

**FACTORS INFLUENCING COMMUNITY PHARMACY PERSONNEL
PARTICIPATION IN PHARMACOVIGILANCE: A CASE OF EMBU
COUNTY, KENYA.**

BY
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DECLARATION

This project report is my original work and has not been submitted for an academic award in any other university.

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DEDICATION

I dedicate this work to my loving parents, Richard and Scholastica, and my sister, Ndanu, who have always encouraged and supported me throughout my education.

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ABBREVIATION AND ACRONYMS

BPCS	Behavioural Pharmaceutical Care Scale
CME	Continuous Medical Education
CPD	Continuous Professional Development
DDI	Drug-Drug Interactions
FDA	Food and Drug Administration
FIP	International Pharmaceutical Federation
HRSA	Health Resources and Services Administration
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
KAPI	Kenya Association of Pharmaceuticals Industry
KPA	Kenya Pharmaceutical Association
MIPV	Medicine Information and Pharmacovigilance
MSF	Médecins sans Frontières (Doctors without Borders)
NAFDAC	National Agency for Food and Drug Administration and Control
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NGO	Non-Governmental Organization
NQCL	National Quality Control Laboratory
PGEU	Pharmaceutical Group of the European Union
PPAC	Pharmacy Practice Activity Classification
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
PSP4H	Private Sector Innovation Programme for Health
PSUR	Periodic Safety Update Report

TFDA	Tanzania Food and Drugs Authority
UK	United Kingdom
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

ABSTRACT

The Kenyan Pharmacovigilance program was officially launched in June 2009 and Kenya joined the WHO programme in 2010 as the 98th member. Community pharmacy personnel are considered drug experts and play a major role in contributing to pharmacovigilance data as they may be the first or final point of contact for patients seeking medication. The personnel therefore need to participate in the spontaneous reporting system. The purpose of the study was to investigate the factors influencing community pharmacy personnel participation in pharmacovigilance in Embu County. The objectives of the study were to establish how training of the personnel dispensing medicines influences community pharmacy personnel participation in pharmacovigilance, to examine how the workload of the dispenser influences community pharmacy personnel participation in pharmacovigilance, to determine how the influx of counterfeits in the pharmaceutical supply chain influences community pharmacy personnel participation in pharmacovigilance and to determine how pharmaceutical care influences community pharmacy personnel participation in pharmacovigilance. A descriptive study design was adopted for this study to assess the attitudes, knowledge and practices of community pharmacy personnel towards participation in pharmacovigilance. The target population was 55 pharmaceutical technologists, 5 pharmacists and one Pharmacy and Poisons Board Inspector. A census was adopted since the sample size of community pharmacy personnel was relatively small. There are only 60 registered community pharmacies located in Embu County. Two sets of questionnaires were used to obtain the necessary data from the respondents. The data collected was analysed using Statistical Package for Social Sciences and presented in form of tables and percentages.

The study revealed that all the factors investigated had an influence on community pharmacy personnel participation in pharmacovigilance due to the under reporting to PPB. Training on pharmacovigilance had been undertaken by a minority of the personnel and reporting Adverse Events and poor quality drugs had been done by very few. A small number of the personnel were aware of the e-shot system and only one had subscribed to it. Therefore the level of reporting and awareness was low. The workload of the dispenser contributes to dispensing errors and majority of the personnel agreed with this statement. Very few of the personnel had attended trainings on workload management and more than half of them held CPD forums once a year to discuss dispensing errors. The influx of counterfeits in the pharmaceutical supply chain should ideally increase the number of poor quality drug reports sent to PPB. However only half of the respondents encountered counterfeit drugs but very few had reported to them PPB. Only a small number of the personnel had received training on identification of counterfeits. The pharmaceutical care concepts were known by majority of the respondents and a significant number of them had designated consultation rooms. The study recommended that stake holders in the pharmaceutical sector should include pharmacovigilance and pharmaceutical care as core disciplines in Pharmacy education and as policies. Other recommendations included use of educational interventions, communication mechanisms and setting up of county pharmacovigilance centres by PPB to include community pharmacy personnel in the pharmacovigilance framework. The study gave areas for further study to be conducted in other counties to establish other factors that influence community pharmacy personnel in pharmacovigilance.

CHAPTER ONE

INTRODUCTION

1.1 Background to the study

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem (WHO, 2002). The WHO was mandated by its member states to develop, establish, and promote international standards with respect to food, biological, pharmaceutical and similar products (WHO, 2002). The disaster caused by the drug, thalidomide, in 1961 led to the initiation of the first systematic international efforts to address drug safety issues. At that time, thousands of infants were born with congenital malformations like phocomelia, a condition where infants had no lower and upper limbs. Thalidomide was the drug of choice for pregnant women who suffered from excessive vomiting and morning sickness during pregnancy. It was readily available in most community pharmacies as an over the counter drug (WHO, 2002).

The roles of community pharmacists have moved from traditional aspects of preparing and dispensing medicines to a more vital role that includes many aspects of pharmaceutical care, such as preventing ADRs and medication errors, providing appropriate and timely information about medicines and medical devices, improving patient satisfaction and quality of life, and improving economic outcomes (Westerlund and Bjork, 2006). The Pharmaceutical Group of the European Union (PGEU), in 2005, stated that community pharmacists both have an important responsibility in monitoring the ongoing safety of medicines and are widely accessible to do it. Community pharmacies are recognized by members of the public as a vital, integral part of the health services in their country, are known to be conveniently accessible places where sound, objective advice on health issues can be obtained and early identification of Adverse Events done (PGEU, 2005).

Oreagba, Ogunleye and Olayemi (2011) did a study in 420 community pharmacies in Lagos, Nigeria and found that 55% of respondents had ever heard of the word 'Pharmacovigilance'. Only 18% of the respondents could define the term 'Pharmacovigilance'. Forty percent of the respondents noted that patients reported ADRs to them at least once a month. Only 20% reported to the relevant authorities. However, only 3% of respondents actually reported an ADR to the National Pharmacovigilance Centre. About 44.6% of the respondents noted that

lack of knowledge about how to report ADRs was the main reason for under reporting. Ninety percent of respondents believed that the role of the pharmacists in ADR reporting was important. They all expressed their willingness to report if they were regularly trained on pharmacovigilance.

A survey of community pharmacies in Indonesia showed that pharmaceutical personnel spent more time overburdened with the supply and demand of medicines and other non-professional work (Hermansyah, Sukorini, Setiawan and Priyandani, 2012). The features of professional work were ensuring prescription appropriateness, preparing the medicine, dispensing the medicine, doing health promotion, managing the health system in pharmacy, counseling for Over the Counter drugs and other professional activities like professional training or forums with other healthcare professionals. The features of non-professional work were staffing (recruitment, staff positioning, scheduling, staff training), housekeeping (cleaning and merchandising the pharmacy) and other non-professional activities like selling non medicinal products such as soap, shampoo, snacks and beverages. Based on the Pharmacy Practice Activity Classification (PPAC), community pharmacy personnel should ensure appropriate therapy and outcomes, dispense medication and devices, do health promotion, disease prevention and contribute to health systems management (Wiedenmayer, Summers, Mackie, Gous, Everard and Tromp, 2006). This was not achievable in practice due to increased workload of non-professional work.

Pharmaceutical care involves including the patient in their treatment while maintaining relationships with the physician to exchange information. Westerlund and Bjork (2006) described the professional role of pharmacist in hospitals and community pharmacies as switching from dispensing and sale of drugs, to patient counselling globally. Pharmacists were included in primary care services in Scotland, to promote access to services (Bryant, Coster, Gamble, and McCormick 2009). Pharmacists are switching from supply and distribution to medicines management services in New Zealand, United Kingdom and Australia. Major reforms of separation of drug prescribing and dispensing, according to which the physicians and the pharmacists both can prescribe and dispense drugs were implemented in Korea (Kwon, 2003).

In Kenya, the Ministry of Health in conjunction with other development partners usually carries out pharmacovigilance trainings for healthcare professionals in public and private

sector health facilities. The Private Sector Innovation Programme for Health (PSP4H) carried out a study on community pharmacies in Nairobi, Machakos, Kilifi and Nyamira counties from January 2014 to April 2014. The report findings indicated that the opportunities for capacity building were few. Only 44% of the pharmaceutical personnel had attended any training in the past two years and only 19% had attended pharmacovigilance trainings. 50 percent of the pharmacovigilance sponsorship was mainly done by non-governmental organizations. Minimal government support was given due to lack of clarity on boundaries between legitimate and illegitimate pharmaceutical personnel and the absence of a clear framework for including the community pharmacy sector in national strategic objectives. There was also insufficient effort by professional bodies to get the government to engage community pharmacy personnel in mainstream policy work and inadequate knowledge on their capacity and training needs (PSP4H, 2014).

In Kenya a suitable and adequate prescription/patient recording system, consisting of a prescription record ledger that is well indexed and up to date is a legal requirement. This may be supplemented by patient profile cards, a computerized system or any other approved recording system. Records of all stocks received, their source, batch number, expiry date and quantity received are also maintained (PPB, 2006). A study comparing community pharmacies in Nairobi, Kenya and Florida, the United States showed that those in Kenya were more economic driven and kept less patient records compared to those in Florida which were more patient oriented and maintained patient records (Parmar, 2008).

A large number of multinational pharmaceutical companies have centralised pharmacovigilance units with trained staff and carry out research and development. There are 42 companies listed as local pharmaceutical manufacturers in Kenya (PSP4H, 2014). None does research and development and they don't have pharmacovigilance units. They control 28% of the market share of medicines in Kenya. Therefore imports make up the bulk of medicine supplies in Kenya. A report by the Pharmacy and Poisons Board (PPB) and the National Quality Control Laboratory (NQCL) in 2005 showed that 30% of multinational pharmaceutical medicines sold in Kenya were counterfeit, representing 40% of the drugs sold in the country (PSP4H, 2014).

The level of pharmaceutical care given to patients differs among pharmaceutical personnel due to their different levels of training. Most personnel do not have the clinical pharmacy

background to take patient history and monitor ADRs. Pharmaceutical care plays a major role in a pharmacovigilance system especially in the detection of ADRs and poor quality drugs. Most community pharmacies exist as standalone facilities with no lab testing or consultation services.

1.2 Problem statement

Pharmacovigilance is not taught at the diploma or undergraduate level as a core discipline in the study of Pharmacy in Kenya. The pharmaceutical technologist or pharmacist is expected to acquire this knowledge as part of on job training or during continuous medical education sessions (CMEs) for continuous development points (CPDs). Therefore there is gross under reporting of ADRs and poor quality drugs to PPB. In a private or public health facility, the CMEs can be conducted on frequent basis, as there are Medicines and Therapeutic Committees (MTCs) to oversee such trainings. This may be lacking in the community pharmacies which are mainly business oriented. The pharmacovigilance program was launched in Kenya in 2009 and extensively rolled out in public health facilities.

Community pharmacies may be the last or first point for patients seeking medication and sound medical advice. It is therefore important for the pharmaceutical personnel to have knowledge on and participate in pharmacovigilance where Adverse Events and poor quality drugs can be detected or reported (Hafeez, Kiani, Din, Muhammad, Butt, Shah, and Mirza, 2004). According to the regional PPB officer Embu County has 60 registered pharmacies and only 5 are owned and superintended by pharmacists. The pharmaceutical personnel usually cater to a large population of patients as community pharmacies outside Embu town are few and scattered within Embu County. The PPB classified Embu town as a large urban centre with a large population and a high concentration and uptake of reproductive health products during its post marketing surveillance of reproductive health products in 2014. The community pharmacies stock more medicines compared to the public health facilities and usually get a high influx of patients due to the constant drug shortages in the county health facilities (PPB, 2014). Embu County has always enjoyed the support of APHIA Plus, a Non-Governmental Organisation affiliated to United States Agency for International Development (USAID), which facilitates training of healthcare professionals on various health programs including pharmacovigilance.

1.3 Purpose of study

The study sought to investigate the factors influencing community pharmacies personnel participation in pharmacovigilance in Embu County.

1.4 Objectives

The objectives of this study were;

1. To establish the influence of training of the personnel dispensing medicines on community pharmacy personnel participation in pharmacovigilance.
2. To examine the influence of workload of the dispenser on community pharmacy personnel participation in pharmacovigilance.
3. To determine the influence of influx of counterfeits in the pharmaceutical supply chain on community pharmacy personnel participation in pharmacovigilance.
4. To determine the influence of pharmaceutical care on community pharmacy personnel participation in pharmacovigilance.

1.5 Research questions

1. How does training of the personnel dispensing medicines influence community pharmacy personnel participation in pharmacovigilance?
2. To what extent does workload of the dispenser influence community pharmacy personnel participation in pharmacovigilance?
3. How does the influx of counterfeits in the pharmaceutical supply chain influence community pharmacy personnel participation in pharmacovigilance?
4. To what extent does pharmaceutical care influence community pharmacy personnel participation in pharmacovigilance?

1.6 Significance of Study

The study sought to establish the training needs of the community pharmacy personnel that would enable identification and reporting of counterfeit or unregistered medicines and suspected ADRs to PPB with ease and frequency. The study results could enable PPB and other policy makers to enact legal and educational interventions that would enable them collect more pharmacovigilance data and curb the counterfeiting trade in community pharmacies.

The study would benefit policy makers and stakeholders to improve the communication mechanisms between PPB and community pharmacies especially when drugs are recalled. The study hopes to increase community pharmacy personnel participation in the spontaneous

reporting system and seek more training opportunities. The professional associations and societies could use the study results to encourage their members to improve their professional skills and embrace pharmaceutical care concepts for proper delivery of healthcare. The results of the study could be used for future research into the setting up of regional pharmacovigilance centres in line with the devolution of health services to streamline reporting and inclusion of community pharmacy personnel in the county health management team as stake holders. The study results could also be used as a point of information for other researchers conducting related studies.

1.7 Delimitation of the study

The study was conducted in Embu County which has 60 registered community pharmacies and is divided into 4 sub counties; Manyatta, Runyenjes, Mbeere North and Mbeere South. The study variables to be investigated were the training and workload of the pharmaceutical personnel, the influx of counterfeits in the pharmaceutical supply chain and the pharmaceutical care among the community pharmacies. The community pharmacies chosen for the study were stand alone facilities which offered outpatient services and were registered by the Pharmacy and Poisons Board (PPB). They are superintended by a registered pharmacist or pharmaceutical technologist for at least ninety percent of the time. Community pharmacies attached to private hospitals that neither offer outpatient services to walk-in patients nor dispense prescriptions from other facilities were excluded from the study. Out of the 60 community pharmacies in Embu County, only 5 are owned by pharmacists while 55 are owned by pharmaceutical technologists.

1.8 Limitations of the study

The study relied on the honesty of the respondents to get acceptable findings. The number of pharmaceutical personnel interviewed may not be representative of the total number of community pharmacies in Embu County. Information on duly registered premises was sought from the Pharmacy and Poisons Board Inspector to ensure that only legitimate personnel were interviewed. The questionnaire was administered within the shortest period possible to reduce external influences on the honesty of the respondents.

1.9 Assumptions of the study

The time allocated for the research was sufficient, that the respondents were honest in their answers and they were aware of the PPB regulations governing the community pharmacy practice.

1.10 Definition of Significant terms

Adverse Drug Reaction (ADR) - A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Biological - A medical product prepared from biologic material of human, animal or microbiologic origin (such as blood products, vaccines, insulin).

Clinical trial - A systematic study on new pharmaceutical products in human subjects (Including patients and other volunteers) in order to investigate any adverse drug reactions before drug registration with the relevant national drug regulators e.g. PPB in Kenya.

Community pharmacy- a drug outlet duly registered by PPB for the purposes of provision of drugs and pharmaceutical care. It is superintended by a duly registered pharmacist or pharmaceutical technologist.

Counterfeit Medicine - Medicine that is deliberately and fraudulently mislabelled, with respect to identity and/or content and/or source.

Dispensing- the process of preparing and giving medicine to a named person on the basis of a prescription. It involves the correct interpretation of the prescriber's wishes, accurate preparation and labelling of medication for use by the patient.

Drug/medicine - Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.

Medicines and Therapeutics Committee- a multidisciplinary team that is formed in all health facilities to assess and set hospital policies for the health care team. It usually has a representative from each cadre or department in the hospital.

National pharmacovigilance centre - A single, governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

Pharmaceutical care - This is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. .

Pharmaceutical technologist - An individual who is duly recognized by the Kenyan law as having acquired a diploma in pharmaceutical technology from a recognized institution in Kenya and is enrolled by the Pharmacy and Poisons Board.

Pharmacist - An individual who has qualified with a bachelor of pharmacy degree (B.Pharm) from a recognized institution in Kenya and is registered by the Pharmacy and Poisons Board.

Pharmacovigilance - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Pharmacy and Poisons Board - Pharmacy and Poisons Board of Kenya that is established by section 35 of CAP 244 laws of Kenya. It is mandated to register pharmacists and enrol pharmaceutical technologists. It also carries out pharmacovigilance, drug registration and regulation of pharmacy practice in Kenya.

Prescription - an instruction written by a duly registered medical practitioner or dentist that authorizes a patient to be provided with medicine or treatment.

Spontaneous reporting - System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority.

Workload - In a community pharmacy it refers to the number of prescriptions filled or the number of patients served in a day.

1.11 Organisation of the study

The study is organised into five chapters.

Chapter one covers the introduction comprising of the background to the study, problem statement, purpose of the study, objectives, research questions and significance of the study. The delimitation, limitations and assumptions of the study are also discussed and the definition of significant terms.

Chapter Two deals with the review of related literature comprising of the introduction, definition of pharmacovigilance and the Kenyan pharmacovigilance framework, training of pharmaceutical personnel, workload of dispensers, influx of counterfeits in the pharmaceutical supply chain and pharmaceutical care. The theoretical and conceptual frameworks are also provided.

