Enhancing pharmacovigilance in Nigeria: Challenges faced by NAFDAC in monitoring of Adverse Drug Reactions in Nigeria

Research dissertation presented in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology.

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August 2020

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I certify that the dissertation entitled:

"Enhancing pharmacovigilance in Nigeria: Challenges faced by NAFDAC in monitoring of Adverse Drug Reaction in Nigeria" submitted for MSc in Pharmaceutical Business and Technology is the product of my own research and I made sure the necessary reference is cited to work of others, a well-deserved acknowledgement is given.

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Acknowledgements:

First and foremost, I would love to give God a profound gratitude for the gift of life and strength to conclude this dissertation/program.

I would love to give special thanks to my family for the support they gave me in all forms, without them it would have been difficult coming to study here or even completing this dissertation and program.

I also want to give a special shout out to National Agency for Food and Drug Administration and Control Staffs, who took their time and showed interest in this study and supported this research regardless of the pandemic era by sparing time from their busy schedules to answer the questionnaires.

And lastly, I would like to thank Griffith College for granting me the un-imaginable opportunity to study here in Dublin, Ireland, despite all the hurdles that almost made my studying here to reach an impasse. I will not forget my supervisor, Prosper Anaedu, MD, without his patience, guidance and understanding, completing this work would have been difficult for me and working with him in the near future would also be a dream come true.

Abstract

This study aims at identifying the challenges being faced by NAFDAC in the monitoring of adverse drug reactions (ADRS) and to proffer solutions for the purpose of enhancing pharmacovigilance activities in Nigeria. To achieve this, the study sought to determine if NAFDAC has the capability to monitor and address reported ADR cases, to identify the factors that hinder the effective monitoring of ADRs and to suggest recommendations that can improve the level of ADR monitoring in Nigeria.

In conducting this study, the quantitative approach was used. A sample size of 152 was generated and data was collected through the aid of close-ended electronic survey questionnaires. Out of the 152 questionnaires administered to respondents, only 139 was answered and submitted. This shows a response rate of 91%. Descriptive statistics with the aid of the Statistical Package for Social Sciences (SPSS) version 20.0 was used to analyse obtained data and results were presented in frequencies and percentages in tables, pie charts and bar charts. In testing the study's hypotheses, simple linear regression and Karl Pearson's correlation were used.

Findings from the study revealed that poor and inconsistent training of staff on recent developments in ADR monitoring, neglect of latest technological solutions in the monitoring of ADR, reluctance of most healthcare professionals to report ADR issues and the refusal of drug users to report experienced ADR issues remain the main factors that hinder NAFDAC from effectively carrying out ADR monitoring in the nation. The study recommends that regular trainings where staff's knowledge are updated with current trends regarding ADR monitoring should be conducted. Also, NAFDAC should adopt the use of latest technological solutions in the monitoring practice of ADRs. Emphasis should be placed on the use of digitised reporting system to make the tracking of ADR cases easier and faster and a well-designed educational program should be implemented to enlighten medical practitioners and users of pharmaceutical products on the need for the reporting of known ADR issues. Effecting these recommendations would improve the level of ADR monitoring in the nation.

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CHAPTER ONE: INTRODUCTION

1.1 OVERVIEW

For centuries, the global society has experienced various forms of diseases which have sent many to their early graves. As each year passes, the rate of diseases has been observed to increase exponentially with a higher fraction being in third-world countries. This phenomenon reveals the burden of responsibility that lies on medical practitioners to seek out ways through which public health can be protected both in developed and developing nations. With medical practitioners having this understanding, several drugs have been manufactured and used in order to cushion the effect these diseases have on the public health of a nation. According to Meyer (2003), a drug is defined as a single active chemical body present in a medicine that is used for the diagnosis, prevention and treatment of diseases. However, the production and use of these drugs have led to some reactions that are seen to be detrimental to the good health of individuals. These reactions are referred to as adverse drug reactions and have been observed to differ from people to people as Meyer (2000) affirmed that one of the major problems in clinical practice and drug development is the difference in people's reactions to drugs administration. Adverse drug reaction refers to any noxious accidental and undesired effects of a drug that occur at doses used for the prevention, diagnosis or treatment of diseases (Shibbiru and Tadesse, 2016).

In medical history, almost six decades ago, the adverse reaction of a drug named "Thalidomide" was known to be responsible for the largest man-made medical catastrophe ever known by man (Vargesson, 2015). This drug which was initially produced for the treatment of morning sickness in pregnant women cost the lives of at least 2,000 children and deformation of over 10, 000 children. Prior to this time, regulation of drug safety was not given serious attention; not until 1961 where the drug was banned from the market after much damage had been done. This prompted the need for monitoring the safety of drugs after-market authorisation must have been given (Santosh and Tragulpiankit, 2011). And this monitoring responsibility demands that medical institutions and agencies develop vigilant measures to ensure the rate of reactions is drastically reduced.

Adverse drug reaction monitoring is the continuous follow-up of unwanted effects observed to come from the use of medical products. Sahu, Yadav, and Chandrakar (2014) defined it as the practice of constantly monitoring the undesirable effects caused from the use of drugs.

Shashi et al. (2016) defined monitoring as a process of evaluating a volatile system in order to guide changes to the system for maintenance or improvement. According to the American Society of Hospital Pharmacists (ASHP) (n.d.), the monitoring and reporting of ADR entails the observation of ADRs, documentation of ADR cases, reporting of ADRs, establishing a framework that allows for monitoring the safety of drug use in highly vulnerable patient population, and finally involves the enlightenment of medical practitioners concerning potential ADRs. All these features must be in a good ADR monitoring program.

Several benefits seem to exist from ADR monitoring programs to medical practitioners, patients and the public at large. The implementation of ADR monitoring programs propels the evaluation of the degree to which a drug is safe and allowed for use on people. This reduces the rate to which drugs have adverse effects on people, thereby improving the health of the general public. Also, medical practitioners who appear ignorant of certain adverse drug effects are enlightened and shown ways through which these effects can be tackled on patients. When adverse drug reactions are reduced, there is a reduced level of hospitalisation, implying that more people are in good health to go about their routine activities. This therefore impacts positively on the economy.

As earlier mentioned, responsibility lies on all medical practitioners, clinicians, dentists, pharmacists, nurses, patients to ensure ADR cases are adequately monitored. ADR monitoring should cover all pharma products, biological, herbal drugs, cosmetics and devices. This is to ensure mitigation of the rate of ADR cases from all corners and ensure the health of the public is highly protected.

The significant role these healthcare professionals play in the treatment of diseases for the good health of the general public cannot be overemphasised. Through their large amount of steady investment in research and development (R&D), pharmaceutical companies have always made efforts to ensure that drugs produced meet the standard requirement in terms of quality, efficacy and safety. Despite this, there is still the cogent need for regulatory agencies as they ensure the strict adherence to laid-out procedures through all phases of clinical trials and post-market authorisation for the purpose of having the best possible outcome for new medicines. Before clinical trials, preclinical trials are usually done on animals to ascertain whether it is safe for trials on humans. Five phases of clinical trials seem to exist. These phases include, phase 0, phase 1, phase 2, phase 3 and phase 4. Phase 0 is simply a

guide to phase 1. It is conducted on a small number of people normally less than 15 to establish a certain degree of safety. Here, medical researchers administer a very minute dose on these small number of people to ascertain a certain degree of safety before administering it in greater quantity in other phases. In Phase 1, a longer duration of time is spent by medical researchers in observing the effects of the newly developed drug on a larger number of people usually between 20 and 80. The major aim of this phase is to identify the highest dosage that can be consumed by a human being without any adverse effects. Phase 0 and Phase 1 usually involve participants who have no underlying health conditions. Phase 2 involves increasing the number of people to increase the confidence in safety level of the drug. Here, the new drug is tried on hundreds of people who are known to have the illness for which the drug was developed to treat. The same dosage given to those in the preceding stage which was discovered to be safe is administered to participants in this phase. Phase 3 is a more confirmatory phase to conclude on the safety of the drug while Phase 4 is the stage where the drugs are monitored to ensure its safety after it has been approved into the market. It is at this stage pharmacovigilance comes into play and it usually characterises a longer period of time than previous phases. This phase is very important to test the safety of the drugs because they are being used by a larger population and therefore there is the need for pharmacovigilance activities like adverse drug reaction monitoring to further protect the health of the public.

Pharmacovigilance is a word derived from French roots and it is defined as “a cyclic process of signal detection, signal strengthening and follow-up” (Santosh and Tragulpiankit, 2011). This means it is a recurring process that involves the careful observation and analysis of related drug-adverse events or cases via different medical perspectives with the focus of constantly improving the reliability of the process and comparing results obtained with another. The World Health Organisation (WHO) (2004) defined pharmacovigilance as the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems”. The significance of pharmacovigilance to the safety of drugs cannot be overemphasised as it is the sole means through which the safety of drugs can be ensured and assured through the drug’s lifecycle. Adopting clinical trials are good but clinical trials are not enough to ensure the safety of a drug when it has been pushed into the market. Clinical trials as earlier revealed are done prior to

the market authorisation of drugs. Pharmacovigilance on the other hand is the only means through which the safety of drugs on individuals are monitored or observed after they have been pushed into the market. It can be said that pharmacovigilance is post-market observation of drugs safety.

In the literature and even practically, the term adverse drug reaction (ADR) and adverse drug event (ADE) have been mistaken to be synonymous concepts. But there exists a difference between them. The WHO (2005) explained adverse drug event (ADE) to be any unpleasant medical event that occurs when drugs are administered to a patient but are not necessarily the cause of that event. This means ADE are unexpected negative circumstances that occur during the treatment of a patient of which the treatment is not the cause. Adverse drug reaction (ADR) on the other hand, as defined by WHO (1972) is "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modifications of physiological function." Scholars and practitioners should be able to tell the difference between these two concepts.

Adverse drug reactions could be mild or harsh when drugs are administered to patients. They are to be termed serious when patients as a result of a dose administered become disabled with even the possibility of death and also when certain behaviours shown by the patients are not in line with what is stated in the Patient Information Leaflets (PILs).

Meyboom et al. (1997) having reviewed works done by other researchers, said that ADR may somehow be unnaturally categorised into three different types: A, B and C. This was also supported by Schatz and Weber (2015) who revealed that ADRs were initially categorised into two subtypes. Type A ADRs are reactions that come as a result of the administration of overdose to a patient. They are usually known and predictable due to the pharmacological effects inherent in the drug. Simply, type A ADRs are reactions that can be determined from the known pharmacology of a drug. Type A ADRs are one of the commonest and most frequent ADR and can be easily avoided by using the right amount of dosage for a patient. They can also be addressed by reducing the dose given to the patient. An example of Type A ADRs is constipation induced by morphine and it can be easily identified before its entrance into the market and can be experimentally studied and reproduced. However, certain issues can arise from this which include:

- A minority of the patients are showing this effect
- When no correlation exists between the effect and the drug dosage.
- When the issue is not important, concurrent or to reproduce in experiment is very difficult
- When it is not a clear process

A typical example for this is the cough inherent in the use of Captopril and other angiotensin-converting enzyme (ACE) inhibitors. This was not observed during the clinical trials but was noticed due to monitoring after allowed into the market. Other examples include bleeding, postural hypotension etc.

Type B ADRs on the other hand are not as common as Type A and are usually unpredictable for a number of reasons which may not have any correlation with the use of the drugs. They are independent of dosage and are observed in a small population of patients implying that the different traits of patients are the determining factors for the reactions observed (Pirmohamed and Park, 2003). Simply, Type B reactions are reactions that cannot be determined from the pharmacology of a drug. They are more dependent on the individual trait of the patients than of the dose administered. Type B ADRs are also called "patients' reactions". They are often serious and are difficult to detect. A major reason for all the features mentioned in Type B is the correlation with time and little backdrop frequency that usually give good reasons to make the drug a suspect. Type B ADRs are mostly allergies; for example, allergy to drug like penicillin leads to anaphylaxis while allergy to anticonvulsant leads to hypersensitivity, etc. Schatz and Weber (2015) revealed that type A reactions were later referred to as *augmented* while type B reactions were referred to as *bizarre*: Type A reactions are simply as a result of overdosage (i.e. dose related) while type B are strange reactions, non-dose related which were not earlier anticipated due to the variations in the traits of patients.

Type C ADRs are those reactions that are dose related and time related. The production of drugs for the past five decades has greatly ameliorated the quality and expectancy of life for people with chronic diseases. However, there have been some vivid changes in some diseases like diabetes mellitus and myasthenia gravis and the problems of late sickness are now determined by the well-being and diagnosis of patients. The type C reactions usually come as a result of the accumulation of dose or with a use of such drugs for a long period of time. The

frequency in the occurrence of natural sickness are determined by the prolonged use of such drugs over a period of time. This is also detrimental to the health of the public. An example is adrenal suppression with corticosteroids. Another example is the effect oral contraceptives have on the commonness of breast tumours or thromboembolic complications with several oral contraceptives.

Further to the above subtypes of ADRs, other types emerged. The first one is the type D ADR. The type D ADR is a type of delayed reaction. It occurs after a long period of treatment and can be as a result of accumulation. An example of this reaction is secondary tumours from chemotherapy, nephropathy from analgesics, etc. Type E ADR which is another type of ADR occurs when treatment using a particular drug on a patient is abruptly put to a stop. For instance, the abrupt *withdrawal* of phenytoin leads to seizures. Summarily, any reaction that occurs immediately after the stoppage of the administration of a drug is called the type E ADR.

Types of ADRs	**Examples**
Type A	Constipation induced by morphine
Type B	(i) Allergy to drug like penicillin leads to anaphylaxis (ii) Allergy to anticonvulsant leads to hypersensitivity
Type C	(i) Adrenal suppression with corticosteroids (ii) Thromboembolic complications with several oral contraceptives.
Type D	(i) Secondary tumours from chemotherapy (ii) Nephropathy from analgesics
Type E	The abrupt *withdrawal* of phenytoin leads to seizures.

i Table 1: Types of ADRs and Their Examples

Consequent upon the foregoing, pharmacovigilance which encompasses all the processes involved in the detection, examination, comprehension and prevention of ADRs was introduced for the purpose of enhancing the safety and balanced use of drugs in order to protect the health of the public.

THE REGULATORY AFFAIRS

For every system or structure, there is always an entity charged with the responsibility of monitoring and coordinating its affairs for the successful attainment of goals. In medical sciences, several regulatory frameworks are set up to ensure the adequate monitoring of its activities. As regards the safety of drugs, it is the major responsibility of the regulatory affairs to ensure safe, effective and high-quality drugs are made available for public use. It is the duty of the regulatory affairs to enact and enforce strict adherence to pharmaceutical regulations related to research and development, drugs registration, manufacturing, principle, delivering, protection of intellectual property and sales. The principal aim of the regulatory affairs is to protect patients from unintentional harm from previously unidentified hazard of the drug.

Subsequent to the medical catastrophe that occurred in the early twentieth (20^{th}) century, the "thalidomide case", the safety concern on all pharmaceutical products greatly intensified. This prompted thorough vigilance in the inspection process of all pharmaceutical products before and after authorisation into markets. This activity became inevitable in order to prevent a reoccurrence of the "thalidomide case". The World Health Organisation (WHO) through its comprehensive drug control programme in 1968 encouraged the implementation of pharmacovigilance in every member nation. All member nations kept up with a single contact-point to collect, review and exchange data from the several incident reports around the globe.

In 2005, the WHO stated in their first set of regulations published, that a hospital or third-party health facility containing more than fifty (50) admission beds needs the services of a pharmacovigilant contact person in order to promote the activities of pharmacovigilance like ADR monitoring and reporting, provision of adequate education and training of medical personnel for the better medical care of patients.

In Nigeria for instance, the regulatory affairs responsible for the monitoring and coordination of all pharmacovigilance activities is the National Pharmacovigilance Centre (NPC) under the supervision of the National Agency for Food Drugs and Administration Control (NAFDAC). NAFDAC which joined the WHO International Drug Monitoring Programme in 2004 has since through the arm of NPC monitored the safety of drugs in the nation.

ADR MONITORING AND PHARMACOVIGILANCE

The principal role of every regulatory body, in the case of Nigeria, NAFDAC is to ensure the consistent, effective monitoring of all marketed drugs for the health of the public. Agencies like this are burdened with the responsibility to ensure that drugs authorised for public consumption are of no threats to the health of the general public. Owing to the high incidence level of adverse drug reactions in the globe especially Nigeria, the significance of pharmacovigilance activities cannot be excused. Pharmacovigilance which has been defined by WHO (2002) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem". Yadav (2008) revealed that the term pharmacovigilance is founded upon three (3) pillars which are as follows:

(i) Obtaining of new information from trusted scientific resources like marketing authorisation holders, healthcare professionals, consumers, international/public bodies, journals, published and updated literature, etc.

(ii) Classification and examination of the above information.

(iii) Circulation of its contents as well as any action taken on specific drug to all health sectors.

Figure 1: ADR monitoring system

(Yadav, 2008)

Yadav (2008) further stated that every ADR report should have the following features which are: (a) patient (b) a drug (c) an adverse reaction (d) composer/reporter of the report. Without these characteristics, such report is just a mere report and nothing more.

Several studies have revealed some factors that hinder ADR monitoring by medical practitioners in the globe. With respect to Nigeria, Ezeuko, Ebenebe, Nnebue and Ugoji (2015), identified some of these factors to include ignorance of pharmacovigilance program, absence of a pharmacovigilance feedback system and methodology for detecting warnings, etc. It is of utmost important for these issues to be addressed since health practitioners (both medical doctors and pharmacists) are the ones responsible for the treatment and care of patients. Attention has to be paid to medical practitioners understanding the significant role pharmacovigilance plays in the health of the public. Moreover, the agency responsible for the supervision of pharmacovigilance activities in Nigeria, NAFDAC has been bequeathed with some challenges that affect the proper monitoring of ADR cases in Nigeria.

1.2 Research Purpose

The study is underlined with the purpose of identifying and exploring the challenges faced by the National Agency for Food Drug Administration and Control (NAFDAC) in monitoring ADR for ameliorating practices in the area of drug safety, reducing the cost of ADR in Nigeria general patient population, improving the rate of reporting, and removing any encumbrances that may hinder the effective impact of NAFDAC. Most of the ADR cases in Nigeria are consequent upon some issues like the drug's wrong information, advanced age-related physiological, biochemical, pharmacokinetics, pharmacodynamics, and abuse. And sometimes, the severity of the ADRs seems to outweigh the benefits which the drug proposes. It is in this event NAFDAC is meant to intervene, but some factors exist that hinder them from effectively carrying out their duty.

