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AN INVESTIGATION INTO THE OCCURRENCE OF ADVERSE DRUG REACTIONS AND PRACTICE OF SPONTANEOUS REPORTING AMONG HEALTHCARE PROVIDERS IN ABUJA, NIGERIA

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ABSTRACT
The study aimed to assess the general knowledge of healthcare providers regarding pharmacovigilance and adverse drug reaction (ADR) reporting, as well as their experience with encountering ADRs in clinical practice and reporting them to the Pharmacovigilance Centre. A cross-sectional descriptive study was conducted using a web-based questionnaire developed with Google Forms. The data obtained from respondents were analyzed after being recorded in spreadsheets. The findings revealed that 54.9% of respondents had received previous pharmacovigilance training, 98% were familiar with the definition of pharmacovigilance, 80.1% were aware of the National Pharmacovigilance Centre located at NAFDAC headquarters, and 76% knew about the "yellow form" for reporting ADRs. Only 36.1% of participants had encountered suspected cases of ADRs within the past year. The frequency of ADR occurrence was significantly associated with the practice setting, and training was identified as a significant factor influencing reporting practices among healthcare providers (X2 = 9.897, Df = 1, P<.05). Although healthcare providers demonstrated good knowledge of pharmacovigilance principles and ADR reporting, their reporting practices were not satisfactory. It is recommended that appropriate measures be implemented to optimize reporting practices.

Keywords: Occurrence, Adverse drug reactions, Practice, Spontaneous reporting Healthcare providers

Introduction

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). 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. 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 people; thus, yielding outcomes that may not be perfectly generalizable (Asiamah M *et al.*, 2022; Opele, Omole and Adebayo, 2019).). Consequently, it is imperative to carry out post – marketing surveillance to enable the prompt detection of less common but very serious ADRs (Gidey K. *et al.*, 2020). Because there is no active medicine completely free from ADRs, the introduction of ADRs reporting system is a vital component of a National Healthcare Delivery System (FMOH NDP, 2021). Therefore, healthcare providers are expected to regard ADR reporting as their professional responsibility, this is because a successful ADR reporting system is necessary to improve patient safety and care resulting in better overall health outcome (Adisa *et al*., 2019; Opele**,** 2022).

It is the responsibility of healthcare providers to identify, document and report ADRs (Adisa *et al*., 2019). They play a pivotal role in early detection and reporting of ADRs (Gidey *et al*., 2020). However, there are many factors that may affect the spontaneous reporting of ADRs, which includes; absence of awareness, confusion about who should report, difficulty with reporting methods, absence of feedback on reports submitted, adverse events resolving rapidly and others. Health professional's knowledge and attitudes are strongly related to the rate of ADR reporting (Gidey *et a*l., 2020). For effective discovery of new cases of ADRs, spontaneous reporting is cardinal, unfortunately under – reporting is its primary limitation. A systematic review of studies carried out in the EU revealed significant and widespread (HCPs) under – reporting of ADRs with median reporting rate of under – reporting of 94 %. The dismal reporting rates may delay regulatory actions to remove drugs with safety profile that is unacceptable from the market place (Gidey *et al*., 2020). For this reason, it is imperative to evaluate the knowledge and practice of healthcare providers regarding ADR reporting for improve reporting practice and to provide insight into the incidence

of ADRs and patterns to be able to make timely, efficient and effective interventions that would protect public health and improve general wellbeing of the populace (Gidey *et al*., 2020).

