A comparative assessment of current and future pharmacovigilance in developed and developing countries - A case study of Ireland and Nigeria

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A dissertation submitted in partial fulfilment of the requirements for the award of MSc in

Pharmaceutical Business and Technology

Innopharma Labs Faculty of Science

Griffith College, Dublin

May 2020.

Candidate Declaration

Candidate Name: Olanrewaju Saheed Jimoh

I certify that the dissertation on:

A comparative assessment of current and future pharmacovigilance in developed and developing countries - A case study of Ireland and Nigeria.

Submitted to the department of Pharmaceutical Business and Technology, Griffith College Dublin is the result of my work, and that where reference is made to the work of others, due acknowledgement is given.

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Acknowledgements:

I am grateful to Mark Campbell, my supervisor for his time, support and feedbacks through this research study. I acknowledge and appreciate all your efforts.

I appreciate the entire staff of Pharmaceutical Business and Technology Department, Griffith College Dublin Campus, for giving me their time and resources throughout the duration of the program.

I also appreciate Adetunji Aderemi who happens to be the head of computing and information technology at the University College Hospitals, My colleagues at Boot pharmacy (Ciara, Eadion, and Tobi) where I was able to access the pharmacists easily.

Lastly, I will like to thank my family for providing me with the much necessary supports and encouragements throughout this program.

I appreciate all the respondents, without whom the conclusions of this study wouldn't have been possible, for taking the time to participate in the survey

ABSTRACT

The thesis objectives are to compare and evaluate the factors about reporting Adverse Drug Reactions in the developed and developing countries among healthcare professionals (Medical doctors and Pharmacists) using Ireland and Nigeria as a case study. Which a questionnaire survey and phone interviews for quantitative and qualitative analysis are carried out respectively within the two regions (Ireland and Nigeria). The challenges faced by medical professionals concerning ADR reporting are achieved based on their knowledge and awareness to determine an effective recommendation to help improve both regions using the comparison results and works of literature gathered.

From the author results and analysis, both groups of healthcare professionals from the two regions were compared to determine their opinion in respect to observation and reporting of ADRs under the categories of under-reporting, ADR reporting methods, regulations and guidelines pertaining ADR report in both Ireland and Nigeria as HPRA and NAFDAC are the regulatory body responsible for handling submitted ADR reports. An Overall total of 122 respondents from both Nigeria and Ireland are received which consists of 47 respondents from Ireland (12 medical doctors and 43 pharmacists) and 75 respondents from Nigeria (32 medical doctors and 43 pharmacists) showing a response rate of 60.0% and 87.5% from 20 and 45 medical doctors and pharmacist from Ireland and response rate of 71.1% and 95.5% out of 45 respondents respectively from both medical doctors and pharmacist from Nigeria. Surprisingly, 98.0% of the correspondents which consist of 12 medical doctors and 35 pharmacists from Ireland responded to knowing how to report ADRs to compare to 71.0% from Nigeria which is quite above average consisting of 26 medical doctors and 27 pharmacists responded to knowing how ADRs is being reported. However, it shows that pharmacists had better knowledge, awareness, understanding, and experience over the medical doctors regarding ADRs reporting. However, 92.0% and 96.0% of respondents of both groups from Nigeria and Ireland respectively opted to ADR reporting being made compulsory as a professional obligation towards achieving and improving pharmacovigilance.

Furthermore, the challenges affecting ADR reporting in Nigeria are associated with the inaccessibility of ADR report forms when needed, complex reporting processes while too busy and lack of time remained the most common challenging factor among this too regions. The least common challenges reported at both regions are level of clinical trial knowledge, a concern that ADR report mighty is wrong among,

fear of legal liabilities, and fear of exposure to legal liabilities from patient or drug manufacturer.

Finally, after proper comparison and recommendation from both sides from the country it shows the need for better improvement in awareness among healthcare professionals in Nigeria been the country with the highest level of challenges compare to their counterpart healthcare professionals and this could be achieved by organizing pharmacovigilance conferences, continuous education programs included in their professional courses and training to improve knowledge of ADR reporting. Establishment of ADR departments in healthcare institutions headed by ADR specialists and offering professional recognition rather than financial rewards are the sustainable recommendation to put in practice in both regions to further improve the practice of ADR reporting in Nigeria and Ireland.

To wrap it up, the need for the regulatory bodies from the developing countries to work in hand with the developed countries to better improves awareness, knowledge, and improvement towards ADRs reporting system.

Key Words: Adverse Drug Reactions (ADRs): knowledge, awareness and challenges, Pharmacovigilance, ADR reporting systems, healthcare professionals, Nigerian Agency for Food and Drug Administration and Control (NAFDAC), National Pharmacovigilance Centre, ADR forms/e-reporting forms and Yellow card scheme, Health Products Regulatory Agency(HPRA),Healthcare Professionals(HCPs).

CONTENTS

LIST OF FIGURES

LIST OF TABLES:

ABBREVIATIONS:

ADRs- ADVERSE DRUG REACTIONS

NAFDAC- NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

NPC- NATIONAL PHARMACOVIGILANCE AGENCY

UMC- UPPSALA MONITORING CENTRE

CDC- CENTRE FOR DISEASE CONTROL AND PREVENTION

USFDA- UNITED STATES FOOD AND DRUG ADMINISTRATION

HCP- HEALTHCARE PROFESSIONALS

EMA- EUROPEAN MEDICINES AGENCY

HPRA- HEALTH PRODUCTS REGULATORY AUTHORITY

MDCN- MEDICAL AND DENTAL COUNCIL OF NIGERIA

PCN- PHARMACEUTICAL COUNCIL OF NIGERIA

NDSAC- NATIONAL DRUG SAFETY AND ADVISORY COMMITTEE

VAERS- VACCINE ADVERSE EVENT REPORTING SYSTEM

CHAPTER ONE

INTRODUCTION

1.0 BACKGROUND OF THE STUDY

"Wherever the art of Medicine is loved, there is also the love of Humanity."

— Hippocrates

Medicine majorly constitutes the use of prescribing and administering drugs by healthcare professionals majorly the pharmacist and the medical doctors. The importance of these two professions is very paramount in fighting diseases and promoting good healthcare as well as the general well-being of humans. Also, the current drug discovery and research within the pharmaceutical industry have led to the will for the need for the safety and efficacy of drug products. The safety of the drug has been a major concern aftermarket authorization due to limited clinical trials which cannot prove the safety of the public health after consumption.

Pharmacovigilance came into existence as a result of a tragic thalidomide event that happens around the 1960s which has helped towards drug safety issues with the ability for quick response drug reporting systems with that of the risk management plan in place to ensure the safety of drug user. Adverse drug reaction has always been a major challenge in the life of drug user and this cannot be avoided but rather can be prevented.

New drugs standard is maintained with the help of strict regulatory standards and guidelines that must be carried out during the clinical trial phases and post-marketing. The standard clinical trial phases include phase 1 which usually comprises of the certain number of human mostly less than 20 and their safety with a lesser dosage of the drug, phase 2 is usually comes up after phase 1 has been successfully performed and this involves safety studies on a larger number of human between 50 to 100 towards the adequate dosage specifications. Phase 3 is usually carried towards a specific condition at which the drug is being produced for the effectiveness in treating a certain condition while phase 4 is conducted to identify the long term effects of the drug after the approval and enters the market. (MS Research Australia, 2020)

Figure 1: phases of clinical trial (MS Research Australia, 2020)

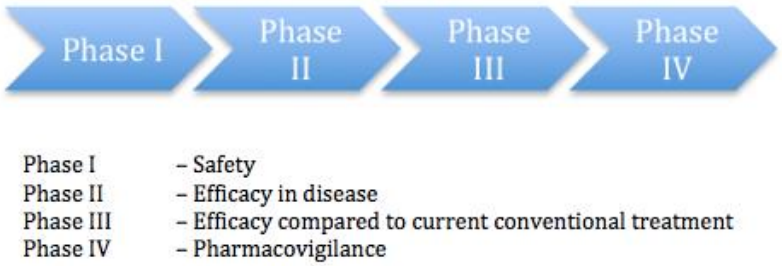


Figure 2: phase 4 trial (Pharmacovigilance)

Furthermore, after drug production and after passing through all the phases of approval, licensing and releasing into the market, it has been gathered that there is always minimal information on such drug safety. This is not coming as a surprise as the number of patients used during clinical trials is relatively low compare to the actual population of the patients dependent on these drugs and prescriptions. This phase led to pharmacovigilance activities of ADR reporting to know how drug products are working after taking and the safety of the people using it as well.

1.2 Research Purpose

This research aims to adequately tackle the challenges and help improve ADR reporting in the developing countries while also assessing to help analyse the level of understanding (knowledge), altitude and experience of ADR spontaneous reporting among medical professionals (Medical doctors and Pharmacist) in both countries in-line with established regulations and guidelines by both relevant authorities. Besides, there is a very low spontaneous reporting practice in developing countries compared to that of the developed countries based on previous research studies. However, this has led to us looking at which area needs improvement in the developing countries using Nigeria as a case study and Ireland as a case study of a developed country.

This research dissertation on current and future drug monitoring reporting was aimed at developing strategies from the case study of Ireland to help improve the quality of reporting in the developing countries towards driving a better positive outcome for patients across Nigeria.

1.3 Significance of the study

Over the years, there has been a major gap in spontaneous reporting of ADRs recommended in healthcare centres and hospitals in the developing countries (Nigeria) which has led to a major gap in the current pharmacovigilance practices among healthcare professionals compared to that of the developed countries (Ireland). So it is important to help engage and improve the challenges facing the developing countries, although many professionals (physician) tend to report only serious adverse reaction related to life threat but the challenges of delays in getting feedback are often a thing of dissatisfaction with the whole process used in the ADRs reporting management.

The HPRA in Ireland serves as the representative for pharmacovigilance practice and ADRs while the National Pharmacovigilance Centre Abuja under the monitoring of NAFDAC serves as a drug monitoring centre which they both help in the evaluation of risk ratio associated with any drug prescription or over the counter drugs. So the need to address the factors mitigating against having an effective ADR reporting as stated by the opinions of healthcare professionals.

1.4 Research Objectives:

1. To investigate the challenges affecting the role of effective ADR reports in developing countries using Nigeria as a case study.

2. To examine the awareness of healthcare professionals around their parts and obligation in viably announcing ADRs in Sub-Saharan Africa

3. To collect and review guidelines and regulations about proper drug delivery and monitoring in developed countries (EU) using Ireland as a case study.

4. To review the guidelines and regulations about ADR in Sub-Sahara Africa. Also, giving recommendations and how to improve the reporting of ADRs among the developing countries.

5. Comparative assessment of drug monitoring for the above-stated countries and how we can use that of the developed countries method to improve that of developing countries.

Research Questions:

1. Are the healthcare professionals aware of ADR reporting system methods and their responsibility towards good pharmacovigilance practice in Nigeria and Ireland?

2. What factors pose as challenges to ADR reporting in Nigeria and Ireland?

3. What is the level of awareness among healthcare professionals in Ireland and Nigeria in relation to ADR announcements?

4. What are the similarities and differences towards ADRs reporting among HCPs in Nigeria and Ireland?

5. What recommendations would help to improve ADR reporting among healthcare professionals in Ireland and Nigeria?

1.5 Structure of the study

The structure of this dissertation was to be carried out based on a qualitative approach with the use of surveys and questionnaires and qualitative approach using phone interviews.

These questionnaires were designed majorly for the medical doctors and pharmacists. This reason was a result of medical doctors are in charge of prescription of drugs at various medical teaching hospitals and healthcare centres while the pharmacist is in charge of dispensing of prescribed drugs in the healthcare centres or community pharmacy.

Each questionnaire is divided into five sections where each questionnaire is sent to both countries (Ireland and Nigeria) for respective feedback.

Section 1 is based on demographics containing age, experience, and occupation.

Section 2 is based on information and level of knowledge on ADR reporting in both Ireland and Nigeria.

Section 3 is based on countries' awareness of ADRs.

Section 4 based on factors that serve as challenges facing ADR reporting in each region.

Section 5 based on factors that can help improve the challenges an ADR reporting in Nigeria and Ireland.

A qualitative study was carried out by conducting phone interviews with healthcare professionals in Nigeria and Ireland to have a better experience and their opinion regarding ADR reporting in both countries, which the result obtained above from both the quantitative and qualitative are used to obtain a balanced conclusion on the purpose of this research.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

Over the years, a lot of studies have being carried out on ADRs and pharmacovigilance but in this chapter the author will be covering both old and recent research and studies that have to do with ADRs reporting and pharmacovigilance among HCPs and what are the root cause, while some countries and most especially the developing world are still faced with the challenges of poor reporting system.

2.2 CONTEXT

According to the World Health Organisation on pharmacovigilance relating to the activities of detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Also, the key roles in ensuring the patients receive safe drugs and the need for intensive monitoring and the need for new processes to help review and discuss the new methodological approach. (Härmark and van Grootheest, 2008).

Moreover, pharmacovigilance is checking for the effect of drug products which also include the characteristics of such drug towards treating a particular disease a process known as pharmacodynamics effects which are usually documented in animal studies during phase 1 and phase 11 studies in humans and phase 111 clinical trial (Montastruc et al., 2006). This led to pharmacovigilance activities which include ADR reporting starting with patients (children, young adults, and the elderly ones) receiving drug therapies to be able to identify how to reduce the rates of adverse reactions from patients

Besides, the World Health Organisation defines drug reaction as ‘‘an unpleasant reaction which occurs as a result from an interventional related to the use of drug products during therapy of disease.’’ Besides, adverse drug reaction reporting can become serious when there are occurrence medical conditions as a result of a particularly given dosage which leads to patient hospitalization, remarkable incapacitation or disability, life-threatening or even deaths. ADRs can be grouped into three major groups which can either be **Minor**; where there is no therapeutic or

hospitalization extension, intervention or antidote. **Moderate**; usually involve a change in current drug therapy where alternative treatment is recommended and this usually requires more days in hospitalization. **Serious/Lethal;** this is usually a life-threatening stage and requires urgent medical attention and intervention which can result in temporary or permanent damage or even death.

Over time, researchers have been able to come up with the classification of ADRs

1. Type A reactions – also known as augmented (dose-related) reactions which are usually related to any form of the pharmacological action and usually comes with a low mortality rate. Besides, they are easily preventable and predictable. Common examples in these categories include side effects such as anticholinergic of tricyclic antidepressants, haemorrhage associated with the use of anticoagulants, etc.

2. Type B reactions- also known as bizarre (not dose-related) reactions which are usually not common and not related to any form of pharmacological mechanisms of the drug. In contrast with type A which has a low mortality rate, the rate of mortality for this type is quite higher and very unpredictable. Examples include idiosyncratic reactions such as acute porphyria, malignant hyperthermia and pseudoallergy (ampicillin rash).

3. Type C reactions- These are referred to as chronic dose-related and time-related reactions. They are side effects that occur as a result of drug accumulation over a long period. Some examples include corticosteroid treatment resulting in organ damage.

4. Type D reactions-also called delayed reactions which are usually uncommon but occur sometime after the use of the drug. Such examples are seen in the use of tetracycline which later causes discoloration in the teeth, also in carcinogenesis and tardive dyskinesia.

5. Type E reactions- usually classified as End of the use reactions which occur mostly after the withdrawal of the drug. Such examples include myocardial ischemia also known as a beta-blocker withdrawal, rebound hypertension after a centrally acting antihypertensive drug.

6. Type F reactions- also know has a Failure reaction which is very common and often caused by drug interactions between two or more drugs. Such an example usually includes an inadequate dosage of an oral contraceptive, particularly when used with specific enzyme inducers. (Edwards and Aronson, 2000)

So, to eradicate ADRs' impact on the public well-being of patients, the introduction of pharmacovigilance came into reality in the healthcare sector. According to the World Health Organisation who *defines ''pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other medical-related issue''* where the main purpose is to help in patient safety by helping with the use of medicinal products.

2.3 REGULATORY AUTHORITIES

The safety of drugs is ensured by several regulatory authorities in different countries and regions; this is done to make sure that there is a safe and efficacious drug at the highest attainable quality to the public. This is usually done at several stages of operation starting from the implementation of pharmaceutical regulations related to product registration, manufacturing, pricing, operation excellence, research and development, and intellectual data protection. Doing this will help protect the patient from any undue side effect by easily identification of any form of predisposing factors while also countering false safety signals from any form of spontaneous reporting or case studies published report.(Sengar and Tripathy, 2011)

COUNTRY	REGULATORY AUTHORITY
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
USA	Food and Drug Administration (FDA)
Ireland	Health Products Regulatory Authority (HPRA)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Netherlands	Medicines Evaluation Board
India	Central Drug Standard Control Organisation (CDSCO)
Italy	Italian Pharmaceutical Agency
Singapore	Centre for Pharmaceutical Administration Health Sciences
Hong Kong	Department of Health: Pharmaceutical Services
Sweden	Medical Products Agency (MPA)
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices

Malaysia	National Pharmaceutical Control Bureau, Ministry of Health
South Africa	Medicines Control Council
Uganda	Uganda National Council for Science and Technology (UNCST)
Japan	Ministry of Health, Labour & Welfare (MHLW)
INTERNATIONAL ORGANISATIONS	
World Health Organisation (WHO)	
Pan American Health Organisation (PAHO)	
International Conference on Harmonisation (ICH)	
World Intellectual Property Organisation (WIPO)	

Table 1: International Organisation and Regulatory Authorities (Sengar and Tripathy, 2011)

The mentioned above regulatory came into existence as a result of the thalidomide effect which influences the world towards drug safety as for the efficacy as well. This led to the world health organization member countries towards establishing national pharmacovigilance centres where healthcare professionals can send individual cases of drug safety and the centre is situated at Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden(Edwards and Aronson, 2000). Moreover, WHO program includes a list of several member countries including Nigeria who joined in the year 2004 and according the first published regulations in 2005 which states that every healthcare institution with patients beds of 50 upward patients must ensure to employ the use of a

pharmacovigilance centre who serves as a reporting centre for any form of ADRs while also promoting and educating healthcare professionals towards reporting any suspected or serious form of ADRs. Although, there are several possible ways of creating awareness for ADRs, despite that spontaneous reporting has been the major and basic method of ADR detection which has helped over the decades but the major challenges facing this is the under-reporting by healthcare professionals (Montastruc et al., 2006).

For instance, the UK system makes use of yellow cards as their mode for reporting ADRs which has contributed to better the standards of pharmacovigilance(Felix et al., 2019).

Also, recent and previous studies have shown a high level of the importance of healthcare professionals as it concerns the spontaneous reporting of ADRs towards a build-up of the pharmacovigilance database. Besides, under-reporting of ADR has been one of the major challenges of spontaneous reporting even though previous studies have established that these responsibilities lie mainly with the medical doctors who prescribe the medications while some other studies also claim the pharmacist and other healthcare professionals also have a vital role to play as well. Lack of sufficient knowledge and follow of guidelines and regulations related to ADR has led to the confusion of who bears the major responsibility of ADR reporting among the healthcare professionals.

Furthermore, there is a need to increase drug monitoring in poor countries, which bear 90percent of the global disease burden. Although most drugs developed are extensively developed and used within the developed countries where there is a high-level global practice, using this safety profile in the developed countries cannot necessarily be generalized to developing countries because this occurrence, pattern, and harshness adverse reactions may differ markedly because of local environmental and genetic influences. Due to this, the WHO program for international drug monitoring has led to the centre set up to help collates adverse drug reaction reports

via the national pharmacovigilance centres of the 81 member countries (www.who-umc.org). However, currently, only six sub-Saharan African countries (South Africa, Zimbabwe, Tanzania, Mozambique, Nigeria, and Ghana) are full members of the program. Less than 27% of lower middle income and low-income economies have national pharmacovigilance systems registered with the WHO program, compared with 96% of the high-income countries in the Organisation for Economic Co-operation and Development. The main reasons for this are lack of resources, infrastructure, and expertise. Thus, although access to medicines is increasing in developing countries, there is a danger that their risk-benefit profiles in indigenous populations will not be fully monitored and acted upon. So what can be done to improve drug safety monitoring in developing countries? (Pirmohamed et al., 2007). Pharmacovigilance: As per World Health Organization (WHO), “Pharmacovigilance is the science and exercises relating to the discovery, evaluation, understanding and avoidance of antagonistic impacts or any other medicate related problems”. Shockingly, when this term is said, it is exceptionally much a case of “Pharmaco what?” There's still a need of understanding on this theme like how it capacities, what are the benefits of sharing ADR information and its reason and significance. In addition, Adverse drug reaction” or an “adverse reaction” implies a reaction to a medication within the people or creatures, which is harmful and unintended, counting need of adequacy, and which happens at any measurement and can too result from an overdose, abuse or manhandle of a pharmaceutical drug (Yadav, 2008).

On the other hand, the term “post-marketing observation (PMS) study” infers an experimentally thorough consider of an item that's affirmed for enlistment in a specific nation, outlined to deliver solid data around drug safety. It isn't suitable to apply the term to clinical trials of enlisted items or to considers planned basically for showcasing purposes notwithstanding of the logical legitimacy of the think about plan. Post-marketing observation considers are for the most part performed on the activity of the supporting company but may be proposed or asked by other parties.

