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SURVEY OF KNOWLEDGE OF PHARMACOVIGILANCE AND ADVERSE DRUG REACTIONS REPORTING AMONG HEALTHCARE PROVIDERS IN ABUJA, NIGERIA

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ABSTRACT

This study aimed to evaluate the general knowledge of healthcare providers regarding pharmacovigilance and reporting adverse drug reactions (ADRs). It also investigated the frequency of encountering patients affected by ADRs in clinical practice and the extent to which healthcare providers reported such cases to the Pharmacovigilance Centre. A cross-sectional descriptive study was conducted using a web-based questionnaire developed with Google Forms as the data management tool. The respondents' data were recorded in spreadsheets and exported for analysis. The study revealed that 54.9% of the respondents had received previous pharmacovigilance training, indicating a positive foundation of knowledge among healthcare providers. Additionally, a high percentage (98%) demonstrated familiarity with the definition of pharmacovigilance, and a considerable majority (80.1%) were aware of the National Pharmacovigilance Centre domiciled at NAFDAC headquarters. Most participants (76%) were also aware of the "yellow form" used for reporting ADRs.

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However, only 36.1% of the participants indicated encountering suspected cases of ADRs in the past year. Among those who encountered ADR cases, more than half observed at least two cases, while a third encountered up to three cases. Unfortunately, the reporting rate to the Pharmacovigilance Centre was low, with only 39.1% of participants reporting such cases. Furthermore, a majority (88.6%) did not receive any feedback after submitting their reports. Additionally, nearly two-thirds of the participants indicated that their practice facilities lacked a designated pharmacovigilance unit. The study identified a significant association between the frequency of ADR occurrence and the practice setting. It also highlighted the significance of training as a determinant of reporting practices among healthcare providers (X2 = 9.897, Df = 1, P<.05). In conclusion, while healthcare providers demonstrated a satisfactory level of knowledge regarding pharmacovigilance, the reporting practices for ADRs were found to be inadequate. This signifies the need for improvement in the reporting system and overall pharmacovigilance practices among healthcare providers.

Keywords: Knowledge, Pharmacovigilance, Adverse drug reactions, Reporting, Healthcare providers

Introduction

A drug is any substance or combination of substances known to have properties capable of treating or preventing diseases in human and animals (Danraka *et al.*, 2021). The role of drugs in disease management is substantial. However, when drugs are administered within their therapeutic dosing regimen, they can produce effects that are unwanted, which may threaten the life of patients. Harmful and unintended effects of drugs are known as Adverse Drug Reactions (ADR) – unwanted action that manifest as part of a drug pharmacological action (Asiamah *et al*., 2022). ADRs are universal challenge of immense concern. Children and adults are affected with relative degree of morbidity and mortality (Asiamah *et al.*, 2022). The incidence of adverse drug reaction has been reported to be about 16.2 %, with 6.5 % of hospitalization directly caused by ADRs (FMOH NNPPIF, 2020). Medicinal products pose safety challenges due to several factors which include the pharmacological activities of the product, the genetic disposition and culture of the patient, the treatment seeking behavior of the patients, (including extensive self - medication), abuse of psychotropic agents, unbridled access to prescription – only medicines, misuse of antibiotics and preference for injections), disease pattern and co – morbidities.

Other factors include drug manufacturing processes, distribution and storage conditions, substandard and falsified medicinal products, and indiscriminate use of traditional, complementary and alternative medicines. (FMOH NNPPIF, 2020). Furthermore, pre – marketing information (i.e., information on adverse reaction available at the time a medicine is registered for use), is usually limited to data obtained from controlled clinical trials, pharmacokinetic and pharmacodynamics studies (FMOH

NNPPIF, 2020); (Opele, Abiala, and Uthman (2022). Generally, only a few patients (< 5000) are studied pre – registration. As a result, only the early and most frequent adverse reactions likely to be detected at the time of registration. Some adverse drug reactions may not be known at the time of registration and can only be detected after the medicine is in use by a larger population of patients (FMOH NNPPIF, 2020). Moreover, safety reports of clinical trials are collated under conditions that are tightly controlled which may not preclude biases secondary to rigid inclusion and exclusion criteria and limited duration of time (Nweze, Awoniyi, Falebita, Familoni & Opele**,** 2023).. For example, the effects of these drugs are often not studied on some members of the population such as children under 5 years, pregnant women and very old. The thrust of pharmacovigilance activity in Nigeria is on creating awareness, and improving the detection and reporting of new ADRs, identifying the rate of increase in frequency of known ADRs, detection of risk factors and potential mechanisms underlying ADRs as well as the valuation of the quantitative aspect of benefit /risk analysis (FMOH NNPPIF, 2020). Pharmacovigilance activities in Nigeria are being coordinated by NAFDAC under the supervision of the Federal Ministry of Health (FMOH NNPPIF, 2020).

