



FORUM FOR COLLABORATIVE HIV RESEARCH

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Increasing Need for ART safety

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- Life long therapy: Potential for long term toxicities not initially reported
- Pre-existing or New Co-Morbidities: drug-drug interactions; drug-disease interactions; disease-disease interactions
- Patient / physician perception of risk & benefit



Pharmacovigilance

- The process of evaluating and improving the safety of marketed medicines.
- Purpose to promote safe clinical use of medicines and prevent adverse drug reactions (ADRs) thereby protecting public health.

Evans and Waller, 2002



WHY IS MONITORING OF TOXICITIES NEEDED IN RESOURCE LIMITED SETTINGS?

Compared to developed world:

- **Rapid scale-up of antiretroviral treatment**
 - Limited expertise, experience among clinicians and patients
- **Difference in populations**
 - Race
 - More women and children, pregnancy
 - Presenting with advanced disease
 - High level of co-morbidities and co-infections
 - Nutritional status
 - Use of traditional medicines
- **Difference in drugs**
 - Standardized first line, 2nd line
 - FDC's, generics
 - Treatment of co-infections



MONITORING OF LONG-TERM TREATMENT ASSOCIATED TOXICITIES IN THE RESOURCE-LIMITED SETTINGS

- Working Group established
- Roundtable discussions
 - October 2005 (Dublin EACS)
 - March 2006 (Madrid, 10th International Cohorts Workshop)
 - March 2007 (Monte Carlo, 11th International Cohorts Workshop)
 - June 2007 (Interest Workshop, Kampala, Uganda)
- Project information available
www.hivforum.org



WORKING GROUP MEMBERS

- Academic experts
- Agencies & organizations:
 - ANRS, CDC, MRC, NIH, PENTA, WHO (HIV, PV)
- Cohort and cohort networks
 - IeDEA, TAHOD, Western Cape
- MSF
- TASO
- Pharmaceutical companies
- National PV programs



PV: Sources of Evidence -1

- *enhancing & facilitating HIV research* Randomised clinical trials (RCTs)
 - most done pre-marketing
 - insufficient power to detect uncommon events
 - generalisability
 - endpoints; efficacy vs safety
- Meta-analysis
 - brings together all available evidence
 - top of the evidence hierarchy



PV Sources of Evidence - 2

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- Spontaneous ADR reporting
 - cornerstone, lactic acidosis, lipodystrophy
 - under reporting, information level
 - only a possible signal
 - extended schemes
- Observational epidemiological research
 - requires high quality population based databases



NEXT STEPS

- Cross-Communication: Work with existing programs, observational databases and cohorts
- Develop standardized data collection format and standard definitions
 - Map existing data collection sites; identify gaps
 - Common definition & collection formats
 - Data validation, management & handling
- IT Infrastructure



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 - (www.hivforum.org)
- WHO
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