Pharmacovigilance Activities in HIV/AIDS Programs in Eight Sub-Saharan African Countries: Opportunities to Enhance Treatment Outcomes and Ensure Patient Safety

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Background

Monitoring adverse drug reactions (ADRs) is becoming a priority for public health programs (PHPs) involved in large scale-ups of new essential medicines. Under an interagency agreement between the US Food and Drug Administration and the US Agency for International Development (USAI), the SPS program assessed pharmacovigilance activities of 32 PHPs in sub-Saharan Africa.

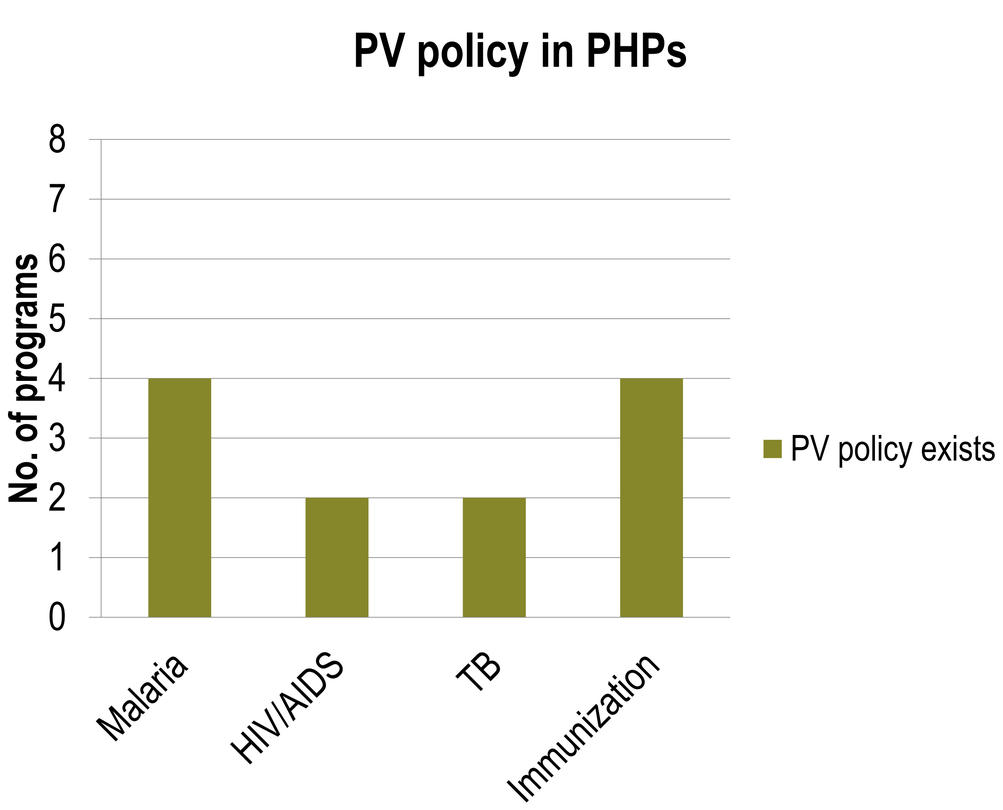
Methods

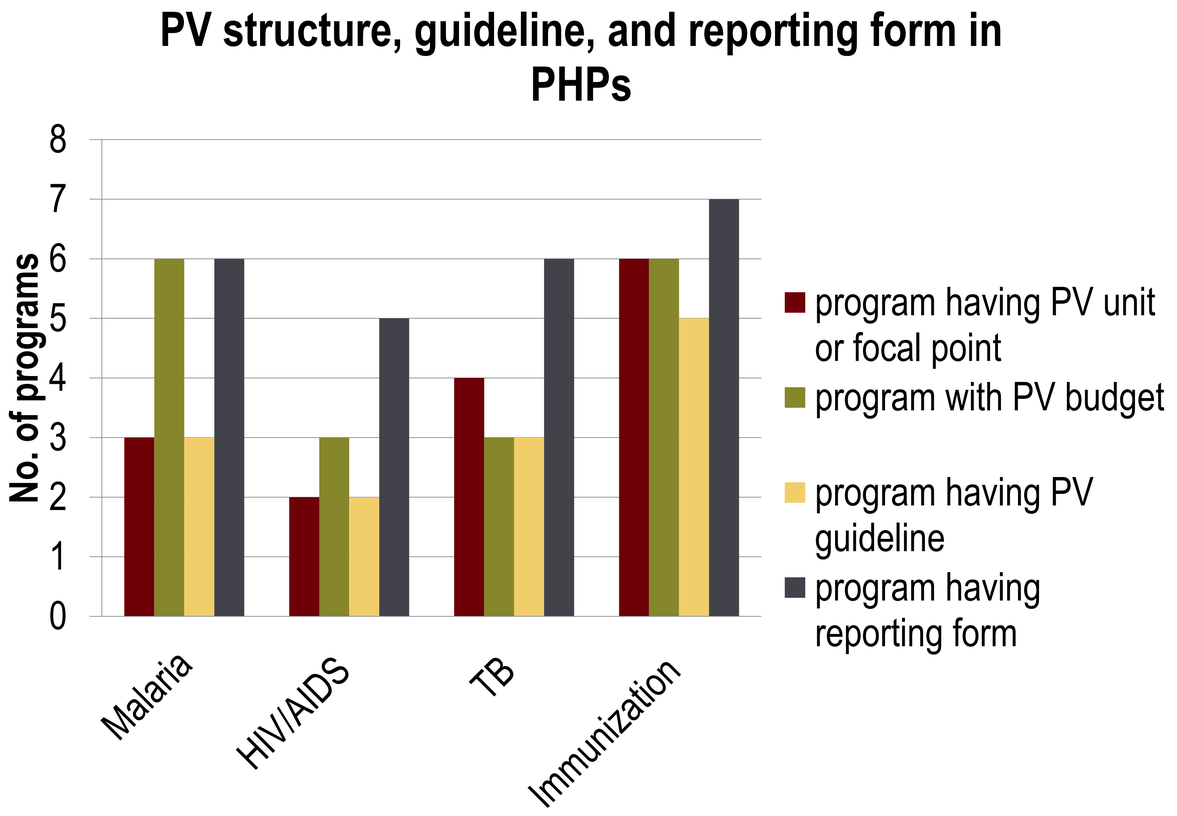
We collected data in 2011 from national malaria, HIV/AIDS, tuberculosis, and immunization programs in Burkina Faso, Democratic Republic of Congo, Ghana, Kenya, Nigeria, Senegal, Tanzania, and Uganda using structured interviews with program managers, clinicians, and national pharmacovigilance center staff.

