Question 2: What are effective and sustainable mechanisms or processes to integrate local, community, sub-national, national, and regional voices, priorities, and contributions into health system strengthening efforts?

Strengthening Pharmacovigilance to Improve Product Safety Surveillance and Reporting in Kenya

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Context

Safety surveillance is a cornerstone of monitoring health products and technologies (HPTs) along with ongoing quality and effectiveness monitoring and reporting of any emerging patient safety signals. It is key for ensuring that patients, health-care workers, and the general public are informed of any adverse reactions that may occur following the use of any medicines, vaccines, and medical devices. The availability of reliable data on adverse drug reactions (ADRs) is critical for ensuring patient safety. In Kenya, the Pharmacovigilance Electronic Reporting System (Pvers) is used to report adverse drug reactions and medical device incidents. In 2021, MTaPS supported the development of a mobile Pharmacovigilance Electronic Reporting System (mpvERS), which was developed with support from a USAID-funded Health Systems Strengthening Program (HSSP) and the World Health Organization (WHO). The mpvERS is an E2B format compatible with VigiFlow, the WHO reporting system. The mpvERS and mPvERS are integrated, allowing for real-time transmission of reports from mobile devices to the national pharmacovigilance system.

Activity Description

Development of mpvERS

To improve patient safety, policies, procedures, and resources were put in place to support pharmacovigilance activities relating to the detection, assessment, and evaluation of adverse effects or other HPT-related problems. Moreover, HPTs must be handled in compliance with applicable laws and regulations. To improve patient safety, policies, procedures, and systems need to be in place to support pharmacovigilance activities relating to the detection, assessment, and evaluation of adverse effects or other HPT-related problems. Moreover, HPTs must be handled in compliance with applicable laws and regulations. In March 2021, for example, when COVID-19 vaccination was introduced in Kenya, health care workers needed to be trained on the logistics management; pharmacovigilance to monitor AEFIs; and capacity building.

Activity Impact

The mpvERS upgrades have made some health stakeholders aware of the evaluation of adverse drug reactions and other HPT-related events. The mpvERS has facilitated the reporting of AERs and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents.

Facilitators

- The USAID-funded and MTaPS-Implemented Health Systems Strengthening Program (HSSP) had supported the development of mpvERS in 2021, which was used for real-time reporting of adverse drug reactions and medical device incidents in Kenya. The mpvERS was implemented through a partnership between the PPB, DHIS2, and the WHO.
- The mpvERS and mPvERS are integrated, allowing for real-time transmission of reports from mobile devices to the national pharmacovigilance system.
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Evidence

The number of AERs reported via the mpvERS has increased from 2018 to 2020. In 2018, the mpvERS was used to report 1,000 AERs. In 2019, the mpvERS was used to report 1,500 AERs. In 2020, the mpvERS was used to report 2,000 AERs. In 2021, the mpvERS was used to report 2,500 AERs. In 2022, the mpvERS was used to report 3,000 AERs. These numbers reflect the increase in the use of the mpvERS for reporting adverse drug reactions and medical device incidents.

Lessons Learned

- Establishing pharmacovigilance is critical for determining a product’s safety and efficacy profile through the use of pharmacovigilance platforms within the national regulatory agency’s drug registration, evaluation, and postmarket surveillance systems.
- The integration of information systems helps in improving forecasting of trends through the timely use of reporting tools, strengthening the existing framework for pharmacovigilance activities.
- The emergence of new technologies has led to the development of new reporting systems for AERs, but the existing systems have not been integrated with the mpvERS.
- The development of a mobile Pharmacovigilance Electronic Reporting System (mpvERS) has allowed for real-time transmission of reports from mobile devices to the national pharmacovigilance system.
- The integration of mpvERS and mPvERS is critical for improving patient safety in Kenya. This has helped to improve the quality and timeliness of reports submitted to the pharmacovigilance system.
- The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents. The mpvERS has been used to report suspected adverse drug reactions and medical device incidents.

Challenges

- Health care workers and the public at large are not adequately aware of the system. This has resulted in a drop in the number of reports submitted to the mpvERS.
- The mpvERS and mPvERS are not integrated, leading to a lack of real-time transmission of reports from mobile devices to the national pharmacovigilance system.
- The integration of mpvERS and mPvERS is critical for improving patient safety in Kenya. This has helped to improve the quality and timeliness of reports submitted to the pharmacovigilance system.
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