DETERMINANTS OF ADVERSE DRUG REACTIONS REPORTING IN RETAIL CHEMISTS IN NAIROBI COUNTY, KENYA

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DECLARATION

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DEDICATION

I dedicate this thesis to my parents, my pillars of love and wisdom. Your pride in me means everything. To my siblings, Wawi, Mwani and Mutha, my oldest friends and my first role models. To my husband George, my best friend and greatest cheerleader. To my girlfriends that I have met at various stages of my life; you constantly challenge me, bring out the best in me and most of all you celebrate me. Last and definitely not least, I dedicate this thesis to Wacu, my heartbeat and the greatest love of my life, you make me want to reach for the stars.

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ABSTRACT

Access to safe essential medicines is a key success indicator of a functional health system of which the private sector such as retail chemists plays a critical role. Despite their obvious benefits, medicines have the potential to cause harm in form of Adverse Drug Reactions that may not be determined in the drug development process. Reporting of Adverse Drug Reactions leads to regulatory action that improve the safety profiles of medicines. However, reporting of adverse drug reactions has not been extensively reviewed in retail chemists. The purpose of this study was to assess the factors that affect reporting of Adverse Drug Reactions in retail chemists. The objectives of this study were to determine the role played by the regulatory body, The Pharmacy and Poisons Board, in reporting Adverse Drug Reactions in the retail chemists; establish the operationalization of pharmacovigilance implementation strategies on Adverse Drug Reactions reporting in the retail chemists; determine the effect of the retail chemist personnel capacity on Adverse Drug Reactions and establish the effect of underlying motivation factors of the personnel on reporting of Adverse Drug Reactions. The research adopted a descriptive cross-sectional study design using structured questionnaires for the staff in the retail chemists and interview schedules. Nairobi County was selected as the study area due to its high concentration of retail chemists. The target population was the personnel in 895 registered chemists according the Pharmacy and Poisons Board database. Using the Yamane sample size calculation formula a study sample size of 276 respondents was elicited as one personnel was considered adequate for each retail chemist which were sampled purposively. The study also targeted key informants at the Department of Medicine Information and Pharmacovigilance at the Pharmacy and Poisons Board. The data collection tools used were the Retail Chemist Personnel Questionnaire and the Key Informant Interview Guide. The data were analyzed using Statistical Package for Social Scientists Version 23. Results shows that there was a positive relationship between the Regulatory body, Pharmacy and Poisons Board factors ($r=0.275$, $p<0.001$), Pharmacovigilance implementation strategies in the retail chemists ($r=0.374$, $p<0.001$), Retail chemist personnel capacity ($r=0.466$, $p<0.001$), Underlying motivation factors ($r=0.466$, $p<0.001$) and Adverse Drug Reactions reporting. Multiple regression analysis showed that in a combined relationship, Pharmacovigilance implementation strategies ($P<0.05$), retail chemist personnel capacity ($P<0.05$) and underlying motivation factors ($P<0.05$), all had a significant influence on adverse drug reporting among Chemist in Nairobi County. In conclusion therefore, this study established that the Pharmacy and Poisons Board did not influence reporting of adverse drug reactions in retail chemists, pharmacovigilance implementation strategies were not fully operationalized to facilitate reporting of adverse drug reactions, retail chemist personnel did not have adequate capacity and knowledge to optimally report adverse drug reactions and while their underlying motivation factors influenced reporting of adverse drug reactions, they were not adequately motivated to report. This study therefore recommends that there should be improved engagement between Pharmacy and Poisons Board and the retail chemists on pharmacovigilance, continuous in-service pharmacovigilance training for retail chemist personnel, review of the adaptability of the implementation strategies in place and provision of consistent feedback on reported adverse drug reaction by pharmacy and poisons board as a strategy to motivate retail chemist personnel to report adverse drug reactions.

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ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reactions
EU	European Union
FIP	International Federation of Pharmacists
ICSR	Individual Case Safety Report
MIPV	Medicines Information and Pharmacovigilance department
MSH	Management Sciences for Health
NDA	National Drug Authority
NMRA	National Medicines Regulatory Authority
NPC	National Pharmacovigilance Centre
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
SOP	Standard Operating Procedure
SPSS	Statistical Package for the Social Sciences
UMC	Uppsala Monitoring Centre
USD	US Dollar
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

According to the World Health Organization (World Health Organization [WHO], 2000) a health system is defined as all the activities whose primary purpose is to promote, restore or maintain health. A health system has six main inter-related pillars which are governance, healthcare financing, service delivery, human resources for health, medical products, vaccines and health technologies and health management information system. This study is embedded in the pillar of medical products and health technologies of which medicines form the main intervention for many health problems due to their ability to treat and prevent diseases. The study lays emphasis on the health system support on mitigating risks related to medicines use. The United States Agency for International Development (USAID) requires that in addition to proper service delivery, health workers should monitoring of the quality of health products through pharmacovigilance (United States Agency for International Development [USAID], 2011).

Despite their obvious benefits, all medicines are chemical in nature and therefore have an intrinsic risk of causing harm to the patient in the form of expected side-effects or unexpected side-effects referred to as Adverse Drug Reactions (ADRs). An ADR has been defined as a noxious and unintended reaction that may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure (Europeans Medicines Agency, 2012). Despite the fact that the safety profile of new medicines is assessed during clinical trials, the process is limited in its scope of population exposure, duration and perspective (Nkwokike & Kwesi, 2010). ADR monitoring is the mainstay of a larger discipline referred to as pharmacovigilance which has been defined by the WHO as the

science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO, 2006).

The first systemic international efforts at monitoring drug safety came about as a result of the Thalidomide disaster in 1961. The drug, Thalidomide, was linked to many congenitally deformed infants as a result of in utero exposure in its use against morning sickness in pregnancy (WHO, 2002). This led to the development of the WHO programme for international drug monitoring now coordinated by the Uppsala Monitoring Centre (UMC) with oversight by an international board. The programme has since expanded to include almost 200 member states whereby national pharmacovigilance systems have been established. UMC utilises an internet web-based database called Vigiflow where ADR reports from the National Pharmacovigilance Centres (NPC) of the member states are collated and analysed to inform regulatory action on medicines (Uppsala Monitoring Centre, 2013). Spontaneous reporting of suspected ADRs by health care professionals to a national pharmacovigilance system remains the mainstay of detecting unsafe medicines; however, underreporting remains a major drawback (Mirbaha et al., 2015).

Developed countries have made great effort towards monitoring medicine safety. This is evidenced by the European Union (EU) which has robust pharmacovigilance system based on strict policy and regulations. The EU utilizes an internet-based database called EudraVigilance which is the cornerstone of European pharmacovigilance and is the principle database of ADR reports from which new or changing safety issues can be detected (Europeans Medicines Agency, 2012). On the flipside, ADR reporting remains low in many of the Asian countries. India has had a formal ADR reporting system established in 1986. However, a survey funded by World Bank revealed that no reporting of ADRs or related

analysis had been done decade preceding the study reported for a period of over ten years and data collected were not analyzed for action (Maigetter et al., 2015).

WHO estimates that Africa bears 90 per cent of the global disease burden and suffers the highest risk of exposure to poor quality medicines and counterfeits due to poor regulatory systems (WHO, 2010). Despite this, pharmacovigilance in the developing countries is considered weak more so in Africa whereby it is seen more as a luxury activity rather than a key health system activity (Strengthening Pharmaceutical Systems [SPS] Program., 2011). African countries are however making strides towards improving medicine safety in the region. Pharmacovigilance activities in Uganda are coordinated by the National Drug Authority (NDA) in collaboration with the ministry of health. Despite Uganda being identified as one of the best performing pharmacovigilance systems in sub-Saharan Africa, the reporting rate has remained low at six ADR reports per million population per year against an estimated population of 30.6 million (Maigetter et al., 2015)Consistent with findings from other sub-Saharan, the low reporting rates were attributed to financial constraints and lack of knowledge of pharmacovigilance systems amongst the healthcare professionals (SPS Program, 2011).

In Kenya, the national pharmacovigilance system was officially launched in June 2009 and the department has since evolved to a centre of excellence in the region. The department of pharmacovigilance has been active in training and sensitizing healthcare workers on pharmacovigilance and as a result, there has been a general upward trend in the number of reports submitted since the inception of the department in 2010. Fifteen ADR reports per million population was submitted in 2010 (Pharmacy and Poisons Board [PPB], 2014). This was against an estimated population of 40 million people (Kenya National Bureau of

Statistics [KNBS], 2009). However, the reports were mainly from hospital settings thus indicating that there was still a gap in detection and collection of data on ADRs from the retail chemists despite its significant contribution to the health system. Due to weak regulatory and supervisory systems, the retail chemists also bear the greater burden of counterfeit products which have an added risk of unprecedented risk of ADRs (WHO, 2008). The national pharmacovigilance guidelines were issued in 2009 and are conspicuously ambiguous on the ADR reporting channels for the retail chemists (PPB, 2009). A comprehensive pharmacovigilance policy was also lacking and instead medicine safety was only implied in the national pharmaceutical policy (Ministry of Medical Services & Ministry of Public Health and Sanitation., 2010).

Nairobi County is home to the capital city of the Republic of Kenya, Nairobi City, which has an estimated population of 4 million people (KNBS, 2009). In the biannual pharmacovigilance newsletter issued by PPB in November 2013, Nairobi was reported to be the leading county in ADR reporting in the period between 2010 –2014 having submitted 13 per cent of all the ADR reports. Out of this, the identified contributing institutions were the major hospitals in the county. The report did not indicate whether any of the reports were from retail chemists despite their high concentration in the county (PPB , 2014). More recently, the quarterly report issued for the fourth quarter of the year 2019 had a similar trend whereby mostly the public county hospitals were ientified and a big portion of the reports was stated to be from “other” sources (Ministry of Health, 2019). Past newsletters indicate that numerous trainings and pharmacovigilance activities have taken place in the county but without specific reference to the retail chemists.

Pharmacovigilance involves monitoring patterns of ADRs, presence of counterfeits and occurrence of medication errors and analyzing this data to inform corrective and preventive regulatory actions. The scope of this study is limited to the monitoring of ADRs. Despite the studies carried out on many drugs in developed countries, their safety profile may not necessarily be applicable to the developing countries such as Kenya. This is due to differing genetic variations across geographical zones (Pirmohamed et al., 2007). Currently, there are approximately over ten thousand medicines registered in the Kenyan market (United Nations Industrial Development Organization [UNIDO], 2010). As the quantity and variety of medicines continues to grow, so does the need for increased medicine safety surveillance. The International Federation of Pharmacists (FIP) recognizes that a healthcare system that incorporates pharmacovigilance in its structure protects the lives of the public by reducing the occurrence of ADRs and subsequent deaths by providing a system through which healthcare stakeholders are able to get information to make timely remedial actions in the event of ADRs (International Federation of Pharmacists [FIP], 2006).

1.2 Statement of the Problem

According to a survey carried out by the government, Kenya has had chronic drug stock outs in the public hospitals (Ministry of Medical Services, 2010). Inhibitive consultation costs charged by clinicians often force the public to buy prescription medicines directly from the retail chemists through a practice commonly referred to as self-medication (Mulunda , 2012). As a result of this growing demand, retail chemists have over the years evolved to jointly form the largest component of pharmaceutical supplies in Kenya in terms of quantity and variety. Numerous media reports have repeatedly raised concern over the professionalism of the personnel working in these retail chemists with many claims of unethical practices fueled by commercial gain. One particular article notes that the sheer number of untrained and unregulated medicines dispensers is troubling (Omete, 2016)). This further exposes the public

to adverse drug reactions due to medication errors or lack of counselling on proper medicine use. Another factor that predisposes to ADRs is the concomitant use of conventional medicines with herbal medications. WHO estimates that 80 per cent of people in Africa have used traditional medicines at some point in their lives, to meet their health care needs (SPS Program., 2011). In spite of this obvious need for active monitoring of medicine safety in the retail chemists, the focus of the pharmacovigilance activities in the country has remained in the public hospitals. The related studies carried out on the area have solely been focused on knowledge and attitudes of healthcare workers in hospital settings. There are no published studies or official reports on the status of pharmacovigilance activities in retail chemists in Nairobi and the factors contributing to this have not been identified.

1.3 Purpose of the Study

The purpose of the study was to assess the factors that affect the implementation of adverse drug reactions reporting in Nairobi County.

1.4 Objectives of the Study

i. To establish the influence that the regulatory body, the Pharmacy and Poisons Board, has on Adverse Drug Reactions reporting in the registered retail chemists in Nairobi County.

ii. To determine the influence of pharmacovigilance implementation strategies on Adverse Drug Reactions reporting in registered retail chemists in Nairobi County.

iii. To determine the influence of retail chemist personnel capacity on Adverse Drug Reactions reporting in registered retail chemists in Nairobi County.

iv. To determine the influence that underlying motivation factors have on Adverse Drug Reactions reporting in registered retail chemists in Nairobi County.

1.5 Research Questions

i. How does the Pharmacy and Poisons Board influence Adverse Drug Reactions reporting in the registered retail chemists in Nairobi County?

ii. To what extent do pharmacovigilance implementation strategies influence Adverse Drug Reactions reporting in the registered retail chemists in Nairobi County?

iii. How does retail chemist personnel capacity influence Adverse Drug Reactions reporting in the registered retail chemists in Nairobi County?

iv. How do underlying motivation factors influence Adverse Drug Reactions reporting in registered retail chemists in Nairobi County?

1.6 Justification of the Study

Lack of resources to monitor safety and quality of medicines, the lack of trained health workers and inadequate regulatory systems in Kenya are factors likely to contribute to significant medicines-related harm. The ministry of health recognizes that the actual financial and economic burden as a result of ADRs remains unknown but could be high if the data from the developed countries is anything to go by (Ministry of Medical Services., 2010). With the growing concerns of counterfeit medicines and increasing cases of unethical practices in retail chemists in the country, this study highlights the gaps in monitoring drug safety in the retail chemists.

1.7 Limitations of the Study

The research depended on information voluntarily given by the personnel in the retail chemists and at the Pharmacy and Poisons Board therefore the answers may have been subjective based on the attitudes of the individuals towards the research. It was also not possible to verify the professional qualifications of the respondents as well as the registration validity of the premises due to lack of the legal mandate to do so. Pharmacovigilance in general is not well established in the sense that it has only recently started being taught in

pre-service training. The study was carried out only in Nairobi County which is of an urban setting therefore generalizations drawn from the study can only be done with caution.

1.8 Delimitations of the Study

Despite the fact that pharmacovigilance is a wide science covering medication errors, ADRs, Adverse Drug Events, counterfeits and poor quality medicines, the study was limited to the detection and reporting of ADRs. The study did not involve researching the knowledge and attitudes of the patients who are the consumers of medicines at the retail chemists and as such the main stakeholders of any system that monitors medicine safety. The study was cross-sectional in design therefore it only captured the prevailing knowledge, attitudes and other prevailing conditions at the time of the study. The research targeted the personnel who were carrying out dispensing of medicines at the time of data collection in the sampled retail chemists in Nairobi County.

1.9 Significance of the Study

The findings of this study are significant to various stakeholders of pharmacovigilance in the Kenyan health system.

1.9.1 Significance to Policy Makers

Findings from this study will act as a point of reference for policy makers on monitoring medicine safety specifically in retail chemists. This will enhance strengthening of the pharmaceutical management especially on matters regulatory and monitoring of drug safety. The policy maker in this case is the national medicines regulatory body, the Pharmacy and Poisons Board.

1.9.2 Significance to Retail Chemists

The study findings will inform best practices which can be adopted to enhance reporting of ADRs in retail chemists.

1.9.3. Significance to Academicians

The results of this study form a basis for further research. The findings of the study will also provide literature on factors specific to Nairobi County in ADR reporting but which can be utilized as background information by researchers wishing to explore this area further.

1.10 Assumptions of the Study

All personnel that dispense medicines have the same professional obligation to report ADRs regardless of their academic qualifications, that is, pharmacists, pharmaceutical technologists and any other cadres that may be present in the retail chemists. The population characteristics under study will remain constant in the period of undertaking data collection and after so that the results of the analysis of that data will be an accurate depiction of the population under study.

1.11 Operational Definition of Terms

Adverse Drug Reaction	An adverse drug reaction is a response to a drug which is noxious and unintended and which may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure.
Community Pharmacy / Retail Chemist:	An independent privately-owned pharmacy that is licensed to dispense medications at recommended prices by a registered pharmacist or pharmaceutical technologist.
Counterfeit medicine:	A medicine that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeit products include products with correct ingredients or wrong ingredients, lacking active ingredients, with incorrect quantities of active ingredients, or fake packaging.
Drug/medicine:	A fully formulated and registered pharmaceutical product that comprises of the dosage form presentation, packaging, and the accompanying information. For the purpose of this research proposal, the terms are used interchangeably.
Generic drug:	A pharmaceutical product that is manufactured and marketed after the expiry date of the patent or other exclusive rights of the innovator company.
Innovator /branded/novel drug:	The pioneer product that has undergone and passed the rigorous tests and evaluations involved in developing the drug product which is then marketed for specified time under the patent laws.
Market Authorisation Holder:	A company responsible for compliance of the regulatory and quality aspects of a pharmaceutical product as required by a national medicines regulatory authority.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter gives comprehensive background information on the various strategies of implementing pharmacovigilance activities by the competent national drug regulatory bodies. It also reviews some of the systemic and personnel related factors that affect the implementation of pharmacovigilance activities with focus being on retail chemists. The literature review takes an in-depth analysis of the current situation on pharmacovigilance globally, regionally (sub-Saharan Africa) as well as within Kenya.

