

**“ADVERSE DRUG REACTION REPORTING”
KNOWLEDGE, ATTITUDE AND PRACTICES OF COMMUNITY
PHARMACY DISPENSERS IN DAR ES SALAAM, TANZANIA**

By

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**A Dissertation Submitted in Partial Fulfillment of the Requirements for the MSc
Programme (Pharmaceutical Management) of Muhimbili University of Health and
Allied Sciences**

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CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled **Adverse Drug Reaction Reporting: Knowledge, Attitude and Practices of Community Pharmacy Dispensers in Dar es salaam, Tanzania** in partial fulfillment of the requirements for the MSc Programme (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

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Supervisor

Date

DECLARATION

I, **Grace Mng'ong'o, Shimwela** declare that this **dissertation** is my own original work and that it has not been presented and it will not be presented to any other University for the similar or any other degree award.

Signature.....

Date

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DEDICATION

To my lovely family,

Dr Meshack Shimwela my wonderful husband and my terrific kids **Joan Lwaki** and **Jean Mulotwa** for their understanding and patience all the time I was doing this work.

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ABSTRACT

Background: Under reporting of adverse drug reactions (ADRs) by healthcare personnel is a common problem of many Pharmacovigilance programs. Lack of involvement of healthcare professionals such as pharmacists and other pharmaceutical dispensers has been cited as one of the reasons for under reporting. Pharmaceutical dispensers in the community pharmacies are in unique position by virtue of their training and profession to observe ADRs in patients, as many patients often try to avoid doctor consultation fees by visiting community pharmacies. The knowledge and ability of dispensers in Tanzanian community pharmacies to identify and report ADRs is however unknown.

Study objective: To determine the knowledge, attitude and practices of dispensers in community pharmacies in Dar es Salaam towards the ADRs reporting.

Methodology: A descriptive cross sectional survey was conducted involving 254 dispensers from selected retail pharmacies in Dar es Salaam region. SPSS version 16 was used for data entry, cleaning and subsequently analysis.

Results: The majority of personnel working in community pharmacies are non pharmaceutical professionals i.e 52% were nurse assistants. Community dispensers have limited knowledge and practices with regard towards ADRs reporting. Only 13.8% of respondents had good ADRs reporting knowledge, while only 8.7% had ever submitted ADRs reports to the relevant authorities. There was a significant difference in the level of knowledge with regard to ADRs reporting between Pharmaceutical professionals (i.e Pharmacists, Pharmaceutical technicians and pharmaceutical assistants) and non Pharmaceutical professionals (P value = 0.000). The knowledge levels correlated positively with profession and attendance of continuous professional education courses (CPE). The majority of dispensers (68.9%) however had a positive attitude towards ADRs reporting.

Conclusion and Recommendations: Community pharmacies dispensers in Dar es Salaam have limited knowledge and experience with regard to ADRs reporting. Thus community pharmacies in Dar es Salaam cannot presently act as centres to collect data on ADRs effectively. The staffing of community pharmacies with unqualified pharmaceutical professionals is the main reason for the lack of knowledge, thus sincere and sustained efforts should be made by the Government through its National Regulatory Authorities and Schools of Pharmaceutical Sciences to ensure that there is an increased output of

pharmaceutical professionals in Tanzania, ADRs reporting forms and guidelines are available in community pharmacies and that continuous professional education is provided to in-service pharmaceutical professionals to improve their ADRs reporting capabilities.

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ABBREVIATIONS

CPE	Continuous Pharmaceutical Education
IOM	United States of America Institute of Medicines
MoHSW	Ministry of Health and Social Welfare
MUHAS	Muhimbili University of Health and Allied Sciences
TADATIS	Tanzania Drugs and Toxicology Information Services
TFDA	Tanzania Food and Drugs Authority
WHO	World Health Organization

CHAPTER ONE

1.0 BACKGROUND

1.1 Introduction

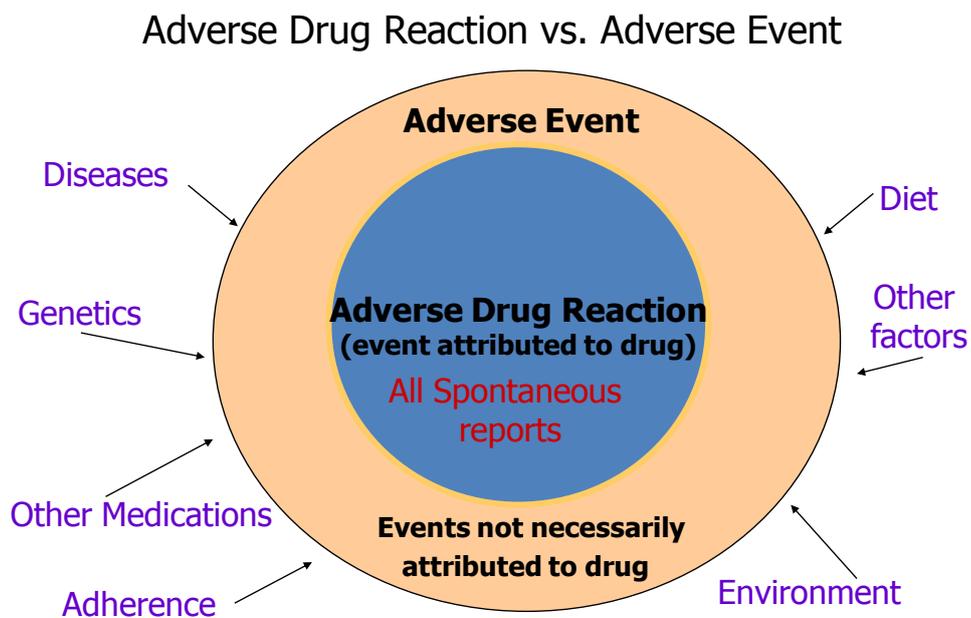
Adverse Events (AEs) are defined as any unfavorable and unintended medical occurrence that in coincidence may present during treatment with a medicinal product but does not necessarily have a causal relationship with this treatment. It includes all adverse reactions or events due to medicinal products and any other incidents thought not to be reactions. Simply, not all AEs are due to medicinal products as some may be resulted from patients' illness or conditions, genetic or environmental factors, diet or any other causes (USAID, SPS, 2009).

Adverse Drug Events (ADEs) are adverse events or injuries resulting from the use of medicinal products and may include harms caused by the product itself or harms from the use of the product (Nebeker et al, 2004). Thus ADEs are directly related to medicines and may be due to poor quality product, medication error (in prescribing, preparing, administering, or taking of medicines) or known and unknown pharmacological properties (resulting from Adverse Drug Reactions) and harm due to lack of efficacy of a medicinal product.

The United States of America Institute of Medicines (IOM) defines Medication Errors (MEs) as any errors occurring in the medication-use process. For examples prescribing the wrong dosage or administering the wrong dosage. Thus even though ADEs are often caused by errors, this term does not necessarily mean that an error occurred; an example of this is when a patient develops an allergic reaction to a drug with no past history of allergies or when he/she has taken a poor quality medicine. This type of ADE is non preventable simply because they cannot be avoided (Aspden et al, 2007). A preventable ADEs on the other hand are those due to MEs and they can be avoided when precautions are taken during prescribing or transcribing of a medication order, or in the dispensing, administration or monitoring of a medication (Franklin et al, 2005).

Consequently Adverse Drug Reactions (ADRs) as another component of ADEs are defined as responses to drugs which are noxious and unintended which occur at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for the modification of physiologic functions (VA Center for Medication Safety, 2006) see figure 1.1. The WHO, further categorizes ADRs into serious and non serious ADRs. A serious ADR is defined as any reaction that is fatal, life-threatening, permanently or significantly disabling, requires or prolongs hospitalization, or relates to misuse or dependence (WHO /UMC 2000).

Figure 1.1 Illustrate the relationship existing between ADRs and AEs (Nebeker et al, 2004)



1.2 Development of Medicinal products

Drug and vaccine development characteristically consists of four phases that are aimed at determining their pharmacological or immunological activities, toxicity, safety and efficacy. The pharmacological or immunological activities and toxicity of the product are determined in animals during the preclinical studies. This is then followed by a series of generally three phases of clinical trials in humans to determine their toxicity, safety and efficacy profile before licensure or market authorization.

Although pre-marketing investigation of a new medicinal product is carefully performed and critically assessed; it does not always reveal all possible side-effects or adverse reactions or events associated with the product (Bankowski et al, 1999). This is due to the fact that during these studies, the medicinal products are usually tested only in a subset of the general population. Moreover clinical studies are done in controlled environments for a limited duration and often done excluding certain groups of people like the elderly, children, pregnant women and patients with co-morbidities. As result one cannot with confidence conclude that the product is safe for all populations after completion of the trial (Zolezzi et al, 2005).

As a result many adverse reactions are detected after medicinal products have been prescribed and dispensed to large number of the general population. This phenomenon is a result of interaction of the medicinal product with multiple potential new co-factors of real world such as difference in human genetics, nutritional status, underlying diseases and food interaction that cannot be factored in when performing clinical trials (Bankowski et al, 1999).

Thus the introduction of new medicinal products into the market always carries the risks of adverse reactions associated with the product that were not detected during pre marketing investigation. The early identification of medicinal product problems may assist in that correctional measures can be taken before the serious harm occurs to a large population. Therefore it is important to monitor and identify events not only those related to previously known or unknown pharmacological properties (Adverse Drug Reactions, ADRs), but also those related to product quality and medication errors (MEs) in prescribing, preparing, administering or taking of medicines (USAID, SPS, 2009).

1.3 Involvement of Health Care Professionals in ADRs monitoring

Consequently, it falls on the health care team members in particular the prescribing physicians, pharmacists and nursing staff to practice an extreme level of alertness in the detection and reporting of adverse reactions associated with medicinal products whether

they are newly introduced in the market or already exists. However, for the healthcare team to detect and report adverse reactions effectively there must be in place an effective system and centre for reporting and disseminating information about observed adverse reactions. This centre will act as data collection centre and reference source for the future verification of the reported adverse reactions.

