Approaches and Tools for Strengthening Pharmaceutical Systems

Safety Monitoring of Medicinal Products: Strengthening Pharmacovigilance Systems

Technical Brief | February 2023

Why is pharmacovigilance important?

Access to safe, effective, affordable, and quality-assured medical products is crucial for universal health coverage and high-performing health care systems. Many low- and middle-income countries (LMICs) have inadequate capacity to monitor the safety of medicines and vaccines, which was further exposed by the COVID-19 pandemic. Medication-related harm accounts for 50% of preventable harm in medical care globally, costing USD 42 billion, according to the World Health Organization (WHO).[1] Therefore, it is crucial to improve drug safety regulation, and this requires implementation of efficient pharmacovigilance (PV) systems in all countries.

PV, according to WHO, involves scientific activities to detect, assess, understand, and prevent adverse effects and other drug-related issues.[2] This involves identifying, evaluating, comprehending, and preventing adverse reactions to medications and other medicine-related issues, with a particular emphasis on safety and efficacy. Integrating PV into a health care system can enhance medication safety by reducing the incidence of adverse drug reactions (ADRs) and establishing a reliable warning network among various stakeholders, such as health care providers, regulatory bodies, manufacturers,

and consumers, to respond promptly and efficiently to safety concerns.[3]

In this document, we present approaches and resources that MTaPS has found effective to strengthen PV and describe how other organizations can apply them in their context.

Approaches and tools for strengthening PV systems

The USAID MTaPS program supports LMICs in strengthening PV systems by using the WHO's Global Benchmarking Tool (GBT) for regulatory systems as a guiding instrument. The GBT objectively evaluates a country's capacity to regulate medical products, and MTaPS collaborates with countries to address any identified gaps and weaknesses in their regulatory systems.

The GBT is a pioneering initiative that provides a comprehensive framework for assessing and enhancing regulatory systems. The tool is comprised of 268 indicators, organized by regulatory function, which enable the classification of a national medicines regulatory authority's (NMRA) maturity level on a four-point scale, ranging from 1 (no formal approach) to 4 (emphasizing continuous improvement). This scoring system offers NMRAs a means of assessing their control

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[1] World Patient Safety Day. September 17, 2022. WHO. https://www.who.int/campaigns/world-patient-safety-day/2022

[2] WHO. Importance of pharmacovigilance: Safety monitoring of medicinal products. Geneva: WHO; 2002. https://apps.who.int/iris/handle/10665/42493

[3] Bencheikh RS, Benabdallah G. (2009). Medication errors: Pharmacovigilance centres in detection and prevention. Br J Clin Pharmacol. 2009;67(6):687–690. https://doi.org/10.1111/j.1365-2125.2009.03426.x

over the regulatory processes for medical product availability in the market. To address areas requiring improvement, an institutional development plan (IDP) is then developed, including corresponding resources and potential partners to support the interventions. The IDP promotes collaboration between technical, advocacy, and funding partners and agencies to reinforce regulatory systems, eliminate redundancies, and promote resource efficiency.[4]

The support MTaPS provides to countries focuses on several key areas, including:

- Establishing the legal and regulatory framework for PV
- Improving the demand for and availability and use of country-level safety data for regulatory and clinical decision making
- Strengthening the processes for risk identification and characterization, risk assessment/evaluation, risk minimization, and safety communication
- Establishing a system for passive and active safety monitoring for high-risk medicines
- Enhancing communication and fostering awareness by training and capacity development of health care professionals and the public

Case studies on PV strengthening

Establishing a functional PV system in the Philippines

The Philippines, like many LMICs, was struggling with a shortage of qualified health workers in critical areas of PV, which was posing a threat to the capacity of the health system to respond to major health challenges and maintain patient safety. To address this issue, MTaPS conducted a workforce needs assessment for the Department of Health (DOH) in 2019 and identified competency gaps, as well as a workforce development plan to fill the necessary positions and institutional arrangements to address staff capacity needs. Technical assistance and capacity building were provided by MTaPS to DOH to professionalize the PV workforce and establish fully functional PV and product registration systems, as well as improve pharmaceutical services to

ensure patient safety and the rational use of health commodities.

