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FACTORS INFLUENCING REPORTING OF ADVERSE DRUG REACTIONS BY HEALTH WORKERS AT DISTRICT HOSPITALS IN MASHONALAND WEST PROVINCE, ZIMBABWE, 2020

BY

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Abstract

Adverse drug reactions (ADRs) contribute significantly to morbidity and mortality, although most cases go undetected, particularly in developing countries, data from the United States shows that Adverse Drug Events are the fourth to sixth leading cause of death. Spontaneous adverse drug reaction reporting is the most widely used and cost-effective method of monitoring the safety of drugs. This method is negatively affected by under reporting by healthcare professionals. This study seeks to determine factors that influence adverse drug reactions reporting by healthcare workers at district Hospitals in Mashonaland West Province, 2020. An analytical cross-sectional study of 237 health care workers randomly selected from the seven district hospitals in Mashonaland West province was conducted. Data collection was by self-administered questionnaire from fifth of December 2020 - 22nd December 2020. Descriptive statistics were used to describe the background characteristics of the healthcare workers and the outcome measures like training and reasons for ADR reporting were summarized as frequencies and percentages. Logistic regression was used to measure association between different variables and reporting of Adverse Drug Reactions. Majority of participants (78.1%) reported introduction of ADR reporting teachings during induction and mandatory training and refresher courses for health workers by (82.7%) as facilitators for ADR reporting. Six variables had a statistically significant association with ADR reporting, these were: knowledge that not all ADRs are known before drug is released (OR 3.4 p-value0.015); years of practice as health worker: 1-10yrs (OR 140.3; p-value 0.000), having been taught how to report ADRs (OR 3.5; p-value 0.014), knowledge of how to report ADRs (OR 2.9; p-value 0.028), awareness of a center were one can report (MCAZ) (OR 0.2 p-value 0.006) and knowledge of who should report (OR 0.1; p-value 0.002). Only 940 (39.5%) confirmed ever receiving training on ADRs. Lack of training and lack of knowledge on ADR reporting system were found to be the factors that were hindering ADR reporting by healthcare workers. Hence the researcher recommended that a multi-sectoral approach be taken to improve on educating health care workers on the processes of ADR reporting.

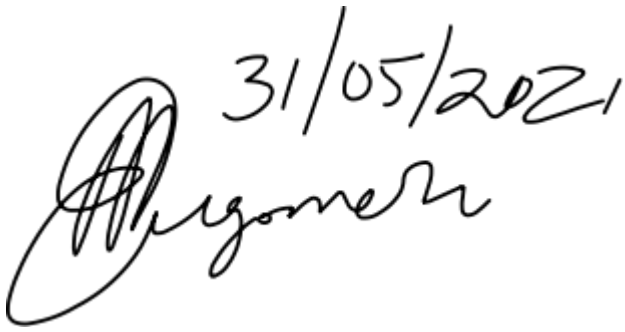
Keywords: Adverse Drug Reactions, Reporting, facilitators, hindering.

Declaration Page

I declare that this dissertation is my original work except where sources have been cited and acknowledged. The work has never been submitted, nor will it be submitted to another university for the award of a degree.

Nancy Gwekwe  30/05/21

Student's full name Student Signature (Date)

Dr E. Mugomeri 

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Dedication

I acknowledge God's Grace in completing this dissertation. This dissertation is dedicated to my children, Kudakwashe, Kupakwashe and Ruvarashe for your patience, love and support. To my colleague, Dr Felistaus, Chishakwe, thank you for the encouragement and wise counsel and to my supervisors, Dr T Mugomeri and Dr Dhliwayo, thank you for your belief in me and for walking and guiding me through.

List of acronyms and abbreviations

AEFI - Adverse Events Following Immunization

ADR - Adverse Drug Reactions

ADEs - Adverse Drug Events

AUREC - Africa University Research Ethics Committee

EPI - Expanded Program for Immunization

ICSR - Individual Case Safety Reports

MCAZ - Medicines Control Authority of Zimbabwe

PCV - Pharmacovigilance

WHO - World Health Organization

TSR - Targeted Spontaneous Reporting

UMC - Uppsala Monitoring Centre

Definition of key terms

An **Adverse Drug Reaction** is a response to a medicinal product which is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicines-related problem. It aims at getting the best outcome from treatment with medicines.

Spontaneous reporting is defined as an unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organization.

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CHAPTER 1 INTRODUCTION

1.1 Introduction

Adverse drug reactions (ADRs) are fairly common and are responsible for a significant number of hospital admissions with reported ranges of 0.3-7%, (Khalil & Huang, 2020). Studies have also shown that ADRs are very costly and the outcome of an ADR can be serious that it can result in injury or death. Early recognition of a drug's potential to cause an ADR is critical in ensuring safety of the users as well as reducing costs attributed to ADRs.

The spontaneous reporting of ADRs is considered as the foundation of post marketing surveillance of drug safety. The main function of spontaneous reporting is the early detection of signals of new, rare and serious ADRs. It is also one of the cheapest methods of monitoring the safety of medicines as utilized by many drugs regulatory agencies worldwide. Therefore, pharmacovigilance programme plays a vital role in ensuring the drugs' safety. In many countries a pharmacovigilance system is operational; however, under-reporting is a major problem (Kalaiselvan, Prasad, Bisht, Singh, & Singh, 2014).

Globally, the existence of formal national Pharmacovigilance (PCV) systems is indicated by participation in the WHO Program for International Drug Monitoring (PIDM). Membership of the PIDM is based on the existence of a designated national PCV center, a spontaneous adverse drug reaction (ADR) reporting system, and the demonstration of technical competence in managing individual case safety reports

(ICSRs) by submitting at least 20 ICSRs to the global ICSR database, VigiBase®, maintained by the Uppsala Monitoring Centre (UMC), Sweden, on behalf of the World Health Organization (WHO), Error: Reference source not found.

Zimbabwe became a member of the WHO International Drug Monitoring program in 1998, through the Medicines Control Authority of Zimbabwe (MCAZ). The MCAZ also serves as the country's PCV center, and the operations are based on WHO guidelines for running a national PCV center. The MCAZ has in the past reported issues of under-reporting of ADRs by practitioners and has been trying to increase awareness and promote reportingError: Reference source not found.

This chapter introduces the importance of reporting adverse drug reactions, defines both Pharmacovigilance and adverse drug reaction (ADRs), giving different forms of ADRs and highlighting their consequences to the patient and the health sector. The researcher highlights the importance of reporting adverse drug reactions by health workers. The researcher also presents objectives of the study and reasons for carrying out the study in this chapter.

1.2. Background to the study

The World Health Organization defines an adverse drug reaction (ADR) as 'a response to a medicinal product which is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function',Error: Reference source not found.

Patients' perspective to ADRs vary in severity and duration, and can be, appreciably, unpleasant and harmful. Management of ADRs usually require dose alteration, halting of treatment, or monitoring future drug administration. Six categories of ADRs are: augmented (dose-related), bizarre (non-dose related), chronic (dose- and time- related), delayed (time-related), end of use (withdrawal), and failure (failure of therapy),Error: Reference source not found.

Pharmacovigilance (PCV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicines-related problem. It aims at getting the best outcome from treatment with medicines, Error: Reference source not found. Good pharmacovigilance will identify the risks within the shortest possible time and will help to establish or identify risk factors for adverse drug reactions. When communicated effectively, this information allows for intelligent, evidence-based prescribing with the potential for preventing many ADRs. Such information will ultimately help each patient to receive optimum therapy at a lower cost to the health system. Adverse drug reactions (ADRs) have been reported to be among leading causes of morbidity and mortality.

The information collected during the premarketing phase is incomplete regarding adverse drug reactions and this is mainly because patients used in clinical trials are limited in number and are not representative to the public at large. In addition, the conditions of use of medicines differ from those in clinical practice and the duration is limited. Information about rare but serious adverse reactions, chronic toxicity, and use in special groups (such as children, the elderly, or pregnant women) or drug interactions is

often incomplete. Therefore, post-marketing surveillance is important to permit detection of less common but sometimes very serious ADRs. Health professionals worldwide should report on ADRs as it can save lives of their patients and others Error: Reference source not found.

Adverse drug events (ADEs) from poor product quality, adverse drug reactions (ADRs), and medication errors contribute significantly to morbidity and mortality. Although most cases go undetected, particularly in developing countries, data from the US shows that ADEs are the fourth to sixth leading cause of death. ADEs constitute a huge cost to the health system, estimated in the US at $177.4 billion in 2000. Economic consequences of adverse events that are not frequently reported include the impact of adverse events on patient adherence to treatment, resistance to medicines, and treatment outcomes. Besides the economic consequences, cases of adverse events affect the credibility of the health system leading to loss of confidence Error: Reference source not found.

Widespread use of electronic medical record databases has enhanced patient safety through automation of signal detections for ADRs, thereby improving healthcare service delivery. In Africa, the establishment and use of such databases is still rare and ADR reporting is largely done manually. Strengthening of PCV systems in sub-Saharan African (SSA) countries has received support from global health initiatives, but reporting is often disease specific (e.g. malaria, vaccines, HIV/AIDS) because of restricted funding streams rather than strengthening countrywide reporting systems. As a result, PCV systems in SSA remain weak, Error: Reference source not found.

At regional level the reporting of ICSRs is extremely low compared with the rest of the world, with the cumulative number of ICSRs from Africa to VigiBase® standing at 103,499 ICSRs, which is equivalent to 0.88 % of the global total number of 11,824,804 ICSRs in VigiBase® at 30 September 2015. The main ICSR reporting countries in Africa in terms of cumulative data in VigiBase® include South Africa, Morocco, Nigeria, Egypt and Kenya, Error: Reference source not found.

1.3 Statement of the Problem

Factors that influence reporting of adverse drug reactions by health workers in Mashonaland West Province have not been investigated, yet there is a possibility of under-reporting of adverse drug reactions. The World Health Organization recommends adverse drug reaction (ADRs) reporting rate of 200 reports per million population per year. The population of Mashonaland West province has been around 1.5 million since 2015 to date (Zimbabwe Statistics Agency [ZIMSTATS], 2020) hence there is possibility that the province is under-reporting with 8,13,11,1 and 38 adverse drug reaction reports in 2016, 2017, 2018, 2019 and 2020, respectively. These reports indicate under-reporting of ADRs across the province hence the need to investigate factors that influence ADR reporting by health workers.

1.4 Research Objectives

1.4.1 Broad Objective-The purpose of the study was to determine factors that influence adverse drug reaction reporting by Health workers at District hospitals in Mashonaland West Province, 2020.

1.4.2 Specific Objectives:

i. To determine level of knowledge of health workers on Adverse drug reaction reporting at District hospitals in Mashonaland West Province 2020.

ii. To determine the socio-demographic factors influencing reporting of adverse drug reactions by health workers at District hospitals in Mashonaland West Province, 2020.

iii. To explore the health systems factors that affect reporting of adverse drug reactions by health workers at District hospitals in Mashonaland West Province, 2020.

1.5 Research Questions

i. What is the health workers' level of knowledge on ADR reporting at District hospitals in Mashonaland West province, 2020?
ii. What is the association between socio-demographic factors and reporting of adverse drug reactions by health workers at District hospitals in Mashonaland West Province, 2020?
iii. What are the health system factors that influence adverse drug reaction reporting by health workers at District hospitals in Mashonaland West Province, 2020?

1.6 Significance of the Study

The study aims to contribute to the safe use of medicines through strengthening of adverse drug reactions reporting by health workers in Mashonaland West Province. The purpose of the study is to establish factors that influence ADR reporting by health workers and such information will inform authorities and give recommendations on how

to improve ADR reporting by health workers which in turn saves lives and reduces costs on the health by patients due to adverse events because of ADRs.