The verification of new potential and harmful reactions often requires the collection and review of Adverse Events (AEs) reports from healthcare workers from different countries. These reports must be properly assessed and validated. Thus, documentation and reporting to the relevant authorities becomes a crucial element in the process of validating AEs profile for any drug (Bankowski et al, 1999). The assessment reports from the documented and validated AEs assist drug regulatory authorities to enforce mandatory warnings and labeling changes on the medications, manufacturer-sponsored post-marketing studies, which may result in modified indications, and/or dosing schedules for the drug, and in the worst cases product withdrawal as a means to safe guard the health of consumers.

Post marketing surveillance of drugs already on the market as means to detect known and unknown adverse reaction is also known as pharmacovigilance. Pharmacovigilance can be defined as a system to monitor the safety and effectiveness of medicines and other pharmaceutical products already in the market (USAID, SPS, 2009) or according to the World Health Organization (WHO) as the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” (WHO 2002).

This system was established as a result of the historical drug related disasters such as the thalidomide tragedy of the early 1960s and the case of sulfonamide elixir in 1973. The loss of human life and disability associated with the above cases have triggered the awareness and prompted the importance of monitoring the AEs and specifically ADRs in pharmacotherapy as a means to safe guarding the health of consumers. See figure 1.2.

Fig 1.2 Victims of vivisection: Thalidomide infants (vaccinetruth.org)



(More than 470 babies with phocomelia were born to mothers treated with thalidomide during pregnancy)

Pharmacovigilance is an arm of patient care aimed at getting the best outcome of treatment with medicines and other related products. It includes all entities and resources that protect the public from medicines related harms whether in personal or public health care. The system aims to achieve this protection through efficient and timely identification, collection and assessment of adverse events (AEs), and by communicating risks and benefits to support decision making about medicines at various levels of the health care system. (USAID, SPS, 2009).

There are two major systems of reporting in Pharmacovigilance these include the passive reporting and active surveillance systems. The passive reporting system or also known as the voluntary reporting system is the most common form of reporting. In this system, there are no active measures taken to find AEs other than encouragement of health care providers and others to report the safety concerns. Active surveillance system on the other hand, is dynamic surveillance system that actively takes measures and force health professionals to report AEs, this particularly the case in clinical trials where cohorts are followed up.

1.4 Pharmacovigilance in Tanzania

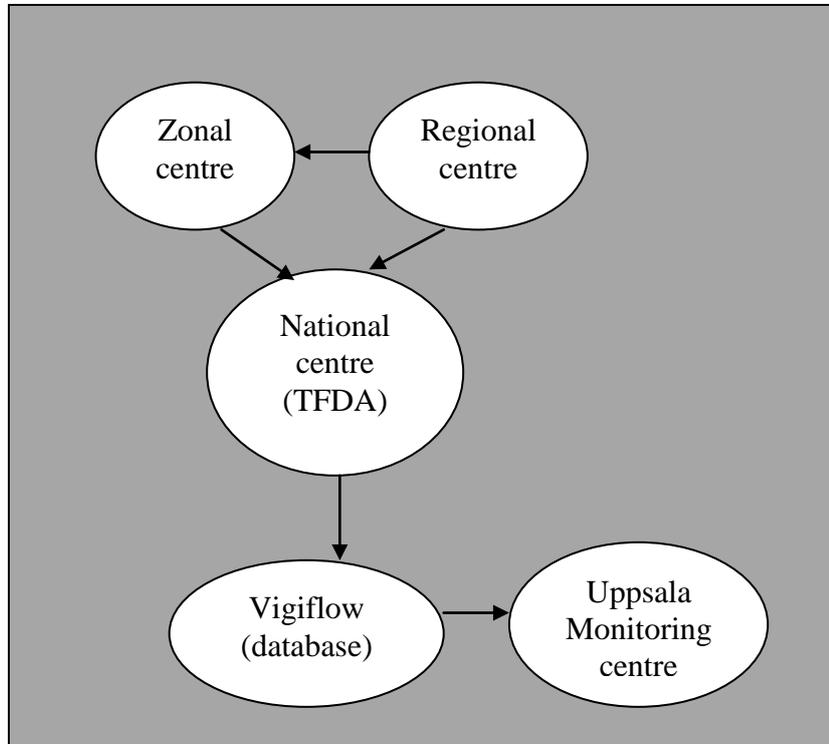
Pharmacovigilance in Tanzania started back in 1989 when the country established the Drug Information Centre known as Tanzania Drug and Toxicology Information Services (TADATIS) at Muhimbili National Hospital formally Muhimbili Medical Centre. The main function of TADATIS was promoting ADRs reporting by health care professionals, analyzing received ADRs reports and submitting reports to the WHO. In addition, TADATIS was responsible for providing pharmaceutical information and education to the public and health care workers about rational use and prescribing of medicines. This centre was later incorporated into the Tanzania Food and Drugs Authority (TFDA) upon its establishment in 2003 and empowered by law to ensure quality, safety and effectiveness of medicines.

In Tanzania Pharmacovigilance system is being implemented largely by using spontaneous reporting (yellow form) method which is coordinated by TFDA together with established zonal pharmacovigilance centres located at Kilimanjaro Christian Medical Centre (KCMC) - Kilimanjaro, Muhimbili National Hospital (MNH) - Dar es Salaam, Bugando Medical Centre - Mwanza and Mbeya Medical Centre- Mbeya.

Like with many other countries, AEs notification in Tanzania has a centralized reporting system, whereby all suspected case reports of AEs are reported to National Drug Regulatory Authority (TFDA) either directly or through the regional and zonal pharmacovigilance centers.

To strengthen and facilitate the ADRs monitoring and reporting system in Tanzania, TFDA has been providing pharmacovigilance awareness trainings for health care professionals, developing standard operating procedures (SOPs) for ADRs data handling and distributing ADRs collecting tools (the yellow forms) for spontaneous reporting. In addition to this, guidelines for spontaneous reporting and monitoring ADRs have been developed to assist health care professionals and other stakeholders in understanding the importance of ADRs monitoring and procedures of reporting ADRs.

Figure 1.3 Tanzanian spontaneous reporting scheme (TFDA Source)



1.5 Spontaneous ADRs reporting

According to the guidelines, one has to complete the ADRs reporting form when the adverse reaction is suspected. The ADRs forms should be obtained, completed and sent to TFDA headquarter offices, TFDA zone offices, Zonal pharmacovigilance centres, Regional Medical Officer's offices, District Medical Officer's offices or the In charges of the regional and district hospitals, health centers, dispensaries and Superintendants of the community pharmacies and private health facilities.

The reporting covers all adverse reactions due to pharmaceutical products, biological (vaccines), herbal drugs, cosmetics and medical devices circulating in Tanzanian market and the followings need to be reported;

- All ADRs as a result of prescription and non-prescription
- All suspected adverse drug reactions regardless of whether or not the product was used in accordance with the product information provided by the company marketing the product

- Unexpected reaction, regardless of their nature or severity, whether not consistent with product information or labeling
- An observed increase in frequency of a given reaction
- A serious reaction, whether expected or not
- All suspected ADRs associated with drug-drug, drug-food or drug-food supplements interactions
- ADRs in special field of interest such as drug abuse and drug use in pregnancy and during lactation
- ADRs occurring from overdose or medication errors
- Unusual lack of efficacy or when suspected pharmaceutical defects are observed

For proper assessment of ADRs case report, the minimum standard information to be provided by the reporter includes information about the patient, description of the adverse drug reactions, the suspected drug or product and the name of reporter.

According to these guidelines, all health care professionals in Tanzania including specialists, doctors, dentists, pharmacists, nurses, assistant medical officers, clinical officers, pharmaceutical technicians, pharmaceutical assistants, traditional medicine practitioners and others health care providers should report suspected ADRs encountered in their patients, as well as products manufacturers and registrants. Those conducting phase I to III clinical trials are also required to report to the TFDA all adverse events encountered during the trials.

1.6 Literature review

Adverse drug reactions (ADRs) are significant causes of morbidity and mortality globally (Franklin et al, 2005). About 6% of all hospital admissions are reported to be due to ADRs (Pirmohamed et al, 1998). The risk of ADRs increases when a patient is hospitalized (Zolezzi M. et al, 2005). In a meta-analysis of 39 prospective studies from USA hospitals to determine the incidence of ADRs in hospitalized patients, the authors reported that ADRs may be the fourth to sixth leading cause of death in hospitalized patients, with serious ADRs occurring in 6.7% and fatal ADRs in 0.32% of the hospitalized cases

(Muehlberger et al, 1997). The Food and Drugs Administration also reported that in 1989 about 120,000 cases of death in USA were due to ADRs (Lazarou et al, 1998).

Apart from the morbidity and mortality associated with ADRs, ADRs are also associated with a considerable economic burden. ADRs have been reported to be associated with a greater length of hospital stay which consequently increases healthcare costs. In USA for example 47.4 billion dollars were spent on approximately 8.7 million drug related admissions in 1994 (Johnson, Bootman, 1995). The findings of the USA Institute of Medicines report estimated that the total costs, including lost income, lost household production, disability, and healthcare costs, due to preventable ADEs was between US\$17 billion to US\$29 billion (Zolezzi M. et al, 2005). What's more is that ADEs are not only costly in terms of health resources but also in terms patients' loss of trust in the health care system which ultimately lead to poor participation. (USAID, SPS, 2009).

In most countries, the spontaneous ADRs reporting programs mainly target physicians as the major source for reporting (Grootheest et al, 2005). However, in an attempt to enhance ADRs reporting globally many countries have advocated that other health professionals such as hospital pharmacists, community pharmacists, nurses and even patients themselves to report suspected ADRs (Davis, 1999; Morrison-Griffiths et al, 2003). The use of the other health professionals seems to have increased the responses rate to voluntary ADRs reporting as can be seen in the case of China. (State Food and Drugs Administration, (SFDA) statement, 2010 by Beijing, April 25 Xinhua).

Pharmacists are the experts of medicines; their education puts their profession in an apt position to be key players of pharmacovigilance. However, the role and contribution of pharmacists and other pharmaceutical professionals in the reporting of ADRs is not extensively been explored. There still seem some mixed opinions globally of whether to allow pharmacists to report ADRs or not. Scandinavian countries are strictly against allowing pharmacists to report ADRs independently (Olsson, 1999; Saarinen, 2002), while on the other hand in Netherlands, 40% of all ADRs reports are submitted by pharmacists (Major, 2002).

