ASSESSING AWARENESS, ATTITUDE, AND PRACTICES TOWARDS SPONTANEOUS REPORTING OF ADVERSE DRUG EVENTS TOGETHER WITH ITS PERCEIVED BARRIERS AMONG CLIENTS ATTENDING COMMUNITY PHARMACIES IN DAR ES SALAAM

Joram Adam, B.Pharm

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Department of Clinical Pharmacy and Pharmacology

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By

Joram Adam

A Dissertation Submitted in (Partial) Fulfillment of Requirement for the Degree of Master of Pharmacovigilance and Pharmacoepidemiology of

Muhimbili University of Health and Allied Sciences
October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences dissertation entitled; **‘‘Assessing awareness, attitude, and practices towards spontaneous reporting of Adverse Drug Events together with its perceived barriers among clients attending community pharmacies in Dar es Salaam”,** in (partial) fulfilment of the requirements for the Degree of Master of Pharmacovigilance and Pharmacoepidemiology of Muhimbili University of Health and Allied Sciences.

_____

Dr. Ritah Mutagonda

(Supervisor)

_____

Date

_____

Dr. Alphonce I. Marealle

(Co-Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Joram Adam,** declare that this **dissertation** is my 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

This dissertation is dedicated to my loving family, whose unwavering support, patience, and encouragement have been the foundation of my academic journey. To my parents, whose sacrifices and love have always been my guiding light, and to my siblings, for their constant motivation and belief in my abilities, I am deeply grateful.

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ABSTRACT

Background: Adverse drug events (ADEs) represent a pressing public health concern, necessitating vigilant surveillance for timely identification and prevention. Spontaneous reporting, a vital aspect of ADEs monitoring, remains insufficiently explored, particularly among patients attended at the community pharmacies. ADEs reporting within community pharmacies is crucial in improving medication safety and patient care.

Aim: The primary objective is to assess the levels of awareness, attitude, and practice concerning the spontaneous reporting of ADEs among patients attending community pharmacies in Dar es Salaam.

Methodology: A cross-sectional survey was conducted among community pharmacy patients to assess their awareness, attitudes, and practices regarding spontaneous ADE reporting. Structured questionnaires were used to gather data on ADE awareness, pharmacovigilance, experiences with adverse drug events, and reporting behaviors. Perceived barriers to reporting were also identified. Descriptive statistics were applied to analyze the data, highlighting key trends and gaps.

Results: The study found that 49% of participants were aware of adverse drug events (ADEs), primarily through social media, while only 12% had heard of pharmacovigilance. Among the patients, 19% had experienced an Adverse Drug Event (ADR), with 71% of these cases being reported, mainly to pharmacists. A significant majority (96%) acknowledged the importance of ADE reporting, reflecting a positive attitude. Common barriers to reporting included a lack of knowledge on ADE recognition and reporting procedures.

Conclusion: This study reveals significant gaps in awareness and practices regarding ADE reporting among community pharmacy patients. Major barriers include a lack of awareness and insufficient knowledge about reporting procedures. Despite positive attitudes towards ADE reporting, practical barriers such as reporting complexity and confidentiality concerns hinder participation. Enhancing patient education, simplifying reporting processes, and ensuring confidentiality are crucial to improve ADE reporting practices and patient safety.

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LIST OF ACRONYMS

ADEs	Adverse Drug Events
ADR	Adverse Drug Reaction
PV	Pharmacovigilance
IRB	Institutional Review Board
SAE	Severe Adverse drug Events
TMDA	Tanzania Medicines & Medical Devices Authority
WHO	World Health Organization

DEFINITION OF TERMS

Adverse Drug Events (ADEs)

An adverse event is any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment (1)

Adverse Drug Reaction (ADR)

Adverse Drug Reaction (ADR): A response to a drug that is noxious and unintended and that occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function (1).

Community Pharmacies

A community pharmacy, also known as a retail or neighborhood pharmacy, is a healthcare facility that provides a range of pharmaceutical services to the local community. These services are primarily related to the dispensing of prescription and over-the-counter medications (2).

Pharmacovigilance

According to WHO PV is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems (1).

Spontaneous reporting

The World Health Organization (WHO) defines spontaneous reporting as the voluntary and unsolicited reporting of suspected adverse drug reactions (ADRs) or any other drug-related problems by healthcare professionals, patients, or consumers (1).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Adverse drug events (ADEs) pose a considerable threat to global patient safety, contributing significantly to morbidity and mortality associated with healthcare (3). These events encompass a wide range of unintended and harmful effects arising from medication use, spanning side effects, allergic reactions, and medication errors (1). Within community pharmacies, where patients routinely access medications and healthcare services, the spontaneous reporting of ADEs emerges as a critical aspect of pharmacovigilance. The awareness, attitudes, and practices of community pharmacy patients concerning ADE reporting play a pivotal role in optimizing medication safety and healthcare outcomes.

Pharmacovigilance, focusing on the detection, assessment, understanding, and prevention of adverse effects or drug-related issues, necessitates the active involvement of patients in reporting their experiences (4). While healthcare professionals, particularly pharmacists, play a central role in monitoring and reporting ADEs, the engagement of patients is indispensable for providing a comprehensive understanding of medication impacts in real-world scenarios (4,5). Within community pharmacies and hospitals, patients often serve as the primary identifiers of ADEs, underscoring the significance of their awareness, attitudes, and practices in spontaneous reporting for effective pharmacovigilance (6,7).

Despite the acknowledged importance of patient involvement, a notable gap exists in the literature concerning the quantitative assessment of community pharmacy patients' perspectives on ADE reporting. Existing studies often concentrate on healthcare professionals or adopt broader public health approaches, leaving a critical knowledge void specific to the dynamics within the community pharmacy setting (8).

The primary aim of this research is to assess the levels of awareness, attitudes, and practices among patients attending community pharmacies regarding the spontaneous reporting of ADEs. By delving into these key dimensions, the study aims to provide valuable insights that can

inform targeted interventions, enhance pharmacovigilance efforts, and contribute to improved medication safety within community pharmacies.

1.2 Problem Statement

The occurrence of ADEs poses a significant threat to patient well-being, and the effectiveness of pharmacovigilance relies on the active participation of patients in reporting such events (9). However, within the community pharmacy context, there is a lack of quantitative understanding regarding patient awareness, attitudes, and practices related to spontaneous ADE reporting because no study has been conducted concerning community patients and ADE reporting in Tanzania. The specific gaps in knowledge regarding ADEs, the willingness of patients to report incidents, and the actual reporting behaviors remain insufficiently explored. This knowledge vacuum impedes the development of targeted initiatives to improve pharmacovigilance in community pharmacies. Thus, there is a pressing need for a comprehensive quantitative investigation to elucidate patient perspectives on ADE reporting, offering essential insights for the development of patient-centric pharmacovigilance strategies.

