FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING AMONG PATIENTS AND HEALTHCARE PROVIDERS IN SELECTED HOSPITALS IN KIRINYAGA COUNTY, KENYA

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Factors Influencing Adverse Drug Reaction Reporting among Patients and Healthcare Providers in Selected Hospitals in Kirinyaga County, Kenya

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DECLARATION

This thesis is my original work and has not been presented for a degree at any other University.

Signature:……Date: ……...

David Muriithi Nyagah

This thesis has been submitted for examination with our approval as University Supervisors.

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JKUAT, Kenya

DEDICATION

I dedicate this work to my family for their endless support, prayers and constant motivation. I would not have completed this study without you.

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ABBREVIATIONS AND ACRONYMS

ACK	Anglican Church of Kenya
ADR	Adverse drug reaction
AERS	Adverse Event Reporting System
CCC	Comprehensive Care Clinic
CI	Confidence interval
CIDP	County Integrated Development Plan
Df	Degrees of freedom
EMEA	European Medicines Agency
FDA	Food and Drug Administration
HIV	Human immunodeficiency virus
K^{th}	Sampling interval
MEDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency
NHIF	National Hospital Insurance Fund
OR	Odds ratio
PIDM	Program for International Drug Monitoring
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance

SF	Sampling fraction
SPSS	Statistical Package for Social Sciences
UMC	Uppsala Monitoring Centre
WHO	World Health Organization
χ^2	Chi-squared
^{0}**C**	degrees Celsius

DEFINITION OF TERMS

Adverse drug reaction: A response to a drug that is noxious and unintended, which occurs at doses typically used in humans for the prophylaxis, diagnosis or therapy of disease, or the modification of physiological function and is related to the pharmacological properties of the drug.

Experience: To undergo an adverse drug reaction.

Pharmacovigilance: is the science and activities relating to detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem.

Reporting (healthcare provider): The yellow form informs the Pharmacy and Poisons Board of an adverse drug reaction.

Reporting (patients): To account to a healthcare professional of an adverse drug reaction one has encountered.

Special clinics: These are Clinics offering medical services to diabetic, hypertensive and Human immunodeficiency virus (HIV) positive patients.

ABSTRACT

In 2020, Kirinyaga County accounted for 5% of adverse drug reaction (ADR) reports submitted to the Pharmacy and Poisons Board (PPB). Despite landing at no. 5 out of 47 in the Counties ADR reporting ranks, the ADR reporting rate could be improved. The study aimed to establish factors influencing ADR reporting among patients and healthcare providers in selected hospitals in Kirinyaga County. This mixed-method study comprised interviewer-administered, self-administered questionnaires and key informant interviews with 360 patients, 224 healthcare providers and 12 section heads. Stratified and purposive sampling methods sampled respondents. Statistical Package for Social Sciences (SPSS) version 27 analyzed quantitative data. The Chi-squared (χ^2) test determined the association between predictor and outcome variables. Binary logistic regression assessed the strength of the association. Fisher's exact test determined significance. P values of <0.05 were considered significant. NVivo version 12 coded qualitative data. Deductive thematic analysis analyzed qualitative data. In total, 166 (46.1%) patients experienced ADRs from medicines they were using. Of this, 145 (87.3%) reported ADRs to healthcare providers within the last three months. Besides, 265 (73.6%) patients were not aware of the patient alert card. Among patients, men were 46.2% less likely to experience ADRs compared to females (odds ratio (OR) 0.538, 95% confidence interval (CI) 0.340–0.852, p=0.008). In total, 159 (74%) healthcare providers never reported ADRs to the PPB within the last three months. The study associated ADR reporting among healthcare providers with increasing age (p=0.001) and education (p=0.023). Additionally, Nurses had an 88.0% lower likelihood of reporting ADRs than Pharmacists (OR 0.120, 95% CI 0.041–0.351, p<0.001). Moreover, health professionals aware of the National PV Center were more likely to report ADRs (OR 3.818, 95% CI 1.995–7.307, p<0.001). Sensitized healthcare workers on ADR reporting were more likely to report ADRs (OR 3.642, 95% CI 1.453–9.130, p=0.006). Each of the hospitals lacked pharmacovigilance (PV) centers. Barriers of ADR reporting identified were: not knowing where to report, fear due to unfriendly healthcare staff and inadequate training. In conclusion, most patients reported ADRs to healthcare providers and patients' gender significantly influenced experiencing ADRs. Healthcare providers' age, level of education, PV training, knowledge of ADR reporting tools and PV center were significantly associated with ADR reporting. Inadequate training and feedback hindered ADR reporting at the facility level. Active involvement of patients and healthcare providers in spontaneous ADR reporting, training of stakeholders in PV activities, providing prompt feedback, establishing a PV center beside the promotion of reporting tools and up-to-date guidelines are highly recommended to enhance ADR reporting in Kirinyaga County.

CHAPTER ONE

INTRODUCTION

1.1 Background information

The World Health Organization (WHO) defines pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO, 2012). The Pharmacy and Poisons Board (PPB) defines an adverse drug reaction (ADR) as a response to a drug that is noxious and unintended, that occurs at doses used in humans for the prophylaxis, diagnosis or therapy of disease, or the modification of physiological function (Kenya-PPB, 2009).

In the United Kingdom (UK), ADRs accounted for 6.5% of all hospital affirmations with a case casualty rate of 0.15%. The charge incurred by the UK to combat ADRs is approximately five hundred million Euros (Kenya-PPB, 2009; Waller & Harrison-Woolrych, 2010). A prospective Singapore study discovered that 8.1% of ADRs led to hospitalization. Eleven ADRs caused permanent incapacity and death. ADRs caused 9,400 extra hospital days annually, oversetting into 48,000 hospital days yearly (Chan *et al.,* 2016). A South African study showed that ADRs accounted for 2.9% of hospital admissions and 16% of inpatient deaths over 30 days were related to ADRs (Mehta *et al.,* 2017). ADRs have contributed to delayed hospitalization, creating a monetary burden in Kenya's health framework, disability and death. In 2019, health professionals reported 151 severe ADRs over four months. Among them, 26.5% led to hospitalization, 17.2% were life-threatening, 4.6% caused disability and 2% caused death (PPB, 2019).

The cutting edge of modern PV dates back to 1961, where thalidomide caused phocomelia, a congenital disorder affecting the appendages of newborns. Thalidomide managed morning sickness among pregnant women. After intensive investigations, Germany withdrew it from the market in November 1961. In 1968, the WHO started the global drug monitoring program. Initially, the program began as a trial in ten states where National PV Programs were running. The nations include

Australia, the UK, the United States of America (USA), Germany, Canada, Ireland, Sweden, Denmark, New Zealand and the Netherlands (Fornasier, Francescon, Leone & Baldo, 2018; WHO, 1972). The Uppsala Monitoring Centre (UMC) holds more than 20 million case reports (PPB, 2019). By the conclusion of 2015, 35 African nations had procured complete enrollment in the program. The program has 148 members and 24 associate countries (WHO, 2020).

The ADR reporting rate in Africa is low, as the number of drug security concerns submitted to the Uppsala monitoring center is 103,499 representing 0.88% of the world case reports (Ampadu *et al.,* 2016). The PPB introduced the National PV Program in June 2009. Kenya joined the global drug monitoring program in 2010 as the 98th member. As of June 2019, Kenya had detailed 12,321 case reports accounting for 0.06% of international medicine security reports. Out of 9,000 health facilities registered in Kenya, 169 submitted ADR reports (PPB, 2019). Spontaneous reporting is the cornerstone of PV in Kenya. However, it is frail as under-reporting, unawareness and poor attitude towards ADR reporting are high among developing countries (Olsson, Pal & Dodoo, 2015).

Previous studies have been inconclusive in exploring the factors affecting ADR reporting. Some studies have reported patient characteristics, such as age, occupation, level of education and awareness of patient reporting mechanism (Nderitu, 2011; Al-Dweik, Stacey, Kohen & Yaya, 2017); facility-level factors such as training, feedback after reporting and availability of ADR tools and PV center (Hamumy, 2015; Obonyo, 2014) while others reported healthcare provider factors such as age, duration of practice, awareness of PV tools and National PV Center and adherence to the ADR reporting guidelines (Carandang, Cao, Jose, Almonte & Tinio, 2015; Ganesan, Vikneswaran, Reddy, Subrahmanyam & Adithan, 2016; Wang'ang'a, 2017). There were also inconclusive determinations of the individual factors affecting ADR reporting. For example, Obonyo (2014) revealed that the gender of healthcare providers did not affect ADR reporting. Kamal, Kamel and Mahfouz (2014) stated that the reverse was true. Exceptionally few studies on ADR reporting among patients and health professionals have been carried out in Kenya. Therefore, the present study was conducted to determine factors influencing ADR reporting

among patients and healthcare practitioners in selected healthcare facilities in Kirinyaga County, Kenya.

1.2 Statement of the problem

ADRs have contributed to delayed hospitalization, reduced treatment adherence, hospital admissions, absent workers, high healthcare costs, disability, high casualty rates, and death (PPB, 2019). In India, ADRs accounted for 6.23% of all hospital affirmations, with 7.01% being severe. The cost incurred over nine months due to combat ADRs was 22,469 US dollars (Geer, Koul, Tanki & Shah, 2016). A South African study reported that three among seven deaths reported to a PV program were ADR-related (Jones *et al.,* 2020). Of the 38 severe ADRs reported in Kenya in 2020, 31.58% led to hospitalization, 13.16% were life-threatening, 13.16% caused disability and 26.32% caused death (PPB, 2020).

Under-reporting of ADRs has severe implications on the treatment outcomes and quality of patient healthcare. Binu, Sarika, Denna, Merin and Riya (2017) noted that although 53% of health professionals in India encountered patients with ADRs, 32.67% reported. An Egyptian study showed that although 112 Physicians identified patients with ADRs, only nine reported ADRs, translating into a reporting rate of 8% (Kamal *et al.,* 2014). As of June 2019, out of 9,000 health facilities listed in Kenya, 169 (1.9%) submitted ADR reports (PPB, 2019). Wang'ang'a (2017) showed that 53.5% of health professionals in Kenyatta National Hospital reported ADRs to the PPB. Although 62.2% of patients in Kiambu District hospital experienced ADRs, most did not report to healthcare providers (Nderitu, 2011). Because of the limited conclusive data in the available literature, the study identified the need to explore factors that influence ADR reporting among patients and healthcare providers in addition to providing interventions to under-reporting.

1.3 Justification

Research on variables affecting ADR reporting among patients is constrained. In the past, studies under seeking factors influencing ADR reporting have used healthcare providers (Ganesan *et al.,* 2016; Nisa, Zafar & Sher, 2018) as the research

population. Little is published on ADR reporting by patients, but the quality of patients' reports has appeared to supplement those of healthcare workers (Blenkinsopp, Wilkie, Wang & Routledge, 2006). The findings will highlight the gaps in ADR reporting by patients and promote patient reporting tools to encourage high-quality and timely reporting.

In 2019, the PPB reported that Antiretroviral and Anti-Hypertensive drugs caused the most ADRs in its quarterly PV newsletter. Human immunodeficiency virus (HIV) positive, Diabetic, and Hypertensive patients form the largest groups in special clinics (Comprehensive Care Clinics (CCC), Diabetic and Heart clinics) in Kirinyaga County. These groups have unremitting conditions and are subjected to prolonged drug therapy, making them susceptible to experiencing ADRs. Additionally, they take multiple drugs simultaneously. The rate of ADRs increases with the number of medicines taken because of drug interactions (Haleem, 2014). This study evaluated the factors impacting ADR reporting in these patients to increase their comprehension of the PV system and improve reporting,

In Kenya, Spontaneous reporting is the cornerstone of PV. It helps identify the risk-benefit profiles of drugs throughout their life cycle, medication errors, product quality, new, unusual and fatal reactions not recognized in clinical trials. Clinical trials are brief, use a limited number of participants, exclude children, people with underlying diseases, the elderly and women of childbearing age (Najafi, 2018). Therefore, not all ADRs of new drugs are known, making ADR reporting very crucial. Spontaneous reporting among developing countries is frail as under-reporting, unawareness and poor attitude towards ADR reporting is high. All healthcare workers ought to be sensitized and equipped with skills in PV such as identifying ADRs, filling ADR forms, sending filled forms to the National PV Center and managing ADRs. The findings will help healthcare practitioners integrate ADR reporting into their daily clinical practice while also highlighting the interventions of obstacles to ADR reporting.

Few studies on ADR reporting have been carried out in Kenya, specifically in Kenyatta Referral Hospital (Hamumy, 2015; Obonyo, 2014; Wang'ang'a, 2017).

There is no evidence of studies conducted in Kirinyaga County, particularly in Kerugoya Referral Hospital, Kianyaga, Kimbimbi and Sagana Sub-County Hospitals, the largest County hospitals where ADR reporting lies in the hands of healthcare providers. This study's findings will reinforce PV and enhance the patient's safety and quality of life by invigorating ADRs' timely reporting.

1.4 Research questions

1. What is the proportion of patients reporting adverse drug reactions to healthcare practitioners in selected hospitals in Kirinyaga County, Kenya?
2. What are the patient-level factors influencing adverse drug reaction reporting among patients in selected hospitals in Kirinyaga County, Kenya?
3. What healthcare provider factors influence adverse drug reaction reporting among healthcare providers in selected hospitals in Kirinyaga County, Kenya?
4. What are the facility-level factors influencing adverse drug reaction reporting in selected hospitals in Kirinyaga County, Kenya?

1.5 Objectives of the study

1.5.1 Broad objective

To determine factors influencing adverse drug reaction reporting among patients and healthcare providers in selected hospitals in Kirinyaga County, Kenya.

1.5.2 Specific objectives

1. To determine the proportion of patients reporting adverse drug reactions to healthcare practitioners in selected hospitals in Kirinyaga County, Kenya.
2. To establish the patient-level factors influencing adverse drug reaction reporting among patients in selected hospitals in Kirinyaga County, Kenya.
3. To determine the healthcare provider factors influencing adverse drug reaction reporting among healthcare providers in selected hospitals in Kirinyaga County, Kenya.

4. To explore the facility-level factors influencing adverse drug reaction reporting in selected hospitals in Kirinyaga County, Kenya.

1.6 Significance of the study

Discoveries from this study will highlight the current status, gaps and barriers of ADR reporting in Kirinyaga County, in addition to recommendations to enhance reporting. The findings will spotlight roles patients and healthcare professionals need to play to progress ADR reporting. Results will help create a comprehensive framework that will make ADR reporting a standard procedure where healthcare providers will adopt it. This study will help administrative bodies roll out strategies to streamline PV practice by making it a straightforward process while training PV at higher institutions to prepare health science students for ADR reporting earlier to practice. Furthermore, the data will inform policy on which medicines to include in the County's drug formulary after a risk-benefit analysis. Suggestions from this study will help emphasize the need for patient and healthcare provider sensitization about the importance of reporting ADRs through routine training and creating a PV center within Kirinyaga County to promote timely reporting. These recommendations will make strides to develop PV practice, encourage rational use of medicine, and contribute to the long-run amelioration of reporting ADRs.

1.7 Study limitations

The scope of the study was limited to one level-5 and three level-4 public hospitals, which affected the generalizability of outcomes, particularly for private hospitals that offer services to affluent communities and enable insured people to access therapeutic services through insurance schemes. Recall and reporting bias could not be ruled out due to self-reported information from quantitative and qualitative findings.

1.8 Conceptual framework

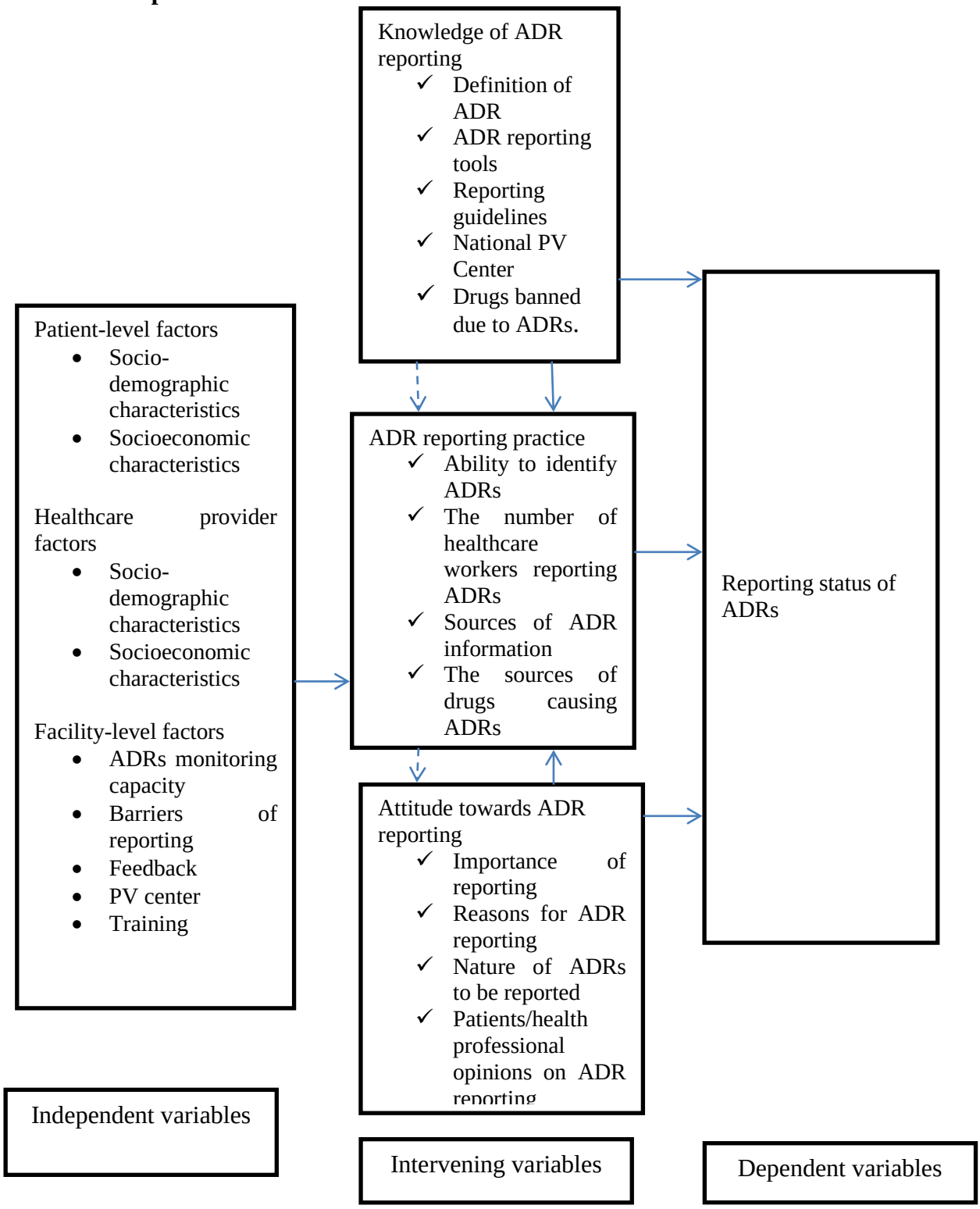

Figure 1.1: Conceptual framework of the study

CHAPTER TWO

LITERATURE REVIEW

2.1 Origin and development of pharmacovigilance

The cutting edge of modern PV dates back to 1961, where thalidomide caused phocomelia, an inherent anomaly affecting the appendages of newborns. Thalidomide managed morning sickness among pregnant women. Germany withdrew it from the market in 1961 after archiving reports of its teratogenic impacts. The ban prompted the ratification of the Kefauver-Harris modification. It required all pharmaceutical plants to guarantee effective and secure pharmaceuticals before conducting clinical trials (Fornasier *et al.,* 2018; Sharma, Kumar, Singh, Bhandari & Singh, 2017).

