

**PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND
PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG
REACTIONS REPORTING IN CENTRAL REGION OF MALAWI**

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Abstract

Aim of the study: To assess level of knowledge, attitude and practices of dispensing healthcare professionals towards adverse drug reactions (ADR) reporting and to determine if there are any differences in knowledge, attitude and practices among dispensing healthcare professionals

Methodology: A descriptive cross-sectional survey using stratified random sampling technique was employed to draw 114 health facilities using categories of public hospitals, private clinics/hospitals and community pharmacies as strata. Every dispensing healthcare professional found in the main pharmacy of the sampled facilities was targeted.

Results: Dispensing healthcare professionals have positive attitude but limited knowledge and poor practice towards ADR reporting. There is significant difference on knowledge towards ADR reporting among healthcare professionals as more of pharmaceutical personnel and medical doctors indicated having knowledge than the other dispensing cadres but there is no significant difference in attitude and practice towards ADR reporting.

Conclusion: Healthcare professionals in central region of Malawi have limited knowledge and poor practice but positive attitude towards ADR reporting. Lack of training, unavailability of reporting tools and lack of information on how to report has greatly influenced the poor practice of ADR reporting. Educational and awareness interventions on pharmacovigilance, use of appropriately trained personnel and provision of required support to healthcare professionals would greatly improve ADR reporting.

Declaration

I declare that this thesis that I now submit for assessment on the programme of study leading to the degree Master of Science in Pharmacy Administration and Policy Regulation has not been submitted for the purpose of a degree at this or any other higher education institution. It is entirely my own work and has not been taken from the work of others, save the extent that such work has been cited and acknowledged within the text of my work.

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Signed:

Dated: 23rd June 2017.

WESTERN CAPE

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List of Abbreviations

ADR	Adverse drug reaction
CBER	Centre for Biologic Evaluation and Research
CDER	Centre for Drug Evaluation and Research
CHM	Commission on Human Medicines
EMA	European Medicines Agency
FDA	Food and Drug Administration
KAP	Knowledge, Attitude, Practice
MHRA	Medicines and Healthcare Products Regulatory Agency
MOH	Ministry of Health
NCA	National Competent Authorities
NHS	National Health Service
NHSREC	National Health Science Research Ethics Committee
PIDM	Program for International Drug Monitoring
PMPB	Pharmacy Medicines and Poisons Board
PV	Pharmacovigilance
SPSS	Statistical Package for Social Sciences
USA	United States of America
WHO	World Health Organization

Chapter 1: Introduction

1.1 Background

Medicines are important molecules that cure or improve quality of lives of people suffering from diseases. While efficacy and potency are the main qualities sought, medicines are also capable of producing some responses that are undesirable and are referred to as adverse drug reactions (ADRs). According to Edwards and Aronson (2000), an adverse drug reaction is the unpleasant reaction that results from the use of a medicinal product and it envisages risk from future administration and calls for prevention or specific treatment, or modification of the dosage regimen, or even withdrawal of the product.

Recent studies have indicated that at least more than half of the patients that are admitted to hospitals are harmed by drugs (Dequito et al, 2011) and that about 28% to 75% of these ADRs are preventable (Sari et al, 2007). It has been revealed in recent studies that deaths related to ADRs are increasing (Edwards & Aronson, 2000) and severe ADRs are among the leading causes of death (Lazarou et al., 1998). This creates a public health problem and an economic burden (Patel et al., 2007). They reduce quality of life and present a substantial financial burden on the health care systems (WHO, 2002).

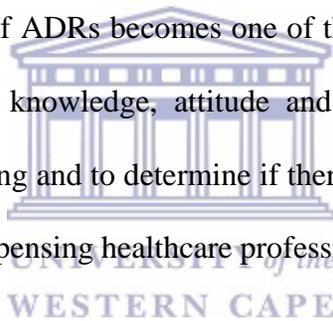
This ultimately brings in an important concept of pharmacovigilance which is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems” (WHO, 2002).

1.2 Problem Statement

The concept of pharmacovigilance has become more important worldwide due to an increase in the number of drug molecules entering the market (Abubakar et al., 2014) and most countries have since established pharmacovigilance centres whose main function is to collect and analyse the

reported information on ADRs and inform health care professionals as well as the public about the most frequent drug related problems at an earliest possible time (Bencheick & Benabdallah, 2009). In Malawi, pharmacovigilance was introduced in 2008 and the pharmaceutical regulatory body, Pharmacy Medicines and Poisons Board (PMPB) was identified as the pharmacovigilance centre. Since the inception of pharmacovigilance in 2008 and despite conducting training to healthcare professionals across the country, PMPB has received fewer than ten adverse drug reaction reports (2008-2015 PMPB Pharmacovigilance file reports). It is unlikely that there are no adverse drug reactions experienced but is an issue of non-reporting.

Considering that healthcare professionals are charged with the responsibility of taking care of the patients; managing and reporting of ADRs becomes one of their important responsibilities. This study therefore intends to assess knowledge, attitude and practice of dispensing healthcare professionals towards ADR reporting and to determine if there are any differences in knowledge, attitude and practice among the dispensing healthcare professionals.



1.3 Research questions

- What knowledge do healthcare professionals have on pharmacovigilance?
- What do healthcare professionals think of adverse drug reactions reporting?
- What do healthcare professionals do when an adverse event has occurred?
- Are there any differences in knowledge, attitude and practice among the healthcare professionals?

1.4 Research Objectives

- To determine knowledge, attitude and current practices of healthcare professionals regarding ADRs

- To determine the relationship between healthcare professionals' socio-demographic characteristics and reporting of adverse drug reactions.

1.5 Significance of the study

There has been no study of this kind in Malawi and the findings of this study will bring in knowledge to healthcare professionals and will enhance their understanding on pharmacovigilance. The study could increase patient safety from ADRs as it will generate awareness among healthcare professionals on the importance of reporting ADRs and this will promote reporting of ADRs



Chapter 2: Literature Review

2.1 Introduction

This chapter discusses reviewed literature which is relevant to this study.

2.2 Adverse drug reactions

The important aspect of medicines is their safety and efficacy but adverse effects are also always associated with medicines use (Edwards & Aronson, 2000). Some of these ADRs are viewed as minor such that they can easily be resolved but some are serious and can cause permanent disability or even death (WHO, 2006).

WHO (1972) defines an adverse drug reaction as a ‘noxious, unintended response that occurs at doses that are normally used in humans beings for prophylaxis, diagnosis or therapy for the disease or for the modification of the physiological function’. According to Edwards and Aronson (2000), an ADR is an “appreciably harmful or unpleasant reaction that results from an intervention related to the use of a medicinal product, which predicts hazard for future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.”

2.2.1 Classification of the Types of ADRs

ADRs classification is mainly based on the classification of Rawlins and Thomson (1977) who placed ADRs into two types, Type A and Type B ADRs based on the predictable pharmacological responses (Aronson & Ferner, 2003). Type A reactions (also known as augmented reactions), are predicted ADRs from pharmacological effects of drugs. They are dose dependent and could be easily prevented by either altering the dose, using another formulation of the same drug that could be administered through another route and also prescribing another medication within the same pharmacological group (Aronson & Ferner, 2003). Type B ADRs are those that cause peculiar

effects (Aronson & Ferner, 2003). They are not common, are unpredictable and depending on the known pharmacological properties of the drug, type B ADRs are independent of the dose and affects a small group of the population (Schatz, 2015).

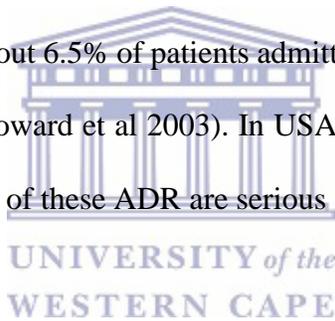
According to Aronson and Ferner (2003), Rawlins and Thomson ADRs classification was perceived to be insufficient as some emerging ADRs that were being reported could be placed into either of the established two classes such that Edwards and Aronson (2000) further extended it into classes C – F where type C refers to ADRs that are associated with persistent therapies for chronic disease conditions with analgesic nephropathy being an example. Type D reactions are the uncommon delayed reactions that are noticed after some period of time and are dose dependent. Type E reactions are those that are associated with the withdrawal of drugs and Type F reactions are associated with failure of therapy due to inherent characteristics of a drug, which basically are dose-related and are supposed to be caused by drug interactions.

Meyboom et al., (2000) considers practical classification of medicine-related problems into one basic system that would properly differentiate appropriate and inappropriate drug use therefore three groups were set; types A (drug actions), B (patient reactions) and C (statistical) adverse effects. Aronson & Ferner, (2003) introduced a three dimensional classification system based on dose relatedness, timing, and patient susceptibility (DoTS) after noting that the extended ADR classification was only based on drug properties (its known pharmacology and dose dependent effects) but did not take into account the properties of the drug reaction which includes time course of its presentation and severity and the properties of the individual (genetics, pathological and other biological differences that present susceptibility). Farcas & Bojita (2009) further argue that the other classes of ADRs have to be considered as subclasses of Type A (dose related) and type B (non-dose related).

2.2.2 Incidences of ADR's

Globally, ADRs are a significant causes of morbidity and mortality (Alomar., 2014) that brings unnecessary economic burden (Sultana et al., 2013) due to the long period that a patient stays in hospital which consequently translates into increased healthcare cost (Classen et al., 1997). Risks of ADRs are increased with hospitalisation (Zolezzi & Parsotam., 2005) and according to Pirmohamed et al., (1998), about 6% of all patient hospital admissions are due to ADRs.

Mehta et al. (2008) reported that in South Africa, about 6.3% of hospital admissions were due to ADRs. In England, about 4% of the National Health Service (NHS) bed occupancy was due to ADRs (Classen et al., 1997) and about 6.5% of patients admitted into the hospitals were having an ADR (Pirmohamed et al., 2004; Howard et al 2003). In USA, ADRs happen in about 10 to 20% of all hospital admissions and most of these ADR are serious (Seidl et al., 1965).



2.2.3 The burden of ADRs on public health

In addition to their impact on human health, ADRs also have a significant impact on the financial, economic and public health system (Sultana et al., 2013). Pharmacoeconomic studies that have been done on the costs of ADRs have revealed that governments pay substantial amounts from health budgets towards covering costs associated with them (WHO, 2002). According to Lundkvist and Johnson (2004), some of the ADRs are preventable and this provides the potential to save the costs, therefore it is important to implement preventative programmes with different strategies that may help reducing costs (Sultana et al., 2013).

