AWARENESS, ATTITUDE AND PRACTICE OF HEALTH CARE PROFESSIONALS TO ADVERSE DRUG REACTION REPORTING IN NNEWI NORTH L.G.A,

ANAMBRA STATE.

BY

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A PROJECT SUBMITTED TO SCHOOL OF POSTGRADUATE STUDIES, NNAMDI AZIKIWE UNIVERSITY, AWKA, IN PART FULFILMENT FOR THE AWARD OF MASTER OF PUBLIC HEALTH (M. P. H.) DEGREE.

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DECLARATION

It is hereby declared that this work is original unless otherwise acknowledged. This work has not been presented to any other institution for either the award of a degree or fellowship or to any journal for publication.

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Pharm. (Mrs.) Amaka Yves-Ann Ezeuko.

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Date.

DEDICATION

This research project is dedicated to my husband Sir. Emmanuel Ezeuko and my lovely children Chioma, Ogechi, Kelechi and Ginika.

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My enormous gratitude goes to GOD ALMIGHTY who kept me alive in spite of my wretchedness and gave me the grace to embark on and realize this project.

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To the entire M.P.H colleagues I say “thank you for making the class exciting”

Pharm. Amaka Yves-Ann Ezeuko.

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ABSTRACT

This descriptive cross sectional survey was conducted on healthcare professionals working at different healthcare facilities in Nnewi North L.G.A of Anambra state to determine their awareness, attitude and practice to ADR reporting. The research was carried out after an approval from Nnamdi Azikiwe University teaching Hospital ethical committee. Written consent was obtained from the heads of different health facilities and informed consent was obtained from individual respondents during the administration of the questionnaires. Simple random sampling technique was used to select the health facilities studied and numbers of different professional groups sampled was proportionately determined. Consecutive recruitment method was used until the required sample was attained.

A total of 372 respondents [including 241 (64.8%) nurses/related health care workers, 109 (29.3%) doctors and 22 (5.9%) pharmacists] were studied. Two hundred and twenty one (59.4%) respondents were not aware of the existence of ADR reporting scheme in Nigeria. 241 (64.8%) of them lack the knowledge of reporting guideline. Though 85.8% of the respondents believe ADR reporting to be their professional responsibility, 310 (83.3%) suspected an ADR without reporting it, Uncertainty of reactions caused by drug, ignorance on how to report, fear, unavailability of reporting forms/guideline and lack of electronic means of reporting were mentioned as obstacles to ADR reporting.

There was indeed poor awareness (40.6%), poor attitude, and poor practice (0.9%) of ADR reporting among health professionals working in Nnewi North Local Government Area of Anambra state.

CHAPTER ONE

INTRODUCTION

1.1. HISTORICAL BACKGROUND

Adverse drug reaction (ADR) has been defined in so many ways. WHO defines ADR as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, therapy of disease, or for the modification of physiological function[1]. A definition by Karch and Lasagna[2] puts ADR as any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose. The American society of health system Pharmacists (ASHP) [3] defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that;

- Requires discontinuing the drug (therapeutic or diagnostic),
- Requires changing the drug therapy,
- Requires modifying the dose (except for minor dosage adjustments),
- Necessitates admission to a hospital,
- Prolongs stay in a health care facility,
- Necessitates supportive treatment,
- Significantly complicates diagnosis,
- Negatively affects prognosis, or
- Results in temporary or permanent harm, disability, or death.

Consistent with this definition, an allergic reaction (an immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction *(*an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs. Other definitions of ADRs exist, including that of the United state Agency for Food and Drug Administration (FDA) [4].

For reporting purposes, FDA categorizes a serious ADR as one in which the patient's outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage. It should be noted that side effect {an effect with predictable frequency; an effect whose occurrence are related to the size of the dose; or an expected, well-known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth due to administration of certain antihistamines or nausea associated with the use of antineoplastics)}, drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications should not be defined as ADRs.[4]

TYPES OF ADVERSE DRUG RACTION

ADRs may be categorized in five groups. The two most common are dose related effects (type A: augmented) and effects related to abnormal interaction between patient and drug (type B: bizarre). [5]

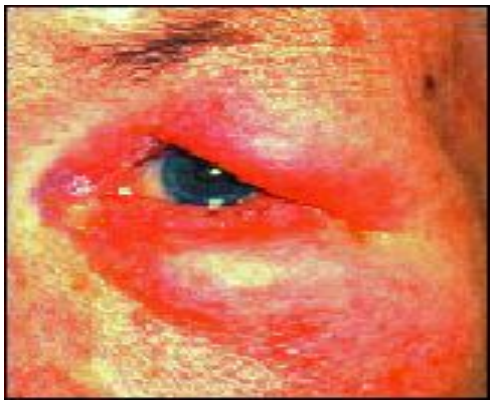
Type A: Adverse drug reactions:

Type A: (augmented) reactions are normal pharmacologic effects of the drug exaggerated to the point of being undesirable or intolerable for patients. Type A ADRs are the most common, accounting for 75-80% of those reported. [4] Reactions of this type

are also called 'predictable', because they are predictable from the pharmacology of the drug, whether caused by an excessive effect of the main pharmacological action (such as hypotension with antihypertensive drugs), or by an undesired secondary pharmacological action (such as the dose-dependent adrenal suppression caused by inhaled corticosteroids, which is of particular concern in children) [4].

Type A reactions are dose-related, occurring at a dose that is too high for the individual, and tend to have a relatively high morbidity. However, because type A reactions are usually slow in onset, the associated mortality rate is lower than in type B reactions. A type A drug reaction is more likely to occur with drugs that have a narrow therapeutic index (such as theophylline), and tend to occur more often in elderly people and neonates.

In general, drugs causing type B and serious type A reactions need to be stopped, whereas drugs causing less severe type A reactions may be continued at a reduced dose.[4] For type A reactions, other management options might include substitution of a similar but more selective drug, or giving additional drugs to antagonize the unwanted effects of the primary agent [3, 6]. Examples - Warfarin or heparin, which causes bruising; or diphenhydramine, which causes drowsiness. Another form of type A reaction involves a drug's recognized pharmacologic property other than the primary desired one. For example, b-adrenergic blocking agents exert their effect on receptors other than those targeted in the heart and vasculature, leading to the potential of bronchospasm due to b-blockade of certain receptors in the pulmonary tree. E.g.



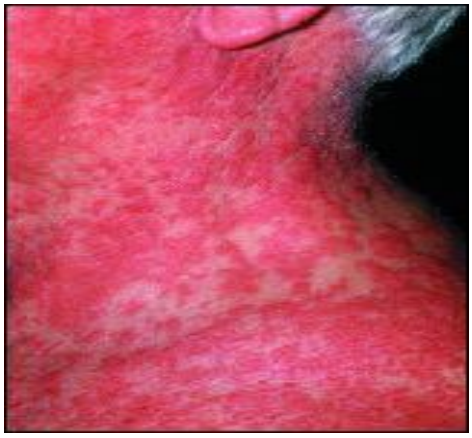
Periorbital swelling caused by a proton pump inhibitor.

Type B Adverse drug reactions:

Type B (bizarre) reactions are often more severe adverse effects unrelated to the known pharmacologic action of the drug and include most immunologic reactions. Unless patients are tested for antibody markers, these reactions are unpredictable and may or may not be dose-dependent. Type B reactions account for about 20-25% of those reported[3]. Because these reactions are not predictable from the pharmacology of the drug {such as Amoxicillin Clavulanic acid causing cholestatic jaundice, anaphylactic reaction to penicillin (rash)}. They are also known as unpredictable idiosyncratic reactions. Individual susceptibility to this type of reaction varies greatly.

Type B reactions are usually rapid in onset and there is a higher risk of mortality than in type A reactions[7]. Patients need to be able to recognize the warning signs of such a reaction if it is known to have occurred before with their medication.

Type B reactions are often allergic, sometimes involving anaphylaxis, which typically occurs on second or third exposure to the drug[7]. Patients with a history of anaphylaxis

and atopic individuals with a history of asthma are more likely to experience anaphylaxis. Other type B reactions include those attributable to unpredictable genetic factors that can affect drug metabolism[2]. Type B reactions usually require the causative drug to be stopped, because the reaction can occur at any dose, and the reaction is usually serious. 

Erythematous rash caused by an unknown drug.

Other types of ADRs include Type C, D and E.[5] While Type C ADR is associated with long-term use and dose accumulation (e.g., phenacetin and interstitial nephritis or antimalarials and ocular toxicity, NSAID induced renal failure), Type D is a delayed effects (dose independent) and occurs some time after use of drug {such as Carcinogenicity (e.g immunosuppressants) and Teratogenicity (e.g., fetal hydantoin syndrome and limb defects with thalidomide in first trimester and)}.[7] On the other hand, type E is a withdrawal syndrome associated with end of use of the drug. It is related to discontinuation that is too abrupt, for example, addisonian crisis after steroid withdrawal [7, 8]. ADR can also be classified based on

- Onset of event: { Acute (within 60 minutes), Sub-acute (1 to 24 hours), Latent (> 2 days)} and

- Severity of reaction: {Mild (bothersome but requires no change in therapy), Moderate (requires change in therapy, additional treatment, hospitalization), Severe (disabling or life-threatening)}

RISK GROUPS FOR ADVERSE DRUG REACTION

All drugs have the potential to cause ADRs, although most produce no ill effects in most patients. ADRs are more likely to occur if doses above the usual recommended level are given, but there are several other predisposing factors/groups[2,9,10] including **Older patients** due to altered drug handling; for example: reduced drug metabolism and elimination by the liver and kidneys, poor drug distribution, and increased sensitivity to the effects of medications; **the young** (neonates, particularly premature babies) due to poor development of metabolizing and elimination enzymes, increased sensitivity and underdevelopment of physiological systems, such as renal function and the blood-brain barrier and the fact that many medicines have not been developed in pediatric doses and are used off-label, so that dosage in children is often inaccurate[9]. **Women** because they are more susceptible to the toxic effects of drugs, including commonly used agents such as digoxin, heparin and captopril. Also, few data are available on the safety of medicines used in pregnant and lactating women. Women may be inadvertently exposed to unsafe products and there is a particular lack of information, education and guidance in resource-limited settings[9]; **Patients with impaired hepatic or renal function**; **Patients taking several drugs**: Polypharmacy increases the risk of ADRs and the likelihood of ADRs increases sharply with the number of drugs administered mainly due to drug interactions. Mistakes may also occur if drug regimens are complicated and

involve several drugs. The number of drugs prescribed should always be kept to a minimum to reduce the risk of drug interactions, and very clear instructions on how to take them should be given, particularly to older patients; **Atopic individuals:** Patients with a history of anaphylaxis and atopic individuals with a history of asthma are more likely to experience anaphylactic reactions (type B adverse effects); **Individuals with specific genetic variations in drug-metabolising enzymes**: Genetic variability in drug-metabolising enzymes is an important contributing factor to the incidence of ADRs (particularly type B reactions), in some individuals [10]. Certain ethnic groups have been identified as being more susceptible to ADRs with particular drugs because of genetic polymorphism. For example, glucose-6-dehydrogenase (G6PD) deficiency, which predisposes to some drug-induced haemolytic anaemias, is more common in people who are African, in Kurdish and Iraqi Jews, and in some Mediterranean people and Filipinos; **Individuals with co-existing disease:** Certain disease states can precipitate ADRs to certain drugs if the disorder alters the pharmacokinetics of a drug (absorption, distribution, metabolism, elimination), or if it increases the individual's sensitivity to the action of a drug (for example, patients with obstructive airway disease are more sensitive to the bronchoconstriction caused by beta-blockers); **Variations in drug formulations that result in the delivery of higher than expected quantities of the active drug can cause ADRs**; and **Error** at any stage in the supply of a medication; for example, confusion can arise over milligrams and micrograms and between similar drug names or a drug might be administered at the wrong dose, or to the wrong site.

FREQUENCY AND OCCURRENCE OF ADRs

ADRs are common. A study by general practitioners estimated that the presenting symptom of 1.7% of their consultations over a six month period was a manifestation of an ADR [11]. Furthermore, 2-6% of hospital admissions are for ADRs. [12,13] Although a shorter timeframe is more common, ADRs can occur months or years after a drug was started and may not be obvious unless a thorough drug history is taken. These long-term ADRs can be predictable: type A reactions (such as osteoporosis with corticosteroids, or bladder cancer in patients taking cyclophosphamide), or idiosyncratic, type B reactions (such as, pulmonary fibrosis with amiodarone). The frequency of adverse reactions are generally described in the manufacturer's product literature as follows[14].

- common → occurring in 1:100 to 1:10 of the patients.
- very common → more than 1:10
- uncommon → 1:1,000 to 1:100
- rare → 1:10,000 to 1 :1,000
- Very rare → less than 1:10,000.

AVOIDING ADRs

Though ADR is common, a study on ADRs in nursing homes suggest that more than half of the events are preventable [15-18] and that 70% are associated with monitoring errors[15]. Also, serious ADRs are more likely to be preventable than those of a less serious nature[15]. Understanding the causes of ADRs is essential to efforts to decrease their frequency and severity.

WHO'S ROLE TO REPORT ADRs

While pharmacists head the establishment of ADRs programs in health institutions and facilitate activities surrounding reporting of ADRs, the core reporting of ADRs is a collective activity of all health professionals.[11,20,21] According to The Guide for Detecting and reporting of Adverse Drug reactions[19], all healthcare 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 orthodox medicines, X-ray contrast media, medical devices, cosmetics, traditional and herbal medicines. This guide also stressed that it is vital to report even when it is uncertain that the medicine in question is the actual cause of the reaction.

MANAGEMENT OF A SUSPECTED ADR

The symptoms of an ADR can be similar to those of diseases with other causes, and there are few specific clinical or laboratory methods to differentiate them[7]. When trying to determine whether an unwanted effect is an ADR, it may be helpful to find out whether the reaction has been reported before for the drug in question.

ADRs must be treated according to their cause and severity. In general, drugs causing type B and serious type A reactions need to be stopped, whereas drugs causing less severe type A reactions may be continued at a reduced dose. Specific management according to Oliver Jones[7] is as follows:

For type A reactions, the management is simply reduction in the dose or withdrawal of the medication. Other management options might include substitution of a similar but more selective drug, or giving additional drugs to antagonize the unwanted effects of the primary agent.

By contrast, type E reactions require reintroduction of the drug and more gradual withdrawal. Type C or D reaction may be irreversible or only partially reversible on drug withdrawal.

Type B reactions are both uncommon, unpredictable, and have high morbidity and mortality. The first step is always the immediate withdrawal of the drug. If the reaction is mild, no further intervention may be necessary. Urticarial rashes, and to a lesser extent non-urticarial rashes, may be treated with antihistamines such as chlorpheniramine and an adrenocortical steroid. In more severe cases, these drugs may be given intravenously or intramuscularly. If angioedema develops with threatened laryngeal oedema, consideration should be given to adrenaline.

Anaphylaxis is a medical emergency. High skilled help should be summoned, including an anaesthetist. The patient should be positioned flat, with feet raised and airway secured. Oxygen should be administered and 0.5-1.0mg of adrenaline given intramuscularly as first line treatment (equivalent to 0.5-1.0ml of 1:1000 adrenaline). This is repeated every ten minutes according to cardiovascular parameters and clinical improvement. Chlorpheniramine (10-20mg) should also be administered by slow intravenous injection, and hydrocortisone (100-300mg), though the onset of action of the latter may not be for several hours. Further deterioration may necessitate

intravenous fluids, nebulised inhalers, and intubation or tracheostomy. Other ADRs may involve any body system and manifest in several different ways. The correct management of these patients should be considered on an individual basis. Often this is delayed by failure to consider an ADR as the underlying cause of a patient's deterioration.