In 1968, the WHO started the global drug monitoring program. The program began as a pilot in ten states: Australia, the UK, the USA, Germany, Canada, Ireland, Sweden, Denmark, New Zealand and the Netherlands (Fornasier *et al.,* 2018; WHO, 1972). It facilitates its operations from a central point in Uppsala, Sweden. The WHO Program for International Drug Monitoring (PIDM) stores ADR information in a database called *VigiBase*, which holds more than 20 million case reports and is accessed by drug manufacturing plants and member states (PPB, 2019). As of 2013, 117 countries collaborated with the program and 27 countries were in the skirt of securing enrollment (WHO, 2013). By September 2015, 35 African nations had obtained complete program registration (Ampadu *et al.,* 2016). The international drug monitoring program has 148 full member states and 24 associate states (WHO, 2020). Kenya became a member of the WHO PIDM in 2010 (WHO, 2020). The benefits of being a member of UMC include access to global medicine safety data through *VigiBase*, feedback about potential ADRs based on communication and analysis of global data through the WHO Pharmaceuticals Newsletter, access to software and terminologies for reporting, analyzing and storing ADR data, support and training on running a PV center, establishment of PV guidelines, access to

publications about good PV practice and access to the global network through training courses and meetings with member countries (WHO, 2014).

2.2 Legal basis and guidelines

The UK PV system is based on an enactment that categorizes PV's practice into two segments: control 2309/93-Article 19 to 26 and 2001/83-article 101 to 108. Article 25 shows that member states ought to report drug safety issues within 15 days to the agency and marketing authorization holders. Section 23 requires a selling authorization holder to have a qualified individual within the community, whose duty is to oversee an ADR database, give feedback after carrying out risk-benefit analysis of drugs and fill omitted information in ADR reports (Mann & Andrews, 2007; Waller & Harrison-Woolrych, 2010).

Mandate 2001/83 title 1 outlines all significant terms utilized in PV. Title 9 requires all members to have a National PV Program to monitor ADRs, while Article 105 stipulates creating a database to share ADR data. Section 117 clarifies the order to revoke a drug based on risk-benefit examination. Directive 2010/20 embodies clinical trials that allow the monitoring of medicines utilized within clinical trials. The law requires the organization or the individual financing clinical trials to store reported ADRs (Mann & Andrews, 2007; Waller & Harrison-Woolrych, 2010).

Volume 9A contains guidelines for this enactment. Volume two specifies information to be enclosed in package embeds and item labels (Waller & Harrison-Woolrych, 2010). In November 2017, Eudra Vigilance permitted selling authorizations to access the database to help accomplish their PV necessities. Marketing authorizations commit to screen ADR information and report all captured signals to the European Medicines Agency (EMEA) and National PV Centers (Fornasier *et al.,* 2018).

2.3 Scope of Pharmacovigilance

PV is the science and activities relating to detecting, assessing, understanding, and preventing adverse effects or other drug-related problems (WHO, 2012). Significant

concerns of PV include: fake and substandard medicines, product quality, medication blunders, insufficient reports about the viability of pharmaceuticals, reports on mild/severe harm, drug elicited mortality, drug abuse and interactions (Swain & Patra, 2014).

2.3.1 Pharmacovigilance indicators

These are measures of inputs, processes, results and impacts that ascertain how well a PV framework executes its objectives. They explain: the present state of PV in a nation, the capacity of PV in a country, monitor PV, provide measures of impact and give feedback to administrative bodies and partners to act on drug safety concerns (WHO, 2015).

The WHO separates these markers into three distinct categories;

- Structural indicators evaluate infrastructure required to hold out PV activities; they include policy, rules, tools, finances, PV center and staff.
- Process markers assess the rolling out of PV exercises and their operation degree; they involve gathering, following up, analyzing, and examining ADR reports.
- Outcome/impact markers measure effects/changes brought about by PV exercises, such as improving patient safety.

2.4 Adverse drug reactions

An ADR is a response to a drug that is noxious and unintended, which occurs at doses typically used in humans for the prophylaxis, diagnosis or therapy of disease, or the modification of physiological function (Kenya-PPB, 2009). ADRs' risk factors include age, race and ethnicity, gender, reduced liver and kidney function, pathological conditions, the drug itself, people who have encountered ADRs in the past and poly-pharmacy (Schatz & Weber, 2015). Males and females experience and report ADRs differently due to gender and sex-related variables. Differences in hormone type and function, genetic composition, physiology, and immunological processes are all sex-related aspects. Because of their lean body mass, females are

more likely to develop type A ADRs. Because of its poor clearance, Zolpidem necessitates dose changes in women; thus, 5mg is preferred to 10mg. The type and reporting of ADRs differ between males and females due to differences in health-information-seeking behavior, treatment adherence, lifestyle, communication, and social roles. Women seek healthcare more frequently than men, resulting in more co-prescriptions and a higher chance of developing ADRs (de-Vries *et al.,* 2019).

2.4.1 ADR reporting tools

- Suspected ADR form (PV 1)

PV 1 is the official tool utilized to report ADRs to the PPB (Appendix 1). The contents of an ADR form include patients' information, adverse reaction, suspected drug and reporter's data. Health staff can obtain it from health facilities, the PPB workplace and the website (Kenya-PPB, 2009).

- Patient alert card (PV 4)

Health personnel utilizes PV 4 to check severe ADRs among patients (Appendix 2). Patients submit it to healthcare professionals during hospital visits to help forestall ADRs' future occurrence (Kenya-PPB, 2009).

2.5 Adverse drug reaction reporting trends

2.5.1 ADR reporting globally

In the UK, ADR reporting lies in the hands of the yellow card scheme. Health professionals have submitted more than 500,000 reports to the Medicines and Healthcare Products Regulatory Agency (MHRA). The UK government introduced an electronic reporting system that permits healthcare providers to report ADRs (Mann & Andrews, 2007). In the US, ADR monitoring depends on spontaneous reporting. The Food and Drug Administration (FDA) launched the Adverse Event Reporting System (AERS) in 1969, a database that utilizes coding based on terms from the Medical Dictionary for Regulatory Activities (MEDRA) and employs data

mining to capture signals. In 1993, the FDA launched *MedWatch*, a reporting scheme to report ADRs and give stakeholders feedback (Haleem, 2014).

Binu *et al.* (2017) cited that 68% of healthcare providers in India never reported ADRs they came across throughout their clinical practice. The study noted that under-reporting was rampant. Under-reporting causes were unawareness of how to report ADRs, lack of multiple alternatives for reporting and poor feedback. The study's qualitative arm noted that healthcare professionals came across various ADRs; however, few reported them to the responsible authority. Barriers to ADR reporting included the conviction that ADR reporting was not imperative as managing the patient and the ADR form was not accessible. De-Angelis, Giusti, Colaceci, Vellone and Alvaro (2015) reported that out of 570 Italian Nurses, 63 reported ADRs. Unawareness was the major determinant that conditioned ADR reporting. In total, 63.5% and 71.6% of health workers were unaware of where to find the ADR form and how to fill it, respectively.

2.5.2 ADR reporting in Africa

Agouzal *et al.* (2009) noted that the prevalence of ADRs within Ibn Sina Teaching and Referral Hospital in Morocco was 4.2%. Women 55.9% experienced ADRs more than men 44.1%. Also, 47.5% of reported ADRs were severe, with a case casualty rate of 0.07%. The reporting rate of ADRs was low; healthcare providers reported 200 cases annually to the Moroccan PV center. Fadare, Enwere, Afolabi, Chedi and Musa (2011) noted that 42% of Medical Officers and 37% of Nurses at Aminu Kano Teaching Hospital in Nigeria were aware of the existing ADR reporting structure. Results showed that 39% and 26% of Doctors and Nurses were unaware of the ADR notification form. Although 80% of healthcare professionals had encountered an ADR during practice, it was astounding to note that 42% had reported it. The findings showed that a lower proportion of Medical Doctors, 38%, reported at least 1 case of ADR compared to Nurses 75%. Interestingly, health professionals reported 75% of case reports in a verbal approach. Reasons cited for under-reporting were negligence of reporting rules, not knowing where to report, and insufficient information on the ADR notification form's existence.

Kamal *et al.* (2014) found that ADR reporting knowledge was low as 16% of general health professionals and 22% of specialists agreed to know a National PV Center in Egypt. Clinicians' perspective towards reporting was commendable, as healthcare workers felt that ADR reporting is vital and obligatory. Out of 112 healthcare providers, who had encountered ADRs throughout their clinical practice, 9 reported ADRs that occurred, with 7 being Specialists. They distinguished under-reporting as a significant gap in ADR reporting.

2.5.3 ADR reporting in Kenya

The PPB started the National PV Program in June 2009. Kenya joined the global drug monitoring program in 2010. In December 2013, the PPB executed an online PV system where stakeholders report substandard drugs and suspected ADRs. In East and Central Africa, Kenya is ranked highest in ADR reporting. This high reporting rate results from active pharmaceutical industries, robust public health infrastructure and programs, a better understanding of PV, a rich formal PV curriculum, and increased interest by healthcare professionals compared to Tanzania and Congo. They joined the WHO PIDM in 1993 and 2010, respectively (Ampadu *et al.*, 2016). As of September 2020, Kenya had submitted more than 14,403 reports to *Vigimed,* accounting for 0.06% of worldwide medicine security reports. Patients can now report ADRs directly at pv@pharmacyboardkenya.org or +254795743049. The PPB provides quarterly feedback to its stakeholders through PV newsletters. In 2020, Pharmacists submitted 57.73% of case reports (PPB, 2020). Females experienced ADRs more frequently than males. Besides, 9.18% of detailed ADRs were fatal. Of the severe case reports, 26.32% caused death, 13.16% were life-threatening, 13.16% caused disability and 31.58% caused prolonged hospitalization. Antiretroviral drugs accounted for the most substantial part of ADRs. Among the organ systems, the skin and appendages were affected most. Nairobi Hospital and Kuria District Hospital reported the majority of cases with 27 and 19 reports separately. Nairobi and Migori Counties had reported the most cases, with 130 and 51 reports independently. Under-reporting was profoundly apparent. Out of 9,000 health facilities listed in Kenya, 169 (1.9%) reported ADRs to the PPB. Kirinyaga County reported 5.31% of all submitted reports (PPB, 2020).

2.6 Factors associated with adverse drug reaction reporting

2.6.1 Patient-level factors

Joshi, Shah, Mistry and Gor (2015) noted a significant relationship between residing in urban areas and Indian patients' knowledge of ADR reporting ($p=0.04$). The level of education among patients was directly proportional to knowledge of ADRs ($p<0.001$). Age and gender were not statistically significant with patients' knowledge of ADR reporting. Staniszewska, Dąbrowska-Bender, Olejniczak, Duda-Zalewska and Bujalska-Zadrożny (2017) found a statistically significant relationship ($p<0.0001$) between the place of residence and knowledge of ADR reporting. The Poland study argued that patients in the city had better PV knowledge than those living in the countryside. The greater knowledge among city dwellers was a consequence of ADR reporting campaigns.

Pahuja *et al.* (2014) disclosed that 74% of Indian patients comprehended what an ADR is. Similarly, 81% of Nigerian patients knew an ADR (Adisa, Adeniyi & Fakeye, 2019). Robertson and Newby (2013) found that 21.2% of South Wales patients knew the ADR reporting scheme for consumers. Al-Dweik *et al.* (2017) discovered that 75% of patients were uninformed of the patient reporting mechanism. Unawareness of the ADR system is a considerable obstacle to ADR reporting (Staniszweska *et al.*, 2017). Joshi *et al.* (2015) noted positive attitudes among Indian patients as 96% believed that ADR reporting is essential and 56% felt that the purpose of ADR reporting was to improve patient safety. Pahuja *et al.* (2014) reported that 78.5% of Indian patients felt that the National ADR reporting scheme should permit direct reporting. Staniszweska *et al.* (2017) reported that 75% of Northern Indian patients felt entitled to report ADRs. Thadani *et al.* (2019) showed that the main reason that spurred Indian patients not to report ADRs was not being sure if ADR was from the medicine or not.

Robertson and Newby (2013) reported that 46.3% of patients had experienced adverse effects from the medicine they were using. Of this, 86% reported ADRs to healthcare providers. Only 21% of respondents who had ADRs used one of the patient reporting schemes to report them, according to the South Wales study. This

occasional use of the ADR reporting scheme was a consequence of not promoting the ADR reporting tools. Adisa *et al.* (2019) noted that 83% of Nigerian patients reported ADRs to Physicians. Pahuja *et al.* (2014) indicated that 53.8% of patients preferred online reporting to report ADRs. Text message, 27.2% and filling ADR forms, 24.4% were the most suggested techniques of ADR reporting by Adisa *et al.* (2019).

2.6.2 Healthcare worker factors

Kamal *et al.* (2014) noted that men had a higher awareness and practice score than their female counterparts, who had a higher attitude score. Egyptian practitioners with a doctoral degree and over ten years of expertise had better knowledge, attitude and practice scores than those with a Master's, undergraduate degree and less than ten years' expertise. Ganesan *et al.* (2016) found that junior Doctors had a higher attitude score than senior Doctors. The South Indian study noted that senior Doctors had higher knowledge and practice scores compared to junior Doctors. A study conducted in the Philippines discovered that age, gender and work environment did not influence practitioners' ADR reporting knowledge and attitude, but years of practice ($p=0.043$) influenced knowledge on ADR reporting (Carandang *et al.*, 2015). The probability of reporting increased with the length of experience. Nadew, Beyene and Beza (2020) revealed that Ethiopian specialists ($p<0.001$), female healthcare providers ($p<0.001$) and professionals with more than six years of expertise ($p=0.025$) were more likely to report ADRs to the National PV Center.

An Ethiopian study conducted among Physicians, Nurses and Pharmacy Personnel unearthed that health professionals with good PV knowledge were six times more likely to report ADRs compared to those with less knowledge ($p<0.001$) (Mulatu & Worku, 2014). An Indian study conducted among Doctors, Pharmacists, Nurses and Dentists noted that 65% of health workers were aware of medicines banned due to ADRs. In the study, Pharmacists had a higher knowledge score followed by Nurses, Doctors and Dentists. In Kenya, Obonyo (2014) found that 76.4% of health professionals were unaware of the PV center. Gurmesa and Dedefo (2016) disclosed that 62.6% of healthcare providers knew the ADR report form. The Ethiopian study

found that Medical Doctors and Pharmacists had better knowledge compared to Nurses. Ezuko, Ebenebe, Nnebue and Ndu (2015) reported that 59.4% of Nigerian health professionals were unaware of the ADR reporting guidelines. The Nigerian study showed that pharmacists were more knowledgeable compared to Doctors and Nurses.

Kassa, Mulu and Geresu (2017) noted an excellent attitude among Ethiopian health professionals as 93% established that ADR reporting was their professional obligation. Physicians and Pharmacy Personnel demonstrated favorable attitudes compared to Nurses and Health Officers. Binu *et al.* (2017) disclosed that ADRs' seriousness spurred reporting among 63.67% of health professionals. According to the Indian study, Pharmacists demonstrated higher attitude scores followed by Doctors, Dentists and Nurses. Wang'ang'a (2017) showed that 88.3% of Kenyan healthcare providers felt that reporting should be done to all ADRs, with Pharmacists scoring higher than Medical Doctors. An Ethiopian study reported similar positive attitudes (Denekew, 2014).

Binu *et al.* (2017) noted that although 53% of Indian health professionals experienced patients with ADRs during their practice, 32.67% reported. Mulatu and Worku (2014) found that 16.2% of Ethiopian health professionals reported encountered ADRs. Of those who reported ADRs, only 4.5% reported to the National PV Center. The unawareness of the PV center could be a result of inadequate feedback and knowledge on the ADR reporting system. Nisa *et al.* (2018) discovered that most health professionals in Pakistan, 33.5% used the internet to gather information about ADRs actuated by new drugs. An Ethiopian study conducted among Doctors, Pharmacy Personnel, Nurses, Health Officers and Midwifery noted a significant relationship between participants' profession and practice ($p=0.023$). Pharmacy Personnel and Nurses recorded a higher practice score than other respondents (Kassa *et al.*, 2017).

2.6.2 Facility-level factors

There are five prerequisites used to assess the capacity to monitor ADRs. These requirements include a PV center with competent staff, financing, clear roles and a

well-organized structure, a spontaneous method of reporting that uses a standard ADR reporting form, a database that analyzes and stores ADR reports, a PV consultative committee that conducts a risk-benefit analysis of drugs and a clear communication channel that permits prompt feedback (Maigetter, Pollock, Kadam, Ward & Weiss, 2015; WHO, 2010).

Obonyo (2014) uncovered that 72% of healthcare workers in Kenyatta National Hospital had not been trained on ADR reporting. Nisa *et al.* (2018) reported similar findings; 86.9% of health workers in Pakistan were not trained to identify and report ADRs. Trained Nurses were inclined to report ADRs more than unsensitized Nurses (Mugoyela, Robert & Masota, 2018). The Tanzanian study found a significant relationship between training and the use of ADR reporting forms in both private ($p=0.001$) and public ($p=0.01$) hospitals. Insufficient training on ADR reporting is a fundamental cause of under-reporting and Varallo, Guimarães, Abjaude and Mastroianni (2014) have listed it as the 8th sin in under-reporting.

