KNOWLEDGE, ATTITUDES AND PRACTICES ASSOCIATED WITH ADVERSE DRUG REACTIONS REPORTING AMONG MEDICAL DOCTORS AND PHARMACISTS AT THE KENYATTA NATIONAL HOSPITAL, NAIROBI COUNTY, KENYA

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Knowledge, attitudes and practices associated with adverse drug reactions reporting among medical doctors and pharmacists at the Kenyatta National Hospital, Nairobi County, Kenya

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DECLARATION

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

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DEDICATION

I dedicate this thesis to my children and wife. You are my greatest inspiration. May the fruits of this achievement bring you joy and happiness.

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LIST OF ABBREVIATIONS/ACRONYMS

AERS	Adverse events reporting system
ADRs	Adverse drug reactions
AIDS	Acquired immunodeficiency syndrome
ARV	Anti-retroviral
EU	European Union
HIV	Human immunodeficiency virus
IDM	International Drug Monitoring
KAP	Knowledge Attitudes Practices
KEMRI	Kenya Medical Research Institute
KNH	Kenyatta National Hospital
MSH	Management Sciences for Health
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
SPS	Strengthening Pharmaceutical Services
SPSS	Statistical Package for the Social Sciences
SSA	Sub – Saharan Africa
UK	United Kingdom
UMC	Uppsala Monitoring Centre
USA	United States of America
USD	United States dollars
WHA	World Health Assembly
WHO	World Health Organization

ABSTRACT

A study of patients on antiretroviral treatment attending the comprehensive care clinic at Kenyatta National Hospital (KNH) revealed high incidence (48.6%) of Adverse Drug Reactions (ADRs) with underreporting being a key problem among healthcare professionals involved. The objective of this study was to determine the knowledge, attitude and practices of medical doctors and pharmacists towards ADRs reporting in KNH. This was a descriptive cross sectional study whose sample size comprised 308 medical doctors and pharmacists working at the KNH, who are key decision makers in the provision of health services. A probability sampling was utilized via a skip interval random technique, to ensure each respondent in the different clinical units in the population were considered. Self-administered semi-structured questionnaires were used as data collection tools for the study that included demographic data. The overall level of knowledge of ADRs by the respondents was 60.5%. Majority of the respondents 187 (60.8%) named common ADRs along with medicines causing them while 219 (71.1%) identified medicines banned due to ADRs and the exact ADRs they caused. Majority of the respondents 199 (64.6%) did report they knew medicines banned due to ADRs. All healthcare professionals were identified by majority of the respondents 278 (90.3%) as qualified to report ADRs. Reporting ADRs was considered a professional obligation by 268 (87.0%) respondents, while 168 (54.5%) were aware of the existence of a Pharmacovigilance Department in Pharmacy and Poisons Board (PPB) in Kenya and these were mainly pharmacists. Overall, pharmacists showed better knowledge, attitudes and practices compared to medical doctors from the χ^2 values calculated.

The study report highlights deficits in the practice of ADR reporting can be resolved only if all healthcare professionals are made aware of the importance of reporting, the reporting system, and their obligation to report ADRs.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

The World Health Organization (WHO) defines an Adverse Drug Reaction (ADR) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” (WHO, 1972). Several classification methods have been proposed to describe ADRs such as by their severity (mild, moderate or severe), source of reported data (reported by patient, observer or machine), by reaction time (acute or latent) and whether the reaction is localized or systemic.

The pharmacological classification which classifies ADRs into Types A-F is most commonly used. Type A (Augmented) is an exaggeration of the drug's normal pharmacological actions, type B (Bizarre) is one due to unexpected reactions (Rawlins and Thompson, 1977), type C (Chronic) which occurs with long term use of a drug, type D (Delayed) which occurs after a period of time has elapsed from cessation of medication, type E (End of use) as a result from sudden stopping or immediate cessation of use (Aronson and White, 1996) and type F which is a failure of therapy (Edwards & Aronson, 2000). An ADR may result from both drug related factors (drug effects, drug use, synergistic effects between a drug and a disease or

between two drugs) and also non-drug related factors (abnormal pharmacokinetics due to genetic factors, age or disease states).

The WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. This has been broadened in recent years to include herbal products, traditional and complementary medicines, blood products, biological, medical devices and vaccines (WHO, 2002).

A study of almost 19000 admissions was able to show that 6.5% of patient admissions to two National Health Service hospitals in the United Kingdom (UK) were related to an ADR (Pirmohamed *et al.*, 2004). A Swedish study had implicated ADRs as 7th most common cause of death (Wester, Jonnson, Sigset, Druid & Hagg, 2008). According to the WHO, costs of ADRs, including hospitalisations, surgery and lost productivity, exceed the cost of medicines in some countries (WHO, 2008). In Europe it was estimated that 197,000 deaths are reported annually from ADRs (European Commission, 2008). The costs of drug-related morbidity and mortality exceeded United States Dollars (USD) 177 billion in 2000 in the United State of America (USA) (Ernst and Grizzle, 2001) while the total estimated annual cost to society due to ADRs in the European Union (EU) was 79 billion euros (European Commission, 2008).

A study done in South Africa concluded that ADRs are an important cause of admissions and contribute to inpatient morbidity in the public healthcare system of 14% (Mehta *et al*., 2008). The majority of reactions were dose related, with a high proportion of reactions being preventable, thus highlighting the importance of improving drug selection, use and monitoring, particularly in vulnerable patient groups. Further they noted that Human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS) appeared to be an important determinant of the profile of patients, drugs implicated and nature of ADRs seen in hospitalized patients in a country with a high burden of this disease.

A similar study on pharmacovigilance for antiretroviral (ARV) drugs in Abidjan, Cote d'Ivoire indicated that ADRs accounted for the most frequent reason (45.5%) for treatment modification and interruptions in patients on ARV treatment (Antoine *et al*., 2011). HIV infected patients receiving ARV treatment were more likely to be admitted with an ADR than those not on ARV treatment. An evaluation of African pharmacovigilance systems carried out by the Management Sciences for Health (MSH), Strengthening Pharmaceutical Systems (SPS) program, reported that insufficient and inadequate resources to monitor safety of medicines; the unreliable supply of quality, safe, and effective medicines; poor penetration of pharmacovigilance training among health care practitioners; and the weak state of the health systems in Africa are likely to contribute to significant medicines-related harm (SPS Program, 2011).

In Kenya, the report further noted that the reporting rate of ADRs remains low despite the launch of the pharmacovigilance programme in 2007. The report indicated that the PPB in Kenya the regulator in-charge of pharmaceuticals, had only received 15 reports per million of the population in 2010 against the WHO recommended reporting rate of greater than 200 reports per million population per year (SPS Program, 2011). The current reporting system involves the use of a Poor Quality Drug Reporting Form ("pink form") to report poor quality medicines and the Suspected ADRs Notification Form ("yellow form") to report suspected ADRs to medicines (Ministry of Medical Services [MoMS] & Ministry of Public Health and Sanitation [MoPHS], 2009). The present study was planned to investigate the Knowledge, Attitudes and Practices (KAP) related to ADR reporting among medical doctors and pharmacists in a tertiary care hospital.

1.2 Statement of the problem

A study done at KNH revealed that there was a high incidence (48.6%) of ADRs among the sampled patients on ARV treatment attending the comprehensive care clinic (Mwangangi, Juma, Scott, Nyamu & Kuria, 2009). A more recent study in the same institution indicated health workers' knowledge on ADRs reporting was a major determinant of reporting (Obonyo, Wang'ombe, Olewe & Ongore, 2014). They noted that health workers who had been trained and had more knowledge on ADR reporting were more likely to report than those who had not been trained and had less knowledge about reporting. In the same study, key informants identified several health provider and health systems factors that affect reporting such as lack

of knowledge on reporting schemes, poor attitudes, unavailability of reporting tools, high workloads and the costs incurred when sending a hard copy report to the PPB.

The PPB reported that ADRs are significantly under-reported in the country citing core teams from 12 ARV therapy ADR surveillance sites in Kenya having identified lack of awareness at lower cadres, increased workload and limited time to report ADRs as major challenges that were facing the reporting of ADRs (Pharmacy and Poisons Board [PPB], 2012). In Africa, there has been increased access to newly introduced essential medicines which call for a greater need to monitor and promote their safety and effectiveness. Studies have documented how ADRs contribute to patient morbidity and hospitalization in Africa indicating figures of 4.5 - 8.4% of all hospital admissions being related to ADRs, 1.5 - 6.3% of patients being admitted as a direct result of ADRs; and 6.3 - 49.5% of all hospitalized patients developed ADRs (SPS Program, 2011).

1.3 Justification of the study

KNH the largest referral and teaching hospital in Kenya has medical doctors and pharmacists being the key decision makers on provision of healthcare services to patients. A recent study in the institution concluded that although most healthcare professionals had seen a patient with a suspected ADR, only a few had ever reported these ADRs (Obonyo *et al.,* 2014). Many medicines related adverse events are predictable and preventable therefore identifying and documenting these events is important to protect patients from preventable harm. This is so especially for new

products, where the information can result in changes to the medicines' recommended use, product labeling, treatment guidelines, or even a product recall.

A comprehensive systems perspective is needed for both active and passive approaches to identify medicines-related problems. There is need to create effective mechanisms to communicate medicine safety information to health care professionals and the public with enhancing of collaboration among a wide range of partners and organizations. Further, incorporation of pharmacovigilance activities at all levels of the health system is of utmost importance as recommended by the SPS program (SPS Program, 2011).

This study's results will act as a guide in the development and improvement of comprehensive pharmacovigilance activities in the health sector and the roles of health care practitioners in these activities.

1.4 Objectives of the study

1.4.1 General objective

To determine the knowledge, attitudes and practices associated with ADRs reporting among medical doctors and pharmacists at the KNH.

1.4.2 Specific objectives

1. To establish the level of knowledge on ADRs reporting among medical doctors and pharmacists at the KNH.

2. To establish the attitudes towards reporting of ADRs among medical doctors and pharmacists at the KNH.
3. To establish the practices of reporting of ADRs among medical doctors and pharmacists at the KNH.

1.5 Research questions

4. What is the level of knowledge on ADRs reporting among medical doctors and pharmacists at the KNH?
5. What are the attitudes towards reporting of ADRs among medical doctors and pharmacists at the KNH?
6. What are the practices of reporting of ADRs among medical doctors and pharmacists at the KNH?

CHAPTER TWO

LITERATURE REVIEW

2.1 History of ADR reporting

The first systematic international efforts were initiated to address drug safety issues after the disaster caused by thalidomide in 1961 where many thousands of congenitally deformed infants were born as a result of exposure *in utero* to an unsafe medicine promoted for use in pregnant mothers. The Sixteenth World Health Assembly (WHA) in 1963 adopted a resolution, WHA 16.36, that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and led, later, to creation of the WHO Pilot Research Project for International Drug Monitoring in 1968 (WHO, 1973). The purpose of the project was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines. From these beginnings the practice and science of pharmacovigilance evolved.

In that same year, ten countries which supported the spontaneous reporting of ADRs joined the WHO research project for International Drug Monitoring (IDM). In 1971, a resolution of the Twentieth WHA laid down the foundations for the WHO IDM Programme, now known as the WHO Medicines Safety Programme (Grootheest, 2003). This programme is supported and co-ordinated by the WHO Collaborating Centre for IDM, commonly known as the Uppsala Monitoring Centre (UMC), which maintains and implements an international database of adverse drug events.

Since the start of the IDM Programme in 1968 much has been accomplished (WHO, 2002):

- The pilot project has developed into the WHO Programme for IDM now co-ordinated by the UMC in Uppsala, Sweden, with oversight by an international board,
- The Programme has expanded to include more than sixty member countries,
- In many countries, regional reporting centres, interest groups, dedicated internal medicine and pharmacology department units, drug and poison information centres and other non-governmental organizations have developed,
- The idea that pharmacovigilance centres are a luxury, affordable only in the developed world, has been replaced by a realization that a reliable system of pharmacovigilance is necessary for public health and for the rational, safe and cost-effective use of medicines in all countries. Where no established regulatory infrastructure exists, a drug monitoring system is an effective and cost-efficient means of detecting and minimizing injury to patients and averting potential disaster.

As of October 2013, 117 countries had joined the programme and 28 associate members were awaiting full membership status (WHO, 2013a).