Other management options include the use of “tracer” drugs that are used to treat common ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, and corticosteroids), or stat orders for laboratory assessment of therapeutic drug levels and Provision of supportive or palliative care e.g., hydration, glucocorticoids, warm / cold compresses, analgesics or antipruritics, rechallenge or desensitization.[7, 15]

Reports of birth defects related to thalidomide use in pregnant women prompted FDA to develop an adverse event surveillance program in 1961[22] and with the amended Food, Drug, and Cosmetic Act of 1962, drug manufacturers were required to report any adverse events associated with their products.

The World Health Organization (WHO), in 1968, created the International Drug Monitoring Program for the purpose of collecting information about Adverse Drug Reactions (ADR) that were not observed during clinical drug trials.[23] This program has been exceptional in identifying the early signs of ADRs .[24] ADR monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs, provide a mechanism for monitoring the safety of drug use in high-risk patient populations, and stimulate the education of health professionals regarding potential ADRs[25].

1.1. STATEMENT OF THE PROBLEM:

Globally, physicians are faced everyday with problems of adverse drug reactions (ADRs) [12, 26 , 27] and about 95% of such cases go unreported Worldwide [28,29]. Even though they are under-reported worldwide, they are much more under-reported in Nigeria[30]. Studies have also shown that adverse drug reaction (ADR) is the 4th to 6th cause of death in the United States[26, 27]. Studies conducted in developed countries have consistently shown that approximately 5% of hospitalized patients are admitted into hospital as a result of an adverse drug reaction while 6-10% of inpatients experience a serious ADR during hospitalization[12]. The percentage of hospital admissions due to ADRs in some countries is approximately 10% [31-34] and treatment of ADRs imposes a high (15-20 %) financial burden on health care [35, 36]. According to Med Watch [2], the Food and Drug Administration's (FDA's) Office of Drug Risk Assessment has stated that these numbers are vastly underestimated, as its research has shown that only 1% of ADRs are reported. The purpose of ADR reporting is to reduce the risk associate with prescribing and administration and ultimately improve patients care, safety and treatment outcome.

The National Agency for Food, Drug Administration and Control (NAFDAC) therefore introduced pharmacovigilance in 2004 to encourage ADR monitoring and reporting in Nigeria. Unfortunately, there is very limited information about adverse drug reactions in developing countries[32], including Nigeria due to poor reporting of ADRs. The information which we receive on adverse drug effect from other countries may not be applicable to Nigeria due to various differences that may influence patient's response [19] including;

- Disease and prescribing practices;
- Treatment seeking behavior e.g. self medication;
- Genetics, Diet, Traditions of people e.g. high carbohydrate, fat, kola nut consumption rate etc;
- Drug manufacturing process used which influence pharmaceutical, quality and composition;
- Drug distribution and use including indications, dose, storage and availability;
- The use of traditional and complementary drugs (e.g. herbal remedies) which may pose specific toxicological problems when used alone or in combination with other drugs; and
- Racial differences.

This study was designed to determine the awareness, attitude and practice of ADR reporting among health care professionals working in Nnewi North L. G. A., Anambra state with a view to encourage health professionals to see ADR monitoring and reporting as a professional obligation. With improvement on ADR reporting in this area, ADR induced morbidity, mortality and death will be drastically reduced.

1.2. OBJECTIVE OF THE STUDY

1.2.1. GENERAL OBJECTIVE

- To determine the awareness, attitude and practice of ADR reporting among health care professionals working in Nnewi North L. G. A, Anambra state.

1.2.2. SPECIFIC OBJECTIVES

- To find out the level of awareness of health professionals in Nnewi North L.G.A to the national Adverse drug reaction reporting scheme/guideline.
- To access the attitudes of health professionals in different settings of health care in Nnewi North L.G.A [Health posts, Primary Health centres (PHC), Private hospitals and tertiary health institution] towards the reporting of ADR.
- To compare the ADR reporting practices of different categories of health care professionals.
- To determine factors influencing the reporting of ADR by health professionals.
- To determine the proportion of health practitioners that has ever had training on ADR reporting.

CHAPTER TWO

LITERATURE REVIEW

2.0. AWARENESS OF HEALTHCARE PROFESSIONALS TO THE NATIONAL ADR REPORTING SCHEME/ GUIDELINES.

Various studies in both developed and developing countries have revealed poor awareness of healthcare professionals to their various National adverse drug reactions reporting scheme/guideline. The poor awareness is more pronounced among healthcare professionals in the developing countries.[30]

Though voluntary reporting of ADR have operated since the early sixties in many developed countries, a study on the health professionals' awareness on pharmacovigilance in 62 hospitals in Jiangsu province, China[37] revealed the participants (health professionals) to have good recognition of basic adverse drug reaction but poor awareness of pharmacovigilance. In a similar study on medical practitioners in Netherlands, though majority of the respondents were aware of ADR reporting scheme, 18% were not aware of the need to report. A study on pharmacist's (Hospital and community pharmacists) attitude to ADR reporting in Hong Kong [38] found out that most of them (87.7%) were not aware of any ADR reporting system existing in Hong Kong. In a study to identify factors, which would predict physicians' failure to send ADR reports in Malaysia, about 40% of the respondents were not aware of the existence of the national reporting system in Malaysia [39]. In a study to investigate the awareness and attitudes of healthcare professionals (doctors, nurses, and administrators) toward the ADR system in China, 52.2% lack of knowledge of the existence of a national ADR reporting system [40]. In a research on the Awareness and

Reporting of Adverse Drug Reactions among Health Care Professionals in Sudan**,** the main reasons for not reporting ADRs were lack of knowledge on how to report (27.0%) and lack of awareness about the existence of national or international reporting systems (26.5%)[41]. In a study where the knowledge of pharmacovigilance practice, reasons for not reporting ADR, and perceptions of the Iranian pharmacists on pharmacovigilance practice was evaluated, 29% of the respondents were not aware of the Iranian Pharmacovigilance Center [42]. Lack of information about the spontaneous reporting system was also reported in Europe and Sweden. [43,44]

A survey among medical residents in France showed that the majority of them had a lower knowledge regarding pharmacovigilance. [45] A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems. [46] A recent study from India also identified that the awareness about pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors. [47]

In Africa, a study on the adverse drug reaction reporting by general medical practitioners and retail pharmacists in Harare, Zimbabwe, showed that 75% of the doctors had not known that a reporting scheme existed in Zimbabwe and non of the participants had ever sent in a report prior to the study [48].

The general lack of awareness of ADR reporting system in Nigeria was reflected by the 63.4% of the respondents who did not know about the existence of a Yellow Card reporting scheme coupled with the fact that only two respondents had ever reported ADRs with a Yellow Card[49]. This proportion is rather very low when compared to a similar reporting scheme among doctors in the United Kingdom, America**,** Netherland,

Spain, China and India[50-53]. These findings suggest the need for interventions to improve the KAP of the healthcare professionals.

2.1. ATTITUDE OF HEALTH PROFESSIONALS IN DIFFERENT SETTINGS OF HEALTH CARE TOWARDS ADR REPORTING.

In most studies, which included doctors working in primary healthcare and in hospitals, the results have shown that hospital staff is less aware of the purposes of the spontaneous reporting system than their counterparts in general practice [54, 55]. However, a report from Canada shows that more reports came from hospital pharmacists (38.8%) compared to 34.8%, which come from their community counterparts[56]. In a study carried out by the department of Health and Human services, USA on the Hospital reporting of ADRs, to determine the nature and frequency of Hospitals' in-house ADR monitoring; and to identify any reasons why hospitals do not report ADR to the Federal drug Agency[57], a significant difference exists in the awareness level among hospitals of different sizes with small hospitals much less likely to be aware of the FDA's reporting process. A total of 51% of the respondent hospitals indicated that they had never reported ADR to the FDA as at 1989 and this response was more among the small (68%) than the medium (42%) and large hospitals (29%). Small, medium, and large hospitals are hospitals with 100 beds or less, 100-499 beds, and 500 or more beds respectively.

2.2. ADR REPORTING PRACTICES OF DIFFERENT COUNTRIES

In a study to investigate and compare the operation of different national spontaneous reporting schemes for adverse drug reactions[58], many differences were found between the schemes operating in different countries. Some schemes had been in operation for over 30 years, while others were more recently established. While most schemes rely on voluntary reports, in two countries (France and Spain), reporting is a legal requirement for healthcare professionals. Reports are accepted from doctors, dentists and pharmacists in all of the countries surveyed; however the role of other health professionals and the general public was found to vary. There were also differences in the types of reactions for which reports are requested, and the products covered by the schemes. In some countries (e.g. Denmark) reports of all reactions are sought, while other countries focus on only serious reactions or reactions to newly marketed products. In Australia, there is a separate scheme for drug-induced congenital malformations and Canada, South Africa and the US run separate schemes for reactions to vaccines. However, other countries include these reactions in the general spontaneous reporting schemes. The numbers of reports received by the countries also varies considerably from a few hundred each year in South Africa to over 20,000 in the US. Nigeria practices a voluntary spontaneous reporting system.

In a multicounty Study of 10 countries on Effective Drug Regulation [59], Uganda is the only one of the 10 countries that does not have a system for monitoring ADR. Each of the other nine countries uses a spontaneous reporting system for health professionals - i.e. health professionals send reports on a voluntary basis. Reporting by the pharmaceutical industry, by contrast, is mandatory in most of the countries. Australia,

Cuba, Estonia, Malaysia, the Netherlands, Tunisia and Venezuela all require marketing authorization holders to report any ADRs for their drug products. In Cyprus and Zimbabwe, reporting by marketing authorization holders is voluntary. No data are available to evaluate the relative effectiveness of voluntary versus mandatory reporting by the pharmaceutical industry.

Consumer ADR reports are collected in the Netherlands, although as a result of consumer participation rather than by design. The drug information telephone line of the Royal Dutch Association for the Advancement of Pharmacy was initially created merely to provide information to the public on all aspects of drug use, but it has also become an additional source of ADR reports. In Australia, an ADR reporting system for consumers is planned.

In those countries where reports are evaluated and recorded, specialized bodies have been set up to review ADR reports. Each country has a different set of operating procedures for this body. In Australia, Malaysia and Zimbabwe, a specialized committee is employed as part of the DRA to carry out the review task. The Adverse Drug Reactions Advisory Committee in Australia, for example, has a system for following up and validating the reports, classifying the reported incidents as "possible", "probable" or "certain" and then referring them to the appropriate parties for further action.

The countries use similar means for disseminating information from the review. In Australia, Cyprus, Estonia and Venezuela, ADR information and the results of report evaluation are published in bulletins which are distributed to physicians and pharmacists. In Tunisia, such information is disseminated at health professionals'

workshops. In Malaysia, review information is also sent to the reporters and the marketing authorization holders as information feedback. In every country, review information is forwarded to the Drug Regulatory Authority. Each of the countries also sends reports to the WHO Collaborating Centre for International Drug Monitoring.

2.3. ADR REPORTING PRACTICES OF DIFFERENT CATEGORIES OF HEALTHCARE PROFESSIONALS.

In order to identify the culprit drugs causing ADRs, several countries have initiated pharmacovigilance programs in the recent past. Because of the variation in drug response among individuals, prescribing habits, drug regulatory system, availability of drugs etc, it has been recommended for every country to set up their own pharmacovigilance programs. [60]

National drug monitoring programs throughout the world differ in their sources of participation in the reporting of ADRs by healthcare professionals[61, 62]. In contrast to Canada or the U S A, where the majority of the reports come from pharmacists, some countries, such as France, Ireland, Malaysia, New Zealand, the Nordic countries, and the UK, have the largest contribution of ADR reports coming from physicians [56]. The reasons for low reporting rates by pharmacists in these countries have not been adequately analyzed. It has been suggested that it may result from the simple fact that pharmacists were excluded from reporting ADRs to the national reporting program, which is the situation in the Nordic countries (e. g, Finland and Sweden)[63]. A study in the UK concluded that hospital pharmacists require more awareness and training to improve their reporting habbit[64].

Even among countries where pharmacists are allowed to report ADRs to their national program, lower reporting rates by pharmacists are observed. New Zealand is a good

example of this case. Between January and June 2004, only 5.7% of ADR reports were submitted by pharmacists compared with about 70% of ADR reports submitted to the MEDWATCH program in the US by pharmacists, most of which are from hospital-based pharmacy practitioners. Canada shows similar trends to the US in ADR reporting; for example, in the fiscal year of 1998–1999, at the British Columbia Regional ADR Centre, most ADR reports were generated by pharmacists (38.8% and 34.8% by hospital and community pharmacists, respectively), physicians' reports accounting for only 10.8%[56].

Although pharmacovigilance programs are successful in improving drug use patterns, under reporting of ADRs is felt as a major problem. [62] In order to improve the reporting rate, it is important to improve the Knowledge, Attitude and Practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance.

The Yellow Card Scheme was established in the United Kingdom in 1964 [65] and ADR reporting was left on the hands of only doctors, dentists, coroners and since April 1997, pharmacists. Unlike nurses in certain European countries, including Ireland, the Netherlands and the USA, UK nurses were not allowed to report suspected ADRs until October 2002[66]. Nurses were allowed the first time in order to aid the monitoring and reporting of any suspected adverse drug reactions associated with the new Meningococcal sero group C Conjugate (Men C) vaccine. In the analysis of the ADR report after the six month exercise, Nurses were the health professionals who provided the largest proportion of reports of suspected ADRs and almost half of all reports during the Men C vaccination campaign. Their reports contained an equal proportion of serious suspected ADRs and the reports were documented as completely as those from GPs and hospital doctors. . Another report of pharmacovigilance study

in United Kingdom finds out that Hospital doctors fall behind General Practitioners (GP) in ADR reporting, however, even GPs' reporting has lagged in recent years [67].

In a study of the knowledge of pharmacovigilance practice of Iranian pharmacists, more than half of the respondents felt that ADR reporting should be voluntary, while 26% felt it was a professional obligation. As for the purposes of ADR reporting scheme, 60% of the pharmacists falsely believed that monitoring ADR spontaneous reports aims at measuring the incidence of ADR. 42% of the pharmacists indicated that they have suspected an ADR without reporting it. Although their ADR center states that all suspected reactions to any drug on the market must be reported, only 17% of the respondents seemed to be aware of this responsibility [42]. In a recent study to evaluate the knowledge, Attitude and Practice (KAP) of the healthcare professionals working in Manipal Teaching Hospital (MTH), Pokhara, Nepal, regarding ADR reporting and pharmacovigilance, the KAP scores were low. Doctors and pharmacists had a slightly higher score than the nurses. [68]

2.4. COMMONLY REPORTED ADVERSE DRUG REACTIONS.

As an increasingly more variable array of new drugs are being introduced into the market and improvement in health services result in a prolonged life expectancy, the frequency and quantity of drugs taken also increases significantly. These facts contribute to more cases of adverse drug reactions (ADRs) [66]. The most frequent observed are cutaneous reactions and that range from generally trivial manifestation, such as pigmentation, to severe life threatening reactions, such as toxic epidermal necrolysis (TEN), Steven Johnson syndrome (SJS), exfoliative dermatitis (ED) and drug hypersensitivity syndrome (DHS) [66]. Their impact is significant in terms of cost and health service resources.[69-72] Cutaneous or allergic reactions accounts for approximately 14% of ADRs in hospital patients and 3% of all disabling injuries during hospitalization.[70, 71]

A study by Li et al[73] at Peking University Third Hospital reported that the incidence of Severe Cutaneous Adverse drug reactions (SCADRs) in the Haidian district was 1.8 cases per million person per year and the incidence rate for SJS, ED, TEN, DHS were 0.8, 0.6, 0.05 and 0.4 cases per million person per year, respectively. Different patterns were observed in categories of clinical types of SCADRs in different countries, where SJS has a higher proportion as compared to other SCADRs in China and Italy. However, Noel et al[74] in India found a higher proportion on TEN.

