Pharmacist stocks shelves with medicines. Credit: Francois Ebah

Strengthening Pharmacovigilance in Rwanda

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Introducing PViMS for Spontaneous Reporting of Adverse Drug Effects

Background

In 2019 in response to the Ebola outbreak in neighboring Democratic Republic of Congo, Rwanda launched a targeted Ebola vaccination campaign for frontline health workers in its border zones. The Ebola vaccine had undergone clinical trials and had already been administered to over 100,000 people in various countries through a "compassionate use" agreement, but it was not yet licensed in Rwanda. Monitoring the safety of the new vaccine was a high priority for Rwanda's Ministry of Health (MOH) and catalyzed the country to strengthen its pharmacovigilance (PV) monitoring.

In line with its mandate to support Rwanda in strengthening its pharmaceutical system, the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2024) assisted the MOH and the Rwanda Food and Drugs Authority (FDA) in introducing the use of an electronic online reporting tool, the PharmacoVigilance Monitoring System (PViMS), for capture of adverse events following immunization (AEFI) reports on the Ebola vaccine, and later supported its expanded use for monitoring of COVID-19 vaccines and newly introduced antiretroviral drugs for HIV treatment. The system is being enhanced to allow for monitoring and reporting of all medical products including those used for maternal, neonatal, and child health.

Problem Statement

Monitoring, reporting, and analysis of adverse events (AE), including AEFIs, in real-life conditions are key components of PV. PV can reveal drug effects not necessarily seen in clinical trials; provide evidence to demonstrate drug safety and efficacy, which can contribute to confidence in the health care system; and inform recommendations and policies for use of a particular medicine or vaccine.

However, as in many low- and middle-income countries (LMICs), PV in Rwanda remains weak. A 2018 World Health Organization (WHO) assessment showed that the Rwandan PV system did not meet minimum standards and data reporting, analysis, and management without an electronic system was a big challenge. Although the country did have an electronic PV system for capturing data on AEs, it did not provide adequate safety monitoring of priority medicines. The system for reporting AEs and substandard and falsified medicines relied primarily on paper-based solutions, making data collection labor-intensive for health care workers, which resulted in backlogs in data reporting. Before the introduction of PViMS, health care workers submitted few AE reports; from March 2018 to June 2021, a total of only 385 reports were submitted to the Rwanda FDA. PV monitoring data was not aggregated in an easy usable format, limiting data analysis and sharing of information for decision making. Rwanda fulfilled its international AE reporting obligations as a member of the WHO Uppsala Monitoring Center before PViMS was introduced, but the WHO Global Benchmarking Tool (GBT) assessment noted that the process of reporting data to the Uppsala Center was carried out manually.

Technical Approach

MTaPS is assisting Rwanda in strengthening its pharmaceutical system to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medical products and related pharmaceutical services. MTaPS collaborates with the Rwanda FDA, which serves as a PV center, responsible for monitoring the safety of medical and pharmaceutical products. MTaPS supports the Rwanda FDA to address gaps identified in the WHO GBT assessment as the Authority aims toward achieving maturity level 3. This is the level at which a regulatory authority is considered stable and well-functioning. MTaPS engages with the Rwanda FDA to support both the public and private pharmaceutical sectors in implementing PV systems by improving their recording and reporting by health care providers and their evaluation and analysis of AEs.

Intervention

PViMS is a web-based application developed by MTaPS' predecessor, the USAID Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, in response to a global need for a country-level online PV tool. PViMS allows for real-time reporting and recording of data on AEs, including AEFIs, and other patient information, including medication history and follow-up visits. A strength of PViMS is that it can be adapted for various medicines/vaccines and can be used for both active and spontaneous PV surveillance. The PViMS tool ensures that medicines safety monitoring reports are quickly received and analyzed and that feedback to clients, patients, and health facilities is disseminated in a timely manner. Additionally, PViMS has the capacity to transmit data directly into the Uppsala Center's VigiFlow® system to facilitate reporting to the WHO.