1.3 Conceptual Framework

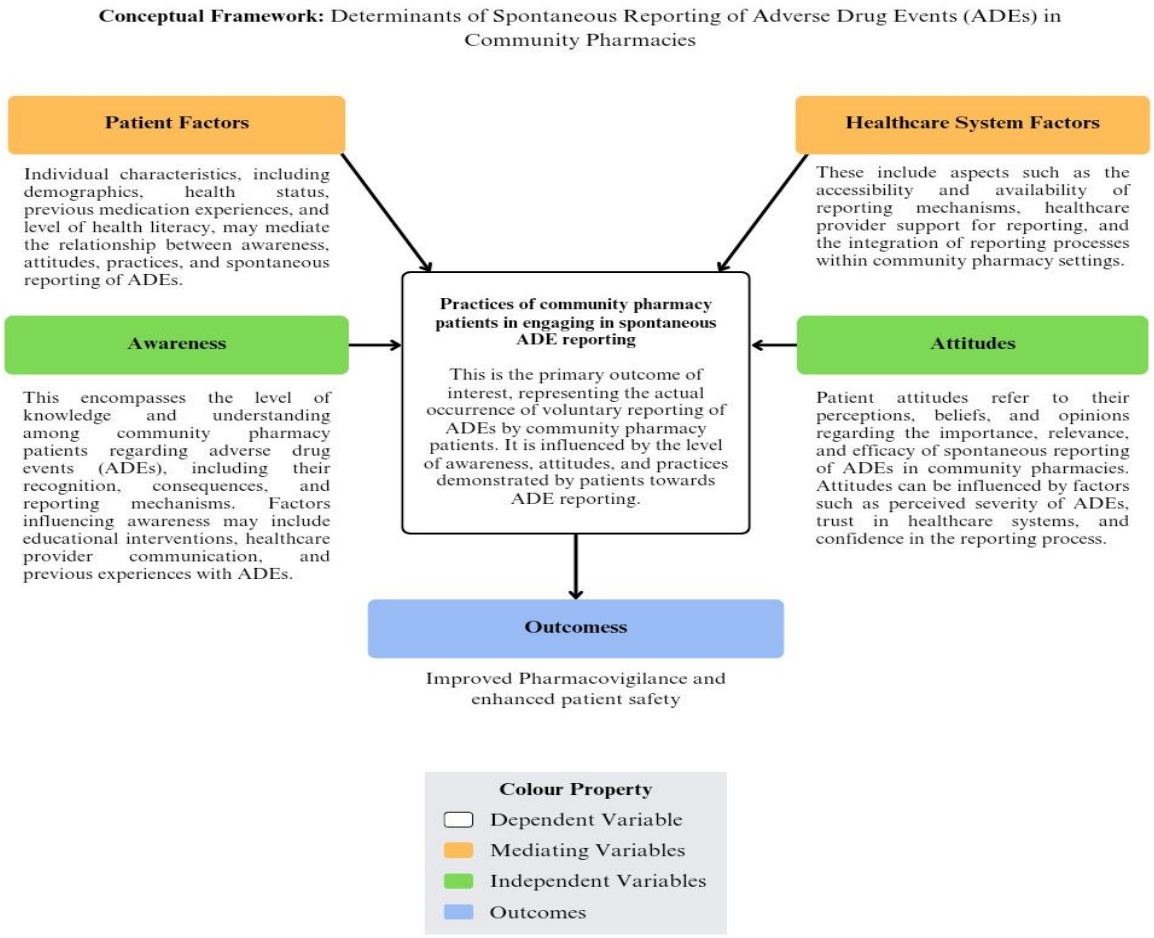


Figure 1: Conceptual framework

In this framework above, the dependent variable is the "Practices of community pharmacy patients in engaging in spontaneous ADE reporting." The independent variables encompass awareness of ADE reporting and attitudes toward its significance, which directly influence reporting practices. Additionally, other independent variables, such as demographic factors (age, gender, marital status, education, and occupation), frequency of pharmacy visits, and presence of chronic health conditions, serve as mediating variables. These mediating variables play a role in shaping awareness, attitudes, and ultimately, reporting practices among community pharmacy patients.

1.4 Rationale of the study

This study on patient awareness, attitudes, and practices regarding the spontaneous reporting of ADEs in community pharmacies is essential for advancing patient-centered pharmacovigilance. By addressing a significant gap in quantitative knowledge about ADE understanding and reporting practices, the research aims to contribute insights that enhance medication safety. The findings have the potential to inform public health policies and optimize services in community pharmacies, fostering collaboration between patients and pharmacists. Understanding patient attitudes towards ADE reporting is crucial for building trust in the pharmacovigilance system, aligning with the broader goal of improving healthcare quality and safety.

1.5 Study questions

1.5.1 Broad research question

What are the awareness, attitudes, practices, and perceived barriers towards the spontaneous reporting of adverse drug events (ADEs) among clients attending community pharmacies in Dar es Salaam?

1.5.2 Specific research Questions

1. What is the extent of awareness among community pharmacy patients regarding the spontaneous reporting of ADEs?
2. What are the attitudes of community pharmacy patients towards spontaneously reporting ADEs?
3. What are the practices among community pharmacy patients concerning the spontaneous reporting of ADEs?
4. What are the perceived barriers to reporting ADEs among patients attending community pharmacies?

1.6 Objectives

1.6.1 Broad objective

To assess the awareness, attitudes, practices, and perceived barriers towards the spontaneous reporting of adverse drug events (ADEs) among clients attending community pharmacies in Dar es Salaam.

1.6.2 Specific objectives

1. To assess patient awareness towards spontaneous reporting of ADEs among community pharmacy patients.
2. To assess patient attitudes towards spontaneous reporting of ADEs among community pharmacy patients.
3. To assess the practices of community pharmacy patients regarding spontaneous reporting of ADEs.
4. To identify perceived Barriers to ADE Reporting among patients attended at the community pharmacy.

CHAPTER TWO

2.0 LITERATURE REVIEW

ADEs continue to be a significant concern, with attention not yet fully directed towards the role of community pharmacy patients in the spontaneous reporting of ADEs. This observation is particularly noteworthy in the context of the country, where a substantial number of individuals access medication services through community pharmacies. This literature review aims to investigate the existing knowledge regarding the awareness, attitudes, and practices of community pharmacy patients concerning the spontaneous reporting of ADEs.

2.1 Awareness among Community Pharmacy Patients

Understanding the awareness levels of community pharmacy patients is foundational to effective ADE reporting. Previous studies involved patients from hospital setting have highlighted the variable levels of awareness among patients, with some being well-informed about ADE reporting processes while others remain largely unaware (6,10). The importance of patient education programs within community pharmacies is evident in enhancing awareness. Educational interventions have shown promising results in improving patient knowledge and understanding of ADE reporting mechanisms, emphasizing the need for targeted initiatives to address this crucial aspect (11,12).

2.2 Patient Attitudes towards Spontaneous Reporting

Patient attitudes towards ADE reporting within community pharmacies are shaped by various factors, including perceived importance, trust in the healthcare system, and individual beliefs. Positive attitudes are associated with a sense of responsibility and a belief in the impact of reporting on overall medication safety (12). Conversely, barriers such as fear of consequences, lack of perceived severity, and uncertainty about reporting procedures contribute to negative attitudes (13). Identifying these key factors is essential for tailoring interventions to improve patient attitudes towards spontaneous ADE reporting.

2.3 Practices of Spontaneous Reporting

The frequency and practices of community pharmacy patients engaging in spontaneous ADE reporting are multifaceted. While studies indicate an underreporting trend, they also highlight the potential for improvement through targeted interventions (14,15). Patient-friendly reporting tools, simplified procedures, and increased accessibility have been proposed as effective approaches to enhance patient engagement (15). Identifying barriers to reporting, such as time constraints and lack of awareness, is crucial for implementing strategies that address these challenges and promote effective reporting practices (14,17).

In summary, gaining a thorough comprehension of the awareness, attitudes, and practices of community pharmacy patients concerning spontaneous reporting of ADEs is crucial for advancing pharmacovigilance. Implementing focused interventions that address these dimensions has the potential to substantially enhance overall medication safety within community pharmacies. The literature reviewed offers valuable insights that not only guide the current study but also lay the foundation for future research endeavors.

2.4 Perceived barriers to ADEs reporting

The spontaneous reporting of adverse drug events (ADEs) is essential for drug safety, but numerous barriers hinder effective reporting. According to previous studies a key barrier is the lack of awareness among patients about pharmacovigilance systems. Many rely solely on healthcare professionals to report ADEs, unaware that they can also participate. In regions like Sub-Saharan Africa, where pharmacovigilance systems are still developing, this gap is more pronounced (17,18)

Another significant barrier is the perceived complexity and time-consuming nature of the reporting process. Healthcare professionals often find the forms cumbersome, especially in busy community pharmacies where time constraints are common (19).

CHAPTER TWO

3.0 METHODOLOGY

3.1 Study design

This study employed a cross-sectional design which was purely descriptive, conducted from February to June 2024, to efficiently gather data on community pharmacy patients' awareness, attitudes, and practices concerning the spontaneous reporting of ADEs. This methodological approach allows for a snapshot assessment, enabling comparative analysis across diverse patient subgroups. Despite limitations like the inability to establish causality, it effectively meets our objectives by providing insights into the current state of ADEs reporting in community pharmacies and factors associated.

3.2 Study area

The study conducted in community pharmacies located within the districts of Temeke, Ilala, and Kinondoni in Dar es Salaam, Tanzania. These 3 districts were selected among 5 districts of Dar Es Salaam due to their high population density and significant representation of community pharmacies. In Dar es Salaam, there are a total of approximately 1236 community pharmacies, with Temeke having around 200, Ilala around 400, and Kinondoni around 450 pharmacies.

3.3 Study population

The study focused on adult clients (aged 18 and above) who visited community pharmacies during the study period. The inclusion criteria encompassed individuals who have a history of purchasing prescriptions or over-the-counter medications from community pharmacies within the specified geographic area.

3.3.1 Inclusion criteria

1. Adults aged 18 and above.
2. Clients who exit from the community pharmacy.
3. Clients who are willing to provide informed consent for participation in the study

3.3.2 Exclusion criteria

1. Individuals with cognitive impairments which may hinder their ability to provide accurate information during the exit interview.

3.4 Sample size calculation

The below formula for estimating sample size in a population proportion was used:

$n = (z)^2 p (1 – p) / d^2$

Where:

n is the required sample size.

Z is the Z-score corresponding to the chosen confidence level (1.96 for a 95% confidence level).

p is the estimated proportion of the population with the characteristic of interest.

d is the desired margin of error.