In Tanzania, the Guidelines for Monitoring and Reporting ADRs, 2006 has listed the following professionals as key players for reporting of ADRs; as, doctors, dentists, pharmacists, nurses, assistant medical officers, clinical officers, pharmaceutical technicians, pharmaceutical assistants, traditional medicine practitioners and others health care providers. Pharmaceutical professionals (ie pharmacists, pharmaceutical technicians and pharmaceutical assistants) although mentioned in the TFDA guidelines have not per se played an active role in ADRs reporting. Most of ADRs reports in Tanzania come from clinical officers. (TFDA, Department of Pharmacovigilance and Clinical Trial Source)

Spontaneous ADRs reporting is still the hall mark of many pharmacovigilance systems although the response rate of voluntary ADRs reporting remains poor globally (Rawlins, 1995). Several studies have been conducted worldwide, to assess the attitudes of health professionals to their national ADRs reporting programs with the aim of identifying reasons for underreporting and to determine what steps to increase reporting rates. Many of these studies have identified some of the major factors associated with underreporting to include; Professionals uncertainty as to whether the reaction was caused by the medication, ADRs considered not important enough to be reported, ADRs are well known or common for them report, unaware of the need to report ADRs, lack of knowledge on how to report ADRs, unavailability of reporting forms, Health professionals too busy to report ADRs, Difficulty in finding the right form, and considering reporting of ADRs as too bureaucratic (Bawazir S.A, 2006).

Other reported barriers to ADRs reporting include; Lack of awareness by health care professionals of the importance of ADRs reporting, Low percentage of staff trained in pharmacovigilance, Lack of priority setting within the medicine regulatory authority and public health programs pharmacovigilance is not emphasized enough, Lack of technical and financial resources at the facility to collect and analyze the data, Weak organizational structure at the medicine regulatory authority, leading to uneven distribution and collection of ADRs forms from health Facilities, Lack of regular follow-up and supervision by the pharmacovigilance coordinator at the medicine regulatory authority (USAID, SPS, 2009). These barriers have also been observed in Tanzania as reported in Consultative Meeting Report for Pharmacovigilance; Tanzania and beyond; 2006.

In a case-control study done in Portugal to assess the influence of pharmacists' attitudes on adverse drug reaction reporting, it was found that under-reporting was strongly associated with certain attitudes, possibly indicating that under-reporting could be minimized through educational interventions targeted at changing such attitudes (Herdeiro et al, 2006). Similar observations were also seen in Malaysia, Hong Kong, India, Iran, Saudi Arabia, New Zealand, and the United Kingdom. (K-N Ting et al, 2010; Lee KK et al, 1994, Madhan Ramesh et al, 2009; Ghazal V. et al, 2008, Bawazir, 2006, Zolezzi M. et al, 2005; Christopher F et al, 2001)

The importance of reporting ADRs cannot be overemphasized. Reporting ADRs is the professional obligations of all healthcare professionals and thus there is great need to create awareness and continuous promote reporting of ADRs among healthcare professionals globally.

1.5 Problem Statement

Spontaneous (yellow card) reporting of ADRs remains to be the foundation of pharmacovigilance and is very comprehensive system for maintaining patient safety. According to the WHO standards, countries with the best reporting rates must generate over 200 reports per 1,000,000 inhabitants per year. However, reporting of serious ADRs rarely exceeds 10% (Rawlins, 1995). For instance, Iran with a population of over 60 million was expected to receive at least 12,000 reports per year. Unfortunately this is not so, considering the fact that only 2,330 reports were sent to the Iranian Pharmacovigilance Centre in the year 2006 (Ramezani, Javid, 2007).

Similarly Malaysia with the fact that it has a good reporting system in place; it still suffers from a low level of reporting from health professionals (McEwen, 2007). The few studies in Malaysia that have investigated the low reporting rates of ADRs amongst the health professionals indicated that up to 40% of the physicians were unaware of the existence of the ADRs reporting system (Aziz et al, 2007; Harun A, 2009).

These low reporting rates are not only restricted to developing nations as studies have also shown that ADRs reporting rate in USA to be as low as 1 - 6% (Chyka, 2000). In United Kingdom since the yellow card spontaneous ADRs reporting scheme was initiated, the number of yellow cards increased to reach a peak in the early 1990s. Since then, the number received annually has fallen slightly and stabilized at about 17,000 per annum. Reporting from hospitals, where most newly marketed drugs will be used, has always been lower than reporting from primary care (Chaplin, 1990).

The situation is not different in Tanzania where despite the presence of the TFDA Guidelines for ADRs monitoring and reporting, the number of submitted reports from both public and private health facilities is still low. For example in the year 2005/2006, TFDA received only 107 ADRs reports, and the number kept on decreasing to reach 26 ADRs reports in the year 2007/2008. The situation is worse in private health facilities, particularly community pharmacies where their contribution in ADRs reporting is minimal (TFDA 2005/2006 and 2007/2008 Annual Reports). As a result of this, the true ADRs burden of the country has not been determined (TFDA ADRs Guidelines, 2006).

The inability to collect and reporting ADRs in many instances is often associated with a high price in terms of patient morbidity and mortality as in the case of thalidomide tragedy in the early 1960s.

1.6 Rationale

The majority of the population uses community pharmacies to get medical advice instead of going to the hospitals as means to avoid consultation charges, hospital bureaucracy and escape the out stock saga common in government health facilities. Thus community pharmacies are the first point of contact of patients with the health care system in many developing countries (Stenson et al, 2001). The general public uses, community pharmacies as loop hole to self medicate, a factor known to contribute towards ADRs either by the drug itself being wrongly dispensed or by causing interactions with other unknown prescription drugs which the patient is taking at the same time. In Tanzania for

instance there is evidence that self medication among Tanzanians is very common (Kagashe et al, 2004, Mwambete, 2010).

Due to the fact that community pharmacies in developing countries act as one stop centers for cash strapped patients to get medical advice and treatment, they make excellent centers to observe and report ADRs. The role of community pharmacies' dispensers can thus be extended to include spontaneous reporting of ADRs with the aim of maintaining patient safety and improving the current national pharmacovigilance system in Tanzania. Immediate measures must be taken to determine the suitability of these sites as ADRs monitoring and reporting facilities.

With this in mind the aim of this study was to determine the knowledge, attitude and practices towards ADRs reporting among community pharmacy dispensers in Dar es salaam. We anticipate that the study findings will assist to determine whether dispensers in the community pharmacies are adequately qualified, equipped and willing to spontaneously report ADRs in the future.

1.7 Research Questions

- What is the knowledge of pharmacists and other dispensers in community pharmacies about ADRs and ADRs reporting?
- What do they do when they come across to cases with ADRs?
- What is their attitude and how do they perceive ADRs reporting?
- Are they equipped with necessary Guidelines, SOPs and reporting forms in their pharmacies?
- What causes poor reporting of ADRs cases?

1.8 Objectives

Broad Objective

To determine the knowledge, attitude and practices towards ADRs reporting among dispensers in community pharmacies in Dar es salaam region.

Specific Objectives

- To determine the knowledge of ADRs reporting among dispensers of community pharmacies in Dar es salaam
- To determine the attitude of community dispensers in Dar es salaam pharmacies towards ADRs reporting.
- To determine the practices of ADRs reporting of community dispensers in Dar es salaam pharmacies.

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study area

The study was conducted in Dar es Salaam region targeted retail pharmacies from all three municipals namely Ilala, Temeke and Kinondoni. Dar es Salaam region was conveniently selected because it is the only region where majority of pharmacies are located and therefore appropriate for the intended sample size. About 56% (304 out of 542) of retail pharmacies in the country are in Dar es Salaam (TFDA Database November 2010).

2.2 Study population

The study involved health professionals working in retail pharmacies as dispensers.

2.3 Study design

The design of the study was cross sectional descriptive.

2.4 Period of study

The study was done from February 2011 to June 2011.

2.5 Sampling and samples size

The following formula was used to obtain the minimum required sample size;

$n = Z^2P(100-P)/\epsilon^2 + 10\%$ for non response; where

n = minimum required sample size

Z = percentage point of the normal distribution corresponding to the level of significance (for 5% significance level, Z =1.96)

P= percentage of pharmacists who are knowledgeable to ADRs reporting (10%)

ϵ = maximum likely error (taken as 2%)

The minimum required sample size was 250 dispensers. However, 300 dispensers from 150 pharmacies were enrolled to cater for non response and loss to follow up. These

pharmacies were selected from a list of 304 retail pharmacies obtained from TFDA by simple random sampling whereby each pharmacy was given a number (1 to 304) written on small pieces of paper. All the 304 papers were placed in a box and shaken to ensure randomization. After each shaking of the box, a paper was picked until a total of 150 papers were picked to constitute a sample of pharmacies for the study.

2.6 Inclusion criteria

Pharmacist in charge of the pharmacy and health personnel employed as pharmaceutical dispenser in respective pharmacy.

2.7 Exclusion criteria

Not willing to participate in the study or dispensers on leave during the study.

2.8 Instrument and pre-testing

Data were collected by using self administered questionnaires translated in both english and swahili languages. Prior the study, a pilot testing of questionnaire's validity was carried out by interviewing 20 dispensers from 10 selected pharmacies to fine tune the questionnaires.

The final questionnaire comprised of five parts containing 31 questions. The first part consisted of eleven questions which covered demographic and continuing education information. The second part contained six questions which were used to assess respondents' knowledge towards ADRs reporting in terms of the meaning of ADRs reporting; profession required to report; where to report; which reactions to be reported and how to report ADRs. A knowledge scale was prepared as a guiding tool in assessment of knowledge level, whereby one point was awarded for each correct answer. Respondents' knowledge was then categorized into two categories, whereby those who answered correctly 4 or more questions were categorized as having "good" knowledge and those answered less than 4 questions were categorized as having "poor" knowledge.