To proffer solution to this problem faced by NAFDAC, the researcher further evaluated the level of information obtained by NAFDAC staff on ADR monitoring and pharmacovigilance activities at large. It is obvious that the rate of ADR monitoring in Nigeria is low, this study seeks to provide ways through which ADR monitoring can be improved for the safety and good health of both patients and the general public in Nigeria.

1.3 Significance of the Study

The National Agency for Food Drug and Administration Control (NAFDAC) through the arm of the National Pharmacovigilance Centre (NPC) is known to be responsible for handling all pharmacovigilance activities in Nigeria. The monitoring of ADRs have become an issue of paramount concern in the medical field due to the increased mortality rate and low life expectancy in the country as revealed by Shelton (2014). There is a need to further the examination of ADRs in hospitals and various medical facilities in order to identify the benefit-risk ratio of drugs for the safety of public health. Moreover, to further safeguard the health of the public, a need for placing emphasis on drug control is crucial for the restructuring and enforcing of an optimal ADR protocol system which spans from the recruitment process through to the laboratory parameters. In spite the importance of ADR monitoring to medical institutions and patients, the rate at which this activity is carried out is appalling. This study seeks to reveal the factors that hinder the effective monitoring of ADRs by the regulatory body in Nigeria.

1.4 Research Objectives

1. To determine if NAFDAC possesses the capability to monitor and address reported ADR cases.
2. To identify the factors that hinder NAFDAC from effectively monitoring ADR in Nigeria.
3. To proffer solutions that will help boost ADR monitoring by NAFDAC.

1.5 Research Questions

1. Does NAFDAC have the capability to monitor and address the reported ADR cases?
2. What are the factors that hinder NAFDAC from effectively monitoring ADR in Nigeria?
3. What are some possible solutions that will help boost ADR monitoring by NAFDAC?

1.6 Research Hypotheses

Hypothesis One:

H_0: NAFDAC ADR monitoring would have no impact on the safety of public health.
$H_{1:}$ NAFDAC ADR monitoring would have an impact on the safety of public health.

Hypothesis Two:

H_0: No relationship exists between ADR monitoring and reduction in ADR cases.
H_1: A relationship exists between ADR monitoring and reduction in ADR cases.

1.7 Structure of the Study

This study is premised upon the epistemological approach of positivism. Due to this, a quantitative approach was adopted in obtaining data. The primary research of this study was

aided through the use of electronic survey questionnaires. The questionnaires were structured to obtain information from staff of NAFDAC Lagos Operational Office located at Plot 1, Industrial Estate, Lagos, Oshodi-Apapa Expressway, Isolo, Lagos, Nigeria. The questionnaires were divided into two categories, section A and section B. Section A is concerned with the socio-demographic information of respondents while section B has to do with items that relate with the variables of the topic.

Moreover, the study comprises five chapters. Chapter one is the introductory chapter which encompasses an overview of the study, research questions, research objectives, research hypotheses and significance of the study. Chapter two on the other hand concerns reviewed literatures related to the study's topic and empirical findings while chapter three deals with the methodology adopted in providing answers to the research questions. Chapter four majorly has to do with the presentation and interpretation of data and how they connect with existing literature. Chapter five which is the final chapter is the concluding part of the study. It clearly reveals the answers to the research questions and recommends solutions for practice and future research.

1.8 Conclusion

With Nigeria being a large market for various products due to its population strength, it is expedient that several measures be put in place to monitor the standard of these products both shipped into its boundaries and locally produced. Of course, medical products are no exception instead, a greater degree of attention are to be paid to them given their direct impact on public health. This awareness prompts the need for the regulatory agency, NAFDAC through the NPC to intensify efforts on promoting pharmacovigilance activities especially ADR monitoring in Nigeria. However, in an attempt to promote pharmacovigilance activities in the country, NAFDAC is faced with some challenges that inhibits its effective implementation. This calls for some investigations to seek out the root causes of these challenges and proffer solutions to them. The monitoring of ADR cases in the Nigerian medical market cannot be comprised or taken for granted due to the significant role it plays in the protection of the health and safety of the general public. Hence, it is pertinent to ensure the establishment of a suitable framework for its effective implementation.

CHAPTER TWO: LITERATURE REVIEW

2.1 INTRODUCTION

Nigeria as a whole has for a long time been characterised by several challenges in the medical sphere. This has given rise to increased mortality and morbidity rates in the nation. In addition to the challenges faced, there exists a low level of monitoring of adverse drug reactions. Drugs being authorised into the market are scarcely monitored to ascertain if there exist other side effects not observed in the clinical trials. The regulatory agency responsible for the monitoring of drugs in the post-market authorisation period have not been effective in the dispensing of their duties and this has contributed to the increased rate of mortality and morbidity experienced in the country. This chapter deals with the extant literature on issues pertaining to ADR monitoring in Nigeria revealing challenges being faced by the regulatory agency in the discharge of their duties.

2.2 BRIEF OVERVIEW OF NIGERIA

Nigeria is known to be the most populous nation in Africa located in the West African sub-region and is popularly referred to as the "Giant" of the continent, bordering Benin in the west, Chad in the northeast, Niger in the north and Cameroon in the east. Nigeria is a country that comprises thirty-six (36) states and its capital city, Abuja. The World Population Review (2020) revealed the Nigerian population to be over 205 million people, making the country the seventh largest in the world. Lagos state, the former capital of the nation inhabits a higher percentage of the population than other states with an estimate of 14,368,332 (World Population Review, 2020). As a developing nation, it has been characterised by lots of health and medical related issues, though the morbidity and the mortality has not been quantified yet (Olowofela, Fourrier-Réglat and Isah, 2016) and has been known to have the lowest life expectancy rate in the West Africa sub-region (*NATIONAL BUREAU OF STATISTICS*, 2020).

The World Health Organisation (W.H.O.) has estimated the life expectancy of Nigerians to be 54.5 years of age ranking Nigeria as the fifth behind Central African Republic, Lesotho, Chad, and Sierra Leone. The low life expectancy in Nigeria is contingent upon several factors of which the low standard of medical facilities is a major one. The diagram below shows a representation of the infant mortality rate and total fertility rates in Nigeria as revealed by Shelton (2014).

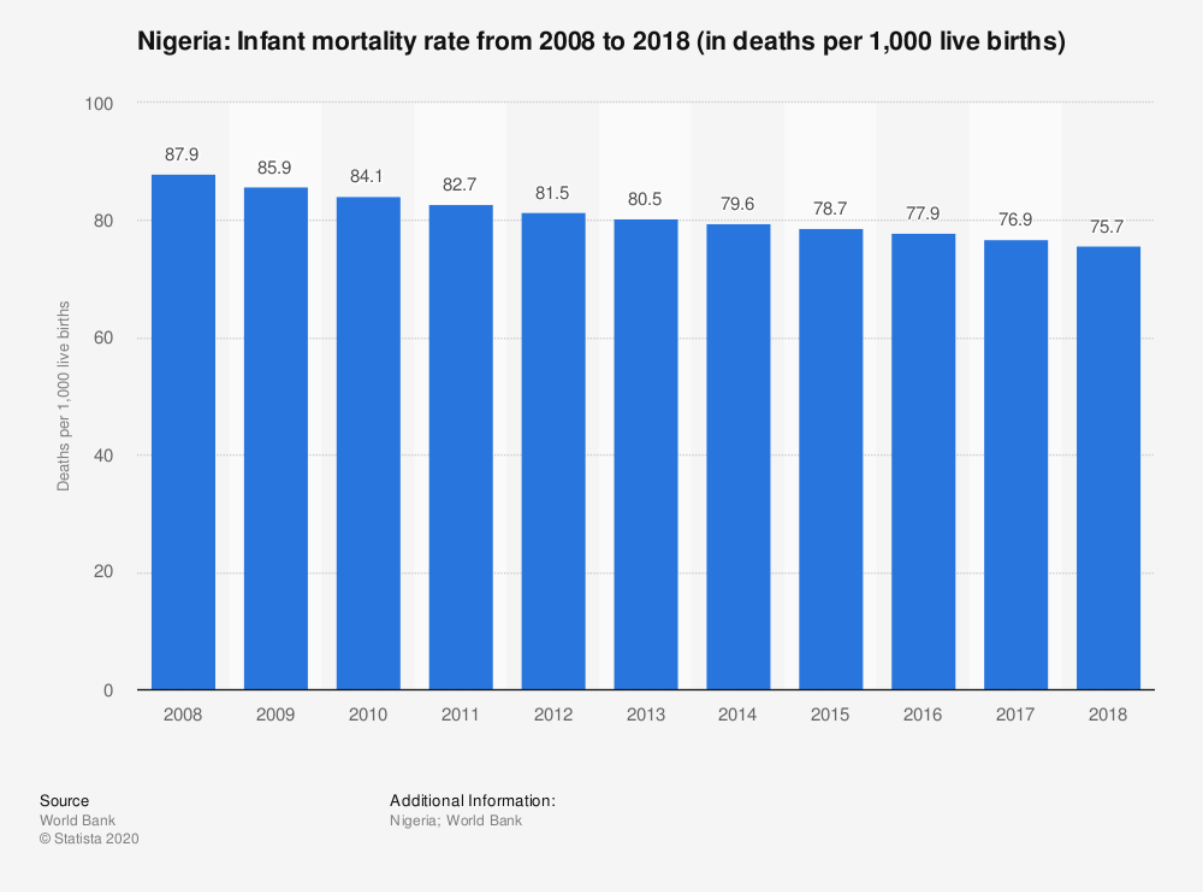

Figure 2: A Graphical Representation of Infant Mortality Rate from 2008 to 2018

(Statista, 2020)

The above graphical representation shows the mortality rate of infants between the year period of 2008 and 2018. From Fig. 2 it is seen that the infant mortality rate is on a downward trend. Despite the decreasing rate of infant mortality rate in Nigeria, UNICEF has revealed that Nigeria is still one of the countries with the highest infant mortality rate in the world (TRTWorld, 2019). Statistics shows that every five children have the tendency to die before reaching the age of five. A major factor responsible for this is the poor medical structure prevalent in the country. The high rate of health issues in the country seems to be beyond the capacity of the medical system available in the nation. Nonetheless, the population of the country is seen to be on the rise with a percentage increase of 3.2 percent annually (VOA, 2019) which is high when compared to other countries. As predicted by the United Nations (UN), the overall population of Nigeria is estimated to be about 401.31 million people by 2050 and if the following figure remains constant, it might get to 728 million people (World Population Review, 2020).

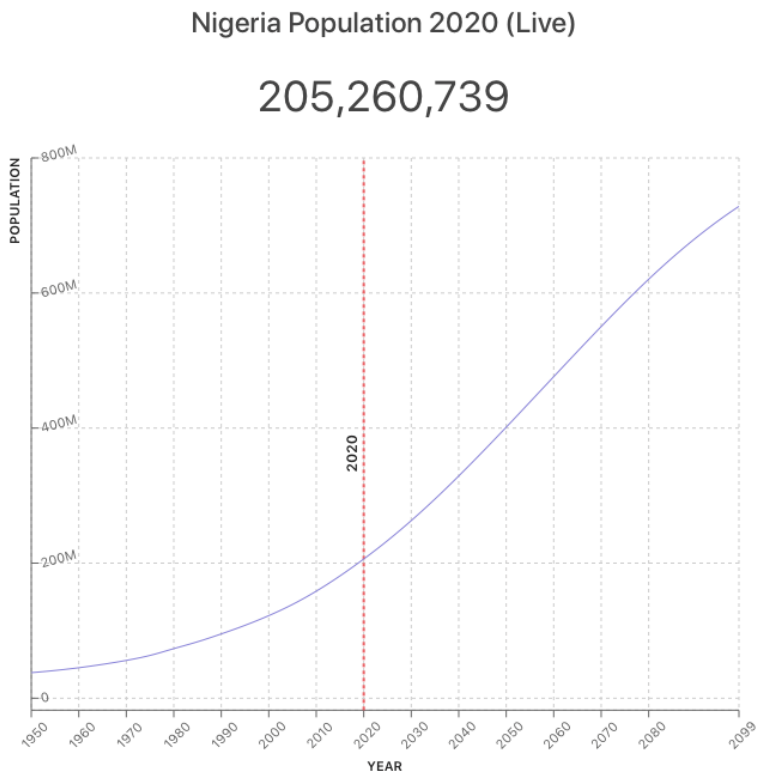

Figure 3: Growth Rate of Nigeria's Population

(*http://worldpopulationreview.com/countries/nigeria-population - Google Search*, 2020)

2.3 THE CURRENT STATE OF ADVERSE DRUG REACTION ACTIVITIES IN NIGERIA

Nigeria has been known to inhabit an epileptic medical system featured by insufficient and inadequate equipment, poor compensation package for medical personnel, poor infrastructural facilities and so on. This of course has contributed to the rate of mortality and morbidity in the country. The low rate of monitoring ADR cases in the country is also an offshoot of the epileptic medical system. According to Premium Times (2016), the National Agency for Food and Drugs Administration and Control (NAFDAC) in a bid to ensure effective ADR monitoring, through its former acting Director-General, Yetunde Oni advocated for the consistent reporting of ADR cases from all medical institutions in order for the agency to take necessary actions. She further revealed that:

> *Due to the inherent nature of medicines, no medicine, no matter how skilfully produced to meet specified quality standards, properly distributed and stored, rationally prescribed and used is 100 percent safe…However, by continuously monitoring all medicines, it is possible to detect those causing unwanted ADRs, understand why they cause ADRs and prevent them from further causing harm to users. This can only be*

done effectively if health care providers detect and report all suspected ADRs and other medicine related problems.

Recall that ADRs are effectively monitored when all medical practitioners pay attention to detection and reporting of suspected cases in every medical institution. This is because medical practitioners especially doctors are usually the first point-of-call for any disorder experienced by patients in their health. As a result, responsibility is bequeathed on them for the detection and reporting of every suspected ADR case.

In 2004, the National Pharmacovigilance Centre (NPC) was officially launched for the purpose of ameliorating the safety of patients in the use of drugs. As revealed by Oni (Premium Times, 2016), every nation that has adopted the pharmacovigilance program is required to have at least two hundred individual safety report case per a million residents in a year. In 2013, 2014, 2015, the number of ADR cases reported was 2162, 988, and 1385 respectively. Moreover in 2016 where the population of Nigeria was estimated to be over 140 million people, the number of reported cases was only 2361. This means Nigeria was supposed to have at least 28,000 cases per year, but this was only an illusion because the data revealed from the agency showed only 2361 cases were reported for that year. These figures indicate that a lot of ADR cases are not reported; and if finally reported, many of those cases are not documented. The non-reporting of these cases implies no action taken which further means that the health and safety of Nigerians are at a huge risk (Adebowale, 2016).

Opadeyi, Fourrier-Reglat and Isah (2018) in their study, exposed more on the current state of pharmacovigilance in Nigeria. According to them, the level of pharmacovigilance activities in Nigeria is still in the *teething* stage. Low level of ADR monitoring seems to characterise the Nigeria medical system due to the poor documentation and huge neglect for the issue of pharmacovigilance by medical practitioners in the country. Moreover, Segun and Fakeye (2013) who ventured into examining the level of awareness had by pharmacy students of the subject matter of pharmacovigilance using a Nigerian university as a case study, revealed that students appear to be ignorant of the sequence of reporting ADR. According to them, this is consequent upon the absence of pharmacovigilance and adverse drug reaction courses in the schools of pharmacy curriculum in Nigeria. The lack of these courses in pharmacy curriculum means pharmacists churned out into the

practical field are not actively involved in the activities of pharmacovigilance which has contributed to the low level of monitoring ADR cases in the country.

Further to the above, in Nigeria, statistics has shown that the elderly, those aged between the age of 65 years and above constitute 3.1 percent of the total population and is rapidly increasing (cited in Tanyi, Andre, and Mbah, 2018). Recall that Hilliard (2017) reported that elderly people are more prone to illnesses than younger individuals by showing that 52.9 percent of men and 53.5 percent of women above 65 years are seen to suffer from severe illnesses or health-related problems. Most of the health problems suffered by these elderly individuals could be as a result of complications derived from the administration of certain drugs. Beijer and de Blaey (2002) confirmed this by stating that a positive correlation exists between adverse drug reactions (ADR) and an increase in age. This, they revealed by further explaining that more patients of the age of 65 years and above are being hospitalised for ADR-related issues than younger individuals. This implies that elderly people suffer more from adverse drug reactions than younger people in Nigeria. Some of the drugs used by elderly individuals that causes ADR include gastrointestinal drugs, cardiovascular drugs, anti-inflammatory medications and anti-cancer medications.

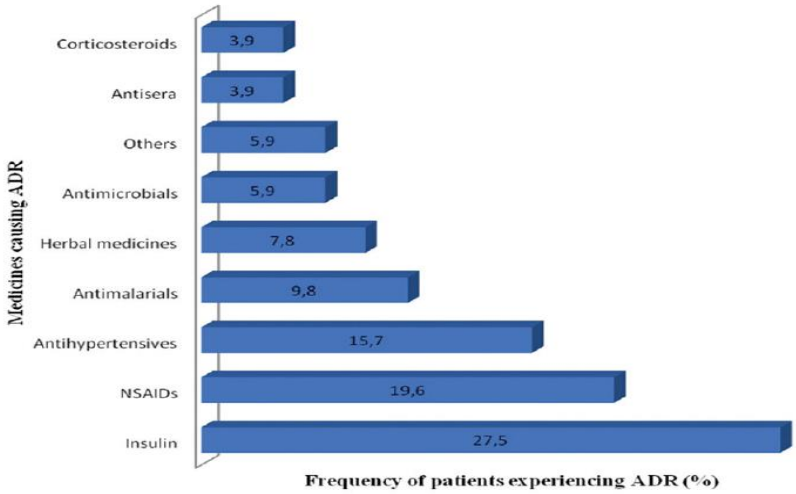

Figure 4: Frequency of the medications that cause ADR in patients in Nigeria between December 2013 to August 2014

(Akhideno, 2019)

In his study, Akhideno (2019) showed the frequency distribution pattern of patients who suffered from ADR and the drug used. In the distribution pattern, insulin was seen to be

at the topmost level as shown in Fig. 4, which resulted in more ADR cases in 14 (27.5 percent) patients. The second was NASIDs which had 10 (19.6 percent) patients followed by antihypertensive at 8 (15.7percent) patients, then, antimalaria, herbal medicines and antibacterial also being causes of ADR, having 5 (9.8 percent) patients, 4 (7.8 percent) and 3 (5.9 percent) patients respectively.

