KNOWLEDGE, ATTITUDES AND PRACTICES OF HEALTHCARE PROFESSIONALS TOWARDS ADVERSE DRUG REACTION REPORTING IN MAFIKENG PROVINCIAL HOSPITAL

by

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Declaration

I, Nametso Patience Segomotso, declare that the dissertation hereby submitted to the University of Limpopo, for the degree of Masters of Public Health has not previously been submitted by me for a degree at this or any other university; that it is my work in design and in execution, and that all material contained herein has been duly acknowledged.

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Abstract

Background: Prevention, monitoring and reporting of adverse drug reactions is still a challenge among healthcare professionals. Even though some adverse drug reactions are minor and can be resolved quickly some can cause permanent disability or death. A recent South African study in a secondary hospital found that 6.3% of medical admissions were due to adverse drug reactions, which is similar to proportions found in developed countries. It is the responsibility of the healthcare professionals to detect, investigate, manage and report adverse drug reactions.

Aim of the study: This study aimed to determine knowledge, attitudes and practices of healthcare professionals (doctors, nurses and pharmacists) regarding the reporting of patients' adverse drug reaction at Mafikeng Provincial Hospital.

Methods: This was a descriptive quantitative study. A questionnaire was used to collect data from 29 doctors, 88 nurses and 5 pharmacists. Data was collected on demographic characteristics of the healthcare professionals, their knowledge, attitudes and practices towards ADR reporting. Data analysis was conducted using STATA (version 11) and Epi info (version 6). A test of association of selected variables was done using Pearson chi–square and logistic analysis to measure the association.

Results: More than half of the participants were male (56.3%) and 53.8% percent of them were younger than 40 years. Majority of the respondents (72.27%) indicated that they do not know how to report ADRs. There was no significant difference in terms of knowledge by age category. None of the healthcare professionals have ever sent their ADR forms to the pharmacovigilance centre. Ninety-one percent (91.53%) felt that reporting of ADR can benefit the public health, 78.63% felt that filling of the ADR yellow form is useful and 98.29% felt that ADR should be compulsory. There was no significant association between knowledge of how to report and attitude towards reporting (X^2=1.0, p= 0.317), no association between knowledge and practice (X^2=0.974, p= 0.324).

Conclusions: This study revealed that more than a third of the respondents (72.29%) did not have the knowledge of the procedure for reporting ADRs. Healthcare professionals had a positive attitude towards ADR; 98.29% of them said that ADR reporting should be compulsory. There was no significant association between knowledge, attitude and practice toward ADR reporting. Healthcare professionals' knowledge can be improved through educational interventions and trainings.

Description of acronyms

ADR	Adverse drug reaction
FDA	Food and Drug Administration
NHS	National Health Service
WHO	World Health Organisation
MCC	Medicines Control Council
NADMEC	National Adverse Drug Event Monitoring Centre
ARV	Antiretroviral
NHS	National health system
IOM	Institute of Medicine
ADE	Adverse drug event
ART	Antiretroviral treatment
EMA	European Medicines Agency
NCAs	National Competent Authorities
CDSCO	Central Drugs Standard Control Organization
NPP	National Pharmacovigilance Programme
CARM	Centre for Adverse Reactions Monitoring
MIC	Medicines Information Centre
MPH	Mafikeng Provincial Hospital
NPC	National Pharmacovigilance Centre
MREC	Medunsa campus research and ethics committee
CE & T	Clinical Evaluation and Trials

Operational definition of terms

MEDWATCH program: Refers to an FDA program designed to monitor adverse events (AEs) from drugs marketed in the US Health professionals report AEs voluntarily to the FDA through MedWatch.

Adverse events - Refers to an unfavorable or unintended sign, symptom, reaction, or disease that is associated in time with the use of an investigational drug, whether or not the event is related to the investigational drug, or is expected

Adverse drug reactions – Is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy

Serious adverse events - Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity,
- is a congenital anomaly/birth defect, or
- requires intervention to prevent permanent impairment or damage

Site effect - Refers to an unintended symptom that results from using a drug.

Pharmacovigilance - A science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identifying new information about hazards associated with medicines and preventing harm to patient

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CHAPTER ONE
INTRODUCTION AND BACKGROUND

1.0. Introduction

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death.

A study conducted to assess the potential preventability of adverse drug reactions (ADRs) directly related to a patient's hospital admission revealed that 62.3% of these events were considered potentially preventable. Approximately 25% of these events were serious to life-threatening. Most resulted from inadequate monitoring of therapy or inappropriate dosing. Patient noncompliance and drug interactions were also common causes (McDonnell and Jacobs, 2002).

According to the World Health Organization (2006) definition, ADR "is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy". A serious ADR according to Bhowmik and Sampath (2010) is one that may be fatal, life threatening, causes or prolongs hospitalization, causes a congenital abnormality and causes disability or incapacity.

ADRs have been regarded as a major public health problem since they represent a sizable percentage of admissions and an economic burden (Patel, Kedia, Bajpai, Mehta, Kshirsagar and Gogtay. 2007). Hence, ADRs have a major impact on public health, reducing patients quality of life and imposing a considerable financial burden on the health care systems at a time when many health care systems are under considerable financial strain.

In some countries, ADRs rank among the top 10 leading causes of mortality (WHO, 2006). In 1996, 108,000 Americans died in hospitals from adverse reactions to FDA-approved drugs properly administered by licensed medical professionals. In the same year, 2.2 million Americans had adverse reactions to FDA-approved drugs. ADRs were found to be a fourth leading cause of death in the United States (Knox, 1998). Other studies revealed that ADRs occur during 10 to 20% of hospital admissions, and about 10 to 20% of these reactions are serious (Seidl, Thornton and Cluff, 1965; Smith, Seidl and Cluff 1966; Hurwitz and Wade, 1969).

Wiffen, Gill, Edwards and Moore (2002) reported that about 3 to 7% of all hospital admissions in the United States are for treatment of adverse drug reactions. The author further suggested in a recent systematic review that 4% of the National Health Service (NHS) bed occupancy (measured in days) in England was due to ADRs.

In South Africa it was found in a study conducted in a secondary hospital that 6.3% of medical admissions were due to an ADR, which is similar to proportions found in developed countries (Mehta, Durrheim, Blockman, Kredo, Gounden and Barnes. 2008).

Post-marketing surveillance programs which are also known as pharmacovigilance programs are essential in every country for monitoring the occurrence of ADRs, as the data derived from within the country may encourage national regulatory decision making. Thus, these programs may contribute to decreased morbidity, mortality, length of stay in hospital, healthcare costs, and liability associated with ADRs (Zolezzi and Parsotam, 2005). Pharmacovigilance is defined by the WHO as a science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identifying new information about hazards associated with medicines and preventing harm to patients (WHO, 2006).

In South Africa the Medicines Control Council (MCC) has a responsibility to ensure the safety, efficacy and quality of all medicines used by the South African public. The national pharmacovigilance programme is coordinated by the MCC. The pharmacovigilance programme has two units for the monitoring of the safety of medicines namely: The National Adverse Drug Event Monitoring Centre (NADMEC) in Cape Town which monitors the safety of all registered medicines and also a focused surveillance unit at Medunsa which is responsible for the monitoring the safety of Antiretroviral (ARV) medicines, complementary medicines and unregistered medicines used during clinical trials (Fomundam and Mathews, 2009).

Countries need to link their pharmacovigilance programmes with the WHO international network of pharmacovigilance centres. As of 2005, the WHO International Drug Monitoring Programme, comprising 78 national pharmacovigilance centres throughout the world, maintained a database containing more than 3.5 million cases reports of suspected ADRs. In fact, less than 27% of lower middle income and low income economies have National pharmacovigilance systems registered with the WHO programme, compared with 96% of the high income countries in the Organisation for Economic Co-operation and Development. South Africa is among the developing countries that has registered its Pharmacovigilance with the WHO programme (WHO, 2006).

Pirmohamed, Atuah, Dodoo and Winstanley (2007), indicated that the main reasons the developing countries are not registered with WHO programme are lack of resources, infrastructure, and expertise. Thus, although access to medicines is increasing in developing countries, there is a danger that their risk benefit profiles in indigenous populations will not be fully monitored and acted upon.

All healthcare providers have roles to play in maintaining a balance between a medicine's benefits and risks. Once a drug is available to the public, making a determination about its safety is the shared responsibility of all who are part of the prescribing process, including patients (WHO, 2006). ADR reporting was initially

regarded as a professional obligation for doctors, pharmacists and other profession except nurses (Hall, McCormack, Arthurs and Feely. 1995). Nurses are also very important in ADR reporting because among healthcare professionals they are often the first contact with patients and they can play a vital role in recognizing suspected ADRs if trained appropriately.

The role of healthcare professionals is vital in recording and reporting suspected ADRs in order that regulatory agencies are alerted of emerging safety concerns and thereby facilitating timely and appropriate action. All health care professionals should be encouraged to report all suspected adverse reactions resulting from medicines (including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is not in the package insert, potentially serious or clinically significant (WHO, 2006).

The information obtained from the reported reactions promotes the safe use of medicines on a national level. A completed ADR form submitted by healthcare professionals could result in additional investigations into the use of the medications in each country and the whole world.

Wilffen et al. (2002) found that underreporting of ADRs by healthcare professionals is a problem worldwide. Even in countries like UK, USA, Asia and Europe were pharmacovigilance was fully practiced underreporting was found to be a major challenge in the healthcare system. Thus Zolezzi Parsotam (2005) highlighted that underreporting may delay signal detection and cause underestimation of the size of a problem.

According to literature review, there are several studies conducted to identify the factors that contribute to underreporting of the healthcare professionals. The most identified discouraging factors were the well-known reactions, an uncertain on how to report, lack of awareness of the requirement for reporting, lack of understanding of the

purpose reporting and insufficient time (Oshikoya and Awobusuyi, 2009; Lee, Chan, Raymond and Critchley. 1994; Green, Mottram, and Rowe, 2001).

1.1 Problem statement

Underreporting of ADRs by healthcare professional to the national pharmacovigilance centre is a challenge in South Africa and globally. The role of healthcare professionals is vital in recording and reporting suspected ADRs in order that regulatory agencies are alerted of emerging safety concerns and therefore facilitating timely and appropriate action. Underreporting may delay signal detection of previously unknown adverse effects of medicines. Adequate knowledge, good practices and positive attitude are essential element in ADR reporting. Search of literature with regards to knowledge, attitudes and practices of South African healthcare professionals towards ADR reporting yielded no results hence it was found important to conduct this study.

1.2 Aim of the study

This study aimed to investigate the knowledge, attitudes and practices of healthcare professionals towards ADR reporting in Mafikeng Provincial Hospital.

1.3 Research objectives

The objectives of the study were to:

- Assess the attitudes of healthcare professionals regarding adverse drug reaction reporting.
- Determine the knowledge of healthcare professionals regarding adverse drug reaction reporting.
- Describe practices of healthcare professionals regarding ADR reporting
- Determine association between knowledge , attitude, practice and ADR reporting by healthcare professionals

1.4 Research Questions

The research questions of this study are as follows:

- What are the attitudes of healthcare professionals regarding adverse drug reaction reporting?
- What is knowledge of healthcare professionals regarding adverse drug reaction reporting?
- What are the practices of ADR reporting by healthcare professionals?
- What is the association between knowledge, attitude, practice and ADR reporting by healthcare professionals?