Assuming a margin of error (d) of 5% (0.05), and the estimated proportion of patients who spontaneously report adverse drug events (p) is around 0.50 (50%).

$n = (1.96)^2 0.50 (1 – 0.50) / (0.05)^2$

n=384.16

Rounding up to the nearest whole number, estimated sample size would be approximately 385 participants. To account for potential non-response, an additional 15% was added to the estimated sample size. Therefore, the final sample size was approximately 443 participants.

3.5 Sampling Techniques

In this study, a systematic sampling technique ensured a representative sample of 443 community pharmacy clients across Temeke, Ilala, and Kinondoni districts. Initially, pharmacies were randomly selected from each district, with a sampling interval established to include every 'k-th' patient. This method addressed challenges posed by large customer populations and guaranteed representative findings.

The study aimed at enrolling 10clients per pharmacy, requiring approximately 43 pharmacies. Proportional allocation across districts resulted in 16 pharmacies from Ilala, 19 from Kinondoni,

and 8 from Temeke. Patients were recruited directly around the pharmacy premises, with trained research assistants explaining the study's purpose, ensuring confidentiality, and offering assistance if needed to optimize response rates and data quality.

3.6 Data collection

Data was collected using an adapted and modified structured questionnaire (**refer to Appendix II**), from previous studies (6,10). Trained personnel administered the questionnaires directly by interviewing community pharmacy patients to assess their awareness, attitudes, and practices regarding the spontaneous reporting of ADEs. This approach ensured standardized and accurate data collection.

3.7 Pre-Test of tool

Before the main study, a pre-test of the structured questionnaire was conducted at selected community pharmacies not included in the study sample. Approximately 20 clients participated in the pre-test. Participants completed the questionnaire, and observations were made to identify any difficulties or confusion in understanding the questions. A debriefing session was then conducted to gather qualitative feedback from the participants, focusing on the clarity and effectiveness of the questionnaire. Based on this feedback, the questionnaire was iteratively refined to ensure it captured the required information effectively. This pre-testing process aimed to enhance the quality of the data collection tool, contributing to the reliability and validity of the main study.

3.8 Study Variables

3.8.1 Dependent Variables

i. Practices of community pharmacy clients in engaging in spontaneous ADEs reporting.

3.8.2 Independent Variables

i. Demographic variables: Age, gender, marital status, educational level, occupation.
ii. Frequency of pharmacy visits.

iii. Presence of chronic health conditions requiring regular medication.
iv. Awareness of ADEs reporting.
v. Attitudes towards spontaneous ADE reporting.

3.9 Data Management and Analysis

3.9.1 Data Management

Effective data management was crucial for our study on ADEs reporting among community pharmacy clients. A structured questionnaire ensured standardized input and minimized errors. Data were securely stored with multiple backups, and personal identifiers were replaced with codes for anonymity. Quality control measures, such as regular checks and manual cleaning, enhanced reliability. Security measures, including restricted access and encryption, safeguarded data. A comprehensive data management plan guided the process, with access strictly controlled. Post-study, the physical dataset was securely archived to ensure integrity and confidentiality.

3.9.2 Data analysis

The data analysis involved several steps to assess community pharmacyclient's' awareness, attitudes and practices regarding spontaneously reporting adverse drug events (ADEs). Initially, raw data from the administered questionnaires were cleaned and checked for completeness. Descriptive statistics, including frequencies and percentages, were calculated to summarize responses. Results were compared with similar studies to contextualize findings within existing research on ADE reporting and pharmacovigilance. This comprehensive analysis provided insights into the factors influencing ADE reporting and informed recommendations for improving patient engagement in pharmacovigilance activities.

3.10 Ethical Clearance

This research adhered to strict ethical principles and guidelines to ensure the well-being, rights, and confidentiality of all participants. Ethical clearance was sought from the MUHAS Institutional Review Board (IRB) or Ethics Committee under the clearance number MUHAS-

REC-04-2024-2140. We upheld the highest ethical standards throughout the study and did not commence data collection until the necessary ethical clearance was obtained. Informed consent was obtained from all participants before their involvement, and they were made aware of their right to withdraw at any time without consequence. Confidentiality and data privacy were rigorously maintained throughout the research process.

CHAPTER FOUR

4.0 RESULTS

Demographics and Background Information

The study included 437 participants, with baseline information summarized in Table 1. Among the participants, 276 (63 %) were female, and the majority 344 (79%) were aged between 18 and 40 years. Regarding marital status, 46% (199) were single, 205 (47%) married, 25 (6%) divorced, and 08 (2%) widowed. Educational levels varied, with the largest group 157 (36%) having completed university or college. In terms of occupation, 45% (197) were self-employed, while 84 (19 %) were civil servants. The majority of participants, 215 (49%) reported visiting the pharmacy regularly, and 353 (81%) did not have chronic health conditions.

Table 1: Baseline Information (n=437)

Variables	Response	Frequency (%)
Gender	Male	161 (37)
	Female	276 (63)
Age	18-40	344 (79)
	41-60	70 (16)
	>60	23 (05)
Marital Status	Single	199 (46)
	Married	205 (47)
	Divorced	25 (06)
	Widowed	08 (02)
Educational Level	Informal education	11 (03)
	Primary	79 (18)
	O-Level Secondary School	119 (27)
	A-Level Secondary School	71 (16)
	University/College	157 (36)
Occupation	Self-Employed	197 (45)
	Unemployed	56 (13)
	Civil servant	84 (19)
	Employed at Private sector	32 (07)
	Retired	18 (04)
	Student	50 (11)
Frequency of Pharmacy Visits	Regulary	215 (49)
	Often	67 (15)
	Occasionaly	122 (28)
	Very rarely	33 (08)
Chronic Health Conditions	Yes	66 (15)
	No	353 (81)
	I prefer not to answer	18 (04)

Clients' Awareness of Pharmacovigilance and Adverse Drug Reactions

As detailed in Table 2, awareness of pharmacovigilance was low, with only 12% having heard of it. However, nearly half (49%) of the participants were aware of ADRs. Social media was the primary source of awareness for 53% of respondents, followed by healthcare providers (16%). Understanding of ADRs varied, with 50% recognizing it as an unexpected reaction after taking a medication. Regarding the understanding of Serious Adverse Event (SAE), 40% identified it as a life-threatening reaction.

Table 2: Clients' awareness of pharmacovigilance and adverse drug reactions (n = 437)

Variables	Response	Frequency (%)
Heard of pharmacovigilance	Yes	53 (12%)
	No	384 (88%)
Heard about ADEs	Yes	216 (49%)
	No	221 (51%)
Source of Awareness	Social media	115 (53%)
	Television	35 (16%)
	Radio	2 (1%)
	Training	2 (1%)
	Health care provider	34 (16%)
	Relative/ Friend	16 (7%)
	Newspaper	1 (0%)
	Street	2 (1%)
	University/college	2 (1%)
	I dont know	7 (3%)
Understanding of ADE	Any effect from a medication one is taking	98 (45%)
	Unexpected reaction after taking a medication	108 (50%)
	Expected reaction after taking medication	10 (5%)
Understanding of SADR	Reaction that requires medical emergency and can cause death	77 (36%)
	Reaction that is uncomfortable but does not stop you from daily activities	15 (7%)
	Reaction that is life-threatening	86 (40%)
	Reaction that is bad enough to interfere with daily activities	16 (7%)
	Reaction that results in hospitalization or prolongs hospitalization	7 (3%)
	I don't know	15 (7%)
Ever heard of Suspected ADR reporting form	Yes	80 (37%)
	No	136 (63%)

Clients' Practices About Adverse Drug Reactions and Reporting

Table 3 highlights clients' practices towards ADRs. Out of 395 patients, 19% had experienced an ADEs, with 71% (30) reporting it, primarily to pharmacists (73%) (22). Common actions taken in response to ADEs included stopping the drug (59%) and using another drug to treat symptoms (17%). Among those who did not report ADEs, reasons included a lack of knowledge on how to report (15%) and the perception that reporting was unnecessary if the reaction resolved on its own (23%). The preferred reporting method was directly to a healthcare professional 62%, (113), and the preferred place was the community pharmacy 60%, (124).