2.4 ADVERSE DRUG REACTION MONITORING

According to Coleman, Ferner and Evans (2006), monitoring is a process that entails examining a system that changes with time for the purpose of guiding those changes in a way that will either keep the system in its current state or improve it. Coleman, Ferner and Evans (2006) further established that three components characterises a monitoring process and they include: proactive and targeted observation, analysis, and action. Proactive and targeted observation entails the predetermined phenomena or occurrences that are to be observed right before the initiation of the process. This component has to be relative to the goal for which the monitoring process is set up. The second component which is "analysis" has to do with the examination of the changes required to be made to the system for it to maintain its desirable state or move it to a better state. The third component which is "action" simply deals with the taking of the steps required to initiate the desired changes.

From the foregoing, adverse drug reaction monitoring is simply a process that entails the observation of adverse reactions that are inherent in a drug for the purpose of safeguarding the health and safety of a given patient population. It is the continuous follow-up of unwanted effects observed to come from the use of medical products. In the view of Sahu, Yadav, and Chandrakar (2014), it is the practice of constantly monitoring the undesired effects from the use of drugs.

Adverse drug monitoring is a process that begins right before the time a new drug is released into the market. At this stage, it is within the jurisdiction of pharmaceutical companies to detect any adverse reaction and therefore provide all the necessary information about the new drug. When such drug is released into the market, it is no longer the sole responsibility of pharmaceutical companies to provide information about adverse reactions of the drug but now requires that all prescribers of the drug do the

same. Also, certain organisations are established to carry out this exercise for the safety of the drug users.

A rationale that justifies the post market monitoring of newly developed drugs is that during clinical trials, information provided by pharmaceutical companies on the adverse reactions inherent in that drug is usually insufficient to ascertain all the possible adverse reactions due to the small number of participants used and the short period of time taken to examine the drug. This therefore creates the need for post-market surveillance to ensure that the drugs remain safe for its continuous consumption by the populace.

Furthermore, Shashindran and Gitanjali (n. d.) revealed some criteria that should be met to determine the existence of adverse drug reactions (ADR) of a particular medication. These criteria include the following:

(i) A temporal connection between the suspected drug and the adverse event.
(ii) Positive dechallenge: This means improvement in patient's health or responses after withdrawing usage of the drug.
(iii) Positive rechallenge: This is the recurrence of the adverse event when the administration of the drug is resumed.
(iv) The absence of confounding effect: This means the adverse event has no correlation or relationship with any related disease.

The World Health Organisation (WHO) in 1971 established a global framework for monitoring adverse drug reactions using information obtained from member nations. This global framework was established as a result of the "thalidomide case" of 1967. Prior to this time, issues related to adverse drug reactions were not taken seriously but the advent of the "thalidomide case" compelled the WHO to focus on the need for the continuous monitoring of drugs even after market authorisation. Due to this, several nations have subscribed to the membership of this drug monitoring program. The National Agency for Food and Drug Administration Control, NAFDAC, the agency responsible for regulating pharmaceutical products in Nigeria joined the WHO International Drug Monitoring Program in 2004 to ensure the practice of drug monitoring in the nation aligns with global best practices and thereby protect the health and safety of the nation's patient population.

It should be noted that in discussing ADR monitoring, it is expedient that ADR reporting is also explained. This is due to the significant role ADR reporting plays in the monitoring of adverse reactions of drugs as Gurmesa and Dedefo (2016) stated that ADR reporting aids the drug monitoring system to detect the undesired and unintended effects of drugs that have already been made available to the public. Adverse drug reaction reporting is simply the documentation and presentation of the adverse reactions of drugs to regulatory authorities. It is usually done by medical practitioners since they interface with patients in the course of administering treatments. It is important for all medical practitioners both traditional and modern to report every suspected ADR case to the appropriate authorities just as Nadew, Beyene, Beza (2020) stated that the early reporting of ADR cases by medical practitioners to regulatory authorities is an insurance for the health and safety of the public against the adverse reaction of drugs. The gross negligence by medical practitioners in the reporting of ADR cases causes a dysfunction in the monitoring practice of ADR cases by regulatory authorities which ultimately puts the entire patient population at risk. In affirmation to the preceding, Kavitha (2010), amongst the steps involved in adverse drug reaction monitoring, revealed ADR reporting to be inclusive. According to her, there are four steps involved in the monitoring of ADRs and they include; (i) detection of adverse drug reaction (ii) evaluation of causality between drug and suspected reaction (iii) documenting of ADR in patient's medical records, and (iv) reporting of ADRs to ADR regulatory authorities or pharmacovigilance centres.

2.4.1 ACTORS RESPONSIBLE FOR ADVERSE DRUG REACTION REPORTING IN NIGERIA

As earlier mentioned, all medical professionals (medical doctors, dentists, midwives, nurses, pharmacists, and traditional medicine practitioners) are known to be the first point of call when addressing the issue of ADR cases. This is because they are charged with the responsibility for the medical care of patients. Given the fact that they constantly interface with the illnesses of patients, they are also charged with the responsibility of reporting ADR cases when detected. Due to this, the National Agency for Food Drugs Administrative Control (NAFDAC), the regulatory agency provides them with the necessary support to report any suspected ADR case in the course of duty without hesitation. Nonetheless, despite the support provided to these medical personnel, the rate of ADR reporting in the nation is seen to be very low. Okezie and Olufunmilayo (2008)

concurred to this when they revealed that the rate of reporting by medical doctors was low despite their high level of awareness and observation of ADR related issues.

As aforementioned, the level of ADR reporting in Nigeria is seen to be very poor and this is contingent upon various factors like fear of litigation, time constraints, increase in the burden of work, etc. Medical doctors most especially have claimed that the reporting of ADR cases have the potential to attract litigations and judicial claims against them and that the issue of keeping patients' data confidential is another factor that inhibits the level of ADR reporting in the country (Oshikoya and Awobusuyi, 2009).

More so, the poor training or low level of emphasis on ADR has contributed to the low reporting of ADR in Nigeria. This was affirmed by Ezeuko, Ebenebe, Nnebue and Ugoji (2015) when it was revealed that out of the 120 doctors surveyed in Lagos State University teaching Hospital (LASUTH), Nigeria, only one doctor had received training on the use of yellow card in the reporting of ADR. This shows a very high percentage of medical practitioners who are unaware of the reporting process of ADR cases. This is abysmally bad for a country like Nigeria which inhabits the highest population of people in the continent of Africa and whose population is still on an upward trend.

Comparing the level of ADR cases in Africa to developed countries in the European Union, studies have shown both continents to have low level of ADR reporting despite the hike in the rate of illnesses in these continents. However, the continent of Africa has been seen to have a much lower rate of ADR reporting than its European counterpart. Ampadu et al. (2016) affirmed this by stating that though the level of individual case safety reporting in Africa has greatly increased, it still comprises less than one percent of the world's data stored in VigiBase. VigiBase is an international database meant for the storing of individual case safety reports and is controlled by the Uppsala Monitoring Centre on behalf of the World Health Organisation (WHO). Individual case safety reports also simply known as safety reports refers to the documenting and reporting of detected adverse reactions of a drug(s) to a particular database.

In 2008, the European Commission revealed that of all hospital admissions, 5 percent are as a result of adverse drug reactions (ADR) and that ADR is the fifth commonest cause of

deaths in the European Union having a mortality of 197, 000 people per annum. As a result, the EU is burdened with a total cost of €79 billion. Furthermore, in a given study conducted by the European Commission, a sum total of 4802 patients were admitted and recorded. From these patients, about 3.2 percent accounted for those who had ADR during their hospitalisation period while 6.2 percent accounted for those who were admitted as a result of ADRs. This means a total of 9.4 percent had ADR-related issues out of the 4802 patients. It was further observed that the hospitalisation duration was prolonged for patients who had ADR issues as against those without ADR issues and also patients who receive above four medications were more prone to ADR-related issues. The study was of the final conclusion that ADR cases occurred during the period of hospitalisation or contributed to the internal drug population of which some or most of them could have been prevented. This finding aligns with that of Giardina et al., (2018) who were of the opinion that women and patients who consume lots of medications are more prone to develop ADR during the period of hospitalisation or as a result of being admitted and that of Fasipe, Akhideno, and Owhin (2019) who concluded that ADRs were a major determinant for the long hospitalisation period of patients.

2.5 PHARMACOVIGILANCE IN NIGERIA

Over the years, Nigeria has constantly been a major market for the local production and importation of medicinal products. This is as a result of the increase in the level of diseases given the high rate of fertility and the large population it is known to inhabit. Owing to this, there is a dire need for vigilance in the monitoring of these locally produced and imported drugs for the protection of its entire populace. In an attempt to safeguard the health and safety of its entire populace from adverse reactions and possibly poisoning of these drugs, Nigeria joined the World Health Organisation (WHO) International Drug Monitoring Programme (IDMP) in 2004. This point marked a dramatic change for pharmacovigilance in the nation. The subscription of Nigeria to the membership of the WHO International Drug Monitoring Programme prompted the establishment of the National Pharmacovigilance Centre (NPC) to regulate pharmacovigilance activities in the nation under the supervision of the National Agency for Food Drug Administration and Control (NAFDAC).

Despite the setting up of this body, the impact of pharmacovigilance activities in the nation is still yet to be felt. Nwalwu and Harrison (2014) consented to this by revealing that despite medical practitioners having a positive perception of the issue of pharmacovigilance, there seems to be little or no practice. This implies that pharmacovigilance is more of a theoretical concept than a practical one in Nigeria. However, there are a few remarkable feats the National Pharmacovigilance Centre (NPC) has achieved in the enforcement of pharmacovigilance in the nation. Several drugs which are known to have harsh adverse reactions have been outlawed and banned from the Nigerian market. An example is the ban placed on a toxic paracetamol mixed with diethylene glycol which cost the lives of a great number of infants and children in 2008. Another example is the ban placed in 2005 on dipyrone as a result of the frequent injection abscess and strange deaths associated with its use. Regardless of these achievements, there is still a lot to do in ensuring the implementation of pharmacovigilance activities in the country. This calls for the National Agency for Food and Drug Administration and Control (NAFDAC) through the arm of National Pharmacovigilance Centre (NPC) to be more vigilant in post-market surveillance in order to increase the level of safety in the use of medical products.

Furthermore, the Nigeria National Drug Policy has revealed that no active drug is completely free from adverse reactions. Hence, the government is committed to instituting adequately equipped pharmacovigilance centres across the nation for the collection, assessment and dissemination of information relating to adverse drug reaction cases in the country. The policy further requires that all medical products are monitored using efficacy, safety and quality as criteria in order to provide regulatory authorities with the right information for necessary actions.

2.5.1 NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

The National Agency for Food and Drug Administration and Control is a federal agency charged with the responsibility of inhibiting the circulation of fake and illegal pharmaceutical products in Nigeria. It is an agency that ensures that pharmaceutical products released into the market are strictly under the nation's health and safety legislation. The National Agency for Food and Drug Administration and Control was set up

by Decree 15 of 1993 under the military regime and was later amended by Decree 19 of 1999. In 2004, the Decree 19 of 1999 was repealed by the National Agency for Food and Drug Administration and Control Act, Cap N1, Laws of the Federation of Nigeria (LFN).

With its headquarters located at Plot 2032, Olusegun Obasanjo Way, Zone 7, Wuse, Abuja, Nigeria, NAFDAC is further responsible for monitoring the production, importation, exportation, distribution, advert, sales and consumption of food, pharmaceutical products and other inedible products essential for human life in the nation. It aims at ensuring the public is aware of basic safety issues and looks to eradicating fake pharmaceutical products both locally and internationally produced from the Nigerian market.

2.5.2 NATIONAL PHARMACOVIGILANCE CENTRE

The National Pharmacovigilance Centre (NPC) is a subdivision of NAFDAC charged with the responsibility of overseeing and regulating pharmacovigilance activities in Nigeria. It is located at the headquarters of the National Agency for Food Drug Administration and Control (NAFDAC) in Abuja, the federal capital of the nation. NPC is a body that receives and store spontaneous reports of adverse drug reactions from medical practitioners in Nigeria (Olowofela, Fourrier-Réglat and Isah, 2016) and also collaborates with other global bodies like the WHO, US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the purpose of improving the safety level of drugs in Nigeria.

Case reports from each state are sent to the zonal centres of NAFDAC via the state coordinators which are then forwarded to the National Pharmacovigilance Centre (NPC). Subsequent to the reception of these reports by the NPC, necessary actions are taken to ensure that drugs available in the market are safe for use by the general patient population. Moreover, the NPC implements pharmacovigilance training for medical practitioners and other stakeholders in a bid to improve the safe use of drugs in the nation (Olowofela, Fourrier-Réglat and Isah, 2016).

2.5.3 PHARMACOVIGILANCE STRUCTURE IN NIGERIA

Figure 5: Pharmacovigilance Structure in Nigeria

(Olowofela, Fourrier-Réglat and Isah, 2016)

From the diagram above, it could be seen that the National Pharmacovigilance Centre, a subdivision of the National Agency for Food and Drug Administration and Control (NAFDAC) is at the highest cadre, implying the authority it possesses to oversee and regulate activities of pharmacovigilance in Nigeria. On the other hand, the National Drug Safety and Advisory Committee (NDSAC) which was established on the 26th of July 2006, was instituted for the purpose of evaluating and reviewing of adverse drug reactions in the nation and also provide information on any pharmacovigilance case in the country. Formerly being seen as part of the Food and Drug Information Centre (FDIC), it later became autonomous to function as a committee charged with the responsibility of post-market surveillance and pharmacovigilance cases in the country.

The structure above shows us that the NPC ensures the implementation of pharmacovigilance in health institutions by providing medical practitioners with the necessary trainings for the implementation of this practice. Also, it is within the jurisdiction of the Centre to ensure serious monitoring, assessment and improvement of public health programs for the health and safety of the general public. Amongst the six aspects that must be addressed for public health programs to succeed, Frieden (2014) asserted that performance management which includes critical monitoring, assessment and improvement must be seriously considered. This shows the necessity of the monitoring factor in the subject matter of pharmacovigilance.

Finally, the NPC is in charge of monitoring and controlling its pharmacovigilance centres in the six zones of the country. The NPC through its zonal centres authorises organisations, profit or non-profit to market specific pharmaceutical products. These organisations are referred to as "market authorisation holders" (MAHs). Once these pharmaceutical products are marketed and are being used by patients, the market authorisation holders remain responsible for monitoring the safety of these products. At any time, adverse reactions from patients' use of these products are observed or suspected, these organisations are required to report to the NPC for appropriate actions.

2.6 ADR MONITORING BY NAFDAC

As earlier stated, the monitoring of ADRs to a large extent depends upon the rate of reporting. The National Agency for Food and Drug Administration and Control has been faced with issues challenging its effective monitoring of pharmaceutical products in the country which majorly points to the low rate of reporting in the nation. Awodele et al. (2018) consented to this by stating that, a flawless ADR monitoring practice for safety in the use of pharmaceutical products is consequent upon a robust system put in place for ADR reporting. Ibrahim Ali, the acting director of the pharmacovigilance/post marketing surveillance also concurred to this by revealing that adverse drug reactions reporting is a responsibility that should be taken seriously because if there are no reports, there can be no documentation for effective monitoring practice (Premium Times, 2016). This has caused NAFDAC to partner with medical institutions and other stakeholders for the obtaining of relevant ADR data in order to make effective the monitoring system for safe use of drugs or medicines in the nation.

Given the necessity for the monitoring of drug safety as revealed in the National Drug Policy, a need for the formulation of a national pharmacovigilance policy was seen as a priority by NAFDAC (Nwokike, 2008). The rationale behind the formulation of this policy is to ensure an excellent pharmacovigilance system that allows for rational and safe use of pharmaceutical products in the nation. The national pharmacovigilance policy reveals the roles every actor has to play in monitoring the safety of medical products. According to this policy, to achieve a better vigilant medical society, there is the need for setting up fixed monitoring and examination frameworks for measuring the performance and impact of authorised drugs already available in the market.

Nwokike (2008) further revealed some factors inhibiting the effective monitoring of ADRs by NAFDAC in Nigeria. According to him, the low rate of ADR reporting in the nation is one factor that cannot be put out. The agency can only monitor the safety level of drugs when ADR cases are detected, adequately documented and reported. However, Nwokike (2008) opined that the complexity of the ADR report forms makes it difficult for medical practitioners who are the principal actors in the detecting, documenting and reporting of cases to do so. Their busy schedules do not allow them the time to fill the complex forms provided for ADR reporting. Frieden (2014) opposed the complexity of these ADR forms by stating that simplicity is a major key to any successful endeavour. Another factor hindering the effective monitoring of ADRs by NAFDAC is the poor collaboration between the agency and public health programs in the nation. Public health programs are implemented to prevent or control diseases and even death. The partnership of NAFDAC with public health programs will improve ADR monitoring by aiding the setting up of adequate systems for data collection, evaluation of causality, and the carrying out of further pharmacovigilance studies using the ADR reports generated from the public health programs.

2.6.1 FACTORS THAT HINDER NAFDAC FROM EFFECTIVE IMPLEMENTATION OF ADR MONITORING IN NIGERIA

Having reviewed several literatures, some factors that inhibit the successful implementation of ADR monitoring by NAFDAC in Nigeria have been identified. In Nigeria, the reporting of ADRs has been made voluntary for medical practitioners but compulsory for market authorisation holders. This is an aspect that should be reviewed in order to improve the monitoring of ADRs by the regulatory agency. The reporting of ADRs should be a mandatory activity for every practitioner/institution in the medical sphere and not relegated to just a few. Although the amount of reports in the database of NPC has increased to 16,222 reports within the period of September 2004 and May 2015 and about 11,000 reports have been transmitted to the international database of the WHO (vigibase), this does not justify an improvement in the monitoring process because the WHO standard requirement of 200 reports per million population is yet to be attained in the nation (Olowofela, Fourrier-Réglat and Isah, 2016).

Varallo et al. (2014) in their study titled, “causes for the underreporting of adverse drug events by health professionals: A systematic review” showed that the major causes of the low

rate of reporting were ignorance, insecurity and indifference. They stated most medical practitioners are not aware of the significant role ADR reporting plays in safeguarding the health of patients and also are afraid of litigation matters that could ensue from the practice. This finding aligns with that of Ezeuko, Ebenebe, Nnebue and Ugoji (2015) who revealed that most of the medical professionals in the nation are unaware of the ADR reporting process and as a result lack interest in the activity. Furthermore, the complexity involved in the ADR reporting process is another factor that contributes to the high rate of under-reporting in the nation and thereby affecting the level of ADR monitoring.

