Pharmacovigilance in Uganda

PHARMACOVIGILANCE TRAINING DAR-ES-SALAAM
22ND NOVEMBER 2009
Presentation outline

- National Pharmacovigilance centre and capacity
  - Objectives
  - Progress
  - Challenges
  - Future plans
- PV in Public health programs
- Most commonly used ARVs
- Problems of top concern
- Training
UGANDA - THE PEARL OF AFRICA
National Pharmacovigilance Center (NPC)

- Overseen by the Head, Drug Information Department of National Drug Authority
- Guided by the Pharmacovigilance committee of the Board
- Composed of 8 personnel.
Was established in 2005
Passive reporting system
The 83rd member country to the WHO Collaborating Centre on International Drug Monitoring.
Objectives of the NPC

- To coordinate Pharmacovigilance activities in the country
  - collect, analyze and evaluate Adverse Drug Reaction reports from Regional Centers and the field on human and veterinary drugs.
- To collaborate with Uppsala Monitoring Centre.
- Promote exchange of drug information with Drug Information Centers within and outside the country.
Database management

- The pharmacovigilance system uses vigiflow for managing reports
- The 11 regional centres established; report to NPC via vigiflow
- There are over 350 suspected ADR reports on the database
  - 121 (out of 350) reports have been committed
    - 42 reports are due to ARVs
Information flow

UMC

NATIONAL PV CENTER

REGIONAL PV CENTER

COORDINATING CAUSALITY ASSESSMENT

HEALTH WORKERS, THE PUBLIC AND OTHER PROGRAMMES

FEEDBACK
PV in Public health programs

- There is some involvement of personnel in the national public health programs
- Some Treatment Programs do monitor adverse events
  - Plans to collaborate with these programs are under way
- The NPC has incorporated a session on safety monitoring on ARVs in the training of trainers’ sessions
The suspected ADR report form
Challenges

- There is still low awareness on ADR reporting which calls for more sensitization.

- Wrong perception of PV - i.e as a program (with financial emoluments) not a practice!

- Human resource - PV activities are done alongside other regulatory and routine activities.

- Functionality of the established centers is compromised by low motivation.
Future plans ...1

- Continue with sensitisation (with emphasis to key stakeholders)
- Start CEM as a means of post market surveillance especially for diseases of public health concern
- Work with NGOs and health consumers advocacy groups in the community
- Orientation of NPC staff at a fully functional Pharmacovigilance centre
Most commonly used ARVs

- Stavudine
- Lamivudine
- Nevirapine
- Efavirenz
- Zidovudine
- Kaletra
Most commonly used ARVs-2

- Abacavir
- Didanosine
- Tenofovir
- Atazanasvir
- Emtricitabine
ARV toxicity problems of top concern

- Steven Johnson reaction to NVP and cotrimoxazole
- NVP related Hepatotoxicity
- Anaemia with AZT
- Peripheral neuropathy d4T
Trained professionals

- The course material used in training is on general pharmacovigilance
- 330 health professionals are trained (Over 1000 sensitized)
ACKNOWLEDGMENT

- Ministry of Health
- World Health Organisation
  - UMC, WHO Uganda, WHO AFRO/HQ
    - For technical support
    - For financial support, especially in enabling NDA to participate in this training
  - Other national centres
    - Participation and Quick response to our queries on Vigimed network
- United States Agency for International Development
  - PEPFAR, PMI for partnering with NDA Pharmacovigilance and quality control activities