Confidentiality was ensured, the identity of the study participants was identified by serial codes. The information records were secured by password and encrypted in drives.

CHAPTER FOUR

4.0 RESULTS

4.1 Proportion of older patients with PIMs presenting to ED-MNH

During the period of six months 4091 older patients presented to ED-MNH. Among them 1429 (34.9%) met inclusions criteria. Of whom we finally analyzed 467(32.7%) after excluding those who had been prescribed with antibiotics which is not included in the STOPP criteria. The proportion of PIMs was found to be 241 (51.6%) among older patients who presented to ED-MNH. figure 2

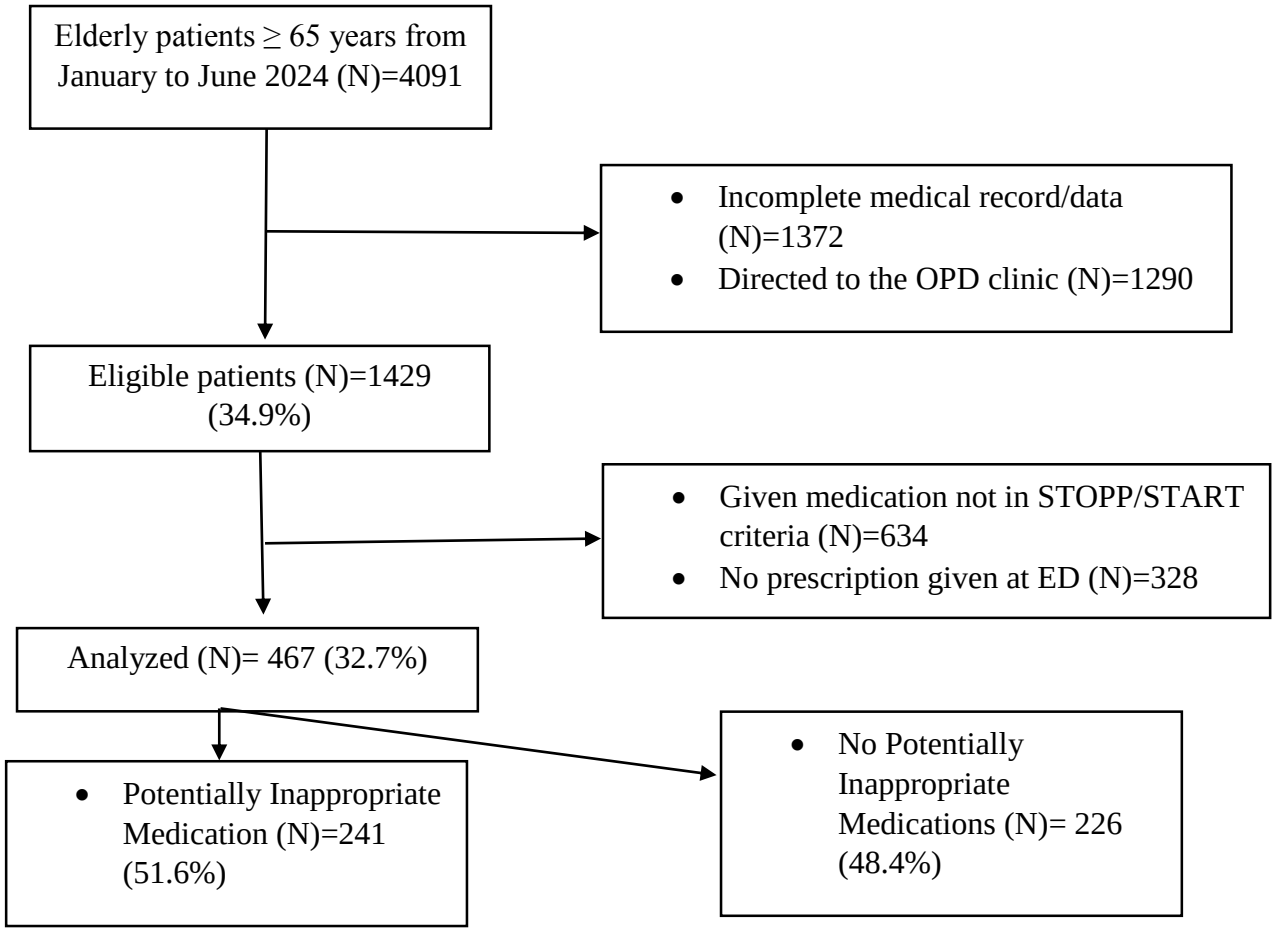


Figure 2: Flow diagram of the elderly participants

4.2 Socio demographic characteristics of elderly patients aged ≥ 65 presented to the MNH-ED

The study involved elders with mean age of 73.5-year-olds, 278(59.5%) males, 275(59.3%) new visits, revisiting and readmissions to ED were 189(40.7%) and 178(41.2%) respectively. More than half 200(56.7%) were self-referral. Most of the elders were attended by registrars and residents 224(48.2%) and 182(39.1%) respectively, 333 (72.2%) attended during day shifts,

Table 1: Socio-demographic characteristics of the study participants N = 467

Variable	Frequency (n)	Percent (%)
Age group (years)		
65 – 70	176	37.7
71 – 75	114	24.4
>75	177	37.9
Gender		
Male	278	59.5
Female	189	40.5
Facility utilization		
New visit	275	59.3
Revisit	189	40.7
Admission type		
New	254	58.8
Readmission	178	41.2
Referral status		
Referred	200	56.7
Self-referral	262	43.3
Insurance status		
Yes	290	62.5
No	174	37.5
Type of shift		
Day	333	72.1
Night	129	27.9
Attending doctor		
Specialist	29	6.2
Resident	182	39.1
Registrar	224	48.2
Intern	30	6.5