2.3 Pharmacovigilance

Incidences of adverse drug reactions have led to the introduction of Pharmacovigilance and ADR reporting systems in many countries. Geiling and Cannon (1938) report that around the early 20th century sulphanilamide tablets and powders were proved to be safe and effective in the treatment of streptococcal infections; however, in 1937 sulphanilamide elixir started to be used but it was associated with the death of about seventy six people during a period of two months of its use. The cause of death was established to be due to a strong toxic chemical di-ethylene glycol (Geiling & Canon, 1938). A similar drug related incident is the thalidomide disaster that occurred in late 1950s and early 1960s (Isah et al., 2012). Thalidomide was used during pregnancy as a treatment for morning sickness. It was associated with severe birth defects after discovering that phocomelic babies were born to mothers who had taken the drug during their pregnancy (Shamim, 2016). It is estimated that over 10,000 babies were born with serious congenital malformations (Vargesson, 2015). These incidences, amongst others, led to the realization that in addition to being beneficial, drugs could also negatively affect patients. As a result, many of the developed countries came up with organized systems for the evaluation of drugs and their associated effects (Groothessdt, 2003). In 1963 the World Health Assembly adopted a declaration that confirmed the requirement for early detection and rapid dissemination of information on adverse reactions due to medicines and medicinal products (Pal et al., 2013). In 1968 some countries collaborated on a spontaneous reporting system of ADRs and in 1972 the World Health Organization Programme for International Drug Monitoring (PIDM) was established which led to the creation of organised systems for the collection and evaluation of individual case safety reports in Member States (Groothessdt, 2003).

According to WHO, pharmacovigilance (PV) refers to the “science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions or any other drug-related problems” (WHO, 2002). Globally PV systems mainly rely on spontaneous reporting whereby suspected ADRs are voluntarily submitted by health professionals and pharmaceutical companies or patients to national coordinating centres (Pal et al., 2013). Spontaneous reporting of ADRs allows for early detection of signals leading to confirmatory investigations that enable timely regulatory decision making (Pal et al., 2013). PV needs to be promoted locally because of increased access to new essential medicines that are being introduced into the market as, despite being extensively studied in their countries of manufacture, their safety profile may not be relevant to other localities as the occurrence, pattern and severity of ADRs may differ because of local environmental and genetic factors (Pirmahomed et al., 2007).

2.4 Pharmacovigilance and ADR reporting systems worldwide

Following the thalidomide tragedy, most countries developed an ADR reporting system mainly based on WHO guidelines (Pal et al. 2009).

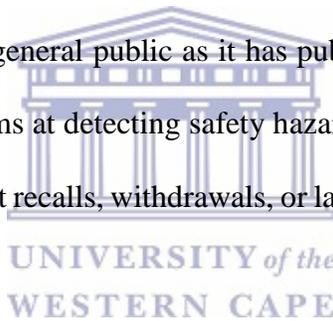
2.4.1 ADR reporting system in Europe

In United Kingdom, the Committee on Safety of Drugs was set up in 1963 to provide advice on medicine safety issues. This evolved and became the Commission on Human Medicines (CHM) in 2005. CHM is part of the Medicines and Healthcare Products Regulatory Agency (MHRA) and it provides expertise to MHRA on safety of medicines (Webb, 2012). The MHRA also introduced the yellow card scheme to facilitate reporting problems relating to drugs and, as a means of ensuring complete safety and effectiveness of medicines, those products that need additional monitoring are identified with an inverted black triangle.

Currently the European Medicines Agency (EMA) coordinates pharmacovigilance systems conducted by the National Competent Authorities (NCA) in the European Union. The pharmacovigilance system is known as Eudravigilance (Borg et al, 2015).

2.4.2 ADR reporting system in United States of America

In United States of America (USA), the Department of Health and Human Services and Food and Drug Administration (FDA) regulate and coordinate the pharmacovigilance system with the help of the Centre for Drug Evaluation and Research (CDER) and Centre for Biologics Evaluation and Research (CBER) (Thula, et al., 2015). In 1993, the FDA devised a pharmacovigilance system known as Medwatch which is a voluntary system for reporting adverse events and it allows information to be shared with the general public as it has publicly available databases (Thula, et al., 2015). The system basically aims at detecting safety hazards signals and if detected, the FDA issues safety alerts or orders product recalls, withdrawals, or labelling changes to protect the public health (Thula, et al., 2015).



2.4.3 Pharmacovigilance in Africa

In Africa, pharmacovigilance is mostly facilitated by World Health Organisation (WHO) through the Programme for International Drug Monitoring (PIDM). The first PV centre in Africa was established in South Africa in 1987 (Dheda, 2016) and two countries, South Africa and Morocco became members of the PIDM in 1992 (Isah, et al, 2012).

The number of countries in PIDM continued increasing such that in 2015 there were 35 countries participating out of 54 African countries (Ampadu, et al., 2016). Issa et al (2012) attest to the existence of weak pharmacovigilance systems in Africa and suggest that there is a need for resources, infrastructure and expertise to strengthen the pharmacovigilance system.

2.4.4 Pharmacovigilance in Malawi

In Malawi, pharmacovigilance was introduced in 2008 and the pharmaceutical regulatory body, PMPB, was identified as the pharmacovigilance centre. Since the inception of pharmacovigilance in 2008 and despite conducting training to health personnel across the country, PMPB has received very few drug adverse events reports (2008-2015 PMPB Pharmacovigilance file reports). During this time Malawi had not yet started submitting reports to Uppsala Monitoring Centre (UMC). The number of reports received at PMPB as a national PV centre were too way below the recommended number of reports by the WHO Uppsala Drug Monitoring program for a national PV centre which is over 200 reports per million inhabitants per year for a national PV centre (Maigetter et al., 2015). This presents a serious problem of non-reporting.

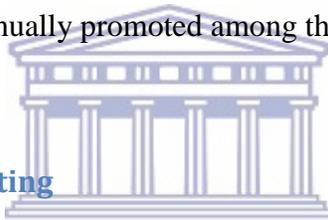
Studies have shown that ADRs are one of the major cause of hospital admissions (Bouvy et al., 2015; Davis et al., 2009; Gallagher et. al., 2012). Keeping in mind that most ADRs are preventable (Hakkarainen, 2012), it is paramount that something be done to encourage reporting of adverse events as this in return will help reduce health costs and the public will be protected from unnecessary exposure to ADRs.

2.5 ADR Knowledge, Attitude and Practices of Health professionals

Previously physicians were the main source of ADR reporting (Groothesdt, 2003); however reporting could be enhanced by involving other healthcare professionals as well as patients to report suspected ADRs (Morrison-Griffiths et al, 2003). Studies relating to assessment of levels of knowledge, attitude and practice of healthcare professionals on ADRs reporting have been done worldwide. These studies were mainly to identify the reasons for not reporting or underreporting and to determine ways to increase reporting rates. The results of most of these studies indicated

some of the major factors for not reporting and underreporting were: lack of time, different care priorities, professional uncertainty if the observed effects are ADRs, whether an ADR is supposed to be reported or not, lack of knowledge on the reporting system of ADRs, heavy workload by health professionals (Bhagavathula et al., 2016; Gurmesa & Dedefo 2016; Gupta et al 2015; Mirbaha et al., 2015; Bhati 2014; Necho & Worku 2014; Isfahani et al., 2013; Belton et al., 1995). Attitude towards ADR reporting was also found to be contributing to underreporting (Bhagavathula et al., 2016; Herdeiro et al., 2006).

It is important to understand that reporting ADRs is the professional obligations of all healthcare professionals. Therefore it is paramount that all healthcare professionals are aware of ADR reporting and that it has to be continually promoted among the healthcare professionals.



2.5.1 Knowledge on ADR reporting

In order to enhance patient's safety, every healthcare professional needs to have knowledge and a positive attitude towards pharmacovigilance and ADR reporting. Several studies done in other countries on knowledge, attitude and practices of healthcare professionals regarding pharmacovigilance and ADR reporting have indicated that healthcare professionals have poor knowledge of the pharmacovigilance and ADR reporting (Gurmesa & Dedefo 2016; Gupta et al., 2015; Necho & Worku., 2014; Elkami et al, 2013; Isfahani et al., 2013; Fadare et al., 2011; Toklu et al. 2008; Lee et al. 1994). This is reflected in many countries including Ethiopia (Gurmesa & Dedefo, 2016); India (Gupta et al., 2015); Malaysia (Elkami et al, 2013); South Africa (Necho. & Worku 2014); Iran (Isfahani et al., 2013); Nigeria (Fadare et al., 2011); Turkey (Toklu et al., 2008) and Hong Kong (Lee et al. 1994).

2.5.2 Attitude towards ADR reporting

Studies done have also shown that healthcare professionals have a positive attitude towards pharmacovigilance and ADR reporting as they consider it to be important (Desai, 2011; Toklu, et al. 2008). However healthcare professionals consider ADR reporting as time consuming and that most of them lack expertise to implement it (Singh et al., 2010). Others views ADR reporting as a tedious process and this leads to either under reporting or non-reporting (Rodgers et al., 1988). However ADR underreporting that is due to healthcare professional attitude could be minimised through educational interventions (Zolezzi et al, 2005; Herdeiro et al., 2006).

2.5.3 Practice of ADR reporting

Studies previously done in other countries such as India (Desai, et al 2011; Upadhyaya, et al 2015; Gupta, et al 2015); USA (Gavaza, 2011) and China (Li, et al 2004) have indicated that there are poor practices of healthcare professionals towards ADR reporting. Results of some studies have attributed poor ADR reporting mainly to lack of knowledge on ADR reporting system (Vallano, et al 2005; Radhakrishnan, et al 2011; Necho & Worku 2014). However some of the factors are related to attitude such as viewing the ADR reporting as tedious and an extra activity on top of their daily activities (Herdeiro et al., 2006; Rodgers et al., 1988). Weak organisational structures of ADR reporting system in countries have also been associated with poor reporting (Desai et al., 2011).

2.6 Conclusion

Most of the studies done worldwide on pharmacovigilance have consistently shown poor knowledge and practice or attitude among health professionals regarding ADR reporting. Most of these studies have recommended training on pharmacovigilance therefore it is important that health professionals should have continual knowledge update in order for them to keep abreast of

current information on pharmacovigilance to maximize patient safety. Pharmacovigilance needs to be incorporated into tertiary training curricula for healthcare professionals to allow for better understanding and implementation.



Chapter 3: Methodology

3.1 Introduction

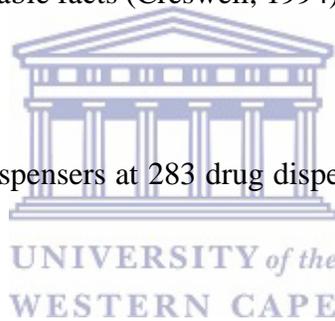
The chapter presents the methodology of the study. The setting, site selection, study design, sampling procedure, sample size are described. Also discussed are the development and validation as well as the ethical consideration.

3.2 Study design

This was a descriptive cross-sectional survey based study as it aimed at describing the state of affairs of the studied parameters in the population at the time of study (Robson, 1993) and it explored the cause(s) of the observable facts (Creswell, 1994).

3.3 Target population

The study population were drug dispensers at 283 drug dispensing health facilities in the central region of Malawi as at June 2016.



3.4 Sampling and sample size

It is important that the sample should be big enough in relation to the study population in order to enhance external validity of the research conclusion (Lenth R.V, 2001). In order to come up with the sample, this study conveniently sampled the central region of Malawi then multistage sampling was employed to sample the districts within the central region and sampling of health facilities within the sampled districts. Due to financial constraints, the central region was conveniently sampled because it was within reach by the researcher.

