Strengthening Patient-Centered Pharmacovigilance in South Africa

In an effort to strengthen national HIV/AIDS pharmacovigilance activities, the National Pharmacovigilance Center (NPC) has established a cost-effective way of promoting the safe, effective use of medicines in South Africa through the implementation of a decentralized pharmacovigilance program. This new initiative is being carried out with support from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, which is funded by the US Agency for International Development (USAID).

The program is aimed at empowering healthcare providers (HCPs) at the facility level in improving the prevention and detection of disease, as well as the management of side effects in patients. HCPs are trained to better establish causality for adverse events, develop subsequent individual case interventions at the facility level, and ultimately ensure quality of care and improve patient outcomes.

In the past, the approach to pharmacovigilance did not extend to the clinical setting or consider the daily management of patients in various healthcare facilities. As is the case in most African countries, South Africa lacks sufficient infrastructure to support necessary pharmacovigilance activities, especially in the rapidly expanding antiretroviral treatment (ART) program, which has approximately two million people on treatment. Another challenge is that most public healthcare providers are not trained to recognize or report adverse drug reactions (ADRs).

The decentralized pharmacovigilance program aims to identify gaps in pharmacovigilance education and providing effective training to HCPs, as well as to identify multidisciplinary clusters as decentralized pharmacovigilance centers throughout the country. These clusters are encouraged to meet on a regular basis to discuss individual cases and offer different views and expertise in order to improve patient treatment outcomes.
Following the successful implementation of the decentralisation program in Mpumalanga Province, the program has now been scaled up to include the North West Province. With the continued assistance of SIAPS in building the capacity of HCPs to analyze and manage adverse events, the extension of the decentralized pharmacovigilance strategy to the North West Province has worked remarkably well leading to several positive outcomes including:

- The training of 118 HCPs (15 physicians, 29 pharmacists, 58 nurses and 16 auxiliary health workers, including medical assistants and medical laboratory technicians and assistants) in pharmacovigilance
- The establishment of twenty clusters in 256 health facilities
- The production of new, revised ADR forms
- The production of the an NPC information bulletin for North West Province

These measures have led to increased levels of reporting, with more than 422 ADR reports received from North West clusters between November 2013 and August 2014, up from zero reports in 2012. To consolidate these gains, SIAPS continues to work very closely with the NPC to produce gap analyses, develop quality enhancement interventions to improve reporting, and manage ADRs at the facility level.