KNOWLEDGE, ATTITUDES AND PRACTICES OF ADVERSE DRUG REACTION REPORTING AMONG NURSES IN A TERTIARY HOSPITAL IN SOUTH WEST NIGERIA

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A mini-thesis submitted in partial fulfillment of the requirements for the degree of Master of Public Health at the School of Public Health,

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November 2018

KEYWORDS

Pharmacovigilance

Adverse Drug Reaction

Nurses

Healthcare Providers

ADR reporting

Tertiary hospital

Knowledge

Attitudes

Practices

Nigeria

ABSTRACT

Background: Healthcare providers are critical to collecting information on drug safety and successful adverse drug reaction (ADR) reporting. The roles of doctors and pharmacists have been recognized as important to voluntary ADR reporting and their roles are consistently being investigated. However, despite the strategic role of nurses in medicine administration, their role in ADR reporting has not been widely explored, particularly in sub-Saharan African countries.

Aim: To assess the knowledge, attitudes and practice of ADR reporting amongst nurses in Lagos University Teaching Hospital (LUTH), a tertiary hospital located in Lagos; the economic centre of Nigeria, as well as the most populous city in the country.

Methodology: A cross-sectional descriptive survey with analytical components was conducted among nurses in a tertiary institution. All nurses working in major specialties - out-patients' clinics, theatre and clinical wards in the facility, were eligible to participate in the study. Student nurses undergoing training or postings in the facility were excluded from the study. A sample size of 124 nurses was calculated using OpenEpi sample size calculator based on an estimated study population of 400 with a 95% confidence interval and an assumed 5% of nurses reporting an ADR based on National Pharmacovigilance Centre database. A sample of 140 nurses was selected in an attempt to realize sample. Cluster sampling was used to randomly select clinics and wards and all nurses in the selected clusters were included in the study. A structured questionnaire consisting of close-ended questions was used. It comprised sections on nurses' characteristics, knowledge of pharmacovigilance concepts, attitudes towards ADR reporting, and barriers to and practice of ADR reporting. Data collected were entered into an Excel spreadsheet and imported to the SPSS version 20 software for analysis. Descriptive analyses were conducted on all the variables and cross-tabulation between selected variables was explored to test for statistical significance using chi-squared test.

Ethics: Approval from the University of the Western Cape Senate Research and Ethics Committee, and the Ethics and Research Board of the LUTH was obtained before commencing the study.

Results: A sample size of 123 was realized which yielded a response rate of 88% (123/140). The study found that 51.2% of nurses reported familiarity with the National Pharmacovigilance Centre, 56.1% with the institution-based Pharmacovigilance Centre and 48.8% with the national ADR reporting scheme. Whilst 62.6% were familiar with the term 'pharmacovigilance', only

23.6% defined the term correctly. Over 90% of respondents felt that nurses were qualified to report ADRs and 62.6% felt it was their professional responsibility. However, in practice, only 7% of nurses had ever reported an ADR. Whilst 29.3% had received training on pharmacovigilance at nursing school only 13.8% had specifically received training on the standard yellow ADR reporting form. A key finding of this study was that nurses who had not received training on the standard yellow ADR reporting form were more likely not to report ADRs (p=0.008).

Conclusion and recommendations: This study revealed poor knowledge, positive attitudes and poor practice of ADR reporting among nurses in a tertiary hospital in south-west Nigeria. The study also revealed low exposure to training on ADR reporting among nurses in the pre-qualification and post-qualification nursing curricula. To improve ADR reporting amongst nurses in the institution under study, it is recommended that structured education and training programmes at undergraduate and post qualification level for nurses on drug safety and ADR reporting should be established; awareness on pharmacovigilance and ADR reporting via various publications such as leaflets, fliers and posters should be initiated, as well as continuous availability of ADR reporting forms in the hospital wards. Further studies which include an educational intervention should be undertaken to provide evidence on the impact of training on ADR reporting among nurses.

DECLARATION

I declare that KNOWLEDGE, ATTITUDES AND PRACTICES OF ADVERSE DRUG REACTION REPORTING AMONG NURSES IN A TERTIARY HOSPITAL IN SOUTH WEST NIGERIA is my own work, that it has not been submitted for any degree or examination in any other university. I also declare that all the sources I have used or quoted have been indicated and acknowledged by complete reference.

Full Name: Osho Folasade M Date: November, 2018

Signed: …….

ACKNOWLEDGEMENTS

I am sincerely grateful to Dr. Hazel Bradley, my supervisor, for her relentless support and understanding throughout this research. I also wish to thank my family, for continuously spurring me on in the face of daunting challenges.

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ABBREVIATIONS

ADR	Adverse Drug Reaction
FMOH	Federal Ministry of Health
HCPs	Healthcare Providers
ICSR	Individual Case Safety Report
KAP	Knowledge, Attitudes and Practice
LUTH	Lagos University Teaching Hospital
NAFDAC	National Agency for Food, Drug Administration and Control
NMCN	Nursing and Midwifery Council of Nigeria
NPC	National Pharmacovigilance Centre
PV	Pharmacovigilance
TOT	Training-of-trainers
WHO	World Health Organization

CHAPTER 1 - INTRODUCTION

1.1 Background

Adverse drug reactions (ADRs) constitute a serious public health problem in Nigeria. About 10 – 20% of hospital in-patients experience adverse reactions (Federal Ministry of Health, 2011). They have been reported to cause 5% hospital admissions and in severe cases have resulted in permanent disabilities and deaths (Federal Ministry of Health, 2011). The World Health Organization (WHO) defines ADRs as "any response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" (NAFDAC, 2008:3).

ADRs are one of the leading causes of hospital admissions and morbidity in developed countries and represent a substantial burden on healthcare delivery systems (Angamo, Chalmers, Curtain & Bereznicki, 2016). Studies conducted in the United Kingdom (UK), suggest that 7% of hospital admissions are attributable to ADRs (Greener, 2014). Similar studies in the United States of America (USA) and Canada reported a prevalence of 4.2% - 30% hospital admissions, while 5.7% - 18.8% was recorded for Australia and 2.5% - 10.6% in Europe (Sultana, Cutroneo & Trifirò, 2013). A three-month prospective study in Spain revealed a 4.2% prevalence of ADRs-related admission (Pedrós, Quintana, Rebolledo, Porta, Vallano & Arnau, 2014). In general, limited data on ADRs is available from low and middle income countries (Angamo et al. 2016).

Although the burden and impact of ADRs may not be accurately ascertained, it is speculated that about 30.1 billion dollars are spent annually on ADRs in the USA (Sultana et al. 2013). In addition to the increased hospitalization, prolongation of hospital stay and cost of additional clinical investigations, there are other indirect costs such as missed days from work and anxiety to patient and care givers (Sultana et al. 2013). Whilst there is paucity of data on medicine safety and the burden of ADRs in Nigeria it is likely to be worse as it is complicated by "*widespread irrational drug use; which is evidenced by the population's preference for injections, misuse of antibiotics and other prescription drugs, unstandardized traditional/herbal medicines, and extensive self-medication*" (Oreagba, Isah & Osakwe, 2014: 14).

An international reporting system for ADRs was first motivated by the thalidomide disaster (Conforti et al. 2012). In the 1950s, thalidomide was a drug indicated for controlling nausea and vomiting in early pregnancy; but later resulted in the birth of limbless babies. This incident revealed the limitations inherent in pre-marketing drug safety evaluation. During clinical trials, the target population, duration of exposure and other factors considered are relatively restricted to

a small population (Srba, Descikova, & Vlcek, 2012). This highlights the importance of active surveillance and monitoring of drugs after granting market authorization and subsequent release into the market.

Nigeria has experienced its fair share of fatalities resulting from the absence of an ADR reporting system; which was further complicated by the 1985-2000 era of faking and quackery, counterfeit drugs, quack doctors, illegal chemist shops and hospitals (Erhun, Babalola & Erhun, 2001). In 1989, over 150 children died as a result of a formulation error in a paracetamol preparation (Olike, 2008). The absence of a functional drug monitoring system in the country escalated the fatalities of these unfortunate incidents.

Good pharmacovigilance systems enable continuous drug safety evaluation after market authorisation (Srba et al. 2012). Spontaneous reporting of ADRs remains one of the most effective methods for detecting new and serious drug reactions (Bäckström, Ekman & Mjörndal, 2007). This method is largely dependent on ADR reporting by healthcare providers. Data gathered from drug monitoring activities enable drug regulatory authorities to make evidence-based decisions with regards to the safety and rational use of drugs. For instance, in Nigeria, withdrawal of Analgin® injection from the market by the drug regulatory body was motivated by reports of necrolysis reported in several patients following its administration (NAFDAC, 2008). Other regulatory actions such as: review of product information leaflet, restriction of use and caution to prescribers have resulted from continuous drug monitoring activities.

The National Pharmacovigilance Centre (NPC) was established in 2004 to coordinate ADR reporting in Nigeria. This centre became the 74th member of WHO international drug monitoring member countries (NAFDAC, 2008). This centre was established to function under the National Agency for Food and Drug administration and Control (NAFDAC), the food and drug regulatory body of Nigeria. This system is reportedly one of the four in sub-Saharan Africa sufficiently structured to ensure drug safety and evaluate risks (Appiah, 2012).

Since its inception till December 2010, The NPC has distributed over 50,000 ADR reporting forms and 5,000 copies of guidelines for detecting and reporting ADRs to healthcare professionals nationwide. The Centre has also trained over 1200 healthcare professionals on detecting and reporting ADRs and other medicine-related problems. The NPC currently collaborates with different healthcare professional organizations and public health programmes in capacity building and conducting training-of-trainers (TOT) workshops (FMOH, 2011). Active participation of health professionals, therefore, determines the success of the pharmacovigilance

system, because they are best positioned to report suspected ADRs observed in patients (NAFDAC, 2008). Embedding this pharmacovigilance system in Nigeria has been facilitated by soliciting cooperation, collaboration and support of healthcare providers and health professionals' associations through sustained advocacy and sensitization programmes for or with the relevant health practitioners and associations (FMOH, 2011).

1.2 Problem Statement

In comparison with other healthcare professionals, nurses "*constitute the majority of a hospital's clinical employees, they are closest to patients, and are responsible for maintaining constant surveillance over their patients' health*" (Nwagwu & Oshiname, 2009: 25). Furthermore, nurses administer most medicines, they are present during occurrence of ADRs and they possess mechanism for documenting and reporting ADRs, hence, rational reasons for including them in ADR reporting (Hall, Mccormack, Arthurs & Feely, 1995).

Voluntary reporting of ADRs is a multidisciplinary task, hence should involve all healthcare providers in the continuum of care, including the patient (Ulfvarson, Mejyr & Bergman, 2007). Extensive work has gone into re-enforcing the role of doctors and assessing their impact in spontaneous reporting of ADRs (Lopez-Gonzalez, Herdeiro & Figueiras, 2009). Similarly, pharmacists as traditional custodians of medicines have customarily adopted the concept of pharmacovigilance as a professional responsibility and have been a major thrust in entrenching the practice in most health facilities (Conforti et al. 2012), including Nigeria. However, the potential impact of nurses, as care-givers and health personnel in closest contact with patients, on ADR reporting has not been sufficiently explored (Gabe, Davies, Murphy, Davies, Johnstone & Jordan, 2011). Rather, studies that have attempted to assess the position of nurses have been complementary to doctors without a full appreciation of the specific niche which they occupy (Rehan, Sah & Chopra, 2012). The traditional roles of nurses in medication administration, patient monitoring and documentation, strategically positions them to detect and report ADRs. If this role could be optimized nurses would have the potential to improve the quality and quantity of reports available for drug safety evaluation. In order to adequately explore the role of nurses in ADR reporting, a logical first step is to assess the knowledge, attitude and practice of ADR reporting amongst nurses in a tertiary hospital in south west Nigeria.