Table 3: Patients' practices /experience about adverse drug reactions and reporting

Variables	Response	Frequency (%)
Experienced ADE	Yes	42 (19%)
	No	174 (81%)
Reported ADE	Yes	30 (71%)
	No	12 (29%)
If yes, to whom do you make the report?	Pharmaceutical dispenser/ Pharmacist	22 (73%)
	Doctor	6 (20%)
	Nurse	2 (7%)
Action taken in the case of adverse effect/reaction	Did nothing because the reaction resolved on its own	2 (5%)
	I did nothing because the reaction was tolerable	5 (12%)
	Stopped the drug	25 (59%)
	Switched to another drug	2 (5%)
	Switched to herbal/traditional medicines	1 (2%)
	Used another drug to treat symptoms of reaction	7 (17%)

If no, why don't you make a report?	Adverse effect/reactions resolved on its own	1 (8%)
	Do not know how to report such reactions	2 (17%)
	Do not know the importance of reporting adverse drug reactions	3 (25%)
	Stopped taking the drug and reaction stopped, thus, no need to report	3 (25%)
	No reason	3 (25%)
Preferred reporting method	ADE reporting form	22 (12%)
	Reporting directly to healthcare professional	113 (62%)
	Short code SMS	19 (10%)
	Through a mobile app	62 (34%)
Preferred reporting place	TMDA	36 (17%)
	Hospital	56 (27%)
	Community Pharmacy	124 (60%)

Table 4 provides a summary of reported ADEs and suspected drugs. The most frequently reported ADE was itching (15 cases), commonly associated with antimalarial drugs like Malafin and Fansidar. Other reported reactions included blisters, rapid heart rate, and diarrhea, with various medications being implicated.

Table 4: Summary of reported adverse events, suspect drugs, and the therapeutic class among patients

Suspected Adverse Events	Frequency	Suspected Medications
Itching	15	Malafin (7), Fansidar (1), Ekelfin (2), Nor T (1), Sulphadar (2), SP tab (1), Pen V (2), Diclofenac (1)
Blisters	4	Sulphadar (1), Orodar (2), ALU (1)
Rapid heart rate	3	Amlodipine Besylate (1), Amlodipine tablets (1), Amlodipine 10mg (1)
Diarrhea	2	Azithromycin tablet (1)
Body inflammation	2	No specific medication
Abdominal discomfort	2	Duocortexin (1), Metronidazole tabs (1)
Headache	1	No specific medication
Rashes	1	No specific medication
Sulphur allergy	1	Ekelfin (1)
Fatigue	2	Athalin (2)
Severely ill	2	Ekelfin (2)
High blood pressure	1	Amlodipine (1)

Clients' Attitude About Adverse Drug Reactions and Reporting

Table 5 presents an overview of clients' attitudes towards reporting adverse drug event (ADEs). A significant majority, 207 (96%) of the respondents, acknowledged the importance of reporting ADEs, while only 6 (3%) did not see it as necessary, and 3 (1%) were uncertain among those who recognized the importance of reporting, the primary reasons included preventing a recurrence of the reaction in other people 100 (48%), making healthcare professionals aware of the drug's effects 80 (38%), ensuring the report reaches the manufacturer (9%, 19), and verifying the authenticity of the drug 8 (4%). A negligible percentage 1 (0%) indicated uncertainty about why reporting is important. For the small group who did not consider reporting necessary, the reasons varied. A significant portion perceived the effects as not serious 3 (37.5%), while others were unsure how to report (25%, 2) or believed the effects resolved on their own 2 (25%). Additionally, 1 (12.5%) were uncertain if the effect was related to the medication.

Table 5: Clients' attitude about adverse drug reactions and reporting

Variables	Response	Frequency (%)
Do you think it is important/necessary to make a report about adverse effects/reactions experienced after taking medicine(s)?	Yes	207 (96%)
	No	6 (3%)
	I don't know	3 (1%)
If yes, why reporting ADEs is Important	To prevent a recurrence of reaction in other people	100 (48%)
	To make healthcare professionals aware of what the drug has caused	80 (38%)
	To make sure the report get to the manufacturer of the drug	19 (9%)
	To make sure the drug is not fake	8 (4%)
	I don't know	1 (0%)
If no, why reporting ADEs is not Important	Not knowing how to report	2 (25%)
	Perceiving the effects as not very serious	2 (25%)
	The effects resolved on their own	3 (37.5%)
	Uncertainty if the effect is related to the medication	1 (12.5%)

Table 6 presents the clients' perceptions of pharmacists' counseling roles. A high percentage 398 (91%) of participants reported that pharmacists informed them about what their medication was used for, and 87% (378) felt that pharmacists ensured they understood the instructions. However, only 196 (46%) reported being educated about possible side effects, and 197 (47%) were informed about actions to take if they forgot to take their medication or overdosed. Overall, 385 (89%) believed that community pharmacies should play a more active role in promoting ADE awareness.

Table 6: Clients' perception of pharmacists' counseling role in adverse drug reaction reporting

Practice	Yes (%)	No (%)	I don't know (%)
Does the pharmacist tell you what your medication is used for?	398 (91%)	26 (6%)	13 (3%)
Does the pharmacist ensure you understand instructions?	378 (87%)	37 (9%)	22 (5%)
Were you asked about other drugs you are taking?	216 (50%)	210 (48%)	11 (3%)
Were you told of risks if you do not take your drugs regularly?	226 (52%)	194 (44%)	17 (4%)
Do pharmacists educate about possible side effects?	196 (46%)	226 (52%)	15 (3%)
Were you informed about what to do if symptoms do not resolve?	220 (49%)	193 (43%)	24 (5%)
Were you informed about other drugs/supplements to avoid?	198 (46%)	221 (51%)	18 (4%)
Do pharmacists talk about lifestyle changes to improve health?	296 (67%)	129 (29%)	12 (3%)
Does your pharmacist inform you about what to do if you forget to take your drug or overdose?	197 (47%)	214 (51%)	26 (6%)
Do you believe community pharmacies should play a more active role in promoting ADE awareness?	385 (89%)	28 (6%)	24 (6%)

Perceived Barriers to ADR Reporting

The analysis revealed several barriers to ADE reporting among community pharmacy clients. The most significant barrier was the lack of awareness about reporting procedures, affecting 174 respondents (58%). Insufficient knowledge of ADR/ADE recognition and reporting was noted by 55 respondents (18%), indicating a need for better education. Concerns about confidentiality

and anonymity were reported by 13 respondents (4%), and limited feedback or follow-up on reported events was a barrier for 14 respondents (5%). The complexity of the reporting process was a concern for 13 respondents (4%). A perception of low importance or impact of reporting was mentioned by 10 respondents (3%). Additionally, 15 respondents (5%) were unsure about the barriers, reflecting a general lack of awareness. The time-consuming nature of reporting was cited by 5 respondents (2%).

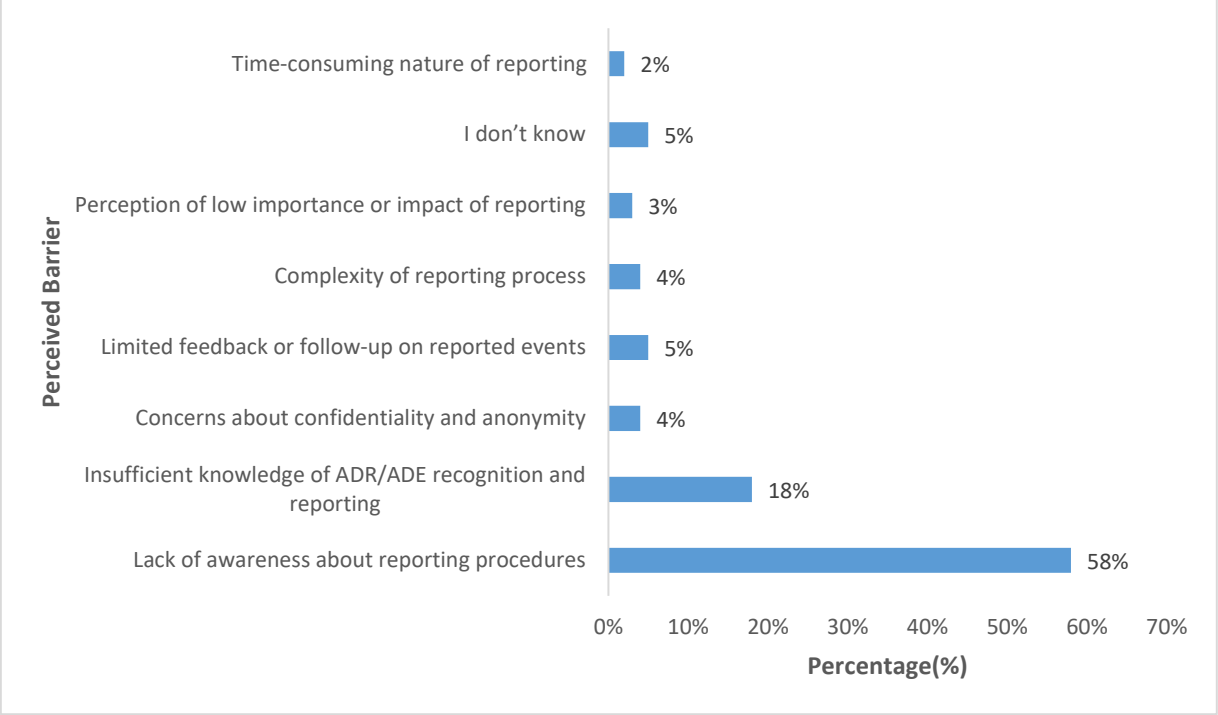


Figure 2: Perceived Barriers to ADR Reporting

CHAPTER FIVE

5.0 DISCUSSION

The findings from this study provide valuable insights into patients' awareness, practices, and attitudes towards adverse drug event (ADEs) and reporting in the community pharmacy setting. The results underscore significant gaps in patients' knowledge and highlight areas where interventions are necessary to enhance pharmacovigilance activities.