Further to the foregoing, some other factors seem to contribute to the ineffective monitoring of ADRs by the NAFDAC. Olowofela, Fourrier-Reglat and Isah (2016) identified poor infrastructural facilities, lack of qualified manpower and poor support from government to be some factors affecting pharmacovigilance in the nation. Nwokike (2008) also revealed that the lack of collaboration between NAFDAC and public health programs is one of the factors inhibiting effective monitoring system in Nigeria. Also, Akunyili (2010) spotted out other factors negatively affecting drug regulation by NAFDAC in the country. According to her, corruption and conflict of interest has been a factor affecting regulation of drugs in the nation. Many fake drugs have been allowed into the Nigerian market due to compromise by inspection personnel. Outside compromise by inspection personnel, many importers have declared falsely the contents of their containers. Investigations in time past have revealed that some of these importers hide fake drugs in different goods like household items, motor spare parts, clothes, etc and pushed them into the market for public consumption. She further revealed that the poor judicial process and legislation is another factor that inhibits the progress of the agency in regulating drugs in the nation. The existing laws against fake drugs are so lenient that defaulters do not see it as a threat to their inhumane activities. These, amongst others have been issues that make NAFDAC seem ineffective in the dispensation of its duties.

2.7 NAFDAC's ACTIVITIES IN POST-MARKET SURVEILLANCE FOR LOCALLY PRODUCED DRUGS

Nigeria has always been known to be a consuming nation and this reflects in almost every of its sector. In the health sector for instance, about 60 percent of the drugs consumed in the nation are imported from other nations especially from China and India (Akunyili, 2010). This implies that about 40 percent of drugs consumed in the nation are locally produced. This calls for the drug regulatory agency under the ministry of health, NAFDAC to ensure the drugs available in the market are safe for public consumption.

The process whereby NAFDAC collects data primarily on the safety of drugs or pharmaceutical products already marketed is simply referred to as post-market surveillance. In discharging its duties, NAFDAC has implemented several processes to ensure the drugs locally produced are safe for use by the general patient population. Some of these processes include inspection, drug or pharmaceutical product registration, enforcement, public awareness, and adoption of modern technologies (Pharmapproach, 2020).

As part of the inspection process, NAFDAC ensures post-market surveillance is done in accordance with the WHO guidelines and initiate predetermined actions for eradicating fake drugs already available in the market. Moreover, the regulatory agency, after inspection of local factories at the initial time of product registration, still goes ahead to inspect them without prior notice once in every three months. The reason for this impromptu inspection is to ensure the local factories keep up with the Good Manufacturing Practice (GMP) which initially guaranteed their product registration. Good Manufacturing Practice (GMP) is simply a practice that ensures that products are consistently produced and controlled in accordance with predetermined quality standards (WHO, 2020). Despite the so-called routine inspection exercise, the impact of this exercise is yet to be felt in the nation.

Concerning drug or pharmaceutical product registration, NAFDAC ensures local factories responsible for the manufacturing of these medical products are certified in accordance with WHO qualifications before being registered. However, one big question is, many of the drugs registered and authorised into the market for public use, have they all been safe? This is a question that requires both an answer and a solution.

Furthermore, as regards enforcement which has to do with the investigation of cases, criminal prosecution, partnering with formal and informal groups, carrying out of surveillance activities to tackle benefactors of the business of fake drugs in the nation, NAFDAC has made a bit of success. Several fake drug dealers over the years have been prosecuted and such drugs outlawed and banned from the market. This in a way has contributed to the safety of the entire public. To further ensure the availability of quality drugs in the market, NAFDAC went ahead to create an improved drug distribution network for easy and effective monitoring. Despite this effort, selfish ambitions amongst stakeholders (of which members of staff of NAFDAC are inclusive) have disallowed the effectiveness of the aspect of enforcement in Nigeria.

Moreover, NAFDAC is authorised under section 14 of the National Agency for Food and Drug Administration and Control Act, Cap N1, Laws of the Federation of Nigeria (LFN) to utilise its financial, human and material resources to publicise its activities. Over the years, NAFDAC has conducted awareness campaigns on fake drugs to almost every part of the society, partnered with relevant stakeholders like the Nigerian Drug Law Enforcement Agency (NDLEA), Consumer Protection Council of Nigeria (CPCN), the Nigeria Police, etc in enlightening the public on how to identify fake drugs in the market.

Finally, one other measure adopted by NAFDAC in post-market surveillance is the use of recent technology in the detection of fake drugs in the market. Technologies such as TruScan, a mobile device used for detecting fake drugs at an instant recently developed by the US military, The Mobile Authentication Service (MAS), a system that aids the detection of fake drugs through the use of a cell phone. It involves the texting of a code placed on the packet of the drug right from the point of manufacture through the use of SMS. After which, a message confirming the originality or non-originality of the product is received. These, amongst others are the technologies employed by NAFDAC in ensuring drugs available in the market are safe for public use.

2.8 ADR MONITORING IN KENYA

Since 2004, the Pharmacy and Poison Board's (PPB), the regulatory authority instituted under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya, initiated the process of ADR monitoring in Kenya in which led to the official launching of the National Pharmacovigilance System in the nation five years later. The principal aim behind the launching of this system

was to ensure the safety of patients in the use of drugs. Since then, the monitoring of adverse drug reactions in the nation has experienced different bottlenecks in the effective implementation of the practice. The reporting of adverse reactions has been manually done with the aid of printed forms; yellow forms for reporting of suspected ADRs and pink forms for reporting of low-quality medicines.

The manual process which characterised the use of printed forms was cost intensive and time consuming. The printed forms have to first be transported to all medical institutions in the country, ensuring every unit in these institutions are in possession of the forms. Also, to get the feedback, the same process is entailed. This rigorous process characterised the ADR monitoring system in Kenya for over three years. And therefore, not so much was achieved in eradicating low quality and poisonous drugs from the nation.

However, on April 13, 2013, Kenya took to a new leaf by digitising the ADR monitoring system in the nation. This was believed to make the entire process easier, faster and less cost intensive. Since the implementation of the digital ADR monitoring system in the nation, there has been increased effectiveness and efficiency in the monitoring process. The PPB has been able to receive more than 6000 adverse reaction reports and more 370 reports of low standard medicines which has geared up the withdrawal of these medicines from the market and shut down of pharmaceutical companies that did not meet up to the standard requirements. The rise in reported cases was affirmed by Barry et al. (2020) in their comparative study revealed that Kenya pharmacovigilance centre had received the highest number of safety reports, showing 35.0 per million residents amongst the four countries. Otieno in 2013 explain that the launching of this monitoring system made Kenya become the first nation both in Africa and the world that utilised mobile technology to digitise reporting for ADR monitoring.

2.9 COMPONENTS OF AN IDEAL ADR MONITORING SYSTEM

An ADR monitoring system is termed to be ideal for use by a regulatory body if it possesses some elements that aid the effective monitoring of adverse reactions of drugs by the general patient population in the nation. As aforementioned, Yadav (2008) was of the viewpoint that an ADR monitoring system must include collection of data from medical practitioners, classification and assessment of collected data and dissemination of outcome on inspected drugs to all health sectors and the general public. According to him, it is implied that report

collection, report analysis and outcome are the major components of an ADR monitoring system. Patidar et al. (2013) supported the need for the localisation of the monitoring practice in every hospital. According to them, every hospital needs to engage in monitoring the adverse reaction of drugs on patients and submit obtained data to the regulatory authority. This implies the need for the enforcement of the monitoring practice in every medical institution. They further established that emphasis on public education against self-medication, training of medical practitioners and the inclusion of ADR in the curriculum of medical students should comprise an ideal ADR monitoring system. Nwokike (2008), on the other hand stated that a good ADR monitoring system should have a simplified and digitised reporting system for every level of medical care delivery, establish safety indicators for drugs and provide trainings.

To buttress further, given the fact Nigeria is a developing nation and looks up to the developed nations, there is a lot that can be gleaned from the European Medicines Agency (EMA) as regards components of an ideal monitoring system. The European Medicines Agency (EMA) is the regulatory authority responsible for the coordination of pharmacovigilance activities in the European Union (EU). It comprises certain components that allows for its effective functioning in the EU. Its components include the Pharmacovigilance Risk Assessment Committee (PRAC) which is responsible for the evaluation and monitoring of drugs safety in the continent; the EudraVigilance, a database for the storage of suspected ADR reports in the EU; the research unit which seeks for ways through which pharmacovigilance activities can be improved; and an evaluative framework that constantly reviews the progress of pharmacovigilance activities with the aim to redirect actions that can further improve the safe use of drugs on/by patients.

2.10 Network Governance Theory

Over the years, the term “network governance” have been labelled with different terms. Miles and Snow (1986) referred to it as “network organisation”, Eccles (1981) called it “quasi-firms”, Piore and Sable (1984) in their opinion, named it “flexible specialisation”, Liebeskind et al. (1996) referred to it as social networks. These have all been used to mean the synchronisation of different firms that involves informal relationships or interactions as against bureaucratic frameworks within firms and formal contractual associations between them. Jones, Hesterly, and Borgatti (1997) defined it as a given set of independent firms

working repeatedly together as a sequence of exchange aided by a network structure in the creation of products or services founded upon implicit and open-ended contracts that are socially and not legally binding to acclimatise to environmental contingencies and to coordinate and safeguard exchanges. It is important to note that legal contracts are not the basis of relationship in this this theory but social contracts.

The Network Governance Theory simply states that for complex and uncertain problems to be solved, concerned individuals or institutions need to form policy networks of different expertise where the networked relationship is socially and not legally binding. This theory is relevant to this study because it aids in the explanation of how and why NAFDAC, the drug regulatory agency in Nigeria should partner with relevant stakeholders both locally and globally in the monitoring of adverse reactions of drugs released into the market for medical use by patients. Network Governance Theory is very pivotal to the practice of pharmacovigilance in Nigeria because it allows for the creation of a network of relevant social partners who would contribute to the policy making process for the safety of the general patient population. The practice of pharmacovigilance is moulded by a network of local and international partners who have direct or indirect influence on the way the practice is carried out in the nation.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 INTRODUCTION

Research methodology is simply referred to as the techniques or methods adopted in the analysing a research problem. This chapter is concerned with the methods adopted in the investigative process of the study. It focuses on the research design, research philosophy, methods of data collection and analysis, ethical considerations, validity and reliability of research instrument, etc.

3.2 RESEARCH APPROACH

This study adopted the use of quantitative method through the aid of electronic survey questionnaires in obtaining data for the study. The justification for adopting the quantitative approach in this study is the space it does not allow for subjectivity and bias and the provision it makes for the generalisation of findings on a wider population. The objectivity of quantitative method allows for conclusions to be based solely on facts and not biases of the researcher. The electronic questionnaires were distributed to staff members of NAFDAC who the target participants for the study were. This prompted the gathering of suitable data for statistical analysis. Findings obtained from the analysis of data collected were compared with findings of previous researches to ascertain the position of the researcher on the given study.

3.3 RESEARCH METHODS

Consequent upon the quantitative nature of this study, the research method adopted is the descriptive research method. A descriptive research is primarily one that deals with the description of a given phenomenon the exact way it is without any interference. It simply involves explaining the state of affairs of a given phenomenon without any external influence on the variables of the research. It is usually concerned with studies that seeks to identify or explain facts.

3.4 RESEARCH PHILOSOPHY

This study is premised upon the research philosophy of positivism. The reason for the adoption of this philosophy is consequent upon the quantitative nature of the study. Positivism is of the ideology that only factual knowledge derived from observations using measurement are reliable and it is in tandem with empiricist view that knowledge is an

outcome of human experiences. This philosophy of positivism limits the researcher to collect data and interpret it objectively and research findings are observable and quantifiable.

The electronic survey questionnaires were administered to staff members of NAFDAC to obtain data for objective analysis and interpretation. The study was free from the interference or individual bias of the researcher but was based solely on observed facts. This is one advantage the positivist ideology provides for a credible research study – freedom from individual bias and influence. This position on objectivity in the analysis and interpretation of data was obtained by the administration of electronic survey questionnaires to the study's participants.

3.5 STUDY AREA & STUDY POPULATION

The study area refers to the geographical area in which the research instrument was administered for the purpose of collection, analysis and interpretation of data. The study area used for this study is the NAFDAC Lagos Operational Office located at Plot 1, Industrial Estate, Lagos, Oshodi-Apapa Expressway, Isolo, Lagos, Nigeria. The justification for the selection of this study area is the easy accessibility to participants due to the researcher's relationship with the gatekeeper of this research site.

Study population on the other hand simply refers to a given population apportioned for examination. Ngechu (2004) defined it as a set of people, services, elements, group of things or households under examination which have a definite set of characteristics. Moreover, these participants are chosen based on the responsibility NAFDAC holds in coordinating the activities of pharmacovigilance in Nigeria through the arm of the NPC.

3.5.1 ELIGIBILITY CRITERIA

Pilot and Hungler (1999) defined eligibility criteria as those features participants in a study must possess in order to be included in the study. For participants to be included in this study, they had to be staff members of NAFDAC Lagos Operational Office, which is situated at Plot 1, Industrial Estate, Lagos, Oshodi-Apapa Expressway, Isolo, Lagos, Nigeria.

3.6 SAMPLING PROCEDURE

Sampling is simply referred to as the process or technique of choosing an appropriate sample, or a representative part of a population in order to determine the features of the entire population (Mugo, 2002). A number of the staff of NAFDAC Lagos Operational Office was selected to represent the entire population of NAFDAC staff in the country. Due to the use of a sample, time and money were conserved. Instead of attempting to investigate the entire staff of NAFDAC nationwide, a few was just selected to represent the entire population. Given the little time to complete this study, collecting, analysing and interpreting data from the entire staff of NAFDAC nationwide would have been a herculean task to achieve and would have become financial burdensome for the researcher to carry out.

3.6.1 PROBABILITY SAMPLING

A probability sampling is simply a sampling method that requires a researcher to select samples from a larger population using techniques premised upon the ideology of probability. In aiming to achieve this study's objectives, the type of probability sampling used was the simple random sampling method. A simple random sampling method is one that provides every item or member of a given population with an equal chance to be selected in a sample. This method was chosen because it creates room for findings obtained to be generalised on the entire population.

3.6.2 SAMPLE SIZE DETERMINATION

Sample is a subgroup of the population to be examined. It is simply a subset of the composite whole of a given population under study. Sample size determination on the other hand refers to the process of selecting a given number of items or members to be included in a statistical sample. In research, it is common knowledge that the larger the sample size, the more accurate the results and the more credible the study. Smaller sample size is believed to generate less accurate results due to the fact they are of lesser representation on the entire population.

To determine the sample size for this study, Cochran's (1963) formula was adopted. The reason for the adoption of this formula is the uncertainty in the precise number of the study's population. Using the Cochran's (1963) formula, the sample size determination can be expressed below:

$$n = \frac{Z^2 pq}{e^2}$$

Where:

e = the desired level of precision (i.e. the margin of error) = 0.05

p = the (estimated) proportion of an attribute present in the population = 0.9

q = 1 – p

= 1 – 0.9 = 0.1

Z = 1.96

$$n = \frac{(1.96)^2 \times 0.9 \times 0.1}{(0.05)^2}$$

$$n = \frac{3.8416 \times 0.9 \times 0.1}{0.0025}$$

$$n = \frac{0.345744}{0.0025}$$

n = 138.30

n = 138 (sample size)

However, given the proposition of Israel (1992), an additional percentage should be given to the generated sample size in order to cover up for the non-response of respondents. As a result, an additional 10 percent was added to the generated sample size of 138 which led into the study's sample size of approximately 152. This can be mathematically expressed below as:

n = 138 x 10% = 13.8

n = 138 + 13.8 = 151.8

n = 152 (Sample size)

3.7 METHODS OF DATA COLLECTION

In carrying out this study, primary research was used. This called for the collection of data directly from participants. Data was collected with the use of electronic survey questionnaires. The rationale behind the use of electronic survey questionnaire is the time, cost and stress saving nature of the research instrument. The questionnaire link was forwarded to the gatekeeper of the study area which in turn forwarded this link to the participants. Adequate attention and follow-up were paid to the gatekeeper to ensure the required number of participants for the study gets access to the questionnaire.

3.7.1 RESEARCH INSTRUMENT

This study made use of a close-ended electronic survey questionnaire in obtaining data from its participants. A close-ended questionnaire is one that limits respondents to only the options made available by the researcher. In this type of questionnaire, participants are not given the freedom of expression in responding to the questionnaire items.

Questionnaires were administered to participants electronically using the platform, Microsoft Form. The questionnaire comprised five sections which are: one, the section relating to the socio-demographic characteristics of the respondents; two, the section relating to respondents' perceptions on NAFDAC's capability to monitor and address ADR issues; three, the section concerned with respondents' views on factors hindering effective ADR monitoring; four, the section proffers solution to help boost ADR monitoring; five, the section relating to respondents' perceptions about public health safety. A total of 20 questionnaire items were given in the research instrument. Five (5) belonging to the first section, eleven (11) belonging to the second section, one (1), which involves multiple answers belonging to the third section, five (5) belonging to the fourth section and four (4) belonging to the last section.

From the fourth section to the fifth section, questions were presented on a 5-point Likert scale. The reason for the use of a 5-point Likert scale format is to increase response rate and quality according to Sachdev and Verma (2004). Given the 5-point Likert scale format, all the variables of a set were assigned specific numerical values. For instance, Strongly Agree (SA) was assigned a value of 1, Agree two (2), Undecided three (3), Disagree four (4), Strongly Disagree five (5).

3.7.2 VALIDITY OF THE RESEARCH INSTRUMENT

According to Srinivasan and Lohith (2017), Validity of a research instrument is simply the degree to which a tool measures what it was designed to measure. Heale and Twycross (2015) defined it as the level to which a concept is correctly measured in a study of quantitative nature. In the words of Sullivan (2011), validity of a research instrument is described as the degree to which a research study provides answers or solutions to a research question(s). Validity, in summary, has to do with the credibility of conclusions derived from a research study.

In carrying out this study, face validity and content validity were used to ascertain the credibility of the research instrument. Odetunde (2011) explained that face validity has to do with whether the questions in a research instrument truly measures what it was designed to measure. Content validity on the other hand is used to determine if the instrument covers relevant contents with respect to the topic's variables. By using face and content validities, the researcher submitted the questionnaire to his supervisor to critically scrutinise and give better opinions on how the research instrument can be further modified to improve its credibility.