Selection Criteria

Inclusion criteria used in this work were as follows:

- All public dispensing health facilities of the central region
- All central region private dispensing health facilities that are registered with PMPB

Exclusion criteria

- Health facilities that did not consent to participation in the study

According to Borg (1983), a sample of 30 per cent of the population is enough to generalize the results on the whole population and this study considered 40 percent. The central region of Malawi is comprised of 9 districts and 40 percent of the districts (4 districts) were sampled for the study: Lilongwe, Mchinji, Dowa and Kasungu. Within the sampled districts, stratified random (probability) sampling technique was used to draw health facilities using categories of private clinic/hospitals, public hospitals and community pharmacies as strata.

Each stratum was then treated independently of the others and 40 per cent of the facilities were sampled for the study. Based on the population of health facilities within these districts, the sample characteristics were as indicated in Table 2 below.

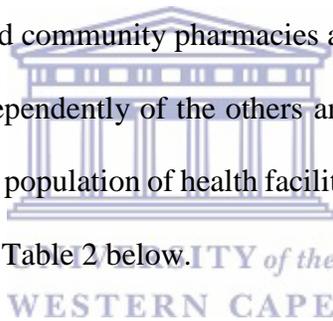


Table 3.1: Sample size and distribution

Category of Facilities (strata)	Total Number in sampled districts	Sample size
Public health facilities	124	50
Retail pharmacies	31	12
Registered private hospitals/clinics	128	52
Total	283	114

For each stratum, random sampling of the facilities was done using a table of random numbers and a total of 114 health facilities, as indicated in Table 1 above, were drawn. In each facility that was sampled, all healthcare professionals who were involved in dispensing medicines in the main

dispensing unit (pharmacy) were included in the study. These healthcare professionals include pharmacists, pharmacy technicians, medical doctors, clinical officers, nurses, medical assistants and health surveillance assistants. From the 114 health facilities, 164 dispensers were enrolled in the study considering that some health facilities had more than one dispenser.

3.5 Data collection method and tools

A self-administered structured (Appendix III) questionnaire was used to collect data considering that the sample population was large and the time available to conduct the survey was limited (Mann, 2003). Questions on ADRs reporting were used to assess dispenser's knowledge, attitude and practice towards ADR reporting. Pilot testing to establish questionnaires' validity was done by administering it to dispensers of 10 public health facilities, 4 private clinics and 2 community pharmacies in Lilongwe district. These facilities were not included in the sample of the study. A period of five working days was given for the participants to respond to the questionnaire. Feedback given from these participants led to making corrections and amendments to the questions that were found to be ambiguous.

The final questionnaire comprised of four sections that covered demographic information, knowledge, attitude and practice towards ADR reporting respectively. Knowledge levels were determined using a series of 8 questions on ADRs, on what they are, reporting structures, who to report to and how to report. Attitude towards ADR reporting, including reasons for non-reporting or underreporting were assessed using 11 statements. Practice of respondents towards ADR reporting was examined using 10 questions, if there is any reporting system in their institutions, if they have encountered any patient with adverse drug reaction and if they have ever reported any adverse event. The information sheet, informed consent and questionnaire were sent via email as an attachment to those participants with email addresses and those that did not have an email

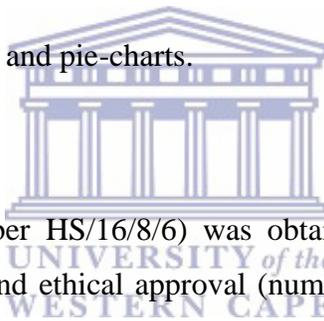
address had hard copies of these documents delivered to them. As done during pilot, a time period of five working days was given for them to respond to the questionnaire and the documents were physically collected from all the respondents.

3.6 Data management and analysis

The questionnaires were given identification numbers and the questions were coded. Data collected were entered and cleaned in Microsoft office Excel (2010) and descriptive statistics were calculated in a Statistical Package for Social Sciences (SPSS) version 16.0. Chi-square test was used to determine the significance of the difference in knowledge, attitude and practice of ADR reporting among the categories of healthcare professionals at significance level of 0.05. Data was summarized using frequency tables and pie-charts.

3.7 Ethical considerations

Ethical clearance (reference number HS/16/8/6) was obtained from ethics committee of the University of the Western Cape, and ethical approval (number 1705) was obtained the Malawi National Health Science Research Ethics Committee (NHSRC). Authorization to conduct the study was obtained from the Ministry of Health, and the District Health Officers for the district hospitals in the central region and PMPB for the licensed dispensing outlets in the central region. Finally, permission to collect data in the facilities was sought from the heads of institutions and/or owners of the facilities and consent for dispensers' participation was sought from dispensers themselves. Participants' anonymity and confidentiality on their information was highly maintained throughout the study by keeping the filled in questionnaires in a lockable cabinet and the information was not used for any other purpose apart from the purpose of this study.



Chapter 4: Results

4.1 Introduction

This chapter presents the findings of the study by drawing together the perspectives and experiences of the different respondents that were involved in the study. The results are in a descriptive form in a form of frequencies with percentages and they have been presented according to the research questions.

One hundred and sixty four (164) questionnaires were administered to dispensing healthcare professionals in 114 sampled dispensing health facilities. Out of the 164 administered questionnaires, 133 were adequately filled, resulting in a response rate of 81%.



4.2: Socio-Demographic Characteristics

Table 4.1: Summary of socio-demographic characteristics of the respondents

Characteristic	(n=133)	Frequency (n)	Percentage (%)
Gender			
Male		94	70.7
Female		39	29.3
Level of education			
Degree		22	16.5
Diploma		70	52.6
Others*		41	30.8
Professional Qualification			
BSc in Pharmacy		12	9
Diploma in Pharmacy		15	11.3
BSc in Medicine		10	7.6
Diploma in Clinical Medicine		30	22.6
Diploma in Nursing		25	18.8
Others*		41	30.8
Training in Pharmacovigilance			
Yes		96	72.2
No		37	37.8
Type of Training			
On the job training and seminars/workshops		16	16.7
On the job training		30	31.3
Seminars/workshops		14	14.5
Class/College University		36	37.5
Employer			
Retail Pharmacies		10	7.5
Public Hospitals		74	55.6
Private Clinics/Hospitals		49	36.8
Experience			
Less than 1 year		4	3
1 to 5 years		40	30.1
6 to 10 years		53	39.8
11 to 15 years		30	22.6
More than 15 years		6	4.5

BSc - Bachelor of Science

*Others include medical assistants and health surveillance assistants.

In this study, the respondents were disaggregated as follows: 70.7% of respondents, as indicated in table 4.1, were males while 29.3% were females implying that majority were males. Academically, 52.6% were diploma holders, 16.5% were degree holders while 30.8 were medical

and health surveillance assistants. In terms of profession, 9% of respondents were pharmacists, 11.3% were pharmacy technicians representing 20.3% for pharmaceutical personnel and the rest (79.7%) were non pharmaceutical professions (i.e medical officers (7.6%), clinical officers (22.6%), medical assistants and health surveillance assistants (30.8%)).

Most of the respondents (55.6%) were from public hospitals, and 44.3% were from the private sector (retail pharmacies (7.5%), private clinics/hospitals (36.8)). The results of this study show that the majority of the respondents (39.8%) had 6 to 10 years' experience, 37.5% received pharmacovigilance training at college/university and 30% of the respondents received on the job training. This finding implies that all the respondents in this study were, in some way, trained.



4.3 Knowledge about ADR reporting

Table 4.2 Summary of responses to questions assessing knowledge to ADR reporting

Question	Respondents with correct answers n=133	
	Frequency (n)	Percentage (%)
Ever heard of ADR	121	91.0
Knowledge of meaning of ADR	40	30.1
Described ADR reporting	33	24.8
Professionals required to report	29	21.8
Described meaning of Pharmacovigilance	27	20.3
Know most important purpose of pharmacovigilance	35	26.3
Know the existence of pharmacovigilance system in Malawi	40	30.1
Know where to report ADRs	56	42.1

Table 4.2 indicates that 91% of respondents have heard of ADRs but only 30.1% knew what ADR reporting is and only 24.8% were able to correctly describe it. This finding implies that knowledge of ADR reporting is minimal among respondents. In fact, only 21.8% of respondents correctly reported that ADRs are supposed to be reported by everyone. They do not think that everyone who dispenses drugs is supposed to report ADRs. A pharmacist was the most (54.1%) chosen profession required to report ADRs. In addition, only 30.1% of the respondents knew about pharmacovigilance and the existence of a pharmacovigilance system in Malawi, 26.3% were able to recognize its purpose.

This finding implies that the system of reporting ADRs is not known by the majority of the respondent although they dispense drugs. Nevertheless, they identified the Pharmacy Medicines and Poisons Board as a place where ADR reports could be sent.

On assessment of overall knowledge, each correct response was scored 1.0 while each incorrect response was scored 0.0, then the overall score was calculated for all the 8 knowledge responses

for each individual. The maximum expected score was 8. The overall mean knowledge score was 5.62 (SD = 15.36) out of a maximum 8. Since data were normally distributed, the mean was used as a cut-off point for those with good knowledge (values \geq mean) and those with poor knowledge (values $<$ mean). Thus, 44 (33%) of the respondents had better knowledge whereas 89 (67%) had poor knowledge as shown in figure 4.2 below.

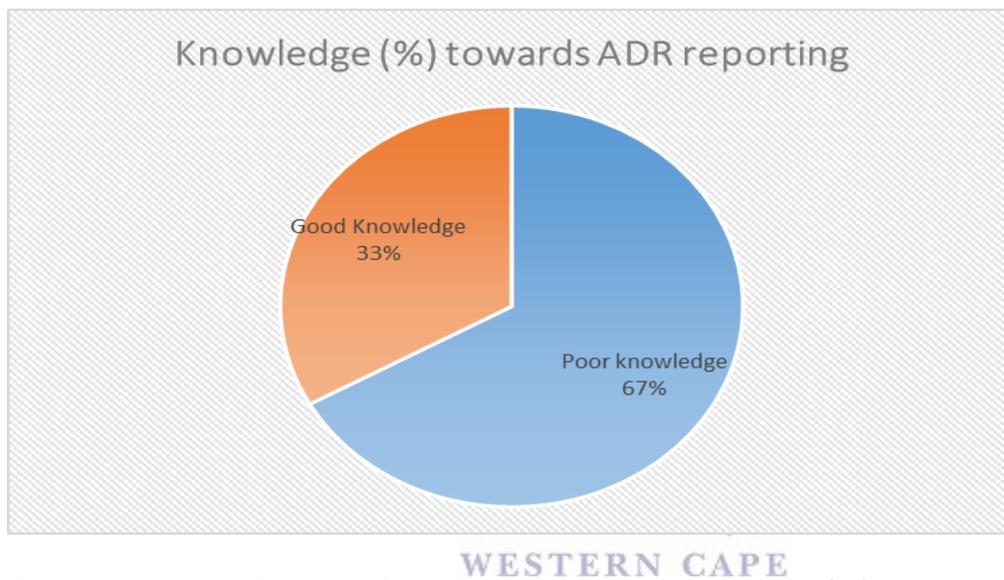


Figure 4.1: Overall proportion of respondents knowledge (%) towards ADR reporting