Nigerian National Pharmacovigilance Center (NPC) was established in 2004, and affiliated to the WHO international drug monitoring and collaborating center, Uppsala (FMOH NNPPIF, 2020). The Nigerian National Pharmacovigilance Policy and Implementation Framework (NNPPIF) was developed in 2012 and reviewed in 2020. The revised edition of the document integrates recent development and advances in pharmacovigilance in line with global best practices (FMOH NNPPIF, 2020). The policy document considered that; it shall be an ethical and professional responsibility for health professionals (pharmacist, medical doctors, nurses, medical laboratory scientists, and herbal medicine practitioners, or healthcare providers working in public, private and non-governmental sectors) to voluntarily report ADRs, medication error, and lack of efficacy. It is also advisable for consumers to report ADRs in their own interest (FMOH NNPPIF, 2020; Lanre-Ogungbile, Sowunmi, & Opele, 2020).).

For Nigeria to achieve the mission of the Nigerian National Pharmacovigilance Policy and Implementation Framework of 2012 as revised in 2020 which is “to set up an efficient surveillance mechanism for early detection of adverse reactions to medicines and vaccines administered to humans, and other medicines related problems, receive and process reports from a safety conscious population of healthcare providers and consumers and take appropriate measures to prevent or minimize medicine-induced harm” (FMOH NNPPIF, 2020). There must be a conscious effort to generate reliable data on the incidences of (ADRs) in the country and also identify the gaps in reporting, the challenges of spontaneous reporting, and the opportunities therein and to make necessary recommendations that would

strengthen the system and optimize reporting of ADRs by healthcare providers. (Asiamah M *et al*., 2022).

The pharmacovigilance yellow form can be filled by healthcare providers in Nigeria who wish to report ADRs (Danraka *et al.*, 2021), though a number of studies have evaluated the knowledge, attitude and practice of reporting adverse drug reaction in Nigeria (Adedeji *et al*., 2018). A recent study from Abuja by Danraka *et al.*, 2021 only focuses on pharmacist, doctors and nurses in three different hospitals within Abuja Municipal Area Council, excluding healthcare professionals in other area of practice such as community pharmacy, private hospitals and clinics, primary healthcare facilities. And, by limiting the survey to only three hospitals in the Abuja Municipal Area council, healthcare providers in the other five (5) area councils (Kwali area council, Abaji area council, Bwari area council, Kuje area council, and Abaji area council) were generally excluded. There is therefore a need for a wider perspective of the reporting attitude of healthcare providers in Abuja. This research aimed to include the various healthcare professionals practicing across the different settings (Tertiary health facilities, Secondary health facilities, Private hospitals and clinics, and community pharmacist), and across the various area councils.

The outcome of these previous researches on ADR reporting in Nigeria has shown reporting of ADRs has yet to be adequately developed. This suggest a vital need for increased awareness of the significance of ADR reporting in Nigeria (Asiamah M *et al*., 2022). Pharmacovigilance provides an opportunity for post – marketing (real-world) collection of drug efficacy and safety information, by that means, patient's drug – related morbidity and mortality can be reduced. In addition, the financial cost associated with the provision of care for patients affected by such problems is reduced by effective pharmacovigilance, thereby promoting medication safety at various levels of the healthcare system (Garashi *et al*., 2022). To promote patient safety and to support the current efforts aimed at strengthening pharmacovigilance system in Nigeria, it is imperative to assess the existing incidences and reporting rates of adverse drug reactions among healthcare providers (Sowunmi, Lanre-Ogungbile, Owopetu & Opele, 2020). Data generated from this study can provide insight into the challenges responsible for under – reporting of ADRs among Nigerian healthcare providers, this data can be used as basis for further development of strategies, policies and plans for improved public health and medicines safety.

In the early 1900's, an ideal drug was described as a "magic bullet" by a German scientist, Dr. Paul Erlich. Such a drug would be aimed precisely at a disease site and would not harm healthy tissues. Although many new drugs are aimed more accurately than their predecessors, none of them, as of yet, hit the target exclusively (Shalini S. Lynch, 2022). Most drugs produce several effects, but usually only one effect (the therapeutic effect) is

