AWARENESS AND ADVERSE DRUG REACTION REPORTING PRACTICES OF COMMUNITY PHARMACISTS AND PATENT MEDICINE VENDORS IN IBADAN SOUTH WEST LOCAL GOVERNMENT AREA

By

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DEDICATION

To the Almighty Father,

The beginning and the end;

The one who holds me high!

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ABSTRACT

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality. Detection and spontaneous reporting of ADRs by private providers could reduce their consequences. Little is known about the awareness and reporting of ADRs among private health care professionals in Oyo State, Nigeria. This study was designed to assess the level of awareness and adverse drug reaction reporting practices of community pharmacists (CPs) and patent medicine vendors (PMVs) in Ibadan South West LGA.

The study design was descriptive and cross-sectional. All the CPs and PMVs who were available and consented to participation in the LGA were enrolled in the study. A total of 21 and 128 CPs and PMVs respectively completed a 29- item validated questionnaire on socio-demographic characteristics, ADRs awareness, experiences and ADRs practices. Awareness of the respondents to ADRs was measured on a 13-point scale, while practice was measured on a 5 point scale. Awareness scores of $\leq$6 and >7 were classified as poor and good respectively. Practice scores of $\leq$ 2 and > 3 were classified as poor and good respectively. Data were analysed using descriptive and inferential statistics at p= 0.05.

A majority, 85%, of CPs reported to have been trained on reporting ADRs while few PMVs (29.0%) reported to have been trained. Trained respondents received training from NAFDAC (PMVs -30.6%), UCH (6.7% CPs and 14.3% PMVs), pharmacist's continuous education (CPs -53.4%) and NDLEA (PMVs -20.4%).A majority of CPs (95.2%) and PMVs (84.4%) were aware of causes of ADRs which included patient sensitivity to a drug (CPs-95.2%; PMVs-77.6%), drug-drug reaction (CPs -100.0%; PMVs -86.1%) and patient using alcohol to swallow medication (CPs -95.0%; PMVs-91.1%). Most of the respondents (CPs-100.0%; PMVs-85.2%) had good awareness about risk factors facilitating ADRs. Familiarity with the ADR reporting process was low as 47.6% CPs and 75.1% PMVs had not encountered any ADR. Of those that encountered ADR (52.4 % CPs; 21.0 % PMVs) 4 weeks preceding the survey, only 5.0% CPs and 2.7% PMVs ever reported. Major reasons for not reporting encountered ADRs were not knowing where to report (CPs -28.6%; PMVs-56.8%), insufficient knowledge (CPs -33.3%; PMVs -32.2%) and ADR reporting being time wasting (CPs 9.5%; PMVs 25.4%). Seminars and education on ADR (90.5% CPs; 83.3% PMVs) and increased sensitization and awareness (85.7% CPs; 62.3% PMVs) were suggested for improving ADR reporting.

The majority of community pharmacists and patent medicine vendors in Ibadan South West have good awareness about adverse drug reaction and but poor awareness on the reporting process, therefore affecting their reporting practice. Educational interventions in form of formal training and seminars are needed to address the awareness -practice gap.

Keywords: Adverse drug reaction, Awareness, Practice, Community pharmacist, Patent medicine vendors

Word count: 435

CERTIFICATION

I certify that this project was carried out by Atolagbe Folorunso Mojisola in the Department of Health Promotion and Education, Faculty of Public Health, College of Medicine, University of Ibadan, Ibadan, Nigeria.

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OPERATIONAL DEFINITION OF TERMS

Adverse drug reaction An Adverse Drug Reaction (ADR) is a response to a drug which is harmful and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy.

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

Community pharmacist A community pharmacist is a health professional that supplies medicines in accordance with a prescription, or when legally permitted, sells them without a prescription and provides counseling to patients at the time of dispensing the drugs.

Patent medicine vendor A patent medicine vendor is a person without formal pharmacy training who sells orthodox pharmaceutical products on a retail basis for profit.

ABBREVIATIONS

ADR:	Adverse Drug Reaction
PVG:	Pharmacovigilance
CP:	Community Pharmacist
PMV:	Patent Medicine Vendor
PMS:	Patent Medicine Store
KAP:	Knowledge, Attitude and Practice
WHO:	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Adverse drug reactions (ADRs) are an important cause of mortality and morbidity worldwide (Akram, Patel, & Manna, 2013; Kamtane & Jayawardhani, 2012). It was not until the disaster caused by thalidomide in 1961 that the first systematic international efforts were initiated to address drug safety issues. At that time many thousands of congenitally deformed infants were born as the result of exposure in-utero to an unsafe medicine promoted for use by pregnant mothers. The Sixteenth World Health Assembly (1963) adopted a resolution that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and led, later, to creation of the WHO Pilot Research Project for International Drug Monitoring in 1968. The purpose of this was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicine (WHO, 2002).

At the point new medicines are registered for use in humans not much is known about those medicines beyond data obtained from clinical trials in controlled settings. Clinical trials for the evaluation of safety, efficacy and quality of new medicines are conducted in patients that may not necessarily represent all type of patients that will use the medicines when they are approved. Limited numbers of patients are exposed to the medicine during clinical trials and research settings differ from the conditions of use when the drug is marketed. Lack of complete understanding of the effects of long-term exposure, co-morbid conditions, and use in elderly, racial groups, children and pregnant women are other limitations of preapproval clinical trials (Nwokike, 2008).

Post-marketing surveillance and Pharmacovigilance activities i.e. reports of adverse drug reactions can help in obtaining real-life information of safety and effectiveness of medicines when they are being used in the population. These post-marketing surveillance activities have resulted in the reappraisal of indications, identification of risk factors and characterization of users, identification of long-term toxicities, quality problems, etc. Rumors and myths about the adverse effects of medicines can spread rapidly and are difficult to refute in the absence of good data. This study is aimed at investigating the awareness and reporting practices of

community pharmacists and patent medicine vendors (PMVs) to reports of ADRs in Ibadan South West Local Government, Oyo State Nigeria.

1.2 Statement of the problem

When a drug is newly formulated, clinical trials are carried out. During this clinical trial, only a small number of patients are exposed to a medication, over a limited period of time, compared to the number that might use it once it is licensed. Rare adverse reactions, occurring in only a small percentage of cases, after a long period of use or when a drug interacts with a particular combination of other medications or conditions, may not be detected during clinical trials (WHO, 2002).

In the US alone, according to the Institute of Medicine report To Err Is Human: Building A Safer Health System, it is estimated that 7000 deaths occur annually due to ADRs. Lazarou , Pomeranz and Corey,1998; in their meta-analysis of incidence of ADR in hospitalized patients reported 2.2 million serious ADRs and 106,000 deaths in 1994, making ADR the 4th-6th leading cause of death. This study excluded errors in drug administration, noncompliance, overdose, drug abuse, therapeutic failures, and possible ADRs.

Pharmacists and PMVs can play an important role in ADR reporting and pharmacovigilance by increasing the number as well as the quality of submitted reports (Kees, Olsson, Couper& Berg, 2004). However, in many countries such as Nigeria, the knowledge of pharmacists and PMVs about ADR reporting is poor and the rate of reporting is low (Oreagba, Ogunleye&Olayemi, 2011).When a reaction is observed, it is important to classify it as serious and report it to the appropriate body (ies). A case study is the report of the cases of renal failure observed in children in the Ahmadu Bello University Teaching Hospital Zaria, who were said to have ingested a teething mixture called “My Pikin” in 2012. As at the time the report was made, about 84 children were said to have died but further deaths were averted through this reports as the harmful batch of the mixture were immediately withdrawn from circulation(Akuse Rosamund & Garnett Foluke, 2013). Adverse drug reactions have a major impact on public health by imposing a considerable economic burden on the society and the health care system. Many factors are associated with ADRs under-reporting among health professionals. These factors have been broadly classified as personal and professional characteristics and their knowledge and attitudes to reporting.

To counter these challenges, the National Agency for Food & Drug Administration & Control (NAFDAC) has developed a National Pharmacovigilance (Drug Safety Monitoring)

Centre (NPC) that monitors and controls reports of adverse drug reactions through the yellow reporting forms. However, it is unknown as to the extent that this has been disseminated to the private sector practitioners and if it has influenced their practices. The author has not read any report of the extent to which CPs and PMVs have been reporting ADR in Nigeria and specifically in Oyo state hereby fueling speculation that underreporting of this phenomenon is rampant. Under reporting of ADRs is therefore a major problem that needs to be countered through improved surveillance, increased education and ease of submission and collection of reports from the appropriate quarters.

1.3 Justification of the study

Studies carried out on under reporting of ADRs have been on health care professionals in the hospitals; though, many patients have more direct contacts with community pharmacists and patent medicine vendors in the purchase of their mediations in the country at the present. The study provided needed information about the situational realities of ADRs awareness, knowledge and reporting practices in the private sector market and will therefore increase confidence to report any adverse drug reaction noticed to such quarters.

This study threw more light on the level of awareness on ADR of CPs and PMVs in Ibadan South West LGA, their experiences with ADRs as well as their ADR reporting practice; so as to improve the actions on pharmacovigilance in community pharmacies and patent medicine stores (PMS).

1.4 Research Questions

This study answered the following research questions:

i. What is the level of awareness of community pharmacists and patent medicine vendors about ADRs?
ii. What are the community pharmacists and patent medicine vendor's experiences with ADRs?
iii. What factors influence reporting or non-reporting of suspected ADRs to the appropriate bodies or organization?

1.5 Objectives of the study

The broad objective of the study was to ascertain the awareness and ADRs reporting practices of community pharmacists and patent medicine vendors in Ibadan South West LGA.

The specific objectives of the study are:

i. To determine the level of awareness of Community Pharmacists and Patent Medicine Vendors on reporting of adverse drug reactions (ADRs)

ii. To assess Community Pharmacists and Patent Medicine Vendors experiences with ADRs

iii. To identify the factors which influence the reporting of suspected ADRs by Community Pharmacists and Patent Medicine Vendors.

1.6 Hypothesis

The following null hypotheses were tested by the study:

i. There is no significant association between the type of profession and the level of awareness on Adverse Drug Reaction among Community Pharmacists and Patent Medicine Vendors

ii. There is no significant association between the type of profession and the measures adopted to deal with patients that experienced Adverse Drug Reaction.

iii. There is no significant association between the years of experience and reporting process of Adverse Drug Reaction reporting process.

CHAPTER TWO

LITERATURE REVIEW

2.1. The Concept of adverse drug reaction

Adverse drug reactions (ADRs) was defined by World Health Organization in 1972 as a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. According to information published by the Medicines and Healthcare Products Regulatory Agency (MHRA) 'an adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs, and is suspected to be related to the drug. The reaction may be a known side effect of the drug or it may be new and previously unrecognized'. This is opposed to an adverse event which 'is any undesirable experience that has happened to the patient while taking a drug but may or may not be related to the drug'(Board of Science, 2006).

It was not until the disaster caused by thalidomide in 1961 that the first systematic international efforts were initiated to address drug safety issues. At that time many thousands of congenitally deformed infants were born as the result of exposure in utero to an unsafe medicine promoted for use by pregnant mothers. The Sixteenth World Health Assembly (1963) adopted a resolution that reaffirmed the need for early action in regard to rapid dissemination of information on adverse drug reactions and led, later, to creation of the WHO Pilot Research Project for International Drug Monitoring in 1968. The purpose of this was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines (WHO, 2002).

At the point new medicines are registered for use in humans not much is known about those medicines beyond data obtained from clinical trials in controlled settings. Clinical trials for the evaluation of safety, efficacy and quality of new medicines are conducted in patients that may not necessarily represent all type of patients that will use the medicines when they are approved. Limited numbers of patients are exposed to the medicine during clinical trials and research settings differ from the conditions of use when the drug is marketed. Lack of complete understanding of the effects of long-term exposure, co morbid conditions, and use in elderly, racial groups, children and pregnant women are other limitations of preapproval clinical trials (Nwokike, 2008). Post-marketing surveillance and Pharmacovigilance activities i.e. reports of adverse drug reactions can help in obtaining real-life information of safety and

effectiveness of medicines when they are being used in the population. These post-marketing surveillance activities have resulted in the reappraisal of indications, identification of risk factors and characterization of users, identification of long-term toxicities, quality problems, etc. Rumors and myths about the adverse effects of medicines can spread rapidly and are difficult to refute in the absence of good data.

The advent of international drug monitoring in the late 1960s (Venulet, 1994) and the directions that drug monitoring took in the following years led to the creation of large data-bases of heterogeneous origins. The data had been collected not only by international organizations such as the World Health Organization (WHO), but also by major pharmaceutical companies with world-wide activities as well as the national drug regulatory agencies for each country.

2.2. Importance of ADR Reporting

Adverse drug reactions (ADRs) occur frequently and globally accounting for a significant number of fatalities each year. It has been estimated that fatalities directly attributable to ADRs are the fourth to sixth leading cause of death in hospitals in the United States, exceeding deaths caused by pneumonia and diabetes (Oshikoya, Chukwura, Njokanma, Senbanjo& Ojo, 2011). In addition to the human costs, ADRs have a major impact on public health by imposing a considerable financial burden on society and the already stretched healthcare systems. By identifying and reporting adverse drug events, conscientious physicians may influence drug labeling or alerts that impact prescribing practices and help protect the public's health. Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. When communicated effectively, this information allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions(Kamtane & Jayawardhani, 2012).Many drugs studied in clinical trials have limited experience in the general population and in special populations such as children and older adults; therefore, reporting on adverse events from real-life use in clinical practice is invaluable (Gatti, 2012).

The most important function of spontaneous reporting systems is the early identification of signals and formulation of hypotheses, leading to further confirmatory investigations or sometimes regulatory warnings and changes of product information leaflet (Pal, Duncombe, Falzon, & Olsson, 2013).

2.3. Types of ADR

There are several interactions that can occur between a drug and another drug, a drug and a disease condition, a drug and the types of food consumed. Many studies have described the classification of ADRs (Lazarou et al, 1998, Farcas and Bojita, 2009) and they are mainly classified into six categories.

Type A or Type 1 Reactions

Type A (augmented) reactions result from an exaggeration of a drug's normal pharmacological actions when given at the usual therapeutic dose and are normally dose-dependent. Type A reactions also include those that are not directly related to the desired pharmacological action of the drug. This type of adverse drug reaction is usually predictable but sometimes unavoidable. It may occur if a drug dose is too high, if the person is unusually sensitive to the drug or if another drug slows the metabolism of the first drug and thus increases its level in the blood. Type 1 reactions are usually not serious but are relatively common. For example, a person taking a drug to reduce high blood pressure may feel dizzy or light-headed if the drug reduces blood pressure too much. A person with diabetes may develop weakness, sweating, nausea, and palpitations if insulin or an oral anti-diabetic drug reduces the blood sugar level too much.