In 2006, WHO highlighted the global shortage of healthcare personnel hampering attainment of minimum health service delivery (WHO, 2006). In 2016, the WHO Health Assembly ratified the 'Global Human Resources for Health Strategy' which amongst other strategies recognized the key role played by mid-level cadres in meeting human resources requirements. Technicians and other pharmacy support workforce cadres were recognized as a key component of the mid-level cadres. However, their roles and responsibilities vary in different countries (Koehler & Brown, 2017). This section therefore focuses in detail on factors that affect healthcare personnel.

2.2 The Role of the Regulatory Body (Pharmacy and Poisons Board)

This section reviews the factors that are directly linked to the operations of the PPB as well as other regulatory bodies in their bid to enhance medicine safety in retail chemists at global, regional and country level.

2.2.1 Funding of the Regulatory Body in Implementing Pharmacovigilance Strategies

Funding in the health sector is required for the purchase and implementation of healthcare interventions. Without funds to support service delivery, eventual service delivery will be

inadequate regardless of available skillset and knowledge. Lack of funds in turn means lack of complementary resources and inputs which negatively impacts motivation of the personnel (WHO, 2000). Availability of funding for pharmacovigilance refers to the existence of a committed budgetary allocation hence ensuring consistent, predictable and available resources for the PV activities (Abwao & Ouma, 2012). Financing for PV is done at national level, regional level and at the facility level. Funding is required in PV for both recurrent expenditure, such as salaries, travel, training and workshops, and capital expenditure, such as infrastructure and equipment (Lalvani, 2012).

Globally, health is a USD 3.5 trillion industry, or equal to 8% of the world's Gross Domestic Product. The countries in the African region spend on average 5.7% of their gross domestic product on health, a figure that has not changed much since 1995, which can be compared with the average of 8.2% for all countries worldwide (WHO, 2005). In April 2001, the African heads of state met in Abuja, Nigeria and pledged that their governments would allocate at least 15% of the national budget to health care financing. However, by 2011, only Tanzania had achieved the Abuja declaration of at least 15% (WHO, 2010). Despite the commitment by the Kenyan government to adhere to the Abuja Declaration, the government health care expenditure has dropped from 8.6 % in the financial year 2001/2002 to 4.6% in the financial year 2009/2010. This figure stagnated at 4.5 per cent in the next two years (Institute of Economic Affairs., 2015). In the fiscal year 2015/2016 the budgetary allocation went down to 3.9 % and were postulated to go down to 3.6% in 2016/2017 national budget (Lakani & Kinuthia, 2016).

Based on the above trend of healthcare financing, it is expected that funding for PV is insufficient in developing countries. (Lalvani, 2012) indicates that developing countries

spend an average of USD 40-100,000 on PV compared to developed countries such as the United States which spends over USD 100 million annually on PV activities. Funding a pharmacovigilance system will usually come second to other competing priorities in the health system(Olsson et al., 2010). From a survey carried out by SPS Program in 46 sub-Saharan Africa, at least 34 countries had a PV centre usually affiliated with the Ministry of Health or the respective National Medicines Regulatory Authority (NMRA). Majority of the reviewed PV centres generally had funding available from government and donor organizations. Out of these, several PV centres were departments of the Ministry of Health with minimal budgetary and financial autonomy from the ministry. Additionally, not all the PV centres had dedicated earmarked budgets for pharmacovigilance activities (SPS Program, 2011).

In Kenya, one of the challenges facing the Kenyan Pharmacovigilance Centre include lack of funds for PV activities (Barry et al., 2020). At the inception of the department in 2007 the requested budget for 2007 was 7.5 million Kenyan Shillings or approximately USD 112,500, although it was not indicated what percentage of this amount was granted. There were several external organizations that planned on funding pharmacovigilance in Kenya, although exact amounts were not available at the time; examples include WHO, Gates Foundation, Health Action International/Africa and World Bank (Barry et al., 2020).

Lack of sufficient funding for pharmacovigilance implies that patient safety activities in a country are not considered a priority. Funding is particularly scarce in countries with young pharmacovigilance systems. A report by SPS Program (2009) recommended that governments should consider reviewing resource allocation for regulatory activities and identify an evidence-based approach for providing adequate resources for monitoring

medicine safety. They also recommend that governments should explore new sources of funding including donor funding, user fees, and percentage of sales turnover to support pharmacovigilance initiatives such as improving ADR reporting in retail chemists. Experts propose that donors should shift focus from availing funds for pharmacovigilance in developing countries and instead create an enabling environment that will build the capacity of the national systems to allow resource mobilization in a sustainable manner (Olsson et al., 2010).

Capacity when used to define an institution refers to availability of committed resources, that is, human resources, required equipment, infrastructure and a clear mandate supported by policy and legislation (SPS Program, 2011). Capacity is determined by the availability of funds to procure the necessary resources. An important component of a country's ability to monitor medicine safety is a national pharmacovigilance system that is supported by the National Medicines Regulatory Authority (NMRA) of the country (Management Sciences for Health [MSH], 2012). A national pharmacovigilance system can be incorporated as a unit in a National Pharmacovigilance Centre (NPC), in a tertiary or research oriented hospital. In the traditional model, the NPC is centralised and consists of one national centre collecting ADR reports from healthcare professionals from all over the country (Maigetter et al., 2015). However, many countries are now moving towards a more decentralised system with a national centre functioning as a focal point for regional or facility based centres (SPS Program, 2009).

A national pharmacovigilance centre should have the capacity to undertake the full scope of pharmacovigilance actvities that encompasses both passive and active surveillance of ADRs. The passive approach involves spontaneous reporting by healthcare proffessionals and

patients while the active approach involves focused and structured activity seacrhing for ADRs in an identified cohort of patients exposed to similar medicine of interest (MSH, 2012). A centralized database for collating and managing ADR reports is a minimum requirement for an NPC as per the WHO standards (Global Fund & WHO, 2010). At the international level, UMC maintains a web based ADR reporting database known as Vigiflow for use by the NPCs from the member states. Developed countries have similar systems such as the Eudravigilance in the EU which has a similar capcity for data collation and analysis (European Commission, 2011).

The national centres vary in their size, resources, support structure and scope of activities. Predictably, the high income countries are more likely to have functional pharmacovigilance centres that are members of the WHO /UMC program (Olsson et al., 2010). The main reasons for this have been cited as lack of resources, infrastructure, and expertise. A survey carried out by SPS, a non-governmental organisation that supports pharmaceutical supply chains, indicated that out of 46 sub-Saharan African countries surveyed, only 33 were official or associate members of the WHO program for international drug monitoring. The report emphasized that membership did not guarantee that the country has a functional pharmacovigilance system in place (SPS Program, 2011).

In the survey by SPS, Uganda was recognised as one of the few countries in sub-Saharan Africa with performing PV systems that have basic structures capable of performing both passive and active surveillance and to some extent evaluate recognized risks and take relevant regulatory actions. The report from the survey emphasized that this scenario was not a depiction of an ideal pharmacovigilance national system (SPS Program, 2011). This is in line

with the findings of a more recent study in Uganda which revealed a low ADR reporting rate across the country (Kiguba et al., 2014).

The Pharmacovigilance department in Kenya was established in 2004 and the National pharmacovigilance system was officially launched in June 2009 together with related guidelines, training materials and reporting tools (Arale, 2013). The department has continued to grow in terms of capacity and dedicated staff and has evolved to be known as the Directorate of Medicine Information and Pharmacovigilance (MIPV). In addition, the Management Sciences for Health/ Health Commodities and Services Management (MSH/HCSM) Program has been supporting PPB to implement a national country-led Pharmacovigilance system (PPB, 2014).

2.2.2 Information Sharing Mechanisms of the Regulatory Body in Implementing Pharmacovigilance Strategies

Of the minimum requirements for a national pharmacovigilance system stipulated by WHO, a clear communication strategy and crises communication plan is key (Global Fund & WHO, 2010). It is also necessary to have formal procedures for collation of data collected, analysis and a clear communication strategy for any decisions resulting from this process (Uppsala Monitoring Centre, 2010). Pharmacovigilance experts recognise evidence from several studies carried out in different parts of the world which reveals the need for continued participation in the ADR reporting process, interventions undertaken as a result of submitted ADR reports should be shared with the parties who submitted the report as part of the feedback (Olsson et al., 2010; MSH, 2012).

When ADRs occur, they should be analysed and reported. Further to this, the significance of the ADRs, either in terms of severity or frequency, should be disseminated to an audience that has professional and technical capacity to interpret the information and make decisions (MSH, 2012). NPCs in developed countries have elaborate communication systems that are supported by legislation. In 2013, the EU passed a new legislation considered a major improvement in the regulation of human medicines in EU in the last two decades. The new legislation promotes the safe and effective use of medicinal products by routinely disseminating facts relevant to the safety profile of medicines available in the healthcare system supply chain (Europeans Medicines Agency, 2012).

In 2011, SPS surveyed the PV information dissemination systems in 46 sub-Saharan African countries. The revelation was that only 20 per cent (9 countries) had published a newsletter and only 33 per cent (15 countries) routinely distributed safety alerts (SPS Program, 2011) Consistent with this report, respondents in a study on PV in Uganda among healthcare professionals revealed that feedback from the National Drug Authority (NDA), the national medicines regulatory body, was infrequent, a factor that contributed to underreporting of ADRs (Kiguba et al., 2014).

In Kenya a newsletter on the status of pharmacovigilance activities in the country is issued by PPB biannually. Since the inception of the pharmacovigilance department, there have been five editions of the Lifesaver published, the latest one having been published in November 2014. Other forms of communication on pharmacovigilance drug safety alerts include email alerts to individual health care practitioners who are subscribers to the automated email alert system developed by the PPB called e-shot. The drug safety alerts are also published on the

PPB website as well as on other health care practitioners professional associations' websites (Pandit, 2012).

In addition, PPB is active in responding to media reports touching on ADRs that are of public concern. An article in the Daily Nation revealed that a popular brand of oral contraceptive, Yasmin®, was still on sale in Kenya despite an ensuing mass tort litigation involving billions of dollars against the German pharmaceutical manufacturing company, Bayer. Several patients reported life threatening side effects as a result of taking the contraceptive. In response to the article, PPB indicated that the product was still on sale because no ADR related to the said contraceptive had been reported (Kubania, 2015). There was no response from PPB to a similar article that raised alarm over the ease with which Kenyans buy non-steroidal anti-inflammatory painkillers with little regard for the underlying life threatening ADRs such as heart attacks and liver damage (Couillard, 2013).

2.2.3 Stakeholder Engagement by the Regulatory Body in Implementing Pharmacovigilance Strategies

Medicine safety affects an entire population without distinction and therefore a sector wide approach is required for its success. A stakeholder in pharmacovigilance has therefore been identified as any person with interest and a key role in the pharmaceutical industry (Davies, 2015) The role of stakeholders was defined in the Erice declaration of 1997 by 34 countries that met in Erice, Sicily, for the International Conference on Developing Effective Communications in PV and is still relevant. It recommended a collective multiple stakeholder engagement in active surveillance and subsequent communication of drug safety which was considered a public health activity with profound implications on a health system. The success of this was pegged on the integrity and collective responsibility of all parties involved (Uppsala Monitoring Centre, 2013). The declaration recognised consumers, health

professionals, researchers, academia, pharmaceutical industry, regulatory authorities, general public, lawmakers and global health organisations as key stakeholders in medicine safety (Hugman, 2006).

One strategy of stakeholder involvement in monitoring medicine safety is to have an active safety advisory committee on PV which is one of the WHO minimum requirements of a NPC (Global Fund & WHO, 2010). This strategy is further clarified in the current WHO PV system assessment manual which advises that an advisory committee should have a minimum of three members of different professional background and should meet regularly (WHO, 2015). In the EU, the European Medicines Agency (EMA) hosts annual stakeholder forums disseminate guidelines on the requirements of the pharmacovigilance legislation and provide a platform for dialogue on pertinent emerging PV issues (European Medicines Agency [EMA], 2016).

Africa presents a grim picture when it comes to stakeholder involvement. A study done on PV in Burkina Faso revealed gaps related to the lack of PV specific regulations and guidelines to coordinate the roles of the stakeholders (Adam, et al., 2013). This was consistent with the survey undertaken by SPS in 2011 which showed that Burkina Faso did not have an advisory committee to the national pharmacovigilance system. In the same survey, Ghana was found to have an active committee with wide stakeholder representation. However, many of the members were not trained on PV. Closer to Kenya, Uganda has an established advisory committee with a clear mandate and is reported to meet often to discuss pharmacovigilance issues (SPS Program, 2011).

The Kenya national pharmaceutical policy recognises ineffective coordination of stakeholders as the cause of fragmentation, duplication and inability to exploit synergies of partnerships and multi sector collaboration (Ministry of Medical Services & Ministry of Public Health and Sanitation, 2010). The Kenya national PV guidelines identify a limited representation of key stakeholders as compared to those recommended in the Erice Declaration. The membership of the expert advisory committees is also limited with key medical disciplines such as public health experts missing (PPB, 2009). The 2011 SPS survey indicated that the committee was not sufficiently active and in the two meetings held in 2010, PV issues were not discussed (SPS Program, 2011). The establishment of a new expert advisory committee is underway with the recruitment of the experts in the industry having been gazetted recently.

Pirmohamed et al., 2007, argue that one of the main reasons why pharmacovigilance systems are not fully functional and effective is inadequate representation of key stakeholder groups who are required to actively participate in reporting of ADRs. MSH advises that a national pharmacovigilance system should support mobilization of resources and PV activities at facility, national and international levels and foster collaboration amongst stakeholders that are key in ensuring medicine safety (MSH, 2012). MSH further advises that the medicine regulatory authority and the pharmacovigilance centre, where these are separate entities, can actively create awareness among different stakeholders through training and contextualized outreach programs. This will help to improve the visibility of pharmacovigilance as a public health priority and prompt more players to be active in its activities. There is continued emphasis that an effective PV system is dependent on the active coordination and cooperation amongst stakeholders (Davies, 2015).

2.2.4 Pharmacovigilance Policy Implementation by the Regulatory Body

A government policy is defined as the basic principles by which a government is guided (Online Business Dictionary, 2016). As per the standards set by WHO, a comprehensive health policy is required at a minimum to have a defined long-term strategic plan which informs points of reference for the short and medium term. Specifically, it should map out the different players and their prioritized expectations. Such a plan achieves the function of consensus building and information dissemination and in so doing so fulfils an important role of governance and stewardship. The responsibility of formulating and implementing health policies lies with the health ministry (WHO, 2010).

In sub-Saharan Africa, only 41 percent (19 out of 46 countries) have a national policy related to PV and medicine safety. Out of these 19 countries, only eight have legal provisions that require market authorisation holders to report ADRs or carry out post-market surveillance (SPS Program, 2011). Most of the drugs marketed by these companies are in the retail chemists. The policy and regulatory mandate is inadequate to protect the public health and monitor medicines in the supply chain in the respective countries. This is indicative of a gap that can only be partially filled by active reporting of ADRs by the personnel in retail chemists. The Kenya pharmaceutical policy recognises low placement of pharmaceutical issues with government structures leading, to weak policy direction and low prioritisation in health decision making. Inadequate policy scope, weak governance structures have led to lack of effective technical oversight of the pharmaceutical sector (Ministry of Medical Services & Ministry of Public Health and Sanitation., 2010).

Periodically, countries are required to review existing or establish pharmacovigilance systems that incorporate effective regulations that enhance public safety (Pandit, 2012).

Inadequacy of policy and regulations is an indication of eventual inability to actively monitor and evaluate medicine safety monitoring (WHO, 2004). Additionally, respective ministries of health should facilitate regular review existing legislation of medicines to ensure the principles of quality, safety, and post-marketing surveillance are harmonized other relevant local laws (SPS Program, 2009)**.** The principles of pharmacovigilance should inform medicine safety strategies in any health policy (Olsson et al., 2010). Existence of a policy containing essential statements on PV indicates that a country is committed to governance and stewardship towards improvement of medicine safety and quality (WHO, 2015).

2.3 Pharmacovigilance Implementation Strategies on Adverse Drug Reporting

This section reviews literature on some of the work that has already been done on ADR reporting in retail chemists in various parts of the world, the African region and in Kenya. The factors are based on WHO strategies for improving ADR reporting.

2.3.1 Utilisation of Standard Operating Procedures

A standard operating procedure (SOP) is defined as an established procedure to be followed in carrying out a given operation or in a given situation (Online Business Dictionary, 2020b). SOPs are important in pharmacovigilance as they standardise the activities carried out. This ensures uniform and consistent data collection and reduction in the mistakes during data collection. Training the health care workers on how to use the SOPs also acts a strategy on empowering them. SOPs guide on responsibilities at various levels of the health system, identification of ADRs, the reporting procedure and on data management (WHO, 2015).

According to the international WHO Good Pharmacy Practices, the SOPs should be available at all healthcare institutions, retail chemists included, and they should be reviewed regularly for value addition. WHO in conjunction with the Uppsala Monitoring Centre as the international pharmacovigilance body has guidelines on the minimum requirements of a PV

centre of which SOPs and national guidelines are key (Uppsala Monitoring Centre, 2013). The developed countries in Europe and the USA have stringent PV SOPs that are regularly reviewed and incorporated in the legislations. This has helped to develop robust PV systems in these countries (Europeans Medicines Agency, 2018).