4.4 Knowledge of ADR reporting disaggregated by gender, profession, designation (workplace) and experience

Table 4.3: Knowledge on ADR reporting by gender, profession, workplace and experience

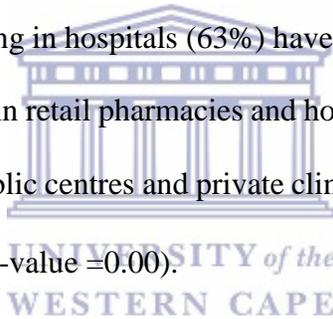
		All (n=133)	Correct		Incorrect		
			Frequency	%	Frequency	%	
Gender	Male	94	34	36%	60	64%	
	Female	39	10	26%	29	74%	
Profession	Pharmacy Technicians	15	8	53%	7	47%	
	Pharmacists	12	9	75%	3	25%	
	Nurses	25	6	32%	19	68%	
	Clinical Officers	30	10	37%	20	63%	
	Medical Doctors	10	7	70%	3	30%	
	*Others	41	4	12%	37	88%	
Designation (Workplace)	Retail Pharmacy	10	6	60%	4	40%	
	Public Facilities	Hospitals	19	14	63%	5	37%
		Health Centres	55	5	9%	50	91%
	Private Clinics/Hospitals	49	19	39%	30	61%	
Experience	Less than 1 year	4	1	25%	3	75%	
	1 to 5 years	40	15	37.5 %	25	62.5%	
	6 to 10 years	56	23	41%	33	59%	
	11 to 15 years	27	5	19%	22	81%	
	More than 15 years	6	0	0%	6	100%	
Overall	n=133		44	33%	89	67%	

*Others – Health Surveillance Assistants, Medical Assistants

Table 4.3 shows that only 36% of the males and 26% of the females have sufficient knowledge of ADR reporting. The results have indicated that 67% of both sexes do not have knowledge on how to report ADRs and there was no significant difference between males and females on their level of knowledge on ADR reporting ($\chi^2 = 1.239$, $df = 1$, p -value 0.811).

Disaggregating the knowledge findings by profession, the results have indicated that more of pharmaceutical personnel (pharmacists – 75%, pharmacy technicians – 53%) and medical doctors (70%) have knowledge towards ADR reporting than other professions (clinical officers – 37%, nurses – 32%, others – 12%). The difference among the professions on knowledge towards ADR reporting is statistically significant ($\chi^2 = 3.114$, $df = 3$, $p\text{-value} = 0.00$).

Analysis by designation of the facility shows that more respondents working in the public health centres (91%) than those working in private clinics/hospitals (61%) do not have sufficient knowledge regarding reporting of ADRs. However, respondents that are working in retail pharmacies (60%) and those working in hospitals (63%) have knowledge on ADR reporting. This finding implies that those working in retail pharmacies and hospitals have sufficient knowledge in comparison to those working in public centres and private clinics and the difference is statistically significant ($\chi^2 = -11.004$, $df = 1$, $p\text{-value} = 0.00$).



In terms of experience, Table 4.3 shows that respondents that had less than 1 year experience (75%), 11 to 15 years of experience (81%) and more than 15 years of experience (100%) had poor knowledge of ADR reporting compared to those with 1 to 5 years (37.5%) and 6 to 10 years (41%) experience in dispensing practice. This finding implies that moderately experienced practitioners are statistically more knowledgeable ($\chi^2 = -10.774$, $df = 1$, $p\text{-value} = 0.00$) than the less experienced and more experienced practitioners

4.5: Attitude of respondents towards ADR reporting

Table 4.4: Summary of responses to questions assessing attitude towards ADR reporting

Question	Responses (n=133)		
	Yes - n (%)	No - n (%)	Not sure -n (%)
Do you think reporting of adverse drug reaction is necessary?	133 (100)	0	0
Do you think ADR reporting is professional obligation for you?	125(93.9)	5 (3.8)	3 (2.3)
Do you think reporting of ADRs is necessary for new drugs?	121 (90.9)	9 (6.7)	3 (2.3)
Do you think reporting of ADRs is necessary for serious adverse drug reaction?	116(87.2)	8(6)	9 (6.8)
Do you think reporting of ADRs is necessary for well recognized drugs?	45(33.8)	76(57)	12 (9)
Do you think reporting of ADR should not be voluntary?	75(56.4)	53 (39.8)	5 (3.8)
Total	77.0%	18.9%	4.0%

Respondents were asked a number of attitude questions towards ADR reporting and results are displayed in Table 4.4. The findings show that all of respondents (100%) agreed that ADR reporting is necessary and 94% of respondents agreed that ADR reporting is part of their professional obligations. The majority of respondents (91%) agreed that it is necessary to report ADRs for new drugs and also the majority (87.2%) agreed that it is necessary to report serious ADRs. Only a few (33.8%) agreed that it is necessary to report ADRs for well recognized drugs and the majority (56.4%) agreed that ADR reporting should be voluntary. Overall, the results indicated that the majority of respondents (77%) had a positive attitude towards ADR reporting and 23% had a negative attitude towards ADR reporting as shown in Figure 4.2, A small number (4.0%) of the respondents were not sure about the ADR reporting.

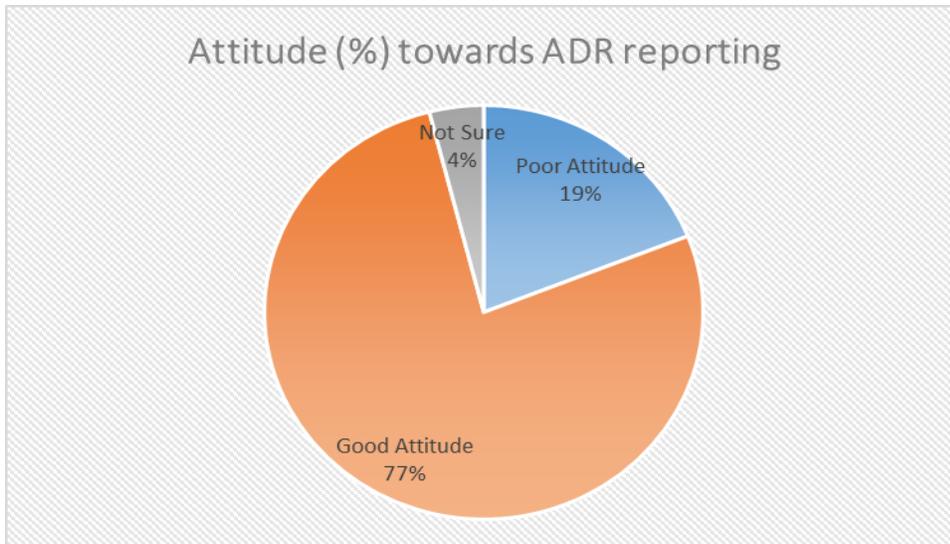


Figure 4.2: Overall proportion of respondents attitude (%) towards ADR reporting



4.6: Practice of respondents towards ADR reporting

Table 4.5: Summary of responses to questions assessing the practice of respondents towards ADR reporting

Question	Responses (n=133)		
	Yes-n (%)	No-n (%)	Not sure-n(%)
Is there any reporting system of ADR within your institution/facility?	16 (12)	85 (63.9)	32 (24)
Have you experienced any ADRs in patients during your professional practice?	79 (59.4)	54 (40.6)	0 (0)
Have you ever reported ADR cases?	3 (2.3)	130 (97.7)	0 (0)
Are there spontaneous reporting forms at your pharmacy?	18 (13.5)	63 (47.4)	52 (39.1)
Have you ever been trained on how to report ADRs?	27 (20.3)	106 (79.7)	0 (0)
Total	21.05%	65.9%	12.6%

To assess their practices, respondents were asked a number of questions regarding what they do and the results are presented in Table 4.5. Examination of the table shows that only 12% of respondents indicated having a system of reporting adverse drug reactions within their institutions. The majority (59%) have experienced ADRs during the course of their professional practice but only 2.3% indicated having ever reported any ADR cases. Only 13.5% reported having reporting forms at their institutions and only (20.3%) reported having been trained in ADR reporting. In summary, there is a poor reporting practice (66%) amongst the respondents as shown in Figure 4.3 below.

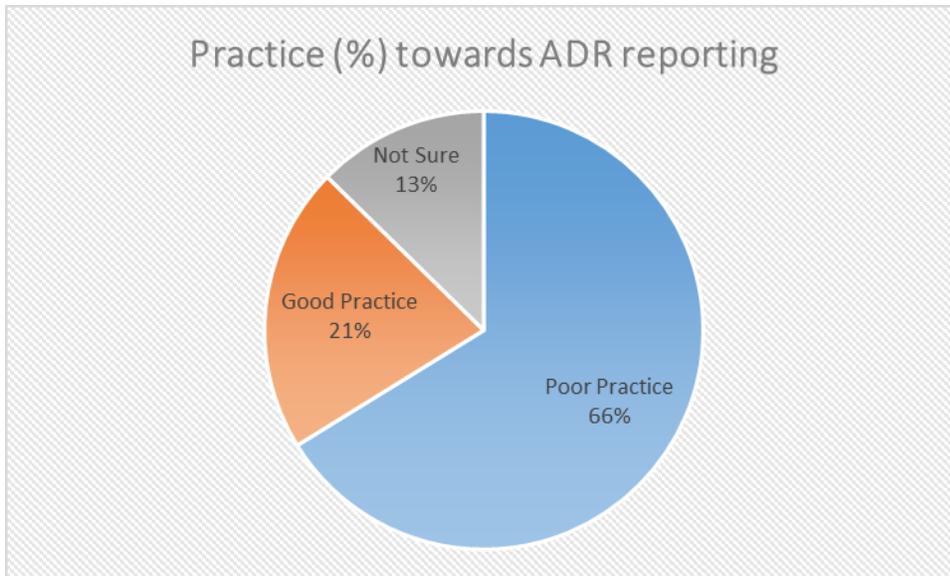


Figure 4.3: Overall proportion of respondents practice (%) towards ADR reporting



4.7: Comparison of knowledge, attitude and practice of ADR reporting among healthcare professionals

Table 4.6: Comparison of practice of ADR reporting among healthcare professionals

	Pharmacist n=12	Pharm. Technicians n=15	Medical Doctors n=10	Clinical Officers n=30	Nurses n=25	Others n=41	All n=133
Knowledge n (%)	9(75%)	8(53%)	7(70%)	10(37%)	6(32%)	4(12%)	41 (31%)
Positive Attitude n (%)	11(92%)	12(80%)	9(90%)	22(73%)	20(80%)	28(68%)	102 (77%)
Positive Practice n (%)	5(42%)	6(40%)	2(20%)	6(20%)	4(16%)	5(12%)	28 (21%)

Table 4.6 shows overall findings of healthcare professionals' knowledge, attitude and practice towards ADR reporting by profession. The results indicate that more of pharmaceutical personnel (pharmacists – 75%, pharmacy technicians – 53%) and medical doctors (70%) have knowledge about ADR reporting than other professions (clinical officers – 37%, nurses – 32%, others – 12%). The difference among the professions on knowledge towards ADR reporting is statistically significant ($\chi^2 = 13.114$, $df = 3$, $p\text{-value} = 0.00$).