Type B or Type 2 Reactions

Type B (bizarre) reactions are novel responses that are not expected from the known pharmacological actions of the drug. They are also called idiosyncratic reactions. These are less common, and so may only be discovered for the first time after a drug has already been made available for general use. This type of adverse drug reaction is largely unpredictable.

Examples include skin rashes, jaundice, anemia, a decrease in the white blood cell count, kidney damage, and nerve injury that may impair vision or hearing.

Type C Reactions

Type C, or 'continuing' reactions, persists for a relatively long time. These kinds of reactions are uncommon and related to cumulative dose of medications.

Type D Reactions

Type D, or 'delayed' reactions, becomes apparent sometime after the use of a medicine. The timing of these may make them more difficult to detect. They are uncommon, usually dose-related and seen on prolonged exposure to a drug or exposure at a critical time.

Type E Reactions

Type E, or 'end-of-use' reactions, is associated with the withdrawal of a medicine. An example is insomnia, anxiety and perceptual disturbances following the withdrawal of benzodiazepines

Type F Reactions

Type F or 'failure of therapy' reactions occur when the medication does not give the expected outcome of which it is used for i.e. there is no effectiveness or efficacy.

The current classification is defined only by properties of the drug—its known pharmacology and the dose dependence of its effects. However, other criteria should be taken into account in a comprehensive classification, including properties of the reaction (the time course of its appearance and its severity) and properties of the individual (the genetic, pathological, and other biological differences that confer susceptibility). A three dimensional classification system based on dose relatedness, timing, and patient susceptibility (DoTS) has been proposed (Aronson & Ferner, 2003).

There are enzymes in the body that metabolize drugs. These also have effects on how individuals react to medicines taken. In some people, the enzymes are more and they therefore metabolize drugs in time. These groups of people are called fast acetylators and the effects of the drugs are quick. Some other people have the enzymes in a smaller proportion and will not metabolize the drugs in time. The drugs will therefore stay longer in the body and could cause an exacerbation of various effects which may not be expected. These people are called slow acetylators.

Drug interactions can occur via several mechanisms; some of which include drug interactions occurring even before drugs enter the body due to formulation incompatibility, or at any point in the process of absorption, distribution metabolism, and elimination; drugs binding to each other in the GI tract, preventing absorption, and reducing systemic availability; drugs interacting in the plasma via protein-bumping reactions (but, despite the emphasis placed on

these in many texts and pharmacology courses, there are no known clinically relevant examples in which this mechanism is responsible)(U.S department of health and human services, Accessed October 2014.)

2.4. Recognition of ADR

ADRs are difficult and sometimes impossible to distinguish from disease being treated since they may act through the same physiological and pathological pathways (NAFDAC, Accessed March 2014).

If an unexpected reaction is observed in a patient it may be difficult to establish its causality and thus if it has resulted from the administration of a drug or combination of drugs. It is important to consider the nature of the reaction, the timing of the reaction in relation to drug administration, the relationship to the dose administered and other possible causes of the reaction including concomitant medications and the patient's underlying disease.

It is not an easy task to determine whether a patient is experiencing an adverse effect from a drug, let alone determining what type of ADR is occurring; the root cause may lie with the drug's pharmacokinetic profile, a patient allergy, a drug-drug interaction, or even human error. This difficulty may partly explain why many ADRs are never recognized as adverse events. Such oversights can lead to the subsequent use of other drugs to correct a drug-induced condition, which is a contributing factor to polypharmacy. Furthermore, unrecognized ADRs may be misdiagnosed as an exacerbation of an existing medical problem or as a new medical problem, with clinicians increasing dosages of current drugs or adding new drugs to treat a medical problem that does not exist. As dosages are increased or more drugs are added to a patient's regimen, the likelihood of drug-drug interactions and other ADRs increases.

It is also wise to review the patient's clinical course, assessing the pertinent characteristics of the patient, the suspected drug, and the adverse event. In particular, the patient's recently administered medications, significant medical problems, and risk factors (such as age, severity of illness, or reduced renal or hepatic function) should be scrutinized for signs of a possible ADR. The patient should be questioned about the use of other agents, such as over-the-counter drugs, herbal supplements, or medications borrowed from others (Kamtane & Jayawardhani, 2012; Lucas & Colley, 1991; Mahmoud et al., 2013).

NAFDAC (2007) gave a step by step approach to help in assessing possible drug- related ADRs. This step wise approach expects the health practitioner to:

1. Take a proper history and do a proper examination of the patient; a full drug and medical history should be taken to check if the adverse reaction be explained by other causes e.g. patient's underlying disease, other drugs including over-the-counter medicines or traditional medicines; toxins or foods?
2. Establish time relationships by asking and answering the question- Did the ADR immediately follow the drug administration?
3. Carry out a thorough physical examination with appropriate laboratory investigations (if necessary) because few drugs produce distinctive physical signs. It is worthy of note that Laboratory tests are especially important if the drug is considered essential in improving patient care or if the laboratory test results will improve management of the patient.
4. Effect of de-challenge and re-challenge should be determined (when necessary). To de-challenge means to withdraw a drug while a re-challenge means to reintroduce a drug after it has been withdrawn. Re-challenge is only justifiable when the benefit of re-introducing the drug to the patient outweighs the risk of recurrence of the reaction. In some cases the reaction may be more severe on repeated exposure. Re-challenge therefore requires serious ethical considerations.
5. Check the known pharmacology of the medicine.

2.5. Prevalence and incidence of ADR reporting among health workers

Adverse reactions are more common than might be expected. Determining the precise number of ADRs that are experienced, however, is virtually impossible given the difficulties in assessing causality and the low proportion of ADRs that are reported(Board of Science, 2006).

It is estimated that only 6% of ADRs are reported worldwide; which implies that ongoing evaluation of the risk-benefit ratio of medications in the market is largely unavailable (Inman, 1976; Bello &Umar, 2011). The rate of ADR reporting by pharmacists in various countries has been reported to vary from 3% to 14.7% (Oreagba, Ogunleye & Olayemi, 2011). Among a population of adults in Cameroon, the rate of ADRs was 3.5% (Mbuagbaw, Mbuagbaw, Chiabi, Bisseck&Nkam, 2008) and among adult medical inpatients in South Africa, the rate was 12.6 %(Mehta, Durrheim&Blockman, 2008).

Literature is scarce on attitudes towards ADR reporting in Nigeria. However, Enwere and Fawole studied ADR reporting by physicians in Ibadan, Nigeria; nearly 90% of physicians surveyed had observed at least one ADR but only 32% had ever reported it. The commonest factors that militate against ADR reporting were lack of knowledge that reporting forms were available (70.9%) and ignorance of reporting procedure (Nwokike, 2008). Another study carried out among physicians in Sokoto, Nigeria recorded a reporting rate of 7% which was said to be close to the 6% recorded worldwide but was said to be lower than the 32% recorded in Ibadan by Enwere O.O and Fawole O.F. (Bello & Umar, 2011).

2.6. Knowledge of ADR and reporting practices among health workers

The National reporting requirement is very demanding and requires that all healthcare workers including traditional medicine practitioners submit reports, all types of events should be reported including known and minor ones for new medicines, and all responses which is noxious and unintended including lack of efficacy should also be reported(Nwokike, 2008).

Pharmacists and patent medicine vendors could play an important role in ADRs reporting, because they are close to patient in communities and have good knowledge about side effects of drugs, so it is logical to involve them more in ADRs reporting. Some findings in a study carried out in Iran show that pharmacy students have favorable knowledge and attitudes about ADRs but the practice of detecting and reporting ADRs were at the lowest level. Results of a similar knowledge, attitude and perception study in India shows that undergraduate pharmacy students had good knowledge but poor attitude and practice compared to prescribers ($p< 0.001$) (Isfahani, Mousavi, Rakhshan, Assarian, & Kuti, 2013).

A study carried out by Kamtane & Jayawardhani, 2012 shows that 89.36% doctors accepted that they do not have knowledge about ADR reporting center which shows inadequate knowledge of doctors about ADR and reporting which is similar to previous reports among resident doctors in Nigeria and doctors in many countries across Europe, America and Asia. There are gaps between knowledge and ADRs reporting among doctors working in a teaching hospital in Lagos, Nigeria (Oshikoya & Awobusuyi, 2009). Several previous studies have documented a lack of knowledge in community pharmacists about ADR reporting. A study carried out among community pharmacists in Saudi Arabia showed that pharmacists have poor knowledge of ADR reporting, few pharmacists have reported ADRs, and the majority are not aware of the process of ADR reporting. Their reasons for not reporting ADRs mainly included lack of awareness about the method of reporting, disclaiming

responsibility for ADR reporting, and the belief that most ADRs in community pharmacies are minor and should not be reported (Mahmoud et al., 2013).

2.7. Factors responsible for under-reporting of ADRs

Under-reporting of ADRs is a worldwide phenomenon and this has been established from previous studies(Kamtane & Jayawardhani, 2012). Gross underreporting of ADRs is a cause of concern, the reason for which may be inadequate funds, lack of trained staff and lack of awareness about detection, communication and spontaneous monitoring of ADRs (Isfahani et al., 2013)

Dr Bill Inman, who pioneered the Yellow Card Scheme, in 1976 highlighted 'Seven deadly sins' that might cause the low reporting rate of ADRs among healthcare professionals(Board of Science, 2006). His description of the 'sins' include: attitudes relating to professional activities (financial incentives: rewards for reporting; legal aspects: fear of litigation or enquiry into prescribing costs; and ambition to compile or publish a personal case series) and problems associated with ADR-related knowledge and attitudes (complacency: the belief that very serious ADRs are well documented by the time a drug is marketed; diffidence: the belief that reporting an ADR would only be done if there was certainty that it was related to the use of a particular drug; indifference: the belief that the single case an individual doctor might observe could not contribute to medical knowledge; ignorance: the believe that it is only necessary to report serious or unexpected ADRs), and excuses made by professionals (lethargy: the procrastination and disinterestedness in reporting or lack of time to find a report card and other excuses)(Oshikoya & Awobusuyi, 2009). In a study carried out among Pakistani physicians, knowledge about Drug Regulatory Authority of Pakistan (DRAP) form of ADR reporting, their perception that ADR reporting generates an extra work and time to actively look for ADR at work were the most significant reasons of ADR under reporting. In another study carried out in Barcelona, Spain showed that lack of time to report an ADR, unavailability of ADR reporting system in hospitals and lack of information about the spontaneous reporting system were the main reasons of under reporting ADRs(Iffat, Shakeel, Rahim, Anjum, & Nesar, 2014). Other factors reported to contributing to under-reporting of ADR includes lack of knowledge of the forms for reporting, ignorance of the rules and procedure for reporting, and not being sure of the type of reactions to be reported. The results

are similar to the studies carried out in China, Nigeria, and Malaysia (Li, Zhang, Chen, Fang, Yu, Liu, Shi & Zeng,2004; Aziz, Siang & Badarudin, 2007; Okezie 2008).

2.8. Interventions to improve ADR reporting

The importance of improving ADR reporting cannot be over emphasized. Many suggestions have been in given in studies carried out as to ways in which ADR reporting can be improved (Oshikoya et al 2009, Kamtane & Jayawardhani, 2012). ADR reporting can be improved through several strategies including the simplification of the reporting form, sensitization of healthcare workers to participate in the process, and engagement of patient in the reporting process through increase in their awareness and by enlightenment. The use of checklist in ADR reporting has been criticized due to several drawbacks including that it allows for poor description of events and ticking only the available options. It has also been argued that while reporting, ADR events recorded should not be restricted or predefined since doing this may cause confusion. It is also argued that unrestricted entries offers the best chance for detecting the unexpected and provides more event data for analysis.

Another method for improving ADR reporting is the use of new technologies such as the mobile phones as well as the internet. Involvement of religious and community leaders in the communication of the importance of pharmacovigilance will increase awareness of their followers and the entire community at large.

Of several measures suggested to improve ADR reporting, worthy of note amongst them include creating awareness about ADR monitoring among health care professionals and consumers, through appropriate educational interventions [e.g. seminars, sensitizations], making ADR reporting forms easily available and simplifying the process of reporting. Feedback from ADR monitoring centers about the causality and severity of ADRs reported would also encourage them to continue reporting (Kamtane et al, 2012).

Educational interventions were mentioned in majority of studies that have been carried out previously with inclusion of courses on ADR and its reporting process in undergraduate programs as well as in continuous professional development courses (Board of Science, 2006; Isfahani et al., 2013; WHO, 2002)

2.9. Use of ADR reports by agencies

According to the National Agency for Food and Drug Administration and Control, all health care professionals/workers, including doctors, dentists, pharmacists, nurses, traditional medicine practitioners and other health professionals are requested to report all suspected adverse reactions to drugs including Western medicines vaccines, X-ray contrast media, medical devices, cosmetics, traditional and herbal remedies.

The information obtained from the report will be used to promote safe use of medicines on a local, national and international level. The reported case will be entered into the national adverse drug reaction database and analysed by expert reviewers.

A well-completed adverse drug reaction reporting form submitted could result in:

- Additional investigations into the use of the medication in Nigeria.
- Educational initiatives to improve the safe use of the medication.
- Appropriate package insert changes to include the potential for the reaction reported by Nigerian health professionals and workers.
- Changes in the scheduling or manufacture of the medicine to make the medicine safer.
- Other regulatory and health promotion interventions as the situation may warrant including change in supply status or withdrawal.

Therefore, the purpose of ADR reporting is to reduce the risks associated with drug prescribing and administration and to ultimately improve patient care, safety and treatment outcome (NAFDAC, Accessed March 2014).

2.10. Conceptual frame work

The Precede-Proceed Model

The precede -proceed model is an evaluation framework proposed in 1974 by Dr. Lawrence W. Green that helps health program planners, policy makers and other evaluators analyze situations and design health programs efficiently. It does not predict or explain factors linked to the outcomes of interest, but offers a framework for identifying intervention strategies to address these factors (Green, 1974). The model views health behavior as influenced by both individual and environmental forces. It has two distinct parts: an "educational diagnosis (PROCEED) and an "ecological diagnosis" (PROCEED). The PRECEDE acronym stands for Predisposing, Reinforcing, Enabling Constructs in Educational/ Environmental Diagnosis and Evaluation. The precede element of the model was developed in the 1970s, while the proceed element was added to the framework in 1991 to take into account the impact of environmental factors on heath. PROCEED stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (Rimer & Glanz, 2005).