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desired for the treatment of a disorder. The other effects may be regarded as unwanted, whether they are intrinsically harmful or not (Shalini S. Lynch, 2022). Medication errors may occur when; drugs are used incorrectly or irrationally by patients, doctors may prescribed the wrong drug, or the right drug with wrong dose, wrong dosage form, or wrong route of administration, pharmacist may dispense the wrong drug, or wrong dose or wrong dosage form to a patient, caregivers incorrectly read the label of the drug container and administer the inappropriate drug or dose, caregiver administer a drug to the wrong person, improper storage conditions, weakening the drug strength, use of an expired drug, drugs administered concurrently with food when the drug is best absorbed in an empty stomach, or without food when food is needed to prevent side effects (Shalini S. Lynch, 2022). While, drug abuse is the irrational use of a drug for purposes not medically indicated (Charles S. Bockman *et al*., 2017). In Europe, (ADRs) cause a relatively large number of morbidity and mortality (Peter E.A *et al*., 2018). It has been estimated that approximately 5 % of all hospital admissions are caused by ADRs, that 5 % of hospitalized patients will experience an ADR during their stay in the hospital, and that ADRs are responsible for about 197,000 deaths annually throughout the EU (Peter E.A *et al*., 2018). These estimates formed the foundation of a major reform of the European regulatory system for pharmacovigilance, which was implemented in 2012 (Peter E.A *et al*., 2018). ADRs among admitted patients was found to be 6.5 % in the United Kingdom, and admissions related to ADRs cost the National health scheme (HHS) up to £ 466 million annually or 0.6 % of annual budget for health (Peter E.A *et al*., 2018). Moreover, the equivalent of up to seven 800 bed space hospitals may be occupied with patients with ADRs at a particular point in time, which amount to 4 % of hospital bed capacity in the UK. ADRs also increased the duration of hospital stay for admitted patients (Libsuye *et al*., 2021).

Objective of the study

The main objective of this study is to examine the knowledge of pharmacovigilance and adverse drug reactions reporting among healthcare providers in Abuja, Nigeria.

Research questions

This study attempts to provide answers to the following research questions;

1. Do Healthcare Providers have adequate knowledge of pharmacovigilance and ADRs reporting?
2. What is the state of Knowledge of healthcare providers concerning basic pharmacovigilance principles and Adverse Drug Reaction (ADRs) Reporting
3. What is the frequency of occurrence of Adverse Drug Reactions in Abuja, and Practice of Spontaneous Reporting among Healthcare Providers?

Hypothesis

The following hypothesis was formulated at a 0.05 level of significance.

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Ho: There will be no significant association between the perceived training of healthcare providers on basic pharmacovigilance principles and their practice of spontaneous ADRs reporting.

Research Method

This study was conducted in Federal Capital Territory (FCT) Abuja, Nigeria. The city is between latitude 8$^{\theta}$35'' and 9$^{\theta}$25'' North of the equator and longitude 6$^{\theta}$ 45'' and 7$^{\theta}$ 45'' East of the Greenwich Meridian with a land area of 8000 sq. km (Obeta S.S *et al.*, 2020). It is bordered to the North by Kaduna state, East by Nasarawa state, South by Kogi state; and to the West by Niger state respectively. Abuja has six area councils namely; Abaji, Bwari, Gwagwalada, Kuje, Kwali and Abuja Municipal Area Council (AMAC) (Obeta S.S *et al.*, 2020). The current metro area population of Abuja has been estimated by http;//www.macrotrends.net to be about 3,652,000 as at August, 2022 with an estimated growth rate of 5.43 %. This, mean that the quoted population access healthcare services from the tertiary health facilities, secondary health facilities, primary healthcare facilities, private clinics and community pharmacy within the city. Like other urban settlements in Nigeria, and, being the federal capital territory, there are a large number of healthcare professionals providing healthcare services in the different health sectors within the metropolis and professional best practices are expected. This actually informed our choice of Abuja to carry out this study. A descriptive, cross – sectional survey was conducted using a web-based (Google Survey) recruitment method. A well-structured self – administered questionnaire was administered to a convenient sample of healthcare professionals in Abuja through social media. Cross – sectional studies most often use to label the particular feature that prevail in certain community, but not to conclude cause and effect associations between different variables.

Presentation of Results

Research question one: Do Healthcare Providers have adequate knowledge of pharmacovigilance and ADRs reporting?

Table 1: General Knowledge of Basic Pharmacovigilance Principles and Adverse Drug Reaction (ADRs) Reporting.

Parameters	Classification	Frequency	Percentage
Ever received any training on pharmacovigilance and adverse drug reaction reporting	No	190	45.1
	Yes	231	54.9
	Total	421	100.0
The word "pharmacovigilance" can be defined as the science and activities relating to detection, assessment, understanding and prevention of adverse effects of drug or other possible drug related problems	No	8	1.9
	Yes	413	98.1
	Total	421	100.0
Aware of any drug that has been banned from use due to Adverse Drug Reaction (ADR)	No	22.6	22.6
	Yes	77.4	77.4
	Total	100.0	100.0
The most important purpose of pharmacovigilance is to assess safety of drugs and to identify previously unrecognized ADRs	No	8	1.9
	Yes	413	98.1

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	Total	421	100.0
Do you believe that all drugs available in the market are safe and effective?	No	392	93.1
	Yes	29	6.9
	Total	421	100.0
Are you aware that there is a National Pharmacovigilance Centre domiciled in NAFDAC headquarters?	No	81	19.2
	Yes	340	80.8
	Total	421	100.0

Table 1 indicates that participants have good knowledge of basic pharmacovigilance principles and Adverse Drug Reactions reporting. More than half (54.9 %) of the participants have received previous trainings on pharmacovigilance and Adverse Drug Reaction reporting. Almost all the participants (98.1 %) knew the widely accepted definition of "Pharmacovigilance", more than two third (77.4 %) were aware of some drugs that have been banned from use due to Adverse Drug Reaction (ADR). Furthermore, almost all the participants (98.1 %) recognized that 'the most important purpose of pharmacovigilance is to assess safety of drugs and to identify previously unrecognized ADRs' and about 93.1 % do not believe that "all drugs in the market are safe and effective". Lastly, only about a quarter (19.2 %) of the participant is not aware that there is a National Pharmacovigilance Centre Domiciled at NAFDAC headquarter.