1.5 Justification of the study

It is envisaged that the results of this study will be presented to the North West Department of Health so that they can assess the impact of under-reporting on public health decisions and come up with initiatives to improve reporting of ADR among patients.

CHAPTER TWO
LITERATURE REVIEW

2.0. Introduction

This chapter discusses reviewed literature which is relevant to this study. The discussion of reviewed literature is arranged into section 2.1 to 2.16.

2.1. Adverse drug reactions (ADRs)

All medicines have the potential to cause ADRs. ADRs arise following the administration of any medicinal products to a patient. According to the WHO (2006) definition, "ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy".

ADRs are a common problem, which affect patients in the hospital and community setting. Most ADRs are relatively mild, and many disappear when the drug is stopped or the dose is changed. Some gradually subside as the body adjusts to the drug. Other ADRs are more serious and last longer. Even though some ADR are minor and can be resolved quickly some can cause permanent disability or death (WHO, 2006).

Digestive disturbances such as loss of appetite, nausea, a bloating sensation, constipation and diarrhoea are particularly common adverse drug reactions, because most drugs are taken by mouth and pass through the digestive tract. However, almost any organ system can be affected. In older people, the brain is commonly affected, often resulting in drowsiness and confusion (Fomundam et al. 2009).

2.2. Incidence of ADRs

A number of authors conducted studies to determine the incidence of ADRs in the health care systems. The findings of the studies were that drug related mortality and

morbidity is one of the health problems faced by both developed and developing countries (Hurwitz et al. 1969; Classen, Pestotnik, Evans, Lloyd and Burke. 1997). The findings were different in terms of size, quality and methodology, making the comparisons to be very difficult. Some authors have assessed the incidence of ADRs in numerous settings, but these estimates vary considerably.

Wester, Jonnson, Sigset, Druid and Hagg (2008) concluded in his study that drug reactions may be the fourth to the sixth leading cause of death in the US which is low when compared to a Swedish study that also implicated that ADRs are 7th most common cause of death.

Seidl et al. (1965) and Hurwitz et al. (1969) reported that about 3 to 7% of all hospital admissions in the United States are for treatment of adverse drug reactions. They further concluded that adverse drug reactions occur during 10 to 20% of hospital admissions, and about 10 to 20% of these reactions are serious.

In England there were a total of 3.8 million acute admissions, suggesting that ADRs causing hospital admission were responsible for the death of 5700 patients (3800 to 7600) every year (Classen et al. 1997). A systematic review conducted by Wifffen et al. (2002) suggested that 4% of the National Health Service (NHS) bed occupancy (measured in days) in England were due to ADRs.

A meta-analysis of 39 prospective studies conducted by Lazarou, Pomeranz and Corey (1998) focused on the incidence of adverse drug reactions in USA hospitals. The authors mentioned that the overall incidence of serious ADRs was 6.7% and the fatal ADRs were 0.32%.Another study in the USA revealed that 108,000 Americans died in hospitals from adverse reactions to FDA-approved drugs properly administered by licensed medical professionals. In the same year, 2.2 million Americans had adverse reactions to FDA-approved drugs (Knox, 1998.)

Two prospective studies that were conducted in the UK showed that 6.5% of patients admitted to hospital were experiencing an ADR (Pirmohamed, James, Meakin, Green,

Scott, Walley, Farrar, Park and Breckenridge. 2004; Howard, Avery, Howard and Partridge. 2003. 2003). The number of admission in UK which is 6.5% was lower than USA which was 10-20%, but higher than England which was 4 % (Seidl et al. 1965; Smith et al. 1966; Hurwitz et al. 1969; Wiffen et al. 2002). Moreover 6.7% of hospital patients suffer serious ADRs in UK which was higher when compared to 3% in India (Knox, 1998; Gor and Desai, 2008).

In South Africa it was found in a study conducted in a secondary hospital that 6.3% of medical admissions were due to an ADR, which is similar to proportions found in developed countries (Mehta, et al. 2008).

2.3. Risk factors associated with ADR development

According to the United Republic of Tanzania Ministry of Health (2006:6), taking several drugs, whether prescription or over-the-counter, contributes to the risk of having an ADR. The risk factors that may pre-dispose induce or influence the development, severity and incidence of adverse reactions in the population of can be:

- Patient factors**:** Genetics, racial differences, diets, diseases, prescribing practices, culture of drug use and traditions of the people e.g. high carbohydrate, fat diet etc.
- Drug interactions, drug distribution, storage and use including indications, dose, availability and other underlying conditions.

2.4. Predisposing factor associated with ADR development

The findings of the study on hospitalised patients at UK (Bates, Spell, Cullen, Burdick, Laird and Petersen. 1997) proves that the predisposing factors like age, gender, co-morbidity, number of drugs taken are the risk factors for the development of ADRs. The results of the study were contrary to the results of the study that was conducted at USA (Bates, Miller, Cullen, Burdick, Williams and Laird. 1999) where

the adverse drug events occurred more frequently in sicker patients who stayed in the hospital longer.

2.5. ADRs due to the antiretroviral drugs (ARVS)

Outcomes of ART have been documented in both developed and developing countries. It was found that those adverse events impact not only the quality of life of the patients but also their clinical management and survival (Malangu and Karamagi, 2010).

A study conducted by Mehta et al (2008) in South Africa revealed that ARTs were the commonest drugs implicated in ADR-related admissions, and among HIV-infected patients those on ARTs were 10 times more likely to have an ADR-related admission. The authors further reported that with this enormous HIV burden, it is not surprising that ARTs are currently the commonest drugs causing severe morbidity in South Africa and that this problem will increase as the ARV roll-out expands.

South Africa is one of the developing countries with the largest antiretroviral treatment (ART) programme with more than 750,000 patients initiated on ART by March 2009; hence it is very difficult to determine what ADRs are caused by ARVs due to underreporting. The country is therefore faced with the major challenge of ensuring and sustaining the quality of service, including preventing and managing of the ADRs, and improving drug adherence, which are critical for the success of such a comprehensive treatment program (Fomundam et al. 2009).

ADR related to the use of antiretroviral drugs may severely jeopardise confidence in the safety of these medicines and alter patient adherence to antiretroviral therapy, not only reducing treatment efficacy with increased morbidity and mortality, but also reducing treatment effectiveness and increasing the risk for emergence of second drug resistance (Fellay, Boubaker, Ledergerber, Bernasconi, Furrer, Battegay, Hirschel, Vernazza, Francioli, Greub, Flepp and Telenti. 2001).

A study by Malangu (2008) reported that adherence is important to the effectiveness of antiretroviral therapy. The author has indentified factors such as the non-prescribed drugs, the presence of side effects such as insomnia, headaches and abdominal pain and eating well as the main facilitator of non-adherence to antiretroviral therapy in HIV-infected patients.

This was proven by Fellay et al. (2001) in a review of over 1000 patients in a Swiss cohort that received combination ARV therapy. The findings were that 47% and 27% of the patients were reported to have clinical and laboratory adverse events, respectively. A recent study on the impact of adverse events of antiretroviral treatment on regimen change and mortality in Ugandan children stated that adverse events were responsible for the 54.5% of regimen changes and 21.4% of deaths in children treated at the study site (Malangu et al. 2010). Roca (2009) further indicated that adverse reactions are common with antiretroviral, and they are an important cause of medication non-adherence and suboptimal control of HIV infection.

2.6. ADR - related costs

ADRs have major public health, financial and economic implications.The financial burden of ADRs increases substantially when ADRs either cause or extend hospitalisation. The average additional stay resulting from an ADR has major cost implications for a health service. It is also important to note that most of the studies to date have largely concentrated on direct costs, and there are no reliable estimates of the social and indirect costs of ADRs, making it difficult to measure the overall economic burden to the patient and society (Lundkvist and Jonsson, 2004).

In USA, the authors managed to include some of the indirect costs of ADRs in their conducted study and the findings showed that the estimate costs, including lost income, lost household production, disability, and healthcare costs, due to preventable ADEs was US$17 billion to US$29 billion (Kohn, Corrigan and Donaldson, 1999).

In London, Gannon (2008) indicated that ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications. The results of the 2008 study at England showed that the total cost to the NHS of ADRs in extra bed days alone would be around £1bn a year (Chartered Institute of Public Finance and Accountancy, 2002) while in London the annual costs was estimated to be £1.89 billion (Gannon, 2008).

Bordet (2001) in a study conducted at France reported that an increase in cost of £ 11,500 for ADRs increases patient's length of stay and totalled approximately one third of the ADRs.

In the UK ,it was found that the estimated costs of a hospital bed was €228 per day and that 5% of the 8.5 million patients admitted to hospitals in England and Wales each year experience preventable adverse events, leading to an additional three million bed days (Chartered Institute of Public Finance and Accountancy, 2002). Another study reported that the financial burden of ADRs is significant; the preventable ADRs provide the potential to save costs, and also that there is an urgent need to develop preventive strategies to reduce this cost burden (Lundkvist et al. 2004).

2.7. Pharmacovigilance

The WHO defines Pharmacovigilance as the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identifying new information about hazards associated with medicines and preventing harm to patients (Pirmohamed et al. 2007).

Pharmacovigilance is also called spontaneous post-marketing surveillance program. Spontaneous reporting is defined as "a system whereby case reports of adverse drug

events are voluntarily submitted by health professionals and pharmaceutical companies to the national pharmacovigilance centre" (WHO, 2006).

Post-marketing surveillance programs are essential in every country for monitoring the occurrence of ADRs, as the data derived from within the country may encourage national regulatory decision making. Thus, these programs may contribute to decreased morbidity, mortality, length-of-stay, healthcare costs, and liability associated with ADRs. As many ADRs often go unrecognized or unreported, an organized ADR monitoring program is one mechanism to more actively detect ADRs, and consequently positively affect the quality of patient care (Zolezzi et al. 2005).

Pharmacovigilance programs use the information generated from the ADR reports to update drug labeling and, on occasions, to re-evaluate the approval or marketing decision. Even if the report does not warrant labeling changes, the information provided can signal potential problems with the use of certain drugs for which recommendations can be provided to decrease the risk, or be further investigated (Zolezzi et al. 2005).

Once the reports are studied and evaluated, the data generated can help to estimate risk patterns, such as identifying populations at risk of developing an ADR with certain medications, investigate the preventability of these ADRs to provide indicators for quality improvement, or signpost for interventions. The dissemination of this information is also a crucial aspect of pharmacovigilance, as it is needed for drug prescribing and regulation (Zolezzi et al. 2005).

The major aims of pharmacovigilance in public health are (WHO, 2006):

- Rational and safe use of medicines by health professionals
- Assessment and communication of the risks and effectiveness of medicines used
- Educating and informing patients

One of the reasons why pharmacovigilance is important is because when a pharmaceutical drug is introduced in the market there are still a lot of things that are unknown about the safety of the new drugs. These medicines are used by various patients for different diseases .These people might be using several other drugs and must be following different traditions and diets which may adversely affect the impact of medicine in them. Also the different brands of same medicine might differ in the manner of their production and ingredients (Pharmaceutical & Drug Manufacturers, 2010).