The third part contained six questions which assessed practice towards ADRs reporting in terms of adherence to the Guidelines for ADRs monitoring and reporting. One and zero scores were merited for adherence and non adherence respectively.

The fourth part of questionnaire consisted of five questions which assessed respondents' attitude towards ADRs reporting. A likert scale was used for assessing attitude level whereby five responses were used as follows; strongly agree, agree, not sure, disagree and strongly disagree. These responses were used to group respondents into positive attitude and negative attitude whereby strongly agree and agree responses were taken as positive attitude and disagree and strongly disagree responses were taken as negative attitude.

The last and fifth part had three questions which were meant to establish barriers against ADRs reporting and education needs to strengthen ADRs reporting system.

2.9 Data collection procedure

During survey, purpose of the study was explained to participants both verbally and by covering letter which was attached with consent form and ethical clearance. Dispensers who agreed to participate in the study were requested to complete questionnaire and hand it back immediately. Those who were very busy at the moment, questionnaires were left to them and collected after a maximum of two working days. The returned questionnaires were checked for completeness, consistency and clarity before collected.

2.10 Ethical Considerations

The study received ethical clearance from MUHAS high degree ethical committee of research and publication committee. Permission to do the study was granted by pharmacy owners after receiving request letter to conduct the study. Consent for dispensers' participation was sought from dispensers themselves and confidentiality on their information was highly maintained.

2.11 Data treatment and analysis

All questionnaires were identified by instituting identification number and the questions were coded. SPSS version 16 was used for data entry, cleaning, categorization of variables and eventually analysis. The Frequency distribution was used to show

distribution of both the outcome and explanatory variables. Chi square test was used to test for associations between the outcome variables and the explanatory variables. P value of less than 0.05 was considered significant.

CHAPTER THREE

3.0 RESULTS

Out of the 300 administered questionnaires, 254 adequately filled questionnaires were returned to researcher resulting in response rate of 84.67%. The non returned questionnaires were due to misplacement in the pharmacies and some were not collected because they were not filled.

3.1 Social demographic characteristics

Table 3.1 Summary of social demographic characteristics of the respondents (n = 254)

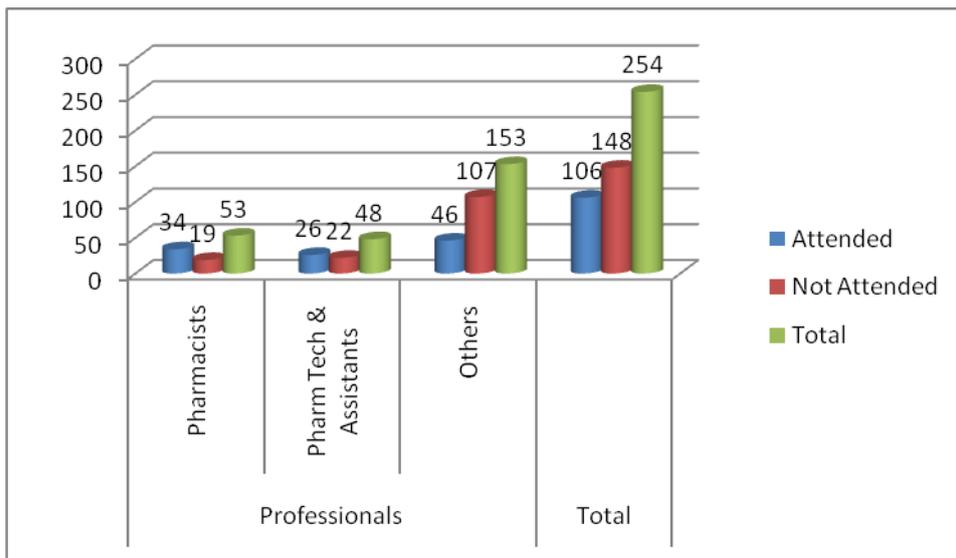
Characteristic	Number	Percentage
Sex		
Female	181	71.3
Male	73	28.7
Age group category (in years)		
below 30	96	37.8
30 to 50	147	57.9
above 50	11	4.3
Median Age	31	
Profession		
Pharmacists	53	20.9
Pharm Tech & Assistants	48	18.9
Others*	153	60.2
Experience in drug dispensing		
5 years and below	102	40.2
6 to 15 years	121	47.6
More than 15 years	31	12.2
Continuing professional education (CPE) Attendance		
Yes	106	41.7
No	148	58.3

* Others included clinical officers, nurse officers and nurse assistants (nurse assistants alone constituted 52.0% of respondents)

The Majority (71.3%) of respondents as indicated in table 3.1 were females. The age of the respondents ranged from 18 to 76 years (median age 31 years). The majority of dispensers (57.9%) were aged between 30 to 50 years. Professionally, 20.9% of respondents were pharmacists, 18.9% were pharmaceutical technicians and assistants and the rest (60.2%) were non pharmaceutical professions (i.e clinical officers, nurse officers and nurse assistants). Among the non pharmaceutical personnel carders of dispensers 52.0% were nurse assistants.

The majority of respondents (87.8%) had 1 to 15 years dispensing experience while the rest (12.2%) had over 15 years of dispensing experience. Over half of the respondents (58.3%) had never attended any continuous pharmaceutical education within last two years. Pharmaceutical professionals were the dispensers that had attended continuous pharmaceutical education the most (pharmacists (64.2%) and pharmaceutical technicians and assistants (54.2%) see figure 3.1

Figure 3.1 Professionals attendance of CPE (n= 254)



3.2 Knowledge about ADRs reporting

Table 3.2 Summary of responses to questions assessing knowledge to ADRs reporting

Question	Respondents with positive responses (n = 254)	
	Number	Percentage
Know the meaning of ADRs reporting	109	42.9
Describe ADRs reporting	42	16.5
Professionals required to report ADRs		
Doctors	148	58.3
Pharmacists	198	77.9
Nurses	91	35.8
Traditional medicines practitioners	27	10.6
Others	20	7.9
Where to report ADRs		
TFDA HQ	171	67.3
TFDA Zonal Offices	117	46.1
Zonal Pharmacovigilance Centre	86	33.9
DMO's Office	68	26.8
Others	6	2.4
Reactions to be reported		
Conventional medicines	212	83.5
Vaccines and blood products	88	34.6
Herbal and traditional medicines	53	20.9
Cosmetics	96	37.8
Medical devices	67	26.4
Know the form used in reporting	81	31.9
Able to mention the form	52	20.5
Know how to report ADRs on the form	90	35.4
Able to explain correctly	74	29.1

Table 3.2 indicates that, only 42.9% of respondents knew what is adverse drug reaction reporting and only 16.5% were able to correctly describe it. Pharmacist was the mostly (by 77.9% of respondents) reported profession required to report ADRs as compared to other professions. TFDA headquarter and zone offices were reported by the majority of respondents (67.3% and 46.0% respectively) as places to send reports of adverse drug

reactions, however only 26.7% indicated the DMO offices. The majority (83.5%) of respondents reported that reactions due to conventional medicines should be reported whereas only 37.8%, 34.6%, 26.4% and 20.9% reported reactions due to cosmetics, vaccines, medical devices and traditional medicines respectively. Only 20.5% of respondents knew the name of the form used in ADRs reporting and only 29.1% knew the details to be put on the form.

Generally, the respondents had poor knowledge with regard to ADRs reporting. Out of 254 respondents, only 35 (13.8%) were able to respond correctly to 4 up to 6 questions assessing knowledge (Knowledge Scale). 219 respondents (86.2%) had poor knowledge on ADRs reporting in terms of what is adverse drug reaction reporting, profession required to report ADRs, where reports are supposed to be sent, which reactions to be reported and how to report the ADRs as could not answer more than three questions correctly see figure 3.2.

Figure 3.2 Knowledge of dispensers towards ADRs reporting

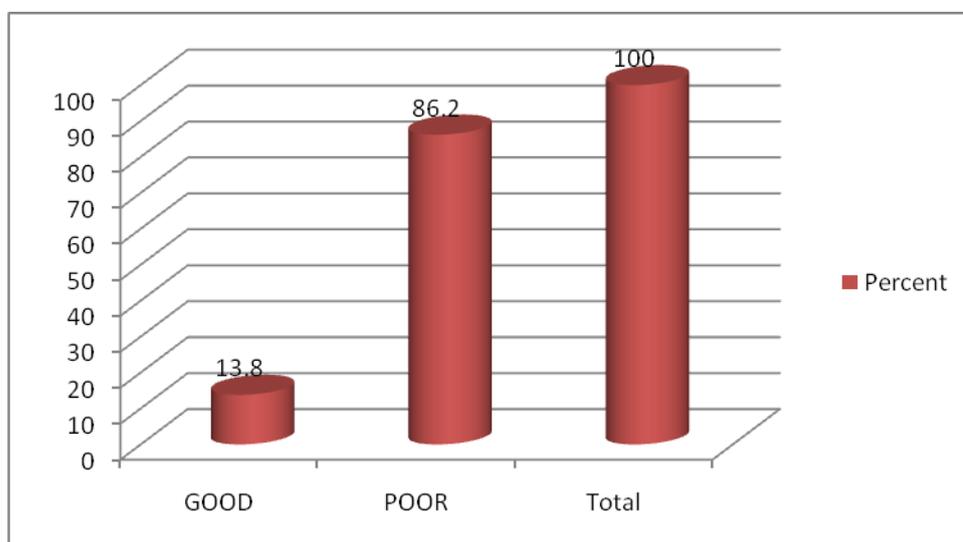


Table 3.3 ADRs reporting Knowledge by sex, age category, profession, education level, dispensing experience and CPE attendance

		Knowledge to ADRs reporting (n=254)		Total	P value
		GOOD	POOR		
Sex	Male	22 (30.1%)	51 (69.9%)	73	0.000
	Female	13 (7.2%)	168 (92.8%)	181	
				$\chi^2 = 27.07, df = 2$	
Age category	below 30	7 (7.3%)	89 (92.7%)	96	0.010
	30 to 50	25 (17.0%)	122 (83.0%)	147	
	above 50	5 (45.5%)	6 (54.5%)	11	
				$\chi^2 = 9.16, df = 2$	
Profession	Pharmacists	22 (41.5%)	31 (58.5%)	53	0.000
	Pharm Tech & Assistants	10 (20.8%)	38 (79.2%)	48	
	Others	3 (2.0%)	150 (98.0%)	153	
				$\chi^2 = 57.72, df = 2$	
Dispensing Experience	5yrs and below	8 (7.8%)	94 (92.2%)	102	0.000
	6 to 15 years	15 (12.4%)	106 (87.6%)	121	
	More than 15 years	12 (38.7%)	19 (61.3%)	31	
				$\chi^2 = 18.62, df = 2$	
Attended CPE	YES	22 (20.8%)	84 (79.2%)	106	0.017
	NO	13 (8.8%)	135 (91.2%)	148	
				$\chi^2 = 8.15, df = 2$	
Total		35 (13.8%)	219 (86.2%)	254	

Table 3.3 illustrates how ADRs reporting knowledge correlates with sex, age, profession, dispensing experience and CPE attendance of the respondents. Male respondents were more knowledgeable about ADRs reporting (30.1%) as compared to female respondents (7.2%) (P value = 0.000). Respondents aged 50 years and above were more knowledgeable (45.5%) about ADRs reporting than those aged below 50 years (P value = 0.010).