1.3 Aim

The aim of this study was to describe the knowledge, attitudes and practice of ADR reporting amongst nurses in a tertiary hospital in south-west Nigeria.

1.4 Objectives

i. To describe the knowledge of pharmacovigilance and the ADR reporting system among nurses

ii. To describe the attitudes of nurses towards ADR reporting

iii. To describe ADR reporting practices of nurses

CHAPTER 2 - LITERATURE REVIEW

Globally, numerous studies have researched the knowledge, attitudes and practices (KAPs) of health care practitioners towards adverse drug reaction (ADR) reporting. These studies have primarily been undertaken to identify and understand reasons for under-reporting, with a view to providing evidence-based recommendations for improving ADR reporting. A number of these studies have focused on the roles of nurses in ADR reporting. This chapter presents a review of studies undertaken on KAP of health professionals towards ADR reporting, with a special focus on studies undertaken among nurses. Furthermore, the barriers and reasons for under-reporting will be discussed as well as the potential role of nurses in improving ADR reporting.

2.1 ADR Reporting Among Healthcare Professionals

Spontaneous reporting of ADRs amongst healthcare practitioners has been described by several researchers and some studies from Asia include: the KAP of ADR reporting amongst prescribers in India (Desai, Iyer, Panchal, Shah & Dikshit, 2011); physicians in India (Kamtane & Jayawardhani, 2012); pharmacists in Nepal (Bhuvan, Alrasheedy & Mohamed, 2013); and hospital pharmacists in Thailand (Jarernsiripornkul, Krska, Pongmanachai & Nasritha, 2009). All these studies revealed an inadequate knowledge of the ADR reporting system. However, a similar study conducted among clinicians and pathologists in a tertiary care hospital in India reported an average knowledge of pharmacovigilance but stated a poor awareness of the ADR reporting system (Datta & Sengupta, 2015). Awareness and attitudes of healthcare workers towards ADR reporting in China was also researched and like other studies reported a poor knowledge of the reporting scheme (Li et al, 2004). However, Gupta et al. (2015) also studied KAP among healthcare professionals in South India and reported a good knowledge of pharmacovigilance and the ADR reporting system. Studies conducted in African countries among doctors in Ghana (Sabblah, Akweongo, Darko, Dodoo & Sulley, 2014) and among healthcare workers in South Africa (Terblanche, Meyer, Godman & Summers, 2017), Uganda (Katusiime, Semakula & Lubing, 2015), Mozambique (Sevene et al, 2008) and Sudan (Elnour, Ahmed, Yousif & Shehab, 2009) also reported poor ADR reporting practice.

Similar KAP research has been conducted in several studies in Nigeria, focusing on doctors in a tertiary institution in south-west Nigeria (Oshikoya & Awobusuyi, 2009), community pharmacists in south-west Nigeria (Oreagba, Ogunleye & Olayemi, 2011), private practice doctors in south-west Nigeria (Awodele, Akinyede, Adeyemi & Awodele, 2011), physicians in north-west Nigeria (Bello & Umar, 2011) and healthcare workers in northern Nigeria (Fadare, Enwere, Afolabi,

Chedi & Musa, 2011). These studies reported comparable findings of poor knowledge of the ADR reporting system and ADR reporting culture but a positive attitude towards ADR reporting.

The literature indicates that the majority of ADR reporting and pharmacovigilance research has been undertaken among doctors, and lately pharmacists, with the minimal inclusion of nurses. Hall et al. (1995:175) stated that initially, there was considerable international difference and variation in the 'right to report' from a completely open system, including patients in the United States, to a system restricted to doctors, dentists and coroners as in the United Kingdom. Hall et al. (1995) further stated that, even in countries with unrestricted ADR reporting by all health professionals, few nurses reported ADRs. Findings from these studies present a poor prognosis for nurses' knowledge, attitude and practice of ADR reporting and it is therefore expedient to evaluate the KAP of nurses towards ADR reporting.

2.2 Nurses' Knowledge of ADR Reporting

Nurses' knowledge of pharmacovigilance and the ADR reporting system, a strong predictor of ADR reporting, has been researched and revealed variable results. Hanafi, Torkamandi, Hayatshahi, Gholami & Javadi (2012) observed knowledge of ADR reporting amongst nurses in a teaching hospital in Tehran, to be generally low. These findings are similar to results of studies conducted in United Arab Emirates (John, Arifulla, Cheriathu & Sreedharan, 2012), Bangalore (Padmavathi, Nagaraju, Divakara, Kumar, Surendranath & Sunil, 2013) and Sweden (Lampa, Åsander, Södergren, & Boström, 2013). A systemic review of KAP studies undertaken among healthcare providers in India from 2011 to 2015 also reported lack of knowledge regarding pharmacovigilance and drug safety (Bhagavathula, Elnour, Jamshed & Shehab, 2016). Additionally, a study of nurses and midwives in Turkey also reported an inadequate knowledge of pharmacovigilance and the reporting system (Alan, Ozturk, Gokyildiz, Avcibay & Karataş. 2013). A study on knowledge and attitudes among healthcare professionals likely to observe ADRs in vaccines was conducted in west Scotland where almost half of study respondents were nursing professionals, and results also corroborated findings from other studies (Pulford & Malcolm, 2010).

On the hand, a cross-sectional study conducted by Rehan et al. (2012) which compared KAP of resident doctors and nurses in India, concluded that nurses had adequate knowledge and awareness of ADR reporting and pharmacovigilance. Rehan et al. (2012) further reported that, pharmacovigilance activities in India experienced a boost following a World Bank funding of the National Pharmacovigilance Programme in India, inclusion of pharmacovigilance training in the

medical college curriculum and extension of pharmacovigilance programmes to cover traditional medicines. Possibly, these interventions may account for the increased knowledge of pharmacovigilance systems amongst nurses as reported in Rehan's study compared to similar studies in India and other countries. In a comparable situation, about 90% of Swedish nurses researched by Bäckström et al (2007) stated that they had sufficient knowledge to report ADRs after the introduction of an educational teaching block to boost ADR reporting.

No research was identified that focused specifically on the knowledge of ADR reporting amongst nurses in Nigeria. All research studies accessed on ADR reporting amongst nurses were undertaken alongside other healthcare professionals and were conducted in northwest Nigeria. These studies reported poor knowledge of the ADR reporting system (Fadare et al. 2011; Umar, Bello, Chika & Oche, 2016).

2.3 Nurses' Attitude to ADR Reporting

Most studies revealed a positive attitude towards ADR reporting by nurses (Pulford & Malcolm, 2010; Bäckström et al. 2007; Rehan et al. 2012; Gupta et al. 2015). Despite the small sample size and convenience sampling method adopted, Fadare et al.'s (2011) study undertaken in northern Nigeria, also reported a positive attitude. Similar findings were also reported among nurses and pharmacists in north-west Nigeria (Umar et al. 2016). In several studies, a positive attitude towards ADR reporting was based on nurses' recognition of the necessity of the ADR reporting system (Rehan et al. 2012; Gupta et al. 2015; Umar et al. 2016), as well as the acceptance of ADR reporting as a professional responsibility. Although some of these studies were undertaken alongside other healthcare professionals, nurses identified ADR reporting as a professional responsibility and expressed a willingness to report it when encountered. On the other hand, the study undertaken among nurses in the United Arab Emirates reported a less than average attitude towards ADR reporting (John et al. 2012). However, there seems to be a growing recognition of ADR reporting as a professional responsibility among nurses. Kelly (2000 in Griffith, 2013: 288) put it succinctly: "*ADRs are a nursing concern and as the professionals closest to the patients, nurses are uniquely placed to monitor all ill-health, including ADRs*". John et al. (2012) observed a positive correlation between knowledge of ADR reporting and attitude towards reporting. Furthermore, positive attitudes of nurses to ADR reporting, if combined with sufficient knowledge and enlightenment, may significantly increase reporting culture.

2.4 Nurses' Practice of ADR Reporting

The UK Yellow Card scheme is a spontaneous reporting system established for reporting of ADRs in the UK using the yellow card (Pulford & Malcolm, 2010). This system relies on the use of a standard yellow form or ADR reporting form by health professionals, patients and the general public to report suspected ADRs. A similar system is in place in most developed countries and many developing countries all over the world (Hazell & Shakir, 2006). In Nigeria, the ADR reporting procedure also requires that ADRs are reported using the ADR reporting form or the standard "yellow form"; this form is designed and specifically distributed by the NPC for the reporting of ADRs (FMOH, 2011:5).

A recent assessment of all ADR reports in the Portuguese database revealed that the quantity of ADRs reported by nurses (6.5%) was far lower to those by doctors and pharmacists (Mendes, Alves & Batel Marques, 2014). Other studies undertaken in Iran reported 9% of nurses had ever reported as against 8.8% and 7.33% observed in studies conducted in United Arab Emirates and Navara, Spain respectively (Hanafi, 2012; John et al. 2012; Zurita-Garaicoechea, Reis-Carvalho, Ripa-Aisa, Jiménez-Mendoza, Díaz-Balén & Oroviogoicoechea, 2015). Another study in India reported a reporting rate of 22.8%, although this study included doctors, nurses and pharmacists (Gupta et al. 2015). Only one study reported a high reporting rate of 75%, however, the sample size employed in this study was small and the convenience sampling method adopted is prone to bias (Fadare et al. 2011). A study conducted among health workers in Uganda also reported that nurses were less likely to have ever reported an ADR compared to doctors and pharmacists (Katusiime, Semakula & Lubing, 2015).

Despite poor reporting rates observed in the above studies, Greener (2014) suggests that since the commencement of ADR reporting in 1968, an increase in nurses' contribution to the United Kingdom database has been observed (Greener, 2014). This claim is based on the increased proportion of standard yellow ADR report forms submitted by nurses for pediatrics from 23.5% in 2001 to 41.8% in 2009 in the United Kingdom (Greener, 2014). According to him, although the contributions of doctors are higher, they have however remained constant (Greener, 2014). Similarly, a retrospective study of ADR reports in the Sweden database between 1990s to 2004 also revealed an increased contribution of nurses reporting from 2-3% to 12% (Ulfavson et al. 2007). In the same way, a review of the Italian pharmacovigilance database from 2004 – 2010 also revealed an increase in ADR reporting among nurses (Leone & Rossi, 2012). However, Leone & Rossi (2012) suggested that the slight increase in ADR reporting, may be attributable to

specific pharmacovigilance activities rather than adherence of nurses to pharmacovigilance practices.

Significantly, several studies conducted in a range of settlings including Nigeria have revealed that rather than report to a National Pharmacovigilance Centre directly, nurses tend to prefer to report ADRs encountered in their patients to doctors or document them in the patient case notes (Hall et al. 1995; Li et al. 2004; Hanafi et al. 2012; Rehan et al. 2015; Fadare et al. 2011; John et al. 2012; Alan et al. 2013).

