USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Approaches and Tools for Strengthening Pharmaceutical Systems

Safety Monitoring of Medicinal Products: Strengthening Medicines Safety Pharmacovigilance Systems

Vivian Rakuomi

Senior Technical Advisor

USAID MTaPS

USAID FROM THE AMERICAN PEOPLE

Why is Pharmacovigilance important?

Pharmacovigilance (PV) involves the identification, evaluation, and prevention of adverse reactions to medications and other medicine-related issues. The emphasis is on **safety and efficacy**.

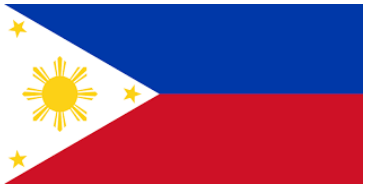
- Medication-related harm accounts for 50% of preventable harm in medical care globally, costing USD 42 billion (WHO 2022).
- Ensuring patient safety and achieving desired health outcomes require **functional** pharmacovigilance systems.
  - Enhanced medication safety by reducing the incidence of adverse drug reactions (ADRs)
  - Creation of reliable warning networks to promptly and efficiently respond to safety concerns

Approaches and tools MTaPS has been using to strengthen PV systems

- 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, assessment, and minimization, and for safety communication
- Establishing a system for passive and active safety monitoring
- Training and capacity development

- Web-based application
- Supports both passive surveillance and spontaneous reporting
- Provides detailed description of adverse event outcomes and generates signals

Case Study: Strengthening PV in the Philippines



The Philippines struggled with a shortage of qualified health workers in critical areas of pharmacovigilance, which threatened the health system's capacity to respond to major health challenges and maintain patient safety. MTaPS supported:

- **Department of Health**—Workforce professionalization
  - Conducted PV workforce needs assessment to identify competency gaps
  - Established workforce development plan to fill the necessary positions and institutional arrangements to address the staff capacity need
- **Food and Drug Administration**—Establishment of a comprehensive PV system that adheres to the WHO Global Benchmarking Tool (GBT) recommendations
  - Reviewed PV best practices
  - Updated the PV national policy outlining the roles and responsibilities at different levels for monitoring the safety of medicines for all patients; the updated policy includes updated terms of reference for the national PV Advisory Committee, reinforcing the importance of PV in the health care system
  - Co-developed course on "Pharmacovigilance Principles and Reporting"
- Implementation of the **Pharmacovigilance Monitoring System (PViMS)** to monitor drug safety for active TB (aDSM).

Case Study: Strengthening PV in Rwanda

Despite having a PV system to capture data on adverse drug reactions, Rwanda had insufficient active safety monitoring for priority medicines. MTaPS has supported the Food and Drugs Authority to:

- ✓ Develop a comprehensive, multi-year national PV plan with well-defined goals, objectives, and a cost-effective implementation strategy
- ✓ Implement the **Pharmacovigilance Monitoring System**
  - Ebola and COVID-19 vaccines adverse events following immunization
    - From June 2021 to September 2022, 1,268 AEFI reports were submitted to the WHO Uppsala Monitoring Centre, of which 317 were considered serious and were investigated
  - Dolutegravir-based ART regimens
- ✓ Develop e-learning courses to build and sustain PV capacity

The use of the PViMS allows for the FDA's timely receipt and analysis of medicine safety monitoring reports, enabling prompt feedback to patients and healthcare professionals.

Case Study: Monitoring Safety of Medicines and Vaccines in West Africa

As of 2015, 35 out of 54 African countries had implemented PV systems, but functionality and maturity varied and no comprehensive data was available on system status.

MTaPS collaborated with the African Medicines Regulatory Harmonization (AMRH) Program, AMRH's Regional Centers of Regulatory Excellence (RCORE), and other stakeholders:

- Agreed on the need for a web-based platform to track PV system indicators
- Developed a web-based platform that collects, tracks, and analyzes results from PV indicators in the WHO GBT
- Working with the 15 member states of ECOWAS and the West African Health Organization, launched the first-ever portal for monitoring the safety of medicines and vaccines in West Africa

The platform allows member states to share PV data and identify regional and national capacity gaps to improve their PV systems.

How can you apply these approaches and tools?

- **WHO Global Benchmarking Tool 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 (WHA) Resolution 67.20 on Regulatory System Strengthening for Medical Products.
  - The GBT provides a standardized framework for the evaluation of national regulatory systems, enabling the WHO to assess their capabilities and identify areas for improvement.
  - This tool supports the 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 (SIAPS) Program, implemented by Management Sciences for Health (MSH).
  - This platform provides a comprehensive solution for pharmacovigilance in low- and middle-income countries (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 adverse events related to medicine use.
  - The platform, when used for both active monitoring and spontaneous reporting, provides a comprehensive approach to pharmacovigilance, thereby improving patient safety in LMICs.

Resources

Additional readings and resources

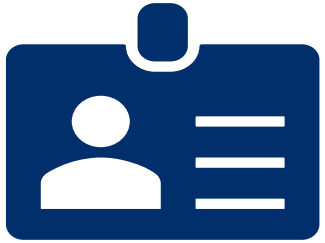
- Medication Without Harm: Implementing Pharmacovigilance (September 2022)
- Kenya Launches Mobile Reporting Tool to Improve Medical Product Safety Monitoring (April 2022)
- 60 years on! Pharmacovigilance continues to contribute to maternal and newborn safety (September 2021)
- Putting the Pandemic Behind 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)

Resources

e-learning and video resources

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

Who to Contact



Vivian Rakuomi, *Senior Technical Advisor*

vrakuomi@mtapsprogram.org