PHARMACOVIGILANCE
NEWSLETTER

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Pharmacovigilance Practice by Community Pharmacists- Challenges & Solutions

Content

Health professionals and patients are encouraged to **report adverse events** or **quality problems** experienced with the use of **vaccines and medicines** to the nearest NAFDAC office or via pharmacovigilance@nafdac.gov.ng or via eReporting platform available on the NAFDAC website www.nafdac.gov.ng or via Med Safety Application available for download on Android and IOS stores.

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EDITOR'S NOTE...

We wish to thank our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC is committed to sending out the quarterly newsletter to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on medicine safety issues, to promote rational use of drugs and to promote reporting of Adverse Drugs Reactions (ADRs) and AEFIs. This edition of the newsletter focuses on: **Pharmacovigilance Practice by Community Pharmacists- Challenges & Solutions**

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions and AEFIs. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

Thank you for your relentless efforts in strengthening Pharmacovigilance System in Nigeria.

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Introduction

Pharmacovigilance is popularly known as drug safety monitoring. Although medicines are intended to heal and prevent ailments, there is no guarantee that they won't themselves cause harm (Gordhon & Padayachee, 2020). Adverse Drug Reactions (ADRs) have been defined by WHO as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man". Half of all ADRs in the U.S.A are due to preventable medication errors, they affect more than 7 million patients, cause 7000 deaths and account for more than 20 billion USD across all care settings annually (Stergiopoulos et al., 2016). The passive post-approval monitoring system is dependent upon voluntary and accurate reporting that identifies a drug and its manufacturer. ADR reporting is essential to ensuring patient safety. Healthcare professionals (HCPs) have an ethical responsibility to report ADRs but unfortunately, spontaneous Underreporting is a global problem (Gordhon & Padayachee, 2020). Successful Pharmacovigilance requires not merely meeting the minimum number of reports but also having good quality reports. Regulatory Agencies have noted the essence of Quality Management Systems in successful Pharmacovigilance practice (Chen et al., 2019). Poor quality and incompleteness of voluntary Adverse Event reporting results in misclassification and an inability to trace observations to the source or suspect product (Stergiopoulos et al., 2016).

Electronic reporting of Adverse events due to medical products is a convenient means for spontaneous reporting, it circumvents the challenges associated with inaccessibility of paper-based ADR reporting forms. The med safety app was launched by the NPC in 2020 and Nigeria became the 15th country globally and 9th in WHO region of Africa to use this app. It is free to download and use; available for Android and iOS phones; it can function (create reports) without internet connection.

Pharmacovigilance Directorate, NAFDAC is collaborating with various partners and stakeholders to implement pharmacovigilance activities in the states such as awareness creation, training of healthcare professionals, and supporting the establishment of Pharmacovigilance committees in health facilities. To further strengthen Pharmacovigilance in all the 37 states of the federation, training of healthcare professionals on pharmacovigilance and the use of the med safety app in selected healthcare facilities is ongoing.

Spontaneous reporting of ADRs is the cornerstone of pharmacovigilance and is important in maintaining patient safety. However, the success of this activity is dependent on the frequency of reporting by the health care professionals. Given the pharmacists' role in the community, spontaneous reporting of suspected adverse reactions to medicines by pharmacists will remain an important element of effective pharmacovigilance. In many developed countries, as is the case in the Netherlands,

community pharmacists play a significant role in ADR reporting. Pharmacist-generated ADR reports in the Netherlands, chiefly originating from community pharmacists, have their own specific characteristics, which make them a valuable addition to the reports received from physicians. In many other countries however the role of the community pharmacist in pharmacovigilance is yet to be appreciated. In an overview covering a large numberof countries participating in the World Health Organization International Drug Monitoring Program, it was demonstrated that the quantitative contribution community pharmacists make to the national systems is small (Oreagba et al, 2011).

Community Pharmacists truly have an important responsibility in monitoring the ongoing safety of medicines and are also widely accessible to do it. Community pharmacies are recognized by members of the public as a vital, integral part of the health services in their country. They are also conveniently accessible places where sound, objective advice on health issues can be obtained. The Pharmaceutical Group of the European Union (PGEU), a professional body that represents the community pharmacists of 29 European Countries reiterated that community pharmacists are a useful and highly accessible resource that should be used to its full potential in the development of national pharmacovigilance systems. Some identified qualities of the community pharmacists include practice experience and continuing professional development leading to comprehensive pharmaceutical knowledge; the ease of access and geographic distribution of pharmacy premises; the importance to the public of the dispensing and advisory roles of pharmacists; the level of computerization of community pharmacies and the pharmacist's role in early identification of ADRs (Oreagba et al, 2011)