Several studies revealed similarities in the quality of ADR reports documented by nurses and physicians (Bäckström et al. 2007). According to Bäckström et al. (2007), ADR reports from nurses were better documented, with information from medical records attached. This corroborates with a study conducted in the United Kingdom, which revealed that the quality of reports and number of reports generated by nurses was similar to doctors (Morrison-Griffiths, Walley, Park, Breckenridge & Pirmohamed, 2003). Furthermore, Hall et al. (1995) found that nurses reported more serious adverse reactions, ADRs to non-oral administered drugs and better documented reports. Most ADRs are attributed to inadequate patient monitoring (Jordan, 2007). Regrettably, monitoring and managing ADRs is currently not the responsibility of any specific professional. Hence, Jordan (2007) recommends that nurses expand their roles to include standardized monitoring of patients with the view to identifying and subsequently reducing the burden of ADRs. .

2.5 Barriers to Nurses' Reporting ADRs

Given the burden of preventable and un-preventable ADRs to individuals and the healthcare system, several researchers have attempted to explore the problem of under-reporting among healthcare providers. One of the earliest researchers was Inman, who created a solid foundation for understanding under-reporting of ADRs among healthcare providers (1996 in Desai et al. 2011). From his research, Inman proposed seven reasons for under-reporting which he termed *"seven deadly sins"*. These reasons are; lack of financial incentives, legal aspects, complacency, 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 will make no difference), ignorance (that only serious ADRs are to be reported) and lethargy (excuses about lack of time or disinterestedness)" (1996 in Desai et al. 2011:132). This novel research created a template for other exploratory, systematic studies which have been undertaken to discover reasons why healthcare professionals under-report ADRs. Lopez-Gonzalez et al (2009) undertook a systematic

review to evaluate the impact of personal and professional factors on ADR reporting. Irujo, Beitia, Bes-Rastrollo, Figueiras, Hernández-Díaz & Lasheras. (2007) also explored reasons for under-reporting among pharmacists in Spain in a case control study. The key reason identified was lack of knowledge, interestingly, most of the reasons identified by Inman were not applicable to pharmacists researched in this study. De-Angelis et al. (2015) proposed intrinsic and extrinsic factors to be responsible for under-reporting among nurses (De-Angelis, Colaceci, Giusti, Vellone & Alvaro, 2015).

Unlike the sevens sins of ADR reporting proposed by Inman (1996 in Desai et al, 2011), major barriers to reporting among nurses in most studies include uncertainty of the ADRs, concern that report may be wrong and inadequate knowledge of the reporting procedure (John. et al. 2012; Lampa et al. 2013; Li et al. 2004). Other reasons observed include lack of knowledge regarding pharmacovigilance and ADRs, ignorance of the reporting centres, inadequate training for detecting and reporting ADRs and unavailability of ADR reporting forms (Padmavathi et al. 2013; Hanafi et al. 2012).

Studies conducted in Nigeria have identified several reasons for under-reporting of ADRs among health workers. One such study undertaken amongst nurses in northwest Nigeria identified lack of knowledge of ADRs and the reporting procedure as the reason for under-reporting (Fadare et al. 2011). While another study conducted in south-west Nigeria identified; unavailability of electronic reporting, unavailability of reporting forms and ignorance to be associated with under-reporting (Ezeuko, Ebenebe, Nnebue & Ugoji, 2015). These studies were undertaken in different regions and at different times hence these may account for the differing reasons for under-reporting of ADRs observed among nurses.

2.6 Potential Role of Nurses in ADR Reporting

Nurses' current limited involvement in ADR reporting has motivated researchers to investigate the potential contribution and constraints of nurses in reporting ADRs. Hall et al. (1995) conducted one of the earliest studies amongst nurses in Ireland during which nurses' ability to identify and report ADRs, when sufficiently educated, was explored (Hall et al.1995). Similarly, in Sweden the quality of ADR reports generated by nurses was assessed following an educational teaching block (Bäckström et al. 2007). Both studies provided similar findings observing that nurses reported more serious ADRs which were also properly documented when compared with those received from doctors. Antimicrobials, intravenous and non-oral preparations characterised the bulk of ADRs reported by nurses which is different from the oral preparations and drugs for

management of chronic conditions reported by doctors. Comparing ADR reports from doctors with nurses, data suggests nurses could enhance the pharmacovigilance system in the UK (Morrison-Griffiths et al. 2003). Hall et al. (1995) proposed several logistical reasons for including nurses in ADR reporting such as: nurses administer most medicines, they are present during occurrence of ADRs, they possess mechanism for documentation and reporting of ADRs and they are a usual source for alerting the prescriber. This reinforces the potentially valuable role of nurses in ADR reporting in any health facility.

However, findings from these studies may not be generalized to nurses in tertiary institutions in Nigeria, for several reasons. Firstly, these studies were interventional as they adopted an educational block in their methodology, thus confounding the actual ADR reporting practice of nurses in real life situation. Also, nurses selected to participate in this study had many years of work experience and good clinical proficiency and thus were not representative of the variability in experience and proficiency which exists in everyday practice (Bäckström et al. 2007).

Studies in Nigeria on the knowledge, attitudes and practice to spontaneous ADR reporting have explored the role of healthcare practitioners and have passively identified the potential role of nurses in boosting reporting rates. Fadare et al. (2011) concluded that the presence of nurses in wards at all times and as first observers of any acute ADR highlights the importance of their participation in the spontaneous reporting scheme. This study will add to the knowledge base of KAP of ADR reporting among nurses in Nigeria and provide insights to interventions required to improve reporting and to build confidence among nurses towards reporting of ADRs to the National Pharmacovigilance Centre.

CHAPTER 3 - RESEARCH DESIGN AND METHODOLOGY

3.1 Study Design

A cross-sectional analytical survey was adopted in conducting this research. Since, this study intended to assess the knowledge, attitude and practice (KAP) of nurses to ADR reporting; sufficient description requires measuring several variables all at once. This cross-sectional survey method therefore guarantees a rapid means of achieving this without compromising the quality of information collected. This study was designed to describe the KAP of ADR reporting amongst nurses.

3.2 Study Setting

Lagos University Teaching Hospital (LUTH), the tertiary hospital under study, is the largest in Nigeria. The government-owned facility is located in the economic centre and most populous state in Nigeria, serving a population of over 18 million people. It has a capacity of 761s with twelve outpatient clinics and eight in-patient wards. The hospital has a large workforce of over 3,500, with nurses constituting about 500 of the total workforce. This facility also serves as the Zonal Pharmacovigilance Centre for south-west Nigeria.

3.3 Study Population and Sampling

This study was conducted amongst nurses working in LUTH, Nigeria. All nurses working in major specialties, out-patient clinics, theatre and wards were eligible to participate in this study. These included; all nurses working in surgery, accident & emergency, children emergency departments and the other five wards in the facility. Staff or intern nurses; referring to nurses who have completed their studies and are currently undergoing the mandatory one-year internship programme, were eligible to participate. Nurses lecturing in the school of nursing located within the facility premises and also working in any of the departments or wards selected were also eligible to participate. Student nurses undergoing training or postings in any of the departments were excluded from this study. Also excluded were nurses employed to work in the LUTH Private Wing; a private section comprising a 15 single rooms and a diagnostic centre.

In calculating the appropriate sample size, an estimate of the population size, hypothesized percentage frequency of outcome factor, confidence limits and design effect were taken into consideration. The total number of nurses working in the facility was initially estimated to be 500; however, closer interaction with the nursing administration revealed a more realistic figure of 400 and this was used to calculate the final sample size. One of the key variables that describe the KAP of nurses to ADR reporting is the percentage of nurses that have ever reported an ADR.

Data available from the National Pharmacovigilance Centre database indicated a total of 15,815 ADR reports with 292 (1.85%) reported by nurses and 1,100 (6.96%) and 11,658 (73.71%) reported by doctors and pharmacists respectively (NPC: NAFDAC Database; 2014). Given the afore-mentioned, the hypothesized outcome was set at 5%. To increase precision and reproducibility of this study, a confidence limit of 5% was specified. A design effect of 2 was used, as specified for cluster sampling. All of the above estimated figures as well as a 95% confidence level were entered into the OpenEpi sample size calculator and a population size of 124 participants was obtained. Due to the possibilities of non-responders, over-sampling by 10% was done to give a total sample size of 137. One hundred and forty (140) nurses were therefore selected to participate in this study.

Cluster sampling was adopted to select the specific clinics/wards from which the nurses were selected. Twelve clusters were identified based on the structural arrangements, location and demarcation of the clinics and wards in the facility. This method was adopted because clinics such as the Guinness Eye Clinic and Dental Out-Patient Clinic are significantly larger than clinics such as Ear Nose and Throat (ENT) and Staff Clinics. Each cluster comprised 25-30 nurses and all nurses in the selected clusters were included in the sample. Six clusters were randomly selected by listing the twelve clusters alphabetically on an Excel sheet and applying the statistical function 'RANDBETWEEN' six consecutive times. Subsequently, two additional clusters were randomly selected from the remaining six clusters using the same statistical method to attain the expected calculated sample size (Table 1).

Table 1: Identified and randomly selected clusters

Cluster No:	Identified clusters	Randomly selected clusters	Additional selected clusters
1	Ground Floor: • *Accident & Emergency* • *Obs & Gynae Surgery* • *Triage* • *Medicine*	Ground Floor: • *Accident & Emergency* • *Obs &Gynae Surgery* • *Triage* • *Medicine*	
2	Clinic Floor One: • *Obstetrics & Gynaecology* • *Surgical Out-Patients*		
3	Clinic Floor Two: • *Paediatrics* • *Surgical* • *ENT*	Clinic Floor Two: • *Paediatrics* • *Surgical* • *ENT*	
4	Clinic Floor Three • *Medical Out-Patient* • *Surgical Endoscopy* • *Family Medicine* • *General outpatient* • *Staff Clinic*	Clinic Floor Three • *Medical Out-Patient* • *Surgical Endoscopy* • *Family Medicine* • *General outpatient* • *Staff Clinic*	
5	Dental Out Patient Clinic		Dental Out Patient Clinic
6	Guinness Eye Clinic	Guinness Eye Clinic	
7	Ward A		
8	Ward B	Ward B	
9	Ward C		
10	Ward D	Ward D	
11	Ward E		
12	Theatre		Theatre

3.4 Data Collection

A structured questionnaire (Appendix I) was used to collect the data. This questionnaire was adapted from a similar study conducted on perceptions of doctors to ADR reporting in a tertiary hospital in Nigeria (Oshikoya & Awobusuyi, 2009). The questionnaire consisted of mainly close-ended questions and covered: characteristics, knowledge of pharmacovigilance concepts, attitudes towards reporting ADRs, practice of ADR reporting and impact of training on ADR reporting.

The questionnaire was pre-tested with eight selected nurses to ascertain comprehension of language used in the questionnaire and establish its suitability in accurately measuring the variables under observation. Nurses selected for the pilot worked in the LUTH private wing, and were excluded from the final study sample. Based on the feedback received from the pre-tested questionnaire, several amendments were made including the introduction of Likert scale for the attitudinal variables, removal of repetitive questions, and inclusion of variable to assess workload.

The study had planned to mobilize five student-nurses familiar with the facility to administer the questionnaires to the nurses, however, the hierarchical relationship of nursing cadres and their heavy workload made this approach unworkable. Instead, the researcher hand delivered questionnaires directly to nurses in selected wards for self-administration. Additional questionnaires were handed to the nursing head in the ward/unit to administer to nurses who were off duty or on a different shift. The completed questionnaires were stored in a locked cabinets and retrieved at an agreed time. In the selected out-patient units, the researcher arranged for nurses to complete the questionnaires during their monthly unit meeting where all nurses working in the particular department are in attendance.

