PHARMACOVIGILANCE
NEWSLETTER

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Pharmacovigilance in Public Health Programmes

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.

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 in Public Health Programmes.**

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 the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems (Kiguba et al., 2023). It includes keeping an eye on the security of pharmaceutical items in use, spotting and looking into drug-related issues, and disseminating information about medications to the general public and healthcare professionals. Pharmacovigilance is crucial to public health initiatives because it guarantees that medications are used judiciously and safely and that any unfavourable drug interactions are swiftly identified and prompt action taken to possibly reduce the impact of any adverse event.

The provision of safe and efficient healthcare services falls under the purview of the public health sector. Public Health Programmes (PHPs) are vertical Programmes that focus on a particular health issue, using direct delivery of medications or vaccines for prophylaxis, treatment, and eradication (Guidelines on Pharmacovigilance for Public Health Programmes, 2022). Some Public health programmes include National TB Control Programme (NTBCP), Institute of Human Virology Nigeria (IHVN), Society for Family Health (SFH), Management Sciences for Health (MSH), the Centre for Integrated Health Programs (CIHP), FHI 360 and AIDS Prevention Initiative in Nigeria (APIN).

Role of Pharmacovigilance in Public Health Programmes

The purpose of entrenching pharmacovigilance in public health programmes (PHPs) is to ensure the safety and efficacy of pharmaceutical products in use. Pharmacovigilance also serves to guarantee that medications are used rationally and safely. It is crucial to continuously monitor a medicine's use since adverse drug reactions might happen even with drugs that have undergone rigorous research and clinical studies (Guidelines on Pharmacovigilance for Public Health Programmes, 2022).

Pharmacovigilance in public health programmes involves monitoring adverse drug reactions and investigating drug-related problems. Adverse drug reactions are any undesirable effect that occurs after the use of a drug, including side effects, toxicity, allergic reactions, and interactions with other drugs. Investigating drug-related problems involves analysing the data collected from adverse drug reaction reports, identifying the cause of the problem, and determining the best course of action to prevent future occurrences.

Pharmacovigilance is a multidisciplinary intervention which requires strategic planning and synergy between relevant stakeholders including Regulatory Agencies, Health Care Providers, Patients and the industry to ensure the safety and efficacy of medicines both in conventional use and public health programmes. Regulatory authorities are accountable for monitoring and regulating drug safety and efficacy by gathering and examining reports of adverse events. Healthcare providers in detecting and reporting adverse drug reactions, ensuring that medicines are prescribed appropriately and communicating drug-related information to patients. Patients can also contribute to pharmacovigilance by reporting adverse drug reactions and sharing their experiences with drugs.

Public health Programmes have a responsibility to ensure that drugs are safe and effective for the populations they serve, and pharmacovigilance is a vital tool in achieving this goal, thereby achieving a decrease in morbidity and mortality rates (Guidelines on Pharmacovigilance for Public Health Programmes, 2022).

Pharmacovigilance Indicators for PHPs

Pharmacovigilance indicators are measures of the inputs, processes, outputs, outcomes, and impacts of development initiatives, Programmes, or policies connected to health systems and services. They give data to assess how successfully a pharmacovigilance Programme is accomplishing its goals (WHO, 2015). WHO pharmacovigilance indicators were recommended as a useful tool towards improving pharmacovigilance activities. Nigeria with a myriad of medicines related issues is encouraging the growth of pharmacovigilance at peripheral centres. As earlier stated, Public health Programmes have a responsibility in ensuring that drugs are safe and can ameliorate the diseases they are meant for. A PHP must have an effective pharmacovigilance strategy in place to keep an eye on the vulnerability of the

people getting these therapies, as well as the safety and safe use of the large quantities of specialized therapeutic items.

The Pharmacovigilance indicators serve as useful guides in the effective running of public health Programmes. According to the World Health Organization, there are nine pharmacovigilance indicators for public health Programmes and they are as follows:

1. Activities related to pharmacovigilance are listed in the operational document of the public health Programme.
2. All main treatment guidelines or protocols in use within the public health Programmes systematically consider pharmacovigilance.
3. Existence of standard ADR reporting form in the setting.
   Subset indicators: The standard reporting form provides for reporting:
   a. Suspected medication errors;
   b. Suspected counterfeit/substandard medicines;
   c. Therapeutic ineffectiveness;
   d. Suspected misuse, abuse of and/or dependence on medicines.
4. Total number of ADR reports collected within the public health Programmes in the previous year.
5. Total number of ADR reports per 1000 individuals exposed to medicines in the public health Programmes in the previous year.
6. Total number of reports on therapeutic ineffectiveness in the previous year.
7. Percentage of completed reports submitted to the National pharmacovigilance centre in the previous year.
   a. Of the reports satisfactorily completed and submitted to the national pharmacovigilance centre, percentage of reports committed to the World Health Organization (WHO) database.
8. Number of medicine-related hospital admissions per 1000 individuals exposed to medicines in the public health Programmes in the previous year and
9. Number of medicine-related deaths per 1000 individuals exposed to medicines in the public health Programmes in the previous year (WHO, 2015).