Pharmacists and other pharmaceutical professionals (i.e pharmaceutical technicians and pharmaceutical assistants) were found to have more knowledge on ADRs reporting than other non pharmaceutical professionals (P value = 0.000). Table 3.3 also indicates the influence of dispensing experience and CPE attendance to ADRs reporting knowledge. Respondents who had more than 15 years experience in dispensing were more knowledgeable (38.7%) as compared to those with 6 to 15 years and below 6 years

experience (P value = 0.000). Furthermore, it was observed that, dispensers who had attended continuous pharmaceutical education (20.8%) had more knowledge on ADRs reporting than those who had not attended (8.8%) (P value = 0.017).

Table 3.4 provides information indicating the influence of continuous education training on the knowledge to ADRs reporting. The majority of (67.0%) respondents who had attended continuous training had heard about ADRs and ADRs reporting as compared to those who had not attended.

Table 3.4 CPE attendance as a source for ADRs reporting knowledge (n =254)

		Heard about ADRs reporting		Total
		YES	NO	
CPE	Attended	71 (67.0%)	35 (33.0%)	106 (100%)
	Not Attended	5 (3.4%)	143(96.6%)	148 (100%)
	Total	76 (29.9%)	178 (70.1%)	254 (100%)

3.3 ADRs reporting Practices

Table 3.5 Summary of responses to questions assessing the Practice towards ADRs reporting

Question	Respondents with positive responses (n= 254)		
	Number	Percentage	
Is there a system of monitoring and reporting ADRs?	95	37.4	
Who is the Focal person? (n= 95)	Pharmacist	79	83.2
	Other Profession	16	16.8
Ever reported ADRs cases?		22	8.7
Where did you report? (n = 22)	To Pharmacist I/C	5	22.7
	Prescribing Doctor	2	9.1
	Pharmaceutical Meetings	1	4.6
	TFDA	14	63.6
Are the forms for spontaneous reporting of ADRs available?		47	18.5
Have you ever filled a spontaneous ADRs reporting form?		25	9.8
What reference materials are available at your pharmacy?	TNF	156	61.4
	Good Dispensing Practice	114	44.9
	List of Registered Medicines	115	45.3
	Guidelines for Monitoring and Reporting of ADR	29	11.4

Table 3.5 indicates that only 37.4% of respondents have a system of monitoring and reporting adverse drug reactions in their pharmacies. Pharmacists were identified (83.2%) the focal persons to report ADRs. Only 8.7% of respondents had ever reported cases of adverse drug reactions and most of them (63.6%) had reported to TFDA. Only a few respondents (18.5%) had ADRs reporting forms (yellow forms) and only 11.4% had Guidelines for Monitoring and Reporting of ADRs in their pharmacies. Only 9.8% of the respondents had ever filled out these forms.

3.4 Attitude towards ADRs reporting

Table 3.6 Summary of responses to questions assessing the Attitude towards ADRs reporting

Statement	Level of agreement of respondents (n=254)	
	Agree	Not Agree
ADRs reporting is part of professional role	249 (98.0%)	5 (2.0%)
Reporting of ADRs is necessary new drugs	203 (79.9%)	51 (20.1%)
Reporting of ADRs is necessary for serious adverse drug reaction	153 (60.2%)	101 (39.8%)
Reporting of ADRs is necessary for well recognized adverse drug reaction	124 (48.8%)	130 (51.2%)
Reporting of should be voluntary	65 (25.6%)	189 (74.4%)

The majority of respondents (98.0%) agreed that ADRs reporting was part of their professional roles. The majority (79.9% and 60.3% respectively) agreed that reporting is necessary for new drugs and serious ADRs, but only a few (25.6%) agreed that ADRs reporting should be voluntary. The majority of respondents (68.9%) had positive attitude towards ADRs reporting system.

Figure 3.3 Attitude of dispensers towards ADRs reporting

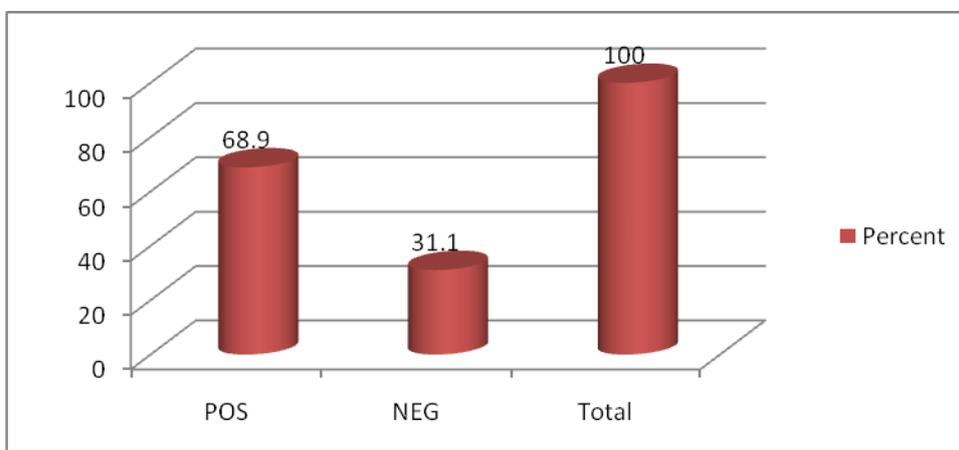


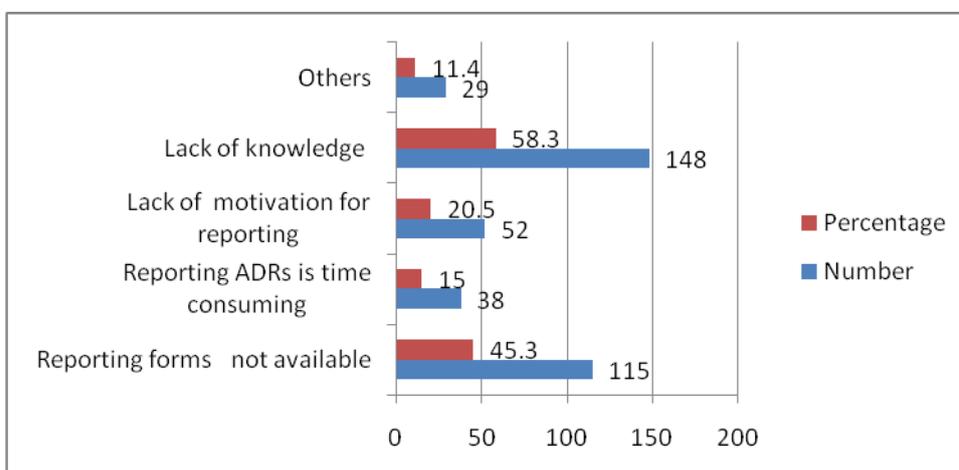
Table 3.7 Level of Attitude by sex, age category and profession

		Attitude towards ADRs reporting (n=254)		Total	P value
		Positive	Negative		
Sex	Male	59 (80.8%)	14 (19.2%)	73	0.019
	Female	116 (64.1%)	65 (35.9%)	181	
	Total	175 (68.9%)	79 (31.1%)	254	
				$\chi^2 = 7.89, df = 2$	
Age category	below 30	54 (56.2%)	42 (43.8%)	96	0.002
	30 to 50	111 (75.5%)	36 (24.5%)	147	
	above 50	10 (90.9%)	1 (9.1%)	11	
	Total	175 (68.9%)	79 (31.1%)	254	
				$\chi^2 = 12.65, df = 2$	
Profession	Pharmacists	42 (79.2%)	11 (20.8%)	53	0.016
	Pharm Tech & Assistants	38 (79.2%)	10 (20.8%)	48	
	Others	95 (62.1%)	58 (37.9%)	153	
	Total	175 (68.9%)	79 (31.1%)	254	
				$\chi^2 = 8.32, df = 2$	

The male respondents had more (80.8%) positive attitude towards ADRs reporting as compared to female respondents (64.1%), (P value = 0.019). Respondents aged 50 years and above had more positive attitude (90.9%) than younger respondents (P value 0.002). Pharmaceutical professionals also appeared to have a more (79.2%) positive attitude than non pharmaceutical professionals (62.1%), (P value = 0.016).

3.5 Barriers to ADR reporting

Figure 3.4 Summary of responses to barriers of ADRs reporting (n = 254)



The majority (58.3%) of respondents reported lack of knowledge on how to report, where to report and when to report as major barrier for ADRs reporting. Nearly half (45.3%) reported unavailability of reporting (yellow) forms, (20.5%) reported lack of motivation and few (15.0%) reported that ADRs reporting is time consuming.

Other reported barriers was the distance to TFDA Offices, reporting forms are not user friendly, inadequate human resources to handle pharmacovigilance issues at pharmacies, poor supervision and follow up by TFDA officials, lack of information and feedback from TFDA, lack of continuous education, and patients' ignorance to reporting, unknown system of reporting and business reasons including security in business.

