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COHORT EVENT MONITORING OF ARVs IN TANZANIA

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Introduction

• Cohort Event Monitoring (CEM) as method of PV was introduced in Tanzania 2009

• Started with CEM of Artemether + Lumefantrine 2009 – 2012
  – Funded by WHO
  – Conducted in selected sites from four regions
  – Analysis done
  – Final report written
  – Manuscript underway
Introduction cont.

• Cohort Event Monitoring for ARVs in Tanzania started in April 2013
  – The project is funded by WHO
  – Conducted in selected Care and Treatment sites for HIV patients from 8 regions
  – Currently there are 32 enrolment sites

• Four ARVs in 2 regimens are followed up;
  – AZT + 3TC + NVP
  – AZT + 3TC + EFV
Objectives

• Broad objective
  - To improve public health by monitoring AE associated with the use of ARVs

• Specific objectives
  - To characterize the known ADRs
  - To identify and detect signals
  - To detect interactions with concomitant medicines
  - To determine safety of ARVs
Methodology

• Programme design
  - Active surveillance by Cohort Event Monitoring (CEM)
  - Non-interventional, prospective, longitudinal observational study
  - Target Medicines used in diseases of Public health importance
Methodology cont.

• Criteria used to select CEM sites
  - Existence of TFDA zonal PV center
  - Existence of TFDA zonal office
  - Willingness of healthcare providers to assist in data collection and patient monitoring
  - Accessibility and easy to reach

• Sites were selected from the following regions;
  - Dar es salaam, Kibaha, Mbeya, Morogoro, Tanga, Mara, Arusha and Mwanza
Methodology cont.

• Tools - designed by WHO and TFDA;
  - CEM manual
  - Treatment Initiation Forms (TIF)
  - Treatment Review Forms (TRF)
  - IEC Materials (brochures and posters)
  - CEMflow (web - database) based in Uppsala
  - Guidelines for Completion of TIF
  - Guidelines for Completion of TRF
Methodology cont.

• Sample size 3000

• Selection of participants

• Inclusion criteria
  - Patients tested HIV positive using available laboratory resources
  - All patients irrespective of their age, sex, weight, condition or severity
  - Who began treatment with monitored medicines for the first time

• Exclusion criteria
  - Unwillingness to participate
Methodology cont.

• Treatment Initiation visit
  - Patient ID (File number)
  - Date of interview
  - Site details
    - Type of H/facility(ies), name of facility, district.
  - Patient details
    - Initials, DOB, Age, Sex, Weight, Height, Tel no.
  - Medical details
    - HIV Clinical stage (WHO Classification) I, II, III, IV
    - Indication for ARVs (Rx of HIV inf, PMTCT or both)
Methodology cont.

• Initiation Visit......
  - Other medical details
    - Any history of exposure to ARVs (PEP or PMTCT)
  - New events in past 30 days
  - Past medical condition of importance
    - Diabetes, TB, HT, Malignancy, Surgical procedure, smoking, chronic alcoholism e.t.c
  - Investigation results
    - Lab results (CD4 count, SGDT, SGOT, HB e.t.c)
    - Radiology results mainly for Chest X-ray
    - Period – corresponding dates
Methodology cont

- Initiation visit ......
  - Medication history in past 30 days
    - Conventional medicines
    - Herbal medicines
    - Traditional medicines
  - Medicines prescribed at this visit
    - Monitored medicines
    - Other medicines
    - Indications, Dosage, Frequency and Route
  - Date of next appointment (2wks then monthly)
Methodology cont...

• Treatment Review Visit
  - Interview date
  - Patient details
  - Medical details; HIV stage e.t.c
  - Events (very important)
    - Description, date of onset, date resolved, severity, seriousness, rechallenge
  - Lab test at this visit
  - Medicines
  - Reporter; name, phone, signature
Progress of the programme

• Training of health care providers
  - medical doctors, pharmacists, nurses etc

• Design, printing & distribute IEC materials
  - TIF 3000, TRF 9000, GTIF 3000 & GTRF 9000

• 1500 patients have been enrolled

• 220 TIF of 220 have been collected

• 310 TRF (220 for 1\textsuperscript{st} FU and 90 for 2\textsuperscript{nd} FU)

• Data entered into the CEMflow (tool for storage and analysis)
Preliminary analysis

- The CEMflow was used for analysis
Schedule of activities

• Ongoing activities
  - Follow up of patients at the sites
  - Collection of all completed forms
  - Data entry into the CEMflow

• National Working Group meeting

• Data analysis & Final report writing

• Preparation of a manuscript

• Meeting with stakeholders
Challenges

• Staff turnover at the CEM sites
• Need of re-fresher training
• Low enrolment rate at the beginning
• Time limitation
  ❖ short period (April – December 2013)
• Number of visits
  ❖ Practicability of five visits
• Regimen changes
• Concomitant medications
• Long term adverse events
Recommendations

• Need of revising incentive schemes

• Continuous monitoring and re-training

• Monitoring special groups (Pregnant women, children!)

• Need to cover all ARV medicines
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THANK YOU