The data collection commenced in August 2015 and was completed in November 2015. This protracted sampling period was due to an industrial strike action by health workers in the facility during this period.

3.5 Data Management and Analysis

Upon retrieving completed self-administered questionnaires from each respondent, the researcher immediately checked the questionnaires to ensure completeness and followed up any gaps.

Data from the questionnaires were entered in an Excel spreadsheet and imported to the SPSS version 20 software used for statistical analysis of data. Descriptive analyses were conducted on all the variables using frequency distributions for numeric variables such as number of years of experience. Categorical data were summarized as frequencies and percentages, and presented

using frequency distributions, bar charts and tables. Cross-tabulation of selected variables was used to explore possible associations between knowledge of pharmacovigilance and ADR reporting practice variables. The Pearson Chi-square test was employed to test for statistical significance of these associations, with $p<0.05$ considered as statistically significant.

3.6 Validity

Validity of this research was ensured by minimizing selection and measurement bias. Since, cluster sampling is prone to selection bias; this was minimized by increasing the sample size. Measurement bias was also minimized by adapting a questionnaire previously used in a similar research in a similar setting in Lagos state. Also, in designing the data collection tool, the Likert scale was introduced in the attitude variables, to minimize measurement error. Furthermore, the questionnaire was piloted amongst eight selected nurses from a private section of the hospital setting which was not included in the study sample, and several adjustments for clarity were made. Finally, stem and branch questions were introduced in the questionnaire to check the repeatability of the most important variables under investigation.

3.7 Reliability

Appropriate data checking was undertaken before data analysis. Data collected on all variables with yes or no options was checked for missing data and implausible observations. Numerical variables were also checked for outliers. When such errors were discovered, the questionnaires were cross-checked and the necessary correction was made to the data set. Oversampling by 10% of actual sample size was done to increase precision and reliability of the study result.

3.8 Limitations

This research provides empirical evidence on the knowledge, attitudes and practices of ADR reporting among nurses. However, since the research was conducted in only one setting, findings cannot be generalized to other contexts although it does provide evidence to facilitate further research in similar settings. Being a cross sectional study, this research cannot provide definite relationship between exposure variables and outcome data collected and more research is required to investigate temporal relationship. Finally, despite the measures incorporated to minimize bias, this study is prone to recall bias, social desirability and selection bias.

3.9 Ethical Considerations

Due consideration was given to the ethical component of this research. Firstly, approval to undertake this research was obtained from the University of Western Cape Senate Research and Ethics Committee (Appendix IV). Secondly, the Ethics and Research Board of the Lagos

University Teaching Hospital was also notified officially (Appendix V) for approval to conduct the research in the facility. This official notification involved submission of the study protocol; which provided detailed information on the research objectives, methodology and potential benefits to the institution and public health. Thereafter, a written approval by the ethics board of the institution to undertake the research in the institution was obtained (Appendix VI). Furthermore, this research was assessed in line with general ethical guidelines stipulated by the Helsinki Declaration for conducting research.

The research was not invasive and had no potential harm to both participants and facility where study was undertaken. A participant information leaflet (Appendix II) as well as written informed consent (Appendix III) accompanied each questionnaire which provided information on the research and researcher. After reading the information leaflet, nurses chose to complete questionnaire. The structured questionnaires were numbered, self-administered and participants were not expected to include their names. Hence, participants' anonymity and confidentiality was maintained. Completed questionnaires were stored in an envelope and safely kept in the researcher's personal cupboard which was access controlled.

Findings from this research will be communicated firstly to the research and ethics board of the institution under study. Furthermore, conferences and periodicals of the National Pharmacovigilance Centre and the Nursing and Midwifery Council Nigeria will be engaged in disseminating results of this research.

CHAPTER 4 - RESULTS

4.1 Introduction

The results chapter is divided into several sections, namely characteristics of nurses included in the study, their knowledge, attitudes and practice of ADR reporting, influence of education and training on ADR reporting and their recommendations for improving ADR reporting. An analytical component cross tabulating these variables is also presented. The identified study sample size was 124 and a sample of 123 nurses was realized. Oversampling by selecting 140 nurses with the intention of obtaining 124 eligible nurses was undertaken. Thus a response rate of 88% was realized.

4.2 Characteristics of Nurses

Table 2 shows characteristics of nurses in the study. Of the total number of nurses 86.2% (106) were female and 30.9% were thirty years of age or less and another 28.5% were between 31 and 40 years. Almost a third of the nurses qualified to practice nursing between 2011 -2015, while nurses that qualified from 1991–1995 were least represented. The majority of nurses, listed the Registered Nursing Degree, and B.Sc. Nursing as their highest qualifications, 39.8% (49) and 30.1% (37), respectively. One nurse (0.8%) each reported having a Master's and Doctorate Degree. Other qualifications were noted by 15 nurses and included diploma programmes and short-courses undertaken in the following fields and specialty areas: nursing science, basic science, pediatric nursing, ophthalmic nursing, dental nursing, hospital management science, accident and emergency, B.Sc. Management, B.Sc. Health Education and peri-operative nursing. Most nurses, 71 (57.7%), had practiced in a teaching hospital for less than one year to 10 years; while, those that had practiced for more than 30 years were the least represented 4 (3.3%). The vast majority of nurses, 84 (68.3%), reported working between 140-180 hours per month.

Table 2: Characteristics of nurses (N = 123)

Characteristic	n (%)
Gender	
Male	17 (13.8%)
Female	106 (86.2%)
Age Group (in years)	
≤ 30	38 (30.9%)
31- 40	35 (28.5%)
41 –50	24 (19.5%)
51- 60	26 (21.1%)
Year of Qualification	
1981-1985	12 (9.8%)
1986-1990	15 (12.2%)
1991-1995	10 (8.1%)
1996-2000	14 (11.4%)
2001-2005	22 (17.9%)
2006-2010	18 (14.6%)
2011-2015	32 (26.0%)
Highest Educational Qualification	
Registered Nursing	49 (39.8 %)
B.Sc. Nursing	37 (30.1%)
Midwifery License	20 (16.3 %)
Master Degree	1 (0.8 %)
Ph.D.	1 (0.8 %)
Other	15 (12.2%)
Number of Years of Practice	
<1 – 10	71 (57.7%)
11 – 20	32 (26.0%)
21 – 30	16 (13.0%)
>30	4 (3.3%)
Number of Working Hours per Month	
<140	18 (14.6%)
140-180	84 (68.3%)
>180	21 (17.1%)

Figure 1 shows the range of nursing cadres included in the study. The most senior professional cadre of nurse is the chief nursing officer cadre, whilst the least is the staff nurse, representing nurses undergoing the mandatory post-qualification internship programme. The highest representation of nurses was in the chief nursing officer cadre.

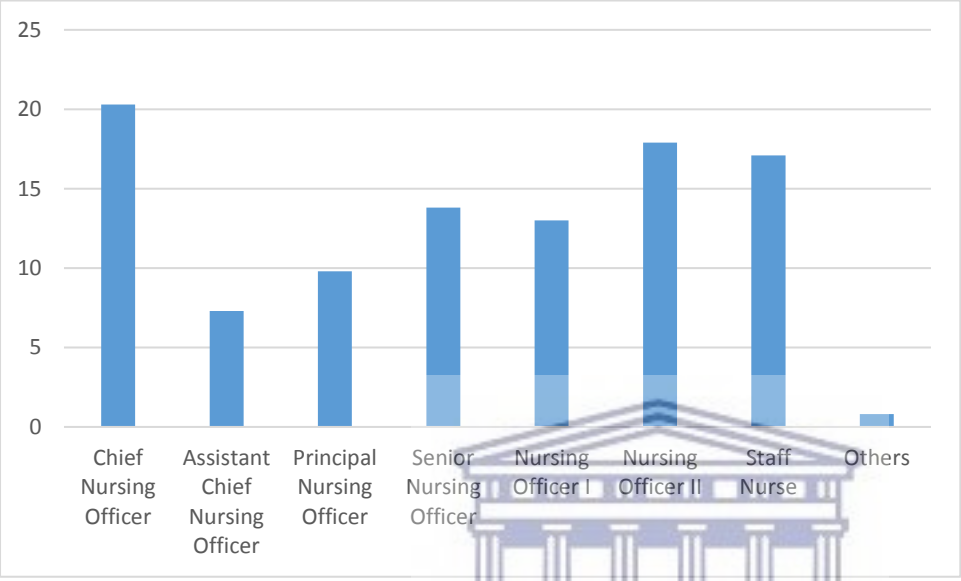

Figure 1: Percentage of professional cadres of nurses (N = 123)

Nurses positioned in wards attend to patients being managed in various departments and specialty areas. Hence, nurses were required to state not more than three departments or specialty areas of patients they attend to. Two hundred and forty-five responses were obtained from one hundred twenty-three nurses. Figure 2, shows that nurses attended to patients from all the departments and specialty areas except radio-diagnosis. More than half of the respondents 71 (57.7%), attended more frequently to surgical cases, while few nurses attended to patients in anesthetics, dentistry and oncology department.

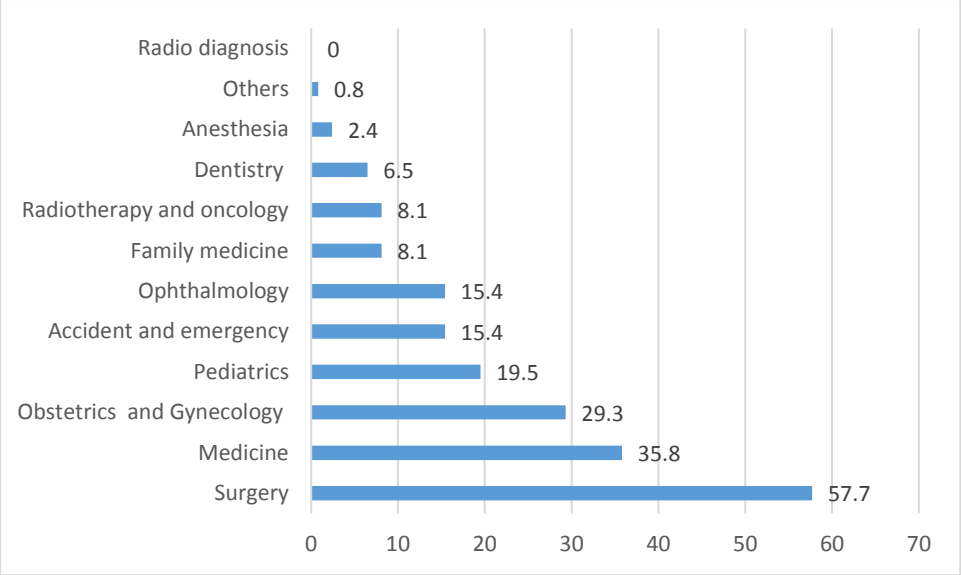

Figure 2: Percentage of departments/ specialty areas attended to by nurses (N =123)

4.3 Knowledge of ADR Reporting

Nurses' views of personnel qualified to report ADRs are shown in Table 3. Unsurprisingly, the majority of nurses, 101 (82.1%), stated that nurses were qualified to report ADRs whereas only 18 (14.6%) considered herbal practitioners as suitably qualified to report ADRs. Interestingly only 87 (70.7%) considered medical doctors qualified to reports ADRs.