4.3 Clinical characteristics of elderly patients aged ≥65 years presented to the MNH-ED of Upanga and Mloganzila campus.

The participants in this study display a diverse range of comorbidities and diagnoses. Hypertension is the most prevalent comorbidity, affecting more than half 247 (52.9%) of the participants and Diabetes was present in 94 (20.1%) participants being the second most comorbidity. Most elderly patients nearly half of the elderly patients 224 (49.0%) participants had two to three medical complaints at the ED. Cardiovascular diagnoses was most frequent specific diagnosis affecting 60 (13.0%) of elderly patients, but significant portion 186 (40.3%) had mixed diagnoses. 278 (60.6%) of elderly patients had two to four diagnoses at presentation at ED, indicating high level of complexity in their clinical presentations and management. (Table 2)

Table 2: Clinical characteristics of the study participants

Variable	Frequency (n)	Percent (%)
Comorbidities*		
Hypertension	247	52.9
Diabetes mellitus	94	20.1
Malignancy	62	13.3
HIV	12	2.6
CKD and ESRD	29	6.2
Stroke	19	4.1
Chronic liver disease	2	0.4
COPD	5	1.1
Other	55	11.8
Number of complaints		
1	217	47.5
2 – 3	224	49.0
>3	16	3.5
Diagnosis*		
Cardiovascular	60	13.0
Respiratory	42	9.1
Nervous system	17	3.7
Gastrointestinal	59	12.8
Musculoskeletal	8	1.7
Urological	55	11.9
Endocrinology	23	5.0

ENT	7	1.5
Trauma	4	0.9
Mixed diagnosis	186	40.3
Number of diagnosis		
1	167	36.4
2-4	278	60.6
>4	14	3.1

*Participants may have more than one comorbidity or diagnosis

4.4 The prevalence of Potentially Inappropriate Medication use in elderly patients over the past five months.

The Potentially Inappropriate Medication use in elderly patients who presented to the MNH-ED over the past 5 months using the STOPP/START criteria version three was 51.61%. Fig 3