MTaPS has been providing support to establish a comprehensive PV system that adheres to WHO GBT recommendations. MTaPS also collaborated with the Philippine Food and Drug Administration (FDA) to review PV best practices and update the national policy for PV, outlining the roles and responsibilities at different levels for monitoring the safety of medicines. The policy includes updated terms of reference for the national PV Advisory Committee, reinforcing the importance of PV in the health care system.

To provide training to the PV workforce, MTaPS and FDA codeveloped the course Pharmacovigilance Principles and Reporting, which aims to introduce general PV principles and concepts, discuss adverse event (AE) reporting systems in the Philippines, and encourage reporting to improve the safety profile of health commodities. Continued investment in the training and development of the health workforce is crucial for sustainable, well-functioning PV systems.

Additionally, MTaPS has been supporting DOH and FDA in implementing the Pharmacovigilance Monitoring System (PViMS) to monitor drug safety for active TB and manage its use in the country, while also providing expanded training for front-line health workers on PViMS usage.

Developing an adverse-events-following-immunization reporting system in Bangladesh

As Bangladesh undertook the ambitious task of vaccinating its population of 160 million against COVID-19, it was critical to ensure the safety of those vaccinated, particularly as novel vaccines created using new technologies were being administered at an unprecedented scale. To strengthen the PV system in Bangladesh, MTaPS collaborated with local partners and WHO to establish an online reporting system for adverse events following immunization (AEFIs) related to COVID-19 vaccines. This reporting system has been vital in enabling timely and effective submission of reports on adverse reactions.

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[4] WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. May 10, 2021. World Health Organization. https://www.who.int/tools/global-benchmarking-tools

To further support effective reporting, MTaPS conducted extensive outreach efforts, including training health care workers and distributing educational materials to health care professionals and the public. These efforts have led to a significant increase in the reporting of AEFIs, resulting in appropriate regulatory action being taken to address these adverse reactions. The MTaPS program in Bangladesh has had a notable impact on bolstering the national PV system, with all efforts contributing to the advancement of WHO GBT maturity levels.

Strengthening Rwanda's FDA

Despite having a PV system to capture data on ADRs, Rwanda has struggled to provide sufficient active safety monitoring for priority medicines. To address these challenges, MTaPS has taken a strategic approach by supporting the Rwanda FDA to enhance its institutional capacity and address weaknesses and gaps identified in its IDP, with the goal of achieving WHO GBT maturity level 3. MTaPS has collaborated with the Rwanda FDA to develop a comprehensive, multi-year national PV plan with well-defined goals, objectives, and a cost-effective implementation strategy. This plan will guide progress toward a robust PV system. Moreover, in collaboration with public health programs for HIV and TB, MTaPS is enhancing the capacity of Rwanda FDA's PV system by implementing electronic tools and protocols, such as PViMS.

- **PViMS:** MTaPS provided support to Rwanda FDA in implementing PViMS for reporting AEs, including those related to Ebola and COVID-19 vaccines. Additionally, MTaPS supported the FDA in adapting PViMS for active safety monitoring of dolutegravir-based antiretroviral therapy regimens. From June 2021 to September 2022, the system received 1,268 AEFI reports, of which 317 were considered serious and were investigated and submitted to the WHO Uppsala Monitoring Centre. Using PViMS allows for timely receipt and analysis of medicine safety monitoring reports by the FDA, enabling prompt feedback to patients and health care professionals.

- **Capacity development:** To sustain capacity building, MTaPS offered technical support in developing online e-learning courses in PV. These courses are designed to provide comprehensive and engaging learning experiences, covering key aspects of PV and empowering individuals with the necessary skills and knowledge to contribute to a robust PV system. Hosted on the FDA server, these courses have been well received to expand learners' understanding of PV.

Monitoring safety of medicines and vaccines in West Africa

As of 2015, 35 out of 54 African countries had implemented a PV system and were full members of the WHO Programme for International Drug Monitoring.[5] However, there has been no comprehensive data published on the functionality or maturity of these systems, which range from basic units within health care institutions to more sophisticated, fully functional national PV centers.

