Pharmacovigilance Information Management System (PViMS) Training for Health Workers at Programmatic Management on Drug Resistant Tuberculosis (PMDT) sites. Photo credit: Patrice Cabasis/MTaPS

Effective and Sustainable Mechanisms for Institutionalizing Active Surveillance for Patient Safety in the Philippines: Pause and Reflect from PViMS Implementation

Technical Highlight November 2023 | Philippines

Background

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems[1]. The Philippines Food and Drug Administration (FDA) issued Administrative Order 2011-0009 to establish and implement a national PV program in the country. This administrative order focuses on the spontaneous reporting of adverse events[2]. WHO defines active tuberculosis (TB) drug-safety monitoring and management (aDSM) as an active and systematic, clinical, and laboratory assessment of patients on

[1] World Health Organization. (2016). Pharmacovigilance. Available at: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance

[2] World Health Organization. (2015). Active Tuberculosis Drug-safety Monitoring and Management (aDSM): Framework for Implementation. Available at: https://iris.who.int/handle/10665/204465

treatment using new anti-TB drugs, novel multidrug resistant TB treatment regimens, or extensive drug resistant TB treatment regimens to detect, manage, and report suspected or confirmed adverse drug reactions. In 2015, the Philippines Department of Health (DOH) Disease Prevention and Control Bureau's (DPCB) National Tuberculosis Control Program introduced aDSM through the operational research that was being conducted at that time. The country opted to implement the intermediate package, where it includes the reporting of all serious adverse events as well as adverse events of special interest, to generate standardized aDSM data that can inform future policy updates on the use of medicines.

Problem statement

In 2015, aDSM was piloted in 10 health facilities, and thereafter in 2016 it was implemented nationwide. This led to a large volume of data generated from all the Programmatic Management on Drug Resistant Tuberculosis (PMDT) sites. The data was complex to handle, as the number of patients participating in active surveillance increased due to the introduction of new treatments such as bedaquiline for TB programs, necessitating the adoption of a sophisticated electronic system to standardize, manage, and analyze the data. In 2016, the United States Agency for International Development Systems for Improved Access to Pharmaceutical Products and Services (USAID SIAPS) program introduced a new information system known as the PV Information Monitoring System (PViMS) to the country.[3] In the same year, the implementation of aDSM became an integral part of the program of nationwide TB services to reduce risks from drug-related harm in patients on novel anti-TB treatment regimens or extensive drug resistant TB treatment regimens. The decision led to the generation of a policy and guidelines through Administrative Order 2020-0025 on the implementation of aDSM in the National Tuberculosis Control Program. While the policy guidance facilitated the aDSM implementation, high volumes of longitudinal data had to be collected and communicated via email for collation and analysis through Excel®, which had to be followed up with manual causality assessment. The manual capture, collate and analysis process created a work burden to health workers which are already stretched and adds complexity to the process to store and maintain safety monitoring data. These necessitated the introduction of a web based PViMS which has enhanced capacity to store and maintain integrity of data and the migration of existing data. By December 2017, however, PViMS was still only implemented in 10 facilities.

Intervention

Recognizing the complexity of the process and high volume of safety monitoring data that is being manually collected and analyzed by the health care workers, USAID MTaPS identified areas of interventions such as 1)support updating and issuance of aDSM policy, 2)support expanding and institutionalizing the use of PViMS to more facilities by training healthcare workers in all PMDT sites, 3)engaging stakeholder at all levels of the system, and 4)conduct supportive supervision[4]. Furthermore, MTaPS enhanced the functionalities of PViMS to enable the implementation of active surveillance activities and linking it to VigiFlow for easy reporting to Uppsala Monitoring Center.

Facilitating policy developments and issuances

MTaPS worked with FDA and DOH in institutionalizing and sustaining active PV surveillance, which required policy issuances. MTaPS supported the development and issuance of three policy documents:

- Administrative Order 2020-0025, "Policy and Guidelines on the Implementation of aDSM of the National Tuberculosis Control Program (NTP)", wherein the PViMS was mentioned as a tool for data collection, analysis, and reporting.

[3] USAID. (2018). Adopting the Pharmacovigilance Monitoring System for the Philippines National Tuberculosis Program. Available at: https://siapsprogram.org/wp-content/uploads/2018/02/17-253-Tech-Brief-PViMS.final_.pdf

[4] MTaPS. (2020). "Reducing health risks and building trust: Pharmacovigilance during COVID-19 and beyond". Toward Stronger Pharma Systems, September 15. Available at: https:/www.mtapsprogram.org/news-blog/reducing-health-risks-and-building-trust-pharmacovigilance-during-covid-19-and-beyond

- Department Memorandum 2022-0087, "Reporting of Adverse Events in PV Monitoring System (PViMS)", which ensures that the DOH Pharmaceutical Division (PD) gives guidance on what data to encode and how.
- Department Memorandum 2022-0201, augmenting the above, entitled "Reporting of Adverse Events to PV Monitoring System (PViMS)", which underscores the details of types of data which should and should not be captured, including the time of data capture.