Elkalmi, Hassali, Ibrahim, Liau and Awaisu (2011) cited minimal feedback as a critical facilitator of under-reporting. Olsson *et al.* (2015) reported that filling the communication gap between regulatory bodies and stakeholders would enhance PV practices. The PPB publishes a quarterly bulletin that keeps partners up to date with recent PV activities (PPB, 2020). Wang'ang'a (2017) identified not knowing where and how to report as critical barriers to ADR reporting in Kenyatta National Hospital. Binu *et al.* (2017) discovered that managing the patient is more important as the main reason discouraging ADR reporting among Indian healthcare providers. Hussain, Hassali, Hashmi and Farooqui (2018) and Hamumy (2015) have reported similar barriers. Al-Dweik *et al.,* (2017) identified: poor awareness of the ADR reporting systems, delayed feedback and fear that reporting would be met with disapproval by their healthcare providers as critical barriers patients in the UK, the Netherlands and Australia experienced in reporting ADRs.

The presence of a PV focal person plummets under-reporting as they are responsible for storing ADR data, showing healthcare providers how to fill, how and where to send ADR forms (Mugoyela *et al.,* 2018). Hamumy (2015) found that participation

of Pharmacists in the wards could curtail under-reporting as pharmacists are knowledgeable about PV activities and their specialization in drugs make them knowledgeable about ADRs. Denekew (2014) suggested the importance of developing a PV center to enhance ADR monitoring. Nderitu (2011) recommended that CCCs start a patient-oriented health training program to educate patients on the ADR reporting system to improve active participation in spontaneous ADR reporting.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study site

The study was conducted in Kirinyaga County in the following health facilities: Kerugoya Referral Hospital (level 5), Kianyaga, Kimbimbi and Sagana Sub-County Hospitals (level 4) (Appendix 3). The vast number of healthcare providers and patients at these facilities influenced their selection. The facilities have a wide range of medicines; thus, patients with ADRs were more likely to be clerked by healthcare providers. These healthcare settings provided an accessible and convenient environment for medical research. Kirinyaga County covers a range of 1,478.1 km^2. It is situated South-East of Nyeri County, North East of Murang'a County, and to the West of Embu County. The population of Kirinyaga County is 610,411. The County features an equatorial rainfall pattern with a temperature range of 8.1 degrees Celsius (^{0}C) - 30.3^{0}C. Valleys and peaks characterize the mountainous landscape. Agriculture and livestock farming are the main economic activities. The County has 202 health facilities. One hundred and nine of these settings are public health facilities. The dispersion of public facilities is 1 level 5 facility, 3 level 4 hospitals, 10 level 3 hospitals, 45 level 2 facilities and 50 level 1 facility. The number of mission hospitals and private clinics is 39 and 54 separately. The doctor-population proportion is 1:36,339. The immunization scope and antenatal care are 98% and 42%, respectively (County Integrated Development Plan (CIDP), 2018).

3.2 Study design and approach

This study was a facility-based cross-sectional study where both quantitative and qualitative data were collected. The approaches gave an in-depth understanding of the data and compensated for the shortcomings and benefits of their advantages. Record review and analysis were used to verify the data collected, where necessary. The study was carried out between April and August 2019.

3.3 Study population

The study targeted patients in special clinics, healthcare providers and departmental heads; the patients in special clinics comprised of Diabetic, Hypertensive and HIV-positive persons. Healthcare providers included Consultants, Medical Officers, Pharmacists, Pharmaceutical Technologists, Nurses and Clinical Officers. Key informants were departmental heads who served as heads of special clinics in each hospital.

According to the health records office, selected hospitals had 5,532 special clinic patients. The CCC had 4,000 HIV-positive patients; the Heart clinic had 1213 hypertensive members, while the Diabetes clinic had the least members with 319 patients. Table 3.1 shows the distribution of patients by special clinics.

Table 3.1: Number of patients in selected hospitals

	Number of patients in selected hospitals				
Special clinics	**Kerugoya**	**Kianyaga**	**Kimbimbi**	**Sagana**	**Total**
Comprehensive Care Clinic	1835	419	979	767	4000
Heart	283	562	131	237	1213
Diabetes	73	155	55	36	319
Total	**2191**	**1136**	**1165**	**1040**	**5532**

Table 3.1 is sourced from the Health Records Office, Kirinyaga County, January 2019.

The selected hospitals had 428 healthcare professionals; however, Nurses were the majority, with 264 members. Table 3.2 shows the distribution of healthcare workers by cadre.

Table 3.2: Number of healthcare professionals in selected hospitals

	Number of healthcare providers in selected hospitals				
Cadre	**Kerugoya**	**Kianyaga**	**Kimbimbi**	**Sagana**	**Total**
Consultants	6	0	1	0	7
Medical Officers	25	8	11	4	48
Pharmacists	9	2	4	0	15
Pharmaceutical Technologist	6	4	4	5	19
Clinical Officers	34	15	16	10	75
Nurses	167	29	49	19	264
Total	**247**	**58**	**85**	**38**	**428**

Table 3.2 is sourced from the Health Human Resource Office, Kirinyaga County, January 2019.

3.4 Sample size determination

3.4.1 Sample size calculation for patients in special clinics

The Cochran formula (Cochran, 1997) generated the sample size as follows;

$$n = \frac{Z^2 PQ}{d^2}$$

Where;

n = minimum sample size required.

Z = 1.96 standard error (the standard deviation at a confidence interval (CI) of 95%.)

P = estimated proportion of patients in special clinics who experienced and reported ADRs (since there was no evidence of published material revealing the proportion of patients in special clinics who experienced and reported ADRs in Kenya, p of 0.5 was used).

Q = (1-p).

D = degree of precision desired (5%).

$$n = \frac{Z^2 PQ}{d^2} = \frac{1.96^2 \times 0.5 \times 0.5}{0.05^2} = 385$$

Finite population (i.e., <10,000) correction equation (Cochran, 1997) adjusted the sample size as follows;

$$n_f = \frac{no}{1+\frac{(no-1)}{N}} = \frac{385}{1+\frac{385-1}{5582}} = 360$$

Where;

n_f = adjusted sample size

n_o = calculated sample size of the finite population

N = total number of the study population

The minimum number of patients in special clinics required for the study was 360.

3.4.2 Sample size determination for healthcare providers

The Cochran formula (Cochran, 1997) calculated sample size as follows;

$$n = \frac{Z^2 PQ}{d^2}$$

Where;

n = minimum sample size required.

Z = 1.96 standard error (the standard deviation at a CI of 95%.)

P = estimated proportion of health professionals who reported ADRs among patients. Wang'ang'a (2017) found that 53.2% of health professionals reported ADRs they encountered; p of 0.532 was used.

Q = (1-p).

D = degree of precision desired (5%).

$$n = \frac{Z^2 PQ}{d^2} = \frac{1.96^2 \times 0.532 \times 0.468}{0.05^2} = 383$$

Finite population (i.e., <10,000) correction equation (Cochran, 1997) modified the sample size as follows;

$$n_f = \frac{no}{1+\frac{(no-1)}{N}} = \frac{383}{1+\frac{383-1}{428}} = 203$$

Where;

n_f = adjusted sample size

n_o = calculated sample size of the finite population

N = total number of the study population

A non-response level of 10% was added to get the minimum number of participants.

$$\frac{10 \times 203}{100} = 21 = 203 + 21 = 224$$

The study required a minimum of 224 healthcare providers.

3.4.3 Inclusion criteria

- HIV-positive patients enrolled and attending the CCC.

- Diabetic patients enrolled and attending the Diabetic clinic.
- Hypertensive patients enrolled and attending the Heart clinic.
- Patients, healthcare providers and departmental heads who consented to participate in the study.

3.4.4 Exclusion criteria

- Patients who were too ill to participate in the study.
- HIV positive, Diabetic and Hypertensive patients with comorbidities.
- Patients, healthcare providers and departmental heads who did not consent to take part in the study.

3.5 Quantitative data collection

3.5.1 Sampling technique

The selected hospitals were purposively sampled due to their accessibility, sizeable outpatient and healthcare provider volume, and a wide range of medicine in the special clinics.

3.5.1.1 Sampling for patients in special clinics

The study utilized a stratified sampling technique, where HIV positive, hypertension and diabetes patients constituted the strata. The sample size of 360 was allocated proportionately to the three strata using sampling fractions (SF) (Table 3.3). The total number of patients in special clinics was 5532 (HIV positive = 4000, hypertension = 1213, diabetes = 319) giving a ratio of 13:4:1.

Total ratio = 18

The sample size required = 360

Table 3.3: Proportionate allotment for patients in special clinics

Sample of patients required per special clinic	SF	The total sample size required	Resulting sample size (SF × Total)
Sample of HIV positive patients	$\frac{13}{18}$	360	260
Sample of Hypertension patients	$\frac{4}{18}$	360	80
Sample of Diabetes patients	$\frac{1}{18}$	360	20

Proportionate allotment to patient volume for selected hospitals was done to get the number of HIV positive, hypertension and diabetes patients required in each hospital (Table 3.4). Finally, daily systematic sampling was used to recruit the patients to be interviewed in each selected hospital. The patient register was used to ascertain potential participants. A random starting point was selected. Every K^{th} (sampling interval) value was determined by dividing the total population by each facility's sample size and selected until the required sample size was achieved; for example, in Kianyaga CCC, a random starting point of 2 was selected, then every 10^{th} patient was selected.

Table 3.4: Number of patients allocated to each hospital

	Number of patients in selected hospitals											
Special clinics	**(SF)**	**Kerugoya**	**Kth**	**(SF)**	**Kianyaga**	**Kth**	**(SF)**	**Kimbimbi**	**Kth**	**(SF)**	**Sagana**	**Kth**	**Total**
Comprehensive Care Clinic	$\frac{1835}{4000}$	119	3	$\frac{419}{4000}$	27	10	$\frac{979}{4000}$	64	5	$\frac{767}{4000}$	50	6	260
Heart	$\frac{283}{1213}$	19	5	$\frac{562}{1213}$	37	3	$\frac{131}{1213}$	9	9	$\frac{237}{1213}$	15	6	80
Diabetes	$\frac{73}{219}$	5	4	$\frac{155}{319}$	10	2	$\frac{55}{319}$	3	7	$\frac{36}{319}$	2	10	20
Total		**143**			**74**			**76**			**67**		**360**

3.5.1.2 Sampling for healthcare providers

A stratified sampling technique was used to sample health practitioners. Healthcare workers were stratified as Consultants = 7, Medical Officers = 48, Pharmacists = 15, Pharmaceutical Technologists = 19, Nurses = 264 and Clinical Officers = 75. The sample size of 224 was proportionately allocated to these cadres (Table 3.5).

Table 3.5: Number of health professionals allocated to each cadre

Cadre	SF	The total sample size required	The number of health professionals required
Consultants	$\frac{7}{428}$	224	4
Medical Officers	$\frac{48}{428}$	224	25
Pharmacists	$\frac{15}{428}$	224	8
Pharmaceutical Technologist	$\frac{19}{428}$	224	10
Clinical Officers	$\frac{75}{428}$	224	39
Nurses	$\frac{264}{428}$	224	138
Total			**224**

Proportionate allotment to size was done to get the number of health professionals required in each hospital (Table 3.6). Finally, daily systematic sampling was used to identify healthcare workers to be studied in each facility. A list of healthcare providers on duty in each facility was used. A random starting point was selected, then every K^{th} health professional on the list was selected until the desired sample size was achieved; for example, in Kerugoya, after picking a random starting point of 1, every 2^{nd} Medical Officer was selected.

Table 3.6: Number of healthcare workers allocated to each hospital

Cadre	SF	Kerugoya	K^{th}	SF	Kianyaga	Kth	SF	Kimbimbi	Kth	SF	Sagana	Kth	Total
Consultants	$\frac{6}{7}$	3	2	$\frac{0}{7}$	0	0	$\frac{1}{7}$	1	4	$\frac{0}{7}$	0	0	4
Medical Officers	$\frac{25}{48}$	13	2	$\frac{8}{48}$	4	7	$\frac{11}{48}$	6	5	$\frac{4}{48}$	2	13	25
Pharmacists	$\frac{9}{15}$	5	2	$\frac{2}{15}$	1	8	$\frac{4}{15}$	2	4	$\frac{0}{15}$	0	0	8
Pharmaceutical Technologists	$\frac{6}{19}$	3	4	$\frac{4}{19}$	2	5	$\frac{4}{19}$	2	5	$\frac{5}{19}$	3	4	10
Clinical Officers	$\frac{34}{75}$	18	3	$\frac{15}{75}$	8	5	$\frac{16}{75}$	8	5	$\frac{10}{75}$	5	8	39
Nurses	$\frac{167}{264}$	87	2	$\frac{29}{264}$	15	10	$\frac{49}{264}$	26	6	$\frac{19}{264}$	10	14	138
Total		**129**			**30**			**45**			**20**		**224**

3.5.2 Quantitative data collection tools

An interviewer-administered questionnaire (Appendix 4) was used to collect data from patients. The tool was adapted with customization from Pahuja *et al.* (2014), Robertson and Newby (2013) and Thadani *et al.* (2019). A self-administered questionnaire (Appendix 5) was used to collect data from healthcare providers. The tool was adapted with modifications from similar studies (Binu *et al.,* 2017; Nisa *et al.,* 2018; Wang'ang'a, 2017). The improvements helped to build on the inconclusive data in the literature. Before data collection, respondents signed a consent form (Appendix 6).

Established reliable and valid instruments adopted from published peer-reviewed journals were adopted with modification. A Pharmacoepidemiologist assessed content validity. Piloting was done to determine face validity. Continuing questions in the tools were checked for internal consistency.

3.5.3 Quantitative data collection procedure

The principal researcher and five assistants (2 Pharmacists and three medical students) took part in data collection. Data collectors were trained for two days. Patients' data collection was done during the day as special clinics began at 8:30 a.m. to 1 p.m. Questionnaires were distributed to healthcare workers in the afternoon and collected after working hours or after three working days. Phone calls were utilized where necessary to remind healthcare providers. Filled ADR forms were reviewed to ascertain reporting by healthcare workers.

3.6 Qualitative data collection

3.6.1 Key informant interviews

Key informant interviews were conducted on heads of special clinics in each selected hospital. They gave their views on facility-level factors influencing ADR reporting in the selected hospitals.

3.6.2 Selection of key informants

Purposive sampling recruited 12 departmental heads, 1 per special clinic in each of the four selected hospitals, namely, 2 Consultants, 3 Medical Officers, 3 Pharmacists, 2 Clinical Officers and 2 Nursing Officers. The selection was based on the experience and extensive first-hand knowledge of health system operations, therapeutic procedures and medications used in special clinics.

3.6.3 Qualitative data collection tools

A standard interview guide (Appendix 7) adapted with revisions from comparable studies (Hamumy, 2015; Obonyo, 2014) collected data. The interview guide contained probing questions regarding the capacity to monitor ADRs, barriers towards reporting, feedback, training and strategies to curb under-reporting. Key informants signed a consent form (Appendix 6) before commencing the interviews.

Various strategies were employed to ensure credibility, transferability, dependability and confirmability of qualitative data. They included: triangulation, preliminary facility visits, asking participants to be frank before interviews, establishing rapport during the introduction, iterative questioning, peer scrutiny and member checks, debriefing sessions between researcher and supervisors, reflective commentary and examination of past findings to assess congruency with present results.

3.6.4 Qualitative data collection procedure

Key informants were approached and requested to participate in the interviews. The principal investigator conducted face-to-face interviews in the afternoon at a convenient place for the key informants. Consent was sought by signing a consent form (Appendix 6). Interviews were audio-recorded and notes were hand-written. Each session lasted between 30 to 40 minutes. Data saturation was achieved after the 10^{th} interview; however, two more interviews were conducted to capture emerging themes.

3.7 Pre-testing of data collection tools

Questionnaires (Appendix 4 & 5) and interview guide (Appendix 7) were pre-tested at the Anglican Church of Kenya (ACK) Mt. Kenya hospital in Kirinyaga County on 36 patients, 23 healthcare workers and 2 section heads and necessary modifications were made. Pre-test findings were not included in the data analysis. ACK Mt. Kenya hospital offers similar services and patient overlap could not occur.

3.8 Data management and analysis

The consistency and completeness of quantitative data were checked after data collection. Review and analysis of filled ADR forms by healthcare workers were done to verify the data collected. Quantitative data were cleaned, coded and analyzed using Statistical Package for Social Sciences (SPSS) version 27 computer program. Descriptive statistics were used to show demographic variables such as age and gender. Knowledge was assessed using yes/no questions and correct responses were awarded one point. Scores >70% were considered knowledgeable, while <70% were considered not knowledgeable. The Chi-squared (χ^2) test determined the association between independent and outcome variables. The strength of association was assessed using binary logistic regression. Fisher's exact test was used to test significance where cells had expected values of <5. Findings were considered significant at a p-value of <0.05. The tables and graphs presented quantitative data.

After the interviews, qualitative data were validated and deciphered into Microsoft Word 2016 within 72 hours. NVivo version 12 coded the data. Deductive thematic analysis analyzed qualitative data—this method centered on main themes related to research objectives. Once themes were generated, the departmental heads' fundamental thoughts were aligned to themes in the respondent's context. Themes were generated for each key informant until saturation was accomplished. Word narrative presented qualitative data.

3.9 Ethical considerations

The Kenyatta University - Ethical Review Committee granted ethical approval (Appendix 8 & 9). The National Commission for Science, Technology and Innovation (Appendix 10) authorized the research. The County Director of Health, Kirinyaga County, permitted to execute the study (Appendix 11). Each respondent signed a consent form (Appendix 6) before commencing the study. All documents having participants' information were stored under lock and key by the principal investigator. No risks were

associated with the study. The thesis will be submitted to the university library for accessibility to students and staff. Feedback was given to all patients and healthcare providers who participated in the study. The dissertation will be helpful to the Pharmacy and Poisons Board and County Director of Health, Kirinyaga County. Results were published in a peer-reviewed journal to allow universal access to the results (Appendix 12).

CHAPTER FOUR

RESULTS

4.1 Introduction

A total of 360 patients were successfully interviewed. The majority of the patients, 87%, reported ADRs to healthcare providers. Among patients, gender was associated with experiencing ADRs. Male patients had a lower likelihood of experiencing ADRs compared to females. Dizziness, headache and rash were the most reported ADRs. Efavirenz, enalapril and Kaletra were the most implicated drugs. Out of 224 healthcare providers, 215 returned questionnaires, giving a response rate of 96.0%. The majority of healthcare providers, 74%, did not report ADRs to the PPB. Healthcare providers' age, professional category and level of education were significant predictors of ADR reporting. Healthcare provider knowledge of the ADR system and PV training were significantly associated with ADR reporting. Inadequate training and feedback were major gaps at the facility level.