2.2 Factors that affect ADR reporting worldwide

2.2.1 Underreporting

Pharmacovigilance programs have been adopted by various countries in order to ensure safe use of drugs, with spontaneous ADR reporting being the cornerstone of these programmes. Spontaneous ADR reporting has contributed to signal detection of unsuspected and unusual ADRs which were previously undetected during the initial evaluation of a drug (Wysowsky & Swartz, 2005; Lexchin, 2006). However, underreporting is one of the major problems associated with success of a pharmacovigilance program (Lee & Thomas, 2003). Even in countries where pharmacovigilance is well established underreporting is a common concern according to Lee and Thomas (2003).

Various factors have been associated with underreporting including ignorance, diffidence, lethargy, indifference, insecurity, complacency. It has been documented that the knowledge and attitudes of health professionals appear to be strongly related with reporting and can be viewed as potentially modifiable factor (Lopez-Gonzalez, Herdeiro, & Figueiras, 2009). For a pharmacovigilance program to be effective there should be active participation by healthcare professionals.

2.2.2 Level of knowledge

In China, over 90 per cent of ADR reports came from hospitals (Chen, Duo & Wu, 2004). The pharmacovigilance cognitive level of healthcare professionals directly impacts on the regional ADR monitoring centres. A study done in Jiangsu province,

China, where health care practitioners were interviewed on their knowledge of pharmacovigilance, it was noted that 50.2% knew pharmacovigilance and 41.4% of them had learned the knowledge on pharmacovigilance through professional magazines while 41.2% learned it from professional training. Among the respondents who knew about pharmacovigilance, 62.2% knew the contents of pharmacovigilance, i.e., drug safety and medical device safety while 68.7% did not think that ADRs and pharmacovigilance were the same concept. The study concluded that a mutual understanding within extensive social groups, especially health professionals, was the first step in establishing pharmacovigilance. Effective communication and training of health professionals were important in the extension of pharmacovigilance.

Another study in China evaluated four aspects: basic concepts of pharmacovigilance, cognition of ADR reporting, cognition of rational administration, and cognition of drug safety information (Xu, Wang & Liu, 2009). The inference was that awareness score of a pharmacist was higher than that from a doctor, a nurse, and other health care practitioners. Pharmacists were the ADR monitoring professionals in China and they may have been more exposed to such knowledge. The data also showed that a higher education level and professional title were associated with a higher awareness score in the study. These data suggest that more professional education of pharmacovigilance was needed and/or that the development of professional disciplines had failed to synchronize with pharmacovigilance.

A report done in France noted that under-reporting, a major drawback of spontaneous ADR reporting, was prevalent even in developed countries with a long history of a functional ADR-reporting system (Thiessard *et al.*, 2005). In some developing countries, the importance of ADR reporting was just being recognized and in Iran, a national ADR-reporting system was established by the Ministry of Health in June 1998. Despite the existence of the national ADR reporting system in Iran, a major problem of voluntary surveillance by healthcare professionals had been the high level of under-reporting (Gholami, Shalviri, Zarbakhsh, Daryabari & Yousefian, 2007).

2.2.3 ADR reporting process

In a study of Suboptimal reporting of adverse medical events to the USA Food and Drug Administration (FDA) Adverse Events Reporting System (AERS) by nurse practitioners and physician assistants, majority of the participants practiced in a setting that had an internal method of reporting adverse events (Ehrenpreis, Sifuentes, Ehrenpreis, Smith & Marshall 2012). However, it did not appear that having an internal reporting system increased the likelihood that participants would report adverse events to the AERS. The majority of participants agreed with the statement that reporting of adverse events would increase if the reporting process were easier considering that the FDA AERS gave the options of reporting online, by mail, by telephone or by fax. These modes of reporting made the task of submitting these reports relatively easy and had a user-friendly interface. However, they still appeared to be burdensome to the health care practitioners in that survey. They further noted that dissemination of information to nurse practitioners and physician

assistants about the relative ease of use of these methods increased the likelihood of reporting to the AERS.

2.2.4 Time taken to report ADRs

Results of a study performed in a tertiary teaching hospital in Barcelona, Spain indicated that lack of time to report an ADR due to the workload of clinical practitioners was detected as the most important reason to ADR underreporting. Other causes of under-reporting in that study were lack of information about the spontaneous reporting system, unavailability of yellow cards, doubt of ADR causality assessment and lack of patient confidentiality (Evans, Berry & Smith, 2006).

2.3 ADR reporting in Africa

2.3.1 Reporting systems

In a study carried out by the MSH/SPS program (SPS, 2011), the capacity for regulating health products in Sub – Saharan Africa (SSA) was found to be inadequate despite an estimated pharmaceutical market size of 3.8 billion to 4.7 billion USD and local manufacturing capacity in 80% of the countries. The WHO defines the minimum requirements for a functional national pharmacovigilance system as having a national pharmacovigilance center, a spontaneous reporting system, a national database, a national pharmacovigilance advisory committee, and a communications strategy.

Based on these minimum requirements, the study developed a systems classification in forty six countries in this region. The classification represented the level of systems' capacity and performance for meeting relevant indicators in five components: policy, law, and regulation; system, structure, and stakeholder coordination; signal generation and data management; risk assessment and evaluation; and risk management and communication.

The study by SPS further showed that the scope of pharmacovigilance is limited in most of the SSA countries. Although 74% have spontaneous reporting systems, less than 50% monitor product quality, medication errors, and treatment failures through existing systems. A pharmacovigilance database exists in 50% of the countries, but coordination and collation of pharmacovigilance data from all sources was inadequate. On average, less than 40% of drug and therapeutics committees in the countries studied had implemented active approaches to monitor and investigate adverse events in the last 5 years, 47% reviewed ADR reports and addressed medicine safety issues, and 23% took some action related to medicine safety in 2010.

2.3.2 Level of knowledge

A study done in a teaching hospital in Lagos, Nigeria, showed that doctors had inadequate knowledge about ADRs suggesting that perhaps, the undergraduate training in pharmacovigilance and medicine risk perceptions may be either insufficient or improperly delivered to prepare the doctors for the task of ADR monitoring and reporting in their future career (Oshikoya & Awobusuyi, 2009).

Ruud, Srinivas and Toverud (2010), noted that spontaneous reporting of ADRs to document the safety of antiretrovirals can be successful only if the health care practitioners at the first level of contact with patients have significant insight into the importance of pharmacovigilance, together with the skills necessary to identify and report ADRs. They further noted that because of a shortage of doctors and pharmacists in the public health sector in South Africa, the down-referral health care system depended on the few professional nurses and the auxiliary staff at the hospital and primary health care levels. These professional nurses required appropriate training to detect and report ADRs as it was shown that the nurses felt a lack of confidence about referring patients with suspected ADRs for treatment purposes, which could be done through empowerment by more training.

2.3.3 Awareness of reporting centres

Oshikoya & Awobusuyi, (2009), noted that a significant number of respondents in their study were not aware of the existence of a national pharmacovigilance centre in Nigeria and amongst those who were aware, only 39.2% were able to correctly identify Abuja as the office. They concluded that lack of knowledge of where ADRs should be reported would automatically affect reporting and as such, awareness programmes; through publicity, would appear necessary to improve ADR reporting in Nigeria.

Further, in the study done in Lagos, it was noted that there was a general lack of awareness of ADR reporting system, as 63.4% of respondents did not know about the existence of a Yellow Card reporting scheme coupled with the fact that only two

respondents had ever reported ADRs with a Yellow Card then. In addition it was reported that like most countries around the world, ignorance (not feeling the need to report well recognised reaction), diffidence (concern that the ADR report may be wrong) and indifference (lack of time to fill in a report and a single unreported case may not affect ADR database) would significantly influence ADR-reporting among the doctors working in a Nigerian teaching hospital. However, they noted that complacency, fear, financial incentives and bureaucracy involved in filling in the Yellow Card would have a little influence on the respondents to report ADRs. Therefore, ADR under-reporting in Nigeria appeared to be associated more with knowledge gaps and attitudes of the doctors rather than with personal and professional characteristics.

2.3.4 Status of ADR reporting

The survey of ADR reporting in SSA showed that in 2010, the highest reporting rates were found in Namibia and Burkina Faso (135 and 131 reports per million of the population respectively). Senegal, Madagascar, Zambia, Kenya, Ghana, Mali, Botswana and Nigeria had ADR reporting rates ranging from 10-34 reports per million populations. Countries with the lowest reporting rates were Malawi, Democratic Republic of Congo, Ethiopia, Mozambique, Guinea, Tanzania, Zimbabwe and Uganda which had reporting rates ranging from 1-6 reports per million population and Angola, Benin, Burundi, Côte d'Ivoire, Rwanda and Sudan which did not submit any ADR reports and therefore had a reporting rate of 0 per million population (SPS Program, 2011).

2.4 ADR reporting in Kenya

2.4.1 Status of ADR reporting

The Department of Pharmacovigilance was set up in 2004 at the PPB with a vision to develop, implement and continuously upgrade an appropriate system for detecting, reporting and monitoring ADRs and other relevant problems with medicines in Kenya. The Pharmacovigilance Program was launched in 2007 to monitor both the safety and quality of medicines through voluntary reporting (MoMS and MoPHS, 2009). In 2010, Kenya became the 98th member of the WHO Medicines Safety Programme (Pharmacy and Poisons Board [PPB], 2010).

Since 2004, the milestones that have been attained in the national pharmacovigilance system include the development of the national pharmacovigilance guidelines, the establishment of the reporting systems and tools, training of health workers on pharmacovigilance, the development of information and education materials on pharmacovigilance, development of a national strategy on post-marketing surveillance of medicines, regular sending out of safety alerts, and the establishment of the Expert Safety Review Panel which reviews all pharmacovigilance -related reports in order to carry out the necessary follow-up interventions. The weaknesses identified include the lack of a national pharmacovigilance policy, limited capacity to generate signals and manage pharmacovigilance data, a limited scope of pharmacovigilance and the presence of counterfeit medicines (PPB, 2010; SPS Program, 2011).

In Kenya, most of the ADR reports are submitted by health workers. Patients can submit ADR reports directly to the PPB but the quality of patient reports has not yet been evaluated (SPS Program, 2011). Key informants in this study postulated that spontaneous reporting of ADRs in Kenya involved three key players: the patient who consumed the drug, experienced the ADR and notified the healthcare worker; the healthcare worker who was responsible for identifying the ADR and filling in the report, and the PPB which was responsible for collecting and analyzing the reports as well as providing reporting tools and supporting resources. The health worker was an important component of ADR reporting because they were the link between the patient and the PPB. The health worker was responsible for educating the patient on the possible adverse effects that they could experience, and was supposed to encourage the patient to report the ADR. If the patient experienced the ADR and reported it to the health worker, the health worker was responsible for identifying the potential adverse drug reaction and reporting it to the PPB.

2.4.2 Training on ADR reporting

The PPB department of pharmacovigilance had developed a detailed 5-day training program for all health care practitioners in Kenya as a minimum standard training on Pharmacovigilance and also developed a guideline for the National Pharmacovigilance System in Kenya to guide health care practitioners on the operations of the pharmacovigilance system. The guidelines give an overview of what pharmacovigilance is, how to detect and classify ADRs and the structural organization of the system in Kenya. It also describes the reporting system to the

National Pharmacovigilance Centre and expected outcomes (MoMS and MoPHS, 2009).

The number of reported ADRs in the PPB database as end of March 2015 stood at 8759, most of which had been reported by pharmacists and pharmaceutical technologists in the country. Several groups of healthcare workers had been trained to report ADRs and the reporting tools had been availed in health facilities. Despite this, reporting rates were still low and the PPB reported that lack of awareness as one of the major impediments of reporting of ADRs. Data from the PPB showed that KNH was submitting few reports despite it being a referral hospital (PPB, 2010). Since health workers were responsible for submitting most of the ADR reports, it was likely that the low reporting rates were being influenced by health worker factors which needed to be determined.

2.4.3 Factors that affect ADR reporting

A study done in Kenya, Uganda and Tanzania (Lalvani, 2007) indicated that lack of sufficient funding, infrastructure, trained staff, and training programs on medicines risk management in pre- and post-service education were major constraints in previous pharmacovigilance surveys.

Different countries have varying requirements for ADR reporting and in countries where ADR reporting was well established such as the USA and the UK, healthcare workers were required to report specific categories of ADRs whereas other categories of ADRs were exempt from being reported for example non-serious

ADRs to established medicines (Strom and Kimmel, 2006). However, the PPB in Kenya required healthcare workers to report all suspected ADRs whether the medicine was newly marketed or established and to report even if the health worker had incomplete information regarding the ADR (MoMS and MoPHS, 2009). Due to the differences in ADR reporting guidelines in different countries, it was necessary to carry out a study in Kenya in order to determine the factors affecting reporting in our local setting.