1.7 Delimitation of the Study

The researcher could have carried out a cohort study for comprehensive results but due to limited resources in terms of time to completion of the dissertation and financial constraints the researcher carried out a cross sectional study.

1.8 Limitation of the Study

There was possibility of bias in the study. Although it was expected that the participants responded with honesty and integrity, there was the possibility that health workers would research the correct answers before submitting their questionnaires, therefor the researcher collected data using an interviewer administered questionnaire to limit this bias. The possibility of recall bias could not be eliminated in this study since it was retrospective in nature.

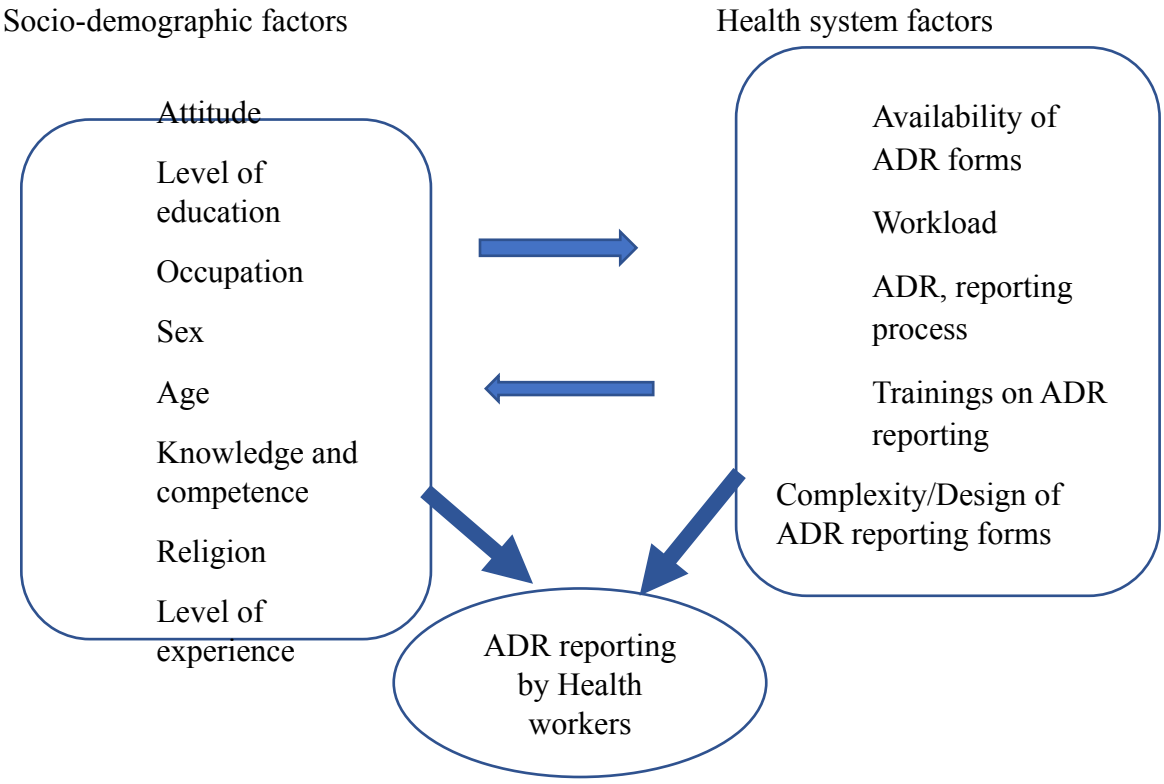
CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presents the review of literature which informed the design and implementation of this study. It illustrates the conceptual framework and provides

definitions of the terms used. It includes the factors that influence reporting of adverse drug reaction (ADR) from other studies done in other settings.

Figure 2. 1: Conceptual Framework



2.3 Relevance of the theoretical frame to the study

The theoretical framework assisted the researcher to organize and provide a context in which the research problem was examined, how data was gathered and analyzed. A theoretical framework is a combination of assumptions, principles and rules that govern the ideas of a broad concept. For a health worker to report ADRs, she/he must first have the requisite knowledge on how and what to report. This knowledge is affected by a number of factors which include other socio-demographic factors and health system factors. Combining the Health belief model and literature review evidence, the

researcher came up with the above conceptual framework which guided in planning and development of data collection tool as well as ways of data analysis.

2.4 Frequency of adverse drug reaction reporting

Generally, studies carried out across the world show that reporting of ADRs by healthcare professionals is poor, regardless of the setting. This is particularly the case, though, in developing country settings. In a cross-sectional study by Gurmesa and Dedefom (2016), conducted in Nekemte Town in Ethiopia, only 48% of the healthcare professionals responded correctly to the knowledge-related assessment questions, 42% to the attitude-related questions and 9,8% to the practice-related assessment questions.

Gurmesa and Dedefom (2016) further stated that only 5% of the ADRs that were encountered in Ethiopia were reported to the national Drug Administration and Control Authority. A study conducted on healthcare workers by Fadare and Enwere (2011) in Kano, Nigeria, revealed that there was low spontaneous ADR reporting, with only 42.7% of the respondents having ever reported an ADR.

A study in Nairobi had a response rate of 81.2%, of which the majority (n=210, 73.4%) were female. The mean age of the 254 participants (87.9%) who indicated their age was 37.3 years with a standard deviation of 8.1 years. The mean duration of practice of the 287 (99.3%) participants was 13.2 years with a standard deviation of 8.1 years

Khoza *et.al.,* (2004) conducted a study of ADR reporting by health workers at a referral hospital in Zimbabwe. Only 52,8% of the respondents knew how to report an ADR in Zimbabwe and 47.1% were unaware of the existence of a formal PCV center in the

country. Of the study participants, only 20% had ever reported an ADR. These Zimbabwean results are consistent with the other two African studies cited above, and with other studies conducted in different countries.

The MCAZ has continuously been looking for funding to strengthen activities by, for example, implementing cohort monitoring of ARVs and improving ADR reporting, (Ministry of Health and Child Care [MOHCC], 2011).

In a study done at Kadoma Hospital, fewer than half (43%) of the participants were aware of at least 2 objectives of the surveillance system but 83% of health workers willing to participate. However, the system was not acceptable, 79% did not perceive the system to be necessary with the majority saying "why should we fill in the forms when the reactions were already known or minor". Though the system was supposed to identify potential patient risk factors for types of events health workers were reluctant to participate as evidenced by only one form filled out of 20 reactions experienced in the district, (Muringazuva et al., 2017).

A study done in Uganda, Mulago National teaching and referral hospital found that only about 16.6% (n=37) of healthcare workers had ever reported an ADR. Very few (n= 84, 37.7%) healthcare workers knew the tools used in ADR reporting. Less than a quarter (n=41, 18.4%) of the healthcare workers knew where to report ADRs. Lack of training was reported as the major (56.5%, 126) deterrent to reporting ADRs by healthcare workersError: Reference source not found.

A study done in United Arab Emirates found that 81%, 83%, and 83.3% of doctors, community pharmacists, and hospital pharmacists, respectively, were not aware of the

existence of a reporting center and 56%, 60%, and 72% were not aware of a reporting procedure. Poor ADR reporting practices were shown by responders; only 19%, 14%, and 12.1% of doctors, community pharmacists, and hospital pharmacists reported ADRs.

In a study in Saudi-Arabia on Attitude and Awareness of Adverse Drug Reaction Reporting by Health Professionals in Seven Hospitals in the Holy City of Makkah, Kingdom of Saudi Arabia the overall response rate for the study was 65.9%. Out of the total 310 participants70.3% were male and 29.7 % were female. Most of the participants were in the age group of 31-40 years (45.8%). Out of total 310 professionals 205 (66.1%) were physicians, 25 (8.1%) dentist, 49 (15.8%) pharmacist and 31 (10.0%) nurses. Most of the professional were having bachelors and master's degree qualification. Thirty-five percent of the health professionals had experience between 11 to 20 years. Most of the professional (34.2%) spent 6-10 hours on continuing education per month Error: Reference source not found.

One study in Saudi-Arabia revealed that 50% of the health professionals think that the ADR reporting and monitoring system had benefited patients by identifying safe drug use. 46.1% professional opinioned that ADR reporting will simply identify rate of incidence. 54.2% of health professionals considered that the reporting system was to identify ADR within the same pharmaceutical class. 48.4% respondents considered the purpose of the ADR reporting was to detect potential ADRs. 42.9% of respondents thought the system served as a source of information about the characteristics of ADRs whereas 30.6% were not sure,Error: Reference source not found.

2.5 Definition and concept of pharmacovigilance

Pharmacovigilance (PCV) is defined as the science of activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions or any other drug-related problems, (WHO, 2002). The most important part of PCV is to collect extensive data related to a medicine's actions throughout the product life cycle, both pre-market (prior to marketing authorization, reflecting clinical trial experience) and post-market (after marketing authorization is granted, and the medicine is used both for its labelled and for off-label indications and in a wider variety of patients and settings).

Zimbabwe, through the Medicines Control Authority of Zimbabwe (MCAZ), became a participating country to the World Health Organization (WHO) International Drug Monitoring program in 1998.

Several studies have been undertaken with the intention to promote and monitor the safety and effectiveness of current and new medicines. A majority of these studies have focused on establishing the knowledge, attitudes and practices of healthcare professionals in various settings when it comes to ADRs and their reporting Error: Reference source not found and Error: Reference source not found. In the same study by Khoza et al., at Parirenyatwa referral hospital, 20% of the study participants had ever reported an ADR. This supports the fact that there is under reporting of ADRs by health workers in Zimbabwe.

The information from ADR reports is used to inform the review of the benefit-risk profile of individual medicines. This process is aimed at risk minimization and this information will contribute to the development of proactive PCV systems by informing

regulators about the activities that are successful and those that are not effective in generating positive health and economic impacts Error: Reference source not found. Proactive approaches allow for early detection and risk minimization of ADRs throughout a medicine's lifecycle.

2.6 Methods of reporting adverse drug reactions

According to WHO, it is the professional responsibility of all healthcare professionals to report ADRs as they are in the best position to detect and report on these events, Error: Reference source not found. ADR reporting is done by two basic methods, namely spontaneous reporting and intensive reporting. Spontaneous reporting is a system whereby reports of suspected ADR cases are voluntarily submitted to the national PCV Centre by healthcare professionals, either directly or via pharmaceutical companies, or by the public (patients or carers). Spontaneous reports are now also known as Individual Case Safety Reports (ICSRs), Error: Reference source not found.

Intensive reporting, also known as cohort event monitoring, involves prospective studies done on patients who have taken or are taking the medicine of interest. All or specific adverse events in these patients are recorded over time in a planned manner. In Zimbabwe reports on adverse drug reactions are received from healthcare professionals and patients. These reports are evaluated and recorded in the WHO Uppsala Monitoring Centre database called Vigibase.

The Pharmacovigilance and Clinical Trials division ensures that the reporters receive appropriate feedback. ADR reporting is done either online or manually. The online ADR reporting platform was launched in 2016. This e-reporting platform was set for

convenient ADR reporting as the forms are available even when one is offline, and only require internet for sending. Manual reporting of ADRs requires one to fill in the ADR form in triplicate, one is sent to MCAZ, the other remains at the health care Centre and the other is send to the district health office, for filing. There are different types of ADR reporting in Zimbabwe, and these include:

i. Targeted Spontaneous Reporting

   The Targeted Spontaneous Reporting (TSR) Program is reporting for specific group of drugs example ARVs, anti-TB, anti-malaria etc. This form of ADR reporting aims at analyzing profiles of combination of particular drugs within populations. They are usually conducted when new regiments are introduced for example ARVs when first line was shifted from Stavudine, Lamivudine, Nevirapine combination to Tenofovir, lamivudine and Efavirenz.

ii. Adverse Events Following Immunization (AEFI) Surveillance

   The main focus of reporting AEFI is to improve the quality of Immunization program through activities that collect, detect, assess, monitor, prevent, and manage Adverse Events Following Immunization (AEFI) for the purposes of improving the quality of life of children. Safety of vaccines is an essential part of the success of immunization program. The National Pharmacovigilance Centre, Medicines Control Authority of Zimbabwe (MCAZ) in collaboration with the Expanded Program on Immunization (EPI) are the main drivers of this initiative.

iii. Spontaneous ADR reporting.