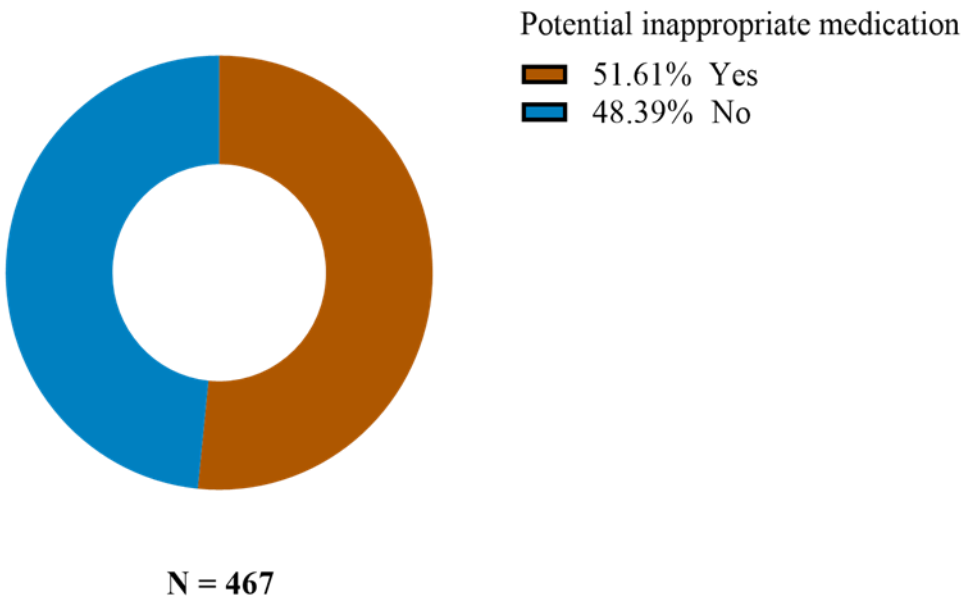


Figure 3: A pie chart showing the prevalence of Potentially Inappropriate Medication use in elderly patients over the past five months.

4.5 Patterns/classes of potentially inappropriate medications:

As per STOPP and START criteria, antibiotics were seen in most frequently PIM (29.9%), because antibiotics were seen to be prescribed with no rationale or clear clinical indication in the elderly patients at MNH-ED and the most second frequently used PIMs at MNH-ED were analgesics, the Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) (13.5%), followed the gastrointestinal medications Proton Pump Inhibitors (PPIs) 11.5%, cardiovascular drugs were 5.6%, endocrinology 3.6% and others as seen in the bar chart. (Fig 4)

