Pharmacovigilance in HIV/AIDS public health programmes: luxury or priority?

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PV/ARVs project coordinator

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Launching a Three-Year Initiative

• Developing pharmacovigilance (PV) for antiretroviral medicines (ARVs) in Public Health programmes.

• **Crucial** for:
  
  1. Patient safety
  2. Treatment development and effectiveness
Launching an initiative based on a three-Year project

- WHO PV project initially funded by the Bill and Melinda Gates Foundation for three years
- Has four components:
  1. Consensus building
  2. Capacity building
  3. Development of research agenda to respond to key questions
  4. Coordination and information sharing
1. Consensus Building

Require development and adoption of:

- Common language around:
  - Definitions
  - Toxicity grading
  - Management algorithms

- Simplified, standardized reporting tools, methods, and training

- Single system for pooling and analysing data: WHO drug monitoring programme

- Common platform for gathering information from and sharing it with all stakeholders
2. Capacity Building

• Collaborating with 6 focus countries to develop the strategy, test and implement tools

• Proposing a "model" for building pharmacovigilance in HIV programmes
2. Capacity Building

Need to find innovative strategies for building PV in ART

- Creating a culture of “drug safety”
- Training and supporting service providers without burdening them (use of new technologies)
- Addressing issues around integration of PV surveillance into existing patient monitoring
- Stimulating interest, incentives, commitment, and ownership of service providers
3. Development of Research Agenda

• Identifying (and selecting the most urgent) key questions re: pharmacokinetics, co-morbidities, contextual specificities, and rapid data gathering

• Doing a mapping to identify ongoing research and resources. Convening partners to pool their strengths and interests
4. Coordination and Information Sharing

- Project management and coordination at three levels of WHO
- Staffing
- Sensitization
- Resources mobilization
- Country support
- WHO website and a database
Achievements to Date

**Consensus building** around definitions, norms, and standards

- Priority definitions developed and tested
- CEM flow developed
- Case definition, toxicity grading and clinical management of AE and toxicities
- Handbook on pharmacovigilance for ARVs
Achievements to Date

Capacity building
✓ 6 focus countries selected, staff recruited
✓ Assessment in progress
✓ First training in Tanzania

Project Advisory Group established

Research agenda set for the first year
2. Country selection criteria: HIV/AIDS

1. **Prevalence** (rates; total number of people living with HIV/AIDS)
   - A > 20%
   - B > 5%
   - C > 1% or > 0.1 in concentrated epidemics

2. **Number of people on treatment**
   - 3 > 50%
   - 2 > 20%
   - 1 > 10%

3. **Cohorts collaboration**

4. **PEPFAR programmes**
   - 2 Focus country
   - 1 Cooperation
   - 0 None

5. **Resources**
## 2. Country selection: HIV

<table>
<thead>
<tr>
<th>Country</th>
<th>Prev HIV</th>
<th>Treatment programme Nr P on treatment</th>
<th>Cohorts coll</th>
<th>PEPFAR</th>
<th>Resources</th>
<th>Value Rank</th>
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<tbody>
<tr>
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<tr>
<td>Botswana</td>
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<td>3 (85%; 85,000)</td>
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<td>A6</td>
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<td>2</td>
<td>C4</td>
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<td>1 (7%; 13,000)</td>
<td>Nat+; leDEA</td>
<td>?</td>
<td>C2</td>
<td>6</td>
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<td>Ivory coast</td>
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<td>1</td>
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<td>2- (22%; 280,000)</td>
<td>leDEA; DREAM</td>
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<td>A5+</td>
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<td>3</td>
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<td>United Republic of Tanzania</td>
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<td>leDEA; DART; DRE/</td>
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<td>B5+</td>
<td>2</td>
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<td>A2+</td>
<td>6</td>
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</table>
Achievements to Date

Coordination and information sharing
✓ First publication prepared
✓ Website and SharePoint created
✓ Network initiated with major international research groups, programs, and cohort implementers, incl. PEPFAR, IeDEA, MS, pharmaceutical industry.

Cohorts Mapping

Resource Mobilization
Challenges

• Ensuring sustainability by integrating this project-driven initiative into:

  ➢ **Treatment management** of a chronic infectious disease with built in toxicities
  ➢ **Health systems strengthening**

• Within WHO: preventing “verticalism” by collaborating with other programmes, under the guidance of EMP

• Ensuring widespread **information sharing**, including the pharmaceutical industry, brand and generic companies

• **Mobilising resources** and ensuring financial sustainability at all levels, supporting countries to access funding (e.g., Global Fund)
Challenges

• In country programmes: finding a "model" and the right balance between:

  ➢ Long-term "systems strengthening" and the need for urgent and targeted information
  ➢ Passive versus active surveillance systems and integration of the two
  ➢ Coordination with cohort implementers and country ownership
Challenges

• Protecting country ownership:
  - Database
  - Decision-making

• Finding the right balance between
  - System building and the need for urgent information
  - Passive and active surveillance

• Building a supportive network involving multiple partners with diverse interests
THANK YOU!