They ought to by and large be outlined to address a sedate security address or speculation (the last mentioned regularly recognized at first by intentional detailing). Also, the Nigerian National Bureau of Statistics has shown records of life expectancy rates in the country to be lowest among the other West African countries while the World Health Organisation estimated it to be around 54.5 years of age. These values attributed to the health issues faced by the country with a high level of mortality rates. Although, irrespective of all these challenges, the country still has a faster population growth rate of about 2.6% which is projected to have over 390 million people by the year 2050. (World Population Review, 2020)

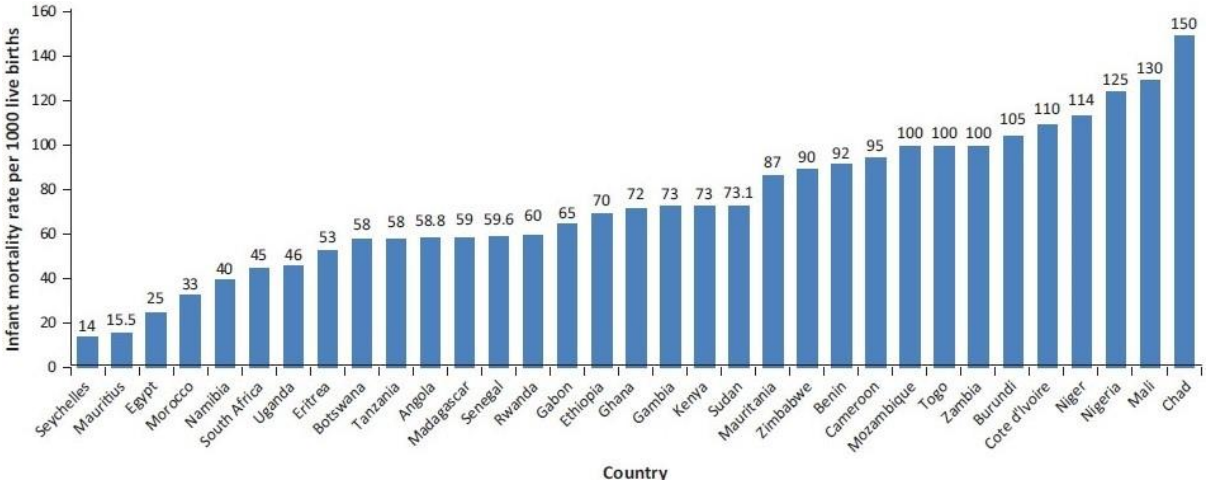


Figure 3: : Infant Mortality rates In Nigeria compare to other developing Africa countries (Alemu, 2017)

2.4 Pharmacovigilance and Adverse Events Reporting in Ireland.

European Union has always made changes to pharmacovigilance legislation which has always include additional monitoring of medicines which aim to help speed up a positive result from adverse drug reaction reporting systems. This legislation has also helped in the easy traceability of our medicine. The European Union legislation on pharmacovigilance as laid down directives which are to further help in protecting the public health by strengthening the monitoring system and these directives are Directive 2001/83/EC and Regulations (EC) No 726/2004. Some of the implementations are in the area of operation which gives details on the guidance of

the number of good pharmacovigilance practice (GVP) modules to help facilitate the performance of pharmacovigilance in the European Union. (HPRA)

Good Vigilances Practices (GVP) Good Pharmacovigilance practices (GVP) are measure put in place to help facilitate the performance of pharmacovigilance in Europe Union and this measure are used in the areas of marketing authorization holders, European medicines Agency and regulatory authorities in the EU member states. (HPRA). In Ireland, market authorization holders must ensures that there is appropriate approval of the market product through thorough pharmacovigilance system in place to be able to take up responsibility for the marketed medicines and inspections will be carried out on daily basis by the HPRA .

Pharmacovigilance Inspections in Ireland.

- Pharmacovigilance inspections in Ireland are carried out to determine that the market authorization holder has the necessary equipment and facilities in place to meet the obligation laydown by HPRA. Besides, it also helps in easy identification and record-keeping of any form of non-compliance which may pose any risk to the public.
- Different types of inspections
- Pharmacovigilance system inspections: this is designed to review the procedures, systems, personnel and facilities used in carrying out compliance concerning regulatory obligations.
- Product-related pharmacovigilance inspections: this focused more on product-related issues including product-specific activities and documentation rather than making use of system review even though this does not stop using the system review along the process.
  Routine inspections: This inspection is carried out based on the risk assessment approach in advance as part of the inspection programs.
- For cause inspection: this is done as a result of information or report which need to be inspected in a way to examine the issue.
  Pre-authorization inspections: usually performed to verify the accuracy and successful implementation of the pharmacovigilance system.
  Notification of Inspection: This is usually carried out by the pharmacovigilance service provider where they get notification within four to six weeks before the proposed inspection date. And information such as
- An updated version of the pharmacovigilance system master file
- Company organization charts and the role of key personnel involved in the pharmacovigilance activities.

- Cases of adverse events
- Data Collection systems list.
- Risk Management Plans and Safety Update Report.
- List of Safety variations submitted
- Approved reference safety information(e.g. summary of product characteristics SmpCs).(HPRA)
- For a publication titled adverse drug reaction reporting: opinions and attitudes of medical practitioners in Ireland which discuss how the safety of drugs in clinical trials practice is being carried out with a 15percent of it being reported where a study of about 207 doctors was carried out which shows that most doctors (97%) in Ireland were not certain about the purpose of reporting scheme while (52%) were uncertain about the availability of report forms and (28%) of them agree to be busy or not certain of the importance of the form. Besides, (90%) of the Doctors agree for improvement and continuous awareness and education about the importance of reporting ADRs.(McGettigan and Feely, 1995)

Another publication with the title knowledge of Adverse Drug Reaction Reporting and the Pharmacovigilance of Biological Medicines: A survey of healthcare professionals in Ireland where the objectives of the study are to assess the level of knowledge and general experience and attitudes towards ADR reporting where 86% of the pharmacist claimed to have a higher awareness of ADR compared with that of Doctors with 35.1%.(O'Callaghan et al., 2018)

In conclusion and comparison of the two stated publications, it shows the importance of pharmacists in the area of ADR reporting while the Doctors need more pharmacovigilance awareness while also improving the system support for easy feedback of ADR reporting.

Besides, the need for ADR reporting is very important to help reduce the mortality rate within the country. According to the Department of health in the year, 2016 where 52.9% of the men and 53.5% of the women are reported to be aged 65 are said to have a different chronic illness or other health problems(Hilliard, 2017). The stated above shows the need for more healthcare demands which require proper monitoring and reporting of any form of ADRs needed to understand the safety of drug practices.

2.5 Pharmacovigilance and Adverse Events Reporting in Nigeria.

As earlier discuss that adverse events is an overview of any harm that occurs to any patient during drug administration which can temporarily be associated with the use of a therapeutic or a medicinal products but may be the actual real cause of the medical occurrence. A very good example of adverse events is adverse drug reactions (ADRs) which are defined as any undesired effects of the drug that occur during dosage intake for prevention or treatment.(Okezie and I., 2008)

The current declining healthcare standards in Nigeria and an increase in the population of about 200 million make the ADRs reporting ineffective which has been a major challenge in Nigeria and developing countries as a whole. Financial benefit and remuneration with an inadequate workforce of healthcare professionals continue to be a major hamper in having a good pharmacovigilance practice and as a result, ADRs reporting become a major problem in clinical practice which also backfires in implementing the WHO guidelines and regulations in related to pharmacovigilance. Another major challenge is the unavailability of advanced healthcare facilities and technology also constitutes the problems facing the implementation and effective ways of ADR reporting.

Furthermore, research also shows that drugs used in the treatment of chronic diseases, treatment of pain relief and to improve health conditions are important in the healthcare system. However, this most common drug has cause various side ADRs such as drowsiness, oedema, headache, fatigue, diarrhoea, and vomiting while some are reactions from neurological conditions, dermatological reactions and gastrointestinal reactions. A sample publication titled pattern of medications causing adverse drug reactions and the predisposing risk factors among medical in-patients in clinical practice: a prospective study, here the author established where the body organ system is usually affected by ADRs where the neurological system has the most affected system with about 33.3% followed by a gastrointestinal system of about 21.6%,17.6% dermatological system, the cardiovascular system of 7.85% in 40 patients and finally the endocrine and the respiratory which were equal with 3.9% patients each.(Akhideno *et al*., 2019)

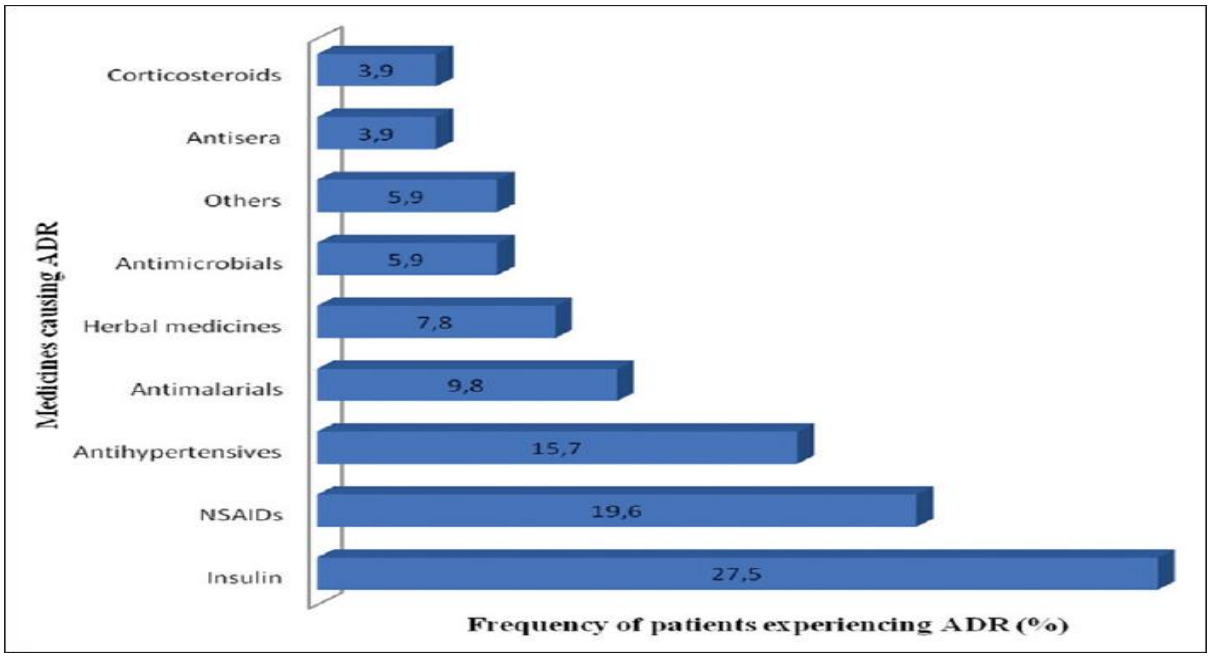


Figure 4: Medications causing adverse drug reactions among medical inpatients in a Nigerian Teaching Hospital from December 2013 to August 2014**.** (Akhideno *et al.*, 2019)

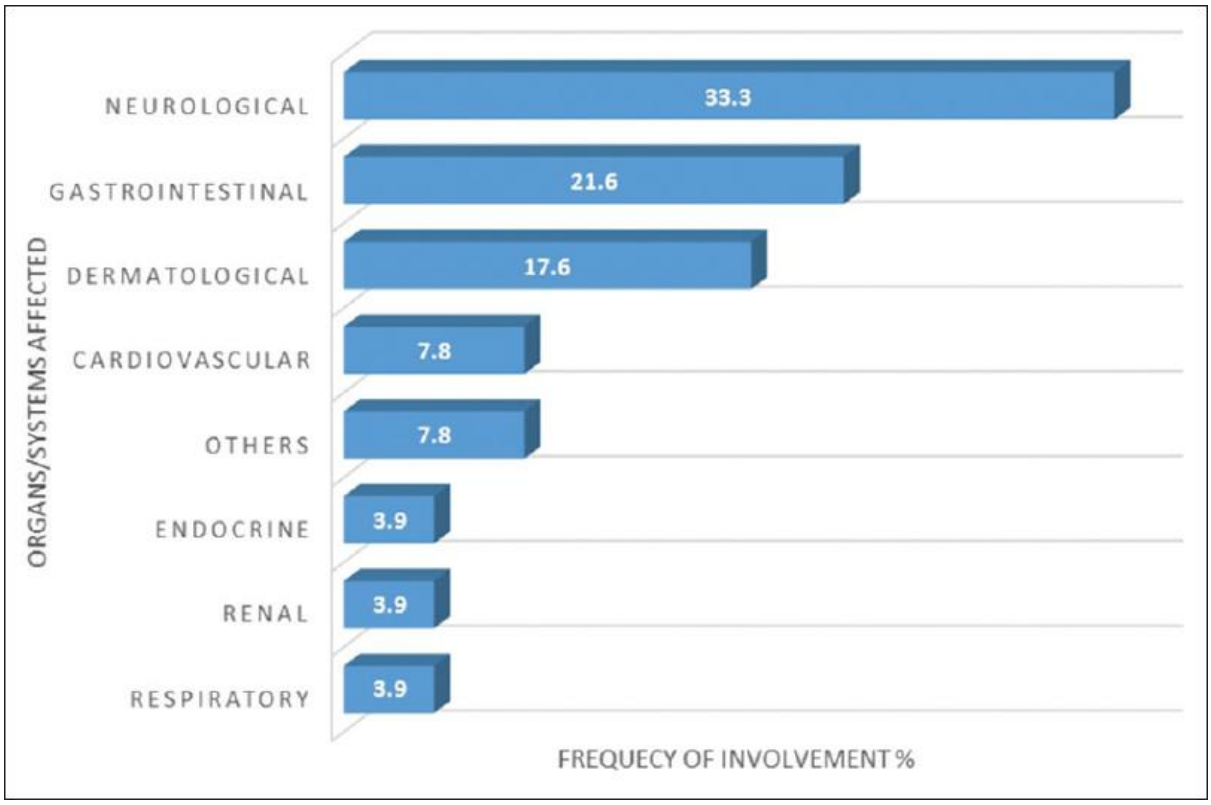


Figure 5: ADR involvement and frequency of body organ/system affected the most. (Akhideno et., 2019)

2.6 Pharmacovigilance and ADR reporting.

As earlier discussed that pharmacovigilance is activities that help in detecting, assessing or preventing any form of drug-related issue or any drug associated with any adverse events. The combination of epidemiological studies and a clinical trial has been a major contribution to the pharmacovigilance studies and ADR reporting. Besides, the reason for the establishment of the pharmaceutical industry is to provide well-being for the public suffering from any health-related issues and in line with the proper regulatory bodies the safety of drugs will be put into consideration. Good pharmacovigilance and post-marketing surveillance have been the major factors helping to improve patient health outcomes and contribute towards future drug research and development and also in the area of clinical trial and coordination.(Talbot and Nilsson, 2002)

For instance, a published article on the evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident Doctors while also suggesting possible ways to improve it. This publication shows the importance and the correlation between pharmacovigilance and ADR and the associated risk factors that occur due to under-reporting among healthcare professionals while also stating the reason to improve on the knowledge of the HCP about pharmacovigilance. Using a questionnaire-based survey where the respondents are resident doctors who provided all information bases on ADR reporting which were considered for analysis. The questionnaire response rate was quite high with about 93.3% from 84 questionnaires while 64.3% admitted to the awareness of pharmacovigilance, 52.4% were also aware of ADR reporting system in India, 83.4% suggested that only serious ADR in related to medicine should be reported, 35.7% believed that only newly produced medicine should be reported even though 68% of the respondent only observed an ADR while only 25% tend to report and ADR. Besides, 8.3% believed that there is a need to improve cooperation among healthcare practitioners and pharmacovigilance authority. From the results, the author concluded that there is a need for an increase in awareness of pharmacovigilance and collaboration within the stakeholders to help improve ADR reporting.(Pimpalkhute et al., 2012)

The case of thalidomide disaster in the 1960s leads the development of the national pharmacovigilance system among the developed countries which most use the spontaneous reporting and other pharmacoepidemiological methods to collect and analyse any form of problems associated with drug usage. In addition, every developed country developed its pharmacovigilance national system which

contributes to the global database such as the one held at the Uppsala Monitoring centre and doing this will need an extensive and costly infrastructure. In a case of the developing countries where healthcare resources are limited, funding and engaging in infrastructural development in such areas can be challenging. For instance, funding system for the pharmacovigilance program in the US tends to work because of the stakeholders ready to work together compare to that of the developing countries because during this will lead to increase in drug costs which will alter the rate of increasing access to medicine while affecting pharmacovigilance and ADR reporting at the long-run. But the WHO needs to work things out between the stakeholders by making them come together to develop a model that will support pharmacovigilance activities in the developing countries which can be done with proper developing of exchange programs between the developed countries and the developing countries to help improve their level of awareness, knowledge and local expertise in the area of pharmacovigilance.(Pirmohamed et al., 2007)

Spontaneous reporting systems are widely adopted for pharmacovigilance most especially when the ADR is rare and common (<1%) and most importantly when it is drug-related condition. Clinical Practice Research Datalink (CPRD) presents an opportunity to be able to analyse and expose any form of potential adverse events in the databases. Some other drug safety data used in the pharmacovigilance studies include published data, pharmaceutical company data from proper updates from the periodic drug safety update reports and data shared intentionally.(Coleman and Pontefract, 2016)

2.7 Who is responsible for Reporting Adverse Drug Reactions?

The medical doctors and pharmacists are the main healthcare professionals responsible for reporting ADRs observed during their practice and involvements with patients showing symptoms. A survey conducted by the European Commission shows that 5.0% of hospital admissions are due to ADRs while the patients experience an ADR while on admissions. Also, according to the EC, about 200,000 patients' mortality is usually a result of ADRs which now represent the fifth most common cause of death within the European Union. About £80 billion is the most budgeted healthcare burden for ADRs in the EU as in 2008 (Giardina et al., 2018). The study of medicine safety is usually associated with the clinical trial carried out on it and this is usually limited until the drug is being introduced to the public for marketing, which led to needing for the importance of reporting any form of ADRs among healthcare professionals to be able to carry out further research on drug investigation(HPRA, 2020)

In Ireland, where Health products regulatory Authority (HPRA) oversees the operation of national adverse drug reaction reporting and monitoring of drug safety. During the drug monitoring process which involves gathering and collecting data for proper updating on drug labelling, drug risk patterns while also encouraging other investigators to prevent these drug reactions. This information gathered helps in making research and improvement needed to be done positively while also serves as a modality that guides researchers, healthcare professionals, and pharmaceutical companies.(Council for International Organisations of Medical Sciences, 2000)

The earliest healthcare professionals to always have contact with patients either community pharmacist or in hospital settings are the Medical doctors and Pharmacists. They are also expected to report any case of ADRs from any drug newly authorize into the market and any old drug products which have been included to be among the drug monitoring list after their approval. Due to all these mentions above, led to the importance of drug safety assessments among the healthcare professionals during their routine when dealing with patients.(HPRA, 2020)

2.8 Challenges Faced Among Healthcare Professionals in Reporting Adverse Drug

One of the most challenges faced in reporting an ADR is usually the language of reporting as most clinicians tend to communicate orally with one another and when dealing with patients. But in a case of reporting there is always a problem of understanding some of the terminologies because the clinicians tend to define a clear case of ADRs or well-known diseases compare to the use of the term in reporting.(Council for International organizations of Medical Sciences, 2000)

A sample research article titled perception of doctors to adverse drug reactions reporting in teaching hospital in Lagos, this research was aimed to evaluate the level of understanding of healthcare professionals towards ADRs reporting where a total 120 medical doctors were evaluated using a questionnaire to ascertain their knowledge and attitude towards ADR reporting and some of the challenges face that resulted in the under-reporting of ADRs are associated with legal actions which involve the fear of litigation, financial incentives associated with professional activities and the belief that a drug has already been well examined before authorization for marketing. Besides, the mentality of indifference that a single ADR reporting does not have any effect on medical knowledge or to national drug safety practice, which led the ignorance of believing that only serious life-threat related drugs should be reported. Another factor is procrastination and lack of enthusiasm towards ADR reporting or lack of time or will towards reporting a case of ADR (Oshikoya and Awobusuyi, 2009)

Furthermore, apart from the mentioned above global issues affecting ADR reporting within the healthcare professionals who are mostly related to that of lethargy and insignificant contribution. Taking a case study of developing countries using Africa for instance where the factors resulting to low ADR reporting has not been studied because according to the author which stated that only two studies have been attempted towards analysing the factors facing under-reporting in African countries which they both indicate lack of adequate knowledge among health professionals. This research was carried out using a questionnaire where 82% respondent are gotten and 89% considered the most qualified among the doctors to report ADRs, only 40% were aware of National Pharmacovigilance Centre in Nigeria, 32% claim to be aware of yellow card reporting scheme while only 48.5% believe reporting of ADR can only be done when the drug has been licensed, authorized and marketed. This resulted in differences among the respondent who believe in ADR reporting should be compulsory to that of those who opposed it being voluntary.(Oshikoya and Awobusuyi, 2009)

The study concluded that there is the inadequacy of knowledge of medical doctors regarding ADRs reporting which is common among the Doctors not just in developing countries but also in developed countries. This research highlighted the need for an improvement in awareness and proper medical training towards pharmacovigilance while also educating and training other health professionals on spontaneous reporting and the use of yellow cards. Although reporting of ADR was highly recommended by the National Pharmacovigilance Centre most health professionals see it as unrecognized while some percentages are not even aware of the existence of NPC even though 39% are aware of the office of NPC location which happens to be in Abuja. Base on this, without proper awareness and knowledge of where to report ADRs, the prevailing rate of reporting will continue to remain poor. The agency which happens to be NAFDAC must ensure a guideline and enforcement towards ADRs among healthcare professionals so has to improve the ADR reporting.(Oshikoya and Awobusuyi, 2009)

Over a decade ago, a study was carried out in Ireland on ADRs reporting among hospital doctors who involve a total of 118 doctors where only 45% had ever reported a case of ADR and fewer than 5% of pre-registration house officers had reported an ADR which also shows that rate of reporting was highly associated with the level of rank among the profession where physician and surgeons have the highest rate of ADR reporting. Evidence also shows the reason where there was no case of ADR publishing among the medical doctors because there was the availability of yellow cards and reminders about reporting any form of ADR which led to an

increase in reports but over time when verbal discussion were withdrawn, reports drastically drop despite continuing availability of yellow cards which suggest that the availability of yellow card alone does not guarantee an increase in ADR reporting which also show fundamental constraints between attitudinal survey and the need to explore a way of making it a cultural attitude towards reporting ADRs(McGettigan et al., 2003).