One study has shown that the mortality rates for SJS were less than 5% whereas the rate for TEN approaches 20%–40%.[69] However, a study by Huff et al found that the number of deaths is up to 18% of patients with SJS, and up to 50% of patients with TEN. In the published reports of the past 50 years, the mortality rates associated with

ED have consistently remained high, ranging from 20%–60%[2] and DHS related deaths are 10%.[75,76]

Onset of SCADRs varies, ranging from hours to 6 weeks after the initiation of therapy but occurs more rapidly with re-challenge.[69,70,77,78] The mean time from first drug administration to onset of SJS or TEN was 1-28 days. A longer incubation period was observed with thiacetazone ((10±6) days), phenytoin ((12±9) days) and carbamazepine ((11±3) days).[69,71] DHS appears in 2 to 6 weeks after administration of the causal drugsR[23,71,77] however this time interval is shorter for abacavir, lamotrigen and nevirapine. ED onset is within 15 to 28 days after the administration of the causal drugs.[78-80]

SCADRs occur at ages ranging from 3 to 85 years.[80,81] However, there has been a case reported from Turkey on DHS in a premature infant, because of anticonvulsant drugs.[82]There have been some reports of the incidence of drug eruptions that increase with patient age. In the UK the percentage of adverse drug eruptions increased from 0.6% for patients aged 0–20 years to 2.7% for patients aged over 50 years. A study by Richard Martin et al[83] found that the overall age relative risk of an adverse drug reaction is between 30 and 59 years of age.

In most cases of ADRs, females are at higher risk than males.[69,70,83-88] However, a study by Li et al[89,73] has shown a male predominance in SCADRs, with an exception for the SJS group where females were predominant. A study by Peyrière et al has shown a male predominance in DHS and ED incidence.[90, 91] A serial study conducted in Thailand showed a male predominance as well in SJS and TEN.[92]

Patients with AIDS have a dramatically increased incidence of TEN and DHS. [69,70, 93] A study by Fiszenson et al[89] found that of the cases of cutaneous adverse drug reactions, 19% were known to be infected by HIV. Patients with HIV are also prone to exfoliative dermatitis drug eruptions.[90] Reactivation of Human Herpes Virus 6 may contribute to the development of DHS.[77] Patients with autoimmune diseases, like lupus erythematous (LE) and an HLA-linked genetic susceptibility, have been reported to have a higher frequency of drug allergies. LE patients have also been shown to have an increasing incidence in antibiotic allergy. [69,70, 84, 94]

In an ADR study among Spanish children (14 years or below),the study reports that the most commonly involved organs and systems to be the skin, digestive tract, and nervous system (62.8%)[95]. The most commonly involved pharmacological groups were antibiotics, respiratory medications, and vaccines (69%). The absolute number of reports is higher in children between 1 and 4 years of age (37.9%). A report from an Indian study also proves dermatological system to be the most commonly affected organ system with skin rash (10.5%) as the most frequently reported reaction.[96]

ADRs are a significant problem in Nigerian children. A retrospective/prospective study at pediatric unit of Lagos state University [97] revealed that the most commonly affected organ/ system was the skin (over 50% of ADRs) and the most frequently reported ADR was rash (Erythema multiforme) which was similar to the findings of other studies [98,**99**-101]. The group of drugs most frequently involved in ADRs in the study was antibiotics. Infectious diseases were, however, the commonest cause for admission to hospital and hence antibiotics were frequently prescribed. Erythema multiforme, the most common ADR in the study, was caused by antibiotics

(ampicillin and co-trimoxazole), antimalarials (sulfadoxime/ pyrimethamine) and anticonvulsants (phenobarbitone). These drugs are well known for this type of ADR[102,103]. The high increase of erythema multiforme was probably a result of the pattern of self-medicated and prescribed drugs used by the patients. In those patients who developed ADRs from a combination of two or more drugs, the skin manifestation was either erythema multiforme or its severe form, SJS, and they were hospitalized for over two weeks.

2.5. FACTORS INFLUENCING THE REPORTING OF ADR BY HEALTH CARE PROFESSIONALS.

2.5.1. Potential obstacles to the reporting of ADRs

Various studies, mainly based on surveys, have assessed the physicians' opinions about the problems in spontaneous reporting of ADRs [104–107].Potential barriers for the spontaneous reporting of ADRs according to the doctors are the following.

The diagnosis of ADRs

Lack of index of suspicion of an ADR could be a problem, although most of the hospital doctors are used to including them in a differential diagnosis list. There are doctors who believe that it is necessary to confirm ADRs, and they do not report anything if they are not completely sure about the exact cause of the ADR. A problem in reporting is to establish a causality relationship between several drugs taken by patients and suspicions of adverse reactions. As one physician stated, 'When a patient is taking a lot of drugs, how can we determine which drug is causing the adverse

reaction?' [104–107] In addition, the doctors sometimes do not have information resources on ADRs and they considered it as a problem in spontaneous reporting.

The organization of the pharmacovigilance

Although most doctors know about the pharmacovigilance programme, there are some who still do not. Many doctors are not acquainted with the objectives and potential usefulness of this pharmacovigilance programme in the hospitals. Many doctors think that barriers to access to people working in the hospital pharmacovigilance section are an important problem in spontaneous reporting. A lack of yellow cards or forms for reporting is another problem that doctors described. As one physician said, 'I have patients with ADRs, but, sometimes, I do not have any yellow cards'[104–107]. An absence of a pharmacovigilance feedback system is seen by many doctors as another barrier to spontaneous reporting and especially for those who are not familiar with the programme. In addition, a further problem is the methodology for identifying warnings. As one physician said, 'I do not know if the process for identifying warnings is reliable'. [104–107]

The clinical workload

Lack of time, and increase in work and other clinical priorities are important problems militating against ADR reporting by the majority of Doctors, and more so when they have to fill out additional forms or records. Many doctors do not report all ADR cases because they usually see so many ADRs in their practice and they cannot report all of them. As many physicians said, 'We see a lot of patients with ADRs', and one physician stated 'I have a lot of work, but I always notify a severe ADR when I see it, although I do not usually notify mild ADRs'. [104–107] A frequent question posed in this

context is ‘What kind of ADR should we report? Other doctors considered forgetfulness as a problem in reporting, because when they see a patient with an ADR in their clinical activity, they usually postpone reporting it, and finally they forget it.

The potential conflicts

One of the obstacles to ADR reporting is their potential to attract legal actions. Several doctors thought that the problems of legal liability and possible judicial claims against doctors and the problems of confidentiality with patients’ data were obstacles to bear in mind. In addition, a few doctors think problems with publication in medical journals are a barrier to reporting.

The study of physicians’ attitude to ADR reporting in Portugal [108] blamed marked underreporting of ADRs on infrequent occurrence of serious ADR and the fact that common or trivial ones did not warrant reporting. In a study to investigate the knowledge and attitudes of healthcare professionals (doctors, nurses and administrators) to adverse drug reactions (ADR) in Wuhan city China [109], the main reasons for underreporting were related to factors on reporting process, address of related centers and unavailability of the Forms.

These factors have been broadly classified as personal and professional characteristics of health carers, and their knowledge and attitudes to reporting [110]. Inman [111] has summarized these factors as the 'seven deadly sins'. 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; and 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). Lopez-Gonzalez et al [110], in their review of determinants of ADRs under-reporting from the global perspective, have shown that three of the seven 'sins' proposed by Inman that are associated with professional activity (financial incentives, fear and ambition to publish) seem to contribute less significantly to under-reporting. Insecurity (the belief that it is nearly impossible to determine whether or not a medicine is responsible for a particular ADR) is another factor associated with under-reporting [110] but was not proposed by Inman. It therefore appears that factors that promote under-reporting may vary from one country to another.

2.5.2. Factors encouraging the Reporting of ADRs/solutions to overcoming obstacles to reporting of ADRs

Suggested solutions by hospital doctors for improving the spontaneous reporting of ADRs are as follows[104-107].

Definition of priorities for spontaneous reporting

Doctors believe it is necessary to define priorities for spontaneous reporting in order to select types of more useful reports because they have much work to do and it is

impossible to report all their suspicions of ADRs. Physicians think that a selection of spontaneous reporting could be made according to the type of suspected drug or the severity of adverse reactions or unexpected ADRs. Doctors proposed clarifying to a greater degree the ADRs that should be reported to different services according to the treated diseases or drugs used in the different clinical services.

Making access and contact easier with the pharmacovigilance centre:

All doctors think that it is necessary to facilitate easy access and a quick contact with a hospital pharmacovigilance group. Different ways proposed to contact someone are by phone, fax or information technologies on the internet (World Wide Web or e-mail). To facilitate the reporting process, reminders in the form of an advertisement, a poster indicating phone and fax numbers, or other ways to contact people were suggested. The availability of more yellow cards or forms for reporting distributed in different wards was suggested, as well as specific mailboxes for ADR notifications located in different hospital areas.

In addition, other possibilities included having specific doctors to contact in different wards, who would be informed of ADRs seen in each clinical service and who would then report directly to the pharmacovigilance programme. However, doctors considered it necessary to have the physical presence of experts from the pharmacovigilance system to notify them about ADRs, because they can help doctors with advice in filling out forms and doctors can remember much more ADRs. Visiting rounds or periodic sessions to discuss clinical cases was the most direct way suggested to facilitate access and contact for spontaneous reporting. Finally, another possible solution suggested to improve reports of ADRs was a revision of clinical

reports when patients are discharged. **Development of information and support activities for reporting ADRs:**

Facilitating information and support when there is a suspicion of an ADR in specific cases was another solution suggested by some physicians. Support could be to give specific information regarding all reported ADRs, or a therapeutic consultation about evidence of specific suspected ADRs and an opinion about the causality assessment of suspected ADRs or the mailing of an assessment of each notified case.

Feedback of the pharmacovigilance activities

Facilitating general information about hospital pharmacovigilance activities was proposed as a useful way to improve spontaneous reporting. Feedback of the pharmacovigilance activities suggested was: a periodic edition of an ADR bulletin with a periodic summary of ADRs reported in the whole hospital and a discussion of the most interesting cases, or a periodic sessions with a summary of specific types of ADRs according to the interest of the each one of the different medical specialties or different medical wards, or regular information about warnings of ADRs according to the international and national drug agencies.

When asked about how ADR reporting could be improved (open question) [112], U K pharmacists gave a wide variety of responses. The most frequently cited comments included education, training and study days or evenings (62), more time to spend on the wards with patients (31), more feedback, reminders and increased awareness (21), encouragement from managers and departments (13), increased collaboration with prescribers and participation on ward rounds (12), increased accessibility of Yellow Cards and cards specifically designed for the use of pharmacists (13) and more

publicity in journals about the scheme (8). Other proposals (frequency less than 7) included on-line access or telephone based reporting, development of local initiatives, increased confidence in dealing with medical staff, making reporting a professional responsibility, a fee for reporting, ADR specialist pharmacists and increasing awareness among other professionals that pharmacists could report ADRs.

2.6. TRAINNING OF HEALTHCARE PROFESSIONALS TO ADR REPORTING.

Education and training have been shown to be the only positive predictor in influencing health professionals to report ADRs[112]. Evidence of the effect of training courses on ADR reporting is more pronounced in the developed countries compared to the developing ones.

In a study to evaluate United Kingdom hospital pharmacist's knowledge and attitude towards ADR reporting, training was received by 109 (37.9%) pharmacists, mostly through internal departmental meetings (67.9%). According to the report, those who had received training were more likely to have reported an ADR, scored higher on the criteria for reporting, were more likely to report ADRs according to the required criteria, and, knew more about the purposes of the Yellow Card Scheme.

A joint research project conducted between the FDA and the Rhode Island Department of Health to educate physicians on the need to report suspected ADRs to the FDA. Two years after the educational efforts began, voluntary reporting by physicians in Rhode Island had increased more than 17-fold. Both the number of reports and the reports of severe reactions increased to a similar degree[113].

According to the Uppsala report [114], an Advanced Course on Pharmacovigilance was held in Cartagena, Colombia and 18 health professionals (medical doctors and pharmacists etc) from eleven Latin-American countries received training in pharmacovigilance skills and pharmacoepidemiological methods. Through a set of practical cases, all steps of the pharmacovigilance process were covered. During the course, participants also described actual pharmacovigilance activities in their countries. Currently, some Latin-American countries such as Costa Rica, Peru, and Venezuela have joined the WHO Programme. A Pharmacovigilance Centre in Chile (Centro de Información de Medicamentos y Farmacovigilancia - CENIMEF) organized a Latin American Pharmacovigilance ADR training course, from 10th to 14th June 2002 in Santiago, Chile. There were 52 participants, who were all professionals from academia, hospitals, community pharmacies and regulatory agencies. Most Latin-American countries were represented: Bolivia, Brazil, Cuba, Guatemala, Panama, Paraguay, Peru, Uruguay, and Venezuela, with the remainder from the host country, Chile. Course activities included lectures, seminars and workshops, with international and national experts leading these activities.

National Pharmacovigilance Centre in Cyprus performed an internal training session on September 27, 2002 and this was followed by a seminar for health professionals on September 28. The pharmacovigilance seminar was attended by 350 doctors, pharmacists and nurses wanting to learn more about what pharmacovigilance are, how it may add to patient safety and what professionals need to do to make the pharmacovigilance system achieve its goals.

Other researchers have proven educational intervention to improve ADR reporting in Portugal[115] and Rhode Island in the USA[116]

In Nigeria, training of health professionals on ADR is very poor. Among the 120 doctors surveyed in LASUT, Nigeria, Only one respondent had received training on how to report ADR with a Yellow Card[30]. However, the respondent did not mention where the training was received. The majority of the respondents (98, 98.9%) are willing to undergo training on how to recognize ADRs and how to report them with a Yellow Card.

2.7. SUGESTED METHOD OF IMPROVING ADR REPORTING

According to the study done in LASUT[30], Suggested methods of improving ADRs reporting and the percentage level of respondent is as summarized in table 1[117] below.

Table 1. Suggested methods of improving ADRs reporting

Methods	Frequency(n= 98)	Percentage (%)
Continuous education, training and seminars	94	95.9
Instituting and encouraging feedback between patients prescribers and dispensers of drugs	69	70.4
Reminders and increased awareness from the ADR Monitoring Committee	67	68.4
Increasing awareness among other professionals that they could report ADRs	62	63.3
Increased collaboration with other healthcare professionals	58	59.2

More publicity about reporting scheme in local journals	56	57.1
Encouragement from the ADR Monitoring Committee and various head of departments	49	50.0
Having an ADR specialist in every department	46	46.9
Encouraging on-line or telephone reporting	45	45.9
Alerting all outpatients to watch out for possible ADR when prescribing new drugs	44	44.4
Remuneration for every reported case of ADR	28	28.6
Spending more time on the wards with patients	26	26.5
Making reporting a professional obligation	25	25.5
Incentives to every outpatient that report ADR	21	21.4
Leaving Yellow Cards on the ward for easy accessibility	6	6.1

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Among the various methods suggested by the respondents to improve ADR reporting, continuous medical education, training and refresher courses (94, 95.9%) were the methods mostly recommended. Leaving the Yellow Card on the ward for easy accessibility (6) was considered the least important method.