To facilitate timely reporting and sharing of information on medicine safety issues by health care workers, the Rwandan MOH and FDA, and other users, MTaPS supported the introduction and implementation of PViMS for spontaneous PV monitoring as follows:

- Engaged in discussion with the Rwanda FDA's Division of PV and Safety Monitoring of Medical Products to understand their needs and gaps that needed to be addressed.
- Met with health care workers to learn more about their needs and the realities of data entry at the facility level.
- Deployed PViMS in October 2020. This process involved configuring PViMS and PV data collection forms based on the needs expressed by the Rwanda FDA.
- Advocated for awareness of the importance of PV and supported the FDA to organize a training workshop on PV and medicines safety for new Rwanda FDA staff and health care service providers serving in medicine and therapeutics committees (MTCs) from public and private health facilities.

The course included content on what and when to report and how to report through PViMS. The trainees included 15 doctors, 9 nurses, and 14 pharmacists (a total of 24 males and 14 females), all of whom are members of MTCs in public and private hospitals. As a result of the training, the Rwanda FDA received some initial reports on AEs for various drugs.

- Launched PViMS in June 2021, initially as a tool for health care providers to report safety monitoring of the Ebola vaccine. Once the electronic PV monitoring system was deployed on the Rwanda FDA server with interfaces for both spontaneous reporting and active safety monitoring reporting, public and private health facilities and individuals began to use it to report AEs.
- Successfully advocated for hiring additional Information technology (IT) staff for the Rwanda FDA's PV unit to support PViMS implementation.
- Supported development of a PV e-Learning course for sustainable PV capacity building. The course is being administered via the Moodle platform installed on the Rwanda FDA server.
- Established a wiki page (with free hosting) to allow for sustainable sharing of PViMS resources across countries.[1]

Results and Achievements

With support from MTaPS, from June 2021 to January 2023, a total of 1,431 AEs and AEFIs were reported through PViMS compared with the 385 general reports that Rwanda FDA had received using paper-based reporting from March 2018 to June 2021. This reflects reporting for Ebola and COVID-19 vaccines and other medicines. Of these, 670 were reviewed, of which 527 (including 467 related to COVID-19) were investigated by the Rwanda FDA and 46 were determined to require causality assessment. All 527 AEs and AEFIs investigated were reported to the WHO Uppsala Monitoring Centre. The Rwanda FDA uses data reported through PViMS to capture unexpected reactions to vaccines and other medicines and uses the data to make regulatory decisions for improved patient safety.

National partners and participating facilities, including district, referral, provincial, and teaching hospitals and health centers have been sensitized to the need for PV. Rwanda now has an adaptable PV system in place. A PV e-Learning course is now available via the Rwanda FDA server to enable continued PV capacity building,

PViMS was demonstrated to work in both public and private health facilities and even the public (patients) are now able to report AEs directly through PViMS. MTaPS' interventions have resulted in implementation of digital PV in Rwanda with the following results:

- Rwanda FDA is receiving more PV information in a comprehensive format than ever before.
- Less health worker time is going into generating each report now.
- Reporting backlogs that plagued earlier PV reporting efforts have been eliminated.
- With more data available to the Rwanda FDA for decision making, there has been an increase in notifications to the market authorization holders on safety concerns.

Country experience has demonstrated that PViMS can work in the Rwandan context for both active and spontaneous PV reporting, since following the initial demonstration of PViMS as a PV reporting tool, the National HIV program requested MTaPS support in adapting PViMS for active safety monitoring of a new dolutegravir (DTG)-based antiretroviral therapy regimen for HIV treatment. With MTaPS support, the Rwandan FDA adapted PViMS for active surveillance of the DTG-based regimen, and recorded data from more than 1,400 enrolled participants. As of May 29, 2023, 9 AEs have been registered in study participants; 3 of the AEs were serious, leading participants to be withdrawn from DTG-based treatment.

Lessons Learned

- **Ensure that the PV system is aligned with end user data needs to maximize utility and encourage wider adoption of the system.** Although initial implementation of PViMS for Ebola reporting worked well, the Rwanda FDA found that the system, as it was, could not meet its needs for analysis; this resulted in partners temporarily stopping their use of PViMS for reporting AEs associated with the Ebola vaccine. Further work up

[1] https://wiki.openrims.org/index.php/Main_Page.

front with the country partner to determine what kind of reports it needed to generate and for what purpose could have ensured that PViMS was configured in advance to meet the needs of the partners. Such a proactive approach to thinking through end user needs is recommended to maximize utility of any new information system solution. To further meet user needs, a module on causality assessment could be incorporated into PViMS to provide more valuable information to users.