To further ensure validity of the research instrument, a pilot study was conducted. A pilot study is simply a mini-investigative process in which research instruments are administered to a small number of participants in order to ascertain the validity of the instruments. Pilot study was done in this study to generate the time that would be taken to complete the questionnaire and to receive feedback on the clarity of questions in the research instrument for the aim of modifying it to generate credible conclusion. In piloting this study, ten (10) questionnaires were administered to some staff members of NAFDAC Lagos Operational Office.

3.7.3 RELIABILITY OF THE RESEARCH INSTRUMENT

Reliability of a research instrument is concerned with the consistency of the results generated. A research instrument is termed to be reliable if the result it generates are repeatable. To ascertain the reliability of this study's instrument, the researcher made use of the Cronbach's alpha coefficient. A Cronbach's alpha coefficient is a convenient test used to measure the internal reliability of a composite score. Sekeran (2003) stated that the closer the Cronbach's alpha coefficient is to 1, the more reliable it is. According to Oyeniyi et al.

(2016), a Cronbach's alpha coefficient should be accepted if its value is at 0.8 or above. They further opined that Cronbach alpha is an appropriate test for questionnaires with the Likert scale format. Hinton, Brownlow, McMurray and Cozens (2004) in their view asserted that a Cronbach's alpha coefficient should be accepted as a moderately reliable scale if it ranges between 0.5 and 0.75.

3.8 METHOD OF DATA ANALYSIS

Data collected from the field survey was analysed with the use of the Statistical Package for Social Sciences (SPSS) version 20.0 using descriptive statistics. The rationale for choosing the SPSS for data analysis is because it provides a wide range of statistical options. Results generated were presented in frequencies and percentage in tables, pie charts and bar charts. The two hypotheses of the study were tested using simple linear regression analysis and Karl Pearson's correlation methods. The simple linear regression analysis is usually used to test the impact of an independent or predictor variable on a dependent or outcome variable while correlation is simply used to test the degree of relationship that exists between two variables.

3.9 ACCESS & ETHICAL CONSIDERATION

It is a well-known fact in the field of research that ethical issues are of paramount concern. When conducting a research study, adequate attention should be paid to ethical issues like confidentiality, informed consent, anonymity, etc (Creswell, 2005). In carrying out this study, access and ethical considerations were strictly adhered to. To all participants of the study, the study's topic was briefly explained and were all duly informed of the study being a pure academic exercise for the attaining of a master's degree. Participants were given the freewill to decide to participate in the study or not, were duly informed about keeping their identities hidden and information confidential and were also informed of no financial involvement if they decided to participate. Every participant who took part in this study, did so willingly.

3.10 CONCLUSION

Conclusively, this study made use of only the quantitative approach with the aid of close-ended electronic survey questionnaires which comprised 20 questions. And these questionnaires were distributed to a sample size of 152 staff member of NAFDAC Lagos Operational Office. The study is built upon the epistemological approach of positivism which advocated for the use of objective means in the observation of facts. Data obtained from the participants were analysed and compared with previous findings of other researchers. The

researcher aimed at determining if NAFDAC possesses the capability to monitor and address reported ADR cases, to identify the limiting factors of NAFDAC's effective ADR monitoring for the purpose of proffering solutions that will aid in improving ADR monitoring by NAFDAC.

CHAPTER FOUR: DATA ANALYSIS AND FINDINGS

4.1 OVERVIEW

This chapter is concerned with the collection, analysis and interpretation of data and presentation of study's findings in a way that is understandable to its readers. It is in this chapter, answers to the study's questions are given. The quantitative information obtained from this chapter helped the researcher to ascertain if NAFDAC possesses the capability to monitor and address reported ADR cases, to identify the factors that hinder NAFDAC from effectively monitoring ADR in Nigeria and to proffer solutions that will aid in boosting ADR monitoring in NAFDAC.

4.2 Demographic Data

4.2.1 Response Rate:

The research questionnaire was administered to a total of 152 respondents who are staff of NAFDAC, Lagos Operational Office. In the administration of the survey questionnaire, only 139 respondents participated and gave acceptable responses. This means the study had a response rate of 91%.

Out of the 139 respondents who participated in the study, 55.4% were male, 42.4% were female while 2.2% refused to disclose their gender. This result shows that most of the respondents who participated in the study were male implying more male are employed in the Agency than their female counterpart.

4.2.2 Age of Respondents:

Concerning the age of respondents, 35.3% were between the ages of 18 and 30 years, 36.7% were between the ages of 31 and 40 years, 12.9% were of the ages 41 and 50 years, 11.5% were between the ages of 51 and 60 while just 3.6% are of the age of 61 years or above. From this analysis, it is seen that most of the respondents who participated in the study are between the ages of 31 and 40 years implying a majority of the staff being within that age range.

4.2.3 Level of Education

As regards respondents' level of education, only 0.7% had no formal education, 40.3% had a graduate level of education while 59.0% had a postgraduate level of education. This implies that most of NAFDAC staff have a postgraduate level of education since a majority of the respondents indicated they had a postgraduate education.

4.2.4 Level in the Firm

With respect to level in the firm, 16.5% of the respondents are at the entry level, 35.3% are at the mid-level, 39.6% are at the senior level while 8.6% are at the management level. This analysis shows that staff at the senior level participated most in the study.

4.2.5 Employment Duration

Concerning employment duration, 22.3% of the respondents indicated that they have been working with the firm for the past two years, 33.1% revealed they have been working with the firm within the range of 3 and 5 years while 44.6% showed that they have been working with the firm for more than five years. This shows that most of the respondents who participated in the study have been working with the firm for more than five years.

Demographics	Frequency (139)	Response Rate (%)
Gender		
Male	77	55.4
Female	59	42.4
Prefer not to say	3	2.2
Age (years)		
18-30	49	35.3
31-40	51	36.7
41-50	18	12.9
51-60	16	11.5
61 and Above	5	3.6
Level of education		
No formal education	1	0.7
Undergraduate	56	40.3
Postgraduate	82	59
Level in the firm		
Entry level staff	23	16.5
Mid-level staff	49	35.3
Senior level staff	55	39.6
Management staff	12	8.6
Employment duration		
0 – 2 Years	31	22.3
3 – 5 Years	46	33.1
Above 5 Years	62	44.6

ii Table 4.1: Demographics Data of Respondents

Source: Field Survey (2020)

4.3 Capacity to Monitor and Address Reported ADR Cases (Questions 7 – 17)

This section revealed the respondents' views on whether NAFDAC has the capacity to monitor and address reported ADR cases in the nation.

Question 7:

In the analysis of respondents' understanding of ADR monitoring, 38.8% indicated that they understand ADR monitoring extremely well, 31.7% revealed that they understand ADR monitoring not too well. 14.4% showed indifference to the question, 11.5% revealed that they somehow do not understand what ADR monitoring all is about while 3.6% showed that they do not understand ADR monitoring well. See Figure 6

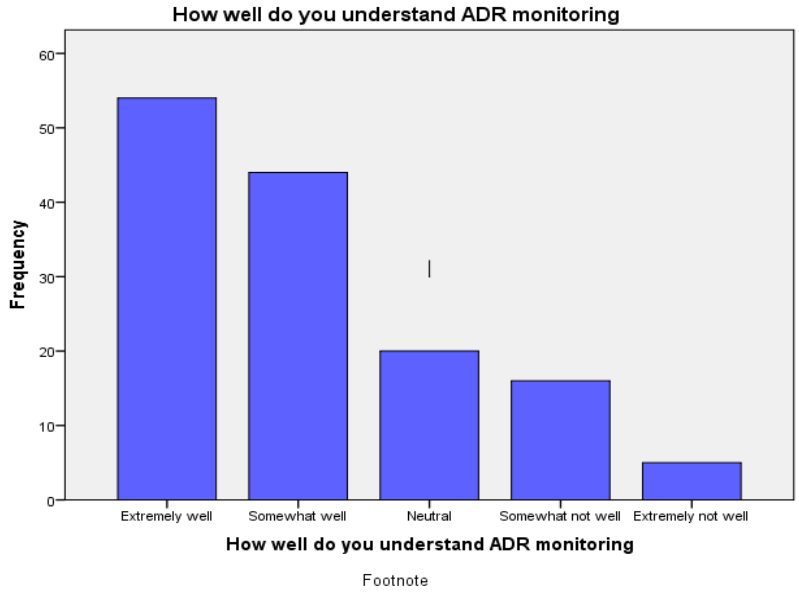

Figure 6: Knowledge of How Well Staff Understand ADR Monitoring

As shown in Figure 6 above, most of the staff revealed they really understand what ADR monitoring is about. This means that NAFDAC has staff who are knowledgeable enough to effectively carry out ADR monitoring in the nation.

Question 8:

Concerning respondents being well provided with the required equipment for active ADR monitoring, 44.6% selected the "yes" option, 42.4% selected the "no" option while 12.9% indicated that they do not know. – See Figure 7.

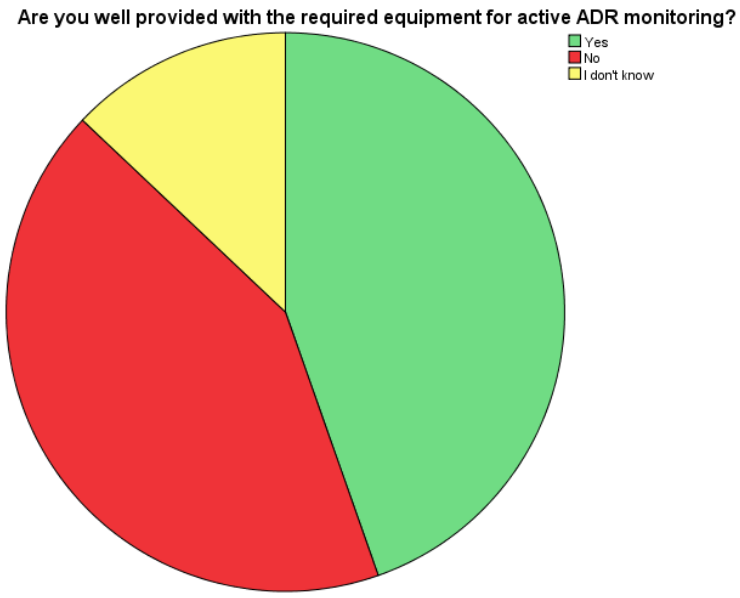

Figure 7: Knowledge of whether the Required Equipment for Active ADR Monitoring Are Well Provided

As depicted by Fig. 7 above, a majority of the staff revealed that they are well provided with the needed equipment for active ADR monitoring. The provision of needed equipment contributes to the agency having the capability to monitor and address ADR cases.

Question 9:

To ascertain if adverse drug reactions reports have been monitored by staff in the past 12 months, 44.6% of the respondents said “yes”, 50.4% said “no” while 5% were not aware. From this analysis, it is seen that most of the staff have not monitored adverse drug reactions reports for the past 12 months. This could be a reason why ADR monitoring is low in Nigeria if just a few members of staff of the regulatory agency have monitored ADR reports in the past one year – See Figure 8.

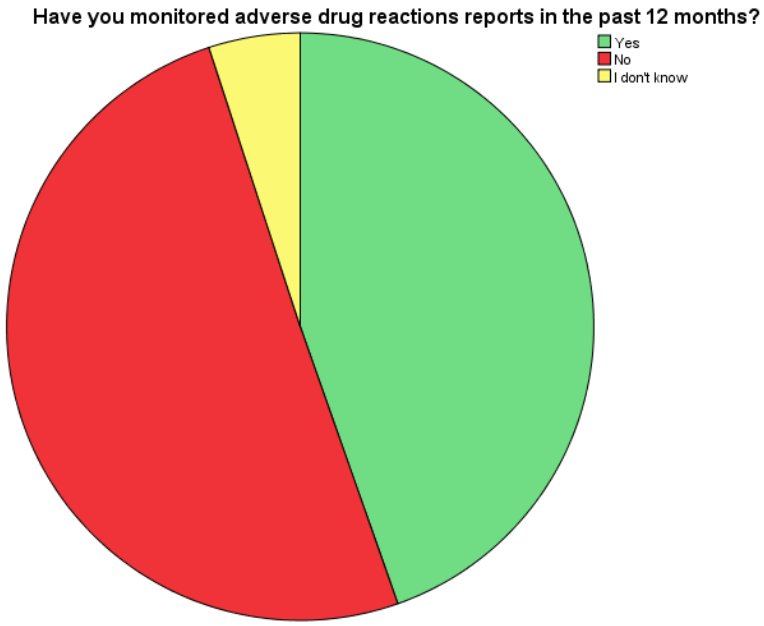

Figure 8: Knowledge of Whether Adverse Drug Reactions Reports Have Been Monitored in the Past 12 Months

Question 10:

Concerning the issue of there being a reliable database for the storage of reported ADR cases, 52.5% of the respondents positively responded by ticking "yes". 25.2% ticked "no" while 22.3% showed they do not know. – See Figure 9 below:

As shown in the figure below, it is quite obvious that a greater population of staff admitted that there is reliable database for the storage of reported ADR cases. This shows the agency has one of the required assets needed for effective ADR monitoring in the nation.

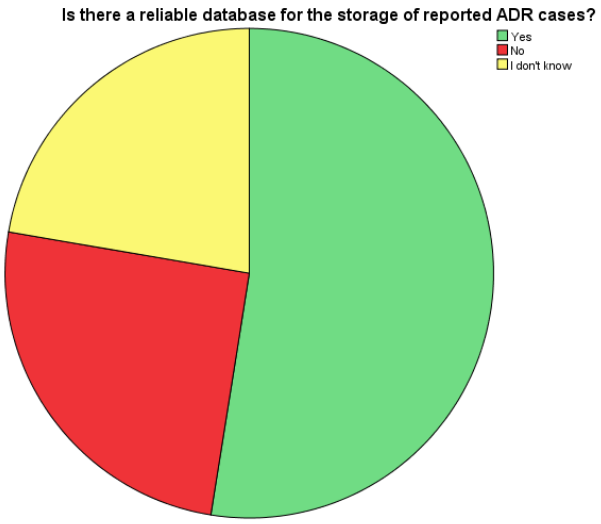

Figure 9: Graphical Representation Showing Whether a Reliable Database for the Storage of Reported ADR Cases Exists

Question 11:

Based on the previous question, in analysing how often is the database for ADR reports updated, 20.1% indicated the database are often updated weekly, 23.7% showed that it is updated monthly, 39.6% indicated that it is updated quarterly, 4% stated it is updated annually while 13.7% showed that it was never updated. – See Figure 10

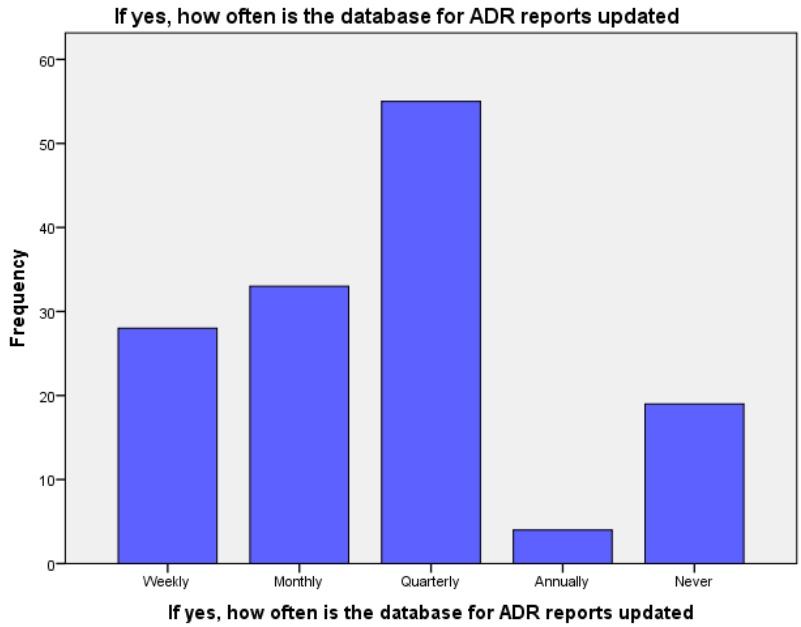

Figure 10: Graphical Representation of How Often the Database for ADR Reports is Updated

Based on the data provided above, the updating of ADR reports quarterly is not encouraging for an effective ADR monitoring system. ADR reports being updated quarterly means the reports are not updated on the database until another three months. This tends to drag or slow down monitoring by the agency.

Question 12

In order to identify if staff often get trained on better ADR monitoring practice, 38.1% indicated "yes" while 61.9% ticked "no". The survey results show that most staff are not trained often on better ADR monitoring practice. Since more than half of the staff in the agency refuted that they are frequently trained on better ADR monitoring practice, it means that most of the staff are outdated on recent developments in ADR monitoring. – See Figure 11

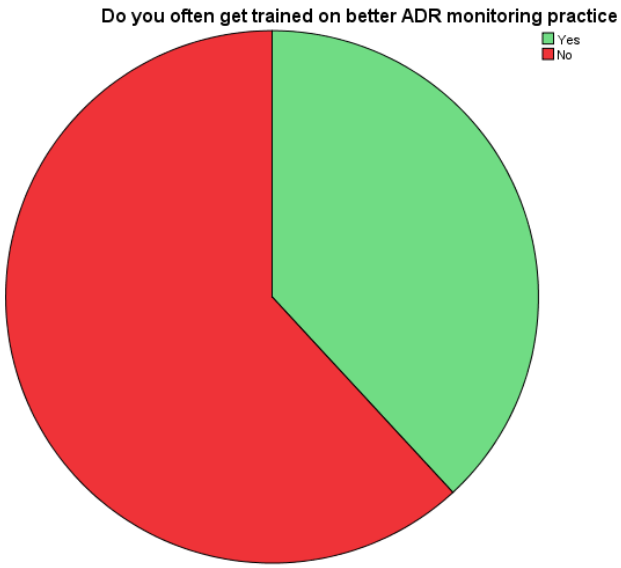

Figure 11: Graphical Representation of Staff Training on ADR Monitoring Practice

Question 13:

As regards there being a good communication network between staff and other relevant stakeholders, 44.6% gave a positive response of "yes", 24.5% gave a negative response of "no" while 30.9% indicated they were unaware. – See Fig. 12

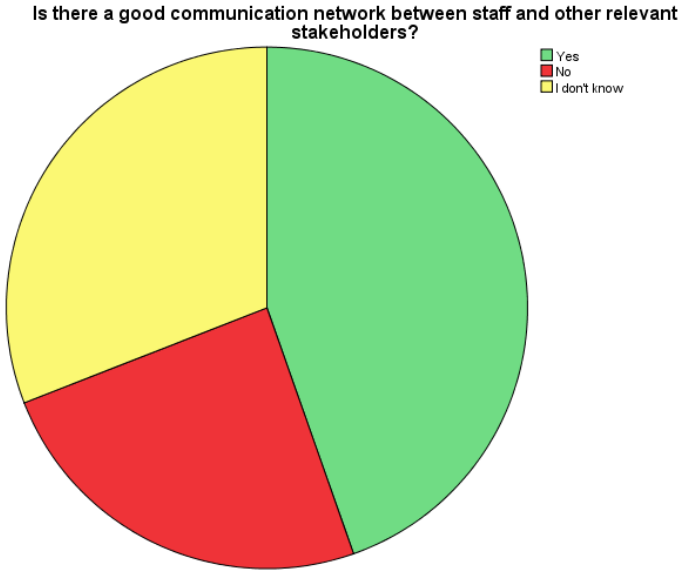

Figure 12: Graphical Representation Showing Respondents' Views on Whether a Good Communication Network Exists between Staff and Other Relevant Stakeholders.