A study in Japan [118] suggested that an online Electronic ADR reporting system be integrated with the existing Hospital Information System (HIS). Other researches [119] suggested integrating adverse drug reaction (ADR) reporting throughout an accelerated doctor of pharmacy program. It is also recommended that pharmacists play a great role in educating other healthcare professionals regarding prevention, detection and reporting of ADRs [120]. A study in children suggested that a functional monitoring and

reporting system for ADRs in children needs to be put in place for early detection. A public enlightenment programme is advised in order to stem the tide of self-medications amongst Nigerian mothers since many of these drugs have the potential for adverse interactions that could cause unwanted drug reactions and the Government should regulate the sales and use of herbal medicines for children[120]. Finally, Physicians should familiarize themselves with the pharmacology of the commonly used drugs in children and weigh the benefit–risk ratio before prescribing.[120]

CHAPTER THREE

METHODOLOGY

3.0. BACKGROUND OF THE STUDY AREA.

Nnewi North Local Government Area is one of the 21 LGAs of Anambra State, South East Nigeria. It is a one town Local Government Area. In other words, the Local Government is Synonymous with Nnewi town. It is an outcome of the split of the former Nnewi Local Government Area (originally created in 1976) into Nnewi North and Nnewi South Local Government Areas, during the Local Government creation exercise of August 1991.The LGA was further split to carve out Ekwusigo LGA, thereby making Nnewi North LGA a one town Local Government in 1996.[121]

The Local Government Area is about 40 minutes drive from the State capital, Awka and about 30 minutes drive from Onitsha. It occupies a central position, bounded in the North by Nnobi and Ichi towns (Idemili South LGA), the South by Ozubulu town (Ekwusigo LGA), and Ukpo, Utuh, Amichi and Azigbo towns (Nnewi South LGA). It is bounded in the east by Nnobi and Awka Etiti (Idemili South LGA), and in the west by Ichi town (Idemili South LGA and Oraifite (Ekwusigo LGA). The Nnewi North LGA lies in the tropical rainforest with typical climatic conditions and two distinct seasons , a rainy season that starts from April or May to September and a dry season which lasts from October to April. The mean temperature is about 30.6 ^{0}C, while the vegetation is made up of thick forest, trees and evergreen vegetation.

The land mass has an area dimension of 72km^2 and an approximate total population of 157,569 people by the population census of 2006. From this an average population

density of 2.189 people per square kilometer can easily be appreciated.[121] The people are ethnically Ibos and the language spoken is Igbo, although English and its adulterations are spoken. The people are predominantly Christians.

Nnewi is the second biggest commercial town to Onitsha, in the state. It is a town famed for industrialization, with raw materials mainly imported from the outside the country. Its industrial outputs includes lubricants, chemicals, motorcycles, and machines spare parts both fairly used and new textiles, household equipment detergents, thus attracting dealers on these products from different parts of the country and beyond. There are few manufacturing and motorcycle assembly industries as well as financial institutions .The transport industry in Nnewi is one of the biggest in the country.

Both the Federal and state Institutions have their offices in Nnewi. Such institutions are the Police, Power Holding Company of Nigeria (PHCN), Nigerian Telecommunication PLC (NITEL), National Population Commission (NPC), and Anambra State Environmental Protection Agency (ANSEPA). The Nnamdi Azikiwe University Teaching Hospital, Nnewi is located here, as well as a number of private hospitals and clinics, 24 Primary Health Care Centres run by the LGA, and maternity homes. There are traditional and religious care providers as well as community and village health workers. There are numerous primary and secondary schools both privately and publicly owned in the LGA. The College of Health Sciences of the Nnamdi Azikiwe University is also located in this LGA.

The inhabitants are mainly traders, with a few bankers, hospital workers, civil servants and artisans. Cement houses or mud houses plastered with cement, with

roofing made of asbestos or corrugated iron sheets, are the most common forms of housing. The town is connected to the National Grid, though power supply is epileptic as demand far outstrips supply. The sources of water supply are primarily borehole. There are many road networks connecting all parts of the LGA. Some of the roads become non-motorable especially during rainy season. Radio and Television signals are received in all the parts of the LGA. Telephone services are also available.

3.1. TARGET POPULATION

The study was conducted at the health facilities including Health posts, Primary Health Centres (PHC), Community pharmacies, Private hospitals, and one tertiary hospital {Nnamdi Azikiwe University teaching hospital (NAUTH)} in Nnewi North L.G.A, Anambra state, Nigeria. There are 12 PHCs and 12 health posts (with 12 nurses and 80 other related health workers (mainly CHEWs) and 114 Private hospitals (with 142 doctors, and 470 nurses) in Nnewi North L.G.A. [121] according to the record provided by Anambra State Ministry of health, Awka. NAUTH is the only teaching hospital in Anambra state with all cadres of health professionals consisting of Doctors (20 hospital consultants, 176 registrar and 79 House officers); Pharmacists (6 Assistant directors for pharmaceutical services (ADPS), 4 Chiefs pharmacists, 7 Principal pharmacists, 14 Pharmacist 1, 35 intern pharmacists and 20 community pharmacists); Nurses (75 chief nursing officers (CNO), 32 assistant chief nursing officers (ACNO), 53 principal nursing officer (PCNO), 55 Senior nursing officers (SNO), 29 Nursing officers one (NO I), 130 Nursing officer two (NO II), 4 staff nurses and other Medical personnel. Hence, the target population was a total of

417doctors {(142 doctors from private hospitals) + 275 doctors (20 consultants + 3 optometrists + 176 registrars +79 house officers from tertiary hospital)} + 85 pharmacists (6 ADPS + 4 chief pharmacists + 7 principal pharmacists + 14 pharmacist I + 35 intern pharmacists from tertiary hospital and 20 community pharmacists) + 940 nurses and related health workers. The target population was therefore 1,442 healthcare professionals working in Nnewi North Local Government Area of Anambra state.

3.2. DESIGN OF THE STUDY

This was a descriptive cross-sectional survey.

3.3. CRITERIA FOR SELECTION OF HEALTH FACILITIES AND RESPONDENTS

Nnamdi Azikiwe University Teaching Hospital (NAUTH) was included in the study as the only tertiary hospital in Anambra state. Private hospitals surveyed were selected randomly from the 114 private hospitals available. The Health posts and PHCs have similar structure and were also randomly selected. On the overall, a total of 4 Health posts, 10 PHCs, 5 community pharmacies, 30 Private hospitals and one tertiary hospital were surveyed. Only the doctors, Pharmacists and nurses with one or more years of experience were included in the study. The house officers, intern pharmacists and the nursing officer two (NO II) were included because they were at the tail end of their one year stay when the study was carried out. All cadres of each profession were included except senior pharmacists because there was none as at the time of the study.

Nurses and other related health workers include the nurses and the CHEWs who also render nursing services in most health posts and primary health centres. A nurse is any person whose job is to take care of the sick or the injured usually in the hospital.[122] Health post was also included in the study because it is a health care facility where few nurses and most of the CHEWs work.

3.4. SAMPLE SIZE

The sample size used was calculated through the statistical method of sample size determination thus[123]:

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

Where n = sample size.

Z = Standard normal deviate at 1.96 confidence interval.

P = Proportion aware of the ADR reporting scheme in Nigeria based on previous study[10] = 0.366(36.6%).

q = 1-P (Complimentary probability)

d = maximum allowable error = 0.05.

$$\therefore n = \frac{4 \times 0.366 (1 - 0.366)}{0.05^2}$$

$$n = \frac{0.928176}{0.0025}$$

$$n = 371.3$$

$$\therefore \quad n = 371.$$

Given room for attrition, the sample size studied was made to be 420. Samples of different categories of healthcare professionals (Doctors, Pharmacists and Nurses/related health workers) surveyed were calculated thus:

Total number of health professionals in Nnewi North L.G.A = 1,442 [Doctors = 417, Pharmacists = 85, Nurses/related workers = 940, giving a ratio of 5: 1: 11]. Total sample required = 420 Hence, total ratio = 17.

Sample of doctors required = 5/17 × 420 = 124.

Sample of pharmacists required = 1/17 × 420 =25.

Sample of nurses required = 11/17 × 420 = 272.

3.5. METHODS OF DATA COLLECTION

A total of 420 healthcare professionals were administered with questionnaires (Appendix 4), including 124 doctors, 25 pharmacists and 272 nurses. Effort was made to distribute the questionnaires proportionately within the cadres of each profession. The questionnaire used was adapted from the previous studies that assessed the attitudes of medical practitioners to ADR reporting in the United Kingdom [122, 123] though slightly modified to suit the Nigerian environment. The questionnaire was structured to obtain the demographics of the health professionals; their awareness of ADR reporting

scheme/guideline; attitudes and practice to reporting; factors that they perceive may influence reporting; and their education and training on ADR reporting. Provision was also made for suggestions on possible ways to improve ADR reporting in Nigeria.

3.6. PRETESTING

A pilot study was conducted with healthcare professionals working in Ekwulobia General Hospital to validate the research questions.

3.7. DATA ENTRY AND ANALYSIS

Data collected was analyzed using SPSS version 17. In the analysis of the knowledge of health professionals to ADR reporting (table 6), the responses of the respondents were assigned values (2 for correct response and 1 for wrong response). From these values, the maximum score (all correct) was determined. Using the maximum value, the knowledge was rated and recoded into three categories (Low, Moderate, and High).

3.8. ETHICAL CONSIDERATION

Copies of the proposal for this research were sent to NAUTH Ethical committee (NAUTHEC) and their approval was gotten and attached to this work (Appendix 3).

3.9. INFORMED CONSENT

Informed consent of the heads of the selected health facilities was gotten officially through letters that sought their consent to carry out the proposed survey in their

institutions. Also informed consent of the individual respondents was sought using the informed consent form (Appendix 2) during the administration of the questionnaires.

3.10. CHALLENGES ENCOUNTERED

1. Rejection of the questionnaire.
2. Reluctance in accepting and filling the questionnaire.
3. Time taken to complete the accepted questionnaire.
4. Loss of some of the questionnaires by the respondents.
5. Incomplete filling of the questionnaires.

Efforts were made to reduce these constraints thus:

Some heads of the health institutions mapped out for the study rejected the study to be carried out in their establishment. As a result, we included other health facilities that were not primarily selected for sampling to make up the required sample. Furthermore, the questionnaire was also rejected by some of the respondents in the selected facilities but with the help of the consent form (which explained the purpose of the study, the procedure, the benefit/risk involved and assured of confidentiality of every information given on the questionnaire) and other explanations, most of them gave informed consent. Because the questionnaire was administered at the duty posts of the respondents, some of them could not provide response to the questionnaire at the time of administration. Therefore, we had to leave some of the questionnaires at the custody of the respondents for one to two days and this led to the lost of some of the questionnaires. At the point of collection, we go through each of the responded questionnaire and call the attention of the respondent if it is not completely filled. This

was to avoid incomplete filling of the questionnaires but some of the respondent dropped their responded questionnaires with their colleague that we could not get contact to them at the time of collection.

CHAPTER 4

RESULTS

4.0. DEMOGRAPHY OF RESPONDENTS.

A total of 420 questionnaires were sent out, 397 returned, and 23 were lost giving a response rate of 94.5%. Out of the 397 returned questionnaires, 25 were rejected due to incomplete filling and 372 (93.7 %.) were valid.

Table 2: Socio demographic variables of respondents.

	Variables	Frequency	Percent (%)
A	**Gender**		
	Male	255	68.5
	Female	177	31.5
	Total	**372**	**100.0**
B.	**Age**		
	21-30	92	24.7
	31-40	140	37.6
	41-50	100	26.9
	51=60	33	8.9
	>60	6	1.6
	No response	1	0.3
	Total	**372**	**100.0**
C.	**Profession**		
	Doctors	109	29.3
	Pharmacists	22	5.9

	Nurses/related health workers	241	64.8
	Total	**372**	**100**
D	**Category of Health workers**		
1.	**Doctors**		
	Specialists	20	18.3
	General practitioners	31	28.4
	Resident doctors	33	30.4
	House officers	25	22.9
	Total	**109**	**100.0**
2.	**Pharmacists**		
	Assistant director for pharmaceutical services (ADPS)	2	9.1
	Chief pharmacists	2	9.1
	Principal pharmacists	4	18.2
	Pharmacist 1	5	22.7
	Intern pharmacists	9	40.9
	Total	**22**	**100.0**
3.	**Nurses/related health workers**		
	Chief Nursing Officer (CNO)	48	19.9
	Assistant Chief Nursing Officer (ACNO)	29	12.0
	Principal Nursing Officer (PNO)	35	14.5
	Senior Nursing Officer (SNO)	40	16.6
	Nursing Officer I(NO I)	35	14.5
	Nursing Officer II(NO II)	42	17.5

Community Health Extension Workers (CHEWs)	12	5.0
Total	**241**	**100.0**
Total	**372**	**100.0**

Out of the 372 respondents studied, 255 (68.5%) were females and 117 (31.5%) were males. Majority of the respondents (37.6%) fall within the age range 31-40 years. They were followed by the age group 41-60 (26.9%), and 21-30 (24.7%). However, the age groups 51-60 years (8.9%) and above 60 years (1.6%) have the lowest number of respondents. One respondent (0.3%) gave no response to age.

Nurses/related health workers constitute greater part of the respondents with a total of 241 (64.8%), followed by doctors, 109 (29.3%) and pharmacists were the least, 22 (5.9%).

Resident doctors were the highest studied among doctors (30.3%) whereas specialists were the least (18.4%).

Majority of the pharmacists studied, 40.9% were intern pharmacists. The chief pharmacists and the Assistant directors for pharmaceutical services (ADPS) constitute the least (9.1%) each respectively.

It is worthy to note that majority of the nurses/related workers studied were the chief nursing officers (19.9%) and the nursing officer two (17.4%). However, the community health extension workers constitute the least population (6.3%) of this group.

Table 3: Distribution of respondents by health facility

Health facility	Frequency	Percentage (%)
Health Post (H P)	4	1.1
Community Pharmacy	5	1.3
Primary Health Centre (PHC)	36	9.7
Private Hospital	174	46.2
Tertiary	155	41.7
Total	**372**	100.0

Majority of the respondents practice in private hospitals (46.2%) and tertiary hospital (41.7%). Community pharmacy and Health posts constituted the least (1.3% and 1.1% respectively) of the respondents studied.

4.1. AWARENESS OF THE ADR REPORTING SCHEME/ GUIDELINE

Table 4: Distribution of health professional's awareness to ADR reporting scheme/guideline

		Awareness		
	Health professionals	**Aware**	**Not aware**	**Total**
A	**profession**			
	Doctors (%)	47 (43.1)	62 (56.9)	109(100.0)
	Pharmacists (%)	18 (81.8)	4 (18.2)	22(100.0)
	Nurses/related workers (%)	86 (35.7)	155 (64.3)	241(100.0)
	Total (%)	**151 (40.6)**	**221 (59.4)**	**372(100.0)**
		X^2 = 18.201, df =2, p =0.000.		
B.	**Professional category**			
1.	**Doctors (%)**			
	Specialists	10(50.0)	10(50.0)	20 (100.0)
	Resident	16(48.5)	17(51.5)	33(100.0)
	General Practitioner	12(38.7)	19(61.3)	31 (100.0)
	House officers	9(36.0)	16(64.0)	25(100.0)
	Total	**47(43.1)**	**62(56.9)**	**109(100.0)**
		X^2 = 1.536, df =3, p =0.674.		
2.	**Pharmacists**			
	ADPS (%)	2(100.0)	0(0.0)	2(100.0)
	Chief (%)	2(100.0)	0(0.0)	2(100.0)
	Principal (%)	3(75.0)	1(25)	4(100.0)

Pharmacist 1	4(80.0)	1(20.0)	5(100.0)
Interns (%)	7(77.8)	2(22.2)	9(100.0)
Total (%)	**18(81.8)**	**4 (18.2)**	**22(100.0)**
	X^2 = 1.124, df =4, p =0.890.		
3. **Nurses/related health workers**			
Chief Nursing Officer (CNO)	19(39.6)	29(60.4)	48 (100.0)
Assistant Chief Nursing Officer (ACNO)	10(34.5)	19(65.5)	29 (100.0)
Principal Nursing Officer (PNO)	18(51.4)	17(48.6)	35 (100.0)
Senior Nursing Officer (SNO)	13(32.5)	27(67.5)	40 (100.0)
Nursing Officer I(NO I)	11(31.4)	24(68.6)	35 (100.0)
Nursing Officer II(NO II)	15(35.7)	27(64.3)	42 (100.0)
CHEWs	0(0.0)	12(100.0)	12 (100.0)
Total	**86(35.7)**	**155(64.3)**	**241 (100.0)**
	X^2 =11.227, df =6, p =0.082.		