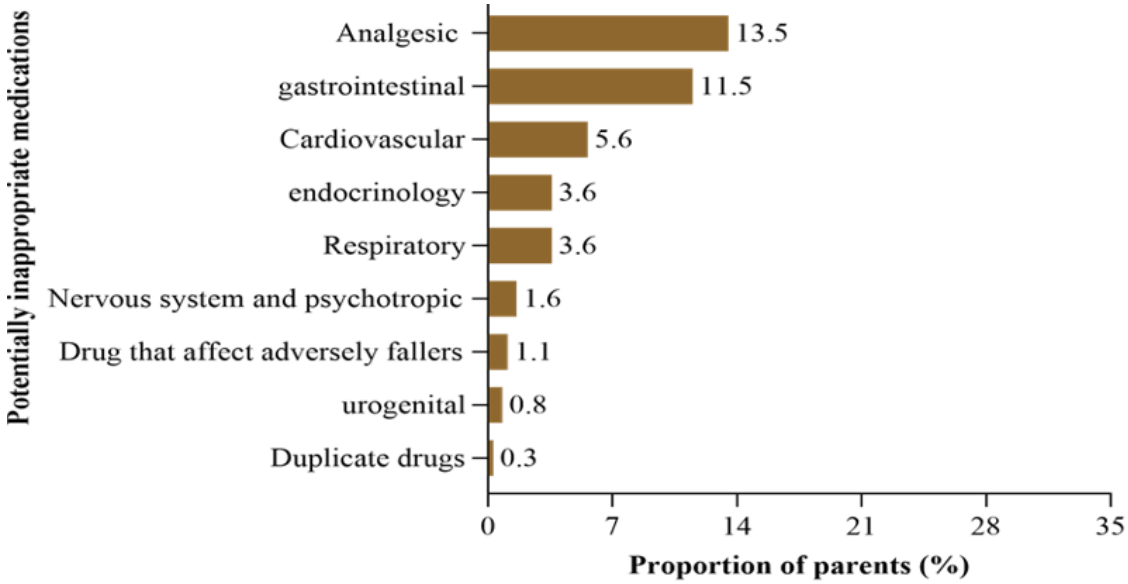


Figure 3: A bar chart showing the Patterns/classes of potentially inappropriate medications

4.6 Factors associated with PIMs among elderly patients presenting to the MNH-ED.

The following factors showed significant association with PIMs among elderly patients presenting to ED. Where by type of shift, of which attending at night p value < 0.015, attending doctor; specialist p value < 0.004, resident p value < 0.028 and registrar p value < 0.029 were significantly associated with PIMs. Number of complain and diagnosis also showed significant association with PIMs p values < 0.001 for both. Other factors were not significant. Table 3

Table 3. Univariate analysis of the factors associated with the PIMs among elderly patients presenting to the MNH-ED.

		Univariable analysis		
Variable	**Category**	**cOR**	**95% CI**	**p – value**
Age group	65 – 70	Ref		
	71 – 75	1.00	0.62 – 1.60	1.000
	>75	1.19	0.78 – 1.80	0.426
Gender	Male	Ref		
	Female	1.22	0.84 – 1.76	0.303
Facility utilization	New visit	Ref		
	Revisit	1.14	0.79 – 1.65	0.490
Admission type	New	Ref		
	Readmission	1.18	0.80 – 1.73	0.401
Referral status	Referred	1.09	0.76 – 1.58	0.634
	Self-referral	Ref		
Insurance status	Yes	1.37	0.94 – 2.00	0.098
	No	Ref		
Type of shift	Day	Ref		
	Night	1.67	1.11 – 2.53	**0.015**
Attending doctor	Specialist	5.19	1.71 – 15.71	**0.004**
	Resident	2.55	1.11 – 5.86	**0.028**
	Registrar	2.51	1.10 – 5.71	**0.029**
	Intern	Ref		
Number of complaints	1	Ref		
	2 – 3	1.99	1.36 – 2.90	**< 0.001**
	>3	1.75	0.63 – 4.86	0.286
Number of diagnosis	1	Ref		
	2 – 4	2.41	1.63 – 3.57	**< 0.001**
	>4	6.05	1.63 – 22.53	**0.007**

4.7 Independent factors associated with PIMs among elderly patients presenting to MNH-ED

The following factors were independently associated with PIMs. Shift type, attending at night (aOR=1.80; 95% CI, 1.14-2.83, p value < 0.011), attending doctor; Specialist Specialist (aOR= 4.00, 95% CI, 1.23 – 13.07, p value < 0.022) and registrar(aOR=2.42, 95% CI, 1.01 – 5.85, p value < 0.049). The increase in number of complain above 2 (aOR=1.57, 95% CI, 1.04 – 2.38, p values < 0.034) and diagnoses (aOR=1.91, 95% CI, 1.24 – 2.93, p value < 0.003). Table 4

Table 4. showing independent factors associated with PIMs among elderly patients presenting to MNH-ED