Additionally, ADRs might also occur when drugs are taken along with traditional and herbal medicines that have also to be monitored through pharmacovigilance. In some cases, adverse drug reaction of certain medicines might occur only in one country's or region's citizens. To prevent all undue physical, mental and financial suffering by patients, pharmacovigilance proves to be an important monitoring system for the safety of medicines in a country with the support of doctors, pharmacists, nurses and other health professionals of the country (Pharmaceutical & Drug Manufacturers, 2010).

2.7.1. Examples of pharmacovigilance in developed and developing countries

Every country has their own particular pharmacovigilance system, though based on WHO guidelines (Fomundam et al. 2009).

2.7.1.1. Pharmacovigilance in Europe

Pharmacovigilance system in Europe is coordinated by the European Medicines Agency (EMA) and conducted by the National Competent Authorities (NCAs). The EMA maintains and develops the pharmacovigilance database comprising all suspected serious adverse drug reactions observed in the European region. Here, the pharmacovigilance system is called EudraVigilance and contains separate but similar

databases of human and veterinary reactions (Pharmaceutical & Drug Manufacturers, 2010).

2.7.1.2. Pharmacovigilance in United States of America

In the United States of America pharmacovigilance has a multi faceted approach. Three branches of pharmacovigilance in the USA can be defined as the FDA; the pharmaceutical manufacturers; and the academic/non-profit organizations like RADAR and Public Citizen. The US Food and Drug Administration (FDA) receive reports about adverse drug reaction and takes appropriate actions for drug safety (Pharmaceutical & Drug Manufacturers, 2010).

2.7.1.3. Pharmacovigilance in India

The whole country is divided into zones and regions for operational efficiency. The Central Drugs Standard Control Organization (CDSCO), New Delhi is at the top of the hierarchy followed by two zonal pharmacovigilance centers namely, Seth GS Medical College, Mumbai and AIIMS, New Delhi (Pharmaceutical & Drug Manufacturers, 2010).

The Peripheral centers record the Adverse Events (AE) and send to the Regional Centers. They in turn collate and scrutinize the data received from the Peripheral Centers and submit to the Zonal Centers. The Zonal Centers will analyze the data and submit consolidated information to the National Pharmacovigilance Centre. The Zonal Centre will also provide training, general support and coordinate the functioning of the Regional Centers (Gupta and Udupa, 2011).

2.7.1.4. Pharmacovigilance in South Africa

The South African National pharmacovigilance programme is coordinated by the Medicines Control Council (MCC). The pharmacovigilance programme has two units for the monitoring of the safety of medicines. The National Adverse Drug Event Monitoring Centre (NADMEC) in Cape Town which monitors the safety of all registered medicines and also a focused surveillance unit at Medunsa which is responsible for the monitoring the safety of Antiretroviral (ARV) medicines, complementary medicines and unregistered medicines used during clinical trials (Fomundam et al. 2009).

2.8. Prevention and monitoring of ADRs

Prevention and monitoring of drugs remain a challenge for clinicians, patients, drug regulators, researchers, government officials and healthcare professionals. Prevention of ADRs helps to minimize the consequential undesirable effects, primary among which are (Knox, 1998):

- Increased admissions to hospitals.
- Increased needs for primary healthcare and an increase in the number of complications during hospitalization in patients.
- Fatalities.
- Increases in the length of hospital stays and increases in the cost of patient care.
- Adverse effects on patients quality of life and their confidence in healthcare and mimicry of disease resulting in unnecessary investigations and/or delay in appropriate treatment.

Adverse Drug Reactions monitoring is a process of continuously monitoring of undesirable effect suspected to be associated with use of medicinal products. It facilitates collection of unbiased safety data observed during clinical practice in 'real

life' circumstances. Drug monitoring is important in detection of lack of efficacy, detection and prevention of counterfeit and substandard products in clinical practice. It is essential that the ADR monitoring program for safety of medicinal product be supported by health care professionals (The United Republic of Tanzania Ministry of Health, 2006).

McDonnell et al. (2002) assessed the potential preventability of ADRs directly related to a patient's hospital admission. The findings were that 62.3% of these events were considered potentially preventable. Approximately 25% of these events were serious to life-threatening. Most resulted from inadequate monitoring of therapy or inappropriate dosing. Patient noncompliance and drug interactions were also common causes.

2.9. Who has to report ADRs?

It is the responsibility of the primary health care provider to detect, investigate, manage and report ADRs. All healthcare professionals including doctors, pharmacists, nurses and other healthcare professionals are encouraged to report ADR. All healthcare providers have roles to play in maintaining a balance between a medicine's benefits and risks. Once a drug is available to the public, making a determination about its safety is the shared responsibility of all who are part of the prescribing process, including patients (Zolezzi et al. 2005).

Healthcare professionals outside the government system should also report adverse reactions. These would include, among others, nongovernmental organisations and charitable health facilities (WHO, 2006). Therefore, it is important to motivate healthcare providers to understand their role and responsibility in the detection, management, documentation, and reporting of ADRs, all essential activities for optimizing patient safety.

2.9.1. Role of nurses on ADR reporting

ADR reporting was initially regarded as a professional obligation for other profession excluding nurses. Among healthcare professionals nurses are often the first contact with patients and they can play a vital role in recognizing suspected ADRs if trained appropriately (Hall et al. 1995). Nurses should also play a role in monitoring the safety of medicines.

2.9.2. Role of pharmacists on ADR reporting

Pharmacists have a central role in drug safety by contributing to the prevention, identification, documentation, and reporting of ADRs (Pirmohamed et al. 2007). Pharmacists advise on drug use or on the introduction to or withdrawal of a drug from the market and are often called upon in establishing the likelihood that an adverse event is in fact an ADR.

Pharmacists clearly understand that no drug product is completely safe and that pre-marketing trials do not fully identify the risks, particularly of recently marketed drugs. As part of the healthcare team, pharmacists advise on drug use or on the introduction to or withdrawal of a drug from the market and are often called upon in establishing the likelihood that an adverse event is in fact an ADR (Zolezzi et al. 2005).

2.9.3. Role of doctors on ARD reporting

Doctors knowledge and experience is essential in the assessment and evaluation of an ADR. The knowledge of drug safety issues can improve the manner in which a doctor takes the clinical history of a patient, with more emphasis on the medication history, and can help to understand the behaviour of drugs better. It can decrease the irrational use of medicines, adverse drug-drug interactions and inappropriate polypharmacy (Shankar, Subish, Mishra and Dubey. 2006).

2.10. Where to report ADRs?

According to WHO, a standardised reporting form should be available to the primary health worker. This person should report the ADRs to the district health officer. The district officer in association with the district investigation team will follow up reports of serious ADRs and submit details to the national pharmacovigilance coordinator for review by the safety review panel (WHO, 2006).

At the global level, the WHO programme for international drug monitoring at the Uppsala Monitoring Centre in Geneva collates adverse drug reaction reports via the national pharmacovigilance centres of the 81 member countries. Less than 27% of lower middle income and low income economies have national pharmacovigilance systems registered with the WHO programme, compared with 96% of the high income countries in the Organisation for Economic Co-operation and Development (Shankar et al. 2006). This indicates that only few countries from the developing countries are reporting ADR to the Uppsala Monitoring Centre.

The main reasons why some of the developing countries are not reporting ADRs to Uppsala Monitoring Centre are lack of resources, infrastructure, and expertise. Thus, although access to medicines is increasing in developing countries, there is a danger that their risk benefit profiles in indigenous populations will not be fully monitored and acted upon (Pirmohamed et al. 2007).

2.11. When to report ?

Any suspected ADR should be reported as soon as possible. Delay in reporting will make reporting inaccurate and unreliable. If possible, healthcare professionals should report while the patient is still in the health facility, this will give a reporter a chance to clear any ambiguity by re-questioning or examining the patient (The United Republic of Tanzania Ministry of Health, 2006).

2.12. Underreporting of ADRs by healthcare professionals.

ADR reporting is one of the effective methods to detect new and serious drug reactions. However, it is well known that there is a high degree of under-reporting. Underreporting of Adverse Drug Reactions (ADRs) is a common problem in Pharmacovigilance programs worldwide. Even in countries like the United Kingdom where Pharmacovigilance programs are well established, a high level of under-reporting was documented (Wiffen et al. 2002).

This high rate of underreporting can delay signal detection and consequently impart negatively on the public health; .e.g. Aspirin in the Gastro-intestinal tract, amydopyrine in agranulocytosis, phocomelia with thalidomide. For the same reason it may take too long before it is recognised that prolonged abuse of a medicinal product can produce deliberate health affects e.g. Phenacetin in renal papillary necrosis (The United Republic of Tanzania Ministry of Health, 2006).

2.12.1. Underreporting of ADRs by pharmacists

National drug monitoring programs throughout the world differ in their sources of participation in the reporting of ADRs by healthcare professionals. In some other countries pharmacists are allowed to report ADR and in some they are not allowed. In Nordic countries e.g. Finland and Sweden pharmacists are excluded from reporting ADRs to the national reporting program (van Grootheest, Mes and de Jong-van den Berg, 2002).

Even among countries where pharmacists are allowed to report ADRs to their national program, lower reporting rates by pharmacists are observed. New Zealand is a good example of this case because pharmacists managed to report only 5.7% of CARM reports as compared with about 70% of ADR reports submitted to the MEDWATCH program in the US by pharmacists (Zolezzi et al. 2005). Another studies conducted at

Britain and China reported the problem of ADR underreporting among pharmacists, (Sweis and Wong, 2000; Lee et al. 1994).

Some authors have shown that pharmacists in countries like Canada and US have largely contributed to ADR reporting. In Canada pharmacists were reporting more ADRs than doctors. In the year 1998–1999, at the British Columbia Regional ADR Centre, most ADR reports were generated by pharmacists (38.8% and 34.8% by hospital and community pharmacists, respectively), physicians' reports accounting for only 10.8% (Zolezzi et al. 2005).

2.12.2. Underreporting of ADRs by doctors

In 1999, the authors in Canada have noted that in countries like France, Ireland, Malaysia, New Zealand, the Nordic countries, and the UK, the largest contribution of ADR reports were coming from doctors (Zolezzi et al. 2005). In other countries like Portugal (Davis, Coulson and Wood, 1999) and USA (Belton, Lewis, Payne, Rawlins and Wood. 1995) underreporting was experienced amongst the doctors.

2.12.3. Underreporting of ADRs by nurses

Search of literature yielded no results based on the underreporting of nurses. A study in France showed that nurses were reporting better reports when compared to doctors. They were reporting different types of suspected ADRs from those reported by doctors (Sacilotto, Bagheri, Lapeyre-Mestre, Montastruc and Montastruc. 1995). Hall et al (1995) in a study performed at England reported that adverse drug reaction reporting by nurses could improve the overall safety of drugs. They concluded that the open access to reporting by nurses would enhance the process immediately, quantitatively, and in time, qualitatively.

