PHARMACOVIGILANCE
NEWSLETTER

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Spontaneous reporting in a hospital setting: barriers and 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: **Spontaneous reporting in a hospital setting: barriers and 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

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). A serious Adverse Event, by definition, results in disability, hospitalization (initial or prolonged), death, or birth defect, or requires medical intervention to prevent serious injury or death, sometimes a patient's reason for admission to the hospital is a serious AE, and could be associated with medication use.

Medicines are intended to heal and prevent ailments however, there is no guarantee that they won't themselves cause harm. Spontaneous reporting of ADRs is a method of post marketing surveillance, providing a means to discover new, rare or unnoticed ADRs (Gordhon & Padayachee, 2020).

Reporting systems are in place through which Health Care Providers can report any adverse event (AE) observed. Unfortunately, a good number of studies have shown that underreporting of adverse events by Health Care Workers is a prevalent and common problem. Two researches have indicated that the FDA receives reports for less than 1% of suspected serious adverse drug events (Stergiopoulos et al., 2016).

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is responsible for drug monitoring. Reporting systems use spontaneous reporting or other pharmaco-epidemiological methods to systematically collect and analyse undesirable events associated with the use of drugs, identify signals or emerging problems, and communicate how to curtail or avoid harm. Findings from adverse event reports present evidence that can be the basis for regulatory actions to protect public health. However, these processes are not without challenges. The importance of Pharmcovigilance includes early detection of increases in frequency of previously known ADRs & interactions, other noxious drug induced problems, detection of increase in unknown ADRs and identification of predisposing risk factors and possible mechanisms underlying ADRs; it also promotes rational and safe use of medicines. The major component of pharmacovigilance is the documentation of adverse drug reactions (ADR). The patients can assist in providing the information about adverse event(s) experienced for documentation (Ugwah-Oguejiofor and Michael, 2012).

The hospital setting, having a clearly defined patient population that is under observation is an ideal setting in which to identify potential adverse drug reaction signals and to report them to the appropriate authority (Pushkin et al, 2020).

In a systematic review of studies across Europe, Asia, Australia, and North and South America, 5% of hospital admissions were associated with ADRs. There is an increased risk of death and length of hospital stay (by

8.25%) in patients who experience ADRs while hospitalized. ADRs are a significant cause of death and other serious outcomes in infants and children aged that are 2 years or less. Underreporting of ADRs is significant and common; a systematic review of 37 studies from 12 countries (including the United States) found a median underreporting rate of 94% (range, 6% to 100%), a lower median rate was identified for serious ADRs (85%). For instance, only 4% to 10% of toxic epidermal necrolysis cases were reported to the Canadian ADR Monitoring Program between January 1995 and December 2000 (Pushkin et al, 2020).

Spontaneous reporting & barriers

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).

In 1976, William Howard Wallace Inman identified **seven "deadly sins" for ADE under-reporting: complacency; fear of litigation; guilt from incorrect prescribing; ambition to publish a case study; ignorance of the process; insecurity about reporting suspicions (diffidence);** and **indifference in role of sharing medical knowledge**. Up to 40 years later, all sins still apply and two particularly stand out: ignorance of process and insecurity about accurately identifying the drug causing the ADE. As such, not only should improvements be made in Health Information Technologies to streamline the reporting process but stakeholders such as regulatory agencies and associations should also provide stronger guidance and continuing training for HCPs to increase awareness of both the importance of reporting events and the processes that should be followed in each setting.

A study revealed that most ADRs are reported by pharmacists and nurses, with physicians reporting the fewest ADRs. In one study, of 349 suspected ADRs reported during hospital admissions in neurosurgical patients over a 3-year period, 41% were reported by pharmacists, 39% by nurses, and 20% by physicians. In another study, 89% of ADRs in pediatric patients over a 10-year period were reported by pharmacists, 10% by nurses, and 1% by physicians. The extent of underreporting is highlighted by studies indicating that interventions to improve reporting by physicians led to a substantial increase in the quantity and quality of spontaneous ADR reports (Pushkin et al, 2020).