In response to this issue, the African Medicines Regulatory Harmonization (AMRH) Program of the African Union, along with other stakeholders, convened a meeting in May 2015 and agreed on the need for a web-based platform to track PV system indicators. Following this meeting, MTaPS collaborated with the African Union Development Agency-NEPAD, the AMRH's regional centers of regulatory excellence in PV, and other stakeholders to develop a web-based platform that collects, tracks, and analyzes results from PV indicators in the WHO GBT. This information is used to assess the status of PV systems in Africa and identify capacity gaps to improve patient safety in the region.

On April 28, 2022, MTaPS, in collaboration with the West African Health Organization and the 15 member states of ECOWAS, launched the first-ever portal for monitoring the safety of medicines and vaccines in West Africa.

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[5] Ampadu HH, Hoekman J, de Bruin ML, Pal SN, Olsson S, Sartori D, Leufkens HG, Dodoo, AN. Adverse Drug Reaction Reporting in Africa and a Comparison of Individual Case Safety Report Characteristics Between Africa and the Rest of the World: Analyses of Spontaneous Reports in VigiBase®. Drug Safety. 2016;39(4):335–345. https://doi.org/10.1007/s40264-015-0387-4

This web-based platform allows member states to share PV data, improve their PV systems, and identify regional and national capacity gaps. The platform provides routine monitoring of PV systems, improved visibility of the maturity status of PV systems in African countries, and strengthened regional collaboration for PV harmonization initiatives.

How can organizations apply these approaches?

Below are resources that can equip organizations with the knowledge and tools to actively strengthen PV in their local contexts.

Tools

- WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems (WHO, 2018): This serves as the primary means of objectively evaluating national regulatory systems, including PV systems, as mandated by the World Health Assembly Resolution 67.20 on Regulatory System Strengthening for Medical Products. The GBT provides a standardized framework for evaluating national regulatory systems, enabling WHO to assess their capabilities and identify areas for improvement. This tool supports efforts to ensure that medical products are safe, effective, and of good quality, thereby contributing to global public health.
- The PharmacoVigilance Monitoring System (PViMS): The PViMS web-based application was developed by the USAID-funded Systems for Improved Access to Pharmaceuticals and Services Program, implemented by Management Sciences for Health. This platform provides a comprehensive solution for PV in LMICs by streamlining the data collection, analysis, and reporting process. By enabling active surveillance activities, PViMS enables stakeholders, including clinicians, regulatory bodies, and implementing partners, to monitor the safety of medicines and identify potential AEs related to medicine use. The platform, when used for both active monitoring and spontaneous reporting, provides a comprehensive approach to PV, thereby improving patient safety in LMICs.

Additional readings and resources

- Medication Without Harm: Implementing Pharmacovigilance (September 2022)
- Kenya Launches Mobile Reporting Tool to Improve Medical Product Safety Monitoring (April 2022)

- 60 years on! Pharmacovigilance continues to contribute to maternal and newborn safety (September 2021)
- Putting the Pandemic Behind Us: Safety and Efficacy of the COVID Vaccine (September 2021)
- COVID-19 Vaccination: MTaPS Builds the Pharmacovigilance Capacity of Health Providers (August 2021)
- Pharmacovigilance Monitoring System (PViMS) – A Tool to Enhance Decision-Making for Patient Safety (August 2021)
- Sex, Gender, and Vaccines: Considerations for COVID-19 Vaccine Immunity (May 2021)
- Eliminating Poor-Quality Medicines through an Effective Regulatory System in Rwanda (May 2021)
- Establishing Pharmacovigilance for a New HIV Drug in Mozambique (June 2020)

e-Learning resources

- Pharmaceutical Systems Strengthening 101 (available in English and in French): This course introduces learners to the basic principles of PSS, including how addressing pharmaceutical system problems advances universal health coverage; combats AMR, HIV and AIDS, malaria, tuberculosis, and other public health threats; and promotes maternal and child health.
- Courses 2022 - PV centres: Uppsala Monitoring Centre has created a range of e-learning courses to address the worldwide demand for PV training. These courses cover various aspects of medicines safety.
- Rwanda FDA Learn Pharmacovigilance: This module provides an overview of PV, including quality defects, medication errors, causality assessment, active surveillance methods, risk management, and data management.

Contact

Please contact MTaPS (Management Sciences for Health) if you would like further assistance.

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