Another recent research which was carried out in Dublin based teaching hospital where ADR actually caused a lot of admission within the hospital which led to evaluation of what is actually leading to this problem.(Walsh et al., 2015)

Recent pharmacovigilance studies have shown very insufficient and inadequate prove over the number of the sample size used for the clinical trial study and this has been a very huge challenge for the pharmacovigilance practice where most studies are dependent on spontaneous reporting of ADRs however, this has resulted in the way of reporting ADRs among healthcare professionals and this finally led to not be able to gather enough database information on ADR despite the use of electronic health records as a source of secondary backup for data. (Lardon et al., 2015)

A publication by St James medical hospital in Ireland also discuss extensively the use of yellow card ADR reporting as an efficient surveillance system for ADRs during clinical practice. This came into reality to be used in the 60s to the disaster that occurs in 1968 where the WHO begin the drug monitoring program as a means for receiving ADR data from every member state country contributing to improving the evaluation of rare and serious adverse reaction(NMIC, 2005)

2.9 Recommendations for Improvement of Adverse Drug Reaction Reporting

According to a recent publication on educational intervention to improve the attitude, knowledge, and practice of healthcare professionals regarding pharmacovigilance in Nigeria where the study aims to evaluate a long term messaging reinforcement towards achieving a good pharmacovigilance practice and this was carried out at six different teaching hospitals. A total of 40 questions are used for the evaluation where a total of 12 questions are related to that of the knowledge of the HCP, 10 related to attitudes surrounding ADR reporting and 18 focusing on ADR practice. After proper research, the result shows that out of 931 HCP in the cross-sectional study correspondence they got the rate of 77.6% with approximately 64.0% for the intervention arm while having 36% at the control arm.(Opadeyi et al., 2019)

In the case of a pre-intervention study where 811 HCP participated, which shows 65% are in the intervention arm and 35% are in the control arms. The result has shown a level of correlation between the post-intervention study and the post-intervention surveys even though there was a distinct increase across the level of knowledge across different groups while that of intervention group shows that the HCP has a high-level knowledge of ADR reporting importance in drug monitoring.(Opadeyi et al., 2019)

Another published research study on the knowledge and attitude of the Healthcare Professionals towards Pharmacovigilance and Adverse Drug Reaction Reporting in Northern Cyprus where a face to face questionnaire was conducted among 90 pharmacists, 96 nurses and 71 physicians at the Turkish Republic of Northern Cyprus that volunteer to participate in the study. The outcome of the study shows that only 13% of pharmacists, 2% of nurses and 20% of physicians knew pharmacovigilance. While also 32%,12% and 54% of the participants claimed that there is ADR case reported from their patients, but 10% and 3 % of the pharmacist, nurses and physician also claimed they report cases of ADR to the concerned organization while the common reason given by the participated HCP was lack of knowledge of the where/how to report a case of ADR, lack of due time, ADR reporting being not mandatory, belief that not part of their responsibility while also avoiding the professionalisms of the job. In conclusion, the research shows that HCP has insufficient knowledge about pharmacovigilance which needs an extensive training program about pharmacovigilance and ADR among HCPs.(Toklu and Soyalan, 2016)

2.9.1 Conclusion

After going through all research study of different literature review around the world and articles from Nigeria and Ireland, It was finally proving that the challenges facing ADR reporting among the HCPs continue to increase with a highly significant rate within the developing world and Nigeria as a case study compare to that of Ireland. Besides, the need to sustain the effort of pharmacovigilance in Nigeria is very key and this can be done by putting in responsible regulatory authorities and health organizations to help in reporting. Inadequate knowledge from the literature review had been a major challenge facing improvement in the rate of ADR reporting the quality of reports.

Moreover, the assumption of HCP in the hospitals and teaching hospitals in the developing country shows that medical doctors are seen as the core HCP leaders of the healthcare management and who is responsible for the bulk responsibility of reporting any ADR case as they are considered as the primary reporters compare to

the others. While in the case of the developed countries where reporting of ADR reactions responsibility are considered by both the pharmacist and Medical Doctors, although with the higher percentage to that of pharmacists compare to other healthcare professionals. Also, the pharmacists are better trained compared to other HCP but shy away from their responsibility due to lack of will and cultural attitude towards ADR reporting.

For instance, a community pharmacist in Nigeria tends to have more cases of ADR compare to the hospital pharmacist because people tend to easily get prescription over the counter medications by simply walking into any community pharmacist which led them been able to report more cases of ADR on both existing and new drugs compare to the counterpart in the hospital and this will help towards proper data coverage and spontaneous reporting of ADRs.

Furthermore, the findings from different research from above show a high level of inadequate knowledge and poor attitude as the main factors affecting the rates of ADR reporting and quality of reports within this two regions. Also, Also from the literature from it shows that most tertiary healthcare centres and teaching hospitals as seen medical doctors as the leaders of healthcare management which has led to the other HCPs thinking the bulk responsibility of reporting ADRs rest on them alone as they are always seen as the first within the healthcare sectors . This has led the pharmacist to believe their role only lies on dispensing already prescribed drugs which end up making them feel less obligated towards ADRs reporting believing is the role of the medical doctors. Beside the community pharmacist in both regions tend to experience more ADRs reactions because people tend to get prescription over the counter by simply walking into any of the nearest pharmacy and scenario is highly common within the developing countries and especially Nigeria as a case, these pharmacists tend to encounters higher number of ADRs from the old and new drugs which will contribute towards spontaneous reporting of ADRs.

Finally, so as to meet up the recommended optimal target lay down by the WHO of 200 reports per million population, the need to further strengthen reporting of ADRs and effective drug monitoring by overcoming the challenges of lack of knowledge among HCPs, slow implementation of policies, ineffective ADR reporting systems and models, lack of willingness towards pharmacovigilance, lack of inadequate infrastructural healthcare system, lack of government support, no financial support to improve ADRs, work hours constraints and poor awareness and knowledge of established guidelines and regulations, lack of proper training and the need for ADR specialist to encourage ADR reporting.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Research Philosophy

The philosophy behind this research is to be able to aim at explaining the information gathered from the respondents which help in giving a concluding study of the research. The progress has helped through measurable large numbers of randomly selected respondents of healthcare practitioners mostly the medical doctors and pharmacists.

The healthcare practitioners are provided with adequate and well structure questionnaires where data are adequately collected, analysed and interpreted without any form of human interference or personal opinion or interest and this was done using an online Microsoft electronic survey to avoid any form of cross interactions with the research participant's opinion. Also, the qualitative approach which covers the phone interviews determined the personal views of the healthcare professionals even though it was subjected to the genuity and reliability of the representation. However, it was associated with high level experienced healthcare practitioners with years of experience in the field which brought the philosophy of interpretivism for proper appropriate result oriented.

3.2 Research Strategy

The strategy behind the research was to evaluate the knowledge and awareness along with the practice of ADR reporting among medical doctors and pharmacist in Ireland and Nigeria while comparing the two results of the two countries along with the challenges faced by each region towards improving ADR reporting rates and to promote long term pharmacovigilance practices within the two regions. The HCPs who received the questionnaires was told the reason behind the research is being conducted by the author as part of the requirement for the awards of M.Sc. in pharmaceutical Business and Technology. The questionnaires were put together in an easy way to answer and with familiar medicals terms for respondents' understanding. It was administered to members of the pharmacist association of Nigeria, Members of University College Hospital across the country while the Ireland survey was distributed to the pharmacists through handling across Dublin Community Pharmacy.

3.3 Research Approach

To have a comparative assessment of current and future pharmacovigilance in the developed and developing countries- A case study of Ireland and Nigeria. While determining the challenges and factors limiting healthcare professionals from having good ADR reporting in both countries, the application of quantitative and qualitative research methods will be used (Survey questionnaires and phone interviews).

The questionnaires were distributed to the HCPs mostly the medical doctors and pharmacists through online Microsoft media where they were requested to help answer and fill the survey. Using this medium enables the author to gather accurate and appropriate information from both countries to help in statistical analysis. The questions tend to help determine the general perspective of the different countries towards ADR reporting while ascertaining awareness about the old and new ways of reporting. Besides, the author was also able to identify the best approach towards ADR reporting within the two regions as well the two major classes of the healthcare professionals while recommending what is suitable and sustainable over a long term period.

The qualitative approach was conducted using a phone interview to have a better understanding about people personal perspective and approach towards ADR in Nigeria and Ireland and this was carried out with highly experienced medical doctors and pharmacist while asking them questions in related in pharmacovigilance and factors they considered challenging and ways of improving ADR reporting within this two regions.

Data collection was done where the analysis was carried out on both groups approached and compared to that the research literature findings to show a coherent concluding study that is being carried out.

Section. No	Primary Data	Part A	Part B
1	Approach	Quantitative analysis	Qualitative analysis
2	Philosophy	Positivism	Interpretivism
3	Source	Questionnaire: Microsoft forms app distributed online	Phone Interviews
4	Structure	5 sections made up of 20 questions	5 – 10 minutes of phone conversations
5	Subjects (Ireland)	Medical Doctors (12) Pharmacists (35)	Medical Doctors (1) Pharmacists (2)
6	Subjects (Nigeria)	Medical Doctors (32 Pharmacist(43)	Medical Doctors (2) Pharmacists (3)

Table 2: Primary Research Data Collection and Methodology

3.4 Survey questionnaire for Healthcare professionals:

The survey questionnaire consisted of 20 questions which are divided into 5 different sections to satisfy the purpose of the research for the Nigeria Healthcare settings while using the same format for the Ireland Healthcare settings. Comparisons of the two results are done using a Microsoft forms app and doing this reinforces the credibility of the philosophy of positivism to encourage the respondents towards expressing their opinion without any form of interference or hesitation.

The first paragraph of the question comes with an introduction which was designed to gain the consent and credibility of the respondents while asking for their permission to use their result for the study. The author also assured them of the safety of the data generated from the survey which will be handled by general data protection regulation (GDPR).

3.5 Primary Data Collection

The questionnaires are structure in a way to give the author the exact research objectives without any interference.

Section 1 is on demographics which consist of five questions in which the respondents are giving the option of picking the right one based on their opinion and this section is categorized base on the level of the HCP, years of experience and age group the HCP fell into.

Section 2: was to check the level of knowledge of HCP concerning ADR reporting and the way the system works both in Nigeria and Ireland with the way of gathering information on ADRs knowledge and the method and process of reporting an ADR. This covers questions such as awareness in terms reporting, should it be voluntary or mandatory towards ADR reporting and the rules and guidelines guiding ADR reporting in Nigeria and Ireland.

Section 3: discussed the awareness of ADR reporting in Ireland and Nigeria which is to help us ascertain the level of understanding and awareness of ADRs and pharmacovigilance practice in Nigeria and Ireland. Besides, the need to understand the frequency at which ADRs are being done and where to submit a report to and what mode of submission is being used in both countries.

Section 4: focuses more on challenges facing ADR reporting in Ireland and Nigeria while giving their opinion in respect to these challenges facing adequate reporting in pharmacovigilance practice and ADR reporting in both countries.

Section 5: These sections tend to do with respondents opinion on providing recommendations for HCP within the two countries while agreeing to some terms as ways of improving ADR reporting

3.6 Sources

The questionnaires were distributed to groups of healthcare professionals over the internet using Microsoft form for the one being sent to Nigeria while some others are handle by hand to hand distribution within community pharmacy (Boots) in Ireland precisely Dublin. A total of 122 participants from both countries which comprise of 44 medicals doctors and 78 pharmacists. Also, Microsoft excel sheet was used to evaluate the result gotten to produced pie and bar charts to present the findings as well as to compare to that of the one gotten from the other country.

Finally, phone interviews were done with highly experience healthcare professionals for a better understanding of the challenges facing ADR reporting in Nigeria and Ireland.

Medical Doctors Selection

NIGERIA

The author contacted the Director of Computing and Information Technology at the University College Hospital in the person of MR ADETUNJI ADEREMI who also happened to be my Uncle. I explained the reason and the purpose of my research to him and how he can help use his office to help me share my survey questionnaires. Also, I contacted the Nigeria Medical Association through its social media platform (Facebook and LinkedIn). As a result, the medical doctor showed a high level of response which makes my research a successful one.

IRELAND

The author contacted some of the teaching hospitals in Ireland (St James Hospital, Connolly Hospital Blanchardstown and Mater Misericordia University Hospital) where the response was low due to the pandemic outbreak disease which most of the medical professionals are busy fighting the curse. However, some responses were gotten which our analysis was based on.

Pharmacists Selection.

The author reached out to pharmacist students of Nigeria towards getting the survey questionnaire and received recommendations from highly experienced pharmacists who help towards getting the result while also using the same platform I used in getting result for the medical doctors.

Ireland

The authors reach out to the community pharmacist and few other pharmacists within the hospital settings which he received good positive feedback.

3.7 Ethical Issues

A brief explanation of the research study was put on the front cover of the survey questionnaires which was provided to the healthcare professionals to have the necessary understanding of what the research is all about while they were duly informed about the research study as a part of the author requirement for his master's degree program.

Also, the author makes sure the questionnaire is well structured in a way that no personal information of the respondent is needed and all questions are strictly based on the research study and objectives. Also, all respondents were duly informed about the right to withdraw from participation at any time if they are not confident enough.

3.8 Inclusion and Exclusion Criteria

The author included an introductory letter to the survey questionnaire which had the approval of their informed consent before proceeding which means it was at the discretion of the participants to either participate or rather withdraw. The survey questions sent through emails and online platforms also contain information about voluntary participation.

However, all healthcare professionals who decided to withdraw or declined to answer the survey questionnaires were considered as excluded from the study.

3.9 Conclusion

The research study was carried out using 20 questions with 5 different sections and was based on both quantitative and qualitative approaches across the medical doctors and pharmacist which are the key healthcare professionals towards positive response. While the qualitative approach involved phone interviews to allow better understanding and insights on the research study and the respondents' thoughts. The data collected in both countries were analysed and compared to each other both in terms of the literature review carried out over the previous research and to better ascertain the challenges facing the ADR in the both region while looking at how each country can help improve this challenges facing ADR reporting.

The subsequent chapter generated the findings and analysis based on the responses generated.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Overview

This section explains the purpose of our research towards tackling the challenges and how to improve ADR reporting in the developing countries among HCPs while using Nigeria as a case study by analysing the level of knowledge, attitude and experience of ADR spontaneous reporting while comparing the results to that of the developed countries-a case study of Ireland. Also, the areas that needs improvement within this two regions and how our research outcomes can help improve the challenges facing the developing countries. The objectives surrounds the investigation of challenges affecting effective ADR reports in the developing countries, examine the awareness of HCPs obligations towards ADR reporting, review guidelines and regulations and finally compare the results of the two stated countries and how they can help improve ADRs and Pharmacovigilance within the regions.

The data generated from our questionnaire and how they are going to be analysed accordingly in comparison to each countries data generated. This data assisted the author towards knowing the challenges faced by two countries in terms of knowledge, awareness, and challenges faced with healthcare professionals towards ADR reporting within the two regions while all providing the basis on how the improvement can be done within the two countries(Ireland and Nigeria).

The author conducted a phone interview with highly skilled and experienced medical doctors and pharmacists who also help put more suggestions and overlap with the share questionnaire results, literature review and their personal views apart from the author's views and understanding regarding ADR reporting within the two regions.

4.2 Demographic Data (Questions 1-4)

4.2.1 Response Rate: The questionnaire was distributed to 154 healthcare professionals in both countries (Ireland and Nigeria), which was distributed equally among the healthcare professionals within the two regions consisting of 90 healthcare profession (45 medical Doctors and 45 Pharmacist) from Nigeria while same was done to Ireland consisting of 20 medical doctors and 45 pharmacists. A total of 122 accepted responses were received with a response rate of 79.2%.

For Nigeria

The total participant who responded was 32 medical doctors out of 45 which 19 are male and 13 being female. In comparison, a total of 43 respondents are pharmacists which the males are 18 and 25 are females.

Although getting the respondents to do the survey was not easy as I need to be sending and posting quick reminder through the entire platform used for sharing the questionnaires. The author received more responses once this quick reminder is done.

For Ireland

The total respondents the author was able to receive were 12 medical doctors out of 20 which 8 are male and 4 are female. In comparison, a total of 35 respondents were pharmacists where will have 23 females and 12 males, respondents.

4.2.2 Level of experience

In Nigeria

Out of the 75 respondent from Nigeria that completed the questionnaires, young adults between the age of 18- 30 years predominantly responded well which led to the author having a total of 53 within the age group compared to others where 17 were between the age of 31 to 40, 4 from 41 to 50 and one respondent was 51 years and above.

Also, many of the respondents who are medical doctors 22 and pharmacist 25 who participated in the questionnaire had experience 1year to 5years with only three medical doctors having an experience of more than 10years.

Healthcare Professionals	Years of Experience				Gender			Total Number of Respondents	Response Rate
	< 1	1 - 5	6 - 10	>10	M	F	U		
Medical Doctors	2	22	5	3	19	13	0	32 out of 45	71.1%
Pharmacist	8	25	8	2	18	25	0	43 out of 45	95.5%

M= Male, F= Female: U=undisclosed

Table 3: Demographics

IN IRELAND

Out of 47 respondents that completed the questionnaire, 27 predominantly between the ages of 18 to 30, 15 between the ages of 31 to 40, three respondents aged between 41 to 50 and just one 51years and above.

Also, the medicals doctors that participated in the survey that had experienced between 1 to 5 years are 8 while the pharmacist that participated who had experienced between the ages of 1 to 5 is 28 with no medical doctor with experience among the participant with experience over 10years.

Healthcare Professionals	Years of Experience				Gender			Total Number of Respondents	Response Rate
	< 1	1 - 5	6 - 10	>10	M	F	U		
Medical Doctors	1	8	3	0	8	4	0	12 out of 20	60.0%
Pharmacist	3	28	3	1	12	23	0	35 out of 45	87.5%

M= Male, F= Female: U=undisclosed

Table 3: Demographics

4. 3 ADVERSE DRUG REACTION (ADR) REPORTING BASED ON KNOWLEDGE.

The responses are remarkable which different response opinions. It shows a positive and encouraging outcome based on the knowledge of the respondents.

Question 5

The analyses are based on the respondent's knowledge of how to report ADRs in Nigeria and Ireland.

IN NIGERIA:

From the pie chart below the analysis shows that the participants' knowledge on how to report an ADRs in Nigeria are 71.0% of the total 75 respondents which consist of 26 medical doctors and 27 Pharmacist that admitted to the knowledge of ADR reporting while 29.0% of respondents (six medical doctors and 16 pharmacists) do not know how to report ADRs in Nigeria- see figure 5a

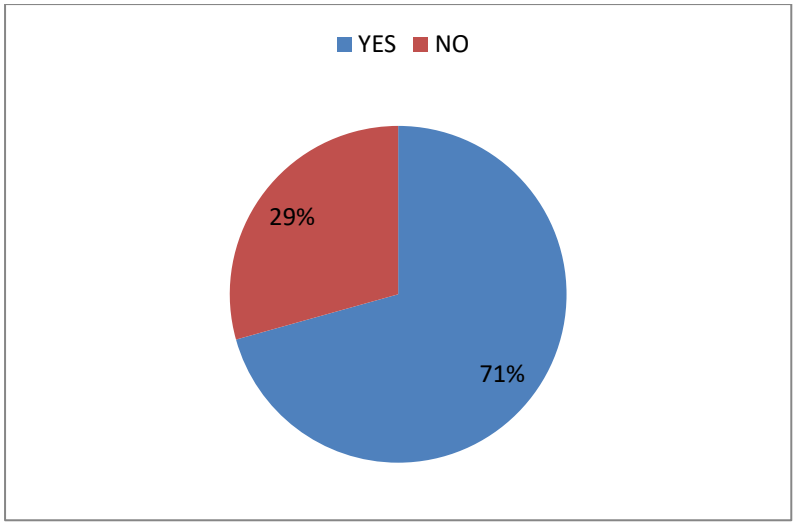


Figure 5a. Knowledge of ADRs among Healthcare Professionals in Nigeria.

IN IRELAND

From the pie chart below the analysis shows that the participants' knowledge on how to report an ADRs in Ireland are 98.0% of the total 47 respondents which consist of 12 medical doctors and 35 Pharmacist that admitted to the knowledge of ADR reporting while 2.0% of respondents (zero medical doctors and one pharmacist) have no knowledge on how to report ADRs in Ireland- see figure 5b

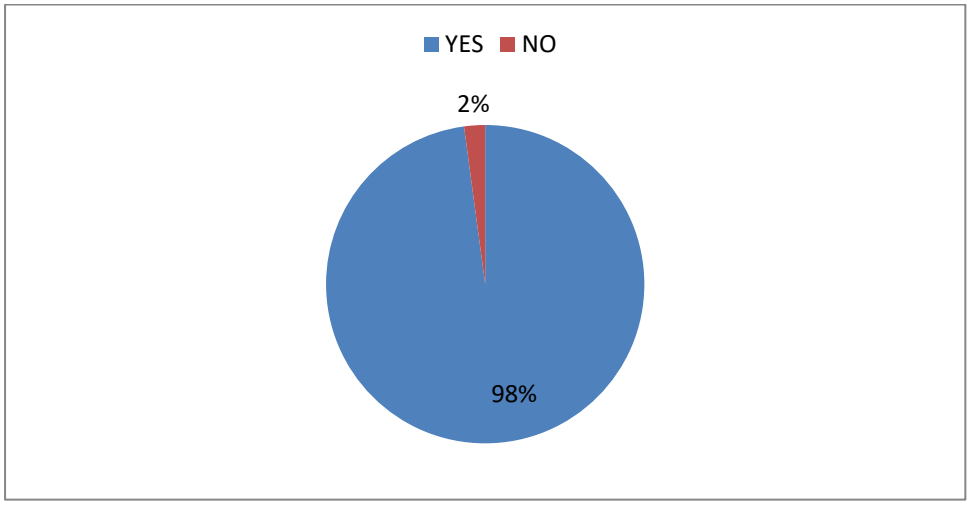


Figure 5b: HCP knowledge about ADRs reporting in Ireland.

