Antiretroviral Pharmacovigilance Training Course

Dar es Salaam,
United Republic of Tanzania

23rd – 28th November 2009
SAFETY MONITORING OF ARVs IN GHANA

NATIONAL AIDS/STI CONTROL PROGRAMME
FOOD AND DRUGS BOARD
Agenda

• Ghana, Background Information
• HIV Situation in Ghana
• ARV therapy
• General Pharmacovigilance activities
  – Training of health professionals
• Pharmacovigilance in Public Health Programmes
The HIV Situation in Ghana:
Ghana Has a Generalized Epidemic

- HIV prevalence is consistently over 1% among pregnant women
- Although sub-populations at high risk may continue to contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain an epidemic independent of sub-populations at higher risk for infection.
• First case of AIDS in Ghana was in 1986

• The median HIV prevalence (ANC)
  – 1994  2.4%
  – 2003  3.6%
  – 2004  3.1%
  – 2005  2.7%
  – 2006  3.2%
  – 2007  2.6%
  – 2008  2.2%
National Estimates

- **In 2008, the estimated adult national HIV prevalence is 1.7%,**

- Estimated 236,151 persons Living with HIV and AIDS
  - Males- 98,306
  - Females- 137,841

- New HIV infections:
  - Adults- 18,564
  - Children- 3,978

- AIDS deaths- 18,082 (2,241 Children)
<table>
<thead>
<tr>
<th>Indicator</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Adults + Children</td>
<td>236,151</td>
</tr>
<tr>
<td>HIV population- Children</td>
<td>20,808</td>
</tr>
<tr>
<td>Prevalence Adult (%)</td>
<td>1.7</td>
</tr>
<tr>
<td>Incidence (%)</td>
<td>0.13</td>
</tr>
<tr>
<td>New HIV infections- Adult</td>
<td>18,564</td>
</tr>
<tr>
<td>New HIV Infections- Children</td>
<td>3,978</td>
</tr>
<tr>
<td>Annual AIDS deaths</td>
<td>15,841</td>
</tr>
<tr>
<td>Annual AIDS deaths- Children</td>
<td>2,241</td>
</tr>
<tr>
<td>Need for ART- Adult (15+)</td>
<td>63,137</td>
</tr>
<tr>
<td>Need for ART- Children</td>
<td>6,086</td>
</tr>
<tr>
<td>Mothers needing PMTCT</td>
<td>13,095</td>
</tr>
</tbody>
</table>
HIV Prevalence By Region

- Eastern: 4.2
- Ashanti: 3.0
- Greater Accra: 3.0
- Western: 2.9
- Brong Ahafo: 2.6
- Central: 2.0
- Upper East: 2.0
- Volta: 1.7
- Upper West: 1.6
- Northern: 1.1

Prevalence
## ART Services Data

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Target as at June 2009</th>
<th>Results as at June 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Number of people with advanced HIV infection receiving ARV combination therapy</td>
<td>37,500</td>
<td>29,010</td>
</tr>
<tr>
<td>2  Number of service delivery points providing ARV combination therapy</td>
<td>59</td>
<td>125</td>
</tr>
</tbody>
</table>
## ART Services Data

<table>
<thead>
<tr>
<th></th>
<th>Cumulative # initiated on ART</th>
<th># of Deaths</th>
<th># who Stopped treatment</th>
<th># Lost to Follow up</th>
<th># Currently on ART</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adults</strong></td>
<td>27,644</td>
<td>1,302</td>
<td>121</td>
<td>1,374</td>
<td>24,847</td>
</tr>
<tr>
<td><strong>Pediatrics</strong></td>
<td>1,366</td>
<td>80</td>
<td>7</td>
<td>19</td>
<td>1,260</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>29,010</td>
<td>1,382</td>
<td>128</td>
<td>1,393</td>
<td>26,107 (90%)</td>
</tr>
</tbody>
</table>
ARV Drug Regimen

1\textsuperscript{st} Line
2\textsuperscript{nd} Line
Alternative 2\textsuperscript{nd} Line
First line regimen

First choice drugs

• First Option
  – Zidovudine 300mg 12hrly + Lamivudine 150mg 12hrly + Nevirapine 200mg daily for 14 days, then 12hrly