Chapter Three deals with the research methodology consisting of the research design, target population, sampling procedure, methods of data collection, validity and reliability, methods of data analysis, operational definition of variables and ethical considerations.

Chapter Four covers data analysis, presentation and interpretation. Chapter Five presents the summary of findings, discussions, conclusions and recommendations.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter covered the definition, importance and the Kenyan pharmacovigilance framework. The factors influencing pharmacovigilance in community pharmacies were also discussed. These were the level of training of pharmaceutical personnel, the workload of personnel dispensing, counterfeits in the pharmaceutical supply chain and pharmaceutical care. The theoretical and conceptual frameworks were also covered.

2.2 Definition of pharmacovigilance

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem (WHO, 2002). The word "pharmacovigilance" is derived from the words *pharmakon*, Greek for drug, and *vigilare*, Latin for to keep watch or to be alert. Pharmacovigilance entails spontaneous reporting of Adverse Drug Reactions (ADRs), medication errors and poor quality medicines to national pharmacovigilance centres.

Pharmacovigilance covers three main areas: product quality, medication errors and adverse drug reactions. Quality issues relate to pharmaceutical products that are defective, deteriorated or adulterated because of poor manufacturing practices, inadequate distribution and storage, poor labelling or tampering (WHO, 2002). Counterfeit products and pharmaceutical donations that have expired, or are close to expiration, fall in this category.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer” (NCC MERP, 2009). Errors can be harmless or detrimental to the patient. An Adverse Drug Reaction (ADR) is a response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function (WHO, 2002). A serious adverse reaction is one that is fatal, life threatening, or permanently or significantly disabling; requires or prolongs hospitalization; or relates to misuse or dependence (WHO/UMC 2000).

An adverse drug event (ADE) is a harmful response that is caused by a drug or the inappropriate use of a drug. An ADR is always an ADE but an ADE might include the result of an overdose because of a dispensing error or errors occurring during the medication use process. Self medication, lack of regulatory control over the sale of medicines and irrational prescribing contribute to ADE incidences (WHO, 2002).

2.2.1 Importance of pharmacovigilance

Adverse drug reactions are common causes of morbidity and mortality in both hospital and community settings. ADRs are responsible for about 5 to 20 percent of hospital admissions (Pirmohamed, James, Meakin, Green, Scott, Walley, Farrar, Park and Alasdair 2004). According to WHO Safety of Medicines Guidelines (2002), the information collected during the pre-marketing phase of drug development was inevitably incomplete with regard to possible Adverse Drug Reactions (ADRs). This was mainly because tests in animals are insufficient to predict human safety, patients used in clinical trials are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited.

Additionally by the time of licensing a product, exposure of less than 5000 human subjects to a drug allows only the more common ADR to be detected and at least 30,000 people need to be treated with a drug to be sure that you do not miss at least one patient with an ADR which has an incidence of 1 in 10,000 exposed individuals. Lastly, the information about rare but serious adverse reactions, chronic toxicity, and use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available.

The aims of pharmacovigilance as stipulated by WHO (2002), are first to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions. The second aim is to improve public health and safety in relation to the use of medicines and the third to contribute to the assessment of benefit, harm, effectiveness and risk of medicines. The fourth aim is to encouraging safe, rational and more effective (including cost-effective) use of medicines and finally to promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

Pharmacovigilance consists of reporting of ADRs, medication errors and poor quality medicines and medical devices to a national pharmacovigilance centre. The reporting can be done by healthcare professionals, patients and the general public. Each pharmacovigilance

centre provides standardized reporting tools for data collection and a database to carry out periodic analysis in relation to drug safety. The data collected is then forwarded to the WHO Programme for International Drug Monitoring co-ordinated, by the Uppsala Monitoring Centre (UMC) in Uppsala, Sweden, with oversight by an international board.

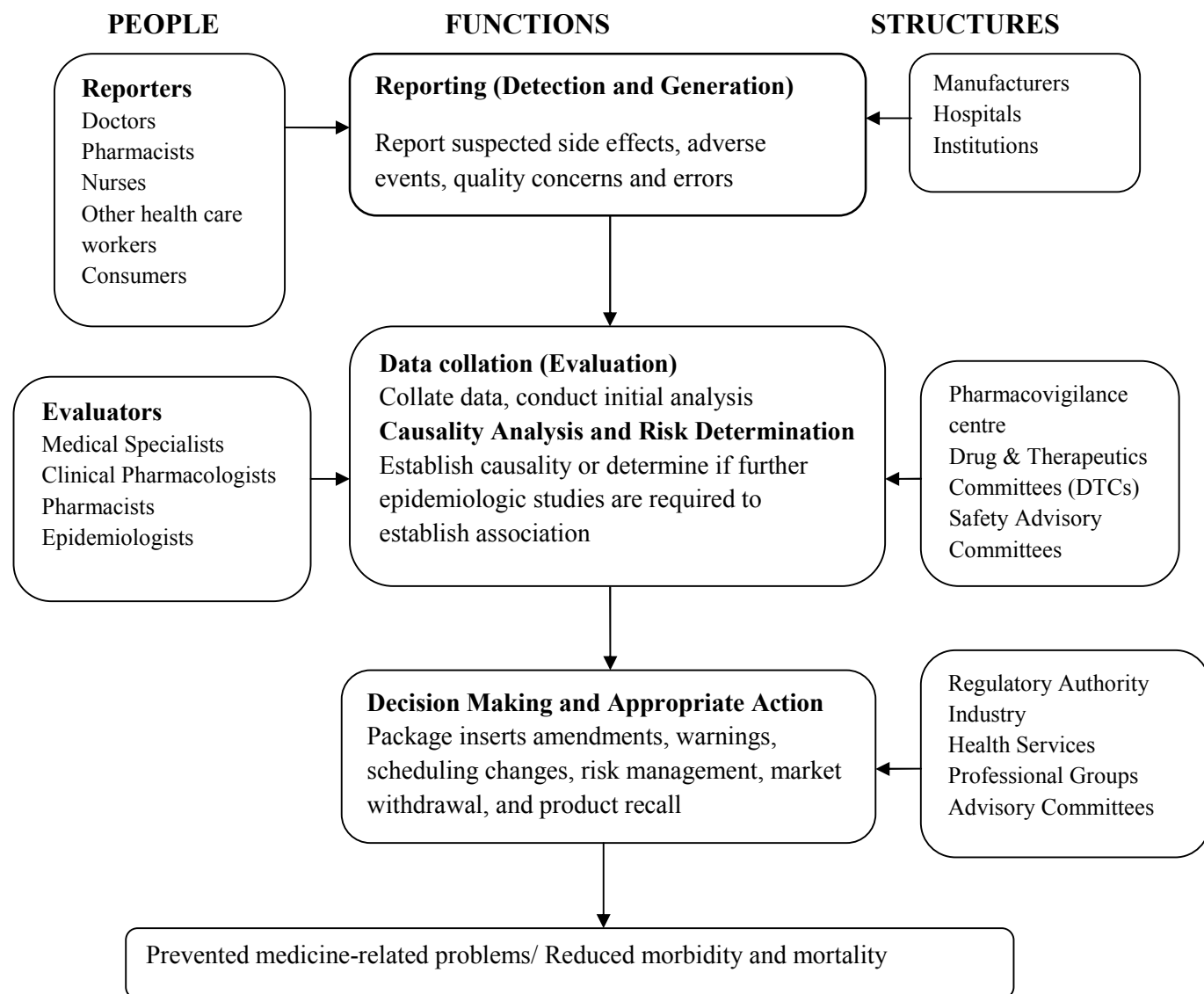


Figure 4.1: Pharmacovigilance framework adapted from Centre for Pharmaceutical Management (2011).

2.2.2 The Kenyan pharmacovigilance framework

The Department of Pharmacovigilance in Kenya was started in 2004 and evolved to Division of Medicine Information and Pharmacovigilance (MIPV) housed at the Pharmacy and Poisons Board (PPB), on Lenana road in Nairobi. It comprised of three sections: Medicines Information, Pharmacovigilance and Post Market Surveillance, and Clinical Trials. It was mandated to enhance patient safety. The National Pharmacovigilance System launched in June 2009 with the theme being “*you need not be certain just be suspicious*” and was built on the capacity building model. Kenya officially joined the WHO program in 2010 as the 98th member worldwide and the 24th member in Africa. The laws that govern pharmacovigilance in Kenya are the Kenya National Drug Policy 1994, the national pharmaceutical policy (draft) 2010 and the Pharmacy and Poisons Act, Cap 244.

There is an Expert Safety Review Panel that exists to provide technical advice on the safety of medicines and clinical trials. The panel comprises of the national coordinator, a clinical pharmacologist, a physician, a pharmacoepidemiologist, an obstetrician, a paediatrician and a pharmacist. The National Quality Control Lab was created to carry out tests on drug batches for drug registration and also for routine inspection purposes. The tools used for pharmacovigilance in Kenya are the Suspected Adverse Drug Reaction Notification Form (yellow form), the Patient Alert Card, the Poor Quality Medicinal Product Reporting Form (pink form) and the Checklist for investigation procedure by District Investigation Team. The PPB publishes biannual newsletters and also posts important safety alerts through an e-mail-based communication system called e-shot. A total of nine alerts were sent out in 2010 according to the WHO.

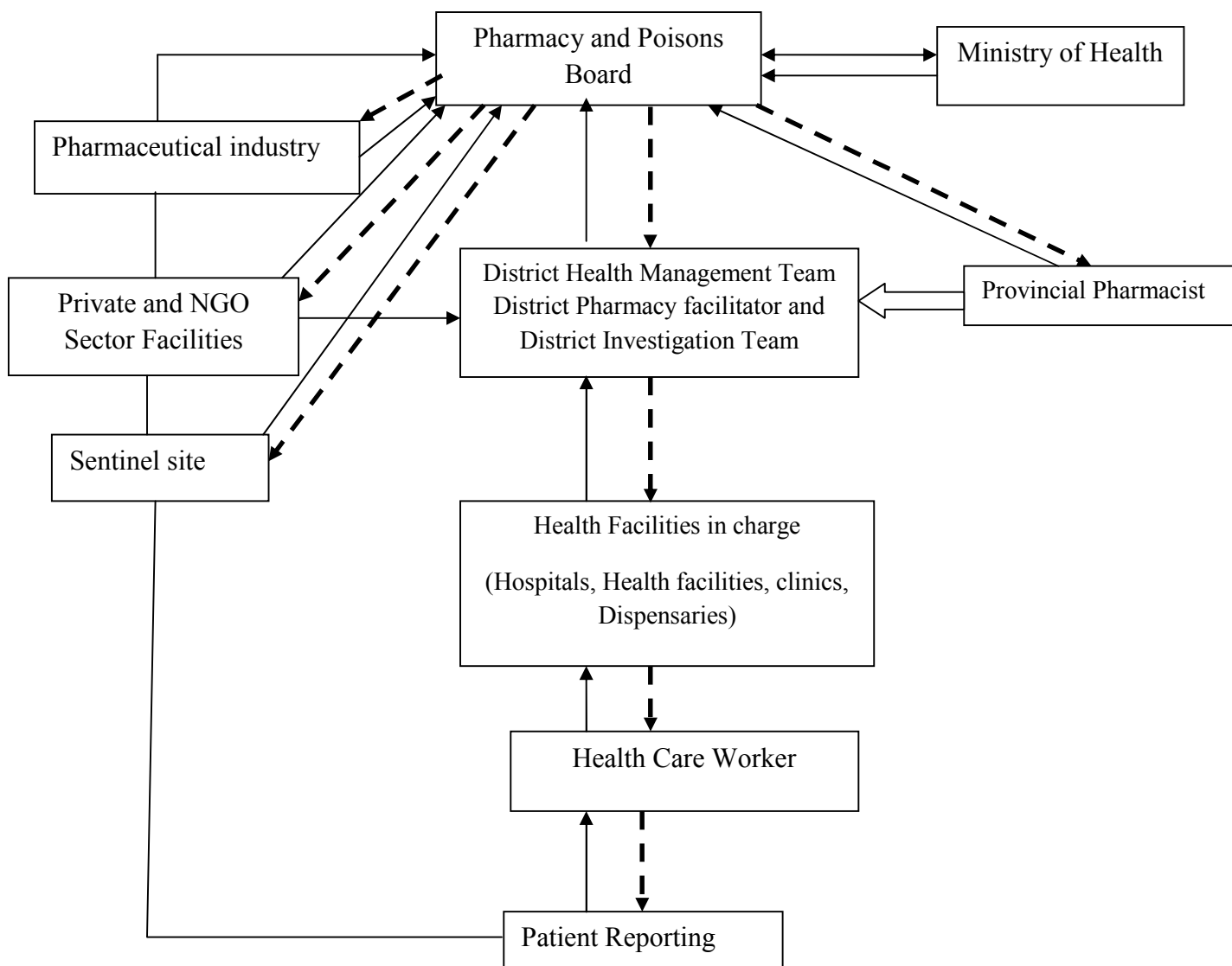
PPB reported that it had trained over 5000 healthcare workers on pharmacovigilance using the capacity building model in its August 2011 newsletter. The targeted healthcare workers were mainly from public healthcare facilities and some private hospitals. There were eleven Sentinel surveillance sites established to monitor suspected ADRs for antiretroviral drugs (PPB, 2011). The most notable achievement of the Kenyan pharmacovigilance program was carried out in September 2011 (Cohn, von Schoen-Angererb, Jambert, Arreghini and Childs, 2013). The PPB recalled more than 15,000 of batches of antiretroviral drugs called Zidolam-N® sold by Hetero Drugs Limited in India. The drugs were found to be a counterfeited version of WHO prequalified medicines and had been donated by Medicines Sans Frontiers (MSF) to a local nongovernmental organization. The irregularities such as discoloration,

moulding, and breakages were reported by patients and health workers to the PPB. The company was obligated to recall all the drugs that had been quarantined. The WHO issued a detailed statement in late September 2011 recommending that patients contact their treatment provider, highlighting that genuine Hetero products with the same batch number were also circulating, and that treatment regimens should not be stopped indiscriminately. This exercise revealed the loopholes in the supply chain management of pharmaceuticals in Kenya and recommendations for more stringent controls and regulations were made (Cohn, von Schoen-Angererb, Jambert, Arreghini and Childs, 2013).

On 23rd April 2013, the PPB launched the electronic pharmacovigilance system, where an application could be downloaded either on a computer or a smart phone from the PPB website. This was proposed to ease data collection, give prompt communication and act as a cost effective measure as opposed to physical distribution on pharmacovigilance forms. The PPB has organised various trainings for different stakeholders in the pharmaceutical industry (PPB, 2014).

In May 2013, 67 representatives of the pharmaceutical industry were trained in pharmacovigilance. In June 2013, 24 pharmaceutical inspectors were trained and equipped with tools for detection, surveillance and reporting of ADRs and poor quality drugs. The undergraduate pharmacy students at the University of Nairobi have started being trained in pharmacovigilance through day long sensitization trainings since October 2013(PPB, 2014).

The PPB also engages the public during various forums like the annual Agricultural Society of Kenya where it has a stand and through social media especially facebook. The two pharmaceutical professional societies in Kenya, the Pharmaceutical Society of Kenya (PSK) and the Kenya Pharmaceutical Association (KPA) also hold annual conferences where pharmacovigilance is usually highlighted (PPB, 2014).



KEY:

- > Flow of Information
- - - - -> Feedback
- > Co-ordination, Training and Monitoring

Figure 4.2: Flow of information in the Kenyan Pharmacovigilance System (PPB, 2009).

2.3 Training and community pharmacy personnel participation in pharmacovigilance

Pharmacovigilance as a core discipline should ideally be taught at the undergraduate level, postgraduate level and professional curricula for every medical, dental, pharmacy, nursing and other allied health disciplines. This early training would enable healthcare professionals to develop the pharmacovigilance culture earlier on in their careers. The WHO offers trainings on pharmacovigilance in conjunction with member states, mostly targeting health care professionals who have completed their basic academic qualifications (WHO, 2002). In many countries the knowledge of pharmacists about pharmacovigilance and ADR reporting is poor and the rate of reporting is low (Van Grootheest, Olsson, Couper and De Jong-van den Berg 2004).

The concept of the “seven-star pharmacist” was introduced by World Health Organization and taken up by International Pharmaceutical Federation in 2000 in its policy statement on Good Pharmacy Education Practice. The concept covered the roles of caregiver, decision-maker, communicator, manager, life-long learner, teacher, leader and researcher (WHO, 1997). As life-long learners and researchers, pharmaceutical personnel should learn how to update their knowledge and skills in addition to using evidence based therapy to promote rational drug use and safety.

According to Wafula , Miriti and Goodman (2012) developed nations like the United States, United Kingdom and Europe, have their community pharmacies run by qualified and registered pharmacists only. The situation is different in developing countries where most drug outlets are run by non-pharmaceutical personnel due to a shortage of pharmaceutical personnel. In Africa, there are specialised drug shops that are run by non-pharmaceutical personnel which provide access to affordable, quality medicines and pharmaceutical services in rural or semi-urban areas where there are few or no registered pharmacies (Wafula, Miriti and Goodman, 2012). Specialised drug shops exist in Kenya for provision of drugs of common ailments like malaria. Inman (1976) proposed a list of attitudes related to the causes of underreporting of ADRs by healthcare professionals described as the ‘seven deadly sins’ which were complacency, fear of litigation, guilt, ambition to publish for financial benefit, ignorance , diffidence and indifference.

A study carried out by Smith and Webly (2012) to investigate the level of pharmacovigilance education provided to pharmacy students on undergraduate pharmacy programmes in the

United Kingdom revealed that the amount of time dedicated to teaching pharmacovigilance was low.

All of the respondents taught pharmacovigilance within an assessed compulsory module. About 23% of the universities did not include pharmacovigilance law within their syllabus. In 54% of the universities, the amount of time devoted to teaching pharmacy students about their role in pharmacovigilance was less than 4 hours in the 4-year course. Only one respondent spent approximately 20 hours, the remaining 38% of the respondents spent between 4 and 8 hours. The report concluded that this could account for the low ADR reporting rate by pharmacists in the United Kingdom.