PRECEDE-PROCEED has nine steps. The first five steps are diagnostic, addressing both educational and environmental issues while the four remaining steps comprise program implementation and evaluation (Matlo, 2012). In the diagnostic steps, various methods are employed to learn about the community's perceived and actual needs. In conducting the social assessment, multiple data collection activities can be used. Examples include key informant interviews, focus group discussions, observations and surveys. Epidemiological assessment may include secondary data analysis or original data collection to prioritize the community health needs and establish goals and objectives. Behavioral and Environmental Assessment identifies factors, both internal and external to the individual, that affect the health problem. Two ways of mapping out these factors include reviewing the literature and applying theory. In Educational and Ecological Assessment, this model identifies antecedent and reinforcing factors that must be in place to initiate and sustain change. Human behavior is shaped by predisposing, reinforcing, and enabling factors. The three types of influencing factors include:

- Predisposing factors, which motivate or provide a reason for behavior; they include knowledge, attitudes, cultural beliefs, and readiness to change.
- Enabling factors, which enable persons to act on their predispositions; these factors include available resources, supportive policies, assistance, and services.

- Reinforcing factors, which come into play after a behavior, has been initiated; they encourage repetition or persistence of behaviors by providing continuing rewards or incentives. Social support, praise, reassurance, and symptom relief might all be considered reinforcing factors.

In the final diagnostic step of the model i.e. the Administrative and Policy Assessment, the intervention strategies reflect information gathered in previous steps; the availability of needed resources; and organizational policies and regulations that could affect program implementation.

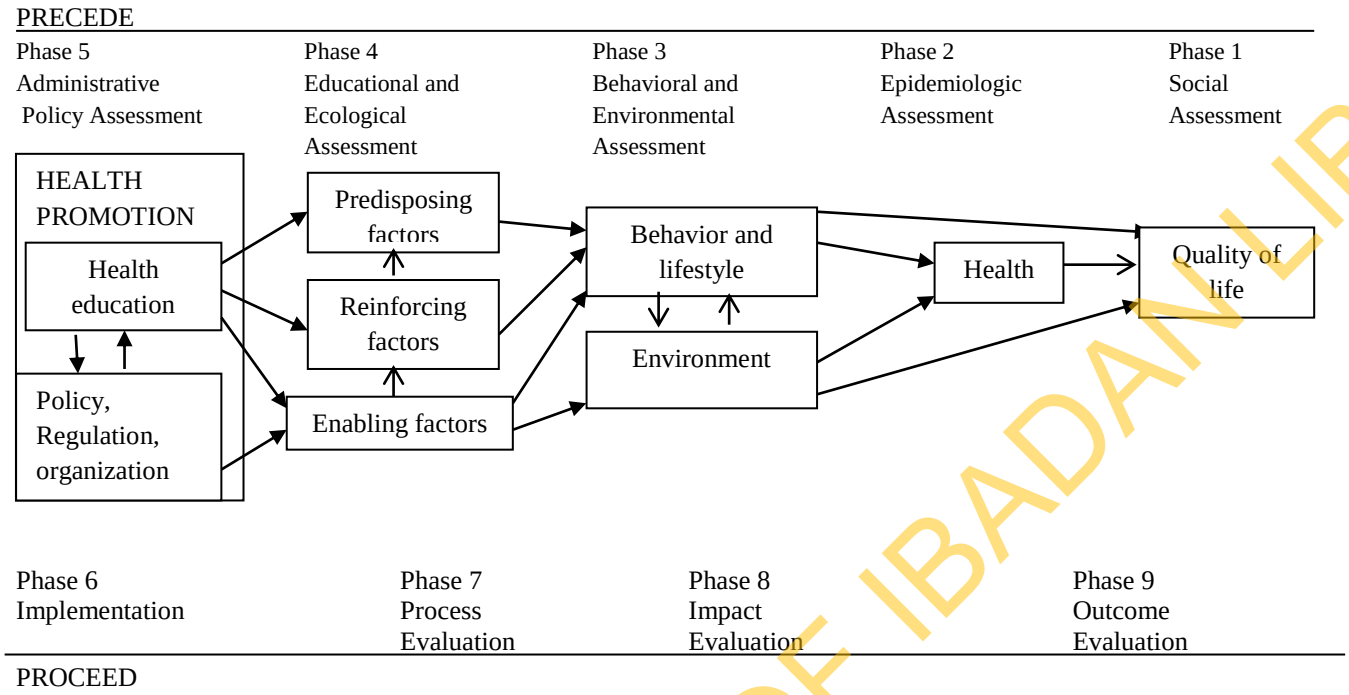

Figure 2.1: Conceptual frame work of the Precede-Proceed Model

Application of the Precede-Proceed Model

For the purpose of this study, the Precede-Proceed Model was adopted and used to explain the study methods.

The social and epidemiological assessment indicates that quality of life of patients can be affected negatively if ADRs seen are not well reported and documented thereby affecting the health of other patients in which these ADRs can be avoided. The behavior i.e. CPs and PMVs reporting practice are influenced by:

- Predisposing factors which include low level of education, low awareness on where to report suspected ADRs despite the high level of awareness on causes and risk factors facilitating ADRs, belief that reporting one case of an ADR will not make any positive impact and the perception that reporting can put them into trouble with law enforcement bodies.
- Enabling factors which include low access to the few available ADR reporting centers, low accessibility to the reporting forms, being busy at work to create time to submit an ADR report as it is a time wasting activity.
- Reinforcing factors which can affect the behavior of CPs and PMVs include lack of incentives when they report ADRs, reassurance of safety and protection for people who report ADRs and provision of healthy policies with respect to reporting ADRs.

Policy and administrative assessment of proper sensitization and health education of the entire community of the patients, CPs and PMVs through seminars, health talks, and mass media intervention will improve the reporting of ADRs. Formulation of policies, creation of more ADR reporting centers as well as creation of online reporting facilities can positively influence reporting practice and behavior of the community pharmacists and patent medicine vendors.

CHAPTER THREE

METHODOLOGY

3.1 Study location

The study was carried out among community pharmacists and patent medicine vendors in Ibadan South West Local Government Area of Ibadan, Oyo State.

Ibadan South West Local Government Area was carved out of the defunct Ibadan Municipal Government (IMG) in 1991with its administrative headquarters located at Oluyole Estate. It covers a landmass of 133,500 square kilometres with a population density of 2,401 persons per square kilometre. The 2010 estimated population for the area was projected as 320,536 people, using a growth rate of 3.2% from 2006 census (www.ibadanland.net, Accessed February 2015) The Local Government Area is bounded by Ibadan North West and Ido Local Government Areas to the north, Oluyole Local Government in the south, Ido Local Government Area in the west and Ibadan North and South East Local Government Areas in the east. There are no serious farming activities in the area being an urban centre. Most of the agricultural products planted outside the area are being processed in the Local Government Area as the local government is a home for small, medium and large scale industries.

3.2 Study design and population

The study was cross-sectional, questionnaire based conducted among a convenience sample of community pharmacists and patent medicine vendors from Ibadan South West Local Government Area of Oyo State, documenting their awareness and ADR reporting practices.

3.3 Data collection tool

The data collecting tool was a questionnaire which was developed in English. It was a semi structured; 29-item questionnaire designed to obtain information regarding demographics of the respondents, awareness and experiences regarding ADR reporting and practice of ADR reporting. Provision was also made for suggestions on possible ways to improve ADR reporting. More than one answer was allowed in some questions.

3.4 Sampling technique

A purposive sampling was used in which the entire population of community pharmacists and patent medicine vendors in Ibadan South West Local Government Area were targeted. A total number of a hundred and fifty four (154) questionnaires were distributed to this population.

3.5 Inclusion criteria

Community pharmacists and patent medicine vendors, who worked in Ibadan South West Local Government Area irrespective of owning a store or not, were included in the study.

3.6 Exclusion criteria

Community pharmacists and patent medicine vendors who were not willing to participate or did not return the questionnaire within the given time were excluded from the study.

3.7 Validity of the instrument

The validity of the questionnaire was through critical expert and peer review in the Department of Health Promotion and Education of the University College Hospital Ibadan and was thoroughly checked for face and content validity.

3.8 Reliability of the instrument

The reliability was done through carrying out a pretest of the drawn out questionnaire. A 10% of total sample (38) not from the target population but with similar characteristics with the target population was used for the pretest of the instrument which was also to ensure the validity and reliability of the instrument. The pretest was carried out among CPs and PMVs in Ibadan North Local Government Area. The data obtained were coded and entered into SPSS version 16 and the Cronbach's Alpha test was applied to it to determine the reliability

co-efficient which gave a value of 0.9. The questionnaire was then revised based on the results obtained from the pretest.

3.9 Data collection procedure

In order to administer the questionnaires, two research assistants were recruited and trained. The research assistants were given adequate information about the objectives of the research project, data collection process and the content of the questionnaire to avoid probable mistakes that could have affected the results of the study. The survey was self-administered with clarifications sought from the research officers when the need arose. The data collection was done between 10 a.m. and 6 p.m. each day for two weeks (Sundays were excluded in the data collection). This was to ensure that the respondents were met in their pharmacies and PMS when visited. Some pharmacies and PMS were visited twice in order to retrieve the questionnaires given to the respondents. An average of eleven (11) questionnaires were collected on a daily basis. The research assistants were supervised by the researcher who also participated in data collection. The research assistants submitted the filled questionnaires to the researcher on a daily basis.

3.10 Data Management and Analysis

When the questionnaires are returned by the respondents, they are reviewed for random and systemic errors and were immediately returned to the respondents for corrections. Each questionnaire collected from the field was given a serial number for easy identification and record keeping. These questionnaires were then kept in a file for proper safe keeping. A coding guide was developed to facilitate data entry. The information in the filled questionnaires were coded with the aid of the developed coding guide and entered into SPSS version 16 for analysis.

Awareness score of adverse drug reactions was calculated for each respondent, using a 13-point awareness scale. Each correct answer had a score of 1, while an incorrect answer or no response had a score of 0. The scores were then summed up to give a composite awareness score for each respondent. A score above 7 was categorized as high awareness score while a score from less than 6 was categorized as low awareness score about adverse drug reaction.Practice was measured on a 5 point scale with each correct answer having a score of

1, while an incorrect answer had a score of 0. The scores were then summed up to give a composite practice score for each respondent. Practice scores of less than or equal to 2 and greater than 3 were classified as poor and good respectively. The data entered into the computer was subjected to descriptive (mean, median, mode) and inferential (Chi-Square) statistical analyses; the findings were presented in tables and figures.

3.11 Ethical Consideration

The completion of the questionnaire by respondents was taken as their consent to participate in the study.

Ethical issues like confidentiality and opportunity to decline interview at any stage was also discussed with each respondent. Only respondents who were able to demonstrate an understanding of the objectives of the study and the implication of their role in it were recruited into the study. They were informed that participation is voluntary and that data collected would be used mainly for research purposes. Anonymity and confidentiality of responses was ensured.

3.12 Limitations of the study

One main limitation of the study was the relatively small number of respondents. Recall bias is also a domineering limitation that could have occurred in the course of this study. The survey was carried out in one Local Government Area of Oyo State which could limit its generalizability.

CHAPTER FOUR

RESULTS

4.1 Socio-Demographic characteristics

A total of 154 questionnaires were distributed to Community Pharmacists (CPs) and Patent Medicine Vendors (PMVs); however 149 questionnaires were retrieved, giving a response rate of 96.75%. Of this population, 21 (14.1%) were pharmacists and 128 (85.9%) were patent medicine vendors (Table 4.1).

The mean age of respondents was 40.32(±12.86) and 33.13(±9.79) years (CPs and PMVs respectively) with the Yoruba ethnic group being the highest number of participants (85.7% CPs, 96.9% PMVs). A majority of the PMVs (73.4%) had Senior Secondary School as their highest level of education completed while CPs reported Tertiary, MSc/postgraduate as their highest level of education (100%). A total of 87 (72.5%) PMVs had one Patent Medicine Store (PMS), 4 (3.3 %) had two; while 29 (24.2%) didn't own a PMS while 12 (60.0%) CPs had one pharmacy store and 8 (40.0%) didn't own any pharmacy store.

A majority of PMVs (71.0%) reported not to have been trained on reporting Adverse Drug Reaction (ADR) with 30.6% reporting to have been trained by National Agency for Food and Drug Administration and Control (NAFDAC), 14.3% in the College of Medicine (UCH) Ibadan, and 20.4% by National Drug Law Enforcement Agency (NDLEA). A vast majority of the CPs on the other hand reported to have been trained on reporting adverse drug reactions (85.0%) with 53.4% reporting to have been trained at the Pharmacist's continuous education programme (MPCD), 26.7% in the university and 6.7% in the College of Medicine (UCH) Ibadan.

Table 4.1a: Demographic characteristics of Community Pharmacists and Patent Medicine Vendors (N=149)

		Community Pharmacists (N=21) Frequency (%)	Patent Medicine Vendors (N=128) Frequency (%)
Respondent's Sex :	Male	10(47.6)	37(28.9)
	Female	11(52.4)	91(71.1)
Mean Age of participants		40.32(±12.86)	33.13(±9.79)
Ethnic Group:	Yoruba	18(85.7)	124(96.9)
	Igbo	2(9.5)	4(3.1)
	Idoma	1(4.8)	
Religion :	Christianity	19(90.5)	67(52.3)
	Islam	2(9.5)	61(47.7)
Highest level of education completed	Tertiary, MSc/postgraduate	21(100)	25(19.5)
	Senior Secondary		94(73.4)
*Others Adult education Junior secondary Post-secondary(grade 2) Standard 6 School of hygiene School of nursing School of health	Others*		9(7.2)
Type of Professional qualification	B.Pharm	20(95.2)	0(0.0)
	MSc	1(4.8)	0(0.0)
	School certificate	0(0.0)	98(76.6)
*Others Health assistant HND NCE Marketer Nursing Community Health Extension Worker	OND	0(0.0)	14(10.9)
	Others*	0(0.0)	16(12.6)
Mean years of Operating		7.62 (± 8.29)	11.42 (±18.87)

Table 4.1b: Demographic characteristics of Community Pharmacists and Patent Medicine Vendors (N=149)

		Community Pharmacists (N=21) Frequency (%)	Patent Medicine Vendors (N=117) Frequency (%)
Number of Stores owned	One	12(60.0)	87(72.5)
	Two	0(0.0)	4(3.3)
	None	8(40.0)	29(24.2)
Training on how to report ADRs:	Yes	17(85.0)	36(29.0)
	No	3(15.0)	88(71.0)
Specification of where respondent was trained	Pharmacists continuous education (MPCD)	8(53.4)	0(0.0)
*Others			
Adeoyo Hospital	University	4(26.7)	0(0.0)
During training			
Zonal NAPMED	College of Medicine (UCH)	1(6.7)	7(14.3)
Can't remember	Association for Reproductive and Family Health(ARFH)	0(0.0)	6(12.2)
Ministry Of Health	NAFDAC	0(0.0)	15(30.6)
	Company seminars	1(6.7)	3(6.1)
	Hospital during internship	1(6.7)	0(0.0)
	NDLEA	0(0.0)	10(20.4)
	Others *	0(0.0)	7(16.2)

4.2 Awareness about Adverse Drug Reaction (ADR)

A high number of respondents (95.2% of CPs and 77.6% of PMVs) were aware of a patient being sensitive to a drug as being a cause of ADR, as well as a drug-drug reaction (100% of CPs and 86.1% of PMVs). 95.0% and 91.1% of CPs and PMVs respectively were positively aware that a patient using alcohol to swallow his/her medication is a cause of ADR while 95.0% and 93.5% CPs and PMVs respectively said a patient using water to swallow his/her medication will not cause an ADR.