2.13. Factors contributing to ADR underreporting

To identify the reasons for underreporting, several studies were conducted where different authors investigated the knowledge, attitudes and practices of healthcare professionals toward the ADR reporting. According to the findings of the studies (Li, Zhang, Chen, Fang, Yu, Liu, Shi and Zeng. 2004; Evans, Berry, Smith, Esterman, Selim, O'Shaughnessy and DeWit. 2006; Kelly, Kaye and Davis. 2004; Oshikoya et al. 2009; Green et al. 2001; Hajebi, Mortaxavi, Salemzadeh and Zian. 2010) healthcare professionals mentioned different factors that have contributed towards their underreporting:

In summary the most mentioned factors were analysed by the international literature as follows:

- lack of resources for surveillance and reporting
- time-consuming reporting process
- lack of feedback
- Voluntary reporting procedure
- well-known reactions
- an uncertain association
- lack of awareness of the requirement for reporting

2.13.1. Discouraging factors among doctors

The most identified factors that have discouraged doctors from reporting were the accessibility of the ADR forms and lack of information on how to report (Belton et al. 1995). The other influencing factors that were identified in a conducted study at Nigeria were a lack of motivation because of poor feedback on reported cases (Enwere and Fawole, 2008), ignorance, diffidence and indifference which were different from other discouraging factors identified among the US doctors. Their discouraging factors were found to be the unavailability of address or telephone

number of the reporting agency and not having enough time to report (Belton et al. 1995).

2.13.2. Discouraging factors among pharmacists

Various authors (Lee and Thomas, 2003; van Grootheest et al. 2002) found that majority of the pharmacists were not reporting because they assumed that an ADR was already known. Other discouraging factors in Netherlands community pharmacist were found to be uncertainty about the causal relationship between the ADR and a drug and also the reporting procedure being too time-consuming, while the main factors in India, were reported to be mild reactions and immediate management of ADRs.

2.14. Improvement of ADR reporting

Different authors (Vitillo, 2000; Li et al. 2004; Evans et al. 2006; Enwere et al. 2008) came up with different recommendations or conclusions on how to avoid underreporting of ADRs by healthcare professionals. They recommended that the following should be provided:

2.14.1. Training

Training in pharmacovigilance is required for staff working at health facility because ADRs are not well understood and, in many countries are seldom detected and reported. Training and capacity building are required to ensure that staff members understands new prescribing practices for new medicines, the correct dosage regimens and how treatment failures are defined (WHO, 2006). This recommendation was made by the researchers at China (Li et al. 2004), Britain (Sweis et al. 2000), Nigeria (Oshikoya et al. 2009) and UK (Davis, Coulson and Wood, 1999).

2.14.2. Centralizing ADR reporting activities

Michel and Knodel (1986); Brvar, Fokter, Bunc and Mozina (2009) concluded in their studies that a completed CARM reports, or the equivalent in-house ADR form, should initially be forwarded to a central area, such as the Medicines Information Centre (MIC), for further assessment. Other suggestion was that a fax line, email, and online ADR reporting forms be available to facilitate communication in alerting the multidisciplinary team to an ADR (Vitillo, 2000).

2.14.3. Incentives

Other authors recommended that incentives should be given for ADR reporting. The incentives examples were: issuing certificates or recognition awards or pens with reminding logos on ADR reporting, this can be used to motivate healthcare professionals to report ADRs (Vitillo, 2000; Pedros and Vallaro, 2009).

2.14.4. Feedback

To improve incident reporting, the authors of the study conducted in Australia indicated that clarification is needed of which incidents should be reported, the process needs to be simplified, and feedback given to reporters (Evans et al. 2006).

2.14.5. Drug safety leaflets

The recommendation made in other studies was that a pharmacovigilance leaflets should be provided to the healthcare professionals regarding drug safety issues (Li et al. 2004; Evans et al. 2006).

2.15. Knowledge of healthcare professionals regarding adverse drug reaction reporting

Knowledge on ADR reporting was not rated the same among healthcare professionals who participated on this kind of study worldwide. The finding of the studies performed at Northern India (Rehan, Vasudev and Tripathi. 2002), Italy (Cosentino, Leoni, Banfi, Leechini and Frigo. 1997) and China (Li et al. 2004) shows that the level of knowledge among the healthcare professionals on ADR reporting was rated to be very low when compared to other countries like UK (Evans et al. 2006), Australia (Christopher, David, Philip and Munir. 2001) and Nigeria (Enwere et al. 2008).

2.15.1. Knowledge of doctors

Several studies were conducted to determine the knowledge of doctors towards ADR reporting but the findings were different. It was noted that doctors in Italy (Cosentino et al. 1997) and Nigeria (Oshikoya et al. 2009) had little information while the doctors in Australia (Evans et al. 2006) had more information concerning ADRs and ADR reporting systems. For example, Australian doctors were aware that their hospital had an incident reporting system while other studies reported that doctors were not informed about the reporting system in their countries (Cosentino et al. 1997).

The findings of a 2009 study at teaching hospital in Lagos, Nigeria showed that knowledge on ADR reporting was inadequate among doctors (Oshikoya et al. 2009) while another study that was performed at the same year at Ibadan, Nigeria showed that some doctors were having good knowledge of ADR (Enwere et al. 2008). The general level of doctors knowledge in Nigeria which is one of the developing countries, was very low when compared to the reporting rate of other doctors in the UK, America, Netherland, Spain, China and India (Oshikoya et al. 2009).

Li et al (2004) reported in his study that when asked what type of ADR should be reported, the majority of the doctors believed that all serious reactions, rare reactions,

and reactions to new products, proven ADRs and suspected ADRs should also be reported.

2.15.2. Knowledge of pharmacists

Even though ADR reporting is a professional obligation of the pharmacists in many countries, their level of knowledge on ADR reporting was found to be different. Several studies have attributed low knowledge (Lee et al. 1994; Toklu and Uysal, 2008), while others adequate knowledge (Christopher et al. 2001; Green et al. 2001) on ADR reporting among the pharmacists.

The results of a study in Hong Kong by Lee et al. (1994) and Toklu et al. (2008) in Turkey found that pharmacists were not having knowledge on how to report and the kind of reaction that need to be reported. It was also noticed that majority of those pharmacists were not even aware of a format of reporting in their areas.

Other studies conducted at England by Christopher et al. (2001) and Green et al. (2001) at United Kingdom revealed that pharmacists were having a reasonable knowledge that all reactions should be reported for newly marketed agents and that serious reactions should be reported for established products.

2.15.3. Knowledge of nurses

Although ADR reporting was previously not seen as a professional obligation for nurses, studies done by Hajebi et al. (2010); Li et al. (2004); Evans et al. (2006) have shown that nurses were having knowledge on ADR reporting. It was found that majority of the nurses have encountered with an ADR and they were also aware that their hospital had an incident reporting system. In a study conducted at Iran (Hajebi et al. 2010), nurses were of the opinion that severe and life threatening cases are the kind of reactions that need to be reported while 80% of nurses in China (Li et al. 2004)

stated that dangerous and rare ADRs as well as side effects of new drugs are the ones that need to be reported.

A study that was conducted at Australia by Evans et al. (2006) has found that the knowledge of nurses on ADR reporting was more when compared to the doctors. It was stated that the nurses were having more knowledge on how to complete an ADR form and also what to do with the completed report when compared to doctors (81.9% v 49.7%).

2.16. Attitudes of healthcare professionals regarding adverse drug reaction reporting

The attitude of healthcare professionals was not the same towards ADR reporting. Some were having a positive attitude (Li et al. 2004; Evans et al. 2006; Christopher et al. 2001) while others were having a negative one (Zolezzi et al. 2005; Toklu et al. 2008). These findings from different studies suggest the need for interventions to improve the attitude of the healthcare professionals.

2.16.1. Attitude of pharmacists

Lee et al. (1994) in Hong Kong reported that, most of the pharmacists agreed that ADR reporting is necessary even though a smaller proportion have done so. Other positive attitudes were observed among the pharmacists at Britain (Sweis et al. 2000) and UK (Zolezzi et al. 2005). Pharmacists were more likely to report serious, rare ADRs, those associated with newly marketed drugs, supportive of the Yellow Card spontaneous ADR reporting scheme, felt that one report can make a difference to the Yellow Card Scheme, and they consider ADR reporting as part of their professional obligation. And also half of the pharmacist felt that ADR should be compulsory.

Unlike other countries, pharmacists in New Zealand did not see ADR reporting as their professional obligation. It was reported in a study conducted in New Zealand that

5.7% of CARM reports were submitted by pharmacists compared with about 70% of ADR reports submitted to the MEDWATCH program in the US by pharmacists (Zolezzi et al. 2005).

2.16.2. Attitude of doctors

There are several reports of other countries which showed the attitudes of doctors in ADR reporting. Other studies were showing positive (Oshikoya et al. 2009), while others negative (Zolezzi et al. 2005; Enwere et al. 2008; Hasford, Goettler, Munter and Muller-Oerlinghausen. 2002) attitudes towards ADR reporting.

A negative attitude was observed on the doctors at Canada (Golafshani, 2003) Nigeria (Enwere et al. 2008) and Germany (Hasford et al. 2002). This was because majority of doctors at Nigeria believed that observing ADRs raises no concern; felt that there is no need to report them because a serious reaction will be well documented by the time a drug is marketed and that one case will not contribute to medical knowledge (Enwere et al. 2008). In Germany, 70 % of respondents believed that observing ADRs raises no concern and there is no need to report them (Hasford et al. 2002). Based on these findings, some authors have suggested that the negative attitudes of healthcare professionals could be associated with underreporting (Munasinghe and Singer, 2001; Enwere et al. 2008).

When compared to other countries, doctors in Nigeria were having a positive attitude towards reporting (Oshikoya et al. 2009). Majority of them felt that ADR reporting was a professional obligation and felt that it should be compulsory. When compared to other healthcare professionals, Nigerian doctors' attitude towards ADR reporting can be rated to be the same as the UK pharmacists (Sweis et al. 2000).

2.16.3. Attitude of nurses

The finding of the studies conducted at Australia (Evans et al. 2006) and UK (Wilson, Bekke and Fylan, 2008) showed that nurses had a positive attitude towards ADR reporting. As a result they were reported to be more likely to report ADR. Another study found that 68% of nurses at Iran (Hajebi et al. 2010) felt that all ADRs are valuable and should be reported.

In the study conducted in Australia (Evans et al. 2006) and UK (Wilson et al. 2008), nurses had a significantly more positive attitude towards reporting than doctors. Nurses were more likely to report than doctors (88% versus 43%) in Australia and (95% versus 80%) in UK.

2.16. **Practices of healthcare professionals regarding ADR report**

The findings of many conducted studies have shown that majority of the healthcare professionals were having knowledge on how to diagnose ADRs. A challenge on those studies was that majority of the participants reported to have not send ADR to reporting centres due to lack of knowledge on where to send those reports (Cosentino et al. 1997; Munasinghe et al. 2001; Li et al. 2004; Evans et al. 2006).