Van Grootheest, Mes and De Jong-Van Den Berg (2002) conducted a questionnaire survey among 200 community pharmacies in the Netherlands randomly selected from the Royal Dutch Society membership list. Only 22% of the respondents believed that all serious ADRs were detected before drug registration. All the respondents considered ADR reporting to be integral to their professional duties. About 82% viewed reporting as part of pharmaceutical care and an indication that they took patient complaints seriously. The need to certify the causality between the drug and the ADR before reporting and to discuss the report with general practitioners was cited by 55%. About 47% had discussed the reports with general practitioners in their local pharmacotherapy groups. The facilitating factors that encouraged ADR reporting were customized feedback from the pharmacovigilance centre reported by 53% and publications in journals cited by 39%. The overall findings of the study concluded that Dutch pharmacists had a positive attitude to ADR reporting and a high reporting rate which needed to be sustained.

Barriers to ADR reporting by pharmacists were identified by a Saudi Arabia study in Riyadh city by Bawazir (2006). These were a lack of knowledge about where and how to report ADRs reported by 68% of the 172 respondents and 62.8% cited unavailability of ADR reporting forms. About 41% of the respondents believed that all serious ADRs were already detected for a newly marketed drug. The need to be sure of the causality between the drug and the ADR before reporting was stated by 94.5% while 78.3% noted that there was need to discuss the report with the prescriber before reporting. The study concluded that educational efforts directed at community pharmacists, readily available and simplified reporting mechanisms and improved feedback to reporters was needed to stimulate pharmacists' participation in the ADR reporting program.

In the United States, the Food and Drug Administration (FDA) gives clear guidelines on how to report Adverse Drug Events (ADEs) through Med-Watch (Brewer and Colditz, 1999). The data gathered from ADE reports alerts the FDA about new hazards and may reveal unusual or rare drug risks that were not discovered through premarketing trials. Central analysis of ADE reports helps in identifying trends and hazards, facilitates learning and the prevention of future drug-related injuries (Leape, 2002). Reported ADEs also inform corrective action like withdrawal or restricted use of drugs designed to improve the safety of medication-use processes. According to a study by Gavaza, Brown, Lawson, Rascati, Wilson and Steinhardt (2011) done in Texas, United States, among the community pharmacies, there were knowledge gaps concerning ADE reporting to the FDA. Only 67.9% of the pharmacists surveyed had never reported ADEs to the FDA while 65.7% reported having inadequate knowledge about ADE reporting. The study results cited that a positive relationship between knowledge and past ADE reporting behaviour. The recommendations made by the study were targeted training and education of pharmacists on ADE reporting. It was also noted that pharmacy students should be targeted through education interventions since only 13.4% of third year students from nine colleges were aware of MedWatch. Only 4% of students demonstrated understanding associated with the MedWatch program thus experiential rotations, work experience and didactic courses were needed.

A study done by Shimwela (2011) in community pharmacies in Dar es Salaam, Tanzania, found that 58.3% of respondents reported lacked the knowledge on how to report, where to report and when to report as major barrier for ADRs reporting. 45.3% reported unavailability of reporting yellow forms as a barrier. Other barriers highlighted in the report were the distance to the Tanzania Food and Drugs Authority (TFDA) Offices, lack of motivation, reporting forms that were not user friendly and inadequate human resources to handle pharmacovigilance issues at pharmacies. Poor supervision and follow up by TFDA officials, lack of information and feedback from TFDA and lack of continuous education and patients' ignorance to reporting were also cited. The unknown system of reporting and security in business were also noted as reasons. The study revealed that 63.8% of respondents were not satisfied with their professional training with regard to ADRs reporting. 96.1% indicated willingness to attend further courses or trainings on pharmacovigilance in order to improve their ability to spontaneously report ADRs.

In Kenya, pharmacovigilance training is mostly undertaken by the Ministry of Health through the Pharmacy and Poisons Board (PPB) and development partners like the United States

Agency for International Development (USAID). The training is carried out targeting health care professionals in the public health care system leaving a wide knowledge gap in the private sector. According to the PPB Pharmacovigilance newsletter (November 2014), pharmacists accounted for 15 percent of the ADR reports received by the board. About 74 percent of the reports were received from consumers or other non-healthcare professionals. The pharmacists who reported were those from public and private health facilities that had benefited from PPB sponsored pharmacovigilance trainings.

Community pharmacies in Kenya are mostly run by pharmaceutical technologists, who undergo a 3 year diploma course in Pharmacy and are enrolled by the PPB after completing registration exams. The Private Sector Innovation Programme for Health (PSP4H) report in 2014 found that 31 % of the pharmaceutical personnel had been trained on disease specific areas such as malaria and HIV, 19% were trained on rational use of medicine and pharmacovigilance while 17% on procurement and supply management of commodities. Trainings were mainly sponsored non-governmental organizations (NGOs). The NGOs sponsored 54% for disease specific trainings, 63% for procurement training, 50% for pharmacovigilance and 54% for rational drug use training.

Irujo, Beitia, Bes-Rastrollo, Figueiras, Hern´andez-D´iaz and Lasheras (2007) conducted a case-control study among 802 community pharmacists in Navarra, Spain. Spain had enacted a Royal Decree 711/2002 that mandated all health professional to collaborate with the spontaneous reporting system for ADRs. The cases were 18 pharmacists who had reported at least two ADRs between 2003 and 2005. Random samples of 60 controls were selected from the 762 pharmacists who had not reported any ADR during the same period. The study indicated that increasing seniority and years of work experience as a pharmacist increased the probability of ADR reporting. Younger and inexperienced pharmacists tended to delegate ADR reporting to medical practitioners. Having participated in educational activities related to the detection and resolution of drug-related problems had a positive influence on ADR reporting. The habit of detecting ADRs as part of pharmacists' duties and having the basic knowledge needed to report ADRs were also positive factors in increased reporting. The most frequently mentioned reasons for not reporting ADRs were the ADR is not serious, the ADR is already known, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and a lack of time. The study recommended provision of appropriate education and training related to ADR reporting.

Elkami, Hassali and Ibrahim (2011) conducted a study among the 210 community pharmacies registered in Penang state in Malaysia. Only 42 community pharmacists agreed to take part in the cross sectional study which aimed at assessing the effectiveness of an educational program for improving pharmacist knowledge in ADR reporting. During the half day seminar that took place at the University Sains Malaysia in April 2009, the participants were given a pre-test to assess their baseline knowledge. A post-test was then carried out after the seminar to assess the effectiveness of the intervention. The results of the post-test showed that 37 participants, representing 88%, knew how to report ADRs to the relevant authorities, compared to 50% during the pre-test. The post-test further showed that 64 % of the pharmacists observed that it was easy to detect ADRs during their daily duties compared to 64% who had earlier stated that it was difficult in the pre-test. The need for information on ADR reporting was indicated by 90% of the participants after the education program and the simplification of ADR reporting was indicated by 64% compared to 48% in the pre-test.

About 70 percent of the participants agreed that ADR reporting was not widely promoted by the relevant authorities in Malaysia compared to 52 percent in the pre-test. All the 42 pharmacists felt that reporting ADRs was part of their pharmaceutical duties after the seminar compared to 31 pharmacists prior to the education program. The study showed that there was a low reporting rate of 9 percent among the participants. The pharmacists who had been involved in Continuous Pharmaceutical Development programs for more than 10 hours a year had higher reporting rates. All the study results indicated that there was need for provision of special practical training by the Malaysian Adverse Drug Reaction Advisory Committee.

Most of the studies reviewed indicated that under reporting of ADRs was the biggest challenge in spontaneous reporting systems. This was mainly due to the lack of or inadequate training in pharmacovigilance at the undergraduate level and during the professional careers even in developed countries. This was compounded by the fact that not all the community pharmacies in developing countries are run by pharmaceutical personnel.

2.4 Workload and community pharmacy personnel participation in pharmacovigilance

Workload measured as the number of prescriptions dispensed per hour or day or number of prescriptions per pharmacist has been shown to be positively associated with dispensing errors (Malone, Abarca, Skrepneck, Murphy, Armstrong, Grizzle, Rehfeld and Woosely, 2007). The workload in the community pharmacy varies according to the location of the pharmacy, availability of a wide range of medicines, patient knowledge on their medicines and complexity of the prescriptions. Community pharmacies are mostly run as business entities driven by profit motive rather than being health oriented. A study done in the United States by Chui and Mott (2003) categorized the perceived workload in community pharmacies into three. These are task related, job related and organization related workload demands.

Task related workload is derived from the individual activities a pharmacist performs as part of their job for example reviewing a patient profile. These tasks depend on the cognitive demands requiring concentration and mental effort, physical demands and temporal demands for example feeling rushed to meet targets. Job related workload is influenced by all the tasks the pharmacist must accomplish either on their own or by coordinating with their staff to get the work done. The ability of the pharmacist to react quickly to prevent adverse drug events or to keep track of more than one process at once falls in this category.

Organization related workload is influenced by organizational or managerial characteristics such as perceived quantity and skill of pharmaceutical personnel and perceived adequacy of the type and usefulness of pharmacy technology. The outcomes of the workload can be patient related for example patient satisfaction and safety and/or pharmacist related for example burnout, performance and job satisfaction. When perceived performance of tasks by the pharmacist is low chances of medication errors is high.

The workload of a pharmacist increases when the number of records to be maintained or the number of patients to be attended to increases. The Pharmacy Practice Activity Classification (PPAC) initiated by American Pharmacists Association, described the professional work standard for community pharmacists as ensuring appropriate therapy and outcomes, dispensing medication and devices, doing health promotion and disease prevention and giving contribution to health systems management (Wiedenmayer, Summers, Mackie, Gouse, Everard and Tromp 2006).

A postal survey was done in Tasmania, Australia by Peterson, Wu and Bergin (1999) among 419 registered pharmacists to identify factors that the pharmacists perceived to contribute to dispensing errors and to determine interventions which could be implemented. The other objectives were to provide an estimate of dispensing error rate in community pharmacy practice and to determine what the pharmacists believed to be a safe dispensing load for an average working day. Most pharmacists (82%) believed that the risk of dispensing errors was increasing due to high prescription volumes, pharmacist fatigue, overwork, interruptions in dispensing and similar or confusing drug names. The factors reducing the risk of dispensing errors were having mechanisms for checking dispensing procedures, a systematic dispensing workflow, improving labelling of drugs, distinctive drug names, improving doctors' handwriting, privacy when counselling patients, counselling patients at the time of supply, keeping one's knowledge up to date and reducing the workload. Majority (72%) stated that they were aware that dispensing errors had left the pharmacy undetected and cited 150 prescriptions per one pharmacist were the number that could be dispensed safely in a day. About 58 % noted that there was need for a regulatory guideline for safe dispensing load in Australia. The study concluded that there was an association between increased workload and more frequent dispensing errors.

Malone, Abarca, Skrepneck, Murphy, Armstrong, Grizzle, Rehfeld and Woosely (2007) conducted a postal survey among 18 community pharmacies located in different states in the United States. A total of 755 usable surveys were returned from 1st January 2003 to 31st March 2003. The pharmacies were requested to run standard software to check for potential drug-drug interactions (DDI), which are drugs that are not supposed to be dispensed simultaneously to the patients). The results of the study indicated that as pharmacists processed more prescriptions per hour, there was less time to evaluate DDI warnings. Low staffing and automation also increased the risk of dispensing DDIs thus causing medication errors. The increased prescription volume was found to be as a result of increased number of unique medications and number of elderly patients taking more medication per person. About 43% of the pharmacists cited increased workload contributed to additional medication errors and DDIs. Interruptions through telephone calls from physicians or patients and questions from pharmacy support personnel or in-store customers also increased the pharmacists' workload. The study concluded that excessive workload impacted negatively on the amount and quality of advice and service provision to patients, dispensing accuracy and acted as a barrier to practice change. The less the time spent doing patient counselling the more likely the likelihood that ADRs will go on unnoticed and unreported.

Alkhateeb, Attarabeen, Latif and Deliere (2015) conducted a study among community pharmacies in West Virginia to identify the pharmacists' perceptions of workload. A total of 596 responses were received out of 1970 mailed questionnaires between April and June 2011. The perceived impact of current workload on the job performance was reported by 35 percent as either negative or very negative. About 54% of participants reported not being able to spend adequate time with patients. Only 40% of participants cited either a negative or very negative impact of workload on the pharmaceutical care provided to patients. There was a negative impact of workload on the abilities of solving drug therapy problems reported by 40% of the respondents. Workload had a very negative impact on job satisfaction and on their abilities to prevent or reduce potential errors among 44% of participants. Only 59% of the participants reported a negative impact of workload on taking adequate breaks.

The situation in Kenya is not any different as most community pharmacies act as business entities rather than health care providers (Parmar, 2008). The numbers of records to be kept according to the PPB Good Dispensing Practices are prescription ledgers and records of stocks including the batch numbers and the expiry dates (PPB, 2006). A health management system consisting of patient profile cards whether computerized or an adequate manual recording system is also a requirement. In practice this does not happen as not all community pharmacies are computerised and most do not have the adequate space to maintain manual records.

According to Cohen (1999), the workload would further be increased by reduced patient understanding of their medication and the complex nature of the prescription in terms of the number of drugs prescribed. When patients cannot distinguish their medications, getting the patients' past medical history can be challenging. Patients heavily rely on health care providers to receive drug information thus increasing the workload for health care professionals (Cohen, 1999). The level of training determines the ability of the pharmaceutical personnel to identify and document ADRs caused by the medication and provide proper counselling.

The research sought to establish other factors that increase the workload on the pharmaceutical personnel and cause them not to report ADRs and poor quality drugs. The pharmacovigilance reporting tools can be cumbersome to fill especially if the pharmaceutical personnel are not adequately trained in filling the forms.

2.5 Counterfeits in the pharmaceutical supply chain and community pharmacy personnel participation in pharmacovigilance

WHO (1999) defines a counterfeit pharmaceutical product as a product that is deliberately and fraudulently mislabelled with respect to identity and/or source. The definition applies to both branded and generic products. According to WHO definition, counterfeit products may include products with correct ingredients, wrong ingredients, without active ingredients, with the incorrect quantity of active ingredient or with fake packaging (WHO, 1999).

Estimates from the WHO show that of the 1 million malaria deaths that occur in Africa each year, 200,000 are the result of counterfeit anti-malarial drugs (WHO, 2003). Harris, Stevens and Morris (2009) state that counterfeit drugs for tuberculosis and malaria kill 700,000 people every year in Africa. The percentage of counterfeit drugs in Africa, parts of Asia and Latin America is between 20 to 30%. North America, parts of Europe and Australia have less than 1% of counterfeit drugs. Medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases.

The reasons that encourage counterfeiting according to the World Health Organisation (2003) are lack of political will, strong national medicines authority and appropriate medicine legislation and weak enforcement including corruption and conflict of interest. Other reasons include shortage or erratic supply of medicines and their inappropriate use, price differentials, inefficient co-operation between stake holders, lack of control over export medicines, trade through several intermediaries and free-trade zones/free ports.

There are three levels in most pharmaceutical supply chains in both the public and private healthcare sectors. These are manufacturers, distributors or wholesalers and retailers. Community pharmacies act as retailers and get their pharmaceutical supplies from distributors or wholesalers. In developed countries like the United States, Europe and Japan, a few large firms control the national wholesale market, while in developing countries hundreds of companies control tiny shares of the wholesale market (Yadav and Smith, 2012). Developing countries have weak fragmented regulatory structures, ill-defined laws and poor ability to enforce regulations unlike developed countries. It was also noted that retail drug shops act as the first point of healthcare contact for many patients and the balance of power was tilted toward the manufacturer leaving patients with little bargaining power.

Manufacturers world over are required by law to enact track and trace systems to know where the products are at any time and follow them down the distribution chain (Altkunkan,

Yasemin, Aykac and Akpinar, 2012). They are also required to do post marketing surveillance, file a Periodic Safety Update Report (PSUR) to national drug regulatory authorities and carry out Good Manufacturing Practices. A PSUR is a mechanism by which a company may summarise and evaluate medicinal products safety data for a particular interval time in a standardised manner for submission to medicines regulatory authorities. Manufacturers are also required by law to register all the drugs they manufacture in each and every country the drugs are distributed in. The drug registration number is also required to be printed on the product's container and/or label. All these mechanisms aid in stepping up pharmacovigilance efforts in terms of ADRs and poor quality drugs detection.

According to Yadav (2009), the distributors or wholesalers usually have written contracts with the manufacturers to purchase pharmaceutical products from them for the purposes of distribution to retailers. The national drug regulatory bodies usually require the distributors to have adequate storage conditions and product tracing capabilities before licensing them to operate in the country. In the United States there are primary and secondary wholesalers. There are three major national wholesalers, a few regional wholesalers, and thousands of secondary wholesalers. Secondary wholesalers are the weakest point in the pharmaceutical distribution chain as they choose stock based on demand forecasts, price, margin, and their customers' willingness to pay (Yadav, 2009).

Community pharmacies handle the bulk of the medicines circulating in the country therefore the pharmaceutical personnel are better placed to carry out pharmacovigilance in terms of reporting poor quality medicines (Van Grootheest, Olsson, Couper and De Jong-van den Berg 2004). There are many pharmaceutical distributors who supply community pharmacies with medicines from various countries of origin. Very few distributors have the capacity to carry out quality assurance tests on the imported medicines (SPS, 2009). Limiting the number of suppliers may be advantageous to community pharmacies as a measure of ensuring quality supply of medicines. Purchasing their supplies from local manufacturing companies may also increase pharmacovigilance as local companies are regularly inspected by the PPB (SPS, 2009). It may also not be easy for community pharmacies to monitor counterfeits as they don't stock bulk quantities of the same drug, unlike in public health facilities. A pharmacovigilance report on Sub Saharan African (SSA) countries noted that the WHO prequalification of Medicines Program did not guarantee the quality of medicines procured from listed suppliers especially when there was no adequate supply chain management in place (SPS, 2011). The report noted that spontaneous reporting systems were beneficial in

empowering health workers and consumers to report drugs of suspected quality as successful product recalls were recorded in Kenya.