A Survey of Adverse Event Reporting Practices Among US Healthcare Professionals

Tufts CSDD created a survey assessing the ADE-reporting process in hospitals (institutional), ambulatory (private practice), and retail pharmacy settings. Survey respondents were asked about their experience in healthcare and reporting ADEs; the process for reporting AEs at their primary treatment setting; thoughts on the reasons for ADEs not being reported and health information systems used for ADE reporting. To assess the ADE-reporting process, respondents were provided 10–18 possible steps in the ADE-reporting process, depending on professional setting. Respondents selected and ordered the steps to create a reporting process map. Using a Likert scale, respondents then reported whether the selected steps were consistently completed at their institution. Data were analysed using descriptive statistics. Qualitative responses were coded and categorized into main themes. The survey was sent to individuals in internal and external databases via e-mail, social media, and HCP and pharmacist associations from three New Jersey, New York, and

Washington. A total of 123 individuals completed the survey.

The Tufts CSDD study evaluated ADR reporting procedures in U.S hospitals, private practices and retail pharmacies and revealed factors that affect the number and quality of spontaneous ADR reports as follows: a lack of education of both Health Care Providers (HCPs) and patients may play a large role in ADE under-reporting. Not having enough time to devote to reporting, due to priorities placed on the provision of care, was the second most common reason selected by HCPs for not reporting ADRs. Employees in such a setting also relied on the pharmacy's Patient Medication Record (PMR) system. Interviewees noted that the incident-reporting systems were not integrated with any of the other electronic systems (e.g. computerized physician order entry [CPOE], EHR/EMR), and that the incident reporting systems did not have a feature that could push ADE data directly to the FDA or drug manufacturer. No hospital electronic system routinely captured manufacturer, expiry date, lot number, and NDC, which are used as US product identifiers in the International Organization for Standardization's Identification of Medicinal Products (ISO IDMP). "Reporting the ADE" was often one of the least consistent steps in the process across all treatment settings. Within the hospital setting, 44 % of respondents were not sure if a formal procedure for reviewing reports submitted to incident reporting existed. When asked who was accountable for reporting ADEs, 33 % of respondents from a hospital or institutional setting, 20 % from an ambulatory or private practice and 36 % from a retail pharmacy were uncertain. The majority (51 %) of the 123 respondents who completed the survey had not reported any ADEs to the FDA or drug manufacturer in the last 5 years. Of respondents who reported an ADE in the last 5 years, 92 % had reported to two or more organizations. Regarding the respondents' perceptions on why HCPs may not have reported ADEs to the FDA or drug manufacturer. The top three reasons were that the patient was receiving more than one therapy so it was difficult to establish which drug caused the ADE (66 % selected 'often' or 'very often'); that the HCP did not have enough time to devote to reporting due to the priority placed on the provision of care (63 % selected 'often' or 'very often'); and that integration between the disparate electronic systems and the reporting form is lacking (53 % of respondents selected 'often' or 'very often'). Lack of a standardized process could explain why 52 % of respondents were unsure about the reporting process and 51 % unsure about to whom they should report. Gaps in technology integration, education and in the process were discovered (Stergiopoulos et al., 2016).

HCPs indicated that the main reasons for under-reporting were difficulty in determining the cause of the ADE, given that most patients receive multiple concomitant therapies (66 % of respondents); that HCPs lack sufficient time to report ADEs (63 %); poor integration of ADE-reporting systems (53 %) and uncertainty about reporting procedures (52 %).

A study evaluating the knowledge, attitudes and practices of healthcare workers towards ADR reporting in Johannesburg

Spontaneous reporting of ADRs, a method of post marketing surveillance, provides a means to discover new, rare or unnoticed ADRs. Underreporting of ADRs is common in South Africa. A study which assessed the knowledge, attitude and practices of health care professionals on ADR reporting in Johannesburg exposed some reasons why health care workers fail to report ADRs adequately.

Thre scope of the study was 10 wards and the Pharmacy department of a tertiary public- sector hospital in Johannesburg, one of the largest Teaching hospitals in South Africa. The descriptive quantitative study employed questionnaires which were distributed by stratified sampling to doctors, nurses and pharmacists at the institution from July to November 2016. The sample for the study was all participating medical doctors; nurses and pharmacists working within the 10 chosen wards and the hospital pharmacy, representing the overall study population of the healthcare professionals at the study site. 338 questionnaires were sent out and 297 HCPs responded.

Most healthcare professionals cited the seriousness of the ADR (90%) as the main encouraging factor in deciding whether to report an ADR. Despite a high level of awareness on ADRs, many respondents were unlikely to report ADRs observed due to time constraints and a lack of knowledge. The benefits of reporting should be emphasized by encouraging continuous professional development in pharmacovigilance and placing more emphasis on relevant education at the undergraduate level.