A high majority of respondents were positively aware that reduced kidney or liver functions (100% CPs and 78.9% PMVs), use of herbal supplements with orthodox medicines (90.5%CPs and 87.2% PMVs), use of medicines borrowed from other people (90.0% CPs and 76.6% PMVs) are risk factors that can facilitate ADR while100.0% of CPs and 98.4% of PMVs considered consumption of fake drugs (%) as risk factors that can facilitate ADR. These are shown in table 4.2 below.

Table 4.2: Community Pharmacists' and Patent Medicine Vendors' Awareness about Adverse Drug Reaction (N=149)

	Community Pharmacists			Patent Medicine Vendors		
	Yes (%)	No (%)	Don't Know (%)	Yes (%)	No (%)	Don't Know (%)
A patient being sensitive to a drug*	20(95.2)	1(4.8)	0	97 (77.6)	21(16.8)	7 (5.6)
Drug-drug reaction*	20(100)	0	0	105(86.1)	9(7.4)	8 (6.6)
A worsening of an existing medical problem*	10(55.6)	6(33.3)	2 (11.1)	80(65.0)	30(24.4)	13(10.6)
Increasing the dosage of medication being taken*	18(85.7)	2(9.5)	1(4.8)	93 (75.6)	26(21.8)	4 (3.3)
Adding a new drug to the ones being taken (Polypharmacy)*	18(94.7)	1(5.3)	0	88 (71.0)	27(21.8)	9 (7.3)
A patient using alcohol to swallow his/her medication*	19(95.0)	1(5.0)	0	113(91.1)	5(4.0)	6 (4.8)
A patient using water to swallow his/her medication*	1(5.0)	19(95.0)	0	5(4.0)	116(93.5)	3(2.4)
Age of the patient*	15(78.9)	4(21.1)	0	47 (37.9)	65(52.4)	12 (9.7)
Reduced kidney or liver function*	21 (100)	0	0	97(78.9)	16(13.0)	10(8.1)
Use of herbal supplements with orthodox medicines*	19(90.5)	2(9.5)	0	109(87.2)	11(8.8)	5 (4.0)
Use of medicines borrowed from other people*	18(90.0)	2(10.0)	0	95(76.6)	24(19.4)	5 (4.0)
Consumption of fake drugs*	20(100)	0	0	122 (98.4)	1(0.8)	1(0.8)
Timing of use of the medicine*	12(63.2)	5(26.3)	2 (10.5)	33(28.2)	70(59.8)	14 (12.0)

***** Missing values were excluded

There is a high level of awareness, 95.2% and 84.4%, among community pharmacists and patent medicine vendors respectively in Ibadan South West LGA on the causes and risk factors facilitating ADRs with a mean awareness score of 10.71± 1.93and 8.95± 2.33 for CPs and PMVs respectively as shown in figure 4.1 below:

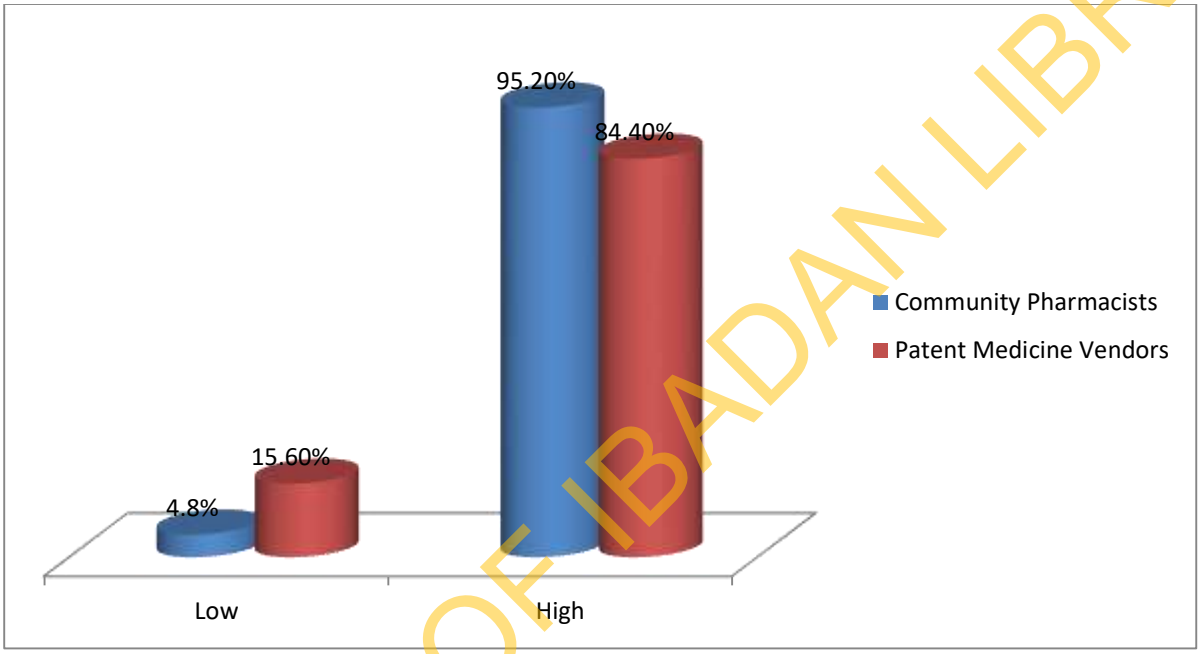

Figure 4.1: Respondents Awareness Categories on ADRs (In percentage)

Low Awareness: < 7

High Awareness: 7-13

The community pharmacists were more familiar with the ADR reporting process in Ibadan (61.9%) than the patent medicine vendors with 83.8% reporting not to be familiar with the reporting process. Of those who were familiar with the reporting process, 25.0% CPs and 11.8% PMVs gave University College Hospital (UCH) and 50.0% CPs and 35.3% PMVs reported NAFDAC as regulatory bodies responsible for the collection of ADR reports.

Table 4.3a: Respondents' Familiarity with ADR reporting process in Ibadan. (N=149)

		Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)*
Familiarity with ADR reporting process	Yes	13(61.9)	19(16.2)
	No	8(38.1)	98(83.8)

*****Missing values were excluded

Table 4.3b: Reported Regulatory body responsible for collection of ADR reports+

(N=32)

	Community Pharmacists Frequency (%)	**Patent Medicine vendors Frequency (%)**
University College Hospital Ibadan	4(25.0)	2(11.8)
Pharmacovigilance Centre	2(12.5)	0
NAFDAC	8(50.0)	6(35.3)
NURI (for family planning)	0	1(5.9)
Hospitals/Doctors	0	5(29.4)
Scratch cards on medications	1(6.3)	0
Pharmacist Council of Nigeria	1(6.3)	0
I cannot remember	0	2(11.8)
NAPMED	0	1(5.9)

+ Multiple responses were allowed

A majority of the CPs (61.9%) gave a positive response as to submitting reports of ADR online while many of the PMVs (47.2%) gave a negative response to submitting ADR reports online and many PMVs (40.0%) and a few CPs (28.6%) didn't know if it was possible to submit ADRs online. This is illustrated in table 4.4 below.

Table 4.4: Online (Electronic) submission of ADR reports (N=149)

		Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)*
Community pharmacist/patent medicine vendors submission of ADR by online (electronic) reporting	Yes	13(61.9)	16(12.8)
	No	2(9.5)	59(47.2)
	Don't know	6(28.6)	50(40.0)

* Missing values were excluded

4.3 Experiences with Adverse Drug Reactions (ADR)

A majority of the respondents (47.6% CPs and 75.1% PMVs) had not encountered any ADR reported to them in the last month preceding the study while 19.0% CPs and 11.7% PMVs had one case of ADR encountered, 23.8% CPs and 6.2% PMVs had two cases encountered (Table 4.5).

Table 4.5: Number of ADRs encountered by respondents in the last month (N= 149)

		Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)*
Number of ADRs encountered in the last month	1	4(19.0)	15(11.7)
	2	5(23.8)	8(6.2)
	3	1(4.8)	4(3.1)
	8	1(4.8)	0
	None	10(47.6)	96(75.1)

* Missing values were excluded

Of the positive response given by the respondents, 54.5 % CPs and 42.9% PMVs reported that itching was one of the types of ADRs encountered in the last month preceding the study; while 63.6% CPs and 32.1% PMVs reported swelling of different parts of the body and weakness each as types of ADR encountered. These are shown in table 4.6 below.

Table 4.6: Types of ADR encountered by respondents⁺ (N= 39)

		Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)
Types of ADR encountered	Swelling of different parts of the body	7(63.6)	9(32.1)
	Weakness	3(27.3)	13(46.4)
	Resistance to the drug/ No effectiveness of the drug	3(27.3)	9(32.1)
	Pain	2(18.2)	2(7.1)
	Vomiting	3(14.3)	4(14.3)
	Menstruation twice a month	3(30.0)	1(3.4)
	Itching	6(54.5)	12(42.9)
	Dizziness	3(27.3)	11(39.3)
	Headache	3(27.3)	12(41.4)

+ Multiple responses were allowed

A high percentage of respondents (63.2% CPs and 71.1% PMVs) had not experienced / encountered any serious ADR in the last six months preceding the study while 21.1% CPs and 14.9% PMVs had encountered just one ADR report in the last six months.

Table 4.7: Number of serious ADRs encountered by respondents in the last six months (N=149)

		Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)
Number of serious ADRs encountered by respondents in the last six months*	1	4(21.1)	17(14.9)
	2	2(10.5)	8(7.0)
	3	0(0.0)	6(5.3)
	4	0(0.0)	2(1.8)
	5	1(5.3)	0(0.0)
	None	12(63.2)	81(71.1)

* Missing values were excluded

On the question of common ADRs respondents had come across in practice, 50.0% CPs and 57.5% PMVs reported itching, 56.2% CPs and 51.7% PMVs-weakness, 37.5% CPs and 49.4% PMVs - dizziness, 81.2% CPs and 32.2% PMVs - rashes and 68.8% CPs and 32.2% PMVs - swelling of the face / body. There were several other common ADRs come across as can be seen in table 4.8 below.

Table 4.8: Common ADRs ever come across in practice by respondents+ (N=103)

	Community Pharmacists Frequency (%)	Patent Medicine vendors Frequency (%)
Swelling of the face/ body	11(68.8)	28(32.2)
Resistance to the drug/ No effectiveness of the drug	3(18.8)	21(24.1)
Weakness	9(56.2)	45(51.7)
Headache	6(37.5)	29(33.3)
Rashes	13(81.2)	28(32.2)
Skin Eruptions	8(50.0)	21(24.1)
Frequent Urination	4(25.0)	3(3.4)
Cough	2(12.5)	5(5.7)
Itching	8(50.0)	50(57.5)
Stooling	2(12.5)	5(5.7)
Vomiting	4(25.0)	11(12.6)
Dizziness	6(37.5)	43(49.4)
Tummy pains/cramps	7(43.8)	25(28.7)

+ Multiple responses were allowed

Majority of the community pharmacists (76.2%) reported cephalosporins as a common drug class associated with the ADRs encountered while 87.5% said sulphonamides were the culprit drugs in the ADRs reported. Other drug classes reported were Arthemeter Combination Therapy (ACT) (62.5%), Non-Steroidal Anti-inflammatory drugs (56.2%) and chloroquine (56.2%).

Among the patent medicine vendors, the report of common drug classes associated with the ADRs encountered varied compared to the community pharmacists. A majority of the PMVs (75.9% and 72.4%) reported chloroquine and Non-Steroidal Anti-inflammatory drugs respectively, while 57.5% said sulphonamides and 42.5% were of the opinion that family planning pills were the drugs that caused the ADRs encountered.

The results are shown in the table below. (Table 4.9)

Table 4.9: Common drug classes associated with the ADRs encountered by respondents+ (N=103)

	Community Pharmacists		Patent Medicine vendors	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Sulphonamides (Septrin, Fansidar)	14	87.5	50	57.5
Diruetics	1	6.2	9	10.3
Penicillins	7	43.8	17	19.5
Cephalosporins	16	76.2	2	2.3
Chloroquine	9	56.2	66	75.9
Antihistamines	1	6.2	6	6.9
Arthemeter Combination Therapy (ACT) (Lonart, Combisunate, Artequine etc)	10	62.5	29	33.3
Non-Steroidal Anti-inflammatory drugs (Ibuprofen, Diclofenac, Aspirin)	9	56.2	63	72.4
Family Planning pills	5	31.2	37	42.5

+ Multiple responses were allowed

When asked about measures adopted to comfort a patient complaining of ADR or side effect, 42.9% CPs and 80.8% PMVs correctly answered to referring the patient to see a physician/doctor, 76.2% CPs and 48.8% PMVs also rightly answered to asking him/her to stop taking the medicine causing the ADR or side effect. 42.9% CPs and 32.0% PMVs reported that they would give him/her a medication to treat his/her condition and ask him/her to stop the medication causing the ADR.