		Multivariable analysis		
Variable	**Category**	**aOR**	**95% CI**	**p - value**
Insurance status	Yes	1.45	0.96 – 2.18	0.076
	No			
Type of shift	Day			
	Night	**1.80**	**1.14 – 2.83**	**0.011**
Attending doctor	**Specialist**	**4.00**	**1.23 – 13.07**	**0.022**
	Resident	2.18	0.90 – 5.30	0.084
	Registrar	**2.42**	**1.01 – 5.85**	**0.049**
	Intern			
Number of complaints	1			
	2 – 3	**1.57**	**1.04 – 2.38**	**0.034**
	>3	1.32	0.45 – 3.83	0.616
Number of diagnosis	1			
	2 – 4	**1.91**	**1.24 – 2.93**	**0.003**
	>4	**5.80**	**1.21 – 27.82**	**0.028**

CHAPTER FIVE:

5.0 DISCUSSION

5.1 Discussion

PIM use is one among health problems affecting most of the elderly patients which may result into adverse drug events, hospitalization, decline of quality of life and even mortality. These results are usually due age related physiological changes which are changes in pharmacokinetics and pharmacodynamics and decline in renal and liver functions(27). This study revealed a more than half of elderly patients who visited the MNH-ED of Upanga and Mloganzila campus had PIM. Our results are almost similar to the previous research conducted by Rancourt et al 2004, in Quebec City indicated that a total prevalence of PIMs among elderly population under study was 51.5%(11). Another study which was done in Africa by Bhagavanthula et al 2021 in Ethiopia indicated that proportional of PIMs was 47.2%(28). A Systematic Review and Meta-Analysis which was conducted by Fangyuan Tian et al. and published in JAMA Network Open in 2023, which included about 273.1 million elderly patients aged 65 years and above found an overall prevalence in African countries of Potentially Inappropriate Medications of was 47.0%; 95% CI(9). All these findings in the previous researches are almost similar to our findings in the MNH-ED over the period of six months from January to June 2024 these similarities could be attributed due to several factors such as; common risk factors which elderly patient often present with such as multiple comorbidities, polypharmacy and complex medical histories. However clinical guidelines and protocol similarities and population characteristics could be among the factors that bring this similarity with other previous studies.

The age distributions among the elderly patients who participated in this study showed majority of patients aged around 65-70 years and more than 75 years which was 37.9%. Previous studies have indicated that the risk of PIMs increases with due to age-related physiological changes in drug metabolism and increase in comorbidity burden in this population. Male elderly participants were more than half 59.5% compared to the female gender. In Contrast to previous studies which showed the most affected group were the

females(29). Women are more likely to be prescribed PIMs, due to a higher prevalence of conditions like osteoporosis and chronic pain(30). The large number of the male patient in this study which is contrary to other previous studies which showed the female being the most affected group could be due to the increased health seeking behavior in male patient at the MNH-ED, high prevalence of certain health conditions such as hypertension and chronic kidney diseases that affect the male gander mostly(31).

In contrast to other previous studies, age, gender did not have significant to predict PIMs(32). The differences in this study results compared to previous studies could be explained due to the difference in sample size, population type, availability of electronic medication records and sitting of these studies.

STOPP criteria suggests avoiding long-term use of NSAIDs and PPIs due to the increases risks of gastrointestinal bleeding, renal impairment and osteoporosis respectively(33).

The clinical characteristics of the study participants highlighted several important aspects of their health status and the complexity of managing their medical conditions. In this study we identified most of the patient had more than one diagnosis this accounted for about 40.3%. this suggests that more of the elderly participants were having multi-morbidities making it difficult to managed elderly patients when it comes to pharmaceutical management. Multi-morbidities predispose this population to polypharmacy due to multiple diseases, improper combination of drugs may result into drug-drug interaction, drug-disease interaction or adverse drug events(34). In this research also we found that most of these patient had specific comorbidities such as hypertension which was in large number followed by the diabetes mellitus as it is seen in the most of the previous researches. One of the researches which was conducted in Malaysia by esra'a samara in 2023 showed that the prolong use of long acting sulfonylurea and peripheral alpha-blockers in patients with diabetes and hypertension predisposes the elderly patients to osteoporosis in women and hypostatic hypotension according to Beers' criteria(35).