Monitoring of ADRs is carried out by various methods, of which voluntary or spontaneous reporting is commonly practiced. This system offers many advantages. It is inexpensive and easy to operate. It encompasses all drugs and patient populations, including special groups. However, under-reporting and an inability to calculate the incidence of ADRs are the inherent disadvantages of this method (Montastruc *et al*., 2006). In order to improve the participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors. A KAP analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study setting

This study was carried out at the Kenyatta National Hospital, Nairobi which is the largest referral and teaching hospital in the country. The hospital is located in a complex covering an area of 45.7 hectares. The hospital has 50 wards, 22 out-patient clinics, 24 theatres (16 specialised) and a casualty department. Out of the total bed capacity of 1800, 209 beds are for the Private Wing. There is a Doctors Plaza consisting of 60 suites for various consultant specialties. The hospital offers a wide range of services that include surgery, pharmaceutical, nutritional, health information and diagnostic services such as laboratories, radiology, imaging and endoscopy among other specialised services. At any given day the hospital hosts in its wards between 2500 and 3000 patients. On average, the hospital caters for over 80,000 in-patients and over 500,000 out-patients annually. It has over 6000 staff members 60% being health care practitioners with approximately 800 medical doctors and pharmacists that include consultants, residents, post-graduates and interns, who are drawn from KNH and the College of Health Sciences of the University of Nairobi at any one time (Table 3.1). The rest (40%) are administrative and support staff.

The hospital was selected as a study setting due to the high number of medical doctors and pharmacists who work there, the large number of patients the hospital

caters for and the fact that apart from being a national referral and teaching hospital, it provided a medical research environment.

Table 3.1 Departments for Medical Doctors and Pharmacists at KNH

Personnel	Department	No. of personnel	%
Medical Doctors	Accidents and Emergencies	10	1.3
	Anaesthesia	85	10.6
	Cancer Treatment Centre	11	1.4
	Dental	26	3.3
	Ear, Nose & Throat Infections	32	4.0
	Internal Medicine	138	17.3
	Neurosurgery	15	1.9
	Ophthalmology	27	3.4
	Orthopedics	15	1.9
	Paediatrics	117	14.6
	Reproductive Health	127	15.9
	Respiratory Infectious Diseases & Comprehensive Care Centre	10	1.3
	Surgery	146	18.3
Pharmacists	Pharmacy	41	5.1
TOTAL		**800**	**100.0**

3.2 Research design

The study was a descriptive cross-sectional study where semi-structured self-administered questionnaires were used as a data collection tool. The tool was sourced from similar studies carried out in other countries. A pilot test was carried out on 20 medical doctors and pharmacists at the Mbagathi District Hospital in Nairobi to streamline the data collection tool. The hospital was selected because it shared a locality with KNH and offered similar clinical services but with a lower number of patients. Similarly the medical doctors and pharmacists working there were the key decision makers in the provision of healthcare services to patients.

3.3 Study population and sampling frame

The population in the study comprised medical doctors and pharmacists working at KNH Nairobi. The sample size for this population was 308 medical doctors and pharmacists who provided health care services in the hospital within the study period. The study focused on those offering clinical services in surgical, medical, diagnostic, health information, private wing, pharmaceutical & nutritional services' units of KNH.

Inclusion criteria:

- Medical doctors and pharmacists directly involved in offering clinical services to patients.
- Medical doctors and pharmacists in a position to detect ADRs in patients.

Exclusion criteria:

- Medical doctors, pharmacists and healthcare professionals who were not directly involved in the clinical care of patients.
- Medical doctors, pharmacists and healthcare professionals who were not in a position to detect ADRs.
- Medical doctors, pharmacists and healthcare professionals that declined to participate in the study.

3.4 Size determination and sampling design

For the study, 308 medical doctors and pharmacists were identified and questionnaires administered to them after consent. Since the proportion of population that encounters ADRs and reports in the hospital was not known, the proportion of persons with the event of interest was estimated at 50 %.

Using the Cochran's formula the minimum sample size (n) was determined as follows (Cochran, 1997):

$$n = \frac{Z^2 P Q}{d^2}$$

Where;

n = Sample size required

Z = The standard deviate at 95% confidence level

P = Proportion of the persons with the event of interest: 50%

Q = [1-P]

d = Level of precision at 5%

$$n = \frac{Z^2 P Q}{d^2} = \frac{1.96^2 \text{ X } 0.5 \text{ X } 0.5}{0.05^2} = 385$$

A 30% non-response level was considered for the minimum number of participants.

$$\frac{385 \text{ X } 30}{100} = 116 = 385 + 116 = 501$$

Further, the sampling required a correction for finite populations;

$$n_f = \frac{n_0}{1 + \frac{n_0 + 1}{N}}$$

Where;

n_f = Sample size required

n_0 = Sample size calculated using Cochran's formula

N = Total number of persons of interest

$$n_f = \frac{n_0}{1 + \frac{n_0 + 1}{N}} = \frac{501}{1 + \frac{502}{800}} = 308$$

Using the above formula, a minimum of 308 participants was required.

3.5 Data collection methods

Probability sampling was utilized via a skip interval random technique ensuring that each respondent in the different clinical units in the population had an equal probability of being chosen. The approximate number of medical doctors and pharmacists in each clinical unit was established, therefore, a proportionate number of respondents were requested to fill in the questionnaire, relative to the total number in that unit and to the total number of medical doctors and pharmacists in the hospital. The respondents included consultants, residents, post graduates and interns who formed key personnel that provided clinical services at the hospital.

The consent administration was done to each individual respondent in all the units offering clinical services before the questionnaire was administered. A semi-structured self-administered questionnaire was used as the data collection tool in this

study. Open and closed - ended questions were used to probe the participants. The questionnaire was divided into appropriate sections with the first section covering the demography of the respondents and the rest of the sections comprising of questions for knowledge, attitudes and practices, the three specific objectives of the study. The questionnaires were distributed as hard copies to the consenting participants who were requested to fill each section appropriately. The questionnaires were then collected after a period of 5 days.

3.6 Pre – Testing of questionnaires

A pilot test was conducted to test the questionnaire for relevance to the study and also to ensure the questions are straight forward and unambiguous, at Mbagathi District Hospital located in Nairobi on 14 medical doctors and 6 pharmacists. Thereafter, the questionnaire was reviewed and a final copy made for dispatch to the targeted respondents in KNH. The hospital provided comparable clinical services, and was situated in the same area as KNH but with a lower number of patients.

3.7 Data management and analysis

The data collected in the study was analyzed by use of descriptive statistics. All questionnaires were examined for completeness. The data was then keyed in into a computer, to create a database for statistical analysis with the SPSS® 20 software program. The knowledge of the participants on ADRs was scored using a pre-decided assignment as per their responses to the questions. As a measure of the level of knowledge in this study, the knowledge section responses were stratified further using a pre-decided assignment of correct responses into low (0 – 2 responses),

moderate (3 – 4 responses) and high (5 responses). All these responses were multiplied by number of respondents and summed up to get a total score which was used to represent the knowledge level. Differences between parameters of estimate were deemed significant at P value less than 0.05 using a χ^2 test. Frequency distribution and percentages were used for ease of comparison. The data once analyzed was stored in the personal computer of the principal investigator and a back-up was stored at a secondary storage area in an external hard disk.

3.8 Ethical considerations

Ethical clearance was obtained from the Kenya Medical Research Institute's (KEMRI) Scientific Steering Committee and the Ethical Review Committee. Permission was granted by the Medical Superintendent of Mbagathi District Hospital to carry out the pre-testing of questionnaires. Ethical clearance was also acquired from the KNH/University of Nairobi - Ethical Research Committee to carry out the study in the hospital. The study was also registered by the KNH Research & Programs Department and received a Study Registration Certificate.

3.9 Limitations of the study

The study was only targeting medical doctors and pharmacists in one referral hospital in Kenya. The results could only be generalized for this cadre of health workers at this referral hospital. Further, the study aimed to establish the current reporting patterns of pharmacovigilance as an activity considering that official systematic reporting was only introduced in the country less than few years ago.

CHAPTER 4

RESULTS

Results indicated that 167 (54.2%; 95% CI 48.5 – 59.9) were males and 141 (45.8 %; 95% CI 40.1 – 51.5) were female (Table 4.1). Medical doctors were 285 (92.5%; 95% CI 89.0 – 95.2) while Pharmacists were 23 (7.5%; 95% CI 4.8 – 11.0) of the respondents. The most common age group among the respondents was 30 – 34 years age 158 (51.3%; 95% CI 45.6 – 57.0). For work experience, majority had worked for 5 – 9 years 154 (50.0%; 95% 44.3 – 55.7) and majority of the respondents were first degree holders 183 (59.4%; 95% CI 53.7 – 64.9).

Table 4.1: Socio-demographic characteristics of medical doctors and pharmacists interviewed in KNH

Characteristics		Participants	%
Gender of respondent	Male	167	54.2
	Female	141	45.8
Age of respondent (years)	25 – 29	52	16.9
	30 - 34	158	51.3
	34 - 39	63	20.5
	40 – 44	10	3.2
	45 – 49	6	1.9
	50 – 54	8	2.6
	≥ 55	11	3.6
Years of work experience	0 – 4	82	26.6
	5 – 9	154	50.0
	10 – 14	41	13.3
	15 – 19	12	3.9
	20 - 24	4	1.3
	25 - 29	8	2.6
	≥ 30	7	2.3
Highest level of formal education	1st Degree	183	59.4
	Post Graduate Degree	105	34.1
	Post Graduate Diploma	3	1.0
	Others	17	6.0
Current department in KNH	Medical Doctor	285	92.5
	Pharmacist	23	7.5

The medical doctors and pharmacists interviewed were from various departments (Table 4.2.).

Table 4.2 Medical doctors and pharmacists interviewed in KNH

Personnel	Department	No. of personnel	%
Medical doctors	Accidents and emergencies	3	1.0
	Anaesthesia	40	13.0
	Cancer treatment centre	3	1.0
	Dental	12	3.9
	Ear, nose & throat infections	10	3.2
	Internal Medicine	56	18.2
	Neurosurgery	3	1.0
	Ophthalmology	11	3.6
	Orthopedics	5	1.6
	Paediatrics	39	12.7
	Reproductive health	43	14.0
	Respiratory infectious diseases & comprehensive care centre	3	1.0
	Surgery	57	18.5
Pharmacists	Pharmacy	23	7.5
TOTAL		308	100.0

Regarding level of knowledge on ADRs reporting among medical doctors and pharmacists at the KNH, majority of the respondents had high knowledge level of common ADRs along with the medicines that cause them (187; 60.8%) with no significant difference among the two professions doctors and pharmacists (χ^2=8.137, df=5, P = 0.149) (Table 4.3). Over 80% of medical doctors were found to have moderate to high knowledge levels compared to 8.8% who had low knowledge levels. Only 4.3% of pharmacists showed low knowledge levels compared to 95.7% who had moderate to high knowledge levels. Of the listed ADRs, Steven Johnsons Syndrome had the highest frequency at 20.5% caused majorly by non-steroidal anti –

inflammatory agents and antibiotics (penicillin and sulphur based). Hepatotoxicity at 8.5% was second followed by hypersensitivity (4.8%), peripheral neuropathy (4.2%) and anaphylactic shock (3.5%).

Table 4.3: Knowledge levels indicated by number of common ADRs listed along with causative medicines among medical doctors and pharmacists interviewed in KNH

Knowledge level	No. of listed ADRs	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Low	0	11(3.9)	1(4.3)	12(3.9)	χ^2=8.137 df=5 P = 0.149
	1	14(4.9)	0(0.0)	14(4.5)	
	2	21(7.4)	0(0.0)	21(6.8)	
Moderate	3	27(9.5)	1(4.3)	28(9.1)	
	4	45(15.8)	1(4.3)	46(14.9)	
High	5	167(58.5)	20(87.1)	187(60.8)	

As a measure of their knowledge, majority of respondents were aware of medicines banned due to ADRs, 219 (71.1%) with a significant difference between medical doctors and pharmacists (χ^2=10.101, df=1, P = 0.001), with the pharmacists 23 (100.0%) showing a higher percentage (Table 4.4). Among medical doctors only 31.2% respondents were unaware of medicines banned due to ADRs, while all pharmacists were aware of banned medicines due to ADRs.

