CEM PROGRAMME IN TANZANIA

Training course for introducing PV in HIV
23rd - 28th November, 2009

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Outline

- Introduction
- Preparatory phase
- Pilot study
- Data collection phase
- Challenges
- Future plans
- Benefits
Introduction

- TFDA started active surveillance using Cohort Event Monitoring (CEM) in 2009.
- The programme is under the Department of Clinical Trials Control and Pharmacovigilance-TFDA
- Currently, CEM of 1st line antimalarial Artemether + Lumefantrine (ALu) is being implemented. It will cover 4 regions (i.e. Dar-es-Salaam, Arusha, Mwanza and Pwani)
Introduction

- Targeted sample size is 10500 cohorts
- 16 sites were identified initially and sites from Kilimanjaro region were dropped after feasibility study (site selection considered existing PV infrastructure, incidence of malaria and potential to attain cohort size (availability and consumption of Alu))
- The activity is expected to take 2 years
CEM sites

- Mwanza (3)
- Pwani (3)
- Arusha (4)
- Dar es Salaam (6)
OPD clinic in One of CEM site Mt. Meru Hospital Arusha
CEM site ALC/seliani hospital
Preparatory phase

- Development of data collection tools (Questionnaires A, B & pregnancy questionnaires)
- Development of CEM Implementation manual (guide for implementers)
- Design & printing of CEM brochures, posters, questionnaires & patient ID cards.
- Feasibility study and sensitization in 4 regions
CEM Implementation Manual
CEM brochures & Patient ID card
Preparatory phase

- CEMFlow development (TFDA/UMC) TANCEM
- A web-based software designed to manage CEM data including analyses.
  - https://tools.who-umc.org/cemflow
Welcome to CemFlow

CemFlow is a tool designed for the purpose of collecting data originating from Cohort Event Monitoring programs.

The tool has been built in cooperation between the World Health Organization and the Uppsala Monitoring Centre.

It is based on data collection questionnaires that were developed and fine tuned jointly among a number of experts from different countries and with different experiences.

Available CEM programs

Please choose a Cohort Event Monitoring program from the list below in order to get started.

- TFDA CEM program for Malaria (TEST)
- TANCEM

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CEM launching - 17th March 2009
CEM launching.....
CEMFlow Orientation & Training
Pilot study

- Pilot study to test CEM tools was conducted at:
  - Mnazi Mmoja HC (Public health facility)
  - Tumaini Hospital (Private hospital)
  - Muhimbili Hospital (Referral hospital)

- Results obtained were used to improve the CEM tools.
Pilot (Mnazi Mmoja HC)
Preparatory phase....... 

- Training and sensitization of the identified collaborators at the DSM CEM sites. (Doctors, Pharmacists, Nurses & Lab Techs)
- Focal persons identified for each site
Data collection phase

- Data collection phase started in July 2009.
- CEM tools have been distributed to all sites in Dar-es-Salaam and Coast region.
- Six sites are now collecting data in DSM.
Data collection phase......

► Identified Doctors fill in questionnaires after seeing patients.
► QA is filled at first visit.
► Patients are encouraged to return to the facilities or follow up by phone.
► QB is filled after 7 days.
► Patients are reimbursed transport fare (1500 TShs ≈ 1.14 USD).
Data collection phase......

► Pharmacists fill in the batch numbers.
► Questionnaires are collected by focal persons and sent to TFDA HQ offices.
► Data entry is done at TFDA.
► So far 1600 filled-in questionnaires (A&B) have been received.
► 255 questionnaires have been entered in CEMFlow.
► Patients are telephone interviewed to verify their existence and hospital attendance.
► Monitoring visits done after every 2 wks.
Challenges

► Data accrual and timely entry in *CEMFlow*.
► Slow internet connectivity - makes data entry boring.
► Being engaged with other office duties while at the same time required to implement CEM (HR inadequate).
► Collecting safety data for a cohort of pregnant women. (Monitoring may need to continue for a longer period in order to get sufficient numbers to evaluate these subgroups at a satisfactory level of statistical significance)
Challenges......

- Budget constraints
Future plans

► Begin implementation in other regions.
► Divert minimal funds allocated for other PV activities for CEM.
► Request for more funds from WHO.
► Recruit 2 more temporary data entry clerks to cope with data pile-up.
► Design and issue Certificate of Recognition for participating in CEM programme.
Benefits so far....

► CEM has enabled us to establish a broad network with a number of stakeholders - health professionals, hospital directors, malaria coordinators, local government authorities, etc.

► Communication has been bolstered.

► Created a platform for discussing various challenges facing health professionals in implementing PV activities incl. spontaneous reporting system.

► Established a good working relationship with the National Malaria Control Programme.

► Awareness on safety reporting has fairly been created.

► Provided an opportunity to learn project management skills.
Thank you
(Asanteni)