Table 4.10: Measures adopted by respondents to comfort a patient complaining of ADR or side effect+ (N=149)

	Community Pharmacists		Patent Medicine vendors	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Give him/her a medicine to treat his/her condition	3	14.3	19	15.2
Refer him/her to see a physician	9	42.9	101	80.8
Just ask him/her to stop taking that medicine	16	76.2	61	48.8
Give him/her a medicine to treat his/her condition AND ask him/her to stop the medication causing the ADR	9	42.9	40	32.0
Other measures adopted *	5	23.8	4	3.1

* If very serious refer to the physician
Tell the patient to drink milk then go to the hospital for better treatment
Tell patient to drink a lot of water
Give nutritional supplements
Refer to the doctor if it is not subsiding
Dosage adjustment and counseling
In a situation where they can't see the doctor in time, the patient should use palm oil to rub his/her body

+ Multiple responses were allowed

Table 4.4 Adverse Drug Reaction reporting practice

Only 1 (5.0%) of the community pharmacists ever reported ADRs come across; this was reported to the UCH Pharmacovigilance centre. 2 (2.7%) PMVs have ever reported ADRs they came across and they gave the primary health centre and a close by hospital as places where they reported to. Among the community pharmacists, 42.1% of them didn't report the ADRs they came across because the condition subsided, 36.8% because there was no reporting form and 31.6% each reported that lack of proximity to a centre and not knowing where to report. Some patent medicine vendors (44.2%) gave reasons of not coming across any ADRs in their practice while 36.5% reported not knowing where to report to as to why they do not report ADRs they have come across.

Table 4.11: Reported Reasons why no report was submitted by respondents+

	Community Pharmacists		Patent Medicine vendors	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Lack of proximity to a centre (especially hospital)	6	31.6	3	2.9
The condition subsided	8	42.1	20	19.2
There was no reporting form	7	36.8	11	10.6
I don't know where to report to	6	31.6	38	36.5
Tight schedule	2	10.5	2	1.9
The reactions reported were not serious	3	15.8	20	19.2
I have not come across any ADR/no patient has ever reported	3	15.8	46	44.2
The complaint was not officially lodged to me	0	0	6	5.8
Referred the patient to the hospital	1	4.8	4	3.1

+ Multiple responses were allowed

76.2% CPs and 48.0% PMVs sometimes discussed an ADR with their colleague, 39.8% PMVs never discussed an ADR with the prescriber of the medications, 80.0% CPs and 48.4% PMVs frequently asked their patient if they are sensitive to medications, 95.2% CPs and 66.7% PMVs frequently asked female patients if they are pregnant when dispensing teratogenic medications, 85.7% CPs and 37.3% PMVs frequently asked if a female patient is breastfeeding when dispensing medicines that are excreted in the mother's milk and might harm the baby while 49.6% PMVs sometimes counsel their patients about ADRs that they may experience from their medications and 76.2% CPs frequently counsel their patients about ADRs they may experience from their medications. This is well illustrated in the figures below.

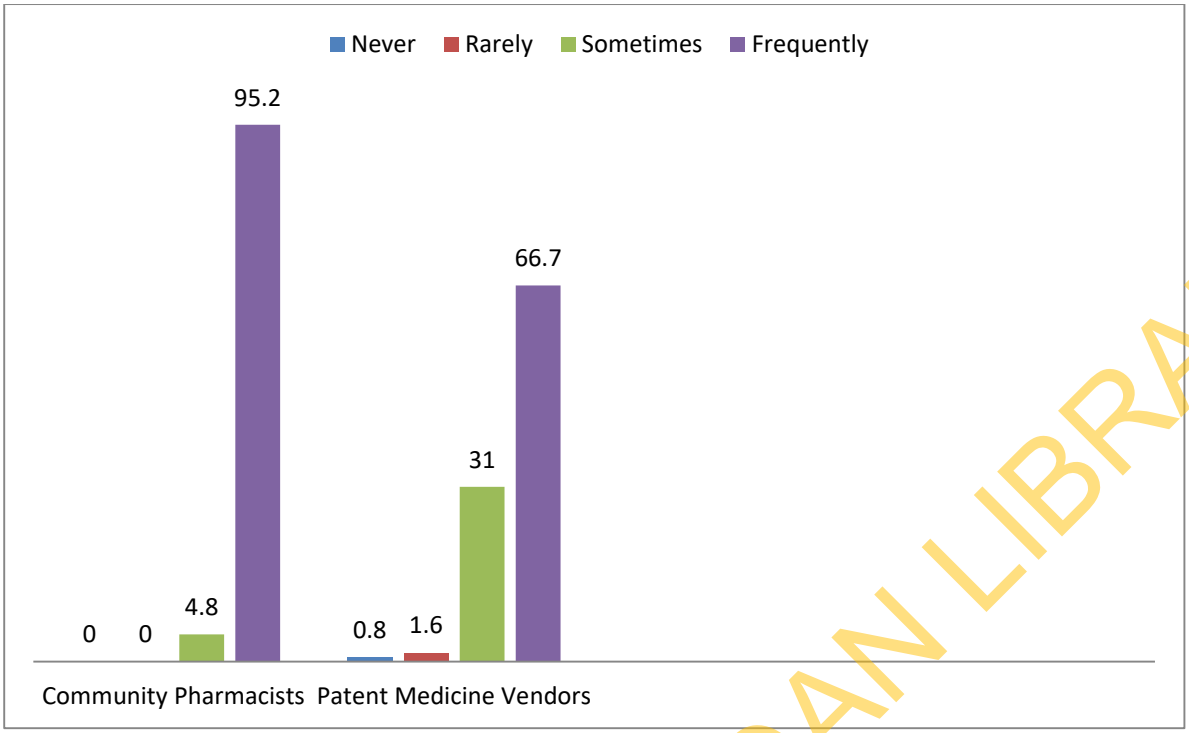

Figure 4.2a: Frequency of discussing ADR with colleague (In percentage)

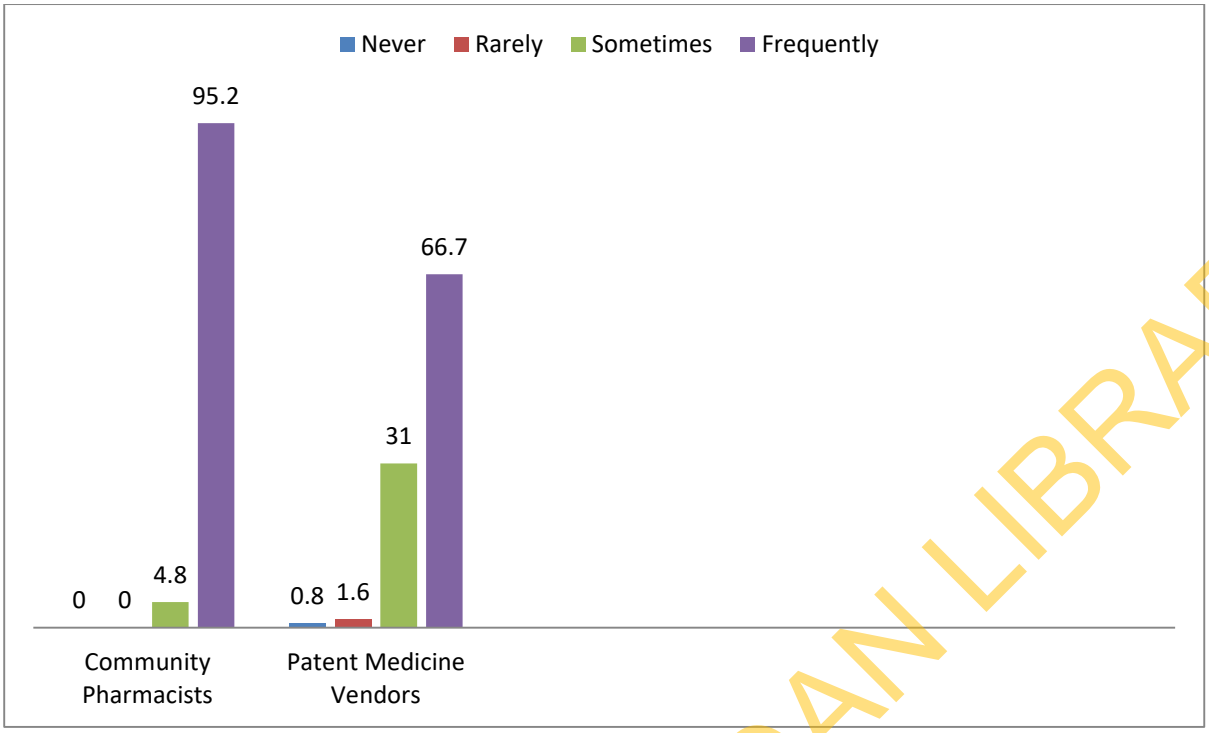

Figure 4.2b: Frequency of discussing ADR with the prescriber of the medications (In percentage)

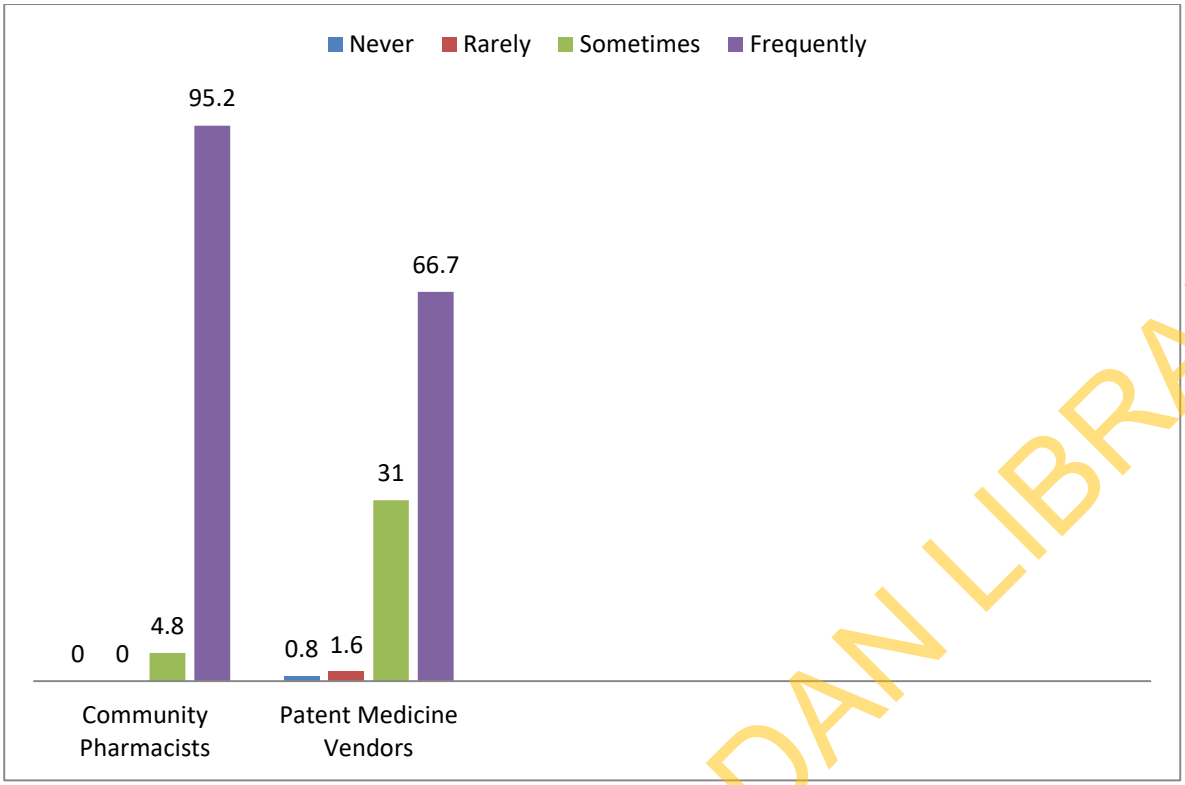

Figure 4.2c: Frequency of asking your patient if he/she is sensitive to medications (In percentage)

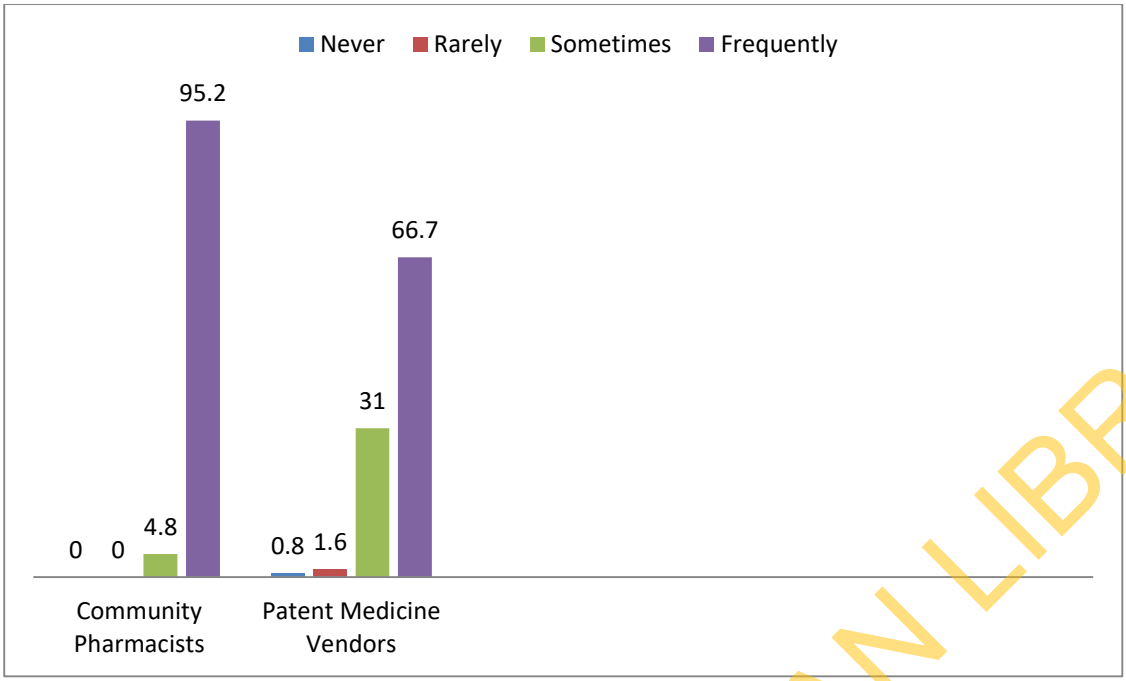

Figure 4.2d: Frequency of asking a female patient if she is pregnant when dispensing a drug that can cause abortion (In percentage)