In this study we also found that the most pattern of PIMs were analgesic and gastrointestinal medication. At the MNH-ED, most elderly patients received NSAIDs category for pain

management. Non-steroidal anti-inflammatory drugs were prescribed to elderly patients without knowing whether they had severe hypertension, gastrointestinal problems such as peptic ulcer disease or renal impairments(15)(36). According to the STOPP and START criteria version 3 prescription to elderly patients predisposes this population to renal problems as they are nephrotoxic, cardiovascular adverse events such as heart failure and increased blood pressure and gastrointestinal bleeding problems when they are prolonged used. This was seen in other previous studies, a study which was done in China 2021 by Fangyuan Tian et al showed that the prolong use of NSAIDs gastrointestinal complications, cardiovascular diseases such as hypertension and heart failure due to fluid retention and renal complication(9). PPIs use in elderly patient who presented with gastrointestinal drugs was seen in 11.5% of patients with gastrointestinal problems though in the system it was not seen if they were prescribed for more than eight weeks due to the ED setting, the PPIs were only prescribed as a single dose during the management at ED. according to the STOPP and START criteria prolong use of PPIs for more than eight weeks(32)(37).

The use of antibiotic is geriatric patient in the additional of developing multidrug resistance, antibiotics are also associated with ADRs. In our study it was found that the large number of elderly patient were prescribed with at least one antibiotic drug at the ED with no rationale. This can lead to ADRs such as hypersensitivity, drug-disease interaction or drug-drug interaction. Previous studies have shown that potentially inappropriate prescription of antibiotics is also associated with gastrointestinal symptoms, renal and cardiac antibiotic-related side effects(38).

Factors associated with potentially inappropriate medication at MNH-ED.

A number of risk factors have been identified and reported in literature for PIMs, such risk factors include as age-related physiologic changes, polypharmacy, increase in age or female sex or Direct association between PIMs and specific diseases—such as hypertension, gastrointestinal diseases, diabetes mellitus and chronic kidney disease(39).

Our study findings showed that age, sex, facility utilization, number of visits at ED whether new visit or multiple previous visit didn’t have statistical significant association with PIMs

which is contrary to other previous researches which shows a significant association of PIMs with increase in age, female gander and multiple ED visits(34). Age was found to be a risk factor in some studies, while others did not find this association.

Multiple complaints of more than two clinical complaints and multi-morbidity with predisposes them to polypharmacy showed a significant association with PIMs among elderly patients who were attended at the Emergency departments of Muhimbili National Hospital(40).

In our study we found that night shifts were associated with PIMs to elderly patients which may align to broader concerns about the impact of environmental and staffing factors on medication patterns especially during the night shifts. Research has shown that night shift characterized by increased workloads, reduced staffing and cognitive fatigue are associated with higher rates of medication errors and PIMs.

Regarding the association between PIMs and physician type we found that specialists and registrars were associated with PIMs prescribing. This may be due to managing the complex cases that cause them to deviate from guidelines due to clinical judgement. This is consistent with findings that senior physicians might feel confident in their decision to give medications which can sometimes result into PIMs. However, residents and interns' doctors may adhere to guidelines and protocols due to supervision, which could explain lower PIM rates among them.

Methods such as following prescribing protocols and guidelines, medication review and reconciliation are a good way to improve prescribing appropriateness(41)(42). Medication review can be done by applying implicit or explicit criteria, which have proven to be a good interventional solution to reduce PIP. In practice, most often it is recommended to use explicit criteria, although sometimes it is difficult due to the long list of criteria and medicine recommended for review. The application of STOPP-3 criteria is a useful tool for PIM reduction, compared to usual pharmaceutical care. Clinical pharmacists' intervention to perform medication reconciliation and apply medication review criteria is a good way to reduce PIM prescribing.