The study revealed a low awareness of pharmacovigilance among participants, with only 12% having heard of it. This lack of awareness is concerning, given the importance of pharmacovigilance in monitoring and improving drug safety. However, nearly half of the participants (49%) were aware of ADEs, primarily through social media. This indicates that while some awareness exists, it is not widespread and is often obtained from informal sources. These findings align with study that has reported low levels of pharmacovigilance awareness in the general population(21).

The study highlighted a significant gap in ADE reporting practices. Despite 42 participants experiencing an ADE, only 30 of these individuals reported it.This reporting rate is relatively high compared to other studies but still indicates that a substantial proportion of ADEs go unreported. The main reasons for not reporting included a lack of knowledge of how to report and the perception that it was unnecessary if the reaction was resolved on its own. These findings suggest a need for better education and awareness programs to inform patients about the importance of reporting ADEs and how to do so effectively (11)(12)(21). Similar barriers to ADE reporting have been identified in other studies (22)(23).

This study identifies key patterns in ADEs associated with common medications. Itching, mainly linked to antimalarials like Malafin and Ekelfin, highlights the need for vigilant dermatological monitoring (24). Rapid heart rate related to Amlodipine emphasizes the importance of cardiovascular monitoring for patients on calcium channel blockers (23)

Blisters linked to drugs like Sulphadar and Orodar, along with gastrointestinal issues such as diarrhea and abdominal discomfort from antibiotics, underscore the necessity for comprehensive patient education and monitoring. The diverse therapeutic classes associated with these ADRs underline the need for a robust pharmacovigilance system (6).

The majority of participants (96%) recognized the importance of reporting ADEs, with the primary motivation being to prevent recurrence in others. This positive attitude towards ADE reporting indicates that clients are willing to participate in pharmacovigilance activities if provided with the necessary knowledge and tools. The high percentage of respondents reported that pharmacists provided information about their medication (94%) and ensured they understood the instructions (89%) indicates a strong adherence to communication practices essential for patient safety. This is consistent with findings from other study, such as Bouvy et al. who noted that effective communication by healthcare professionals is critical for minimizing ADEs and enhancing patient adherence (21)(24).

However, there remains a notable gap in education about the possible side effects of medications (41%). This discrepancy highlights an area where pharmacists could enhance their patient interactions by consistently including discussions about potential adverse effects. Other studies similarly found that patients often lack sufficient information about potential side effects, which can lead to underreporting of ADEs (21)(25).

Clients' preferred methods and places for reporting ADEs indicate practical considerations for improving pharmacovigilance systems. The majority favored direct reporting to healthcare professionals and community pharmacies, suggesting that integrating ADE reporting into routine pharmacy visits could enhance reporting rates. The preference for mobile application and short code SMS also highlights the potential for leveraging technology to streamline the reporting process and make it more convenient for patients. This observation aligns with findings from studies indicating that technology can play a significant role in improving patient-reported outcomes in drug safety (26).

Also, the study highlights perceived barriers ADE reporting, emphasizing the need for improved pharmacovigilance. The primary barrier, lack of awareness about reporting procedures (58% of respondents), aligns with findings by published in 2017), that stress the importance of patient education in enhancing ADE reporting rates(5). Insufficient knowledge of ADE recognition and reporting (18%) also underscores the need for comprehensive educational programs (22,24). Concerns about confidentiality and anonymity (4%) suggest the need for secure, anonymous reporting systems to encourage patient participation (27). Limited feedback or follow-up on reports (5%) indicates that improving communication with patients about the impact of their reports could enhance reporting rates (7). The complexity of the reporting process (4%) highlights the need for simplified, user-friendly systems (28). Additionally, 3% of respondents perceived ADE reporting as having low impact, pointing to the need for awareness campaigns to demonstrate the value of patient reports in drug safety (29). These findings emphasize the necessity for targeted educational initiatives, streamlined reporting procedures, and enhanced feedback mechanisms to improve ADE reporting and patient safety.

Overall, the findings of this study highlight both strengths and areas for improvement in current practices related to ADE awareness and reporting. While pharmacists are generally effective in communicating essential information about medications, there is a clear need for more comprehensive education about potential side effects and the importance of reporting ADEs. Educational interventions should be tailored to address the specific needs of different demographic groups, including varying educational levels, ages, and occupational statuses. Additionally, enhancing the accessibility and convenience of ADE reporting mechanisms, particularly through the use of technology, could significantly improve reporting rates and ultimately contribute to safer healthcare practices.

CHAPTER SIX

6.1 Limitation

This study has several limitations that must be considered when interpreting the results. First, the cross-sectional design of the study prevents the establishment of causality between the variables examined. Additionally, the study was conducted in a specific geographical location, and regional differences in healthcare practices and patient behaviors might influence the results.

6.2 Conclusion

This study reveals significant gaps in awareness and practices regarding ADE reporting among community pharmacy patients. Major barriers include a lack of awareness and insufficient knowledge about reporting procedures. Despite positive attitudes towards ADE reporting, practical barriers such as reporting complexity and confidentiality concerns hinder participation. Enhancing patient education, simplifying reporting processes, and ensuring confidentiality are crucial to improve ADE reporting practices and patient safety.

6.3 Recommendations

Based on the findings of this study, several recommendations are proposed. By addressing these recommendations, healthcare systems can significantly improve the detection and management of ADRs, ultimately enhancing patient safety and healthcare outcomes

1. Educational Campaigns: Implement comprehensive programs to increase patient awareness of ADRs and the importance of reporting, including how to identify and report ADRs.
2. Public Awareness Initiatives: Conduct campaigns across various media channels to emphasize the significance of ADR reporting and its impact on healthcare quality and patient safety.
3. Further Research: Conduct studies to explore barriers to ADR reporting across different settings, focusing on cultural factors, literacy, and healthcare professionals' roles. These insights will help improve pharmacovigilance systems and tailor interventions for diverse populations

REFERENCES

1. WHO 2022. Safety of Medicines. World Heal Organ Geneva. 2002;2002.2(2002):20.
2. Tanzania G of. The Tanzania Food, Drugs and Cosmetics (Pharmacovigilance) regulations, GN 296. 2018.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta- analysis of prospective studies. J Am Med Assoc. 1998;279(15):1200–5.
4. World Health Organization (WHO). Pharmacovigilance: ensuring the safe use of medicines. World Health [Internet]. 2004;1–6. Available from: http://pvtoolkit.org/toolkit/readers/pv_ensuring_safe_medicine_use.pdf
5. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. Br J Clin Pharmacol. 2017;83(2):227–46.
6. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC Health Serv Res. 2019;19(1):1–14.
7. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK "Yellow Card Scheme": literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess. 2011 May;15(20):1–234, iii–iv.
8. Mwakawanga DL, Kilonzi M, Philipo EG, Martine A, Mbilinyi T, Kileo NF, et al. Pharmacovigilance and Adverse Drug Reactions Reporting: Healthcare Providers' Experiences from Southern Highland Tanzania. Adv Pharmacol Pharm Sci. 2023;2023.
9. Sienkiewicz K, Burzyńska M, Rydlewska-Liszkowska I, Sienkiewicz J, Gaszyńska E. The Importance of Direct Patient Reporting of Adverse Drug Reactions in the Safety Monitoring Process. Int J Environ Res Public Health. 2021 Dec;19(1).

10. Pagotto C, Varallo F, Mastroianni P. Impact of educational interventions on adverse drug events reporting. Int J Technol Assess Health Care. 2013;29(4):410–7.

11. Kitisopee T, Assanee J, Sorofman BA, Watcharadmrongkun S. Consumers' adverse drug event reporting via community pharmacists: three stakeholder perception. J Pharm Policy Pract [Internet]. 2022;15(1):1–10. Available from: https://doi.org/10.1186/s40545-022-00417-z

12. Kim S, Yu YM, You M, Jeong KH, Lee E. A cross-sectional survey of knowledge , attitude , and willingness to engage in spontaneous reporting of adverse drug reactions by Korean consumers. 2020;1–11.