On attitude, the results indicate that all healthcare professionals have positive attitude towards ADR reporting and there is no significant difference in attitude towards ADR reporting among healthcare professionals ($\chi^2 = 3.718$, $df = 3$, $p\text{-value} = 0.556$).

Overall, the results indicate that there is poor practice of reporting ADRs among healthcare professionals. However, the results shows that more of pharmaceutical personnel (pharmacist - 42%, pharmacy technicians – 40%) have a better reporting practice as compared to other healthcare professionals but the difference is not statistically different ($\chi^2 = 4.594$, $df = 3$, $p\text{-value} = 0.211$).

4.8 Barriers to ADR reporting

Table 4.7: Reasons for not reporting ADR

Statement	Level of Agreement of respondents N=133		
	Agree (%)	Disagree (%)	Not sure (%)
System of reporting too bureaucratic	45 (33.8)	69 (51.8)	19 (14.2)
Too busy to send an ADR report	71 (53.4)	57(42.9)	5(3.6%)
Report form not available when needed	113(84.9)	20 (15.1)	0 (0)
Feel that you would be exposed to legal liability by reporting an ADR	68 (51.1)	55(41.4)	10(7.5)
You believe that only safe drugs are marketed	35 (26.3)	98 (73.9)	0 (0)
Unsure how to report an ADR	121(91)	12 (9)	0 (0)

Table 4.7 shows that the majority of respondents indicated that being unsure on how to report an ADR (lack of knowledge) and unavailability of ADR reporting forms (91% and 84.9 respectively) as major barriers to ADRs reporting. Others (53.4%) reported being too busy to send the report and about half (51.1%) of the respondents reported “concern about’ exposure to legal liability by reporting ADRs as barriers to ADR reporting.

Other reported barriers were inadequate human resources to handle pharmacovigilance issues at some institutions, lack of information to sensitise healthcare workers as well as the public on pharmacovigilance and ADR reporting by PMBP.

Chapter 5: Discussion and Conclusion

5.1 Introduction

This chapter provides a summary discussion on the healthcare professionals' knowledge, attitudes and practices towards ADR reporting. All the research questions and the reasons for not reporting have been addressed in this chapter. In summary, the findings of this study have demonstrated that healthcare professionals do not have adequate knowledge on ADR reporting. There was a difference in their knowledge as pharmaceutical professionals (pharmacists and pharmacy technicians) and medical doctors had more knowledge as compared to other healthcare professionals (clinical officers, nurses, medical assistants). The results have indicated that there is poor practice of reporting ADRs but there is a positive attitude towards ADR reporting among dispensing healthcare professionals in central region of Malawi.

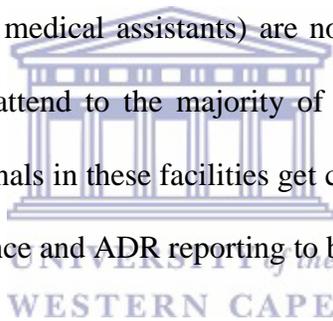
5.2 Knowledge of dispensing healthcare professionals towards ADR reporting

The concept of pharmacovigilance and ADR reporting in Malawi is fairly new. Despite the majority indicating that they have been trained on pharmacovigilance (77%), the results of this study has shown that most dispensing healthcare workers are not aware of ADR reporting. It has been found that the majority (67%) of respondents do not know how to report ADRs. Only 33% of the dispensers were knowledgeable about ADR reporting in terms of what is to be reported, who should report, when to report, how to report and where to report the ADRs. These results are also consistent with the findings of the studies done in Saudi Arabia (Almandil, 2016), China (Li et al., 2004), and Italy (Cosentino et al., 1997) where only a few respondents indicated having sufficient knowledge of ADR reporting.

The results have indicated that only 30% of the respondents have ever heard about ADR reporting and only a few (25%) were able to explain what it is and describe ADR reporting correctly. Overall,

the results indicate that there is poor knowledge of ADR reporting among the healthcare professionals.

The poor knowledge of healthcare professionals towards ADR reporting could be partly attributed to the fact that most of the respondents (79%) were non pharmaceutical professionals. This could indicate that ADR reporting might have been considered as a professional obligation by pharmaceutical personnel rather than by other professions. Issues of pharmacovigilance and ADR reporting may not have been taught during their basic training. The results have shown that apart from the doctors, most of the non-pharmaceutical professionals that are working as dispensers in private clinic/hospitals (clinical officers, medical assistants and nurses) and in public health centers (health surveillance assistants and medical assistants) are not aware of ADR reporting. Private clinics and public health centers attend to the majority of the Malawian population and it is important that healthcare professionals in these facilities get considered for the training, seminars and workshops on pharmacovigilance and ADR reporting to build their capacity.

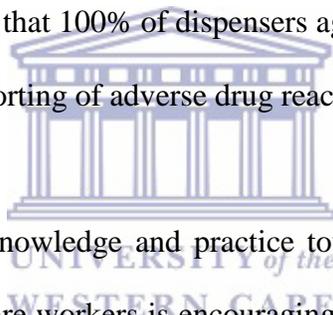


In addition, most of the respondents have indicated that they have known about pharmacovigilance and ADR reporting as part of their basic training in college. This is evidenced by the fact that those that have more experience in dispensing, meaning they did their basic education in the past when issues of ADR reporting were not being taught or emphasised, do not have knowledge on ADR reporting as regards to what it means, how they can report and where to report to. This makes it important that PMPB and training institutions work seriously on training, workshops and also on continuing professional education where issues on pharmacovigilance could be taught. This will enable other dispensing personnel such as HSAs, who do not go through tertiary education, to have knowledge on pharmacovigilance and ADR reporting.

The findings of this study have indicated that dispensing healthcare workers have limited knowledge regarding pharmacovigilance and ADR reporting in particular. This is worrisome as it may lead to delays in signal detection and bring a negative impact to the public health system, such as increased hospital admissions that may lead to increased healthcare costs, increased morbidity and mortality.

5.3 Attitude of dispensing healthcare professionals towards ADR reporting

The results of this study have revealed that the majority (77%) of dispensers have a positive attitude towards ADR reporting. These results are similar to the results noted in ADR reporting by community pharmacists in Holland (Groothessdt et al, 2003) and United Kingdom (Green, 2001). This study finding indicates that 100% of dispensers agreed that ADR reporting is necessary and 94% agreed that reporting of adverse drug reactions is part of their professional obligation.



Having noted that there is poor knowledge and practice towards ADR reporting, the positive attitude among dispensing healthcare workers is encouraging because it signifies their eagerness to be reporting ADRs. Therefore, as already discussed, it is imperative that PMPB as a regulatory authority, the Ministry of Health (MOH) together with other relevant stakeholders should use this positive attitude as a foundation for building capacity for the healthcare workers in all health facilities. Efforts have to be made towards information dissemination regarding pharmacovigilance so that healthcare workers should be well equipped with knowledge. This could be done through provision of sufficient training, conducting seminars/workshops, continuing professional development education and making available relevant tools such as guidelines and reporting forms and also enabling easy communication to facilitate coordination and reporting of the ADRs. This has to target all the health workers as patients' safety is a shared responsibility and everyone who comes across an ADR should be able to decide on the appropriate course of action.

5.4 Practice of dispensing healthcare professionals towards ADR reporting

From the results, it has been shown that lack of knowledge on what is to be reported, who should report, where to report and how to report, in addition to unavailability of ADRs reporting forms influences the practice towards ADR reporting among dispensers in the health facilities. The results have indicated that only 20% have ever been trained on how to report ADRs, only 12% knew that their hospitals had a reporting system and 14% claimed to have ADR reporting forms available within their institutions. On reporting of ADRs, 59% of respondents claimed to have ever experienced an ADR during their professional practice but only 3.3% of the respondents indicated having ever submitted ADR reports. The results show that there is poor practice of reporting ADRs which could be attributed to lack of training and lack of awareness on detection, assessment, investigation and reporting of an ADR as well as due to unavailability of reporting tools in the health facilities.

This study finding of poor practice of healthcare workers towards ADR reporting is similar to the results of a study done in Ethiopia where only 36 (27%) of healthcare professionals had encountered patients with ADRs and only 14 (38.8%) of the healthcare professionals reported the ADRs (Gurmesa & Dedefo 2016). The results are also similar to the findings of the study that was done in Malaysia whose findings indicated that only one pharmacist had submitted an ADR report (Ting et al, 2010) and also in Turkey where only 6.7% of the pharmacists submitted the ADR reports (Toklu et al, 2008).

Lack of training and awareness on ADR reporting and also lack of an established pharmacovigilance system in Malawi has led to poor knowledge on ADR reporting. This, coupled

with unavailability of tools such as ADR guidelines and ADR reporting forms in most health facilities, has considerably led to poor practice of ADRs reporting.

5.5 Comparison of knowledge, attitude and practice towards ADR reporting

The results of this study have shown that there is significant difference in knowledge towards ADR reporting among the healthcare professionals with more of pharmaceutical personnel and medical doctors having knowledge as compared to other cadres. These results are consistent with results of studies done in Saudi Arabia (Amandil, 2016; Abdel-Latif & Abdel-Wahab, 2014) and Northern Cyprus (Toklu et al., 2016) where more pharmaceutical personnel had knowledge towards ADR reporting than other professions.

The results of the study have indicated that there is no difference among healthcare professionals' attitude and practice towards ADR reporting. These results are consistent with the results of the studies conducted in Ethiopia (Gurmesa & Dedefo, 2016), Nepal (Santosh et. al., 2013), and Turkey (Toklu et al, 2008). However; on practice towards ADR reporting, the results suggests that more of pharmaceutical personnel have a better reporting practice as compared to other healthcare professionals but the difference was not statistically different. These results are similar to the results of the study done by Toklu et al., (2016) in Northern Cyprus where more of the pharmacists indicated having ever reported an ADR than other healthcare professions.

5.5 Barriers to Adverse Drug Reactions reporting

This study has revealed that there are a number of barriers that prevent effective reporting of ADRs. These barriers include unavailability of reporting forms, and in situations where the forms are available, health care workers are unsure on what to report, thus lack of knowledge on what to report, who should report, when the report should be made and where to report to. These results

are consistent with other studies that were conducted in Netherlands for community pharmacists (Groothessdt, et al. 2002) and medical practitioners in Italy (Cosentino, 1997)

As a way of enhancing pharmacovigilance activities, these barriers need to be thoughtfully considered and dealt with. In addition to solving these barriers, it is also important to ensure that there is good communication within the health system so as to create a better relationship among the healthcare workers and also a good collaboration between PMPB, MOH, training institutions and other relevant stakeholders.