• Second Option
  • Zidovudine 300mg 12hrly + Lamivudine 150mg 12hrly + Efavirenz 600mg nocte

12/11/2009
First line regimen

Second Choice drugs

• First Option
  – Stavudine 30mg 12hrly + Lamivudine 150mg 12hrly
    + Nevirapine 200mg daily for 14 days, then 12hrly

• Second Option
  – Stavudine 30mg 12hrly + Lamivudine 150mg 12hrly
    + Efavirenz 600mg nocte
Second line regimen

First Alternative
• Abacavir + Tenofovir + Nelfinavir
  » or
• Abacavir + Tenofovir + Lopinavir/r

Second Alternative
• Didanosine + Abacavir + Nelfinavir
  » or
• Didanosine + Abacavir + Lopinavir/r
## ADR Reports
### Spontaneous Reporting

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Reports</th>
<th>ART</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>95</td>
<td>2</td>
<td>2.10%</td>
</tr>
<tr>
<td>2006</td>
<td>111</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>2007</td>
<td>123</td>
<td>2</td>
<td>1.63%</td>
</tr>
<tr>
<td>2008</td>
<td>107</td>
<td>6</td>
<td>5.61%</td>
</tr>
<tr>
<td>Jan-Sept. 2009</td>
<td>132</td>
<td>21</td>
<td>15.91%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>568</strong></td>
<td><strong>31</strong></td>
<td><strong>5.46%</strong></td>
</tr>
</tbody>
</table>
## Nature of ADRs

<table>
<thead>
<tr>
<th>Description</th>
<th>Total Number in Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin rashes</td>
<td>15</td>
</tr>
<tr>
<td>dizziness/drowsiness</td>
<td>5</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4</td>
</tr>
<tr>
<td>Weakness</td>
<td>4</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4</td>
</tr>
<tr>
<td>Nightmares</td>
<td>4</td>
</tr>
<tr>
<td>Drop in haemoglobin</td>
<td>3</td>
</tr>
<tr>
<td>Others (diarhoea, oedema, abdominal pains, bloody stools, etc)</td>
<td></td>
</tr>
</tbody>
</table>
ADR Reporting

• VigiFlow since 2007
• Two members of staff of FDB involved
• Reports sent after causality assessment
• 120 (90.91%) reports committed to VigiFlow since Jan. 2009
• 120 (90.91%) reports committed to vigiflow in 2009 alone.

Search and statistics not fully...
## ADR Reporting

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Reports Received</th>
<th>No. Committed to vigiflow</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>95</td>
<td></td>
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<td>94</td>
<td>87.85</td>
</tr>
<tr>
<td>2009</td>
<td>132</td>
<td>120</td>
<td>90.91</td>
</tr>
<tr>
<td>Total</td>
<td>568</td>
<td>241</td>
<td>42.43</td>
</tr>
</tbody>
</table>
PV in Public Health Programmes

- Cohort Event Monitoring of Antimalarials sponsored by the NMCP

- Sensitization for Yaws and TB control Programmes

- Pharmacovigilance presentation to managers of all PHPs during annual review meeting

- Cohort Event Monitoring at four ART sites (by CTCPT, UGMS)
  - Police Hospital (Greater Accra Region)
  - St. Martins de Porres Hospital (Eastern Region)
  - Koforidua Regional Hospital (Eastern Region)
  - Atuah Government Hospital (Eastern Region)
Training

• Publication of a handbook on management of Adverse Drug Reactions to ARVs (CTCPT)

• Number of healthcare professionals trained in pharmacovigilance since meeting in Geneva in April 2008
  – 2008:-301
  – 2009:-433

• National ART training for the over 130 sites place emphasis on ADR
Challenges

• Underreporting
• Lack of Institutional collaboration and commitment
• Inadequate resources
  – Human
  – Financial
  – Logistics
Way Forward

• Sensitization and training of ART medical teams on PV
• Incorporation of Pv reporting into existing ART reporting requirements
  – Data officers to be trained to support clinical staff in this regard
• Effective institutional collaboration
• Harmonization of reporting forms
• Leadership commitment and advocacy
• Proposal to review AEFI Reporting Form