3.6 Professional training

The study revealed that the majority (63.8%) of respondents were not satisfied with their professional training with regard to ADRs reporting. Most of respondents (96.1%) indicated willingness to attend further courses or trainings on pharmacovigilance in order to improve their ability to spontaneously report ADRs.

CHAPTER FOUR

4.0 DISCUSSION AND CONCLUSION

This is the first study in Tanzania to assess the knowledge, practice and attitude of pharmaceutical dispensers towards ADRs reporting and pharmacovigilance, despite the fact that pharmacovigilance system has been present for more than 20 years now. The findings of this study suggest that there may be several factors that are contributing towards the poor reporting of ADRs among dispensers in community pharmacies

What was evident from the study is that there is a gross problem of reporting adverse events and specifically the ADRs by community pharmacies. The study findings indicate that there is poor knowledge towards ADRs reporting among dispensers in the community pharmacies. The study indicates that only 13.8% of the interviewed dispensers were knowledgeable to ADRs reporting in terms of what is to be reported, who should report, when to report, how to report and where to report the ADRs encountered in the patients. For example the study revealed that only 42.9% claimed to know the meaning of ADRs reporting although very few (16.5%) were able to explain correctly what the ADRs reporting is. The findings of this study do not differ much from studies conducted in other countries assessing the KAP (Knowledge, Attitude and Practices) towards ADRs monitoring and reporting system among the health care professionals. For example studies involving community pharmacists in Saudi Arabia, Iran and Malaysia reported the poor knowledge towards ADRs reporting among the pharmacists (Bawazir S.A. et al, 2006, Ghazal V. et al, 2008, and K-N Ting et al, 2010). The study done in Saudi Arabia indicated that 86.8% of surveyed community pharmacists were not aware of the country's ADRs reporting program while another study in Iran 30% of pharmacists were not aware of Iranian pharmacovigilance centre. The findings of this study and those done in other countries all confirm that pharmacists and other pharmaceutical dispensers have limited knowledge regarding pharmacovigilance and ADRs reporting in particular.

The poor knowledge of dispensers in this study was however contributed mainly by the fact that many of them were of the non pharmaceutical cadre, 52.0% being the nurse assistants. This was reflected in the significant difference in knowledge (P value = 0.000)

towards ADRs reporting when comparing pharmaceutical and non pharmaceutical professionals in the community pharmacies. Moreover, attendance of CPE was shown to significantly increase the ADRs reporting knowledge of dispensers in the community (P value = 0.017), as observed that pharmaceutical professionals had a tendency to attend more CPE than non pharmaceutical professionals. The importance of CPE in promoting ADRs reporting has been shown by several studies around the world. For example a study in the UK concluded that pharmaceutical personnel require continuing education in order to raise further the profile of their role in reporting of suspected ADRs to their national pharmacovigilance program (Davis et al, 1999). While an Indian study to investigate attitudes and perception of medical practitioners on ADRs reporting recommended the improvement of continuous trainings among the healthcare profession to enhance ADRs monitoring and reporting (Sourav Ghosh et al, 2010).

Lack of knowledge on what is to be reported, who should report, when to report, how to report where to report, together with unavailability of ADRs reporting forms influenced the practice towards ADRs reporting among dispensers in community pharmacies. From the study it could be observed that only 20.5% knew the name of ADRs reporting form (yellow form) and only 29.1% were able to explain correctly how to report ADRs including how to fill the details of reporting form. It was thus not surprising to find that only 9.8% of dispensers claimed to have filled the yellow forms and that only 8.7% had ever submitted ADRs reports to the relevant authorities. The finding that the majority of community dispensers in Dar es salaam rarely practiced filling out and submitting ADRs forms was reinforced by the fact that only few dispensers (26.8%) knew that offices of District Medical Officers was also an approved sites to send the duly filled ADRs reporting forms. Poor practice among Tanzanian pharmaceutical dispensers with regard to ADRs reporting is similar to the findings of Malaysia and Turkish community pharmacists. In Malaysia only one pharmacist submitted ADRs reports to the regulatory authority (K-N Ting et al, 2010), whereas only 6.7% of Turkish pharmacists send ADRs reports to their National pharmacovigilance centre (Zerrin Toklu H et al, 2008) .

Unavailability of ADRs reporting forms and ADR guidelines in community pharmacies also considerably influenced the practice of ADRs reporting. The study revealed that community pharmacies are not adequately equipped with necessary guidelines and tools to guide and facilitate dispensers in monitoring and reporting of ADRs at their working places. The study found that only 18.5% of dispensers claimed to have ADRs reporting forms available in their pharmacies and that only 11.4% had Guidelines for Monitoring and Reporting of ADRs. This is contrary to the claimed efforts of National Drug Regulatory Authority (TFDA) that much effort was undertaken to disseminate these tools (Dat Tran et al, 2006) all over Tanzania. Availability of appropriate guidelines and reporting forms was expected to provide proper guidance and procedures to be followed by dispensers during reporting of ADRs including how to fill in the details of yellow forms, which would have greatly facilitated the pharmacovigilance exercises in Tanzania.

Despite of the poor knowledge and practices exhibited by the dispensers in Dar es salaam, the study revealed that majority (68.9%) of dispensers had positive attitude towards ADRs reporting. These results are very similar to figures reported for community pharmacists in Holland (Grootheest AC van et al, 2002) and United Kingdom (Houghton J, et al, 1999). Our findings show that 98.0% of dispensers agreed that ADR reporting is important and part of their professional roles. Furthermore the majority (79.9% and 60.2%) agreed that reporting of ADRs is necessary for new medicinal products and serious adverse drug reactions respectively. The positive attitude towards ADRs reporting signifies that dispensers are willing and eager to learn and practice if knowledge about ADRs reporting is imparted to them and that they are adequately equipped and facilitated. Their willingness is indicated by the fact that the majority (96.1%) of dispensers were willing to attend further courses or trainings on pharmacovigilance in order to improve their ability to spontaneously report ADRs of patients who visit their pharmacies for care. The challenge thus remains to policy makers, regulatory authority and other stakeholders to put more emphasis on pharmacovigilance, by providing sufficient and adequate trainings and opportunities for community pharmaceutical dispensers.

The present study revealed a number of barriers that prevent dispensers of community pharmacies from reporting ADRs effectively. These barriers include the presence of

unqualified personnel in community pharmacies, lack of knowledge on what is to be reported, who should report, when to report, how to report and where to report among dispensers in community pharmacies, and unavailability of reporting forms and relevant guidelines in the pharmacies. In addition to these observed barriers, the respondents also mentioned the complexity and lack of user friendliness of reporting forms lack of feedback from TFDA on reported ADRs, lack of motivation, inadequate human resources to handle pharmacovigilance issues in the pharmacies and ADRs reporting is time consuming as barriers for ADRs reporting. All these barriers contribute to poor ADRs reporting in community pharmacies hence pharmacovigilance stakeholders such as TFDA, MoHSW would have to devise strategies that will try to remove or reduce them so that ADRs can be effectively monitored through the community pharmacies.

ADRs reporting rate may be enhanced by overcoming these barriers as seen in other studies in the world. Some of these barriers can be solved through proper management and advertising of pharmacovigilance program such as disseminating of reporting forms and appropriate guidelines making them widely available; and creating a closer relationship between dispensers and ADRs reporting centres by strengthen feedback of pharmacovigilance activities to reporters. In order to facilitate the ADRs reporting, the reporting system should be reviewed to become user friendly. For example instead of using only the approved yellow forms which have been proved to be unavailable in most areas, there should be flexibility of using other means such as electronic yellow forms that can be retrieved online. The lack of knowledge seen among community dispensers could be addressed through intensive training and workshops about the concept of pharmacovigilance, spontaneous ADRs reporting and the structure of ADRs reporting system in Tanzania.

Pharmacists in other countries contribute heavily to spontaneous reporting programs (Bawazir S.A, 2006). It is reported that Canadian, Australian, Dutch, Japanese, Spanish and Portages' community and hospital pharmacists contribute 88.3%, 40.3%, 40.2%, 39%, 25.9%, and 23.4% of all ADRs reports received by their national programs, respectively (Grootheest K van, et al, 2004). In our study, most (77.9%) of interviewed dispensers were of the opinion that pharmacists were right professionals required to report ADRs,

especially when one takes into consideration their professional background in pharmacotherapy and their roles as superintendants in the community pharmacies. Pharmaceutical professionals have a central role to play in monitoring and evaluating drug safety by contributing to the prevention, identification, documentation, and reporting of ADRs (Kees van Grootheest et al, 2003). This provides a confidence in investing train of pharmaceutical cadre to report all ADRs encountered in their pharmacies.

In conclusion, the results of our study clearly indicate despite of positive attitude that the community dispensers in Dar es salaam currently, lack sufficient knowledge and practice to perform ADRs reporting effectively. As large proportion of the Tanzanian population depend on community pharmacies as first point of contact for health care, stakeholders in pharmacovigilance should strive to ensure that community pharmacies are staffed with qualified personnel and appropriate tools to ensure effective ADRs reporting.

Thus sincere and sustained efforts are required to create awareness about pharmacovigilance through provision of appropriate education and trainings, increasing the numbers of pharmaceutical cadre and availability of reporting forms in community pharmacies.

CHAPTER FIVE

5.0 RECOMMENDATIONS

TFDA should provide continuous and regular educational training to pharmaceutical dispensers on the importance of pharmacovigilance and their roles as health professionals, in order to improve their ability to identify and report ADRs.

TFDA should strengthen the existing pharmacovigilance system by advocating an active rather than passive monitoring system of pharmacovigilance in Tanzania. The new system should provide feedback to healthcare personnel for reported ADRs so as to encourage and motivate them to report more. In addition TFDA should make ADRs reporting forms a regulatory requirement for establishment and running a community pharmacy. This will ensure their availability and thus promote reporting.

The MoHSW in collaboration with Ministry of Higher Education, Science and Technology should find measures to improve the output of pharmaceutical professional cadres from Universities and Schools in order to increase the current ratios of pharmaceutical professionals per population. Increased number of pharmaceutical cadre would ultimately replace non pharmaceutical cadres in community pharmacies whose knowledge is not sufficient for ADRs reporting to be done effectively. Furthermore there is also a need to review pharmaceutical curriculum at all levels to incorporate Pharmacovigilance and ADRs reporting system.