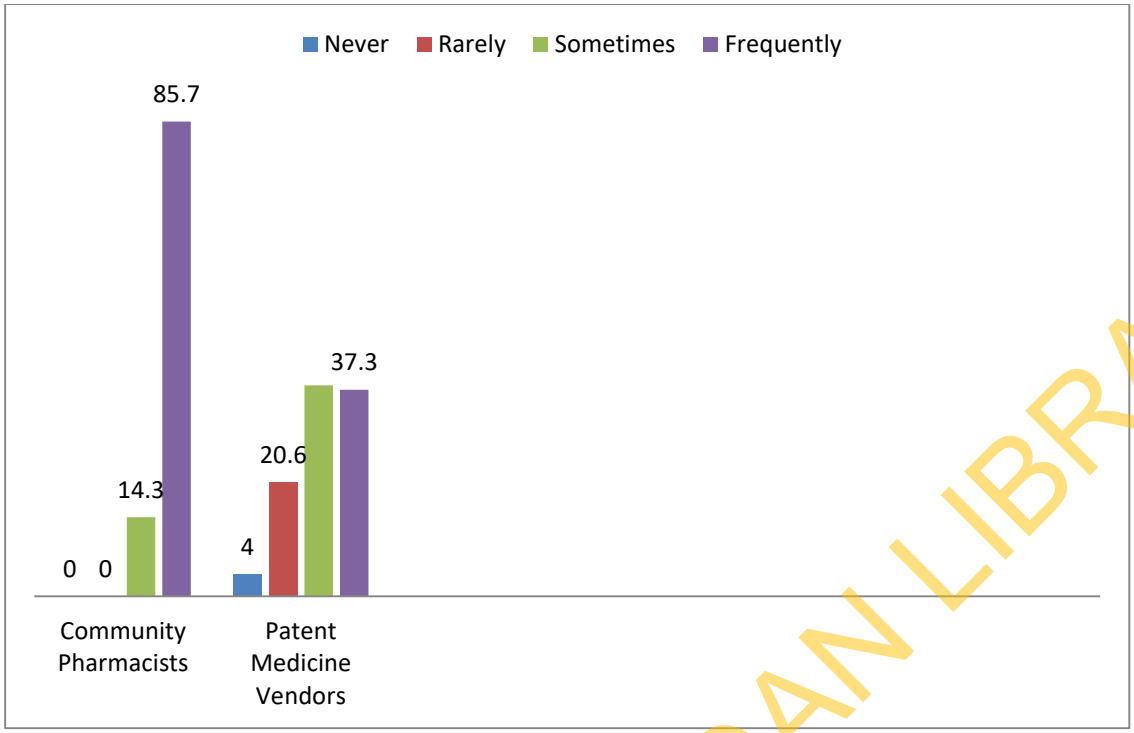

Figure 4.2e: Frequency of asking a female patient if she is breastfeeding when dispensing medicines that are excreted in the mother's milk and might harm the baby (in percent)

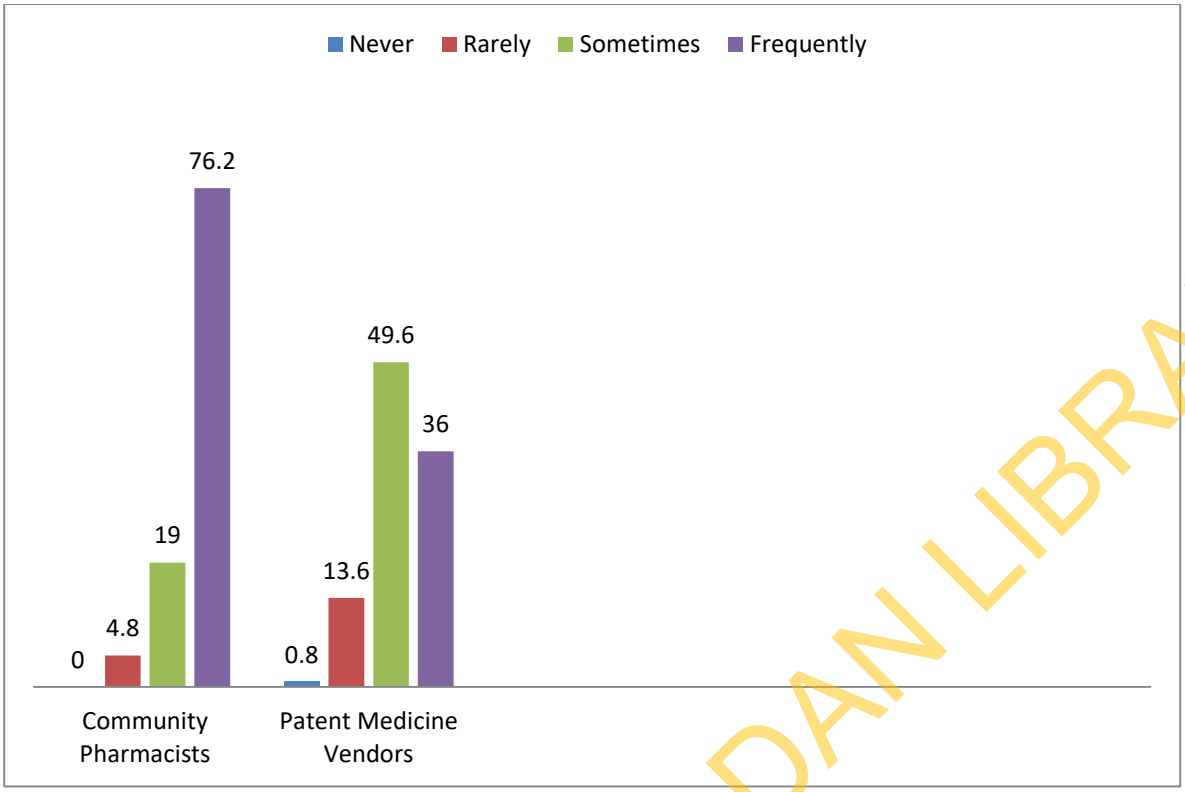

Figure 4.2f: Frequency of counseling your patient about ADRs that they may experience from use of their medications. (In percentage)

4.5 Factors influencing under-reporting of suspected ADRs

Of the causes/factors highlighted in the instrument, the community pharmacists reported busy schedule, difficulty to pin point suspected drug and insufficient medical knowledge (38.1%, 38.1% and 33.3% respectively) as the major causes of under reporting of ADRs while the patent medicine vendors reported not knowing whom to report to, insufficient medical knowledge and ADR reporting being a time wasting activity with no outcome (56.8%, 32.2% and 25.4% respectively) as the major cause of under-reporting of ADRs.

Table 4.12: Reported Causes of under-reporting of ADRs by respondents[+] (N=149)

	Community Pharmacists		Patent Medicine vendors	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Only safe drugs are available in the market.	0	0	12	10.2
Reporting does not influence the treatment scheme.	3	14.3	18	15.3
Busy schedule.	8	38.1	17	14.4
Lack of incentives.	4	19.0	16	13.6
Doctor should rather collect data and publish himself/ herself.	0	0	7	5.9
Difficult to pin point suspected drug.	8	38.1	22	18.6
ADR reporting is a time wasting activity with no outcome	2	9.5	30	25.4
ADR is known to the doctor alone.	0	0	14	11.9
Don't know whom to report	6	28.6	67	56.8
Reporting could show ignorance.	1	4.8	7	5.9
Difficult to admit injury (harm) to the patient.	1	4.8	9	7.6
Insufficient medical knowledge.	7	33.3	38	32.2
Submitting one report doesn't make any difference.	0	0	16	13.6
Other causes of under-reporting of ADRs*	4	19.1	10	7.8

***** Fear of apprehension for selling fake drugs
Fear of shop being locked or sealed
It can put one into trouble
Ineffectiveness of our leaders
I have not seen any ADR
Collecting Centre is not close to my work place/not easily accessible
ADR in Nigeria is not taken serious
Lack of awareness

+ Multiple responses were allowed

Various suggestions were made as possible ways of improving ADR reporting. A vast majority of the respondents (90.5% CPs and 83.3% PMVs) suggested seminars and education on ADR for both patients and store owners. Another majority (85.7% CPs and 62.3% PMVs) feel that an increased sensitization and awareness on ADR reporting will be beneficial.

Creation of more ADR reporting centres (in hospitals and Local Governments) had a frequency of 81.0% CPs and 38.6% PMVs while making these centres easily accessible had a frequency of 71.4% CPs and 21.1% PMVs. A percentage of the community pharmacist respondents (57.1%) think that the guideline for ADR reporting should be made simple while 71.4% think electronic submission of reports should be created.

Among other suggestions made for improving ADR reporting were: Yellow forms for reporting should be made available (52.4% CPs and 7.0% PMVs), provision of incentives for people reporting (23.8% CPs and 10.5% PMVs), collective reporting to their association leaders for onward submission to appropriate quarters (19.0% CPs and 11.4% PMVs), Pharmacovigilance officials should go round to collect filled forms (33.3% CPs and 6.1% PMVs) and protection from NAFDAC for people reporting (19.0% CPs and 7.9% PMVs).

Table 4.13: Respondents' Suggestions on ways ADR reporting can be improved[+] (N=149)

	Community Pharmacists		Patent Medicine vendors	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
There should be incentives	5	23.8	12	10.5
Seminars / Education on ADR for patients and store owners	19	90.5	95	83.3
Sensitization / Awareness on ADR reporting	18	85.7	71	62.3
Making the centres easily accessible	15	71.4	24	21.1
Simple step guideline for ADR reporting	12	57.1	13	11.4
Pharmacovigilance officials should go round to collect filled forms	7	33.3	7	6.1
Yellow forms for reporting should be made available	11	52.4	8	7.0
Create more ADR centres (In hospitals and Local Governments)	17	81.0	44	38.6
Post marketing surveillance	9	42.9	2	1.8
Electronic submission of reports should be created	15	71.4	8	7.0
People should make out time to submit the reports	6	28.6	4	3.5
Protection from NAFDAC for people reporting	4	19.0	9	7.9
Collective reports to leaders for onward submission to appropriate quarters	4	19.0	13	11.4
Creation of centres within the community	1	4.8	1	0.8

+ Multiple responses were allowed

Table 4.14: **Hypothesis 1 (H_o1):** There is no significant association between the type of profession and the level of awareness on Adverse Drug Reaction

		Awareness categories		Total	X^2 Cal	df	P
		Low (%)	High (%)				
Type of profession	**Community pharmacist**	1(4.8)	20(95.2)	21	6.033	2	0.04
	Patent Medicine Vendor*	16(13.7)	101(86.3)	117			

* Missing responses were not included

The table above shows that the community pharmacist had a significantly higher awareness than the patent medicine vendors ($p< 0.05$). The null hypothesis stated above is therefore rejected and conclude that there is a significant association between type of profession and the level of awareness on ADR.

Table 4.15: **Hypothesis 2 (H_o2):** There is no significant association between the type of profession and the measures adopted to comfort a patient with an Adverse Drug Reaction.

		Categories of measures adopted		Total	X^2 Cal	df	P
		Low (%)	High (%)				
Type of profession	**Community pharmacist**	10(47.6)	11(52.4)	21	2.009	2	0.366
	Patent Medicine Vendor	39(33.3)	78(66.7)	117			

* Missing responses were not included

Table4.15 shows that the patent medicine vendors had a higher value on the measures adopted to comfort a patient with an ADR than the community pharmacists; however there is no significant difference (P> 0.05) between the type of profession and the measures adopted to comfort a patient with an ADR we therefore fail to reject the null hypothesis stated above.

Table 4.16: **Hypothesis 3 (H_o3):** There is no significant association between the years of experience and familiarity with reporting of Adverse Drug Reaction reporting process.

		Years of experience		Total	X^2 Cal	df	P
		0-20 years (%)	21-40 years (%)				
Familiarity with ADR reporting process*	**Yes**	30(23.6)	2((33.3)	32	0.296	1	0.587
	No	97(76.4)	4(66.7)	101			
	Total	127	6	133			

* Missing responses were not included

In the table above, it is stated that the respondents with years of experience less than twenty years (20years) were the most category not familiar with the ADR reporting process than those with years of experience above twenty years; nevertheless, there is no significant difference (P> 0.05) in familiarity with ADR reporting process by years of experience. We therefore fail to reject the null hypothesis.

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATION

This study was a questionnaire based study which involved community pharmacists and patent medicine vendors in Ibadan South West Local Government of Oyo State. It evaluated their awareness, experiences and practice of adverse drug reaction reporting. Findings gotten from this study are discussed using the information and statistics obtained in the quantitative analysis. And the effects of the findings, conclusion and recommendation are presented here.

Socio-demographic characteristics

The study showed that there are more patent medicine vendors in operation than the pharmacists in the community; with more female than male respondents. The Yoruba ethnic group had the highest number of participants which may have been due to the part of the country the study was carried out. A majority of the PMV respondents had Senior Secondary School as their highest level of education completed which is the minimum educational requirement for being a patent medicine vendor.

A high number of PMVs reported not to have been trained on Adverse Drug Reaction (ADR) reporting (71.0%) which is close to that reported by Nwokike (78.0%) among healthcare workers in TB DOTS clinics in Nigeria. Those who had been trained reported their training to have been carried out by National Agency for Food and Drug Administration and Control (NAFDAC), in the College of Medicine (UCH) Ibadan and by National Drug Law Enforcement Agency (NDLEA). A reverse was the case among the community pharmacists. Most of the CP respondents (85%) reported to have been trained and mentioned the Pharmacist's continuous education programme (MPCD), during university education, during internship and work related trainings. This fact can be collaborated with findings among pharmacy students in Iran(Isfahani et al., 2013) which shows that the students favorable knowledge and attitudes about ADRs because they are being taught in their curriculum. Results of a similar KAP study in India shows that undergraduate pharmacy students had good knowledge with regards to ADRs monitoring and reporting.

Awareness about Adverse Drug Reaction (ADR)

A high number of the respondents (both CPs and PMVs) had good awareness that a patient being sensitive to a drug, a drug-drug reaction, a patient using alcohol to swallow his/her medication are causes of ADR and were also correct in saying that a patient using water to swallow his/her medication will not cause an ADR.

A vast majority were also aware of possible risk factors which could facilitate adverse drug reactions. These risk factors included reduced kidney or liver functions, use of herbal supplements with orthodox medicines, use of medicines borrowed from other people and consumption of fake drugs. However, the age of the patient being a risk factor to facilitate adverse drug reaction was not clearly stated by this study while many respondents said timing of use of the medicine was not a risk factor facilitating adverse drug reaction which was wrong.