In Kenya the distribution of pharmaceutical distributors and wholesalers is highly skewed in favour of major towns, resulting in excessive competition for the pool of retailers (Barnes, O'Hanlon, Feeley, McKeon, Gitonga, and Decker, 2009). There are blurred boundaries between the different levels, with some distributors and wholesalers engaging in directly retail business. This has contributed to low quality of services through parallel importation at the retail level and pilfering medicines from the public sector (Wafula, Abuya, Amin and Goodman 2013). The excessive fragmentation has also been linked to reduced economies of scale, resulting in poor supply of medicines to retailers operating away from major towns. The retailers are the final level of the pharmaceutical supply chain that has a direct link to the patient. In developed countries only pharmacists can own and operate community pharmacies due to the high supply of pharmacists. In developing countries non pharmaceutical personnel are allowed to operate community pharmacies (Wafula, Miriti and Goodman 2012). In both cases the community pharmacies need to be licensed by the national drug regulatory bodies.

Odili, Osemwenkha, Eke and Okeri (2006) conducted a descriptive study among community pharmacists practicing in Lagos State, Nigeria to assess the methods of identification of counterfeit drugs. All the 69 respondents agreed that there was a fake and counterfeit drug problem in Nigeria, and 74% considered drug counterfeiting a major problem. Only 26 percent thought it was moderate. About 86% of the respondents procured their drug products personally, while 14.5% were not personally involved in drug procurement. The commonly used visual security techniques before drug purchasing were Seals or embossments cited by 83%, character of print noted by 77% and Holograms used by 68%. The respondents' most likely action after a counterfeit drug encounter was to return the drug back to the supplier noted by 65.2%. About 50.7% stated that they reported to professional bodies while only 18.8% reported to the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC). About 61% of the respondents had experienced stocking some counterfeit products in their premises. Detection of fake drugs by use of regulatory markings on drug packaging was done with 83% of the respondents checking for NAFDAC registration numbers while manufacturers' name/address was checked by 71%. The expiry/date of manufacture of drug was checked by 69% of respondents while 39% checked for batch number. The study showed that there was a high awareness of counterfeit drugs by the community pharmacists but a low reporting rate to national drug regulator.

According to Kibwage, (2008) the earliest counterfeit medicines encountered in Kenya were skin preparations, driven by the high level of abuse by women who used them as skin lighteners. He also observed that the most frequently counterfeited medicines in developed countries were expensive lifestyle medicines such as hormones, analgesics, antibiotics, steroids and antihistamines. Anti-malarial drugs, antiretroviral drugs, anti-cancer and anti-viral, antibiotics were among the most counterfeited drugs found in developing countries like Kenya. Kibwage also noted that there was no systematic way of identifying counterfeit drugs in Kenya but that counterfeits were encountered during the course of quality control tests by the NQCL and after reports of poor efficacy or observation by consumers and healthcare professionals. His study concluded that that marketing surveillance was low due to corruption, lack of adequate personnel for inspection, poorly equipped and understaffed quality control facilities and non- deterrent sanctions.

In August 2008, a knowledge, attitude and practice study was performed in a national sample of 794 pharmacists who participated in an Iranian Pharmacist Association congress by Shahverdi, Hajimiri, Pourmalek, Torkamandi, Gholami, Hanafi, Shahmirzadi and Javadi (2012). There were questions about supply counterfeit drugs in the exceptional circumstances and 69.4% of participants approved selling counterfeit drugs which are the same in packaging with the brand ones. About 53.5% believed it was fine to provide medication from unregistered suppliers in case of a drug shortage while 72.8% stated that it was fine to dispense counterfeit drugs with no significant therapeutic effect. Only 69.4% reported to agree to use counterfeit drugs which were packed differently from the original ones in exceptional cases. About 28% of the respondents did not blame pharmacist for adverse drug events due to use of counterfeit drugs while 36.9% believed that more than 50% of community pharmacies countrywide were dispensing counterfeit drugs. Only 4% of the participants believed that educational programs could provide pharmacists with enough knowledge to prevent dispensing of counterfeit drugs. About 18.3% cited that individual pharmacists' intervention can prevent dispensing of counterfeit drugs. Exchanging counterfeit drug with suppliers and not informing the authorities about this practice was reported by 54.5% of the community pharmacists. Only 10.08% stated that they had attended special training courses about identifying counterfeit drugs. The study concluded that there was need for training of pharmacists on how to identify and report counterfeits to the relevant authorities. It also identified that lack of legislation and regulatory control had led to the supply and distribution of counterfeits.

Khan, Akazawa, Dararath, Kiet, Sovannarith, Nivanna, Yoshida and Kimura (2011) conducted a cross sectional study among managing executives of 62 registered pharmaceutical wholesalers in Cambodia in 2009 on their knowledge of, perception on, and practices related to counterfeiting issues through a semi-structured questionnaire. Only 27% of the managers and 8% were doctors. About 12.9% of the wholesalers had encountered counterfeit medicines. A majority of 59.7% defined counterfeit medicines as medicines without registration, while 56.5% believed that counterfeit medicines were fraudulently manufactured. About 27.4% of the respondents defined counterfeit medicines as medicines without a batch/lot number while 19.4% those containing harmful ingredients or a reduced amount of active ingredients. Only 8.1% responded that they did not know what counterfeit medicines were. During procurement, 66.1% of the wholesalers considered whether the product is registered in Cambodia, while 64.5% considered the credibility and quality of the products. About 61.3% considered the reputation of the manufacturers. When receiving a consignment, 80.6% of wholesalers checked the intactness of medicines and 72.6% checked the specification and amount of medicines. Around 71% of the participants checked the Cambodian registration number, 56.5% checked that the packaging was intact and 54.8 % checked batch and lot numbers. Participants who checked the dates of manufacture and expiration were 48.4% and 9.7% checked analytical certificates. Out of 62 wholesalers, 14.5% had received medicines that arrived without packages or were separated from their packaging and had to be repacked before distribution. The study recommended that information-sharing components in the form of advocacy workshops or meetings needed be arranged on a regular basis to strengthen the regulatory systems. It was also noted that distributors and wholesalers needed orientation and sensitization on countermeasures against counterfeit medicines to protect against the intrusion of counterfeit medicines into the pharmaceutical supply chain.

A study was undertaken in Khartoum and Gadaref in Sudan by Alfadl, Hassali and Ibrahim (2013) in June 2010 to seek the perceptions of policy makers and community pharmacists on counterfeit drug demand. Six policy makers and five community pharmacists were interviewed on their understanding of counterfeit drugs and their awareness of the presence of counterfeit drugs in the Sudanese market. All the respondents were well versed on the definition and had encountered counterfeit drugs in their professional practice. They all agreed that the major factor that made consumers vulnerable to counterfeit drugs was the unaffordable prices of legitimate drugs and lack of knowledge on the side effects of counterfeit drugs. Most of the participants believed that Sudanese consumers linked high

price of medicines to high quality and vice versa. It was noted all the respondents believed that consumers and pharmacists had low awareness of societal consequences of purchasing counterfeit medicines. All interviewees believed that people with high economic status and were educated (in some cases) tended to be less vulnerable to counterfeit drugs than poor people and the uneducated. The respondents all stated that the consumers and healthcare professionals had little or no knowledge on counterfeit drugs. All the participants agreed that sensitization and education was needed on a large scale in Sudan among all stakeholders.

A descriptive, cross-sectional, questionnaire study was conducted in September 2014 by Nagaraj, Tambi, Biswas, Ganta, Kumawat, and Mathur (2015) among 100 medical practitioners, 100 dentists and 100 pharmaceutical wholesalers in Jaipur in India. The aim of the study was to assess the knowledge, attitude and practice of the participants towards counterfeit drugs. The results showed that only 22 percent of the participants knew about counterfeit drugs. 71 percent of the participants believed that unregistered pharmacies were the most common source of procuring these drugs. Only 36 percent of the participants stated that they could not distinguish between genuine and fake drugs. Around 66 percent of the participants had never come across a counterfeit drug in their professional life. 81 percent of the participants stated that they warned the patients not to buy medicines from unknown sources, which reflected their practice behaviours. The study concluded that none of the pharmaceutical wholesalers had knowledge about the drug testing laboratories in India and some did not have an authorized degree.

There was an observation that increasing age resulted in improvement of the attitude attributed to the fact that as older individuals felt ethically stronger and more responsible for the society. The pharmaceutical wholesalers were less aware of the threats posed by counterfeit medicines to patients' health as compared to the doctors, thus they preferred the use of counterfeit drugs in cases of shortage. However, the pharmaceutical wholesalers were found to exhibit best practice behaviours in reporting counterfeits to drug authorities among the study participants. Overall it was noted that there was need for designing and implementing continuing educational programs among all the cadres on identification and reporting of counterfeit drugs. The study findings recommended the need for enforcement of vigilant laws on the unauthorized pharmaceutical wholesalers.

The ability of community pharmacy personnel to detect and report counterfeits to national drug regulators greatly influences pharmacovigilance activities. The PPB offers the e-shot warning system to send out pharmacovigilance alerts on quarantined medicines and maintains

an updated list of registered drugs on its website. The study seeks to establish the knowledge, perceptions and practices of community pharmacies located in Embu town regarding counterfeit medicines.

2.6 Pharmaceutical care and community pharmacy personnel participation in pharmacovigilance

Pharmaceutical care was defined by Hepler and Strand (1990) as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It involves the recognition, solving, and prevention of problems associated with the use of medicinal products, as well as the provision of information necessary for patient safety. The essential elements of pharmaceutical care are involving patients in their own care by offering an option to discuss health and drug-related issues with the pharmacist and screening patient medication records stored in a pharmacy to find patients who would benefit from a discussion with the pharmacist. Helping patients achieve their individual treatment goals and developing and maintaining a positive relationship with the patient's physician for all three stakeholders (patient, patient's physician, and pharmacist) to be equally involved in the patient's treatment are also elements.

According to Cipolle, Strand and Morley (1998), there is a difference between dispensing pharmacy and pharmaceutical care in a community pharmacy setting. Dispensing pharmacy is a product business where the inventory generates revenue; spaces are organized to display and sell products, documentation is done to meet legal requirements and decisions focus on the business. Pharmaceutical care entails a service business where patient care generates revenue; spaces are organized to meet patient's need, documentation supports patient care and decisions focus on the patient. Therefore pharmaceutical care allows for scheduled follow up of patients determined by risk and benefit of drug therapies and needs of the patient, which is a core element of pharmacovigilance.

Odedina and Segal (1996) conducted a study to develop and validate a behavioural pharmaceutical care scale (BPCS) for measuring pharmacists' efforts towards providing pharmaceutical care. In October 1993, 793 BPCS booklets were mailed to randomly selected community pharmacies in Florida, United States of America. The BPCS had 14 domains which were Documentation, Patient assessment, Implementation of therapeutic objectives and monitoring plans, Patient advising and counselling, Patient record screening, Verification of patient understanding, Referral and consultation, Counselling location, Filled prescription validation, Informational support, Evaluation of patient satisfaction, Competency

improvement, Performance evaluation and Provision of medical information. The BPCS was found to be a reliable, valid and sensitive tool that could be used for the provision of pharmaceutical care as it provided detailed information on each step involved. The documentation and patient counselling could be used as essential patient centred elements in reporting of suspected ADRs.

The International Pharmaceutical Federation (FIP) did a survey in 1997 on aspects of pharmacy practice in 30 countries using questionnaires (Mil, 2000). The results were used to establish the FIP database. There were 20 countries from Europe, Japan and Korea from East Asia, Canada and United States from North America. African countries in the survey were Eritrea, Ghana, Kenya, Nigeria and Zimbabwe while Australia represented the fifth continent. Several factors viewed as barriers to achieving pharmaceutical care were investigated.

The primary factors under investigation were the workload of pharmaceutical personnel, the available space in the pharmacy for private patient consultation and the financial situation of the pharmacies. The results indicated that Kenya, Nigeria, the Netherlands and Australia had a low number of customers per pharmaceutical personnel compared to Eritrea, Sweden and Hungary. Pharmacies in Eritrea, Ghana, Italy, Korea and Kenya were found to have less space on average per customer. Iceland, Norway and the USA pharmacies had lower operating costs and higher annual turnover. The secondary factors included the education levels of pharmaceutical personnel and the proportion of patients visiting the same pharmacy which indicates the possibility of continuity of care. The presence of computerised medical records for ease of drug use review and the quality of the relationships with physicians to enable exchange of information and change of therapy were also investigated. The last secondary factor was the level of communication skills.

The survey noted that only Zimbabwe and Australia had 3 years university education. The rest had 4- 6 years. Kenya and Ghana reported a 5 percent probability of patients visiting the same pharmacy. Croatia and Eritrea had the highest with 30 percent. All pharmacies in Australia, Canada and Netherlands had computerised medication records and carried out routine medical surveillance for suspected ADRs. Only 11 countries (excluding Kenya) taught communication skills in undergraduate pharmacy courses. Tertiary factors under consideration were the possibility to perform clinical laboratory tests in the pharmacy, customised labelling of drugs and delivering patient information leaflets to strengthen patient counselling. Pharmacies in Australia, United Kingdom, Kenya, Netherlands, Switzerland and

the United States performed blood tests. About 72 percent of the countries (including Kenya) labelled drugs while dispensing. Only 56 percent delivered patient information leaflets.

Strand, Cipolle and Morley (1992) used the term pharmaceutical services to represent all the services that pharmacists require to resolve a patient's drug therapy problems. These services ranged from the provision of medicines information to patient counselling to medicines distribution. An 8-month observational study was conducted in Kampala, Uganda by Anyama and Adome (2003) in two pharmacies from December 2001 to July 2002. There were 567 client observations collected from the two pharmacies. The pharmaceutical care seeking patterns observed in the study were that 14.7 percent of the patients visited the community pharmacies to fill prescriptions. About 28.8 percent of patients visited to receive treatment recommended by the pharmaceutical care provider after presentation of complaints, while 56.5 percent of patients made verbal requests for drugs or related products with the intention to self-medicate. About 32.3 percent of non-patient clients who were third party patients seeking pharmaceutical services. This indicated that there was inadequate direct-to-patient medication use counselling. The study results implied that there was need to increase the involvement of community pharmacy staff in pharmaceutical care and educational interventions were necessary to improve drug use practices. It was also noted that there was need to strengthen referral systems from community pharmacies and formulation of evidence based interventions.

A national survey was conducted in Nigeria among 1500 pharmacists in hospital, pharmaceutical industry and community pharmacy settings by Oparah and Eferakeya (2005) between November 2001 and October 2002. The aim of the study was to explore Nigerian pharmacists' attitudes towards pharmaceutical care, and determine significant attitudinal differences in different practice settings. There was a response rate of 67 percent where 76 percent of the 1005 respondents indicated willingness to embrace pharmaceutical care. About 96 percent of the pharmacists believed pharmaceutical care would enhance patients' appreciation of the pharmacist. About 84 percent reported their intention to practice pharmaceutical care even if there is no additional income. A majority of 93 percent said that they would participate in any training program to enable them to practice pharmaceutical care while 20 percent claimed their pharmacy layout was suited for patient-centered practice. About 75 percent of the respondents indicated a positive attitude towards pharmaceutical care. The study has showed that the attitudes of Nigerian pharmacists towards pharmaceutical care were favourably high irrespective of the practice settings. The pharmacists expressed

willingness to implement pharmaceutical care, participate in educational interventions to increase their knowledge, skills and improve their pharmacy layouts.

An assessment of community pharmacists' attitudes towards professional practice in the Republic of Moldova was carried out by Cordina, Safta, Ciobanu and Sautenkova (2008) through a questionnaire mailed to 600 community pharmacies. The data was gathered over a 3 month period between December 2006 and February 2007. A response rate of 61.7 percent was achieved and the respondents assigned higher scores to activities relating to pharmacy management and dispensing, which were activities associated with the more traditional functions of pharmacists. Such activities included ensuring that the pharmacy was well supplied with medicines, ensuring that the medicines were of good quality and explaining to the patient how to take the medication and for how long. The questions relating to pharmaceutical care activities relating to keeping patient records and monitoring patient's progress after dispensing the scores had lower scores. The study concluded that the respondents were not fully convinced that pharmaceutical care activities were the responsibility of the pharmacist and did not accept the concept of the pharmacist as a provider of patient care. There were very few cases reported of establishment of professional relationship with doctors to enable joint therapeutic management of patient. Consulting with other pharmacists about specific patient problems and establishing communication with other healthcare professionals or agencies to refer patients with social problems was also strained and lacking. The study concluded that the pharmacists in Moldova appeared deeply rooted in the traditional approach of pharmacy practice but the younger pharmacists were embracing new trends in pharmaceutical care.

A cross sectional study was carried out in 486 community pharmacies in four Brazilian cities (Reis, Guidoni, Giroto, Rascado, Mastroianni, Cruciol and Pereira, 2015). Only 112 pharmacists participated with 41 percent correctly identifying the concept of pharmaceutical care. About 70.5 percent performed it in their pharmacies and only 40 percent were trained in pharmaceutical care. Those pharmacists who recognised that pharmaceutical care should be documented were 80 percent. The biggest obstacles to pharmaceutical care were noted as lack of space for private counselling at 53.6 percent and 14 percent cited lack of research materials like books and computers. Brazil had developed the Brazilian Pharmaceutical Care Consensus in 2002 to act as standard operating procedures for pharmacist.