As evidenced from the above figure, most of the staff have a good communication network between themselves and other relevant stakeholders. This is an advantage for the agency to perform better when it comes to monitoring ADRs in the nation.

Question 14:

In ascertaining whether the agency have a strong network of partners which help in the collection, reviews and reports of ADRs, 48.2% of the respondents indicated "yes", 19.4% indicated "no" while 32.4% revealed they are unaware. It can be seen from this analysis that a majority of staff admitted that the agency has a strong network of partners that assists in the collection, review and reports of ADR. This means that the agency has the required connections to ensure effective monitoring of ADRs in the nation.

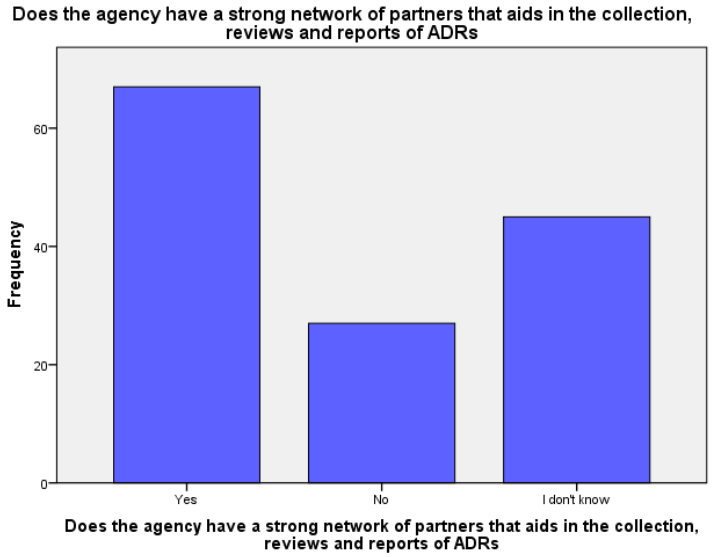

Figure 13: Graphical Representation Showing Respondents' Views on Whether the Agency Have a Strong Network of Partners That Aids in the Collection, Reviews and Reports of ADRs

Question 15:

To show whether there are sufficient laboratory facilities for further scientific assessment of ADR related drugs, 52.5% said "yes", 28.1% said "no" while 19.4% revealed they are unaware. As seen in this analysis, a higher percentage of staff admitted that there are enough laboratory facilities for further scientific assessment of ADR related drugs. Of course, the scientific examination of drugs needs sufficient equipment to be able to provide accurate results for decision-making. This can be graphically represented in Figure 14 below:

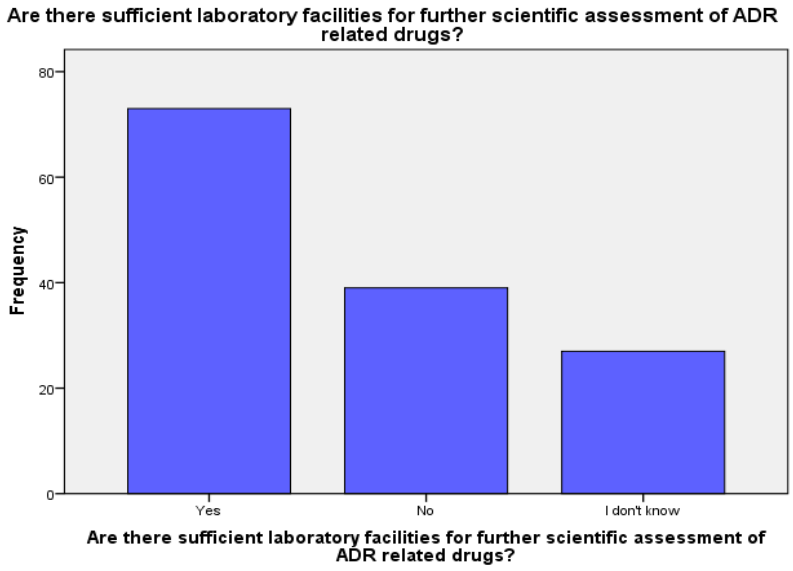

Figure 14: Graphical Representation Showing Whether There Are Sufficient Laboratory Facilities for Further Scientific Assessment of ADR Related Drugs.

Question 16:

Concerning having an idea of the necessary actions required after an ADR related drug is discovered/reported, 64% revealed that they do have an idea, 14.4% indicated they do not have an idea while 21.6% could not decide if they had an idea or not. Below is a graphical representation of respondents' views:

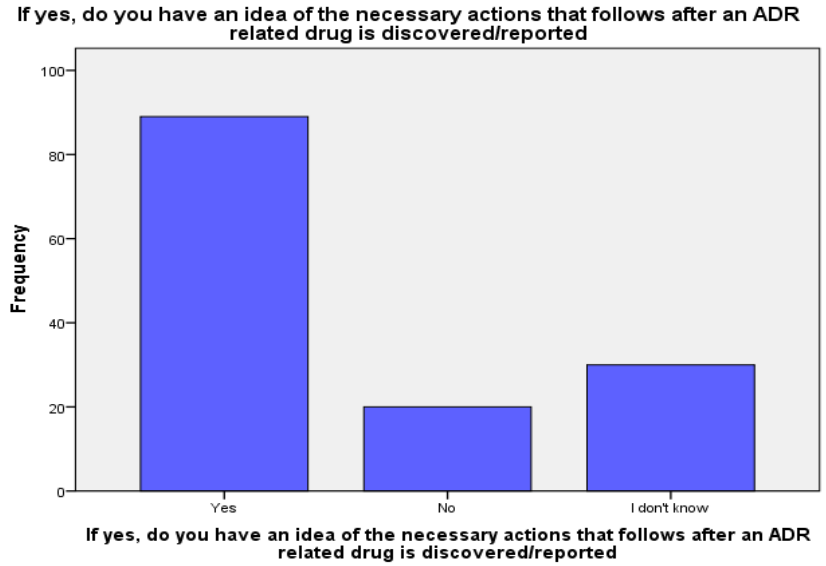

Figure 15: Graphical Representation Showing If Staff Have an Idea of The Necessary Actions After an ADR Related Drug Is Discovered/Reported.

As depicted by figure 15, most of the staff reported that they are aware of the necessary actions to be carried out when an ADR related drug is discovered/reported. This tallies with previous finding on question 6 which showed that most of the staff are well aware of ADR monitoring practice.

Question 17:

As regards there being a well-designed program to educate medical practitioners and consumers on ADRs, 48.2% gave a positive response of "yes", 18.7% gave a negative response of "no" while 33.1% revealed they are unaware. – See Figure 16 below:

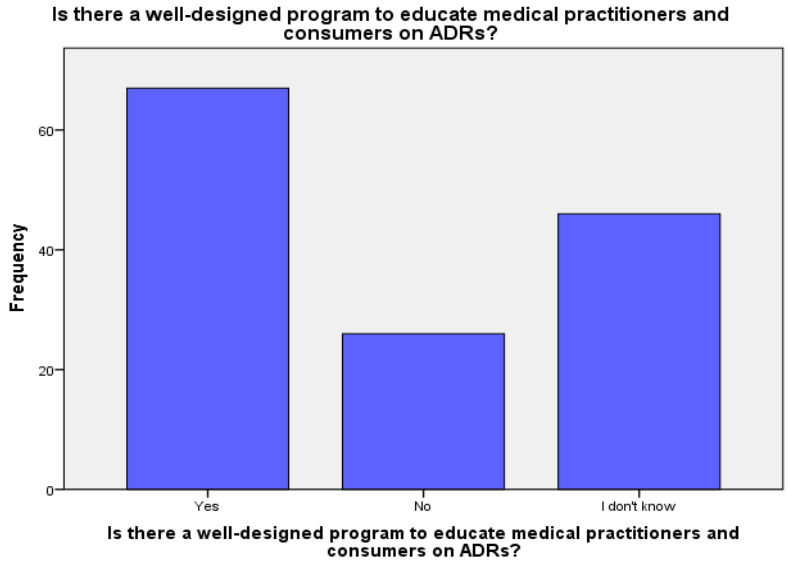

Figure 16: Knowledge on Whether a Well-designed Program for the Education of Medical Practitioners and Consumers on ADRs

Most of the staff admits that there exists a well-structured activity for the education of medical practitioners and consumers on ADR. This calls for a better implementation process in order to achieve desired results.

4.4 Factors Hindering NAFDAC from Effectively Monitoring ADRs in Nigeria

Question 18:

In identifying factors hindering NAFDAC from effectively performing ADR monitoring in Nigeria, different options were presented to respondents to choose from to reveal their perceptions on the issue. The researcher aimed at extracting factors from NAFDAC staff that have been limiting the agency from effectively monitoring drugs in the nation.

49.6% of the respondents indicated that the lack of knowledge on monitoring practice of ADR is one of the factors hindering NAFDAC from effectively monitoring ADRs in Nigeria while 50.4% refuted that.

As regards poor and inconsistent training of staff on recent ADR monitoring development, 66.2% gave a positive response of “yes” while 33.8% gave a negative response of “no”. It can be seen from this analysis that one of the factors hindering NAFDAC from effectively monitoring ADRs in Nigeria is poor and inconsistent training of staff on recent developments in ADR monitoring.

Moreover, 36.0% revealed that rigorous process in the collection, review and storage of ADR reports is a factor while 64.0% indicated that it is not a factor.

Concerning inaccessibility to information stored on the Agency's database, 36.0% gave a response of "yes" while 64.0% gave a negative response of "no".

With respect to absence of necessary laboratory equipment for scientific assessment of drugs, 42.4% selected the "yes" option while 57.6% selected a "no" option.

52.5% revealed that neglect for latest technological solutions is a factor hindering NAFDAC from effectively monitoring ADRs while 47.5% negated it.

48.9% of the respondents showed that poor partnership between the Agency and relevant stakeholders is a factor limiting NAFDAC's monitoring of ADRs while 51.1% opposed the statement.

Concerning poor administration of the Agency, 51.8% admitted it as a factor limiting NAFDAC from effectively monitoring ADRs in Nigeria while 48.2% negated it. As regards corruption and conflict of interest, 61.2% gave a positive response of "yes" while 38.8% gave a negative response of "no".

Also, as regards the shortage of staff to properly monitor ADR and address ADR reports, 63.3% said "yes" while 36.7% said "no".

57.6% of the respondents gave a positive response to the questionnaire item of most healthcare professionals being afraid of legal issues while 42.4% gave a negative response of "no".

Finally, for this section, 69.8% of the respondents admitted that people do not report experienced adverse drug reactions while 30.2% negated the statement.

Factors Hindering NAFDAC from Effectively Monitoring ADRs in Nigeria	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Lack of Knowledge on the Monitoring Practice of ADR	69	49.6	70	50.4
Poor and inconsistent training of staff on recent developments on ADR monitoring	92	66.2	47	33.8
Rigorous process in the collection, review and storage of ADR reports	50	36.0	89	64.0
Inaccessibility to information stored on the Agency's database	50	36.0	89	64.0
Absence of necessary laboratory equipment for scientific assessment of drugs	59	42.4	80	57.6
Neglect for latest technological solutions in the monitoring of ADRs	73	52.5	66	47.5
Poor partnership between the Agency and relevant stakeholders	68	48.9	71	51.1
Poor administration of the Agency	72	51.8	67	48.2
Corruption and conflict of interest	85	61.2	54	38.8
Shortage of staff to properly monitor ADR and address ADR report	88	63.3	51	36.7
Most of the healthcare professionals are afraid of legal issues	80	57.6	59	42.4
People do not report experienced adverse drug reactions	97	69.8	42	30.2

iii *Table 4.2: Factors Hindering NAFDAC from Effectively Monitoring ADRs in Nigeria*

4.5 Solutions That Will Help Boost ADR Monitoring by NAFDAC

Consequent upon the factors identified by this survey as responsible for the ineffective monitoring of ADRs by NAFDAC, this section is geared towards proffering solutions that will aid NAFDAC to greatly improve in its monitoring operations of ADR-related issues in the country so as to safeguard the health of the general public. A great fraction of staff agreed with all the proposed solutions in the survey as being effective in the improvement of the level of ADR monitoring in Nigeria by NAFDAC.

Question 19 (i – v):

As regards the statement of staff being constantly trained in tandem with global best practices in the issue of ADR monitoring, 83.5% strongly agreed, 11.5% agreed, 2.9% were neutral while 2.2% disagreed with no one strongly disagreeing. Cumulatively, 95.0% agreed while just 3 2.2% disagreed. From this analysis, it can be deduced that staff should be constantly trained in alignment with global best practices with regards to ADR monitoring. Below is a graphical representation of respondents' views:

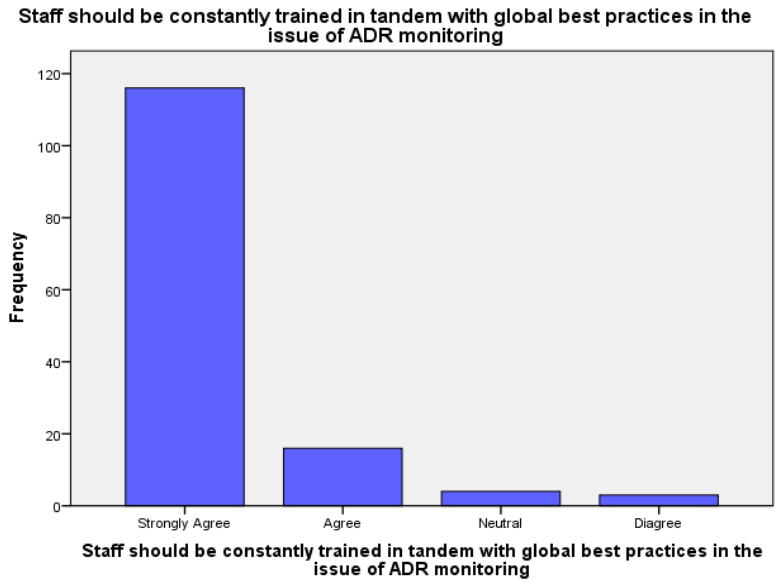

Figure 17: Graphical Representation Showing Respondents' Views on Constant Training

74.1% strongly agreed with the statement that staff need to be provided with necessary laboratory equipment for further scientific examination of drugs, 18% agreed, 5.0% were neutral, 2.2% disagreed while 0.7% strongly disagreed. Cumulatively, 92.1% agreed while just 2.2% disagreed. This analysis shows that it is important for staff to be provided with the needed laboratory equipment for further scientific examination of drugs.

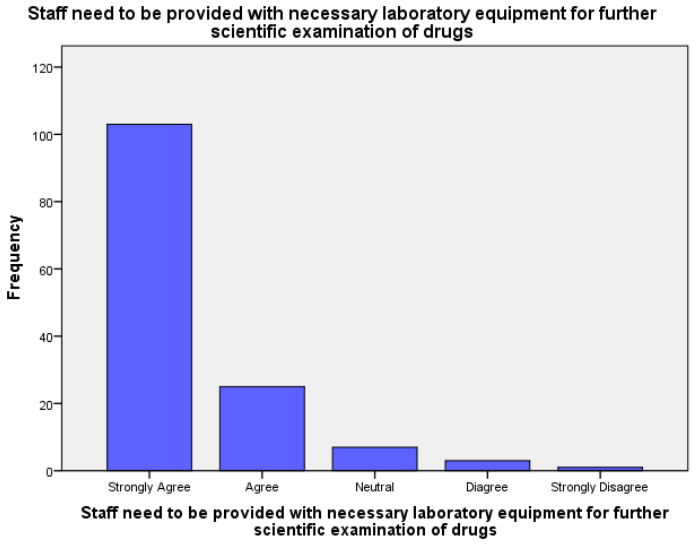

Figure 18: Graphical Representation of Respondents' Views on the Need for Laboratory Equipment

As regards there being an easy access to ADR data stored on the Agency's database, 65.5% strongly agreed, 25.2% agreed, 7.9% were neutral while 0.7% each disagreed and strongly disagreed. Summarily, 90.7% agreed while just 1.4% disagreed. This connotes the need for staff to be granted easy access to ADR data stored on the Agency's database. – See Figure 19 below:

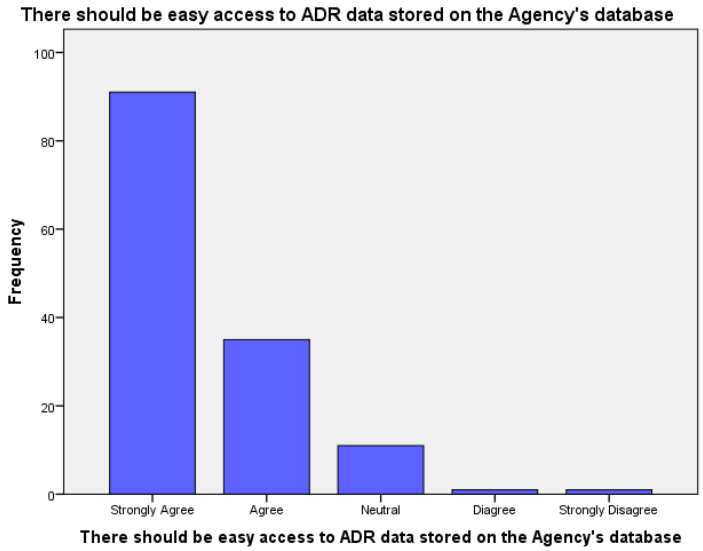

Figure 19: Graphical Representation of Respondents' Views on the Easy Access to Agency's Database