The Pharmacy Council of New Zealand recommends that since all pharmacies are unique and therefore the SOPs should be aligned accordingly. However, the council recognises that some of the general principles that apply include; the SOPs should be contextualized to the pharmacy; be functionally acceptable to all the personnel working in that pharmacy based on their technical competence; be applicable at all times and not only be used when the supervisor under whose instructions the SOP was created (Pharmacy Council of New Zealand, 2018). The Pharmaceutical Society of Ireland identifies the benefits of SOPs as assuring the quality of data, ensuring good practice is followed and enabling delegation even to part time staffs (The Pharmaceutical Society of Ireland, 2020). Both agencies recognise the potential of SOPs in that they can exploited as training tools, especially in PV which is dependent on on-job-trainings for long term success.

A survey carried out across sub-Saharan African countries by SPS revealed that SOPs were generally lacking in many of the countries (SPS Program, 2011). A similar study done in Ghana showed that there were virtually no SOPs in the selected health institutions. Further to this, only 25 per cent out of the healthcare workers interviewed from the ministry of health and selected public health programmes (PHPs) could confirm the existence of SOPs at national level (Nkwokike & Kwesi, 2010).

The situation in Kenya closely resembles that of Ghana. Despite widespread mention of PV SOPs in the national guidelines, health institutions specifically the retail chemists do not have any SOPs. Any ADRs are captured and reported by the market authorisation holders (MAH) using their own SOPs (SPS Program, 2011). The danger of not having SOPs is that data is likely to be wrongly entered resulting in general haphazard reporting system that is not only incompatible with international standards, but also inefficient and difficult to utilise for decision making (WHO, 2015).

2.3.2 On-The-Job Training on Pharmacovigilance

On-the-job-training, sometimes referred to as a one-on-one training, is undertaken at the work place where one competent personnel instructs another one how to perform a task. It may not always be ideal but it is easy to carry out and adapt to suit situation and specific needs (McDonnell, 2012). It is often not resource intensive as no additional training equipment is needed. The main disadvantage is that OJT interferes with the work schedule of the trainer and the trainee especially in high workload services such as a retail chemist (Bohlander & Snell, 2012).

Lack of training in pharmacovigilance has been cited by Olsson et al., (2010), as one of the causes of under reporting in many pharmacovigilance centres internationally. As per the WHO and UMC standards, the national medicines regulatory authorities (NMRAs) have the responsibility of ensuring that all the healthcare workers, more so the pharmacy personnel, are trained in pharmacovigilance (WHO, 2010). However, institutions and individuals have a personal responsibility of acquiring pharmacovigilance skills through self-directed learning in the form of continuous professional development and mentorship programs at the facility level. A successful case study of the positive impact of PV on–job-training on ADR reporting is the training of physicians in Netherlands. The skills-based training resulted in a

significantly higher number of ADR reports after completion of this work place based training as opposed to lecture-based pharmacovigilance training method (Gerritsen et al., 2011).

Training on relevant concepts of pharmacovigilance such as possible occurrence of ADRs should also be extended to the patients. Lawton and Armitage (2012) argue that the role of the patient is gradually changing from that of a person with little information to the present-day patient who is well informed and willing if not demanding to participate in their own treatment. In some of the developed countries the importance of the patients as a source of information on ADR has been acknowledged. In Netherlands, patients are trained and recruited at the pharmacy when a drug is dispensed to them for the first time. They are then registered onto an online portal the national ADR reporting system where they can submit relevant information on any suspected ADR (Brown & Bahri, 2019).

In a study carried out among community pharmacists in Portugal, ADR underreporting was consistently associated with attitudes and behaviours related to professional responsibility. Educational intervention was viewed as being an important and effective strategy that could help decrease the level of ADR underreporting. However, in the focus group discussion, the pharmacists indicated that the effects of training tend to wear out over time. Similar results were obtained in other studies in Europe and Asia whereby the respondents reported that continuous training imparted skills and knowledge as well as emphasizing behaviour change that increased ADR reporting (Irujo et al., 2007; Mirbaha et al., 2015).

In the fifth edition of the PPB PV newsletter, the Lifesaver, inconsistent ADR reporting rates were reported. According to the MIPV team, the spikes observed in reports received probably

represented months following ADR sensitization of health workers by PPB and partners (PPB, 2013). This indicates that there is need for continuous self- directed training at the facility level as opposed to one off trainings by an external body. The staff at the retail chemists can take advantage of available opportunities to sensitize patients on the possibility of occurrence ADRs and the importance of reporting them. This would not only improve compliance to medication by but also foster a sustainable partnership that would allow incidences of ADRs to be reported in a timely manner.

2.3.3 Utilisation of Data Collection Tools for Adverse Drug Reactions Reporting

Data collection in healthcare is defined by WHO as "the ongoing systematic collection, analysis, and interpretation of health data necessary for designing, implementing, and evaluating public health prevention programs" (WHO, 2016). In ADR reporting, WHO requires availability of a national spontaneous reporting system with a standard individual case safety report (ICSR) also known as an ADR reporting form as another minimum requirement for a national pharmacovigilance centre (Global Fund & WHO, 2010). The tool captures standard ADRs and relevant demographic information of the patient such as age, sex and concomitant medication used by the patient. The ADR reporting tool should be adapted from the international standards of practise established by the WHO and UMC. Ideally, if a country has a national PV program, the reporting form is standardised for use in all settings throughout the country (SPS Program, 2009)

Developed countries have rapidly embraced widespread use of computers through automated electronic reporting tools. The system is reported to work well in countries such as Sweden, Netherlands, the US and Britain (Feng & Sharma, 2013). Despite the advanced systems, some developed countries however still experience logistical problems in data collection.

This is evidenced in a study done in Portugal targeting retail chemists in an urban centre. The respondents blamed lack of ADR reporting forms, extensive and tedious information required on the ADR forms and malfunctioning of the automated reporting tools as the main reason for low rates of reporting ADRs (Duarte et al., 2015). This is consistent with the results of studies carried separately in India and in the United Arab Emirates on factors contributing to under reporting of ADRs in retail chemists cite unavailability of reporting tools as one of the key reasons why the pharmacy personnel did not report ADR (Hazhmi & Naylor, 2013; Prakasam et al., 2012).

According to Bukirwa et al., 2008, in Africa the establishment and use of electronic reporting tools and database is rare due to costs, infrastructure and technical expertise required therefore reporting of ADRs is predominantly done manually. In their analysis of PV in developing countries, widespread inaccessibility to ADR reporting tools and the complexity of the tools were major contributors to under reporting. This is confirmed by a section of healthcare workers interviewed in Uganda who confessed that they found the pharmacovigilance reporting tools complicated and tedious to fill (Maigetter et al., 2015). PPB reports that Kenya has standard ADR reporting tools distributed widely in the health facilities (Kimatu, 2009). Recently, an electronic system was put in place which is compatible with the UMC VigiFlow thereby allowing easy transmission of collated reports to the UMC database (Arale, 2013). There have been no official reports on any survey undertaken by PPB to confirm availability of ADR reporting tools in retail chemists or access to the online reporting tool.

2.4 Retail Chemist Personnel Capacity

The section summarises the key findings from various studies on the capacity of the personnel and their effect on ADR reporting at facility levels. The capacity of an individual to

undertake a task is defined as one's ability to accomplish the task (Merriam Webster Online Dictionary, 2020a). The aspects of capacity reviewed were knowledge and attitude.

2.4.1 Knowledge of Retail Chemist Personnel on Adverse Drug Reactions Reporting

Knowledge has been defined as information, understanding, or skill that you get from experience or education (Merriam Webster Online Dictionary, 2020b). One of the objectives of a national pharmacovigilance system is to ensure health care personnel are adequately trained on various aspects of pharmacovigilance and its effective communication to the public (Thobeli, 2015). WHO recommends collaboration between the national pharmacovigilance centres and health worker training institutions to foster skills and knowledge on the principles and methods of pharmacovigilance (WHO, 2015).

Experts recognise that there is frequently an inadequate understanding of ADRs even among highly trained healthcare professionals, a factor that limits reporting of ADRs when they occur in patients (MSH, 2012). Although ADR reporting is a professional obligation of all health care professionals, Bjork (2009), notes the unique role of the pharmacists in retail chemists in that they meet the patients when dispensing medicines to them. According to Bjork, the pharmacists can act as a locus for PV because they have an appropriate level of education, they are easily accessible to the population and have information that can put into perspective drug related problems. FIP encourages pharmacists to undertake continuous professional development activities to improve their role in pharmacovigilance activities (FIP, 2006).

Out of all the ADR reports received in Portugal by the NPC from healthcare professionals and patients, majority were sent by pharmacists with a higher contribution being from the pharmacists working in retail chemists (Duarte et al., 2015). However, only 38 percent of those interviewed had ever submitted an ADR report. The main barrier cited was uncertainty

between the ADR and the specific drug. The respondent pharmacists admitted that it was not uncommon for a pharmacist to graduate without receiving training on how and why to report ADRs. The respondents recommended stronger emphasis on PV in the curricula of pharmaceutical sciences. A similar study among community pharmacists in South India in 2012 revealed that less than half of the community pharmacists interviewed could define or had good knowledge of pharmacovigilance. Further, only 11.8% pharmacists interviewed had ever reported an ADR through the pharmacovigilance system (Prakasam et al., 2012). These studies indicate that existence of a functional pharmacovigilance system is not sufficient since the success of pharmacovigilance is based on consistent reporting by the healthcare workers, especially the pharmacists who are the custodians of the pharmaceutical supply chain.

In Uganda, a study indicated that only 52 percent of the respondents had ever heard about PV. 30 percent were aware of Uganda's NPC but only 3 percent had ever submitted an ADR report (Kiguba et al., 2014). In Tanzania, a study carried out amongst retail chemist professionals working as dispensers showed that only 20.5% knew the name of ADRs reporting form and an equally small number could accurately explain how to report ADRs including how to fill the details of reporting form. However, from this study there was evidence that the majority of respondents did not have adequate professional training with regard to ADRs reporting (Shimwela, 2011).

A study done in Kenya at the Kenyatta National Referral Hospital revealed that pharmacists and pharmaceutical technologists were more likely to be aware of pharmacovigilance during pre-service training (Obonyo, 2014). The fifth edition newsletter by PPB (2013), on pharmacovigilance, The Lifesaver, reported that pharmacists accounted for 15% of the ADR

reports received over a four-year period of 2008-2012. In addition, PPB has managed to institute Pharmacovigilance training at pre-service level at the Kenya Medical Training College and the University of Nairobi which trains pharmacy staff to diploma and degree level respectively. A post graduate Master's course in Pharmacoepidemiology and Pharmacovigilance was introduced recently at the University of Nairobi. It is expected that this will help to boost the capacity of pharmacovigilance activities in the country. The Kenyan PV guidelines commit to ensuring continuous medical education through professional associations specifically, Kenya Pharmaceutical Association for pharmaceutical technologists and Pharmaceutical Society of Kenya for the pharmacists (PPB, 2009).

2.4.2 Attitude of the Retail Chemist Personnel towards Adverse Drug Reactions Reporting

Attitude is defined as the predisposition to respond positively or negatively towards a certain idea, object, person, activity or situation. Attitude influences an individual's choice of action and responses to challenges, incentives and rewards (Cambridge English Dictionary, 2020). Some of the factors that have been reported to affect attitude towards reporting ADR by health care professionals include fear of punishment for failing to prevent the ADR and fear of liability as an individual or as a facility. Perception of ADR reporting as an added task to their workload and lack of feedback from the pharmacovigilance system on previously reported ADRs have also been reported to contribute to a general negative attitude towards ADR reporting (MSH, 2012). Another factor affecting attitude to ADR reporting include complacency whereby the healthcare workers feel the ADR is already documented therefore no need to report it to the relevant body (Mirbaha et al., 2015).

Focus group discussions of pharmacists working in retail chemists in an urban centre in Portugal confirmed that despite their strong conviction that reporting ADR was an important

professional obligation, a negative attitude towards the exercise was persistent. They revealed some of the reasons for underreporting resulted from the pharmacists' attitude towards ADR reporting and PV in general (Duarte et al., 2015). Similarly, in a study in India by Maigetter et al., (2015) a key informant reported that despite having patients present with ADRs, doctors often refused to report for fear of being seen to prescribe harmful drugs to patients and as such losing their credibility. The recommendation by the researchers was to have continuous support of the healthcare workers by the national PV centre in a bid to change their attitude towards ADR reporting.

A study carried out in Nnewi North in Nigeria, in a local government hospital with a catchment population of 391,222 people and a mix of health care workers of doctors, pharmacists and nurses and nursing related cadres. The study revealed ignorance of the bureaucratic reporting systems, lack of incentives, legal implications of reporting, unavailability of electronic reporting system, unavailability of reporting tools and lack of time as the barriers to ADR reporting by the healthcare workers (Ezeuko et al., 2015). Consistent with these findings, a study targeting healthcare professionals in Uganda revealed other factors that contributed to a negative attitude towards ADR reporting. 14 per cent of these healthcare professionals felt that reporting an ADR put their careers at risk for fear of punitive measures in case they were blamed for causing the ADR. 27 per cent admitted that they felt they should be financially compensated for providing the ADR reporting service. This was despite the fact the majority of these respondents agreed that they have a professional obligation to report ADRs (Kiguba et al., 2014).

However, a study done in Kenya on personnel factors affecting ADR reporting at Kenyatta National Referral Hospital, identified that attitude towards ADR reporting did not affect

actual practice of ADR reporting. The study indicated that knowledge and not attitude determined whether or not the healthcare workers reported ADRs (Obonyo, 2014). According to FIP, all pharmacists have a universal professional responsibility in pharmacovigilance regardless of the role variations according to countries (FIP, 2006).

2.5 Underlying Motivation Factors towards Adverse Drug Reporting

Motivation has been defined as the internal and external factors that stimulate desire in people to be continually interested and committed to a job or role, or to make an effort to achieve a goal. Motivation results from the interaction of both conscious and unconscious factors such as the intensity of the desire to achieve a goal, the reward value of attaining the goal and the expectations of the individual of themselves and of his or her peers (Online Business Dictionary, 2020a)The aspects of underlying motivational factors reviewed are motivation related to scope of work and effect of one's gender on their work.

2.5.1. Impact of Staff Motivation on Adverse Drug Reactions Reporting

Several studies have linked under reporting of ADRs amongst health care professionals to lack of motivation. Some of the factors that have been associated with motivation or lack of it with regard to ADR reporting include lack of feedback from the regulatory bodies where the reports are submitted and lack of incentives for reporting an ADR. Other factors include the perception of ADR reporting as added workload and general lack of motivation as a professional (MSH, 2012).

At the facility level such as retail chemist level, supervision by senior staff reinforces correct procedures and a feedback loop that assures the personnel that their efforts are meaningful. It also helps the personnel have confidence that the reports will not reflect negatively on their institutions and that no punitive measures for reporting ADRs will be undertaken. This has the potential to improve ADR reporting. In a study in Portugal targeting community

pharmacists, one respondent was quoted as saying “PV in the end is made by motivation or consideration”. Many of the pharmacists indicated that their failure to report ADRs is due to lack of will and not lack of time as often assumed. The study results cited some of the factors contributing to this attitude were lack of feedback from the authority, dislike of the bureaucratic reporting system and overall apathy towards the exercise (Duarte et al., 2015).

A study done amongst community pharmacists in India identified lack of remuneration as one of the reasons for not reporting ADRs (Adepu, 2014). This was consistent with a similar study done in Uganda but targeting not just pharmacists but various cadres of health professionals. The study revealed that 29 percent of the respondents felt that they should receive a financial incentive for reporting ADRs (Kiguba et al., 2014). In both cases, the results were somewhat surprising because the respondent had also agreed that they felt ADR reporting was their professional obligation. However, the positive effects of incentives, both financial and non-financial such as educational credits and have been demonstrated in various studies (Mirbaha et al., 2015).

In the ideal setup, ADR reporting should be one of the recognized and accepted pharmacists’ regular routine duties, yet the lack of time undertaking tasks other than medicine dispensing in daily practice has been continually cited as a barrier to reporting ADRs in several studies (Irujo et al., 2007). This is consistent with responses from studies done in Uganda (Kiguba et al., 2014) and in Portugal (Duarte et al., 2015)which showed that reporting ADRs was viewed as an additional duty to healthcare professionals who felt they were already busy with the work at hand. Conversely, respondents in a different study stated that lack of time was not a primary barrier to spontaneous ADR reporting (Cavaco & Krookas, 2014).

A report on the status of PV in 55 low and middle income countries noted with concern that only about 60% of the surveyed pharmacovigilance centres give individualized feedback that a report has been received (Olsson et al., 2010). Research in Uganda shows that such feedback is crucial as it motivates the health worker to know that their contribution is welcome and appreciated (Bukirwa et al., 2008). In Kenya, a report on PV in the Antiretroviral therapy program indicate that training healthcare workers providing ART services on pharmacovigilance followed by supportive supervision resulted in increased detection, monitoring, patient management, and reporting of ADRs (Kimeu et al., 2013).

2.5.2. Gender Influence on Adverse Drug Reactions Reporting

The online Business Dictionary (2020) defines gender as the culturally and socially constructed differences between men and women that vary from place to place and time to time. In the context of pharmacovigilance, varying studies give varying results on gender as a determinant for ADR reporting. Therefore, factors that are likely to influence gender variations in terms of ADR reporting tend to more logistical than inherent factors. These include; the numbers and working hours of either gender in the retail chemists, the influence of gender on the motivation to report ADRs and the effect of any apparent gender discrimination on the motivation to report ADRs (Gardner & Stowe, 2006).