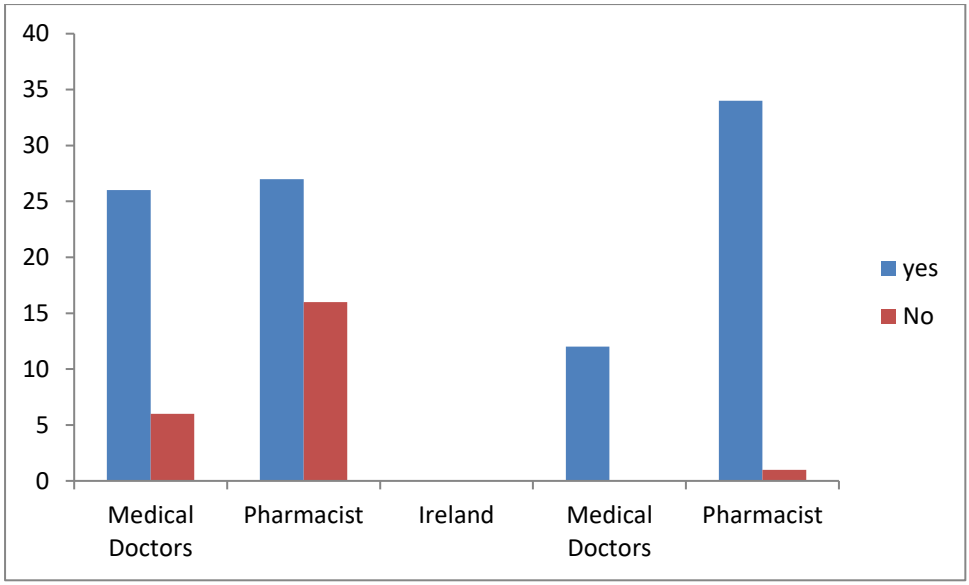


Figure 5C: Comparison of the knowledge of ADRs report between Nigeria and Ireland.

From our analysis above it shows that both countries have above average knowledge among healthcare professionals on how to report ADRs as shown from the survey. However, the pharmacists in both countries have overwhelming knowledge than their medical doctor's counterparts as it pertains to ADR reporting.

Question 6:

This question serves as a follow up to ascertain the source of their knowledge towards ADR reporting within the two regions.

IN NIGERIA:

45% of the respondents (13 medical doctors and 21 pharmacists) who admitted to getting their source of knowledge for ADR from professional textbooks and journals, 36% of respondents (12 medical doctors and 15 pharmacists) agreed to get their source of knowledge from verbal communication from colleagues, followed with 15% (4 medical doctors and 7 pharmacists) getting their knowledge from newsletters from regulatory agencies and lastly the 4% (1 medical doctor and 3 pharmacists) who admitted to getting their knowledge from internet and social media.

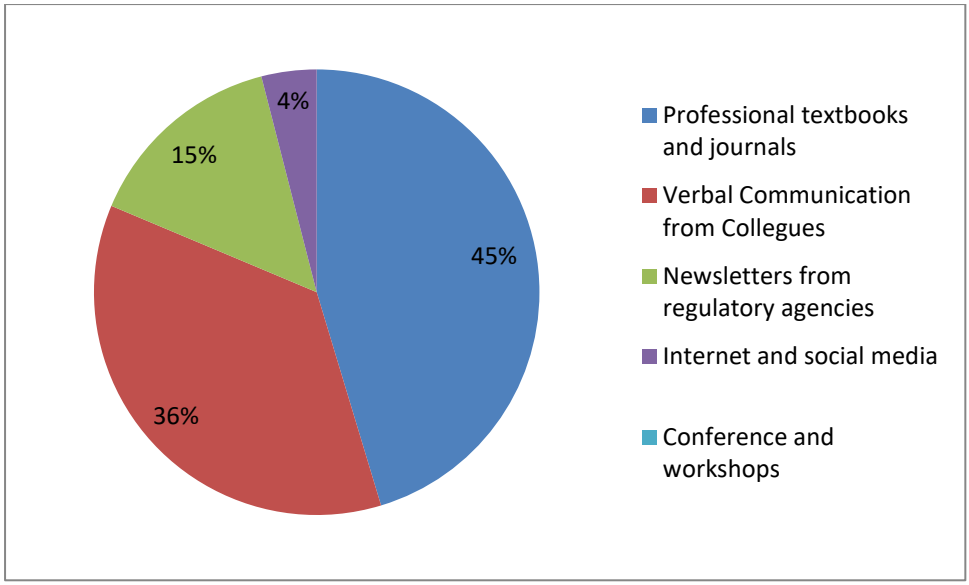


Figure 6a Source of Knowledge for reporting ADRs in Nigeria.

IN IRELAND

41% of the respondents (5 medical doctors and 14 pharmacists) who admitted to getting their source of knowledge for ADR from professional textbooks and journals, 28% of respondents (4 medical doctors and 11 pharmacists) agreed to get their source of knowledge from verbal communication from colleagues, followed with 19% (2 medical doctors and 7 pharmacists) getting their knowledge from newsletters from regulatory agencies, 4% (1 medical doctor and 3 pharmacists) who admitted to getting their knowledge from internet and social media and lastly 1 pharmacist admitted in getting their information and knowledge from conference and workshops.

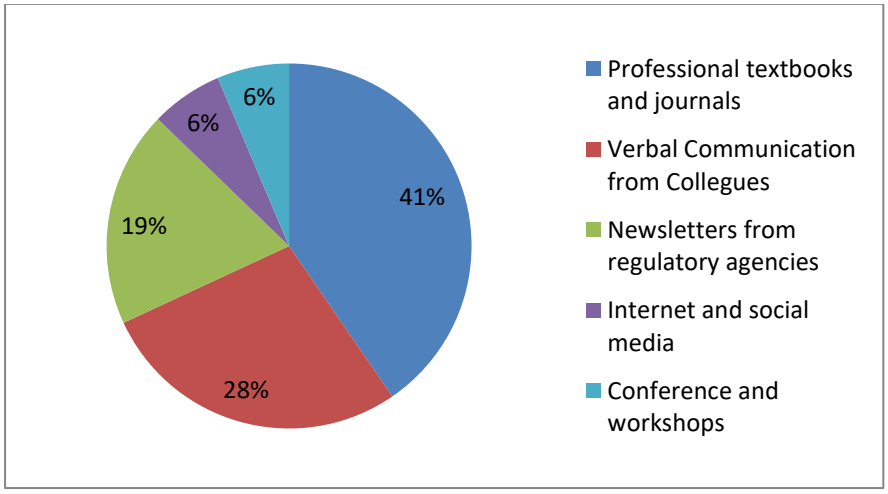


Figure 6b Source of Knowledge for ADR reporting in Ireland.

This two analysis shows that the medical doctors and pharmacists in Ireland and Nigeria tend to utilize professional journals and verbal communication more as their source of knowledge. In Ireland, the medical doctors and pharmacist tend to go show a trend that they get their information on different platforms which bring the awareness of their ADR reporting within the region when compare to the Nigeria where others claim to their information from NAFDAC newsletters and social media and no presence of any conference or workshop.

Question 7

To ascertain the source of the knowledge acquire the need to know the organisation responsible for handling ADR reporting in Ireland and Nigeria.

An overwhelming majority 62% respondent (22 medical doctors and 27 pharmacists) agreed to identify with the National Agency for Food and Drug Administration and Control (NAFDAC), 20% identified with Pharmacist Council of Nigeria which the respondent are (4 medical Doctors and 11 pharmacists), 7% respondents(2 medical doctors and 3 pharmacists) identified to Medical and dental council of Nigeria. 11% of identified with world health organization which consists of 4 medical doctors and 2 pharmacists.

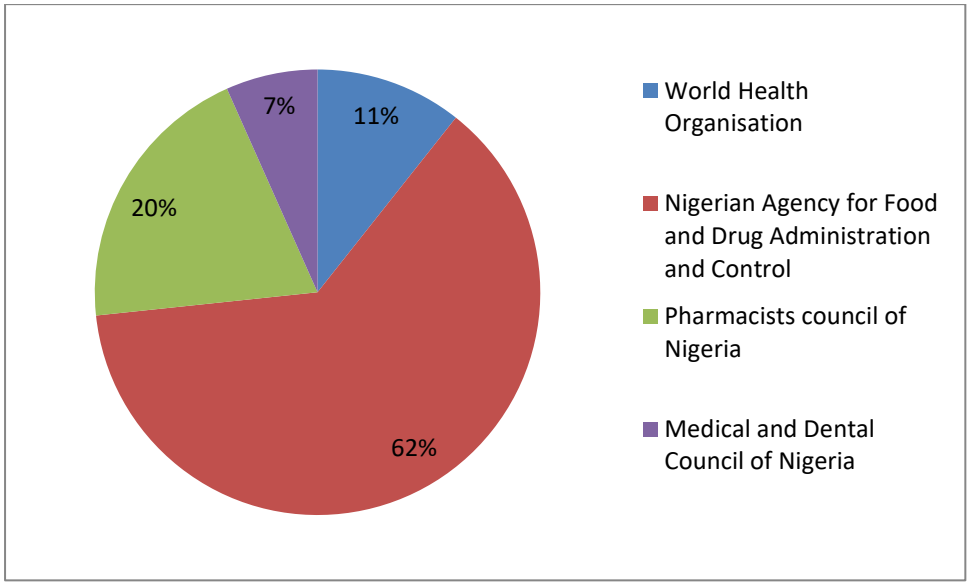


Figure 7a: Organization responsible for handling pharmacovigilance and ADRs reporting in Nigeria.

IN IRELAND

An analysis from the chart below shows an overwhelming outcome with 92% respondent (8 medical doctors and 32 pharmacists) agreed to identify with the Health Products Regulatory Authority (HPRA), 4% Irish Medical Council which the respondent is (2 medical Doctors only), 4% respondents(2 medical doctors and 3 pharmacists) identified to pharmaceutical society of Ireland.

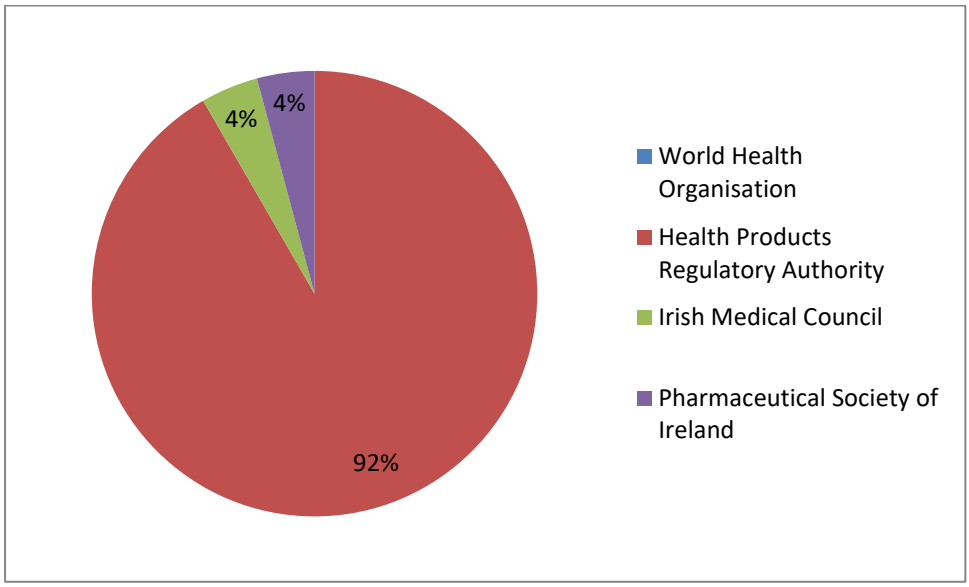


Figure 7b: organisation responsible for handling ADRs in Ireland.

Comparison of the two results from both regions, As confirmed from the result from Nigeria it shows few medical doctors and pharmacist still incorrectly confirm to recognizing pharmacist council of Nigeria as the body responsible while an overwhelming majority agreed to recognized the NAFDAC body as the primary authority for handling pharmacovigilance within the region. In Ireland, the vast majority of the medical doctors and pharmacists recognized well with the Health Products Regulatory Authority (HPRA) which shows how knowledgeable and informed in terms of ADRs reporting compare to that of Nigeria.

Question 8:

To ascertain the mode of reporting ADRs in both countries we need to know which ADR method the HCP are familiar with.

IN NIGERIA

The healthcare professionals in Nigeria ascertain that ADRs methods are carried out with 51% of respondents (12 medical doctors 26 pharmacists) ascertaining to the use

of Yellow Card/ADR forms, 25% of respondents (8 medical doctors 11 pharmacists) confirmed that ADR E reporting is the method used, 24% respondents (12 medical doctors 6 pharmacists) ascertain the method to both yellow cards and ADR E reporting.

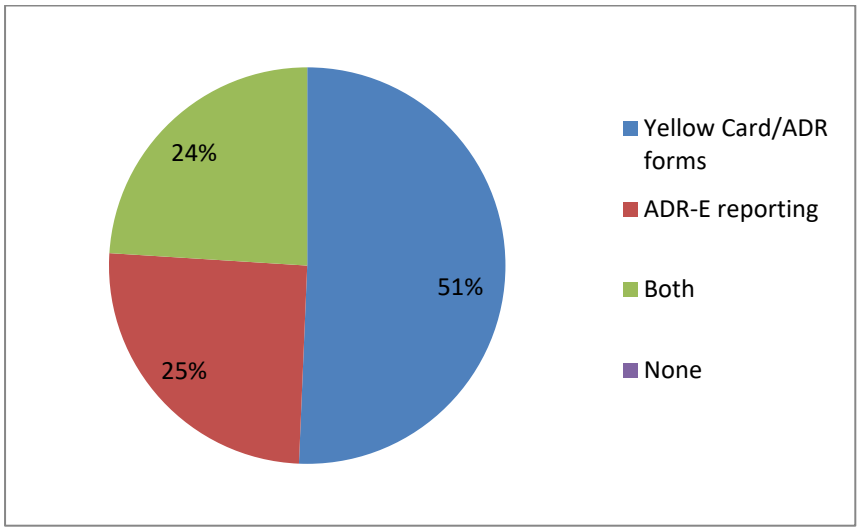


Figure 8a: Methods familiar to ADR reporting in Nigeria among the HCP.

IN IRELAND

The healthcare professionals in Ireland ascertain that ADRs methods are carried out with 26% of respondents (3 medical doctors 8 pharmacists) ascertaining to the use of Yellow Card/ADR forms, 23% of respondents (3 medical doctors 11 pharmacists) confirmed that ADR E reporting is the method used, 51 % respondents (6 medical doctors 16 pharmacists) ascertain the method to both yellow cards and ADR E reporting.

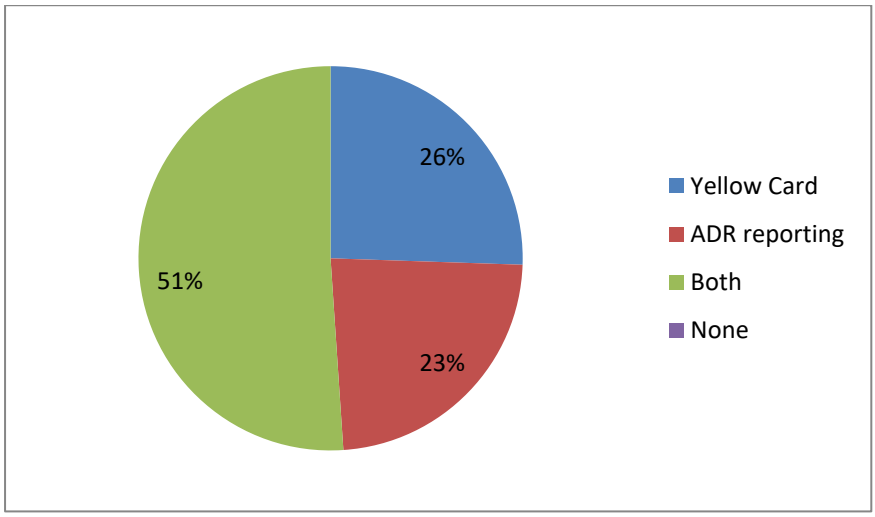


Figure 8b: Familiar methods of reporting ADRs in Ireland.

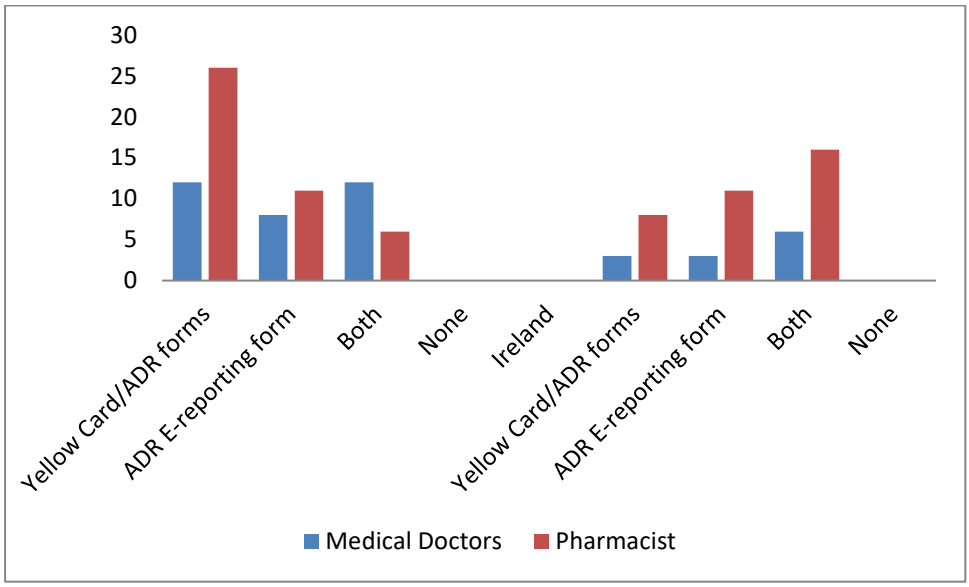


Figure 8C: Comparison of the methods of ADRs reporting between Medical Doctors and Pharmacist in both countries.

As shown above it shows that HCP in Ireland are more familiar with using both the Online E-ADR reporting form and Yellow Card/ADR forms with majority of the HCPs agreeing to this. While in contrast to HCP in Nigeria they seem to be more familiar with the use of Yellow Card/ADR forms than every other method available for reporting ADRs. In addition, the medical doctors in both regions reporting were worse than the pharmacists who tend to be more familiar with reporting of ADR.

Q 9:

To ascertain our result from Q8, the need to find out the most important criteria for submitting an ADR report in Nigeria. 4.0% of the respondent (1 medical doctor and 2 pharmacists) went with unusual reactions, 8.0% (2 medical doctors and 4 pharmacists) of the respondents agreed with criteria related to new products reactions, 9.0% (five medical doctors and 2 pharmacists) selected criteria related to Life-threatening while 79.0% (24 medical doctors and 35 pharmacists) admitted to the all of the listed options as the important criteria for reporting ADR.

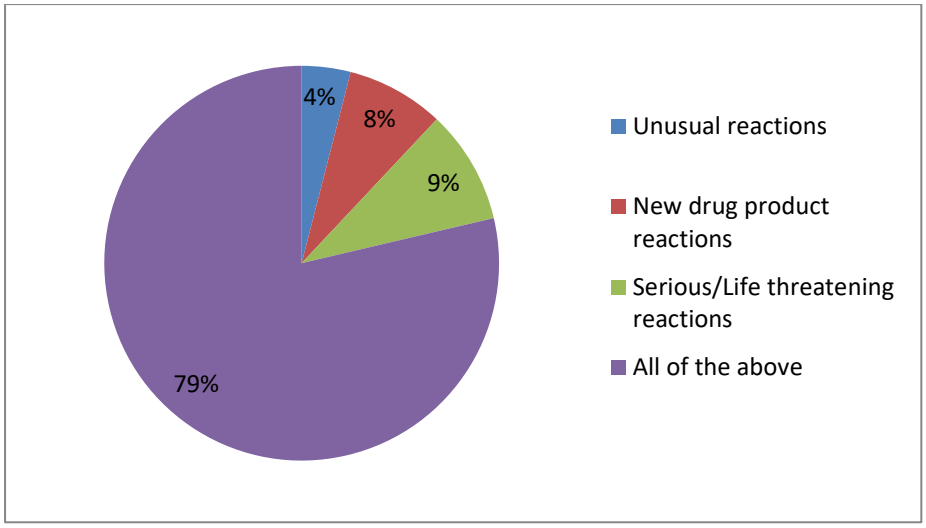


Figure 9a: Criteria for submitting an ADR report in Nigeria

IN IRELAND

4.0% of the respondent (2 medical doctors) agreed with unusual reactions, 4.0% (1 medical doctor and 1 pharmacist) of the respondents agreed with criteria related to new products reactions, 9.0% (3 medical doctors and 1 pharmacist) selected criteria related to Life-threatening while 83.0% (6 medical doctors and 33 pharmacists) admitted to the all of the listed options as the important criteria for reporting ADR

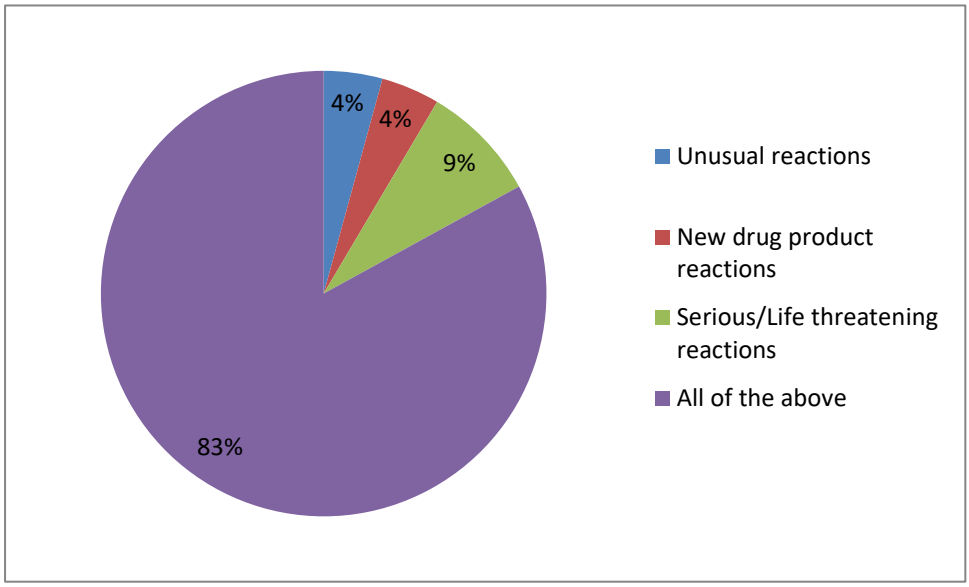


Figure 9b: Criteria for submitting ADR reporting in Ireland.