2.16.1. Practice of doctors

Studies proved that majority of the doctors at Italy, China and Nigeria have ever diagnosed an ADR in their profession (Munasinghe et al. 2001; Li et al. 2004; Evans et al. 2006; Oshikoya et al. 2009). Li et al. (2004) found in a study conducted at China that 62% of the doctors had encountered an ADR that was not reported at all. These findings are similar to a study that was performed at India whereby 43% of the participants were having awareness regarding National Pharmacovigilance Centre even though only 2.9% have reported suspected ADRs to ADR reporting and monitoring centres (Gupta et al. 2011). This trend was also observed on the doctors

working at Nigeria hospitals (Oshikoya et al. 2009). The most common places on which doctors were primarily sending their ADR reports were found to be the hospital pharmacy, another department in the hospital and the pharmaceutical industry (Green et al. 2001; Evans et al. 2006).

Eland, Belton, van Grootheest, Meiners, Rawlins and Stricker. (1999) observed good practices from the doctors at Netherland, were among those who have diagnosed ADRs, more than 50% of them have sent their ADR reports to the national pharmacovigilance centre.

2.16.2. Practice of nurses

The findings of a study conducted at Iran (Hajebi et al. 2010) were that 70% of the nurses had never encountered an ADR when compared to a similar study in China (Li et al. 2004), were 85% of nurses had encountered with an ADR before.

Regarding, the place where ADR are supposed to be send, nurses had a different insight on that. The findings made by Hajebi et al. (2010) were that, most nurses used to send their reports to physicians in the ward (56%), head nurse (26%), and pharmacy (13%). In the study in China, nurses has stated hospital pharmacies, pharmaceutical companies and drug centres within the province, as the main places for reporting ADRs.

Just like other healthcare professionals, reporting to the national pharmacovigilance was a challenge among nurses. According to the findings made by different authors, none of the nurses have ever reported ADR to reporting centre (Li et al. 2004; Evans et al. 2006; Hajebi et al. 2010).

2.16.3. Practice of pharmacists

A challenge that was found by some authors was that even though majority of the pharmacists were having adequate knowledge on how to diagnose ADRs, only few were reporting to the national pharmacovigilance centres (Christopher et al. 2001; Lee et al. 1994; Toklu et al. 2008). Majority of the pharmacist were claiming to have reported ADRs to the hospital and doctors, hence it can be concluded that hospital pharmacists require continuing stimulation and education about reporting in order to raise further the profile of their role in reporting of suspected ADRs to their national pharmacovigilance program.

Various authors (Christopher et al. 2001; Lee et al. 1994; Toklu et al. 2008) reported in their studies that pharmacists were having little knowledge on how to report and on the kind of reaction that need to be reported. The very same findings were noticed in Hong Kong (Lee et al. 1994) and Turkey (Toklu et al. 2008), whereby majority of the pharmacists were not even aware of any ADR reporting system in their area.

CHAPTER THREE
METHOD

3.0. Introduction

This chapter presents the methodology of the study. It describes the setting, site selection, study design, sampling procedure and the sample size. This chapter also discusses data analysis, validation of the questionnaire as well as the ethical consideration.

3.1. Study design

This was a quantitative descriptive cross sectional study conducted among the healthcare professionals (nurses, doctors, pharmacists) working at Mafikeng Provincial Hospital (MPH) in Mafikeng (North West Province).

3.2. Study setting and site selection

The study was conducted at MPH which is a level 2 hospital with limited level 3 services. The hospital does not offer all services such as oncology, neurology etc, and for those type of services patients are referred to other facilities outside the province like Charlotte Maxeke Johannesburg Academic Hospital and Chris Hani Baragwanath Hospitals respectively.

The hospital has a fast improving antiretroviral therapy wellness centre without ADR Monitoring Committee that is charged with the responsibility of reviewing all suspected cases of ADRs and forwarding the list of confirmed cases to the National Pharmacovigilance Centre (NPC).

3.3. Target population and sampling procedure

A target population for this study was all nurses, doctors and pharmacists working at MPH. A purposive sampling including all healthcare professionals was conducted. Because the target population was small no sampling was necessary, all those willing and qualifying to participate were included. According to the personnel data base from human resources department, there was a total number of 48 doctors, 140 professional nurses and 5 pharmacists employed at the hospital in 2009. During the conducting of the study only 29 doctors, 88 professional nurses and 5 pharmacists were willing to participate on the study.

3.4. Inclusion criteria

All registered nurses, doctors and pharmacists working at MPH in 2009.

3.5. Exclusion criteria

All students and enrolled nurses were excluded from the study. Healthcare professionals working at MPH who refused to participate in the study were also excluded.

3.6. Instrument and data collection process

In this study a questionnaire was used as a data collection tool (see appendix 2). A questionnaire was adapted from the previous studies on the attitude, knowledge and practices of healthcare professionals on ADR reporting (Belton et al 1995; Ekman and Bäckström, 2009), with a little modification to suit the South African environment. A questionnaire was comprised with sections that looked at the demographic characteristics (which were age, gender professional role and the years of experience), knowledge, attitudes, practices and reasons of for not reporting ADRs by the

participants. One assistant nurse working at MPH was requested to distribute and collect a questionnaire to the participants.

The assistant nurse distributed questionnaire attached to a consent form (appendix 1) to the healthcare professional who were willing to participate in the study. Participation was voluntary and no incentives were given to the participants. The completed questionnaires were collected from the assistant after a month.

3.7. Validity of the study

Validity of the study was ensured by pilot- testing the questionnaire to a sample of healthcare professionals with similar characteristics. A pilot test was performed by distributing the questionnaire to 6 pharmacists, 2 doctors working in the directorate Clinical Evaluation and Trials (CE & T) and also 1 doctor and 4 nurses working at the Comprehensive Care, Management and Treatment Unit at the National department of health .

The participants were given a week (7 days) to complete a questionnaire. Feedback given by the participants was considered and corrections were made accordingly. Questions adjustments were made to the questionnaire to improve its validity as well as answering the research questions of the study.

3.8. Reliability of the study

To ensure the reliability of data, a researcher was capturing data while the assistant nurse was reading the information from the questionnaire. To determine accuracy of capturing a printout was cross-checked with the questionnaires by the researcher. The sheet where data were captured was pre-designed by the researcher who set therein validation rules for each variable to prevent the capturing of incorrect data.

3.9. Bias

Participants bias was a important limitation of the study since only those who agreed to participate were provided with a questionnaire to complete.

3.10. Data analysis

In this study a descriptive data analysis was conducted using STATA (version 10) and Epi info (version 6). Data was coded and entered into excel spreadsheets and the imported to STATA and Epi info for analysis. Each category of a variable was coded with a number. For example, in other questions that appears on a questionnaire the answer 'Yes' was coded as 1; and 'No' as 2. The descriptive statistics was including mean, median, standard deviation and frequency. A test of association was done using Pearson chi–square. A cross tabulation was also used in bivariate analysis.

Results were presented as numbers with percentages or graphic presentations for categorical variables. The relationship between the position of the respondents and their general knowledge of ADRs or their in depth knowledge of the illustrated hypothetical cases was determined by using a chi-square at $P < 0.05$ significant level.

3.11. Ethical considerations

Ethical standards for conducting the study was maintained as follows:

- Ethical clearance was requested and obtained from the university of Limpopo, Medunsa campus research and ethics committee (MREC) and school; of public health research committee
- Permission to conduct the study was requested and obtained from Mafikeng Provincial Hospital Management
- Informed consent from participants was obtained prior to conducting the study

- Confidentiality of participants was maintained at all times. Participants information obtained from the questionnaires was kept confidential .
- Participants were informed that participation is voluntary and that they could withdraw from the study at any stage if they so desire without any penalty.

CHAPTER FOUR
RESULTS

4.0 Introduction

In this chapter the results are presented in a descriptive form. Descriptive statistics will include mean, median, standard deviation and frequency. The results are in a form of frequencies with percentages and presented in a table or graphic form. A test of association was done using Pearson chi –square with $P < 0.05$ significant level.

4.1 Demographic characteristics of respondents

Table 4.1: Frequency distribution of demographic characteristics of the respondents (N=119)

Demographic characteristics	**Frequency (N)**	**Percentage (%)**
Age		
<40y	64	53.78
>40y	55	46.22
Total	**119**	**100**
Gender		
Male	67	56.30
Female	52	43.70
Total	**119**	**100**
Profession		
Nurse	88	74.58
Doctor	25	21.19
Pharmacist	5	4.24
Total	**118 (*=1)**	**100**

∗ = missing data

Table 4.1 summarizes selected demographic characteristics of the study participants. A total number of 119 healthcare professionals were recruited to participate in this study. A number included 88 nurses, 25 doctors and 5 pharmacists (one participant did not indicate his profession). More than half of the participants were male (56.3%) and 53.8% percent of them were younger than 40 years.

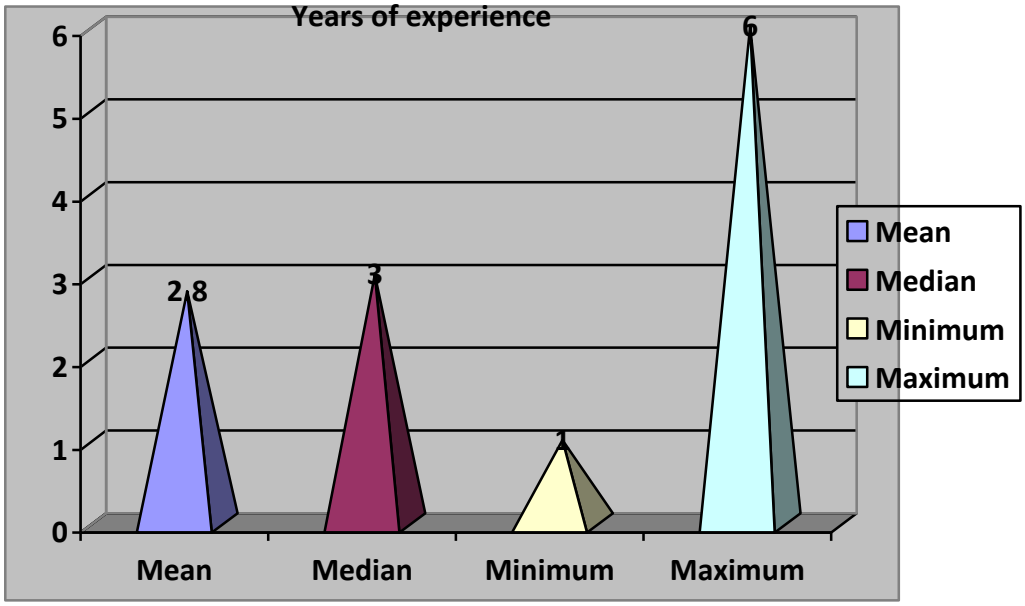

Figure 1: Years of experience of the respondents

From the results presented in figure 1, it can be observed that the minimum years of experience of the respondents was 1 and the maximum years was 6 with a mean of 2.85 years (SD = 1.448).

4.2 Reasons for not reporting ADRs

Table 4.2: Reasons for not reporting ADRs (N=119)

Responses	**Frequency (N)**	**Percentage (%)**
Lack of time	20	16.81
Uncertain of how to report	43	36.13
Forgetfulness	9	7.56
Lack of feedback	22	18.49
ADR was well known	9	7.56
Unavailability of reporting forms	16	13.45
Total	**119**	**100**

As can be seen on table 4.2, lack of time (16.81%), uncertain of how to report (36.13%), lack of feedback (18.49%) and unavailability of reporting forms (13.45%) was identified by the participants as the major reasons that might have contributed for not reporting ADRs.