Table 4.4: Knowledge level indicated by awareness of medicines banned due to ADRs among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	196(68.8)	23(100.0)	219(71.1)	χ^2=10.101 df=1 P = 0.001
No	89(31.2)	0(0.0)	89(28.9)	

Both groups of professionals listed at least one banned medicine due to its ADR 199 (64.6%) with a significant difference between them (χ^2=10.477, df=2, P = 0.005), (Table 4.5). Similarly, 22 (95.7%) of the pharmacists, indicated at least one banned medicine due to ADRs. Amongst the medical doctors' respondents who were aware of banned medicines, 37.2% did not list any compared to 62.8% who listed at least one. The most common medicine listed as banned due to ADRs by the respondents was thalidomide (43.3%), followed by nimesulide (20.7%) and rofecoxib (10.3%).

Table 4.5: Knowledge level indicated by listing medicines banned along with resultant ADRs among medical doctors and pharmacists interviewed in KNH

Number of medicines	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
0	106(37.2)	1(4.3)	107(34.7)	χ^2=10.477
1	177(62.1)	22(95.7)	199(64.6)	df=2
2	2(0.7)	0(0.0)	2(0.6)	P = 0.005

Findings from the study indicated that close to half the respondents (147; 47.7%) had moderate to high knowledge of medicines that should be reported for any ADRs observed, again showing a significant difference between medical doctors and pharmacists (χ^2=14.407, df=5, P = 0.013), (Table 4.6). Pharmacists had a higher knowledge level at 74.0% compared to 26.0% low knowledge, while medical doctors had a moderate to high knowledge level of 45.6% compared to 54.4% low level knowledge in classes that should be reported for ADRs. The most common class of medicine highlighted by the respondents was antibiotics at 22.0% followed by analgesics (6.2%), anti-retrovirals (5.5%), anti-cancers (4.0%) and anti-malarials (3.0%).

Table 4.6: Knowledge of classes of medicines that should be reported for ADRs observed among medical doctors and pharmacists interviewed in KNH

Knowledge level	No. of classes of medicines	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Low	0	67(23.5)	2(8.7)	69(22.4)	χ^2=14.407 df=5 P = 0.013
	1	53(18.6)	1(4.3)	54(17.5)	
	2	35(12.3)	3(13.0)	38(12.3)	
Moderate	3	37(13.0)	3(13.0)	40(13.0)	
	4	20(7.0)	6(26.1)	26(8.4)	
High	5	73(25.6)	8(34.9)	81(26.3)	

Results from the study showed that an ADR reporting scheme may help in identifying safe drugs 200 (64.9%), identifying predisposing factors to ADRs 180 (58.4%) and identifying previously unrecognized ADRs 159 (51.6%) showing no significant differences between the two professions as a measure of knowledge level (Table 4.7).

Table 4.7: What an ADR reporting scheme would be used for among medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a. To identify safe drugs	Yes	187(65.6)	13(56.5)	200(64.9)	χ^2=0.773 df=1 P = 0.378
	No	98(34.4)	10(43.5)	108(35.1)	
b. To calculate incidence of ADRs	Yes	125(43.9)	6(26.1)	131(42.5)	χ^2=2.750 df=1 P = 0.097
	No	160(56.1)	17(73.9)	177(57.5)	
c. To identify predisposing factors to ADRs	Yes	165(57.9)	15(65.2)	180(58.4)	χ^2=0.470 df=1 P = 0.493
	No	120(42.1)	8(34.8)	128(41.6)	
d. To identify poor quality drugs	Yes	22(7.7)	1(4.3)	23(7.5)	χ^2=0.350 df=1 P = 0.554
	No	263(92.3)	22(95.7)	285(92.5)	
e. To describe a patient's condition	Yes	30(10.5)	1(4.3)	31(10.1)	χ^2=0.898 df=1 P = 0.343
	No	255(89.5)	22(95.7)	277(89.9)	
f. To identify previously unrecognized ADRs	Yes	148(51.9)	11(47.8)	159(51.6)	χ^2=0.144 df=1, P = 0.705
	No	137(48.1)	12(52.2)	149(48.4)	
g. As a source of information about the characteristics of the ADRs	Yes	116(40.7)	9(39.1)	125(40.6)	χ^2=0.022 df=1 P = 0.883
	No	169(59.3)	14(60.9)	183(59.4)	
h. For comparison of ADRs of medicines within the same therapeutic class	Yes	102(35.8)	13(56.5)	115(37.3)	χ^2=3.910 df=1 P = 0.048
	No	183(64.2)	10(43.5)	193(62.7)	

All health professionals were identified as most qualified to report ADRs 278 (90.3%) followed by physicians 220 (71.4 %), pharmacists 241 (78.2 %), nurses 207 (67.2%) and clinical officers 198 (64.3 %) with this showing no significant differences between medical doctors and pharmacists (Table 4.8).

Table 4.8: Health professionals deemed as qualified to report ADRs by medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a. Physician	Yes	207(72.6)	13(56.5)	220(71.4)	χ^2=2.706 df=1 P = 0.100
	No	78(27.4)	10(43.5)	88(28.6)	
b. Dentist	Yes	126(44.2)	6(26.1)	132(42.9)	χ^2=2.854 df=1 P = 0.091
	No	159(55.8)	17(73.9)	176(57.1)	
c. Pharmacist	Yes	221(77.5)	20(87.0)	241(78.2)	χ^2=1.108 df=1 P = 0.293
	No	64(22.5)	3(13.0)	67(21.8)	
d. Nurse	Yes	189(66.3)	18(78.3)	207(67.2)	χ^2=1.378 df=1 P = 0.240
	No	96(33.7)	5(21.7)	101(32.8)	
e. Clinical Officer	Yes	185(64.9)	13(56.5)	198(64.3)	χ^2=0.653 df=1 P = 0.419
	No	100(35.1)	10(43.5)	110(35.7)	
f. Nutritionist	Yes	65(22.8)	5(21.7)	70(22.7)	χ^2=0.014 df=1 P = 0.906
	No	220(77.2)	18(78.3)	238(77.3)	
g. Pharmaceutical Technologist	Yes	113(39.6)	8(34.8)	121(39.3)	χ^2=0.211 df=1 P = 0.646
	No	172(60.4)	15(65.2)	187(60.7)	
h. All Healthcare professionals	Yes	257(90.2)	21(91.3)	278(90.3)	χ^2=0.031 df=1 P = 0.861
	No	28(9.8)	2(8.7)	30(9.7)	

On attitudes towards reporting of ADRs among medical doctors and pharmacists at the KNH, the findings of the study showed that majority of respondents indicated that reporting should be done on all ADRs 272 (88.3%) again showing no significant difference between them (χ^2=1.298, df=1, P = 0.255), (Table 4.9).

Table 4.9: ADRs that are to be reported among medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a. None	Yes	16(5.6)	1(4.3)	17(5.5)	χ^2=0.065 df=1 P = 0.798
	No	269(94.4)	22(95.7)	291(94.5)	
b. All ADRs	Yes	250(87.7)	22(95.7)	272(88.3)	χ^2=1.298 df=1 P = 0.255
	No	35(12.3)	1(4.3)	36(11.7)	
c. All serious ADRs	Yes	22(7.7)	1(4.3)	23(7.5)	χ^2=0.350 df=1 P = 0.554
	No	263(92.3)	22(95.7)	285(92.5)	
d. ADRs to new drugs	Yes	11(3.9)	1(4.3)	12(3.9)	χ^2=0.014 df=1 P = 0.907
	No	274(96.1)	22(95.7)	296(96.1)	
e. Unknown ADRs to old drugs	Yes	16(5.6)	1(4.3)	17(5.5)	χ^2=0.065 df=1 P = 0.798
	No	269(94.4)	22(95.7)	291(94.5)	
f. ADRs to herbal/complementary drugs	Yes	3(1.1)	0(0.0)	3(1.0)	χ^2=0.244 df=1 P = 0.621
	No	282(98.9)	23(100.0)	305(99.0)	
g. ADRs to Vaccines	Yes	4(1.4)	0(0.0)	4(1.3)	χ^2=0.327 df=1 P = 0.567
	No	281(98.6)	23(100.0)	304(98.7)	

Results also indicated respondents would be encouraged to report ADRs if the reaction was serious 171 (55.5 %) and if the reaction was unusual 192 (62.3 %) showing no significant difference between the medical doctors and pharmacists (Table 4.10).

Table 4.10: Factors encouraging ADR reporting among medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a. If the reaction was serious	Yes	159(55.8)	12(52.2)	171(55.5)	χ^2=0.113 df=1 P = 0.737
	No	126(44.2)	11(47.8)	137(44.5)	
b. If the reaction was unusual	Yes	179(62.8)	13(56.5)	192(62.3)	χ^2=0.358 df=1 P = 0.550
	No	106(37.2)	10(43.5)	116(37.7)	
c. If the reaction was unnoticeable	Yes	2(0.7)	0(0.0)	2(0.6)	χ^2=0.162 df=1 P = 0.687
	No	283(99.3)	23(100.0)	306(99.4)	
d. If the reaction was certainly an ADR	Yes	18(6.3)	1(4.3)	19(6.2)	χ^2=0.142 df=1 P = 0.706
	No	267(93.7)	22(95.7)	289(93.8)	
e. If the reaction was well recognized for a particular drug	Yes	13(4.6)	1(4.3)	14(4.5)	χ^2=0.002 df=1 P = 0.962
	No	272(95.4)	22(95.7)	294(95.5)	
f. If the reaction was to a new product	Yes	219(7.4)	1(4.3)	22(7.1)	χ^2=0.293 df=1 P = 0.588
	No	264(92.6)	22(95.7)	286(92.9)	

Slightly above half of the respondents indicated that they would be discouraged from reporting ADRs if they did not know where to report them 159 (51.6%) similarly showing no significant difference between the two professions (χ^2=0.660, df=1, P = 0.416), (Table 4.11).

Table 4.11: Factors discouraging ADR reporting among medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Not knowing where to report	Yes	149(52.3)	10(43.5)	159(51.6)	χ^2=0.660, df=1, P = 0.416
	No	136(47.7)	13(56.5)	149(48.4)	
Not knowing how to report	Yes	110(38.6)	6(26.1)	116(37.7)	χ^2=1.419, df=1, P = 0.234
	No	175(61.4)	17(73.9)	192(62.3)	
Knowing the representatives of the causative drug	Yes	18(6.3)	2(8.7)	20(6.5)	χ^2=0.199, df=1, P = 0.656
	No	267(93.7)	21(91.3)	288(93.5)	
Concern that the report may be wrong	Yes	-	-	-	–
	No	285(100.0)	23(100.0)	308(100.0)	
Lack of access of ADR reporting forms	Yes	51(17.9)	4(17.4)	55(17.9)	χ^2=0.004, df=1, P = 0.952
	No	234(82.1)	19(82.6)	253(82.1)	
Non-remuneration for reporting	Yes	-	-	-	–
	No	285(100.0)	23(100.0)	308(100.0)	
Lack of time to fill-in a report and a single unreported case may not affect ADR database	Yes	14(4.9)	2(8.7)	16(5.2)	χ^2=0.619, df=1, P = 0.432
	No	271(95.1)	21(91.3)	292(94.8)	
Not being sure of what caused the ADR	Yes	4(1.4)	0(0.0)	4(1.3)	χ^2=0.327, df=1, P = 0.567
	No	281(98.6)	23(100.0)	304(98.7)	
Concern that reporting may generate extra work	Yes	6(2.1)	1(4.3)	7(2.3)	χ^2=0.482, df=1, P = 0.488
	No	279(97.9)	22(95.7)	301(97.7)	
Lack of time to actively look for ADRs while at work	Yes	2(0.7)	1(4.3)	3(1.0)	χ^2=2.933, df=1, P = 0.087
	No	283(99.3)	22(95.7)	305(99.0)	
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	Yes	14(4.9)	1(4.3)	15(4.9)	χ^2=0.015, df=1, P = 0.904
	No	271(95.1)	22(95.7)	293(95.1)	
Not having time to report	Yes	33(11.6)	3(13.0)	36(11.7)	χ^2=0.044, df=1, P = 0.833
	No	252(88.4)	20(87.0)	272(88.3)	
Do not feel the need to report a recognized ADR	Yes	4(1.4)	0(0.0)	4(1.3)	χ^2=0.327, df=1, P = 0.567
	No	281(98.6)	23(100.0)	304(98.7)	
Lack of confidence to discuss the ADR with other colleagues	Yes	1(0.4)	0(0.0)	1(0.3)	χ^2=0.081, df=1, P = 0.776
	No	284(99.6)	23(100.0)	307(99.7)	
Knowledge that no action will be taken	Yes	2(0.7)	1(4.3)	3(1.0)	χ^2=2.933, df=1, P = 0.087
	No	283(99.3)	22(95.7)	305(99.0)	
Fear of the negative impact the report may have on the company that produced or marketed the drug	Yes	1(0.4)	0(0.0)	1(0.3)	χ^2=0.081, df=1, P = 0.776
	No	284(99.6)	23(100.0)	307(99.7)	
Patient confidentiality issues	Yes	4(1.4)	1(4.3)	5(1.6)	χ^2=1.155, df=1, P = 0.282
	No	281(98.6)	22(95.7)	303(98.4)	
Legal liability issues	Yes	10(3.5)	0(0.0)	10(3.2)	χ^2=0.834, df=1, P = 0.361
	No	275(96.5)	23(100.0)	298(96.8)	

Majority of the respondents opined that ADR reporting was a professional obligation 268 (87.0%) showing no significant difference between medical doctors and pharmacists (χ^2=1.732, df=2, P = 0.421) with pharmacists showing a higher percentage 22 (95.7%) among respondents (Table 4.12).