Engaging stakeholders

MTaPS continuously collaborated with the DOH DPCB, PD and FDA in updating relevant PV-related policies supporting the expansion and use of PViMS for aDSM. MTaPS also engaged with other stakeholders such as the Lung Center of the Philippines (LCP) which is responsible to coordinate and facilitate research in DRTB and serves as a training arm of National Tuberculosis Control Program for newly recruited PMDT doctors and nurses.

Revitalizing the use of the PViMS

To expand the implementation, MTaPS collaborated with the DOH DPCB and PD, FDA, LCP, and other stakeholders on the implementation of aDSM reporting using PViMS. MTaPS facilitated a series of trainings on the use of PViMS, in conjunction with LCP's training for newly hired PMDT nurses and doctors. A total of 44 doctors and nurses were trained in the use of PViMS for aDSM. In addition to the PMDT nurses and doctors, the DOH PD led a face-to-face refresher training for public health pharmacists and national drug policy compliance officers from each region and all 199 PMDT facilities, co-funded by Philippine Business for Social Progress.

The revitalization and expansion of PViMS enabled DOH to conduct aDSM causality assessment for serious adverse events, determine their frequency (rates), and detect signals in a single platform. Causality assessment sessions were regularly done every quarter to determine the causal relationship between the adverse event and the medication for all the reports through PViMS. After each session, DOH generated a report to be sent to FDA and subsequently submitted to the Uppsala Monitoring Center.

Further, MTaPS worked with the DOH PD and FDA to make PViMS data interoperable with the FDA's information system, VigiFlow. PViMS was enhanced to send data directly to VigiFlow via the WHO specified E2B file format. These files are generated after conducting causality assessments and are then uploaded to VigiFlow for signal detection. This interoperability ensures that there is no need for further manual recapture of adverse events and ensures data integrity in the transmission of adverse events to VigiFlow. This also then ensures that there is only one source of data used for signal detection. To ensure sustainability of the use of PViMS, MTaPS, in coordination with the PD, conducted regular quarterly follow-up and monitoring visits at Batangas Medical Center, Tagaytay City Health Office, and Lipa City Health Office on the use of PViMS for aDSM reporting.

Results and achievements

MTaPS supported three policy documents issued by DOH and facilitated the implementation of PViMS at PMDT facilities. The policy documents provided guidance and clarifications on what to report and when.

PViMS supported the reporting of large amounts of data on adverse events at PMDT facilities with their limited human resources. It also instituted ease of causality assessment for the DOH DPCB, including greater simplicity in reviewing correlations and duration of treatment to make informed decisions associated with adverse events. Furthermore, the enhancement to the functionality of PViMS which allowed interoperability with VigiFlow and then subsequently the transmission of data from VigiFlow to Vigibase at the Uppsala Monitoring Center. The new interoperability also facilitated the exchange of large amounts of data with different platforms.

Since the start of the PViMS rollout in 2021, MTaPS has been able to reach 100% of 199 PMDT facilities. To date, 597 adverse events have been reported through PViMS and causality assessments have been conducted. Using the data that is being collected and analyzed in PViMS, health care workers were able to easily address adverse events, ensured safety of patients while continuing and adhering to treatments for improve health outcomes.

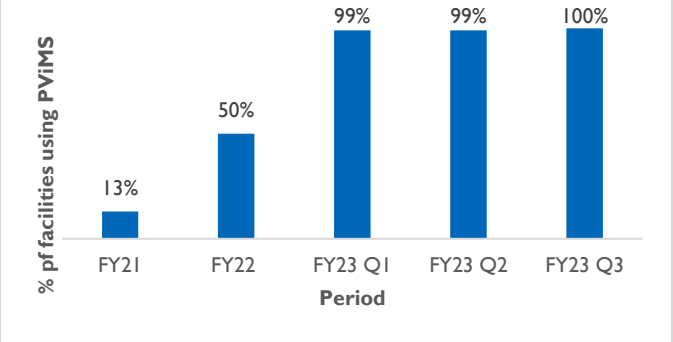

Figure 1: Percentage of sentinel facilities in the Philippines (n=199) trained and using PViMS for TB medicine safety monitoring

Conclusions

- DOH should continuously provide capacity development and training on PViMS to newly hired doctors and nurses. Using PViMS for adverse events and causality assessment will assist in mitigating the issue of a lack of adequate human resources.
- DOH should institutionalize the use of eLearning contents on PV, already uploaded to the DOH Academy through MTaPS support, by newly hired doctors and nurses.
- DOH, in collaboration with the Centers for Health and Development, should continue to provide supportive supervision and mentorship to PMDT facilities to ensure the sustainability of adverse event reporting.
- To ensure continuous improvement of PViMS, MTaPS has confirmed the establishment of the global platform OpenRIMS (https://openrims.org), where access to system documentation, source code, and a discussion forum is openly available. OpenRIMS is continuously adapting to Digital Public Good Principles and building on the Principles for Digital Development and aligning with International Standards. The DOH should use this web site to continuously monitor which new features have been added to PViMS (which is now called OpenRIMS-PV) and upgrade whenever necessary.

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About USAID MTaPS

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2024) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

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