According to Gardner and Stowe, 2006, a gender shift has occurred within the practice of pharmacy with more women joining the profession over the last two decades. Contemporary sociological studies into retail pharmacy practice in the US found that women were more likely to work part time due to family responsibilities. The same report indicates that women are also more likely to remain employees rather than employers throughout their careers and both situations could affect their earnings (Traulsen et al., 2003). A Canadian study on pharmacists' earnings documents a continuing discrepancy between men and women in

favour of the men, a trend that is closely replicated in Rwanda and Tanzania (Newman et al., 2011). In a study assessing knowledge, attitude and practices of community pharmacists towards ADR reporting, of the 154 pharmacists who completed the questionnaire, 116 (75.3 %) were female and 38 (24.7 %) were male (Duarte et al., 2015). In direct contrast to this, a similar study in Saudi Arabia, had no female participants due to the convention in Kingdom of Saudi Arabia (KSA) of females not being employed as community pharmacists (Hazhmi & Naylor, 2013).

However, different studies have shown that the growing number of female pharmacists report greater job satisfaction with regard to their immediate job situation and the state of their profession as compared to their male counterparts. Similarly, women have been reported to have more interest in the direct patient care aspects of their practice in comparison to their male counterparts (Gardner & Stowe, 2006). Enquiring and reporting of ADRs can be considered as one of the direct patient care oriented activity as it requires establishing rapport with the patients in order to identify ADRs. Gardner and Stowe, 2006, also argue that as born nurturers, females may have a natural tendency to establish the pharmacist-patient relationships that encourage dialogue with patients which would provide opportunity for ADR reporting and follow up. In Portugal, Duarte et al., 2015, established that gender did not influence spontaneous reporting in that study setting.

A study done in Uganda on the recognition and reporting of ADRs amongst surveyed healthcare professionals reported that older age and being male were associated with higher ADR reporting rates (Kiguba et al., 2014). A study in Tanzania similarly established that the male respondents had more (80.8 per cent) positive attitude towards ADRs reporting as compared to 64.1 per cent of female respondents (Shimwela, 2011). Conversely, a study in

Spain showed that the results of the study indicate that age and gender did not influence spontaneous reporting in the study setting (Irujo et al., 2007). Consistent with the findings in Spain, in her study of personnel factors affecting ADR reporting by health care workers in a hospital in Kenya, Obonyo ,2014, found that gender did not influence ADR reporting.

Despite these research findings, a 2010 study in Kenya using focus groups to elucidate barriers related to gender in pre-service education of health workers found significant differences in the numbers male and female students in key occupational programs (Newman et al., 2011). There were 32 per cent females undertaking a Bachelor's degree in pharmacy and 47 per cent in the diploma program. Later, human resources information system gender reports were generated to explore the gender composition of various medical fields and promotion rates between male and female health workers. These findings are an indicator of underlying inequality in the available opportunities that is linked to occupational segregation. Newman et al., (2011) and Newman (2008) separately suggest that countries do not have a clear picture of the gender diversity of health workforces, the constraints and disadvantages related to this diversity, the varying gender concentration in particular health occupations and the consequences these problems pose in terms of recruitment, productivity, and retention.

Newman (2008) states that there is need for gender and HRH to carry out research focused on gender aspects in order to provide reliable insight of how these affects health workers more so in developing countries According to Gardner and Stowe, 2006, in the USA, frontline health workers, such as pharmacists, were the fastest growing segment of all health care occupations in 2003 out of which 79% were female. Yet despite women's significant numerical dominance in the health labour force, gender as a variable, is not adequately reviewed to assess the impact on healthcare systems.

2.6. Reporting of Adverse Drug Reactions

2.6.1 Introduction

Adverse drug reactions are harmful and unexpected consequences of taking medicines. Reporting such reactions is necessary so that the information can be collated and analysed to improve drug safety monitoring and related research that can save lives (Bailey et al., 2016). Reporting of ADRs can either be in the form of event monitoring which entails earmarked surveillance for ADRs for a specific medicine within a specified group of people (Suku et al., 2015). Spontaneous reporting depends on the voluntary and unsolicited identification and reporting of ADRs by patients and healthcare workers to a pharmacovigilance centre. It is considered the cornerstone of detection of new ADRs within health systems (Rabbur & Emmerton, 2005). Spontaneous reporting is however hampered by several factors especially those that directly affect the healthcare providers such as lack of time due to competing tasks, lack of motivation and lack of knowledge and confidence in identifying ADRs (Reza & Emmerton, 2005). Due to this, underreporting of ADRs remains a major global problem (Güner & Ekmekci, 2019). Successful spontaneous reporting of ADRs is supported by a functional pharmacovigilance system, identification of ADRs and active reporting by the healthcare personnel (WHO, 2015).

2.6.2 System of reporting adverse drug reactions

Following the Thalidomide disaster of the mid twentieth century, whereby pregnant women took a drug named thalidomide for morning sickness leading to severe birth defects in the born children, there was a global concerted effort establish a medicine safety system. The founding countries were Australia, Canada, several European countries, New Zealand and the United States of America. This program has grown to include more states globally. This led to the creation of the WHO Program for International Drug Monitoring that is coordinated by

the Uppsala Monitoring Centre which receives, collates and analyses ADRs from all over the world (WHO, 2015). The UMC receives reports from national pharmacovigilance centres.

WHO has defined the minimum requirements for a national pharmacovigilance system to facilitate ADR reporting as; a national pharmacovigilance centre, existence of national spontaneous reporting system with standardized ADR reporting forms, a national database for storing reports, an expert advisory committee and a clear communication strategy (Global Fund & WHO, 2010). Further to this, organizations and facilities such as retail chemists are required to have their own pharmacovigilance systems to facilitate reporting of ADRs to the national pharmacovigilance centres.

Adenuga et al., 2020, have described some of the key elements of facility-based pharmacovigilance systems as continuous professional education on pharmacovigilance, facility-based policies, stakeholder engagement and existence of workable SOPs. WHO also recommends use of SOPs for pharmacovigilance related activities (Uppsala Monitoring Centre, 2013). Skills based on-the-job training is one of the strategies towards improvement of reporting amongst health professionals (Gerritsen et al., 2011). Availability of ADR reporting tools has also been widely indicated by researchers as contributing factor to a successful facility PV system (Liu et al., 2015; Irujo et al., 2007; Güner & Ekmekci, 2019).

2.6.3 Identification of Adverse Drug Reactions

Occurrence of ADRs remains a global concern with new medicines entering the markets. Due to the limited scope of the pre-clinical studies, several ADRs are only detected after the medicines are introduced to the general market (Gurmesa & Dedefo, 2016). The ability to detect and correctly identify an ADR is therefore the starting point for spontaneous reporting

of ADRs within a health system which is an effective and relatively inexpensive method of detecting ADRs that were not discovered in premarketing clinical studies in the drug development process (Kasliwal, 2012).

Lack of basic knowledge about ADRs has been cited as one of the causes of underreporting in many health systems (Liu et al., 2015). Lemay et al., 2018**,** identified that many clinicians in Kuwait were able to detect ADRs despite the fact they did not report it. In addition, many of the ADRs may present as the symptoms of the disease for which treatment is being administered therefore obscuring detection. Further to this, many healthcare professionals assume that all serious ADRs have already been detected and documented in the pre-clinical studies (Herdeiro et al., 2006).

While not all ADRs are preventable, recognizing and documenting an ADR associated with a specific medicine can lead to regulatory action that safeguards other patients (Pillans, 2008). Associating an ADR to a specific suspected drug with certainty remains a challenge and largely depends on clinical expertise and experience rather than available tools (Khan et al., 2016). Studies on pharmacovigilance have shown that many healthcare personnel lack the capacity to confidently associate ADR to a specific medicine and this deters them from reporting the ADR (Datta & Sengupta, 2015).

2.6.4 Professional responsibility to report Adverse Drug Reactions

Professional responsibility to report an ADR determines whether a healthcare professional considers ADR reporting part of their scope of work. Underreporting has been directly linked to healthcare professionals who bear the responsibility of identifying and reporting ADRs as they occur in patients (Terblanche et al., 2018). One study reports that only an

estimated 6% of all ADRs are reported (Hazell & Shakir, 2006). Reporting of ADRs depends on the ability of the healthcare professionals to detect and take initiative to report ADRs (Kasliwal, 2012). In Netherlands, a high sense of professional responsibility to report ADRs has been a key success factor for the vibrant PV system with high ADR reporting rates (Mes et al., 2002).

Strong professional responsibility to report ADRs has also been reported in other places in several countries (Ezeuko et al., 2015; Kiguba et al., 2014; Liu et al., 2015). Despite this, actual reporting is still below expectation in many places (Liu et al., 2015). Herdeiro et al. (2006) established that pharmacists' knowledge, beliefs, attitudes and motivation are what ultimately determine ADR reporting. In a study carried out amongst physicians in Italy, 94% of the respondents indicated that they had a strong professional responsibility to report an ADR yet only 6.5% had ever reported an ADR (Biagi et al., 2013).

2.7 Theoretical Framework

Spontaneous voluntary ADR reporting by healthcare professionals is the backbone of pharmacovigilance in identifying risks associated with medicines not detected in the drug development process. This study is formulated against the WHO/UMC framework of pharmacovigilance that requires consistent active surveillance and reporting of ADRs by health care professionals handling medicines.

The success of this system is dependent on input by both the National Pharmacovigilance Centre (NPC) as well as the healthcare professionals at service delivery point. The NPC is entrenched in the health system and should receive all necessary support in terms of funding and resources for the success and sustainability of pharmacovigilance activities.

Pharmacovigilance should also be supported by an explicit policy on monitoring medicines safety and other relevant legislations (WHO, 2015). The policy and the pharmacovigilance legislation should be proactive and risk based rather than passive models and as such the core activities should be focused at point of the pharmaceutical supply chain that has the highest risk for ADRs. Risk levels have a direct correlation to high variety and quantity of medicines, inadequate regulation and risk of unethical practices.

Based on this risk matrix, retail chemists in developing countries have the highest potential of having patients develop ADRs. The NPC should also recognise the key role of stakeholders and establish a coordinated manner of engagement to exploit the potential of the synergy through proper communication. Information dissemination determines the success of the coordination of the key pharmacovigilance stakeholders who include the policy makers, finance department, the NPC, pharmaceutical industry and the healthcare professionals in a cyclic manner. International pharmacovigilance standards should be locally contextualized to lay down the strategies that could be utilised at facility level such as retail chemists to increase ADR reporting rates. These strategies include on-the-job training, use of pharmacovigilance SOPs and utilisation of standard reporting tools.

Considering that ADR reporting has not been widely accepted or legally stipulated as a regular clinical practice by the healthcare workers, the capacity of the personnel in terms of knowledge and attitude as well as underlying motivation factors that have been previously researched upon and found to influence ADR reporting. These factors require to be explored further in a local context and their potential for success exploited appropriately. Gender is specifically unique in that it is usually captured as a random variable in many related studies but rarely analysed in a disaggregated manner to determine how it influences ADR reporting.

In this study, gender has been reviewed as an underlying motivation factor due to equality practices of equal pay, equal workload and equal opportunity to get knowledge on pharmacovigilance.

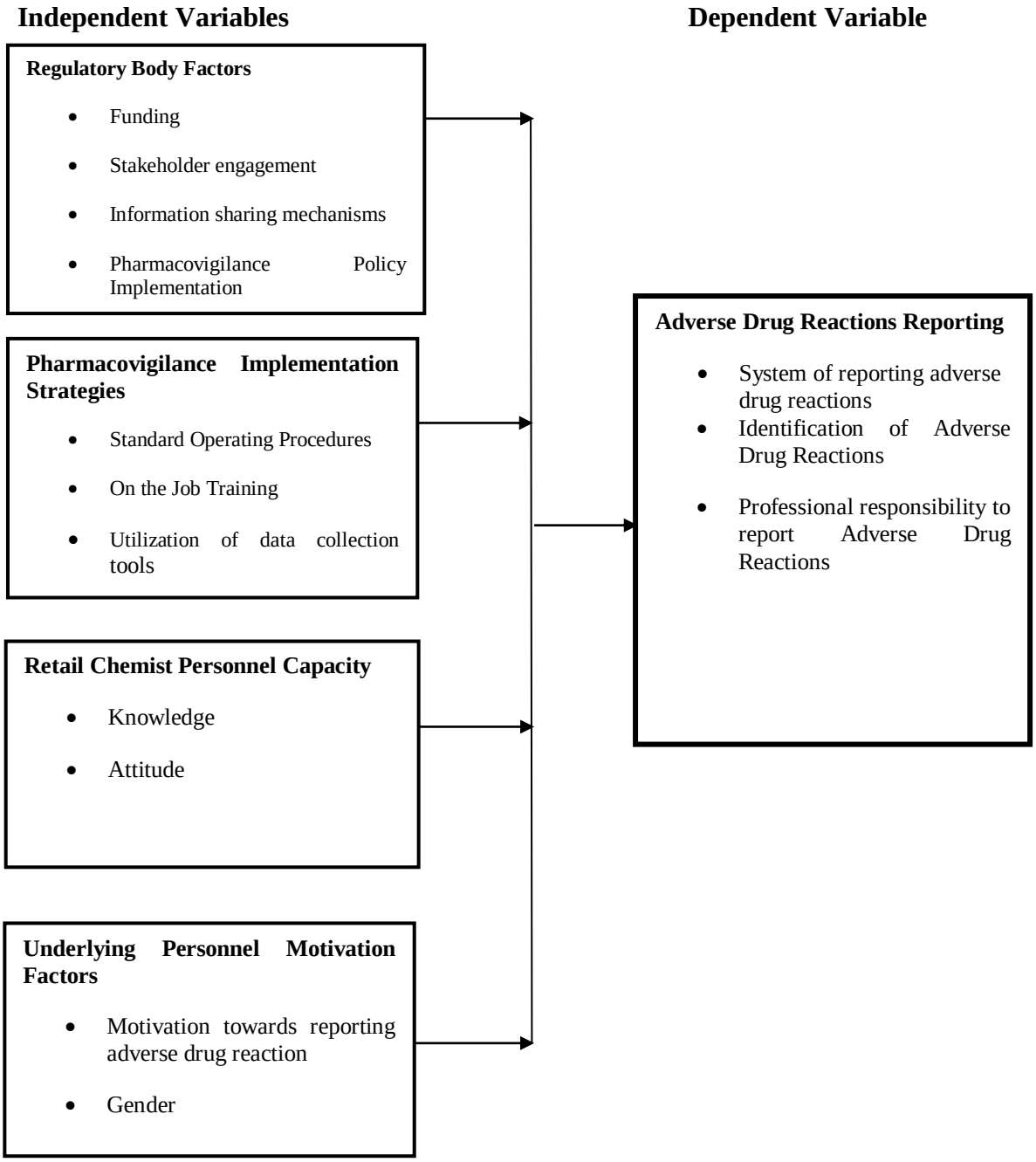
A systems strategy allows us to visualize various decision-making points and processes within a health system such as policy development. Systems' thinking can be related with ADR reporting because multiple processes and players within the health system determine the availability, the training, remuneration and motivation of personnel as well as the material requirements that facilitate ADR reporting. Improved needs assessment and coordination between the various stakeholders promote better medicine safety surveillance (WHO, 2015).

2.8 Conceptual Framework

This is a diagrammatic representation of how regulatory body, pharmacovigilance implementation strategies, capacity and underlying motivation factors directly influence the dependent variable of ADR reporting in the retail chemists.

Figure 2.1

Conceptual Framework



2.9 Conclusion

At the national level, strategies towards reporting of adverse drug reactions should be aligned to the sectors where the ADRs are most likely to cause harm and go undetected. The national medicines regulatory body should therefore have adequate financing and resources to fulfill this mandate in the entire medicines supply chain within the health system. States should seek to review and reform national legislation, policy and practices that undermine that ADR reporting. The retail chemists with support from regulatory bodies are required to implement the pharmacovigilance implementation strategies set out by WHO. All cadres of pharmacy practice in particular should be trained on the criticality of pharmacovigilance in a health system. They should also have internal systems to build capacity towards this and ensure staff are motivated to report ADRs.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This section covers the research design, target population, study location, sampling techniques, instrumentation and data collection, pre-testing, validity and reliability, data analysis and ethical consideration.

3.2 Research Design

This was a cross sectional descriptive study design with both qualitative and quantitative approaches. The qualitative aspect of the study targeted the key informants at the Pharmacy and Poisons Board working in the Department of Medicine Information and Pharmacovigilance. The purpose was to get their input on challenges that PPB faces when implementing pharmacovigilance activities. Quantitative data focused on the independent and dependent variables and the questionnaire for the retail chemist personnel was developed using a 5-point Likert scale.

3.3 Target Population

Records provided by PPB indicated that there were 895 registered chemists within Nairobi County. The study targeted to have a single respondent from each of these retail chemists. There were also three selected permanent staff of the Medicines Information and Pharmacovigilance department of the PPB that is responsible for PV activities in the country that were interviewed as key informants.

3.4 Study Location

The study was conducted in the metropolitan of Nairobi County which is also the capital city of the Republic of Kenya and at the Pharmacy and Poisons Board (PPB).

3.5 Sampling Process

3.5.1 Sample Size Determination

The study sample was selected using the Yamane formulae for calculation of sample size at 95% confidence level and P value at 0.05 (Yamane, 1967).

$$n = \frac{N}{1 + N (e^2)}$$

n = Sample size

N = Population size

e = error margin

= 268 Respondents

Using this formula, a sample size of 276 respondents was selected for the purpose of this study.

3.5.2 Sampling Procedure

The database on the registered chemists did not adequately identify the location of the chemists therefore the study employed purposive sampling whereby the most easily accessible chemist in various parts of the county were sampled. In addition, the number of personnel was not known beforehand and in addition, it was considered that a single respondent was sufficient to provide the information required per retail chemist. The identity of the chemist was cross checked against the PPB database of registered retail chemists to ensure it qualified for the study. The respondents interviewed, were those who were available at the time of data collection. No distinction was made between the various cadres beforehand.