4.3 Knowledge of respondents on ADR reporting

Table 4.3: Knowledge of respondents on ADR reporting (N=119)

Variable	Frequency (N)	Percentage (%)
Do you know how to report ADRs?		
Yes	33	27.73
No	86	72.27
Total	119	100
What kind of reactions needs to be reported?		
Known reaction	15	12.71
Unknown reaction	24	20.34
Life threatening	46	38.98
Don't know	33	27.97
Total	118 (* =1)	100
How are ADRs reported		
Telephone	34	28.57
Mail	37	31.09
E-mail	7	5.88
Don't know	41	34.45
Total	119	100

*= Missing data

Table 4.3 provides the information on the knowledge of healthcare professionals regarding ADR reporting. Majority of the respondents (72.27%) indicated that they do not know how to report ADRs. Among the 118 participants only 38.98% were knew that life threatening reactions needs to be reported while others (27.97%) indicated that they do not know what kind of reactions need to be reported. Alost 35% of the respondents did not know the format in which ADRs are reported whilst 31.09% answered correctly that ADRs are reported by mail.

Table 4.3 (a): Knowledge by age category (N=119)

Responses	**<40 years**	**>40 years**	**All**
Yes	16(25%)	17(30.91%)	33(27.73%)
No	48(75%)	38(69.09%)	86 (72.27%)
Total	**64(100%)**	**55(100%)**	**119(100%)**

Chi-square = 0.515, DF=1, p-value =0.47

As can be seen on table 4.3(a), majority of respondents of all age categories (<40 years and >40 years) did not know how to report ADRs (75% versus 69% respectively).

Table 4.3(b): Knowledge by gender (N=119)

Responses	**Male**	**Female**	**All**
Yes	18(26.87%)	15(28.85%)	33(27.73%)
No	49(73.13%)	37(71.15%)	86 (72.27%)
Total	**67(100%)**	**52(100%)**	**119(100%)**

Chi-square =0.057, DF= 1, p-value =0.811

Table 4.3(b) shows knowledge of respondents by gender. There was no significant difference among males and female on their level of knowledge on how to report. Both genders were reported to have no knowledge on how to report ADRs (73% and 72% respectively, P-value 0.811).

Table 4.3(c): Knowledge per profession (N=118)

Do you know how to report ADRs?				
Responses	**Nurse**	**Doctor**	**Pharmacists**	**All**
Yes	13(14.77%)	17(68. %)	3(60%)	33(27.97%)
No	75(85.23%)	8 (32%)	2(40%)	85(72.03%)
Total	**88 (100%)**	**25(100%)**	**5(100%)**	**118(100%)**

Chi-square = 30,040, DF = 2, P-value = 0.000. 2 cells with expected counts less than 5

Even though the overall knowledge of all respondents on how to report ADR was low (72.03%) in table 4.3 (c), the results has indicated that there was a significant difference between the respondents in terms of their profession (x^2=30.04, DF =2, p-value =0.00). Majority of doctors (68%) and pharmacists (60%) were having knowledge on how to report when compared to nurses (14.77%).

Table 4.4 (a): Knowledge about kind of ADR to be reported by age category (N=118)

Responses	**<40yrs**	**>40yrs**	**All**
Known reaction	6 (9.52%)	9 (16.36%)	15 (12.71)
Unknown reaction	15(23.81%)	9(16.35%)	24 (20.34%)
Life threatening reaction	22(34.92%)	24(43.64%)	46(38.98%)
Don't know	20 (31.75%)	13 (23.64%)	33 (27.97%)
Total	**63 (100%)**	**55(100%)**	**118(100%)**

Chi-square = 3.144, DF = 3, P-value =0.370

As shown on table 4.4a, among who reported life threatening reaction as a reaction that needs to be reported, 43.6% was older (<40 years) when compared to 34.9% of the younger ones (>40 years). Majority of the younger respondents indicated that they don't know which kind of ADRs need to be reported when compared to the older ones (31.75% versus 23.64%).

Table 4.4 (b): Knowledge by gender (N=118)

Responses	**Male**	**Female**	**All**
Known reaction	10 (15.15%)	5 (9.62%)	15 (12.71%)
Unknown reaction	14 (21.21%)	10 (19.23%)	24 (20.34%)
Life threatening reaction	23(34.85%)	23 (44.23%)	46 (38.98%)
Don't know	19(28.79%)	14 (26.92%)	33 (27.97%)
Total	**66(100%)**	**52 (100%)**	**118 (100%)**

Chi-square =3.144, DF =3, p-value = 0.370

In terms of gender (table 4.4b), life threatening reaction as a reaction that need to be reported was correctly indicated mainly by female participants when compared to the male one (44.23% versus 34.85%).

Table 4.4 (c): Knowledge by profession (N=117)

Responses	**Nurse**	**Doctor**	**Pharmacists**	**All**
Known reaction	12(13.64%)	2 (8.33%)	1(20%)	15(12.82%)
Unknown reaction	17 (19.32%)	4 (16.67%)	2(40%)	23 (19.66%)
Life threatening reaction	33 (37.5%)	12 (50%)	1(20%)	46 (39.32%)
Don't know	26 (29.55%)	6 (25%)	1(20%)	33(28.21%)
Total	**88(100%)**	**24(100%)**	**5(100%)**	**117 (100%)**

Chi-square = 3.298, DF=6

Table 4.4c presents the summary of the healthcare professionals level of knowledge on the kind of reactions that have to be reported. Half (50%) of the doctors mention life threatening reactions followed by nurses and pharmacists (37.5% versus 20%) respectively. Two of the participants did not respond to this question.

4.4 Knowledge of the format of reporting

Table 4.5(a): Knowledge of the format of reporting by age category(N=119)

Responses	**<40 years**	**>40 years**	**All**
Telephone	17 (26.56%)	17 (30.91%)	34 (28.57%)
Mail	20 (31.25%)	17 (30.91%)	37(31.09%)
E-mail	2 (3.12%)	5 (9.09 %)	7 (5.88)
Don't know	25 (39.06%)	16 (29.09%)	41 (34.45%)
Total	**64 (100%)**	**55 (100%)**	**119 (100%)**

Chi-square= 2.840, DF=3, P-value =0.417. 2 cells with expected counts less than 5

According to table 4.5 (a), there was no significant difference in terms of knowledge by age category. Almost an equal number of older and younger respondents reported that mail is the right format of reporting (30.91% versus 32.25%, P-0.417).When compared to the older respondents, majority of the younger participants indicated that they don't know a format that is used for reporting (29.09% versus 39.06%).

Table 4.5 (b): Knowledge of format of reporting by gender (N=119)

Responses	**Male**	**Female**	**All**
Telephone	13 (19.4%)	21 (40.38%0	34 (28.57%)
Mail	23(34.33%)	14(26.92%)	37 (31.09%)
E-mail	6 (8.96%)	1 (1.92%)	7 (5.88%)
Don't know	25 (37.31%)	16 (30.77%)	41 (34.45%)
Total	**67 (100%)**	**52 (100%)**	**119(100%)**

Chi-square= 7.853, DF=3, P-value =0.049. 2 cells with expected counts less than 5

In terms of gender (table 4.5b), 37.3% of the male participants reported that they don't know the format of ADR reporting when compared to 30.8% of the female ones.

Table 4.5 (c): Knowledge of format of reporting by profession (N=118)

How are ADRs reported?				
Responses	**Nurse**	**Doctor**	**Pharmacists**	**All**
Telephone	25 (28.41%)	7 (28%)	1(20%)	33 (27.97%)
Mail	26 (29.55%)	9 (36%)	2 (40%)	37 (31.36%)
E-mail	6 (6.82%)	0	1(20%)	7 (5.93%)
Don't know	31 (35.23%)	9(36%)	1(20%)	41 (34.75%)
Total	**88 (100%)**	**25 (100%)**	**5(100%)**	**118 (100%)**

Chi-square= 4.1, DF=6

In terms of knowledge by profession (table 4.5c), 40% of the pharmacists had reported mail as a means of reporting when compared to 36% of doctors and 29.6% of nurse.

Another 35.2% of the nurses, 36% of the doctors and 20% of the pharmacists have shown that they don't know how ADRs are reported.

4.5 Attitude towards ADR reporting

Table 4.6: Attitude towards ADR reporting (N=119)

Variable	Frequency (N)	Percentage (%)
Do you feel that reporting of ADR can benefit the public health?		
Yes	108	91.53%
No	10	8.47%
Total	118(*=1)	100%
Do you feel that one report can make a difference?		
Yes	106	89.08%
No	13	10.92%
Total	119	100%
Do you feel that filling of the ADR yellow form is useful?		
Yes	93	79.48%
No	24	20.51%
Total	117(*=2)	100%
ADR reporting should be compulsory or voluntarily?		
Voluntarily	115	98.29%
Compulsory	2	1.71%
Total	117(*=2)	100%

∗ = Missing data

As shown on table 4.6, majority of the respondents had a positive attitude towards ADR reporting. Ninety-one percent (91.53%) felt that reporting of ADR can benefit the public health, 89% felt that one report can make a difference, 78.63% felt that

filling of the ADR yellow form is useful and 98.29% felt that ADR should be compulsory.

4.6 Practices of healthcare professionals towards ADR reporting

Table 4.7: Practices of healthcare professionals towards ADR reporting

Variable	Frequency (N)	Percentage (%)
Have you ever diagnosed an adverse drug reaction?		
Yes	78	68.42%
No	36	31.58%
Total	114(*=5)	100%
Did you report the reaction?		
Yes	19	16.38%
No	97	83.62%
Total	116(*=3)	100%
Do you know how to report ADRs?		
Yes	62	54.39%
No	52	45.61%
Total	**114(*=5)**	**100%**
If reported, where did you report the reaction?		
Pharmaceutical company	3	8.57%
Hospital	10	28.57%
Doctor	22	62.86%
Pharmacovigilance centre	0	0
Total	35(*=72)	100%

The summary of the practices of healthcare professionals towards ADR reporting are presented on table 4.7. Almost two third of the respondents (68.42%) reported to have

diagnosed ADRs even though 16.38% claimed to have reported the reactions once. Fifty four percent (54.4%) of the respondents claimed to have knowledge on where to report even though none of them have ever sent their reports to the pharmacovigilance centre. They reported to have sent their reports to the pharmaceutical company (8.57%), hospital (28.57%) and doctors (62.86%).

