Long-Term Monitoring of Treatment Related Adverse Events in the Resource Limited Setting

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Introducing pharmacovigilance into resource limited setting 1

- PV and public health programmes (PHP)
- National Centres vs. disease-related centres
- Identification of signals
  - Procedure for PV
  - Existence of functional advisory committees
  - Causality Assessment
  - Data management (Vigibase Online)
- Communication of signals (denominator)
  - By whom
  - In what way

Introducing pharmacovigilance into resource limited setting 2

- Research vs. surveillance
  - Informed consent
    - research or surveillance?
    - Antimalarial PV project: SP, LAPDAP Projects
  - Hypothesis testing following signal detection
  - Methods; Availability of personnel and facilities, collaboration with external agencies
  - Central coordination
- CIOMS/WG working group on PV and Drug Development in Resource-limited countries
- Integration of research into surveillance
  - Building a research culture (teams, facilities, technical support)

The Ghana Example

- Full members (2001) of WHO Programme
- 65th member of WHO Programme (2001)
  - 65th member; 1st full member from West Africa, one of only 2 NC in West Africa
  - Only 6 NCs in sub-Saharan Africa
- Active collaboration with PHPs
  - EPI, Malaria Programme
  - National HIV/AIDS Control Programme (??)

Ghana Example 2

- Development of forms for monitoring Adverse Events to ARVs
- ARV Adverse Event Form
- Forms incorporated into LMIS
- Field tested in the ONLY four facilities offering ARVs in the public sector
  - Scaling up?
  - Interest and support from NACP/Donors/International Organisations
  - Need for PV paramount
- PV systems supports and stabilises public health programmes ESPECIALLY in times of crisis

Ghana's Example 3

- Application of gathered information to policy
  - Through the Ghana Health Service, Ministry of Health and the Ghana National Drugs Programme
  - Drug Regulatory Authority involved in decisions taken
- Plans for the future?
  - Active PV programmes for public health
  - Combination of spontaneous reporting and intensive monitoring (e.g. SP in IPT)
- Information, networking, collaboration required
  - UMC/WHO (already existing)
  - More active collaboration with NACP
  - Involvement in international initiatives and partnerships

Cohorts, Databases, Collaborations

- Populations covered
  - All patients reporting to 4 pilot treatment centres
  - Aim to cover all patients on ARVs
  - Intensive monitoring supplemented with spontaneous reporting
- Level of toxicity data being collected
  - All suspected adverse EVENTS are being collected
  - Aim to improve reporting culture as well as to identify signals of drug safety
  - Patient management purposes key to program
- Format/Technology
  - Simplified Adverse Event Forms
  - Data management with Vigibase online

Way Forward

- Increasing need to incorporate pharmacovigilance into ALL public health programmes which offer long-term treatment with medicines
- Capacity building for PV
- Collaboration with PHP
- Secure funding for sustainability
- Potential benefits to patient care (system can collect data to demonstrate usefulness of PV)