Pharmacy Council should include continuous pharmaceutical education in Pharmacovigilance as part of licensures requirements of pharmaceutical dispensers in Tanzania.

5.1 STUDY LIMITATIONS

The major limitation of this study however is that the findings were restricted to only dispensers in community pharmacies of only one region. The findings would have been more meaningful if the study was carried out in more than one region, and that it included qualitative approach (in depth interviews, focus group discussions) in order to get a better understanding of the knowledge, opinions and attitudes of community dispensers towards ADRs reporting. In addition to this the views of the National Drug Regulatory Authority (TFDA) were not captured in this study.

CHAPTER SIX

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CHAPTER SEVEN

7.0 APPENDICES

7.1 Questionnaire- English version

QUESTIONNAIRE TO DETERMINE KNOWLEDGE, ATTITUDE AND PRACTICES TOWARDS ADVERSE DRUG REACTIONS REPORTING AMONG DISPENSERS IN COMMUNITY PHARMACIES IN DAR ES SALAAM REGION.

Code No.....

INSTRUCTIONS
PLEASE USE YOUR TIME TO ANSWER THE QUESTIONS IN THIS QUESTIONNAIRE WITH YOUR BEST CAPABILITY. CIRCLE THE BEST CHOICE IN THE MULTIPLE CHOICE QUESTIONS. YOU ARE ALLOWED TO CIRCLE MORE THAN ONE RESPONSE WHEN NECESSARY. IF YOU FIND DIFFICULT IN UNDERSTANDING THE QUESTION, PLEASE ASK FOR CLARIFICATION BEFORE ANSWERING.

1. Sex
 - a) Male
 - b) Female

2. Age (in years)

3. Profession
 - a) Pharmacist
 - b) Pharmaceutical technician
 - c) Clinical officer
 - d) Nurse assistant
 - e) Other (mention)

4. Highest level of Education (mention where obtained)

- a) O- Level.....
 - b) A- Level.....
 - c) Diploma
 - d) Bachelor.....
 - e) Other (mention).....
5. Experience in drug dispensing (in years)
- a) Less than 1 year
 - b) 1 to 5
 - c) 6 to10
 - d) 11 to 15
 - e) More than 15 years
6. How many minutes do you take to attend a patient?
- a) Less than 5
 - b) 6-10
 - c) 11-15
 - d) 16-20
 - e) More than 20
7. How many patients do you attend per day?
- a) Less than 5
 - b) 6-10
 - c) 11-15
 - d) 16-20
 - e) More than 20
8. How many working hours per day do you spend in a pharmacy?
- a) Less than 5
 - b) 6-10
 - c) 11-15
 - d) 16-20

e) More than 20

9. Have you ever attended any continuous pharmaceutical education (CPE)?

- a) Yes (go to Question 10)
- b) No (go to Question 12)

10. How many times have you attended CPE within last two years?

- a) None
- b) Once
- c) Twice
- d) Thrice
- e) More than thrice

Knowledge on ADRs Reporting

11. Have you heard any information about adverse drug reaction (ADR) reporting in any of attended CPE?

- a) Yes
- b) No

12. Do you know the meaning of adverse drug reactions (ADRs) reporting?

- a) Yes
- b) No

If yes what is it?

.....

.....

.....

13. Which profession is required to report suspected cases of ADRs?

- a) Doctors
- b) Pharmacists
- c) Nurses
- d) Traditional medicine practitioners

e) Others (mention)

14. Where are the reports for ADRs supposed to be sent

- a) TFDA headquarter offices
- b) TFDA zonal offices
- c) Zonal Pharmacovigilance Centre
- d) District Medical Officer's offices
- e) Others (mention)

15. What reactions should be reported?

- a) Those due to Conventional medicines,
- b) Those due to vaccines and blood products,
- c) Those due to Herbal medicines including traditional medicines
- d) Those due to Cosmetics
- e) Those due to Medical devices

16. Do you know the form used in spontaneous reporting of ADRs?

- a) Yes
- b) No

If yes name the form

17. Do you know how to report ADRs

- a) Yes
- b) No

If yes explain at least three (3) things to be considered during reporting.....

.....

.....

.....

.....

Practices on ADRs reporting

18. Is there a system of monitoring and reporting ADRs at your pharmacy?

- a) Yes
- b) No

If yes who is the focal person

19. Have you ever reported ADR cases in your pharmacy?

- a) Yes
- b) No

If yes where did you report

20. Are the forms for spontaneous reporting of ADR available in your pharmacy?

- a) Yes
- b) No

21. Have you ever filled a spontaneous reporting ADR form?

- a) Yes
- b) No

22. Are reference materials available at your pharmacy?

- a) Yes
- b) No

23. What reference material(s) is (are) available for use in your pharmacy?

- a) Tanzania National Formulary
- b) Good Dispensing Manual
- c) List of registered drugs
- d) Guidelines for Monitoring and Reporting Adverse Drug Reactions
- e) Others (Mention).....

Attitudes on ADRs reporting

In the following table, please respond to the statements on your left hand side by put a tick (√) on correct response at your right hand side

s/n	statement	Strong agree	Agree	not sure	Disagree	Strong disagree
24.	ADR reporting is part of professional role					
25.	Reporting of ADRs is necessary for new drugs					
26.	Reporting of ADRs is necessary for serious adverse drug reaction					
27.	Reporting of ADRs is necessary for well recognized adverse drug reaction					
28.	Reporting of ADR should be voluntary					

29. What do you think are barriers to ADRs reporting?

- a) Reporting forms are not available
- b) Reporting ADRs is time consuming
- c) Lack of motivation for reporting
- d) Do not have enough knowledge on how to report, where to report and when to report
- e) Others (mention)

30. Do you think your professional training has adequately prepared you to spontaneously report ADRs of the patients attending your pharmacy?

- a) Yes
- b) No

31. Would you be interested to attend a course to improve your ability to spontaneously report ADR of the patients attending your pharmacy?

- a) Yes
- b) No

Thank you for your participation

7.2 Questionnaire- Swahili Version

**DODOSO KWA AJILI YA KUPIMA UFAHAMU, MTAZAMO NA UTENDAJI
WA WATOA DAWA KATIKA MADUKA YA DAWA MKOA WA DAR ES
SALAAM KUHUSU UTOAJI WA TAARIFA ZA MADHARA YATOKANAYO NA
MATUMIZI YA DAWA.**

Fomu Namba.....

MAELEKEZO

**TAFADHALI TUMIA MUDA WAKO KUJIBU MASWALI YALIYOMO
KATIKA DODOSO HILI KWA UWEZO WAKO WOTE. JIBU KWA
KUZUNGUSHIA CHAGUO SAHIHI. AIDHA UNaweza KUCHAGUA
JIBU SAHIHI ZAIDI YA MOJA PALE ITAKAPOBIDI. ENDAPO
UTAPATA TATIZO LA KUELEWA, TAFADHALI OMBA UFAFANUZI
KABLA YA KUJIBU SWALI HUSIKA.**

1. Jinsia
 - a) Mme
 - b) Mke

2. Umri (miaka)

3. Taaluma
 - a) Mfamasia
 - b) Fundi dawa sanifu
 - c) Clinical officer
 - d) Muuguzi Msaidizi
 - e) Nyingine (taja)

4. Kiwango cha juu cha elimu (taja sehemu ulipoipata)
 - a) O- Level.....

- b) A- Level.....
 - c) Stashahada
 - d) Shahada.....
 - e) Nyingine (taja).....
5. Uzoefu katika kutoa dawa (miaka)
- a) Chini ya mwaka 1
 - b) 1- 5
 - c) 6- 10
 - d) 11- 15
 - e) Zaidi ya miaka 15
6. Je, unatumia dakika ngapi kumuhudumia mgonjwa mmoja?
- a) Chini ya dakika 5
 - b) 6-10
 - c) 11-15
 - d) 16-20
 - e) Zaidi ya dakika 20
7. Je, ni wateja wangapi unahudumia kwa siku?
- a) Chini ya 5
 - b) 6-10
 - c) 11-15
 - d) 16-20
 - e) Zaidi ya 20
8. Je, ni masaa mangapi kwa siku unakuwepo katika famasi kuhudumia wateja?
- a) Chini ya masaa 5
 - b) 6-10
 - c) 11-15
 - d) 16-20
 - e) Zaidi ya masaa 20

9. Je, umewahi kuhudhuria mafunzo endelevu yoyote yahasuyo dawa?
- Ndiyo (nenda swali la 10)
 - Hapana (nenda swali la 12)
10. Je, ni mara ngapi umehudhuria mafunzo hayo katika kipindi cha miaka miwili iliyopita?
- Hakuna
 - Mara moja
 - Mara mbili
 - Mara tatu
 - Zaidi ya mara tatu

Ufahamu kuhusu utoaji taarifa wa madhara ya dawa

11. Katika mafunzo hayo uliyohudhuria, Je umewahi kusikia lolote kuhusu utoaji wa taarifa wa madhara yatokanayo na matumizi ya dawa?
- Ndiyo
 - Hapana
12. Je, unafahamu maana ya utoaji taarifa wa madhara yatokanayo na matumizi ya dawa **“(ADR) reporting”**?
- Ndiyo
 - Hapana

Kama ndiyo, elezea maana yake

.....

.....

13. Je, ni taaluma gani inatakiwa kutoa taarifa za wagonjwa wanaopata madhara yatokanayo na matumizi ya dawa?
- Daktari
 - Mfamasia
 - Muuguzi

- d) Mtaalamu wa tiba asilia
- e) Nyingine (taja)

14. Je, ni wapi taarifa za madhara yatokanayo na matumizi ya dawa zinapaswa kupelekwa?

- a) TFDA makao makuu
- b) Ofisi za kanda za TFDA
- c) Vituo vya kanda vya taarifa za dawa
- d) Ofisi za waganga wakuu wa halmashauri/ wilaya
- e) Nyingines (taja)

15. Je, ni madhara gani yanapaswa kutolewa taarifa?

- a) Yale yatokanayo na dawa za kisasa
- b) Yale yatokanayo na dawa za chanjo
- c) Yale yatokanayo na dawa za mitishamba na dawa asilia
- d) Yale yatokanayo na vipodozi
- e) Yale yatokanayo na vifaa tiba

16. Je, unaifahamu fomu maalum ya kutolea taarifa ya madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

Kama ndiyo, taja jina la fomu hiyo.....