Majority of the respondents, 221 (59.4%) were not aware of the existence of the national ADR reporting scheme/guideline while 151 (40.6%) were aware. The Pharmacists were more aware compared to other health professionals studied and the professional difference in awareness was statistically significant (x^2 = 18.201, df = 2, p=0.000).

The specialists were shown to be more aware (50.0%) compared to other categories of doctors. However, no statistical significant difference exists in awareness within this profession (X^2 =1.536, df =3, p =0.674).

In pharmacy profession, there were 100% awareness among the chief pharmacists and the ADPS cadres and less among the pharmacist 1 (80%), and principal pharmacists (75%). The difference in awareness within the profession was not statistically significant (X^2 =1.124, df =4, p =0.890).

Awareness was better among the Principal nursing officers (51.4%), the chief nursing officers (39.6%), and nursing officer II (35.7%). The Community Health Extension Workers show no awareness to the scheme (0.0%). However, the differences in awareness within this group have no relation to their professional category (X^2=11.227, df =6, p =0.82).

Table 5: Distribution of awareness of respondents to ADR reporting scheme/guideline by Health facility

Awareness	Health facility (%)					Total (%)
	Health post	PHC	Community pharmacy	Private hospital	Tertiary hospital	
Aware	0 (0.0)	14 (38.9)	2 (40.0)	68(39.5)	67 (43.2)	151(40.6)
Not aware	4 (100.0)	22 (61.1)	3(60.0)	104(60.5)	88 (56.8)	221(59.4)
Total	4 (100.0)	36 (100)	5 (100.0)	172(100.0)	155(100.0)	372(100.0)

X^2 =3.303, df = 4, p =0.509

Respondents from tertiary health facility showed greatest awareness (43.2%) of the scheme and the reporting guideline followed by Community pharmacists (40.0%). Respondents from health post showed no awareness at all (0.0%). Nevertheless, this difference in awareness across the facilities was not significant (X^2 =3.303, df = 4, p =0.509).

4.2. KNOWLEDGE OF RESPONDENTS TO ADR REPORTING CRITERIA

Table 6: Distribution of respondent's Knowledge of ADR reporting criteria by Profession

Knowledge of ADR reporting Criteria	**Profession**			**Total (%)**
	Doctors (%)	Pharmacists (%)	Nurses/related workers (%)	
Moderate Knowledge	26 (74.3)	13 (65.0)	56 (73.7)	95 (72.5)
High knowledge	9 (25.7)	7 (35.0)	20 (26.3)	36 (27.5)
Total	**35 (100.0)**	**20 (100.0)**	**76 (100.0)**	**131 (100.0)**

X^2 =0.674, df =2, p =0.714.

A total of 131 (35.2%) respondents have knowledge of the criteria for reporting ADR whereas 241 (64.8%) of respondents lack this knowledge. The responses of those who have the knowledge were weighted and recoded into three categories – low, moderate and high knowledge of ADR reporting criteria for better presentation.

Only thirty-five (32.1%) out of 109 (100%) doctors studied have the knowledge of these criteria. Among doctors with the knowledge, 26 (74.3%) have moderate knowledge and 9(25.7%) have high knowledge. The pharmacists show more knowledge than doctors since 20 (90.9%) out of the 22 (100%) pharmacists studied have the knowledge of ADR reporting criteria. 13 (65.0%) have moderate knowledge and 7 (35.0%) high knowledge.

76 (31.3%) nurses out of 241 (100%) studied have the knowledge. Among the Nurses/related workers who have the knowledge, 56 (73.7%) have moderate and 20 (26.3%) have high knowledge of the reporting criteria. In general, most of the health professionals who have this knowledge have moderate knowledge of the criteria and none of the respondents exhibited Low knowledge of the ADR reporting criteria. However, the knowledge of these criteria has no relationship with profession (X^2 =0.674, df =2, p =0.714).

Table 7: Distribution of respondent's knowledge of ADR reporting criteria by health facility

knowledge of criteria	Health facility				Total (%)
	PHC (%)	Community Pharmacy (%)	Private hospital (%)	Tertiary hospital (%)	
Moderate	13 (92.9)	3 (75.0)	38(70.4)	41(69.5)	95(72.5)
High	1(7.1)	1(25.0)	16(29.6)	18(30.5)	36(27.5)

$X^2 = 3.315$, df =3, p =0.346

With the exception of the health post which completely lack the knowledge of ADR reporting criteria, most of the other health facilities studied had moderate while a few had high knowledge of ADR reporting criteria. The knowledge of ADR reporting criteria does not depend on the level of the health facility where one worked.

4.3. ATTITUDE OF HEALTH PROFESSIONALS TO ADR REPORTING

Table 8: Attitude of health professionals to ADR reporting

S/n	Variables	Profession			Total (%)
		Doctors (%)	Pharmacists (%)	Nurses/others (%)	
1	Believed ADR reporting to be a professional responsibility	91(83.5)	20(90.9)	208(86.3)	319(85.8)
2	Suspected ADR but did not report it.	100(91.7)	16(72.2)	194(80.5)	310(88.3)
3	Did not report because of not sure (uncertain) that the reaction was caused by drug	33(33.0)	12(75.0)	111(56.9)	156(50.2)
4	Considered ADR too trivial to be reported	35(35.0)	5(31.3)	82(42.1)	122(39.2)
5	Considered ADR too well known to be reported	29(29.0)	6(37.5)	80(41.2)	115(37.1)
6	Report has no effect at all	12(12.0)	1(6.3)	60(30.6)	73(23.4)
7	Would report if prescription was by another physician	86(78.9)	15(71.4)	172(71.7)	273(73.8)
8	Would report if patients bought the drug without prescription	83(76.1)	13(61.9)	172(71.7)	268(72.2)

9	Would report if therapeutic advice was	58(53.2)	14(66.7)	155(64.3)	227(61.2)

A total of 319 (85.8%) out the 372 (100%) respondents believe ADR reporting to be their professional responsibility and a great number of these respondents 310 (88.3%) have actually suspected an ADR without reporting it. The reasons for not reporting and the conditions they feel may influence reporting were listed in table 8 above and were further discussed below.

Table 9: Distribution of health professionals who believe ADR reporting to be their professional responsibility

	Health professionals	ADR reporting is a professional responsibility		
		Yes	**No**	**Total**
A	**profession**			
	Doctors (%)	91 (83.5)	18 (26.5)	109(100.0)
	Pharmacists (%)	20 (90.9)	2 (9.1)	22(100.0)
	Nurses/related workers (%)	208 (86.3)	33 (13.7)	241(100.0)
	Total (%)	**319 (85.8)**	**53 (14.2)**	**372(100.0)**
		X^2 =0.998, df =2, p =0.607.		
B.	**Professional category**			
1.	**Doctors (%)**			
	Specialists	20 (100.0)	0 (0.0)	20 (100.0)
	Resident	28 (84.8)	5 (15.2)	33(100.0)
	General Practitioner	26 (83.9)	5 (16.1)	31 (100.0)
	House officers	17 (68.0)	8 (32.0)	25(100.0)
	Total	**91 (83.5)**	**18 (16.5)**	**109(100.0)**
		X^2 =8.353, df =3, p =0.039.		
2.	**Pharmacists**			
	ADPS (%)	2(100.0)	0(0.0)	2(100.0)
	Chief (%)	2(100.0)	0(0.0)	2(100.0)

	Principal (%)	4 (100.0)	0 (0.0)	4(100.0)
	Pharmacist 1	5 (100.0)	5 (100.0)	5(100.0)
	Interns (%)	7(77.8)	2(22.2)	9(100.0)
	Total (%)	**20 (90.9)**	**2 (9.1)**	**22(100.0)**
		X^2 =3.178, df=4, p=0.529		
3.	**Nurses/related health workers**			
	Chief Nursing Officer (CNO)	43 (89.6)	5 (10.4)	48 (100.0)
	Assistant Chief Nursing Officer (ACNO)	28 (96.6)	1 (3.4)	29 (100.0)
	Principal Nursing Officer (PNO)	30 (85.7)	5 (14.3)	35 (100.0)
	Senior Nursing Officer (SNO)	37 (92.5)	3 (7.5)	40 (100.0)
	Nursing Officer I(NO I)	27 (77.1)	8 (22.9)	35 (100.0)
	Nursing Officer II(NO II)	35 (83.3)	7 (16.7)	42 (100.0)
	CHEWs	8 (66.7)	4 (33.3)	12 (100.0)
	Total	**208 (86.3)**	**33 (13.7)**	**241 (100.0)**
				X^2 =11.038, df =6, p =0.087

Pharmacists (90.9%) believed more than the nurses (85.3%) and the doctors (83.5%) that reporting of ADR is their professional responsibility. However, the difference in belief between these professional groups has nothing to do with their profession (X^2 =0.998, df =2, p =0.607).

Most of the doctors studied (83.5%) have this belief, with the specialists believing entirely (100%) on this responsibility. The general practitioners (83.9%) and the house officers (68.0%), were at the bottom list of the category of doctors who believed. This

difference in belief within this professional group was statistically significant (X^2 =8.353, df =3, p =0.039).

With the exception of 22.2% of the intern pharmacists who did not believe ADR reporting to be their professional responsibility, other pharmacists (senior cadres) believe entirely that reporting ADR is their professional responsibility. This could be probably due to more years of experience, although the differences within this group was not statistical significant (X^2 =3.178, df=4, p=0.529).

The ACNOs show outstanding believe (96.6%) that ADR reporting is their professional responsibility among the nurses. Though the belief among this profession was not directly proportional to cadre, it is still obvious that senior cadres (CNO, ACNO, PNO and SNO) had better appreciation of this responsibility than the junior ones (NO I, and NOII,) The CHEWs took last position (66.7%) among this group. The difference in believe however was probably due to chance (X^2 =11.038, df =6, p =0.087).

Table 10: Distribution of respondents who believe that ADR reporting is their professional responsibility by Health facility

ADR reporting is a professional responsibility	**Health facility (%)**					**Total (%)**
	Health post	PHC	Community pharmacy	Private hospital	**Tertiary hospital**	
Yes	1(25.0)	24(66.7)	5(100.0)	152(88.4)	137(88.4)	319(85.8)
NO	3(75.0)	12(33.3)	0(0.0)	20(11.6)	18(11.6)	53(14.2)
Total	4(100.0)	36(100.0)	5(100.0)	172(100.0)	155(100.0)	372(100.0)

$X^2 = 25.495$, df =4, p=0.000

Respondents from community pharmacy believe in its entirety (100%) that reporting ADR is their professional responsibility compared to the other health facilities studied. Respondents from tertiary and private health facilities had the same percentage (88.4% each) probably because they have similar professional structure. However, respondents from health posts had poor belief (25.0%) on this responsibility. The belief on ADR reporting being a professional responsibility depends so much on the health facility in which the respondent practices ($X^2 = 25.495$, df =4, p=0.000).

Table 11: Distribution of health professionals who suspected ADR but did not report.

	Health professionals	Suspected ADR but did not report. Yes	No	Total
A	**profession**			
	Doctors (%)	100 (91.7)	9 (8.3)	109(100.0)
	Pharmacists (%)	16 (72.7)	6 (27.3)	22(100.0)
	Nurses/related health workers (%)	194 (80.5)	47 (19.5)	241(100.0)
	Total (%)	**310 (83.3)**	**62 (16.7)**	**372(100.0)**
		X^2=8.727, df =2, p=0.013		
B.	**Professional category**			
1.	**Doctors (%)**			
	Specialists	20 (100.0)	0 (0.0)	20 (100.0)
	Resident	30 (90.9)	3 (9.1)	33 (100.0)
	General Practitioner	30 (96.8)	1 (3.2)	31 (100.0)
	House officers	20 (80.0)	5 (20.0)	25 (100.0
	Total	**100 (91.7)**	**9 (8.3)**	**109(100.0)**
		X^2 =7.417, df =3, p =0.060		
2.	**Pharmacists**			
	ADPS (%)	2 (100.0)	0 (0.0)	2 (100.0)

Chief (%)	2(100.0)	0(0.0)	2(100.0)
Principal (%)	6 (66.7)	3 (33.3)	9 (100.0)
Pharmacist 1	4 (80.0)	1 (20.0)	5 (100.0)
Interns (%)	7(77.8)	2(22.2)	9(100.0)
Total (%)	**16 (72.7)**	**6 (27.3)**	**22 (100.0)**
	X^2 =2.842,df =4, p =0.585		
3. **Nurses/related health workers**			
Chief Nursing Officer (CNO)	45 (93.3)	3 (6.3)	48 (100.0)
Assistant Chief Nursing Officer (ACNO)	21 (74.4)	8 (27.60)	29 (100.0)
Principal Nursing Officer (PNO)	30 (85.7)	5 (14.3)	35 (100.0)
Senior Nursing Officer (SNO)	34 (85.0)	6 (15.0)	40 (100.0)
Nursing Officer I(NO I)	24 (68.6)	11 (31.4)	35 (100.0)
Nursing Officer II(NO II)	31 (73.8)	11 (26.2)	42 (100.0)
CHEWs	9 (75.0)	3 (25.0)	12 (100.0)
Total	**194 (80.5)**	**47 (19.5)**	**241(100.0)**
			X^2 =12.299, df =6, p =0.056.

Though most of the respondents believe ADR reporting to be their professional responsibility, unfortunately, 83.3% of the respondents have suspected an ADR without reporting it. It is also unfortunate that doctors, who are the prescribers of drugs are most guilty (91.7%) of this poor attitude. As much as 80.5% of the nurses/related health workers who are the patients care givers, having more time to observe the patients have also noticed some ADRs and left them unreported. Majority of the pharmacists (72.7%)

who should be experts on pharmacovigilance and expected to correct the lapses from the doctors have also suspected ADRs without reporting them. This is a very serious health situation and could be detrimental to the patient, community and the nation at large. The professional difference in this attitude to reporting is statistically significant (X^2=8.727, df =2, p=0.013).

It is worthy to note that all the specialists studied (100.0%) have suspected but did not report ADRs. Among doctors, house officers were the least who suspected and never reported ADRs. However, the differences in this attitude within the group is not related to year of practice (X^2 =7.417, df =3, p =0.060).

Similar to doctors, the most senior cadres among pharmacists [the ADPs (100%) and the chief pharmacists (100%)] have all suspected ADRs and left them unreported. Even though most pharmacists accept reporting of ADR as their responsibility, all the cadres showed poor attitude to reporting, although the difference was not significant statistically within the profession (X^2 =2.842, df =4, p =0.585).

It is also important to note that the CNOs (93.8%) constitute most of the population of the nurses who suspected but did not report ADRs. The CHEWs were also outstanding (75.0%) in this poor attitude. Nevertheless, no significant difference exists between these categories and their poor reporting attitude (X^2 =12.299, df =6, p =0.056).

Table 12: Health facility distribution of respondents who suspected but did not report ADR

Suspected but not reported ADR	Health facility (%)					Total (%)
	Health post	PHC	Community pharmacy	Private hospital	Tertiary	
Yes	1 (25.0)	32(88.9)	5 (100.0)	148(86.0)	124 (80.0)	310 (83.3)
No	3 (75.0)	4 (11.1)	0 (0.0)	24(14.0)	31 (20.0)	62 (16.7)
Total	4 (100.0)	36(100.0)	5 (100.0)	172(100.0)	155 (100.0)	372(100.0)

X^2=13.752, df =4, p= 0.008.