This is unsolicited communication by health care professionals or consumers that describes one or more ADRs in a patient who was given one or more medicinal products and that does not derive from a study or any organized data collection.

2.7 Factors influencing reporting of adverse drug reactions.

Under-reporting of ADRs is a global trend affecting both developed and developing countries. An appreciation of the factors that influence ADR reporting will inform strategies that need to be implemented to increase the number and quality of ADR reports.

Some constraints to ADR reporting according to findings of a study done in Saudi Arabia were that according to 66.8% professionals ADR reporting forms were not available whereas 55.1 professionals did not know how to report ADR. 62.6% professionals agreed that they did not know the reporting address of ADR. According to 50.4% professionals reporting form was too complicated whereas 58.1% believe that reporting ADRs was time consuming. One of the major constrain in reporting of ADR was insufficient clinical knowledge (64.9%). 52% of professionals believe that all ADR were already known. 57% of health professionals stated that the lack of ADRs reporting may reflect the fear to report such events,Error: Reference source not found.

A study in Nigeria showed that overall, 58(72.5%) health workers had heard of pharmacovigilance**,** but only 3(5.2%) correctly understood the pharmacovigilance concept. Twelve (15.0%) showed adequate knowledge of ADRs, while 37(46.2%) demonstrated positive attitude towards ADR reporting. Thirty (37.5%) health workers had come across ADR reporting form, while 79(98.8%) expressed willingness to report

all ADRs encountered. Of the patients, 31(8.6%) had heard of pharmacovigilance, 143(39.7%) correctly cited ADR definition, while 67(18.6%) reported the previously experienced ADRs. Informing healthcare professional (38; 38.8%) was the most common measure taken by patients when they experienced reaction(s). Nurses significantly had adequate knowledge of ADRs ($p < 0.001$) compared to other cadres, Error: Reference source not found

A study on pharmacists in United Kingdom showed that all pharmacists reported both serious and mild ADRs from drugs with black triangle among children as well as adults. About 95%tore-based pharmacists were more likely to be more confident about which ADRs to report [0.680, 95% Confidence Interval 0.43-3.59]. Lack of time 46.4% (n=64), and pharmacists' perception that ADR is not serious enough to report (65.2%; n=90) were identified as barriers to ADR reporting. Majority 63.0% (n=87) of the pharmacists identified training and information about what to report and access to Information Technology (IT), access to internet connection 61.6% (n=85) was reported as facilitators to ADR reporting process. Training and information about what to report 63.0% (n=87) and access to information technology to report 61.6% (n=85) were identified as the two main facilitators to improve reporting of ADRs.

Further analysis reported that female pharmacists with less job experience strongly emphasized on the need for provision of access to IT OR 0.859 [0.394 -1.872] and information about how to report an ADR, OR 0.845 [0.385 -1.855] in order to improve the reporting of ADRs, Error: Reference source not found.

A study in Nairobi showed that previous pharmacovigilance training was found to be significantly associated with reporting of adverse drug reactions (p=0.000). Health

workers were more likely to report adverse drug reactions if they had been trained. Health workers' knowledge on adverse drug reactions was significantly associated with reporting of adverse drug reactions (p=0.0021) with reporters having higher mean knowledge scores than the non-reporters. Previous pharmacovigilance training (p=0.000, Odds Ratio 14.04, 95% CI: 3.19-61.76) and knowledge (p=0.033, Odds Ratio 1.19, 95% CI: 1.01-1.40) were found to be the strongest predictors of reporting adverse drug reactions when logistic regression was carried out.

The key informants identified several health provider and health systems factors that affect reporting of adverse drug reactions. Lack of knowledge about the adverse drug reaction reporting scheme and poor attitudes were identified as health worker factors that hindered adverse drug reaction reporting. Health systems factors that hindered the reporting of adverse drug reactions were the unavailability of reporting tools, high workloads and the costs incurred when sending a hard copy report to the Pharmacy and Poisons Board. The same study showed that most health workers (n=210, 72.7%) had not received any training on pharmacovigilance, Error: Reference source not found.

A study in Nnewi in Nigeria, 372 respondents studied, 255 (68.5%) were females, and 117 (31.5%) were males. The modal age range (37.6%) was 31–40 years. Nurses/related cadres were in the majority with a total of 241 (64.8%), then doctors, 109 (29.3%) and pharmacists, 22 (5.9%). The study shows that distribution of respondents with training on ADR reporting was generally poor among the health workers studied, but pharmacists had an appreciable training on ADR reporting (50.0%) than nurses (19.5%) and the doctors (13.8%). The difference in training among the health workers was not significant ($\chi^2 = 5.187$, $df = 3$, $P = 0.16$).

In the same study in Nigeria three hundred and sixty-eight (98.9%) respondents gave suggestions on how to improve ADR reporting. The suggestions include, awareness and provision of reporting forms/guideline, electronic reporting process. The difference among suggested ways to improve ADR reporting by the respondents was not significant ($\chi^2 = 0.84682$, $df = 4$, $P = 0.36$), (Ezeuko, Ebenebe & Ugoji, 2015).

A study in Namibia on the public health setting healthcare workers surveyed, 43.1% were nurses, 63.4% of the respondents knew about the ADR reporting system in Namibia, 76.7% knew the pharmacovigilance/ADR reporting centre in Namibia, while 37.3% had reported an ADR before. Nurses were less likely to be knowledgeable and report ADRs. The independent predictor of ADR reporting was the nursing cadre; adjusted odds ratio (AOR) = 0.17 (95% CI: 0.07, 0.401, $P < .01$). Pre- and in-service trainings including introduction of electronic reporting platforms were some of the identified ways of optimizing the pharmacovigilance and ADR reporting systems by the respondents. As pharmacovigilance in Namibia relies on spontaneous reporting of ADRs, there is a need for advocacy and workforce strengthening for ADR reporting in the public health sector, Error: Reference source not found.

In a study in Ethiopia on ADR reporting by doctors, adverse drug reaction reporting was found to be low with only 94(27.4%) of doctors having ever reported ADRs to national pharmacovigilance center. Gaps in guidelines availability, reporting systems and structure, pre-service and in-service training, and awareness of doctors on impact of reporting were some of the factors that were reported to influence ADR reporting by doctors. Hence, improving access to ADR reporting form, decentralizing the safety

monitoring system, and conducting awareness training on ADR reporting were found to be essential to improve the ADR reporting practice.Error: Reference source not found.

Factors that determine whether healthcare professionals (HCPs) report ADRs are determined by the attitudes the HCP has towards ADR reporting. In a number of studies, for example Kalaiselvan et al*.,* (2014), most HCPs pointed out that the following reasons hinder them from reporting ADRs: lack of adequate training (knowledge), lack of time, lack of feedback, fear of not being taken seriously, lack of financial incentives, fear of legal proceedings and lethargy. These reasons affect both developing and developed countries to a similar extent.

Lack of adequate knowledge on ADR takes many forms. It can be a failure to understand what to report, who to report to or how the reporting tool works or even the existence of a PCV center or ADR reporting program. In Iran, Vessel and Mardani (2008), assessed pharmacists' knowledge, attitudes and practices (KAP) with respect to the reporting of ADRs, and reported that 25% of the pharmacists who had witnessed an ADR reported it. Furthermore, 30% of the pharmacists in Iran were not aware of an ADR reporting program in the country, and 43% of community pharmacists indicated that the reason they did not report ADRs was because they were uncertain of the association between the drug and the reaction.

Lack of understanding of the Yellow Card reporting scheme which is used in the UK also significantly contributed to the high under-reporting rates in that country. In a study by Error: Reference source not found, to evaluate clinical pharmacists' interventions aimed at improving KAP of healthcare workers about ADRs in a teaching hospital in

Iran, it was reported that 91.5% of hospital workers where the study was carried out had never reported an ADR and 49% were not aware of the existence of a national PCV center. In Iran, pharmacists were reported to be more aware of PCV compared to other healthcare professionals.

A study in Saudi Arabia revealed that 47.1% (n=146) of the responders were aware of existence of ADR reporting and monitoring system. 51.9% professional said that ADRs reporting program was present in their hospital. 59.1% professional were not aware of the existence of National Pharmacovigilance Centre (NPC) in Saudi Food and Drug Authority (SFDA). 55.5% had learnt about the ADRs programme from official work and thirty-six percent of respondents thought the MOH was the department which was responsible for receiving the ADRs reports and interpreting them, Error: Reference source not found.

Some studies (Eniojukan et al., 2015) have shown that healthcare professionals with advanced qualifications tend to report ADRs more than do their colleagues with lower qualifications, or with less familiarity with medicines. Doctors and pharmacists could be expected to report more ADRs than other HCPs, due to a greater understanding pharmacology and of the impact ADRs have on the healthcare system. In a study that was carried out in Northern Cyprus by Toklu et al., (2016) to determine the knowledge, and attitudes of healthcare professionals in their country towards PCV, doctors and pharmacists in the study claimed to have reported more ADRs than did nurses.

There are other factors that potentially affect reporting, but that are unique to a particular setting. In Africa and most developing nations for example, health systems are weak. There is lack of trained health personnel and there are insufficient and inadequate resources for PCV. All these factors are likely to contribute to both a significant increase in the incidence of ADRs and to low rates of reporting.

Oreagba et al*.,* (2011) have reported that Nigeria, and Africa as a whole, still has a long way to go when it comes to issues of PCV. Twenty percent of pharmacists in Nigeria reported ADRs despite 40% of them receiving reports of ADRs from patients on a monthly basis. Pharmacists in the country were seen to have poor KAP when it comes to ADR reporting. Reasons for poor reporting, like in the other studies mentioned above, included lack of awareness about PCV and lack of incentives for reporting. In addition, there is also a high workload which is a result of the loss of healthcare professionals due to emigration. This is the case with Zimbabwe where, in 2004, the doctor: patient ratio was reported to be 1: 6000, specifically as a result of losses to emigration (Chibango, 2013). Such a high workload will negatively impact on PCV activities.

Legislative requirements are also a factor that affects ADR reporting, and these differ between countries. A systematic review carried out by Hazell and Shakir (2006) of ADR studies carried out in twelve countries (in the UK, Germany, France, Spain, Norway, Demark, Sweden, Canada, Hong Kong, US, Netherlands and Italy) showed that ADR under-reporting ranged from 6% to 100%, with a median rate of 94% across all included studies. The wide range was related to the different methodologies that were employed in the studies that were reviewed. In some countries like Sweden, pharmacists were not

allowed at the time to report ADRs to the national program (Zolezzi and Parsotam, 2005) and this might mean that some ADRs were completely missed.

2.7.1 Interventions to improve Adverse Drug Reaction Reporting

Several interventions have been employed by researchers in different settings to determine if they can improve ADR reporting by HCPs (Gurmesa and Dedefom 2016; Lopez-Gonzalez et al., 2015). These interventions include educational activities such as continuing professional development (CPD) sessions; reminders such as letters, emails or posters, the modification of the ADE reporting form (simplification of reporting); modification of reporting procedures (reporting by telephone or electronically); incentives, enhancing availability of resources required when reporting such as reporting forms; and providing continuous motivation through feedback provision.