Concerning NAFDAC adopting latest technological solutions in the monitoring of ADRs, 73.4% of the respondents strongly agreed, 19.4% agreed, 5.8% were neutral, 0.7% each disagreed and strongly disagreed. Summarily, 92.8% agreed while 1.4%) disagreed. This analysis indicates that adopting latest technological solutions in the monitoring of ADRs should be done by NAFDAC. – See Figure 20 below:

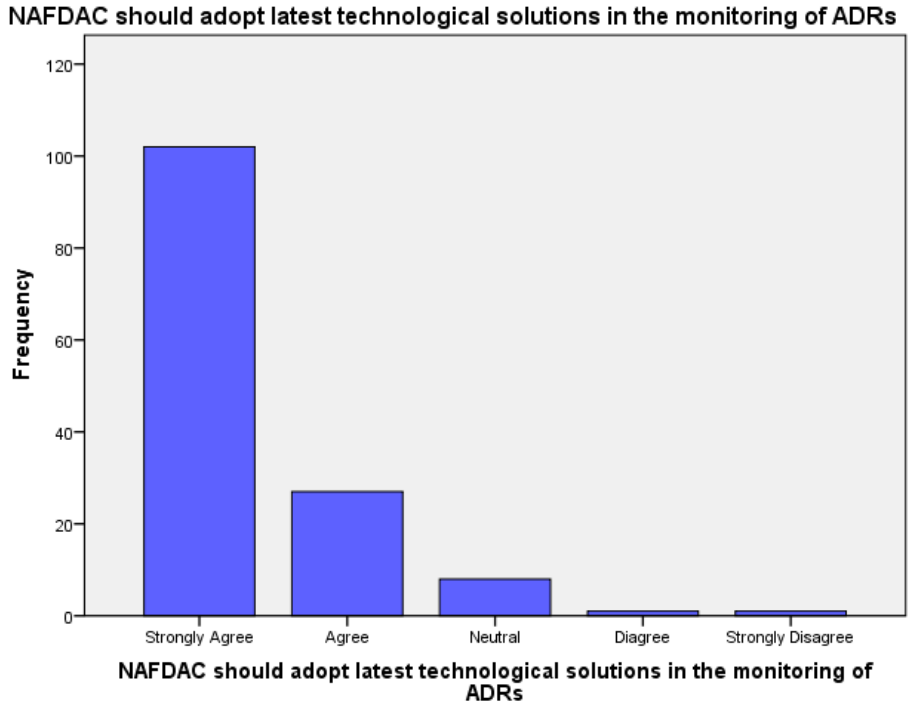

Figure 20: Respondents' Views on the Adoption of Latest Technological Solutions in the Monitoring of ADRs

With respect to implementing a well-designed program for the education of medical practitioners and consumers on ADR issues, 74.1% strongly agreed, 19.4% agreed, 5.0% were neutral, while 1.4% disagreed with no one strongly disagreeing. This shows that 93.5% agreed with just 1.4% disagreeing. From this analysis, a well-designed program for the education of medical practitioners and consumers on ADR issues should be implemented. This can be graphically represented below:

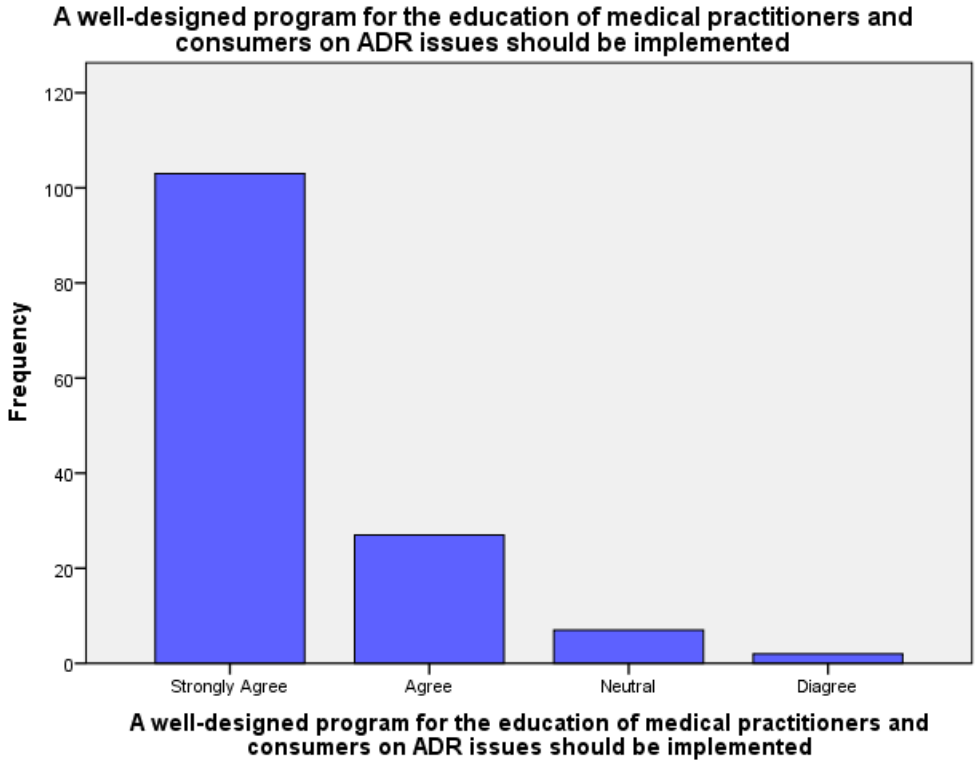

Figure 21: Respondents' Views on the Need for the Implementation of an Educational Program for Medical Practitioners and Consumers

4.6 Public Health Safety

This section is concerned with respondents' views on how ADR monitoring could safeguard the health of the general public. This section consists of four (4) questionnaire items which shows how public health can be protected with the use of ADR monitoring.

Question 20 (i - iv)

In ascertaining if the addressing of ADR issues will drastically reduce deaths, 60.4% of the respondents strongly agreed, 29.5% agreed, 7.9% were neutral, 0.7% disagreed while 1.4% strongly disagreed. Cumulatively, 89.9% agreed while 2.1% disagreed. This analysis shows a greater percentage of staff admitting that addressing ADR issues will drastically reduce deaths implying the danger not addressing ADR issues pose to the safety of public health in the nation – See Figure 22 below:

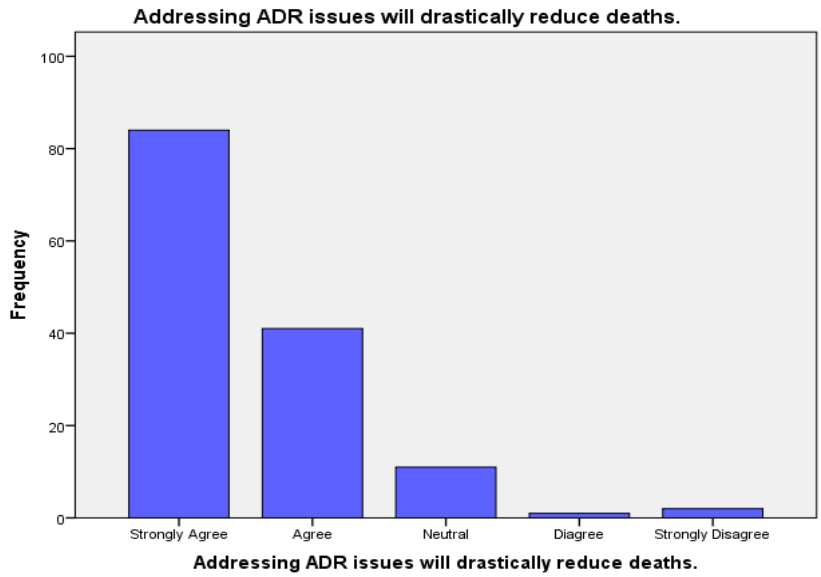

Figure 22: Respondents' Views on Deaths being Reduced by Addressing ADR Issues

Concerning the issue of effective ADR monitoring increasing safety in the use of drugs by the public, 62.6% strongly agreed, 30.2% agreed, 5.0% were neutral, 1.4% disagreed while 0.7% strongly disagreed. Summarily, 92.8% agreed while 2.1% disagreed. – See Figure 24 below:

As shown in the figure below, almost all staff consented to the fact that effective ADR monitoring will increase safety in the use of drugs by the public. This shows that staff are fully aware of how crucial the practice of ADR is to the safety of lives.

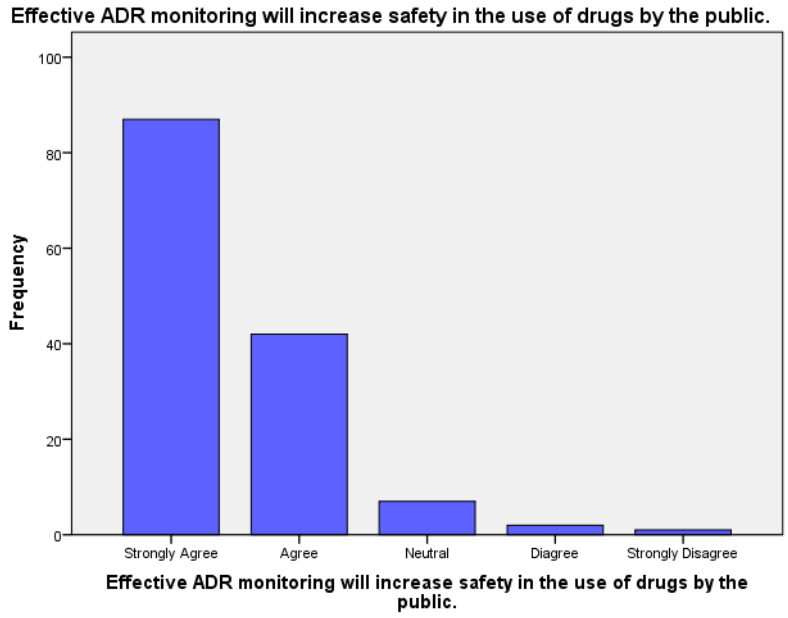

Figure 23: Respondents' Views on Effective ADR Monitoring Increasing Safety in the Use of Drugs

With respect to the issue of ADR cases being reduced as ADR monitoring is intensified, 57.6% strongly agreed, 28.8% agreed, 9.4% were neutral, 4.3% disagreed with no respondent strongly disagreeing. Summarily, 86.4% of the respondents agreed while 4.3% disagreed. – See Figure 24 below:

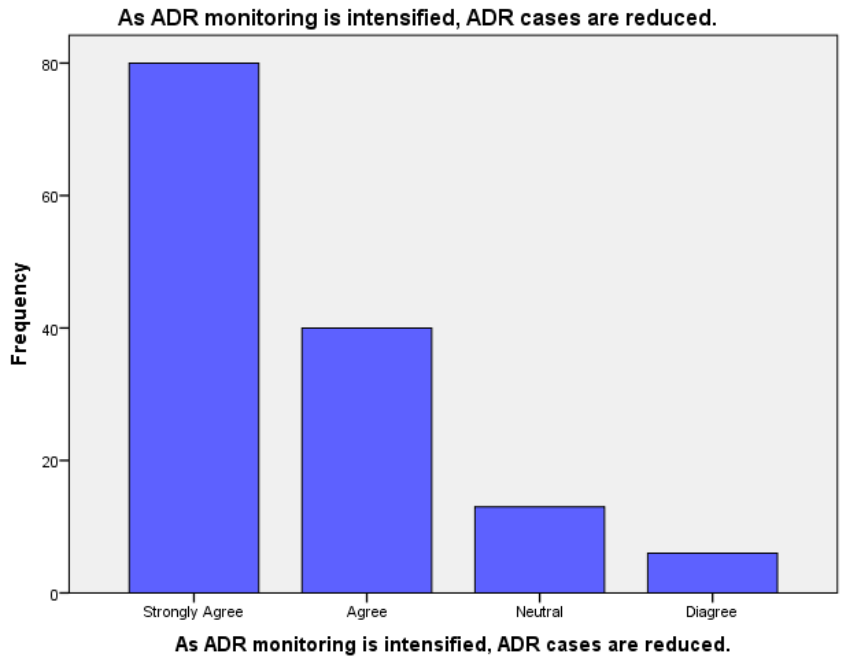

Figure 24: Respondents' Views on ADR Cases being Reduced by the Intensifying of ADR Monitoring

Based on the responses given by the survey, most staff indicated that ADR cases reduces when ADR monitoring is intensified. With this understanding, this means the rate of ADR cases is high since it is reported that the level of ADR monitoring is low in the nation.

Finally, concerning the reduction in ADR cases showing the existence of an effective monitoring practice, 46.8% of the respondents strongly agreed, 37.4% agreed, 10.8% were neutral, 4.3% disagreed while 0.7% strongly disagreed. Cumulatively, 84.2% agreed while 5.0% disagreed. – See Figure 25

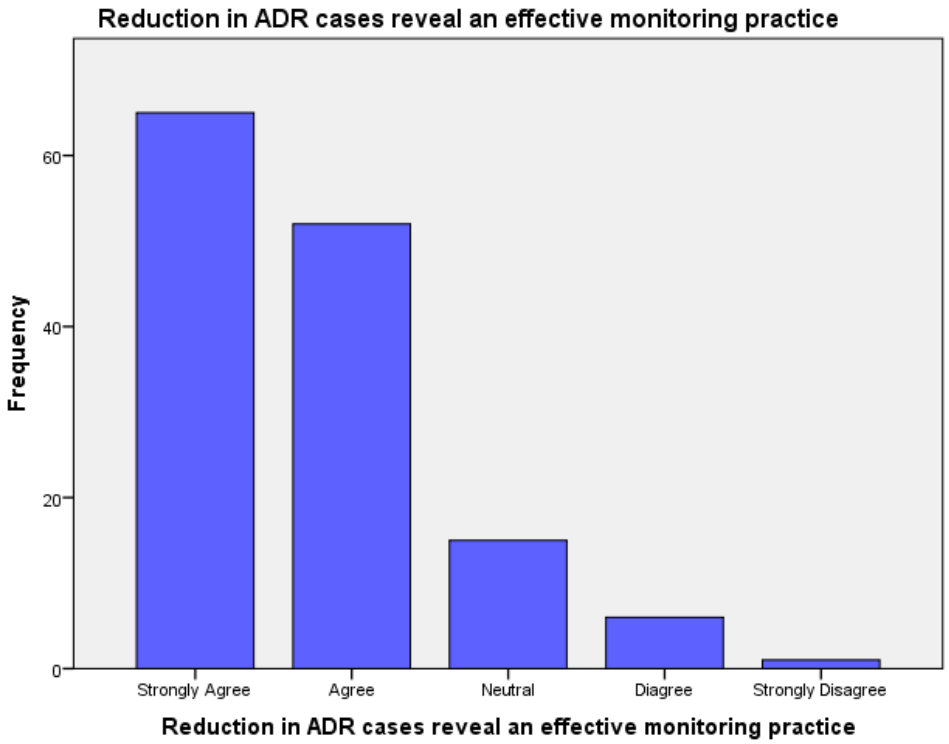

Figure 25: Respondents' Views on Reduction in ADR Cases Revealing an Effective Monitoring Practice

The above responses given by most of the staff shows that when there is an effective monitoring practice, there would be a consequent reduction in ADR cases. This implies an inverse relationship between an effective ADR monitoring practice and reduction in ADR cases.

4.7 Research Hypotheses

4.7.1 Hypothesis One:

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.299[a]	.089	.083	1.34698

a. Predictors: (Constant), ADR monitoring

iv Table 4.3.1: Model Summary

ANOVA[a]

Model		Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	24.425	1	24.425	13.462	.000[b]
	Residual	248.568	137	1.814		
	Total	272.993	138			

a. Dependent Variable: Public Health Safety

b. Predictors: (Constant), ADR monitoring

v Table 4.3.2: ANOVA

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.646	.388		4.243	.000
	ADR monitoring	.068	.018	.299	3.669	.000

a. Dependent Variable: Public Health Safety

vi Table 4.3.3: Coefficients

The first research hypothesis of this study states that NAFDAC ADR monitoring would have no impact on the safety of public health. In Table 4.3 above, we see the Model Summary shows the Adjusted R square to be 0.83. This implies that 83% of the variance of public health safety can be explained by NAFDAC's ADR monitoring. Also, Table 4.3.2, the ANOVA gives a presentation of the study's model to be significant. This is because the p-value which is 0.000 is lesser than the significance level of 0.05. The model significance can be given as, F (1, 137) = 13.462, p = 0.000.

Moreover, as regards Table 4.3.3 which gives a presentation of the regression coefficient of ADR monitoring to be 3.669, also showed that ADR monitoring to be with a p-value of 0.000. Given the fact that the independent variable is with a p-value of 0.000 which is lesser than the significance level of 0.05, the null hypothesis would be rejected while the alternative hypothesis would be accepted. Consequent upon this, it can therefore be concluded that ADR monitoring would have an impact on the safety of public health.

4.7.2: Hypothesis Two:

Correlations

		ADR monitoring	Reduction in ADR Cases
ADR monitoring	Pearson Correlation	1	.274**
	Sig. (2-tailed)		.001
	N	139	139
Reduction in ADR Cases	Pearson Correlation	.274**	1
	Sig. (2-tailed)	.001	
	N	139	139

**. Correlation is significant at the 0.01 level (2-tailed).

vii Table 4.4: Correlation

This research hypothesis states that no relationship exists between ADR monitoring and reduction in ADR cases. To test this hypothesis, Karl Pearson's correlation (r) within the significance level of 0.05 was used. In Table 4.4, it is seen that a weak positive relationship exists between the two variables at 0.274. Moreover, in ascertaining the acceptance or rejection of this hypothesis, Table 4.4 shows the p-value to 0.001 which is lesser than the significance level of 0.05. As a result of this, the null hypothesis is rejected while the alternative hypothesis is accepted. This therefore means that a relationship exists between ADR monitoring and reduction in ADR cases.

4.8 Conclusion

The analysis and findings of this study have revealed that most NAFDAC staff understand the concept of ADR monitoring. This has provided the study with a solid foundation for answering its research questions because responses given by the study's participants can be trusted due to their understanding of the study's main subject matter – ADR monitoring. Forty (40) questionnaire items were analysed in accordance with their categorisation on the electronic questionnaire. In this chapter, it was identified whether NAFDAC has the capability to effectively monitor and address reported ADR cases. Also, the factors that inhibit NAFDAC from effectively carrying out the function of ADR monitoring was highlighted and finally possible solutions that could aid NAFDAC in fulfilling this obligation was also shown.

Furthermore, it was discovered that monitoring of ADRs would impact positively on the safety of public health and that a positive relationship exists between ADR monitoring and reduction in ADR cases. These findings reveal the significant role ADR monitoring plays in safeguarding

the public health of the people of a nation. In the health sector of every nation, it is advisable for ADR monitoring to be taken seriously due to the significant role it plays in protecting the strength of a nation – her people.