Comparison of the reporting attitude of respondents from different settings of health facilities studied revealed a significant difference in attitude to reporting (X^2=13.752, df =4, p= 0.008). Most of the poor attitude was seen in community pharmacy (100%). This attitude seems to depend so much on the health facility where the respondent practices.

Table 13: Professional distribution of respondents who did not report because of uncertainty that reaction was caused by drug

Did not report because of uncertainty	Profession (%)			Total (%)
	Doctors	**pharmacists**	**Nurses/related workers**	
Yes	33 (33.0)	12 (75.0)	111 (56.9)	156 (50.2)
No	67 (67.0)	4 (25.0)	84 (43.1)	155 (49.8)
Total	100 (100.0)	16 (100.0)	195 (100.0)	311 (100.0)

X^2=19.295, df=2, p=0.000

Further questions to obtain the reasons for the poor reporting attitude of the respondent showed that 50.2% of the respondents who did not report suspected ADR were uncertain that the reaction was caused by drug. Pharmacists showed a leading position on this attitude (75.0%) followed by the Nurses/related health workers (56.9%). Doctors appeared the least (33.0%), showing doctors to be more certain of the reactions caused by drugs compared to other professionals. This difference in attitude between the professionals does not relate to their profession (X^2=19.295, df=2, p=0.000).

Table 14: Professional distribution of respondents who did not report because the reaction was too trivial to be reported

Reaction was too trivial to be reported	Profession (%)			Total (%)
	Doctors	pharmacists	Nurses/related workers	
Yes	35 (35.0)	5 (31.3)	82 (42.1)	122 (39.2)
No	65 (65.0)	11 (68.8)	113 (57.9)	189 (60.8)
Total	100 (100.0)	16 (100.0)	195 (100.0)	311 (100.0)

$X^2 = 1.829$, df =2, p =0.401

Nurses (42.1%) came outstanding among the health professionals who considered the suspected ADR to be too trivial to be reported followed by the doctors, although the difference existing between these professional groups has nothing to do with their profession ($X^2 = 1.829$, df =2, p =0.401).

Table 15: Professional distribution of respondents who did not report because the reaction was too well known to be reported

reaction was too well known to be reported	Profession (%)			Total (%)
	Doctors	pharmacists	Nurses/related workers	
Yes	29 (29.0)	6 (37.5)	80 (41.2)	115 (37.1)
No	71 (71.0)	10 (62.5)	114 (58.8)	195 (62.9)
Total	100 (100.0)	16 (100.0)	194 (100.0)	310 (100.0)

$X^2 = 4.236$, df =2, p =0.120

The nurses (41.2%) also believed more that the suspected ADR were too well known to be reported when compared to the pharmacists (37.5%) and the doctors (29.0%). This attitudinal difference also occurred by chance ($X^2 = 4.236$, df =2, p =0.120)

Table 16: Professional Distribution of respondents who would report if the medication was prescribed for their patient by another physician

Would report if medication was by another physician	Profession (%)			Total (%)
	Doctors	pharmacists	Nurses/related workers	
Yes	86(78.9)	15(71.4)	172(71.7)	273(73.8)
No	23(21.1)	6(28.6)	68(28.3)	97(26.2)
Total	109(100.0)	21(100.0)	240(100.0)	370(100.0)

X^2=2.091, df=2, p=0.352.

Majority of the respondents, 73.8% stated that they would have reported if drugs were prescribed for their patients by another physician. Interestingly, all the health professionals show outstanding positions (78.9% of doctors, 71.4% of pharmacists and 71.1% of nurses/related health workers) to this attitude confirming that fear of legal case against the reporter play a major role in poor reporting attitude. This attitude does not depend on profession (X^2=2.091, df=2, p=0.352).

Table 17: Professional distribution of respondents who would report if the patient had bought the medication without prescription

Would report if patient bought the medication without prescription	Profession (%)			Total (%)
	Doctors	**pharmacists**	**Nurses/related workers**	
Yes	83(76.1)	13(61.9)	172(71.7)	268(72.4)
No	26(23.9)	8(38.1)	68(28.3)	102(27.6)
Total	109(100.0)	21(100.0)	240(100.0)	370(100.0)

X^2=1.989, df =2, p=0.370.

72.4% of the respondents would report if their patients had purchased the medication without prescription. Chief among the professionals who reacted positively were doctors (72.4%) followed by the nurses (71.7%). This attitude has no relation to profession (X^2=1.989, df =2, p=0.370).

4.4. PRACTICE OF ADR REPORTING AMONG HEALTH PROFESSIONALS

Table 18: Distribution of respondent who reported ADR by category

Profession	Rank	Suspected ADR (%)	Suspected but not reported ADR (%)	Reported ADR (%)
Doctors	House Officer (n=25)	21 (84.0)	20 (80.0)	1 (4.0)
	Resident Doctors(n=33)	30 (90.9)	30 (90.9)	-
	G/Practitioners (n=31)	30 (96.8)	30 (96.8)	-
	Specialists (n=20)	20 (100)	20 (100.0)	-
	Total	**101 (92.7)**	**100 (91.7)**	**1 (1.0)**
Pharmacists	Intern Pharmacists (n=9)	6 (66.7)	6 (66.7)	-
	Pharmacist 1 (n=5)	4 (80.0)	4 (80.0)	-
	Principal Pharmacist (n=4)	2 (50.0)	2 (50.0)	-
	Chief Pharmacists (n=2)	2 (100.0)	2 (100.0)	-

	ADPS (n=2)	2 (100.0)	2 (100)	-
	Total (n=22)	**16 (72.7)**	**16 (72.7)**	**-**
Nurses/related health workers	CHEWs (n=12)	9 (75.0)	9 (75.0)	-
	NO II (n=42)	32 (76.2)	31(73.8)	1 (2.4)
	NO I (n=35)	25 (71.4)	24 (68.6)	1 (2.8)
	SNO (n=40)	36 (90.0)	34 (85.0)	2 (5.0)
	PNO (n=35)	30 (85.7)	30 (85.7)	-
	ACNO (n=29)	22 (75.9)	21 (74.4)	1 (1.5)
	CNO (n=48)	45 (93.8)	45 (93.8)	-
	Total (n=241)	**199 (82.6)**	**194 (80.5)**	**5(2.1)**

There was generally poor practice of ADR reporting among the health professionals studied. A total of 199(82.6%) of the nurses/related workers suspected ADR and as many as 194 could not report. Hence, only 5 nurses actually reported. Only 1 out of the 109 doctors reported an ADR and none of the pharmacists reported any suspected ADR.

Table 19: Distribution respondent who reported ADR by Health facilities

Variables	Health facility (%)				
	Health post	**PHC**	**Community pharmacy**	**Private hospital**	**Tertiary**
Suspected ADR (%)	1 (25.0)	33 (91.7)	5 (100.0)	151(87.8)	126 (81.3)
Suspected but not reported ADR (%)	1 (25.0)	32 (88.9)	5 (100.0)	148 (86.0)	124(80.0)
Reported ADR (%)	0 (0.0)	1 (2.8)	0 (0.0)	3 (1.8)	2 (1.3)

Three out of the 6 reports came from the private hospital, two from the tertiary health institution and one from the primary health centres. It is impressive that most of the reports came from the private health institution.

4.5. FACTORS INFLUENCING ADR REPORTING BY HEALTH CARE PROFESSIONALS

Table 20: Factors influencing ADR reporting by health care professionals.

S/N	Factors	Frequency (%)	Profession (%)			Total (%)
			Doctors	Pharmacists	Nurses/related workers	
1	No Electronic reporting process	311(83.6)	90(82.6)	19(90.5)	202(84.2)	311(84.1)
2	No reporting forms.	247(66.4)	89(89.0)	10(62.5)	148(75.9)	247(79.4)
3	Ignorance of how to report	181(58.2)	59(59.0)	4(25.0)	118(60.5)	181(58.2)
4	Bureaucratic reporting process.	124(33.3)	44(44.0)	6(37.5)	74(37.9)	124(39.9)
5	No incentive/financial	101(27.2)	23(23.0)	8(50.0)	70(35.9)	101(32.5)
6	Legal case against the reporter	99(26.6)	21(21.0)	5(31.3)	73(37.4)	99(31.8)

7	No enough time to report ADR	76(20.4)	22(22.0)	5(31.3)	49(25.1)	76(24.4)

The factors believed by the respondents to influence ADR reporting were arranged on the decreasing order of frequencies (table 19). Among the factors, unavailability of electronic reporting (83.6%), unavailability of reporting forms/guideline (66.4%) and ignorance (58.2%) were the chief complaints whereas legal implication of reports (26.6%) and time factor (20.4%) were the least mentioned. The first three prominent factors were further analyzed to get the distribution of health professionals involved and the results were shown below.

Table 21: Distribution of respondents who stated unavailability of electronic reporting as obstacle to reporting

Profession	Rank (%)	Unavailability of electronic reporting (%)		Total (%)
		Yes	No	
Doctors	House Officers	21 (84.0)	4 (16.0)	25(100.0
	Resident Doctors	24 (72.7)	9 (27.3)	33 (100.0)
	G/Practitioners	29 (93.5)	2 (6.5)	31 (100.0)
	Specialists	16 (80.0)	4 (20.0)	20 (100.0)
	Total	**90 (82.6)**	**19 (17.4)**	**109(100.0)**
	X^2=4.945, df=3,p=0.176			
Pharmacists	Intern Pharmacists	9 (100.0)	0 (0.0)	9 (100.0)
	Pharmacist 1	4 (100.0)	0 (0.0)	4 (100.0)
	Principal Pharmacist	4 (100.0)	0 (0.0)	4 (100.0)
	Chief Pharmacists	1 (50.0)	1 (50.0)	2 (100.0)
	ADPS	1 (50.0)	1 (50.0)	2 (100.0)

	Total	**19 (90.5)**	**2 (9.5)**	**21 (100.0)**

X^2=9.395,df=4, p=0.052

Nurses/related health workers	CHEWs	10 (83.3)	2(16.7)	12 (100.0)
	NO II	39 (95.1)	2 (4.9)	41(100.0)
	NO I	26 (74.3)	9 (25.7)	35(100.0)
	SNO	39 (97.5)	1 (2.5)	40(100.0)
	PNO	25 (71.4)	10 (28.6)	35(100.0)
	ACNO	22(75.9)	7(24.1)	29(100.0)
	CNO	41(85.4)	7(14.6)	48(100.0)
	Total	**202 (84.2)**	**38 (15.8)**	**240(100.0)**

X^2=17.418, df=6, p=0.008

With the exception of the most senior cadres of pharmacists studies (ADPs and Chief pharmacists), other cadres believed entirely that unavailability of electronic reporting process has a negetive influence to reporting of ADRs.

General practitioners (93.5%) and house officers (84.0%) are outstanding among the doctors who stated unavailability of electronic reporting process as obstacle to ADR reporting, implying that both senior and junior doctors oppose bureaucratic process of ADR reporting. The difference within this group was as well not significant (X^2=4.945, df=3, p=0.176).

Similarly, the SNO (97.5%) and the NO II (95.1) constitute majority of the nurses who stated unavailability of electronic reporting process as obstacle to ADR reporting, showing that the feeling cut across both senior and junior categories of nurses. However, this factor has a lot to do with professional categories among nurses (X^2=17.418, df=6, p=0.008).

Table 22: Distribution of respondents who stated unavailability of reporting forms as obstacle to reporting

Profession	Rank (%)	Unavailability of reporting forms (%)		Total (%)
		Yes	No	
Doctors	House Officers	18 (90.0)	2 (10.0)	20 (100)
	Resident Doctors	24 (80.0)	6 (20.0)	30 (100.0)
	G/Practitioners	30 (100)	0 (0.0)	30 (100.0)
	Specialists	17 (85.0)	3 (15.0)	20 (100.0)
	Total	**89 (89.0)**	**11 (11.0)**	**100 (100.0)**
	X^2=6.537, df=3, p=0.088			
Pharmacists	Intern Pharmacists	5 (83.3)	1(16.7)	6 (100.0)
	Pharmacist 1	2 (50.0)	2 (50.0)	4 (100.0)
	Principal Pharmacist	1 (50.0)	1 (50.0)	2 (100.0)
	Chief Pharmacists	1 (50.0)	1 (50.0)	2 (100.0)
	ADPS	1 (50.0)	1 (50.0)	2 (100.0)
	Total	**10 (62.5)**	**6 (37.5)**	**16 (100.0)**

X^2=1.778, df=4, p=0.777

Nurses/related health workers	**CHEWs**	9 (100.0)	0 (0.0)	9 (100.0)
	NO II	26 (83.9)	5 (16.1)	31 (100.0)
	NO I	22 (88.0)	3 (12.0)	25 (100.0)
	SNO	26 (76.5)	8 (23.5)	34 (100.0)
	PNO	22 (73.3)	8 (26.7)	30 (100.0)
	ACNO	16 (76.2)	5 (23.8)	21 (100.0)
	CNO	27 (60.0)	18 (40.0)	45 (100.0)
	Total	**148 (75.9)**	**47 (24.1)**	**195 (100.0)**

X^2=12.269, df=6, p=0.056

Doctors (89.0%) stated lack of ADR reporting forms as an obstacle to reporting more than the nurses (75.9%) and the pharmacists (62.5%).

Table 23: Health facility distribution of respondents who stated unavailability of reporting forms as obstacle to reporting

unavailability of reporting forms	Health facility (%)					Total (%)
	Health post	PHC	Community pharmacy	Private hospital	Tertiary	
Yes	1(100.0)	25 (78.1)	4 (80.0)	116(77.9)	101(81.5)	247 (79.4)
NO	0 (0.0)	7 (21.9)	1 (20.0)	33 (22.1)	23 (18.5)	64 (20.6)
Total	1(100.0)	32(100.0)	5(100.0)	149 (100.0)	124(100.0)	311 (100.0)

X^2=0.830, df=4, p=0.934

Respondents from various health facilities felt similar on the issue of unavailability of reporting forms being an obstacle to reporting. Only one respondent responded to the question from health post. This factor does not depend on the health facility on which a respondent practices (X^2=0.830, df=4, p=0.934).

Table 24: Distribution of respondents who stated ignorance as obstacle to reporting

Profession	Rank (%)	Ignorance of how to report ADR (%)		Total (%)
		Yes	No	
Doctors	House Officers	12 (60.0)	8 (40.0)	20 (100)
	Resident Doctors	14 (46.7)	16 (53.3)	30 (100.0)
	G/Practitioners	23 (76.7)	7 (23.3)	(30) (100.0)
	Specialists	10 (50.0)	10 (50.0)	20 (100.0)
	Total	**59 (59.0)**	**41 (41.0)**	**100 (100.0)**
	X^2=6.435, df=3 p=0.092			
Pharmacists	Intern Pharmacists	2 (33.3)	4 (66.7)	6 (100.0)
	Pharmacist 1	2 (50.0)	2 (50.0)	4 (100.0)
	Principal Pharmacist	0 (0.0)	2 (100.0)	2 (100.0)
	Chief Pharmacists	0 (0.0)	2 (100.0)	2 (100.0)
	ADPS	0 (0.0)	2 (100.0)	2 (100.0)

	Total	**4 (25.0)**	**12 (75.0)**	**16 (100.0)**
	X^2=3.556, df=4, p=0.469			
Nurses/related health workers	**CHEWs**	8 (88.9)	1 (11.1)	9 (100.0)
	NO II	14 (45.2)	17 (54.8)	31 (100.0)
	NO I	14 (56.0)	11 (44.0)	25 (100.0)
	SNO	25 (73.5)	8 (26.5)	34 (100.0)
	PNO	13 (43.3)	17 (56.7)	30 (100.0)
	ACNO	8 (38.1)	13 (61.9)	21 (100.0)
	CNO	36 (80.0)	9 (20.0)	45 (100.0)
	Total	**118 (60.5)**	**77 (39.5)**	**195 (100.0)**
	X^2=23.988, df=6, p=0.001			

It should be noted that ignorance of how to report ADR runs through both all categories of doctors and nurses/related workers but among pharmacists, ignorance was purely the problem of the junior cadres.