Despite the high awareness of community pharmacists and patent medicine vendors in Ibadan South West LGA on causes and risk factors of adverse drug reactions, this study showed that they were not familiar with the process of reporting adverse drug reactions in Ibadan. This is similar to results obtained in studies carried out by Mahmoud et al., 2013. And the results in this study showed that the CPs were more familiar with the reporting process than the PMVs; this could be as a result of the training pharmacists obtain in the undergraduate curriculum as well as the continuous development programme they undergo after graduation, which is not applicable to the PMVs. With those who were familiar with the reporting process, some respondents correctly gave University College Hospital (UCH), the Pharmacovigilance Centre and NAFDAC as the regulatory bodies responsible for the collection of ADR reports. A higher number of the CP respondents gave a positive response to the possibility of submitting adverse drug reactions online, many of the PMVs gave a negative response to submitting ADR reports online while some didn't know if it was possible. There is an allowance for the report of ADR on the website of NAFDAC which leads to submission of a complaint online but it does not give room for the proper submission of an ADR (www.nafdac.gov.ng).

Experiences with Adverse Drug Reactions (ADR)

A vast majority of the respondents had not encountered any ADR reported to them in the last month preceding the study while a few had cases ranging from one to three encountered which is similar to the study conducted in Saudi Arabia (Bawazir, 2006). This result shows that awareness among the patients on reporting any reaction is low though some say the patients would rather go directly to the hospital to complain about any adverse drug reaction they experience. Of the respondents who had had an encounter with an adverse drug reaction reported, itching, swelling of different parts of the body and weakness were types of ADR encountered.

Other types of ADRs reported to have been encountered in the last month were headache, dizziness, resistance to the drug / no effectiveness of the drug, vomiting, pain, menstruation twice a month, coughing, swelling and redness of the eyes and sleeplessness. Of all these, the most common they have come across in practice were itching, weakness, dizziness, rashes and swelling of the face / body with chloroquine, Non-Steroidal Anti-inflammatory drugs (NSAIDs), sulphonamides, family planning pills and Arthemether Combination Therapy (ACT) as the classes of drugs associated with these reactions.

The most common approach perceived by community pharmacists to manage patients suffering from ADRs was to ask him/her to stop taking that medicine while the patent medicine vendors perceived referring the patient to a physician as the most common approach.

Adverse Drug Reaction reporting practice

Only one of the CP respondents in this study had ever reported an ADR; and this was reported to the UCH Pharmacovigilance centre while two PMVs had reported ADRs and this was through giving referrals to the nearby hospital and primary health centre close to them. The rate of reporting obtained from this study (5.0%- CPs and 2.7%-PMVs) is low when compared to the rate of ADR reporting by pharmacists in various countries reported to vary from 3% to 14.7% (Oreagba, Ogunleye and Olayemi, 2011; Su Ji and Su., 2010; Vessal, Mardani and Mollai, 2009; Toklu and Uysal, 2008; Lee et al., 1994).

The results from this study indicates that the patent medicine vendors have not reported any ADR because they have not come across any ADR/no patient has ever reported to them, didn't know where to report to, the condition subsided and they felt that the reactions reported were not serious while the community pharmacists who didn't report gave reasons of the condition subsiding, lack of reporting forms, not knowing where to report to and lack of proximity to a centre (especially hospital). These reasons are similar to those obtained from previous studies carried out (Kamtane & Jayawardhani, 2012; Nwokike, 2008).

More CPs reported frequently asking the patients if they were sensitive to medications, were breastfeeding when dispensing medicines that are excreted in the mother's milk and counseled their patients about ADRs that they may experience from their medications than the PMVs while a high number of the respondents (both CPs and PMVs) frequently asked if the female patient was pregnant when dispensing teratogenic medications.

Factors influencing under-reporting of suspected ADRs

One of the most reported causes of under-reporting ADRs identified in this study among patent medicine vendors was that they did not know whom to report to. Other barriers to reporting ADRs identified among the PMVs included insufficient medical knowledge and a feeling that ADR reporting is a time wasting activity with no outcome. The community pharmacists in this study reported difficulty to pin point suspected drug, busy schedule as well as insufficient medical knowledge as factors influencing underreporting of ADRs. These factors and or causes mentioned were similar to those mentioned in studies carried out among physicians in India by Kamtane & Jayawardhani, 2012 and among pharmacists in India too by Akram et al., 2013.

For both CPs and PMVs, the fear of shops being locked or sealed were mentioned while only the PMVs mentioned apprehension by law enforcement agencies for selling fake drugs as barriers to reporting adverse drug reactions in this study.

Ways of improving ADR reporting

Improving reporting rates of ADRs is primarily about improving awareness of the need to report and the mechanisms used to submit a Yellow Card. Various suggestions were made as possible ways of improving ADR reporting with a vast majority of the respondents (CPs and

PMVs) suggesting seminars and education on ADR for both patients and store owners.. Some other respondents felt that an increased sensitization and awareness on ADR reporting will be beneficial. This is comparable to reports of studies carried out by Bello & Umar, 2011; Iffat et al., 2014; Kamtane & Jayawardhani, 2012.

Some other suggestions made for improving reporting of ADRs in this study were creation of more ADR reporting centers (in hospitals and Local Governments) and making these centres easily accessible, the guideline for ADR reporting should be made simple, provision for electronic submission of reports, yellow forms for reporting should be made available, provision of incentives for people reporting, collective reporting to their association leaders for onward submission to appropriate quarters, Pharmacovigilance officials should go round to collect filled forms and protection from NAFDAC for people reporting.

From the study, it was seen that there is a significant association between professional qualification and the level of awareness on ADR; while no significant association was observed between the professional qualification and the measures adopted to comfort a patient with an ADR and between the years of experience and familiarity with reporting of Adverse Drug Reaction reporting process.

Implication for Health Promotion and Education

Findings from this study have health promotion and education consequences and propose the need for multiple interventions directed at confronting the occurrence. Awareness on the importance of reporting adverse drug reactions must be raised among community pharmacists and patent medicine vendors as well as patients. This can be achieved through public enlightenment and community health education in the provision of seminars and health talks. Information and communication materials such as posters promoting messages on the importance of reporting any suspected adverse drug reaction should also be used.

Capacity building of the community pharmacists and patent medicine vendors through improvements in the training process is a very important step in improving ADR reporting. This can be achieved through a review of the academic curriculum and inclusion of courses which will enlighten pharmacy students on ADRs and its reporting process as well as in the training curriculum of PMVs. Refresher courses even after graduation which will include new and recent developments in the various types of ADRs and the likes should also be

encouraged as there is always a new drug formulation and policy being developed. The provision of the yellow forms for reporting ADRS too is a way of building the capacity of the community pharmacists and patent medicine vendors.

The results of this study would be sent to bodies concerned (such as the Pharmacist Council of Nigeria (PCN), NAFDAC and Federal Ministry of Health) for considerations and deliberations which will help in the development of policies that will guide the reporting of adverse drug reactions and its benefits.

Conclusion

The importance of reporting ADRs cannot be overemphasized. Reporting these ADRs and subsequent actions taken on such reports are of public health importance as they help to reduce the burden of healthcare costs and improve patients' wellbeing as there are many ADRs which are preventable. Prompt recognition of adverse drug reactions, adequate and effective clinical management of their outcome is mandatory in promoting patients' safety(Farcas et al 2009).

This study on the awareness and reporting practices of community pharmacists and patent medicine vendors in Ibadan South West LGA Oyo State to reporting adverse drug reactions shows that their awareness about adverse drug reactions is high; however, the reporting practice is poor. Lack of knowledge and or familiarity about location of the reporting centers, lack of adequate numbers of reporting centers and ineffectiveness or the lack of use of the reports submitted were reasons found in this study for their poor practice.

For improvement of adverse drug reaction reporting practice, it is imperative to imply educational interventions both in undergraduate and postgraduate programs to update knowledge about drug safety and encourage healthcare professionals (especially community pharmacists and patent medicine vendors) to report ADRs spontaneously and intensively. Awareness campaigns targeted at community pharmacists, patent medicine vendors and patients are also important as well as creation of more reporting centers.

Recommendations

From the study carried out, knowledge gaps were identified. It is therefore recommended that:

1. Policy makers and professionals should provide environments that promote educational programs, campaigns, policies and procedures with a detailed goal of increasing awareness on adverse drug reactions and it's reporting.
2. More ADR reporting centers with effective and efficient staff capacity should be created especially in hospitals and Primary Health Centers; these centers should also be made easily accessible.
3. A less cumbersome ADR reporting guideline should be made available in the form of booklets and posters at conspicuous locations in health care facilities to serve as a constant reminder.
4. Easily accessible and user friendly electronic ADR reporting form should be made available.
5. There should be creation of awareness and sensitization for patients to report any kind of reaction that occurs to them especially after the consumption of any medication.

Suggestions for further research

A high number of the respondents had not had any ADR reported to them; this might have been due to lack of awareness of patients on reporting any ADR they experience. This can be a desire for further research on the level of awareness of patients on adverse drug reactions and its underlying causes.

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APPENDIX 1

AWARENESS AND REPORTING PRACTICES OF COMMUNITY PHARMACISTS AND PATENT MEDICINE VENDORS IN IBADAN SOUTH WEST LOCAL GOVERNMENT AREA TO REPORTING ADVERSE DRUG REACTIONS.

My name is Atolagbe Folorunso, a post graduate student of the Department of Health Promotion and Education, Faculty of Public Health, College of Medicine, University of Ibadan. The purpose of this study is to evaluate the awareness and reporting practices of Community Pharmacists and Patent Medicine Vendors in Ibadan South West Local Government to reporting Adverse Drug Reactions. **An Adverse Drug Reaction (ADR) is a response to a drug which is harmful and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy.**

The results from this study will help serve as input into the design of proper means of reaching out to Community Pharmacists and Patent Medicine Vendors on appropriate documentation of reporting Adverse Drug Reactions. The results can also be helpful in the formulation of policy documents on reports of Adverse Drug Reactions.

Your identity, responses and opinion will be kept confidential and will be used for the purpose of this research. Please do not write your name on the questionnaire. Kindly answer the questions below as accurately as possible to ensure the success of the research; your participation is voluntary and you may request to withdraw at any time. Thank you.

Local Government Area _____

Q NO	ITEMS	RESPONSES (MAKE SURE YOU FILL ALL COLUMNS)
SECTION 1: DEMOGRAPHICS		
001	Respondent's sex	MALE .... 1 FEMALE..... 2
002	What was your age as of your last birthday?	☐☐ YEARS
003	What is your ethnic group?	YORUBA..... ..... 1 IGBO..... ..... 2 OTHER _____ ..... 7 (SPECIFY)

Q NO	ITEMS	RESPONSES (MAKE SURE YOU FILL ALL COLUMNS)
004	What is your religion?	CHRISTIANITY..... ..... 1 ISLAM .... 2 TRADITIONAL .... 3 OTHER _____ ..... 4 (SPECIFY)
005	What is your highest level of education completed?	NO FORMAL EDUCATION.....1 RELIGIOUS EDUCATION .....2 ADULT EDUCATION.....3 PRIMARY .....4 JUNIOR SECONDARY.....5 SENIOR SECONDARY.....6 POST-SECONDARY (GRADE 2)7 TERTIARY……8 OTHER _____.....9 (SPECIFY)
006	Professional qualification	_____
007	How long have you been operating as a PMV/community pharmacist (in years)	
008	How many PMV/pharmacy shops do you own?	
009.	Have you ever been trained on how to report ADR? ***(If no, please go to q11)***	Yes [ ] No [ ]
010.	If yes, please specify where you were trained	

SECTION 2: Awareness about Adverse Drug Reaction

011. Which of the following can cause Adverse Drug Reaction? **Please tick ( ) the appropriate box for each question**

SN	Indicator	Yes	No	Don't know
I.	A patient being sensitive to a drug			
ii.	Drug-drug reaction			
iii.	A worsening of an existing medical problem			
iv.	Increasing the dosage of medication being taken			
v.	Adding a new drug to the ones being taken (polypharmacy)			
vi.	A patient using alcohol to swallow his / her medications			
vii.	A patient using water to swallow his / her medications			

012. Which of the following are risk factors that can facilitate Adverse Drug Reaction?

SN	Indicator	Yes	No	Don't know
i.	Age of the patient			
ii.	Reduced kidney or liver functions			
iii.	Use of herbal supplements with orthodox medicines			
iv.	Use of medications borrowed from other people			
v.	Consumption of fake drugs			
vi.	Timing of use of the medicine			

013a. Are you familiar with ADR reporting process? (i.e. how and where to submit an ADR report) in Ibadan? Yes [ ] No [ ] ***(If no, please go to q14)***

013b. If yes, what is the regulatory body responsible for collecting ADR reports? _____

014. Can Community Pharmacists / Patent Medicine Vendors submit adverse drug reactions (ADR) by electronic (online) reporting? Yes [ ] No [ ]I don't know [ ]

SECTION 3: Experiences with Adverse Drug Reactions

015. In the last month, how many ADRs have you encountered? _____

0016. What types of ADR did they have? ***(Please√( ) tick the appropriate options)***

SN	Indicator	
i	Swelling of different parts of the body	
ii	Weakness	
iii	Resistance to the drug/No effectiveness of the drug	
iv	Pain	
v	Vomiting	
vi	Menstruation twice a month	
vii	Itching	
viii	Dizziness	
ix	Headache	
x	Others (please specify) _____ _____	

017. In the last six (6) months, how many **serious** ADRs have you encountered? - _____

018. What are the most common five ADRs that you have ever come across in your practice? ***(Choose 5 of the options listed below)(If you have not come across any ADRs, please go to question 020)***

SN	Indicator	
i.	Swelling of face / body	
ii.	No efficacy / resistance	

iii.	Weakness	
iv.	Headache	
v.	Rashes	
vi.	Skin eruptions	
vii.	Frequent urination	
viii.	Cough	
ix.	Itching	
x.	Stooling	
xi.	Vomiting	
xii.	Dizziness	
xiii.	Tummy pain / cramps	
xiv.	Others (please specify)_____ _____	

019. What are the most common five drug classes that you think are associated with these ADRs? ***(Please tick 5 common drug classes listed)***

SN	**Indicator**	
i.	Sulphonamides (septrin, fansidar)	
ii.	Diuretics	
iii.	Penicillins	
iv.	Cephalosporins	
v.	Chloroquine (4-aminoquinolone)	
vi.	Antihistamines (piriton, loratidine)	
vii.	Arthemether Combination Therapy (ACT) (lonart, combisunate, artequine etc)	
viii.	Non-steroidal anti-inflammatory drugs (NSAIDS) (Ibuprophen, Diclofenac, Aspirin)	
ix.	Family planning pills (Combination 3)	
x.	Others (Please specify)_____ _____	

020. If a patient comes to you in the pharmacy/ patent medicine store complaining of a side effect or adverse reaction, what measure do you adopt to comfort the patient? ***(You can tick (✓) more than one option)***

S/N	**Indicator**	
i.	Give him/her a medicine to treat his/her condition	
ii.	Refer him/her to see a physician	
iii.	Just ask him/her to stop taking that medicine	
iv.	Give him/her a medicine to treat his/her condition AND ask him/her to stop the medication causing the ADR	
v.	Others (please specify) _____ _____	

SECTION 4: Adverse Drug Reaction reporting practice

021a. Do you report ADRs that you come across? Yes [ ] No [ ]
021b. If yes, where did you submit the report?
_____

021c. If no, why did you not report it? (What are the main reasons?) ***(You can tick more than one option)***

SN	Indicator	
i.	Lack of proximity to a center (especially hospital)	
ii.	The condition subsided	
iii.	There was no reporting form	
iv.	I don't know where to report to	
v.	Tight schedule	
vi.	The reactions reported were not serious	
vii.	I have not come across any Adverse Drug Reaction / no patient has ever reported	
viii.	The complaint was not officially lodged to me	
ix.	Others (please specify)_____ _____	

Please tick (✓) the appropriate box for each question

S/N	Indicator	Never	Rarely	Sometimes	Frequently
022.	How often do you discuss an ADR with your colleague?				
023.	How often do you discuss an ADR with the prescriber?				
024.	How often do you ask your patient if he/she is sensitive to medications?				
025.	How often do you ask a female patient if she is pregnant when dispensing a drug that can cause abortion? (teratogenic medications)				
026.	How often do you ask a female patient if she is breastfeeding when dispensing medicines that are excreted in the mother's milk and might harm the baby?				
027.	How often do you counsel your patient about ADRs that they may experience from their medications?				