4.2 Socio-demographic characteristics of patients in special clinics

Results indicated that out of 360 patients included in the study, 98 (27.2%; 95% CI 22.8–32.5) were aged between 46 and 55 years. The majority of patients, 248 (68.9%; 95% CI 63.9–73.3), were female. Out of all patients, 210 (58.3%; 95% CI 53.1–63.3) were married. Additionally, 330 (91.7%; 95% CI 88.9–94.4) patients were employed. Concerning the highest level of education, 205 (56.9%; 95% CI 51.9–61.9) patients had reached primary school level while 345 (95.8%; 95% CI 93.6–97.8) were Christians, as shown in Table 4.1

Table 4.1: Socio-demographic characteristics of patients in special clinics

Characteristics		Participants (N = 360)	%	95% CI
Age group (years)	<18	7	1.9	0.6 - 3.6
	18–25	12	3.3	1.7 - 5.3
	26–35	52	14.4	10.8 – 18.1
	36–45	93	25.8	21.1 - 30.3
	46–55	98	27.2	22.8 – 32.5
	56–65	51	14.2	10.8 - 17.8
	>65	47	13.2	9.4 - 16.7
	Total	**360**	**100.0**	
Gender	Female	248	68.9	63.9 - 73.3
	Male	112	31.1	26.7 – 36.1
	Total	**360**	**100.0**	
Marital status	Unmarried	150	41.7	36.7 - 46.9
	Married	210	58.3	53.1 – 63.3
	Total	**360**	**100.0**	
Occupational status	Employed	330	91.7	88.9 - 94.4
	Unemployed	30	8.3	5.6 – 11.1
	Total	**360**	**100.0**	
Highest level of education	Post-secondary	26	7.2	4.7 – 10.0
	Secondary school	102	28.3	23.3 – 33.0
	Primary school	205	56.9	51.9 - 61.9
	No formal education	27	7.5	5.0 – 10.3
	Total	**360**	**100.0**	
Religion	Christian	345	95.8	93.6 - 97.8
	Muslim	2	0.6	0.0 - 1.4
	Others	13	3.6	1.9 - 5.8
	Total	**360**	**100.0**	

4.3 The proportion of patients who reported ADRs within the last three months

Out of 360 patients included in the study, 166 (46.1%) experienced ADRs from medicines they were using (Table 4.2). Patient records and booklets confirmed the findings.

Table 4.2: Proportion of patients who experienced ADRs from medicines they were using

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)
Experienced ADRs	65 (45.5)	38 (51.4)	34 (44.7)	29 (43.3)	166 (46.1)
Didn't experience ADRs	78 (54.5)	36 (48.6)	42 (55.3)	38 (56.7)	194 (53.9)
Total	**143 (39.7)**	**74 (20.6)**	**76 (21.1)**	**67 (18.6)**	**360 (100.0)**

Out of 166 (46.1%) patients who experienced ADRs, 145 (87.3%) reported ADRs to healthcare providers (Table 4.3). Patient record analysis confirmed the findings.

Table 4.3: Proportion of patients who reported ADRs they encountered

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)
Reported ADRs	56 (86.2)	35 (92.1)	29 (85.3)	25 (86.2)	145 (87.3)
Didn't report ADRs	9 (13.8)	3 (7.9)	5 (14.7)	4 (13.8)	21 (12.7)
Total	**65 (39.2)**	**38 (22.9)**	**34 (20.5)**	**29 (17.5)**	**166 (46.1)**

4.4 Patient-level factors influencing ADR reporting

Females 126 (75.9%) experienced ADRs more frequently than males (Table 4.4). The ADRs among patients were significantly associated with gender (χ^2 = 7.072, degrees of freedom (df) =1, p=0.009).

Table 4.4: Association between patients' socio-demographic factors and experiencing ADRs

Characteristics		Experienced ADRs		Totals (%)	χ^2 and p-value
		Yes (%)	No (%)		
Gender	Male	40 (35.7)	72 (64.3)	112 (31.1)	$\chi^2 = 7.072$
	Female	126 (50.8)	122 (49.2)	248 (68.9)	p=0.009
	Total	**166**	**194**	**360**	
Age group (years)	<18	4 (57.1)	3 (42.9)	7 (1.9)	$\chi^2 = 10.067$ p=0.120
	18–25	3 (25.0)	9 (75.0)	12 (3.3)	
	26–35	22 (42.3)	30 (57.7)	52 (14.4)	
	36–45	51 (54.8)	42 (45.2)	93 (25.8)	
	46–55	36 (36.7)	62 (63.3)	98 (27.2)	
	56–65	26 (51.0)	25 (49.0)	51 (14.2)	
	>65	24 (51.1)	23 (48.9)	47 (13.2)	
	Total	**166**	**194**	**360**	
Marital status	Unmarried	73 (48.7)	77 (51.3)	150 (41.7)	$\chi^2 = 0.676$
	Married	93 (44.3)	117 (55.7)	210 (58.3)	p=0.453
	Total	**166**	**194**	**360**	
Occupational status	Employed	149 (45.2)	181 (54.8)	330 (91.7)	$\chi^2 = 1.467$
	Unemployed	17 (56.7)	13 (43.3)	30 (8.3)	p=0.254
	Total	**166**	**194**	**360**	
Highest level of education	Post-secondary	14 (53.8)	12 (46.2)	26 (7.2)	$\chi^2 = 3.378$ p=0.340
	Secondary school	48 (47.1)	54 (52.9)	102 (28.3)	
	Primary school	88 (42.9)	117 (57.1)	205 (56.9)	
	No formal education	16 (59.3)	11 (40.7)	27 (7.5)	
	Total	**166**	**194**	**360**	
Religion	Christian	160 (46.4)	185 (53.6)	345 (95.8)	$\chi^2 = 0.573$ p=0.889
	Muslim	1 (50.0)	1 (50.0)	2 (0.6)	
	Other	5 (38.5)	8 (61.5)	13 (3.6)	
	Total	**166**	**194**	**360**	

Binary logistic regression ascertained the strength of the association between gender and experiencing ADRs. The study noted that males had a 46.2% lower likelihood of experiencing ADRs than females (odds ratio (OR) 0.538, 95% CI 0.340–0.852, p=0.008), as presented in Table 4.5.

Table 4.5: Association between gender and experiencing ADRs.

Characteristic		OR (95% CI)	p-value
Gender	Female	1	
	Male	0.538 (0.340, 0.852)	0.008

The χ^2 test determined the association between socio-demographic factors and ADR reporting. No significant relationship was reported between patients' characteristics and ADR reporting, as described in Table 4.6.

Table 4.6: Association between patients' socio-demographic variables and ADR reporting

Characteristics		Reported ADRs		Totals (%)	χ^2 and p-value
		Yes (%)	No (%)		
Gender	Male	37 (92.5)	3 (7.5)	40 (24.1)	$\chi^2 = 1.265$
	Female	108 (85.7)	18 (14.3)	126 (75.9)	p=0.295
	Total	**145**	**21**	**166**	
Age group (years)	<18	4 (100.0)	0 (0.0)	4 (2.4)	$\chi^2 = 1.235$ p=0.980
	18–25	3 (100.0)	0 (0.0)	3 (1.8)	
	26–35	18 (81.8)	4 (18.2)	22 (13.3)	
	36–45	45 (88.2)	6 (11.8)	51 (30.7)	
	46–55	31 (86.1)	5 (13.9)	36 (21.7)	
	56–65	23 (88.5)	3 (11.5)	26 (15.7)	
	>65	21 (87.5)	3 (12.5)	24 (14.5)	
	Total	**145**	**21**	**166**	
Marital status	Unmarried	62 (84.9)	11 (15.1)	73 (44.0)	$\chi^2 = 0.689$
	Married	83 (89.2)	10 (10.8)	93 (56.0)	p=0.483
	Total	**145**	**21**	**166**	
Occupational status	Employed	131 (87.9)	18 (12.1)	149 (89.8)	$\chi^2 = 0.428$
	Unemployed	14 (82.4)	3 (17.6)	17 (10.2)	p=0.455
	Total	**145**	**21**	**166**	
Highest level of education	Post-secondary	12 (85.7)	2 (14.3)	14 (8.4)	$\chi^2 = 1.699$ p=0.649
	Secondary school	41 (85.4)	7 (14.6)	48 (28.9)	
	Primary school	79 (89.8)	9 (10.2)	88 (53.0)	
	No formal education	13 (81.3)	3 (18.8)	16 (9.6)	
	Total	**145**	**21**	**166**	
Religion	Christian	140 (87.5)	20 (12.5)	160 (96.4)	$\chi^2 = 1.382$ p=0.562
	Muslim	1 (100.0)	0 (0.0)	1 (0.6)	
	Other	4 (80.0)	1 (20.0)	5 (3.0)	
	Total	**145**	**21**	**166**	

The greater part of patients, 313 (86.9%), were aware of what an ADR is with no significant association between patients in the selected hospitals and awareness of ADR occurrence ($\chi^2 = 4.740$, df = 3, p=0.192) (Table 4.7).

Table 4.7: Patients' awareness of ADR occurrence

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)	χ^2- value
Yes	125 (87.4)	62 (83.8)	63 (82.9)	63 (94.0)	313 (86.9)	$\chi^2 = 4.740$ df = 3
No	18 (12.6)	12 (16.2)	13 (17.1)	4 (6.0)	47 (13.1)	p=0.192

The majority of patients in special clinics, 265 (73.6%), did not know of the ADR reporting tool for patients with a statistically significant association between the patient alert card use among the patients in selected hospitals (χ^2 = 31.735, df = 3, p<0.001) (Table 4.8).

Table 4.8: Patients' knowledge showed by use of the patient alert card

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)	χ^2- value
Yes	60 (42.0)	11 (14.9)	9 (11.8)	15 (22.4)	95 (26.4)	χ^2 = 31.735 df = 3
No	83 (58.0)	63 (85.1)	67 (88.2)	52 (77.6)	265 (73.6)	p<0.001

Practically all patients in special clinics, 359 (99.7%), concurred that ADR reporting is crucial. There was no significant association between patients in the four hospitals and attitudes towards the importance of ADR reporting (χ^2 = 3.401, df = 3, p=0.392) (Table 4.9).

Table 4.9: Patients' attitude on whether ADR reporting is important

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)	χ^2- value
Agree	143 (100.0)	73 (98.6)	76 (100.0)	67 (100.0)	359 (99.7)	χ^2 = 3.401 df = 3 p=0.392
Disagree	0 (0.0)	1(1.4)	0 (0.0)	0 (0.0)	1 (0.3)	

The majority of patients in special clinics, 347 (96.4%), opined that the main reason for ADR reporting was to have their medication changed with no significant relationship between patients in the selected hospitals and awareness of the reasons for ADR reporting ($\chi^2 = 0.605$, df = 3, p=0.919) (Table 4.10).

Table 4.10: Patients' awareness of reasons for ADR reporting

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)	χ^2- value
To change medication	138 (96.5)	71 (95.9)	74 (97.4)	64 (95.5)	347 (96.4)	χ^2 = 0.605
To improve patient health	5 (3.5)	3 (4.1)	2 (2.6)	3 (4.5)	13 (3.6)	df = 3 p=0.919

Of those who had experienced ADRs, 156 (94.0%) patients claimed to have sourced medication that initiated the ADR from a hospital. There was no significant association between the patients in the selected hospitals who encountered ADRs and sources of medicine ($\chi^2 = 5.385$, df = 3, p=0.102) (Table 4.11).

Table 4.11: Patients' source of medicines among those who experienced ADRs

Response	Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	Total (%)	χ2- value
From a hospital	62 (95.4)	35 (92.1)	34 (100.0)	25 (86.2)	156 (94.0)	χ2 = 5.385
From a retail pharmacy	3 (4.6)	3 (7.9)	0 (0.0)	4 (13.8)	10 (6.0)	df = 3 p=0.102

The χ^2 test was used to assess the association between the above patient factors and ADR reporting. For the variables analyzed, there was no significant relationship. The factors did not influence reporting ADRs among patients. Table 4.12 shows the findings.

Table 4.12: Association between patient factors and ADR reporting

Response	Awareness of ADR occurrence		Total (%)	χ^2 and p-value
	Yes (%)	**No (%)**		
Reported ADRs (%)	136 (93.8)	9 (6.2)	145 (87.3)	$\chi^2 = 1.785$
Didn't report ADRs (%)	18 (85.7)	3 (14.3)	21 (12.7)	df = 1 p=0.181
	Patients' knowledge indicated by the use of the patient alert card			
	Yes (%)	**No (%)**		
Reported ADRs (%)	38 (26.2)	107 (73.8)	145 (87.3)	$\chi^2 = 0.053$
Didn't report ADRs (%)	6 (28.6)	15 (71.4)	21 (12.7)	df = 1 p=0.796
	Patients' awareness of reasons for ADR reporting			
	To change medication (%)	**To improve patients' health (%)**		
Reported ADRs (%)	136 (93.8)	9 (6.2)	145 (87.3)	$\chi^2 = 1.378$
Didn't report ADRs (%)	21 (100.0)	0 (0.0)	21 (12.7)	df = 1 p=0.605
	Patients' source of medicine among those who experienced ADRs			
	Hospital (%)	**From a retail Pharmacy (%)**		
Reported ADRs (%)	138 (95.2)	7 (4.8)	145 (87.3)	$\chi^2 = 2.899$
Didn't report ADRs (%)	18 (85.7)	3 (14.3)	21 (12.7)	df = 1 p=0.117

Efavirenz, enalapril and insulin caused the most ADRs among the reported antiretrovirals, antihypertensives and antidiabetics. Dizziness initiated by efavirenz, 38 (10.6%), was the principal ADR occurring in Kerugoya, Kimbimbi and Sagana hospitals (Table 4.13).

Table 4.13: Distribution of ADRs experienced in the selected hospitals and associated medicine.

ADR	Medicine	Number of patients with ADR				Total (%)
		Kerugoya (%)	Kianyaga (%)	Kimbimbi (%)	Sagana (%)	
Dizziness	Efavirenz	14 (21.5)	6 (15.8)	12 (35.3)	6 (20.7)	38 (10.6)
Headache	Enalapril	4 (6.2)	3 (7.9)	4 (11.8)	5 (17.2)	16 (4.4)
Rash	Kaletra	6 (9.2)	1 (2.6)	4 (11.8)	2 (6.9)	13 (3.6)
Peripheral edema	Nifedipine	8 (12.3)	3 (7.9)	2 (5.9)	0 (0.0)	13 (3.6)
Vomiting	Tenofovir	3 (4.6)	6 (15.8)	2 (5.9)	1 (3.4)	12 (3.3)
Neuropathy	Lamivudine	5 (7.7)	1 (2.6)	4 (11.8)	1 (3.4)	11 (3.1)
Pruritus	Enalapril	4 (6.2)	2 (5.3)	2 (5.9)	3 (10.3)	11 (3.1)
Hypoglycemia	Dolutegravir	6 (9.2)	1 (2.6)	0 (0.0)	1 (3.4)	8 (2.2)
In effectivity	Nevirapine	2 (3.1)	2 (2.6)	2 (5.9)	1 (3.4)	7 (1.9)
Diarrhea	Kaletra	2 (3.1)	0 (0.0)	1 (2.9)	3 (10.3)	6 (1.7)
Lipoatrophy	Insulin	0 (0.0)	4 (10.5)	0 (0.0)	1 (3.4)	5 (1.4)
Fatigue	Metformin	1 (1.5)	4 (10.5)	0 (0.0)	0 (0.0)	5 (1.4)
Hyperacidity	Amlodipine	0 (0.0)	1 (2.6)	0 (0.0)	3 (10.3)	4 (1.1)
Hallucination	Efavirenz	3 (4.6)	1 (2.6)	0 (0.0)	0 (0.0)	4 (1.1)
Coughing	Enalapril	3 (4.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
Sweating	Nogluc	1 (1.5)	1 (2.6)	0 (0.0)	1 (3.4)	3 (0.8)
Gynecomastia	Lactone	1 (1.5)	1 (2.6)	0 (0.0)	1 (3.4)	3 (0.8)
Anemia	Methyldopa	1 (1.5)	0 (0.0)	1 (2.9)	0 (0.0)	2 (0.6)
Chest pain	Hydralazine	1 (1.5)	1 (2.6)	0 (0.0)	0 (0.0)	2 (0.6)
Total		**65 (18.1)**	**38 (10.1)**	**34 (9.4)**	**29 (8.1)**	**166 (46.1)**

Among the patients who reported ADRs, 38 (26.2%) used the patient alert card to report ADRs to healthcare workers. The drop-off box was the least used channel to report ADRs, as shown in Table 4.14.

Table 4.14: Methods used to report ADRs among patients

Channels of reporting	Number of patients	Percentage (%)
Verbal approach	94	64.8
Telephone	9	6.2
Patient alert card	38	26.2
Drop-off box	4	2.8
Total	**145**	**40.3**

4.5 Socio-demographic characteristics of healthcare providers

The majority, 127 (59.1%; 95% CI 52.6–65.6) healthcare providers, were female. Among 215 healthcare providers, 122 (56.7%; 95% CI 51.2–63.3) were aged between 26 and 35 years (Table 4.15) and the cadre with the largest proportion were Nurses, 129 (60.0%; 95% CI 53.5–67.0). For the duration of practice, 168 (78.1%; 95% CI 72.6–83.3) healthcare practitioners had 1 to 10 years of work experience. Results attested that 149 (69.3%; 95% CI 63.3–75.8) healthcare providers were diploma holders.

Table 4.15: Socio-demographic characteristics of healthcare providers

Characteristics		Participants (N = 215)	%	95% CI
Gender	Male	88	40.9	34.4 – 47.4
	Female	127	59.1	52.6 – 65.6
	Total	215	100.0	
Age group (years)	18-25	43	20.0	14.4 – 25.6
	26-35	122	56.7	51.2 – 63.3
	>35	50	23.3	17.2 – 28.8
	Total	215	100.0	
Professional category	Nurse	129	60.0	53.5 – 67.0
	Clinical Officer	39	18.1	12.6 – 23.7
	Medical Officer/Consultant	29	13.5	9.3 – 18.1
	Pharmacy staff	18	8.4	4.7 – 12.1
	Total	215	100.0	
Duration of practice (years)	<1	16	7.4	4.2 – 11.2
	1–10	168	78.1	72.6 – 83.3
	>10	31	14.4	9.8 – 19.5
	Total	215	100.0	
Highest level of education	Graduates	66	30.7	24.2 – 36.7
	Diploma	149	69.3	63.3 – 75.8
	Total	**215**	**100.0**	

4.6 Healthcare provider factors influencing ADR reporting

The majority of health professionals, 159 (74.0%), did not report identified ADRs among patients to the PPB within the last three months (Table 4.16). The number of filled ADR reports in the facilities confirmed this.