Table 25: Health facility distribution of respondents who stated ignorance as obstacle to reporting

Ignorance of how to report ADR	Health facility (%)					Total (%)
	Health post	PHC	Community pharmacy	Private hospital	Tertiary	
Yes	0 (0.0)	18 (56.3)	1 (20.0)	94 (63.1)	68 (54.8)	181 (58.2)
No	1 (100.0)	14 (43.8)	4 (80)	55 (36.9)	56 (45.2)	130 (41.8)
Total	1 (100.0)	32 (100.0)	5 (100.0)	149 (100.0)	124 (100.0)	311 (100.0)

X^2=6.480, df=4, p=0.166

Though awareness program is needed in all the health facilities studies, private hospitals appear to be the most important facility needing this intervention. Nevertheless, the difference in ignorance existing between these facilities was not significant (X^2=6.480, df=4, p=0.166).

4.6. TRAINING OF RESPONDENTS ON ADR REPORTING

Table 26: Distribution of respondents with training on ADR reporting

Profession	Rank (%)	Training on ADR reporting (%)		Total (%)
		Yes	No	
Doctors	House Officers	4 (16.0)	21 (84.0)	25 (100)
	Resident Doctors	5 (15.2)	28 (84.8)	33 (100.0)
	G/Practitioners	1 (3.2)	30 (96.8)	31 (100.0)
	Specialists	5 (25.0)	15 (75.0)	20 (100.0)
	Total	**15 (13.8)**	**94 (86.2)**	**109 (100.0)**
	X^2=5.187, df=3, p=0.159			
Pharmacists	Intern Pharmacists	5 (55.6)	4 (44.4)	9 (100.0)
	Pharmacist 1	3 (60.0)	2 (40.0)	5 (100.0)
	Principal Pharmacist	1 (25.0)	3 (75.0)	4 (100.0)
	Chief Pharmacists	1 (50.0)	1 (50.0)	2 (100.0)

	ADPS	1 (50.0)	1 (50.0)	2 (100.0)
	Total	**11 (50.0)**	**1 (50.0)**	**22 (100.0)**

X^2=1.311, df=4, p=0.859

Nurses/related health workers	**CHEWs**	0 (0.0)	12 (100.0)	12 (100.0)
	NO II	10 (23.8)	32 (76.2)	42 (100.0)
	NO I	9 (25.7)	26 (74.3)	35 (100.0)
	SNO	6 (15.0)	34 (85.0)	40 (100.0)
	PNO	9 (25.7)	26 (74.3)	35 (100.0)
	ACNO	5 (17.2)	24 (82.8)	29 (100.0)
	CNO	8 (16.7)	40 (83.3)	48 (100.0)
	Total	**47 (19.5)**	**194 (80.5)**	**241 (100.0)**

X^2=5.981, df=6, p=0.425

Though ADR training was generally poor among all the health professionals studied, pharmacists were seen to have appreciable ADR reporting training (50.0%) than nurses (19.5%) and the doctors (13.8%). The difference in training between the professionals was statistically significant (X^2=15.247, df=2, p=0.000).

Among the doctors studied, specialists showed better evidence of training on ADR reporting (25.0%). Though ignorance of how to report was more pronounced among the junior cadres of pharmacists, acquired training on ADR reporting was some worth higher on the junior cadres.

Training on ADR reporting was similar on all the categories of nurses. The CHEWs had never had any form of training on ADR reporting.

Table 27: Health facility distribution of respondents with training on ADR reporting

Training on ADR reporting	Health facility (%)					Total (%)
	Health post	PHC	Community pharmacy	Private hospital	Tertiary	
Yes	0 (0.0)	10 (27.8)	3 (60.0)	28 (16.3)	32 (20.6)	73 (19.6)
NO	4 (100.0)	26 (72.2)	2 (40.0)	144 (83.7)	123 (79.4)	299 (80.4)
Total	4 (100.0)	36(100.0)	5 (100.0)	172(100.0)	155(100.0)	372 (100.0)

X^2=8.984, df=4, p=0.061

There was generally poor training of health professionals on ADR reporting from all the health facilities studied with community pharmacy as the most trained (60.0%) and Health post, the worst (0.0%). The difference in training among the health facilities was not statistically significant (X^2=8.984, df=4, p=0.061).

Table 28: Distribution of the type of training respondents had on ADR reporting

Type of training had on ADR reporting	Profession (%)			Total (%)
	Doctors	pharmacists	Nurses/related workers	
Prior to professional training	3 (16.7)	0 (0.0)	5 (10.4)	8 (10.3)
During professional training	8 (44.4)	4 (33.3)	23 (47.9)	35 (44.9)
Workshops/seminars	7 (38.9)	8 (66.7)	20 (41.7)	35 (44.9)
Total	18 (100.0)	12 (100.0)	48 (100.0)	78(100.0)

X^2=3.933, df=4, p=0.415

Majority of the pharmacists (66.7%) acquired their training on ADR reporting through workshops and seminars and none of them had any of such training prior to professional training. Doctors and nurses stated that they had training from the entire three sources stated (table 28), though majority of the training came during professional training.

4.7. RESPONDENTS SUGGESTIONS TO IMPROVE ADR REPORTING.

Table 29: Suggested ways to improve ADR reporting in Nigeria

Suggested ways to improve ADR reporting in Nigeria	**Profession** (%)			**Total** (%)
	Doctors	**Pharmacists**	**Nurses/related workers.**	
Awareness (workshops/media)	62 (58.5)	15 (68.2)	153 (63.8)	**230** (62.5)
Provision of reporting guidelines and reporting forms by NAFDAC	18 (17.0)	2 (9.1)	22 (9.2)	42 (11.4)
Legislation and incentive	11 (10.4)	1 (4.5)	20 (8.3)	32 (8.7)
Decentralization of reporting centres	6 (5.7)	2 (9.1)	11 (4.6)	19 (5.2)
Drugs to be handled by only trained personnel	1 (0.9)	0 (0.0)	18 (7.5)	19 (5.2)
Reporting by cell phones, fax e-mails	5 (4.7)	2 (9.1)	3 (1.3)	10 (2.7)
ADR monitoring by NAFDAC	17 (2.8)	0 (0.0)	7 (2.9)	1(2.7)
Rational prescribing	0 (0.0)	0 (0.0)	5 (2.1)	5 (1.4)
Prompt response by NAFDAC	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
Total	**106(100.0)**	**22 (100.0)**	**240(100.0)**	**368(100.0)**

Three hundred and sixty eight respondents (98.9% of the respondents) gave their suggestions on how to improve ADR reporting in Nigeria while 4 respondents (1.1%) did not respond at all.

The suggestions made by the respondents to improve ADR reporting were arranged in their decreasing order of frequency in table 28 with awareness and provision of reporting forms/guideline coming topmost on the list. It should be noted that electronic reporting process took a very low position among these factors though it was the most prominent factor health professionals said will improve ADR reporting.

CHAPTER 5

DISCUSSION

The health professionals involved in the study were the doctors, pharmacists and nurses/other related health workers. This is not because they are the only health workers expected to report ADR but because they are the major groups involved in drug handling. As a result, they are expected to be in more contact with the patients than other health care workers. Also, patients are likely to give feedback (including reaction to the administered drugs) to these groups after their medication. Moreover, it will be very cumbersome for this research to cover all health care workers. The nurses related health workers studied were the CHEWs and they were grouped together with the nurses because they perform nursing services in most health posts and PHCs.

It should be noted that only 22 pharmacists were studied against 109 doctors and 241 nurses. The samples were proportionately selected from the population of these professional groups in the study area (85 pharmacists, 417 doctors, and 940 nurses). This gave a ratio of 1: 5: 11 on which the selection was based. The poor population of pharmacists could be partly because private hospitals hardly employ pharmacists and in tertiary hospitals where the services of pharmacists are employed, one pharmacist can serve as many as 5 doctors whereas a doctor could require the service of up to 5 nurses.

This study revealed poor awareness of health care professionals (40.6%) in Nnewi North Local Government Area of Anambra state to the national ADR reporting scheme/guideline. This finding is similar to other studies in China where 52.2% of the health professionals lack the knowledge of the existence of their national ADR

reporting scheme [40] and another study in Jiangsu province, China where the health professionals were found to have a good recognition of basic knowledge of ADR, but poor awareness of pharmacovigilance[37], Hong Kong (87.7%)[38] Zimbabwe (75%)[48] , Nigeria (63.4%)[49] and Malaysia where 40% of the health professionals were not aware of the existence of ADR reporting scheme[39].

The pharmacists were shown to be more aware of the scheme (81.8%) compared to the doctors (43.1%) and nurses (35.7%). This is understandable since pharmacists are expected to be experts on drugs and pharmacovigilance by virtue of their profession. The finding is similar to the study done among Iranian pharmacists on pharmacovigilance practice where 71% of them were aware as against only 29% who were not aware of the Iranian Pharmacovigilance Center[42]. Also in a study in the USA, majority of the reports come from pharmacists (38.8% and 34.8% by hospital and community pharmacists, respectively) while physicians' reports accounted for only 10.8%[56]. Contrary to these findings, some countries, such as France, Ireland, Malaysia, New Zealand, the Nordic countries, and the UK, have the largest contribution of ADR reports coming from the physicians [56]

Within each professional group, awareness of ADR reporting scheme was seen to be higher among the senior categories probably due to exposure from many years put into practice.

Across the health facilities, awareness of respondents were seen to be directly proportional to the level of the health facility- Health post (not aware), PHC (38.9%), private hospital (39.5), community pharmacy (40.0%), and tertiary health facility

(43.2%). This is understandable considering the caliber of personnel working in the tertiary health institutions and the fact that tertiary health institutions are in a better position to organize seminars, workshops and training for its workers. The finding is similar to the study by the US Health and Human services which revealed more awareness of large hospitals (71%) [57] to the ADR reporting process compared to medium (58%) and small hospital (32%).

As much as 64.8% of the health professionals studied was shown to lack the knowledge of the ADR reporting criteria. Perhaps this could be the reason why some respondents stated that they could not report because of uncertainty of reaction caused by drugs. If these respondents had the knowledge of these criteria, they would have known that they were required to report even when they were unsure that the drug in question was the actual cause of the reaction[19]. Generally, pharmacists had better knowledge of this criteria (90.9%) compared to the doctors (32.1%) and the nurses (31.3%). This could also be because pharmacists believe ADR reporting to be their professional responsibility more than other health professionals. For better understanding, the knowledge of the criteria was further categorized into Low, Moderate and high knowledge. It was found out that among doctors with the knowledge, 26 (74.3%) have moderate knowledge and 9(25.7%) have high knowledge. While 13 (65.0%) of the pharmacists have moderate knowledge, 7 (35.0%) have high knowledge. Among the nurses who have the knowledge, 56 (73.7%) have moderate and 20 (26.3%) have high knowledge of the reporting criteria. Since most of the respondents have moderate knowledge of ADR reporting, it is therefore clear why most of the suspected ADR have

gone unreported. These findings therefore suggest the need for interventions to improve the awareness of the healthcare professionals to ADR reporting.

The study also revealed very poor attitude to reporting among the different health care professionals studied. Majority of the respondents (85.8%) actually believed ADR reporting to be their professional responsibility. Incidentally, 316 respondents (84.9%) have diagnosed/noticed an ADR in a patient under their care and out of these; as many as 310 respondents (84.0%) did not report the suspected ADRs. However, only 6 respondents (0.9%) have actually reported the suspected ADRs. It is very disheartening that 84% of ADR cases have gone unreported and could have led to many hospital admissions, prolongation of stay in the hospital, disability and even death of the patients in question. This could have caused pains, broken hearts, and waste of resources to individuals, families, communities, and even the nation. Five of the reports came from the nurses (table 34) and one came from the doctors (house officer). Unfortunately, none of the pharmacists who are believed to be experts on drugs and pharmacovigilance had ever reported any suspected ADRs. This finding is contrary to the studies in Canada[56] where most ADR reports were generated by pharmacists, and studies in France, Ireland, Malaysia, New Zealand, and the Nordic countries where most of the reports came from physicians [56]. In a study in Nepal, doctors and pharmacists had a slightly higher ADR reporting score than the nurses[68]. Nevertheless, in a study in the United Kingdom during a vaccination campaign[66], nurses were the health professionals who provided the largest proportion of reports of suspected ADRs. Indeed, it was expected that most of the reports should come from the pharmacists, followed by the doctors and then the nurses but the reverse was the case. Among other reasons, laxity

could be seen as being responsible for the poor ADR reporting attitude of pharmacists because they believe almost entirely that ADR reporting is their professional responsibility, had better awareness of the reporting scheme/guideline, had better knowledge of the ADR reporting criteria and yet could not report any of the suspected ADRs. The negligence also occurred among doctors. Only a house officer (1.0%) was able to report the suspected ADR out of the 101(72.7%) of the doctors that suspected ADRs. Unfortunately none of the senior doctors who had given in many years into practice and had suspected most of the ADR had ever reported. Although lack of reporting forms were stated as one the major reasons for not reporting, those that reported were evidence that the reporting forms could have been sourced from alternative places like the internet if little effort was made. This also suggests the need for more awareness programs on pharmacovigilance and the need to report ADRs.

With respect to the health facilities studied, the result showed that 3 out of the 6 reports came from the private hospitals, two from the tertiary hospital and one form the PHC. No report came from the community pharmacy and health posts. This is similar with studies, by Bateman DN et al [54] and Belton KJ et al [55] where the results revealed that hospital staff was less aware of the purposes of the spontaneous reporting than their counterparts in general practice.

Chiefly among the reasons stated by the respondent who failed to report suspected ADR include uncertainty of reactions caused by drugs (50.2%), suspected ADRs being too trivial to be reported (39.2%), and reports having no effect at all (23.4%). However, most of the respondents stated that they would have reported if: (I) the prescription was from another physician (73.8%), (ii) the drugs were purchased by their patients

without prescription (72.2%), and (iii) therapeutic advice was offered to the patient by phone (61.2%). Though these findings are in accordance with the reports of Inman [111] on the reasons for poor ADR reporting by healthcare professionals, the guideline for detecting and reporting ADRs[19] states that all healthcare professionals/workers including doctors, pharmacists, nurses, dentists, traditional medicine practitioners and other health professionals are requested to report all suspected adverse drug reactions including orthodox medicines, X-ray contrast media, medical devices, cosmetics, traditional and herbal medicines. This guide also stressed that it is vital to report even when it is uncertain that the medicine in question was the actual cause of the reaction. It is therefore necessary that this reporting guideline is made available to various health professionals to aid health workers in reporting ADR reactions.

Out of the 372 respondents surveyed, only 73 (19.6%) have had training on ADR reporting while 299 (80.4%) had not. This is very poor and would exert a serious negative influence on ADR reporting and patient's outcome if no intervention is made. As well, pharmacists had better training (50%) than the nurses (19.5%), and the doctors (13.8%). This could be attributed to their profession which deals on drugs and pharmacovigilance. The training was better pronounced among the junior levels of the professional groups studied suggesting an improvement in the academic curriculum in the present time which may have exposed the younger professionals to some basic training on ADR reporting. The specialists who were outstanding among trained doctors may have acquired their ADR report training through workshops and seminars.

On the factors that influence ADR reporting, the respondents mentioned a lot of factors with unavailability of electronic means of reporting (84.1%), lack of reporting forms and guideline (79.4%) and ignorance on how to report (58.2%) being the most prominent (table 36). Other factors mentioned include bureaucratic reporting process, no incentive/financial attachment to reporting, fear of legal cases from report and time to fill the reporting forms. This finding is similar with studies done in United Kingdom[105] and Ireland[106] on factors influencing ADR reporting by health workers.