Furthermore, a few numbers of African countries have conventional ADR reporting systems. Countries include, South Africa, Morocco, Tunisia, Tanzania, Zimbabwe, Ghana, Nigeria, Egypt, Mozambique, Togo, and Uganda, all of which are full members of the WHO program for International Drug Monitoring. Lack of adequate training and funding has been the major deterrent to progress (Haines H.M *et al*., 2020). However, with 35 African countries now part of the WHO Program for International Drug Monitoring, pharmacovigilance activities in the region are expected to increase (Haines H.M *et al*., 2020). By December 2019, the number of participating countries had risen to 136, with 30 associated member countries beginning to initiate their own pharmacovigilance systems. Nigeria became the 74th country to join the WHO Programme for International Drug Monitoring in September 2004 (FMOH NNPPIF, 2020). There is limited awareness about drug safety issues among consumers in Nigeria. Irrational use of medicines is highly prevalent and the safety profile of most medicines in the population is not well characterized (FMOH NNPPIF, 2020). National ADRs reporting rates (reports per million population per annum) varied widely among countries and income group.

Countries with high income have the highest average ADR reporting rate, with 130 reports per million inhabitants per year, followed by upper – middle income countries with 27 reports per million inhabitants per year, lower middle-income countries with 12 reports per million population per year and the low-income countries (Nigeria falls within this range) with 3 reports per million inhabitants per year. Low-income countries represent only less than 1 % of the total global ADRs reports to VigiBase (Asiamah M*et al*., 2022). For effective monitoring of ADR of the existing and newly introduced drugs by the pharmacovigilance systems, WHO recommends that the spontaneous reporting of adverse drug reaction should be above 200 reported cases per a million population (Asiamah M *et al*., 2022). The current population of Nigeria is estimated at 216,435,521 as of July 10th, 2022, according to Worldometer refined latest United Nations data (Worldometer, 2022). Following the WHO recommendations, it would be expected that Nigeria reports at least forty-three thousand (43,000) ADRs per year for Optimum Pharmacovigilance Performance (Asiamah M *et al*., 2022).

An Adverse Drug Reaction (ADR) is defined as ‘an appreciable, harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen or withdrawal of the product’. Since 2012, the definition has

included reactions occurring as a result of error, misuse, or abuse, and to suspected reactions to medicines that are unlicensed or being used off - label in addition to the authorized use of the medicinal product in normal dose (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). 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 Y.Z *et al.*, 2021).

In Nigeria and other developing countries, information on the in – hospital incidence of ADRs is limited, also, the culprit medications and the cost of management (Peter E.A *et al*., 2018). A study designed to evaluate the incidence and prevalence of ADRs among medical inpatients in Nigeria by Peter E.A *et al*., 2018, observed a 6.5 % incidence of ADRs occurring during hospital admissions, while 3.6 % of patients were admitted due to an ADR. The prevalence of ADR was also found to be about 10.1 % which is similar to the ADR prevalence in some European countries. The cost of treating ADR was found to be ₦161668.00, equivalent to 1.9 % of the total cost of all medications used by the patients during admission. The fatality rate for ADRs was 7.8 %, while ADR – related mortality rate was 0.8 %. (Aduragbenro D.A *et al.*, 2020). ADR may occur when a physician is reluctant to treat with adequate doses of a drug for fear of causing drug toxicity (AGS. 2019). Other causes of ADRs may include; manufacturing errors, errors in supply, prescribing errors, error in administering the drug, or taking drugs, serious attention to these factors will result in preventing or reducing the occurrence of unwanted drug actions which could have been avoided if health care providers spent enough time to pinpoint these problems (Suraj U.K *et al*., 2023). Pharmacist must utilize essential tools such as effective counselling, and patient education to minimize ADRs (Daphne E.S.M. 2023).

Healthcare providers should exploit the availability of information technology as part of their medication decision making process to furnish themselves with up-to-date knowledge of drug – dosing interactions, ADRs and other important information needed to use medications in an optimum manner (Daphne, 2023). Pharmacist should also focus on the elderly, since they form the majority of those subject to polypharmacy (AGS 2019). For each benefit to come out of a medication, there is always a possibility for some risks; benefits should always outweigh risks for the purpose of providing the best treatment with the least number of medications at the most economic price. Majority of ADRs could potentially be ameliorated or prevented with simple strategies and rational prescribing (AGS 2019).