Table 4.16: Proportion of healthcare providers who reported ADRs to the PPB within the last three months

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)
Yes	25 (19.4)	10 (25.6)	9 (31.0)	12 (66.7)	56 (26.0)
No	104 (80.6)	29 (74.4)	20 (69.0)	6 (33.3)	159 (74.0)

Key informant interviews showed that health professionals perceived delayed feedback from the PPB as a demotivator of regular ADR reporting. One key informant said,

"We get feedback from the PPB after a long time; this discourages healthcare professionals from reporting as they feel that no action will be taken." (Interviewee 012, Clinical Officer).

Interviewees felt that instantaneous feedback from the PPB would simplify patient follow-up and motivate healthcare workers to report ADRs. The PPB should develop a suitable channel to give feedback. One key informant felt that the PPB should publish the PV newsletters monthly. A key informant said,

"… If the PPB gives prompt feedback on the action to be taken against reported drugs along with sending its representatives to the ground, then ADR reporting rates will surge." (Interviewee 09, Clinical Officer).

Socio-demographic characteristics were compared between reporters and non-reporters to determine association. A statistically significant relationship was reported between age ($\chi^2 = 12.891$, df = 2, p=0.001), professional category ($\chi^2 = 18.773$, df = 3, p<0.001) and the level of education ($\chi^2 = 5.263$, df = 1, p=0.028) as enumerated in Table 4.17.

Table 4.17: Association between healthcare provider characteristics and ADR reporting

Characteristics		Reported ADRs		Totals (%)	χ^2 and p-value
		Yes (%)	No (%)		
Gender	Male	27 (30.7)	61 (69.3)	88 (40.9)	$\chi^2 = 1.662$
	Female	29 (22.8)	98 (77.2)	127 (59.1)	p=0.210
	Total	**56**	**159**	**215**	
Age group (years)	18-25	4 (9.3)	39 (90.7)	43 (20.0)	
	26-35	31 (25.4)	91 (74.6)	122 (56.7)	$\chi^2 = 12.891$
	>35	21 (42.0)	29 (58.0)	50 (23.3)	p=0.001
	Total	**56**	**159**	**215**	
Professional category	Nurse	25 (19.4)	104 (80.6)	129 (60.0)	
	Clinical Officer	10 (25.6)	29 (74.4)	39 (18.1)	
	Medical Officer/Consultant	9 (31.0)	20 (69.0)	29 (13.5)	$\chi^2 = 18.773$ p<0.001
	Pharmacy staff	12 (66.7)	6 (33.3)	18 (8.4)	
	Total	**56**	**159**	**215**	
Duration of practice (years)	<1	3 (18.8)	13 (81.3)	16 (7.4)	
	1–10	43 (25.6)	125 (74.4)	168 (78.1)	$\chi^2 = 1.081$
	>10	10 (32.3)	21 (67.7)	31 (14.4)	p=0.608
	Total	**56**	**159**	**215**	
Highest level of education	Graduates	24 (36.4)	42 (63.6)	66 (30.7)	$\chi^2 = 5.263$
	Diploma	32 (21.5)	117 (78.5)	149 (69.3)	p=0.028
	Total	**56**	**159**	**215**	

Binary logistic regression established the association between statistically significant characteristics and ADR reporting. The odds of reporting ADRs increased with age. Healthcare providers >35 years were seven times more likely to report ADRs than those between 18 and 25 years (OR 7.060, 95% CI 2.186–22.800, p=0.001). Additionally, Nurses, Clinical Officers and Medical Officers/Consultants had an 88.0% (p<0.001), 82.8% (p=0.005) and 77.5% (p=0.020) lower likelihood of reporting ADRs, respectively. The odds of reporting ADRs increased with the level of education. Graduates were two times more likely to report ADRs than Diploma holders (OR 2.089, 95% CI 1.106–3.946, p=0.023). Table 4.18 shows the results.

Table 4.18: Association between statistically significant healthcare provider characteristics and ADR reporting.

Characteristics		OR (95% CI)	p-value
Age group (years)	18-25	1	
	26-35	3.321 (1.098, 10.046)	0.034
	>35	7.060 (2.186, 22.800)	0.001
Professional Category	Pharmacist staff	1	
	Nurse	0.120 (0.041, 0.351)	<0.001
	Clinical Officer	0.172 (0.051, 0.581)	0.005
	Medical Officer/Consultant	0.225 (0.064, 0.791)	0.020
Highest level of education	Diploma	1	
	Graduates	2.089 (1.106, 3.946)	0.023

Although the County had a focal PV person who supervised PV activities, key informant 03, a Nurse, suggested deploying pharmacists in the wards. Pharmacists understand the pharmacological and pharmacokinetic profiles of drugs better than other cadres. They would assist the Nurses, Medical Officers and Consultants, who had a lower likelihood of ADR reporting to capture, report and manage ADRs.

"… The County has a focal person who champions PV activities. She underwent further studies at the University of Nairobi and is responsible for the practice in the County." (Interviewee 04, Senior Pharmacist).

"The administration should permit Pharmacists to take part in ward rounds and deploy others to the wards to help in ADR identification and documentation." (Interviewee 03, Nurse).

Regarding knowledge of ADR reporting, 111 (51.6%) health professionals were not aware of drugs withdrawn from the market due to ADRs. There was a significant relationship between the healthcare provider cadres and knowledge of drugs withdrawn from the market because of ADRs ($\chi^2 = 19.669$, df = 3, $p<0.001$) (Table 4.19).

Table 4.19: Healthcare providers knowing drugs withdrawn from the market because of ADRs

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2- value
Yes	48 (37.2)	22 (56.4)	19 (65.5)	15 (83.3)	104 (48.4)	$\chi^2 = 19.669$ df=3 p<0.001
No	81 (62.8)	17 (43.6)	10 (34.5)	3 (16.7)	111 (51.6)	

The majority of healthcare providers, 154 (71.6%), were unaware of the National PV Center. There was a significant association between cadres of healthcare providers and awareness of the National PV Center ($\chi^2 = 32.966$, df = 3, p<0.001), as shown in Table 4.20.

Table 4.20: Healthcare providers knowing the National PV Center

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2- value
Yes	28 (21.7)	7 (17.9)	11 (37.9)	15 (83.3)	61 (28.4)	$\chi^2 = 32.966$ df=3 p<0.001
No	101 (78.3)	32 (82.1)	18 (62.1)	3 (16.7)	154 (71.6)	

The qualitative findings showed that the selected hospitals' lack of PV centers contributed to the National PV Center's unawareness. The District Health Management team that had inadequate resources to monitor ADRs facilitated PV activities. A key informant reported:

"There is no PV center to manage drug safety concerns, but a committee that's scarcely financed and has unsatisfactory human capital." (Interviewer 04, Senior Pharmacist).

The study's findings indicated that 113 (52.6%) health professionals were unaware of the ADR report form. There was a significant association between cadres of healthcare providers and awareness of the existence of ADR form ($\chi^2 = 18.476$, df = 3, p<0.001) (Table 4.21).

Table 4.21: Healthcare providers knowing the existence of the ADR report form

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2- value
Yes	57 (44.2)	18 (46.2)	10 (34.5)	17 (94.4)	102 (47.4)	$\chi^2 = 18.476$
No	72 (55.8)	21 (53.8)	19 (65.5)	1 (5.6)	113 (52.6)	df=3
						p<0.001

Key informant interviews showed that the facilities had a spontaneous method of reporting that utilized an ADR form. The yellow form was the only one of the 5 WHO minimum prerequisites that the facilities had conformed to, indicating the inadequate capacity to monitor ADRs. One key informant opined:

"From the WHO least prerequisites, the health facilities only have a spontaneous reporting method that uses a yellow form." (Interviewer 07, Pharmacist).

The ADR form's unawareness contributed to inadequate access to ADR forms, a significant health system barrier that affected reporting.

"I have come across numerous ADRs in my department, but the main challenges that have discouraged me from reporting are inadequate access to ADR report forms and not knowing where to report due to inadequate PV knowledge." (Interviewee 02, Medical Officer).

Other health system-related barriers identified were: understaffing, lack of a PV Center, insufficient training and delayed/no feedback. Health professional-related barriers included: not knowing where to report, inadequate access to ADR report forms, time constraints to report, not sure what caused the ADR, belief that managing the patient is more important and knowing that no action will be taken. The reported patient-associated barriers included fear of unfriendly healthcare personnel, unawareness of patient reporting mechanisms, delayed feedback, and long-distance coverage to report ADRs.

The majority of health professionals, 123 (57.2%), were unaware of ADR reporting guidelines. There was a significant association between cadres of healthcare providers and awareness of ADR reporting guidelines ($\chi^2 = 19.661$, df = 3, $p<0.001$) (Table 4.22).

Table 4.22: Healthcare providers knowing the ADR reporting guidelines

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2- value
Yes	49 (38.0)	11 (28.2)	17 (58.6)	15 (83.3)	92 (42.8)	$\chi^2 = 19.661$
No	80 (62.0)	28 (71.8)	12 (41.4)	3 (16.7)	123 (57.2)	df=3
						p<0.001

Results revealed that 132 (61.4%) healthcare providers felt that all ADRs ought to be reported with a significant association between healthcare professional cadres and reporting serious and life-threatening ($\chi^2 = 9.257$, df = 3, p=0.016) and all ADRs ($\chi^2 = 15.894$, df = 3, p=0.001) (Table 4.23).

Table 4.23: Healthcare providers' attitude towards the nature of ADRs that should be reported

Response		Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2 - Value
Serious and life-threatening	Yes	31 (24.0)	12 (30.8)	1 (3.4)	2 (11.1)	46 (21.4)	$\chi^2 = 9.257$ df = 3 p=0.016
	No	98 (76.0)	27 (69.2)	28 (96.6)	16 (88.9)	169 (78.6)	
Severe and cause disability	Yes	6 (4.7)	4 (10.3)	2 (6.9)	0 (0.0)	12 (5.6)	$\chi^2 = 2.630$ df = 3 p=0.431
	No	123 (95.3)	35 (89.7)	27 (93.1)	18 (100.0)	203 (94.4)	
Mild	Yes	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.5)	$\chi^2 = 4.616$ df = 3 p=0.400
	No	129 (100.0)	38 (97.4)	29 (100.0)	18 (100.0)	214 (99.5)	
Caused by new drugs	Yes	15 (11.6)	4 (10.3)	0 (0.0)	1 (5.6)	20 (9.3)	$\chi^2 = 4.105$ df = 3 p=0.235
	No	114 (88.4)	35 (89.7)	29 (100.0)	17 (94.4)	195 (90.7)	
Caused by vaccines	Yes	3 (2.3)	0 (0.0)	1 (3.4)	1 (5.6)	5 (2.3)	$\chi^2 = 2.424$ df = 3 p=0.419
	No	126 (97.7)	39 (100.0)	28 (96.6)	17 (94.4)	210 (97.7)	
All the above	Yes	74 (57.4)	18 (46.2)	25 (86.2)	15 (83.3)	132 (61.4)	$\chi^2 = 15.894$ df = 3 p=0.001
	No	55 (42.6)	21 (53.8)	4 (13.8)	3 (16.7)	83 (38.6)	

Most healthcare workers, 93 (43.3%), got the information concerning ADRs initiated by new brands from continuous medical education. The internet, 57 (26.5%), was the second most preferred source of ADR information, as illustrated in Figure 4.1.

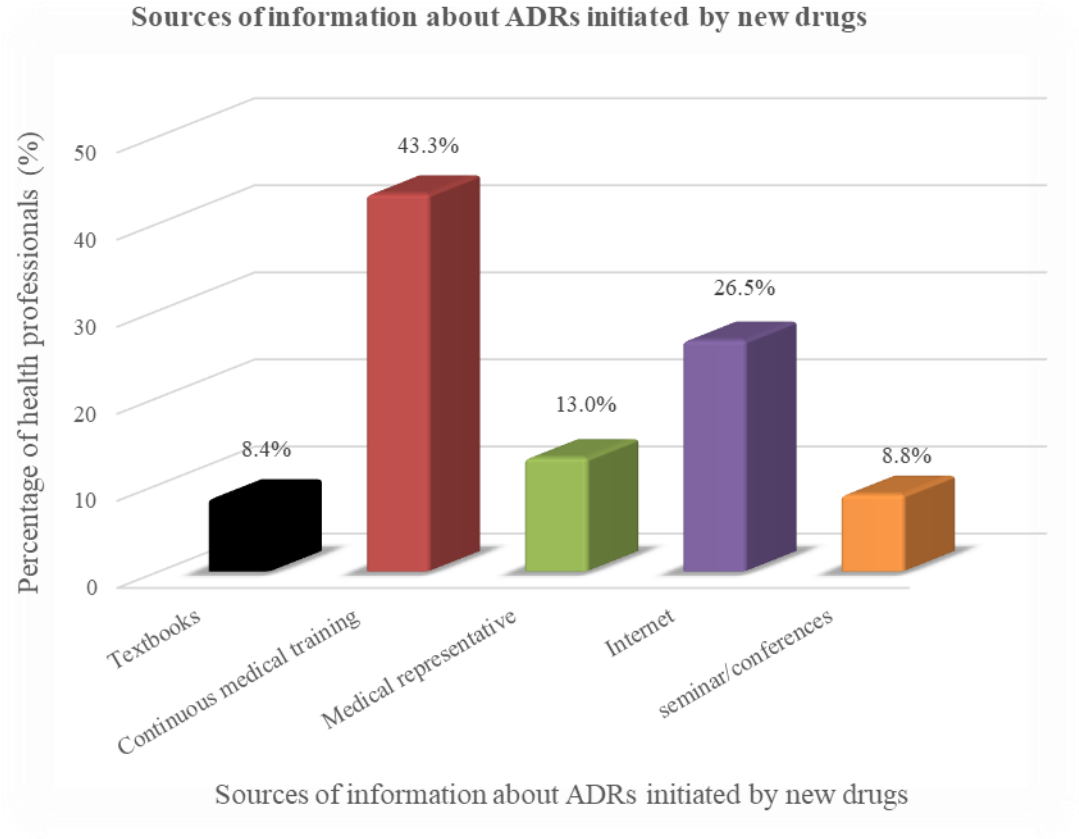

Figure 4.1: Sources of information about ADRs initiated by new brands

There was no significant association between cadres of healthcare workers and sources of information about ADRs initiated by new medicine brands, as presented in Table 4.24.

Table 4.24: Sources from which healthcare providers got information about ADRs initiated by new brands

Response		Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2 - Value
Textbooks	Yes	12 (9.3)	4 (10.3)	2 (6.9)	0 (0.0)	18 (8.4)	$\chi^2 = 1.614$ df = 3
	No	117 (90.7)	35 (89.7)	26 (93.1)	18 (100.0)	197 (91.6)	p=0.619
Continuous medical education	Yes	56 (43.4)	19 (48.7)	9 (31.0)	9 (50.0)	93 (43.3)	$\chi^2 = 2.574$ df = 3
	No	73 (56.6)	20 (51.3)	20 (69.0)	9 (50.0)	122 (56.7)	p=0.466
Medical representative	Yes	14 (10.9)	7 (17.9)	7 (24.1)	0 (0.0)	28 (13.0)	$\chi^2 = 7.061$ df = 3
	No	115 (89.1)	32 (82.1)	22 (75.9)	18 (100.0)	187 (87.0)	p=0.057
Internet	Yes	36 (27.9)	7 (17.9)	7 (24.1)	7 (38.9)	57 (26.5)	$\chi^2 = 3.096$ df = 3
	No	93 (72.1)	32 (82.1)	22 (75.9)	11 (61.1)	158 (73.5)	p=0.387
Seminar/ Conferences	Yes	11 (8.5)	2 (5.1)	4 (13.8)	2 (11.1)	19 (8.8)	$\chi^2 = 1.936$ df = 3
	No	118 (91.5)	37 (94.9)	25 (86.2)	16 (88.9)	196 (91.2)	p=0.589

Overall, 21 (9.8%) health professionals were trained in ADR reporting. There was a significant relationship between healthcare workers' cadres and training on ADR reporting ($\chi^2 = 39.337$, df = 3, $p<0.001$). Table 4.25 enumerates the results.

Table 4.25: Healthcare providers' training status of ADR reporting

Response	Nurse (%)	Clinical Officer (%)	Medical Officer/Consultant (%)	Pharmacy staff (%)	Total (%)	χ^2- value
Yes	2 (1.6)	6 (15.4)	3 (10.3)	10 (55.6)	21 (9.8)	$\chi^2 = 39.337$ df=3 p<0.001
No	127 (98.4)	33 (84.6)	26 (89.7)	8 (44.4)	194 (90.2)	

Key informant interviews substantiated these findings. Most health professionals had not acquired ADR reporting training because the County did not prioritize training. The pharmacy department underwent training locally on commodity management, reporting tools and guidelines, capturing ADRs and reporting procedures. One key informant opined:

"We have inadequate training in ADR reporting because training all healthcare workers is challenging as the County views buying of drugs and therapeutic devices as a more imperative role." (Interviewee 08, Nurse).

The results found a statistically significant relationship between ADR reporting and knowledge of drugs withdrawn from the market due to ADRs (p=0.008), knowledge of the National PV Center (p<0.001), knowledge of the ADR report form (p<0.001), knowledge of the ADR reporting guidelines (p=0.029) and training (p=0.006) as shown by Table 4.26.

Binary logistic regression assessed the strength of the association. Healthcare providers with knowledge of drugs withdrawn from the market due to ADRs were 2.4 times more likely to report ADRs (OR 2.409, 95% CI 1.282–4.525, p=0.006). Furthermore, healthcare providers aware of PPB's existence were 3.8 times more likely to report

ADRs (OR 3.818, 95% CI 1.995–7.307, p<0.001). Healthcare providers aware of the ADR form were 4.4 times more likely to report ADRs (OR 4.391, 95% CI 2.242–8.601, p<0.001). Healthcare providers with knowledge of the ADR reporting guidelines were two times more likely to report ADRs (OR 1.992, 95% CI 1.076–3.689, p=0.028). Trained healthcare workers were more likely to report ADRs (OR 3.642, 95% CI 1.453–9.130, p=0.006). Table 4.26 shows the results.