- **Demonstrate functionality of PViMS to build both compliance and demand for the system.** At the facility level, following training on PViMS, trained health providers increased their reporting on AEs. At the national level, once other health programs saw PViMS in action for Ebola vaccine reporting, they expressed interest in also using PViMS, resulting in the system being adapted to monitor AEs for all medicines, COVID-19 vaccines, and a new antiretroviral treatment for HIV.
- **Actively build awareness about PV.** To improve reporting of AEs, both health care providers and the public need to be made aware of PV. PV training is effective but has reached only a small number of health workers. E-training is a potential solution to reaching more health workers. With MTaPS support, a PV e-Learning course was developed and uploaded onto Rwanda FDA servers; the course is currently being promoted through health professional associations. Additionally, professional association meetings can be used to create awareness on reporting safety of medical products among different health care workers. Radio, TV, and social media can be used to reach both health workers and the general public.
- **Make reporting as easy as possible**. MTaPS trained facilities on reporting AEs and provided paper forms to collect data. However, allowing providers to upload AE data directly from their phones—rather than via a computer—could improve compliance. Similarly, allowing patients to directly report AEs to the provider via a phone app could improve timeliness of data collection and allow immediate provider follow-up to help the patient. IT options exist for this but need to be adapted for the country.
- **Ensure that partners are on board with the time needed to adapt the PV reporting and recording system.** Although partners often hope for a working PV solution in 1–2 months, even adapting an existing platform such as PViMS takes time. Working with stakeholders to help them understand the importance and time frame of the adaptation process—and to ensure that users' needs are clearly articulated and considered—will allow them to adjust expectations, help avoid disappointment, and foster partner buy-in and ownership.
- **Advocate to get the required human resources in place to implement a PV system.** MTaPS successfully advocated with the Rwanda FDA to add several additional IT specialists to their PV unit to manage PViMS. Rwanda, as with many LMICs, faces shortages of qualified IT specialists; the country will need to address this issue as it looks to further digitization of the health care sector and other sectors.

Pathway to Sustainability

Throughout its support for PViMS, MTaPS has helped this system become both operational and entrenched in government plans and systems for continued implementation. Rwanda's costed multi-year national PV plan includes PViMS implementation. Under its budget, the Rwanda FDA brought on additional IT staff to support PViMS implementation. Plans are in place for PViMS to link to the Rwanda FDA's online Integrated Regulatory Information Management System (IRIMS). PV/PViMS training materials developed with MTaPS support have been translated into a PV e-Learning course for sustainable PV capacity building. The course is being administered via the Moodle platform installed by the Rwanda FDA. Furthermore, MTaPS has established a wiki page (with free hosting) to allow for sustainable sharing of PViMS resources across countries.[2]

[2] https://wiki.openrims.org/index.php/Main_Page.

Conclusions

With technical assistance from MTaPS, the Rwanda FDA has installed and deployed PViMS to support the collection, management, and analysis of spontaneous AE reporting in Rwanda. The Rwanda FDA needs to build capacity on the use and management of PViMS among health care providers who are responsible for regular reporting of AEs, including AEFIs, through the system. Over its remaining project lifetime, MTaPS will continue to work with the Rwanda FDA to enhance PViMS to address identified gaps in reporting of AEs, improve ease of data entry, update the user manual, and make the system more user friendly. MTaPS will also support the Rwanda FDA to successfully link the PViMS and the IRIMS being introduced in the Authority, which will facilitate PV data use and decision making on safety of medicinal products registered in Rwanda. MTaPS will improve interoperability of Rwanda's PViMS with the WHO AE reporting system and will support the Rwanda FDA in finalizing its draft communications strategy and increasing public awareness on AEFI/AE detection and prevention through printing of information, education, and communication materials for health care providers. Over the longer term, the Authority will need to continue its outreach work to raise public awareness of PV and AE reporting among both health care workers and the general public and adapt the PViMS system in Rwanda to accommodate reporting of AEs to the WHO, as is done in some other countries.

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Authors

This publication was written by Abimana Rwandenzi Eugene, Antoine Gatera, Kim Hoppenworth, Jean Mirimo

For more information, please contact memory@msh.org

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.