13. Al Meslamani AZ. Underreporting of Adverse Drug Events: a Look into the Extent, Causes, and Potential Solutions. Expert Opin Drug Saf [Internet]. 2023 May 4;22(5):351–4. Available from: https://doi.org/10.1080/14740338.2023.2224558

14. Almubark RA, Aljadani RH, Alqahtani AS, Alshammari TM, BinDhim NF. National Cross-Sectional Study of Community-Based Adverse Drug Reactions in Saudi Arabia. Drugs - Real World Outcomes [Internet]. 2020;7(2):161–70. Available from: https://doi.org/10.1007/s40801-020-00186-8

15. Pal S, Olsson S, van Grootheest K, van Hunsel F, Harmark L. Experiences with Adverse Drug Reaction Reporting by Patients. Drug Saf. 2012;35(1):45–60.

16. Costa C, Abeijon P, Rodrigues DA, Figueiras A, Herdeiro MT, Torre C. Factors associated with underreporting of adverse drug reactions by patients: a systematic review. Int J Clin Pharm. 2023 Dec;45(6):1349–58.

17. Al Dweik R, Stacey D, Kohen D, Yaya S. Factors affecting patient reporting of adverse drug reactions: a systematic review. Br J Clin Pharmacol. 2017;83(4):875–83.

18. Olsson S, Pal SN, Dodoo A. Pharmacovigilance in resource-limited countries. Expert Rev Clin Pharmacol. 2015;8(4):449–60.

19. Herdeiro MT, Figueiras A, Polónia J, Gestal-Otero JJ. Influence of pharmacists' attitudes on adverse drug reaction reporting: A case-control study in Portugal. Drug Saf. 2006;29(4):331–40.

20. Sirili N, Kilonzi M, Mwakawanga DL, Mohamedi JA, Thobias JM, Clement A, et al. Awareness, Actions, and Predictors of Actions on Adverse Drug Reaction Reporting among Patients Attending a Referral Hospital in Southern Highland Tanzania. Adv Pharmacol Pharm Sci. 2023;2023.

21. Adisa R, Adeniyi OR, Fakeye TO. Knowledge, awareness, perception and reporting of experienced adverse drug reactions among outpatients in Nigeria. Int J Clin Pharm [Internet]. 2019;41(4):1062–73. Available from: https://doi.org/10.1007/s11096-019-00849-9

22. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: A systematic review. Drug Saf. 2009;32(1):19–31.

23. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. Br J Clin Pharmacol. 2017 Feb;83(2):227–46.

24. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of Adverse Drug Reactions in Europe: A Review of Recent Observational Studies. Drug Saf [Internet]. 2015;38(5):437–53. Available from: http://dx.doi.org/10.1007/s40264-015-0281-0

25. Aagaard L, Strandell J, Melskens L, Petersen P, Hansen E. Global Patterns of Adverse Drug Reactions Over a Decade: Analyses of Spontaneous Reports to VigiBase™. Drug Saf. 2012 Oct 17;35.

26. Banerjee AK, Ingate S. Web-based patient-reported outcomes in drug safety and risk management: Challenges and opportunities? Drug Saf. 2012;35(6):437–46.

27. Sabblah GT, Darko DM, Mogtari H, Härmark L, van Puijenbroek E. Patients' Perspectives on Adverse Drug Reaction Reporting in a Developing Country: A Case

Study from Ghana. Drug Saf. 2017;40(10):911–21.

28. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: A systematic review. Drug Saf. 2006;29(5):385–96.

29. Herxheimer A, Crombag R, Alves TL. Direct Patient Reporting of Adverse Drug Reactions A Fifteen-Country Survey & Literature review. Heal Action Int [Internet]. 2010; Available from: www.haiweb.org

APPENDICES

Appendix I: Consent form (English version)

INFORMED CONSENT FORM

No. ☐☐☐

Consent to participate in the study entitled:

Assessing awareness, attitude, and practices towards spontaneous reporting of ADEs among patients attending community pharmacies

Introduction:

Dear participant, My name is Joram Adam, and I am a master's student in Pharmacovigilance and Pharmacoepidemiology at Muhimbili University of Health and Allied Sciences. I am conducting this study to investigate the awareness, attitudes, and practices of community pharmacy patients regarding the reporting of Adverse Drug Events (ADEs). By gathering this information, I will contribute actionable insights that will ultimately enhance medication safety and improve healthcare outcomes within community pharmacy settings. Your participation in this study is greatly valued and will help us in achieving our goal of ensuring safer medication use for everyone. Thank you for considering being a part of this important research endeavor

Confidentiality:

Your name or organization will not be in any of the documentations or reports so that no one will be able to identify you. The information obtained from you will be stored safely,

All information obtained from you will be handled in confidential manner and access will only be to the study investigators.

Risk expected:

No risk is associated with this study.

Your rights:

Your participation is voluntarily; you are free to agree or refuse to participate in this study. You are free to leave at any time and the information obtained already will not be used for this study.

Benefits:

This information will contribute actionable insights that will ultimately lead to safer medication use and improved healthcare outcomes in community pharmacy settings.

Whom to contact:

In case of any question associated with participation in the study kindly contact: +255712433133, Joram Adam at Muhimbili University of Health and Allied Sciences, PO Box 65013 School of Pharmacy.

You can also contact the supervisors of this research Dr. Ritah Mutagonda and Dr. Alphonce Marealle from Muhimbili University of Health and Allied Sciences or the office of Director of Research and Publications, Muhimbili University of Health and Allied Sciences, PO Box 65001, Dar es Salaam.

I……. confirm that, I have read and understood the contents of this form.

My questions have been answered. I agree to participate in this study.

Signature of the participant……Date……..

Name of the participant……

Signature of the researcher…… Date of signed consent...../…/……

Appendix II: Consent Form (Swahili version)

Fomu ya kupata idhini

Namba

Idhini ya Kushiriki katika Utafiti Wenye Kichwa:

Kuchunguza ufahamu, mtazamo, na mazoea kuhusu kuripoti kwa hiari Matukio ya Dawa Yasiyofaa (ADEs) miongoni mwa wagonjwa wanaohudhuria maduka ya dawa ya kijamii:

Mpendwa mshiriki, Jina langu ni Joram Adam, na mimi ni mwanafunzi wa shahada ya uzamili katika usalama wa dawa na epidemiolojia ya dawa katika Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ninafanya utafiti huu ili kuchunguza ufahamu, mitazamo, na mazoea ya wagonjwa wa maduka ya dawa katika jamii kuhusu kuripoti Matukio ya Madhara ya Dawa (ADEs). Kwa kukusanya habari hii, nitachangia ufahamu unaoweza kutekelezeka ambao mwishowe utaimarisha usalama wa dawa na kuboresha matokeo ya huduma za afya katika mazingira ya maduka ya dawa katika jamii. Ushiriki wako katika utafiti huu ni muhimu sana na utatusaidia kufikia lengo letu la kuhakikisha matumizi salama ya dawa kwa kila mtu. Asante kwa kukubali kuwa sehemu muhimu ya utafiti huu

Usiri:
Jina lako au shirika halitaorodheshwa kwenye nyaraka au ripoti yoyote ili hakuna mtu atakayeweza kukutambua. Taarifa zilizopatikana kutoka kwako zitahifadhiwa kwa usalama. Habari yoyote inayopatikana kutoka kwako itashughulikiwa kwa njia ya siri, na ufikiaji utakuwa wa wachunguzi wa utafiti tu.

Hatari Inayotarajiwa: Hakuna hatari inayohusishwa na utafiti huu.

Haki Zako: Ushiriki wako ni hiari; uko huru kukubaliana au kukataa kushiriki katika utafiti huu. Uko huru kuondoka wakati wowote, na habari iliyopatikana hadi wakati huo haitatumika kwa utafiti huu.

Faida:

Taarifa zinazopatikana zitachangia maoni yanayoweza kutekelezeka ambayo mwishowe yataongoza kwenye matumizi salama ya dawa na matokeo bora ya huduma ya afya katika mazingira ya maduka ya dawa ya jamii.

Nani wa Kuwasiliana Naye:

Kwa maswali yoyote yanayohusiana na ushiriki katika utafiti tafadhali wasiliana: +255712433133, Joram Adam katika Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, Sanduku la Posta 65013, Shule ya Dawa. Unaweza pia kuwasiliana na wasimamizi wa utafiti huu Dk. Rittah Mutagonda na Dr Alphonce Marealle kutoka Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili au Ofisi ya Mkurugenzi wa Utafiti na Machapisho, Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, Sanduku la Posta 65001, Dar es Salaam.

Mimi, ……. ninathibitisha kuwa nimesoma na kuelewa maudhui ya fomu hii. Maswali yangu yamejibiwa. Ninasema kukubaliana kushiriki katika utafiti huu.