Comparison:

As depicted from the answers received and chat above from the two regions, it shows that higher percentage of the pharmacist and medical doctors identified their important criteria to that serious/life-threatening reactions, unusual reactions and new drug product reactions as all being important to reporting an ADR in both Ireland and Nigeria.

4.4 Adverse Drug Reaction Reporting based on Awareness and Experience in Ireland and Nigeria. (Q10 to19)

Question 10:

IN NIGERIA:

This study is basically to analyse the HCP that is mainly responsible for reporting ADRs,

62% respondents which represent majority of the HCP, 21.0% respondent admitted to pharmacist being the main person responsible for ADR reporting, 17.0% respondents selected medical doctors.

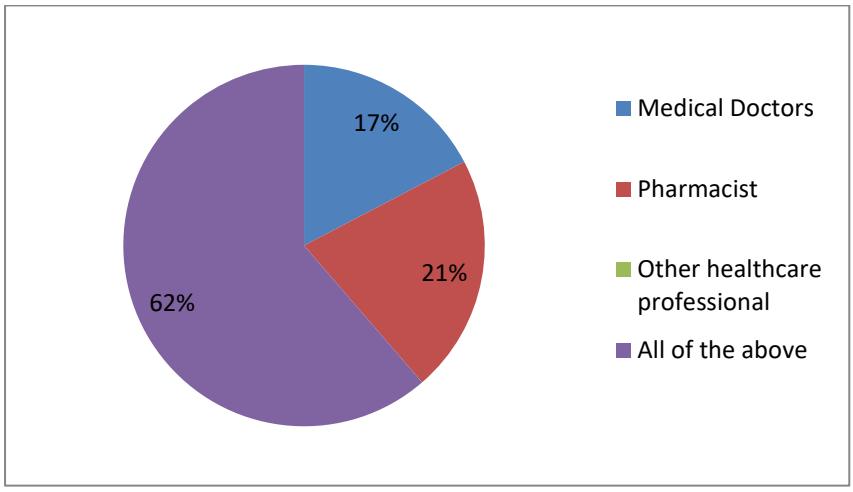


Figure 10a. Who is mainly responsible for ADRs reporting in Nigeria?

IN IRELAND

70% respondents of the respondents admitted to every HCP are responsible for reporting ADRs, 6.0% respondent admitted to pharmacist being the main person responsible for ADR reporting, 24.0% respondents selected medical doctors.

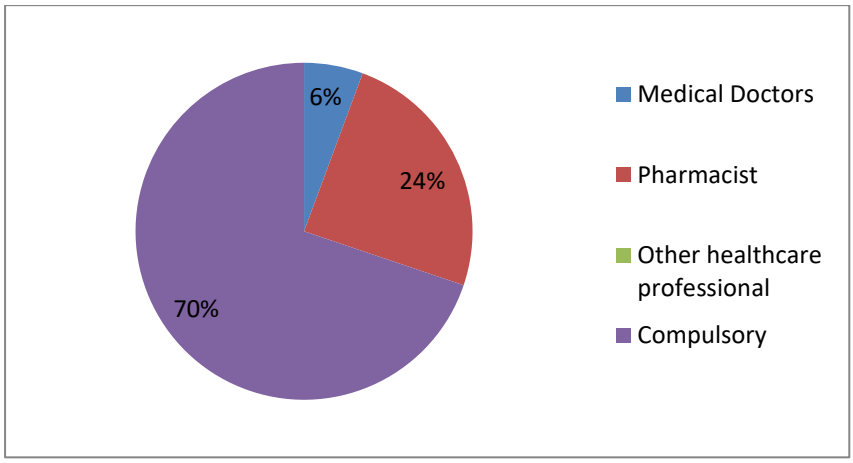


Figure 10b. Who is mainly responsible for ADRs reporting in Nigeria?

Comparison:

From both countries' comparisons, it is interesting to know that both the pharmacists and medical doctors within these two regions identified that any HCP were equally responsible for reporting ADRs within the two regions. Also, when comparing the result of that of the medical doctors and pharmacists within these two regions it shows that many pharmacists still believed that the main responsibility still lies with their profession alone rather than the pharmacist.

Question 11:

An overwhelming 92.0% (30 medical doctors and 39 Pharmacist) of respondents agreed that ADR reporting should be compulsory in Nigeria with only 8.0% (2 medical doctors and 4 pharmacists of the respondents suggested to it been voluntary.

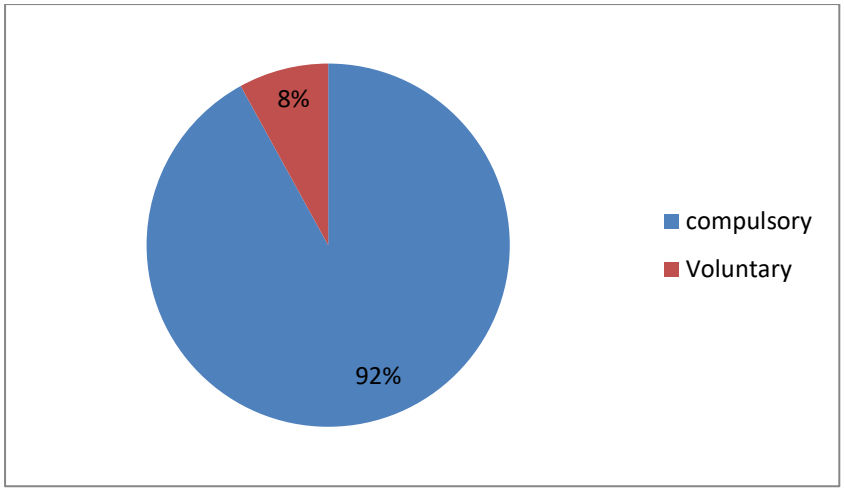


Figure 11a: Should ADR reporting be compulsory or voluntary in Nigeria?

IN IRELAND

An overwhelming outcome of 96.0% (10 medical doctors and 31 Pharmacist) of respondents agreed that ADR reporting should be compulsory in Ireland with only 4.0% (2 medical doctors and 5 pharmacists of the respondents suggested to it been voluntary.

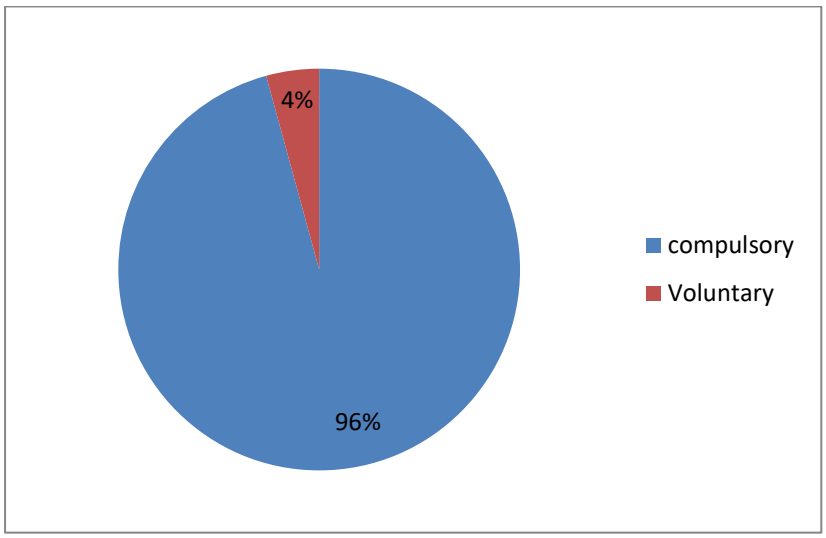


Figure 11b: Should ADR reporting be either compulsory or voluntary in Ireland?

Comparison:

Going by the analysis shown above, it shows that majority of the HCP in both regions clearly would opt for ADR reporting to be compulsory like should be part of the obligation in both countries while the need for ADR reporting is highly favourable.

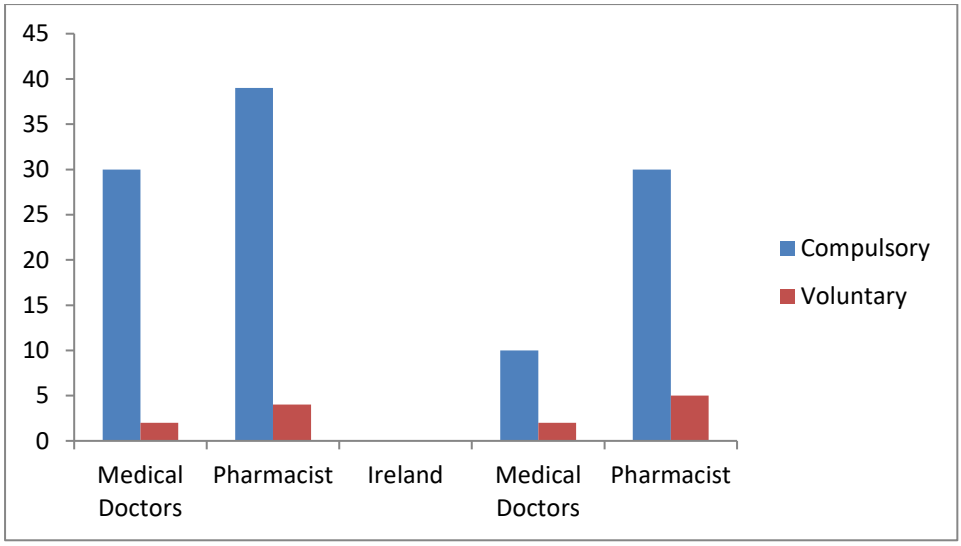


Figure 11C: Comparison of the two countries towards compulsory or voluntary ADR reporting.

Question 12

To determine the level at which ADRs are usually observed among HCP in Nigeria, 62.0% of the respondents (12 medical doctors and 35 pharmacists) admitted to observing ADR within their practice in the past 12 months while 27.0% (12 medical doctors and 8 pharmacists) had not observe any case over the past 12 months, 11% (8 medical doctors and 2 pharmacists) were unsure maybe they have observe ADRs during the past 12 months.

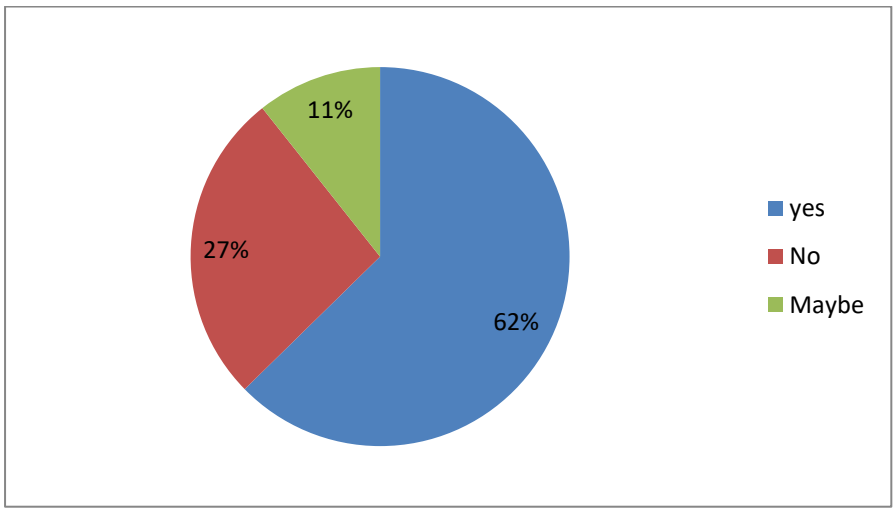


Figure 12a: Have you observed ADR within the past 12 months in Nigeria?

IN IRELAND:

The results in Ireland is very interesting and overwhelming as the level at which ADRs are usually observed among HCP in Ireland, 72.0% of the respondents (7 medical doctors and 27 pharmacists) admitted to observing ADR within their practice in the past 12 months while 28.0% (5 medical doctors and 8 pharmacists) had not observed any case over the past 12 months.

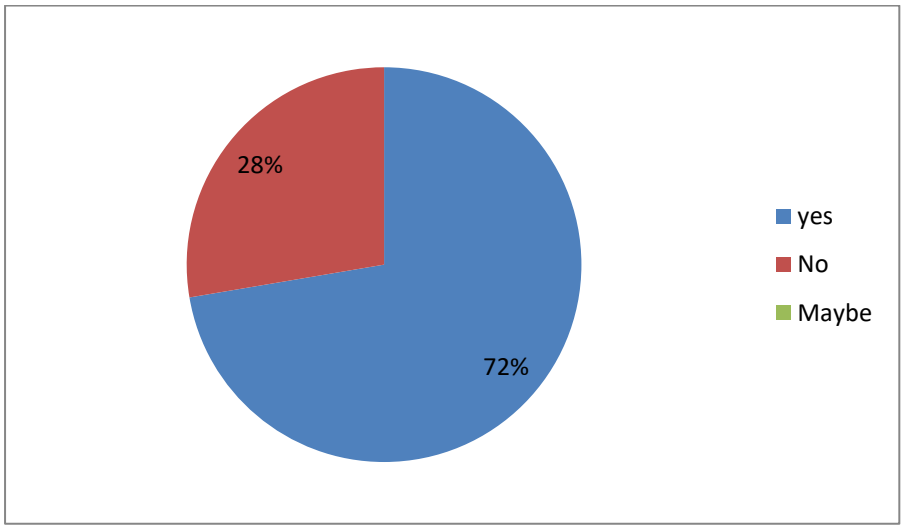


Figure 12b: Have you observed ADR within the past 12 months in Ireland.

Question 13:

To ascertain our result from previous question, will need to know how many ADRs on an average do the HCP observed within same 12 months period.

IN NIGERIA

89.0% (26 medical doctors and 41 pharmacists) of the respondents admitted to them observing less than 25 ADRs within the past 12 months period while the remaining 11.0% (6 medical doctors and 2 pharmacists) respondents admitted to observed 25 more ADRs within the same period.

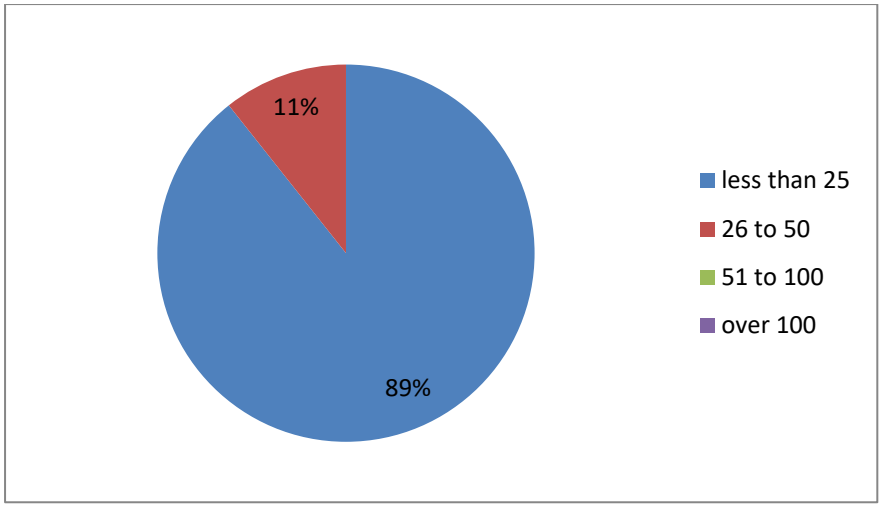


Figure 13a: ADRs observe within 12 months period in Nigeria.

IN IRELAND

87.0% (7 medical doctors and 34 pharmacists) of the respondents admitted to them observing less than 25 ADRs within the past 12 months period while the remaining 13.0% (5 medical doctors and 1 pharmacist) respondents admitted to observed 25 more ADRs within the same period

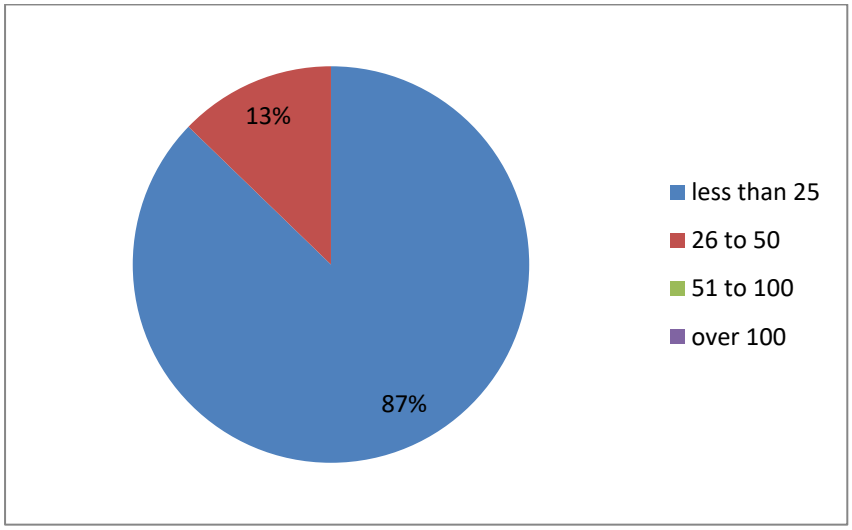


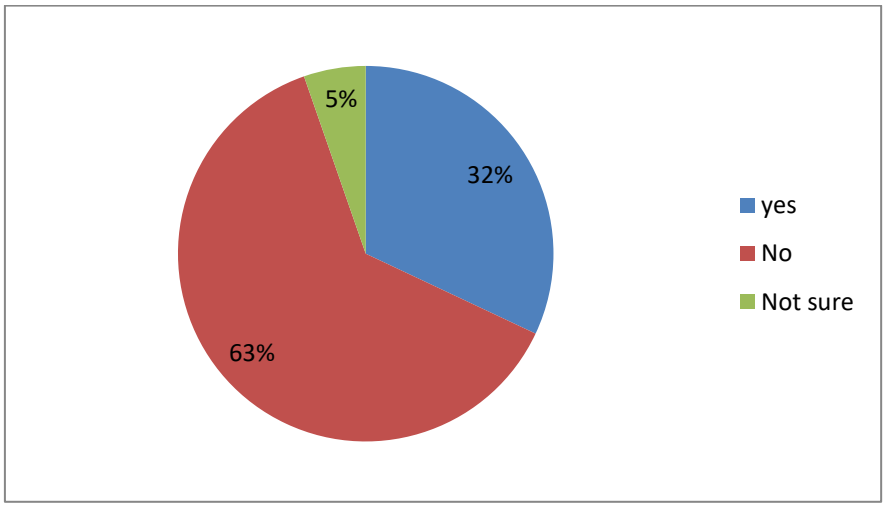
Figure 13b: Average ADRs observed within the past 12 months in Ireland.

Comparison:

From the response from the two regions, it shows there is a high frequency of observation of ADRs in both countries among both healthcare professionals. Besides, the pharmacist seems to observe higher ADRs in their practice compare to the medical doctors.

Question 14:

The most fascinating thing about the respondents here in Nigeria where 32.0% of respondents (6 medical doctors and 18 pharmacist) admitted to only reports ADRs within the past 12 months, considering the facts that there was higher number of HCPs who had observed ADRs in this same time period. While 63.0% of the respondents (24 medical doctors and 23 pharmacist) admitted to not have reported any case of ADRs within this same period and lastly 5.0% of the respondents(2 medical doctors and 2 pharmacists) were unsure of whether they did report a case or not.



14a: Reported an ADR in the past 12 months in Nigeria.

IN IRELAND

55.0% of respondents (10 medical doctors and 16 pharmacists) admitted to only reports ADRs within the past 12 months, considering the facts that there was higher number of HCPs who had observed ADRs in this same time period in Ireland. While 45.0% of the respondents (2 medical doctors and 19 pharmacists) admitted to not have reported any case of ADRs within this same period.