Table 4.12: Whether ADR reporting was a professional obligation among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	246(86.3)	22(95.7)	268(87.0)	χ^2=1.732
No	31(10.9)	1(4.3)	32(10.4)	df=2
Don't Know	8(2.8)	0(0.0)	8(2.6)	P = 0.421

A majority of respondents indicated reporting one ADR contributed to an ADR reporting scheme 288 (93.5%) again showing no significant difference between the two professions (χ^2=1.726, df=2, P = 0.422), with all pharmacists reporting so (Table 4.13).

Table 4.13: Whether reporting of one ADR made a significant contribution to a reporting scheme among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	14(4.9)	0(0.0)	14(4.5)	χ^2=1.726
No	265(93.0)	23(100.0)	288(93.5)	df=2
Don't Know	6(2.1)	0(0.0)	6(1.9)	P = 0.422

Majority of respondents further opined that ADR reporting should be made compulsory 215 (69.8%) showing no significant difference between medical doctors and pharmacists (χ^2=0.942, df=1, P = 0.332), (Table 4.14).

Table 4.14: What ADR reporting should be made among medical doctors and pharmacists interviewed in KNH

Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a. Compulsory	Yes	201(70.5)	14(60.9)	215(69.8)	χ^2=0.942 df=1 P = 0.332
	No	84(29.5)	9(39.1)	93(30.2)	
b. Remunerated	Yes	32(11.2)	1(4.3)	33(10.7)	χ^2=1.053 df=1 P = 0.305
	No	253(88.8)	22(95.7)	275(89.3)	
c. Voluntary	Yes	66(23.2)	3(13.0)	69(22.4)	χ^2=1.272 df=1 P = 0.259
	No	219(76.8)	20(87.0)	239(77.6)	
d. Hide the identity of the reporter	Yes	15(5.3)	0(0.0)	15(4.9)	χ^2=0.142 df=1 P = 0.706
	No	270(94.7)	23(100.0)	293(95.1)	
e. Hide the identity of the prescriber	Yes	5(1.8)	0(0.0)	5(1.6)	χ^2=0.410 df=1 P = 0.522
	No	280(98.2)	23(100.0)	303(98.4)	

In investigating the practices of reporting of ADRs among medical doctors and pharmacists at the KNH, 152 (49.4%) as most respondents indicated that they had encountered ADRs in their practice, showing no significant difference between the two professions (χ^2=2.085, df=5, P = 0.837), (Table 4.15).

Table 4.15: Number of ADRs encountered in practice among medical doctors and pharmacists interviewed in KNH

Number of ADRs	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
0 - 4	59(20.7)	4(17.4)	63(20.5)	
5 - 9	27(9.5)	4(17.4)	31(10.1)	
10 - 14	21(7.4)	1(4.3)	22(7.1)	χ^2=2.085, df=5, P = 0.837
15 - 19	4(1.4)	0(0.0)	4(1.3)	
> 20	141(49.5)	11(47.8)	152(49.4)	
Do Not Remember	33(11.6)	3(13.0)	36(11.7)	

Of those who had encountered ADRs in their practice, all 152 (55.9%) considered the ADRs as serious with no significant difference between the two professions (χ^2=2.070, df=4, P = 0.723), (Table 4.16).

Table 4.16: Number of serious ADRs encountered in practice among medical doctors and pharmacists interviewed in KNH

Number of ADRs	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
0 - 4	59(23.4)	4(20.0)	63(23.2)	
5 - 9	27(10.7)	4(20.0)	31(11.4)	
10 - 14	21(8.3)	1(5.0)	22(8.1)	χ^2=2.070 df=4 P = 0.723
15 - 19	4(1.6)	0(0.0)	4(1.5)	
> 20	141(56.0)	11(55.0)	152(55.9)	

Half of the respondents, 164 (53.2%) reported that after encountering ADRs they reported the same (Table 4.17). There was a significant difference between medical

doctors and pharmacists (χ^2=11.346, df=1, P = 0.001) with pharmacists 20 (87.0%) indicating a higher percentage than medical doctors 144 (50.5%).

Table 4.17: Whether the encountered ADRs were reported among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	144(50.5)	20(87.0)	164(53.2)	χ^2=11.346 df=1 P = 0.001
No	141(49.5)	3(13.0)	144(46.8)	

Results indicated that of those who encountered ADRs and reported them, majority did so to their supervising consultants, 104 (63.4%). There was a significant difference between medical doctors and pharmacists (χ^2=18.597, df=6, P = 0.005) with 14 (70.0%) of the reporting pharmacists reporting to PPB related channels (Table 4.18).

Table 4.18: Where the ADR Report was made by medical doctors and pharmacists interviewed in KNH

Where ADR report was made	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Consultant	98(68.1)	6(30.0)	104(63.4)	
District Pharmacovigilance Office	2(1.4)	0(0.0)	2(1.2)	
Patient File	4(2.8)	0(0.0)	4(2.4)	χ^2=18.597 df=6 P = 0.005
Pharmacist in Charge	9(6.2)	1(5.0)	10(6.1)	
PPB	27(18.8)	11(55.0)	38(23.2)	
PPB Through Filling The Yellow Form	3(2.1)	2(10.0)	5(3.0)	
PPB Website	1(0.7)	0(0.0)	1(0.6)	

Results also indicated that majority of the respondents, 178 (57.8%) listed at least two or more sources of information on ADRs with no significant difference between the two professions (χ^2=4.212, df=5, P = 0.519), (Table 4.19). From the findings of the study, the most common source of information for the respondents was textbooks at 23.6% followed by colleagues (13.1%), internet (11.7%), medical journals (10.3%) and the drug index and the British National Formulary (9.4%).

Table 4.19: Number of information sources on ADRs among medical doctors and pharmacists interviewed in KNH

Number of information sources	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
0	1(0.4)	0(0.0)	1(0.3)	
1	123(43.2)	6(26.1)	129(41.9)	
2	67(23.5)	7(30.4)	74(24.0)	χ^2=4.212 df=5 P = 0.519
3	59(20.7)	8(34.8)	67(21.8)	
4	21(7.4)	1(4.3)	22(7.1)	
5	14(4.9)	1(4.3)	15(4.9)	

Majority of respondents were not aware of the existence of an ADRs reporting centre in KNH 108 (35.1%) with a significant difference between medical doctors and pharmacists (χ^2=16.475, df=1, P = 0.000), (Table 4.20). Medical doctors had a high percentage (68.1%) of those who did not know compared to those who knew (31.9%), while only 26.1% of the pharmacists did not know compared to those who knew (73.4%).

Table 4.20: Awareness of the existence of an ADRs reporting centre in KNH among medical doctors and pharmacists interviewed

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	91(31.9)	17(73.9)	108(35.1)	χ^2=16.475 df=1 P = 0.000
No	194(68.1)	6(26.1)	200(64.9)	

Pharmacists were aware of the existence of the reporting centre, 17 (73.9%) while only 91 (31.9%) of medical doctors were aware. Of those who were aware of the

center, 78 (72.5%) indicated a pharmacy in KNH or the pharmacy department of the hospital with no significant difference between the two professions (χ^2=6.673, df=7, P=0.464), (Table 4.21).

Table 4.21: Where the medical doctors and pharmacists interviewed in KNH identified as the location of the reporting centre

Location of centre in KNH	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Do not know	5(5.4)	0(0.0)	5(4.6)	
Medicine and poison information center	6(6.5)	1(5.9)	7(6.4)	
Not sure	7(7.6)	3(17.6)	10(9.2)	
PPB	3(3.3)	0(0.0)	3(2.8)	χ^2=6.673 df=7 P = 0.464
Pharmacy department	34(38.0)	10(58.8)	44(41.3)	
Pharmacy in KNH	31(33.7)	3(17.6)	34(31.2)	
School of Pharmacy	3(3.3)	0(0.0)	3(2.8)	
Therapeutics committee	2(2.2)	0(0.0)	2(1.8)	

The results further showed that at least half of the respondents, 168 (54.5%) were aware of the existence of a Pharmacovigilance Department in PPB in Kenya (Table 4.22) with a significant difference between medical doctors and pharmacists (χ^2=16.940, df=1, P=0.000). Among the medical doctors, 139.9 (48.8%) did not know, while only 4.3% among the pharmacists did not know.

Table 4.22: Awareness of existence of an ADRs reporting centre in PPB in Kenya among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	146(51.2)	22(95.7)	168(54.5)	χ^2=16.940 df=1
No	139(48.8)	1(4.3)	140(45.5)	P = 0.000

Respondents indicated that their most preferred method of sending ADR reports to the Pharmacovigilance Reporting Centre in KNH was email and using a website 197 (64.0%) with no significant difference between the two professions (χ^2=1.068, df=1, P=0.301), (Table 4.23).

Table 4.23: Method most preferable to send ADR reports to the reporting centre among medical doctors and pharmacists interviewed in KNH

	Response		Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
a.	Direct Contact	Yes	112(39.3)	11(47.8)	123(39.9)	χ^2=0.645 df=1
		No	173(60.7)	12(52.2)	185(60.1)	P = 0.422
b.	Post	Yes	6(2.1)	0(0.0)	6(1.9)	χ^2=0.494 df=1
		No	279(97.9)	23(100.0)	302(98.1)	P = 0.482
c.	Telephone	Yes	22(7.7)	1(4.3)	23(7.5)	χ^2=.350 df=1
		No	263(92.3)	22(95.7)	285(92.5)	P = 0.554
d.	Email/Website	Yes	180(63.2)	17(73.9)	197(64.0)	χ^2=1.068 df=1
		No	105(36.8)	6(26.1)	111(36.0)	P = 0.301

An overwhelming majority reported they would be interested in getting feedback on action for ADR reports forwarded to the reporting centre 297 (96.4%) with no significant difference between medical doctors and pharmacists (χ^2=0.921, df=1, P=0.337), (Table 4.24).

Table 4.24: Interest in feedback on action for ADR reports forwarded to the reporting centre among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	274(96.1)	23(100.0)	297(96.4)	χ^2=0.921, df=1,
No	11(3.9)	0(0.0)	11(3.6)	P = 0.337

With regards to training, results showed that majority of respondents had never been trained on how to report ADRs 227 (73.7%) with a significant difference between the two professions (χ^2=29.074, df=1, P=0.000), (Table 4.25). Pharmacists had a higher percentage that had been trained 17 (73.9%) compared to 26.1% who had not been trained, while among the medical doctors only 22.5% had been trained compared to 77.5% who had not.

Table 4.25: Status of medical doctors and pharmacists interviewed in KNH on being trained on how to report ADRs

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	64(22.5)	17(73.9)	81(26.3)	χ^2=29.074 df=1
No	221(77.5)	6(26.1)	227(73.7)	P = 0.000

Of those that had been trained, majority had done so under the hospital set up 31 (38.3%) with no significant difference between the two professions (χ^2=1.028, df=2, P=0.598), (Table 4.26).

Table 4.26: Venue of training done on how to report ADRs among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
PPB/MSH	17(26.6)	6(35.3)	23(28.4)	χ^2=1.028 df=2 P = 0.598
Seminar/Continuous medical education	23(35.9)	4(23.5)	27(33.3)	
Hospital training	24(37.5)	7(41.2)	31(38.3)	

Of those who had never have been trained, majority indicated that they would be interested in undergoing a training for the same 222 (97.8%) again with no significant difference between the medical doctors and pharmacists (χ^2=0.139, df=1, P=0.709), (Table 4.27).

Table 4.27: Interest in being trained on how to report ADRs among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	216(97.7)	6(100.0)	222(97.8)	χ^2=0.139 df=1 P = 0.709
No	5(2.3)	0(0.0)	5(2.2)	

The results on practices further indicated that 243 (78.9%) had shared information about ADRs with no significant difference between the two professions (χ^2=2.298, df=1, P=0.130), (Table 4.28).