To achieve the primary aim of this work, this study attempts to provide answers to the following research questions;

1. What percentage of healthcare providers in Abuja have encountered at least a single case of suspected ADR(s) during normal practice in the last twelve months?
2. What is the predictive determinant of spontaneous reporting of suspected cases of Adverse Drug Reaction?

Hypothesis

Ho: There will be no significant association between the Possibility of Adverse Drug Reaction Incidence and Healthcare Practice Settings.

Research Method

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. Cross – sectional studies is mostly used to draw interpretations about probable connections or to gather preliminary data to support further research and experimentation (Sharif M.A *et al.*, 2021). A well – structured, self – administered questionnaire was developed to assess the incidence of adverse drug reaction, knowledge and practice of adverse drug reaction reporting by healthcare professionals in Abuja. The questionnaire was adapted from five (5) similar studies that investigated the knowledge, attitude and practices of adverse drug reactions; (Danraka M.A, *et al.*, 2021, Kim Seung Yeon *et al.*, 2020, Sharif M.A *et al.*, 2021, Adisa R. *et al*., 2019 and Gidey K. *et al*., 2020) with little modifications.

Presentation of Results

Research question 1: What percentage of healthcare providers in Abuja have encountered at least a single case of suspected ADR(s) during normal practice in the last twelve months?

Table 1a: Factors That May Discourage/Hinder the Healthcare Provider from Promptly Reporting a Suspected Case of Adverse Drug Reaction (ADRs).

Parameters	Classification	Frequency	Percentage
Which of the following factors may discourage/hinder you from reporting a suspected case of Adverse Drug Reaction (ADR) during clinical practice?	Believe that a single unreported case may not affect the global or national ADR database.	29	6.9
	Difficulty in deciding whether an ADR has occurred	81	19.2
	Absence of financial compensation	36	8.6
	Concern that my report may be wrong	59	14.0
	Insufficient time in practice setting to actually screen patients for suspected ADR.	129	30.6
	Do not feel sufficiently trained to identify and report ADR correctly.	65	15.4
	Fear of the negative impact my report may have on the manufacturing or marketing company.	22	5.2
	Total	421	100.0

Table 1a shows the responses of the study participants regarding the different factors that may discourage/hinder them from promptly reporting all suspected cases Adverse Drug Reaction (ADRs) during clinical practice. The table shows that majority (30.6 %) of the study participants believed that "Insufficient time in practice setting to actually screen patients for suspected ADRs" is a very significant factor that negatively influenced their ability to report all suspected cases of ADRs. Other factors can be seen in the table above. When asked to mention any other factor that may negatively influenced their ability to report all suspected cases of ADRs, aside the factors listed above, the participants mentioned, most notably: poor or delayed responses/interventions from the pharmacovigilance Centre to the previous report submitted, because it becomes doubtful if the report was actually useful and discourages them from further reporting subsequent cases. The absence of pharmacovigilance unit in majority of the facilities to monitor reporting and encourage healthcare providers to perform their duty of spontaneous ADRs reporting is another factor many respondents considered to be very influential in this regard.

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Table 1b: Factors That May Discourage/Hinder the Healthcare Provider from Promptly Reporting a Suspected Case of Adverse Drug Reaction (ADRs).

Parameters	Classification	Frequency	Percentage
Which of the following factors may discourage/hinder you from reporting a suspected case of Adverse Drug Reaction (ADR) during clinical practice?	Believe that a single unreported case may not affect the global or national ADR database.	29	6.9
	Difficulty in deciding whether an ADR has occurred	81	19.2
	Absence of financial compensation	36	8.6
	Concern that my report may be wrong	59	14.0
	Insufficient time in practice setting to actually screen patients for suspected ADR.	129	30.6
	Do not feel sufficiently trained to identify and report ADR correctly.	65	15.4
	Fear of the negative impact my report may have on the manufacturing or marketing company.	22	5.2
	Total	421	100.0