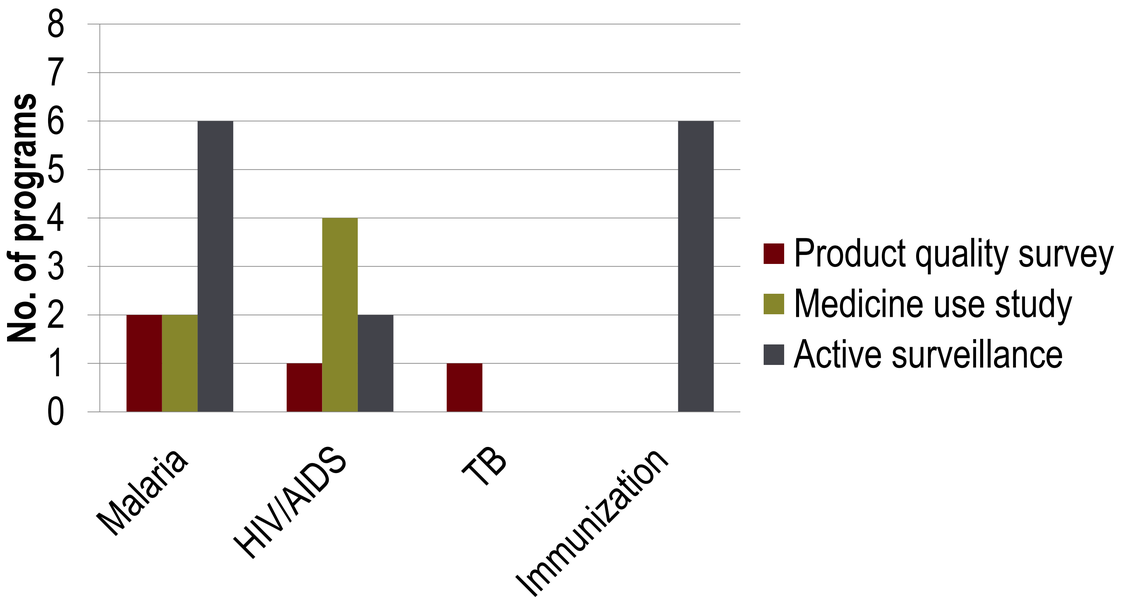
Result

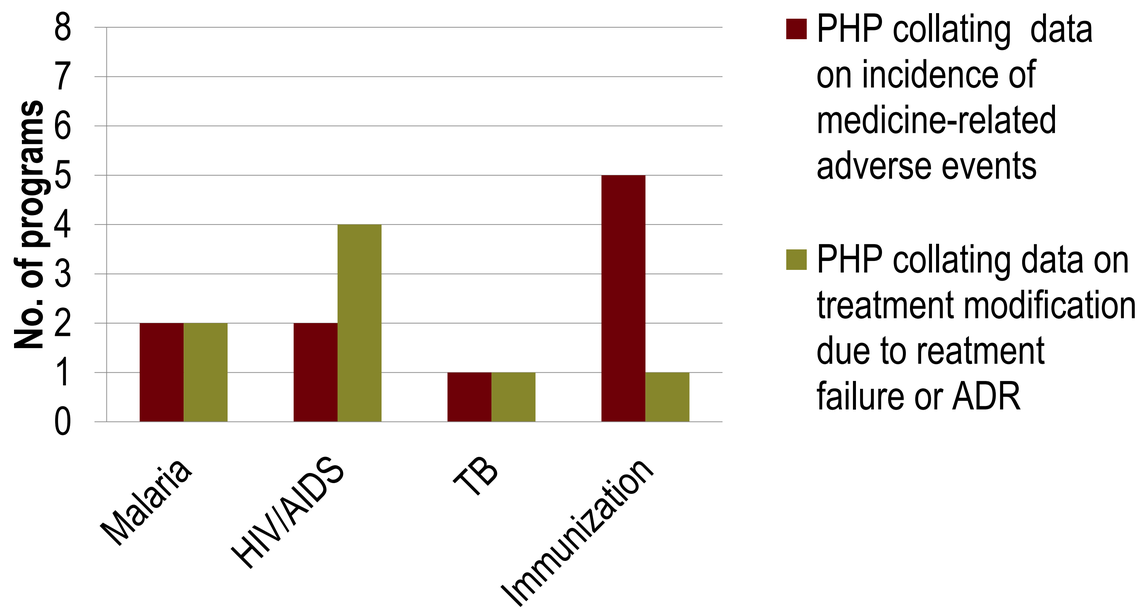
Among 32 PHPs, 12 programs (38%) have policy statements on pharmacovigilance and 15 (47%) have basic infrastructure, such as a pharmacovigilance unit or focal person. HIV/AIDS programs were more likely to lack basic infrastructure than malaria and immunization programs. PHPs did not routinely collect and share ADR data with national pharmacovigilance centers; only 10 programs (31%) in total and 2 of 8 HIV/AIDS programs routinely collect ADR data. The national pharmacovigilance databases in five of eight countries do not contain data from PHPs. Data on treatment modification/interruption was documented fairly well in HIV/AIDS programs; 0.90–4.33% of HIV/AIDS patients experienced at least one treatment modification/ interruption.

A number of PHPs are now engaged in active surveillance, particularly malaria and immunization programs. However, only two of eight HIV/AIDS programs have implemented active surveillance in the last five years. Risk management and communication activities were lacking across all PHPs. Only one HIV/AIDS program circulated safety alerts related to antiretrovirals and used their pharmacovigilance data to revise treatment guidelines.









Conclusions

PHPs in sub-Saharan Africa, especially HIV/AIDS programs, are not adequately implementing pharmacovigilance activities, thereby missing opportunities for applying risk management to enhance treatment outcome and patient safety. PHPs should enhance pharmacovigilance within the existing PHP surveillance structures and integrate safety data into national pharmacovigilance databases in collaboration with national pharmacovigilance centers.

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