Table 4.28: Sharing information on ADRs among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Yes	222(77.9)	21(91.3)	243(78.9)	χ^2=2.298 df=1 P = 0.130
No	63(22.1)	2(8.7)	65(21.1)	

Majority of the respondents indicated that they shared this information with colleagues 187 (77.0%) with no significant difference between the medical doctors and pharmacists (χ^2=0.571, df=4, P = 0.966), (Table 4.29). The hospital pharmacist was a distant second 34 (14.0%).

Table 4.29: Person with whom information on ADRs was shared among medical doctors and pharmacists interviewed in KNH

Response	Medical doctor (%)	Pharmacist (%)	Total (%)	χ^2 – Value
Colleagues/health workers	171(77.0)	16(76.2)	187(77.0)	χ^2=0.571 df=4 P = 0.966
Patients	6(2.7)	1(4.8)	7(2.9)	
PPB	11(5.0)	1(4.8)	12(4.9)	
Hospital pharmacist	31(14.0)	3(14.3)	34(14.0)	
Drug representatives	3(1.4)	0(0.0)	3(1.2)	

CHAPTER 5

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

A total of 308 respondents filled and returned the questionnaires. This current study indicated level of knowledge and awareness of existence of ADRs by medical doctors and pharmacists working in KNH at the time of the study, was fairly good as they were able to name common ADRs along with medicines causing them, identified medicines banned due to ADRs and exact ADRs they caused. Further, respondents listed classes of medicines for which ADRs should be reported, identified what an ADR reporting scheme may aid in and identified professionals who were qualified to report ADRs. Majority of both professionals were also able to correctly indicate what the reporting scheme would help in, by ruling out incorrect values such as identifying poor quality drugs and describing a patient's condition.

Overall the knowledge score for all respondents using a pre-decided assignment as per their responses to the questions was 60.5%. This was much higher than reported by a study in India (Desai, Iyer, Pancal, Shah and Dikshit, 2011) with overall mean score of knowledge at 38.2% at Civil Hospital in Ahmedabad, India. The current study, also found out that pharmacists reported a higher percentage knowledge score (68.6%) than medical doctors (59.9%). Similarly, a study in China showed that pharmacists exhibited higher knowledge on ADRs awareness and reporting scheme compared to doctors and other health professionals (Houming, Wang & Liu, 2009).

In China pharmacists are the ADR monitoring professionals and may be more exposed to such knowledge.

In India, spontaneous ADR reporting by all health professionals has been recommended by the national pharmacovigilance program (Bavdekar & Karande, 2006). In this study, respondents reported that all healthcare professionals were qualified to report ADRs with no significant difference between the two professions, pharmacists and medical doctors ($\chi 2$=0.031, P = 0.861). Pharmacists were identified as the second most qualified followed by medical doctors, nurses and clinical officers in that order. This was contrary to a study carried out in Ahmedabad, India (Desai *et al.*, 2011) where less than half of respondents identified nurses, pharmacists, and dentists to be capable of reporting ADRs. Interestingly, in the same study in India, 26.2% of the respondents opined that patients should also be allowed to report ADRs. Similar findings were also observed in a Mumbai study where respondents did not identify nurses and pharmacists as qualified reporters which indicated lack of awareness of principles and practice of pharmacovigilance among the respondents (Gupta & Udupa, 2011).

Another study in India noted that involvement of other health care professionals and paramedical staff goes a long way in improving spontaneous reporting of ADRs (Khan, Goyal, Chandel & Rafi, 2013). Comparatively, and despite the recommendation by the Nigerian authority (National Pharmacovigilance Centre, 2004), a study in that country found that respondents did not recognize or consider individuals and physiotherapists as qualified to report ADRs.

Most respondents opined they were inclined to report all ADRs and there was no significant difference between the two professions ($\chi 2=1.298$, P = 0.255). This was relative to if the ADRs were serious (7.5%), of new medicines (3.9%), unknown in old medicines (5.5%), of herbal or complimentary medicines (1.0%) neither of vaccines (1.3%). This was similar to a study done in Europe (Vallano *et al.*, 2005) where doctors considered all suspected reactions to any marketed drug and all serious suspected ADRs as worth reporting.

A study done in China reported that 62.0% doctors would want to report an event if it was an already well recognized adverse reaction (Qing *et al*., 2004). Studies done in Mumbai, India reported over 80.0% of the respondents were more inclined to report ADRs if they were of new medicines, serious or unusual (Gupta & Udupa, 2011). In the study by Desai *et al.* (2011), 51.0% of respondents stated that they would like to report all ADRs, while 56% said that they would like to report only serious ADRs. As against this, 34.2% said they would report ADRs caused by new drugs. In the same study most respondents, did not emphasize on reporting ADRs to herbal and non-allopathic medicines similar to this current study. A study by Khan *et al*. (2013) noted that most respondents were not aware of the dangers caused by newly introduced and medicines in India. The same applies in Kenya where very many medicines are introduced annually and hence the need to monitor them for ADRs.

Oshikoya & Awobusuyi (2009) reported that in a study done in Nigeria, most respondents were willing to report reactions to newly marketed drugs and serious reactions to established products because they perceived post-marketing surveillance as an important part of pharmacovigilance. Further they noted that higher number of respondents would report serious ADRs to antibiotics, herbal medicines and antimalarial medicines when compared with over the counter drugs and topical agents. They observed that post marketing drug surveillance encouraged ADR reporting if reaction was serious and unusual in nature.

The current study noted that most respondents would be encouraged to report ADRs if reaction was serious ($\chi 2=0.113$, P = 0.737) and unusual ($\chi 2=0.358$, P = 0.550). On the other hand they would be discouraged to report because of not knowing where to report ($\chi 2=0.660$, P = 0.416). The observations had no significant differences between the two professions. Similarly, the study in Lagos in Nigeria (Oshikoya and Awobusuyi, 2009) reported that respondents were encouraged to report ADRs if reaction was serious (77.8%) and unusual (70.7%) in nature while other factors that would influence ADR reporting included if reaction was to a new product (58.6%), certainty that reaction was truly an ADR (45.5%), and if reaction was well recognized for a particular drug (46.5%). Contrarily, the main factors that would discourage the respondents from reporting ADRs in the same study was the fear of the report being wrong (47.5%).

The study in Indore, India, by Khan *et al.* (2013) reported that respondents were encouraged to report ADRs if the reaction was serious (79.4%), to a new product

(72.1%), and unusual (60.3%), which is similar to results obtained in the study in China (Qing *et al*., 2004). Chopra, Wardhanb & Rehan, (2011) in a study done in New Delhi, India reported respondents gave the main reasons for not reporting ADRs as lack of adequate knowledge about what and where to report (45%), lack of time (20%), non-availability of ADR forms (15%). Other reasons given were lack of confidence whether ADR is due to medicine, and fear that routine ADR reporting will damage their image. The study in India by Gupta and Udupa (2011) reported that among the discouraging factors in reporting ADRS were; concern that report may be wrong 80.9%, did not know how to report, where to report and when to report 95.2%, lack of time to fill-in report and a single unreported case may not affect ADR database 72.9%, non-remuneration for reporting 16.2%, concern that reporting may generate extra work 41.1% and lack of time to actively look for ADRs while at work 77.1%.

This study identified ADR reporting as a professional obligation with no significant difference among the pharmacists and medical doctors ($\chi 2=1.732$, $P = 0.421$). Only 2.7% respondents indicated not knowing if it was a professional obligation. Other studies showed similar findings but at slightly lower percentages of 80.9% (Gupta and Udupa, 2011) and 66.2% (Khan *et al*., 2013) in India and 64.6% in Nigeria (Oshikoya & Awobusuyi, 2009). Respondents in KNH also indicated that reporting of only one ADR made a significant contribution to an ADR reporting scheme with no significant difference among the pharmacists and medical doctors ($\chi 2=1.726$, $P = 0.422$). Similarly, the Mumbai study by Khan *et al*. (2013) reported a percentage of 69.1% for the same question.

The study in KNH reported that ADR reporting should be compulsory 215 (69.8%; $\chi 2=0.729$, P = 0.323) as opposed to remunerated (10.7%), voluntary (22.4%), hide the identity of the reporter (4.9%) nor hide the identity of the prescriber (1.6%) again with no significant difference among the pharmacists and medical doctors. In the Nigerian study, about half (52.5%) of the respondents opined that ADR reporting should be compulsory, 36.4% stated that ADR reporting should be voluntary, 22.2% felt ADR reporters should be remunerated, 18.2% have their identity hidden and 4.0% indicated identity of the prescribers should be hidden. This is in contrast to the findings of the study by Gupta and Udupa (2011), where a majority of the doctors opined that ADR reporting should be voluntary (86.9%) and remunerated (73.6%) while only 13.7% felt that it should be made compulsory. Interestingly, 57% wanted the identity of the reporter be kept confidential, which they opined correlated with a high prevalence of anxiety among the resident doctors regarding the correctness of identification of an ADR. In another study in the South of India on community pharmacists, 60.8% of the respondents indicated that ADR reporting should be made compulsory (Prakasam, Nidamanuri and Kumar, 2012) similar to this study at 75.6%.

Desai *et al*. (2011) made an interesting observation that 13% of their respondents did not think that reporting ADRs was important. The observations were similar to a study done in a teaching hospital in Spain, where the potential obstacles to spontaneous reporting of ADRs were identified to be difficulty in diagnosis of ADRs, lack of knowledge regarding the ADR reporting system, clinical workload on

the doctors, a concern for patient confidentiality, and possible legal implications of reporting (Vallano *et al.,* 2005). Houming *et al.* (2009) in their study in China reported that 95.4% of respondents believed that it is necessary to report ADRs, 62.6% believed that all adverse reactions should be reported, and 27.9% and 24.3% respondents believed that the report should be only about serious and the new ADR, respectively. Only 1.1% thought that there was a general need to report adverse reactions, and 45.2%) surveyed thought that everyone had the responsibility to report an ADR.

In this study majority of the respondents reported that they had encountered ADRs in their practice with 178 (57.8%) reporting having encountered 10 or more ADRs. There was no significant difference between the two professions ($\chi 2=2.085$, P = 0.837). Further, respondents reported that over 50% of the ADRs encountered were serious again with no significant difference between the medical doctors and the pharmacists ($\chi 2=2.070$, P = 0.723). In contrast and alarmingly, Gupta and Udupa (2011) reported that the fact that very few resident doctors in the two hospitals in Mumbai and Pune in India had ever reported an adverse event to any of the national centers (2.9%) despite 90% of the respondents considering the ADR monitoring system of their own hospitals (22.6%) as important then. They hypothesized that the management and propaganda of ADR monitoring was not perfect and needed serious rethinking. Qing *et al*. (2004) observed similar findings in China.

Reasons for under-reporting of ADRs have been summarized by Inman (1996) as the "seven deadly sins". This includes financial incentives (rewards for reporting), legal

aspects (fear of litigation), complacency (belief that the serious ADRs are already documented when a drug is introduced in the market), diffidence (belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug), indifference (belief that a single report would make no difference), ignorance (that only serious ADRs are to be reported), lethargy (excuses about lack of time or disinterestedness). Some of these sins complacency, ignorance and lethargy, were also documented in Ramesh and Parthasarathi (2009), Gupta and Udupa (2011) and Ghosh, Ali, Chhabra, Prasad & Gupta. (2010).

Similarly, the study by Desai *et al*. (2011) a major reason observed for ADR underreporting was ignorance about the reporting system, while the financial and legal aspects were given less importance. Ignorance was more evident in the resident doctors as compared to the faculty doctors. This suggests that an intervention to generate awareness on how to report ADRs may be necessary for this group of respondents. Further, the same study reported that a majority of the prescribers had observed up to five ADRs a week, a positive reflection on the clinical skills and awareness about ADRs among the prescribers. Around half of the respondents reported that up to 10% of the ADRs observed were of a serious nature. However, the actual practice of reporting ADRs was different than the knowledge and attitudes exhibited by the respondents. Even as ADR reporting was considered to be important by a large majority of the respondents, the actual reporting was very low. Just 15% of the respondents stated that they had reported an ADR previously.