Educational activities have been shown to improve reporting of adverse drug reactions. Studies by (Desai et.al., 2011; Khan et al., 2013; Ruud et al., 2010) have attributed lack of knowledge as a hindering factor in reporting of ADRs. As such, one solution is to address this is by educating healthcare professionals and increasing awareness of pharmacovigilance.

Lopez-Gonzalez et al*.,* (2015) conducted a study in Spain to determine if educational interventions will improve ADR reporting among physicians, using two complementary approaches, one active and one passive. The active group had group sessions and the passive group had educational material sent to them. The study showed that ADR reporting in the intervention group increased by 65.4% during the period of follow-up.

In Iran, Hanafi et al., (2014) employed a pharmacologist and a pharmacist who were specialized in PCV to give a lecture to nurses on the importance of PCV and ADR reporting. In the lecture, the nurses were also taught how to fill in the Iranian Yellow Card when reporting an ADR. The study determined that an educational intervention increases ADR reporting amongst nurses and that it also has a positive impact on their knowledge, attitudes, and practices towards the reporting of ADRs. However, this was a one-off intervention, and the sustainability of the change was not assessed. From the study it appeared to be imperative that continuing awareness programmer in the form of Continuing Professional Development (CPD) encounters will address grey areas as it would repeatedly and continually emphasize the importance of ADR reporting.

Electronic reporting has revealed that some healthcare professionals have suggested that the introduction of electronic reporting systems will improve their ADR reporting. A study on the use of electronic reporting to aid ADR reporting in children in Scotland, found that there was an 80% response rate with electronic reporting compared to 83% with the paper-based cards. Nonetheless, the respondents, who comprised of pediatricians and pharmacists, indicated that they preferred to use the electronic method for reporting. Although the introduction of an electronic reporting system may improve accessibility to the reporting tool and save time, it alone does not significantly improve ADR reporting. Other factors, such as limited knowledge and a lack of incentives, also need to be addressedError: Reference source not found.

In many studies, incentive provision to healthcare professionals has shown to improve reporting of adverse drug reactions. Lack of incentives have been reported as an obstacle

to reporting ADRs. Incentives can be in the form of educational credits, notepads, coffee mugs or financial payments.

In Sweden, Backstrom and Mjorndal (2006) evaluated the effect of incentives on ADR reporting. Two counties in Sweden were studied, one as the control and one as the intervention site. The intervention county received an incentive in the form of two lottery tickets for every ADR reported in each period of six months. The intervention group reported 59% more ADRs compared to the previous year, and 40% of these were assessed to be serious ADRs. The control group only had a slight increase in the first three months, with the number of reports decreasing at the end of the study. The study concluded that economic inducements could increase the number of ADR reports.

The British Medical Association [BMA] (2006) noted that at least 30% of Green Cards which were issued in Southampton for Prescription Event Monitoring (PEM) were not returned by general practitioners (GPs), citing a lack of financial incentives.

However, some incentives, especially financial, if paid directly to health care practitioners, may create a perverse incentive to report ADRs. This will inadvertently result in an increase of reported ADRs, some of which may be supported by tenuous evidence. In addition, prescribers might be inclined to prescribe newer medicines which are likely to have more adverse effects in order to gain more incentives (Berniker, 2004).

2.4 Chapter summary

Literature review gives the over-view picture of what other similar or almost similar studies found concerning the subject under study. It also helps in coming up with the

conceptual framework from which the researcher derives study design and how to conduct study.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter sets out to describe the approach which was used to determine the factors that influence ADR reporting by health workers. It includes a description of the study design, sampling, data collection, statistical analysis, potential biases and limitations. The study used both quantitative and qualitative techniques. The reasons for the addition

of the qualitative component to the quantitative study are two-fold: to help understand the results of the quantitative study and to generate new ideas regarding the other factors related to the health systems or the patients that affect the reporting of adverse drug reactions.

3.2 The Research Design

Research design is defined as an ultimate plan to answer the research questions. Research design refers to the structured approach followed by the researcher to answer the research questions. A cross-sectional analytical study was adopted in conducting this research. Since, this study intended to determine factors that influence ADR reporting by health worker the analytic cross-sectional design was used since it offered a cost-effective way of gathering information from many people in a relatively short period. This cross-sectional study method therefore guaranteed a rapid means of achieving this without compromising the quality of information collected.

3.3 Population and sampling

3.3.1 Study setting

This study was carried out at all district hospitals in Mashonaland West province.

3.3.2 Study Population

Study population included nurses, medical doctors, pharmacy technicians, radiologists, dentists, physiotherapists, pharmacists and laboratory scientists who were available during the study period. Key informants included the District Medical Officer (DMO), Matron and District Pharmacist.

3.3.3 Inclusion and exclusion criteria.

Inclusion criteria: Nurses, medical doctors, pharmacy technicians, radiologists, dentists, physiotherapists, pharmacist, and laboratory scientists with at least six months as healthcare workers at the time the study was carried out were included in the study. Out-patients registers and T12 for the period January 2019 to December 2019 were included in the study, these registers were reviewed so that the researcher identifies unreported ADR cases if any.

Exclusion criteria: Health workers with less than six months practicing as a healthcare worker at time the study is carried out were excluded from the study. Out-patients registers and T12 before January 2019 and beyond Deceber2019 were used in conducting the study.

3.3.4 Sample size calculation

The researcher calculated the ample size using Cochran formula n = Z2*p q/d2

Where n is the minimum sample size

Z = 1.96 z score at 95% Confidence Interval

p = the proportion of health workers that make ADR reports, set at 20%, according to the ADR reporting from previous study done at Parirenyatwa by Khoza et al., 2004.

q = 1-p

d = The researcher's margin of error is 5% (0.05)

Therefore, the minimum sample size n = (1.96)2 x 0.2 x 0.8 / (0.05)2 = 245.

Adjusting for none-response rate of 10%

The maximum sample size was calculated as, 245/ 0.9 =272

Final sample size was anything between 245 and 273. The participants were divided into sub-groups on the basis of their designation. Six sub-groups of, doctors, nurses, pharmacy staff, dentist, physiotherapist and lab staff were formed, and participants were sampled in the ratio 2:29:1:1:1:1 respectively. The ratios were determined by the distribution of all healthcare workers in-post at the district hospitals at the time the study was carries out.

Therefore, the number of doctors was 2/35 x 273 = 15

Number of nurses was 29/35 x 273 = 226

Number of pharmacy staff = 1/35 x 273 = 8

Number of lab staff = 1/35 x 273 = 8

Number of dentists=1/35x273=8

Number of rehabilitation staff =1/35x273=8

Seven facilities were included in the study of which one was used for pre-testing of data collection tools. To calculate number of participants to be recruited per facility the maximum sample size was divided by the number of facilities that were included in the study.

Participants that were recruited per facility:

Number of doctors was 15/6= 2.5. Doctors were anything between 2 and 3.

Number of nurses was 226/6 =37.6 Nurses were anything between 36 and 37.

Number of pharmacists and pharmacy technician was 8/6=1.3. Pharmacist and pharmacy technician were anything between 1 and 2.

Number of Laboratory scientists and technicians was 8/6 =1.3. Laboratory scientist and technician were anything between 1 and 2.

Number of dentists was 8/6=1.3. Dentists and dental therapists were anything between11 and 2

Number of rehabilitation staff was 8/6=1.3. Rehabilitation staff was anything between 1 and 2

3.3.5 Sample size of patient records:

A census of out-patient registers and T12 forms for period January 2019 to December 2019 was done to determine number of all ADRs at the facilities for comparison with the ones reported on ADR forms and submitted.

3.3.6 Sampling

Stratified sampling was done, in which case the participants were divided into sub-groups on the basis of their designation. Six sub-groups of, doctors, nurses, pharmacy staff, dentists, rehabilitation staff and lab staff were formed, and participants were sampled in the ratio 2:29:1:1:1:1 respectively. The ratios were determined by the distribution of all healthcare workers in-post at the district hospitals at the time the study was carried out.

The researcher used purposive sampling to select key informants as participants at every district hospital. The healthcare workers who were be available and willing to participate during the period of data collection participated in the study.

3.4. Data Collection Instruments.

An interviewer-administered questionnaire and checklist were used for data collection from healthcare workers. The questionnaires contained both closed and open-ended questions. Questions in the questionnaires and the checklist were guided from literature. Most of the questions were adopted from a similar study done by Mafundikwa Tafadzwa in Harare, 2017. The questions were divided into sections to answer all objectives. The first section collected data on socio-demographic variables like sex distribution of participants, age distribution of participants, designation of participants as well as years of experience as a health worker of the participants.

The next section was asking questions that determine level of knowledge of healthcare workers on adverse drug reaction reporting. The last section was asking questions on the factors that influence adverse drug reaction reporting.

3.4.1 Study variables

The dependent variable was making an ADR report. To assess for the outcome, which was reporting an ADR, demographics such as age, designation, and years of practice as a health worker as well as system factors like whether one was taught on ADR reporting, frequency of refresher trainings, availability of resources, workload and knowledge of how to report were independent variables.

3.5. Data collection procedure

Review of ADR registers and Forms reported for the period January 2019 to December 2019was conducted. The outpatient registers and T12 were checked for any adverse drug

reaction treated cases during the period January 2019 to December 2019. Reports on the ADRs and minutes of meetings were checked. A checklist was used to assess for the availability of the resources needed for running the ADR surveillance system. The Interviewer-administered questionnaire was adapted from a similar study conducted on effects of KAP on ADR reporting by Mafundikwa (2017). The questionnaire consisted of mainly close-ended questions and covered on knowledge of pharmacovigilance concepts, attitudes towards reporting ADRs, system factors affecting reporting of ADR reporting and demographic factors on ADR reporting. Data was collected from the health workers using the interviewer administered questionnaire.

3.5.1 Provision for observing COVID-19 restrictions during the period of data collection.

Researcher used interviewer administered questionnaire to avoid or minimize contact with the participants. The researcher observed social distancing and wearing of masks during data collection. The researcher sanitized all the time.

3.6. Analysis and Organization of Data

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 16 Categorical predictor variables such as sex was summarized as frequencies and percentages and the continuous predictor variables such as age were summarized using the means and standard deviation for normally distributed data and using the median and interquartile range for skewed data. Different key determinants for the reporting of ADRs were screened using $\chi 2$ tests for categorical variables. Logistic regression was used to assess the relationship of socio-demographic, health system factors and reporting

of adverse drug reactions by health workers. Results were expressed as ORs with 95% CI.

3.7. Ethical Consideration

Written informed consent was obtained from all the respondents before the start of the study. Participation in this research was voluntary and participant information was kept confident.

Confidentiality of participants was attained through anonymization (use of numbers for participant identity/ID in place for names). Ethical approval was sort from Mashonaland West Provincial Medical Director's office, District medical officers, Medical superintendent and Africa University Research Ethics Committee (AUREC).

3.8. Chapter summary

This section was describing, the methodology used in carrying out this study. The procedure of data collection and sampling of the study participants as well as sample size calculation was described in detail. Data analysis methods to be employed is also detailed in this section.

CHAPTER 4: DATA PRESENTATION, ANALYSIS, AND INTERPRETATION

4.1 Introduction

This chapter presents the results of the analysis of the data collected from respondents using a questionnaire. The findings are reported according to the objectives and research questions of this study.

4.2 Socio-demographic characteristics of health workers at Mashonaland West Province district hospitals.

In total, 237 participants, participated in this study, yielding a response rate of 96%.

This section presents the descriptive statistics pertaining to the demographic characteristics of the respondents, namely: age, sex, years of practice as a health worker, religion and designation.