Table 4.8(a): Ever diagnosed by age category (N=114)

Have you ever diagnose an adverse drug reaction?			
Responses	**<40 years**	**>40 years**	**All**
Yes	41(66.13%)	37 (71.15%)	78 (68.42%)
No	21 (33.87%)	15 (28.85%)	36 (31.58%)
Total	**62 (100%)**	**52 (100%)**	**114 (100%)**
Chi – Square = 0.330, DF = 1, P – Value = 0.565			

With regard to age category (table 4.8a), older respondents have diagnosed more ADRs when compared to the younger ones (71.15% versus 66.13%, p-value = 0.565)

Table 4.8 (b): **Ever diagnosed by gender (N=114)**

Have you ever diagnose an adverse drug reaction?			
Responses	**Male**	**Female**	**All**
Yes	41(65.08%)	37 (72.55%)	78 (68.42%)
No	22 (34.92%)	14 (27.45%)	36 (31.58%)
Total	**63 (100%)**	**51 (100%)**	**114 (100%)**
Chi – Square = 0.728, DF = 1, P – Value = 0.394			

According to table 4.8b, 72.55% of the females reported to have ever diagnosed an ADR in their profession when compared to 65.08% of the male one.

Table 4.8 (c): Ever diagnosed by profession (N=113)

Have you ever diagnose an adverse drug reaction?				
Responses	**Nurse**	**Doctor**	**Pharmacists**	**All**
Yes	52 (61.90%)	22 (91.67%)	3 (60%)	77 (68.14%)
No	32 (38.10%)	2 (8.33%)	2 (40%)	36 (31.86%)
Total	**84 (100%)**	**24 (100%)**	**5 (100%)**	**113 (100%)**
Chi – Square = 7.776, DF = 2, P – Value = 0.020 **2 cells with expected counts less than 5.0**				

In table 4.8 (b), there was a significant difference among the respondents in terms of the diagnosis of ADR (x^2= 7.77, p-value=0.02). Ninety one percent (91.67%) of doctors ever diagnosed ADRs when compared to 60% of pharmacists and 61.9% of nurses.

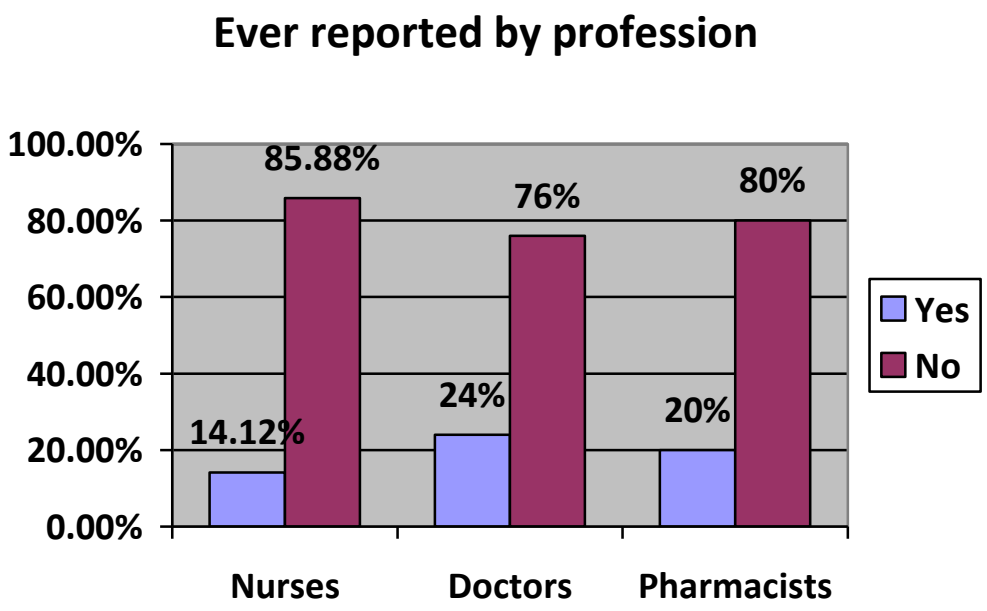

Figure 2: Ever reported by profession

According to figure 2, the results showed that among nurses, 14.1% ever reported ADRs, 24% of doctors, and 20% of pharmacists did so.

Table 4.9(a): Ever reported by gender (N=116)

Have you ever reported an ADR to any reporting centre?			
Responses	**Male**	**Female**	**All**
Yes	13 (20%)	6 (11.76%)	19 (16.38%)
No	52 (80%)	45 (88.24%)	97 (83.62%)
Total	**65 (100%)**	**51 (100%)**	**116 (100%)**

Chi – Square = 1.415, DF = 1, P – Value = 0.234

As shown in table 4.9a, 80% of male respondents have never reported ADRs to reporting centre when compared to 88% of female ones.

Table 4.9 (b): Ever reported by age (N=116)

Have you ever reported an ADR to any reporting centre?			
Responses	**<40 years**	**>40 years**	**All**
Yes	6 (9.68%)	13 (24.07%)	19 (16.38%)
No	56 (90.32%)	41 (75.93%)	97 (83.62%)
Total	**62 (100%)**	**54 (100%)**	**116 (100%)**

Chi – Square = 4.368, DF = 1, P – Value = 0.037

With regards to the age category (table 4.9b), the results showed that older professionals (<40 years) significantly reported more ADR than younger (> 40 years) ones (24.1% versus 9.7%, p=0.037)

4.7 Association between knowledge, attitude and practice towards ADR reporting

Table 4.10a: Association between knowledge and practice (N= 116)

Have you ever reported an ADR to any reporting centre?			
Responses	**Ever-reported**	**Know how to report**	**All**
Yes	7 (21.87%)	12 (14.29%)	19 (16.38%)
No	25 (78.12%)	72 (85.71%)	97 (83.62%)
Total	**32 (100%)**	**84 (100%)**	**116 (100%)**

Chi – Square = 0.974, DF = 1, P – Value = 0.324 OR = 1.68(0.89, 4.740)

As shown in table 4.10a, there was no significant association between knowledge of how to report and practice of reporting (X^2 = 0.94, p= 0.324). Therefore, those participants who ever reported were 1.68 more likely to have knowledge on how to report ADRs as compared to those who never reported.

Table 4.10b: Association between attitude and practice (N=116)

Have you ever reported an ADR to any reporting centre?			
Responses	**Ever-reported**	**Know how to report**	**All**
Yes	8 (13.11%)	11 (20%)	19 (16.38%)
No	53 (86.89%)	44 (80%)	97 (83.62%)
Total	**61 (100%)**	**55 (100%)**	**116 (100%)**

Chi – Square = 1.001, DF = 1, P – Value = 0.317, OR.0.60

According to table 4.10b, there was no significant association between having ever reported and having a positive attitude towards ADR reporting (X^2 = 1.0, p= 0.317). The odd ratio was calculated to be 0.60 (0.22, 1.63), meaning those participants who ever reported was 0.60 more likely to have a positive attitude.

Table 4.10c: Association between knowledge and attitude towards ADR reporting (N=119)

Have you ever reported an ADR to any reporting centre?			
Responses	**Ever-reported**	**Know how to report**	**All**
Yes	18 (29.51%)	15 (25.86%)	33 (27.73%)
No	43 (70.49%)	43 (74.14%)	86 (72.27%)
Total	**61 (100%)**	**58 (100%)**	**119 (100%)**

Chi – Square = 0.197, DF = 1, P – Value = 0.657 OR = 1.2

As can be seen in table 4.10c, there was no association between knowing how to report and having a positive attitude (X^2= 0.197, P= 0.657).Those who knew how to report were 1.2 times likely to have a positive attitude about ADR reporting.

CHAPTER FIVE
DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

This chapter outlines a summary discussion on the healthcare professionals' knowledge, attitudes and practices towards ADR reporting. All the four research questions and the reasons for not reporting are addressed in this chapter. The last section discusses the association between knowledge and practice, attitude towards ADR reporting and practice and finally the knowledge and attitude towards ADR reporting. In summary the findings of this study have demonstrated that: Healthcare professionals have insufficient knowledge on ADR reporting. There was a difference in their knowledge as nurses had a lesser knowledge when compared to doctors and pharmacists. Healthcare professionals were having a positive attitude towards ADR reporting and there was no association between knowledge, attitude and practice towards ADR reporting

5.1 Knowledge of healthcare professionals on ADR reporting

It was found in this current study that more than a third (72.27%) of respondents do not know how to report ADRs. Similar findings have been reported in Northern India (Rehan et al. 2002), Italy (Cosentino et al. 1997) and China (Li et al. 2004) were majority of the participants were having poor knowledge on ADR reporting, but different from the findings of other studies conducted at UK (Evans et al. 2006), Australia (Christopher et al. 2001) and Nigeria (Enwere et al. 2008) were adequate knowledge on how to report was identified among the healthcare professionals. It is a serious concern to realise that such a large proportion of the participants do not know how to report ADRs because this can delay signal detection and impact negatively on the public health. Thus, lesser knowledge on how to report may contribute to decreased morbidity, mortality, length of stay in hospital, healthcare costs, and liability associated with ADRs

The present study showed that in terms of knowledge by profession, nurses had lesser knowledge than doctors and Pharmacist on ADR reporting. One possible explanation could be ADR reporting was initially regarded as a professional obligation for other profession except nurses. These results suggest that the role of nurses in ADR reporting should be clarified and that they should start to be given an open access to reporting (Hall et al. 1995), as they are often the first contact with patients.

Overall in the current study, most doctors knew how to report ADRs and half of them answered correctly that life threatening reactions are one of the reactions that need to be reported. These findings were also observed on the studies conducted by van Grootheest et al. (2002) and Ekman et al. (2009) were majority of the doctors were having knowledge on the kind of reactions that have to be reported. Surprisingly, more than 60% of the doctors were not aware of the format of reporting on this study. This is consistent with the findings of a study conducted by Oshikoya et al. (2009) in Nigeria whose results also revealed majority of the doctors were not aware of the format of reporting. This is clearly an indication that awareness on ADR reporting will be very essential among the doctors even though some of them reported to have knowledge on ADR reporting.

Although results of the current study showed that pharmacists had better knowledge of ADR reporting than nurses, the study revealed that they still have insufficient knowledge on how to report ADRs and the kind of ADRs to be reported. This is consistent with the results of a study by Lee et al. (1994) in Hong Kong and Toklu et al. (2008) in Turkey were insufficient knowledge on the kind of reactions to be reported was identified among the pharmacist. This suggests that the uncertainty on how to report was greater among the pharmacists hence they need to be informed about pharmacovigilance, clinical pharmacy practice and encouraged to report all reactions even if they are not certain that the product caused the event or not having all the details. Contrary to this study's findings the previous studies by Christopher et

al. (2001) and Green et al. (2001) showed that pharmacists had more knowledge on the kind of reactions that have to be reported.

5.2 Attitudes of healthcare professionals on ADR reporting

Overall, the attitude of healthcare professionals in this study was positive. The study found that majority of the respondents felt that reporting of ADR can benefit the public health, one report can make a difference and filling of the ADR yellow form is useful. It was good to notice that majority of the participants in this study considered ADR reporting as important. However, it is the responsibility of the pharmacovigilance centre to maintain this positive attitude of the healthcare professionals by informing them about the importance of reporting and the newly updates on pharmacovigilance.

When it came to specific professions, the findings of the current study were similar to other studies at Britain (Sweis et al. 2000) and UK (Christopher et al. 2001) were pharmacists were reported to have a positive attitude towards ADR reporting but different from the study at New Zealand, were negative attitude was observed among pharmacists (Zolezzi et al. 2005).