Saini ya Mshiriki: _____ Tarehe: _____

Jina la Mshiriki: _____

Saini ya Mtafiti: _____ Tarehe ya Idhini iliyosainiwa: //_____

Appendix III: Questionnaire (English Version)

Spontaneous Reporting of Adverse Drug Events - Community Pharmacy Patient

Section 1: Demographic Information

1. Age: _____
2. Gender:
   Male
   Female
3. Marital status :
   Married
   Single
   Widowed
   Divorced
4. Educational Level:
   Informal
   Primary
   O-Level Secondary School
   A-Level Secondary School
   College/University
5. Occupation
   Unemployed
   Self-employed
   Civil servant
   Retired
   Student
   Other (please specify): _____

6. How frequently do you visit community pharmacy?

   Regularly

   Often

   Occasionally

   Very rarely

7. Do you have any chronic health conditions for which you regularly take medications?

   Yes

   No

   I prefer not to answer

   Section 2: Awareness

8. Have you heard of pharmacovigilance?

   Yes

   No

9. Have you heard about Adverse Drug Events (ADEs)/ADR before?

   Yes

   No

10. If yes, what is your source of awareness of pharmacovigilance OR ADEs)/ADR?

    Social media

    Television

    Radio

    Others ,specify……

    Can't remember

11. If yes, how would you define an Adverse Drug Event?

    Any effect from a medication one is taken

    Unexpected reaction after taking a medication

    Expected reaction

    I do not know

12. What is your understanding of a serious adverse drug reaction (SADR)?
    Reaction that requires medical emergency and can cause deatha
    Reaction that is bad enough to interfere with daily activitiesa
    Reaction that is life-threateninga
    Reaction that results in hospitalisation or prolongs hospitalisationa
    Reaction that is uncomfortable but does not stop you from daily activities
    Reaction that is mild or slightly uncomfortable
    I don't know
13. Ever heard of Suspected ADR reporting form?
    Yes
    No
14. Where can you obtain information about adverse drug reactions?
    Drug leaflet
    Pharmacist
    Physician
    Internet
    Nurse
    Relative/Friend
    Other (please specify): _____
15. What was your source of learning about the possibility of reporting Adverse Drug Events?
    Healthcare provider
    Community pharmacy
    Online sources
    Friends or family
    Other (please specify): _____

16. Are you aware that Adverse Drug Events (ADEs) can range from mild side effects to severe reactions?

    Yes

    No

    Section 3: Attitude & Practices

17. Have you ever personally experienced an Adverse Drug Event?

    Yes

    No

18. If yes, Could you please recall any adverse effects you experienced after using medication?

    Yes

    No

19. If yes, what specific issues or problems did you experience.....?

    ……

20. Do you remember which medication you were using when you experienced this issue?

    Yes

    No

21. If yes, which medication specifically?.....

22. If yes, did you report the Adverse Drug Event?

    Yes

    No

23. If yes, to whom do you make the report?

    Physician

    Pharmacist

    Nurse

    Other healthcare workers

24. If yes, action taken in the case of adverse effect/reaction

    Stopped the drug

    Did nothing because the reaction was tolerable

    Did nothing because the reaction resolved on its own

    Used another drug to treat symptoms of reaction

    Switched to herbal/traditional medicines

    Switched to another drug

    Other (please specify): _____

25. If no, why don't you make a report?

    Do not know the importance of reporting adverse drug reactions

    Adverse reaction may not be very serious

    Do not know how to report such reactions

    Not sure if adverse reaction is related to the medication

    Adverse effect/reactions resolved on its own

    Belief that all drugs have side effects

    Stopped taking the drug and reaction stopped, thus, no need to report

    No reason

    Other (please specify): _____

26. How would you prefer to report an Adverse Drug Event?

    Online form

    Paper form at the pharmacy

    Through a mobile app

    Reporting directly to healthcare professional

    Other (please specify): _____

27. In the event of experiencing an Adverse Drug Event, would you prefer reporting it to the

    Community pharmacy

    Regulatory body (TMDA)

    Health care facilities

28. Do you think one should make reports about adverse effects/reactions experienced after medicine(s) is/are taken?
    Yes
    No
    Don’t know
29. Do you think it is important/necessary to make a report about adverse effects/reactions experienced after taking medicine(s)?
    Yes
    No
    Don’t know
30. If yes to 29, why do you think it is important?

    To make the healthcare professionals aware of what the drug has caused
    To make sure the drug is not fake
    To prevent a recurrence of the reaction in other people
    To make sure the report get to the manufacturer of the drug
    Don’t know
31. If no to question 29, why do you consider it not important?
    Lack of awareness of the importance of reporting
    Perceiving the effects as not very serious
    Not knowing how to report
    Uncertainty if the effect is related to the medication
    The effects resolved on their own
    Belief that all drugs have side effects
32. Lack of knowledge or understanding of the importance of reporting adverse drug reactions
    Doubt about the impact of reporting
    Lack of time
    Lack of trust or concerns about the confidentiality and security of information
    Not seeing direct results from making a report

Other.(Specify)……

33. During prescription refll,(before leaving the pharmacy) does the pharmacist tell you what your medication is used for?

    Yes

    No

    Don’t know

34. Does the pharmacist make sure you understand the instructions given to you about how to take your drugs?

    Yes

    No

    Don’t know

35. Were you asked about other drugs you are taking?

    Yes

    No

    Don’t know

36. Were you told of the risk involved when you do not take your drugs regularly or if you stop taking your drugs abruptly?

    Yes

    No

    Don’t know

37. Do pharmacists educate/enlighten you about the possible side efects of your drugs?

    Yes

    No

    Don’t know

38. Were you told by your pharmacist what to do if the symptoms you experienced do not resolve?

    Yes

    No

    Don’t know

39. Were you informed about other drugs/supplements you should not take while taking your drugs?
    Yes
    No
    Don’t know
40. Do pharmacists talk about lifestyle changes to improve your health?
    Yes
    No
    Don’t know
41. Does your pharmacist inform you about what to do if you forget to take your drug or if you take an over dose?
    Yes
    No
    Don’t know
42. Do you believe community pharmacies should play a more active role in promoting Adverse Drug Event awareness?
    Yes
    No
    Don’t know
43. What specific barriers do you perceive in the current Adverse Drug Event reporting system that need to be addressed?
    Lack of awareness about reporting procedures
    Complexity of reporting process
    Concerns about confidentiality and anonymity
    Limited feedback or follow-up on reported events
    Time-consuming nature of reporting
    Insufficient knowledge on ADR recognition and reporting
    Perception of low importance or impact of reporting
    Other (please specify)……

Appendix IV: Questionnaire (Swahili Version)

Maswali kwa Wagonjwa wa Maduka ya Dawa za Jamii (Toleo la Kiswahili)

1. **Sehemu 1: Taarifa za Kidemografia**

   Umri: _____

   Jinsia:

   Mwanaume

   Mwanamke

2. Hali ya mahusiano:

   Nimeoa/Nimeolewa

   Siko katika ndoa

   Mjane

   Nimeachana

3. Kiwango cha Elimu:

   Elimu isiyo rasmi

   Shule ya Msingi

   Shule ya Sekondari - Kidato cha Nne

   Shule ya Sekondari - Kidato cha Sita

   Chuo Kikuu/chuo cha kati

4. Kazi

   Bila kazi

   Mwenye kujiajiri

Mtumishi wa Umma

Mstaafu

Mwanafunzi

Nyingine (taja): _____

5. Mara ngapi huwa unatembelea duka la dawa la jamii?

   Mara kwa mara

   Mara nyingi

   Mara chache

   Mara chache sana

6. Una tatizo la kiafya la muda mrefu ambalo hulazimika kutumia dawa mara kwa mara?

   Ndiyo

   Hapana

   Ningependa kutotaja

7. Je, umewahi kusikia kuhusu famakovijilansi?

   Ndiyo

   Hapana

8. Je, umewahi kusikia kuhusu Matukio Mabaya(madhara/maudhi) yanayohusiana na Matumizi ya Dawa (ADEs)/ADR hapo awali?

   Ndiyo

   Hapana

9. Ikiwa ndiyo, chanzo chako cha kujua kuhusu famakovijilansi au Matukio Mabaya(madhara/maudhi) yanayohusiana na Matumizi ya Dawa (ADEs)/ADR ni kipi?