A total of 237 participants, participated of whom 68(28.7%) were male and 169(71.3%) were females. The age range was 22 to 58 years with mean age 35.65 years and standard deviation of 9.2years. Majority of the participants were nurses, one hundred and ninety-nine (81.6%), the rehabilitation staff having the least participants 3(1.2%). The demographic details of the respondents are provided in Table 4.1

Table 4.1: Socio-demographic characteristics of health workers

Characteristic	Participants n=103 Frequency	Reported (Yes) Percent	Participants n=134 Frequency	Reported (No) Percent	Total Frequency	Percent%
Sex:						
Female	76	73.8	93	69.4	169	71.3
Male	27	26.2	41	30.6	68	28.7
Designation:						
Doctor	4	3.9	7	5.2	11	4.6
Nurse	88	85.4	111	82.8	199	84
Pharmacist or pharm-tech	1	1	7	5.2	8	3.4
Laboratory staff	3	2.9	3	2.2	6	2.5
Rehabilitation staff	2	1.9	1	0.7	3	1.3
Radiographer or therapist	3	2.9	3	2.2	6	2.5
Dentist or therapist	2	0.9	2	1.5	4	1.7
Religion:						
Christianity	98	95.1	129	96.3	227	95.8
African Tradition	5	4.9	5	3.7	10	4.2
Age range in years:						
21-30	22	21.4	29	21.6	51	21.5
31-40	61	59.2	70	52.2	131	55.3
41-50	12	11.7	21	15.7	33	13.9
51-60	8	7.8	14	10.4	22	9.3
Years of practice as health worker						
1 to 10 years	97	94.2	41	32	138	59.7
11yrs<	6	5.8	87	2.6	93	40.3

Table 4.2: Relationship between socio-demographic characteristics and reporting of adverse drug reactions

Did you report	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Sex						
Female	5.4	1.838945	4.89	0.000	2.7	10.5
_cons	.6	.1770463	-1.59	0.112	.4	1.1
Years of practicing as health worker 1-10years	1.1	.0233973	2.17	0.030	1.0	1.1
_cons	1.4	.3829298	1.33	0.182	.8	2.4
Designation						
Doctor	1 (empty)					
Nurse	2.6	1.184551	2.16	0.030	1.1	6.4
Pharmacist or technician	1 (empty)					
Laboratory scientist or tech	.5	.3211308	-1.02	0.306	.2	1.7
Dentist or therapist	1 (omitted)					
_cons	1.8	.6825065	1.59	0.111	.8	3.8

On a bivariate analysis there was a significant relationship between sex and reporting of adverse drugs by health workers, with females having an odds of 5.4 and a p-value of 0.00, years of experience as a health worker was also significantly associated with reporting of adverse reaction reporting. Amongst the different professions, being a nurse had an odds of 2.6 to reporting of adverse drug reactions and a p-value of 0.03.

4.3 Level of knowledge of health workers on adverse drug reactions reporting

Only 38% (90) of the participants could define what an adverse drug reaction was. The majority did not have the basic knowledge of the ADR surveillance system and how it works, with most questions having less than 50% score of persons who got the correct

responses to the questions given. Having knowledge of which ADRs to report had the best score with 77.6% of the participants giving the correct response. Below is a table summarizing knowledge of participants on ADR reporting.

Table 4. 3: Knowledge of ADR reporting versus frequency and percent of participants

Characteristic		n (%
What is an adverse Drug reaction?	Know	90 (38)
	Don't know	147(62)
Know who should report ADRs:	Know	96 (40.5)
	Don't know	141 (59.5)
Awareness of the existence of the MCAZ:	Aware	139 (61.5)
	Not aware	87 (38.5)
Number of forms to be filled when reporting,		
	Know	74 (36.5)
	Don't know	128(63.1)
Knowledge of which ADRs to report	Know	184 (77.6)
	Don't know	53(22.4)
Knowledge of how to report ADRs,		
	Know	89(39.4)
	Don't know	137(60.6)
Are the entire ADRs known before a drug is released into market?		

Yes	36(42.4)
No	117(49.4)

Table 4. 4: *Knowledge of adverse drug reaction reporting and frequency of health workers*

Variable	Frequency n=237	Percent (%)
Which ADR must be reported?		
Untreatable	216	88
Serious	215	88
New	229	97
Where should you report adverse drug reactions		
Medicines Control Authority of Zimbabwe	147	62
The manufacturer	214	87
Why should adverse drug reactions be reported?		
For identification of new ADRs	107	45
To improve patient safety	86	36
To measure incidence of ADRs	182	76

4.4 System factors that influence reporting of adverse drug reactions by health workers

Of the 237 participants only 48% confirmed that they had received some form of training on ADR reporting either in-service or pre-service. Majority of the participants received training on ADR reporting from college or university (31.3%). Knowledge on reporting of ADRs was gained through on job training, workshops, formal trainings organized at institutional level as well as pre-service training at college and or university.

Data collected using the checklist shows that, Adverse drug reaction reporting forms are available at almost all institutions except for one were they failed to locate the booklet.

Only one institution (14%) had a particular individual selected as the focal person for ADR reporting, all other institutions regarded the pharmacy and the community office as responsible for overall overseeing of the ADR reporting process.

Two institutions out of the seven that participated (28.5%) had never submitted ADR forms since January 2019, to the time the study was conducted. The forms were filled in triplicate but never pulled out for submission. One of the institutions had some forms dating back to 2017 that were not yet submitted to MCAZ.

Comparison between the ADRs reported and recorded on the forms versus the T12 and OPD register data, there was a slight difference with three institutions having between three-five more ADR cases in the T12 or OPD registers compared to the ones recorded on the ADR reporting forms. None of the participating institutions had carried out trainings on ADR reporting in the past two years. All participating institutions use the paper- based form of reporting ADRs yet none of them had backup for ADR reported data in case of fire or theft or other disasters.

Six key informants participated in the study. They confirmed availability of basic resources required for reporting ADRs like stationary (ADR reporting booklet, pens), however the website-based reporting was not feasible due to lack of resources, internet, computers or smart phones, etc. All the key informants emphasized on the need for training of healthcare workers on ADR reporting. Need for feedback from MCAZ and introduction of ADR reporting in the curriculum of all health care workers were highlighted as some of the drivers to ADR reporting by healthcare workers.

There is lack of training on adverse drug reaction reporting amongst health workers (table 4), with the majority 66.8% revealing that they have never received any in service training. Amongst the five factors mentioned by participants as barriers to ADR reporting by health workers (see figure 5), the most common were not knowing where to report (66%) and not knowing how to report (54%). Fear of legal liability issues was highlighted as a barrier by the least number of participants (8.8%). Of the factors that encourage reporting of ADRs by health workers, 82.7% reported that mandatory training and refresher courses would enhance reporting also 78% regarded training during induction as one of major facilitators to reporting.

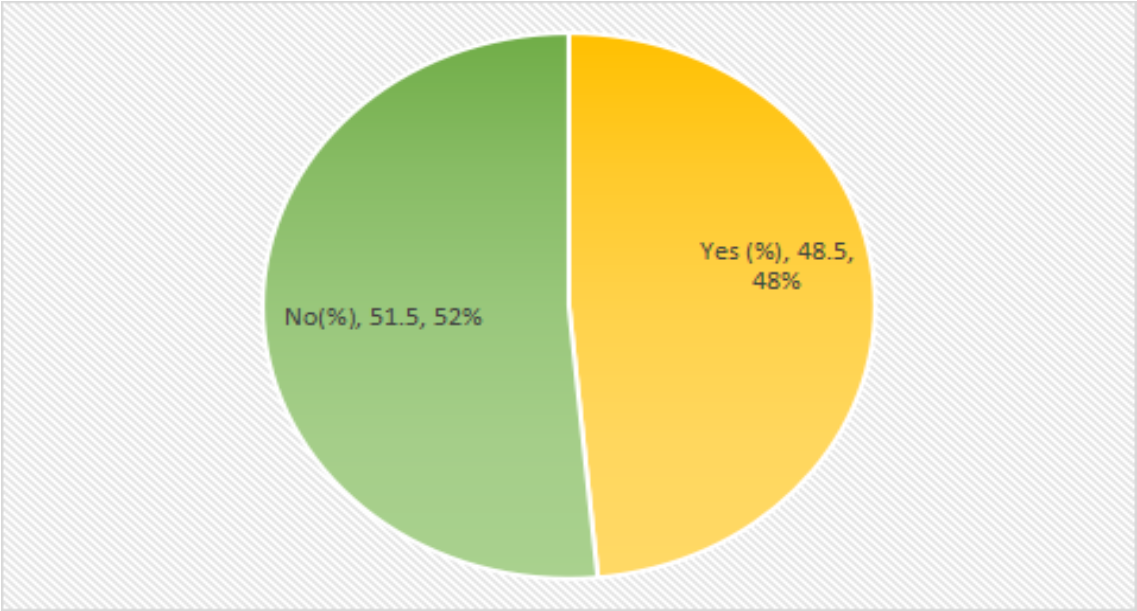


Figure 4. 2: Percent of participants who received training on reporting of adverse drug reactions and those who never received training.

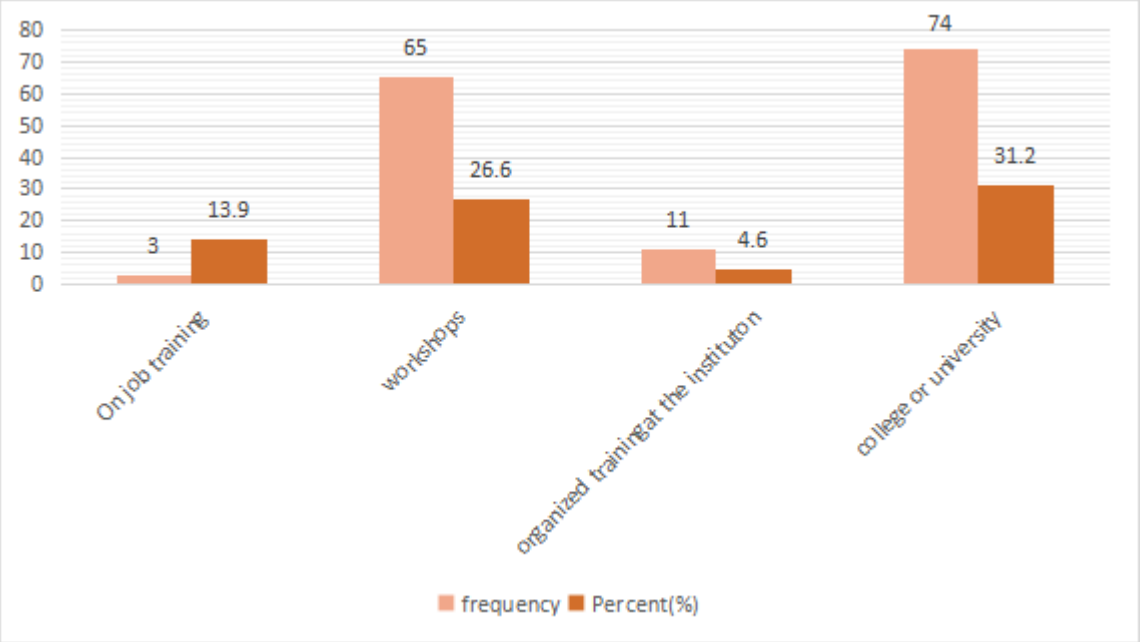


Figure 4. 3: Graph of frequency and percent of participants who received different forms of training on reporting of adverse drug reactions.

