Republic of Zambia
Progress on implementation of Pharmacovigilance in the NATIONAL ARV PROGRAMME
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OUTLINE of presentation

- Background
- ART Implementation
- Legal mandate of PRA
- Implementation
- Current Analysis
- Challenges
- The way forward
## Background Statistics

<table>
<thead>
<tr>
<th>Year</th>
<th>Patients on ART</th>
<th>Disease Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>143</td>
<td>236,000</td>
</tr>
<tr>
<td>2003</td>
<td>2,000</td>
<td>242,151</td>
</tr>
<tr>
<td>2004</td>
<td>15,325</td>
<td>248,638</td>
</tr>
<tr>
<td>2005</td>
<td>51,764</td>
<td>256,653</td>
</tr>
<tr>
<td>2006</td>
<td>78,683</td>
<td>273,642</td>
</tr>
<tr>
<td>2007</td>
<td>164,435</td>
<td>295,540</td>
</tr>
<tr>
<td>2008</td>
<td>228,050</td>
<td>338,315</td>
</tr>
<tr>
<td>2009 q2</td>
<td>245,382</td>
<td>359,391</td>
</tr>
<tr>
<td>2009</td>
<td>287,445 (Target)</td>
<td>359,391</td>
</tr>
</tbody>
</table>

### Patients on ART and AIDS burden

(68.3% Access thru 363 sites)
ART programme Implementation

- **2003-Pilot phase**
  - Two sites – UTH and NCH

- **2004- Development Phase**
  - Building capacity-human, systems and infrastructure
  - Added 8 provincial hospitals

- **2005- Expansion Phase**
  - More patients and facilities
  - 322 (target is 350 centers by mid 2008)
  - Total number accessing ARVs 156,753 (December 31 2007)

- **2006-2008 Further Expansion Phase**
  - Continued expansion at health center level (65% access)

- **2009-2010 “Reaching out to remote communities” Phase**
  - Continued expansion at rural health center level
  - 363 ART sites to date
Policy Change Support

- Enabling political will to allow commencement of PV activity for Antiretroviral Therapy
- Provision of initial funds for PV activity
- Specific objective to address PV activities in the MOH strategic plan 2006-2008 (rolling plan to 2009) for ART
- Legal and regulatory framework adopted
ORGANISATIONAL STRUCTURE OF PVU

Ministry of health

PRA

National Pharmacovigilance unit

Provincial Pharmacovigilance

District Pharmacovigilance

Public and Private Health Centres/Hospitals

Patient And Public

Peripheral Laboratories

Reference Laboratories

Investigation teams (HIV/AIDS, TB, EPI, MALARIA & others)

Professional Bodies

Manufacturers/Distributors

UNZA / TDRC

Expert Review Panel

World Health Organisation

Uppsala Monitoring Centre

Key
Reporting/ info flow
Lab work & reporting info flow
Legal framework

- One of the functions of the Pharmaceutical Regulatory Authority (PRA) in the new legislation which came into effect in November 2004, is post-marketing surveillance and monitoring of ADRs.

- The PRA is coordinating all PV activities. Pharmacovigilance Unit (PVU) was on 16th June 2006 and is set up at PRA.
Implementation-TWG

- TWG to set up the PV system
  - Developed training package, ADR reporting tools, system design, coordinating trainings
  - HIVDRSS incorporated in the PV system
  - Supervisory visits to monitor implementation
Implementation - Planning

- Original plan was centered on Anti-malarials at the National Malaria Control Centre.
- The aim was to revise the initial plan to be more inclusive for all drugs including ARVs, TB, Malaria and Vaccines
Implementation-Design

- Design of PV and HIVDRSS systems
- Manuals developed for training of trainers with financial help from Health Services Systems Project (HSSP under PEPFAR) and WHO.
- Different forms for resistance monitoring in HIV/AIDS, Malaria and TB have been developed.
Implementation-Infrastructure

- Secured a building (needs rehabilitation) for conference, admin offices, data center and utility rooms
- Procure field vehicles
- Procured office equipment for data analysis and training (laptop, computers, printers, LCD, screens, etc)
Implementation-Training

- Trainers (63) have been trained which included doctors, pharmacists, nurses, clinical officers, lab technicians from the Public and Private Sector
  - Health workers in NGO’s e.g. CHAZ, CIDRZ
  - Defense forces medical services and UNZA
  - Health workers (21) from the private sector
- Total number trained is over 580 HCWs
Current Analysis

- Well established health programmes such as TB, HIV/AIDS, Malaria
- Availability of Resources from Global Fund, PEPFAR (thru HSSP and CDC) and UN system
- Training conducted on cost sharing basis with health facilities
Current Analysis

- Some ADR/ADE reports received (now approx. 130 reports annually) and acknowledgement of receipt of reports is done almost immediately.
- Causality assessments are yet to be done.
- Need to link system to SmartCare system (Zambia’s Electronic Medical Records System)
Challenges

- No full time secretariat and short listing for a coordinators for PVU and for HIVDRSS activities (funding yet to be secured)
- Mechanisms to encourage more reporting by health workers
- Bring on board **all** National Health programmes including the private sector
- Motivation of reporters especially health care professionals
Way Forward

- Provide support to the pharmacovigilance at provincial and district levels.
- Sensitization of members of professional bodies and associations e.g. MAZ, PSZ, Diabetes and Epilepsy associations
- Fully operationalise NPV Secretariat
- Publication of “Medicines Monitor”
Way Forward

- Incorporate pharmacovigilance in pre-service professional training for medical, pharmacy, nursing etc.
- Public sensitization on pharmacovigilance
- Secure funds for infrastructure and causality assessments of reports
Thank you...