Table 2: Healthcare Provider's General Knowledge of Pharmacovigilance and Adverse Drug Reaction (ADRS) Reporting

Parameters	Classification	Frequency	Percentage
Defining an Adverse Drug Reaction (ADR)?	Any noxious or unintended effect of a drug occurring at normal dose during normal use.	218	51.8
	Adverse health outcomes as a result of abuse or misuse	20	4.8
	Harm caused by medication error.	18	4.3
	Harm resulting from the use of substandard or counterfeit drugs.	116	11.6
	All of the above	49	27.5
	Total	421	100.0
Adverse reactions to medicine have been known to result in the following.	Hospitalization/prolonged hospitalization.	13	3.1
	Permanent disability	48	11.4
	Increased hospital cost	52	12.4
	Death	33	7.8
	All of the above	275	65.3
	Total	421	100.0
All adverse Drug Reactions (ADRs) are known before a medicine, medicinal product or medical appliance is marketed.	No	302	71.7
	Yes	119	28.3
	Total	421	100.0
Do you know about the "yellow	No	106	25.2

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form" (NAFDAC ADR - Reporting Form)	Yes	315	74.8
	Total	421	100.0
Aware that you can download the NAFDAC Medicine Safety Mobile Application for ADR reporting from your Google play store, or Apple store	No	260	61.8
	Yes	161	38.2
	Total	421	100.0
Do you know that you can access the pharmacovigilance "yellow form" from NAFDAC website (NAFDAC e - reporting platform) online, fill and submit	No	224	53.2
	Yes	197	46.8
	Total	421	100.0
Are you aware that NAFDAC has a "Pharmacovigilance Rapid Alert System for Consumer Reporting" (PRASCOR) text messaging system for reporting ADRs?	No	248	58.9
	Yes	173	41.1
	Total	421	100.0
Who do you think is responsible for reporting ADRs	Pharmacist only	51	12.1
	All healthcare providers	370	87.9
	Total	421	100.0
What do you think should be reported as ADRs? (you may choose more than one option)	All suspected reactions to medicine/products, herbal products, medical appliances, and blood vaccines and products	211	50.1
	Problems such as medication error and lack of efficacy.	28	6.7
	Problems such as medication error and lack of efficacy	17	4.0
	All of the above	165	39.2
	Total	421	100.0
As a healthcare provider, what do you think is your responsibility in pharmacovigilance? (you may choose more than one option)	Detect and report all suspected cases of ADRs and intervene appropriately; Educate patients on rational use of medicines	75	17.8
	Counsel patients on the need to report suspected ADRs promptly to their healthcare provider	102	24.2
	Review and evaluate patients for potential or actual ADRs during follow up	13	3.1
	Inform medical healthcare providers on ADRs	9	2.1
	All of the above	222	52.7

Table 2 further supports healthcare provider's general knowledge of pharmacovigilance and Adverse Drug Reaction (ADRs) reporting. This indicates that more than half (51.8 %) of the respondents have fair understandings of the traditional definition of Adverse Drug Reactions (ADR): Any noxious or unintended effect of a drug occurring at normal dose during normal use. About one

third (27.5 %) of the respondents indicates a knowledge of the recent (2012) WHO modification of the definition of Adverse Drug Reaction to include: adverse health outcomes as a result of abuse or misuse, harm caused by medication error, harm resulting from the use of substandard or counterfeit drugs - (all the above). Majority (65.3 %) of study participants knew that Adverse Drug Reaction can lead to: hospitalization/prolonged hospitalization, permanent disability, increased hospital cost and probable death (all the above). However, only (28.3%) said “yes” all adverse Drug Reactions (ADRs) are known before a medicine, medicinal product or medical appliance is marketed, which is quite not correct. A good knowledge was indicated by more than a third (71.7 %) of the respondents that said “NO”. The assessment also indicates that healthcare providers have a good knowledge of when to report, what to report, who is to report and where to report. This can be seen in table 4.2b above. More than two third (74.8 %) of the respondents knew about the NAFDAC “yellow form” for reporting ADR, almost all (87.9 %) of the respondents agreed that “all healthcare providers” are responsible for reporting ADRs. There was generally a poor awareness of NAFDAC e – reporting platform by healthcare providers in Abuja. More than half (61.8 %) of the participants are not aware of the NAFDAC medicine safety mobile Application, 53. 1 % of study participants are not aware that the “yellow form” can be filled and submitted electronically on NAFDAC website. Also, 58.9 % were not aware that NAFDAC has a “Pharmacovigilance Rapid Alert System for Consumer Reporting" (PRASCOR) text messaging system for reporting ADRs.