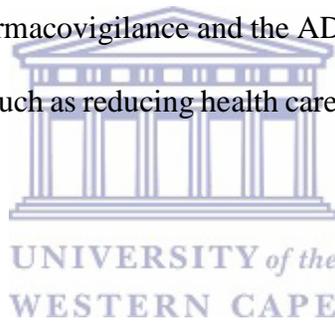
5.6 Conclusion

This study has revealed that most (67%) dispensers do not have adequate knowledge on ADR reporting. This inadequate knowledge on ADR reporting may have led to poor practice of reporting ADRs by dispensing healthcare professionals as only (3.3%) of the respondents indicated having ever reported an ADR. Lack of knowledge regarding the concept of pharmacovigilance, lack of reporting tools and information on how to report has greatly influenced the poor practice of reporting. Lack of training and awareness to the public, in addition to lack of continued support in health facilities in terms of availability of reporting tools (guidelines and forms), has led to poor knowledge and practice towards ADR reporting by dispensers. Availability of reporting tools in health facilities is essential as it ensures continuity of the system; this is particularly important considering the high turnover of staff, especially in public hospitals. This study has also revealed that most respondents that are from private clinics/hospitals and public health centers did not have sufficient knowledge on how to report ADRs as compared to those from bigger hospitals. With respect to ADR reporting, it is important that educational interventions should target dispensers in all health facilities regardless of their facility designation status as this will strengthen the

pharmacovigilance and ADR reporting practice because everyone will have adequate knowledge on signal detection, assessment and reporting of an ADR.

The positive attitude of dispensing healthcare professionals and their understanding that it is their professional obligation to report ADRs is very encouraging because it ensures that there will be ADR reporting if they can be trained and supported by providing them with necessary reporting tools.

All healthcare professionals play a key role in patient care as well as patient safety and all are important in pharmacovigilance programs. Therefore it is important to train all healthcare professionals in order improve pharmacovigilance and the ADR reporting. Improvements in ADR reporting have several advantages such as reducing health care costs and this will benefit the public health system.



Chapter 6: Recommendation and Limitation

6.1 Introduction

Based on the findings of the study, this chapter provides proposed recommendations for consideration and highlights the limitations of this study.

6.2 Recommendation

PMPB, as a regulatory body that is responsible for the coordination of pharmacovigilance and ADR reporting activities within Malawi, in collaboration with the Ministry of Health, training institutions and other relevant stakeholders should provide educational interventions towards ADR reporting to all healthcare professionals in the country. These educational interventions should also be targeting those that are from private clinics/hospitals and those at primary care level (health centers) as well as those from retail pharmacies and drug stores because together these facilities serve the majority of patients. Training will help healthcare professionals know what they can do and how to report and they would be encouraged to report as they would be able to understand that it is also part of their role as healthcare professionals as it also contribute to patient safety.

During training, it is important that the issue of communication is emphasized and encouraged because effective communication among healthcare professionals will facilitate signal detection and reporting of ADR cases. Integrating pharmacovigilance activities with routine clinical practice would greatly improve the reporting culture among healthcare professional. In addition, as a way of improving pharmacovigilance programs in the country, public awareness on reporting and how to report has to be initiated and intensified. This could be done by advertising and encouraging patients self-reporting to their nearest health facility or to the pharmacovigilance center. The public awareness could be done through radio programs, radio jingles, posters or brochures. PMPB as a

responsible regulatory authority, with assistance from other relevant stakeholders, should design the reporting forms and make them easily available and accessible so that the public may use them for reporting ADRs. These forms should be designed in a format that is easy to understand and fill in but should be able to capture all relevant information to allow for case investigation. Patients' awareness regarding reporting ADRs is vital to improve their knowledge and attitude towards ADR reporting.

As a way of strengthening the pharmacovigilance system and its activities on ADR reporting in the country, PMPB has to ensure that there is continued support to all trained healthcare professionals in the country in terms of ensuring that reporting tools (guidelines and reporting forms) are available and easily accessible. PMPB needs to be very active in monitoring pharmacovigilance activities by enhancing communication and follow up mechanisms. There has to be regular follow up and mentoring of healthcare professionals that have been recently trained. In order to facilitate this follow up, PMPB has to encourage the identification of a focal person among the trained healthcare professionals within an institution to coordinate pharmacovigilance activities.

PMPB, in collaboration with MOH, training institutions and other healthcare professional regulatory bodies should work towards review of curricula at all levels of healthcare professional training to incorporate and improve pharmacovigilance and ADR reporting topics. Considering that other cadres, especially the health surveillance assistants (HSAs) are being utilized as dispensers in most public health centers and that they do not go through tertiary education, the MOH in collaboration with training institutions and other relevant stakeholders should work towards increasing pharmaceutical professional cadres that should take charge of medicine dispensing in health facilities. This will enhance pharmacovigilance activities within these

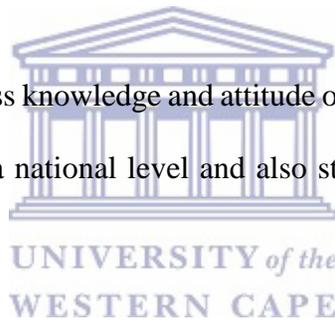
institutions and will encourage and improve the reporting culture of ADRs among healthcare professionals in Malawi.

6.3 Limitations of the study

The limitation of the study is that it was done in one region of Malawi (the central region), and could not be generalized to the whole population of dispensing healthcare professionals in Malawi.

The study results would have been more generalizable if the study was done in more than one region and if it had included a qualitative approach (in-depth interviews) in order to get a wider and in-depth understanding on respondents' knowledge, attitude and practice towards ADR reporting.

Other studies could be done to assess knowledge and attitude of consumers towards ADR reporting to the healthcare professionals at a national level and also studies could be done to identify the determinants of ADR reporting.



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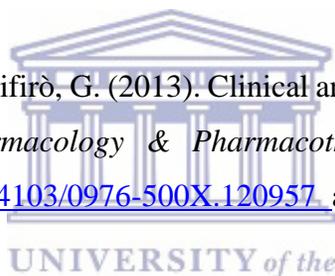
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Appendices

Appendix I: Information Sheet

PARTICIPANT INFORMATION SHEET

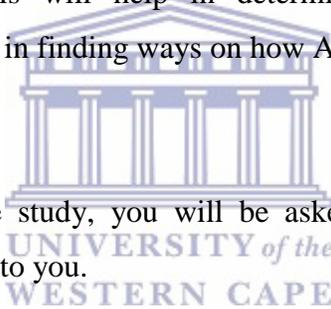
PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTIONS REPORTING

Purpose of the Study

The purpose of the study is to assess knowledge, attitude and practice of healthcare professionals that are involved in dispensing medicines in health facilities in Malawi towards Adverse Drug Reactions (ADRs) reporting. This will help in determining the cause of the observed underreporting and it will also help in finding ways on how ADR reporting could be enhanced.

Participation

If you agree to participate in the study, you will be asked to answer the questions in the questionnaire that will be provided to you.



Confidentiality

The information that will be collected from you will be strictly confidential as the filled questionnaires will be kept in a lockable cabinet and the information will not be used for any other purpose apart from the purpose of this study.

Risks

Apart from the time taken for you to fill in the questionnaire, there's no other risk that is anticipated. In case you do not feel comfortable to answer some questions in the provided questionnaire, feel free to skip them.

Benefits and Rewards

Your participation in the study will enable us know more about healthcare professionals knowledge, attitude and practices towards reporting of ADRs. Collectively, the information

gathered in this study will be used by policy makers to strengthen the Pharmacovigilance system and this will benefit all Malawians. However, please be informed that there are no monetary benefits in this study.

Rights to Withdraw

Your participation in this study is completely your choice and nothing will happen to you if you decide not to participate or stop participating in the study. Your refusal to participate or withdrawal from the study will not involve any penalty.

Who to Contact

If you have question(s) about this study, you should contact the following:

Ms Chrissy M.W Chulu (principal investigator)

Pharmacy Medicines and Poisons Board, P.O Box 30241, Lilongwe 3

Mobile phone: 0999 396 635/ 0888 348 358

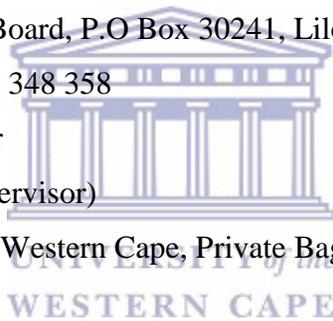
Email: chrissychulu@gmail.com or

Professor Nadine Butler (study supervisor)

School of Pharmacy, University of Western Cape, Private Bag X17, Bellville 7535, South Africa.

Tel: Tel: [+27 21 9592472](tel:+27219592472)

Email: nbutler@uwc.ca.za



Appendix II: Informed Consent

INFORMED CONSENT

PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTIONS REPORTING

I, Chrissy M W Chulu, (researcher) confirm that this information will remain confidential

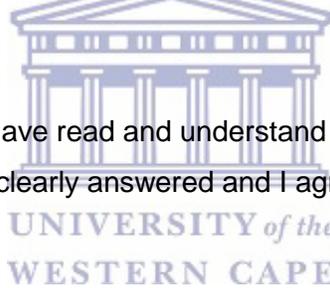
Signature: _____

Date _____

I, _____

am willing to participate in this study. I give you permission to come to my work premises to conduct the interview.

Signing this document indicates I have read and understand the participant information sheet provided. My questions have been clearly answered and I agree to participate in this study.



Name of Participant: _____

Signature of Participant: _____

Date: _____

Name of Researcher: _____

Signature of Researcher: _____

Date: _____



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Appendix III: Questionnaire

Instructions

Thank you for accepting to complete this questionnaire and please answer it to the best of your knowledge.

In the multiple choice questions, please tick (✓) the best choice but you may also tick more than one response where you think is appropriate. Where the questions are not clear to you, you are free to ask before attempting to answer.

Section 1: Demographic information

1. Gender

- | | |
|---------------------------------|---|
| <input type="checkbox"/> Male | 1 |
| <input type="checkbox"/> Female | 2 |

2. Age (in years)



3. Highest level of qualification

- | | |
|--|---|
| <input type="checkbox"/> Certificate | 1 |
| <input type="checkbox"/> Diploma | 2 |
| <input type="checkbox"/> Higher Diploma | 3 |
| <input type="checkbox"/> Degree | 4 |
| <input type="checkbox"/> others (specify)..... | 5 |

4. Professional qualification

- | | |
|---|---|
| <input type="checkbox"/> Pharmacy Assistant | 1 |
| <input type="checkbox"/> Pharmacy Technician | 2 |
| <input type="checkbox"/> Pharmacist | 3 |
| <input type="checkbox"/> Nurse | 4 |
| <input type="checkbox"/> Clinical Officer | 5 |
| <input type="checkbox"/> others specify)..... | 6 |

5. Name of your employer

- | | |
|--|---|
| <input type="checkbox"/> Ministry of Health | 1 |
| <input type="checkbox"/> CHAM | 2 |
| <input type="checkbox"/> Retail Pharmacy | 3 |
| <input type="checkbox"/> Private Clinic/hospital | 4 |
| <input type="checkbox"/> NGO | 5 |
| <input type="checkbox"/> others (specify)..... | 6 |

6. Name of your facility.....

7. Designation of your facility

- | | |
|--|---|
| <input type="checkbox"/> Central Hospital | 1 |
| <input type="checkbox"/> DHO | 2 |
| <input type="checkbox"/> MOH H/C | 3 |
| <input type="checkbox"/> CHAM H/C | 4 |
| <input type="checkbox"/> Private Clinic/Hospital | 5 |
| <input type="checkbox"/> NGO Clinic | 6 |
| <input type="checkbox"/> Retail Pharmacy | 7 |