Table 3: Persons qualified to report ADRs according to nurses (N = 123)

	Frequency n	Percentage %
Medical doctors	87	70.7
Dentists	47	38.2
Nurses	101	82.1
Pharmacists	79	64.2
Physiotherapists	22	17.9
Herbal medicine practitioners	18	14.6
Community health workers	53	43.1
Individual persons	57	46.3

Table 4 shows nurses' familiarity of pharmacovigilance and the ADR reporting system. The study found that 77 (62.6%) nurses reported familiarity with the pharmacovigilance terminology, while more than half of respondents stated awareness of the National Pharmacovigilance Centre as well as the Pharmacovigilance Centre within the institution under study. It was noteworthy that there were 37.4% non-responders on the awareness of the National Pharmacovigilance Centre and the institution-based Pharmacovigilance Centre.

Table 4: Nurses knowledge of the pharmacovigilance and ADR reporting system (N=123)

Knowledge of pharmacovigilance and ADR reporting	**Yes n (%)**	**No n (%)**	**No Response n (%)**
Familiarity with terminology 'Pharmacovigilance'	77 (62.6%)	46 (37.4%)	-
Awareness of the National Pharmacovigilance Centre (NPC)	63 (51.2%)	14 (11.4%)	46 (37.4%)
Awareness of the existence of Pharmacovigilance Centre in the institution under study (LUTH)	69 (56.1%)	8 (6.5%)	46 (37.4%)
Awareness of the standard yellow ADR reporting form for reporting ADRs in Nigeria	60 (48.8%)	63 (51.2%)	-

The study clarified nurses' familiarity with the terminology "pharmacovigilance" by requesting its definition in free text. Of the 77 (62.6%) nurses that stated familiarity with the concept, 53 (43.1%) attempted to give a definition and only 29 (23.6%) defined pharmacovigilance correctly (Table 5).

Table 5: Nurses' knowledge of the pharmacovigilance definition (N =123)

Knowledge of pharmacovigilance terminology	**n (%)**
Correct Definition; Activities and science of monitoring and reporting adverse drug reactions using the standard yellow ADR reporting form to the National Centre	29 (23.6%)
Good Idea; Defining the drugs as monitoring of drug reactions without mentioning the ADR terminology or Drug safety	21 (17.0%)
Incorrect; Included quality of drug	3 (2.4%)
No Response	71 (57.7%)

In assessing nurses' knowledge on ADR reporting, nurses were asked the identify agents for which ADRs should be reported. More than half (50.4%) of the nurses stated that ADRs should be reported on all the mentioned agents, however, less than 20% of nurses believed that ADRs should be reported on herbal medicines (Table 6).

Table 6: Nurses' knowledge of agents to report ADRs (N =123)

	N	**Percentage**
Vaccines	45	36.6
Herbal medicines	17	13.8
Over the counter (OTC) medicines	28	22.8
Antibiotics	48	39.0
Antimalarial	43	35.0
Topical agent	34	27.6
X-ray contrast media	25	20.3
Consumables medical products	19	15.4
All of the above	62	50.4

4.4 Attitudes towards ADR Reporting

This study employed a 5-point Likert scale to assess the attitudes of nurses towards ADR reporting, by inquiring factors that may encourage or discourage ADR reporting. The responses were merged to a three response-type which is shown in Table 7. The study found that 103 (83.7) nurses were encouraged to report ADRs if reactions were serious while only 68 (55.3) nurses stated that reactions to well recognized reactions would be reported. Nurses said that concern that report may be wrong (43.9%), lack of time to fill-in a report (45.5%) and level of clinical knowledge in identifying ADRs (43.9%) discourage them from reporting ADRs. While similar percentages of nurses stated that lack of remuneration (42.3%), reporting generating extra work (43.1%), fear of impact on company (42.3%) and reporting an already known ADR would not discourage them from ADR reporting. However, interestingly, nurses also stated that ADR reporting should be a professional obligation (62.6%) and should also be compulsory (73.2%).

Table 7: Factors encouraging or discouraging ADR reporting (N=123)

Attitude Variables	Strongly Agree/ Agree n (%)	Undecided n (%)	Strongly disagree/ Disagree n (%)	Non Response n (%)
Factors encourage ADR reporting				
If the reaction was serious	103 (83.7)	3 (2.4)	5 (4.3)	12 (9.6)
If the reaction was unusual	98 (79.7)	5 (4.1)	6 (4.9)	14 (11.3)
If the reaction was to a new product	96 (78.0)	7 (5.7)	5 (4.1)	15 (12.2)
If the reaction was well recognized for a particular drug	68 (55.3)	13 (10.6)	17 (13.8)	25 (20.3)
Factors discouraging ADR reporting				
Concern that report may be wrong	54 (43.9)	11(8.9)	39(31.7)	19 (15.5)
Lack of time to fill-in a report	56(45.5)	13(10.6)	34(27.6)	20 (16.3)
Non-remuneration for reporting	40(32.5)	12(9.6)	52(42.3)	19 (15.5)
Concern that reporting may generate extra work	39(31.7)	14(11.4)	53(43.1)	17 (13.8)
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	54(43.9)	13(10.6)	41(33.3)	15 (12.2)
Do not feel the need to report a known ADR	36(29.3)	11(8.9)	57(46.4)	19 (15.5)
Fear of the negative impact the report may have on the company	38(30.9)	12(9.8)	52(42.3)	21 (17.0)
Other attitude question				
ADR reporting should be a professional obligation for nurses	77(62.6)	9(7.3)	19(15.5)	18 (14.6)
Reporting only one ADR makes a significant contribution to the ADR reporting scheme	70(56.9)	12(9.8)	13(10.6)	28 (22.7)
ADR reporting should be compulsory	90(73.1)	6(4.9)	12(9.8)	15 (12.2)
ADR reporting should be voluntary	35(28.5)	5(4.1)	18(14.6)	65 (52.8)

4.5 Practice of ADR Reporting

With respect to the practice of ADR reporting, about 50% of nurses reported that they had encountered an ADR in the course of practice, whilst only 7 (5.7%) nurses had actually reported ADRs. However, the non-responders for both inquiries were 18.7% and 26% respectively (Table 8).

Table 8: Frequency of nurses' that have encountered and reported ADRs with the standard yellow ADR reporting form (N=123)

Variable	Response	N	%
Encountered ADRs in patient	Yes	62	50.4
	No	37	30.1
	No-response	23	18.7
	Total	123	100.0
	Response	**N**	**%**
Reported ADRs with the standard yellow form	Yes	7	5.7
	No	84	68.3
	No-response	32	26.0
	Total	123	100.0

Nurses stated that they had identified ADRs 66 times in a range of different medicines and Table 9 shows the top ten on the list of these medicines. Heading the list were sulphonamides, followed by penicillin and chloroquine.

Table 9: Medicines for which nurses have encountered ADRs (N=66)

Drugs	**n**	**%**
Sulphonamides	25	37.88
Penicillin	9	13.64
Chloroquine/Quinine	6	9.09
ACTs	4	6.06
Paracetamol	3	4.55
Quinolones	3	4.55
Benzodiazepines	2	3.03
Blood products	2	3.03
Chloramphenicol	2	3.03
Goserelin	2	3.03
Metronidazole	2	3.03
Others (Promethazine, Pyrantel Pamoate, Anti-Tetanus Toxoid, Tramadol, Analgin and Un-named Vaccine)	6	9.09
Total	**66**	**100**

4.6 Education and Training to improve ADR Reporting

Almost 30% of nurses stated that they had received training on pharmacovigilance in nursing school while only 17 (13.8%) had received training on how to report ADRs using the standard yellow form reporting scheme (Table 10).

Table 10: Frequency of nurses exposed to training on pharmacovigilance in nursing school and training on the yellow form ADR reporting scheme (N=123)

Variable	Response	N	%
Exposure to training on pharmacovigilance in nursing school	Yes	36	29.3
	No	68	55.3
	No response	19	15.4
	Total	**123**	**100.0**
Exposure to training on the standard yellow ADR reporting form	**Response**	**N**	**%**
	Yes	17	13.8
	No	77	62.6
	No response	28	22.8
	Total	**123**	**100.0**

4.7. Recommendations for improving ADR Reporting

A total of 77 (62.7%) nurses provided suggestions on possible ways of improving ADR reporting; The top three recommendations made were; training, public awareness and availability of the standard yellow ADR reporting forms. Other recommendations are documented in Table 11.

Table 11: Nurses suggestions on possible ways for improving ADR reporting (N=119)

Recommendations	**n**	**%**
Seminars, training and education	46	38.6
Public awareness using print and mass media	28	23.5
Availability of standard yellow ADR reporting forms	11	9.2
Pharmacist clinical rounds	5	4.2
Prompt feedback	4	3.4
Remuneration	4	3.4
Increase man-power	3	2.5
Prompt and urgent reporting	3	2.5
Establishment of PV committee in hospital	2	1.7
Include in patient case note/ documentation	2	1.7
Investigation of report and follow-up	2	1.7
Others: Concise standard yellow ADR reporting form Free ADR management in hospital Integrating PV in private practice Non-stigmatization of reporter, regulatory authority involvement, Proper patient profiling before drug administration, Stop self-medication, telephone reporting and accessibility of reporting centres	9	7.6
Total	**119**	**100%**

4.8 Comparative Analysis of Variables

This study incorporated an analytical component using the cross tabulation to compare critical variables, which included comparisons between nurses that have ever reported an ADR using the standard yellow ADR reporting form with a range of variables.

Table 12 presents the p-values and chi-square values obtained when the relationships between nurses that have reported ADRs and four knowledge and training variables were tested. The statistical test of significance for association is accepted when the p-value <0.05.

Table 12: Comparisons of nurses that have ever reported an ADR using the yellow form with range of variables

Variable		Ever reported an ADR using the standard yellow form		n	Pearson Chi-square value	p-value
		Yes	No			
Ever received PV training in nursing school	**Yes**	4 (13.3%)	26 (86.7%)	n=88	3.041	0.081
	No	2(3.4%)	56 (96.6%)			
Ever received training on how to report ADR using the standard yellow form	**Yes**	3 (21.4%)	11 (78.6%)	n=82	**6.930**	**0.008**
	No	2 (2.9%)	66 (97.1%)			
Familiarity with PV terminology	**Yes**	6 (10.3%)	52 (89.7%)	n=75	1.912	0.167
	No	0	17 (100%)			
Awareness of the ADR reporting system in Nigeria	**Yes**	**3 (6.7%)**	**42 (93.3%)**	n=79	0.128	0.720
	No	**3 (8.8%)**	**31 (91.2%)**			

The p-values presented in Table 12 revealed that there was no significant association between nurses who had reported ADRs and those who had received PV training in nursing school (p=0.081). Similarly, no statistically significant association was identified neither between nurses who had reported ADRs and those who reported familiarity with the PV terminology (p=0.167), nor nurses who reported ADRs and those with awareness of the yellow form reporting system (p=720). While, comparing nurses who reported ADRs with those who had received training on

how to report ADRs using the standard yellow ADR reporting form, the association between these variables was found to be statistically significant (p=0.008). The results revealed that nurses who had not received training on how to report ADRs using the standard yellow ADR reporting form were more likely not to report ADRs. Therefore, in this study training on ADR reporting was positively associated to ADR reporting.