5.2 STRENGTHS

This was the first retrospective study which was conducted at MNH-EDs effectively utilized the STOPP and START criteria, which are validated tools for assessing medication appropriateness in elderly patients.

Furthermore, the study highlights significant associated factors such as polypharmacy, multiple comorbidities, and multiple clinical complaint, which are critical for understanding and addressing PIMs in this vulnerable population.

5.3 LIMITATIONS:

The was a lot of missing medical record data on types of medications and specific type of chronic diseases the patients had from the Wellsoft Software which led to the exclusion of many elderly patients.

It was a single centered setting which involved the Muhimbili National Hospital emergency departments of Upanga and Mloganzila campus, making it difficult to nationalize the problem of potentially inappropriate medication.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study revealed a high prevalence of PIM among elderly patients presenting at MNH emergency department, with antibiotics, analgesic, and gastrointestinal drugs, being the most common PIM. Several factors such as multiple morbidities, number of clinical complaints, type of the attending doctor, night shifts, were among the risks factors for PIMs that were identified. The findings underscore the critical need for improved prescribing practices, particularly in patient's polypharmacy, multi-morbidity, and multiple clinical complaints.

6.2 Recommendations:

Given the high prevalence of PIMs identified in this study, it is recommended that target intervention be implemented to improve prescribing practices for elderly patients at MNH-ED. This can be intervened by; regular training and awareness on the applications of validated tools such as STOPP/START criteria and Beers criteria, strengthening on electronic prescription system that are incorporated with these validated tool so as to alert on PIMs, and patient and caregivers education about the risks associated with PIMs and importance of adherence to prescribed medications, also having the clinical pharmacist at the ED would be of great help in reducing PIM, because the clinical pharmacist will be able to implement medication safety to elderly patients by comprehensive medications reviews and by collaborating with other healthcare providers to elderly patient care and safety.

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8.0APPENDICES

8.1 Appendix I: Consent form

STUDY TITLE; PATTERN AND FACTORS ASSOCIATED WITH POTENTIALLY INAPPROPRIATE MEDICATIONS AMONG ELDERLY PATIENTS ATTENDING TO MUHIMBILI NATIONAL HOSPITAL EMERGENCY DEPARTMENT

My name is **Dr. Patrick Venance Lumato,** resident doctor in the emergency department at Muhimbili National Hospital. I am currently conducting a study titled as above as part of my studies requirements. I hereby request an affirmation to access electronic health system patient health records to complete my questionnaire for a retrospective cross sectional study I am conducting at your facility.

The purpose of the study: To determine the pattern and factors associated with potentially inappropriate prescription among elderly patients attending to Muhimbili National Hospital Emergency Department

Benefit of the study; this study will be beneficial to all elderly patients who attend health care facilities

Risk: No risks to patients expected to be posed as the study is going to be done retrospectively.

Confidentiality: all information collected in this study will be confidential, so any data accessed and collected will not be known to anyone other than the study team. Redcap case report form will be used with password to ensure strong confidentiality.

Payment: No payments will be considered to any participant in this study

If you have any question or problem, you can contact the following

PRINCIPAL RESEARCHER,

Dr. Patrick Venance Lumato

Muhimbili National Hospital

Department of emergency Medicine

Phone number: +255753559800

Email: pven671@gmail.com

Dr. Nahya salim Masoud

Chairman of Research and Publications Committee,

Muhimbili University of Health and Allied Sciences

P.O.Box 65001

Dar Es Salaam

Telephone +255-22-2152489

8.2 Appendix II: Data Collection Tool

DEMOGRAPHIC INFORMATION:

MR Number: …….