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Research question 2: What is the state of knowledge of healthcare providers concerning basic pharmacovigilance principles and Adverse Drug Reaction (ADRs) Reporting?

Table 3: The state of knowledge of healthcare providers concerning basic pharmacovigilance principles and Adverse Drug Reaction (ADRs) Reporting

Parameters	Classification	Frequency	Percentage
Ever received any training on pharmacovigilance and adverse drug reaction reporting	No	190	45.1
	Yes	231	54.9
	Total	421	100.0
The word "pharmacovigilance" can be defined as the science and activities relating to detection, assessment, understanding and prevention of adverse effects of drug or other possible drug related problems	No	8	1.9
	Yes	413	98.1
	Total	421	100.0
Are you aware of any drug that has been banned from use due to Adverse Drug Reaction (ADR)	No	22.6	22.6
	Yes	77.4	77.4
	Total	100.0	100.0
The most important purpose of pharmacovigilance is to assess safety of drugs and to identify previously unrecognized ADRs?	No	8	1.9
	Yes	413	98.1
	Total	421	100.0
Do you believe that all drugs available in the market are safe and effective?	No	392	93.1
	Yes	29	6.9
	Total	421	100.0
Are you aware that there is a National Pharmacovigilance Centre domiciled in NAFDAC headquarters?	No	81	19.2
	Yes	340	80.8
	Total	421	100.0

Table 3 above indicates that participants have good knowledge of basic pharmacovigilance principles and Adverse Drug Reactions reporting. More than half (54.9 %) of the participants have received previous trainings on pharmacovigilance and Adverse Drug Reaction reporting. Almost all the participants (98.1 %) knew the widely accepted definition of "Pharmacovigilance", more than two third

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(77.4 %) were aware of some drugs that have been banned from use due to Adverse Drug Reaction (ADR). Furthermore, almost all the participants (98.1 %) recognized that 'the most important purpose of pharmacovigilance is to assess safety of drugs and to identify previously unrecognized ADRs' and about 93.1 % do not believe that "all drugs in the market are safe and effective". Lastly, only about a quarter (19.2 %) of the participant is not aware that there is a National Pharmacovigilance Centre Domiciled at NAFDAC headquarter.

Table 4: Healthcare Provider's General Knowledge of Pharmacovigilance and Adverse Drug Reaction (ADRS) Reporting

Parameters	Classification	Frequency	Percentage
Defining an Adverse Drug Reaction (ADR)?	Any noxious or unintended effect of a drug occurring at normal dose during normal use.	218	51.8
	Adverse health outcomes as a result of abuse or misuse	20	4.8
	Harm caused by medication error.	18	4.3
	Harm resulting from the use of substandard or counterfeit drugs.	116	11.6
	All of the above	49	27.5
	Total	421	100.0
Adverse reactions to medicine have been known to result in the following.	Hospitalization/prolonged hospitalization.	13	3.1
	Permanent disability	48	11.4
	Increased hospital cost	52	12.4
	Death	33	7.8
	All of the above	275	65.3
	Total	421	100.0
All adverse Drug Reactions (ADRs) are known before a medicine, medicinal product or medical appliance is marketed.	No	302	71.7
	Yes	119	28.3
	Total	421	100.0
Do you know about the "yellow form" (NAFDAC ADR - Reporting FORM)	No	106	25.2
	Yes	315	74.8
	Total	421	100.0
Were aware that you can download the NAFDAC Medicine Safety Mobile Application for ADR reporting from your Google play store, or Apple store	No	260	61.8
	Yes	161	38.2
	Total	421	100.0
Do you know that you can access the pharmacovigilance "yellow form" from NAFDAC website (NAFDAC e - reporting platform) online, fill and submit	No	224	53.2
	Yes	197	46.8
	Total	421	100.0
Are you aware that NAFDAC has a "Pharmacovigilance Rapid Alert System for Consumer Reporting" (PRASCOR)	No	248	58.9
	Yes	173	41.1
	Total	421	100.0

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text messaging system for reporting ADRs?			
Who do you think is responsible for reporting ADRs	Pharmacist only	51	12.1
	All healthcare providers	370	87.9
	Total	421	100.0
What do you think should be reported as ADRs? (you may choose more than one option)	All suspected reactions to medicine/products, herbal products, medical appliances, and blood vaccines and products	211	50.1
	Problems such as medication error and lack of efficacy.	28	6.7
	Problems such as medication error and lack of efficacy	17	4.0
	All of the above	165	39.2
	Total	421	100.0
As a healthcare provider, what do you think is your responsibility in pharmacovigilance? (you may choose more than one option)	Detect and report all suspected cases of ADRs and intervene appropriately; Educate patients on rational use of medicines	75	17.8
	Counsel patients on the need to report suspected ADRs promptly to their healthcare provider	102	24.2
	Review and evaluate patients for potential or actual ADRs during follow up	13	3.1
	Inform medical healthcare providers on ADRs	9	2.1
	All of the above	222	52.7