Table 1b shows the responses of the study participants regarding the different factors that may discourage/hinder them from promptly reporting all suspected cases Adverse Drug Reaction (ADRs) during clinical practice. The table shows that majority (30.6 %) of the study participants believed that "Insufficient time in practice setting to actually screen patients for suspected ADRs" is a very significant factor that negatively influenced their ability to report all suspected cases of ADRs. Other factors can be seen in the table above. When asked to mention any other factor that may negatively influenced their ability to report all suspected cases of ADRs, aside the factors listed above, the participants mentioned, most notably: poor or delayed responses/interventions from the pharmacovigilance Centre to the previous report submitted, because it becomes doubtful if the report was actually useful and discourages them from further reporting subsequent cases. The absence of pharmacovigilance unit in majority of the facilities to monitor reporting and encourage healthcare providers to perform their duty of spontaneous ADRs reporting is another factor many respondents considered to be very influential in this regard.

Table 2: What Can be done to Encourage and Improve the Spontaneous Reporting of all Suspected Cases of ADR by Healthcare Providers?

Suggestions	Frequency	Percentage
Training of health workers on how to detect and report ADRs	168	40.4
Financial motivation	56	13.3
Yellow forms should be available in all the ward and sensitization should be given to all medical staff	47	11.2
All hospital should have pharmacovigilance unit	32	7.6
Mandatory reporting should be implemented in all health facilities	77	19.4
Frequent enforcement and monitoring by the head of department	18	4.3
Proper awareness of the need to report ADR	18	4.3
Total	416	100.0

Table 2 shows the various factors that could improve the spontaneous reporting of ADRs as suggested by our respondents. Majority (40.4 %) of the respondents believed that effective training of healthcare providers on the detection and reporting of ADRs would be necessary to improve the spontaneous reporting of Adverse Drug Reactions in all healthcare facilities. Mandatory reporting of ADRs by all healthcare providers was also considered by about 19.4 % of the respondents as significant means that could be exploited to improve spontaneous reporting or ADRs. Other factors as suggested by the respondents can be seen in the table above.

Hypothesis

Ho: There will be no significant association between the Possibility of Adverse Drug Reaction Incidence and Healthcare Practice Settings.

Table 3: Chi – Square Analysis Showing the Association between Incidence of Adverse Drug Reaction and Practice Settings.

Incidence		Practice setting							
		Private hospitals/clinics	Community Pharmacy	Secondary Health Institution	Tertiary health institution	Total	X^2	Df	P. value
One	Count	13	35	35	38	121			
	% of Total	5.1%	13.7%	13.7%	14.9%	47.5%			
Two	Count	2	4	28	26	60			
	% of Total	0.8%	1.6%	11.0%	10.2%	23.5%			
Three	Count	15	12	27	0	54	56.929	9	0.000
	% of Total	5.9%	4.7%	10.6%	0.0%	21.2%			
More than 3	Count	1	7	3	9	20			
	% of Total	0.4%	2.7%	1.2%	3.5%	7.8%			
Total	Count	31	58	93	73	255			
	% of Total	12.2%	22.7%	36.5%	28.6%	100.0%			

Significant at .05 level of significance

Table 3 revealed a statistically significant association between incidence of Adverse Drug Reaction and practice settings (X^2 = 56.929, Df = 9, P<.05). From these studies, healthcare providers from tertiary institutions have more tendency to encounter adverse drug reactions than healthcare providers in

other practice areas. This could be accounted to by the volume of patients patronizing each of these settings. The tertiary institution tends to have higher number of patients than the others considering that it is a referral center. Therefore, the "null hypothesis" is rejected.