Age; 60-65, 66-70, 71-75, >76

SEX: M or F

CO-MORBIDITIES:

Hypertension, Diabetes, CKD or ESRD, Chronic Liver Disease, Malignancy , HIV, COPD, Depression, Stroke, Others mention…….. tick one

REFERRAL; Referred Yes or No

INSURED; Yes or No

TYPE OF SHIFT; Day or Night

ATTENDING DOCTOR; Specialist, Resident, Registrar, Intern Doctor

NUMBER OF COMPLAINS; 1, 2-3, >4

NUMBER OF DIAGNOSIS; 1, 2-4, >5

TYPE OF DIAGNOSIS;

Cardiovascular, Respiratory, Nervous system,
Gastrointestinal system, Musculoskeletal system, Urological system,
Endocrine system, ENT, Dental, Eye, Trauma, Mixed diagnosis

TYPES OF MEDICATIONS PRESCRIBED AT ED BY STOPP/START CRITERIA; tick required only

- **Cardiovascular;** Digoxin>125mcg, beta blocker, calcium channel blocker or mixed medication calcium and beta blocker
- **Respiratory;** Steroids in COPD systemic use
- **Nervous system and psychotropic drugs**; Tricyclics(amitriptyline), benzodiazepines (diazepam, midazolam)

- **Gastrointestinal system,** Proton pump inhibitors, anticholinergic-antispasmodic (hyoscine)
- **Musculoskeletal system**; NSAIDS in history of PUD or UGIB
- **Urogenital system;** bladder anti-muscarinic(Ditropan/oxybutynin) in dementia
- **Endocrine system**; insulin sliding scale, glibenclamide,
- **Analgesics;** strong opioid in mild pain, ASA in >70years, NSAIDS
- **Duplicate drugs; 2** Opioids, 2 NSAIDS, 2 SSRI(fluoxetine)
- **Drugs that affect adversely fallers;** Benzodiazepine (diazepam, midazolam), antipsychotic (olanzapine, haloperidol?
- **Antibiotics;** Ceftriaxone, Metronidazole, ciprofloxacin
- **None**

Total number of medications prescription; <4, 5-9, ≥10

DISPOSITION TYPE

- Discharged home
- Admitted to ICU
- Admitted to normal ward
- Admitted to ED theatre
- Died in ED

8.3 Appendex III – Ethical Clearance

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATIONS

Ref. No.DA.282/298/01.C/2366 Date: 10/07/2024

MUHAS-REC-07-2024-2366
PATRICK VENANCE LUMATO
COLLEGE OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: TITLE: PATTERN AND FACTORS ASSOCIATED WITH POTENTIALLY INAPPROPRIATE MEDICATIONS AMONG ELDERLY PATIENTS PRESENTING TO MUHIMBILI NATIONAL HOSPITAL-EMERGENCY DEPARTMENT

Reference is made to the above heading.

I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 10/07/2024
EXPIRATION DATE OF APPROVAL: 10/07/2025

STUDY DESCRIPTION:
Purpose:
This will be a retrospective cross sectional study including older patients over 65 years of age presented to ED of MNH of Upanga and Mloganzila from march 2024 to May 2024. Broad Objective: To determine the pattern and factors associated with PIMs among older patient presenting at Muhimbili National Hospital's Emergency Department.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2015708.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.



Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee

8.4 Appendex IV – Permission letter –MNH

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote:

Ref. No.: MNH/TRCU/PERM/2024/445 Date: 10th July, 2024

Head of Department

Emergency Medicine

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name of student	Patrick Venance Lumato
Title	"Pattern and Factors Associated with Potentially Inappropriate Medications Among Elderly Patients Presenting to Muhimbili National Hospital – Emergency Department".
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Said Kilindimo (MUHAS)
Co – supervisor	Dr. Alphonce Simbila (MNH)
Period	10th July, 2024 to 30th September, 2024

Approval has been granted to the above principal investigators to collect data at MNH. Data dissemination at MNH will be overseen by Dr. Alphonce Simbila as MNH Co – supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Sincerely,

Dr. Charles K. Pallangyo

For: Head of Clinical research, Training and Consultancy Unit

C.c DMS

C.c Dr. Alphonce Simbila

C.c **Patrick Venance Lumato**

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