

# Comprehensive Assessment of Pharmacovigilance Systems and their Performance in Sub-Saharan Africa

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Theme: State-of-the art health systems research

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## BACKGROUND

Africa's increased access to new essential medicines calls for concerted efforts to monitor and promote the safety, quality, and effectiveness of those medicines. Poor product quality, adverse drug reactions, and medication errors contribute significantly to morbidity and mortality and have a huge impact on the health care system. To better understand the issue and its effect on public health, the US Food and Drug Administration and USAID established an interagency agreement carried out by the USAID-funded, MSH-led Strengthening Pharmaceutical Systems (SPS) Program, SIAPS' predecessor.

## OBJECTIVE

The study's objective was to describe and analyze the performance of national pharmacovigilance (PV) systems in 46 sub-Saharan African (SSA) countries in protecting the public from harm and improving health outcomes.

## RESULT

Of the 46 SSA countries studied, 87% do not have a functional PV system, 59% do not have a national policy related to medicine safety, 70% lack legislation to monitor adverse events, 26% do not have a national PV center, and 61% lack a medicine safety advisory committee. Only 28% have a platform or strategy to coordinate in-country stakeholders. Although 74% have spontaneous adverse event reporting systems, less than 50% monitor product quality, medication errors, or treatment failures through existing systems. Reporting rates were low, with only 2 countries collecting more than 100 reports per million population in 2010. Active approaches to identify and evaluate medicines-related risks are limited and only 48% conducted active surveillance activities in the last 5 years; 50% maintain a PV database, but information is not used for decision making. Only 20% published medicine safety newsletters, 33% distributed safety alerts, and 37% took at least 1 form of regulatory action as a result of PV activities in 2010. The figure shows the groups of countries based on PV systems performance. Only 4 countries were classified as having a complete set of essential components for a performing PV system.

## CONCLUSION

PV activities are already taking place in most of the SSA countries. Greater efforts are needed to link existing activities to create a comprehensive PV system. Countries should develop strategic plans to incorporate both passive and active approaches, coordinate with all stakeholders, and strengthen risk management and communication, which will improve patient safety and health outcomes.

More than 700 deaths associated with medicines contaminated with diethylene glycol were reported in 9 countries including Nigeria and South Africa.

Source: SPS. 2011. *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance.*

## METHOD

The study used literature review, a mailed survey, and an in-depth assessment to evaluate PV systems and their performance in the 46 SSA countries. The Indicator-based Pharmacovigilance Assessment Tool\* was adapted and used for data collection, and countries were grouped on the basis of their PV policies and legislation, systems and structures, and ability to generate and use data for preventing morbidity and mortality related to medicines use.

\* Strengthening Pharmaceutical Systems (SPS) Program. 2009. *Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries.* Submitted to the US Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health. Available at [http://pdf.usaid.gov/pdf\\_docs/PNADS167.pdf](http://pdf.usaid.gov/pdf_docs/PNADS167.pdf)



"A good pharmacovigilance system that costs only about one dollar for every thousand dollars spent on the purchase of medicines can prevent such harm from medicine use."

Dr. Lee Jong-Wook, former Director General, World Health Organization, speaking at the 11th International Conference of Drug Regulatory Authorities