Discussion of Findings

The study also indicates that majority of the respondents (87 %) were aware that it is the responsibility of all healthcare providers to report suspected cases of ADRs. This is in contrast with the results of previous studies (Fauzi T *et al.,* 2022), where majority of the participant held the perception that pharmacovigilance is pharmacist's driven activity which results in the delegation of reporting responsibility. Dealing with ADRs requires a multi – professional approach by healthcare providers including medical practitioners, pharmacist and nurses – both in public and in private healthcare settings to safeguard population health (Adenuga. B.A *et al*., 2019). The Nigerian National Pharmacovigilance Policy and Implementation Framework as reviewed in 2020 states clearly that "medical doctors, pharmacist, nurses, medical laboratory scientists and traditional herbal medicine practitioners, healthcare providers or healthcare practitioners practicing in public, private and Non – Governmental sectors shall report ADRs and other medicine related problems to the Zonal Pharmacovigilance Centre or nearest NAFDAC office".

Furthermore, this study revealed that out of the 421 respondents, about a third (36.1 %) had encountered a suspected case of ADRs in their clinical practice within the last twelve months. This is similar to previous findings (Danraka *et al.,* 2021). Considering that in Nigeria, there is a limited awareness about drug safety issues among consumers, the high prevalence of irrational drug use, the overwhelming burden of infectious disease such as HIV/AIDS, and Tuberculosis and the fact that safety profile of most medicines used by the population is not well characterized (NNPPIF. 2020). We may expect this figure to be higher than observed in this study, the low indices could be attributed to the problems in identifying possible ADRs by healthcare professionals. Majority of the healthcare professionals and clinicians face a challenge in identifying ADRs, the drug suspected and also in separating the relative contribution of the drug and disease to a patient's chief complaint. Many possible ADRs may also go unrecognized due to insufficient clinical knowledge among healthcare professionals making it difficult for them to decide if a finding is a possible ADR or not and there are no active surveillance systems set up to provide practical assistance in interpretation of possible ADRs (Avicek D *et al.*, 2020).

In estimating the occurrence rate, and practice of spontaneous reporting, it was found out that two third of those who have encountered a suspected case of ADRs, have encountered at least a one suspected case of ADR in the last twelve month while almost half of them said they have encountered at least two or more cases within the last twelve month.

However, more than half of those who have encountered at least a single case of ADR during clinical practice within the last twelve month have not reported such cases to the National Pharmacovigilance Centre and less than a third of them (29 %) have reported up to 50 % of the suspected cases they have encountered. This suggests a poor interest in reporting suspected cases of ADRs among healthcare professionals, though they have demonstrated a good level of knowledge of pharmacovigilance and ADRs reporting, it did not, however, translate to satisfactory reporting practice. Meaning that, knowledge can be an important factor in ADRs reporting, it is not the only determinants of reporting intents among healthcare providers. The findings are also similar to previous findings in Nigeria (Waheed A.A *et al*., 2021) and (Danraka *et al*., 2021).

Majority of those who have submitted their report to the NPC indicated that they have not received any feedback from the Pharmacovigilance centre they have submitted. Appropriate feedback mechanism on reported ADRs to healthcare providers, stakeholders and /consumers is one of the strategic thrust for the National Pharmacovigilance System (NNPPIF. 2020). The NPC is expected to give reasonable and timely feedback on report submitted by healthcare providers and consumers as this would serve as vehicle to encourage Meanwhile, almost all (87 %) 0f the study participants believed that prompt reporting and monitoring of suspected cases of ADRs is beneficial to their patients, these findings are consistent with those of previous study (Alsheikh MY *et al*., 2022). A third of the respondents indicated they have a functioning unit designated to coordinate pharmacovigilance activities within their facilities. This explained the poor ability to recognize potential ADRs among healthcare providers and the low interest in reporting identified potential/actual ADRs. The National Pharmacovigilance Policy and Implementation Framework of 2020, recommended the establishment of pharmacovigilance system in healthcare facilities including public health programmes as one of the strategic thrust of National Pharmacovigilance.