Purposive sampling was also used to select 3 key informants from the Pharmacy and Poisons Board. Those interviewed were: The Head - Department of Pharmacovigilance and two other pharmacists from the same department. This Department deals with pharmacovigilance activities in the country.

3.6 Methods of Data Collection

The data collected was both qualitative and quantitative and addressed the study objectives. The retail chemist employee questionnaire was self-administered and there were interviews with the selected staff at the Pharmacy and Poisons Board and the key informant guide was filled appropriately. The instruments for data collection were:

3.6.1 Healthcare Provider Questionnaire

The questionnaire was self-administered and had two sections – Section A focused on demographics of the respondent and included their gender, age category, job cadre, education level and the years in service. Section B was in form of a Likert scale with responses ranging from “Strongly Agree, Agree, Not Sure, Disagree and Strongly Disagree” and focused on the study variables including – The Regulatory body related factors specifically determining there is available funding to allow the Pharmacy and Poisons Board implement pharmacovigilance strategies in the retail chemists, stakeholder engagement between PPB and the retail chemists, the information sharing mechanisms employed by PPB and the level of policy implementation by PPB within the retail chemist infrastructure; Pharmacovigilance Implementation strategies in retail chemists specifically establishing availability and use of written standard operating procedures, On-the-job training and utilization of pharmacovigilance data collection tools; Capacity of the retail chemist personnel specifically determining knowledge, attitude, motivation and gender influence towards reporting of adverse drug reactions.

3.6.2 Key Informant Interview Guide

For the staff at the Pharmacy and Poisons Board, Key informant interviews were administered to 3 staff working in the department of Medicines Information and Pharmacovigilance. The purpose was to get their input on the status of pharmacovigilance activities with regard to the retail chemists.

3.7 Operationalization of Variables

The independent variable which was reporting of adverse drug reactions was measured by considering the existence of a reporting system in the retail chemist, the ability of the respondents to identify an ADR and the attitude towards ADR reporting all which were assessed using a Likert scale. The predictor variable of the regulatory body factors was measured by checking the Likert scale score of perception of the employees on the capacity of the Pharmacy and Poisons Board in terms of funding, engagement with retail chemists, presence of a national pharmacovigilance policy and whether the respondents had read at least one publication of the pharmacovigilance newsletter.

The pharmacovigilance predictor variable on implantation strategies was measured by enquiring on the presence of standard operating procedures, availability of ADR reporting and attendance of either formal training outside the chemist or in-house training. Retail chemist personnel capacity was measured in a two-fold manner. The aspect of knowledge was measured by the Likert scale on attendance of formal pre- service training and the knowledge of existing pharmacovigilance system and requisite reporting tools. Motivation and attitude were measured by gauging the response on questions that targeted the respondents' outlook on ADR reporting as added work and as an area of interest for which further training was desirable. Underlying motivation factors of gender and receipt feedback from PPB were additionally assessed as a way of gauging the capacity of the health worker.

Table 3.1

Operationalization of Dependent and Independent Variables

	Variables	Indicators	Type	Data collection tool
Independent Variables	PPB factors	• Funding • Stakeholder engagement • Information Sharing Mechanisms • Pharmacovigilance Policy implementation	Likert Scale/interview schedule	Structured questionnaire Semi-structured questionnaire
	Pharmacovigilance Implementation Strategies	• Standard Operating Procedures • On-Job-Training • Utilization of data collection tools	Likert scale	Structured questionnaire
	Retail Chemist Personnel Capacity	• System of reporting adverse drug reactions • Identification of adverse drug reactions • Professional responsibility to report adverse drug reactions	Likert scale	Structured questionnaire
Dependent variable	Adverse Drug Reactions Reporting		Likert scale	Structured questionnaire

3.8 Pre-testing

The structured questionnaire targeting retail chemist personnel was pre-tested prior to the study in order to detect any misunderstandings, ambiguities and difficulties that might have been encountered by respondents in the retail chemists. According to Perneger et al., 2014, small samples of up to 15 participants that are common in pre-tests may be inadequate to detect even basic problems and as such a default sample size of 30 is recommended. Based

on this, 30 chemists in Kiambu County were selected as the sample size for the pre-test to which the questionnaire was administered to 60 respondents. This enabled the researcher to revise the questions asked on each of the study variables.

3.10 Instrumentation

The study was carried using structured questionnaires for the personnel in the retail chemists. The structure of the questionnaire was a section for demographic characteristics of the respondents and a second section with structured questions with responses on the 5- point Likert Scale (1-5); Strongly Disagree = 1: Disagree= 2: Not Sure = 3: Agree =4: Strongly Agree = 5an. An interview schedule was administered to the key-informants at the Pharmacy and Poisons Board. The interview schedule had two sections; the first section covered demographic characteristics and the second section had open ended questions.

3.10.1 Validity

Validity refers to how well a test measures what it is purported to measure (Taylor & Francis, 2013). Validity was enhanced for the data collection tools by pre-testing them in selected retail chemists. Review was done to assess the clarity of instructions, ease of understanding and interpretation of the questions. The internal validity of the research was dependent on validity of the data collection tools. These were assessed for content validity through a pre-test to determine if it elicited responses consistent with the research objectives. Use of a Likert scale for the closed ended questions ensured the construct validity of the tools as the respondents were able to give uniform measurable responses on attitude, knowledge and practices. The research assistants were trained and engaged in the pre-testing exercise to minimize inconsistency amongst them. The main threat to the external validity is the Pygmalion effect which is defined by (Mugenda, 2008) as the influence of a researcher's expectations on the subjects in a study. This was limited by confining the instructions to the

very basic to avoid conveying any expectations to the research subjects. The validity of the study was determined from the data that was collected.

3.10.2 Reliability

Reliability is the degree to which an assessment tool produces stable and consistent results (Taylor & Francis, 2013). Cronbach's Alpha was used to measure the internal consistency of the study instruments used in this study. According to Cronbach (1951), there is internal consistency of study items when the alpha value lies in between 0.70 to 1.00. In Table 3.2 below, all the constructs in this study returned a Cronbach Alpha of above 0.7 and a combined score of 0.867 indicating internal consistency for all the variables.

Table 3.2

Reliability Statistics: All Items

Cronbach's Alpha	**Number of Items**	
Regulatory body/PPB factors (X_1)	4	0.721
Pharmacovigilance strategy (X_2)	7	0.754
Retail Chemist Personnel Capacity (X_3)	9	0.741
Gender (X_4)	4	0.739
ADR reporting (Y)	4	0.804
Overall reliability	**28**	**0.867**

3.11 Methods of Data Analysis and Presentation

Data was coded and entered into SPSS version 23. Data cleaning was done and analysis was undertaken. Descriptive analysis was undertaken for the demographic data and the five study variables. Mean and standard deviation were obtained for the 5- point Likert Scale (1-5); Strongly Disagree = 1: Disagree= 2: Not Sure = 3: Agree =4: Strongly Agree = 5. For each

indicator of the study variables, a mean cut off of above 3.4 indicated Agree while below 3.4 was Disagree. The descriptive statistics were further combined from a five-point Likert scale (Strongly agree, Agree, Not Sure, Disagree and Strongly Disagree) to a two-point Likert scale of (Agree and Disagree). It was assumed that those not sure were more likely not to undertake ADR reporting, this was done to allow for understanding of the study variables. The Strongly agree and Agree were combined into Agree and the Not Sure, Disagree and Strongly Disagree were combined into Disagree.

Bivariate analysis was undertaken using Spearman's' Rho product method based on 0.05 (5%) level of significance, to compare each independent variable with dependent variable. The coefficient of correlation (r), determined the degree of the relationship. Multiple regression was undertaken to estimate a model that explained the influence that the independent variables has on the dependent variable in a combined relationship. The regression analysis was based on 5% level of significance (*P-value* = 0.05). A Goodness of fit test for the proposed model, using Analysis of Variance (ANOVA) was also obtained to establish if the study model was fit for estimation. The multiple regression analysis was carried out to establish the nature of the relationship based on the model in equation (i).

$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + e$…….....……...Equation (i)

Where;

Y=Adverse Drug Reaction Reporting

X_1= Regulatory body/PPB factors

X_2= Pharmacovigilance strategy

X_3= Retail Chemist Personnel Capacity

X_4= Underlying motivation factors

β_0 is a constant (which is the value of dependent variable when all the independent variables; X_1, X_2, X_3, and X_4 are held constant).

β_{1-4} are the regression coefficients or change induced by X_1, X_2, X_3, and X_4

e = error of prediction

3.12 Ethical considerations

Ethical approval and clearance was sought from the Kenya Methodist University and from the National Commission for Science, Technology and Innovation (NACOSTI), see Appendix IV and V respectively. Approval to interview the personnel at the Department of Medicine Information and Pharmacovigilance was sought from the Registrar to the Pharmacy and Poisons Board, see Appendix V. Further to this, the scope of the study was discussed with the key respondents to further clarify the purpose of the study. Administration of a Consent Form (Appendix 1) was an assurance to the retail chemist personnel that they were not identifiable in the questionnaire and the information that they provided would be treated as confidential and would be utilized to improve medicine safety surveillance in Kenya. The respondents were not offered any form of compensation to ensure objectivity and they were also informed that they could withdraw from completing the questionnaire at any point. The author of this research did not receive any financial compensation from any party to facilitate this work and therefore has no conflict of interest to declare. This is an original work without any falsification of content for which due diligence has been done to prevent plagiarism.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

This chapter covers research results and discussion based on the data collected and analyzed. This section covers the demographic characteristics of the respondents; the descriptive statistics of both the dependent variable and independent variables; Bivariate Linear Correlation Analysis: of all Variables then for each of the four variables; the Inferential Statistical Analysis.

4.2 Response Rate

The study targeted key informants working in the Pharmacy and Poisons Board and personnel in retail chemists in Nairobi County. Questionnaires for data collection were administered to the various respondents and were collected at the end of the interviews. Out of 276 targeted questionnaires, 250 were returned but only 248 were good for analysis. The response rate was then (248/276)*100 = 89.9%.

4.3 Demographic Characteristics of the Respondents

The study sought to find out the demographic characteristics of the respondents in terms of their gender, age, job cadre, education level and years of service. The demographic results of this study are presented in Table 4.1.

Table 4.1

Demographic Characteristics of Respondents

Characteristics	Respondents n (%)
Gender	
Female	137 (55)
Male	111 (45)
Total	248 (100)
Age Category of Respondents in Years	
20-29	143 (58)
30-39	88 (36)
40-49	17 (7)
Total	248 (100)
Cadre of Respondents	
Clinical Officer	22 (9)
Nursing Officer	5 (2)
Pharmaceutical Technologist	204 (82)
Pharmacist	14 (6)
Any other	3 (1)
Total	248 (100)
Education Level	
Secondary school	1 (1)
Certificate	5 (2)
Diploma	198 (80)
Graduate	41 (17)
Masters and above	3 (1)
Total	248 (100)

4.3.1 Age Category of Respondents

The demographic characteristics of the respondents as shown in Table 4.1, reveal that 111 (45%) of the respondents were male and 137 (55%) were female. Those between ages 20-29 accounted for 143 (58%) of the respondents, those between ages 30-39 were 88 (35%) and those with ages 40-49 were 17 (7%).

Studies undertaken on reporting ADRs amongst pharmacy personnel in other parts of the world have only correlated length of experience with actual reporting and have had varying results. In Portugal, (Duarte et al., 2015) established that age did not influence spontaneous reporting in that study setting that had a mean age of 37 years (22-69 years) and a mean duration of work experience in community pharmacy as 11 years (range of 2 months to 37

years). A study from Saudi Arabia revealed a youthful workforce (94% of the respondents) of between 23-40 years of age (Hazhmi & Naylor, 2013). In Tanzania, Shimwela (2011) also showed a youthful workforce of median age of 31 years with 40.2% having 5 years and below of experience and 47.6% having between 6 to 15 years of experience. Shimwela (2011) also demonstrated that respondents aged 50 years and above had a more positive attitude towards ADR reporting than their younger counterparts.

Quinones and Teachout (2001), define professional experience as the cumulative occurrences that an individual undergoes which are as a result of participating or undertaking job related tasks. However, people with same tenure of similar jobs may have significant differences in the number and type of tasks performed. Due to this complexity, they go further to elaborate the measures of work experience as tenure (total time spent in a given occupation), amount of work defined as number of repetitions of a particular task and specificity of experience to a particular task within the confines of the job description. In this regard, reporting of ADRs would be a specific task within the general job description of dispensing medicines even though it is not explicitly stated so. Do to this, longer tenure of dispensing may have provided an employee with more opportunity to come across ADRs in patients and subsequently offer them specific experience and knowledge on ADR reporting as a consequence of the activity. Tenure is largely influenced by the age of the employees due to the school system that determines when one becomes a qualified professional.

4.3.2 Cadre of Respondents

The respondents included 14 pharmacists (6%), 204 pharmaceutical technologists (82%) 22 clinical officers (9%), 5 Nursing officers (2%) and 3 respondents who refused to identify their professional qualifications.

4.3.3 Professional Qualification of Respondents

Majority of the respondents were diploma holders and were 198 (80%), 41 (17%) were degree holders, 3 (1%) were master's holders while those with certificate qualifications were 5 (2%). One respondent (<1 %) indicated they had achieved secondary school qualification. It is worth noting that there were more Clinical Officers than Pharmacists dispensing in the retail chemists. These demographic findings indicate that CAP 244 regulations are being flouted by having cadres that are not legally mandated to carry out the business of pharmacy (Pharmacy and Poisons Act, 2012). The International Federation of Pharmacists, which is responsible for setting the standards of pharmacy practice globally recognizes regulation of the pharmacy practitioner as one of the levels of medicines control that occurs in a health system. The other two levels are marketing approval process and third-party players such as distributors (FIP, 2006). In line with this standard, the Kenyan law that governs pharmacy practice and regulation of medicines, The Pharmacy and Poisons Act, CAP 244, defines two healthcare cadres that can legally carry out the business of pharmacy. The two cadres consist of the diploma level of Pharmaceutical technologist and the degree level of Pharmacist (Pharmacy and Poisons Act, 2012). Professionals from either cadre after registration with the PPB are allowed to superintend a retail chemist. However, the recently released Good Distribution Practices that define the standards for distribution of medical supplies indicate that a pharmaceutical technologist is required to have worked for a minimum of three years post enrolment experience before they can individually superintend a chemist (PPB, 2019).

This finding is in line with what Shimwela, 2011, found in the sampled retail chemists in Dar es Salaam whereby there were only 20.9% pharmacists and 18.8% pharmaceutical technicians and assistants with the rest (60.2%) being non-pharmaceutical professions such as

clinical officers, nurse officers and nurse assistants. In their assessment of the Kenyan healthcare system, Abuga et al., 2019, depict a sad state of affairs in the retail chemists which are not prohibited from employing other healthcare cadres as long as there is a pharmacist or pharmaceutical technologist superintending the premises. The consequence of this has been an infiltration of untrained persons, who after gradually attain some skill level to enable them carry out dispensing of medicines. The researchers acknowledge that much is still unknown on the impact of this task shifting on the quality of service provided in these facilities, one of those services being pharamcovigilance.

The study also sought to find out the length of professional experience in dispensing medicines in a retail chemist. The mean duration of dispensing medicines was 4.6 years with a standard deviation of 3.1. The longest serving respondent had 20 years of experience while the respondent with the shortest experience of dispensing medicines in a chemist had done so for 2 months. Further, the study sought to find out the years of service of the respondents. The results indicate that 5 longest serving personnel at the respective chemists was 20 years with the shortest being one month. The mean duration of service at the chemists was 2.6 years with a standard deviation of 2.4. The implication of these demographics is that majority of the respondents had significant experience in dispensing medicines in a retail chemist.

4.4 Descriptive Statistics

4.4.1 Regulatory Body Factors

The Regulatory body (PPB) factors were assessing the respondents' perception of the role played by PPB in facilitating ADR reporting. With a Mean cut off of above 3.4 set as agree and below 3.4 being disagree, the results show that majority of the respondents 161 (65%) (M = 3.25; SD = 0.69) felt that PPB lacks adequate funds to coordinate pharmacovigilance activities such as ADR reporting in the chemists. Olsson et al., 2010, confirm this state of

affair in their report that indicated funding for pharmacovigilance was not considered a priority in many health systems. In 2011, SPS also discovered in their survey that in several Sub Saharan countries, Kenya included, the funding for pharmacovigilance was not earmarked as such but rather was part of a greater budgetary plan (SPS Program, 2011).