8. Experience in drug dispensing (in years)

- | | |
|---|---|
| <input type="checkbox"/> less than 1 year | 1 |
| <input type="checkbox"/> 1 to 5 | 2 |
| <input type="checkbox"/> 6 to 10 | 3 |
| <input type="checkbox"/> 11 to 15 | 4 |
| <input type="checkbox"/> more than 15 years | 5 |

9. Have you ever received any training on Pharmacovigilance?

- | | |
|------------------------------|---|
| <input type="checkbox"/> Yes | 1 |
| <input type="checkbox"/> No | 2 |

10. If yes in question above, what type of training was it?
- On job training & seminar/workshop 1
 - Seminar/workshop 2
 - On the job training 3
 - Class (college/university) 4

SECTION 2: Knowledge on ADR reporting

11. Have you ever heard of adverse drug reactions reporting?
- Yes 1
 - No 2

12. Do you know what adverse drug reactions reporting mean?
- Yes 1
 - No 2



13. If Yes, please explain.....

14. The healthcare professionals responsible for reporting ADRs in a hospital is/are
- Doctor 1
 - Nurses 2
 - Pharmacist 3
 - All of the above 4

15. Pharmacovigilance is defined as;
- The science detecting the type and incidence of ADR after drug is marketed 1

- The science of monitoring ADR's occurring in a Hospital 2
- The process of improving the safety of the drug 3
- The detection, assessment, understanding and prevention of adverse effects 4

16. The most important purpose of Pharmacovigilance is

- To identify safety of the drug 1
- To calculate incidence of ADRs 2
- To identify predisposing factors to ADR's 3
- To identify previously unrecognized ADR's 4



17. Do you know the existence of a National Pharmacovigilance Programme in Malawi?

- Yes 1
- No 2
- Not sure 3

18. In Malawi which regulatory body is responsible for monitoring ADRs?

- Medical Council of Malawi 1
- Pharmacy Medicines and Poisons Board 2
- Pharmaceutical Society of Malawi 3
- Nurses Council of Malawi 4

Section 4: Attitude towards ADR reporting

19-24; 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	Yes	No	Not sure
19	Do you think reporting of adverse drug reaction is necessary?			
20	Do you think ADR reporting is professional obligation for you?			
21	Do you think reporting of ADRs is necessary for new drugs			
22	Do you think reporting of ADRs is necessary for serious adverse drug reaction			
23	Do you think reporting of ADRs is necessary for well recognized adverse drug reaction			
24	Do you think reporting of ADR should be voluntary			

25 - 30: Reasons for not reporting

Please indicate by responding to the statement by ticking (√) on the appropriate answer

S/N	Statement	Agree	Disagree	Not sure
25	System of reporting too bureaucratic			
26	Too busy to send an ADR report			
27	Report form not available when needed			
28	Feel that you would be exposed to legal liability by reporting an ADR			
29	You believe that only safe drugs are marketed			
30	Unsure how to report an ADR			

Section 3: Practice of ADR reporting

31. Is there any reporting system of ADR within your institution/facility?

- Yes 1
- No 2

32. Have you experienced any ADRs in patients during your professional practice?

- Yes 1
- No 2

33. Have you ever reported ADR cases?

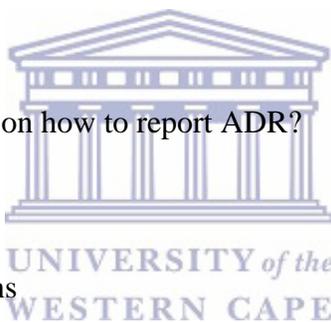
- Yes 1
- No 2

34. Are there spontaneous reporting forms at your pharmacy?

- Yes 1
- No 2

35. Have you ever been trained on how to report ADR?

- Yes 1
- No 2



36 – 40: Types of reported reactions

In the following table, please indicate if you would report the statement to pharmacovigilance center by ticking (✓) on the appropriate answer

S/ N	Statement	Yes	No	Not sure
36	Serious suspected reaction to established products			
37	All suspected reactions to new products			
38	Life-threatening reactions (risk of death) regardless of product age			
39	Disability (significant, persistent or permanent) regardless of product age			
40	Hospitalization (initial or prolonged) regardless of product age			

Appendix IV: UWC Ethical Approval Letter



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14 November 2016

Mrs CMW Chulu
School of Pharmacy
Faculty of Science

Ethics Reference Number: HS/16/8/6

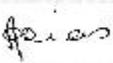
Project Title: Pharmacovigilance: An Assessment of Knowledge, Attitude and Practice of Healthcare Professionals toward adverse drug reactions in Malawi.

Approval Period: 14 November 2016 – 14 November 2017

I hereby certify that the Humanities and Social Science Research Ethics Committee of the University of the Western Cape approved the methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval. Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.



*Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape*

PROVISIONAL REC NUMBER - 130416-049

Appendix V: NHSRC Ethical Approval Letter



Appendix VI: Research Project Proposal

**PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND
PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG
REACTIONS REPORTING IN CENTRAL REGION OF MALAWI**

by

Chrissy M.W Chulu

RESEARCH PROJECT PROPOSAL



Abstract

Besides efficacy and potency as the main qualities sought for in medicines, they are also capable of producing adverse drug reactions (ADR), which if not properly managed can lead to serious consequences including death. In Malawi, despite establishing Pharmacovigilance and ADR reporting systems in 2008, less than ten ADR's have so far been reported. The aim of this study will be to assess knowledge, attitude and practices (KAP) for ADR reporting. Specifically, it will assess (1) the level of knowledge, attitude and practices of healthcare professionals on ADR reporting, (2) determine if there are any differences in knowledge, attitude and practice among the healthcare professionals towards ADR reporting.

This study will be conducted in the central region of Malawi. It is a descriptive cross-sectional survey study using stratified random (probability) sampling technique will be employed to draw 132 health facilities using categories of public hospitals, private clinics/hospitals and community pharmacies as strata. Every health professional that dispenses medicines in the main dispensing unit (pharmacy) in the sampled facilities will be targeted. Data will be collected using a structured questionnaire and descriptive statistics will be calculated in a Statistical Package for Social Sciences (SPSS) version 16.0. Chi-square test will be used to determine the significance of the difference in KAP among the categories of healthcare professionals at significance level of 0.05.

Description of acronyms

ADR	Adverse drug reaction
EMA	European Medicines Agency
FDA	Food and Drug Administration
KAP	Knowledge, Attitude, Knowledge
MOH	Ministry of Health
NHS	National Health Service
NHSREC	National Health Science Research Ethics Committee
PMPB	Pharmacy Medicine and Poisons Board
WHO	World Health Organisation
SPSS	Statistical Package for Social Sciences



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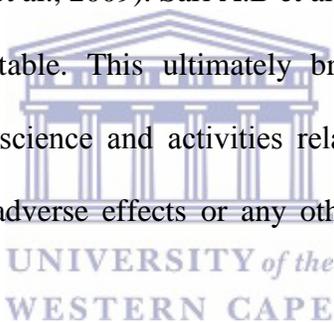


Chapter 1: Introduction

Medicines are important molecules that cure or improve lives of people suffering from diseases.

While efficacy and potency are the main qualities sought, medicines are also capable of producing some responses that are undesirable and are referred to as adverse drug reactions. WHO (1972) defines adverse drug reactions (ADR) as being noxious, unintended, and undesired effects of a drug or drugs that usually occurs after taking a drug at a normal doses for diagnosis, prophylaxis, and treatment.

Recent studies have indicated that at least more than half of the patients that are admitted to hospitals are harmed by drugs (Dequito A.B et al, 2011) and that severe ADR's are among the leading cause of death (Lazarou J. et al., 2009). Sari A.B et al, (2007) indicates that about 28% to 75% of these ADRs are preventable. This ultimately brings in an important concept of pharmacovigilance which is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems” (WHO, 2002).



1.1 Problem Statement

The concept of pharmacovigilance has become more important worldwide due to an increase in number of drug molecules entering the market (Abubakar A.R et al., 2014). Most countries have since established pharmacovigilance centres whose main function is to collect and analyse the reported information on ADRs and inform health care professionals as well as the public about the most frequent drug related problems at an earliest possible time (Bencheick R.S et al., 2009).

The main objective of pharmacovigilance is to protect patients from ADR's and it becomes imperative that healthcare professionals especially prescribing physicians, pharmacists and nurses are vigilant in the detection, assessment and reporting of ADR's. WHO recommended reporting rates are that a country must generate over 200 reports per 1,000,000 inhabitants per year (WHO, 1972) however

according to Rawlins M.D, (1995) reports of serious adverse events in most countries rarely exceed 10%. Hazell L. et al (2006) conducted a systematic review involving studies from twelve countries and found out that the underreporting rate was 85%. This review provides evidence of significant and widespread under-reporting of ADRs to spontaneous reporting systems including serious or severe ADRs (Hazell et al, 2006).

Studies have been conducted worldwide in order to assess the knowledge, attitudes and practice of healthcare professionals towards ADR reporting with the aim of identifying reasons for underreporting and to determine what needs to be done in order to increase ADR reporting rates. Underreporting of ADR's happens worldwide even in the developed countries as Chyka P.A (2000) reports that in USA reporting rates are as low as 1-6%.

In Malawi, pharmacovigilance was introduced in 2008 and the pharmaceutical regulatory body, Pharmacy Medicine and Poisons Board (PMPB) was identified as the pharmacovigilance centre. Since the inception of pharmacovigilance in 2008 and despite conducting training to healthcare professionals across the country, PMPB has received a few reports on adverse drug reaction (2008-2015 reports). It is unlikely that there are no adverse drug reactions being experienced and this therefore presents a very serious problem of underreporting and is worrisome.

Considering that healthcare professionals are charged with the responsibility of taking care of the patients; managing and reporting of ADR's becomes one of their important responsibilities. This study therefore intends to assess knowledge, attitude and practice of healthcare professionals towards ADR reporting in order to establish the cause of the observed underreporting.

1.2 Purpose of the study

The purpose of this study is to assess knowledge, attitude and practice of healthcare professionals towards ADR reporting in central region of Malawi.

1.3 Research questions

- What knowledge do healthcare professionals have on pharmacovigilance?

- What do healthcare professionals think of adverse drug reactions reporting?
- What do healthcare professionals do when an adverse event has occurred?

1.4 Research objectives

The specific objectives for this study are to:

- Assess the level of knowledge, attitude and practices of healthcare professionals on ADR reporting
- Determine if there are any differences in knowledge, attitude and practice among the healthcare professionals towards ADR reporting
- Establish association between knowledge, attitude and demographic variables of sex, experience, age and education level.

1.4 Significance of the study

There has been no study of this kind in Malawi and the findings of this study will bring in knowledge and enhance understanding on pharmacovigilance among healthcare professionals. The study will help increase patient safety from ADRs as it will identify the problems underlying the underreporting of ADRs and also generate awareness among health professionals on importance of reporting ADRs.

Chapter 2: Methodology

2.1 Study design

This is a descriptive cross-sectional survey based study as it aims at describing the state of affairs of the studied parameters in the population at the time of study (Robson C., 1993) and it will explore the cause(s) of the observable facts (Creswell, 1994).