In the current study, 53.2% of the respondents indicated that they had reported the ADRs they had encountered with a significant difference between the pharmacists (87.0%) and medical doctors (50.5%) ($\chi 2=11.346$, P = 0.001). Only 43 (32.3%) of the respondents indicated they had used PPB and its related structure for reporting ADRs, with a significant difference between the two professions ($\chi 2=18.597$, P = 0.005) with 70.0% of the pharmacists reporting to PPB and its related structures compared to only 27.1% of the medical doctors reporting to the same channels. Majority of the medical doctors (68.1%) indicated they had reported to consultants. Correspondingly, in the Mumbai and Pune study, of respondents who had reported an ADR previously, 41.0% had reported to an ADR reporting center, 33.3% to the concerned pharmaceutical company, while 15.4% had reported them at conferences or in journals. ADRs reported to pharmaceutical companies were part of a clinical trial protocol or as a personal interaction with the respective medical representatives. In contrast to the study in KNH, other studies carried out in previous years have shown inadequate knowledge of doctors about ADRs and reporting, among resident doctors in Nigeria (Enwere and Fawole, 2008) and doctors in many countries across Europe (Herdeiro, Figueiras, Polonia & Gestal-Otero, 2005) and Asia (Rehan, Vasudev and Tripathi, 2002 and Qing *et al.*, 2004). This according to their deductions, perhaps pointed to lack of training in pharmacovigilance and medicine risk perceptions or the training at under and post graduate may be either insufficient or improperly delivered to prepare the doctors and pharmacists for the task of ADR monitoring and reporting in their future career.

Over 50 % of the respondents in the current study 178 (57.8%) reported at least two or more of their sources of information on ADRs with no significant difference between the pharmacists and medical. The three most popular sources of information were medical/pharmaceutical textbooks, medical journals and the drug index a local publication on medicines in the Kenyan market. In comparison the Desai *et al*. (2011) study reported that source of information about ADRs to new drugs among their faculty doctors respondents was scientific journals for knowledge about ADRs to new drugs, which was significantly higher than the resident doctors who depended on text books for this information.

The number of respondents who were aware of the existence of an ADRs Reporting Centre in KNH was only 35.1% ($\chi 2=16.475$, P=0.000) with a significant difference between the two professions as pharmacists showed a higher percentage (73.9%) compared to 31.9% for the medical doctors. Those who were aware of a Pharmacovigilance Department in PPB in Kenya were 54.5% similarly with a significant difference between the two professions ($\chi 2=16.940$, P=0.000) as pharmacists showed a higher percentage (95.7%) compared to 51.2% for the medical doctors. This implied that most of the training that had been carried out as observed from the respondents, targeted pharmacists and thus there was a need to engage medical doctors among other health professionals so as to improve ADRs awareness, knowledge and reporting levels. Comparing the KNH situation with that of a teaching hospital in Nigeria, a significant number of the respondents in the latter were not aware of the existence of a national pharmacovigilance centre in Nigeria and amongst those who were aware, only 39.2% were able to correctly identify

Abuja as the office (Oshikoya & Awobusuyi, 2009). The direct impact of this is that lack of knowledge of where ADRs should be reported would automatically affect reporting, therefore, awareness programs; through publicity, would appear necessary to improve ADR reporting in any teaching hospital set up.

Similarly in the Mumbai study, few respondents could identify B.J. Medical College as an ADR reporting center in Gujarat (under the older National Pharmacovigilance Program of India then) and only 3% could identify any reporting system in the world (Khan *et al*., 2013). The researchers opined it as intriguing, considering the fact that the prescribers at that institution had been reporting ADRs for last five years to that Center and had reported 1740 ADRs by then. Further analysis into the reasons for that response was warranted as they suggested then, implying that periodic feedback and continuous sensitization to the existing pharmacovigilance system and ADR reporting was necessary to maintain the interest and awareness of the prescribers.

Chopra *et al*. (2011) in a study done in New Delhi showed that 73% of the doctors in their institute of study were aware of the existence of a National Pharmacovigilance Programme in India which is in contrast to what was reported by Gupta & Udupa (2011). However, less than half (47%) of the doctors were aware of the current status of ADR reporting at that institute they were studying which again was similar to a study by Fadare, Enwere, Afolabi, Chedi & Musa (2011). Similarly Khan *et al.* (2013) in their study in Indore, India, reported that 69.1% of their participants were aware of the existence of Pharmacovigilance Programme of India, while 80.9% doctors were aware of the ADR Monitoring Centre in the institute.

The KNH study reported that majority of the respondents would prefer to report ADRs to the reporting center via email or a website (64.0%) with direct contact coming in the second most popular method at 39.9%. This however did not have any significant difference among the two professions. The Mumbai study in comparison, reported that electronic media like emails or websites (56%) and reporting by a personal communication to the reporting center (42%) were the methods preferred by most respondents (Gupta & Udupa, 2011). Prakasam, *et al*. (2012) in their study of community pharmacists in Southern India reported that 56.1% of respondents would prefer to fill in ADR reporting forms online, 17.1% send them by physical mail, 2.4% inform by telephone, 14.6% hand over them directly and 4 9.8% opted for alternative means such as filling the ADR form or their internal ADR forms and handing over to company sales and medical representatives.

Majority of the respondents (73.7%) indicated they had not been trained on how to report ADRs and this had a significant difference among the two professions ($\chi 2=29.074$, P=0.000) with the pharmacists showing a higher percentage (73.9%) compared to 22.5% for the medical doctors. This observation was similar to that made by Houming *et al*., (2009) in China, where pharmacists are the ADR monitoring professionals and may be more exposed to such knowledge. Further, majority of the respondents in the KNH study (78.9%) reported to have shared information about ADRs with no significant difference, and a majority also indicted that they shared this with their colleagues (77.0%) in the wards during rounds who included nurses and other paramedics, during unit/departmental meetings, during

reviews of patients, during continuous medical education forums, consultants, as they conduct clinics and trainings/seminars. In contrast, Gupta and Udupa, (2011) reported that only 38.8% respondents said that they shared information about ADRs observed by them, mostly with their colleagues and teachers.

The current study indicated most respondents would be interested in getting feedback on action taken on reported ADRs to the necessary authorities (96.9%). Similarly studies by Gupta and Udupa, (2011) and Desai *et al*. (2011) also reported that feedback provided to the reporters about the causality of ADRs reported by them would also encourage them to continue reporting. They also reported that they would like to be trained on ADR reporting (97.5%) for those who have never been trained.

Almost all the respondents showed interest in education and training (97.8%). Continuous Medical Education, training and refresher courses were the most cited means of improving ADR reporting. This certainly shows that the medical doctors and pharmacists are willing to improve their knowledge of ADR reporting and increase their participation in the reporting scheme if education and awareness on the reporting scheme is instituted in the hospital. Other methods recommended by the respondents such as instituting and encouraging feedback between patients, prescribers and dispensers of drugs, receiving reminders and increased awareness from ADR Monitoring Committees, and increasing the awareness of other healthcare professionals on reporting ADRs are very important and can certainly be considered as examples of a good practice that should be instituted in the hospital. Most of these recommendations had been implemented in the several countries and have yielded

good results (Inman, 1996; and Vallano *et al.*, 2005) and all efforts should be made at implementing these methods in KNH.

5.2 Conclusions

5.2.1 Level of knowledge on ADR reporting

1. The knowledge score for all respondents using a pre-decided assignment as per their responses to the questions was 60.5% with pharmacists reporting a higher knowledge score than medical doctors, indicating 39.5% had less knowledge.
2. All healthcare professionals were identified as qualified to report ADRs.

5.2.2 Attitude towards ADR reporting

1. Respondents were inclined to report all ADRs and would be encouraged to report ADRs if reaction was serious and unusual; while on the other hand they would be discouraged to report because of not knowing where to report.
2. ADR reporting was identified as a professional obligation with majority of the respondents indicating that ADR reporting should be compulsory.

5.2.3 Practices of ADR reporting

1. Majority of the respondents reported that to have encountered ADRs in their practice and further, indicating that over 50% of the ADRs encountered were serious.
2. Over 50.0% of the respondents indicated to have reported the ADRs they had encountered in their practice with the pharmacists showing a higher percentage than medical doctors.

3. Only 32.3% of respondents indicated they had used PPB and its related structure for reporting ADRs, with the pharmacists showing a higher percentage than medical doctors. Majority of the medical doctors indicated they had reported to consultants.
4. Respondents who were aware of the existence of an ADRs Reporting Centre in KNH was only 35.1% with pharmacists showing a higher percentage compared to medical doctors. Those who were aware of a Pharmacovigilance Department in PPB in Kenya were 54.5% again with pharmacists showing a higher percentage compared to medical doctors.
5. The KNH study also reported that majority of respondents would prefer to report ADRs to the reporting center via email or a website.
6. It was also noted that majority of the respondents had not been trained on how to report ADRs with pharmacists showing a higher percentage compared to medical doctors.
7. All respondents showed interest in education and training with continuous medical education, training and refresher courses being cited the most preferred means.

5.3 Recommendations

1. The respondents with less knowledge on ADRs should be taken through the training program. The training should include all health care professionals as the study concluded.

2. The deficits in the practice of ADR reporting can be resolved only if all healthcare professionals are made aware of the importance of reporting, the reporting system, and their obligation to report ADRs.
3. It would be highly recommended that focus group discussions be held with all healthcare professionals in KNH to highlight the importance of ADR reporting.
4. Since KAP study has certain limitations, it would be inappropriate to plan interventions based on the findings of this study alone. This study provides an insight into the possible interventions that could be planned in future.
5. Continuous medical education, reminders and awareness on the yellow forms by PPB in KNH and on their website reporting schemes should be instituted and implemented at the hospital. This will make the doctors fully accept ADR reporting as their role.
6. Attitudinal and cultural changes are very necessary for a long term improvement of ADR reporting where it is to be viewed as an integral part of the clinical activities of medical doctors and pharmacists and to a large extent all healthcare professionals who come into contact with patients.
7. The gaps between KAP and ADRs reporting among medical doctors and pharmacists working in KNH will be filled by improved training in ADR reporting and risk perceptions of drugs.

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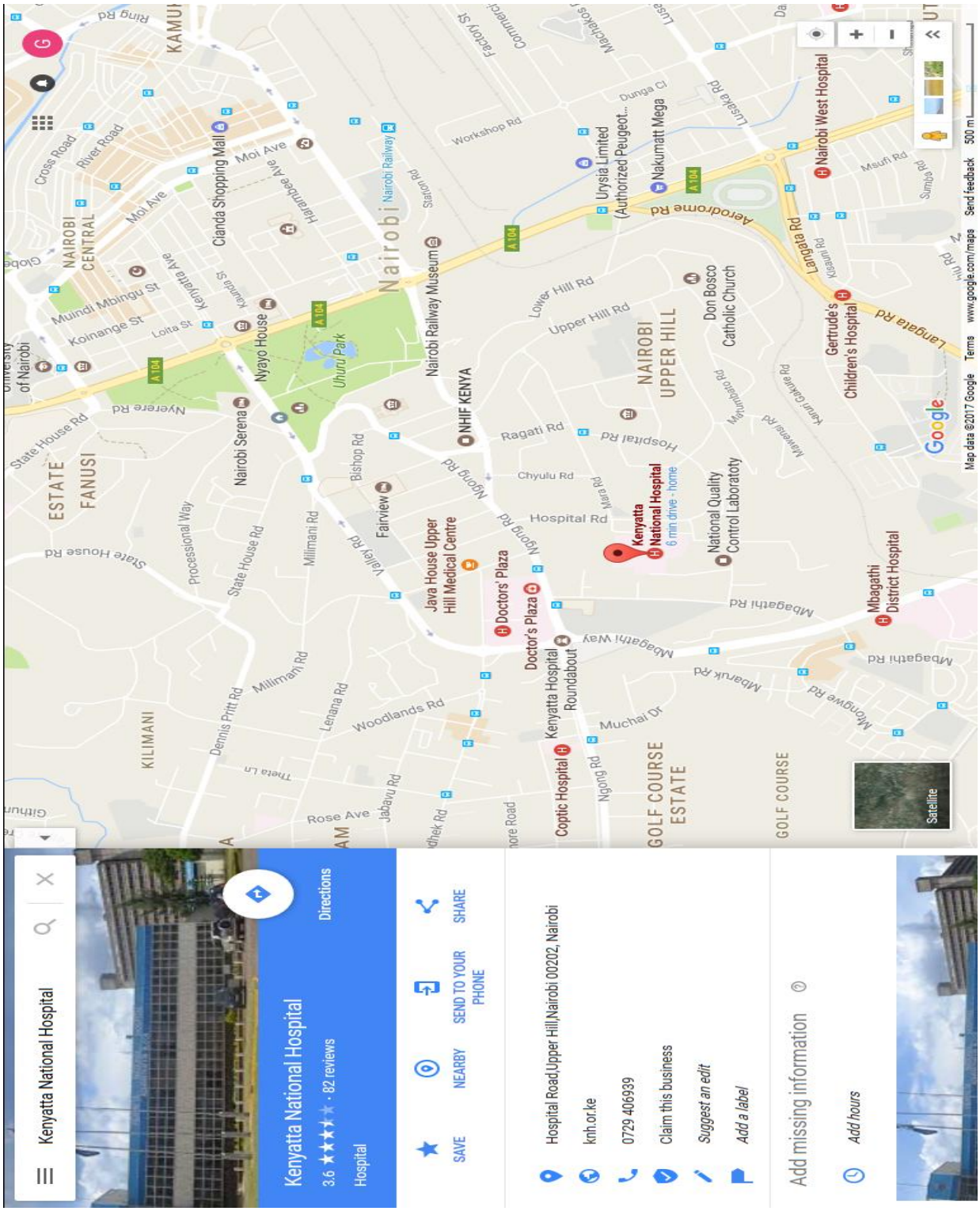
APPENDICES

7.1 Appendix 1 - Map of study site



7.2 Appendix 2 - Informed consent form

This information will be communicated orally in English.