CHAPTER 5 - DISCUSSION

This chapter discusses the main findings of the study which assessed ADR reporting amongst nurses in a tertiary hospital in south-west Nigeria. Overall, the study found poor knowledge and practices of ADR reporting amongst nurses whilst at the same time found positive attitudes towards reporting. Factors affecting ADR reporting amongst nurses are also discussed as well as the impact of training and education on ADR reporting. The results are compared to similar studies conducted amongst nurses in other settings. A key finding of the study was that nurses who had not received training on ADR reporting using the standard yellow form were not likely to report ADRs. Considering nurses' roles in patient care and safety, it is critical to have a clear understanding of their knowledge, attitudes and practice towards ADR reporting (Ammouri, Tailakh, Muliira, Geethakrishnan & Kindi, 2015).

5.1 Nurses' Knowledge of ADR Reporting

Nurses' displayed a poor knowledge of pharmacovigilance and the ADR reporting system with only 51.2% reporting familiarity with the National Pharmacovigilance Centre, 56.1% aware of the institution-based Pharmacovigilance Centre and 48.8% aware of the standard yellow ADR reporting form . Although more than 60% of nurses stated familiarity with the 'pharmacovigilance terminology' only 23.6% were able to give a correct definition of 'pharmacovigilance'. These results are similar to those found in a studies among and nurses in India and Iran (Hanafi et al. 2012; Padmavathi et al. 2013). Contrarily, John et al. (2012) and Gupta et al. (2015) reported that 83.5% and 62.4% nurses respectively identified the correct definition of PV and ADR among a list of options. Possibly, if nurses in the afore-mentioned two studies were required to define PV or ADR in free text, the results might have been more comparable with this and the other identified studies.

With respect to the knowledge of the ADR reporting procedures and existence of centres, other studies also reported inadequate knowledge of the ADR reporting schemes. Similar figures to this study were reported in a study conducted in Nigeria among other health professionals which found that 39.0% doctors in private practice, 32.3% doctors in tertiary facilities, 44.6% health workers and 35.9% community pharmacists were knowledgeable of the ADR reporting scheme in Nigeria respectively (Awodele et al. 2011; Oshikoya & Awobusuyi 2009; Fadare et al. 2011; Oreagba et al. 2011).

Given that the tertiary hospital which is the study was conducted is a Zonal Pharmacovigilance Centre and has an institution-based multi-disciplinary Pharmacovigilance Committee, it appears that nurses' representation on the institutions' multidisciplinary pharmacovigilance committee has not sufficiently increased overall knowledge of ADR reporting amongst nurses. Furthermore, being the nucleus of all pharmacovigilance activities in the region, it could be expected that pharmacovigilance awareness would trickle down from this facility to other facilities within the zone. Regrettably, the poor knowledge observed among nurses in this study portends a poor knowledge of pharmacovigilance among nurses in other health facilities in the zone.

5.2 Nurses' Attitudes towards ADR Reporting

In this study, the overall attitude of nurses towards ADR reporting was observed to be positive. This is deduced from the findings that 82.1% nurses stated that nurses are qualified to report ADRs, 62.6% agreed ADR reporting was a professional obligation and 73.1% asserted that ADR report should be mandatory. Several other studies have reported positive attitudes of nurses towards ADR reporting (Pulford & Malcolm 2010; Rehan et al. 2012; Hanafi et al. 2012; Fadare et al. 2011). A study conducted in northern Nigeria, reported that respondents; comprising nurses and pharmacists, were enthusiastic towards ADR reporting (Umar et al. 2016). In Rehan et al. (2012) study, all nurses stated ADR reporting to be important and other studies revealed that 78.3%, 97% , 94% and 96.2% nurses stated ADR reporting as necessary and essential (Padmavathi et al. 2013; Gupta et al. 2015; Ganesan Vikneswaran, Reddy, Subrahmanyam & Adithan. 2016; Terblanche et al. 2017). Furthermore, Ganesan et al. (2016) reported that 67% nurses researched in south India identified ADR reporting as a professional obligation; which is comparable to findings from this study.

Other studies from the United Kingdom and Bangalore, India also reported that 60% and 95% nurses agreed that ADR reporting be mandatory (Pulford & Malcolm 2010; Padmanvathi et al. 2013), whilst in Nigeria, as with many other countries, ADR reporting is voluntary for healthcare professionals (NAFDAC, 2008). Hence, further studies may be required to explore the possibility of mandatory ADR reporting system for healthcare professionals in Nigeria. However, an analysis of the spontaneous reporting system in Europe reported that the legal obligation of health practitioners to report ADRs did not positively impact on reporting activity (Srba et al. 2012).

Although this study did not compare nurses' attitudes to knowledge and practice of ADR reporting, other studies including that of John et al. (2012) observed a positive correlation between knowledge and attitudes. In addition, Umar et al. (2016) observed professional experience to be related to attitude towards ADR reporting. Notwithstanding, the generally positive attitude displayed by nurses in the studies reviewed suggest nurses' appreciation of the importance of ADR reporting as well as an acceptance of their strategic role in the system. Hence, this should be exploited in improving ADR reporting amongst nurses.

5.3 Nurses' Practice of ADR Reporting

Despite the overall positive attitude displayed by nurses' towards ADR reporting, only half of the respondents reported ever encountering ADRs in the course of practice, while less than 10% had ever reported ADRs. Under-reporting appears to be a global problem as all the studies reviewed revealed poor ADR reporting among nurses. Reporting rates ranged from 2.4%, 2.9%, 8.8%, 9%, 14% to 22.8% respectively (Alan et al. 2013; Li et al. 2004; John et al. 2012; Hanafi, Torkamandi, Hayatshahi, Gholami, Shahmirzadi & Javadi. 2014; Ekman, Petersson, Tågerud & Bäckström. 2012; Gupta et al. 2015). In comparison with other health professionals, a study in Portugal found that nurses reported smaller numbers but more serious ADRs (Mendes et al. 2014). Only one study reported a high reporting rate among nurses. This study was conducted in northwest Nigeria among resident doctors and nurses and revealed that 75% (14) of nurses had encountered and also reported ADRs (Fadare et al. 2011). The Fadare et al. (2011) study had a small sample size and adopted a convenience sampling method; hence the result obtained may not be truly representative. Furthermore, a review of ADR reports submitted to the National Pharmacovigilance Centre from its onset in 2004 till 2013 revealed that only 1.85% of ADRs were reported by nurses (NPC: NAFDAC Database. 2014). The reality of under-reporting of ADRs among nurses in this setting is apparent.

The peculiarities of the Nigerian environment demand that nurses play a critical role in promoting public health through ADR reporting. In addition to being highly populated, Nigeria is a country largely dependent on imported medicines with limited investment in pharmaceutical research and development (Erhun et al. 2001; Pharmanews. 2017). Hence, majority of the new drug molecules distributed in Nigeria depend on drug information from empirical data, anecdotes and clinical trials undertaken in other black populations. Given this background, the national policy on pharmacovigilance was developed to address the dearth in drug information. Hence, in addition to promoting ADR reporting, the policy document ensures documentation of medication errors,

medicine interaction, abuse/misuse of medicines, counterfeit medicines, and lack of effectiveness of medicines (FMOH, 2011). For public health to benefit from this system, nurses; being the most populous health professional in the hospital setting and also the health personnel closest to the patients; must actively participate in identifying and documenting medicine-related problems thereby promoting rational use of medicines.

Interestingly, nursing practice has a system in place; which if fully implemented and integrated, is capable of significantly impacting the practice of ADR reporting. The system is called the nursing process. Kozier et al. (2008, as cited in Onyemenam, 2013:1) defines the nursing process as a "patient-centred and scientific method of problem solving for structuring the nursing care in order to achieve a maximum level of change towards the expected outcome". This process is strongly hinged on documentation and it involves assessment of patient problems and evaluation of expected and unexpected responses following medicine administration. While, the concept of nursing process is beyond the scope of this study, further studies will be required to demonstrate its impact in ADR reporting practices. This aspect of nursing best practices should be explored in designing strategies towards improving ADR reporting.

5.4 Key Factors Affecting Nurses' ADR Reporting

This study found that nurses were more likely to report if ADRs are serious, unusual and/or resulted from new drug products. This finding is similar to studies conducted by Li et al. (2004), John et al. (2012), Ekman et al. (2012) and Katusiime, Semakula & Lubing, (2015). On the other hand, the study revealed that nurses' level of clinical knowledge in identifying ADRs, concern that report may be wrong and lack of time to fill-in a report form were the key factors discouraging ADR reporting among nurses. Again, similar findings were reported by John et al. (2012) in a study conducted among nurses in United Arab Emirates and by Zurita-Garaicoechea et al. (2015) in a systematic study undertaken on ADR reporting in Spain. In addition to lack of knowledge, Li et al. (2004) reported non-availability of reporting forms and the lack of contact address of the National Centre as discouraging ADR reporting. Also, in a study undertaken in Nigeria, lack of an electronic reporting procedure was further identified as discouraging ADR reporting (Ezeuko et al. 2015). In this study poor clinical knowledge of ADRs appears to be the key factor undermining ADR reporting among nurses. Hence, incorporating case studies into the questionnaire (Oshikoya & Awobusuyi 2009) or assessing ADR reports submitted by nurses (Mendes et al. 2014; Ranganathan, Houghton, Davies & Routledge. 2003; Conforti et al. 2012)

may provide insight into nurses' clinical knowledge of ADRs and further assess nurses' ability to identify and report ADRs.

Nonetheless, nurses' ability to identify ADRs may be inferred from the drugs for which nurses stated ever encountering or reporting ADRs. Over 90% of drugs for which nurses' stated ever encountering or reporting ADRs on, were on well established, widely recognized and documented reactions of medicinal products with a long history of use and for which extensive research exist. Such medicines include; first generation antibiotics (sulphonamides, penicillins, quinolones) antimalarials and analgesics. This agrees with findings observed from a study that assessed the quality and quantity of ADR reports submitted by nurses in the Italian ADR database (Conforti et al. 2012). The study reported that nurses were more likely to report ADRs related to drugs they are more familiar with, such as analgesics and benzodiazepines (Conforti et al. 2012). Hence, the ability of nurses to identify ADRs related to more complex or newer drug molecules is doubtful. Possibly, nurses may attribute actual new ADRs with disease progression since their clinical knowledge on ADR of new medicines is inadequate. Perhaps, in further recognition of nurses' relative poor knowledge of drug safety, Ekman et al. (2012) suggested that nurses be integrated in the reporting system in order to improve their biological and pharmacological knowledge of drugs. Hence, nurses' participation in the ADR reporting scheme would in addition to boosting ADR reports, increase nurses' clinical knowledge of medicines and drug safety.

Lack of time to complete a report was also identified as a key factor discouraging nurses from submitting an ADR report in this study and this was supported by several other studies (Datta & Sangupta 2015; Gupta et al. 2015; Katusiime, Semakula & Lubing, 2015). To assess the possible impact of workload on ADR reporting, data on the average number of working hours per month of nurses in this study was collected; however, given the descriptive nature of this study, relationship between these variables was not explored. Regardless, studies have identified the negative impact of a high workload on patient care and safety (Berry & Curry 2012). Any long term intervention designed to improve patient safety by improving ADR reporting would require addressing the challenge of huge workload.

