



Building the Capacity of Health Care Workers to Enhance Pharmacovigilance for ART and Patient Safety

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Introduction-1

- Global public health initiatives in developing countries have increased access to medicines including those for:
 - HIV/AIDS, Malaria, and Tuberculosis (TB)
- Since inception of the national HIV/AIDS program in 2003, use of highly active antiretroviral therapy (HAART).
- Local toxicity profiles of antiretroviral medicines (ARVs) in Kenya were not available
- Absence of national Pharmacovigilance (PV) system in early 2000
 - The Pharmacy and Poisons Board (PPB) established the PV department in 2004
 - Launch of PV system in June 2009

Introduction-2

- By August 2010, about 400,000 Kenyans were receiving HAART, but the PPB had received only 451 adverse drug reaction (ADR) reports
 - Challenge of spontaneous (voluntary) reporting
- Burden of Antiretroviral medicines (ARVs) toxicity-Stavudine (d4T)
 - Majority of patients on HAART were on d4T
 - Lack of substantial evidence of toxicity to support adoption of newer therapies

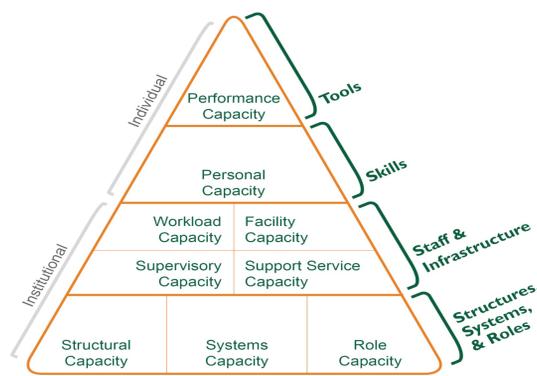
Materials and Methods-1

- The Strengthening Pharmaceutical Systems (SPS) and HCSM Programs in collaboration with the NASCOP and PPB developed:
 - package of training materials, tools, and job aids to build local human resource capacity on pharmacovigilance for HAART.
 - package incorporated a continuous quality improvement component comprising action plan development and supportive supervision.
- Selection of 12 ART sites for boosted/ sentinel surveillance
 - Definition of selection criteria; facility assessments

Materials and Methods- 2

- In Sept 2010, capacity building of 51 facility staff- multidisciplinary teams on pharmacovigilance
 - off site five day training
 - provided with reporting tools, patient alert cards, job aids, and guidelines.
- Initiation of health facilities on surveillance role for ADR to ART – on site buy in by health facility management into role
- Sensitization of health facility staff on pharmacovigilance – on site full day sensitization session
- Follow up supportive supervisory visits – annual progress review, challenges identification and preparation of quality improvement plans
- Health facility staff forum-annual knowledge & experience sharing forum

The Capacity Building Model

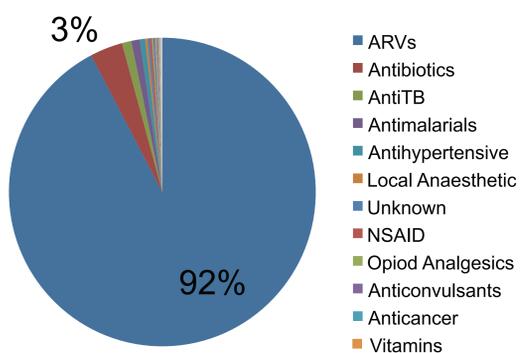


Potter, C., and R. Brough. 2004. Systematic Capacity Building: A Hierarchy of Needs. *Health Policy and Planning*. 19(5): 336-345.

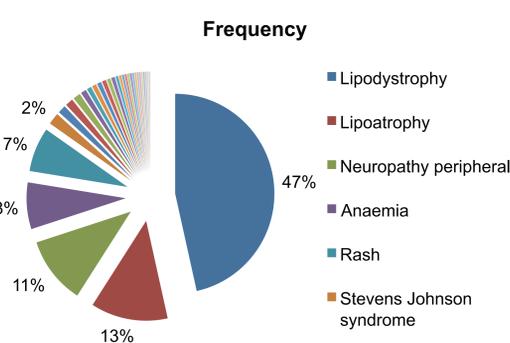
Results

- Increase in ADR reporting
 - September 2011 - 49% of 1178 ART-related ADR reports were from the 12 intervention sites (total of 51 ART sites had reported)
 - 79% of reports by December 2011 (n=2331)
 - 92% of reports by January 2013 (n=4893)
- Local data on stavudine toxicity backed changes in the treatment guidelines to incorporate tenofovir to first-line HAART medicines.
- Improved national estimate of ART related ADR burden
 - 0.745% as at end Jan 2013 (4518/606,793)
 - 0.433% as at end Dec 2011 (2331/538,983)

Distribution of ADRs by class of Distribution of ADRs by class of medicine as at 31st Jan 2013 (n = 4893)



Reported reactions by end Jan 2013 (n = 4893)



Conclusion

- Training healthcare workers providing ART services on pharmacovigilance followed by supportive supervision resulted in **increased detection, monitoring, patient management, and reporting of ADRs.**
- Such an approach is a means to obtain local data to **inform treatment guidelines and promote patient safety.**
- Scale up of sentinel sites and interventions is recommended.

Literature Cited

- Potter, C., and R. Brough. 2004. Systemic Capacity Building: A Hierarchy of Needs. *Health Policy and Planning*. 19(5): 336-345.

Acknowledgements

- National AIDS and STI control Program
- Pharmacy and Poisons Board
- 12 ART sentinel Sites
- MSH/Health Commodities and Services Management Program
- CDC
- USAID