TITLE: Knowledge, Attitudes and Practices Associated with Pharmacovigilance Reporting among Medical Doctors and Pharmacists at The KNH, 2013.

PRINCIPAL INVESTIGATOR: George Wang'ang'a

PROJECT SUPERVISORS:

Prof. Simon M. Karanja,

School of Public Health, Jomo Kenyatta University of Agriculture and Technology

Prof. Jennifer A. Orwa,

Chief Research Officer, Kenya Medical Research Institute, Centre for Traditional Medicine & Drug Research

INTRODUCTION: My name is George Wang'ang'a a student at the Institute of Tropical Medicine and Infectious Diseases (ITROMID), College of Health Sciences, Jomo Kenyatta University of Agriculture and Technology. I am pursuing a degree of Master of Science in International Health offered in conjunction with the Kenya Medical Research Institute (KEMRI).

This study by my team and I seeks to determine adverse drug reactions and pharmacovigilance reporting among medical doctors and pharmacists at the Kenyatta National Hospital (KNH) and the associated practices. The study will aid the

improvement of pharmacovigilance activities in the health sector in Kenya. This study has been approved by the KEMRI Ethical Review Board. I would like to seek your permission to participate in the study, please read the consent form below.

PURPOSE OF STUDY: To determine the knowledge, attitudes and practices associated with ADRs and pharmacovigilance reporting among medical doctors and pharmacists at the KNH. The study will last for approximately three months and will involve handing out of self–administered questionnaires and their collection once filled from participants at the hospital.

YOUR ROLE: Your role in this study, should you agree to participate, shall be to fill in the questionnaire provided as best and as honestly as you can. Your inclusion in this study is purely at your own voluntary will. You are free to decline participating in this study without any penalty. Should you understand the scope of your involvement in this study and wish to participate, you are still free to pull out of this study at any point for whatever reason without any consequences or loss of any benefits incurred.

PROCEDURES: If you agree to participate in the study, you will be issued with a questionnaire that will take you approximately 20 minutes to completely fill.

BENEFITS: You will not benefit directly from filling in the questionnaire, but by participating you may contribute towards the development of comprehensive pharmacovigilance activities in the health sector in Kenya and the roles health care

practitioners can play in these activities.

RISKS: Participation in this study is expected to have no risks.

CONFIDENTIALITY: After the questionnaire is collected from you it will be stored safely at the institution, KEMRI, by the principal investigator who is the only one who can access it. Your name will not be linked with your questionnaire and no single response will be reported on its own, but as a summation of all the responses. Your personal information will never be made public to other researchers or anyone else. At the end of this study, all names will be destroyed.

CONTACT OF PRINICIPAL INVESTIGATOR:

FOR QUESTIONS ABOUT THE STUDY, PLEASE CONTACT:

The principal investigator,

Dr. George Wang'ang'a

ITROMID, KEMRI

P.O. Box 54840- 00200

Nairobi

Tel: (02) 2722541 / 0722300274

Email address: gwwanganga@gmail.com

OR

CONTACT OF KEMRI ERC:

Secretary, KEMRI Ethics Review Committee,

P.O. Box 54840-00200,

Nairobi.

Tel: (020) 2722541 / 0722205901 / 0733400003

Email address: ERCAdmin@kemri.org

COMPENSATION: There will be no form of direct compensation in this study.

CONSENT AND SIGNATURE:

I confirm that I have read the information above and wish to participate in this research being conducted by George Wang'ang'a, ITROMID, KEMRI, P.O. Box 54840 Nairobi Kenya. I understand that I am free to ask any questions or to withdraw from participation at any time without penalty.

Name: _____

Signed: _____ Date**:** _____

7.3 Appendix 3 - Questionnaire

Knowledge, attitudes and practices associated with Adverse Drug Reactions reporting among medical doctors and pharmacists at the Kenyatta National Hospital, Nairobi County, Kenya

Dear Respondent

Attached is a questionnaire that seeks your opinion on knowledge, attitudes and practices associated with pharmacovigilance activities amongst medical doctors and pharmacists at Kenyatta National Hospital. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects brought about by medicines and medicine-related products. I would be grateful if you would complete the questionnaire as best and as honestly as you can. The information you give will be beneficial to the development of comprehensive pharmacovigilance activities in the health sector in Kenya and the roles health care practitioners can play in these activities. Any information provided will be treated with utmost confidentiality and no single response will be reported on its own, but as a summation of all the responses. You will require an estimated time of about 20 minutes to fill in the questionnaire.

Thanking you for your time.
GEORGE WANG'ANG'A

Please respond to the questions below by circling the number of your choice or filling in the blank spaces provided.

SECTION I: BIODATA

Gender of Respondent **1.** Male **2.** Female

Age (years) _____

Years of Work Experience _____

Highest Level of Formal Education **1.** 1st Degree **2.** Postgraduate Degree **3.** Postgraduate Diploma **4.** Others (please specify)

_____

Current Department _____

Specialty

In the next section you have been provided with choices from which to pick. Please indicate your views about each of the following statements by circling the number that most closely matches your opinion or indicate in writing any that is not specified.

Kindly note that multiple responses to the questions are allowed.

SECTION II:

Knowledge

1. Kindly list five common Adverse Drug Reactions (ADRs) along with the medicines that cause them.

Medicine	ADR
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

2. Are you aware of any drug/medicine that has been banned due to ADRs?

1. Yes
2. No

3. If yes, name them along with the ADR they cause.

Medicine	ADR
_____	_____
_____	_____
_____	_____

4. Kindly list the classes of medicines that should be reported for any ADRs observed.

_____ _____
_____ _____
_____ _____

5. Which of the following do you think an ADR reporting scheme may help in?

a. To identify safe drugs
b. To calculate incidence of ADRs
c. To identify predisposing factors to ADRs
d. To identify poor quality drugs
e. To describe a patient's condition
f. To identify previously unrecognized ADRs
g. As a source of information about the
h. For comparison of ADRs of medicines within the same

characteristics of the ADRs therapeutic class

6. Which of the following health professionals in your view are qualified to report ADRs?

a. Physician **b.** Dentist **c.** Pharmacist

d. Nurse **e.** Clinical Officer **f.** Nutritionist

g. Pharmaceutical Technologist **h.** All Healthcare Professionals

j. Others (please specify) _____

Attitudes

7. In your view which ADRs should be reported?

a. None **b.** All ADRs

c. All serious ADRs **d.** ADRs to new drugs

e. Unknown ADRs to old drugs **f.** ADRs to herbal/complementary drugs

g. ADRs to Vaccines **h.** Others (please specify)

_____

8. Which of the following factors may encourage you to report an ADR?

a. If the reaction was serious **b.** If the reaction was unusual

c. If the reaction was unnoticeable **d.** If the reaction was certainly an ADR

e. If the reaction was well recognized for a particular drug **f.** If the reaction was to a new product

g. Others (please specify) _____

9. Which of the following factors may discourage you from reporting an ADR?

a. Not knowing where to report **b.** Not knowing how to report

c. Knowing the medical sales representatives of the causative drug **d.** Concern that the report may be wrong

e. Lack of access of ADR reporting forms **f.** Non-remuneration for reporting

g. Lack of time to fill-in a report and a single unreported case may not affect ADR database **h.** Not being sure of what caused the ADR

i. Concern that reporting may generate extra work

j. Lack of time to actively look for ADRs while at work

k. Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred

l. Not having time to report

9. Continued. . . . Which of the following factors may discourage you from reporting an ADR?

m. Do not feel the need to report a recognized ADR

n. Lack of confidence to discuss the ADR with other colleagues

o Knowledge that no action will be taken

p. Fear of the negative impact the report may have on the company that produced or marketed the drug

q. Patient confidentiality issues

r. Legal liability issues

s. Others (please specify) _____

10. ADR reporting is a professional obligation

a. Yes
b. No
c. Don't Know

11. Reporting of only one ADR makes no significant contribution to a reporting scheme

a. Yes
b. No
c. Don't Know

12. ADR reporting should be;

a. Compulsory
b. Remunerated
c. Voluntary
d. Hide the identity of the reporter
e. Hide the identity of the prescriber

Practice

13. How many ADRs have you encountered in your practice? _____

14. Out of these, how many in your view are serious ADRs?

_____

15. Have you ever reported any of the ADRs you have encountered above?

a. Yes
b. No

16. If the above is yes, where or to whom did you report?

_____

_____

17. Kindly list your source of information on ADRs.

_____ _____

_____ _____

_____ _____

18. Are you aware of the existence of a Pharmacovigilance/ ADRs Reporting Centre in Kenyatta National Hospital?

a. Yes
b. No

19. If the above is yes, where is the Centre located? (please specify)

_____

20. Are you aware of a Pharmacovigilance Department in Pharmacy and Poisons Board in Kenya?

a. Yes
b. No

21. Which method would you prefer to send an ADR report to the Pharmacovigilance Reporting Centre in Kenyatta National Hospital?

a. Direct Contact **b.** Post

c. Telephone **d.** Email/Website

e. Others (Please Specify) _____

22. Would you be interested in getting feedback on the action taken for the ADR report you have forwarded to the Pharmacovigilance Reporting Centre?

a. Yes
b. No

23. Have you ever been trained on how to report ADRs?

a. Yes
b. No

24. If the above is yes, where were you trained? (please specify)

_____

25. If the above is no, would you be interested in undergoing a training for the same?

a. Yes
b. No

26. Have you ever shared information about ADRs with anyone?

a. Yes

b. No

27. If the above is yes, how and with whom?

_____

28. Suggest possible ways of improving ADRs reporting (please list as many points as possible)

_____

_____

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29. Kindly add any other comment that you think would contribute to this study.

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Thank you for your time and cooperation

7.4 Appendix 4 - Ethical approval (KEMRI ERC)

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya
Tel (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

KEMRI/RES/7/3/1 **January 14, 2014**

TO: **MR. GEORGE WANG'ANG'A (PRINCIPAL INVESTIGATOR)**

THROUGH: **DR. JENNIFER ORWA,**
ACTING DIRECTOR, CTMDR,
NAIROBI

Forwarded
21. 1. 2014

Dear Sir,

RE: SSC PROTOCOL NO. 2713 REVISED (*RESUBMISSION*): KNOWLEDGE, ATTITUDES AND PRACTICES ASSOCIATED WITH PHARMACOVIGILENCE REPORTING AMONG MEDICAL DOCTORS AND PHARMACISTS AT THE KNH

Reference is made to your letter dated 9th January, 2014. The ERC Secretariat acknowledges receipt of the revised document on 10th January, 2014.

This is to inform you that the Ethics Review Committee (ERC) reviewed the document listed above and approved the application for another year.

This approval is valid from today, **14th January, 2014** through to **13th January, 2015**. Please note that authorization to conduct this study will automatically expire on **13th January, 2015**. If you plan to continue with data collection or analysis beyond this date please submit an application for continuing approval to the **ERC** secretariat by **2nd November, 2014.**

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the SSC and ERC for review prior to initiation.

Yours faithfully,

EAB

DR. ELIZABETH BUKUSI,
ACTING SECRETARY,
KEMRI/ETHICS REVIEW COMMITTEE

7.5 Appendix 5 - Ethical approval (KNH-UON ERC)

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/118 Link:www.uonbi.ac.ke/activities/KNHUoN 5th May 2014

George Wang'ang'a
TM 309-2088/12
JKUAT

Dear George

Research proposal: Knowledge, Attitudes and Practices associated with Pharmacovigilance reporting among Medical Doctors and Pharmacists at the KNH (P246/05/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 5th May 2014 to 4th May 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
Supervisors: Dr. Simon M. Karanja, Dr. Jennifer A. Orwa