Patients' choice of pharmacy depends on location of the pharmacy (i.e. accessibility), fast service, friendly staff, appearance of the pharmacy, good range of products and services, convenient opening hours and pharmacists' professional knowledge (Wirth, Tabone, Azzopardi, Gauci, Zarb-Adami and Serracino-Inglott , 2010). The opportunity to discuss health issues in private consultation and the prices of the drugs are also considerations. In Kenya, not all community pharmacies take patient history or retain prescriptions, although this is a legal requirement by PPB. This makes it harder for pharmaceutical personnel to follow up patients. Some community pharmacies do offer consultation services and maintain a relationship with physicians therefore establishing patient loyalty.

The study seeks to investigate whether pharmaceutical care is carried out in community pharmacies in Embu County and to what extent it has contributed to the pharmacovigilance activities.

2.7 Theoretical Framework

The Oakland Theory of Total Quality Management (TQM) as defined by John Oakland in 1989 states that TQM is an approach to improve competitiveness efficiently and flexibility for the whole organization. TQM is a comprehensive, organization-wide effort to improve the quality of products and services, applicable to all organizations. Oakland developed two models of TQM which are the Oakland model of TQM in 1989 and the 4P's and 3C's model in 2004. Both models proposed hard and soft components of TQM. The hard components were a documented quality management system, quality management tools and techniques, teamwork, people, process, planning and performance. The soft components were a participation culture, communication networks and commitment (Oakland, 1995).

The pharmacovigilance system tends to build on the Genichi Taguchi definition of quality in 1979 where he stated that quality is the loss a product causes to society after being distributed to the customer. The loss may be incurred as a result of either variability of product functions or harmful side effects that occur when the producer's actions result in uncompensated loss to others. In the case of medicines, any ADR or discrepancy in medicine quality causing morbidity or mortality of patients makes those medicines be defined as poor quality drugs which are unfit for human use. The pharmacovigilance framework comprises of people, structures and processes to ensure Total Quality Management of any healthcare system in terms of protection of public health and regulation of the pharmaceutical industry. Pharmacovigilance therefore utilises the soft and hard components of TQM to achieve its aims and overcome the challenges associated with implementation of pharmacovigilance.

Quality management systems create consistency that ensures that quality is guaranteed at right from the start of the production process, every time and in all departments of the organisation. The systems require constant reviews and audits to maintain the consistency. The use of quality tools and techniques is necessary to attain the highest levels of TQM in any organisations. In pharmacovigilance the pharmaceutical industries are expected to adhere to Good Manufacturing Practices (GMP) as formulated by the national drug regulators in which their medicines are produced and marketed. Quality control and Quality assurance tests are also carried out and documented for every medicine produced. Distributors (wholesalers) and retailers (community pharmacies) are also expected to keep records to ensure batch tracing of all the medicines as stipulated in the Good Distribution Practices of the country. This is done to ensure that the drugs produced are of high quality thus reducing the health risks to the end users. The national drug regulators are expected to maintain an Adverse Drug Reactions Database and develop data collection tools which should be easily available to all stakeholders for reporting. Policies and guidelines pertaining to pharmacovigilance are also the responsibility of the national drug regulators. Community pharmacies could ideally provide the largest source of data of suspected ADRs, medication errors and poor quality medicines for national drug regulators. This is due to the high number of patients and medicines that these establishments handle at any given time.

Teamwork can be used in problem solving as an economic and quick tool in decision making. Oakland noted that during teamwork problems were exposed to a greater diversity of knowledge, skill and experience. There is also a boost in morale, an increase in the variety of problems tackled and more team recommendations were more likely to be implemented. In pharmacovigilance teamwork is achieved when healthcare professionals, consumers and the general public use spontaneous reporting to forward reports on suspected ADRs and poor drug quality issues to national drug regulators.

The customer supplier chain reflects the process of ownership, management and improvement throughout the organisation. There are external and internal customers in any organisation. The internal customers are the employees of the organisation and contribute to the quality of the final product or service being offered. The external customers are the end users of the products. In pharmacovigilance national drug regulators need to work in partnership with the manufacturers, distributors and retailers to ensure the medicines produced comply with the set standards. Community pharmacies are the largest internal

customers in the pharmaceutical distribution chain and they would therefore provide feedback to both the manufacturers and drug regulators about the drug quality and ADRs.

Planning entails the development and deployment of policies and strategies; the setting up of partnerships and resources and designing in quality. One of the components of a pharmacovigilance system is having policies, laws and regulations to govern pharmacovigilance activities. Enforcement of these laws can be done in the form of monetary penalties or withdrawal of medicines from the pharmaceutical market. Performance involves establishment of a performance measurement yardstick for the organisation, carrying out regular audits and reviews and benchmarking the organization with others. The World Health Organisation encourages its member states to share drug safety information through its Vigibase database.

A process entails gaining an understanding of the activities and events in the organisation, quality management systems and continuous improvement efforts. Training of healthcare professionals in pharmacovigilance enables them to increase the quality and frequency of reporting. Under reporting is the biggest challenge to pharmacovigilance system. People entail the management of human resources, culture, teamwork, communication systems and networks, innovation, training and learning. The pharmacovigilance framework seeks to involve healthcare professionals, patients, media and policy makers as partners in the pharmacovigilance process.

Top management commitment was seen to provide a culture that respects the individual and fosters creativity. The managers provide employees with an understanding of why quality is important, set achievable standards and provide training on quality. The managers of the national drug regulators and pharmaceutical industries need to work in partnership with politicians and policy makers to ensure pharmacovigilance activities take place according to the set policies and laws. This ensures that there is political will to ensure the high quality of medicines produced. Managers in the pharmaceutical wholesale and retail sectors also need to create opportunities for all their employees to get pharmacovigilance awareness and training.

Communication and commitment also build a culture of trust and interdependence as everyone in the organisation feels responsible for ensuring the quality of products and services provided by the organisation. Organizational culture is a pattern of shared beliefs and values, shared meaning, shared understanding and shared sense making (Morgan 1986).

Schein (1985) defined it as the pattern of basic assumptions that a given group has invented, discovered, or developed in learning to cope with its problems of external adaptation and internal integration, and that have worked well enough to be considered valid, and, therefore to be taught to new members as the correct way to perceive, think, and feel in relation to those problems. A culture of pharmacovigilance can be fostered through development of the curriculum to entrench pharmacovigilance in healthcare professional training period. On job training is also crucial in initiating new qualified personnel into the activities.

2.8 Conceptual framework

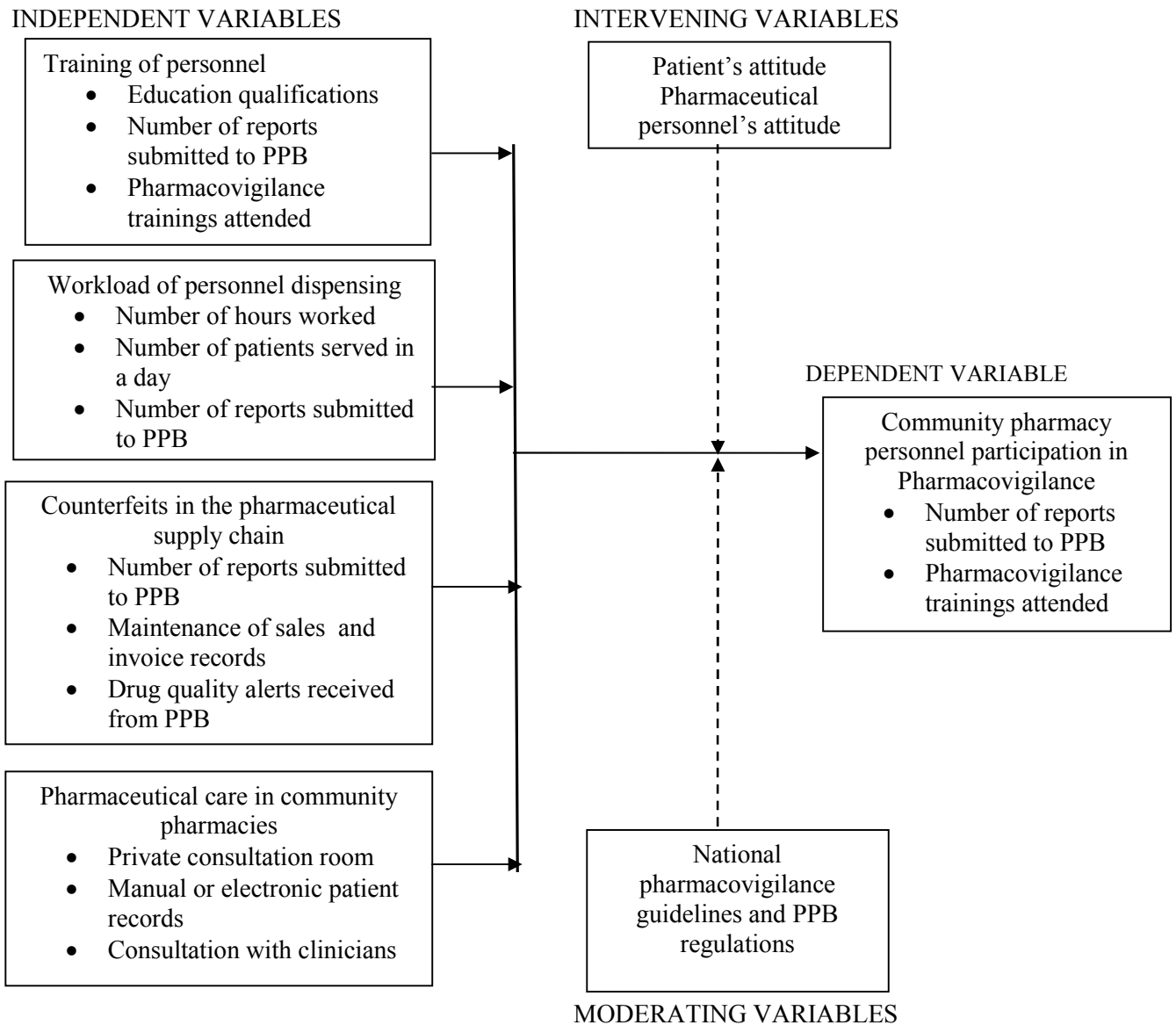


Figure 4.3: Conceptual framework

2.9 Summary of Literature review

The chapter has covered several available global and Kenyan studies relating to pharmacovigilance among community pharmacies in relation to the study variables of training and workload of community pharmacy personnel, the influx of counterfeit drugs in the pharmaceutical supply chain and pharmaceutical care among community pharmacy. Most of the studies concluded that there was need for training and enforcement of regulations to ensure participation of community pharmacy personnel in pharmacovigilance.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter contains the research design, target population, sample size and sampling procedures. Research instruments, methods of data collection, methods of data analysis operational definition of variables and ethical considerations are covered.

3.2 Research Design

The design for the study was a descriptive survey design. Kothari (2004) defines descriptive research as the description of the state of affairs as it exists at present. A survey is an attempt to collect data from members of a population in order to determine the current status of that population with respect to one or more variables (Gay, 1981). A survey design is therefore a self-report study which requires the collection of quantifiable information from the sample for statistical analysis. It was suitable for the study because it sought to obtain information by asking individual respondents about their perceptions, attitudes, behaviours or values about the existing pharmacovigilance system. The information collected was used to explain the current level of participation in pharmacovigilance among community pharmacy personnel in Embu County.

3.3 Target Population

The target population is the population to which a researcher wants to generalize the results of a study (Mugenda and Mugenda, 2003). The pharmaceutical personnel, who comprised of pharmacists and pharmaceutical technologists, working in the community pharmacies in Embu County and one key informant, a Pharmacy and Poisons Board inspector based in Embu County, were the targets of the study. There are 60 registered community pharmacies operating in Embu County with only 5 being owned by pharmacists and the other 55 owned by pharmaceutical technologists. Therefore 5 pharmacists and 55 pharmaceutical technologists were the respondents of the study. The community pharmacies chosen were stand-alone facilities which offered outpatient services and were registered by the Pharmacy and Poisons Board (PPB). They were superintended by a registered pharmacist or pharmaceutical technologist for at least ninety percent of the time. Community pharmacies

attached to private hospitals that neither offered outpatient services to walk-in patients nor dispensed prescriptions from other facilities were excluded from the study.

3.4 Sample size and Sampling procedure

The census method was adopted due to the small size of the target population, to provide detailed information on the study objectives and was suitable for the heterogeneity of the target population (Mugenda and Mugenda, 2003). The census method refers to complete enumeration of a universe which may be a specific group of people or a locality to collect data. The total population pharmaceutical personnel working within Embu County was selected consisting of 55 pharmaceutical technologists, 5 pharmacists and one key informant.

3.5 Data Collection instruments

Two questionnaires were administered to the target population. A questionnaire consists of a number of questions printed or typed in a definite order on a form or set of forms (Kothari, 2004). The community pharmacy personnel questionnaire was divided into five sections. The first section comprised of demographic information, the other four sections contained questions that sought to establish information based on the objectives of the study. A combination of structured questions was used to collect quantitative data and unstructured questions to collect qualitative data from the respondents. This allowed easier administration of the questionnaire and analysis of the data. It also enabled the respondents to give insight into their feelings, backgrounds, hidden motivations, interests and decisions (Mugenda and Mugenda, 2003). Contingency questions were employed to simplify the respondents' tasks such that irrelevant questions are not answered. Some matrix questions were included for ease of completion of the questionnaire and comparison of responses.

3.5.1 Pilot testing of the instrument

A questionnaire needs to be pretested to a selected sample which is similar to the actual sample under study and using identical data collection procedures (Mugenda and Mugenda, 2003). The pre-test sample should be between 1 and 10 percent of the sample size. The questionnaire was administered to 20 community pharmacy personnel consisting of 7 pharmacists and 13 pharmaceutical technologists in Meru County. Pretesting would reveal vague questions, deficiencies in the questionnaire such as unclear directions or cluttered questions and suggestions made by respondents would be used to improve it. The feedback from the pilot testing would be used to establish the validity of the data collection instrument before it was administered to the target population.

3.5.2 Validity of the instrument

Validity refers to utility and indicates the degree to which an instrument measures what it is supposed to measure. It is also the extent to which differences found with a measuring instrument reflect true differences among those being tested (Kothari, 2004). Construct validity is a measure of the degree to which data obtained from an instrument meaningfully and accurately represents a theoretical concept (Mugenda and Mugenda, 2003). This was measured based on the theoretical framework of the study. Content validity was assessed using two pharmacovigilance experts from the University of Nairobi who had carried out previous research in pharmacy practice and work at the Ministry of Health. The University supervisor was also consulted due to her vast knowledge and experience in training and curricula development. Criterion-related validity refers to the use of a measure in assessing subjects' behaviour in specific situation. This was measured by the scores of the subjects in relation to the practise of pharmacovigilance.

3.5.3 Reliability of the instrument

Reliability is best defined by the stability aspect, determined by comparing results of repeated measurements and the equivalence aspect, where two investigators compare observations of the same event. The stability aspect is concerned with securing consistent results with repeated measurements of the same person and with the same instrument. The equivalence aspect considers how much error may get introduced by different investigators or different samples of the items being studied. The split half method was used to assess reliability which required only one testing session. The items in the questionnaire were divided into even and odd numbered items and administered to the pilot group. The scores from the two groups of items were correlated using spearman-Brown prophecy formula.

$$\begin{aligned} \text{Reliability of scores on total test} &= \frac{2 + \text{reliability for } \frac{1}{2} \text{ test}}{1 + \text{reliability for } \frac{1}{2} \text{ tests}} \\ &= 0.74 \end{aligned}$$

Data with a high Split- half reliability will have a high correlation coefficient. According to Fraenkel and Wallen (2000), if the results produce a reliability coefficient greater or equal to 0.7 the instrument is considered reliable. Both questionnaires had a correlation coefficient of 0.74 and were therefore reliable.

3.6 Data collection procedures

Initial visits were made to each community pharmacy to seek permission from the community pharmacy personnel in charge of the premises to administer the questionnaire. Data was collected from the respondents through questionnaires which were left at the respondents' premises for filling and collected at the agreed date, which was not more than three days. The key informant questionnaire was given to the PPB inspector and collected within three days.

3.7 Data Analysis Techniques

The questionnaires were collected and checked for completeness. This involved data editing to eliminate duplication of information and vague responses which would have interfered with the outcome of computer analysis. Data coding was done where the variables were noted in form of symbols or numeric characters to reduce the amount of data entry required. The data was then tabulated into frequency and cumulative tables in preparation for computer manipulation. The quantitative data was analysed using statistical Package for Social Sciences software version 22. The qualitative data was organized into themes according to the study objectives. Percentages and frequency distribution tables were used to draw inferences between the dependent and independent variables for data presentation. The level of significance was 5%. The analysis of variance (ANOVA) was also used to determine the differences between the respondents in the study and to show correlation between the dependent and independent variables.