Table 4 further supports healthcare provider's general knowledge of pharmacovigilance and Adverse Drug Reaction (ADRs) reporting. This indicates that more than half (51.8 %) of the respondents have fair understanding of the traditional definition of Adverse Drug Reactions (ADR): Any noxious or unintended effect of a drug occurring at normal dose during normal use. About one third (27.5 %) of the respondents indicates a knowledge of the recent (2012) WHO modification of the definition of Adverse Drug Reaction to include: adverse health outcomes as a result of abuse or misuse, harm caused by medication error, harm resulting from the use of substandard or counterfeit drugs - (all the above). Majority (65.3 %) of study participants knew that Adverse Drug Reaction can lead to: hospitalization/prolonged hospitalization, permanent disability, increased hospital cost and probable death (all the above). However, only (28.3%) said "yes" all adverse Drug Reactions (ADRs) are known before a medicine, medicinal product or medical appliance is marketed, which is quite not correct. A good knowledge was indicated by more than a third (71.7 %) of the respondents that said "NO". The assessment also indicates that healthcare providers have a good knowledge of when to report, what to report, who is to report and where to

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report. This can be seen in table 4.2b above. More than two third (74.8 %) of the respondents knew about the NAFDAC "yellow form" for reporting ADR, almost all (87.9 %) of the respondents agreed that "all healthcare providers" are responsible for reporting ADRs. There was generally a poor awareness of NAFDAC e – reporting platform by healthcare providers in Abuja. More than half (61.8 %) of the participants are not aware of the NAFDAC medicine safety mobile Application, 53. 1 % of study participants are not aware that the "yellow form" can be filled and submitted electronically on NAFDAC website. Also, 58.9 % were not aware that NAFDAC has a "Pharmacovigilance Rapid Alert System for Consumer Reporting" (PRASCOR) text messaging system for reporting ADRs.

Research question 3: What is the frequency of occurrence of Adverse Drug Reactions in Abuja, and Practice of Spontaneous Reporting among Healthcare Providers?

Table 5: Frequency of Occurrence of Adverse Drug Reactions in Abuja, and Practice of Spontaneous Reporting among Healthcare Providers.

Parameters	Classification	Frequency	Percentage
Have you encountered any suspected case of Adverse Drug Reaction (ADR) in your clinical practice during the last 12 months?	No	269	63.9
	Yes	152	36.1
	Total	421	100.0
If your response is "YES" to number (25) above, how many cases of suspected ADRs have you encountered in the last 12 months?	1.00 case	35	23.5
	2.00 cases	72	47.5
	3.00 cases	32	21.2
	>3 cases	13	7.8
	Total	152	100
If you have encountered ADR(s) before in your practice, have you ever reported (filled and submit the ADR reporting form -YELLOW FORM) to the pharmacovigilance unit?	No	93	61.0
	Yes	59	39.0
	Total	152	100.0
If your response is "YES" to question above, what would you say is the percentage of the ADRs you have encountered, have you reported (filled and submit the ADR reporting form) to the pharmacovigilance Centre/Unit?	< 25 %	52	35.9
	25 -50 %	27	18.1
	51 -74 %	45	29.9
	75 - 94 %	20	13.8
	95 -100 %	8	2.4
	Total	152	100.0
How many cases of Adverse drug reactions have you reported (filled and submit the NAFDAC YELLOW FORM) in the last 12 month?	0.00 case	89	58.6
	1.00 case	16	10.8
	2.00 cases	28	18.2
	3.00 cases	14	8.9
	>3 cases	5	3.5
	Total	152	100
What is the average number of patient(s) you see per day?	1-10 patients	124	29.5
	11-20 patients	109	25.9
	21-30 patients	114	27.1
	31-40 patients	36	8.6
	41- 50 patients	12	2.9
	above 70	26	6.2

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	patients		
	Total	421	100.0
After submitting your report, did you receive any feedback from the pharmacovigilance Centre you submitted to?	No	134	89.5
	Yes	16	10.5
	Total	150	100.0
If yes to the question (9) above, were you satisfied with the feedback you received?	No	9	53.2
	Yes	7	46.8
	Total	16	100.0
How often do you counsel your patients on possible ADRs?	Occasionally	129	31.0
	Sometimes	86	20.7
	Always	195	47.0
	Never	7	1.3
	Total	417	100.0
Do you think that prompt reporting and monitoring of suspected cases of ADRs is beneficial to your patient	No	14	3.3
	Yes	407	96.7
	Total	421	100.0
Is there a designated pharmacovigilance unit in your facility?	No	266	63.7
	Yes	152	36.3
	Total	419	100.0
Which of the following factor(s) may increase the possibility of occurrence of an Adverse Drug Reaction (ADR)	Multiple drug use	58	13.8
	Past history of an ADR or Allergy	59	14.0
	Overdose	73	17.3
	Disease State	10	2.4
	All of the above	221	52.5
	Total	421	100.0