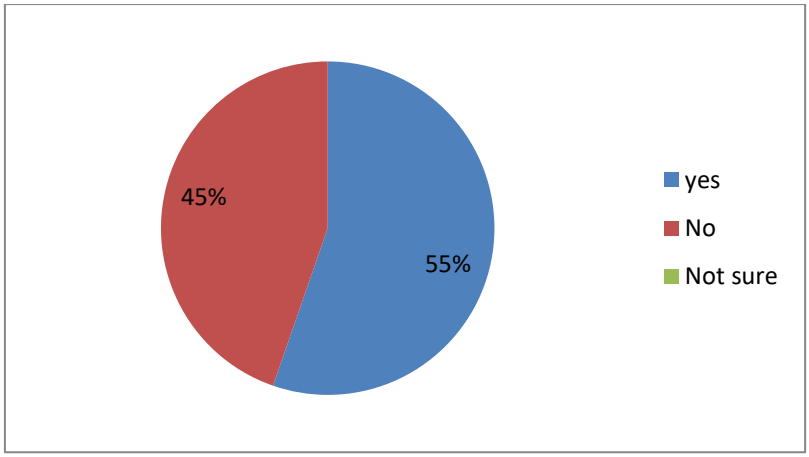


Figure 14b: Reported an ADR in the past 12 months in Ireland

Comparison: There is a big difference in both country cases in term of ADR reported within the past 12 months where Ireland tend to have higher percentage of HCPs who had reported more ADR compare to the other region even though the percentage is still low while Nigeria had higher percentage of HCPs who admitted to not reported any cases of ADR considering the level at which they observe an ADR on average within the same period. See figure below

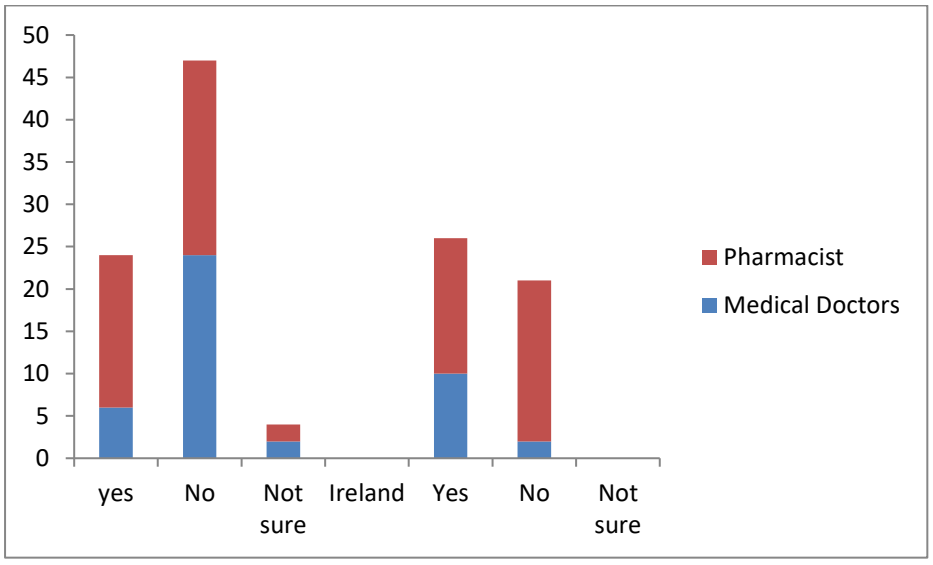


Figure 14C: Comparison by HCPs in both countries towards ADRs reported in the past 12 months.

Q15

From the analysis of number of ADRs reported on the average within the two regions.

IN NIGERIA,

32.0% of respondents (10 medical doctors and 14 pharmacists) admitted to have reported a case of ADR of less than 5 within the time period, 8.0% of respondents (2 medical doctors and 6 pharmacists) agreed to have reported a case between 6 to 10 ADRs within same time period, while we have 5.0% respondents (1 medical doctor 3 pharmacists) who admitted to have a case between 11 to 20 ADRs within same period. Surprisingly, an overwhelming outcome of 55.0% of respondents (19 medical doctors and 20 pharmacists) did not respond to the question. Moreover, it is important to know that no participant admitted to have reported a case more than 20 within the past 12 months according to the survey.

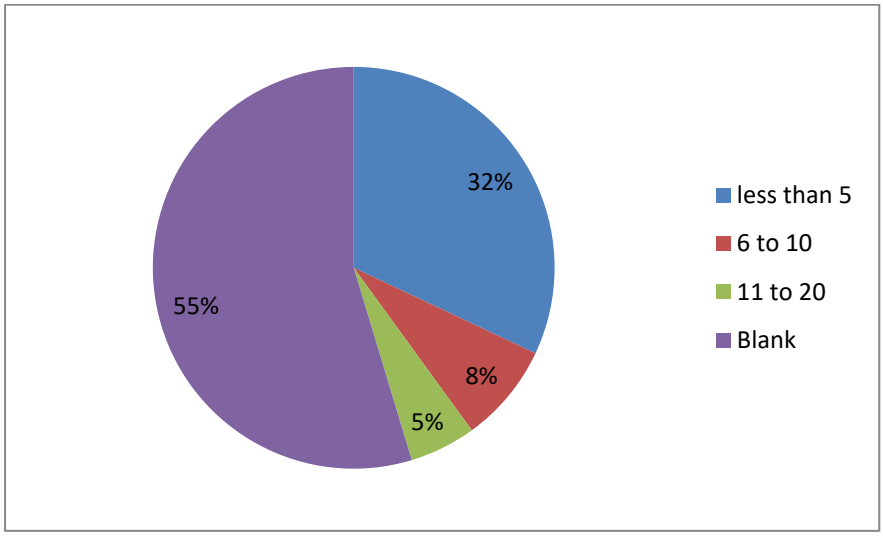


Figure 15a Average ADRs reported in the past 12 months in Nigeria.

IN IRELAND:

An overwhelming results coming from Ireland as 59.0% of respondents (6 medical doctors and 21 pharmacists) admitted to have reported a case of ADR of less than 5 within the time period, 11.0% of respondents (five pharmacists) agreed to have reported a case between 6 to 10 ADRs within same time period, while we have 2.0% respondents (2 pharmacists) who admitted to have a case between 11 to 20 ADRs within same period. Surprisingly, an overwhelming outcome of 28.0% of respondents (6 medical doctors and 7 pharmacists) did not respond to the question. Moreover, it

is important to know that no participant admitted to have reported a case more than 20 within the past 12 months according to the survey.

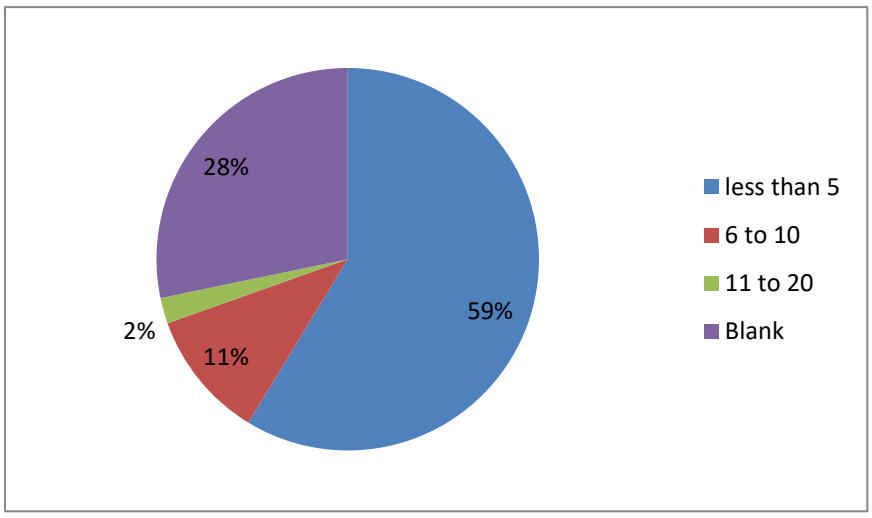


Figure 15b: Average ADRs reported in the past 12 months in Ireland.

Comparison:

The answers from the two region analysis as seen above shows that HCPs in Ireland have less than 5 cases of ADRs compare to the HCPs in Nigeria. In addition, this further strengthens the previous result and fact that most HCPs who admitted to have submitted less ADR reports within that 12 months compared to the number of ADRs observed within that same period.

Question 16:

From all our analysis from the observation to the reporting and submission of ADRs within this two region, this part tend to help us analysis where this report are been submitted to ascertain the previous analysis.

IN NIGERIA:

3.0% of the respondents submitted their ADRs to the nearest pharmacovigilance centre, 16.0% of the respondents submitted to their professional associations while 21.0% of the respondents admitted to reporting to the pharmaceutical company/Drug Manufacture. Surprisingly, the majority of the HCPs who choose 60.0% admitted to submitting to other sources which show a high level of disparity in the survey which would further be established through phone interviews with well experienced HCPs to qualify this research study.

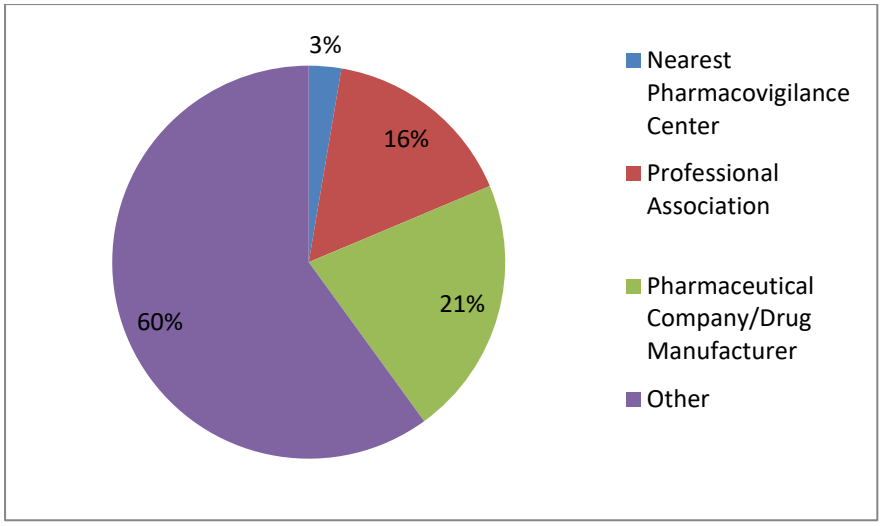


Figure 16a: Who did you submit ADR reports in Nigeria?

IN IRELAND:

An overwhelming 62.0% of the respondents (5 medical doctors and 24 pharmacists) submitted their ADRs to the nearest pharmacovigilance centre, 23.0% of the respondents (4 medical doctors and seven pharmacists) submitted to their professional associations while 15.0% of the respondents(2 medical doctors and 5 pharmacist) admitted to reporting to the pharmaceutical company/Drug Manufacture.

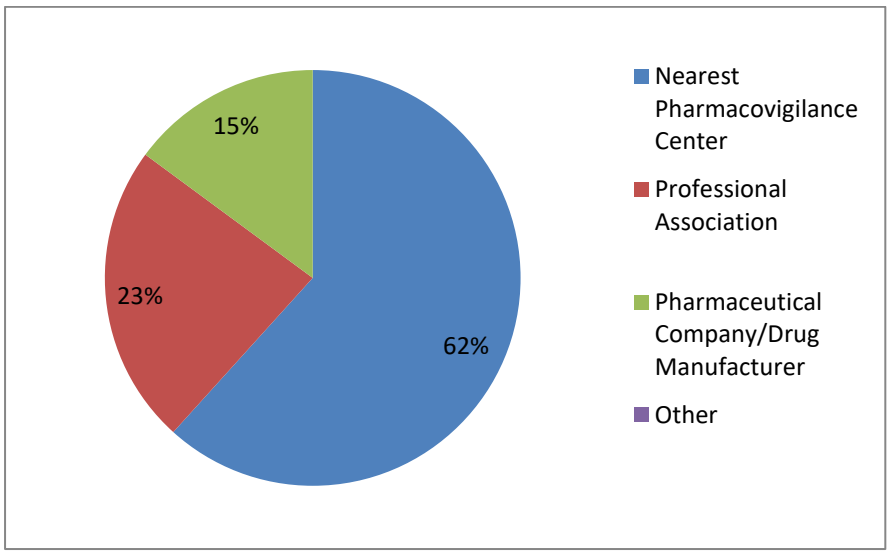


Figure 16b: Who did you submit ADR reports in Ireland?

Comparison:

Surprisingly, the majority of the HCPs who choose 62.0% admitted to submitting to nearest pharmacovigilance centre which show a high level of awareness and

knowledgeable they have towards ADRs reporting in Ireland. Also, pharmacists were more aware of the National Pharmacovigilance Centre in Ireland compare to the HCPs in Nigeria who tend to go with others. See figure below

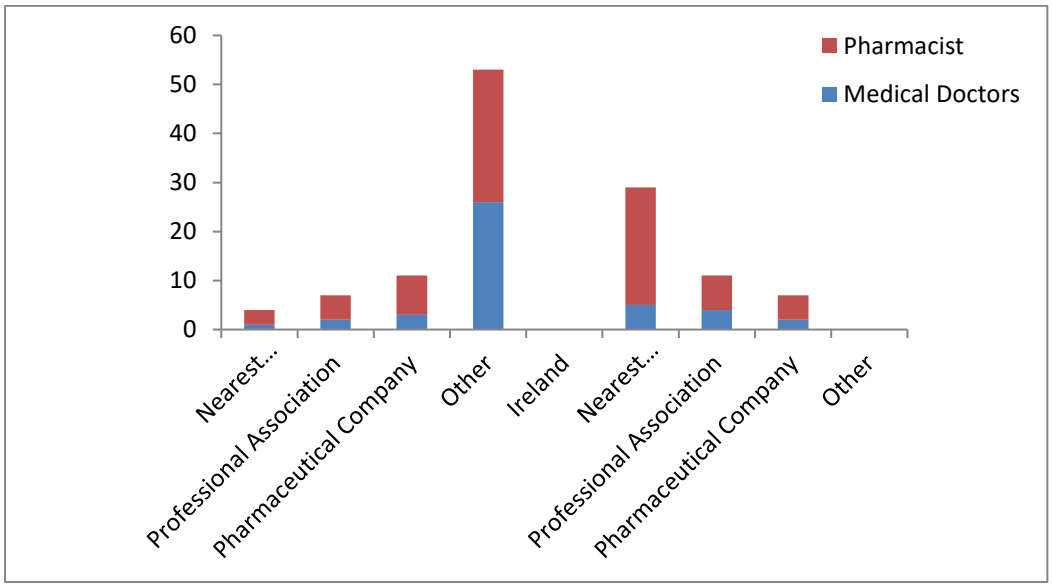


Figure 16C: Comparison of how HCPs from both countries submit ADR reports.

Question 17:

24.0% of the respondents in Nigeria admitted to receiving acknowledgement and feedback on every ADR reported while an overwhelming 76.0% of respondents admitted to not receiving any feedback or acknowledgement on every reports made on ADRs.

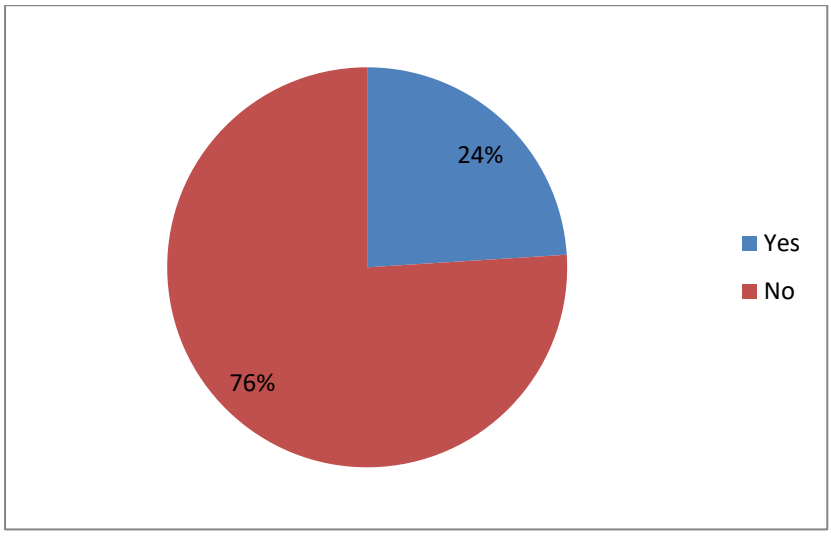


Figure 17a: ADR report acknowledgement or feedback in Nigeria.

IN IRELAND:

68.0% of the respondents (3 medical doctors and 29 pharmacists) in Ireland admitted to receiving acknowledgement and feedback on every ADR reported while an overwhelming 32.0% of respondents(9 medical doctors and 6 pharmacists) admitted to not receiving any feedback or acknowledgement on every reports made on ADRs. See the figure below

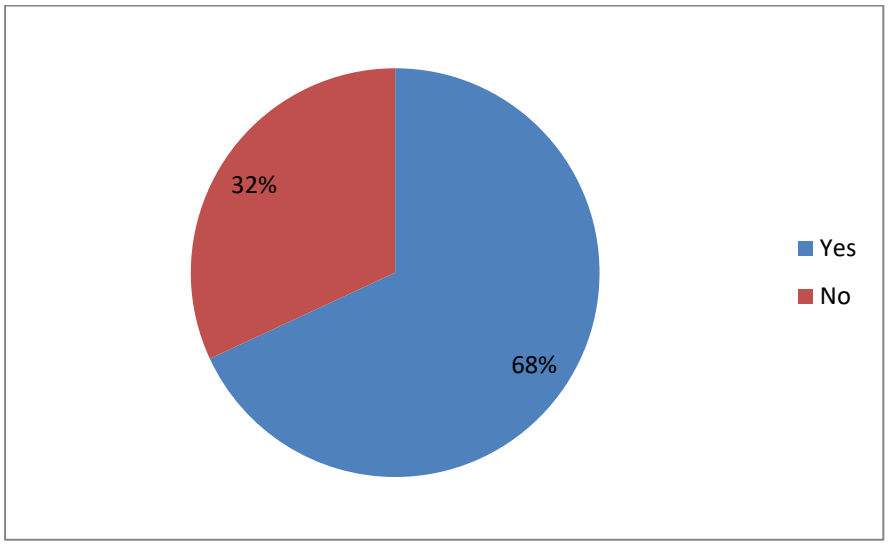


Figure 17b: ADR report acknowledgement or feedback in Ireland.

Comparison:

From the result from Nigeria, it shows that there is poor acknowledgement and follow-up culture among the regulatory authority in charge of handling ADR in Nigeria while there is high level of feedback regulatory authorities in Ireland which sounds like a good cultural attitude among the regulatory body.

Question 18:

This section explains how familiarise are the HCPs towards the guidelines and regulations pertaining to ADR reporting between the two regions.

IN NIGERIA:

83.0% of the respondents (28 medical doctors and 34 pharmacists) admitted to not been familiar with the Nigerian guidelines and regulations pertaining to ADR reporting while 17.0% of the respondents (4 medical doctors and 9 pharmacists) who were familiar with the guidelines and regulations relating to ADR reporting. See the figure below

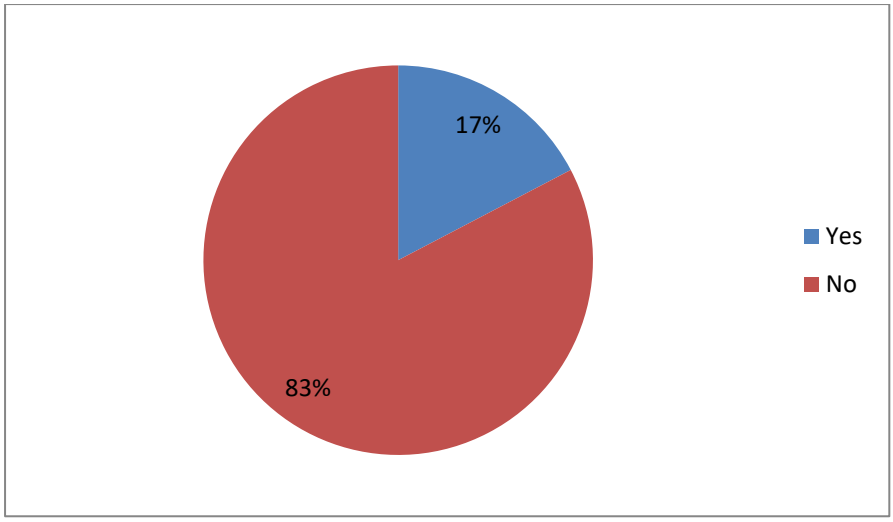


Figure 18a Nigerian guidelines and regulations for ADR reporting

IN IRELAND:

19.0% of the respondents (8 medical doctors and 1 pharmacist) admitted to not been familiar with the Ireland guidelines and regulations pertaining to ADR reporting while 81.0% of the respondents (4 medical doctors and 34 pharmacists) who were familiar with the guidelines and regulations relating to ADR reporting

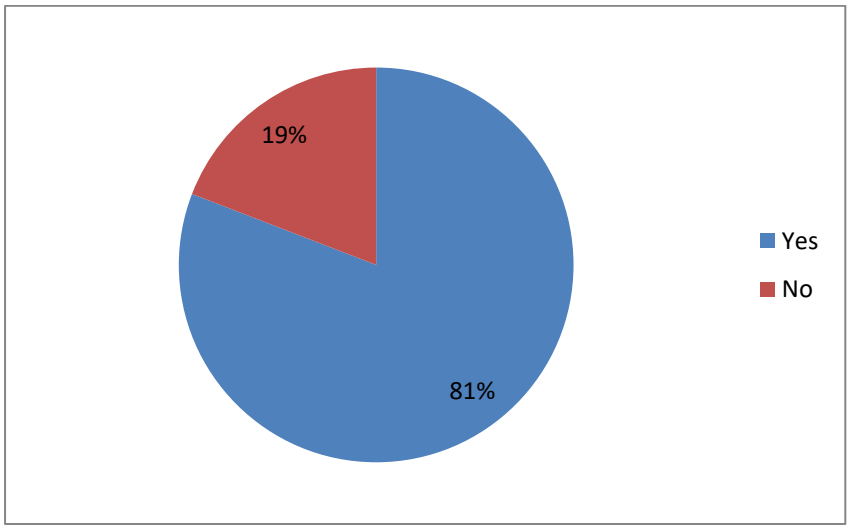


Figure 18b: Ireland guidelines and regulations for ADR reporting.

Comparison:

Analysis the two results from the two regions shows the medical doctors and pharmacists in Nigeria were not familiar with the guidelines and regulations governing ADR reporting within Nigeria while in Ireland the majority of the

healthcare professionals seems to be familiar to the guidelines and regulations governing ADR reporting, the pharmacists edged over the medical doctors in both regions in terms of guidelines and regulations pertaining to ADR reporting.

Question 19:

To support out analysis towards the attitude of the healthcare professionals towards improving their knowledge on ADR reporting in both countries.

IN NIGERIA:

As confirmed from the answers, the medical doctors and pharmacists were both interested in updating themselves in terms of knowledge about ADR reporting despite low level of awareness and guidelines pertaining to ADR in Nigeria. 92.0% of the respondents (28 medical doctors and 34 pharmacists) admitted to updating themselves while the remaining 8.0% of the respondents (4 medical doctors and one pharmacist) would rather not consider that.