In the subsequent chapter, more conclusions in direct relationship to the research questions stated in chapter one shall be provided by the researcher. This chapter will characterise comparison between this study's findings and previous scholarly works and shall recommend areas for further research.

CHAPTER 5: CONCLUSIONS

5.1 Answering the Three Main Research Questions:

Question 1: Does NAFDAC have the capability to monitor and address the reported ADR cases?

Consequent upon the responses given by the study's participants who are well aware of the practice of ADR monitoring, it can be deduced that NAFDAC indeed has the capability to monitor and address reported ADR cases. Staff are well aware of the significance of ADR monitoring, they are well provided with the required equipment for ADR monitoring, a reliable database for the storage of ADR reports is available, the agency also has a good network of partners that aids in the collection, review and reports of ADR, a good communication network exists between staff and other relevant stakeholders and the staff are knowledgeable enough to know what to do when an ADR related drug is discovered or reported. These existing features reveal that the Agency has the capability to monitor and address every reported ADR case.

However, despite NAFDAC having this capability to monitor and address every reported ADR case, the level of ADR monitoring in the country is still low. This could be as result of some challenges that impede the effectiveness of the Agency in the monitoring of ADRs in the nation. In the next section, some factors that hinder the Agency's effective performance in the issue of ADR monitoring shall be stated.

Question 2: What are the factors that hinder NAFDAC from effectively monitoring ADR in Nigeria?

As shown by the survey conducted, staff revealed some major factors that negatively affect the agency from effectively monitoring ADRs in the nation. Some of the factors identified by staff are similar to those affecting the effective monitoring of ADRs in other African nations. These factors include; poor and inconsistent training of staff on recent developments on ADR monitoring, neglecting use of latest technological solutions in the monitoring of ADR, poor administration of the agency, corruption and conflict of interest, insufficient qualified manpower to carry out the activities of ADR monitoring, reluctance of most healthcare professionals to report ADR issues due to the fear of litigation or legal matters, and finally

consumers of drugs who experience adverse drug reactions do not report their experiences to appropriate authorities.

Despite the capability of NAFDAC to monitor and address ADR cases, these factors are what contribute to the inability of the agency to effectively carry out ADR monitoring in the nation. For NAFDAC to increase the level of ADR monitoring in the nation, it is expedient that these challenges be addressed so as to improve safety of public health. As proven by the study's hypotheses where it was seen that ADR monitoring has a statistically significant impact on the safety of public health and that a positive relationship exists between ADR monitoring and reduction in ADR cases, the role ADR monitoring plays in the medical sphere of any nation cannot be overemphasised.

Question 3: What are some possible solutions that will help boost ADR monitoring by NAFDAC?

Having identified the issues that hinder NAFDAC from effectively monitoring ADRs in the nation, this section reveals some suggestions that will help boost the monitoring of ADRs by NAFDAC. As shown by the quantitative analysis, staff are lacking constant training and hence are not up to date with the latest developments in the monitoring practice of ADRs. Due to this, it is pertinent for agency to conduct constant trainings that are in tandem with global best practices in order to be effective in the monitoring of ADRs. Also, staff should be provided with necessary laboratory equipment for further scientific examination of drugs. Although this is not a challenge being faced in the agency currently as revealed by the survey, but it is expedient for the agency to maintain provision of needed equipment for scientific examination of drugs.

Consequent upon the difficulty being experienced by staff in gaining access to the agency's database, the study recommends that easy access to ADR data stored on the agency's database be granted to staff so as to hasten the process of addressing reported ADR issues. There should not be unnecessary protocol for staff to be granted access as that would definitely slow down the monitoring process of reported ADR-related issues.

Moreover, due to the rapid advancement in technology, NAFDAC should be flexible enough to adopt recent or latest technological solutions in the monitoring practice of ADRs. This would also aid in improving the monitoring process by making it easier and faster to address ADR issues. Finally, as revealed by the survey, it is shown that the reluctance of medical

practitioners due to fear of litigation and people (patients) who experience adverse drug reactions after the use of certain drugs affect negatively the effectiveness of ADR monitoring by the agency. Due to these issues, there should be a well-designed program that will educate medical practitioners and consumers on the need to report ADR issues so that appropriate actions can be taken by NAFDAC for the purpose of reducing the level of ADR-related cases in the nation.

5.2 Comparing and Contrasting Results from Primary and Secondary Research

Results from the primary research showed that NAFDAC has what it takes to effectively monitor and address reported ADR issues but still have been struggling to meet up to expectations in this regard. Due to the low level of ADR monitoring in the nation as revealed by Opadeyi, Fourrier-Reglat and Isah (2018) who stated that the Nigerian medical system is characterised by low level of ADR monitoring, the study sought to reveal the challenges being faced by NAFDAC in the implementation of ADR monitoring and to proffer solutions for the improvement of the practice for both the safety and good health of the general public in Nigeria.

As revealed by the study's findings, certain factors hinder NAFDAC from its effective monitoring of ADRs in the nation. One of which is corruption and conflict of interest. This was also identified by Akunyili (2010) in the literature as one of the major reasons for the poor regulation of drugs in the country. According to her many fake drugs have been allowed into the market due to the selfish interest of the agency's officials. The study's reconfirmation of corruption and conflict of interest being a factor affecting effective drug monitoring means that adequate attention should be paid to address this issue in order to see an improved ADR monitoring system in the nation.

Another challenge identified by the primary research which NAFDAC faces is insufficient qualified manpower to carry out monitoring activities. Insufficiency in the number of qualified personnel to advance monitoring activities in the nation is one challenge also identified by Olowofela, Fourrier-Reglat and Isah (2016). People (human resources) have been known to be the backbone of every organisation. The limitation of every organisation is indirectly the limitation of its workforce. For an organisation to move forward, competent hands have to

be involved in the activities of the organisation. Consequent upon this understanding, NAFDAC has to pay attention to the quality of people it absorbs into its workforce.

Furthermore, Nwokike (2008) stated that the level of ADR monitoring is contingent upon the level of ADR reporting. Primary research conducted showed that the refusal or reluctance of medical practitioners and consumers of drugs is one of the challenges that affects the effective monitoring of ADRs by the regulatory agency.

5.3 Concluding Thoughts

5.3.1 Contributions and Limitations of the Research

Having generated a sample size of one hundred and fifty-two (152) with a response rate of 91% (i.e. gaining 139 responses) despite the short duration for the completion of the study, data was analysed with the aid of the Statistical Package for Social Sciences (SPSS) of which was presented in frequencies and percentages using tables, pie charts and bar charts for better explanation and understanding. While there are very little or no research papers on ADR monitoring with reference to Nigeria, this study investigated into the reason why the level of ADR monitoring in the country is low by revealing that it is not because NAFDAC does not have the capability to monitor and address reported ADR cases but that there are some challenges which hinder the agency from effectively carrying out its duty in the area of ADR monitoring. Responses through the use of electronic survey questionnaires were received from staff of NAFDAC operational office in the commercial capital of the nation, Lagos state.

The major limitation of this study is the dearth in research papers concerning this subject of ADR monitoring with respect to Nigeria. This in a way affected the study as there was little or no foundation for the study to be built on in the body of knowledge. Moreover, the short time frame for the completion of this study is another factor as adequate attention was not paid to the study in a bid to meet up with slated deadline for submission.

Another limitation is that the study focused on a particular branch of NAFDAC, that is, Lagos Operational Office, to make conclusions on the capability of the agency and the issues affecting the effective monitoring of ADRs in the entire nation by the agency. Using a particular branch out of 36 branches is not sufficient enough to conclude on the agency's capability and the issues affecting its effective operations. This calls for further research to be carried out to include more branches under investigation.

While the study contributed its own quota to the body of knowledge, other areas responsible for the low level of ADR monitoring in the nation are yet to be explored. This calls for further research to be conducted in order to identify other reasons why the level of ADR monitoring is low in the country.

Finally, in carrying out this study, only the quantitative approach was adopted. This means that the study failed to answer more on why ADR monitoring is low in Nigeria. Due to this, further study should be carried out with the use of a mixed-method approach in order to suffice for the weaknesses in this research.

5.3.2 Recommendations for Practice

As revealed by the research findings, one of the challenges affecting NAFDAC's effective monitoring of ADR is the inconsistent training of staff on latest developments in ADR monitoring. Not keeping staff abreast with recent developments in the monitoring of ADRs is a significant factor that hinders the effective practice of ADR monitoring by the regulatory agency. As a result, regular trainings where staff's knowledge are updated with current trends with respect to ADR monitoring should be conducted.

Furthermore, staff should be granted easy access to the agency's database in order to hasten the process of addressing reported ADR cases. The difficulty experienced by staff in order to gain access to the database is one of the major factors that slows down or hinders the effective monitoring process of the agency. This issue has to be addressed if the agency is to experience an improved performance in the monitoring of ADRs in the nation.

To further ameliorate the level of impact of NAFDAC on the issue of ADR monitoring, NAFDAC should adopt the use of latest technological solutions in the monitoring practice of ADRs. Technology is known to make work easier and faster and adopting technological inventions or innovations in ADR issues would contribute greatly to the effective monitoring of ADR cases by the regulatory agency, NAFDAC in the nation.

It is without doubt that ADR monitoring stems from the reporting of ADRs. One of the factors limiting NAFDAC's ineffective monitoring of ADR is the reluctance of medical practitioners and consumers to report ADR cases. And the when ADR cases are not reported, the practice of monitoring cannot be carried out. This is another major factor that deters the agency from effectively performing its duties. Consequent upon this, NAFDAC should implement a well-

designed program for the education of medical practitioners and consumers on the importance of ADR reporting. This would enhance NAFDAC's effectiveness in the monitoring process and consequently reduce ADR issues in the nation.

5.3.3 Recommendations for Future Research

With respect to ADR monitoring in Nigeria, further research should be conducted to explore other reasons why the level of ADR monitoring is low. Due to the dearth in research papers on ADR monitoring, it is recommended that further research be carried out in this area so as to improve the level of knowledge in this area.

Moreover, further research should be expanded to include more branches of the regulatory agency, NAFDAC. There are branches of NAFDAC in each of the 36 states in Nigeria and it is recommended that more than one branch be used as study areas to gain a wider and more reliable conclusion on the agency's capability to monitor and address reported ADR cases and to identify other factors that hinder the agency from effectively carrying out the monitoring practice of ADRs in the nation.

Also, this study made use of only the quantitative approach. This means that this study carries within it the weakness or cons of quantitative approach. As a result, it is recommended for further studies to be carried out with the use of mixed-method approach. A mixed-method approach is the combination of both quantitative and qualitative approaches in the study of a given phenomenon. The use of this method will aid both approaches to complement their strengths and weaknesses thereby giving the research a more credible outcome. These recommendations would give a more reliable and deeper understanding on the issue of ADR monitoring in Nigeria.

5.4 Final Conclusions

In concluding this study on whether NAFDAC has the capability to monitor and address reported ADR cases in Nigeria and subsequent to the review of relevant literature on the topic, the researcher found this study to be very insightful as it helps in filling existing lacunas in the literature concerning ADR monitoring in Nigeria. As earlier mentioned, there is so much dearth in the literature on ADR monitoring in Nigeria of which this study addressed.

As seen in the literature review, the level of ADR monitoring in Nigeria is lower when compared to its African counterpart, Kenya. This is because the Pharmacy and Poison Board, the agency responsible for drug regulation in Kenya adopted the use of latest technological innovations in their reporting system. The digitised reporting system being used by Kenya greatly contributed to the effective monitoring system it currently has. The researcher concludes that of a truth the Nigerian regulatory agency, NAFDAC has the capability to effectively monitor and address ADR issues but that attention should be given to the use of technological solutions in the carrying out of ADR monitoring practices as seen in Kenya. This would in turn increase the agency's effectiveness in the monitoring of ADRs in the nation. Moreover, the staff revealed some other factors that hinder the effective monitoring of ADRs by NAFDAC. These factors include; poor and inconsistent training of staff, poor administration of the agency, corruption and conflict of interest, lack of qualified manpower, reluctance of most healthcare professionals to report ADR issues, and consumers who refuse to report ADR experiences after consumption of a drug.

Most of the staff opted for the organising of constant trainings that are in line with global best practices so as to have a competent workforce that can effectively carry out ADR monitoring in the nation. This shows the willingness of staff to improve themselves in order for the agency to be effective in its duties. The researcher also points out that while NAFDAC has the capability to monitor and address reported ADR cases, they have not utilised that capability in ensuring ADR monitoring is effectively done. This might be due to factors such as poor administration, corruption and conflict of interest, etc as aforementioned.

Due to the foregoing, it is expedient for the administrative arm of NAFDAC to take cognisance of all the factors stated in this study that hinder the agency from effectively monitoring ADRs in the nation and address them. Only when this is done would the impact of the agency be felt in the issue of ADR monitoring in the nation.

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Challenges Faced by NAFDAC in Monitoring of Adverse Drug Reaction in Nigeria

Dear Participant

I believe you are doing great

This survey is being used as part of my dissertation research to fulfil the requirements for the degree of Masters (MSc) in Pharmaceutical Business and Technology at Griffith College Dublin.

The study is underlined with the purpose of identifying and exploring the challenges faced by the National Agency for Food Drug Administration and Control (NAFDAC) in monitoring ADR for ameliorating practices in the area of drug safety, reducing the cost of ADR in Nigeria general patient population, improving the rate of reporting, and removing any encumbrances that may hinder the effective impact of NAFDAC. Most of the ADR cases in Nigeria are consequent upon some issues like the drug's wrong information, advanced age-related physiological, biochemical, pharmacokinetics, pharmacodynamics, and abuse. And sometimes, the severity of the ADRs seems to outweigh the benefits which the drug proposes. It is in this event NAFDAC is meant to intervene, but some factors exist that hinder them from effectively carrying out their duty.

The survey consists of five(5) sections aimed at collecting information on participant's demographics, NAFDAC capacity to monitor ADR, limiting factors factors to effective ADR monitoring by NAFDAC, solutions that will help boost ADR monitoring by NAFDAC and recommendation on public safety.

This survey will take no longer than 7 minutes to complete, and by completing this survey, you are giving your consent for the use of the information you provide to be used for the purpose of this study.

* Required

1. I have read and understood the above information, and I agree to participate in this research. *

- ◯ Yes
- ◯ No

Next

Never give out your password. Report abuse

Socio-demographic Characteristics

Please tick [√] the appropriate option in the spaces provided

2. Sex *

- ○ Male
- ○ Female
- ○ Prefer not to say

3. Age *

- ○ 18 - 30 years
- ○ 31 - 40 years
- ○ 41 - 50 years
- ○ 51 - 60 years
- ○ 61 and above

4. What is your highest level of education? *

- ○ No formal education
- ○ Secondary education
- ○ Undergraduate
- ○ Postgraduate

5. Level in the Firm *

- ○ Entry level staff
- ○ Mid-level Staff
- ○ Senior level Staff
- ○ Management

6. Employment Duration *

- 0 - 2years
- 3 - 5years
- Above 5years

Capacity to Monitor and Address Reported ADR Cases

Please tick [√] the appropriate option in the spaces provided

7. How well do you understand ADR monitoring

- Extremely well
- Somewhat well
- Neutral
- Somewhat not well
- Extremely not well

8. Are you well provided with the required equipment for active ADR monitoring? *

- Yes
- No
- I don't know

9. Have you monitored adverse drug reactions reports in the past 12 months *

- Yes
- No
- I don't know

10. Is there a reliable database for the storage of reported ADR cases *

- Yes
- No
- i don't know

11. If yes, how often is the database for ADR reports updated

- Weekly
- Monthly
- Quarterly
- Annually
- Never

12. Do you often get trained on better ADR monitoring Practice *

- Yes
- No

13. Is there a good communication network between staff and other relevant stakeholders *

- Yes
- No
- I don't know

14. Does the agency have a strong network of partners that aids in the collection, reviews and reports of ADRs? *

- Yes
- No
- I don't know

15. Are there sufficient laboratory facilities for further scientific assessment of ADR related drugs *

- Yes
- No
- I don't know

16. If yes, do you have an idea the necessary actions that follows after an ADR related dug is discovered/reported?

- Yes
- No
- I don't know

17. Is there a well-designed program to educate medical practitioners and consumers on ADRs? *

- Yes
- No
- I don't know

18. Which of the following factors hinderS NAFDAC from effective ADR monitoring in Nigeria?

Please choose all that apply *

- [ ] • Lack of knowledge on the monitoring practice of ADR
- [ ] • Poor and inconsistent training of staff on recent developments on ADR monitoring
- [ ] • Rigorous process in the collection, review and storage of ADR reports
- [ ] • Inaccessibility to information stored on the Agency's database
- [ ] • Absence of necessary laboratory equipment for scientific assessment of drugs
- [ ] • Neglect for latest technological solutions in the monitoring of ADRs
- [ ] • Poor partnership between the Agency and relevant stakeholders
- [ ] • Poor administration of the Agency
- [ ] • Corruption and conflict of interest
- [ ] Shortage of staff to properly monitor ADR and address ADR report
- [ ] Most of the healthcare professionals are afraid of legal issues.
- [ ] People do not report experienced adverse drug reactions

Solutions that will Help Boost ADR Monitoring by NAFDAC

Please tick [√] the appropriate option that best represents your opinion on the statement using the following response scale. 1 – Strongly Agree, 2- Agree, 3- Can't Say, 4-Disagree, 5- Strongly Disagree

19. *

	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
Staff should be constantly trained in tandem with global best practices in the issue of ADR monitoring.	○	○	○	○	○
Staff need to be provided with necessary laboratory equipment for further scientific examination of drugs	○	○	○	○	○

There should be easy access to ADR data stored on the Agency's database.	○	○	○	○	○
NAFDAC should adopt latest technological solutions in the monitoring of ADRs.	○	○	○	○	○
A well-designed program for the education of medical practitioners and consumers on ADR issues should be implemented.	○	○	○	○	○

Public Health Safety

Please tick [√] the appropriate option that best represents your opinion on the statement using the following response scale. 1 – Strongly Agree, 2- Agree, 3- Can't Say, 4-Disagree, 5- Strongly Disagree

20. *

	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
Addressing ADR issues will drastically reduce deaths.	○	○	○	○	○
Effective ADR monitoring will increase safety in the use of drugs by the public.	○	○	○	○	○
As ADR monitoring is intensified, ADR cases are reduced.	○	○	○	○	○
Reduction in ADR cases reveal an effective monitoring practice	○	○	○	○	○