Table 4.3: *Frequency and percent of health workers versus training on ADR reporting*

How often do you get trainings on ADR reporting	Frequency	Percent (%)
more than once a year	9	4.1
at least once a year	63	29.0
never	145	66.8

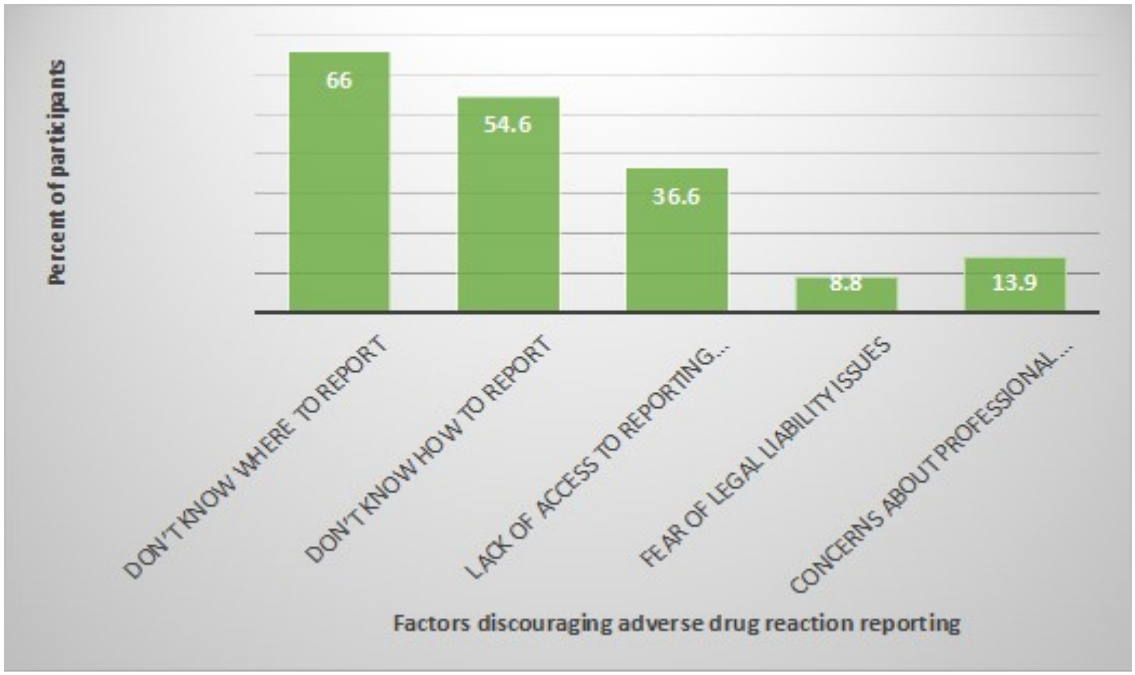


Figure 4.4: Graph of factors that hinder adverse drug reactions reporting by health workers.

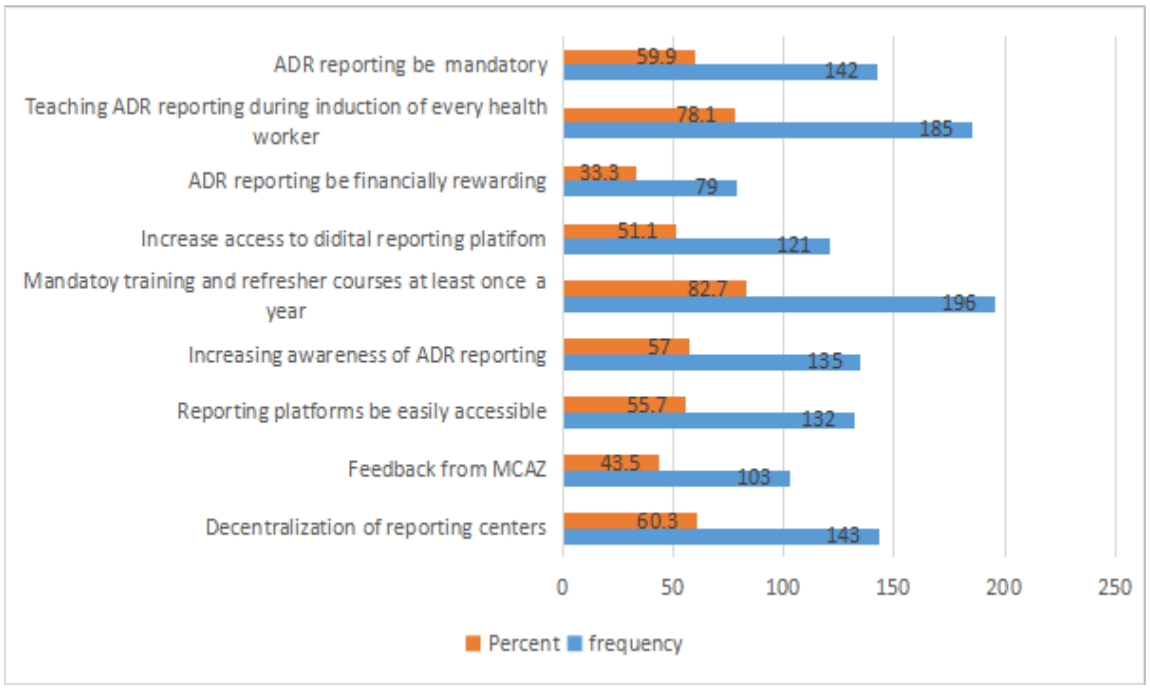


Figure 4.5: Graph of Factors that encourage ADR reporting vs frequency.

Table 4.4: *Participants' preferred methods of reporting ADRs versus frequency*

Reporting method/platform	Frequency	Percent
Physically going to MCAZ	55	23.2
Text messages	80	33.7
Telephone	26	10.9
Email	33	13.9

The paper-based method of reporting is most popular and current, yet only 23% of the participants chose it as a preferred method of reporting with the majority 33% preferring use of text messages to report. On a binary logistic regression there was a significant association between having been trained on adverse drug reaction reporting and reporting, (OR1.8 p-value 0.00). There was no significant association between those frequency of getting training and reporting of adverse drug reaction.

4.3 Association of socio-demographic factors and system factors with reporting of adverse drug reaction reporting by health workers

Participants' socio-demographic characteristics (gender, age, designation and duration of service), system factors like training and knowledge indicators such as awareness of the purpose of ADR reporting, awareness of who should report ADRs, awareness of the existence of pharmacovigilance centers were assessed for their association with ever reporting an ADR in a multi-nominal logistic regression analysis. All socio-demographic characteristics of participants were associated with ever reporting an ADR. Six variables had a statistically significant association with ADR reporting,

these were: knowledge that not all ADRs are known before drug is released (OR 3.4 p-value0.015); years of practice as health worker: 1-10yrs (OR 140.3 p-value 0.00), having been taught how to report ADRs (OR 3.5 p-value 0.014), knowledge of how to report ADRs (OR 2.9 p-value 0.028), awareness of a center were one can report (MCAZ) (OR 0.223 p-value 0.006) and knowledge of who should report (OR 0.1 p-value 0.002).

Table 4.5 : Multi-nominal logistic regression of factors that influence reporting of adverse drug reactions by health workers

Logistic regression

b. Have you ever reported an ADR?	Crude OR	p-value	AOR	95% Cl for Adjusted OR	
				Lower Bound	Upper Bound
Intercept	-3.0	0.274			
[range Years of practicing as health worker in years =1-10]	4.9	0	140.3	21.3	925.2
[range Years of practicing as health worker in years =11 and greater]	0b	.	.	.	.
[doctor]	-2.7	0.344	0.1	0	18.7
[nurse]	0.1	0.973	1.1	0	212.1
[pharmacist or pharm tech]	-1.9	0.537	0.2	0	59.2
[Laboratory scientist or technician]	-0.0	0.998	0.9	0	465.7
[rehabilitation staff]	2.3	0.555	9.5	0	17048.1
[Radiographer or x-ray operator]	0.2	0.955	1.2	0	472.6
[Dentist or therapist]	0b	.	.	.	.
[N7What is an Adverse Drug Reaction ADR =don’t know]	-0.4	0.43	0.7	0.3	1.8
[N7What is an Adverse Drug Reaction =knows]	0b	.	.	.	.

[Who should report ADRs =don't know]		-2.6	0.002	0.1	0	0.4
[Who should report ADRs =knows]	0b	.	.	.	.	
[N10Are the entire Adverse Drug Reactions known before the drug is released i=knows]		1.2	0.015	3.4	1.3	8.9
[N10Are the entire Adverse Drug Reactions known before the drug is released i=don't know]	0b	.	.	.	.	
[Which ADRs must be reported =knows]		0.6	0.183	1.9	0.7	4.9
[Which ADRs must be reported =don't know]	0b	.	.	.	.	
[N12Where you ever taught how to report ADRs =yes]		1.2	0.014	3.5	1.3	9.4
[N12Where you ever taught how to report ADRs =no]	0b	.	.	.	.	
[N14Do you know how to report an ADR =yes]		1.1	0.028	2.9	1.1	7.5
[N14Do you know how to report an ADR =no]	0b	.	.	.	.	
[N16Are you aware of center in Zimbabwe where you can report ADRs =yes]		-1.5	0.006	0.2	0	0.7
[N16Are you aware of center in Zimbabwe where you can report ADRs =no]	0b	.	.	.	.	
[N19How many forms do you complete when reporting an ADR=knows]		0	0.981	1	0.4	2.7

[N19How many forms do you complete when reporting an ADR =don’t know]	0b	.	.	.	.

4.4. Chapter Summary

The findings of this study are consistent with findings of other studies though some factors differ. The differences could be due to the different environments where participants operate in, both systems differences and socio-demographic differences. This study has revealed the general under-reporting of adverse drug reactions by health workers in Mashonaland West province. Most of the participants highlighted that lack of knowledge on the adverse drug reaction reporting surveillance system was the major hindering factor. It is evident that the gap of lack of knowledge can be addressed through training of health workers both in-service and pre-service. Checklist data comparing between the ADRs reported and recorded on the forms versus the T12 and OPD register data, had small differences with some institutions not reporting diagnosed ADRs. There is lack of training on ADR reporting in all the participating institution with none of them having carried out some formal training on ADR reporting in the past 2 years.

CHAPTER 5 SUMMARY, CONCUSION AND RECOMMENDATIONS

5.0 Introduction

This chapter discusses the findings of this study in relation to the available published literature. The researcher gives a summary of the study findings and discussing whether study objectives were met by the study findings while giving any conclusions on the hypothesized phenomena. The researcher gave recommendations to the reporting body MCAZ and provincial and hospital executives on how best to improve ADR reporting in view of the outcomes of the study. Areas for further study were highlighted by the researcher.

5.1. Discussion

5.1.1 Socio-demographic factors of health workers at district hospitals in Mashonaland West Province

Contrary to the findings of the study by Mafundikwa (2017) where 63.6% of the respondents were male, in this study majority of the participants were females 169(71.3%) and 68 (28.7%) were males. This study is in line with global trends towards a female-dominated profession. Another study conducted in South Africa, a neighboring country, had more female than male respondents (Joubert and Naidoo, 2016) these results correspond with the findings of this study.

The mean age was 35 and standard deviation of 9 these findings correspond with the results in a study by Mafundikwa (2017) where mean age of the respondents was 30.1

years, with a narrow range from 25 to 40 years. This study's findings also correspond with the study done in Nairobi where mean age of the participants was 37.3 years with a standard deviation of 8.1 years. The mean duration of practice of the participants was 13.2 years with a standard deviation of 8.1 years.

A study in Nairobi had a response rate of 81.2%, of which the majority (n=210, 73.4%) were female, these findings are consistent with the findings of this study were the response rate was 96%.