3.8 Operational definition of variables

Table 3.1 Operationalization of variables

Objective	Independent Variables	Indicators	Measurement scale	Type of data analysis	Dependent variable
Establish how personnel training influences pharmacovigilance in community pharmacies	Training of dispensing personnel	Number of pharmacovigilance trainings attended Number of suspected ADRs and poor quality drug reports submitted to PPB Education qualifications	Ordinal Ratio	Descriptive	Community pharmacy personnel participation in Pharmacovigilance
Examine the effect of personnel workload on pharmacovigilance in community pharmacies	Workload of dispensing personnel	Number of personnel working in the community pharmacy Number of hours worked by personnel Number of patients served per day Number of suspected ADRs and poor quality drug reports submitted to PPB	Ordinal Ratio	Descriptive	Community pharmacy personnel participation in Pharmacovigilance
Determine the effect of counterfeits in the pharmaceutical supply chain on pharmacovigilance in community pharmacies	Counterfeit medicines	Drug quality alerts received from PPB and drug companies. Number of suspected poor quality drugs reports submitted to PPB Trainings on identification of counterfeit drugs attended.	Ordinal Ratio	Descriptive	Community pharmacy personnel participation in Pharmacovigilance
Determine the influence of pharmaceutical care	Pharmaceutical care	Availability of room for private consultation Maintenance of manual or	Ordinal Ratio	Descriptive	Community pharmacy personnel participation

al care on pharmacovig ilance in community pharmacies		computerized patient medication records Consultation with the prescribing clinicians Number of suspected ADRs and poor quality drugs submitted to PPB			in Pharmacovig ilance
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3.9 Ethical considerations

The study respondents were assured of their confidentiality through informed consent on the questionnaire. The names of the participants and community pharmacies were not indicated on the questionnaire to ensure that they gave more honest responses. Permission to conduct the survey was sought from each community pharmacy superintendent through a letter of transmittal issued by the university during the initial visits. The county pharmacist and the regional Pharmacy and Poisons Board officers were informed about the purpose study taking place and that no allowances would be provided for those participating in the study. Respondents were notified that there was no monetary compensation for any questionnaire filled since participation was voluntary. Any sensitive or confidential information about patients or their medical records were not included in the study. Accurate reporting of the findings was emphasized to ensure that the findings were relevant to the study objectives.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION AND INTERPRETATION

4.1 Introduction

This chapter entails the data analysis, presentation, interpretation and discussion of the findings according to the data collected using the questionnaires. The study objectives were to establish how training of the personnel dispensing, the workload of the dispenser, the influx of counterfeits in the pharmaceutical supply chain and pharmaceutical care influence community pharmacy personnel participation in pharmacovigilance.

4.2 Questionnaire return rate

The questionnaire return rate for the community pharmacy personnel was 85% with 51 questionnaires having being returned out of the 60 questionnaires administered. The key informant questionnaire was also filled and returned. The questionnaires were administered to the qualified pharmaceutical personnel who gave their consent to participate in the study. Return visits to the community pharmacies were done to encourage the respondents to fill the questionnaire. According to Mugenda and Mugenda (2003), a return rate of 50% is adequate for analysing and reporting in social studies, 60% return rate is good while 70% and over is very good.

4.3 Demographic information of the respondents

The respondents were requested to give their gender, age, academic qualifications and work experience in the community pharmacy as part of their demographic information.

4.3.1 Distribution of the respondents by gender

The study sought to establish the age distribution of the 52 respondents who participated in the study. The results are presented in Table 4.1.

Table 4.1
Distribution of the respondents by gender

Gender	Frequency	Percent
Male	27	51.9
Female	25	48.1
Total	52	100.0

The number of males was 51.9% and that of the female respondents was 48.1% giving relatively equal representation of both genders. The key informant was of the male gender.

4.3.2 Distribution of the respondents by age

Information on the age category of the respondents was collected and is presented in Table 4.2.

Table 4.2
Distribution of the respondents by age

Age category	Frequency	Percent
18-24 years	5	9.6
25-35 years	35	67.3
36-45 years	5	9.6
46 and above	7	13.5
Total	52	100.0

Majority of the respondents (67.3%) were between the ages of 25 to 35 years showing that most of the respondents were in the youth category. This age category would be the most suitable to be trained and participate in the pharmacovigilance program.

4.3.3 Distribution of the respondents by academic qualifications

The respondents were requested to indicate their academic qualifications. The information is presented in Table 4.3.

Table 4.3
Distribution of the respondents by academic qualifications

Academic qualifications	Frequency	Percent
Postgraduate	0	0
Bachelor	4	7.7
Diploma	43	82.7
Certificate	5	9.6
Total	52	100.0

Majority of the respondents (82.7%) had a diploma in pharmacy while 9.6% had certificates in pharmacy. The key informant had a Bachelor of pharmacy degree along with 3 other respondents making up 7.7%. None of the respondents had postgraduate qualifications. The diploma in pharmacy course is widely accessible and affordable in various medical colleges around the country unlike the bachelor of pharmacy degree. Certificates in pharmacy are no longer recognised by the PPB but a few respondents still had them.

4.3.4 Distribution of the respondents by work experience

The level of work experience of the respondents was established and the results are presented in Table 4.4.

Table 4.4
Distribution of the respondents by work experience

Work experience	Frequency	Percent
Less than 1 year	5	9.6
1 to 5 years	17	32.7
6 to 10 years	21	40.4
11 to 15 years	2	3.8
More than 15 years	7	13.5
Total	52	100.0

Table 4.4 indicates that 40.4% of the respondents had 6 to 10 years work experience and 32.7%, including the key informant, had 1 to 5 years work experience. Only 5 respondents (9.6%) had less than one year experience. This implies that majority of the respondents have served in community pharmacies long enough to be able to participate in the Kenyan pharmacovigilance program which was launched in 2009.

4.4 Training of personnel and participation in pharmacovigilance

Lack of training in pharmacovigilance can lead to under reporting to National Drug Regulatory bodies. Educational interventions may greatly influence the knowledge, attitude and practices of pharmaceutical personnel towards pharmacovigilance and can be used to establish a culture of pharmacovigilance.

4.4.1 Awareness of pharmacovigilance

The respondents were asked whether they had ever heard of pharmacovigilance. Their responses are given in Table 4.5.

Table 4.5
Awareness of pharmacovigilance

Awareness of pharmacovigilance	Frequency	Percent
Yes	43	84.3
No	8	15.7
Total	51	100.0

From Table 4.5 majority of the personnel (84.3%) were aware of pharmacovigilance while 15.7% were not. The level of awareness on pharmacovigilance was high probably due to constant print and electronic media campaigns by PPB on the importance of pharmacovigilance.

4.4.2 Attendance of pharmacovigilance trainings

The respondents were further asked about their attendance of pharmacovigilance trainings. Their responses are as shown in Table 4.6.

Table 4.6
Attendance of pharmacovigilance trainings

Attendance of training	Frequency	Percent
Yes	17	33.3
No	34	66.7
Total	51	100.0

Only 33.3% of the respondents had received training in pharmacovigilance from the responses given. The topics covered in the trainings were ADR reporting and the importance of pharmacovigilance. The PPB officer had received training on pharmacovigilance in 2013 when PPB trained its officers at Maanzoni lodge in Machakos County. The respondent also noted that PPB did not offer community pharmacy personnel pharmacovigilance due to lack of capacity to train. This indicates that the educational interventions offered to community pharmacy personnel were very few. Most of the respondents who had received training had

been working for less than one year indicating that aspects of pharmacovigilance had been taught during their diploma in pharmacy course.

4.4.3 Reporting of suspected Adverse Events and poor quality drugs

The respondents were asked to indicate whether they had ever reported an Adverse Event or a poor quality drug to the PPB using the official forms. The results are shown in Table 4.7.

Table 4.7

Reporting of a suspected Adverse Event using the Pharmacy and Poisons Board (PPB) forms

Reporting of adverse events	Frequency	Percent
Yes	2	3.9
No	48	94.1
Total	51	100.0

From the responses given, only 2 respondents (3.9%) had reported poor quality drugs to PPB. Majority (94.1%) indicated that they had never reported Adverse Events or poor quality drugs to the PPB. One respondent sent one online Adverse Event report in 2015 while the other respondent sent 2 manual poor quality drug reports in 2015. The key informant had encountered a manual report of an Adverse Event and a poor quality drugs from one community pharmacy personnel. The reporting of suspected Adverse Events and poor quality drugs was significantly low probably due to the low number of respondents who had attended pharmacovigilance trainings.

4.4.4 Awareness of the PPB e-shot alert system

In this case, the respondents were asked to indicate whether they were aware of the PPB e-shot email alert system. Their responses are as shown on Table 4.8.

Table 4.8
Awareness of the PPB e-shot email alert system

Awareness of E-shot	Frequency	Percent
Yes	19	37.3
No	32	62.7
Total	51	100.0

According to Table 4.8 the most of the respondents (62.7%) were not aware of the PPB e-shot email alert system. The e-shot system requires one to have an email address and internet facilities at their premises for transmission of alerts. The system was widely disseminated in public health facilities when it was launched due to the relatively centralised drug supply chain.

Table 4.9
Subscription to the PPB email alert system

Subscription to e-shot	Frequency	Percent
Yes	1	5.3
No	18	94.7
Total	19	100.0

Out of the 19 respondents who were aware of the PPB e-shot alert system only one (5.3%) had subscribed to it as shown in Table 4.9. The respondent had attended pharmacovigilance training where subscription to the e-shot alert system was covered. The low level of awareness of the e-shot system means that majority of the respondents may receive of the PPB alerts on drug recalls or reported Adverse Events.

4.4.5 Attitude towards Adverse Events

The respondents were asked to indicate their opinions on statements about Adverse Events. Their responses are as shown on Table 4.10.

Table 4.10
Attitude towards Adverse Events

Statement	Frequency		
	I Agree	I Disagree	I don't know
Reporting Adverse Events could lead to serious legal implications like law suits.	15	36	0
It is necessary to be sure that the Adverse Event is caused by the use of a particular drug before reporting it.	40	9	2
All serious Adverse Events are well documented by the time a drug is marketed.	28	21	2
Detecting and reporting Adverse Events is an important professional role of the community pharmacy personnel.	49	1	1
Total	132	67	5

Table 4.10 indicates that 36 respondents (70.6%) disagreed that reporting Adverse Events could lead to serious legal implications. 40 respondents (78.4%) agreed that it was necessary to be sure that the Adverse Event is caused by the use of a particular drug before reporting it. 28 respondents (54.9%) agreed that all serious Adverse Events are well documented by the time a drug is marketed. 49 respondents (96.1%) agreed that detecting and reporting Adverse Events is an important professional role of the community pharmacy personnel.

Majority of the personnel had a positive attitude towards reporting Adverse Events as they stated it was part of their professional duties and expressed no fear of lawsuits. However more than half felt the need to be sure of the causality between the drug and the Adverse Event and that all serious Adverse Events were documented before drugs were marketed. This showed complacency as a major attitude of the pharmaceutical personnel.

4.4.6 Factors hindering reporting of Adverse Events and poor quality drugs

Several factors hinder pharmaceutical personnel from reporting Adverse Events and poor quality drugs. The respondents were asked to indicate the reason(s) they perceived caused this hindrance. Their responses are as shown in Table 4.11.

Table 4.11***Factors hindering reporting of Adverse Events and poor quality drugs***

Reason	Frequency	Percentage
There are no reporting forms available at my premises.	40	78.4
I do not know how and where to report.	12	23.5
Reporting Adverse Events and poor quality drugs is time consuming.	8	15.7
I have insufficient clinical knowledge on identifying Adverse Events.	6	11.8

According to the responses given in Table 4.11, 78.4% of the respondents indicated that there were no reporting forms available at their premises while 23.5% stated that they did not know how and where to report. 15.7% felt that reporting Adverse Events and poor quality drugs is time consuming. 11.8% indicated that they had insufficient clinical knowledge on identifying Adverse Events.

Majority stated there were no reporting forms available at their premises meaning they were not aware of the e-reporting introduced by PPB in 2013 that requires a smart phone and internet connection. The lack of knowledge on how and where to report, identification of Adverse Events and the time consuming nature of filling the forms could be addressed at pharmacovigilance trainings.

The key informant stated that lack of training, fear of law suits; unethical practices and ignorance by health care professionals were the most notable barriers to reporting Adverse Events and poor quality drugs. The respondent indicated the factors that would encourage greater participation of community pharmacy personnel were training on the importance of pharmacovigilance during professional meetings, offering CPD courses on the same, timely feedback for submitted reports and introduction of pharmacovigilance in the learning institutions to cater for new professionals.

4.5 Workload in community pharmacies and participation in pharmacovigilance

The workload was established according to the number of hours worked, the number of patients served in a day, the average time spent dispensing to each patient and the frequency of Continuous Professional Development forums.

4.5.1 Number of Hours worked at the community pharmacy

The respondents gave their responses on the number of hours worked as presented in Table 4.12.

Table 4.12
Number of Hours worked at the community pharmacy

Number of hours worked	Frequency	Percent
1 to 5 hours	0	0
6 to 10 hours	26	51.0
11 to 15 hours	23	45.1
More than 15 hours	2	3.9
Total	51	100.0

Table 4.12 shows that 51% of the respondents worked for 6 to 10 hours and 45.1% worked for 11 to 15 hours. Only 3.9% indicated that they worked for more than 15 hours. Very few respondents operated their community pharmacies for 24 hours. The majority of the respondents spent a considerable amount of time in their practice therefore they would ideally frequently encounter and report Adverse Events and poor quality drugs.

4.5.2 Number of patients served in a day

The number of patients served in a day by the respondents is as shown in Table 4.13.

Table 4.13
Number of patients served in a day

Number of patients served	Frequency	Percent
Less than 10 patients	0	0
11 to 20 patients	6	11.8
21 to 30 patients	17	33.3
More than 30 patients	28	54.9
Total	51	100.0

Table 4.13 shows that 54.9% of the respondents served more than 30 patients in a day while 33.3% served 21 to 30 patients in a day. Only 11.8% served 11 to 20 patients. Majority of the respondents therefore handled a high volume of patients and could receive Adverse Events or poor quality reports. The number of patients served depends on the geographical location of the community pharmacy, the working hours and the prices or variety of the drugs stocked.

4.5.3 Average time spent dispensing to each patient

The average time spent dispensing to each patient by the respondents is represented in Table 4.14.

Table 4.14
Average time spent dispensing to each patient

Average time spent dispensing	Frequency	Percent
Less than 5 minutes	7	13.7
6 to 10 minutes	41	80.4
11 to 15 minutes	3	5.9
More than 15 minutes	0	0.0
Total	51	100.0

Majority of the respondents (80.4%) spent 6 to 10 minutes dispensing to each patient. Only 5.9% spent 11 to 15 minutes dispensing to patient while 13.7% spent less than 5 minutes dispensing. This may indicate that majority of the respondents allocate adequate time to their patients for medication counselling. The time spent dispensing depends on the complexity of the prescription in terms of the number of drugs prescribed or drug-drug interactions and the knowledge of the patient on their medications.

4.5.4 Frequency of CPD forums to discuss dispensing errors

The frequency of CPD forums to discuss dispensing errors was indicated by the respondents as shown in Table 4.15.

Table 4.15
Frequency of CPD forums

Frequency of CPD forums	Frequency	Percent
Daily	2	3.9
Once a week	5	9.8
Once a month	16	31.4
Once a year	28	54.9
Total	51	100.0

Majority of the respondents (54.9) indicated that they carried out CPD forums once a year. Only 3.9 % (2) held CPD forums daily. The frequency of CPD forums was relatively low. This may mean that many dispensing errors could recur unnoticed.

4.5.5 Opinion on whether dispensing errors contribute to Adverse Events

The respondents were asked for their opinion on whether dispensing errors contribute to Adverse Events. Their responses are as shown in Table 4.16.

Table 4.16
Dispensing errors and contribution to Adverse Events

Response	Frequency	Percent
Yes	49	96.1
No	2	3.9
Total	51	100.0

Majority of the respondents (96.1%) agreed that dispensing errors contribute to Adverse Events and only 2 respondents (3.9%) disagreed. This shows that most respondents had some knowledge on dispensing errors and understood their consequences. Dispensing errors are preventable in most cases by pharmaceutical personnel since they may be the last point of contact with the patients.

4.5.6 Causes of dispensing errors

There are various factors that cause dispensing errors in a community pharmacy setting. The pharmaceutical personnel were asked state the factors they agreed with. The responses are as shown in Table 4.17.

Table 4.17
Causes of dispensing errors

Cause	Frequency	Percent
Sound-alike look-alike effect	29	56.9
Poor handwriting on the prescriptions	35	68.6
Ambiguous dispensing instructions	23	45.1
Lack of time to counsel patient	26	51.0

The information from Table 4.17 shows that 56.9% of the pharmaceutical personnel felt that the sound-alike look-alike effect caused dispensing errors while 68.6% felt that poor handwriting on the prescriptions was a cause. 45.1 % cited ambiguous dispensing instructions and 51% stated there was no time to counsel patients. The respondents could relate and

identify the stated causes of dispensing errors to their daily professional routine of dispensing medications. Pharmaceutical personnel are drug experts and are required to interpret prescriptions to ensure efficient medication counselling to patients. The causes indicated have a negative impact on the task and job related workload of the personnel thus increases the chances of dispensing errors occurring.

4.5.7 Number of personnel working at the community pharmacy

The community pharmacy personnel were asked to specify the number of personnel working at the community pharmacy and their cadre. The responses are as show in Table 4.18.

Table 4.18
Number of personnel working at the community pharmacy

Cadre	Number	Frequency	Percentage
Pharmacists	1	3	5.8
Pharmtechs	1	29	56.9
Pharmtechs	2	19	37.3
Total		51	100.0

According to Table 4.18 majority of the respondents (56.9%) had at least one Pharmtech (Diploma holder) working at the community pharmacy at any given time. Only 5.8% (3) had pharmacists. This shows that pharmtechs were the most common cadre given the accessibility and affordability of the diploma course in pharmacy.

4.5.8 Strategies to reduce dispensing errors

Community pharmacy personnel can put several strategies in place to reduce dispensing errors. The respondents were asked to indicate the strategies they carry out. The responses are as presented in Table 4.19.

Table 4.19
Strategies to reduce dispensing errors

Strategy	Frequency		
	Always	Sometimes	Never
Assigning clear roles to all staff.	40	11	0
Taking regular breaks.	15	33	3
Organising the drugs in the workplace	48	3	0
Counterchecking of prescriptions.	43	8	0
Total	146	55	3

Majority of the respondents (78.4%) indicated that they always assign clear roles to all staff to reduce dispensing errors. 64.7% of the pharmaceutical personnel took regular breaks sometimes with 5.9% never taking breaks. 94.1% stated that they always organised drugs in the workplace. Majority of the personnel (84.3%) always counterchecked prescriptions. The respondents employed the various stated strategies to reduce dispensing errors while performing their professional duties.

4.5.8 Training on workload management or Good Dispensing Practices

Training on workload management or good dispensing practices is essential to ensure reduced dispensing errors. The respondents were asked to indicate whether or not they had attended any training. The responses are as shown in Table 4.20.