Table 5 shows that only about a third (36.1%) of the 421 respondents have encountered suspected case of an Adverse Drug Reaction (ADR) in their clinical practice during the last 12 months. About a third (23.5 %) of them said they have encountered one case of adverse drug reaction in the last twelve (12) months, almost half (47.5 %) of the respondent said they have encountered about two cases of ADRs in the last twelve month and a few (7.8 %) said they have encountered more than three cases of ADRs in the last twelve month. More than half (61.0 %) of the respondents who have encountered at least a case of ADRs during normal practice in the last twelve month have not reported such cases to the pharmacovigilance Centre. Those who were able to report at least 50 % of the total cases of ADRs they have encountered in the last twelve month are about a third (29 %) of the respondents, and about 89 % of those who have reported, have never received any feedback from the pharmacovigilance Centre after submitting their report. Furthermore, almost all (96 %) of our respondents believed that spontaneous reporting of all suspected cases of ADRs to the Pharmacovigilance Centre is

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beneficial to their patient, though more than half (63 %) of them do not have a designated pharmacovigilance unit in the facility they practice.

Test of Hypothesis: There will be no significant association between perceived training on pharmacovigilance principles and the practice of spontaneous adverse drug reaction reporting among healthcare providers.

Table 6: Chi – Square Analysis showing the Association between Perceived Training on Pharmacovigilance and the Tendency for Spontaneous Reporting of ADRs

	Adverse Drug Reaction (ADR) reporting					
Perceived training on pharmacovigilance	**No**	**Yes**	**Total**	X^2	**Df**	**P value**
No	8 3.1%	108 42.4%	116 45.5%			
Yes	0 0.0%	139 54.5%	139 54.5%	9.897	1	.002
Total	8 3.1%	247 96.9%	255 100.0%			

Table 6 revealed a statistically significant association between health workers perceived training on pharmacovigilance and the tendency to report suspected cases of adverse drug reactions to the pharmacovigilance centre ($X^2 = 9.897$, Df = 1, P<.05). This implies that exposure to relevant training on pharmacovigilance can have a significant influence on adverse drug reaction reporting among healthcare providers. Therefore the "null hypothesis" is rejected in favor of the "alternative hypothesis".

Discussion of Findings

The result of the survey indicated good knowledge of pharmacovigilance and adverse Drug reaction reporting among healthcare providers in Abuja. Almost all (98.1 %) the respondents are conversant with the definition of "pharmacovigilance" and further demonstrated their understanding of the concept of pharmacovigilance and adverse drug reaction with follow up responses. Almost all the respondents recognized that the most important purpose of pharmacovigilance is to "asses safety of drugs and identify previously unrecognized adverse drug reaction" and about a third of the respondents are aware of some drugs that have been banned in Nigeria due to adverse drug reaction. This result is consistent the findings of previous studies (Danraka *et al*., 2021). More than half of the respondents have received previous training on pharmacovigilance and adverse drug reaction reporting. Recent study (Waheed Adeola A. *et al*., 2021) suggest that the only determinant of ADR reporting was lack of training. Similarly, another study from Namibia (Adenuga. B.A *et al*., 2019) on Optimizing ADR reporting in public healthcare setting

in Namibia" indicated that training and education around pharmacovigilance could empower current systems of reporting. Almost all the respondents do not believe that all available drugs in the market are safe, and effective as some of them have the potential to cause and appreciable degree of "unexpected" harm to the user during normal use. This finding is also consistent with the studies conducted by Danraka *et al*., 2021.

Conclusion

In conclusion, the study revealed a good level of knowledge of pharmacovigilance principles and adverse drug reaction reporting systems among healthcare providers in Abuja, though this level of knowledge did not directly translate into satisfactory reporting practices as majority of the cases of suspected ADRs encountered by the study participants were not reported. This may be attributed to poor level of awareness among healthcare providers, inadequate training or capacity building on pharmacovigilance and ADRs reporting. Adequate training has been identified as a significant determinant of ADRs reporting practices among healthcare providers. Effort should be geared toward creating awareness among healthcare providers on the necessity of ADRs reporting and the positive impact it could have on health of the patients. There is also a need for continuous and effective communication between the healthcare providers and the NPC in the way of feedback, advocacy, continuing professional development and training.

Recommendations

Based on these findings, several recommendations can be made. Firstly, it is crucial to enhance education and training programs on pharmacovigilance and ADR reporting for healthcare providers. This could include regular updates and refresher courses to ensure they are well-informed and equipped to identify and report ADRs effectively. Secondly, efforts should be made to establish designated pharmacovigilance units within healthcare facilities to facilitate systematic reporting and monitoring of ADRs. These units can serve as central points of contact for healthcare providers and provide guidance on reporting procedures. Additionally, there should be a mechanism in place to provide timely feedback to healthcare providers who report ADRs, acknowledging their contribution and promoting a sense of accountability. Finally, collaboration between healthcare providers and the National Pharmacovigilance Centre should be strengthened to foster a culture of reporting and ensure effective communication and coordination in the pharmacovigilance process.

