Pharmacovigilance (PV) in HIV treatment in Ukraine: Situation Analysis

Dar es Salaam
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Why PV in HIV is important?

- Few regimens, many combinations
- Originators and generics
- Co-morbidities (TB, Hep.C, etc.)
- ADRs result in poor adherence
  - Poor adherence => resistance
  - Resistance => new regiment
  - New regiment => new ADRs
  - New ADRs =>......,- poor adherence.....
Overview

- Background: Ukraine and HIV

- National PV Program: a summary on
  - Regulations
  - Governance
  - Existing capacity, HR, trainings
  - PV methodologies
  - Number, type and quality of ADR: known and unknown

- PV for Antiretroviral drugs

- Analysis and next steps
Background: Main Modes of HIV Transmission

**Predominant transmission group**
- MSM
- Heterosexual
- Injecting Drug Use
- Data unavailable

Population of Ukraine – 46 millions

Over 99 000 officially registered PLWH (350 000 estimated)

Prevalence of HIV in age group of 15 years and older is 0.82%

2007 – 17 699 new cases

2008 – 18 963 - 7.3% Increase!

14 256 people are on ARV treatment as of October 1, 2009; 4,322 – need!

260 treatment sites: 60 prescribe ARVs, 200 – distribute

93% of all patients are on first line and 7% on second line regimen;

5,7% of patients on ARV have Hep. C, 5,7 % - active TB and 6,6 % are active IDUs;
ARV regimens

- 1st line regimen:
  - EFV+AZT/3TC;
  - EFV+TDF+FTC (or 3TC) (access to TDF provided from 2008)

- Alternative 1st line regimen:
  - LPV/rtv +AZT/3TC;
  - LPV/rtv+TDF+FTC (or 3TC) (access to TDF provided from 2008)

- Preferred 2nd line regimen:
  - LPV/rtv + ddl + ABC

- Alternative 2nd line regimen:
  - LPV/rtv+ ddl + 3TC
  - LPV/rtv + TDF + ABC or
  - LPV/rtv + TDF + (3TC ± AZT) or
  - LPV/rtv+ ddl + AZT or
  - LPV/rtv + TDF + ddl
  - LPV/rtv+TDF+FTC
AIDS Centers, PV Branches

- National AIDS Center
- Regional Level
- Municipal/District Level
- Small towns/Community Level
- PV Center and Branches
PV: Governance

MOH

State Pharmacological Center

State Inspectorate for Quality Control of Medicinal Products

Pharmacovigilance

Quality Control of Medicinal Products

Identification of hazardous influences of medications

Permanent or temporary termination of use through the license recall
State Pharmacological Center (SPC):
- 25 regional offices
- 15 central and 75 regional staff positions
  - 80% of SPC staff are clinicians with training in pharmacology
  - Only four hours devoted for PV during Pharmacology course in Medical Schools
  - Post-graduate training is provided by National Academy of Postgraduate Studies
  - SPC has biannual meetings for all regional experts for information sharing
  - In June 2007, a two day workshop on PV in HIV was conducted by the leading Ukrainian specialists on ARV treatment for regional representatives of the SPC
PV: Mechanism

WHO-UMC

Ministry of Health of Ukraine

State Pharmacological Center

Physicians

Producers

Patients, NGOs, etc

Passive reporting

STI/HIV/AIDS Programme, WHO CO/Ukraine

State Pharmaceutical Center, 2009
Dynamics of ADRs reporting

ADRs ALL


283 298 257 670 3246 4190 4102 4147 5283 6949 5294

ADRs ALL
540 ADRs reports starting 2004

ADRs in HIV


1 4 12 140 149 234
Reported ARVs

- Lamivudine / Zidovudine tablets – 13%
- Efavirenz capsules – 11%
- Lamivudine/Zidovudine capsules – 10.5%
- Nevirapine – 8.5%
- Stavudine capsules – 8%
Structure of the ADRs

- Changes in central and peripheral nervous system: 21.20%
- Allergic reactions: 24.40%
- Red blood cells disorders: 16.20%
- Gastro-intestinal system disorders: 21.70%
- Other: 16.20%

Legend:
- Changes in central and peripheral nervous system
- Allergic reactions
- Red blood cells disorders
- Gastro-intestinal system disorders
- Other
100% were predictable
- 61% - not serious
- 39% - serious

96,3% resolved without consequences
3,1 – with consequences
0,6 – no change
## Strength and Weaknesses for PV in HIV

### Strengths:
- PV (spontaneous) system is in place
- Guiding body and regulations are available;
- Regional network;
- Local Database exists;
- Some experience in ARVs ADRs reporting;
- Full member of the WHO Programme for International Drug Monitoring
- Capacity building opportunities
- Support by National AIDS Center

### Weaknesses:
- Low number of reports
- No new data
- Low awareness level about PV in HIV among service providers and specialists of the Center in general;
- Low motivation of HIV specialists to report ADRs;
- Lack of reciprocal communication with professional medical community
- Lack of standardized training curriculum on PV, including on PV in HIV care;
- No experience in CEM
Needs for improvement

- For PV Center:
  - Spontaneous system strengthening
  - Strengthen manufacturers responsibility for ADR reporting
  - Better follow-ups with HIV specialists. Information sharing

- For HIV Service
  - CEM projects implementation and tools
  - Cooperation with PV Center
  - Research on HepC, MDR, XDR TB co-morbidities

- For HIV specialists
  - Trainings on ADRs in HIV care, integrated into trainings and academic curricula
  - ADRs monitoring and reporting guidelines
  - Patients monitoring forms and reporting
  - Communication materials development

- For PV specialists
  - Trainings on PV in HIV and ADRs in ARV
Plans

- Coalitions building (PLWH, USAID, etc.)
- KAP Survey of PV and HIV specialists
- Communication materials and reporting tools development and/or improvement
- Trainings of PV and HIV specialists on PV in HIV
- CEM tolls adaptation and piloting
<table>
<thead>
<tr>
<th>Objectives</th>
<th>Timeline</th>
<th>Consultants/Partners</th>
<th>Budget</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>1. a) Instrument development; b) Survey distribution and implementation c) Survey analysis and reporting</td>
<td>X</td>
<td>YES</td>
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<td><strong>A consultant from SPC</strong> will be contracted to provide overall technical expertise for the activities implementation and coordination within the SPC system</td>
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<td>2. a) IEC materials design b) IEC testing c) print d) distribution e) improvement of data collection from design</td>
<td>X</td>
<td>YES</td>
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<td><strong>Communication specialist/agency</strong> will be contacted to develop and design IEC materials</td>
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<td>3. a) Training for SPC reps b) Training for HIV specialists</td>
<td>X</td>
<td>YES</td>
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<td><strong>Trainings</strong> will be developed based on the WHO HQ recommendations and developed guidelines</td>
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<td><strong>One joint event for SPC representatives an HIV specialist may be sufficient</strong></td>
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<td>4. a) CEMFlow adaptation b) CEMFlow piloting</td>
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<td>UMC</td>
<td></td>
<td><strong>Translation and adaptation</strong> of the CEMFlow software will be coordinated with UMC and HIV Department in HQ</td>
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<td>TOTAL</td>
<td>Nov. 2009 – Apr. 2010</td>
<td>WHO HQ/WHO CO/SPC/NAC/UMC</td>
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Thank you for support!

- Dr. Micheline Diepart, WHO HQ
- Dr. Shanthi Pal, WHO HQ
- Dr. Gundo Weiler, WHO CO in Ukraine
- Dr. Elena Matveevaa, SPC, Kyiv, Ukraine
THANK YOU!
Questions, please!
And Welcome to Ukraine!