Table 4.20
Training on workload management or Good Dispensing Practices

Response	Frequency	Percent
Yes	15	29.4
No	36	70.6
Total	51	100.0

Table 4.20 shows that 70.6% of the respondents had not attended any training on workload management or Good Dispensing Practices. The 15 respondents (29.4%) who had attended trainings indicated the topics covered as Good Dispensing Practices, Dispensing errors and rational drug use. The level of training on workload management or Good Dispensing Practices among the respondents was low indicating that more educational interventions would be needed.

4.6 Counterfeits in the pharmaceutical supply chain and participation in pharmacovigilance

The influx of counterfeit drugs in the pharmaceutical supply chain is a notable problem that is further compounded by a highly fragmented supply chain consisting of many wholesalers, erratic drug supplies or shortages, lack of a price control policy and lack of adequate batch tracking by stakeholders in the pharmaceutical sector.

4.6.1 Definition of a counterfeit drug

The respondents were asked to define a counterfeit drug. 96.1% (49) of the personnel described it as a substandard drug lacking the active pharmaceutical ingredients, an imitation or fake that is not registered by PPB and is therefore illegal. Only 2 respondents (3.9%) did not define a counterfeit drug.

4.6.2 Training on identification of counterfeit drugs

Respondents were asked if they had ever attended any special training course on identification of counterfeits. The responses are as presented on Table 4.21.

Table 4.21
Training on identification of counterfeit drugs

Response	Frequency	Percent
Yes	7	13.7
No	44	86.3
Total	51	100.0

Majority of the respondents (86.3%) had never attended any special training course on identification of counterfeits. The 7 respondents (13.7%) attended trainings: 1 in 2009, 3 in 2014 and 3 in 2015. The level of training on counterfeit drugs among the respondents was low. Most of the respondents who attended such trainings had practised for less than one year indicating that they did so during their diploma in pharmacy course.

4.6.3 Encounters with a counterfeit drug

The respondents were asked to indicate if they had encountered a counterfeit drug and reported it to the PPB. The responses are as shown in Table 4.22.

Table 4.22
Encounters with counterfeit drugs

Response	Frequency	Percent
Yes	23	45.1
No	28	54.9
Total	51	100.0

According to Table 4.22 the number of personnel who had encountered counterfeit drugs was 45.1%. Those who had not encountered counterfeit drugs were 54.9%. This indicated a low level of awareness on identification of counterfeits. The key informant noted that lack of price control policies, lack of a mandatory batch tracking provision in the supply chain up to the retailer levels and unauthorized ports of entry and porous borders had led to the influx of counterfeits in the pharmaceutical supply chain.

4.6.4 Reporting counterfeits to PPB

Out of the 23 respondents who had encountered counterfeit drugs in their practice, only one had reported it to PPB in 2009 using a manual reporting form as presented in Table 4.23.

Table 4.23

Reporting counterfeits to PPB

Response	Frequency	Percent
Yes	1	4.3
No	22	95.7
Total	23	100.0

The level of reporting counterfeits to the PPB was very low. The key informant stated that several interventions had been implemented by PPB to curb the influx of counterfeits other than receiving reports from community pharmacy personnel. These were creation of new authorised ports of entry, recruitment of additional inspectors, logistical support in terms of transport and regional offices and media campaigns encouraging the public to report to PPB directly.

4.6.7 Details Checked When Receiving Medicines

The respondents were asked to indicate their usual practices during procuring and receipt of medicines. The responses are shown in Table 4.24.

Table 4.24
Details Checked When Receiving Medicines

Details checked	Frequency		
	Always	Sometimes	Never
Brand name and the name of manufacturer(s)	38	13	0
Dates of manufacture, expiration and the batch/lot number	48	3	0
Certificates of Analysis and the PPB registration number	13	19	19
Intactness of packaging and medicines	42	9	0
Total	141	44	19

Majority of the pharmaceutical personnel (74.5%) indicated that they always checked the brand name of the drugs and the name of the manufacturers. 94.1% (48) of the personnel always checked the dates of manufacture, expiration and the batch number. Only 19 respondents (37.3%) cited that they never checked the certificates of analysis and the PPB registration number. 42 respondents (82.4%) cited that they always checked for the intactness of the packaging and medicines. The key informant indicated that PPB officers gave verbal alerts to community pharmacy personnel and encouraged them to visit the PPB website to get updates during their routine inspections. Most of the respondents indicated the use of at least one of the stated details when receiving drugs. The most underutilised method was checking of the certificates of analysis and the PPB registration number which may indicate that majority of the respondents had a high probability of stocking unregistered drugs.

4.6.8 Strategies used to detect counterfeits

The respondents were asked to indicate the methods they use to detect counterfeit drugs. The responses are presented in Table 4.25.

Table 4.25
Strategies used to detect counterfeits

Strategy	Frequency		
	Always	Sometimes	Never
Close scrutiny of the medicines to check for defects	34	17	0
Manufacturing company alerts	19	28	4
Alerts from PPB	26	20	5
Complaints from patients and health care providers	25	23	3
Total	104	88	12

According to Table 4.25 most of the personnel (66.7%) always scrutinised the medicines closely to check for defects. 54.9% (28) of the respondents stated that they used manufacturing company alerts sometimes and 7.8% (4) never used such alerts. The personnel who always used alerts they had received from PPB was 51% (26). Complaints from patients and other healthcare providers were always used by 49% (25) of the pharmaceutical personnel. Alerts on counterfeit drugs are usually received from medical representatives and PPB officers during their routine visits to the community pharmacies. Complaints from patients can only be established if the patients revisit the community pharmacy for follow up while complaints from other healthcare providers depend on the established working relationships among them.

4.7 Pharmaceutical care and participation in pharmacovigilance

Patient oriented therapy, consultation with other healthcare providers, documentation and follow up make up the concepts of Pharmaceutical Care that can aid in detection of Adverse Events and poor quality drugs.

4.7.1 Awareness of concepts of Pharmaceutical Care

The respondents were asked whether they were aware about the concepts of pharmaceutical care. Their responses are as shown in Table 4.26

Table 4.26
Awareness of concepts of Pharmaceutical Care

Response	Frequency	Percent
Yes	44	86.3
No	7	13.7
Total	51	100.0

Majority of the respondents (86.3%) were aware of the concepts of pharmaceutical care while 13.7% (7) were not. This indicates a high level of awareness among a significant number of the respondents on the concepts of pharmaceutical care. The concepts may have been covered in the coursework or during forums held by professional bodies.

4.7.2 Presence of designated consultation room

The participants were asked if they had a designated private area or room where patients can be counselled and get consultation. The responses are presented in Table 4.27.

Table 4.27
Presence of designated consultation room

Response	Frequency	Percent
Yes	39	76.5
No	12	23.5
Total	51	100.0

The 12 respondents who did not have consultation rooms gave lack of space in the premises as the main reason. This maybe the case as most of the space is used for storage of drugs.

4.7.3 Pharmaceutical care activities

The respondents were asked to indicate the pharmaceutical care activities they carry out in their practice. Table 4.28 presents the findings.

Table 4.28
Pharmaceutical care activities

Pharmaceutical care activity	Frequency		
	Always	Sometimes	Never
Documenting information on written records or computerized notes.	18	26	7
Follow up of patients	19	30	2
Establishing a professional relationship with doctors	23	27	1
Verification of patient understanding	40	11	0
Total	100	94	10

The pharmaceutical personnel who kept written or computerized notes sometimes were 51% (26). Follow up of patients was carried out sometimes by 58.8 % (30) of the personnel. 52.9% (27) of the personnel established a professional relationship with doctors for joint therapeutic management sometimes. 78.4% (40) of the personnel always verified patient understanding of their medications.

The frequency of documentation of patient records, follow up and joint therapeutic management with doctors was relatively low with some respondents never carrying out the stated activities. This may be attributed to the patients' choice of pharmacy depending on the location of the pharmacy, fast service, friendly staff, appearance of the pharmacy, good range of products and services, convenient opening hours, personnel's professional knowledge, private consultation and the prices of the drugs.

4.7.4 Reference materials available

The respondents were asked to state the reference materials available at their community pharmacies. The responses are as presented in Table 4.29

Table 4.29
Reference materials available at the premises

Reference material	Frequency	Percentage
Kenya Drug Index	49	96
Essential Medicines list	7	13.7
British National Formulary	29	56.9
The Internet	31	60.8
WHO Guidelines	2	3.9
Drug information leaflets	32	62.7

Other reference materials quoted were the Martindale, Internal hospital formulary, Clinical guidelines for level 2 and 3 facilities and Ministry of Health brochures. Most of the respondents had reference materials at their premises with the Kenya Drug Index being the most common due to its wide availability, ease of use and yearly updated editions. Most medicines contain drug information leaflets in their secondary packaging.

4.7.5 Barriers to implementing pharmaceutical care

Several factors were cited by the pharmaceutical personnel as indicated in Table 4.30.

Table 4.30
Barriers to implementing pharmaceutical care

Factor	Frequency	Percentage
Lack of space	12	23.5
Lack of time to counsel patients	7	13.7
Self-medication by patients	10	19.6
Lack of training in Pharmaceutical Care	6	11.8
High workload	11	21.6
Price wars among community pharmacies	5	9.8
Total	51	100

The personnel cited lack of space (23.5%), lack of time (13.7%), self-medication by patients (19.6%), lack of training in Pharmaceutical Care (11.8%), high workload (21.6%) and price wars among community pharmacies (9.8%). Most of the respondents were aware of pharmaceutical care and could identify at least one barrier to implementing pharmaceutical care in their community pharmacy practice.

4.8 Inferential statistics

Inferential statistics are used to generalise findings to populations represented by the samples under study, to determine what tends to happen and to establish the strength of the relationship between the independent and dependent variables. The analysis of variance (ANOVA) was used to analyse the significant differences between the samples selected and to establish a relationship between the dependent and independent variables. The results are presented in the ANOVA Tables according to the study objectives.

4.8.1 Training of personnel and participation in pharmacovigilance

The predictors for the independent variable that was training of personnel were attendance of pharmacovigilance trainings, reporting of Adverse Events or poor quality drugs to PPB and awareness of e-shot email alert system. The dependent variable was community pharmacy personnel participation in pharmacovigilance. The significance level was 5%.

Table 4.31
ANOVA for training of personnel

	Model	Sum of Squares	df	Mean Square	F	Sig.
	Regression	.999	3	.333	1.379	-.259 ^a
1	Residual	11.354	47	.242		
	Total	12.353	50			

The significance given is 0.259 which means that 25.9% of the variance among the respondents can be explained or predicted by the training of the personnel while 74.1% cannot be explained.

This means that the low levels of attendance of pharmacovigilance trainings, low rates of reporting of Adverse Events or poor quality drugs and lack of awareness of the e-shot system have an impact on the community pharmacy personnel participation in pharmacovigilance.

4.8.2 Workload of personnel and participation in pharmacovigilance

The predictors for the independent variable that was workload of personnel were attendance of workload trainings, the number of hours worked at the community pharmacy, the number of patients served in a day and the frequency of CPD forums to discuss dispensing errors. The dependent variable was community pharmacy personnel participation in pharmacovigilance. The significance level was 5%.

Table 4.32
ANOVA for workload of personnel

	Model	Sum of Squares	df	Mean Square	F	Sig.
	Regression	10.017	4	2.504	1.066	-.384 ^a
1	Residual	108.022	46	2.348		
	Total	118.039	50			

The significance given is 0.384 which means that 38.4 % of the variance among the respondents can be explained or predicted by the workload of the personnel while 61.6% cannot be explained.

This means that the low levels of attendance of workload trainings, increased working hours, high volume of patients served in a day and low frequency of CPD forums to discuss dispensing errors have an impact on the community pharmacy personnel participation in pharmacovigilance.

4.8.3 Influx of counterfeits and participation in pharmacovigilance

The predictors for the independent variable that was influx of counterfeit drugs into the pharmaceutical supply chain were attendance of trainings on identification of counterfeit drugs, encounters with counterfeit drugs, number of poor quality drug reports sent to PPB and use of alerts from PPB when procuring drugs. The dependent variable was community pharmacy personnel participation in pharmacovigilance. The significance level was 5%.

Table 4.33

ANOVA for influx of counterfeits in the pharmaceutical supply chain

	Model	Sum of Squares	df	Mean Square	F	Sig.
1	Regression	1.702	4	.425	1.838	.138 ^a
	Residual	10.651	46	.232		
	Total	12.353	50			

The significance given is 0.138 which means that 13.8% of the variance among the respondents can be explained or predicted by the influx of counterfeit drugs into the pharmaceutical supply chain while 86.2% cannot be explained. This means that the low levels of attendance of trainings on identification of counterfeit drugs, low rates of reporting poor quality drug to PPB and use of alerts from PPB when procuring drugs have an impact on the community pharmacy personnel participation in pharmacovigilance.

4.8.4 Pharmaceutical care and participation in pharmacovigilance

The predictors for the independent variable that was pharmaceutical care were the presence of a designated private consultation room, manual or electronic patient records, patient follow up and consultation with other health providers. The dependent variable was community pharmacy personnel participation in pharmacovigilance. The significance level was 5%.

Table 4.34
ANOVA for Pharmaceutical care

	Model	Sum of Squares	df	Mean Square	F	Sig.
	Regression	1.671	3	0.432	1.389	-.249 ^a
1	Residual	10.354	47	.233		
	Total	12.353	50			

The significance given is 0.249 which means that 24.9% of the variance among the respondents can be explained or predicted by pharmaceutical care while 75.1% cannot be explained.

This means that the presence of a designated private consultation room, manual or electronic patient records, patient follow up and consultation with other health providers have an impact on the community pharmacy personnel participation in pharmacovigilance.

CHAPTER FIVE

SUMMARY OF FINDINGS, DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter entails a summary of the findings based on the responses given by the participants of the study and in relation to the study objectives. The discussion of the findings is covered with regard to the existing body of knowledge found in the literature review. The conclusions of the study and suggestions for future research studies are given.

5.2 Summary of the study

The summary of findings is presented according to the thematic areas of the study.

5.2.1 Influence of training of the personnel dispensing medicines on community pharmacy personnel participation in pharmacovigilance.

Majority of the respondents (84.3%) had heard of pharmacovigilance but only 33.3 % had received training in pharmacovigilance. A significant number of the respondents (94.1%) had never reported any adverse event or poor quality drugs to the Pharmacy and Poisons Board (PPB) using the standard yellow and pink forms. Only 2 respondents had ever reported to PPB and 19 were aware of the “e-shot” email alert with only 1 respondent subscribing to it.

Most pharmaceutical personnel (70.6%) disagreed that reporting adverse events could lead to legal implications. Majority of the respondents agreed that it was necessary to be sure that an adverse event is caused by use of a particular drug before reporting it and that all serious adverse events were well documented by the time a drug is marketed. A significant number of respondents (96.1%) agreed that detecting and reporting AEs is an important professional role. Majority of the personnel (78.4%) indicated that there were no reporting forms available at their premises and a few respondents stated they didn't know how and where to report. Some personnel noted that reporting was time consuming and that they had insufficient clinical knowledge on identifying ADRs.

5.2.2 Influence of workload of the dispenser on community pharmacy personnel participation in pharmacovigilance.

More than half of the respondents (51%) stated that they work for 6 to 10 hours. Most personnel worked in shifts and only a few community pharmacies were open for 24 hours on a daily basis. On the number of patients served in a day 54.9% of the respondents served more than 30 patients in a day therefore most of the respondents served a high volume of patients. The average time spent dispensing to each patient indicated by 80.4% of the respondents was 6 to 10 minutes. This shows that patients may have sufficient time to get medication counselling. Most respondents (54.9%) stated that they participated in CPD forums at least once a year. This portrays that the frequency of such CPDs forums was low.

Majority of the respondents (96.1%) agreed that dispensing errors contributed to Adverse Events. Most respondents cited that poor handwriting and lack of time to counsel patients contributed to dispensing errors. Almost half cited ambiguous dispensing instructions and the sound alike look alike effect contributed to dispensing errors. Most respondents (56.9%) had at least one pharmitch working at the premises and only 5.8% had one pharmacist working. The strategies put in place to reduce dispensing errors cited by majority of the respondents were always assigning clear roles to all staff, organising drugs in the workplace, taking regular breaks and counterchecking of prescriptions. Only 29.4% had ever attended any training on workload management or good dispensing practices.

5.2.3 Influence of influx of counterfeits in the pharmaceutical supply chain on community pharmacy personnel participation in pharmacovigilance.

Most respondents (96.1%) described a counterfeit drug as substandard, imitated, fake and illegal product that should not be in circulation. Majority of the pharmaceutical personnel (86.3%) had not attended any training on identification of counterfeit drugs therefore the general knowledge on pharmacovigilance was low. Only 45.1% of the respondents had encountered counterfeit drugs in their practice and only 1 personnel reported it to PPB. This low level of training could be used to explain the lack of reporting to PPB. During procurement and receipt of drugs, majority of the respondents always checked the brand name, the name of manufacturers, the dates of manufacture, expiration, the batch number, the intactness of the packaging and the medicines. This showed that most respondents were aware of the presence of counterfeits in the supply chain. On detection of counterfeit drugs more than half of the personnel always scrutinised the medicines closely to check for defects,

used alerts from the manufacturing company or PPB and received complaints from patients, clinicians and other community pharmacy personnel. Most respondents used the same suppliers for their pharmaceutical commodities.

5.2.4 Influence of pharmaceutical care on community pharmacy personnel participation in pharmacovigilance.

Most community pharmacy personnel (86.3%) were aware about the concepts of pharmaceutical care. Designated private rooms for counselling were found in 76.5% of the community pharmacies therefore most patients could access one aspect of pharmaceutical care. The few respondents who did not have consultation rooms gave lack of space as the main reason. Very few respondents always documented patient medication information on written or computerized notes and followed up patients. Less than half of the respondents (45.1%) always established a professional relationship with doctors. However majority of the respondents (78.4%) always verified patient understanding of medication dosage instructions, contraindications and side effects. The most common reference materials available in majority of the community pharmacies were the Kenya Drug Index, Drug information leaflets, The Internet and the British National Formulary. The barriers to implementing pharmaceutical care cited by most of the respondents were lack of space for consultation, high workload and self-medication by patients.