Majority of the respondents also felt that PPB did not often engage the chemists as stakeholders in pharmacovigilance activities 149(60%) (M = 3.22; SD = 0.82). Many respondents had not read even one publication of the PPB newsletter on ADR reporting, the lifesaver 127(51%) (M = 3.21 SD = 1.02). As of 2011, SPS reported very few countries in Sub Saharan Africa had published a newsletter, a situation that was also replicated in Uganda where Kiguba et al., 2014, reported infrequent feedback from the regulatory body. Moreover, half of the respondents did not know if there is a national policy on ADR reporting. The results may explain that the PPB despite being the regulatory body does most of its activities without engaging the chemist as stakeholders on pharmacovigilance matters. These results are in line with (Roy & Ma, 2018) who did a study in Canada and found that the release of a new more comprehensive ADR reporting policy was not associated with increased ADR reporting by pharmacists in the study setting. The Chi-Square results indicate that there was a significant difference ($P<0.001$) in the responses by individuals under each category of Agree and Disagree. See Table 4.2**.**

Table 4.2:

Regulatory Body Factors

Regulatory body factors (X1)		Disagree	Agree	Mean	Std. Dev	Chi Square	*P Value*
		n (%)	n (%)				
i.	PPB has sufficient funds to coordinate pharmacovigilance activities such as ADR reporting in the chemists.	161 (65)	87 (35)	3.25	0.69	255.185[a]	0.001
ii.	PPB often engages the chemists as stakeholders in pharmacovigilance activities such as ADR reporting.	149 (60)	99 (40)	3.22	0.82	184.298[a]	0.001
iii.	I have read at least one publication of the PPB newsletter on ADR reporting, The Lifesaver.	121 (49)	127 (51)	3.21	1.02	180.589[a]	0.001
iv.	There is a national policy on ADR reporting by chemists.	125 (50)	123 (50)	3.30	0.85	182.565[a]	0.001

Further, the results in Table 4.2 are in line with the feedback from the key informants from the department of medicines information and pharmacovigilance. On pharmacovigilance funding, it was reported that:

"There is a dedicated budget for pharmacovigilance activities but it is not possible to state the actual percentage of this amount against the general budget for the entire board." KI01

"The funding available has not been sufficient to implement activities at retail chemist level, however the target has been moreso on health care workers hence targeting hospitals". KI01

"There is minimal engagement on pharmacovigilance activities at retail chemist level and no strategies in place yet to engage retail chemists on ADR reporting.". KI03

"Dissemination of information has been also more focused on the public health facilities and county health workers". KI02

"The national guidelines available are for general use and they do not specifically mention retail chemists".KI01

This response is in line with the findings of the European Commission that highlighted lack of sufficient funding for PV activities as one of the challenges facing the Kenyan Pharmacovigilance centre (European Commission, 2011). SPS in their survey highlighted that despite many sub-Saharan countries having pharmacovigilance centres registered with WHO this rarely translated into them being fully functional centres in terms of capacity (SPS, 2012). On the status of pharmacovigilance information dissemination systems in 46 sub-Saharan African countries, only 20 per cent (9 countries) had published a newsletter and only 33 per cent (15 countries) routinely distributed safety alerts (SPS Program, 2012). PPB has made strides in establishing a quarterly report that is published on the official website but it remains unclear if all the stakeholders are aware of this report.

Kabore et al., 2013, in Burkina Faso revealed gaps in specific regulations and guidelines required to coordinate the roles of stakeholders in pharmacovigilance activities. This was consistent with the researcher's evaluation of the guidelines which were found to lack guidance on ADR reporting in the retail chemists. The findings are also supported by the Kenya National Pharmaceutical Policy issued in 2010 by the ministries of health which recognized the low placement of pharmaceutical issues in government structures and inadequate policy scope that has led to lack of effective technical oversight of the

pharmaceutical sector (Ministry of Medical Services & Ministry of Public Health and Sanitation, 2010)

4.4.2 Pharmacovigilance Implementation Strategies

This variable was assessing the operationalization of recommended strategies that enhance reporting of adverse drug reactions in retail chemists. These strategies are: presence and use of standard operating procedures, on-the -job training and utilization of data collection tools. The results of the respondents are presented in Table 4.3.

From Table 4.3. majority of the respondents 175 (71%) (M = 3.63; SD = 0.80) agreed with the statements on availability of standard operating procedures in the chemists and that most of them had been trained on them. However, a majority refuted the fact that these SOPs were reviewed regularly 128 (52%) (M = 3.24; SD = 0.98). The interpretation of these results is that most retail chemists have a documented system of reporting adverse drug reactions. These findings are contrary to the survey done by SPS in the Sub-Saharan African countries that indicated most health facilities had no written SOPs (SPS, 2012) as well as a study in Ghana revealed that only 25% of facilities had any SOPs (Nkwokike & Eghan, 2010). Regular and collaborative review of SOPs at the retail chemists has the potential to not only ensure ADRs are documented and reported systematically but also provide an enriching learning opportunity for employees on pharmacovigilance.

Majority of the respondents confirmed to have attended a formal training outside the chemist on reporting of ADRs 170 (69%) (M = 3.54; SD = 1.01) 71% of the respondents agreed to have received on job training at the chemists on ADR reporting in form of regular updates (M=3.53, SD = 1.00). In a study done in Portugal, researchers established that a short targeted training had the potential to improve ADR reporting amongst physicians (Irujo et al., 2007). It is important in an area as dynamic as pharmacovigilance to have regular trainings

especially for retail chemist personnel who deal with a wide variety of medicines. This would seek to cater for changes in the pharmaceutical world as well boost confidence in ADR recognition, causality establishment and ADR reporting.

According to most of the respondents, manual ADR reporting tools were available at the chemist 137 (55%) (M = 3.38; SD = 1.15) A good number was also aware of the online of the online ADR reporting tool on the PPB official website, 140 (56%) (M = 3.38; SD = 0.90). In 2009, PPB reported widespread availability of the manual reporting tools (Kimatu, 2009). The situation was nevertheless quite different in India where unavailability of ADR reporting tools was cited as one of the main barriers to ADR reporting (Prakasam et al., 2012). With the advent of smart phones technology, the use of online ADR reporting has the potential to improve reporting rates in retail chemists. However, user interface suitability should be dynamic to suit different technological capabilities amongst the retail chemist personnel.

Table 4.3:

Pharmacovigilance Implementation Strategies

	Pharmacovigilance Strategies (X2)	Disagree	Agree	Mean	Std. Dev	Chi square	*P Value*
		n (%)	n (%)				
i.	There are written pharmacovigilance Standard Operating Procedures (SOPs) at this chemist.	73 (29)	175 (71)	3.63	0.80	331.315[a]	.001
ii.	I am trained on how to use the pharmacovigilance SOPs	45 (18)	203 (82)	3.77	0.87	411.113[a]	.001
iii.	The SOPs are reviewed regularly	128 (52)	120 (48)	3.24	0.98	129.944[a]	.001
iv.	I have attended a formal training on ADRs detection and reporting outside the chemist.	78 (31)	170 (69)	3.54	1.01	244.419[a]	.001
v.	I am regularly updated on any new information on ADR detection and reporting at this chemist.	72 (29)	176 (71)	3.53	1.00	310.065[a]	.001
vi.	Manual ADR reporting forms (the yellow forms) are available at the chemist.	111 (45)	137 (55)	3.38	1.15	82.081[a]	.001
vii.	Most staff in this chemist are aware of the online ADR reporting form on the PPB official website.	108 (44)	140 (56)	3.38	0.90	203.331[a]	.001

4.4.3 Retail Chemist Personnel Capacity

This variable was assessing the capability of retail chemist personnel to report ADRs based on their knowledge level and attitude towards ADR reporting. The results are presented in Table 4.4. whereby majority of the retail chemist employees have general knowledge of pharmacovigilance 151 (61%) (M = 3.47; SD = 0.80) and an almost equal majority have undergone formal pre-service training in pharmacovigilance, 163 (66%) (M = 3.44; SD = 1.01). This is consistent with the fact that PPB has in collaboration with various faculties instituted pharmacovigilance training as part of the curriculum. Further to this, Obonyo (2014) in her study carried out in a multi-cadre environment revealed that pharmacists and pharmaceutical technologists were more likely to report ADRs than other cadres. This was further evidenced by the fact that a majority of the respondents were familiar with the national pharmacovigilance system 176 (71%) (M = 3.53; SD = 0.98) and were conversant with the pharmacovigilance ADR reporting tool 155 (63%) (M = 3.34; SD = 1.08). Consistent with this, in their study in Portugal, Caraco et al., discovered that a significant number of pharmacists interviewed felt that in order to boost ADR reporting, pharmacovigilance should be a compulsory course in pre -service training.

Majority of the respondents indicated they were motivated to report ADRs 190 (77%) (M = 3.67; SD = 0.86) which was consistent with the finding that 83% of the respondents stated that their workload allowed them to report ADRs (M = 3.73; SD = 0.81). This is in line with what researchers found out in a similar study in Netherlands whereby 82% of respondents indicated that ADR reporting was an inherent component of pharmacutical care and ultimately should not be viewed as extra work (Barry et al., 2020). It is worth to note that having the relevant knowledge and having the right attitude does not necessarily translate into actual reporting of ADRs.

Table 4.4:

Retail Chemist Personnel Capacity

	Retail Chemist Personnel Capacity (X3)	Disagree	Agree	Mean	Std. Dev	Chi Square	*P Value*
		n(%)	n(%)				
i.	Most staff in this chemist understand what pharmacovigilance activities are.	97 (39)	151 (61)	3.47	0.80	164.935[a]	0.001
ii.	Most staff are aware of the role of the PPB in Pharmacovigilance	95 (38)	153 (62)	3.50	0.85	135.968[a]	0.001
iii.	I have formal pre-service (during the diploma, under graduate or post graduate studies) training in Pharmacovigilance	85 (34)	163 (66)	3.44	1.01	274.702[b]	0.001
iv.	I am familiar with the national pharmacovigilance reporting system	72 (29)	176 (71)	3.53	0.98	323.089[b]	0.001
v.	I am familiar with the national pharmacovigilance ADR reporting tool, The Yellow Form.	93 (38)	155 (63)	3.34	1.08	257.202[b]	0.001
vi.	I am interested in getting further training in ADR reporting and pharmacovigilance generally	46 (19)	202 (81)	3.89	0.84	306.234[b]	0.001
vii.	I am motivated to report ADRs	58 (23)	190 (77)	3.67	0.86	379.298[b]	0.001
viii.	My workload allows time to report an ADR.	43(17)	205 (83)	3.73	0.81	515.427[b]	0.001
ix.	The supervisor encourages ADR reporting	72 (29)	176 (71)	3.57	0.90	322.806[b]	0.001

4.4.4 Underlying Motivation Factors

This variable was assessing perception of the effect of receiving feedback from PPB on motivation to report ADRs and the social economic aspects at the workplace related to one's gender that may impact motivation to report an ADR. These gender related factors were equal pay across both genders, equal working hours and equal access to training on pharmacovigilance. The results are presented in Table 4.5.

Table 4.5:

Underlying Motivation Factors

	Underlying Motivation Factors(X4)	Disagree	Agree	Mean	Std. Dev	Chi Square	P Value
		n (%)	n (%)				
i.	Both male and female employees work similar hours and shifts.	83 (33)	165 (67)	3.56	0.93	235.871[a]	0.001
ii.	Both male and female employees are paid equally therefore are equally motivated to report ADRs	91 (37)	157 (63)	3.55	0.89	214.863[a]	0.001
iii.	Both male and female employees have equal chances to attend training on pharmacovigilance.	43 (17)	205 (83)	3.87	0.71	412.202[a]	0.001
iv.	Receiving feedback from PPB would motivate me to report ADRs in future	11 (4)	237 (96)	4.19	0.53	316.742[b]	0.001

As a demographic characteristic, gender was not considered a significant determining factor for reporting ADRs. Majority of the respondents stated that both male and females worked similar hours 165 (67%) (M = 3.56; SD = 0.93) and were paid equally 157 (63%) (M = 3.55; SD = 0.89). In Portugal, Duarte et al., 2015, established that gender did not influence spontaneous reporting in that study setting as was the case in a study done in Spain (Irujo et

al., 2007). Receiving feedback from PPB was considered by an overwhelming majority 237 (96%) (M = 4.19; SD = 0.53) a major motivational factor towards ADR reporting. This is in line with the findings of a study in Uganda that established that feedback from the National Drug Authority (NDA), the national medicines regulatory body, was infrequent, a factor that contributed to underreporting of ADRs (Kiguba et al., 2014). Still in Uganda, Bukirwa et al., 2008, established that feedback is vital and health care personnel were more likely to report ADRs in future if they got a response that their effort was recognized.

4.4.5 Adverse Drug Reactions Reporting

This was the dependent variable of the study which sought to gauge presence of an ADR reporting system, ability of the retail chemist to detect ADRs, perception of the importance of ADR reporting both as a professional responsibility as well as its importance in a health system. The results are presented in Table 4.6. Majority of the respondents confirmed that indeed there was a system to report ADRs 220 (89%) (M = 3.90; SD = 0.64). Presence of a system of reporting is confirmation that patients do present at the chemists with ADRs and some action is taken. Further to this most of the respondents confirmed the ability to detect an ADR 177 (71%) (M = 3.67; SD = 0.67).

The inability to establish causality between a drug and an adverse drug reaction is normally a major barrier to ADR reporting even amongst very experienced clinicians. Hazhmi & Naylor (2013) found that in Saudi Arabia for pharmacists to report an ADR, 94% of them stated they must be sure of the causality between the drug and the ADR despite being motivated to report, having all the necessary tools and having the knowledge about reporting. Therefore, the capacity displayed here should be leveraged upon by PPB to capture ADRs presenting at retail chemists.

Most of the respondents felt that they had a professional responsibility to report adverse drug reactions 227 (92%) (M = 4.12; SD = 0.64) and that reporting ADR was important in promoting medicine safety in a health system 229 (92%) (M = 4.17; SD = 0.66). Consistent with this is the research done in the Netherlands that showed 82% of the community pharmacists viewed ADR reporting as their professional responsibility (Mes et al., 2002).

Table 4.6:

Dependent Variable: Adverse Drug Reactions Reporting

Adverse Drug Reaction Reporting (Y)	**Disagree n (%)**	**Agree n (%)**	**Mean**	**Std. Dev**	**Chi Square**	**P Value**
i. There is a system of how to report Adverse Drug Reactions (ADRs) at this chemist.	28 (11)	220 (89)	3.90	0.64	580.387[a]	0.001
ii. Most staff in this chemist are able to detect an ADR.	71 (29)	177 (71)	3.67	0.67	394.137[a]	0.001
iii. I have a professional responsibility as a healthcare professional to report ADRs.	21 (8)	227 (92)	4.12	0.64	270.677[b]	0.001
iv. Reporting ADRs is important in promoting medicine safety in a health system	19 (8)	229 (92)	4.17	0.66	241.710[b]	0.001

4.5 Bivariate Analysis of all Variables

A bivariate analysis was undertaken in a bid to determine the relationship between the independent variables and the dependent variable as shown in Table 4.7.

Table 4.7

Bivariate Analysis Correlating Independent Variables and Dependent Variable

			ADR reporting	Pharmacy & Poisons Board	Pharmacovigilance strategy	Retail Chemist Personnel Capacity	Underlying Motivation factors
Spearman's rho	**ADR reporting**	Correlation Coefficient	1.000				
		Sig. (2-tailed)	.				
		N	248				
	Pharmacy & Poisons Board	Correlation Coefficient	.275**	1.000			
		Sig. (2-tailed)	.000	.			
		N	248	248			
	Pharmacovigilance strategy	Correlation Coefficient	.374**	.472**	1.000		
		Sig. (2-tailed)	.000	.000	.		
		N	248	248	248		
	Retail Chemist Personnel Capacity	Correlation Coefficient	.466**	.504**	.562**	1.000	
		Sig. (2-tailed)	.000	.000	.000	.	
		N	248	248	248	248	
	Underlying motivation factors	Correlation Coefficient	.416**	.274**	.396**	.491**	1.000
		Sig. (2-tailed)	.000	.000	.000	.000	.
		N	248	248	248	248	248

Results shows that there was a positive relationship between the independent variables; regulatory body/PPB factors, pharmacovigilance strategy, retail chemist personnel capacity, and underlying motivation factors, and the dependent variable (ADR reporting). The coefficient of correlation of Regulatory body/PPB factors and ADR reporting was ($r=0.275$, $p<0.001$). This indicates a statistically significant but weak correlation. The statistical significance indicates that the regulatory body which serves at the national pharmacovigilance center, determines the success of ADR reporting by actively engaging health care providing institutions such as retail chemists to disseminate guidelines, offer technical support and provide feedback whenever ADRs are reported. The weak correlation

between PPB factors and ADR reporting in retail chemists points out the disconnect between the two entities as established from the key informants who stated that lack of sufficient funding and capacity prevents meaningful engagement between PPB and the retail chemists on pharmacovigilance activities.

The coefficient of correlation between pharmacovigilance implementation strategies and ADR reporting was $r=0.374$, $p<0.001$. This indicates a statistically significant but weak correlation as $r<5$. The statistical significance means that the implementation strategies proposed by WHO to improve ADR reporting are indeed relevant for consistent ADR reporting. The weak correlation suggests that while there are SOPs, on the job training and data collection tools in place, they have not been fully exploited towards ADR reporting in the retail chemists and further research would be required to interrogate the barriers to the contextual applicability of these strategies. It is easy to have SOPs in place but having personnel use them consistently is a difficult feat to achieve. The standard operating procedures in particular may not have been adequately implemented in the retail chemists. A study in Spain showed that extensive and tedious information required on the ADR forms and malfunctioning of the automated reporting tools were the main reason for low rates of reporting ADRs (Duarte et al., 2015). The training methods may also not be suitable for ADR reporting as was the case in the Netherlands where it was only after a skills - based training practitioner trainees was there a significant improvement in number of ADR reports rather than the more common classroom based pharmacovigilance training method (Gerritsen et al., 2011).

The positive correlation between ADR reporting and Retail Chemist Personnel Capacity ($r=0.466$, $p<0.001$) indicated that the capacity of the personnel in terms of knowledge on

pharmacovigilance and attitude towards ADR reporting significantly impacts ADR reporting. The correlation was <0.5 suggesting that personnel in the retail chemists may still not have sufficient knowledge on ADR reporting. Lack of adequate knowledge on a suspected ADR will determine the attitude towards either reporting or not reporting the ADR. This is supported by Hazhmi and Naylor, (2013), who established in a study setting in Kingdom of Saudi Arabia that majority of the pharmacists would only report if they felt they had sufficient knowledge to establish causality between the suspected culprit drug and the resulting ADR. Inadequate knowledge on pharmacovigilance would inform attitudes towards ADR reporting such as complacency whereby the personnel feel the ADR is already documented, therefore no need to report it to the relevant body (Mirbaha et al., 2015). FIP recommends contnuous training by pharmacy personnel on pharmacovigilance (FIP, 2006).