An interesting finding in this study was the professional experience of nurses that participated in this study; which was assessed from data collected on number of years of practice, cadre, age and year of qualification. In this study, over a third of nurses were below thirty years and more than

half of the nurses had practiced for ten years and less. Furthermore, almost fifty percent graduated in the last ten years and more than sixty percent of the nurses belonged in the lower professional cadre. From these findings, it may be construed that majority of nurses that participated in this study are relatively inexperienced. Due consideration should be given to the impact of nurses' professional experience on ADR reporting. Several studies have identified the potential impact of professional experience on ADR reporting. Ekman et al. (2012) observed that nurses with lesser experience were less knowledgeable about how and when to report ADRs. In a study conducted among Spanish pharmacists, it was observed that older pharmacists with longer work experience and that were participants in a continuing education programme were more likely to report ADRs (Irujo et al. 2007). A study conducted in Uganda among health workers revealed that health workers with 10 years' experience were four times more likely to report ADRs than those with five years' experience and below (Katusiime, Semakula & Lubing, 2015). Similarly, a study conducted among nurses and pharmacists in northern Nigeria revealed that professional experience appeared to be related to a positive attitude towards ADR reporting (Umar et al. 2016). Furthermore, a study conducted among doctors in private practice in Lagos; south-west Nigeria, also reported professional experience to be related to ADR reporting (Awodele et al. 2011). These findings may be consequent on the fact that senior professionals (higher cadre), by virtue of their position, may be exposed to more educational interventions. Whereas, in this study, the uneven distribution may imply that younger and less experienced nurses agreed to participate in this study rather than older and more experienced nurses, it may also reflect the actual distribution of nurses involved in clinical nursing practice in the facility under study.

In an extensive discourse presented on the challenges of nursing profession in Nigeria, Ibiyosi (2011) identified non-transference of experience by the senior nurses to the younger nurses as a major challenge plaguing the nursing practice in Nigeria. According to him, senior nurses leave professional care to student nurses or pupil midwives and the most experienced nurses, by virtue of their senior position, retire into administrative duties, hence are not available to transfer their wealth of experience and exposure imbibed over the years to younger nurses (Ibiyosi, 2011). He thereafter recommended that for nursing experience to positively impact patient outcomes all cadres in the nursing practice must be involved and committed to clinical practice. Ammouri et al. (2015) proposed the establishment of a mentorship programme to provide an opportunity for experienced nurses to teach, mentor and model patient safety culture to novice nurses Such recommendations could indirectly boost ADR reporting among nurses.

5.5 Training and Education of Nurses on ADR Reporting

In this study, nurses' exposure to training on the standard yellow form ADR reporting scheme was observed to be low. This finding is similar to that of studies conducted among health workers in south-eastern Nigeria (Ezeuko et al. 2015), Sudan (Elnour et al. 2009), doctors in Ghana (Sabblah et al. 2014) and nurses in Sweden (Ekman et al. 2012). Lopez-Gonzalez et al. (2015) opines that doctors; being the head of the medical team, continue to be an important pillar of spontaneous reporting of ADRs worldwide, and are therefore the main target of educational programmes in pharmacovigilance. It may be inferred that nurses in this study may have been covertly marginalized in exposure to training opportunities on pharmacovigilance and ADR reporting. This study also revealed that nurses who had not received training on the standard yellow form reporting system were more likely not to report ADRs ($p=0.008$). Furthermore, this study revealed that majority of nurses stated training and education as the key recommendation for improving ADR reporting. Similarly, Zurita Garaicoechea et al. (2015) identified education and training, as one of the main strategies required to encourage ADR reporting. Several studies have corroborated training as a key strategy for improving ADR reporting (John et al. 2012; Irujo et al. 2007; Sabblah et al. 2014). A study conducted in northwest Spain revealed that introducing an educational intervention to improve ADR reporting among doctors resulted in almost 70% increase in ADR reporting within eight months of initiating intervention (Lopez-Gonzalez, Herdeiro, Piñeiro-Lamas & Figueiras, 2015). Also, noteworthy is a study conducted among health workers in two rural communities in Mozambique in which fourteen months after the first training health workers had reported 67 ADRs to the National Pharmacovigilance Unit (Sevene et al. 2008). Although, in this study the training was supplemented with quality assurance visits as well as an onsite focal person who facilitated communication with the National Pharmacovigilance Unit. Hence, researchers in several studies have consistently adopted educational interventions in a bid to improve ADR reporting (Bäckström et al. 2007; Hanafi et al. 2014). Although, Johansson-Pajala et al. (2015) maintain that education alone does not guarantee an increase in pharmacovigilance activities (Johansson-Pajala, Martin, Fastbom & Jorsäter Blomgren, 2015), nonetheless, sufficient evidence exists from numerous studies on the positive impact of training on ADR reporting among nurses and other healthcare professionals (Hall et al. 1995; Bäckström et al. 2007; Lopez-Gonzalez et al. 2015).

In this study almost 40% nurses obtained the Registered Nursing Certificate as the highest educational qualification. Registered Nursing is a three-year school of nursing certificate

programme which has no equivalence to any higher institution qualification in Nigeria and qualifies nurses to practice in any health institution (Ojo, 2010; Olabisi, 2015). This may bring into question the adequacy of the nursing training programme in enabling nurses to report ADRs. This study also revealed that only one nurse had a masters and a doctorate degree. This presents a poor projection of educational exposures among nurses. The highest qualification attained by nurses has been found to be a strong predictor of nurses' educational exposure with some studies suggesting educational qualifications of healthcare practitioners are linked to knowledge and reporting of ADRs. Such studies include those conducted among prescribers (Desai et al. 2011), doctors (Awodele et al. 2011) and hospital pharmacists (Jarernsiripornkul et al. 2009). Among nurses, Alan et al. (2013) revealed that knowledge of ADR reporting was higher among nurses with degrees. Similarly, in a study conducted among nurses and pharmacists in north-west Nigeria, the impact of respondent qualification on ADR reporting was found to be significant (Umar et al. 2016). Studies have therefore posited low level of education among nurses to be a major challenge plaguing the nursing practice in Nigeria (Ojo, 2010; Afoi, Emmanueul, Garba, Gimba & Afuwai. 2012; Olabisi, 2015).

5.6 Limitations

Since the research was conducted in only one setting, findings may not be generalized to other contexts although the study does provide evidence to facilitate further research in similar settings. Being a cross sectional study, this research cannot provide definite relationships between nurses' characteristics, knowledge variables, attitudinal variables and practice variables collected. Hence, more research is required to investigate temporal relationship and strength of association between these variables. Finally, despite the measures incorporated to minimize bias, given the study sample size and sampling method adopted, this study is prone to recall, social desirability and selection bias.

CHAPTER 6 - CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

This study revealed poor knowledge, positive attitudes and poor practice of ADR reporting among nurses in a tertiary hospital in south-west Nigeria. This is of concern given that nurses play a key role in medicine administration and safety monitoring and are the health professional in closest contact with patients. Nurses in this study possessed an inadequate knowledge of the National Pharmacovigilance Centre and the yellow form reporting system in Nigeria. However, they displayed an acceptance of professional responsibility towards ADR reporting and a willingness to report ADRs when encountered. This study found lack of clinical knowledge, fear that report may be wrong and lack of time in completing a report as the key factors that discourage nurses from reporting ADRs, whilst severity of an ADR and reactions to a new drug were identified as factors that encouraged nurses to report ADRs.

Nurses' exposure to training on the standard yellow ADR reporting form was observed to be low. This study adopted an analytical component which compared ADR reporting with knowledge and training variables and found no statistically significant association between ADR reporting and familiarity with pharmacovigilance terminology, awareness of the standard yellow ADR reporting form and PV training in nursing school. However, a key finding of this study was that nurses who had not received training on the standard yellow ADR reporting form were more likely not to report ADRs. However, further research which includes an educational intervention block could provide evidence to substantiate the positive impact of training on ADR reporting among nurses. Such studies could also include clinical case studies in addition to analyzing ADR reports submitted by nurses.

Nurses in this study highlighted training, increasing awareness on Pharmacovigilance/ADR reporting and ensuring availability of ADR reporting forms as ways to improve ADR reporting among nurses. Other recommendations included participation of pharmacists' in clinical ward rounds, prompt feedback on ADRs reported to the PV Centre and increased nurses' remunerations.

6.2 Recommendations

Several recommendations are proposed to improve ADR reporting amongst nurses in the institution under study by increasing their knowledge of pharmacovigilance and the ADR reporting system.

1. Establishment of structured education and training programmes for nurses on drug safety and ADR reporting. In addition, all cadres of nurses, especially those involved in drug administration and patient monitoring, should be exposed to clinical presentations on new drug molecules, as this may increase nurses' clinical knowledge of ADRs.

2. In partnership with the institutional head, the institution-based Pharmacovigilance Centre should establish a system that ensures constant availability of ADR reporting forms in all wards. The Centre should also sustain awareness on pharmacovigilance and ADR reporting via various publications such as leaflets, fliers and posters.

3. Further research that employs a larger sample size and conducted at several clinical settings, such as private hospitals and secondary health facilities should be undertaken. In addition, studies that assess nurses' actual clinical knowledge of ADRs and intervention studies to determine the impact of education and training on ADR reporting are also recommended.

4. Finally, the National Pharmacovigilance Centre (NPC) as part of its mandate should undertake pharmacovigilance advocacy and sensitization programmes among relevant stakeholders such as Federal Ministry of Health, Nursing and Midwifery Council of Nigeria and academic institutions. These advocacy visits should recommend the inclusion of pharmacovigilance concepts and the ADR reporting system in the pre-qualification and post-qualification nursing curricula. In addition, the Nursing and Midwifery Council, should ensure the inclusion of ADR reporting as part of the nursing process documentation in all health facilities. It is hoped that these initiatives may contribute towards the long term institutionalization of ADR reporting among nurses.

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APPENDICES

Appendix I Data Collection Tool: Questionnaire

HRC NO: ADM/DCST/HREC/APP/039

KNOWLEDGE, ATTITUDES AND PRACTICES OF ADVERSE DRUG REACTION (ADR) REPORTING AMONG NURSES IN A TERTIARY HOSPITAL IN SOUTH WEST NIGERIA

SN: **Date:**

Name of Data Collector: .....

Signature: .....