REFERENCES

Adisa R, Tomilayo I.O, (2019). Awareness, Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting Among Health Workers and Patients in Selected Primary Healthcare Centers in Ibadan, Southwestern Nigeria *BMC Health Services Research*

*2019:*19;926 URL; https://doi.org/10.1186/s12913-019-4775-9

Aduragbenro D.A Adedapo, Waheed A. Adedeji, Ifetoluwanimi A. Adedapo, Kayode S. Adedapo (2020). Cohort Study on Adverse Drug Reactions in Adults Admitted to the Medical Wards of a Tertiary Hospital in Nigeria. *British Journal of clinical pharmacology/volume* 87, issue 4 / p. 1878 – 1889.

Asiamah M, Kwadwo O.A, Priscilla N, Nina d, Anthony D. (2022). Spontaneous Reporting of Adverse Drug Reaction among Healthcare Professionals in Ghana. *Archives of Public Health 80:33*. URL: https://doi.org/10.1186/s13690-021-00783-1

Danraka A.M, Usman F.S, Onavbavba G. (2021). Assessment of Knowledge, Attitude and Practice of Drug Reaction Reporting Among Health Workers in Selected Health Facilities in Abuja. *Journal of Biology, Agriculture and Healthcare*. Vol. 11, No 8, May 2021.

Friday Samuel Wakoma (2018). Preventive nephrology: Panacea to Ameliorating the Gruesome Burden of Kidney Failure in Sub - Saharan African Countries. *Inaugural Lecture Series no. 150*. Department of Medicine, Faculty of Clinical Sciences, College of Health Science, University of Port Harcourt. Nigeria.

Garashi H.Y, Steinke D.T, Ellen I.S (2022). A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators. *Therapeutic Innovation & Regulatory Science* https://doi.org/10.1007/s43441-022-00415-y. April, 2022

Gidey K, Mohammedamin S, Berhane Y. H, Solomon A, Yirga L. N. (2020). Health Care Professional Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting in Ethiopia: A Cross – sectional Studies. *BMJ Open* 2020;10 e034553

Lanre-Ogungbile, O.A, Sowunmi, C.O & Opele, J.K**.** (2020). Self-Management Practices among Diabetic Women of Reproductive Age in a Tertiary Hospital, Osun State, Nigeria. *Global Journal of Health Science*, 12(11); 73-82. URL: https://DOI.org/10.5539/gjhs.v12n11p73

Libsuye Y.Z, Muluken C.A, Gashaw M.W (2021). Assessment of Knowledge, Attitude, and Practice of Adverse Drug Reaction Reporting Among Community Pharmacy in Gondar Town, Ethiopia. *Research square*. URL: https://doi.org/10.21203/rs.3.rs-1188341/v1

Nweze, GN, Awoniyi, O.M, Falebita, T.F., Familoni J.K, & Opele, J.K. (2023). Development Communication as Tool for Addressing Health Disparities and Challenges in Nigerian Communities: Obstaclelabour

Opportunities for Future Direction. *African Journal of Human Kinetics, Recreation and Health Studies*. 1(2);91-109. Available at https://journals.co.za/doi/full/10.31920/2976-7784/2023/v1n2a6

Obeta S.S, Ibrahim B, Lawal L.A *et al*., (2020). Prevalence of Canine Babesiosis and their Risk Factors among Asymptomatic Dogs in the Federal Capital Territory, Abuja, Nigeria. *Parasite Epidemiology and Control*, October 2020. Doi: 10. 1016/j.parepi.2020. e00186.

Opele, J.K, Abiala, J.O & Uthman, K (2022). Health Information seeking behaviour of residents of Ota, Ogun State, Nigeria**.** *Journal of Library Services and Technologies, 3(2),101-111*.
DOI**:** *http://doi.org/10.47524/jlst.v3i2.102*

Peter E. A, Olumuyiwa J. F, Ambrose O. I (2018). The Incidence and Prevalence of Adverse Drug Reactions among Medical Inpatients in a Nigerian University Teaching Hospital. *Journal of current research in science and medicine* DOI. Http://www.jcrsmed.org.

Shalini S. Lynch (2022). Overview of Drugs. *MSD Manual Consumer Version*. University of California, San Francisco School of Pharmacy. May, 2022.

Sowunmi, C.O, Lanre-Ogungbile, O.A, Owopetu, C.A. & Opele, J.K. (2020). Demographic Variables and Self-Management Practices as Correlates of Glycemic Control among Reproductive Age Diabetic Women in a Tertiary Hospital in Ile-Ife, Osun State, Nigeria. *Texila International Journal of Public Health; 1-10*