2.2 Target population

The study population will be all dispensing health facilities in the central region of Malawi. Only healthcare professionals working at the main dispensing unit (pharmacy) of these facilities will be targeted.

Selection Criteria

Inclusion criteria

- All public dispensing health facilities of the central region
- All central region private dispensing health facilities that are registered with PMPB

Exclusion criteria

- Health facilities that would not like to participate in the study

2.3 Sampling and sample size

It is important that the sample be big enough in relation to the study population in order to enhance external validity of the research conclusion (Lenth R.V, 2001). To come up with the sample, this study will use multistage sampling; sampling of the districts in the central region and sampling of health facilities within the sampled districts.

According to Borg (1983), a sample of 30 per cent of the population is enough to generalize the results on the whole population and this study considered 40 percent. The central region of Malawi is comprised of 9 districts and 40 percent of the districts will be sampled for the study. Within the sampled districts, stratified random (probability) sampling technique will be used to draw health facilities using categories of private clinic/hospitals, public hospitals and community pharmacies as stratas.

Each stratum will then be treated independently of the others and 40 per cent of the facilities will be sampled for the study. Through random sampling, Lilongwe, Mchinji, Dowa and Kasungu districts were sampled for the study. Basing on the population of health facilities within these districts, the sample characteristics will be as indicated in Table 2 below.

Table 1: Sample size and distribution

Category of Facilities (strata)	Total Number in sampled districts	Sample size
Public health facilities	124	50
Retail pharmacies	31	12

Registered private hospitals/clinics	128	52
Total	283	114

Under each stratum, the number and names of facilities determined as a sample will be randomly chosen from the list of facilities. This will be done through random sampling using a table of random numbers and a total of 114 health facilities as indicated in Table 1 above will be identified from the three strata. In each facility that has been sampled, all healthcare professionals that are involved in dispensing medicines in the main dispensing unit (pharmacy) will be included in the study.

2.4 Data collection method and tools

Self administered structured questionnaires will be used to collect data considering that the sample population is large and the time available to conduct the survey is limited (Mann C.J., 2003). In addition the tool is straight forward to complete as well as to analyse, which will help save time and money (Manion and Cohen 2000). As a pilot study, the set questionnaire will be administered to 10 government health facilities, 4 private clinics/hospitals and 2 community pharmacies in Lilongwe district.

The questionnaire will be sent via email to those participants that will have an email address and those that do not have the email address the questionnaires will be delivered to them. A time period of five working days will be given for them to respond to the questionnaire.

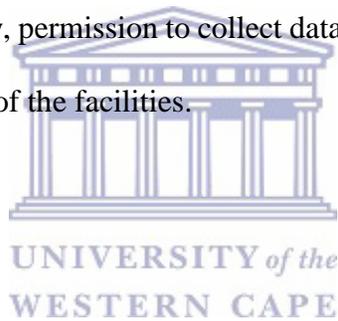
2.5 Dissemination of results

The findings of this study will be shared with the facilities that have participated in the study as well as to policy makers in the Ministry of health so that more informed decisions could be made that would ultimately lead to improving patients safety in all health facilities in Malawi. The results will also be presented in conferences and may also be published if an opportunity arises.

Chapter 3: Ethical considerations

With the view that the study will gather information from participants, in order to promote autonomy and understanding; participants will be provided with all information pertaining to purposes, and methods to be employed through a participant information sheet and an informed consent form. A questionnaire to be used will be self-explanatory and anonymous to promote understanding and confidentiality.

Ethical clearance will be obtained from the ethics committee of the University of the Western Cape, South Africa and the Malawi National Health Science Research Committee (NHSRC). Authorization to conduct the study will be obtained from the Ministry of Health, and the District Health officers for the district hospitals in the central region and PMPB for the licensed dispensing outlets in the central region. Finally, permission to collect data in the facilities will be sought from head of institutions and/or owners of the facilities.



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Appendices

Cover Letter

Pharmacy Medicines and Poisons Board,
P.O Box 30241, Lilongwe 3
Telephone: 01 755165; 0999396635

Greetings!

I am Chrissy M.W Chulu, pursuing my Masters in Pharmacy Administration and Policy with University of Western Cape. As a requirement, I am doing a thesis project and I have proposed to do my survey research in Malawi. In this survey, I intend to assess the knowledge, attitude and practice towards adverse drug reactions (ADRs) reporting of healthcare professionals that are involved in drug dispensing in health facilities of central region in Malawi.

As one of the healthcare professionals, your facility was randomly selected to participate in this study and I therefore request a moment of your time to complete the attached questionnaire. The questionnaire is self explanatory and on average it may take you about 5-10 minutes to complete. Please be assured that this is an anonymous survey and there's absolutely no risk and your participation will help in understanding the reasons behind ADR's underreporting. This will help in finding ways to strengthen the ADR reporting system in Malawi. In addition, there are no monetary gains in this study. If you accept to participate in this exercise, please, sign the attached consent form.

Thank you in advance for your time and willingness to participate.

Regards

Chrissy Chulu

Student, MSc in Pharmacy Administration and Policy

University of Western Cape

Participant information sheet

PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTIONS REPORTING

Purpose of the Study

The purpose of the study is to assess knowledge, attitude and practice of healthcare professionals that are involved in dispensing medicines in health facilities in Malawi towards Adverse Drug Reactions (ADRs) reporting. This will help in determining the cause of the observed underreporting and it will also help in finding ways on how ADR reporting could be enhanced.

Participation

If you agree to participate in the study, you will be asked to answer the questions in the questionnaire that will be provided to you.

Confidentiality

The information that will be collected from you will be strictly confidential as the filled questionnaires will be kept in a lockable cabinet and the information will not be used for any other purpose apart from the purpose of this study.

Risks

Apart from the time taken for you to fill in the questionnaire, there's no other risk that is anticipated. In case you do not feel comfortable to answer some questions in the provided questionnaire, feel free to skip them.

Benefits and Rewards

Your participation in the study will enable us know more about healthcare professionals knowledge, attitude and practices towards reporting of ADRs. Collectively, the information gathered in this study will be used by policy makers to strengthen the Pharmacovigilance system and this will benefit all Malawians. However, please be informed that there are no monetary benefits in this study.

Rights to Withdraw

Your participation in this study is completely your choice and nothing will happen to you if you decide not to participate or stop participating in the study. Your refusal to participate or withdrawal from the study will not involve any penalty.

Who to Contact

If you have question(s) about this study, you should contact the following:

Ms Chrissy M.W Chulu (principal investigator)

Pharmacy Medicines and Poisons Board, P.O Box 30241, Lilongwe 3

Mobile phone: 0999 396 635/ 0888 348 358

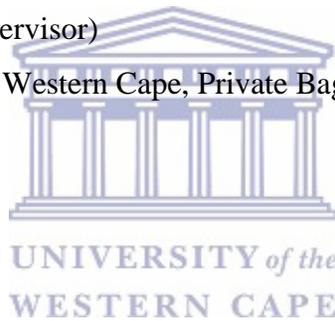
Email: chrissychulu@gmail.com or

Professor Nadine Butler (study supervisor)

School of Pharmacy, University of Western Cape, Private Bag X17, Bellville 7535, South Africa.

Tel: Tel: [+27 21 9592472](tel:+27219592472)

Email: nbutler@uwc.ca.za



Informed Consent

PHARMACOVIGILANCE: AN ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICE OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTIONS REPORTING

I, Chrissy M W Chulu, (researcher) confirm that this information will remain confidential

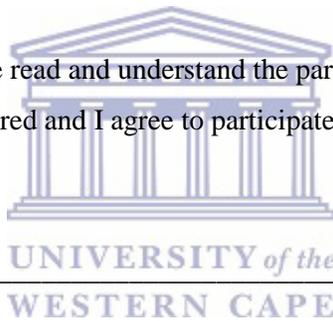
Signature: _____

Date _____

I, _____

am willing to participate in this study. I give you permission to come to my work premises to conduct the interview.

Signing this document indicates I have read and understand the participant information sheet provided. My questions have been clearly answered and I agree to participate in this study.



Name of Participant: _____

Signature of Participant: _____

Date: _____

Name of Researcher: _____

Signature of Researcher: _____

Date: _____

- b. The science of monitoring ADR's occurring in a hospital
- c. The process of improving the safety of the drug
- d. The detection, assessment, understanding and prevention of adverse effects

34. The most important purpose of Pharmacovigilance is

- a. To identify safety of the drug
- b. To calculate incidence of ADRs
- c. To identify predisposing factors to ADR's
- d. To identify previously unrecognized ADR's

35. Do you know the existence of a National Pharmacovigilance Programme in Malawi?

- a. Yes
- b. No
- c. Not sure

36. In Malawi which regulatory body is responsible for monitoring ADRs?

- a. Medical Council of Malawi
- b. Pharmacy Medicines & Poisons Board
- b. Pharmaceutical Society of Malawi
- d. Nurses Council of Malawi

Section 3: Practice of ADR reporting

37. Is there any reporting system of ADR within your institution/facility?

- a. Yes
- b. No

38. Have you experienced any ADRs in patients during your professional practice?

- a. Yes
- b. No

39. Have you ever reported ADR cases?

- a. Yes
- b. No

40. Are there spontaneous reporting forms at your pharmacy?

- a. Yes
- b. No

41. Have you ever been trained on how to report ADR?

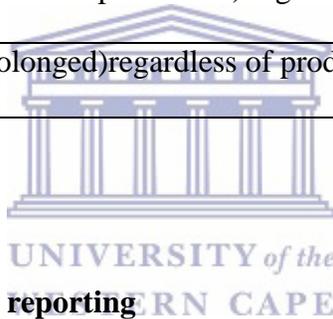
a. Yes

b. No

24 – 28: Types of reported reactions

In the following table, please indicate if you would report the statement to pharmacovigilance centre by ticking (✓) on the appropriate answer

S/ N	Statement	Yes	No	Not sure
24	Serious suspected reaction to established products			
25	All suspected reactions to new products			
26	Life-threatening reactions (risk of death) regardless of product age			
27	Disability (significant, persistent or permanent) regardless of product age			
28	Hospitalization (initial or prolonged) regardless of product age			



Section 4: Attitude towards ADR reporting

32-27; 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	Yes	No	Not sure
29	Do you think reporting of adverse drug reaction is necessary?			
29	Do you think ADR reporting is professional obligation for you?			
30	Do you think reporting of ADRs is necessary for new drugs			
31	Do you think reporting of ADRs is necessary for serious adverse drug reaction			
32	Do you think reporting of ADRs is necessary for well recognized adverse drug reaction			
33	Do you think reporting of ADR should be voluntary			

34 -39: Reasons for not reporting

Please indicate by responding to the statement by ticking (✓) on the appropriate answer

S/N	Statement	Agree	Disagree	Not sure
34	System of reporting too bureaucratic			
35	Too busy to send an ADR report			
36	Report form not available when needed			
37	Feel that you would be exposed to legal liability by reporting an ADR			
38	You believe that only safe drugs are marketed			
39	Unsure how to report an ADR			

Thank you for your participation in the study