   Mitandao ya kijamii

   Televisheni

   Redio

   Nyingine, eleza……

   Siwezi kumbuka

10. Ikiwa ndiyo, je madhara/maudhi yatokanayo na matumizi ya dawa unaweza kuelezeaje?

    Athari yoyote kutokana na dawa unayotumia

    Matokeo ya kutegemewa baada ya kutumia dawa

    Matokeo yasiyotegemewa baada ya kutumia dawa

    Sijui

11. Je, unaelewa nini kuhusu athari(madhara/maudhi) mabaya makubwa ya dawa (SADR)?

    Athari inayohitaji huduma za dharura za matibabu na inaweza kusababisha kifo

    Athari ambayo inazuia shughuli za kila siku

    Athari inayoweza kusababisha hatari ya maisha

    Athari inayosababisha kulazwa hospitalini au kuongeza muda wa kulazwa hospitalini

    Athari ambayo siyo rahisi lakini haikuzuia shughuli za kila siku

    Athari ambayo ni hafifu au isiyosumbua sana

    Sijui

12. Umewahi kusikia kuhusu fomu ya kuripoti(madhara/maudhi) ADR inayotiliwa shaka?

    Ndiyo

    Hapana

13. Unapata wapi taarifa kuhusu athari(madhara/maudhi) mbaya za dawa?

    Mwongozo wa dawa

    Mtaalamu wa dawa

    Daktari

    Mtandaoni

    Muuguzi

    Jamaa/Rafiki

    Nyingine (taja): _____

14. Chanzo chako cha kujifunza kuhusu uwezekano wa kuripoti Matukio Mabaya yanayohusiana na Dawa kilikuwa ni nini?
    Mtoa huduma ya afya
    Duka la dawa za jamii
    Mtandaoni
    Marafiki au familia
    Nyingine (taja): _____

15. Je, una ufahamu kwamba Matukio Mabaya yanayohusiana na Dawa (ADEs) yanaweza kuwa kutoka kwa madhara madogo hadi athari kubwa?
    Ndiyo
    Hapana

16. Je, umewahi kwa kibinafsi kupata Tukio Baya(madhara/maudhi) la Dawa?
    Ndiyo
    Hapana

17. Ikiwa ndiyo, unaweza kumbuka athari yoyote uliyoipata baada ya kutumia dawa?
    Ndiyo
    Hapana
18. Ikiwa ndiyo, tatizo au shida uliyopata ni ipi?
    ……..
19. Je, unakumbuka dawa uliyokuwa unatumia kupelekea kupatata tatizo hilo?
    Ndiyo
    Hapana
20. Ikiwa ndiyo, ni dawa gani hasa? .....
21. Ikiwa ndiyo, uliripoti Tukio Baya la Dawa?
    Ndiyo
    Hapana
22. Ikiwa ndiyo, uliripoti kwa nani?
    Daktari
    Mtaalamu wa dawa
    Muuguzi
    Wafanyakazi wengine wa afya
23. Ikiwa ndiyo no. 17, hatua gani ulichukua kufuatia athari/madhara hiyo?
    Kusitisha dawa
    Sikuifanyia chochote kwa sababu athari ilikuwa inavumilika
    Sikuifanyia chochote kwa sababu athari ilipona yenyewe
    Kutumia dawa nyingine kutibu dalili za athari
    Kugeukia dawa za asili/matibabu ya jadi
    Kugeukia dawa nyingine
    Nyingine (taja): _____
24. Ikiwa hapana 22, kwa nini haukutoa taarifa?
    Sifahamu umuhimu wa kuripoti athari mbaya za dawa
    Athari siyo mbaya sana
    Sifahamu jinsi ya kuripoti athari hizo

Sina hakika kama athari inahusiana na dawa

Athari imepotea yenyewe

Ninaamini kuwa dawa zote zina madhara

Niliacha kuchukua dawa na athari zikakoma, hivyo, hakuna haja ya kuripoti

Sina sababu

Nyingine (taja): _____

25. Unapendelea vipi kuripoti madhara/maudhi yanayotokana na matumizi ya Dawa?

Fomu mtandaoni

Fomu ya karatasi dukani

Kupitia programu ya simu

Kuripoti moja kwa moja kwa wataalamu wa afya

Nyingine (taja): _____

26. Ukikumbana na Tukio Baya la Dawa, ungependelea kuripoti kwa

Duka la dawa za jamii

Mamlaka ya udhibiti (TMDA)

Hospital

27. Je, unafikiri kuwa unatakiwa kutoa ripoti kuhusu madhara/maudhi unayopata baada ya kutumia dawa?

Ndiyo

Hapana

Sijui

28. Je, unaona ni muhimu kutoa ripoti kuhusu athari/adhari unayopata baada ya kutumia dawa?

Ndiyo

Hapana

Sijui

29. Ikiwa ndiyo kwa 29, kwa nini unaona ni muhimu?

    Kuwafahamisha wataalamu wa afya kuhusu madhara yanayosababishwa na dawa

    Kuhakikisha dawa siyo bandia

    Kuzuia kurudiwa kwa athari kwa watu wengine

    Kuhakikisha ripoti inafikishwa kwa mtengenezaji wa dawa

    Sijui

30. Ikiwa hapana kwa 29, kwa nini unaona sio muhimu?

    Kutokujua umuhimu wa kuripoti

    Kuona athari siyo mbaya sana

    Kutokujua jinsi ya kuripoti

    Kutokuwa na uhakika kama athari ni kuhusiana na dawa

    Athari zilipona yenyewe

    Kuamini kuwa madawa yote yana madhara

    Kupungukiwa na maarifa au ufahamu wa umuhimu wa ripoti za athari za dawa:

    Kushuku matokeo ya ripoti

    Kutokuwa na muda

    Kutokuwa na imani au wasiwasi kuhusu usiri na usalama wa taarifa

    Kutoona matokeo ya moja kwa moja kwa kutoa ripoti

31. Wakati wa kupata dawa zako, je, muuzaji wa dawa anakueleza matumizi ya dawa hizo?

    Ndiyo

    Hapana

    Sijui

32. Je, muuzaji wa dawa anakuhakikishia kwamba unaelewa maelekezo kuhusu jinsi ya kutumia dawa zako?

    Ndiyo

    Hapana

    Sijui

33. Je, uliulizwa kuhusu dawa nyingine unazotumia?
    Ndiyo
    Hapana
    Sijui
34. Je, uliambiwa kuhusu hatari zinazohusiana na kutokuchukua dawa zako kwa utaratibu au kama utaacha ghafla?
    Ndiyo
    Hapana
    Sijui
35. Je, wafamasia wanakuelimisha kuhusu madhara yanayowezekana ya dawa zako?
    Ndiyo
    Hapana
    Sijui
36. Je, uliambiwa na mfamasia wako ni hatua gani utachukua ikiwa dalili unazopata hazitatatuliwa?
    Ndiyo
    Hapana
    Sijui
37. Je, uliambiwa kuhusu dawa/supliments nyingine ambazo hupaswi kuzitumia wakati unatumia dawa zako?
    Ndiyo
    Hapana
    Sijui
38. Je, wafamasia wanazungumzia mabadiliko ya mtindo wa maisha ili kuboresha afya yako?
    Ndiyo
    Hapana
    Sijui

39. Je, mfamasia wako anakueleza ni hatua gani utachukua ikiwa utasahau kuchukua dawa au ukichukua kipimo cha ziada?
    Ndiyo
    Hapana
    Sijui
40. Je, unaamini maduka ya dawa za jamii yanapaswa kuchukua jukumu kubwa zaidi katika kuhamasisha uelewa kuhusu Matukio Mabaya yanayohusiana na Dawa?
    Ndiyo
    Hapana
    Sijui
41. Ni vikwazo gani unavyohisi katika mfumo wa sasa wa kuripoti Matukio Mabaya yanayohusiana na Dawa vinavyohitaji kushughulikiwa?
    Kutokuwa na ufahamu wa taratibu za kuripoti
    Ugumu wa mchakato wa kuripoti
    Wasiwasi kuhusu usiri na kutokujulikana
    Mrejesho mdogo au kutofuatilia matukio yaliyoripotiwa
    Muda mrefu wa kufanya ripoti
    Maarifa duni kuhusu kutambua na kuripoti ADR
    Mtazamo wa umuhimu mdogo au athari za kuripoti
    Kutokuwa na ushirikiano na rekodi za afya za elektroniki au mifumo mingine
    Nyingine (taja)……
    Sijui

Appendix V: Approval for 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 INNOVATION

Ref. No.DA.282/298/01.C/2140 Date: 02/04/2024

MUHAS-REC-04-2024-2140
JORAM ADAM
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: ASSESSING AWARENESS, ATTITUDE, AND PRACTICES TOWARDS SPONTANEOUS REPORTING OF ADVERSE DRUG EVENTS AMONG PATIENTS ATTENDING COMMUNITY PHARMACIES IN DAR ES SALAAM

Reference is made to the above heading.

I am pleased to inform you that the Chairman 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: 02/04/2024
EXPIRATION DATE OF APPROVAL: 02/04/2025

STUDY DESCRIPTION:
Purpose:

To evaluate patient awareness, attitudes, and practices toward spontaneous reporting of ADEs in community pharmacies.

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-%2014554.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