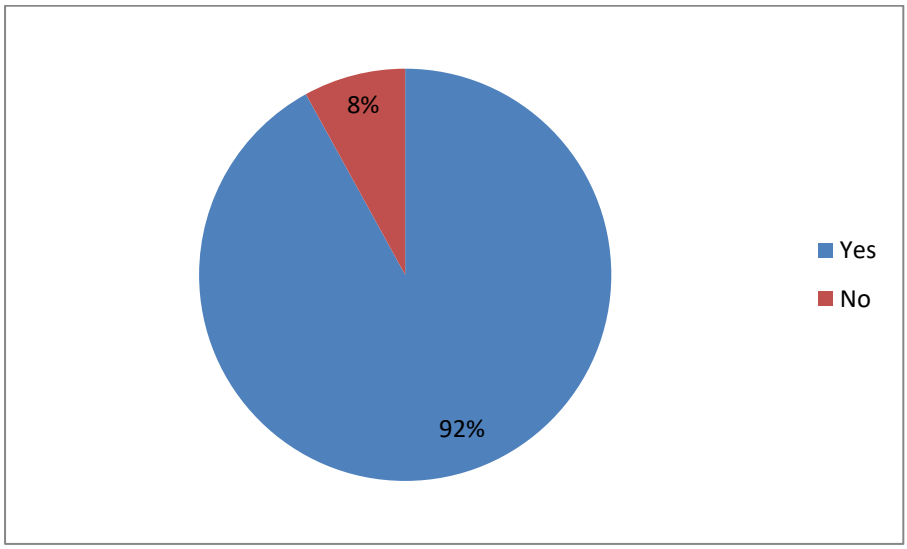


Figure 19a: Updating Knowledge on Nigerian ADR reporting system among HCPs.

IN IRELAND:

Out of the 19.0% respondents who are unfamiliar with the Ireland regulations and guidelines pertaining ADR reporting, 78.0% of the respondents which consist of (3 medical doctors and 4 pharmacists) are ready to update their knowledge while the remaining 22.0% of the respondents (1 medical doctor and 1 pharmacist) are not ready to consider.

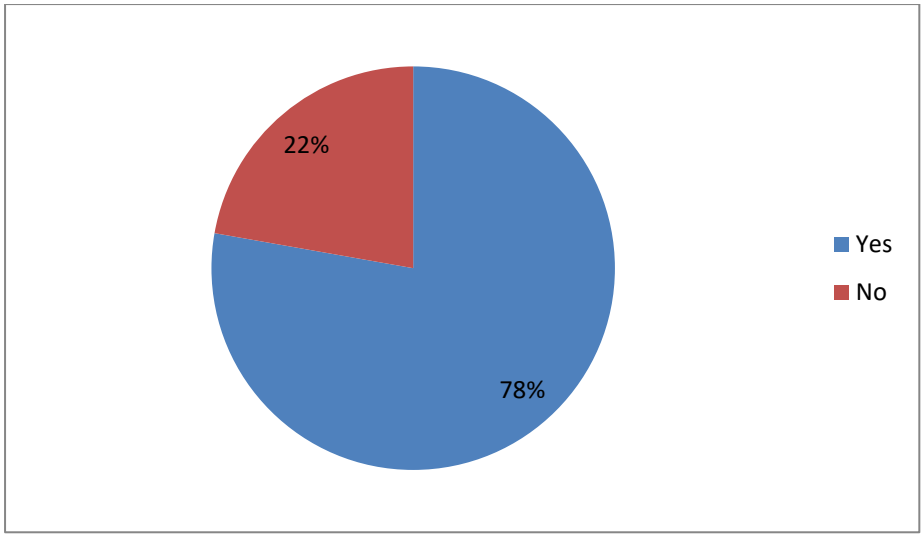


Figure 19b: updating knowledge on Ireland ADR reporting systems.

4.5 Adverse Drug Reaction (ADR) Reporting-Challenges in Nigeria and Ireland (Question 20 i-ix)

Question 20**:**

IN NIGERIA:

This part helps in analysis the challenges among the HCPs in reporting ADRs in Nigeria, options are given to the respondents to best ascertain their opinion in related to the subject while the author hope to gain more insightful knowledge and position of Medical doctors and Pharmacists in Nigeria on factors that pose as a challenge which they either agree, disagree or neutral about it.

75.0% of the respondents in Nigeria agreed that too busy and no enough time to send ADR reports was a factor while 16.0% disagree with 9.0% been neutral about it.

62.0% of the respondents agreed to complex reporting process in Nigeria is one of the major factor, 21.0% are neutral about this with 17.0% of respondents disagree to this.

82.0% of the respondents agreed to not been able to access ADR report form which serves as a challenge for ADR reporting, 12.0% respondents disagreed and 4.0% respondents are neutral.

Surprisingly, 50% of the respondents admitted to the fear of exposure to legal liabilities from patients or drug manufacturers while 33.0% are neutral about it, 17.0% of the respondents disagree with this.

57.0% of the respondents disagree to the concern that ADR report might be wrong, 29.0% are neutral about this with 19.0% agreed that concerns of ADR reporting might be wrong a major challenging factor to ADR reporting.

27.0% of the respondents disagree with the concern of filling an ADR report is an unpaid work, 52.0% are neutral to this while 21.0% agreed to the motive of filling an ADR report is an unpaid work.

36.0% of respondents agreed that the level of knowledge acquired make it difficult to diagnose ADR reporting while 49.0% of respondents disagreed that the level of knowledge does not have effect on ADR reporting and 20.0% of respondents remained neutral.

29.0% of respondents attributed to the fear of negative impact of report and disciplinary queries towards colleagues, 52.0% disagreed with 19.0% respondents staying neutral.

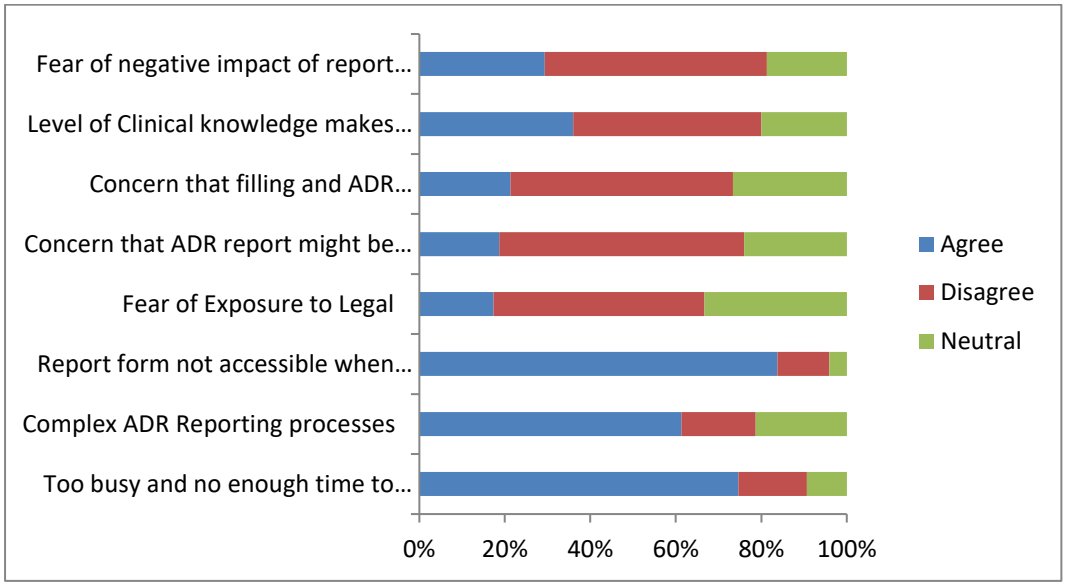


Figure 20a: Challenges among healthcare professionals in reporting ADRs in Nigeria

IN IRELAND

68.0% of the respondents in Nigeria agreed that too busy and no enough time to send ADR reports was a factor while 17.0% disagree with 15.0% been neutral about it.

8.0% of the respondents agreed to complex reporting process in Ireland is one of the major factor, 11.0% are neutral about this with 81.0% of respondents disagree to this.

10.0% of the respondents agreed to not been able to access ADR report form which serves as a challenge for ADR reporting, 79.0% respondents disagreed and 11.0% respondents are neutral.

Surprisingly, 8.0% of the respondents admitted to the fear of exposure to legal liabilities from patients or drug manufacturers while 13.0% are neutral about it, 79.0% of the respondents disagree with this.

87.0% of the respondents disagree to the concern that ADR report might be wrong, 9.0% are neutral about this with 4.0% agreed that concerns of ADR reporting might be wrong a major challenging factor to ADR reporting.

92.0% of the respondents disagree with the concern of filling an ADR report is an unpaid work, 4.0% are neutral to this while 4.0% agreed to the motive of filling an ADR report is an unpaid work.

19.0% of respondents agreed that the level of knowledge acquired make it difficult to diagnose ADR reporting while 60.0% of respondents disagreed that the level of knowledge does not have effect on ADR reporting and 21.0% of respondents remained neutral.

2.0% of respondents attributed to the fear of negative impact of report and disciplinary queries towards colleagues, 94.0% disagreed with 4.0% respondents staying neutral. See figure below

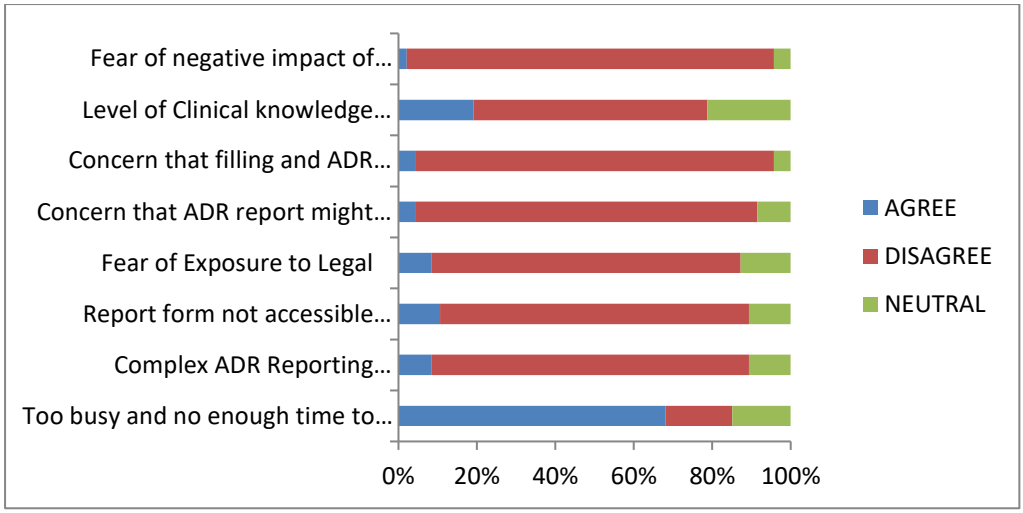


Figure 20b: Challenges among health professional in reporting ADRs reporting in Ireland.

Comparison:

Assessing the two countries challenges facing ADRs reporting among healthcare professionals. From the results above, the three major challenges in Nigeria are: too busy and enough time to send an ADR report, complex adverse drug reaction reporting and lastly report form not easily accessible. While in Ireland the only major challenge they have is being too busy and no enough time to send an ADR report. See table below

	IRELAND	NIGERIA
Too Busy and Enough Time to Send an ADR Report	✓	✓
Complex ADRs Reporting Processes	×	✓
Report Form not Accessible when Needed	×	✓
Fear of Exposure to Legal Liabilities from Patient of Drug Manufacturer	×	×
Concern That ADR Report Might be Wrong	×	×
Concern That Filling an ADR Report is Extra Unpaid Work	×	×
Level of Clinical Knowledge Makes it Difficult to Diagnose an ADR	×	×
Fear of Negative Impact of Report and Disciplinary Queries towards Colleagues	×	×

Table 20c: Similarities and Differences in Challenges faced by HCPs towards ADRs Reporting.

4.6 ADVERSE DRUG REACTION REPORTING-RECOMMENDATIONS

Drawing from the entire dissertation and survey carried out from both side aimed at how the respondents can help provides recommendations proposed to be effective towards improving ADR reporting within the two countries (Nigeria and Ireland).

IN NIGERIA

65.0% of the respondents agreed that pharmacovigilance conferences and continuous education will improve awareness towards effective ADR reporting with just 26.0% of respondents remaining neutral.

91.0 of the respondents agreed that including adverse drug reaction reporting courses and modules to professional training would be effective towards ADR reporting while 9.0% of the respondents decided to be neutral.

96.0% of the respondents agreed to the review of current regulations to make ADR reporting a professional obligation among healthcare professionals while 4.0% are neutral about it.

74.0% of the respondents agreed to incorporate remuneration for every ADR case reported to encourage good pharmacovigilance practices among healthcare professionals, 12.0 of respondents disagree and 14.0% of the respondents are neutral about it.

97.0% of the respondents agreed to increasing publicity of ADR reports schemes in local healthcare journals would be effective towards improving ADR reporting while 3.0% are neutral about it.

88.0% of the respondents agreed that establishing an ADR department headed by an ADR specialist to encourage drug safety practices in health institution towards ADR reporting in Nigeria while 12.0% remained neutral…See figure below

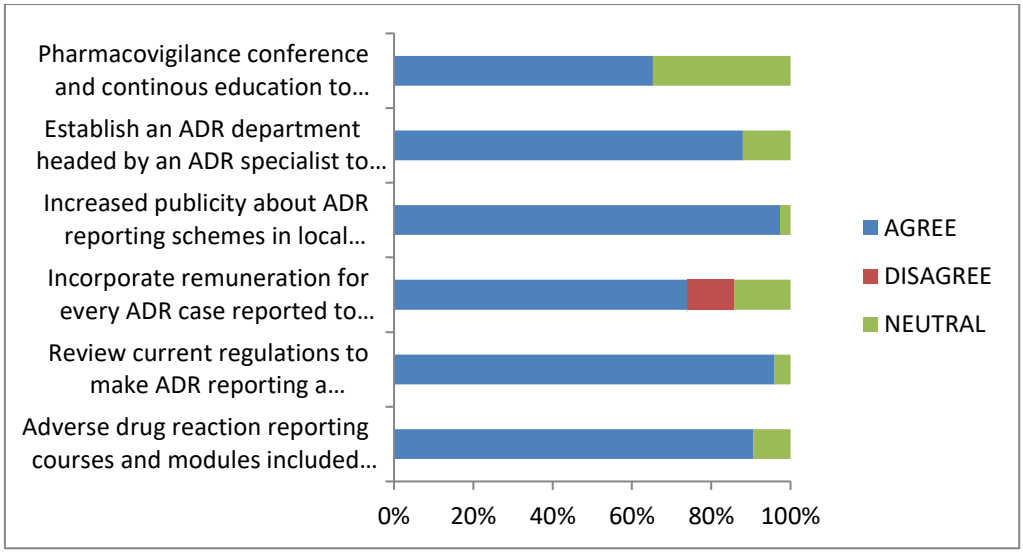


Figure 20c: Effective recommendations to improve ADR reporting among healthcare professionals In Nigeria

IN IRELAND

71.0% of the respondents agreed that pharmacovigilance conferences and continuous education will improve awareness towards effective ADR reporting with just 23.0% of respondents remaining neutral.

98.0 of the respondents agreed that including adverse drug reaction reporting courses and modules to professional training would be effective towards ADR reporting while 2.0% of the respondents decided to be neutral.

83.0% of the respondents agreed to the review of current regulations to make ADR reporting a professional obligation among healthcare professionals while 17.0% are neutral about it.

6.0% of the respondents agreed to incorporate remuneration for every ADR case reported to encourage good pharmacovigilance practices among healthcare professionals while surprisingly 68.0 of respondents disagree and 26.0% of the respondents are neutral about it.

79.0% of the respondents agreed to increasing publicity of ADR reports schemes in local healthcare journals would be effective towards improving ADR reporting while 21.0% are neutral about it.

58.0% of the respondents agreed that establishing an ADR department headed by an ADR specialist to encourage drug safety practices in health institution towards ADR reporting in Nigeria, 4.0% disagree and 38.0% remained neutral.

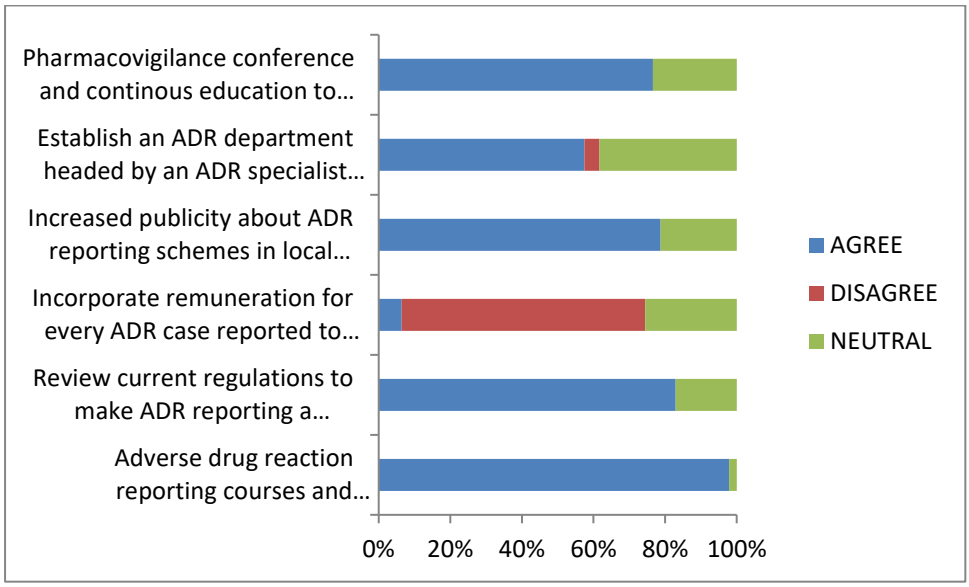


Figure 20d: Effective recommendations to improve ADR reporting among healthcare professionals In Ireland.

	IRELAND	NIGERIA
Adverse Drug Reaction Reporting Courses and Modules Included during Professional Training to Improve Knowledge	✓	✓
Review Current Regulations to Make ADR Reporting A Professional Obligation Among Healthcare Professionals	✓	✓
Incorporate Remuneration for Every ADR Case Reported to Encourage Good Pharmacovigilance Practices Among Healthcare P	×	✓
Increased Publicity About ADR Reporting Schemes In Local Healthcare Journal	✓	✓
Establish an ADR Department Headed By An ADR Specialist to Encourage Drug Safety Practices In Health Institution	✓	✓

Table 20D: Comparison of Effective Recommendations to Improve ADR reporting among healthcare professionals in Nigeria and Ireland.

4.7 Qualitative Analysis:

4.7.1 Comparison of phone Interview with two highly experienced medical doctors from Nigeria and one medical doctor from Ireland (Over 7yrs of experience respectively)

The author explored the opportunity giving to him by the Director of computing and Information technology department at the University College Hospital to reach out to two medical doctors (internal consultants) who I then explore their opinion, perceptions towards ADR reporting in Nigeria and what can be done in terms of challenges faced by medical doctors towards ADRs reporting which their consent for the interview was based on an anonymous.

The two specialists observed an average of 15 ADRs over the past 1 year (12 months) but never make any effort of submitting any ADR reports because the once they have submitted over the years never had any impact on the management of the patient rather they prefer to ignore. Also, they also agreed that they never get feedbacks or updates in related to the previous reported cases and while some rather come late due to the regulatory inactiveness of ADR reporting in Nigeria.

Surprisingly, the two medical doctors were not aware of any ADR e-reporting form available on the website and only one person is aware of national pharmacovigilance situated at the geopolitical zone while only one specialist admitted to having access to yellow cards or ADR forms which can be tedious at times getting them from Director Office due to protocols.

More so, the author asked the specialist about the gap observed from the survey where most young respondents with less than five years' experience admitted to other option about where they submit their ADR reports. They explained to the fact that most young doctors tend to submit to senior colleagues as a result of cultural practice among medical practitioner where the hierarchy is a key factor and why most young doctors are unaware of their responsibilities to directly report to the agency in charge of ADRs.

Furthermore, the specialists also admitted to the review of the entire process of ADR reporting so as to encourage healthcare professionals towards active reporting while also recommending more educational programs like seminars within each place and the importance of ADR reporting while also making suggestion of incentives to help encourage the younger professionals to report ADRs.

The medical doctor from Ireland (Over 5 years of experience) when this was discussed with him about the analysis on doctors being too busy and no enough time to report an ADR reports as the majority agreed to this from the survey, which he did agreed to the analysis while stating that there the responsibility actually lies on the pharmacist to report an ADR reaction although agreed that doctors can also report any form of ADR. Also, the author ask about if incentives are added maybe it will encourage the doctors but the specialist responded with an interestingly answer which is far more different from that of the Nigerian Specialist which he states in his opinion ''this would act as an inducement, and anything involving remuneration would compromise integrity which is unethical''.

4.7.2 Comparison of phone interview with highly experienced pharmacists in Nigeria and Ireland (Over 5 to 7years experience).

The author utilized the same platform he was giving by the head of information and technology at the University College Hospital to speak to three experienced pharmacists over 45 years above while their opinion on ADRs among Nigerian pharmacists which they all gave an impressive answer with the agreement of all the information obtained will be under anonymity.

In Nigeria, the pharmacists all understood the importance of pharmacovigilance and have the necessary knowledge of ADRs reporting but admitted to poor performance of the practices among colleagues due to most cases observed had been reported over time and as a results of no response and feedback from the regulatory authorities still makes ADRs under reporting. In addition, they admitted to observing ADRs in their respective practices but accepted to never report any case over the past 12 months. Also, they are aware of the regulatory authorities responsible for handling pharmacovigilance and ADRs.

Furthermore, the pharmacists also explained the reason behind high rates of ADR observed among HCPs in Nigeria which they claim was as a result of easy accessibility of drugs in pharmacies where most patients and people can purchase self-medications without prescription while most pharmacist tend to assume the role of the medical doctors due to lesser cost and as a result lead to less report of ADRs reporting. Another major controversy is the inaccessibility of the yellow cards when needed and unfamiliarity of the ADR E-reporting.