A study involving health care workers at Johannesburg

A study assessed the knowledge, attitude and practices of health care professionals on ADR reporting at 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 study sample consisted of 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.

Conclusions from the study include the following: **pharmacists were the most likely group to know how to report (82.6%) (p< 0.001). Half of the respondents (50%) stated they knew how to report an ADR, and most (77%) stated that they were familiar with the adverse drug reporting form.** Respondents favored all the options as the reasons for the importance of ADRs, with patient safety (94%) featuring as the most important reason. 97% of participants stated they had previously received training on ADR reporting and knew how to report them. Although, 58.59% of participants had encountered adverse drug reactions, only 16.50% had reported them ($p < 0.001$). The discouraging factors discovered from responses were prioritizing patient management, lack of knowledge and the time-consuming requirement of reporting. 77% of the respondents stated that they were familiar with the adverse drug reporting form. 54% of the nurses were unaware of how to report an ADR, while 54% of doctors and 83% of pharmacists stated they knew how to report. **Only 23% of the total interns knew how to report ADRs. This shows a relationship between the level of practice and the knowledge of ADR reporting. 93% of respondents felt physicians should be held responsible, followed by nurses and pharmacists.** The most common reference for ADR reporting used was the internet (80%). Only 11% of respondents had received previous pharmacovigilance training. Of the 174 respondents, 59% had encountered an ADR in practice yet only 17% had reported the encountered ADR. The vast majority of respondents (74%) submitted less than 1 ADR per year. This could be attributed to the low percentage of respondents who had previously attended pharmacovigilance training. Pharmaceutical and Therapeutics Committees (PTC) should be recognized as an important channel for communication within institutions. A range of factors discouraged respondents from reporting ADRs, including feelings that it is more important to prioritize managing the patient. Other reasons included a lack of knowledge about the reporting system, which is consistent with other studies. Most healthcare professionals cited the seriousness of the ADR (90%) as the main encouraging factor in deciding whether to report an ADR (Gordhon & Padayachee, 2020).

A study involving health care workers at Sokoto, Nigeria

A study on health workers and hospital patients was carried out in Sokoto, Nigeria. The study was conducted at the Usmanu Danfodiyo Teaching Hospital (tertiary hospital) and Sokoto State specialist hospital (Secondary hospital); these two hospitals are the most attended in the state and their population are typical of what is being investigated. A purposive sampling technique was used in the selection of 2 major hospitals in Sokoto. Questionnaires and oral interview were used to evaluate the health workers and patients on their demographics and knowledge about pharmacovigilance and ADR reporting.

This research aimed to determine the knowledge of pharmacovigilance amongst health workers and hospital patients in Sokoto and to suggest possible ways of improving the ADRs reporting system. 86.6% of health workers and 33.7% of patients knew about pharmacovigilance; 8.1% of health workers and 0% of patients have seen the yellow form for the reporting of ADR respectively. None of the health workers had ever reported on the yellow form. In the free comment on ways of improving pharmacovigilance, 44.2% suggested remuneration of those filling the ADR form, 87.9% suggested mass education of the general public, 77.1% suggested training the pharmacists, doctors and others who are expected to fill the forms. 63.9% suggested establishment of ADR committee in the hospitals while 55.9% believed that making the yellow form available would encourage reporting. The knowledge of pharmacovigilance amongst health workers and hospital patients in Sokoto is very poor. Adequate awareness needs to be created by education of the general populace also in their mother tongue. Establishment of ADR committees, making the yellow form available and training relevant staff were suggested as ways of advancing pharmacovigilance.

The salient role of health workers in spontaneous reporting

A study by Pushkin et al postulates that Hospital Physicians are in a position to be an Integral Component of ADR reporting. The emergency department or medical ward may offer an ideal opportunity to recognize AEs and possible associations with medications. Medications are often initiated in the hospital where ADRs can occur under direct patient observation, therefore physicians, nurses, and pharmacists may all be in a position to recognize these events and respond accordingly. The hospital is an ideal setting because it involves a small yet controlled population of ill patients. If a hospitalized