17. Je, unafahamu jinsi ya kutoa taarifa za madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

Kama ndiyo, elezea walau mambo matatu (3) ya kuzingatia wakati wa utoaji wa taarifa

.....

.....

.....

.....

Utendaji kuhusu utoaji taarifa wa madhara ya dawa

18. Je, katika famasi hii, kuna mfumo au utaratibu wa kufuatilia na kutoa taarifa za madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

Kama ndiyo, je ni nani msimamizi wa shughuli hii

19. Je, katika famasi yako, umewahi kutoa taarifa za wagonjwa waliopata madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

Kama ndiyo, ni wapi ulitoa taarifa

20. Je, katika famasi yako kuna fomu za kutolea taarifa za madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

21. Je, umewahi kujaza fomu za kutolea taarifa za madhara yatokanayo na matumizi ya dawa?

- a) Ndiyo
- b) Hapana

22. Je, kuna vitabu vya rejea katika famasi yako?

- a) Ndiyo
- b) Hapana

23. Ni aina gani ya vitabu vya rejea vilivyopo na kutumika hapa wakati unahudumia wagonjwa?

- a) TNF
- b) Mwongozo wa utoaji sahihi wa dawa
- c) Orodha ya dawa zilizosajiliwa na TFDA
- d) Mwongozo wa ufuatiliaji na utoaji taarifa wa madhara yanayotokana na matumizi ya dawa
- e) Vingine (taja).....

Mtazamo kuhusu utoaji taarifa wa madhara dawa

Katika jedwali hili, weka alama ya tiki (√) katika sehemu husika mkono wako wa kulia kukubaliana na maelezo yaliyopo mkono wa kushoto

Na	maelezo	makubali kabisa	makubali kiasi	sina uhakika	sikibali kiasi	sikubali kabisa
24.	utoaji wa taarifa za madhara yatokanayo na matumizi ya dawa ni moja ya jukumu la kitaaluma					
25.	utoaji wa taarifa za madhara yatokanayo na matumizi ya dawa ni muhimu kwa dawa mpya					
26.	utoaji wa taarifa za madhara yatokanayo na matumizi ya dawa ni muhimu kwa madhara makubwa					
27.	utoaji wa taarifa za madhara yatokanayo na matumizi ya dawa ni muhimu kwa madhara yanayojulikana zaidi					
28.	utoaji wa taarifa za madhara yatokanayo na matumizi ya dawa unapaswa kuwa wa hiari					

29. Kwa mtazamo wako, nini vikwazo katika kutoa taarifa za madhara yatokanayo na matumizi ya dawa?

- a) Kukosekana kwa fomu za kutolea taarifa
- b) Muda mrefu unatumika kutoa taarifa za madhara yatokanayo na matumizi ya dawa
- c) Kutokuwepo motisha baada ya kutoa taarifa
- d) Kukosa ufahamu wa kutosha juu ya namna ya kutoa taarifa, wapi taarifa zipelekwe na ni wakati gani wa kutoa taarifa

e) Nyingine (taja)

30. Je unafikiri mafunzo ya kitaaluma uliyopata yamekuandaa vya kutosha katika utoaji taarifa wa madhara yatokanayo na matumizi dawa kwa wagonjwa unaowahudumia?

- a) Ndiyo
- b) Hapana

31. Je, utakuwa tayari kupata mafunzo ili kuboresha uwezo wako wa kutoa taarifa kuhusu madhara yatokanayo na matumizi ya dawa kwa wagonjwa unaowahudumia?

- a) Ndiyo
- b) Hapana

Aksante kwa ushirikiano wako

7.3 Consent Form- English Version

CONSENT TO PARTICIPATE IN A STUDY TITLED “ADVERSE DRUG REACTION REPORTING” KNOWLEDGE, ATTITUDE AND PRACTICES OF DISPENSERS IN COMMUNITY PHARMACIES

Greetings!

My name is Grace Mng’ong’o Shimwela from Muhimbili University of Health and Allied Sciences. I am involved in a study on Adverse Drug Reaction Reporting”, knowledge, attitude and practices of community pharmacies dispensers in Dar es salaam region

Purpose of the Study

250 dispensers will be used in this study to assess their knowledge, practice and attitude towards Adverse Drug Reactions (ADRs) reporting as the basis for determining the factors contributing towards underreporting and therefore finding the mechanisms to enhance reporting of ADRs.

Participation

If you agree to join the study, you will be required to answer and fill all the questions in the questionnaire which will be provided to you.

Confidentiality

All information we will collect from you will be treated confidentially and will not be used for any other purpose other than this study.

Risks

We do not expect that any harm will happen to you because of joining in this study.

Rights to Withdraw and Alternatives

Taking part in this study is completely your choice. If you choose not to participate in the study or if you decide to stop participating in the study you will continue to be treated normally. You can stop participating in this study at any time, even if you have already

given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits

If you agree to take part in this study you will be among those who will contribute towards strengthening the system of ADRs reporting. Your information and other's participating in the study will collectively be used by policy makers in strengthening the system which would benefit other Tanzanians. You will receive the new information about this study upon completion.

Who to Contact

If you ever have questions about this study, you should contact the following:

Ms Grace Mng'ong'o Shimwela (principal investigator)

Muhimbili University of Health and Allied Sciences, P.O. Box 65013, Dar es salaam

Mobile phone: 0713 604094, or

Dr Doreen Mloka (study supervisor)

Muhimbili University of Health and Allied Sciences, P.O. Box 65013, Dar es salaam

Tel: 0222150748

Also, if you will have questions about your rights as a participant, you may call Prof. Muhsin Aboud, Chairman of the College Research and Publications Committee, P.O. Box 65013, Dar es Salaam. Tel: 2150302-6.

Signature

Do you agree to participate? *Write the word 'yes' if you agree*.....

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of investigator _____

Date of signed consent _____

7.4 Consent Form- Swahili Version

FOMU YA KUKUBALI KUJIUNGA KWA HIARI KATIKA UTAFITI KUHUSU UTOAJI TAARIFA WA MADHARA YATOKANAYO NA MATUMIZI YA DAWA

Salamu!

Mimi naitwa Grace Mng'ong'o Shimwela kutoka Chuo Kikuu cha Afya ya Sayansi ya Tiba Muhimbili. Ninafanya utafiti kuhusu utoaji wa taarifa za madhara yatokanayo na dawa , uelewa, mtazamo na utendaji wa watoa dawa katika maduka ya dawa Mkoa wa Dar es salaam.

Malengo ya utafiti:

Jumla ya watoa dawa 250 watahirikishwa katika utafiti huu wenye nia ya kubaini sababu zinazofanya wahusika kuttoa taarifa hizo, ili hapo baadae zitafutwe mbinu za kuboresha utoaji wa taarifa kwa Mamlaka zinazohusika.

Ushiriki katika utafiti

Kwa kushiriki katika utafiti huu utatakiwa kujibu kwa kujaza maswali yaliyopo kwenye dodoso utakayopatiwa.

Usiri

Taarifa zote zitakazopatikana kutoka kwako zitakuwa ni siri na hazitatumika sehemu nyingine isipokuwa katika utafiti huu tu.

Madhara

Hatutegemei kitu chochote kibaya kutokea kwa kushiriki katika utafiti huu.

Kukubali kwa hiari kushiriki kwenye utafiti:

Ushiriki kwenye utafiti huu ni kwa hiari. Unaombwa kukubali kwa hiari. Endapo utaamua kutoshiriki au endapo utaamua kujiondoa katika utafiti utaendelea kubaki na haki zako za msingi kama kawaida. Unaweza kujiondoa katika utafiti wakati wowote, na pale

utakapotaka kujiunga tena utapokelewa kuendelea na utafiti. Kukataa kujiunga ama kujitoka katika utafiti hakutasababisha adhabu au kupoteza haki yako ya msingi.

Faida za utafiti

Ukikubali kujiunga na utafiti utakuwa mmojawapo wa wale watakaofanikisha kuboresha mfumo wa utoaji wa taarifa wa madhara yatokanayo na matumizi ya dawa sehemu yoyote Tanzania. Utasaidia kuwawezesha watunga sera na wataalamu wa afya kufanya maamuzi yenye faida kwa umma mzima. Utapatiwa taarifa zozote mpya zitakazopatikana kupitia utafiti huu. Hatutegemei utaingia gharama zozote kwa kushiriki kwenye utafiti huu.

Mawasiliano

Kama una swala lolote kuhusu utafiti huu tafadhali wasiliana na:

Bi Grace Mng'ong'o Shimwela (mtafiti mkuu)

Chuo Kikuu cha Afya na Sayansi ya Tiba Muhimbili, S.L.P 65013, Dar es salaam

Simu ya mkononi : 0713 604094, au

Dkt Doreen Mloka (msimamizi wa utafiti)

Chuo Kikuu cha Afya na Sayansi ya Tiba Muhimbili, S.L.P 65013, Dar es salaam

Simu Na: 0222150748

Kama utakuwa na swala lolote kuhusu haki yako kama mshiriki katika utafiti huu wasiliana na:

Prof Muhsin Aboud, Mwenyekiti wa kamati ya Utafiti na Uchapishaji, Chuo kikuu cha Afya na Sayansi ya Tiba, S.L.P 65013, Dar es salaam.

Simu Na : 2150302-6.

Sahihi kwa wanaokubali

Je, unakubali? Andika ndio kama umekubali.....

Mimi nimeisoma fomu hii na kuelewa lengo la utafiti huu na maswali yangu yamejibiwa na sasa nakubali kwa hiari kujiunga na utafiti huu.

Sahihi ya mshiriki.....

Sahihi ya mtafiti.....

Tarehe ya kusaini.....