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

Improved Access. Improved Services. Better Health Outcomes.

Photo by MSH staff

MTaPS objectives

1. Pharmaceutical-sector governance strengthened
2. Institutional and human resource capacity for pharmaceutical management and services increased, including regulation of medical products
3. Availability and use of pharmaceutical information for decision making increased and global learning agenda advanced
4. Pharmaceutical-sector financing, including resource allocation and use, optimized
5. Pharmaceutical services, including product availability and patient-centered care, to achieve health outcomes improved

The MTaPS Program is from the American People through USAID

Based on its decades of expertise in strengthening health systems to save lives and improve the health of people in low- and middle-income countries, USAID supports better governance and integrated, innovative, and sustainable strategies to strengthen pharmaceutical systems.

Funded by the US Agency for International Development and led by Management Sciences for Health (MSH), the goal of the five-year USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

USAID FROM THE AMERICAN PEOPLE

STRENGTHENING MEDICINES SAFETY PHARMACOVIGILANCE SYSTEMS

Functional pharmacovigilance (PV) systems protect patient safety related to the use of medicines, promoting better health outcomes and a healthier population.

PV is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible medicine-related problems.[1]

Adverse effects of medicines, particularly those that are unexpected, can negatively affect patients' health and quality of life and further strain and undermine trust in the health care delivery system. PV—both passive (i.e., voluntary) and active (e.g., cohort event monitoring)—is critical for determining the true safety and efficacy profile of a product in a given population once on the market, including identification of effects not necessarily seen in clinical trials.

The regulatory capacity of low- and middle-income countries (LMICs) to monitor and mitigate safety, quality, and efficacy issues remains dangerously weak. This is a major risk, especially as many new medicines have been introduced in LMICs at the same time as or instead of in high-income countries in recent years. Most LMICs do not have even minimally functional systems to effectively monitor, mitigate, and avert the adverse effects of these medicines to the detriment of patients, the quality of care, and the sustained achievement of desired health outcomes.

USAID MTaPS supports LMICs to build or strengthen PV systems and develop capacity to generate, analyze, and use safety data to improve health outcomes and the quality of care using the WHO Global Benchmarking Tool (GBT) for regulatory systems as a guiding instrument. This approach includes:

- Supporting countries to establish the legal and regulatory framework for PV
- Improving the demand for and supply and use of country-level safety data for clinical decision making
- Strengthening the processes for risk identification and characterization, risk assessment/evaluation, risk minimization, and safety communication
- Supporting the establishment of a system for active safety monitoring for novel and other high-risk medicines

[1] https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

MTaPS' support for countries in the area of PV includes:

Establishing legal provisions, regulations, and guidelines:

- Drafting/updating regulations, policies, strategic plans, and national guidelines for passive and active safety surveillance
- Updating forms for reporting suspected adverse drug reactions, adverse events following immunization, medication errors related to medicines, and suspected quality defects
- Developing and updating SOPs and decision support tools

Strengthening risk identification and characterization:

- Working with health facilities, Drug and Therapeutics Committees, and pharmacies to increase reporting of suspected adverse drug reactions, feedback to providers, and the use of safety data to improve clinical decision making
- Collaborating with universities to design and implement active surveillance activities for rapid identification, characterization, and mitigation of adverse events associated with high-risk and novel medicines and technologies (e.g., tenofovir/lamivudine/dolutegravir (TLD); bedaquiline; Ebola vaccines).
- Providing tailored electronic data management solutions such as the pharmacovigilance information management system (PViMS)[2] that support the effective collection and analysis of data from spontaneous and active surveillance systems, are interoperable with other electronic tools such as the WHO-UMC VigiFlow, and are compliant with international data standards for pharmacovigilance (i.e., E2B).
- Advocating for reform to require increased participation of the pharmaceutical industry, distributors, and health facilities in PV at the country and regional levels

Strengthening risk assessment and evaluation:

- Supporting medicines regulatory authorities to improve analysis of safety data from spontaneous and active surveillance systems, including reports of previously undocumented/unknown reactions, generation of new safety signals, and causality assessment
- Working with stakeholders to improve the technical capacity of countries' work forces and increase availability of local PV experts

Minimizing risk:

- Advising medicines regulatory authorities on strategies to enforce regulatory decisions emanating from safety surveillance findings
- Updating standard treatment guidelines and improving pharmacy practices based on results from surveillance findings

Supporting participation in regional and global initiatives:

- Working with countries to participate as full members of the WHO Program for International Drug Monitoring[3] implemented by the Uppsala Monitoring Centre and contribute to VigiBase, the global medicines safety database[4]

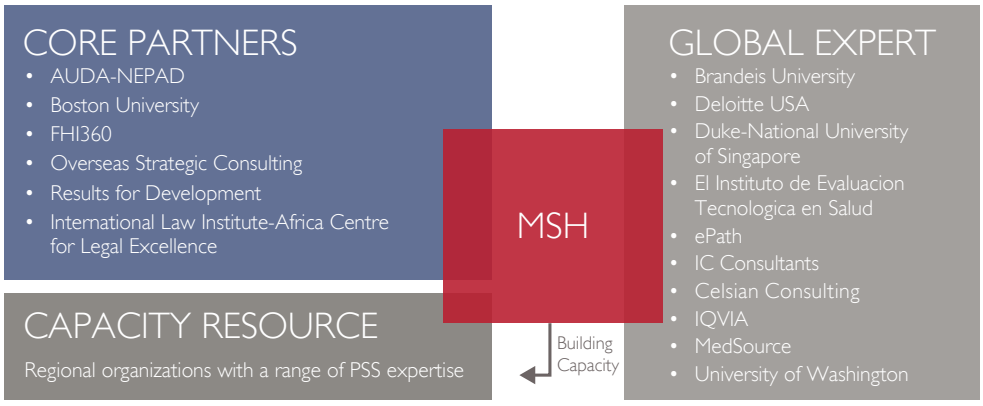
Improving transparency, accountability, and communication

- Facilitating the process of informing and educating the public and health providers on safety monitoring using both spontaneous reporting and active surveillance systems
- Facilitating communication of safety information and review of treatment guidelines based on PV data
- Involving civil society organization and consumer associations in efforts to strengthen PV systems and patient safety programs

2 http://siapsprogram.org/tools-and-guidance/pvims/
3 https://www.who.int/medicines/areas/quality_safety/safety_efficacy/National_PV_Centres_Map/en/
4 https://www.who-umc.org/vigibase/vigibase/

The MTaPS Consortium

Led by Management Sciences for Health (MSH), the MTaPS consortium comprises core partners, global experts, and capacity resource partners. Core partners and global experts are listed below. Capacity resource partners include local organizations with regional or country-based knowledge, technical expertise, and networks (African Health Economics and Policy Association, African Collaborating Centre for Pharmacovigilance and Surveillance, Ecumenical Pharmaceutical Network, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa, U3 SystemsWork, and the University of Ibadan) and other partners (Columbus Consulting, Empower Swiss, and Softworks).



For more information, contact:

Principal Technical Advisor
Comfort Ogar
comfortogar@mtapsprogram.org

USAID Program Team
Alexis Leonard
aleonard@usaid.gov

Lisa Ludeman
eludeman@usaid.gov

Tobey Busch
tbusch@usaid.gov

This document is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.