Table 4.26: Association between knowledge and training on ADR reporting among healthcare providers

Response	Yes (%)	No (%)	Total (%)	χ^2 and p-value	OR (95% CI)	p-value
	Knowledge of drugs withdrawn from the market due to ADRs					
Reported ADRs	36 (64.3)	20 (35.7)	56 (26.0)	χ^2 = 7.679	2.409 (1.282, 4.525)	0.006
Didn't report ADRs	68 (42.8)	91 (57.2)	159 (74.0)	df = 1 p=0.008		
Knowledge of the National PV Center						
Reported ADRs	28 (50.0)	28 (50.0)	56 (26.0)	χ^2 = 17.429	3.818 (1.995, 7.307)	<0.001
Didn't report ADRs	33 (20.8)	126 (79.2)	159 (74.0)	df = 1 p<0.001		
Knowledge of the ADR report form						
Reported ADRs	41 (73.2)	15 (26.8)	56 (26.0)	χ^2 = 20.172	4.391 (2.242, 8.601)	<0.001
Didn't report ADRs	61 (38.4)	98 (61.6)	159 (74.0)	df = 1 p<0.001		
Knowledge of the ADR reporting guidelines						
Reported ADRs	31 (55.4)	25 (44.6)	56 (26.0)	χ^2 = 4.885	1.992 (1.076, 3.689)	0.028
Didn't report ADRs	61 (38.4)	98 (61.6)	159 (74.0)	df = 1 p=0.029		
Training in ADR Reporting						
Reported ADRs	11 (19.6)	45 (80.4)	56 (26.0)	χ^2 = 8.379	3.642 (1.453, 9.130)	0.006
Didn't report ADRs	10 (6.3)	149 (93.7)	159 (74.0)	df = 1 p=0.006		

Qualitative findings highlighted the perceived interventions that would improve ADR reporting, several similar themes emerged. Key informants addressed the need to develop a PV center in Kirinyaga County to supervise PV activities. An active committee that is equipped with ample funds and human resources should manage the center.

"… Developing a PV center in the County will promote reporting, follow-up and prompt feedback." (Interviewee 09, Clinical Officer).

Key informants proposed that the frequency of ADR reporting should be used as an indicator to appraise the health staff's performance. The move would propel healthcare workers to consider ADR reporting as their role and incorporate it.

"We intend to use ADR reporting to gauge the overall performance of health workers; this will make them take ADR reporting seriously." (Interviewee 07, Pharmacist).

Interviewee (01) opined that ADR history taking must be part of the prescribing standard operating procedures to promote early detection. A section for ADR history taking should be included in the prescription sheet to identify medication allergies and previous ADRs.

"… A separate card for ADR history taking should be given to the patient before they enter the consultation room and health professionals should fill the form before prescribing medication to patients." (Interviewee 01, Consultant).

Patients in special clinics were followed up routinely through phone calls to ensure that ADRs were captured early, reported and managed. Suspected drugs were recalled and quarantined using their batch numbers. An alternative medicine supplanted the reported drug.

“We identify the batch number of the suspected drug during follow-up and caution health staff not to administer the drug. The Pharmacist in charge recalls the drug.” (Interviewee 06, Medical Officer).

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

The reporting of ADRs among selected cadres of healthcare workers and a select group of patients attending special clinics; was conducted using a cross-sectional study design that employed both quantitative and qualitative approaches. The study revealed that the majority of patients, 87% reported ADRs to healthcare providers. Female patients were more likely to experience ADRs compared to male patients (p=0.008). Among healthcare providers, Graduates (p=0.023) and healthcare workers >35 years (p=0.001) were inclined to report ADRs. Knowledge PV tools and exposure to training were significantly associated with ADR reporting among healthcare providers.

5.1.1 The proportion of patients who reported ADRs

This study revealed that 46.1% of patients experienced ADRs from their medicines compared to 46.3% in an Australian study (Robertson & Newby, 2013). A comparable Kenyan survey reported a higher proportion at 62.2%, whereas an Indian study recorded a lower figure at 33% (Joshi *et al.*, 2015; Nderitu, 2011). This difference could be attributed to differences in the studies such as sample population, study setting, medicine use and handling practices.

The majority of patients, 87.3% in this study, reported encountered ADRs to health professionals. Patient records supported the finding. This proportion was higher than results reported by Australian and Nigerian studies, where 84.6% and 83.1% reported ADRs to healthcare providers, respectively (Adisa *et al.,* 2019; Robertson & Newby, 2013). A lower proportion of Indian patients, 67.5%, reported ADRs to health professionals (Thadani *et al.,* 2019). This study's high reporting proportion may be due

to increased patient awareness about reporting ADRs or adequate patient knowledge about ADRs caused by their medications. Nderitu (2011) found that most patients in Kiambu District Hospital never reported ADRs as they did not differentiate ADRs from the disease symptoms.

5.1.2 Patient-level factors influencing ADR reporting

This study showed that ADR occurrence among patients was statistically associated with gender (p=0.009), a finding similar to Schatz and Weber (2015). Additionally, men were less likely to experience ADRs compared to females in this study. According to de-Vries *et al.* (2019), women had a higher risk of having ADRs than men in 89% of case reports in the Netherlands. Gender-based and sex-related factors are to blame for the greater risk among females. Females have lower body weight and medication clearance, thus a higher risk of ADRs. Women's health information-seeking behavior is more active than men's; hence women are more likely to get co-prescriptions, resulting in a higher risk of ADRs (de-Vries *et al.,* 2019). Rademaker (2011) argued that hormonal factors, decreased liver clearance, lean body mass and disparities in cytochrome P450 activity among women contribute to increased risk. In this study, age (p=0.98), gender (p=0.295) and level of education (p=0.649) were not statistically significant with ADR reporting. Joshi *et al.* (2015) reported that education level (p<0.001) was associated with reporting ADRs, but not age and gender. Staniszewska *et al.* (2017) found that residence was the only socio-demographic factor influencing ADR reporting (p=0.0013). City residents were exposed to ADR reporting through Campaigns that were scarce in the Countryside. This difference may be the consequence of differences in the study setting, healthcare setting and sample population.

In this study, 86.9% of patients comprehended an ADR than 81% in a Southwestern Nigerian study (Adisa *et al.,* 2019). An Indian study reported a lower proportion at 74% (Pahuja *et al.*, 2014). This difference could be ascribed to increased awareness of ADRs created by healthcare professionals on patients. In this study, most patients, 73.6%, were

unaware of the patient alert card compared to 75% in a systematic review article by Al-Dweik *et al.* (2017). An Australian study reported a slightly higher figure at 87.5% (Robertson & Newby, 2013). Not knowing the patient reporting tool could be attributed to the insufficient promotion of the patient alert cards by health professionals to patients. For each of these knowledge items, there was no statistically significant relationship with ADR reporting.

The majority of patients in this study possessed positive attitudes towards ADR reporting. In total, 99.7% of patients felt that it is imperative to report ADRs. An Indian study reported a slightly lower figure at 96% (Joshi *et al.*, 2015). The preeminent motive that spurred ADR reporting among patients in this study was to have their regimen changed. This factor was not significantly associated with ADR reporting ($p=0.605$). Likewise, healthcare workers have utilized medication cessation to reduce ADRs in the Netherlands (Van-Hunsel, Passier & Van-Grootheest, 2009). Joshi *et al.* (2015) reported a different opinion where the explanation behind Indian patients' reporting was to increase medication safety.

In this study, 94% of patients sourced medication that initiated ADRs from a hospital compared to 88.4% in Australia, who got from a pharmacy with a prescription (Robertson & Newby, 2013). This acquisition of medicine from a hospital may be because patients in Kirinyaga County rely on hospitals through the National Hospital Insurance Fund (NHIF) to furnish them with medicine. The majority are on multiple drug therapy; subsequently, obtaining all medication at the pharmacy is not cost-effective.

Among the 166 patients that experienced ADRs, the chief ADR and the related drug were picked. Dizziness associated with efavirenz, headache associated with enalapril, rash associated with Kaletra and peripheral edema associated with nifedipine were the main ADRs experienced by patients in this study. The findings mirror a PPB PV report that showed dizziness, rash, headache, drug ineffective, gynecomastia and pruritus were

the most reported ADR terms (PPB, 2019). ADRs such as anemia were reported to healthcare workers through lab work after patients presented with fatigue, weakness, chest pain and headaches.

Among 145 patients who reported ADRs in this study, 38 used the patient alert card to report. A higher proportion of patients, 42% attending Kerugoya Referral Hospital, were knowledgeable of the ADR reporting tools than other facilities. This high proportion may be the consequence of the presence of a PV focal person, a higher proportion of graduate healthcare providers at the facility and the facility being located in an urban center while the other facilities were located in a more rural setting. The study noted that verbal approach 64.8% was the most utilized reporting method in contrast to a Nigerian study where text message and filling ADR forms were the most preferred techniques (Adisa *et al.,* 2019), perhaps because of the unavailability of other options, such as the patient alert card.

5.1.3 Healthcare provider factors influencing ADR reporting

The study noted that 26.0% of healthcare providers reported ADRs to the PPB within three months. The number of filled ADR reports in the facilities supported the finding. This proportion was lower than an Indian study, where 32.6% reported ADRs in their professional practice (Binu *et al.,* 2017). This proportion was greater than that found in the Philippines, where 14.0% of health professionals reported ADRs within six months (Carandang *et al.,* 2015). The difference could be attributed to differences in the healthcare setting and the inclusion of more cadres.

In this study, age ($p=0.001$), level of education ($p=0.028$) and professional category ($p<0.001$) were significantly associated with ADR reporting. Kassa-Alemu and Biru (2019) also showed a significant relationship between the profession and reporting ADRs ($p<0.05$); pharmacy personnel had adequate PV knowledge compared to Nurses, Physicians and Health Officers; however, Obonyo (2014) opined that socio-

demographic factors did not affect ADR reporting. Nadew *et al.* (2020) found that females ($p<0.001$), working > 6 years ($p=0.025$), and being a specialist ($p<0.001$), but not age, were significantly associated with ADR reporting.

This study showed that the odds of reporting increased with age; older healthcare workers were more statistically likely to report ADRs ($p=0.001$). Ganesan *et al.* (2016) reported similar findings. This association may be the consequence of the positive perception of more senior health staff towards reporting. When compared to pharmacists, other cadres reported ADRs less frequently. A similar finding was reported by the PPB quarterly PV report that showed that pharmacists submitted most of the ADR reports (PPB, 2019). Gurmesa and Dedefo (2016) showed that Nurses registered the lowest knowledge and practice scores, while Pharmacists recorded the highest. A comparable Kenyan study revealed that pharmacists accounted for 85.2% of submitted ADRs, while Nurses accounted for 3.7% (Hamumy, 2015), implying a reporting variation between different cadres; however, Pharmacists are more knowledgeable about the ADR system. Healthcare providers with higher education levels were statistically more likely to report ADRs ($p=0.023$), a result found by Nadew *et al.* (2020). The possible reason may be that graduates have better knowledge and experience on ADR reporting, thus better ADR reporting than diploma holders.

This study uncovered gaps in knowledge among healthcare providers analogous with studies in Ethiopia (Mulatu & Worku, 2014) and Other Countries (Binu *et al.,* 2017; Nisa *et al.,* 2018). The findings reflected inadequate knowledge of medications withdrawn from the market due to ADRs on 51.6% of healthcare providers. This proportion is higher than a previous Kenyan study, where 71.1% were aware of medicines banned due to ADRs (Wang'ang'a, 2017). The proportion is lower than a Pakistan study, where 24.3% were aware of medicines banned due to ADRs (Nisa *et al.,* 2018). This deficient awareness might be ascribed to healthcare providers not gathering and updating their ADR knowledge consistently. In this study, 28.4% of healthcare

practitioners demonstrated the National PV Center's awareness, whereas, in India, 58.67% opined to be aware (Binu *et al.,* 2017). Not knowing where ADR report forms are submitted nationally would significantly affect reporting and identify the communication gap between the facilities and the National PV Center.

This study reflected the ADR report form's unawareness on 52.6% of healthcare providers compared to 62.6% in a West Ethiopian study (Gurmesa & Dedefo, 2016). This unawareness may result from the ADR report form's insufficient promotion and implies that healthcare providers are not educated on the ADR reporting scheme. In this study, 57.2% of healthcare practitioners were unaware of ADR reporting guidelines, whereas 59.4% of Nigerian healthcare providers were unaware (Ezuko *et al.,* 2015). This unawareness may be the consequence of unavailability or insufficient promotion of the reporting guidelines for healthcare providers.

The study noted that health professionals with knowledge of drugs withdrawn from the market ($p=0.006$), ADR form ($p<0.001$), reporting guidelines ($p=0.028$) and National PV Center ($p<0.001$) were twice as likely to report ADRs. The result was consistent with studies conducted in India and Ethiopia (Binu *et al.,* 2017; Mulatu &Worku, 2014; Nadew *et al.* 2020). This significant association implies that knowledge of the ADR reporting system is a crucial determinant of ADR reporting.

The majority of health staff, 90.2%, had not been trained on ADR reporting. Mulatu and Worku (2014) and Wang'ang'a (2017) reported slightly lower figures at 77.4% and 73.7%, respectively. Qualitative findings of this study showed that the County prioritized procurement of medicines and medical equipment, leading to a lower proportion of trained healthcare providers. This study showed that trained healthcare providers were more likely to report ADRs ($p=0.006$). Mugoyela *et al.* (2018) and Obonyo (2014) reported similar findings, implying that ADR reporting training enhances the ADR reporting scheme's understanding and is a crucial determinant of ADR reporting.

This study discovered that 61.4% of health professionals felt that reporting should be done to all ADRs. This proportion was lower than a survey conducted in Nairobi, Kenya, where 88.3% opined that reporting should be done on all ADRs (Wang'ang'a, 2017). On the contrary, 30.1% of healthcare professionals in a West Ethiopian study felt that reporting should be done on serious ADRs (Gurmesa & Dedefo, 2016). It is a profound issue that some health professionals in this study do not know that all ADRs should be reported. This unawareness could be ascribed to the ADR reporting scheme's unawareness, inadequate training, and experience among health professionals.

Pharmaceutical companies introduce new brands into the market routinely; hence information concerning ADRs should be updated regularly. In this study, 43.3% of healthcare providers got information about ADRs actuated by new brands from continuous medical education in contrast to a Pakistan study where 68.4% sourced information from the internet (Nisa *et al.,* 2018), perhaps because of the unavailability of other sources, such as the internet. The limited internet connection can be a hindrance to obtaining up-to-date ADR information.

Countries with a functional ADR reporting system send at least 200 million ADR reports to the UMC (WHO, 2002). Considering the 610,411 population in Kirinyaga County, the expected rate would be 122 reports annually, translating to at least ten reports per month. Assuming the sampled healthcare providers reported once within the three months, 56 reports suggest reasonable reporting rates considering it was only a sample population. However, this rate could be enhanced by filling gaps in reporting.

5.1.4 Facility-level factors influencing ADR reporting

The present study revealed that the selected hospitals could not monitor ADRs effectively as they conformed to one WHO prerequisite for a functional PV system. A study by Maigetter *et al.* (2015) conducted in India, Uganda and South Africa to assess the practice of PV concerning the WHO minimum prerequisites found similar findings.

Although the countries had a spontaneous reporting scheme, it was frail as ADR forms and reporting guidelines were not available. This finding could be ascribed to inadequate funding or poor coordination of PV activities in Kirinyaga County. A competent PV system is imperative in ensuring the safety and rational use of medicine.

This study found that feedback from the PPB was never given or was not timely. A Malaysian study reported a consistent result where most healthcare providers opined to receive minimal feedback after reporting (Elkalmi *et al.,* 2011). This delayed feedback may be the consequence of the communication gap between the PPB and health facilities. Insufficient feedback influences under-reporting and healthcare workers feel less motivated to report as they think the PPB will take no action. Strengthening communication between the National PV Center and health facilities is necessary to improve ADR reporting.

In this study, the majority of health professionals had no formal training on ADR reporting. A qualitative study conducted among healthcare providers in Pakistan reported similar findings (Hussain *et al.,* 2018). Insufficient training on ADR reporting is a fundamental cause of under-reporting and has been listed as the 8^{th} sin in under-reporting (Varallo *et al.,* 2014). The hospitals should take an interest in training healthcare providers and patients routinely to improve ADR reporting. Mugoyela *et al.* (2018) revealed a significant relationship ($p=0.010$) between training and ADR reporting.

Comparable studies in Malaysia and Kenya identified unawareness of the existence of ADR reporting scheme, not knowing where to report, failure of patients to disclose ADRs, high workload, insufficient ADR reporting tools, inadequate training and feedback as significant barriers of ADR reporting (Elkalmi *et al.,* 2011; Hamumy, 2015). These are consistent with this study's findings that revealed barriers to ADR reporting as inadequate training and feedback, not enough ADR reporting tools, healthcare workers not knowing where to report and poor patient-healthcare personnel

relationships. Other studies have reported similar barriers across the globe (Hussain *et al.,* 2018; Maigetter *et al.,* 2015; Schartz & Weber 2015).

To overcome these obstacles, healthcare providers suggested that there should: be patient follow-up, a focal PV person to supervise ADR reporting, ADR forms and guidelines available in all hospital departments, a PV center in the County, routine healthcare provider-centered training on ADR reporting, deploying Pharmacists to the wards, ADR history taking, using ADR reporting to gauge health practitioner performance and lobbying for prompt feedback from the National PV Center. These seem to be the foundation of measures to enhance ADR reporting as similar suggestions have been proposed and proven by various studies across the globe (Denekew, 2014; Katekhaye, Kadhe, John & Pawar, 2017; Olsson *et al.,* 2015).

5.2 Conclusions

1. The study noted that most patients reported ADRs to healthcare professionals. Out of the 46.1% who experienced ADRs from their medicines, 87.3% reported ADRs to healthcare providers.
2. Gender significantly affected the occurrence of ADRs among patients ($p=0.009$). Most patients were unaware of the ADR reporting tool, as 26.4% knew the patient alert card.
3. Among healthcare providers, increased age ($p=0.001$) and level of education ($p=0.028$) increased the odds of reporting ADRs. Statistically significant associations were found between healthcare providers and training in ADR reporting ($p=0.006$), knowledge of the ADR report form ($p<0.001$), reporting guidelines ($p=0.028$) and National PV Center ($p<0.001$).
4. The study reported that all selected hospitals lacked PV centers to monitor ADRs. Limited access to ADR forms, inadequate training and feedback were significant hindrances to ADR reporting at the facility level.

5.3 Recommendations

1. There is a need to enhance PV knowledge among patients by promoting/publicizing the patient alert card; thus, patient reporting rates will surge.
2. Promotion of the ADR report form, guidelines and the National PV Center among healthcare providers should be implemented at the hospitals. Standard ADR report forms and updated reporting guidelines should be made available in all hospital departments; thus, reporting rates will be enhanced.
3. A PV center should be developed in Kirinyaga County to address drug safety issues. The PPB should equip it with ample funds, machinery and focal PV persons.
4. Ensuring that all health professionals undergo continuous training on ADR reporting, coordination between the PPB and health facilities, providing prompt feedback on ADR reports and monthly PV reports by the PPB are highly recommended.
5. Further research involving both inpatients and outpatients;should be conducted:-
    - to establish reporting rates after implementing the above recommendations.
    - to give a holistic finding on ADR reporting determinants.
    - across all counties' hospitals to make the reporting process hassle-free and harmonize ADR reporting practice.