They all recommend incentives and awareness to improve ADR reporting while also suggestion obligations towards ADRs reporting to improve the attitudes and culture among healthcare professionals.

IN IRELAND

The author was only able to talk to the community pharmacist due to the present pandemic outbreak which they all accepted to more awareness still needs to continue and culture obligation need still need to be put in place for effective ADRs reporting.

In comparison, the Ireland pharmacists declined to incentives towards improving ADRs among pharmacist as they see this as an inducement which will compromise the ethics of their job.

CHAPTER 5: CONCLUSIONS

As from the analysis presented above, it has shown that majority of the medical doctors and pharmacists in Nigeria have very low level (average) knowledge of ADR reporting in Nigeria compare to healthcare professionals (medical doctors and Pharmacists) in Ireland who seems to have a high knowledge of awareness and reporting of ADRs. Although, both countries HCPs identify correctly with ADRs and the criteria considering in reporting a case whether unusual, serious or new drug development reactions. In addition, the need for cultural practice among the HCPs in Nigeria towards an effective reporting system while not depending on incentives to get a case reported as this will induce the integrity of the report and professionals as stated by the Irish Healthcare Professionals.

However, this brought the need of the role of NAFDAC through the national Pharmacovigilance Centre to raise up their responsibility of raising awareness, providing and encouraging better drug monitoring and safety practice among the HCPs in Nigeria as it is been done with the Health Product Regulatory Authority of Irelands .

Moreover, the HCPs tend to be well knowledgeable about guidelines and regulations concerning ADRs in Ireland compare to HCPs in Nigeria where only few are even aware of the availability of ADR E-reporting on the NAFDAC website and this is due to negligence of previous reports that has not gotten a feedback or a follow up and this has resulted to poor reporting rates in medical doctors and pharmacists who are expected to be the primary reporters of ADRs.

Furthermore, during my phone conversation with the pharmacists they also lay emphasis on easy access to drug prescription over the counter as being the major factor causing poor ADRs reporting.

Finally, this study finally lay down the facts that both medical doctors and pharmacists challenges are different from each other. Although they tend to agree to ADR reporting should be made compulsory in both Nigeria and Ireland while both countries recommendation provided both received a high rates for approval among both groups of healthcare professionals except the part of incorporation of remuneration foe every ADR case reported to encourage good pharmacovigilance practices among healthcare profession which the Ireland HCPs are against as they see it as an inducement which is unethical rather ADRs reporting should be part our every HCPs culture.

5.1 The five main research questions:

Question 1: ***Are the healthcare professionals aware of ADR reporting system methods and their responsibility towards good pharmacovigilance practice in Nigeria and Ireland?***

From the study carried out by the author and based on qualitative analysis with highly experienced medical doctors and pharmacists, it shows that the HCPs from Ireland have a high level of awareness and knowledge compare to their counterparts' professionals from Nigeria who happens to be above average towards ADRs reporting within their territory. The Ireland HCPs tend to gain their awareness actually varies across professionals textbooks and journals, verbal communication among colleagues and Newsletter from regulatory agencies compare the Nigeria HCPs who gain their awareness mostly from professional textbooks and journals.

However, the responsibility of promoting awareness of ADR reporting by the National Pharmacovigilance Centre under the structure of National food and drugs administration and control (NAFDAC) still shows a high level of gap base on the author research compare to their counterparts regulatory authority in Ireland, where the majority of the HCPs recognized with the Health Products Regulatory Authority even though both HCPs from the region still wanted regular awareness of pharmacovigilance programs and getting feedback in order the bridge the gap affecting under reporting of ADRs reporting in Nigeria.

Question 2: What factors pose as challenges to ADR reporting in Nigeria and Ireland?

As proven from the quantitative and qualitative analysis carried out from the above research, both HCPs from Nigeria and Ireland agreed to the global factors causing under reporting which includes inadequate healthcare resources, lack of proper staff training, long hours of work with limited staff numbers in healthcare institutions.

Besides, the inaccessibility of ADR forms when needed by the HCPs from Nigeria make it more difficult to encourage ADRs reporting, regulatory failure towards not providing feedback on time and the complex reporting process contribute to low ADR reports. However, the counterpart HCPs from Ireland are doing better in this field even though more still need to be done to be able to achieve an optimum level of ADRs reporting within the two regions.

3. What is the level of awareness among healthcare professionals in Ireland and Nigeria in relation to ADR announcements?

The level of awareness among the HCPs in Nigeria is very poor which has resulted in under reporting of ADRs. However the National Pharmacovigilance Centre under the leadership of the National Agency for Food and Drugs Administration needs to step up their awareness promotion in Nigeria so has to cover up the awareness challenges faced by the HCPs by providing a well-structured ADR reporting system with an established guidelines to make it effective. In Ireland, the HCPs show a high level of awareness by recognizing easily with the reporting system and with the regulatory in charge of ADRs reporting.

4. What are the similarities and differences towards ADRs reporting among HCPs in Nigeria and Ireland?

The major and only similarity the HCPs from both regions agreed on is too busy and no enough time to report an ADR case. Besides, the HCPs from Nigeria still attributed to other factors that contributed to under reporting among HCPs which includes fear of exposure to legal liabilities, concern that filling ADR report is extra unpaid work, Concern that ADR report might be wrong.

5. What recommendations would help to improve ADR reporting among healthcare professionals in Ireland and Nigeria?

From the study above, HCPs from both regions attributed to under reporting with HCPs having a high stake on this compare to their counterpart HCPs from the other region but both end up agreeing to improvement and recommendations that need to take place to better improve ADRs reporting. The factors are attributed to poor training of staff, limited staff numbers within the community and healthcare institutions. Also, the accessibility of ADRs form need to be fixed while having a proactive regulatory authority that provide feedback on time, easy ADR reporting processes to avoid under reporting among HCPs from both region as against what was stated in the study.

Furthermore, the pharmacists from both region seemingly more knowledgeable than the medical doctors from both regions, ADRs reporting regulation and guidelines should be review and adequately implemented to improve reporting especially within the Nigeria HCPs. Also, both HCPs from Nigeria and Ireland agreed to organising conference, continuous training and awareness programs to better

improve ADR reporting while proving accessibility of reporting methods to the professionals.

Surprisingly, HCPs from both regions agreed to the review of the current regulations pertaining ADR reporting while also making it obligatory among HCPs. Establishment of ADR department at every healthcare institution should be encourage so as to foster better drug monitoring and safety within these institutions. Incorporation of remuneration for every ADR report submitted was encourage and met by majority of the HCPs from Nigeria while the Ireland HCPs disagree and during my phone interview to further justify this they all subjected to the fact that it may act as an inducement which would compromise the integrity and ethics of the work. While the author actually believes that incorporating an incentives may have a side effect on the ADR reports in Nigeria considering the regularly observed cases there rather it should be in form of recognition and awards rather than financial reimbursements in order to improve pharmacovigilance within this two regions and most especially Nigeria.

5.2 Comparing and contrasting of results from both primary and secondary research.

From our study above, it shows that both HCPs from Nigeria and Ireland have an above knowledge of ADR reporting which is encouraging when compared to similar studies from the author literature review. In addition, both HCPs from the two regions are willing to update their knowledge which is highly remarkable as a positive attitude and culture towards the subject. However, poor awareness towards guidelines and regulations pertaining to ADR reporting and the underutilization of the ADR e-reporting form within Nigeria has make it very difficult towards having an effective ADR reporting when compare to their counterpart country who have more effective ADR reporting system. Although under reporting remain a global challenge but varied across regions reason while there is a big disparity among the two countries studied and some factors associated with these are inaccessibility of reporting methods, lack of awareness and knowledge of ADRs reporting procedures which are same to those observed within the two regions and most especially Nigeria. The studies are noted in the previous studies of high mobility and mortality rates in Nigeria.(Fadare et al., 2011), and that of the knowledge of ADRs reporting among HCPs in Ireland.(O'Callaghan et al., 2018)

Moreover, this study also shows that Pharmacist are more seen to favourable help improve the outcomes regarding ADR reporting than their medical doctors because they have better knowledge in relation to ADRs reporting and easily recognized with the national pharmacovigilance centre within their regions with better work time and less busy schedules compare to medical doctors and this will enable them submit ADR reports more often. Although both groups admitted to inaccessibility of reporting methods most especially in Nigeria compare to their counterpart in Ireland which present as a challenging factor towards good reporting practices.(Oshikoya and Awobusuyi, 2009)

Furthermore, in improving ADRs reporting in Nigeria would greatly help reduce the running cost within the healthcare sector and reducing mortality rates as well which is related to theme through previous studies so as to encourage more awareness and education among the HCPs within this region. However, the regulatory body also have a role to play in sensitizing the HCPs towards good pharmacovigilance has the developing world are really lacking behind as compare to the western countries. The effort of the Health Product Regulatory Authority (HPRA) has been highly commendable towards awareness, knowledge resources and e-reporting as an alternative on their website. As suggested, HCPs from the both countries still agreed on reviewing of the regulations and guidelines guiding ADRs reporting while also making it an obligatory for HCPs within the region. While financial incentives as suggested sounds as an inducement which will compromise the integrity of the work, rather professional recognition could be encourage towards implementing an effective ADR reporting practice in Ireland and Nigeria.(Opadeyi et al., 2019)

5.3 Concluding Thoughts

5.3.1 Contributions and limitations of the Research.

The research has been moderately adequate having generated data from questionnaires from HCPs from two different countries amounting to one hundred and twenty-two respondents (75 and 47 respondents from Nigeria and Ireland respectively) despite the relatively limited available time and pandemic outbreak challenges for the study. Data are generated and analyzed based on our research objectives and questions with the use of tables and charts for better interpretation and perception. While most research papers focus on just a particular region with a single group of healthcare professionals but this research study compared two different regions (Nigeria and Ireland) with both medical doctors and pharmacists in one study.

The following limitations are observed during the course of the research which is:

- A relatively small number of respondents from the HCPs from Ireland compare to their counterpart from Nigeria which is understandable to be as a result of the pandemic outbreak.
- There is a small number of responses in terms of highly experienced medical doctors and pharmacists within the two regions.
- Relatively small numbers of highly experienced HCPs were interviewed over the phone due to the pandemic outbreak.
- The personal bias of the respondents and the diverse opinions of a participant who failed to answer some questions from some part of the survey could have affected the outcomes.

The author also believes the challenges facing ADR reporting and pharmacovigilance among our HCPs differs in Nigeria and Ireland as the level of awareness, level of education and economic developments has vastly differed among these two regions (Ireland and Nigeria).

The author contributory factor based on his research and analysis shows that both HCPs from Nigeria and Ireland agreed to the response of too busy and no enough time to send reports while Nigeria HCPs agreed more on the inaccessibility of ADR forms and yellow cards when needed, complex reporting processes and excessively work schedules and time pressure on them. Although the study shows above-average knowledge and positive attitude among HCPs from the both region, more

HCPs from Nigeria still shows more disagreeing responses than expected which leave us to further research.

5.3.2 Recommendations

Further research needs to carried out to cover other healthcare professionals most especially the nurses since they represent a critical part of healthcare professionals so it has to better improve ADRs reporting while a wide range of numbers of HCPs should be considered. The need to also add non-healthcare professionals to improve the reports of ADR as some cases are observed outside medical settings which will further increase the ADR database in Ireland and Nigeria.

Also, the need for the regulatory body to learn from the Ireland regulatory system (HPRA) as the study shows a considerable understanding, knowledge, and awareness among HCPs in this region with a good cultural practice compare to their counterpart from Nigeria.

Besides, the need to address the lack of awareness among HCPs in Nigeria as there is a big gap between them and the Ireland HCPs. Since most HCPs from Nigeria acknowledge to getting their information and understanding of ADRs reporting from professional training, textbooks, or journals with less from regulatory authority considering the voluminous resources on their website compare to their counterpart HCPs from Ireland which all sources are adequately use to improve their awareness and knowledge of ADRs reporting and pharmacovigilance.

Moreover, the need for healthcare institutions and community pharmacists should establish an ADRs specialist within their jurisdiction to better improve the attitudes and cultural practice among HCPs within the two regions which will lead to proper ADRs database records for ADRs observed.

Furthermore, the regulatory bodies have potential challenges faced by them which the needs for questioning and interview to be carried out to further ascertain the challenges faced towards ADRs reporting system and pharmacovigilance model used to achieve their purpose. Besides, the need for other professional bodies like Irish Medical Council, Pharmaceutical Society of Ireland, the medical and dental council of Nigeria, Pharmaceutical Council of Nigeria to all partners with their respective regulatory authorities to help advance ADRs and pharmacovigilance to better improve pharmacovigilance and ADRs reporting.

To wrap it up, the need for National Agency for Food and Drugs who oversee the National Pharmacovigilance Centre in Nigeria to work with the Health Products

Regulatory Authority to better advance pharmacovigilance and ADR reporting in Nigeria in areas of awareness, knowledge, spontaneous reporting model and advance technology towards improvement in ADRs reporting.

5. 4 Final Conclusions and Reflexion.

In concluding the comparative research and analysis on the awareness, knowledge, and challenges of ADR reporting among healthcare professionals in Nigeria and Ireland, with proper literature review across the globe this has been very helpful towards achieving and filling the gaps regarding the perspectives among the two key health professionals within the two regions while also creating ways at which ADR reporting can be optimally achieved in Nigeria as a case study of developing countries.

However, from the literature review, it shows there is a general global crisis of under-reporting rates although above average in the western countries compares to the developing countries. This all falls under a general factor which includes lack of awareness and knowledge, inadequate resources to identify and observe or report potential ADRs. Although, the Nigerian healthcare professionals have an average knowledge of ADRs and the criteria needed to report surprisingly they focus more on knowledge acquisition rather than its cultural practice and implementation.

Moreover, the rate of ADR reporting rates significantly continue to lower within the developing countries and Nigeria as a whole despite the relatively high rates of observation of ADRs in the healthcare institution and this is due to increase in self-medication and increase in healthcare cost within this region as compared to the western countries and Ireland as a country. The need to address the ease of purchasing drugs over the counter without proper prescription from the medical doctors has facilitated ADR prevalence and lack of stringent laws concerning this has resulted in poor implementation of adequate ADRs reporting practices.

Furthermore, the majority of the medical doctors from both regions cited the inaccessibility of yellow cards/ADR forms as when needed and inadequate awareness as the factor behind under-reporting of ADRs within them even though these responsibilities lie solely on the pharmacist.

Finally, HCPs from both regions opted for a review of regulatory regulations and guidelines pertaining to ADRs reporting by ensuring it becomes a cultural practice because the negligence as resulted in an overwhelming unwillingness among medical doctors and pharmacists to improve the drug monitoring and drug safety practice. The author notes that while both Heath Product Regulatory Agency (HPRA) and

National Agency for Food Drug Administration and Control (NAFDAC) have an improved website with numerous resources pertaining pharmacovigilance and proving E- reporting online, the NAFDAC body in charge of pharmacovigilance in Nigeria lacks behind towards educating their healthcare professionals on ADR reporting and creating easy processing system along with awareness to ensure these are fully effective. The Organisation of seminars and continuous education should also be encouraged to help improve ADRs reporting in Nigeria and Ireland.

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Appendix: Survey Questionnaire

ADVERSE DRUG REACTION (ADR) REPORTING IN IRELAND: HEALTHCARE PROFESSIONALS SURVEY

Dear Respondent,

I am Olanrewaju Saheed Jimoh, a post-graduate student of Griffith College Dublin, Ireland. As part of the requirements for the Degree of Masters (MSc) in Pharmaceutical Business and Technology, I am carrying out a research on comparative assessment of current and future pharmacovigilance and Adverse Drugs Reactions in developed Countries and developing countries- A case study of Ireland and Nigeria.

Adverse drug reaction is an unwanted and/or harmful reaction experienced by a patient following drug therapy. According to the World Health Organisation (WHO), it is defined as a response to a medicine which is harmful, unintended and which occurs at doses normally used in human for the prevention, diagnosis or treatment of diseases, or for the modification of physiological function.

Adverse Drug reaction reporting is critical in improving pharmacovigilance in developing countries. This oversees the science and activities that relates to the knowledge, detection, assessment and prevention of adverse events or any drug-related issue.

The survey is made up of 5 sections aimed at collecting information on the participants' demographics, knowledge, awareness, challenges and recommendations for improvement of ADR in Ireland and how we can use this outcomes and survey to improve that of the developing countries.

The privacy of every participant is highly assured as no response will be linked to any participant and will be strictly confidential. All data generated will be handled in line with the General Data Protection Regulation (GDPR).

Thank you for your participation.

Olanrewaju Saheed Jimoh

Telephone: 0899840325

ADVERSE DRUG REACTION (ADR) REPORTING IN IRELAND: Healthcare Professional Survey

DEMOGRAPHICS

1. What is your gender?
    a. Male
    b. Female
    c. Prefer not to say
2. What is your age group?
    a. 18-30
    b. 31-40
    c. 41-50
    d. 51 and above
3. Which healthcare professional is completing the survey?
    a. Medical Doctor
    b. Pharmacist
    c. Other
4. How long have you been practicing in your field?
    a. Less than a year
    b. 1 year to 5 years
    c. 6 years to 10 years
    d. Over 10 years

ADVERSE DRUG REACTION (ADR) REPORTING

KNOWLEDGE

5. Do you know how to report ADRS in Ireland?

a. Yes

b. No

6. If yes, what is your source of knowledge for ADR reporting?

a. Professional textbook and journals

b. Verbal Communication from Colleagues

c. Newsletters from regulatory agencies

d. Internet and Social Media

e. Conference and Workshops

7. Which organisation is responsible for pharmacovigilance and handling ADR reports in Ireland?

a. World Health Organisation

b. Health Products Regulatory Authority

c. Irish Medical Council (IMC)

d. Pharmaceutical Society of Ireland.

8. Which of the following methods of reporting ADRs in Ireland is familiar to you?

a. Yellow Card/ADR forms

b. ADR E-reporting form

c. Both

d. None

9. In your opinion, which is the most important criteria for submitting an ADR reports?

a. Unusual reactions

b. New drug product reaction

c. Serious/Life threatening reactions

d. All of the above

ADVERSE DRUG REACTION (ADR) REPORTING.

Please place a tick beside the answer to each question

AWARENESS

10. In your opinion, who is mainly responsible for reporting ADRs?

a. Medical Doctor

b. Pharmacist

c. Other healthcare Professional

d. All of the above

11. In your opinion, should ADR reporting be either compulsory or voluntary.

a. Compulsory

b. Voluntary

12. Have you observed an adverse drug reaction within your practice in the past 12 months?

a. Yes

b. No

c. Maybe

13. If yes, how many ADRs on average have you observe within the same time period?

a. Less than 25

b. 26 to 50

c. 51 to 100

d. Over 100

14. Have you reported an ADR in the past 12 months?

a. Yes

b. No

c. Not Sure

15. If yes, how many ADR have you reported on average in the same time period?

a. Less than 5

b. 6 to 10

c. 11 to 20

d. More than 20

16. To whom do you submit the adverse drug reaction reports?

a. Nearest Pharmacovigilance Centre

b. Professional Association

c. Pharmaceutical Company/Drug Manufacturer

d. Other (please state)……

17. Did you receive any acknowledgement or feedback for reporting on ADR?

a. Yes

b. No

18. Are you familiar with Ireland regulations and guidelines pertaining to ADR?

a. Yes

b. No

19. If No, would you consider updating your knowledge about Ireland ADR reporting systems?

a. Yes

b. No

ADVERSE DRUG REACTION (ADR) REPORTING

PLEASE INDICATE A, B OR C IN THE BRACKET BELOW TO INDICATE YOUR LEVEL OF AGREEMENT, WHERE:

a. Agree

b. Disagree

c. Neutral

CHALLENGES

20 As a healthcare professional, which of these do you consider as a challenge in reporting ADRs?

- TOO BUSY AND ENOUGH TIME TO SEND AN ADR REPORT ( )
- COMPLEX ADR REPORTING PROCESSES ( ).
- REPORT FORM NOT ACCESSIBLE WHEN NEEDED ( )
- FEAR OF EXPOSURE TO LEGAL LIABILITIES FROM PATIENT OR DRUG MANUFACTURER. ( )
- CONCERN THAT ADR REPORT MIGHT BE WRONG? ( )
- CONCERN THAT FILLING AN ADR REPORT IS EXTRA UNPAID WORK ( )
- LEVEL OF CLINICAL KNOWLEDGE MAKES IT DIFFICULT TO DIAGNOSE AN ADR ( )
- FEAR OF NEGATIVE IMPACT OF REPORT AND DISCIPLINARY QUERIES TOWARDS COLLEAGUES ( )

ADVERSE DRUG REACTION (ADR) REPORTING

PLEASE INDICATE A, B OR C IN THE BRACKET BELOW TO INDICATE YOUR LEVEL OF AGREEMENT, WHERE:

d. Agree

e. Disagree

f. Neutral

IMPROVEMENT

Which recommendation do you consider as effective to improve ADR reporting in Ireland?

- ADVERSE DRUG REACTION REPORTING COURSES AND MODULES INCLUDED DURING PROFESSIONAL TRAINING TO IMPROVE KNOWLEDGE ( )

- REVIEW CURRENT REGULATIONS TO MAKE ADR REPORTING A PROFESSIONAL OBLIGATION AMONG HEALTHCARE PROFESSIONALS. ( )

- INCORPORATE REMUNERATION FOR EVERY ADR CASE REPORTED TO ENCOURAGE GOOD PHARMACOVIGILANCE PRACTICES AMONG HEALTHCARE PROFESSIONALS. ( )

- INCREASED PUBLICITY ABOUT ADR REPORTING SCHEMES IN LOCAL HEALTHCARE JOURNAL ( )

- ESTABLISH AN ADR DEPARTMENT HEADED BY AN ADR SPECIALIST TO ENCOURAGE DRUG SAFETY PRACTICES IN HEALTH INSTITUTION ( )