Another positive attitude which was in line with the current study was noted among the doctors in Nigeria (Oshikoya et al. 2009). Differently, in other countries like Canada (Golafshani, 2003), Nigeria (Enwere er al. 2008) and Germany (Hasford et al. 2002) doctors were reported to have a negative attitude towards ADR reporting because they believed that observing ADRs raises no concern and that there is no need to report them. The finding of the studies conducted at Australia (Evans et al. 2006), Iran (Hajebi et al. 2010) and UK (Wilson et al. 2008) also showed that nurses had a positive attitude towards ADR reporting because they felt that all ADRs are valuable and should be reported.

It was disappointing to realise that the overwhelming majority of the participants (98.3%) in this study were against an idea that ADR reporting be made compulsory. This however contradicts the findings as reported by Oshikoya et al. (2009) in Nigeria where it was found that respondents felt that ADR reporting should be compulsory. This attitude suggests that respondents did not consider ADR reporting as a professional obligation.

5.3 Practices of healthcare professionals on ADR reporting

In clinical practice, over 68% of healthcare professionals in the current study had at some point diagnosed ADRs. However, 83.6% of the 68% of those who diagnosed ADRs did not report them to any reporting centres and those who reported claimed to have reported the suspected ADRs to the pharmaceutical companies, hospital and doctors. It is likely that most of the reported ADR cases were actually not formal written reports, but oral reports made during an informal conversation hence they were not reported to any reporting place. This high rate of underreporting of ADRs to the reporting centres was also observed among the pharmacists at Britain and China (Sweis et al. 2000; Lee et al. 1994) and doctors at Portugal (Davis et al. 1999), USA (Belton et al. 1995) and Nigeria (Enwere et al. 2008). These findings could be the results of unavailability of reporting forms at the hospitals and also inadequate knowledge on the existence of the pharmacovigilance centre.

Among those respondents who claimed to have diagnosed ADRs in their professions, only few (<25%) managed to report those reactions to other places except the pharmacovigilance centre. This can certainly be considered to be an example of a bad practice in the current study which seems to be common worldwide. This finding is in line with the previous studies performed among pharmacist at New Zealand (Zolezzi et al. 2005) and Hong Kong (Lee et al. 1994) and also the nurses at Iran (Hajebi et al. 2010) and China (Li et al. 2004) were healthcare professionals were sending their ADR reports to the e.g. hospitals , doctors pharmaceutical companies etc, but contrary to the findings in Canada, Australia, Netherlands, Japan, Spain and Portugal were

majority of the healthcare professionals submitted their ADR reports to their national reporting centres (van Grootheest et al. 2002). These findings are a clear indication that majority of the participants did not even know of the existence of a pharmacovigilance centre hence education and training is very much necessary at present.

In this study the results showed that age and gender did not influence the practices of the respondent's .In terms of practices by profession, majority of doctors reported to have at some point diagnosed ADRs when compared to nurses and pharmacists. These findings could be the results of lack of clinical confidence in the diagnosis of an ADR among nurses and pharmacists hence it will be important if healthcare professionals could be trained on causality assessment to maintain a degree of certainty that the drug had caused an ADR.

5.4 Reasons for not reporting

It was found in this study that there are main reasons that might have contributed towards underreporting of ADRs among the participants such as lack of time, uncertain on how to report, lack of feedback and unavailability of reporting forms. This is consistent with other studies conducted among Netherlands community pharmacist (van Grootheest et al. 2002) and doctors at Nigeria (Enwere et al. 2008) and US (Belton et al**.** 1995). Other reasons, such as forgetfulness and ADR were well known were not the key reasons in this study. From these results, it is clear that respondents did not know the procedure for the ADR reporting and monitoring procedure.

5.5 Association between knowledge, attitude and practices towards ADR reporting.

It was noticed in this study that there was no significant association between knowledge, attitude and practice toward ADR reporting. This finding suggests that

healthcare professionals be provided by a continuing stimulation and education about reporting in order to raise further the profile of their role in reporting ADRs to the national pharmacovigilance program as highlighted by Davis et al. 1999.

The study did not find the association between knowledge and practice toward ADR reporting. This finding is consistent with previous studies by Rehan et al. (2002); Cosentino et al. (1997) and Li et al. (2004), where majority of respondents irrespective of their knowledge on ADR reporting were reported to have never reported any ADR to any place.

There was also no significant relationship between attitude and practice towards ADR reporting in this study meaning those participants who ever and never reported ADRs were likely to have an equal chance of having a positive attitude towards ADR reporting. This finding is consistent with findings by Green et al. (2001); Lee et al. (1994) and Oshikoya et al (2009) were majority of the respondents agreed that ADR reporting is necessary even though a smaller proportion have ever reported .

If was found in this study that there was no relationship between knowledge and attitude towards ADR reporting as those who knew how to report were 1.2 times likely to have a positive attitude about ADR reporting when compared to those who did not know how to report. This finding is also similar to the findings of the previous studies were nurses had positive attitude towards reporting even though majority they were not having knowledge on ADR reporting (Evans et al. 2006; Hasford et al. 2002).

5.6 Limitation of the study

The limitations of this study was that although the majority of the MPH doctors and nurses were visited and informed about the study, the response rate was only just over half of their number. There was a poor response rate and non-response to some questions by the healthcare professionals. A sample size was very small making the

results not generalizable to a larger population. This study was also conducted in one setting and views of healthcare professionals from other similar setting could not be explored.

5.7 Conclusion

Underreporting of ADR reporting by healthcare professionals were indentified on this study. Majority of the respondents reported to have diagnosed ADR but none of them have ever reported the national pharmacovigilance centre. Uncertainty on how to report was identified as one of the major reasons that have influenced the respondents not to report.

More than a third of the respondents (72.29%) did not know how ADRs are reported. Healthcare professionals had a positive attitude towards ADR; 98.3% of them reported that ADR should be compulsory. Uncertainty on how to report was identified as one of the major reasons that have influenced the respondents not to report. There was no significant association between knowledge, attitude and practice toward ADR reporting. Healthcare professionals' knowledge can be improved through educational interventions and trainings.

5.8 Recommendation

Based on the findings of this study, the following recommendations are suggested:

- The National pharmacovigilance Centre should ensure that all healthcare professionals are trained and informed about pharmacovigilance and ADR reporting. They have ensure the availability of the reporting forms by distributing them to the medical offices, drugstores, hospitals and any other health providing system.
- All healthcare professionals should be trained on the detection, investigation and management of ADRs to increase their knowledge on ADR reporting.

- Mafikeng Provincial Hospital have to ensure the following: written hospital policy, better cooperation with clinicians, Training, simplifying the system, allocates time for ADR reporting, publicity and promotion.
- Guidelines and standards which describes the practical details of the intended information flow need to be developed by the pharmacovigilance centers

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Appendix 1: Consent form for participants

Dear Participants

I am inviting you to participate in a research project to study the attitudes and knowledge of healthcare professionals regarding Adverse Drug Reaction reporting in Mafikeng Provincial hospital. Along with this letter is a short questionnaire that asks a variety of questions about healthcare professionals' attitudes and knowledge regarding adverse drug reaction reporting. I am asking you to look over the questionnaire and, if you choose to do so, complete it and give it back to me. The survey should take you about 20 minutes to complete. I hope you will take the time to complete this questionnaire and return it.

The results of this project will be useful in determining the reasons for underreporting of adverse drug reactions by healthcare professionals. Through your participation I hope to share my results by publishing them in a scientific journal.

I do not know of any risks to you if you decide to participate in this survey and I guarantee that your responses will not be identified with you personally. I promise not to share any information that identifies you with anyone. You should not put your name on the questionnaire.

If you have any questions or concerns about completing the questionnaire or about being in this study, you may contact me at 072 389 0388. The Medunsa Research Ethics Committee (MREC) at the University of Limpopo has approved this study.

Sincerely

_____

Patience Segomotso
Researcher

Appendix 2: Questionnaire for the study

QUESTIONNAIRE

Name of Researcher: Patience Segomotso
Contact Details: 072 389 0388
PLACE: …….
DATE: ...……

This questionnaire consist of five sections (Section A, B ,C, D and E). Please make sure that you respond to all the sections.

SECTION A: DEMOGRAPHIC CHARACTERISTICS

1. Age (years) ☐
2. Gender
   Female ☐ Male ☐
3. Professional role
   Nurse ☐ Doctor ☐ Pharmacist ☐
4. Years of experience
   0-4 ☐ 5- 9 ☐ 10-14 ☐ 15-19 ☐ 20-29 ☐ 30-40 ☐

SECTION B: KNOWLEDGE

In this section the knowledge of the healthcare professionals towards ADR reporting will be determined.

1. Do you know how to report ADRs?
   Yes ☐ NO ☐
2. What kind of ADRs needs to be reported?
   Known reaction ☐ Unknown reaction ☐
   Life threatening reaction ☐ Don't know ☐
3. How are adverse drug reactions reported?
   Telephone ☐ Mail ☐
   E-mail ☐ Don't know ☐

SECTION C. ATTITUDE

In this section the attitudes of healthcare professionals towards ADR reporting will be assessed.

1. Do you feel that reporting of ADR can benefit the public health?

   Yes ☐ No ☐

2. Do you feel that one report can make a difference?

   Yes ☐ No ☐

3. Do you feel that filling of the ADR yellow form is useful?

   Yes ☐ No ☐

4. Do you feel that reporting of ADR should be compulsory?

   Yes ☐ No ☐

SECTION D: PRACTICE

In this section the practices of healthcare professionals towards ADR reporting will be assessed.

1. Have you ever diagnosed an ADR?

   Yes ☐ No ☐

2. Did you report the reaction?

   Yes ☐ No ☐

3. Have you ever reported an ADR to any reporting centre?

   Yes ☐ No ☐

4. Do you know how to report ADR?

   Yes ☐ No ☐

5. If reported, where did you report that reaction?

   Hospital ☐ Pharmaceutical company ☐

   Pharmacovigilance centre ☐ Doctor ☐

SECTION D: REASONS FOR NOT REPORTING

In this section the reasons for not reporting ADRs will be assessed. (Please tick what is appropriate)

Reasons	✓
Lack of time	
Uncertain of how to report	
Forgetfulness	
Lack of feedback	
ADR was well known	
Unavailability of reporting forms	
Lack of time	

Appendix 3: MREC approval certificate

UNIVERSITY OF LIMPOPO
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MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

MEETING: **03/2011**
04/2009

PROJECT NUMBER: MREC/PH/44/2009: PG

PROJECT :

Title:	Attitudes, knowledge and practices of healthcare professionals regarding Adverse Drug Reaction (ADR) reporting in Bophelong hospital.
Researcher:	Mrs NP Segomotso
Supervisor:	Busi Ntuli-Ngcobo
Department:	Social Behavioural Health Sciences
School:	Public Health
Degree	MPH

DECISION OF THE COMMITTEE:

MREC approved the new project.

DATE: 13 April 2011

RESEARCH & POSTGRADUATE 2011 -04- 13 MEDUNSA CAMPUS

PROF GA OGUNBANJO
CHAIRPERSON MREC

Note:
i) **Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.**
ii) **The budget for the research will be considered separately from the protocol.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

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