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APPENDICES

Appendix I: Suspected ADR notification form

PV 1

MINISTRY OF HEALTH
THE PHARMACY AND POISONS BOARD
P. O. Box 27663-00506 NAIROBI
Tel: (020)-2716905 / 6 Ext 114 Fax: (020) 2713431/2713409.
Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

☐ Initial Report
☐ Follow-up Report

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

NAME OF INSTITUTION: ..... INSTITUTION CODE: .....

ADDRESS: ..... CONTACT: .....

PATIENT'S NAME/ INITIALS: ..... IP/OP. NO.: ..... D.O.B: .....

PATIENT'S ADDRESS: ..... WARD/CLINIC: ..... GENDER: ☐ Male ☐ Female
(Name/Number)

ANY KNOWN ALLERGY: ☐ No ☐ Yes (specify) .....

PREGNANCY STATUS: ☐ Not Pregnant ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester

WEIGHT (kg): .....

HEIGHT (cm): .....

DIAGNOSIS: (What was the patient treated for) .....

BRIEF DESCRIPTION OF REACTION: .....

LIST OF *ALL* DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (Include OTC and herbals)(use reverse side of this form for additional drugs)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (√) SUSPECTED DRUG(S)
1						
2						
3						
4						
5						

SEVERITY OF THE REACTION: (Refer to scale overleaf)
☐ Mild
☐ Moderate
☐ Severe
☐ Fatal
☐ Unknown

ACTION TAKEN:
☐ Drug withdrawn
☐ Dose increased
☐ Dose reduced
☐ Dose not changed
☐ Unknown

OUTCOME:
☐ Recovering / resolving
☐ Recovered / resolved
☐ Requires or prolongs hospitalization
☐ Causes a congenital anomaly
☐ Requires intervention to prevent permanent damage
☐ Unknown

CAUSALITY OF REACTION: (Refer to scale overleaf)
☐ Certain
☐ Probable / Likely
☐ Possible
☐ Unlikely
☐ Conditional / Unclassified
☐ Unassessable / Unclassifiable

ANY OTHER COMMENT: .....

NAME OF PERSON REPORTING: ..... DATE: .....

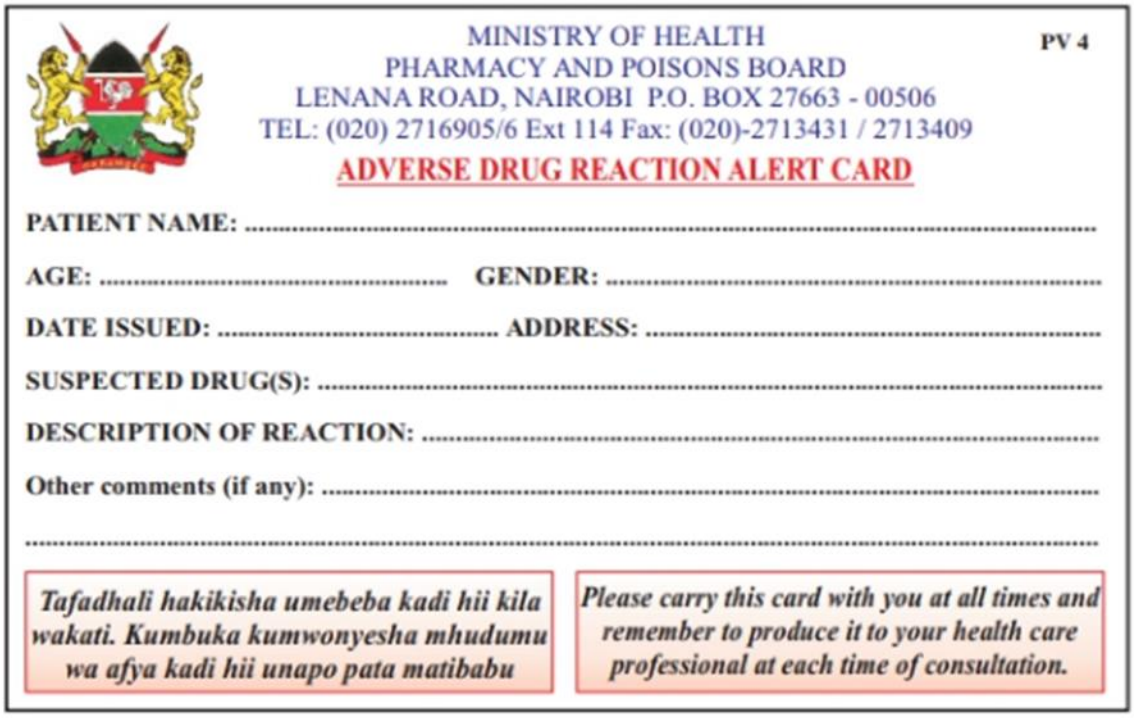
E-MAIL ADDRESS: ..... PHONE NO. .....

DESIGNATION: ..... SIGNATURE: .....

You need not be certain ... just be suspicious !

Your support in this Pharmacovigilance program is appreciated.
Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event.
Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request.
Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to:
The Pharmacy and Poisons Board on the above address

Appendix II: Patient alert card



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506
TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409

PV 4

ADVERSE DRUG REACTION ALERT CARD

PATIENT NAME: .....

AGE: ..... **GENDER:** .....

DATE ISSUED: ..... **ADDRESS:** .....

SUSPECTED DRUG(S): .....

DESCRIPTION OF REACTION: .....

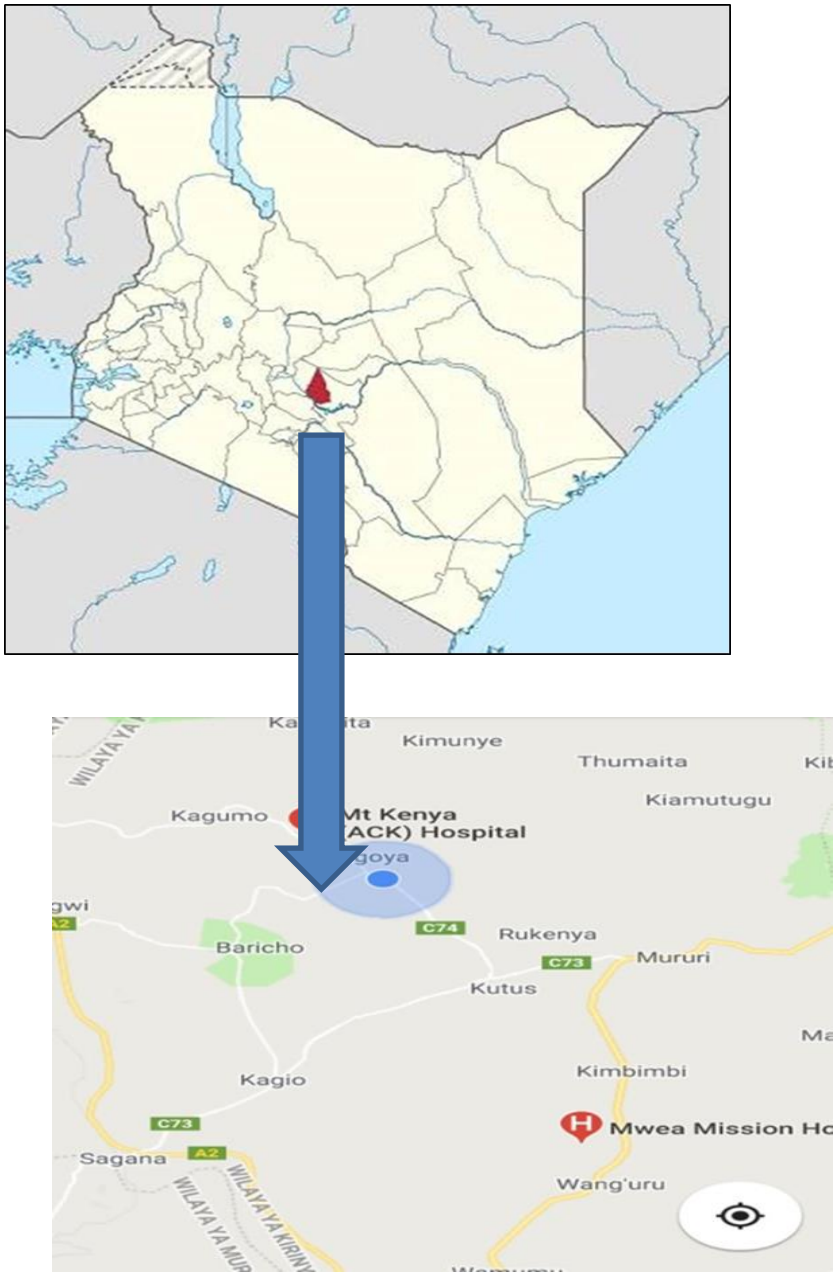
Other comments (if any): .....

.....

Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha mhudumu wa afya kadi hii unapo pata matibabu

Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.

Appendix III: Map of Kirinyaga County



Appendix IV: Patients in special clinics questionnaire

FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING AMONG PATIENTS IN SELECTED HOSPITALS IN KIRINYAGA COUNTY, KENYA

a) Socio-demographic factors

1. Age_____ years
2. Gender:
   - □ Male
   - □ Female
3. Marital status?
   - □ Single
   - □ Married
   - □ Widowed
   - □ Separated
4. What is your occupation? _____
5. What is your work status?
   - □ Full-time
   - □ Part-time
   - □ Pensioner Retired
   - □ Other
6. The highest education level/qualification?
   - □ Primary school
   - □ Secondary school
   - □ Certificate
   - □ Diploma
   - □ University

- No formal education

7. Where do you reside/live?
   - Urban center
   - Rural area
8. Religion? _____

b) Knowledge

9. Do you know what an ADR is? _____
10. Year/month/date you began taking medication _____
11. Are you aware of the names of medicines you are taking right now?
    - Yes
    - No
12. If yes, name any three:
    - _____
    - _____
    - _____
13. Are you aware that there is an ADR reporting instrument for patients to record and report ADRs?
    - Yes
    - No
14. Which ADR reporting tool are you aware of? _____

c) Attitude

15. Do you think it is essential to report an ADR?
    - Strongly Agree
    - Agree
    - Disagree
    - Strongly Disagree
16. Do you think that patients ought to be included in the ADR reporting scheme?
    - Strongly Agree

- Agree
- Disagree
- Strongly Disagree

17. Who do you think is responsible for reporting ADRs?
    - Medical Officer
    - Nurse
    - Pharmacist
    - Clinical Officer
    - Patients
18. What are the challenges experienced in reporting ADRs by patients?
19. What do you think ought to be done to enhance ADR reporting by patients?
20. Which of the following ADRs should be reported?
    - Serious and life-threatening
    - Severe and cause disability
    - Mild
    - Caused by old drugs
    - Caused by new drugs
    - Caused by traditional/alternative medicine
    - Caused by vaccines
    - All the above
21. What do you think is the reason for ADR reporting?
22. According to you, which do you think is the best strategy to sensitize patients on ADR reporting?

d) Practice

23. Have you ever encountered adverse drug reactions from any medicine that you are currently taking?
24. Which of the following ADRs have you ever experienced? Indicate the chief drug that caused it

- □ Rash
- □ Gynecomastia
- □ Neuropathy
- □ Dizziness
- □ Pruritus
- □ Jaundice
- □ Anemia
- □ Lipoatrophy
- □ Diarrhea
- □ Drug ineffective
- □ Vomiting
- □ Hallucination
- □ Headache
- □ Others, please specify - _____

25. The last time you encountered an ADR, from where did you get the medication?
    - □ From a hospital
    - □ From a pharmacy with a prescription
    - □ Over the counter at the pharmacy
    - □ Herbal/ alternative medicine
    - □ Cannot recall/do not know
26. Did you report the ADR to a health professional (within the last three months)?
    - □ Yes
    - □ No
27. To Whom did you report?
    - □ Medical Officer
    - □ Clinical Officer
    - □ Pharmacist

- Nurse
- Consultant
- Pharmaceutical Technologist
- Pharmacy and Poisons Board
- Other

28. Through which did you report the ADR?

- Telephone
- Patient alert card
- Email
- Drop off box
- Told health professional about the issue

29. Why didn't you tell anyone about the ADR?

- The ADR was not life-threatening.
- I discontinued taking the drug.
- It was not necessary.
- I am a general practitioner/health worker.
- I never knew the ADR was related to medicine.
- I do not know.
- Other.

30. Do you get feedback after reporting ADRs?

- Yes
- No

31. Which method or channel do you get feedback through?

- Telephone
- Drop off box
- From the physician
- Letter
- Other

Appendix V: Healthcare provider questionnaire

FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING AMONG HEALTHCARE PRACTITIONERS IN SELECTED HOSPITALS IN KIRINYAGA COUNTY, KENYA

a) Socio-demographic Characteristics

1. Age_____ years
2. Gender:
   - □ Male
   - □ Female
3. What is your profession?
   - □ Dentist.
   - □ Medical Officer.
   - □ Nurse.
   - □ Clinical Officer.
   - □ Consultant.
   - □ Pharmacist.
   - □ Pharmaceutical Technologist.
4. Highest level of education
   - □ MBCHB
   - □ Master
   - □ PhD
   - □ Bachelors
   - □ Diploma
5. Average patients per day: _____
6. How long have you practiced your profession?

   Years: _____

If less, indicate period of practice below;

Months: _____

7. Current department: _____

b) **Knowledge**

8. Do you think that ADR is the same as a side effect?
   - Yes
   - No
9. Are you aware of any drug that has been withdrawn from the market due to ADR?
   - Yes
   - No
10. If yes, list the medicines and the ADR they cause

Medicine	ADR Caused
• _____	• _____
• _____	• _____
• _____	• _____

11. Are you aware of the existence of a National Pharmacovigilance Center in Kenya for reporting ADRs?
    - Yes
    - No
12. If yes, where is the National Pharmacovigilance Center located? _____

13. Where is the International Drug Monitoring Center for ADRs located? _____

14. Do you know of the existence of the ADR reporting form?
    - □ Yes
    - □ No

15. If yes, is the ADR form accessible?
    - □ Yes
    - □ No

16. Which of the following information ought to be contained in an ADR reporting form?
    - □ Patient details.
    - □ Reporter's details.
    - □ Suspected drug.
    - □ Adverse reaction.
    - □ All the above.

17. Do you know of the existence of guidelines for reporting ADRs?
    - □ Yes
    - □ No

18. Which of the following healthcare providers should report ADRs?
    - □ Consultant.
    - □ Dentist.
    - □ Medical Officer.
    - □ Clinical Officer.
    - □ Pharmacist.
    - □ Pharmaceutical Technologist.
    - □ Nurse.
    - □ All healthcare providers.

c) Attitude

19. Do you feel that ADR reporting is an obligation for all healthcare professionals?

- Yes
- No

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

- Yes
- No

21. Which of the following factors may spur you to report suspected ADRs?

- If the reaction was severe/ serious.
- If the reaction was unusual/rare.
- Involvement of a new drug.
- Confidence in the diagnosis of ADR.
- If incentives are given after reporting.
- Others. (Please state)

22. Which of the following factors may debilitate you from reporting?

- Not knowing where to report
- Do not think ADR reporting is important
- Managing the patient is more vital
- ADR is not serious
- Lack of access to ADR report forms
- Under-staffing
- Legal repercussions
- ADR reporting may generate extra

work

- Patient confidentiality issue
- Lack of incentives
- Lack of time to report
- The knowledge that no action will be taken
- Not sure what caused the ADR
- Thinking that one report does not make a difference

23. Which of the following ADRs ought to be reported?
    - Serious and life-threatening
    - Severe and cause disability
    - Mild
    - Caused by old drugs
    - Caused by new drugs
    - Caused by traditional/alternative medicine
    - Caused by vaccines
    - All the above
24. Do you feel that ADR reporting improves the quality of patient care?
    - Yes
    - No
25. In your view, should ADR reporting be?
    - Mandatory
    - Voluntary
    - Remunerated

- Hide identity of the reporter
- Hide the identity of the patient

d) **Practices**

26. Have you ever encountered patients with ADR in your clinical practice within the past three months?
    - Yes
    - No
27. If yes, how many ADRs have you encountered? _____
28. If yes, which types of ADRs are ordinarily reported? _____
29. Do you know how to report ADRs?
    - Yes
    - No
30. Have you ever reported the ADRs encountered?
    - Yes
    - No
31. Do you follow the guidelines when reporting ADRs?
    - Yes
    - No
32. To whom/where did you report the reaction?
    - _____
33. Is there an ADR reporting center located inside the hospital?
    - Yes
    - No
34. Which of the following methods do you prefer to use when sending an ADR form?
    - Direct contact
    - Post
    - Telephone

- Email/website
- Others (please state)

35. Are you given the feedback from the National Pharmacovigilance Center on the action taken against reported drugs?
    - Yes
    - No
36. From which of the following sources do you get information concerning ADRs initiated by new drugs?
    - Textbooks
    - Continuous medical education
    - Journals
    - Medical representative
    - Internet
    - Seminar/conferences
37. Have you ever attended training programs on ADR reporting?
    - Yes
    - No
38. If yes, who trained you? _____
39. If not, are you interested in undergoing training for ADR reporting?
    - Yes
    - No

Appendix VI: Consent form

My Name is David Muriithi Nyagah. I am a Master's degree student from Jomo Kenyatta University of Agriculture and Technology. I am conducting a study on ``Factors influencing adverse drug reaction reporting among patients and healthcare providers in selected hospitals in Kirinyaga County, Kenya''. The Ministry of Health will use the information to improve and reinforce adverse drug reaction reporting to boost public health and patients' safety in Kenya's hospitals and other regions.

Procedures to be followed

Participation in this study will require that I ask you some questions with your consent. I will record the information from you in a questionnaire or electronically using a smartphone. You have the right to refuse participation in this study. Patients will get the same care and medical treatment, whether you agree to join the study or not and your decision will not change the care you will receive from the hospital today or that you will get from any other hospital at any additional time. Please remember that participation in the study is voluntary. You may ask questions related to the study at any time. You may refuse to respond to any questions and you may stop an interview at any time. You may stop being in the study at any time. The decision will not affect service delivery from this hospital or any other organization now or in the future.

Discomforts and risks

Some of the questions you will be asked may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you choose so. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait before receiving your routine services.