1. Demographics

1.1. Age (please tick)

- ❑ ≤ 30
- ❑ 31 – 40
- ❑ 41 - 50
- ❑ 51 – 60
- ❑ > 60

1.2. Gender? (a) male (b) female

1.3. Which year did you qualify as a Nurse……(specify)

1.4. Highest Degree obtained

- ❑ Registered Nurse (RN)
- ❑ Masters Degree
- ❑ B. Sc Nursing
- ❑ Ph. D
- ❑ Midwifery license
- ❑ Others(Specify)……

1.5. How many years have you practiced in a teaching hospital? ……. (specify)

1.6. How many hours do you work per month…….(specify)

1.7. Which patients do you attend most usually to? (tick top three departments)

- ❑ medicine
- ❑ surgery
- ❑ obstetrics and gynecology
- ❑ pediatrics
- ❑ family medicine
- ❑ accident and emergency
- ❑ Others (specify)……
- ❑ Ophthalmology
- ❑ radio diagnosis
- ❑ radiotherapy and oncology
- ❑ anesthesia
- ❑ dentistry

1.8. Current position/level (a) Assistant Director (b) Chief Nursing Officer (c) Assistant Chief Nursing Officer (d) Principal Nursing Officer (e) Senior Nursing Officer (f) Nursing officer I (g) Nursing officer II (h) Staff Nurse (i) Others (specify)……

2. Knowledge of ADR Reporting

2.1. Which of the following person (s) do you think is (are) qualified to report adverse drugs reactions? (tick all that apply)

- ❑ medical doctors
- ❑ dentists
- ❑ nurses
- ❑ pharmacists
- ❑ physiotherapists
- ❑ herbal medicine practitioner
- ❑ community health worker
- ❑ individual persons

2.2. Are you familiar with the terminology 'Pharmacovigilance'? (a) yes (b) no

2.3. If yes to 2.2 above, what does it mean?.....

……

……

2.4. Are you aware of the existence of the National Pharmacovigilance Centre (NPC) in Nigeria? (a) yes (b) no

2.5. Are you aware of the existence of a Pharmacovigilance centre in LUTH (a) yes (b) no

2.6. Are you aware of the yellow form reporting scheme for reporting ADRs in Nigeria? (a) yes (b) no

2.7. For which of the following agents should ADRs be reported (tick all that apply)

- ❑ vaccines
- ❑ herbal medicines
- ❑ over the counter (OTC) drugs
- ❑ antibiotics
- ❑ antimalarials
- ❑ topical agents
- ❑ X-ray contrast media
- ❑ Consumables medical products
- ❑ all of the above

3. Attitudes to reporting ADRs (circle appropriate scale)

(1 – Strongly Agree; 2 – Agree; 3 – Undecided; 4 – Disagree; 5 – Strongly Disagree)

3.1. Factors that may encourage you to report an ADR

❑ if the reaction was serious	[1]	[2]	[3]	[4]	[5]
❑ if the reaction was unusual	[1]	[2]	[3]	[4]	[5]
❑ if the reaction was to a new product	[1]	[2]	[3]	[4]	[5]

- ❑ if the reaction was well recognized for a particular drug [1] [2] [3] [4] [5]

3.2. Factors that may discourage you from reporting an ADR?

- ❑ Concern that the report may be wrong [1] [2] [3] [4] [5]
- ❑ Lack of time to fill-in a report [1] [2] [3] [4] [5]
- ❑ Non-remuneration for reporting [1] [2] [3] [4] [5]
- ❑ Concern that reporting may generate extra work [1] [2] [3] [4] [5]
- ❑ Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred [1] [2] [3] [4] [5]
- ❑ Do not feel the need to report a known ADR [1] [2] [3] [4] [5]
- ❑ Fear of the negative impact the report may have on the company that produced or marketed the drug. [1] [2] [3] [4] [5]

3.3. ADR reporting Should be a professional obligation for nurses [1] [2] [3] [4] [5]

3.4. Reporting only one ADR makes a significant contribution to the yellow form reporting scheme [1] [2] [3] [4] [5]

3.5. ADR reporting should be:

- ❑ compulsory [1] [2] [3] [4] [5]
- ❑ voluntary [1] [2] [3] [4] [5]

4. Practice of ADR Reporting

4.1. Have you ever come across an ADR in a patient? (a) yes (b) no

4.1.1. If yes to 4.1 above;

a. Name(s) of drug(s): …….

b. Reaction(s) observed: ……..

4.2. Have you ever reported an ADR using the yellow form (a) yes (b) no

4.2.1. If yes to 4.2 above,

a. How many? ……

b. Name(s) of drug(s)? .....

c. Route of Administration (a) Oral (b) IV (c) IM (d) Topical (e) SC (f) Others……

d. What was (were) the reaction(s)? .....

4.2.2. If yes to 4.2, was the information on the yellow form very clear to you about what to report? (a) yes (b) no

5. Education and training/improving ADR reporting

5.1. Did you receive training on Pharmacovigilance in nursing school (a) yes (b) no

5.2. Have you ever been trained on how to report ADR with a yellow form? (a) yes (b) no

5.2.1. If yes to 5.2 above, then

a. When? .....(specify date; day, month/year if possible)

b. Where/ name of programme/course? .....

c. By whom/ which organization? .....

d. Duration ……..(how many hours, days, weeks or months)

5.3. Suggest possible ways of improving ADR reporting (please list as many points as possible)

……

……

……..

……..

Appendix II Participant Information Sheet

FACULTY OF COMMUNITY AND HEALTH SCIENCES
School of Public Health

Private Bag X17, Bellville, 753
South Afric
Tel: +27 (0) 21 959 2809/216
Fax: +27 (0) 21 959287
Email: soph-comm@uwc.ac.za Website
http://www.uwc.ac.za/faculties/chs/sop

INFORMATION SHEET

Project Title: Knowledge, Attitudes and Practices of Adverse Drug Reaction (ADR) Reporting Among Nurses in a Tertiary Hospital in South West Nigeria

This is a research project being conducted by Osho F. M, a Pharmacist working with National Agency for Food and Drug Administration and Control (NAFDAC) in fulfilment of requirements for completing a Master in Public Health at the University of the Western Cape. We are inviting you to participate in this research project because you are a nurse working in Lagos University Teaching Hospital; the facility under study. The purpose of this research project is to describe the knowledge, attitude and practice of ADR reporting among nurses.

You will be required to complete a self-administered questionnaire involving questions on socio-demographics, knowledge of, attitudes to and the practice of ADR reporting. This questionnaire would be administered to you while at work and a maximum of twenty minutes would be required for completion.

We will do our best to keep your personal information confidential. To help protect your confidentiality, the questionnaires will be numbered and you will not be expected to put your name. Even the researcher will not be able to match participants with questionnaire filled. Hence, your anonymity and confidentiality will be maintained.

There are no known risks associated with participating in this research project.

This research is not designed to help you personally, but the results may help the investigator learn more about the potential role of nurses in promoting drug safety through ADR reporting. We hope that, in the future, other people might benefit from this study through improved understanding of nurses' role in ADR reporting and Pharmacovigilance. Furthermore, sequel to implementation of recommendations

proposed from this study, avenues for training and capacity building of nurses may be specified; which could consequently improve the quality of healthcare delivery provided by nurses in this institution.

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

This research is being conducted by Osho F. M, School of Public Health at the University of Western Cape. If you have any questions about the research study itself, please contact: Osho F. M, at Number 77, Lagos Street, Ebute-metta, Lagos, Telephone no: 234-8133037868, E-mail address: folaosho286@gmail.com.

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Director:

Prof Helene Schneider

School of Public Health

University of the Western Cape

Private Bag X17

Bellville 7535

hschneider@uwc.ac.za

Appendix III Consent Form

CONSENT FORM

Title of Research Project: KNOWLEDGE, ATTITUDES AND PRACTICES OF ADVERSE DRUG REACTION (ADR) REPORTING AMONG NURSES IN A TERTIARY HOSPITAL IN SOUTH WEST NIGERIA

The study has been described to me in language that I understand and I freely and voluntarily agree to participate.

My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name……..

Participant's signature…….

Date…..

Appendix IV UWC Senate Research Committee Ethical Clearance

UNIVERSITY of the
WESTERN CAPE

OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

29 January 2015

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Mrs FM Osho (School of Public Health)

Research Project:	The knowledge attitudes and practices of adverse drug reaction reporting among nurses in a Tertiary Hospital in South West Nigeria
Registration no:	14/10/44

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Private Bag X17, Bellville 7535, South Africa
T: +27 21 959 2988/2948 . F: +27 21 959 3170
E: pjosias@uwc.ac.za
www.uwc.ac.za

Appendix V Letter of Permission to Undertake Research in Facility

77, LAGOS STREET,
EBUTE METTA,
LAGOS.
19TH FEBRUARY, 2015

THE CHAIRMAN,
HEALTH RESEARCH ETHICS COMMITTEE,
LAGOS UNIVERSITY TEACHING HOSPITAL,
IDI-ARABA,
LAGOS.

Dear Sir,

PERMISSION TO UNDERTAKE RESEARCH AMONG NURSES IN YOUR FACILITY

In fulfilment of requirements for completing a Master in Public Health (MPH) at the University of Western Cape, South Africa, I, Osho Folasade Monisola, a Pharmacist working with National Agency for Food and Drug Administration and Control (NAFDAC) request permission to undertake a research in your most prestigious institution.

The research is intended to explore the "**Knowledge, Attitudes and Practices of Adverse Drug Reaction (ADR) Reporting among Nurses in a Tertiary Hospital in South West Nigeria".** Data for this research will be collected via self-administered structured questionnaires comprising questions on socio-demographics, knowledge of, attitudes to and the practice of ADR reporting.

This research is not invasive and poses no known risks or potential harm to both participants and your facility. Rather, potential benefits accrued from participating in this research include an increase awareness on the importance of ADR reporting amongst nurses in your facility with the aim of boosting safety monitoring of medicines.

This research has been approved by the University of the Western Cape's Senate Research Ethics Committee.

Please, find attached copies of the following:

a. The research protocol
b. Questionnaire
c. Letter of consent
d. Notification of supervision by an Institutional consultant

I look forward to a favorable response.

Yours faithfully,

Osho F. M (Mrs)
folamonisola@yahoo.com
08133037868, 08059243642

Appendix VI Approval to Undertake Research by Facility Health Research and Ethics Committee

LAGOS UNIVERSITY TEACHING HOSPITAL

HEALTH RESEARCH AND ETHICS COMMITTEE

PRIVATE MAIL BAG 12003, LAGOS, NIGERIA

e-mail address: luthethics@yahoo.com

Chairman
PROF. N. U. OKUBADEJO
MB, ChB, FMCP

Administrative Secretary
MR. D. I. AKPAN
B.Sc. BUS. ADMIN, MPHSAN

Chief Medical Director
PROF. AKIN OSIBOGUN
FMCPS (Lagos), MPH (Columbia), FMCPS, FWACS

Chairman, Medical Advisory Committee
DR. M. O. OGUNLEWE
BDS, FWACS

LUTH HREC REGISTRATION NUMBER: NHREC: 19/12/2008a
Office Address: Room 107, 1st floor, LUTH Administrative Block
Telephone: 234-1-5810737, 5852187, 5852208, 5852158, 5852111

25th February, 2015

NOTICE OF EXEMPTION

PROJECT TITLE: "KNOWLEDGE, ATTITUDES AND PRACTICES OF ADVERSE DRUG REACTION (ADR) REPORTING AMONG NURSES IN A TERTIARY HOSPITAL IN SOUTH WEST NIGERIA".
HEALTH RESEARCH COMMITTEE ASSIGNED NO.: ADM/DCST/HREC/APP/039
NAME OF PRINCIPAL INVESTIGATOR: OSHO FOLASADE M.
ADDRESS OF PRINCIPAL INVESTIGATOR: SCHOOL OF PUBLIC HEALTH, FACULTY OF COMMUNITY AND HEALTH SCIENCES, UNIVERSITY OF THE WESTERN CAPE, SOUTH AFRICA.
DATE OF RECEIPT OF VALID APPLICATION: 19-02-15

This is to inform you that the research described in the submitted protocol, the consent forms, and all other related materials where relevant have been evaluated and are exempted from full review by the Lagos University Teaching Hospital Health Research Ethics Committee (LUTHHREC).

All informed consent forms used in the study must carry the HREC assigned number and duration of HREC approval of the study. In multiyear research endeavor to submit your annual report to the HREC early in order to obtain renewal of your approval and avoid disruption of your research.

The National code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the code. The HREC reserves the right to conduct compliance visits to your research site without previous notification.

PROF. N. U. OKUBADEJO
CHAIRMAN, LUTH HEALTH RESEARCH ETHICS COMMITTEE