Underlying Motivation Factors had a correlation coefficient of ($r=0.416$, $p<0.001$) which showed a positive relationship with ADR reporting. Worth noting is that though the relationship was significant it was below r=0.5, thus implying a weak relationship. This suggests that motivation is a determinant of ADR reporting. However, the retail chemist personnel are not adequately motivated towards ADR reporting as part of their scope of work. A study in India identified lack of remuneration as one of the reasons for not reporting ADRs (Adepu, 2014). Other possible contributing factors that have been identified by other researchers include lack of time for performing functions other than medicine dispensing in daily practice (Irujo et al., 2007) and general apathy towards ADR reportimg (Duarte et al., 2015).

4.6. Multiple Regression of all predictor variables

The regression model in Table 4.8 specifies coefficient of determination R^2 as 0.263. This means that variables in this study explained about 26.3 % of variations in ADR reporting. This study further sought to establish the extent to which the independent variables; regulatory body/PPB factors, pharmacovigilance implementation strategies, retail chemist personnel capacity and underlying motivational factors influence ADR reporting in retail chemists in Nairobi County. The summary model results in Table 4.9 shows that overall *P*-value was less that 0.05 (5%). This shows that the overall regression model is significant at 95% level of significant. It further inferred that the independent variables had a significant influence on ADR Reporting among personnel in retail chemists in Nairobi County. Autocorrelation was assessed using the Durbin Watson statistics, it could be inferred that there was no autocorrelation among the study variables had a Durbin Watson of 1.905 which is very close to 2.00, on Table 4.8.

Table 4.8

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.513[a]	.263	.251	1.42006	1.905

a. Predictors: (Constant), Underlying motivation factors, Pharmacy & Poisons Board, Pharmacovigilance implementation strategies, Retail chemist personnel capacity

b. Dependent Variable: ADR Reporting

Results in Table 4 .9 indicate that the prediction model of ADR reporting being influenced by the four study variables (Regulatory body/PPB factors, Pharmacovigilance implementation strategies, Retail Chemist Personnel Capacity and Underlying motivation factors) was valid and significant as indicated by a $P<0.05$.

Table 4.9

Analysis of Variance

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	174.751	4	43.688	21.665	.000[b]
	Residual	490.023	243	2.017		
	Total	664.774	247			

a. Dependent Variable: ADR Reporting
b. Predictors: (Constant), Pharmacy & Poisons Board, Pharmacovigilance implementation strategies, Retail Chemist Personnel Capacity and Underlying motivation factors)

Table 4.10

Regression Weights

Model		**Unstandardized Coefficients**		**Standardized Coefficients**	**T**	**Sig.**	**Collinearity Statistics**	
		B	**Std. Error**	**Beta**			**Tolerance**	**VIF**
1	(Constant)	8.609	.829		10.387	.000		
	Pharmacy & Poisons Board	.052	.067	.049	0.775	.439	.760	1.315
	Pharmacovigilance strategy	.057	.025	.149	2.236	.026	.685	1.459
	Retail Chemist Personnel Capacity	.101	.028	.262	3.626	.000	.583	1.716
	Underlying motivational factors	.162	.046	.213	3.502	.001	.819	1.221

a. Dependent Variable: ADR Reporting

The VIF index was below 10 for all the variables indicating that there was no multicollinearity. From Table 4.10, the constant was significant with $P<0.05$. This infers that even without the study variables in this study ADR reporting would still be ongoing. This can be supported by the contribution of 26.3% of the study variables to ADR reporting, and 73.7% can be explained by other variables not in this study. In a combined relationship,

Pharmacovigilance strategies (P<0.05), Retail Chemist Personnel Capacity (P<0.05) and underlying motivation factors (P<0.05), all had a significant influence on ADR reporting among retail chemist personnel chemist in Nairobi County. The study model can thus be presented as shown below;

$$Y=8.609 + 0.052X_1 + 0.057X_2 + 0.101X_3 + 0.162X_4 + e$$

From the finding, Y-Intercept (B_0=8.609) depicts that holding all independent variables in this study constant, ADR reporting will still be functional. Further, from the findings on Regulatory Body Factors (X_1, $B_{1=}$ 0.052, P=0.439) implies that a unit change in Regulatory Body Factors will improve ADR Reporting by 5.2 %, however the improvement is not statistically significant at 5% level of significance. This can be explained by the lack of engagement by the PPB with retail chemists on pharmacovigilance activities due to inadequate funding and capacity on the part of the PPB. This would explain why majority of the respondents were not sure if there was a pharmacovigilance policy in the country. This implies that until the retail chemists are fully aware of and appreciate the role of the PPB in pharmacovigilance, any interventions PPB launches towards ADR reporting may not have significant success. That said, in the quest to formulate guidelines and a policy of ADR reporting, PPB should be guided by studies such as one by Roy & Ma (2018) who established that a policy change in Canada to a new more comprehensive ADR reporting policy was not associated with increased ADR reporting by pharmacists in the study setting.

On Pharmacovigilance implementation strategies, (X_2, $B_{2=}$ 0.057, P=0.026) implies that a unit change of X_2, will improve ADR reporting by 5.7%, and the improvement is statistically significant at P<0.05. The interpretation of this is that these strategies that have been proposed by WHO to improve ADR reporting (WHO, 2015) have an effect on the capacity

and the motivation of the personnel. The quality of the SOPs, the training content and availability of ADR reporting tools is determined by the extent to which the national pharmacovigilance center has disseminated best practices. Generally, availability of SOPs in any facility ensures consistency and promote best practices of an activity such as ADR reporting. This is further strengthened by continuous on-job training both on the procedures defined by the SOPs and to reinforce knowledge and positive attitude towards ADR reporting. These results are in agreement with Hazhmi & Naylor, 2013, who established that in the Kingdom of Saudi Arabia, one of the main constraints to ADR reporting was unavailability of ADR reporting tools access to which would improve ADR reporting.

Further, retail chemist personnel capacity, (X_3, B_3=0.101, P<0.001) implies that a unit change of X_3, retail chemist personnel capacity will improve ADR Reporting by 10.1%, and the improvement is statistically significant at P<0.05. This finding is in line with Mes et al., 2002, who established that community pharmacists in the Netherlands were knowledgeable and motivated about ADR reporting and because of this, the country has one of the highest ADR reporting rates. The positive effect in a combined model with the other variables shows that the capacity of the personnel is interrelated with the other variables. Knowledge levels on pharmacovigilance after pre-service training largely depend on the extent of information dissemination by the national pharmacovigilance center. Knowledge and attitude will affect the motivation to report ADRs and vice versa.

Finally, from the findings, on effect of Underlying Motivation Factors on ADR reporting, (X_4, B_4=0.162, P=0.001) shows that a unit change of underlying motivational factors considered in this study X_4, will improve ADR Reporting by 16.2 %, and the improvement is statistically significant at P<0.05. From definition, motivation refers to the internal and

external factors that stimulate desire in people to be continually interested and committed to a job or role. This therefore implies that motivation to report ADRs is influenced by, and itself influences other factors such one's capacity to recognize, establish causality and report an ADR as per the available implementation strategies. As a healthcare worker, having one's contribution recognized especially in a technical area such as ADR reporting, can be a great motivating factor to not only report future incidences but to also influence colleagues to report. This shows how motivation is affected by PPB factors. These results are consistent with Mes et al., 2002, who in addition established that receiving feedback after reporting an ADR was the prime motivation for community pharmacists to report ADRs. The effect of motivation in a combined model such as this is adequately summed up by a statement from a respondent in a study targeting community pharmacists in Portugal, who was quoted as saying "Pharmacovigilance in the end is made by motivation or consideration" (Irujo et al., 2007).

These findings therefore indicate that if the results of this study are to be implemented, then underlying motivation factors, retail chemist personnel capacity and pharmacovigilance strategies would be the start point. PPB should ensure that any reported ADRs are acknowledged and any resultant decisions taken are duly communicated to the reporters. This study also reveals that the chemist personnel seem not to understand the role played by PPB in ADR reporting and this calls for PPB to close the gap on pharmacovigilance in retail chemists. This can be done by ensuring that in addition to licensure, the chemists are also actively engaged on pharmacovigilance through the existing communication channels that may not require hefty budgetary allocations.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

The chapter provides a highlight of summary of the study findings, conclusion and the recommendations based on the research objectives.

5.2 Summary of findings

The purpose of the study was to establish the determinants of adverse drug reactions reporting in Nairobi County. Specifically, the study sought to assess how the regulatory body (The Pharmacy and Poisons Board), pharmacovigilance implementation strategies, retail chemist personnel capacity and underlying motivation factors affected reporting of adverse drug reactions in retail chemists. A total of 248 retail chemist personnel were interviewed out of which 137 (56%) were female and 111(44%) were male. The mean age was 29.6 years. The pool of respondents comprised of 204 (82%) pharmaceutical technologists and only 14 (6%) pharmacists with other cadres who are not legally licensed to dispense accounting for 30 (12%). On education level, 198 (80%) had attained a diploma as the highest level of education, 41(17%) were graduates and only 3(1%) had a Master's degree or higher. The median length of experience in dispensing medicines had been 4 years and median length of stay in the chemist at the time of research had been 2 years.

On the influence of the Pharmacy and Poisons Board on ADR reporting, the study found that PPB generally lacked the necessary funds and capacity to carry out pharmacovigilance activities in retail chemists. The bivariate linear correlation analysis showed a significant though weak relationship between regulatory body factors and ADR reporting ($r=0.275$, $p<0.001$). In a combined linear model, PPB was found to not have a significant role in

influencing ADR reporting in retail chemists in Nairobi County (p value = 0.439). This can be explained by the disconnect between critical role of PPB in pharmacovigilance and its engagement with the retail chemists and due to this, the retail chemist personnel were not aware of the role of the PPB in pharmacovigilance.

The study established that pharmacovigilance implementation strategies in the retail chemists influence ADR reporting significantly with the respondents confirming existence of standard operating procedures, on- job training and ADR tools. Through the bivariate analysis, a positive but weak correlation between pharmacovigilance implementation strategies and ADR reporting was established ($r=0.374$, $p<0.001$). This could be explained by the fact that despite the implementation of all the reviewed strategies, this was not the main determinant for the retail chemist personnel to report. In a combined model, pharmacovigilance implementation strategies were found to significantly affect ADR reporting (p value = 0.026). This was attributed to the direct and positive interdependency with the other variables, for instance, requiring a positive attitude to participate in on-job training on pharmacovigilance.

There was a significant influence of the capacity of the personnel, in terms of knowledge and attitude, on reporting of adverse drug reactions in the retail chemists in Nairobi County. The respondents indicated a positive attitude towards ADR reporting supported by an impressive aptitude for pharmacovigilance. The bivariate analysis established a positive but weak correlation between retail chemist personnel capacity and ADR reporting ($r=0.466$, $p<0.001$). In a combined model, retail chemist personnel capacity was found to significantly affect ADR reporting ($P<0.001$). This can be attributed to the fact that knowledge and attitude

determine whether the personnel can correctly identify an ADR, utilize the implementation strategies in place to report an ADR correctly to the PPB.

Underlying motivation factors were established to be a critical success factor for sustained reporting of adverse drug reactions in the retail chemists in Nairobi County. The respondents overwhelmingly indicated that they had a professional responsibility to report ADRs as important activity in a health system. This was evidenced by bivariate analysis that showed a positive correlation with ADR reporting. ($r=0.416$, $p<0.001$). In a combined model analysis, underlying motivational factors showed statistical significance (p value $p<0.05$). This can be concluded to be due to the fact that after all resources have been put in place and personnel have been trained to impart knowledge and the right attitude to report an ADR, in the end it is determined by the inherent motivation to actually submit an ADR report.

5.3 Conclusion

In conclusion, the study established that the variables assessed had an impact on ADR reporting in retail chemists in Nairobi County. On the research question of establishing how the Pharmacy and Poisons Board influence ADR reporting, this study found out that despite its criticality in pharmacovigilance, Pharmacy and Poisons Board does not influence ADR reporting in retail chemists. This was attributed to lack of meaningful engagement by the board with the retail chemists on pharmacovigilance matters due to inadequate funding and capacity.

The study established that the pharmacovigilance implementation strategies affect ADR reporting to a significant extent by having relevant on-job training, standard operating procedures and ADR reporting tools in place. The study also confirmed improvement on the

operationalization of these strategies will have a positive effect on ADR reporting in retail chemists in Nairobi County. The study therefore concludes that these strategies have not been adequately operationalized to facilitate ADR reporting in retail chemists in Nairobi County.

For the research question on how retail chemist personnel capacity influence ADR reporting in retail chemists in Nairobi County, the study established that knowledge and attitude towards ADR reporting determines the actual reporting of ADR. Knowledge and attitude determine whether the personnel can correctly identify an ADR, establish causality between the ADR and suspected drug and go ahead to utilize the reporting tools in place to report an ADR correctly to the PPB. The study concludes that the knowledge level which may in turn inform attitude towards ADR reporting is inadequate to achieve effective ADR reporting in retail chemists in Nairobi County.

Finally, this study determined that underlying motivation factors related to equal pay, equal workload and equal opportunity between male and females as well as receiving feedback from PPB was key to the success of consistent ADR reporting in retail chemists. Despite having all the tools and knowledge on pharmacovigilance, motivation to carry out a task that is widely viewed as additional work is in the end what determines if the personnel will report an ADR or not. The study concluded that the personnel in retail chemists in Nairobi County are not adequately motivated to report ADRs.

5.4 Recommendations

This study recommends the following for each objective:

a. On the role of PPB in ADR reporting in retail chemists, PPB is required to play a more active role in promoting adverse drug reaction reporting in the retail chemists

through active information dissemination and engaging the retail chemists as key stakeholders in pharmacovigilance.

b. On pharmacovigilance implementation strategies, PPB should review the adaptability of the proposed implementation strategies. In particular, the usability of available reporting tools and the potential of the electronic tools in view of available technology, functionality of standard operating procedures and appropriateness of the pharmacovigilance on-job- training methods.
c. To enhance retail chemist personnel capacity, PPB in conjunction with retail chemist personnel should facilitate continuous skills-based training on pharmacovigilance through existing platforms such as professional association bodies for retail chemist personnel.
d. PPB should establish a robust feedback sharing mechanism to retail chemist employees for reported Adverse Drug Reactions as a way of motivating them to report ADRs.

5.5 Recommendations for Further Research

Future studies need to consider triangulation of the study instruments and include more study tools not considered in this study. This will help in improving the reliability of the results obtained. Further research should be carried out to determine the factors that hinder retail chemist personnel from reporting ADRs. There is also need for further research to establish the contextual suitability of the recommended pharmacovigilance strategies at retail chemist level. Further research should be undertaken to establish knowledge gaps on pharmacovigilance amongst retail chemist personnel.

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APPENDICES

APPENDIX I – INFORMED CONSENT FORM

June Wanjiru Njiru
P.O. Box 26392-00100, Nairobi
0707629640

Kenya Methodist University
P. 0 Box 267-60200
MERU, Kenya

SUBJECT: INFORMED CONSENT
Dear Respondent,

My name is **June Wanjiru Njiru**. I am an MSc student from Kenya Methodist University.

I am conducting a study titled: *Implementation of adverse drug reactions reporting in retail chemists; a case of Nairobi County*. The findings will be utilized to strengthen the health systems in Kenya and other low-income countries in Africa.

As a result, countries, communities and individuals will benefit from improved quality of healthcare services. This research proposal is critical to strengthening health systems as it will generate new knowledge in this area that will inform decision makers to make decisions that are research based.

Procedure to be followed

Participation in this study will require that I ask you some questions and also access all the hospital's department to address the six pillars of the health system.

I will record the information from you in a questionnaire check list. You have the right to refuse participation in this study. You will not be penalized nor victimized for not joining the study and your decision will not be used against you nor affect you at your place of employment.

Please remember that participation in the study is voluntary. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time. You may also stop being in the study at any time without any consequences to the services you are rendering.

Discomforts and risks

Some of the questions you will be asked are on intimate subject and may be embarrassing or make you uncomfortable. If this happens; you may refuse to answer if you choose. You may also stop the interview at any time. The interview may take about 40 minutes to complete.

Benefits

If you participate in this study you will help us to strengthen the health systems in Kenya and other Low-income countries in Africa. As a result, countries, communities and individuals will benefit from improved quality of healthcare services. This field attachment is critical to strengthening the health systems as it will generate new knowledge in this area that will inform decision makers to make decisions that are research based.

Rewards

There is no reward for anyone who chooses to participate in the study.

Confidentiality

The interviews will be conducted in a private setting within the hospital. Your name will not be recorded on the questionnaire and the questionnaires will be kept in a safe place at the University.

Contact Information

If you have any questions you may contact the following **Supervisors**:

Ms. Eunice Mwangi - Email address; eunicelucki@yahoo.co.uk

Mr Musa Oluoch – Email address: musadot123@gmail.com

Dr. Wanja Head of Department of Health Systems Management of Kenya Methodist University, Nairobi Campus– Email address: wanja.tenambergen@kemu.ac.ke

Participant's Statement

The above statement regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary.

I understand that my records will be kept private and that I can leave the study at any time. I understand that I will not be victimized at my place of work whether I decide to leave the study or not and my decision will not affect the way I am treated at my work place.

Signature…….

Name of Participant…….

Date……..