patient's illness could be determined to be related to a particular medication, reporting this ADR would be of importance to the larger patient population as a whole. A patient's medical history, concurrent conditions, and treatments are well known and identified in the hospital setting, and therefore it is easier to understand a given reaction than in the less controlled outpatient setting. Reporting every ADR would be of value because important signals could be identified that would not be known otherwise, eg, harmful or allergenic excipients, faulty formulations, disintegration problems from poorly manufactured tablets, use of new raw materials, etc. Health care providers do not need to be certain that an AE is caused by a drug in order to report it. Adverse event reporting is only a hypothesis generating mechanism, identifying potential safety signals. The responsibility for assessing causality and changes in the benefit-risk profile of products lies with drug safety specialists at the regulatory agency or manufacturer. Pharmacovigilance by health care providers enables these specialists to assess, analyze, and report AEs and potential ADRs quickly, in cooperation with the Regulatory Authority to maintain public safety. The more reports of AEs or potential ADRs received by the NRA or manufacturers, the more likely that safety signals will be quickly identified (Pushkin et al, 2010).

With the launch of the **Medsafety app** by NAFDAC, Health professionals and patients can conveniently **report adverse events** experienced with the use of **vaccines and medical products** to NAFDAC (the Medsafety Application is available for download on Android and IOS stores). Another eReporting platform is available on the NAFDAC website www.nafdac.gov.ng.

Conclusion

Spontaneous reporting of adverse events by health care workers is essential to Pharmacovigilance. Some of the main causes of under-reporting include William Howard Wallace Inman's description, **"ignorance, insecurity, and indifference.** Underreporting leads to incomplete data and can lead to unnoticed signals in ADRs. How much information is gathered and duly reported largely depends on the awareness and assertiveness of the professional. The reasons for the underreporting of ADRs by healthcare professionals have been researched globally. Inability to recognize ADRs, ignorance of the reporting requirements, lack of reporting forms, feeling of guilt following the occurrence of adverse effects and fear of litigation prevent Health care Professionals from adhering fully to the framework of reporting, resulting to inadequate or incomplete data (Gordhon & Padayachee, 2020).

The Johannesburg study informs that health care workers should not be discouraged from reporting ADRs due to feelings that it is more important to prioritize managing the patient or the non-seriousness of the ADR. The benefits of reporting should be emphasized by encouraging continuous professional development in pharmacovigilance, placing more emphasis on relevant education at the undergraduate level and training & re-

training of health care workers on pharmacovigilance (Gordhon & Padayachee, 2020).

The availability of eReporting platforms in Nigeria has made online reporting very convenient in contrast to the use of only paper-based yellow forms.

References

Chen, Y., Niu, R., Xiang, Y., Wang, N., Bai, J., & Feng, B. (2019). The Quality of Spontaneous Adverse Drug Reaction Reports in China: A Descriptive Study. Biological & Pharmaceutical Bulletin, 42(12), 2083–2088. Retrieved December 10, 2021 from https://doi.org/10.1248/bpb.b19-00637

Gordhon, Y., & Padayachee, N. (2020). Evaluating the knowledge, attitudes and practices of healthcare workers towards adverse drug reaction reporting at a public tertiary hospital in Johannesburg. International Journal of Africa Nursing Sciences, 12, 100191. Retrieved December 9, 2021 from https://doi.org/10.1016/j.ijans.2020.100191

Pushkin, R., Frassetto, L., Tsourounis, C., Segal, E. S., & Kim, S. (2010). Improving the reporting of adverse drug reactions in the hospital setting. *Postgraduate medicine*, *122*(6), 154–164. https://doi.org/10.3810/pgm.2010.11.2233

Ugwah-Oguejiofor, C. J., & Michael O.U., (2012). Health workers and hospital patients knowledge of pharmacovigilance in Sokoto, north-West Nigeria. *Nigerian Journal of Pharmaceutical Sciences,* 11, 2.

Stergiopoulos, S., Brown, C. A., Felix, T., Grampp, G., & Getz, K. A. (2016). A Survey of Adverse Event Reporting Practices Among US Healthcare Professionals. Drug Safety, 39(11), 1117–1127. Retrieved December 9, 2021 from https://doi.org/10.1007/s40264-016-0455-4