SECTION 5: Factors influencing reporting of suspected ADRs

028. In your opinion which of the indicators below is cause of under-reporting of ADRs? ***(You may select more than one option)***

SN	Indicator	
i.	Only safe drugs are available in the market.	
ii.	Reporting does not influence the treatment scheme.	
iii.	Busy schedule.	
iv.	Lack of incentives.	
v.	Doctor should rather collect data and publish himself/ herself.	
vi.	Difficult to pin point suspected drug.	
vii.	ADR reporting is a time wasting activity with no outcome	
viii.	ADR is known to the doctor alone.	
ix.	Don't know whom to report	
x.	Reporting could show ignorance.	
xi.	Difficult to admit injury (harm) to the patient.	
xii.	Insufficient medical knowledge.	
xiii.	Submitting one report doesn't make any difference.	
xiv.	Others (please specify). _____ _____ _____	

SECTION 6 WAYS OF IMPROVING ADR REPORTING

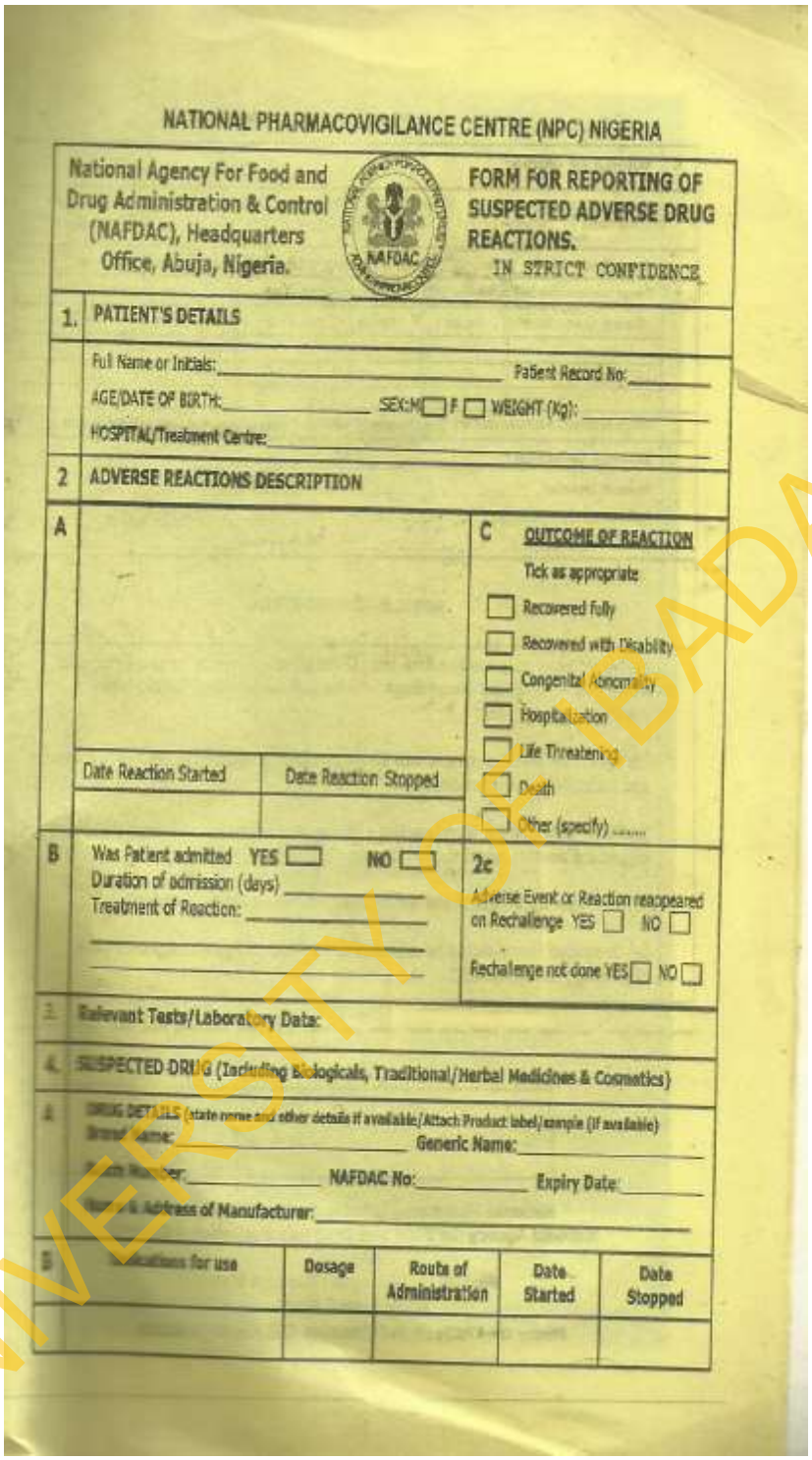
029. Suggest possible ways of improving ADR reporting ***(please tick as many options as possible)***

SN	Indicator	
i.	There should be incentives	
ii.	Seminars / Education on ADR for patients and store owners	
iii.	Sensitization / Awareness on ADR reporting	
iv.	Making the centers easily accessible	
v.	Simple step guideline for ADR reporting	
vi.	Pharmacovigilance officials should go round to collect filled forms	
vii.	Yellow forms for reporting should be made available	
viii.	Create more ADR centers (in hospitals and Local Governments)	
ix.	Post marketing surveillance	
x.	Electronic submission of reports should be created	
xi.	People should make time to submit the reports	
xii.	Protection from NAFDAC for people reporting	
xiii.	Collective reporting to leaders for onward submission to appropriate quarters	
xiv.	Others (Please specify)_i._____ ii._____	

Thank you for your effort.

APPENDIX 2

Copy of the yellow form used for reporting in Nigeria (front page)



NATIONAL PHARMACOVIGILANCE CENTRE (NPC) NIGERIA

National Agency For Food and Drug Administration & Control (NAFDAC), Headquarters Office, Abuja, Nigeria.

FORM FOR REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS.

IN STRICT CONFIDENCE

1. PATIENT'S DETAILS

Full Name or Initials: _____ Patient Record No: _____

AGE/DATE OF BIRTH: _____ SEX: M ☐ F ☐ WEIGHT (Kg): _____

HOSPITAL/Treatment Centre: _____

2 ADVERSE REACTIONS DESCRIPTION

A

Date Reaction Started	Date Reaction Stopped

C OUTCOME OF REACTION

Tick as appropriate

- ☐ Recovered fully
- ☐ Recovered with Disability
- ☐ Congenital Abnormality
- ☐ Hospitalization
- ☐ Life Threatening
- ☐ Death
- ☐ Other (specify) .....

B

Was Patient admitted YES ☐ NO ☐

Duration of admission (days) _____

Treatment of Reaction: _____

2c

Adverse Event or Reaction reappeared on Rechallenge YES ☐ NO ☐

Rechallenge not done YES ☐ NO ☐

3. Relevant Tests/Laboratory Data:

4. SUSPECTED DRUG (Including Biologicals, Traditional/Herbal Medicines & Cosmetics)

A DRUG DETAILS (state name and other details if available/Attach Product label/sample (if available)

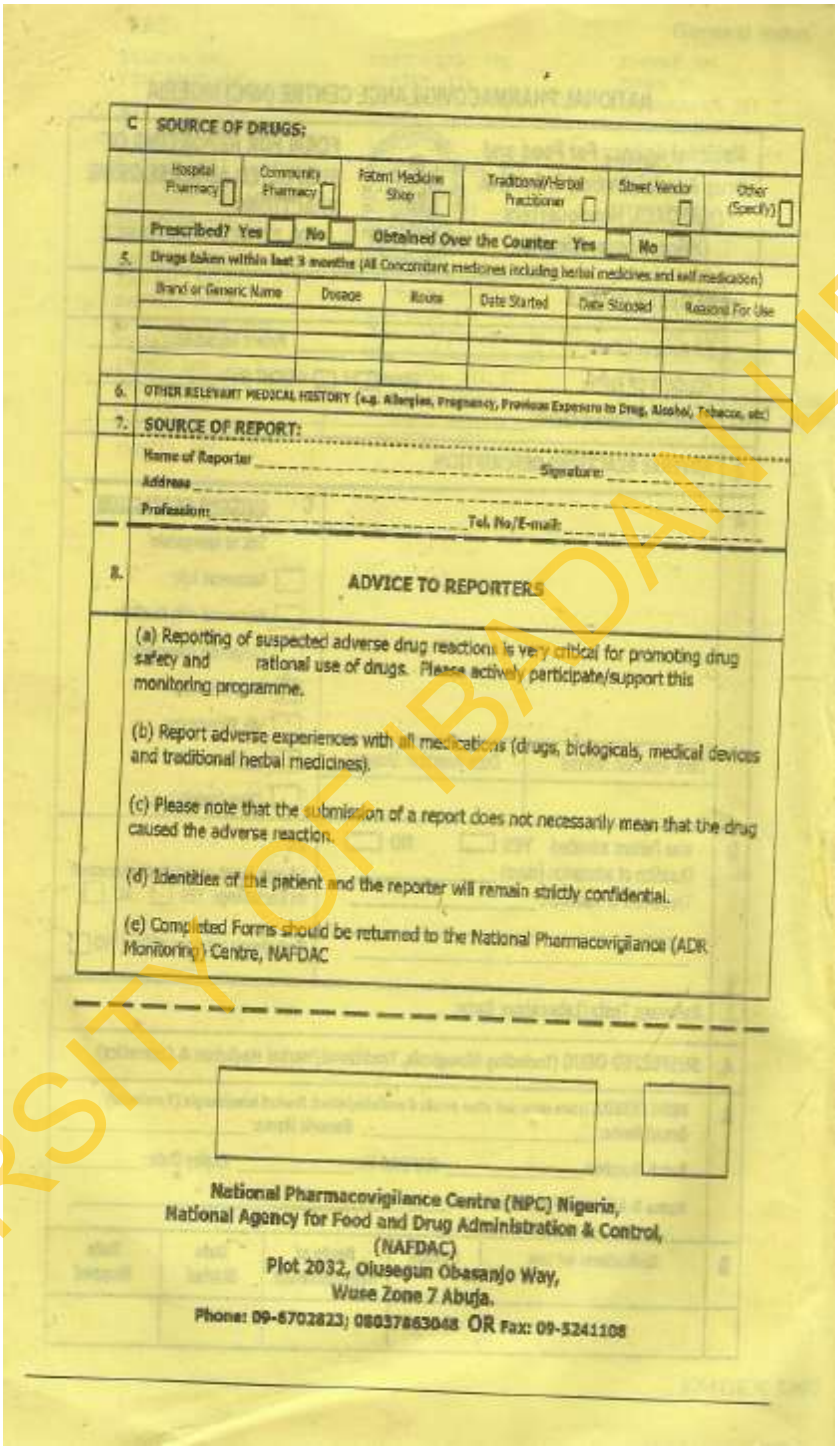
Brand Name: _____ Generic Name: _____

Batch Number: _____ NAFDAC No: _____ Expiry Date: _____

Name & Address of Manufacturer: _____

B Indications for use	Dosage	Route of Administration	Date Started	Date Stopped

Copy of the yellow form used for reporting in Nigeria (back page)



C SOURCE OF DRUGS:

Hospital Pharmacy ☐ | Community Pharmacy ☐ | Patent Medicine Shop ☐ | Traditional/Herbal Practitioner ☐ | Street Vendor ☐ | Other (Specify) ☐

Prescribed? Yes ☐ No ☐ Obtained Over the Counter Yes ☐ No ☐

5. Drugs taken within last 3 months (All Concomitant medicines including herbal medicines and self medication)

Brand or Generic Name	Dosage	Route	Date Started	Date Stopped	Reason For Use

6. OTHER RELEVANT MEDICAL HISTORY (e.g. Allergies, Pregnancy, Previous Exposure to Drug, Alcohol, Tobacco, etc)

7. SOURCE OF REPORT:

Name of Reporter _____ Signature: _____

Address _____

Profession: _____ Tel. No/E-mail: _____

8. ADVICE TO REPORTERS

(a) Reporting of suspected adverse drug reactions is very critical for promoting drug safety and rational use of drugs. Please actively participate/support this monitoring programme.

(b) Report adverse experiences with all medications (drugs, biologicals, medical devices and traditional herbal medicines).

(c) Please note that the submission of a report does not necessarily mean that the drug caused the adverse reaction.

(d) Identities of the patient and the reporter will remain strictly confidential.

(e) Completed Forms should be returned to the National Pharmacovigilance (ADR Monitoring) Centre, NAFDAC

National Pharmacovigilance Centre (NPC) Nigeria,
National Agency for Food and Drug Administration & Control,
(NAFDAC)
Plot 2032, Olusegun Obasanjo Way,
Wuse Zone 7 Abuja.
Phone: 09-6702823; 08037863048 OR Fax: 09-5241108