Investigator's Statement

I, the undersigned, have explained to the volunteer in a language s/he understands the procedures to be followed in the study and the risks and the benefits involved.

Name of Interviewer…… **Date**…….

Interviewer Signature……

APPENDIX II: PHARMACY PERSONNEL QUESTIONNAIRE

Part A: Demographics

1. Gender: Male ☐ Female ☐
2. What is your age in Years _____
3. What is the highest level of education attained?
   i. Secondary School
   ii. Certificate
   iii. Diploma
   iv. Graduate
   v. Masters and above
   vi. Any Other (specify)_____
4. What is your professional qualification?
   i. Pharmacist
   ii. Pharmaceutical Technologist
   iii. Clinical Officer
   iv. Nursing Officer
   v. Any Other (specify) _____
5. How long have you been working in this chemist? _____
6. How long have you been dispensing medicines in a chemist? _____

Part B: State the extent to which you agree with the following statements with Strongly Agree (SA), Agree (A), Not Sure (NS), Disagree (D) or Strongly Disagree (SD) with 5 being strongly agree (SA) and 1 being strongly disagree (SD).

Pharmacy and Poisons Board related factors (X1)		**SA (5)**	**A (4)**	**NS (3)**	**D (2)**	**SD (1)**
a	PPB has sufficient funds to coordinate pharmacovigilance activities such as ADR reporting in the chemists.					
b	PPB often engages the chemists as stakeholders in pharmacovigilance activities such as ADR reporting.					
c	I have read at least one publication of the PPB newsletter on ADR reporting, The Lifesaver.					
d	There is a national policy on ADR reporting by chemists.					
Pharmacovigilance Implementation Strategies in Retail Chemists (X2)		**SA (5)**	**A (4)**	**NS (3)**	**D (2)**	**SD (1)**
i.	There are written pharmacovigilance Standard Operating Procedures (SOPs) at this chemist.					
ii.	I am trained on how to use the pharmacovigilance SOPs					
iii.	The SOPs are reviewed regularly					
iv.	I have attended a formal training on ADRs detection and reporting outside the chemist.					
v.	I am regularly updated on any new information on ADR detection and reporting at this chemist.					
vi.	Manual ADR reporting forms (the yellow forms) are available at the chemist.					
vii.	Most staff in this chemist are aware of the online ADR reporting form on the PPB official website.					

Retail chemist personnel capacity (X3)		**SA (5)**	**A (4)**	**NS (3)**	**D (2)**	**SD (1)**
i.	Most staff in this chemist understand what pharmacovigilance activities are.					
ii.	Most staff are aware of the role of the PPB in Pharmacovigilance					
iii.	I have formal pre-service (during the diploma, under graduate or post graduate studies) training in Pharmacovigilance					
iv.	I am familiar with the national pharmacovigilance reporting system					
v.	I am familiar with the national pharmacovigilance ADR reporting tool, The Yellow Form.					
vi.	I am interested in getting further training in ADR reporting and pharmacovigilance generally					
vii.	I am motivated to report ADRs					
viii.	My workload allows time to report an ADR.					
ix.	The supervisor encourages ADR reporting					
Underlying motivational factors (X4)		**SA (5)**	**A (4)**	**NS (3)**	**D (2)**	**SD (1)**
i.	Both male and female employees work similar hours and shifts.					
ii.	Both male and female employees are paid equally therefore are equally motivated to report ADRs					
iii.	Both male and female employees have equal chances to attend training on pharmacovigilance.					
iv.	Receiving feedback from PPB would motivate me to report ADRs in future					
Dependent Variable- Reporting of ADR in retail chemists (Y)		**SA (5)**	**A (4)**	**NS (3)**	**D (2)**	**SD (1)**
i.	There is a system of how to report Adverse Drug Reactions (ADRs) at this chemist.					
ii.	Most staff in this chemist can be able to detect an ADR.					
iii.	I have a professional responsibility as a healthcare professional to report ADRs.					
iv.	Reporting ADRs is important in promoting medicine safety in a health system					

APPENDIX III - KEY INFORMANT INTERVIEW GUIDE FOR THE PHARMACY AND POISONS BOARD STAFF

Department_____
Position _____
Regulatory Body related factors that affect ADR reporting in Retail Chemists:

1. **Health Policy**

Does the health policy affect the implementation of Pharmacovigilance activities, specifically ADR reporting, in retail chemists?

2. **Funding**

Does availability of funding affect the implementation of Pharmacovigilance activities, specifically ADR reporting, in retail chemists?

Is there a dedicated budget for Pharmacovigilance activities?

Does the capacity of the Medicines Information and Pharmacovigilance Department affect the implementation of Pharmacovigilance activities, specifically ADR reporting, in retail chemists?

3. **Stakeholder Engagement**

Does stakeholder engagement affect the implementation Pharmacovigilance activities, specifically ADR reporting, in retail chemists?

What strategies are in place to engage retail chemists as key stakeholders in Pharmacovigilance?

4. **Information Dissemination Strategies**

Does the Pharmacovigilance information dissemination strategy in place affect the implementation of the pharmacovigilance activities in Nairobi County?

What strategies are used to disseminate information to personnel in retail chemists?

APPENDIX IV – KEMU ETHICAL CLEARANCE

KENYA METHODIST UNIVERSITY
P. O. BOX 267 MERU - 60200, KENYA
TEL: 254-064-30301/31229/30367/31171
FAX: 254-64-30162
EMAIL: INFO@KEMU.AC.KE

8TH NOVEMBER, 2016
Njiru June Wanjiru
HSM-3-6530-3/2010
Kenya Methodist University

Dear June,

SUBJECT: ETHICAL CLEARANCE OF A MASTERS' RESEARCH PROJECT

Your request for ethical clearance for your Masters Research project titled **"Implementation of Adverse Drug reactions reporting in Retail Chemists; A Case of Nairobi County"** has been provisionally granted to you in accordance with the content of your project proposal subject to tabling it in the full Board of Scientific and Ethics Review Committee (SERC) for ratification.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the SERC for re-review and approval **prior** to the activation of the changes. The Proposal number assigned to the project should be cited in any correspondence.
3. Adverse events should be reported to the SERC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for SERC review. The SERC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The SERC may conduct audits of all study records, and consent documentation may be part of such audits.

5. SERC regulations require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the SERC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

Please note that any substantial changes on the scope of your research will require an approval.

Thank You

Dr. Wamachi
Chair, SERC
Cc: Dean, RD&PGS

APPENDIX V: NACOSTI APPROVAL

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Ref No: 223397

Date of Issue: 30/July/2020

RESEARCH LICENSE

This is to Certify that Miss., June Wanjiru Njiru of Kenya Methodist University, has been licensed to conduct research in Nairobi on the topic: DETERMINANTS OF IMPLEMENTATION OF ADVERSE DRUG REACTIONS REPORTING IN RETAIL CHEMISTS; A CASE OF NAIROBI COUNTY, CENTRAL BUSINESS DISTRICT for the period ending: 30/July/2021.

License No: NACOSTI/P/20/5944

223397

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

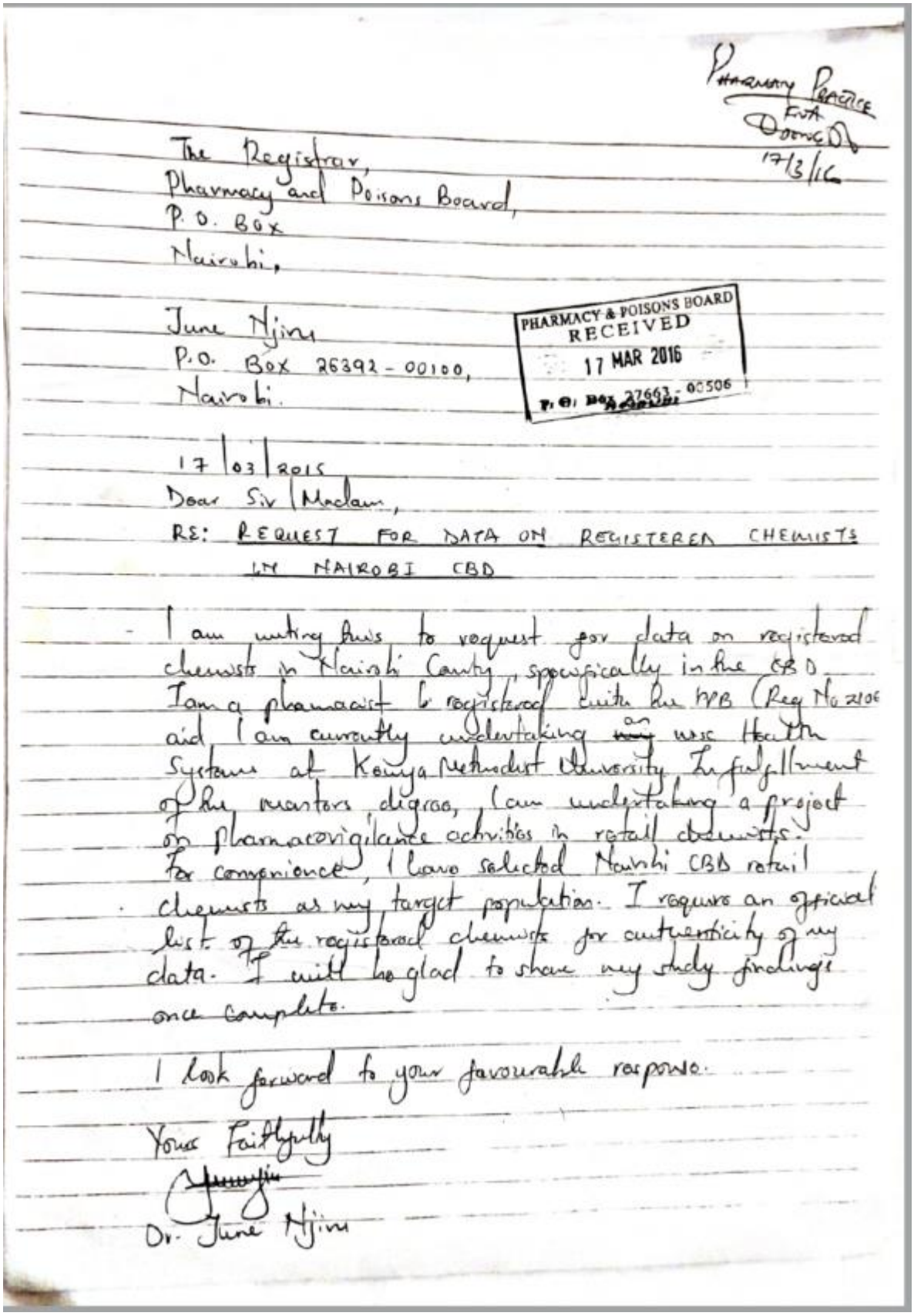
The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014

CONDITIONS

1. The License is valid for the proposed research, location and specified period
2. The License any rights thereunder are non-transferable
3. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research
4. Excavation, filming and collection of specimens are subject to further necessary clearence from relevant Government Agencies
5. The License does not give authority to tranfer research materials
6. NACOSTI may monitor and evaluate the licensed research project
7. The Licensee shall submit one hard copy and upload a soft copy of their final report (thesis) within one of completion of the research
8. NACOSTI reserves the right to modify the conditions of the License including cancellation without prior notice

National Commission for Science, Technology and Innovation
off Waiyaki Way, Upper Kabete,
P. O. Box 30623, 00100 Nairobi, KENYA
Land line: 020 4007000, 020 2241349, 020 3310571, 020 8001077
Mobile: 0713 788 787 / 0735 404 245
E-mail: dg@nacosti.go.ke / registry@nacosti.go.ke
Website: www.nacosti.go.ke

APPENDIX VI – PHARMACY AND POISONS BOARD RESEARCH CLEARANCE



Pharmacy Practice
Eva
17/3/16

The Registrar,
Pharmacy and Poisons Board,
P. O. Box
Nairobi.

PHARMACY & POISONS BOARD
RECEIVED
17 MAR 2016
P. O. Box 27663 - 00506

June Njiru
P.O. Box 26392 - 00100,
Nairobi.

17/03/2015

Dear Sir/Madam,

RE: REQUEST FOR DATA ON REGISTERED CHEMISTS IN NAIROBI CBD

I am writing this to request for data on registered chemists in Nairobi County, specifically in the CBD. I am a pharmacist & registered with the PPB (Reg No 2106 and I am currently undertaking an MSc Health Systems at Kenya Methodist University. In fulfillment of the masters degree, I am undertaking a project on pharmacovigilance activities in retail chemists. For convenience, I have selected Nairobi CBD retail chemists as my target population. I require an official list of the registered chemists for authenticity of my data. I will be glad to share my study findings once complete.

I look forward to your favourable response.

Yours Faithfully

Dr. June Njiru

APPENDIX VII – LETTER OF APPROVAL FOR RESEARCH DATA

June Njiru,
P.O. Box 26392-00100,
Nairobi, Kenya.
Email: junenjiru@gmail.com

The Registrar,
Pharmacy & Poisons Board,
Ministry of Health,
P. O. Box 27663 – 00506,
Nairobi, Kenya.

PHARMACY & POISONS BOARD
RECEIVED
24 MAR 2017
P. O. Box 27663 - 00506
NAIROBI

23rd March 2017.

Dear Sir,

RE: REQUEST FOR APPROVAL FOR RESEARCH DATA COLLECTION

I am writing this to request your approval to collect data from the Medicines Information and Pharmacovigilance Department (MIPV). I am a registered pharmacist currently pursuing Msc Health Systems Management at the Kenya Methodist University.

In partial fulfillment of the course, I am undertaking a research project, Implementation of Adverse Drug Reactions Reporting in Retail Chemists; A Case of Nairobi County. The specific objectives of the study are to determine the capacity of the Pharmacy and Poisons Board in implementing ADR reporting in the registered retail chemists, to determine the operationalization of pharmacovigilance implementation strategies on ADR reporting in registered retail chemists and to establish the retail chemist personnel influencing implementation of pharmacovigilance strategies on ADR reporting. My target population is personnel from registered retail chemists in Nairobi County. In addition, I have identified the personnel from the MIPV department as key informants in the research and it is for that purpose that I seek approval from your office.

Attached, please find a copy of the ethical approval from the University and a copy of a previous related approved request that I had made to your office for information on the retail chemists. Pharmacovigilance is a topic of great personal interest I believe the research is relevant and timely to the Kenyan health system. I will be happy to share my findings with the MIPV department. I look forward to your favorable response.

Sincerely,

Dr June Njiru

APPENDIX VIII: CONFIDENTIALITY AGREEMENT

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

STUDENT CONFIDENTIALITY AGREEMENT

In the course of evaluation of my study, i will gain access to certain information, which is proprietary to Pharmacy and Poisons Board and other interested parties.

I shall treat such information (hereinafter referred to as "**the Information**") as confidential and proprietary to PPB or the aforesaid parties. In this connection, i agree:

(a) Not to use the Information for any purpose other than discharging my obligations under this agreement;
(b) Not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

I shall not communicate any observations and/or findings as well as any resulting recommendations and/or decisions of your work to any third party, **except as explicitly** agreed by PPB.

I understand that any information (written, verbal or other form) obtained during the performance of my duties must remain confidential. This includes all information about members, clients, families, employees and other associate organizations, as well as any other information otherwise marked or known to be confidential.

I understand that any unauthorized release or carelessness in the handling of this confidential information is considered a breach of the duty to maintain confidentiality.

I further understand that any breach to maintain confidentiality in my study could be grounds for immediate suspension of attachment with PPB and/or possible liability in any legal action arising from such breach.

I confirm that I have no situation of real, potential or apparent conflict of interest including financial or other interests in, and/or other relationship with, a party, which:

(i) May have a vested commercial interest in obtaining access to any part of the Information referred to above; and/or

(ii) May have a vested interest in the outcome of evaluation of the application.

I shall promptly notify the Registrar, PPB of any change in the above circumstances, including if an issue arises during the course of my work.

All documents supplied to me in connection with this application shall be accepted in strict confidence and shall be held in safe and secure custody at all times.

I hereby accept and agree with the conditions and

Declaration:

I, the undersigned, do hereby agree to adhere to the provisions contained in this agreement.

I hereby declare that ~~I have/~~ do not have (*delete what is NOT applicable*) a Conflict of Interest with the following application(s)/any of the applications that I have been requested to review (*delete what is NOT applicable*)

Reference number (s) of application (s) with which I have a conflict of interest

JUNE WANJIRU NJIRU
(Student Name)

(Signature)

10/04/2017
(Date)

APPENDIX IX: APPROVAL FROM PHARMACY AND POISONS BOARD

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
Telephone: 020-2716905/6, 020-3562107
Cellphone: 0733-884411/0720 608811
Fax: 2713409
Email: admin@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

LENANA ROAD
P.O. BOX 27663-00506
NAIROBI

When replying please quote:

PPB/DBS/HR/GEN/Vol. I/17/003 6th April 2017

June Njiru
P. O Box 26392-00100
NAIROBI

Email: junenjiru@gmail.com

Dear Madam,

RE: Research project in Msc. Health Systems Management

Reference is made to your letter received at PPB on 24th March 2017, requesting for data collection on ***"Implementation of adverse drug reactions reporting in retail chemists; A case of Nairobi County."***

The Board allows you to go on with the study on conditions of the stipulated student confidentiality agreement enclosed herein.

Be informed that Pharmacy & Poisons Board shall terminate your study should any of the stated conditions be violated. You are further required to provide a copy of your final project work for information and future reference to the Medicines Information and Pharmacovigilance Directorate.

Yours faithfully,

Dr. F. M. Siyoi
For: REGISTRAR

CK/em