

# Long-term monitoring of treatment related adverse events in adults

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# Outline of the Presentation

- Status of antiretroviral use in resource limited settings (RLS)
- Scope of adverse events
- Implications of these events
- Challenges of monitoring adverse events in RLS
- Conclusions

# Status of ART in the Resource Limited Settings

- Number on ART still relatively very small
  - 500,000 out of 25M in sub-Saharan Africa
- However, positive global response to increase ARV access since 2002
  - WHO 3 by 5 initiative
  - Global fund for AIDS, TB & Malaria by the UN
  - PEPFAR support for 14 RLS countries



World Health Organization



The 3 by 5 Initiative

TREAT THREE MILLION PEOPLE LIVING WITH HIV/AIDS BY 2005

## 700 000 people living with AIDS in developing countries now receiving treatment

**Joint media release WHO/UNAIDS/Global Fund/US Government**

26 JANUARY 2005 --|-- By the end of 2004, 700 000 people living with AIDS in developing countries were receiving antiretroviral (ART) treatment thanks to the efforts of national governments, donors and other partners.

<b>Region</b>	<b>On ART by June 05</b>	<b>% Coverage</b>	<b>On ART by Dec 04</b>
<b>Sub-Saharan Africa</b>	<b>500,000</b>	<b>11%</b>	<b>310,000</b>
<b>L. America + Caribbean</b>	<b>290,000</b>	<b>62%</b>	<b>275,000</b>
<b>E, S, SE Asia</b>	<b>155,000</b>	<b>14%</b>	<b>100,000</b>
<b>Europe + C. Asia</b>	<b>20,000</b>	<b>13%</b>	<b>15,000</b>
<b>N. Africa + M. East</b>	<b>4,000</b>	<b>5%</b>	<b>4,000</b>

# The scope of adverse events in RLS

- The burden of long-term adverse events in RLS is not well known
  - Not long enough experience with ART
- Commonly encountered events include:
  - Hematological disorders
  - Liver toxicity
  - Metabolic toxicity
  - Neurological complications
    - ✓ CNS and peripheral nerve toxicities

# The Implications of adverse events

- Majority of patients initiated on ART are too sick
  - In 3315 DART pts, b/l median CD4+ 100
- Differentiating signs and symptoms due to HIV disease and drug toxicity may be difficult
  - Worse in less experienced health worker
- Delay in diagnosis and management of the toxicities

# The Implications of adverse events

- Erosion of patient's confidence in ART
  - Due to real and assumed toxicity
- Decrease in patient adherence and development of resistance
  - Subsequently leading to treatment failure
- Negative impact on national programs
  - PMTCT – Nevirapine
  - ART scaling up programs
    - ✓ Resistance makes the programs too expensive



# The challenges of monitoring adverse events in RLS

- Inadequate infrastructures
  - Laboratories poorly equipped + limited reagents
  - Referral services too few and too far
- Lack of trained personnel
  - To diagnose and investigate the adverse events
- Quality of services variable within and across countries
  - Implications on data sharing

# The challenges of monitoring adverse events in RLS

- Variable health information systems
  - Electronic vs. manual data capture
  - Quality of data collected equally variable from unit to unit and country to country
- Difficulties of communication
  - Variable or non existence IT facilities and training
- Unwillingness to share information
  - Issues of data ownership

# Conclusion

- As the ART access is rapidly scaled up:
  - There is urgent need to map out the burden of adverse events in the RLS
  - To monitor them
  - To share the results
  - To plan interventions jointly in order to minimize their negative impact on ART programs in RLS.