In this study 103 (43.5%) of the participants had reported at least an ADR during their service, this is consistent with the findings of a study in Ethiopia on ADR reporting by doctors, where adverse drug reaction reporting was found to be low with only 94(27.4%) of doctors having ever reported ADRs to national pharmacovigilance center Error: Reference source not found. The study findings are also are consistent with the outcome of a study by Error: Reference source not found, to evaluate clinical pharmacists' interventions aimed at improving KAP of healthcare workers about ADRs in a teaching hospital in Iran, were 91.5% of hospital workers where the study was carried out had never reported an ADR and 49% were not aware of the existence of a national PCV center. In another study by Oreagba et al., (2011) it was reported that twenty percent of pharmacists in Nigeria reported ADRs. Though the current study had 43.5% of healthcare workers having reported ADRs there is still needed to improve the reporting rate.

5.1.2 Health worker level of knowledge on reporting of adverse drug reactions

In a study in Iran by Vessel and Mardani (2008), 30% of the pharmacists in Iran were not aware of an ADR reporting program in the country, these findings are consistent with the outcome of this study were 87 (38.5%) of the participants didn't know of existence of MCAZ. In a study by (Khalili et al., 2012), to evaluate clinical pharmacists' interventions aimed at improving KAP of healthcare workers about ADRs in a teaching hospital in Iran, it was reported that 49% were not aware of the existence of a national PCV center, these findings are in consistent with the findings of this study. Another study done in United Arab Emirates found that 81%, 83%, and 83.3% of doctors, community pharmacists, and hospital pharmacists, respectively, were not aware of the existence of a reporting center and 56%, 60%, and 72% were not aware of a reporting procedure these finding are contrary to the current study findings were 38.5% of health care workers did not have knowledge of an existing pharmacovigilance center. There was a significant association between awareness of a center were one can report (MCAZ) (OR 0.223 p-value 0.006) in this study.

A study in Namibia on the public health setting healthcare workers surveyed, 43.1% were nurses, 63.4% of the respondents knew about the ADR reporting system in Namibia, 76.7% knew the pharmacovigilance/ADR reporting center in Namibia, while 37.3% had reported an ADR before, these are consistent to findings of this study were less than 50% of the health workers (38.5%) did not know existence of the pharmacovigilance center in the country.

Regarding system factors that hinder or encourage reporting of ADRs by healthcare workers this study found that only 48.5% of the participants had received some form of training either in-service or pre-service, on how to report ADRs, with 33% having received in service training on ADR reporting at least once and the majority 145 (66%) confirming that they never received any in-service training. These findings correspond with the findings of a study done in Uganda, Mulago National teaching and referral hospital where lack of training was reported as the major deterring factor (56.5%, 126) to reporting. Error: Reference source not found.

In a study on pharmacists in United Kingdom all pharmacists reported that they would report both serious and mild ADRs from drugs with black triangle among children as well as adults. Pharmacists' perception that ADR is not serious enough to report (65.2%; n=90) were identified as barriers to ADR reporting. These findings are similar to the results of this study where 88%,97% of participants confirmed they would report serious and new adverse drug reactions respectively.

Eighty-six (36%) of health workers in this study think the reason why adverse drug reactions must be reported is to improve patient safety. These findings correspond with the findings of a study in Saudi-Arabia which revealed that 50% of the health professionals think that the ADR reporting and monitoring system had benefited patients by identifying safe drug use. Though 46.1% professionals in the study in Saudi Arabia opinioned that ADR reporting will simply identify rate of incidence this study revealed that majority (76%) believe reporting is meant to measure incidence. 54.2% of health professionals considered that the reporting system was to identify ADR within the same pharmaceutical class. 48.4% respondents considered the purpose of the ADR reporting

was to detect potential ADRs, these results are similar to the findings of this current study with 45%(107) of the health workers highlighting that reporting of adverse drug reactions is for identification of new ADRs. The Saudi-Arabia study revealed that 42.9% of respondents thought the system served as a source of information about the characteristics of ADRs whereas 30.6% were not sure,Error: Reference source not found.

A study done in Uganda, Mulago National teaching and referral hospital found that lack of training was reported as the major (56.5%, 126) deterrent to reporting ADRs by healthcare workers. (Katusiime et al., 2015), this is corresponding with the results of this study were 82.7% of health care workers and all (100%) key informants highlighted the need for training to improve ADR reporting.

Another variable that was found to be statistically significantly associated with reporting of ADRs, was being taught on ADR reporting (OR 3.465 p-value-0.014). These findings correspond with results from findings of a study by Lopez-Gonzalez *et al.,* (2015), in Spain were educational interventions were offered while another group did not receive any intervention. The study showed that ADR reporting in the intervention group increased by 65.4% during the period of follow-up.

Some studies (Eniojukan et al., 2015) have shown that healthcare professionals with advanced qualifications tend to report ADRs more than do their colleagues with lower qualifications, or with less familiarity with medicines. Doctors and pharmacists could be expected to report more ADRs than other HCPs, due to a greater understanding pharmacology and of the impact ADRs have on the healthcare system. In a study that was carried out in Northern Cyprus by Toklu et al., (2016) to determine the knowledge,

and attitudes of healthcare professionals in their country towards PCV, doctors and pharmacists in the study claimed to have reported more ADRs than did nurses these findings are contrary to the findings of this study were more nurses reported ADRs compared to doctors and pharmacists and pharmacy technicians.

5.1.3 System factors that influence reporting of adverse drug reactions by health workers

In this study system factors that were reported as barriers to reporting adverse drug reactions were not knowing where to report (66%) and not knowing how to report (54%), these findings are consistent to the findings of the study done in Saudi-Arabia where 55.1 professionals did not know how to report ADR and 62.6% professionals agreed that they did not know the reporting address of ADR,Error: Reference source not found.

Fear of legal liability issues was highlighted as a barrier by the least number of participants (8.8%), these findings are contrary to what the study in Saudi Arabia revealed where 57% of health professionals stated that the lack of ADRs reporting may reflect the fear to report such events,Error: Reference source not found.

This study revealed availability of the resources for adverse drug reaction reporting surveillance system with 6 (85%) of the participating institutions having the ADR reporting booklet and or forms from the checklist findings and supported by the information from the key informants. These findings are contrary to the results from a study in Saudi-Arabia where, 66.8% professionals reported that ADR reporting forms were not available, Error: Reference source not found.

5.2 Conclusion

It can be concluded that healthcare workers at the district hospitals in Mashonaland West lacked training on ADR reporting especially the in-service training and this factor was one of the major deterring factors to ADR reporting. There is also evidence that the participants lack knowledge on ADR reporting surveillance system as evidenced by the low percent (less than 50%) of participants getting the correct responses on most questions on knowledge of the surveillance system. From the records there is very small variances between the numbers of ADRs diagnosed and those reported, however this cannot rule out existence of ADRs that could be misdiagnosed or not being reported due lack of knowledge by both the clients and the health care workers.

5.3 Recommendations

Multi-sectoral interventions are required to overcome the barriers that health care workers encounter in reporting ADRs. There is need for Hospital Executives to organize training on ADR reporting at institutional level. There is also need for all district hospitals to engage MCAZ and carry out workshops to teach health workers on ADR reporting surveillance system.

5.4 Suggestions for future research

The research was done in one Province at district hospitals only and cannot be generalized the whole province.

A bigger study involving all levels of health care would give a more conclusive result for the whole province. There is need for research that includes the clients/patients as well.

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APPENDICES

Appendix 1: Consent Form

My name is Nancy Simbisai Gwekwe. I am studying towards a master's in public health with Africa University, Zimbabwe. You are being invited to consider participating in research on Factors that influence adverse drug reactions reporting by health workers. The purpose of this research is to contribute to the safe use of medicines by strengthening reporting of adverse drug reactions by health workers in Mashonaland West province, by identifying factors that hinder or facilitate their involvement at present. The study is expected to use the quota sampling approach and will be conducted in Mashonaland West. It will involve use of an interviewer administered questionnaire. The duration of your participation if you choose to enroll and remain in the study is expected to be less than 15 minutes. Based on the findings, the study will inform the Health workers and Medicines control Authority where it stands with regards to issues of pharmacovigilance and what needs to be done to improve the current situation. Your participation in this study is entirely voluntary and you can withdraw participation at any point. No penalties or costs will be incurred as a result of withdrawing participation also

no incentives or reimbursements will be given**.** I……..have been informed about the study entitled "Factors influencing Adverse Drug Reactions (ADRs) reporting by health workers. I understand the purpose and procedures of the study I have been given an opportunity to answer questions about the study. I declare that my participation in this study is entirely voluntary.

_____ _____

Signature of Participant **Date**

In the event of any problems or concerns/questions you may contact Africa University Research Ethics Committee on (020)60075/60026 extension 1156 or email aurec@afruicau.edu

Appendix 2: Adverse drug reaction (ADR) reporting questionnaire

Please tick the appropriate responses

Section a: Socio-demographic details

1. Age in years: ----------

2. Gender: Male ☐ Female ☐

(i). Years of practicing as a health worker in years ----------

3. Designation: Doctor ☐ Nurse ☐ Pharmacist ☐ Pharmacy technician ☐

Other, specify……...

3(i). Any formal post-graduate training (e.g. post-graduate diploma, Masters or doctoral qualification)?

Yes ☐ No ☐

If yes, please specify qualification----------

4. Religion (Tick appropriate box). Christianity ☐ African tradition ☐ Muslim ☐

Other, specify……

Section B: Knowledge on ADR reporting

5. What do you understand by an adverse drug reaction?

……

……

……

6**.** Who should report ADRs? (You can tick many)

Doctors ☐ Nurses ☐ Pharmacists ☐ Dentist ☐ clients ☐

Pharmacy technicians' ☐ I don't know ☐

7. Have you ever attended to a patient with an ADR or a suspected ADR? Yes ☐ No ☐

(b) How often do you encounter ADRs? (E.g. once a week)

……

(c). If Yes to 7, did you report it? Yes ☐ No ☐ (c) Where did you report? .....

8. Are the entire Adverse Drug Reactions known before the drug is released into the market? Yes ☐ No ☐

9. What type of Adverse Drug Reaction is necessary to report?

(i) Untreatable ADRs ☐ (ii) Serious ADRs ☐ (iii). New ADRs ☐

(iv). Known ADRs. ☐ (v). All ADRs ☐ (iv) I don't know ☐

10. Where you ever taught how to report an adverse drug reaction? Yes ☐ No ☐

If yes where, and when (year)? …….

11. Do you know how to report an adverse drug reaction? Yes ☐ No ☐

(b). If Yes, How did you gain knowledge of ADR reporting?

(i). From University/College/School ☐ (ii).From Workshops ☐

(iii). On Job Training ☐ (iv). Organized training by Hospital Human resources ☐

(v). Other, Specify……..

12. How often do you get trainings on adverse drug reaction reporting? E.g. Once a month Specify…….....

13. Are you aware of any center or reporting system in Zimbabwe where you can report ADRs?

Yes ☐ No ☐

If yes, please specify----------

14. What platforms are available for reporting ADRs in Zimbabwe? List all you are aware of,

……

……

……

15. Have you ever reported an ADR in the past 12 months?

Yes ☐ No ☐

16. How many forms must you fill in when reporting an adverse drug reaction? .....

17.Where should the completed forms of ADRs be submitted?

(i) MCAZ ☐ (ii) The concerned pharmaceutical company.☐

(iii) Other (please specify) .....

18.Who gets benefit of reporting an ADR? (You can tick more than one option)

(i) Client ☐ (ii) Heath worker ☐ (iii). Everyone ☐ (iv) I don't know☐

(v) Medicines Control Authority of Zimbabwe (MCAZ) ☐

19. On average, how many Adverse Drug Reactions do you encounter per week?

(i) 0-5 ☐ (ii) 6-10 ☐ (iii). more than 10 ☐ (iv) I don't know ☐

20. Are you aware of any drug that has been banned due to ADR?

YES ☐ NO ☐

If yes, name the drug and the ADR it caused

……

……

21. How important do you think it is to report ADRs?

(i)Very Important ☐ (ii). Important ☐ (iii) Not very important ☐

Section C: Factors that could influence ADR reporting.