The study participants attributed the unsatisfactory reporting of ADRs among healthcare providers to the following factors; insufficient time during practice to actually screened patients for potential ADRs, detect actual ADRs and report, difficulty in deciding whether and ADR has occurred, some do not feel sufficiently trained to detect and report ADRs appropriately, absence of pharmacovigilance unit in most of the facilities, and lack of response by the pharmacovigilance centre to previous reports. Underreporting of ADRs is common not only in Nigeria but globally. The reasons for underreporting vary for different countries (Alsheikh MY *et al*., 2022). In this study, insufficient time during practice appeared to be the most significant deterrent to spontaneous ADRs reporting among healthcare providers. Lack of time was also considered the most significant barrier to reporting in Australia (Li et al., 2018), while in

Germany, the lack of good training and long forms to complete were considered a dominant negative factor (laven *et al*., 2018). There is a critical need globally to resolve the reporting barriers to improve reporting (Alsheikh MY *et al.*, 2022; ; Sowunmi, Lanre-Ogungbile, Owopetu, & Opele, 2020).

The respondents in this study indicated that continuous training and retraining of healthcare providers on Pharmacovigilance and adverse drug reaction reporting to keep them updated on current changes regarding information on ADRs would significantly serve to improve reporting. ADR reporting form should be made available in all hospital's wards and pharmacies and should also be made relatively simple and easy to fill. Effort should also be made to create awareness among healthcare providers on reporting principles and platforms. The findings are consistent with previous findings (Avicek *et al*., in 2020), their paper published on the "Analysis of under-reporting of Adverse Drug Reaction: Scenario in India and neighboring countries ". The respondents also suggested enforcement of mandatory reporting by all healthcare providers in all facilities as a possible way forward in changing the paradigm. This is also consistent with findings made in Sierra Leone (Fauzi T *et al*., 2022) while reporting on the "Inconsistent Country-Wide Reporting of Adverse Drug Reactions to Antimicrobials in Sierra Leone (2017–2021): A Wake-Up Call to Improve Reporting". National Pharmacovigilance Policy and Implementation Framework as reviewed in 2020 states that; healthcare professionals shall regard pharmacovigilance practice as a professional and ethical responsibility, it shall be mandatory for Marketing Authorization Holders, including all public health programmes to report ADRs, and it is advisable for consumers in their own interest to report ADRs.

Conclusion

In conclusion, the study revealed 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

The findings of this study have several practical implications that should be taken into consideration. Firstly, it is crucial to emphasize the importance of establishing active pharmacovigilance

units in all healthcare institutions across the country. These units would be responsible for monitoring and assessing the safety of medications and medical interventions. By having dedicated pharmacovigilance units, healthcare facilities can better identify and address adverse drug reactions and other medication-related issues.

Secondly, healthcare facilities need to ensure an adequate number of trained personnel to facilitate effective pharmacovigilance activities. This includes recruiting sufficient manpower with the necessary expertise to carry out pharmacovigilance tasks, such as monitoring, reporting, and analyzing adverse events. Creating an enabling environment for pharmacovigilance activities is essential to foster a culture of patient safety and proactive identification of potential risks associated with medications.

Lastly, the national pharmacovigilance center should play an active role in acknowledging and responding to Individual Case Safety Reports (ICSRs) received from healthcare providers. Regular acknowledgment of reports and timely dissemination of feedback information to healthcare providers is crucial. This feedback loop helps to enhance communication, promote learning, and improve the overall pharmacovigilance process. By providing feedback, healthcare providers can stay informed about the outcomes of their submitted reports and gain valuable insights into medication safety.

In summary, the practical implications of this study highlight the need for establishing pharmacovigilance units, recruiting adequate manpower, and ensuring effective communication between the national pharmacovigilance center and healthcare providers. These measures are essential for promoting medication safety, enhancing patient care, and ultimately improving the overall healthcare system.

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