Benefits

Participating in this study will help us identify the gaps in ADR reporting and the present standing of ADR reporting among patients and healthcare providers. Through the study, you will understand your role, contribution and significance in ADR reporting. If you are found to have a problem, you will be advised on treatment.

Reward (applicable to patients only)

If you agree to participate in this study, you will not queue to receive your routine services after providing me with the required information.

Confidentiality

The interviews will be conducted in a private setting within the selected hospitals. Your name will not be recorded on the questionnaire and will not be disclosed at any point or after the study. Information obtained from you will be kept confidential and used for the planning reason for the study. The questionnaire will be kept in a locked cabinet for safekeeping at my University; results will be disseminated without uncovering your identity. Everything will be kept private.

Contact information

If you have any questions, you may contact David Muriithi (Principal researcher) on 0704377866 or Prof. Simon Karanja (Supervisor 1) On 0726424669 or Dr. Daniel Mokaya (Supervisor 2) On 0733704573 or the Kenyatta University Ethical Review Committee Secretariat on chairman.kuerc@ku.ac.ke, secretary kuerc@ku.ac.ke. Ercku2008@gmail.com, or 0208714388.

Participant's statement

The above information regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care I will receive from the hospital today or that I will get from any other hospital at any other time.

Code of participant_____

Signature or thumbprint_____Date_____

Investigator`s statement

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

Name of interviewer_____

Interviewer signature_____Date_____

Appendix VII: Key informants' interview schedule

FACILITY-LEVEL FACTORS INFLUENCING ADVERSE DRUG REACTIONS REPORTING IN SELECTED HOSPITALS IN KIRINYAGA COUNTY, KENYA

1. Does your institution have a pharmacovigilance center that investigates any emerging drug safety issues? Is there any concrete financing for the center? Is there sufficient human capital in the center? (*Probe)*
2. Do you know any least prerequisites by WHO for a functional pharmacovigilance system? Has your establishment conformed to any of the minimum requirements? (*Probe)*
3. Name the tool used for ADR reporting? Is the tool readily accessible in your department? Is the tool user-friendly or onerous? Why? (*Probe)*
4. Do you know that there are existing reporting guidelines that ought to be followed when reporting ADRs? Are they available in your department? Are they followed when reporting ADRs? (*Probe)*
5. How do you find the process of reporting ADRs? What are some of the methods utilized to report ADRs by your department? (*Probe)*
6. Is feedback on the proposal/action taken after reporting communicated to the institution? What means does the institution utilize to deliver feedback to the patients and healthcare workers? (*Probe)*
7. Have members of staff been trained or sensitized on ADR reporting? (*Probe)*
    a. Where did the training take place? Locally, nationally, through workshops?
    b. How many departmental members have undergone training?
    c. What were the key themes the practitioners were trained on during the training forums?
8. What do you think are the challenges encountered when reporting ADRs by healthcare providers? (*Probe)*

9. Name any interventions put in place by the pharmacovigilance department to reduce under-reporting of adverse drug reactions? (*Probe)*
    a. Do you sensitize patients to the potential ADRs when dispensing drugs?
    b. Do you talk about submitted cases in continuous medical education forums or departmental meetings?
10. What measures do you think should be implemented to improve your department's present state of ADR reporting? (*Probe)*

Appendix VIII: Ethical Approval

KENYATTA UNIVERSITY
ETHICS REVIEW COMMITTEE

Fax: 8711242/8711575
Email: chairman.kuerc@ku.ac.ke
kuerc.secretary@ku.ac.ke
Website: www.ku.ac.ke

P. O. Box 43844,
Nairobi, 00100
Tel: 8710901/12

Our Ref: **KU/ERC/ APPROVAL/VOL.1** (250) Date: 20th March, 2019

David Muriithi Nyagah
P.0 Box 43844-00100
Nairobi

Dear David,

APPLICATION NUMBER: PKU/988/E94: "FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING AMONG PATIENTS IN SPECIAL CLINICS AND HEALTH CARE PROVIDERS IN SELECTED HOSPITALS IN KIRINYAGA COUNTY, KENYA"

1. IDENTIFICATION OF PROTOCOL

The application before the committee is with a research topic **"Factors Influencing Adverse Drug Reaction Reporting Among Patients In Special Clinics And Health care Providers In Selected Hospitals In Kirinyaga County, Kenya"** received on 27th February, 2019 and discussed on 12th March, 2019

2. APPLICANT

David Muriithi Nyagah

3. SITE

Selected Hospitals in Kirinyaga County, Kenya

4. DECISION

The committee has considered the research protocol in accordance with the Kenyatta University Research Policy (section 7.2.1.3) and the Kenyatta University Ethics Review Committee Guidelines and **APPROVED that the research may proceed for a period of ONE year from 12th March, 2019**

Appendix IX: Ethical Approval (Rear Side)

5. ADVICE/CONDITIONS

i. Progress reports are submitted to the KU-ERC every six months and a full report is submitted at the end of the study.
ii. Serious and unexpected adverse events related to the conduct of the study are reported to this committee immediately they occur.
iii. Notify the Kenyatta University Ethics Committee of any amendments to the protocol.
iv. Submit an electronic copy of the protocol to KUERC.

When replying, kindly quote the application number above.
If you accept the decision reached and advice and conditions given please sign in the space provided below and return to KU-ERC a copy of the letter.

KENYATTA UNIVERSITY
OFFICE OF THE CHAIRMAN
25 MAR 2019
ETHICS REVIEW COMMITTEE
P.O BOX 43844 - 00100 NAIROBI

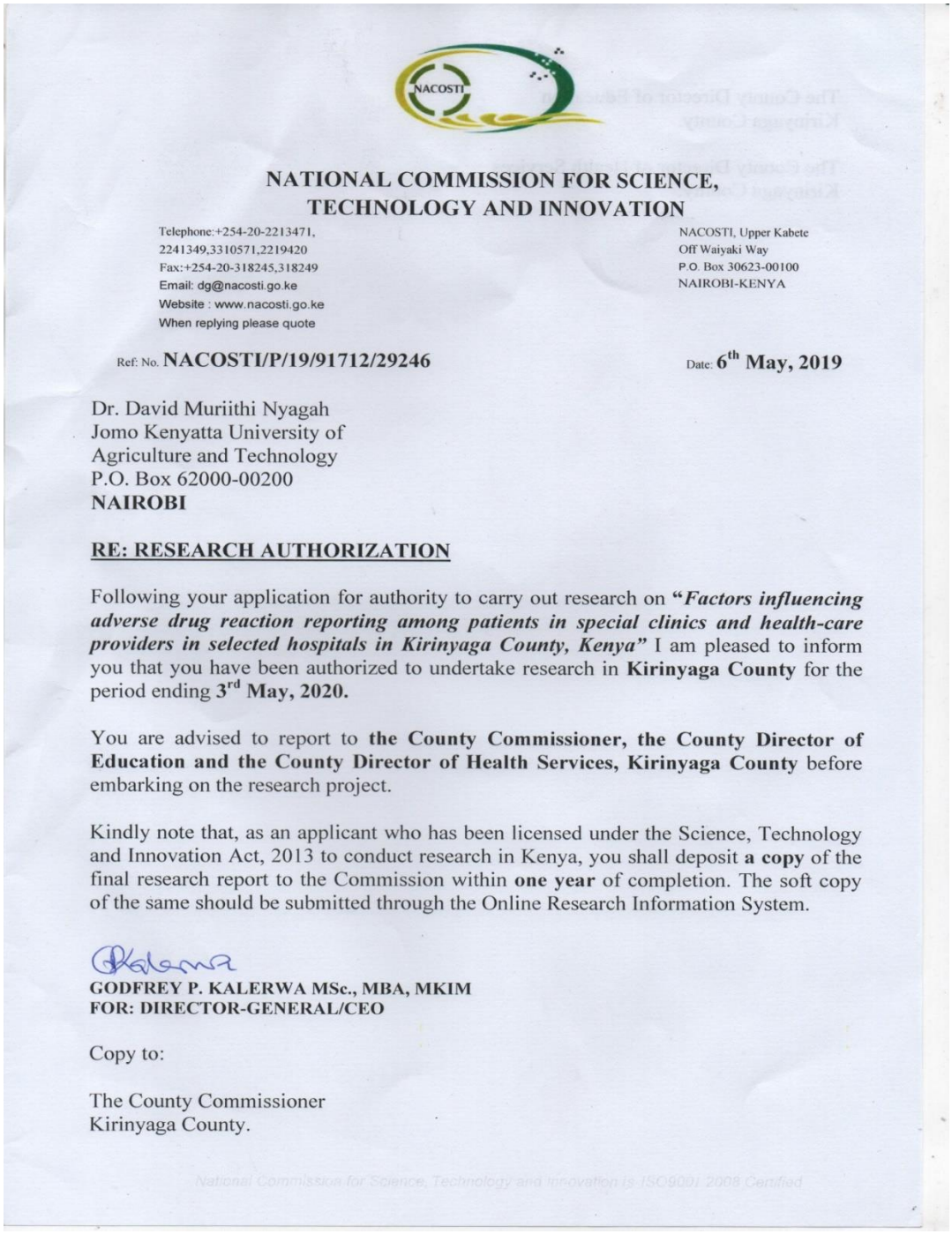
PROF. JUDITH KIMIYWE
CHAIRMAN ETHICS REVIEW COMMITTEE

I David Muriithi Nyaga .....accept the advice given and will fulfill the conditions therein.

Signature..... Dated this day of 25/3/ ..... 2019.

cc.
DVC-Research Innovation and Outreach

Appendix X: Research Authorization (NACOSTI)



NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY AND INNOVATION

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2241349,3310571,2219420
Fax:+254-20-318245,318249
Email: dg@nacosti.go.ke
Website : www.nacosti.go.ke
When replying please quote

NACOSTI, Upper Kabete
Off Waiyaki Way
P.O. Box 30623-00100
NAIROBI-KENYA

Ref: No. **NACOSTI/P/19/91712/29246**

Date: **6th May, 2019**

Dr. David Muriithi Nyagah
Jomo Kenyatta University of
Agriculture and Technology
P.O. Box 62000-00200
NAIROBI

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ***"Factors influencing adverse drug reaction reporting among patients in special clinics and health-care providers in selected hospitals in Kirinyaga County, Kenya"*** I am pleased to inform you that you have been authorized to undertake research in **Kirinyaga County** for the period ending **3rd May, 2020.**

You are advised to report to **the County Commissioner, the County Director of Education and the County Director of Health Services, Kirinyaga County** before embarking on the research project.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit **a copy** of the final research report to the Commission within **one year** of completion. The soft copy of the same should be submitted through the Online Research Information System.

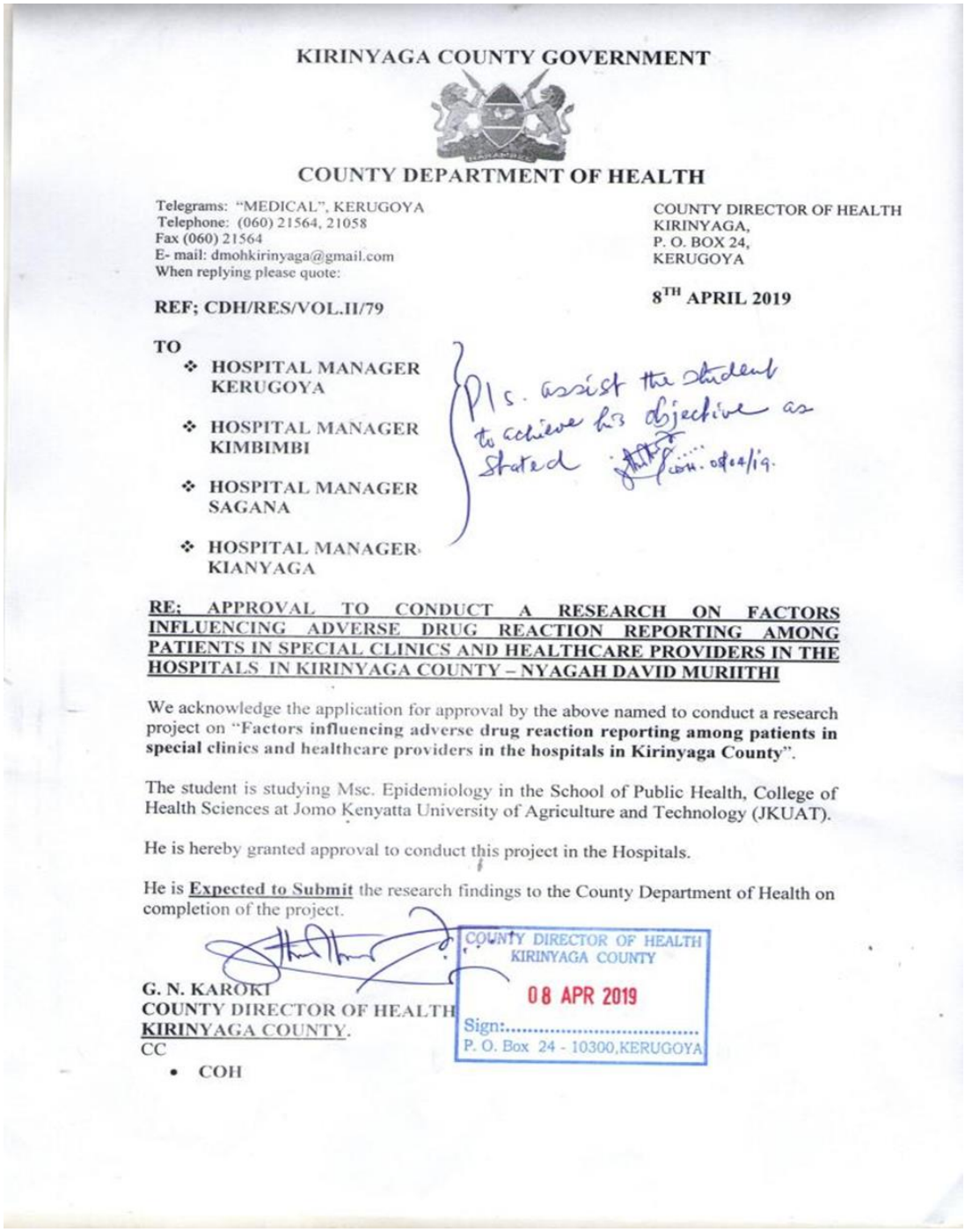
GODFREY P. KALERWA MSc., MBA, MKIM
FOR: DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioner
Kirinyaga County.

National Commission for Science, Technology and Innovation is ISO9001: 2008 Certified

Appendix XI: Permission to Conduct Research



KIRINYAGA COUNTY GOVERNMENT

COUNTY DEPARTMENT OF HEALTH

Telegrams: "MEDICAL", KERUGOYA
Telephone: (060) 21564, 21058
Fax (060) 21564
E- mail: dmohkirinyaga@gmail.com
When replying please quote:

COUNTY DIRECTOR OF HEALTH
KIRINYAGA,
P. O. BOX 24,
KERUGOYA

REF; CDH/RES/VOL.II/79

8TH APRIL 2019

TO

- HOSPITAL MANAGER KERUGOYA
- HOSPITAL MANAGER KIMBIMBI
- HOSPITAL MANAGER SAGANA
- HOSPITAL MANAGER KIANYAGA

Pls. assist the student to achieve his objective as stated ... COH. 08/04/19.

RE; APPROVAL TO CONDUCT A RESEARCH ON FACTORS INFLUENCING ADVERSE DRUG REACTION REPORTING AMONG PATIENTS IN SPECIAL CLINICS AND HEALTHCARE PROVIDERS IN THE HOSPITALS IN KIRINYAGA COUNTY – NYAGAH DAVID MURIITHI

We acknowledge the application for approval by the above named to conduct a research project on "**Factors influencing adverse drug reaction reporting among patients in special clinics and healthcare providers in the hospitals in Kirinyaga County**".

The student is studying Msc. Epidemiology in the School of Public Health, College of Health Sciences at Jomo Kenyatta University of Agriculture and Technology (JKUAT).

He is hereby granted approval to conduct this project in the Hospitals.

He is **Expected to Submit** the research findings to the County Department of Health on completion of the project.

COUNTY DIRECTOR OF HEALTH
KIRINYAGA COUNTY
08 APR 2019
Sign:.....
P. O. Box 24 - 10300,KERUGOYA

G. N. KAROKI
COUNTY DIRECTOR OF HEALTH
KIRINYAGA COUNTY.

CC

- COH

Appendix XII: Publication

ISSN (O): 2349-5332
CODEN: IRJPHY

Open Access

FACILITY-LEVEL FACTORS AND BARRIERS TOWARDS ADVERSE DRUG REACTION MONITORING AMONG HEALTHCARE PROVIDERS IN KIRINYAGA COUNTY, KENYA: A QUALITATIVE STUDY

David Muriithi Nyagah*, Daniel Mokaya, Simon Muturi Karanja.

School of Public Health, Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya. P.O. Box 62000 – 02000 Nairobi, Kenya.

Submitted on: 12.02.2020; Revised on: 22.03.2020; Accepted on: 05.04.2020

ABSTRACT:

Background: Under reporting of adverse drug reactions (ADR) has serious ramifications on the treatment outcomes and quality of healthcare for patients. Lack of reporting tools, guidelines, training and feedback have contributed significantly to under reporting. Objective: To explore facility-level factors and barriers associated with ADR monitoring among healthcare providers in Kirinyaga County, Kenya. Methods: A qualitative study utilising in-depth interviews was conducted among 12 departmental heads in 1 level 5 and 3 level 4public hospitals in Kirinyaga County, Kenya. A pre-tested interview guide was utilised to collect data. Audio taped interview transcripts were coded using NVivo version 12 software. Data were analysed using deductive thematic analysis. Findings from the study were presented using verbatim quotes and tables. Results: Deductive thematic analysis resulted in 5 themes, namely (1) Capacity to monitor ADRs; (2) Training; (3) Feedback; (4) Barriers of ADR reporting;(5) Perceived solutions for improved ADR reporting. Overall, all hospitals lacked pharmacovigilance (PV) centers. Additionally, frequency of feedback from the Pharmacy and Poisons Board (PPB) was low. Barriers of ADR reporting that were identified included: not knowing where to report, inability to access healthcare providers, unfriendly healthcare personnel and lack of training. Conclusion: The study noted that selected hospitals had limited capacity to monitor ADRs. Additionally, lack of training and feedback were major hindrances to ADR reporting at facility-level. Continuous training, providing prompt feedback in addition to developing a PV centre are highly recommended in order to promote ADR reporting and rational use of medicine in Kirinyaga County.

KEYWORDS: Adverse drug reaction; pharmacovigilance; healthcare provider; barriers; facility-level factors.

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