22**.** What are the reasons why health workers must report ADRs?

(i). For identification and detection of new ADRs ☐

(ii). To improve patients' safety ☐

(iii). To measure the incidence of ADRs ☐

(iv). To share information about ADRs with colleagues in the healthcare division ☐

(v).Other,specify

……..

23. In your opinion, list at least four factors you think hinder health works from reporting ADRs?

(i)

……

……

(ii)

……

……...

(iii)

……

…….

(iv)

……

……..

24. What factors discourage you from reporting ADRS (You may tick more than one)

(i). Do not know how to report ☐ (ii). Do not know where to report ☐

(iii). Do not think it is important ☐ (iv) Lack of access to ADR Reporting forms ☐

(v). Legal liability issues ☐

(vi) Concerns about professional liability ☐ others (please specify) ----------

25. What are the factors that could encourage reporting of ADRs in your own opinion.

(i). ADR reporting in the hospital by healthcare professional should be mandatory ☐

(ii)ADR reporting in the hospital should be taught every health worker during induction. ☐

(iii)ADR reporting in the hospital should be financially rewarded. ☐

(iv). Digital ADR reporting platforms should be easily accessible to everyone. ☐

26. What factors do think will encourage ADR reporting. (You can tick many)

(i). ADR reporting trainings and refresher courses must be mandatory and done frequently (at least once a year) ☐

(ii). ADR reporting awareness to the public and health workers must be increased.☐

(iii). ADR reporting platforms must be accessible to everyone, not internet based e.g. text messages on phone. ☐

(iv). Feedback from MCAZ must be easily accessible ☐

(v). There is need for decentralization of ADR reporting centers.☐

27. Which method would you prefer to send ADR information? (Tick only one)

☐ Direct contact Telephone call ☐ Post ☐ Email/ on website ☐

Other (please specify).....

28. Do you ever get feedback from MCAZ? Yes ☐ No☐

29. Do you regard getting feedback form MCAZ as important? Yes ☐ No☐

30. What do you think could be done at departmental, institutional, District, Provincial and National level to improve ADR reporting by healthcare workers? ..

……

……

……

……

……

……..

THANK YOU FOR YOUR TIME

Appendix 3: Checklist

	response
1.Are the Adverse drug reaction reporting Forms available? (Check physical availability)	YES No
2.Is there a particular person in charge of ensuring that all ADRs at the institution are compiled and reported to MCAZ as soon as possible	Yes No
3.If Yes, Who (designation) e.g. nurse,	

4.How many ADRs have been encountered at the institution for period between January 2020 and October 2020? Check T12 and OPD Register	
5.How many ADRs have been reported for the period under review (January 2020 to October 2020). Check ADR reporting forms booklet and ADR reporting registers	
6.Of those ADRs that were reported how many were submitted to MCAZ	
7.Is there any backup for ADR reporting data records in the event of an incident like fire?	Yes No
8.What form of backup is available	
9.Are there any trainings done on ADR reporting done? (request for training schedule and module, note when last training was done and who in terms of designation attended)	
10.Is there internet connectivity and laptop/desk top or smart phone to report ADRs via the online platform. (check for physical availability)	Yes No

Appendix 4: Key informants questionnaire on Adverse Drug Reaction

Please tick the appropriate responses

Section A: Socio-demographic details

1. Age in years: ----------

2. Gender: Male ☐ Female ☐

(i). Years of practicing as a health worker in years ----------

3. Designation: Doctor ☐ Nurse ☐ Pharmacist ☐ Pharmacy technician ☐

Other, specify……...

3(i). Any formal post-graduate training (e.g. post-graduate diploma, Masters or doctoral qualification)?

Yes ☐ No ☐

If yes, please specify qualification----------

4. Religion (Tick appropriate box). Christianity ☐ African tradition ☐ Muslim ☐

Other, specify……

Section B: Knowledge on ADR reporting

5. What do you understand by an adverse drug reaction?

……

……

……

6**.** Who should report ADRs? (You can tick many)

Doctors ☐ Nurses ☐ Pharmacists ☐ Dentist ☐ clients ☐

Pharmacy technicians' ☐ I don't know ☐

7 What type of Adverse Drug Reaction is necessary to report?

(i) Untreatable ADRs ☐ (ii) Serious ADRs ☐ (iii). New ADRs ☐

(iv). Known ADRs. ☐ (v). All ADRs ☐ (iv) I don't know ☐

Section C: Factors that influence ADR reporting

8. Are the health workers at this institution trained on Adverse drug reactions reporting?

Yes ☐ No ☐

(i). If yes, what form of training on Adverse Drug Reactions reporting are the health care workers offered? (i) Institutional organized training by Human Resources ☐

(ii). Workshops ☐ (iii) On Job training ☐ (iv) I don't know ☐

How often are workers trained on adverse drug reaction reporting, e.g. once a week……..

9. Are there any meetings held where ADRs at institutional level are discussed?

Yes ☐ No ☐

10. Who has the overall responsibility of compiling and submitting all ADRs at this institution to Medicines Control Authority of Zimbabwe (MCAZ)…….

11. Have you ever received feedback on ADRs from MCAZ? Yes ☐ No ☐

If Yes, has the feedback been conveyed to all healthcare workers, and how?.....

12. Are the resources required for ADR reporting always available and accessible to health care workers? (Tick the appropriate sections)

Resource	Always available	Sometimes available	Never available	Current availability

				status
ADR reporting forms (booklet)				
Pens				
Internet connectivity				
Computer or Smart phone/ tablet				
Internet bundle				

13. What mechanisms could be put in place to encourage healthcare workers report ADRs?

(i)

…….

(ii)

…….

(iii)

…….

14. From your experience and opinion what factors hinder the ADR reporting by healthcare workers?(write as many as you

can) .....

.....

.....

.....

15. From your experience and opinion what factors could facilitate the ADR reporting by healthcare workers? (write as many as you can). .

……

……

……

THANK YOU

Appendix 5: Provincial Medical Director's approval letter

MINISTRY OF HEALTH AND CHILD CAR
PROVINCIAL MEDICAL DIRECTOR
(Mashonaland West Province)
P.O Box 139
Chinhoyi
Zimbabwe

7 December 2020

The Provincial Medical Director
Mashonaland West Province

Dear sir

RE: **REQUEST FOR PERMISSION TO CARRYOUT STUDY ON FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING BY HEALTHCARE WORKERS AT ALL DISTRICT HOSPITALS IN MASHONALAND WEST PROVINCE.**

I am Ms Nancy Gwekwe a Master of public health student. I hereby submit my application for permission to conduct a study on Factors influencing adverse drug reaction reporting by health workers at all District Hospitals in Mashonaland West Province , as part of my studies in Master of Public Health Degree with Africa University during the period October 2020 to December 2021.

My conduct details are: email- gwekwen@africau.edu, phone number- 0787717717

Your favorable response will be greatly appreciated.

Yours faithfully

Ms Nancy Gwekwe

Appendix 6: Banket Hospital approval letter

067214-2321/2
067214-3328

ZIMBABWE

Reference:

Ministry of Health and Child Welfare
Banket District Hospital
P O Box 28
BANKET

15 October 2020

Ministry of Health and Child Care
PROVINCIAL MEDICAL DIRECTOR
P.O Box 139
Chinhoyi
ZIMBABWE

REQUEST FOR PERMISSION TO CARRY OUT A STUDY ON FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING BY HEALTH CARE WORKERS AT BANKET DISTRICT HOSPITAL

This serves to confirm that, you have been granted permission to carry out a study at Banket hospital on factors influencing Adverse Drug Reaction reporting by Health Care workers at Banket hospital.

Thank you

T. Dandadzi
DISTRICT MEDICAL OFFICER-Zvimba

Appendix 7: Chegutu Hospital approval letter

MINISTRY OF HEALTH AND CHILD CARE
PROVINCIAL MEDICAL DIRECTOR
(Mashonaland West Province)
P.O Box 139
Chinhoyi
Zimbabwe

6 October 2020

The District Medical Officer
Chegutu Hospital
Mashonaland West Province

Dear sir

RE: **REQUEST FOR PERMISSION TO CARRYOUT STUDY ON FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING BY HEALTHCARE WORKERS AT CHEGUTU DISTRICT HOSPITAL IN MASHONALAND WEST PROVINCE.**

I am Ms Nancy Gwekwe a Master of public health student. I hereby submit my application for permission to conduct a study on Factors influencing adverse drug reaction reporting by health workers at Chegutu District Hospital , as part of my studies in Master of Public Health Degree with Africa University during the period October 2020 to November 2021.

My conduct details are: email- gwekwen@africau.edu, phone number- 0787717717

Your favorable response will be greatly appreciated.

Yours faithfully

Ms Nancy Gwekwe

To: All departments.

Kindly assist Ms Gwekwe

MINISTRY OF HEALTH & CHILD CARE
CHEGUTU DISTRICT HOSPITAL
DISTRICT MEDICAL OFFICER
14 DEC 2020
P.O. BOX 340, CHEGUTU
ZIMBABWE

Appendix 8: Kadoma Hospital approval letter

Telephone: +263-68-22066
All correspondences to be addressed to the Medical Superintendent
Fax: +263-68-22073
E-mail: kadomahospital@gmail.com

ZIMBABWE

Reference:

Ministry of Health and Child Care
Kadoma General Hospital
P O Box 540
KADOMA

17 December 2020

Nancy Gwekwe
PMD Mash West
P.O. Box 139
CHINHOYI

ETHICS APPROVAL FOR RESEARCH AT KADOMA GENERAL HOSPITAL

The above matter refers.

I do hereby write to inform you that the Ethics Review Committee approved for you to carry a study titled **"factors influencing adverse drug reaction reporting by health care workers at Kadoma General Hospital in Mashonaland West Province"**

Kindly furnish the instructor with a final copy of your write up.

Yours Sincerely

MEDICAL SUPERINTENDENT
KADOMA GENERAL HOSPITAL
17 DEC 2020
P.O. BOX 540, KADOMA
ZIMBABWE

Dr K. L. Masendeke
Chairperson – Kadoma General Hospital Ethics Review Committee

Appendix 9: Karoi Hospital approval letter

MINISTRY OF HEALTH AND CHILD CARE
PROVINCIAL MEDICAL DIRECTOR
(Mashonaland West Province)
P.O Box 139
Chinhoyi
Zimbabwe

6 October 2020

The District Medical Officer
Karoi Hospital
Mashonaland West Province

Dear sir

RE: **REQUEST FOR PERMISSION TO CARRYOUT STUDY ON FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING BY HEALTHCARE WORKERS AT KAROI DISTRICT HOSPITAL IN MASHONALAND WEST PROVINCE.**

I am Ms Nancy Gwekwe a Master of public health student. I hereby submit my application for permission to conduct a study on Factors influencing adverse drug reaction reporting by health workers at Karoi District Hospital as part of my studies in Master of Public Health Degree with Africa University during the period October 2020 to November 2021.

My conduct details are: email- gwekwen@africau.edu, phone number- 0787717717

Your favorable response will be greatly appreciated.

Yours faithfully

MIN. OF HEALTH AND CHILD CARE
KAROI DISTRICT HOSPITAL
DISTRICT MEDICAL OFFICER
10 DEC 2020
P.O BOX 67, KAROI
ZIMBABWE

Ms Nancy Gwekwe

Approved
DR F Mashe
MEDICAL (W2)