5.3 Discussion of findings

The discussion of findings is presented according to the study objectives.

5.3.1 Influence of training of the personnel dispensing medicines on community pharmacy personnel participation in pharmacovigilance.

Training and education of community pharmacy personnel on pharmacovigilance increases the quality and quantity of reports sent to national regulatory bodies through the spontaneous reporting systems (Elkami, Hassali and Ibrahim, 2011). The study showed that most of the pharmaceutical personnel had not attended any pharmacovigilance training and therefore their reporting rate was low. The results further show that even those who had attended such trainings still had a low reporting rate. Although most of the respondents had a positive attitude towards reporting of Adverse Events as a professional duty, a significant number stated they did not know how or where to report and there were no reporting forms at their premises. According to Bawazir (2006), educational efforts directed at community pharmacy personnel, readily available and simplified reporting mechanisms and improved feedback to reporters is needed to stimulate participation in spontaneous reporting systems. The

Pharmacy and Poisons Board needs to empower community pharmacy personnel through regular educational interventions to increase their participation in the pharmacovigilance program. The ANOVA analysis gave a significance value of 0.259 meaning there is some relationship between training of personnel in pharmacovigilance and community pharmacy personnel participation in pharmacovigilance.

5.3.2 Influence of workload of the dispenser on community pharmacy personnel participation in pharmacovigilance.

Dispensing errors are believed to be the most prevalent type of medical errors and are a significant cause of preventable adverse events (Malone, Abarca, Skrepneck, Murphy, Armstrong, Grizzle, Rehfeld and Woosely, 2007). From the findings of the study majority of the personnel felt that dispensing errors contribute to Adverse Events. Most of the personnel worked for 6 to 10 hours and attended CPD forums to discuss dispensing errors once a year, which is a very low frequency. Workload training was undertaken by few respondents therefore increasing the chances of dispensing errors recurring. Most of the respondents could identify with the causes of dispensing errors and had put in place some of the stated strategies to reduce the dispensing errors. Thus increased workload leads to increased dispensing errors. According to Alkhateeb, Attarabeen, Latif and Deliere (2015), there is a negative impact of increased workload on the abilities of community pharmacy personnel to prevent or reduce potential dispensing errors and reduced time spent on counselling patients. The ANOVA analysis gave a significance value of 0.384 meaning there is some relationship between workload of the dispenser and community pharmacy personnel participation in pharmacovigilance

5.3.3 Influence of influx of counterfeits in the pharmaceutical supply chain on community pharmacy personnel participation in pharmacovigilance.

According to Yadav and Smith (2012), developing countries have weak fragmented regulatory structures, ill-defined laws and poor ability to enforce regulations unlike developed countries. It was also noted that retail drug shops act as the first point of healthcare contact for many patients and the balance of power was tilted toward the manufacturer leaving patients with little bargaining power. This leads to an increased influx of counterfeit drugs into the drug supply chain. The findings from the study suggest that most of the pharmaceutical personnel had encountered a counterfeit drug but only few reported it to PPB.

Some of the personnel had attended trainings on identification of counterfeits. The key informant also noted that batch tracking of medicines in the pharmaceutical supply chain at

the retail level was very poor. According to Odili, Osemwenkha, Eke and Okeri (2006), despite the high level of awareness of counterfeit drugs by community pharmacy personnel, low reporting rates to national drug regulators still persists. Advocacy workshops or meetings held on regular basis to provide sensitization on countermeasures against counterfeit medicines need to be provided to curb their influx into the pharmaceutical supply chain (Khan, Akazawa, Dararath, Kiet, Sovannarith, Nivanna, Yoshida and Kimura, 2011). The ANOVA analysis gave a significance value of 0.138 meaning there is some relationship between influx of counterfeits in the pharmaceutical supply chain and community pharmacy personnel participation in pharmacovigilance.

5.3.4 Influence of pharmaceutical care on community pharmacy personnel participation in pharmacovigilance.

Pharmaceutical care involves the recognition, solving and prevention of problems associated with the use of medicinal products and provision of safety information to the patient (Helper and Strand, 1990). A significant number of the respondents were aware of the concepts of pharmaceutical care and had designated private consultation rooms at their premises. According to the study respondents the notable barriers to implementing pharmaceutical care were lack of space, high workload, lack of time to counsel patients, self-medication, lack of training and price wars. The key informant also noted that there was no policy for price controls of medicines. Lack of pharmaceutical care means that Adverse Events and poor quality drugs occur undetected. Cordina, Safta, Ciobanu and Sautenkova (2008) noted that lack of established professional relationships and consultation with other healthcare professionals to enable joint therapeutic management of patients, lack of maintenance of patient medical records and lack of patient follow up leads to lack of pharmaceutical care. According to Oparah and Eferakeya (2005), educational interventions could assist community pharmacy personnel to increase their knowledge, skills and improve their pharmacy layouts in order to carry out pharmaceutical care. The ANOVA analysis gave a significance value of 0.249 meaning there is some relationship between training of pharmaceutical care and community pharmacy personnel participation in pharmacovigilance

5.4 Conclusions

From the study, it can be concluded that lack of training of personnel in pharmacovigilance has a negative impact on community pharmacy personnel participation in pharmacovigilance. Workload was a major factor influencing the community pharmacy personnel participation in pharmacovigilance as it greatly concerns dispensing errors. The influx of counterfeits in the

pharmaceutical supply chain was a major factor influencing the community pharmacy personnel participation in pharmacovigilance because most personnel encountered counterfeits and did not report them. Pharmaceutical care was a major factor influencing the community pharmacy personnel participation in pharmacovigilance as it involves patient follow up, consultation with other healthcare professionals and documentation.

5.5 Recommendations

The study found that there was a low level of training and participation in pharmacovigilance among the pharmaceutical personnel. The Pharmacy and Poisons Board (PPB), the Pharmaceutical Society of Kenya (PSK), the Kenya Pharmaceutical Association (KPA), the Ministry of Health and stakeholders in the pharmaceutical sector should consider introducing Pharmacovigilance as a core discipline in the pharmacy curriculum both at the diploma and undergraduate levels. Educational interventions like seminars and workshops should be used by PPB and professional bodies to inform and empower practising community pharmacy personnel on pharmacovigilance. This would create a culture of pharmacovigilance. A pharmacovigilance policy should be enacted in law and regional pharmacovigilance centres set up at the county level by stakeholders to include community pharmacy personnel in the national pharmacovigilance framework.

The study found that increased workload had a negative impact on the pharmaceutical personnel's ability to prevent dispensing errors thus decreased participation in pharmacovigilance. The frequency of CPD forums to discuss dispensing errors was relatively low. The regulatory body PPB and the professional bodies should carry out workload studies and enact policies to reduce dispensing errors. This should include the staffing levels, working hours and workload management strategies that can be adopted by all community pharmacies.

The study found that there was a low level of training of personnel on identification and reporting of counterfeit drugs in the pharmaceutical supply chain. Communication mechanisms like mobile phone alerts between community pharmacy personnel and PPB should be set up to strengthen efforts to curb counterfeit drugs. This would lead to greater dissemination of information, which is a core element of spontaneous reporting systems.

The study found that the level of pharmaceutical care offered by the personnel was relatively low in terms of documentation of patient information, consultation with other healthcare professionals and patient follow up. This in turn led to a low level of participation in

pharmacovigilance. A pharmaceutical care policy should be enacted in law by all stakeholders to ensure quality pharmaceutical care services are provided by all community pharmacy personnel to patients. Pharmaceutical care should also be introduced as a core discipline in the pharmacy curriculum both at the diploma and undergraduate levels. This will enable community pharmacies to shift their orientation from the commercial aspect towards healthcare provision.

5.6 Suggestions for Future study

The areas suggested for further study are

1. Similar studies investigating the factors that influence participation of community pharmacy personnel in pharmacovigilance in other counties.
2. Studies on factors influencing the implementation of pharmacovigilance guidelines by the Pharmacy and Poisons Board and other policy makers.
3. Studies to establish other challenges that influence community pharmacy personnel participation in pharmacovigilance.

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APPENDICES
APPENDIX 1: LETTER OF TRANSMITTAL OF DATA COLLECTION
INSTRUMENTS

SYLVIA MWELU MAVEKE,
P.O BOX 33 -60100,
EMBU.

Dear Sir/Madam,

RE: REQUEST FOR YOUR PARTICIPATION IN A RESEARCH STUDY.

I am a final year Master of Arts in Project Planning and Management student at the University of Nairobi currently undertaking a research on “**Factors Influencing Community Pharmacies personnel participation in pharmacovigilance in Embu County**”. I humbly request for your participation through filling in a questionnaire at your own convenience. All the information provided will be used for research purpose only and your identity will be treated with utmost confidentiality. Your contribution and cooperation will be highly appreciated.

Yours faithfully,

Sylvia Mwelu Maveke.

APPENDIX 2: COMMUNITY PHARMACY PERSONNEL QUESTIONNAIRE

Please answer the questions below by ticking or by writing your responses in the space provided. Please do not write your name on the questionnaire and give honest responses to the best of your ability. Your responses will be kept confidential and mainly for research purposes.

A. DEMOGRAPHIC INFORMATION

1. Kindly state your gender
Male Female
2. Which age category do you fall under?
 18- 24
 25-35
 36-45
 46 and above
3. State your academic qualifications
 Postgraduate (M.Pharm)
 Bachelor of pharmacy (B.Pharm)
 Diploma in pharmacy
 Certificate in pharmacy
 Other
4. How long have your dispensed in a community pharmacy?
 Less than 1 year
 1 to 5 years
 6 to 10 years
 11 to 15 years
 More than 15 years

B. Training in Pharmacovigilance

1. Have you ever heard of pharmacovigilance?
Yes No
2. Have you ever attended any training on pharmacovigilance?
Yes No

If yes, kindly state the year and topics covered.

.....
.....
.....
.....
.....

3. Have you ever reported a suspected Adverse Event using the yellow form or poor quality drugs using the pink form to the Pharmacy and Poisons Board (PPB) of Kenya?
Yes No

If yes, how many reports have you submitted? Kindly indicate the year of submission, the type of report and whether it was a manual or online report.

.....

4. Are you aware of the PPB email alert system called “e-shot”?

Yes [] No []

If yes, have you subscribed to it?

Yes [] No []

5. Kindly indicate your response using a tick for the following statements about Adverse Events.

	I Agree	I Disagree	I don't know
a. Reporting Adverse Events could lead to serious legal implications like law suits.			
b. It is necessary to be sure that the Adverse Event is caused by the use of a particular drug before reporting it.			
c. All serious Adverse Events are well documented by the time a drug is marketed.			
d. Detecting and reporting Adverse Events is an important professional role of the community pharmacy personnel.			

6. Which factors hinder you from reporting suspected Adverse Events and poor quality drugs to the PPB? Kindly tick the reason(s) you agree with.

a. There are no reporting forms available at my premises.	
b. I do not know how and where to report.	
c. Reporting Adverse Events and poor quality drugs is time consuming.	
d. I have insufficient clinical knowledge on identifying Adverse Events.	

C. Workload in Community pharmacies

1. Kindly indicate your responses using a tick.

Number of hours worked at the community pharmacy	1 to 5 hours	6 to 10 hours	11 to 15 hours	more than 15 hours
Number of patients served in a day	less than 10 patients	11 to 20 patients	21 to 30 patients	more than 30 patients
Average time spent dispensing to each patient	less than 5 minutes	6 to 10 minutes	11 to 15 minutes	more than 15 minutes
Frequency of Continuous Professional Development forums to discuss dispensing errors	Daily	Once a week	Once a month	Once a year

2. In your opinion, do you think dispensing errors contribute to Adverse Events?
 Yes [] No []

3. Indicate using a tick the factors that cause dispensing errors by the community pharmacy personnel.

Sound alike Look alike effect (Similar names , colours or designs in packaging of medicines)	
Poor handwriting on the prescriptions	
Ambiguous dispensing instructions	
Lack of time to counsel patient	

4. How many pharmacists or pharmtechs work in your community pharmacy on a daily basis? Specify cadre and number.

.....

.....

.....

.....

5. What strategies have you put in place to reduce dispensing errors?

	Always	Sometimes	Never
Assigning clear roles to all staff to avoid distractions and multitasking.			
Taking regular breaks.			
Organising the drugs in the workplace			
Counterchecking of prescriptions.			

6. Have you ever attended any training on workload management or good dispensing practices?

Yes [] No []

If yes, state the year and the topics covered.

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D. Counterfeits in the Pharmaceutical supply chain

1. Define a counterfeit drug in your own words.

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2. Have you ever attended any special training course about identification of counterfeit drugs and how to deal with this problem?

Yes [] No []

If yes, state the year of attendance.

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3. Have you ever encountered a counterfeit drug in your practice?

Yes [] No []

If yes, did you report it to PPB?

Yes [] No []

Kindly state the year you reported it

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4. Which of these details do you check for when receiving the medicines you have procured? Kindly indicate your responses using a tick

	Always	Sometimes	Never
Brand name of the medicines and the name of manufacturer(s)			
Dates of manufacture, expiration and the batch/lot number of the medicines			
Certificates of Analysis of each medicine and the PPB registration number on the package			
Intactness of packaging and medicines by checking the seals, colour and physical condition of packaging and medicines e.g. presence of mould or caking of suspensions			

5. Which methods do you use to detect counterfeit drugs? Kindly indicate your responses using a tick.

	Always	Sometimes	Never
Close scrutiny of the medicines to check for defects in colour and physical condition of drugs			
Manufacturing company alerts during CMEs and through their medical representatives			
Alerts from PPB through their newsletters, the media or their website.			
Complaints from patients, clinicians and other community pharmacy personnel on drug efficacy of specific medicines			

E. Pharmaceutical care in community pharmacies

1. Have you heard about the concepts of pharmaceutical care?

Yes []

No []

2. How often do you carry out the following activities? Kindly indicate your response using a tick.

	Always	Sometimes	Never
Documenting information about the patients' medication information on written records or computerized notes.			
Follow up patients to evaluate their progress and identifying drug related problems.			
Establishing a professional relationship with doctors to enable joint therapeutic management of patient.			
Verification of patient understanding of medication dosage instructions, contraindications and side effects.			

3. Do you have a designated private area or room where patients can be counselled and get consultation?

Yes []

No []

If No, explain why.

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4. What reference material(s) is (are) available at your community pharmacy?

- a. The Kenya Drug Index
- b. The Essential Medicines List of Kenya
- c. The British National Formulary (BNF)
- d. The Internet
- e. WHO Guidelines for Monitoring ADRs
- f. Drug information leaflets
- g. Others (list one)

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5. State one factor that acts as a barrier to implementing pharmaceutical care in your community pharmacy.

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APPENDIX 3:

KEY INFORMANT QUESTIONNAIRE FOR THE PPB INSPECTOR

Please answer the questions below by ticking or by writing your responses in the space provided. Please do not write your name on the questionnaire and give honest responses to the best of your ability. Your responses will be kept confidential and mainly for research purposes.

1. Kindly state your gender
Male Female
2. Which age category do you fall under?
 18- 24
 25-35
 36-45
 46 and above
3. State your academic qualifications
 Postgraduate (M.Pharm)
 Bachelor of pharmacy (B.Pharm)
 Diploma in pharmacy
 Certificate in pharmacy
 Other
4. How long have you worked as a PPB inspector?
 Less than 1 year
 1 to 5 years
 6 to 10 years
 11 to 15 years
 More than 15 years
5. Have you received any training on pharmacovigilance?
Yes No
If yes, state the year and venue
.....
.....
If no, state the reason why
.....
.....
.....
6. Have you ever encountered a suspected Adverse Events or poor quality drug reported by community pharmacy personnel to the PPB?
Yes No
7. What do you think are the barriers to reporting Adverse Events and poor quality drugs to PPB by the community pharmacy personnel? State at least three.
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APPENDIX 4

LIST OF COMMUNITY PHARMACIES IN EMBU COUNTY

1. Jabez pharmacy
2. Njeru chemist
3. New day chemist
4. Sunview chemist
5. Mbeti pharmacy
6. Uzima pharmacy
7. Tan pharmacy
8. Mak-care pharmacy
9. Benchmark chemist
10. Kirimari chemist
11. Shadya chemist
12. Dallas Tiba chemist
13. Eastern prestige chemist
14. Neema pharmacy ltd
15. Wambugu pharmacy
16. Priory pharmacy
17. Janmag chemist
18. Liberty pharmacy
19. Samuka pharmacy
20. Embu pharmacy
21. Neema pharmacy 'B'
22. Embu children pharmacy
23. Aberdeen pharmacy
24. Ndamunge chemist
25. Icon pharmacy
26. Polystop chemist
27. Itabua chemist
28. My chemist Oil Libya
29. Elmunash chemist
30. Aga Khan Hospital Pharmacy
31. Riba pharmacy
32. Reancy chemist
33. Good shepherd Chemist
34. Afya Max pharmacy
35. Antacross Pharmcare
36. By faith chemist
37. First Siakago chemist
38. Frams chemist
39. Goodhope pharmacy
40. Gracom chemist
41. Jinenee chemist
42. Kianjokoma chemist
43. Mbeti pharmacy ltd
44. Medcare chemist
45. Rex chemist
46. Pemu pharmcare
47. Providence chemist
48. Thusi pharmacy
49. Victor point pharmacy
50. Winhope dispensing chemist
51. Bondoni chemist ltd
52. Tiddy's chemist
53. Care pharmacy
54. Lileti chemist
55. Highlands chemist
56. Modern dispensing chemist
57. Imara medical centre
58. Daka chemist
59. Jilcare pharmacy
60. Abepha chemist