A survey on the knowledge, perceptions and practice of pharmacovigilance amongst community pharmacists in Lagos state, southwest Nigeria

This study aimed to investigate the knowledge, perceptions and practice of Pharmacovigilance amongst community pharmacists in Lagos State, Southwest Nigeria Also, their attitude towards ADRs reporting was investigated. Lagos is one of the largest cities in Nigeria with a growing population of about 17 million inhabitants. The city of Lagos has the highest number of pharmacies (according to year 2009 Pharmacists Council of Nigeria data). In the present study, a total of 420 registered

pharmacies, covering 40% of all the registered community pharmacies in Lagos, were visited between February and July 2009. A cross-sectional observational survey was used in this study. A multistage random sampling technique was employed in the selection of the pharmacies. Following the Lagos state association of community pharmacists zonal coordination list, community pharmacies in Lagos state fall into 12 zones; 35 pharmacies per zone were randomly selected from each zone given a total of 420. The duly registered superintendent pharmacists who are in direct supervision of the selected pharmacies were included in the study.

The face-to-face questionnaire method was conducted with the pharmacists. The questionnaire consisted of questions about the socio-demographic characteristics of the pharmacists, their post graduate qualification, knowledge, perceptions and practice of pharmacovigilance as well as their attitudes towards ADR reporting and reporting rate. Furthermore, four themes that were suggestive of pharmacists' attitude towards pharmacovigilance were identified. Respondents were required to state the extent to which they agreed or disagreed with the questionnaire items. Another seven themes were constructed to examine pharmacists' willingness to practice and factors that affect the practice of pharmacovigilance. The responses were either a true, false, cannot say or no.

Out of 400 questionnaires administered, 332 questionnaires were properly filled and vailable for analysis. The results revealed the following: about 55% of respondents have ever heard of the word Pharmacovigilance out of which less than half (representing only 18% of all respondents) could define the term 'Pharmacovigilance'. There was a statistically significant association between years of experience and knowledge of pharmacovigilance ($p < 0.05$) however, there was no statistically significant association between having a post-graduate degree and knowledge of pharmacovigilance ($p > 0.05$). Forty percent of the pharmacists stated that patients reported ADRs to them at least once a month, and 20% of pharmacists reported to Pharmaceutical Companies, Pharmacists Council of Nigeria, Pharmaceutical Society of Nigeria and National Pharmacovigilance Centre. However only 3% of the above respondents reported an ADR to the National Pharmacovigilance Centre (NPC). The main reasons for poor reporting according to respondents were lack of knowledge about reporting format for ADRs (44.6%) and lack of incentives for ADR reporting (9.6%). 90% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential. Community pharmacists were asked if they had an essential role to play in ADR reporting. Majority of respondents strongly agreed that community pharmacists had an essential role to play in ADR reporting. They also strongly agreed that community pharmacists should regularly update their knowledge/skills regarding the provisions of pharmacovigilance.

The study confirmed that the community pharmacy practice provides opportunities for adverse drug reaction reporting and monitoring patients' response to treatments under real-life conditions. The main findings from this study was that the knowledge and practice of pharmacovigilance amongst

Nigerian community pharmacists was poor; community pharmacists in Lagos had poor knowledge about pharmacovigilance and the reporting rate was also poor. The key points from the study in Lagos show that the success of passive pharmacovigilance is dependent on the frequency of reporting by the health care professionals. Community pharmacists in Lagos had poor knowledge about pharmacovigilance however, If trained, are willing to practice pharmacovigilance.

There are reports from other countries which emphasize the problem of underreporting amongst community pharmacists and the very few ADR reports that reach the National Pharmacovigilance Centre. In a similar study in Turkey only 6.7% of community pharmacists reported ADRs to their NPC while 11% of community pharmacists in Iran reported to their NPC. Reasons for poor reporting according to respondents in this study include lack of awareness about pharmacovigilance and lack of incentives for ADR reporting. One important reason for poor reporting as implied from this study is inaccessibility to the ADR forms, as 88% of respondents claimed that they did not have access to the forms.

Conclusion

Globally, the underreporting of adverse events is still a prevalent and common problem. In Nigeria, there is limited information on the activities of community pharmacists in pharmacovigilance. The role of community pharmacists in spontaneous ADR reporting is crucial in the pharmacovigilance system. Spontaneous reporting of ADRs is the cornerstone of pharmacovigilance and is important in maintaining patient safety.

NAFDAC, a WHO Maturity Level 3 (ML3) Regulatory Agency is strengthening Pharmacovigilance in all the 37 states of the federation by training of healthcare

professionals on pharmacovigilance and the use of the med safety app. Electronic reporting of Adverse events due to medical products is a convenient means for spontaneous reporting, it circumvents the challenges associated with inaccessibility of paper-based ADR reporting forms. The available e-reporting channels are the med safety app and the link to e-reporting on the NAFDAC-website (https://primaryreporting.who-umc.org/NG).

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