A study on the state of pharmacovigilance in the South-South zone of Nigeria

A study was conducted to assess the status of pharmacovigilance in tertiary hospitals in the south-south zone of Nigeria **using WHO pharmacovigilance indicators,** with the aim of improving the Pharmacovigilance system in the zone. This cross-sectional descriptive survey was conducted in six randomly selected tertiary hospitals and data was collected using the WHO core pharmacovigilance indicators. Following a meeting with the various heads of the institutions, the focal Pharmacovigilance persons or committees were interviewed. Out of the six hospitals visited, all institutions had a pharmacovigilance centre, only three could however be described as functional or partially functional. Only one centre had a financial provision for pharmacovigilance activities. Of note was the absence of the national adverse drug reaction reporting form in one of the hospitals. The number of adverse drug reaction reports found in the databases of the centres ranged from none to 26 for the previous year and only one centre had fully committed their reports to the National Pharmacovigilance Centre. There were few documented medicine-related admissions and a poor documentation of pharmacovigilance activities characterised all centres.

Core structural indicators

Responses were obtained from the interviewed personnel for the assessment questions of the 10 structural indicators for all the institutions studied. Three of the six institutions had a standardized functional accommodation for pharmacovigilance activities while 1 had non-functional rooms and 2 had none. Only one hospital had regular financial provisions for pharmacovigilance. The secretariat in 4 centres had a full-time staff to carry out pharmacovigilance activity while 2 had part time staff. There were no standard forms available which addressed the subset of assessment questions covering the scope of pharmacovigilance in all of the centres.

Core process indicators

The total number of reports in the local database ranged from 0 to 831. There were limited numbers of reports on ADRs, medication errors, lack of therapeutic effectiveness etc. in most of the centres. Documentation of feedback and causality assessment carried out on reports in the centres was poor in this study.

Core outcome/impact indicators

The number of medicine-related hospital admissions per 1000 admissions ranged from 0.00958/1000 to 1.67/1000 and there were no documentations of medicine related deaths in the death registers in the 6 hospitals. The documentation of pertinent data was inadequate, rendering evaluation of other impact pharmacovigilance indicators in the institution difficult.

Derivables from the study

The study in the South-south zone of Nigeria highlighted some strengths and weaknesses of the pharmacovigilance sub-healthcare system in general. Structures were gradually being put in place and there was a general acceptance of the need for pharmacovigilance in all the institutions visited despite institutional challenges. The availability of the newly developed **Nigerian national pharmacovigilance policy** in

some of the centres is a testament to the will of the Nigerian government to institutionalize patient safety through good pharmacovigilance practice. It suggests that the interest of the key stakeholders in the pharmacovigilance sector is needed to sustain the development of the pharmacovigilance system. The study revealed poor budgeting for pharmacovigilance in most centres as only a centre (UBTH) had financial provision for pharmacovigilance. The availability of relevant staff and committees are paramount to the growth of pharmacovigilance; hospitals with developed committees and personnel disposition had slightly better reports. Adequate funding of pharmacovigilance is crucial to support the development of active pharmacovigilance programs, provision of training, feedback, information dissemination, capacity development and maintenance of the centre (Opadeyi et al., 2018).

Conclusion

Pharmacovigilance should be given adequate attention in all public health programs and institutions. All stakeholders need to ensure that the health of the general public is safeguarded by adequate budgeting & funding for pharmacovigilance, capacity building, adequate documentation, feedback and maintenance of health facilities. As enumerated by the study conducted in South-South zone of Nigeria, there is a need to uphold the pharmacovigilance systems and sustain the documentation of pharmacovigilance activities characterized in all centres and public health programmes nationwide (Opadeyi et al., 2018). The nine WHO Pharmacovigilance indicators serve as useful guides and regular pharmacovigilance evaluations with pharmacovigilance indicators would translate to better pharmacovigilance processes and outcomes.

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