While the doctors and nurses were more concerned with unavailability of reporting forms, Ignorance on how to report and bureaucratic reporting process, the pharmacists were also interested in financial incentives to reporters. However, all the health professionals studied observed Unavailability of electronic reporting process as the most important factor hindering ADR reporting. It is therefore important that a standard electronic means of reporting be provided to all health facilities and made accessible to all professionals.

The respondents however suggested that in order to improve ADR reporting rate, it is important to improve the Knowledge, Attitude and Practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. Majority of the factors suggested include:

- More awareness of ADR reporting should be created through training, seminar and workshop programmes (62.5%).

- NAFDAC should make accessible, available and in an enough quantity reporting forms and reporting guidelines to all the offices of health care professionals at all levels of health care facilities (11.4%)
- Hospitals should formulate policy in favour of ADR reporting and offer incentives in the form of official recognition to the best ADR reporter of the year (8.7%)
- Electronic means of reporting (cell phones, fax and e-mails) should be provided to lesson bureaucratic process of reporting (2.7%), and
- Continuous monitoring of ADR reports by NAFDAC officials at all levels of health care facilities would go a long way to promoting ADR reporting (2.7%).

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.0. CONCLUSION

The Awareness of ADR reporting scheme was generally poor (40.6%) among doctors, pharmacists and nurses working in Nnewi North L.G.A of Anambra state, Nigeria.

The attitude to reporting was also seen to be poor even among those who were aware of the scheme. Though majority (85.8%) of the health professionals studied believed ADR reporting to be their professional responsibility, 84.0% out of 84.9% of the respondents who suspected ADR did not report. The poor attitude was blamed on the poor knowledge of ADR of respondents, already established ADR which might not need to be reported, mildness of suspected reactions and the fact that reporting may not have any effect. However, fear is not left out since majority of these respondents who failed to report stated that that they would have reported if the drug in question was prescribed to their patients by another physician or the drugs purchased by their patients without prescription.

The poor awareness and attitude to ADR reporting consequently lead to poor reporting practice among the health professionals studied. Only 0.9% of those who suspected ADR actually reported. This was largely attributed to unavailability of electronic means of reporting (84.1%), lack of reporting forms and guideline (79.4%) and ignorance on how to report (58.2%).

Out of the 372 respondents surveyed, only 73 (19.6%) have had training on ADR reporting while 299 (80.4%) had not. This explains the reason for the poor awareness, attitude and practice to ADR reporting among doctors, pharmacists and nurses in Nnewi North Local Government Area and suggests the need for serious intervention to improve on them.

With good awareness, attitude and practice to ADR reporting, a better treatment outcome will be achieved, drug induced hospitalization and disability reduced, health and productivity improved and a better economy will be achieved.

6.1. RECOMMENDATIONS

- There is need for serious intervention by NAFDAC to improve awareness, attitude and practice of ADR reporting of health professionals in the study area through training, and workshops/seminar. Other awareness system like media should be used to facilitate coverage. NAFDAC could also train some health professionals who can help train other health workers on ADR reporting.

- Incorporation of training on ADR reporting into academic curriculum of Medical school, Pharmacy school and school of Nursing would go a long way to improving ADR monitoring and reporting.

- To lesson bureaucratic reporting process, a standard electronic reporting medium should be made available to doctors, pharmacists and nurses with an uninterrupted internet services. For effective reporting, the reporting medium can be integrated into the pharmacy drug information unit of the health facilities and have a pharmacist available at all times to aid the reporting process. In this

way, doctors and other busy health workers can have their suspected ADR reported through the drug information pharmacist without putting in much time.

- In the absence of effective electronic reporting process, we recommend that reporting forms, reporting guideline and other logistics be mass-produced and made available to the desks of doctors, pharmacists and nurses at all levels of health care system. This is because greater than 95% of the respondent studied stated having not set eyes on ADR reporting forms.
- NAFDAC should monitor ADR reporting by sending delegates from time to time to the various health facilities. Their presence in the facilities will of course sensitize health workers to put more effort in ADR reporting.
- To encourage reporters, NAFDAC should tender reply to those who report and occasionally adopt a motivational system like incentives. Incentives could be in the form of issuing certificate to the best/most reporter of the year. The photograph of such person(s) could be placed at strategic places for others to see and emulate. Such recognition can also be used as a means of earning promotion in the health institutions.

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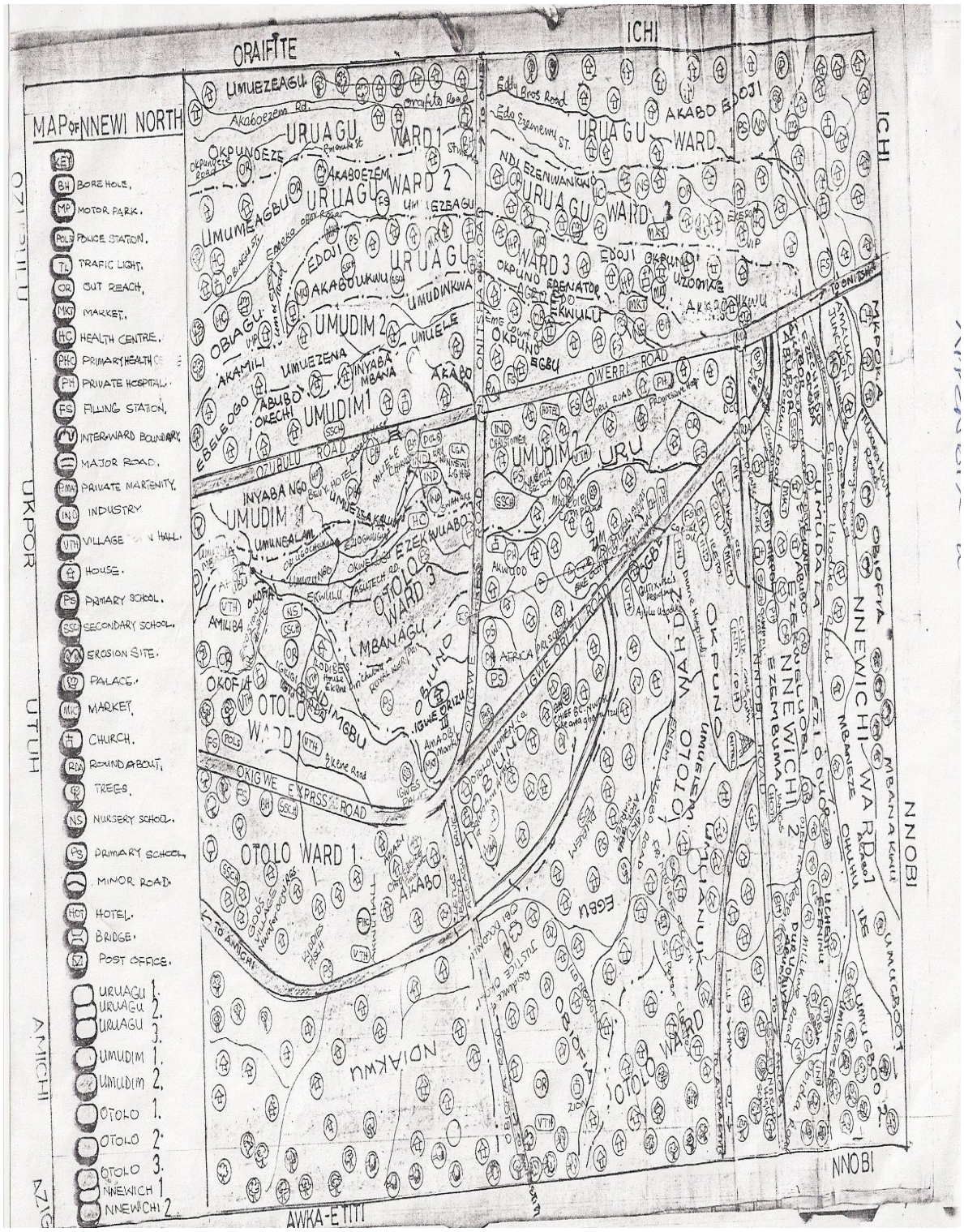
APPENDIX 1

Map of Nnewi North Local Government Area



APPENDIX 2.

INFORMED CONSENT FORM

Sir / Madam,

I am Ezeuko, Amaka Yves-Ann, an MPH student of Department of Community Medicine, Nnamdi Azikiwe University, Nnewi campus. I am carrying out a study on The Awareness, Attitude and Practice of Adverse drug reaction (ADR) reporting among health care professionals in Nnewi North Local Government Area, Anambra State.

Purpose of the study

The reason for the study is to promote early detection of drug safety problems in patients, improve rational use of drugs by health professionals and reduce medicine induced morbidity and mortality.

Procedure.

This will include asking you questions on your view on the above topic in a form called questionnaire. We will assist you to fill the forms. It will take about 3 minutes to fill the forms. Your honest and sincere responses to the questionnaire will help us understand better issues relating to Adverse drug reaction reporting among health care professionals in Nnewi North L. G. A.

Participation

You are free either to participate or not in this project. You also have the right to withdraw at any time, if you choose to. However, participation is voluntary and no

payment will be made to the participants. The investigator is also not paid for this study as it is done for academic reasons.

Confidentiality

I wish to assure you that nobody will know what you have written in your form. You do not have to write your name.

Risk / Benefit

- There are no known risks in participating in the study. However, findings from the study will be used to develop ways to promote early detection of drug safety problems in patients, improve rational use of drugs by health professionals and reduce medicine induced morbidity and mortality.

Consent

Now that this study has been well explained to me and I fully understand the study purpose and process, I shall be willing to take part in the programme.

Sign……..

APPENDIX 3

NNAMDI AZIKIWE UNIVERSITY TEACHING HOSPITAL

P.M.B. 5025, NNEWI, ANAMBRA STATE, NIGERIA

Prof. S. N. Nnatu
MB, BCH, FWACS, FICS, FMCOG, FRCOG London
Chairman
Board of Management

B.O. Chukwuma
B. Sc., MA, MHA, AHA
Director of Administration/
Secretary to the Board

Prof. R. O. Ofiaeli
MBBS (IB), FMCS, FICS, FWACS,
Chief Medical Director/
Chief Executive

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Our Ref: NAUTH/CS/66/VOL.3/59

Your Ref:

Date: 29/4/2010

Pharm Ezeuko Amaka Yves-Ann
Department of Community Medicine,
Nnamdi Azikiwe University,
Awka.

ETHICAL COMMITTEE APPROVAL

RE: THE AWARENESS, ATITTUDE AND PRACTICE OF HEALTH CARE PROFESSIONALS (DOCTORS, PHARMACISTS AND NURSES) TO ADVERSE DRUG REACTION (ADR) REPORTING IN NNEWI NORTH L.G.A ANAMBRA STATE.

I write to inform you that after due consideration of your revised research proposal, approval is hereby conveyed for you to commence the study.

.....
Dr. P.U Ele
Chairman, NAUTH Ethical Committee

.....
J.U. Ugochukwu (Mrs)
Sec., NAUTH Ethical Committee

APPENDIX 4.

QUESTIONAIRE ON THE AWARENESS, ATTITUDE AND PRACTICE TO ADR REPORTING AMONG HEALTH CARE PROFESSIONALS.

This research is intended to survey the Awareness, attitude and practice of doctors, pharmacists, and nurses/ related health workers in Nnewi North L.G.A, Anambra State to the national Adverse Drug Reaction (ADR) reporting scheme and to identify reasons for failing to report ADRs with a view to:

- Convince health professionals that reporting ADRs is their professional and moral obligations.
- Aid health professionals in becoming vigilant in the detection and reporting of ADRs and other drug-induced problems. And
- Reduce morbidity and mortality associated with ADRs.

(**Please, all responses will be treated with utmost confidentiality**)

	1	2	3	4	5
1. What is your age as at last birth day (yrs)	**20-30**	**31-40**	**41-50**	**51-60**	**> 60**

2. What is your sex 1 **M** 2 **F**

3. What is your profession? 1 Doctor 2 Pharmacist 3 Nurse

4. If a doctor,

What is your rank/position? **Please thick the appropriate one**.

Specialist	Resident Dr.	G P	House Officer
1	2	3	4

5. **If a pharmacist**, what is your rank?

ADPS	Chief Pharm.	Principal Pharm.	Pharm. 1	Intern Pharm.
1	2	3	4	5

6. **If a nurse/related health worker**, what is your rank?

CNO	ACNO	PNO	SNO	NO I	NO II	NO II
1	2	3	4	5	6	

Where do you practice? Please thick inside the box.

1. Primary Health Care (PHC) ☐
2. Health Post (HP) ☐
3. Private hospital ☐
4. Tertiary Hospital (NAUTH) ☐
5. Community Pharmacy ☐

7. Do you think that reporting of ADRs is your professional responsibility? **Yes** **No**
8. Are you aware of the national ADR reporting scheme/guideline? **Yes** **No**
9. Are you aware of any criteria from NAFDAC specifying which adverse drug reactions you should report? **Yes** **No**

If yes, which ones? (Please indicate below- Questions 10 to 18)

10. All suspected reactions to a new drug including minor ones **Yes** **No**
11. All suspected reactions to a new drug excluding minor one **Yes** **No**
12. All serious or unexpected and minor reactions to established or well known drugs. **Yes** **No**

13. All serious or unexpected (unusual) reactions to established or well known drugs.

Yes No

14. An increased frequency to a given reaction Yes No

15. ADR in special field of interest like drug use in pregnancy and lactation, excluding drug abuse. Yes No

16. ADR associated with drug withdrawals. Yes No

17. All ADR excluding those occurring from overdose or medication error Yes No

18. All ADR excluding those occurring from overdose or medication error Suspected

Yes No

19. ADR capable of causing death, danger to life, admission to hospital, prolongation of hospitalization, and birth defects. Yes No

20. Have you ever diagnosed or noticed an adverse drug reaction in a patient under your care? Yes No

21. Have you ever suspected an adverse drug reaction but not reported it Yes No

If you have suspected, but not reported an adverse drug reaction, was it because: (tick as many as applicable)

22. You were uncertain that the reaction was caused by a drug? Yes No

23. You considered the ADR too trivial (mild) to be reported? Yes No

24. You considered the ADR too well known to report? Yes No

25. You did not know how to report adverse drug reactions? Yes No

26. Reporting adverse drug reactions is too bureaucratic a process? Yes No

27. You do not have enough time to report adverse drug reactions? **Yes** **No**

28. You were concerned that your report could be used in a legal case for damages by the patient? **Yes** **No**

29. No availability of ADR reporting forms? **Yes** **No**

30. There is no incentive or financial compensation for the time spent on reporting ADR? **Yes** **No**

31. Reporting of an ADR has no effect at all? **Yes** **No**

Would you report an adverse drug reaction if

32. The medicine had been prescribed for your patient by another physician? **Yes** **No**

33. The patient had purchased the medicine (without prescription) themselves? **Yes** **No**

34. Would you rather report an ADR, if you could report by phone, fax, and/or E-mail? **Yes** **No**

35. Would you report an ADR if therapeutic advice/consultation was offered by phone? **Yes** **No**

36. Have you ever had any form of training on ADR reporting? **Yes** **No**

37. **If yes, at what level(s)?** Prior to Professional training | During Professional training | Workshops/ Seminars

38. What would you suggest to improve ADR reporting in Nigeria? ----------

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Thanks for your maximum co-operation.

List of abbreviations:

Dr = Doctor

Pharm. =Pharmacist

ADR = Adverse drug reaction

CNO = Chief nursing officer

ACNO = Assistant chief nursing officer

PNO = Principal nursing officer

SNO = Senior nursing officer

NO II = Nursing officer one

NO I = Nursing officer two.

CHEWS = Community Health Extension workers

NAFDAC = National Agency for Food, Drug Administration and control.

[Yes] = 1

[No] = 2