CURRENT PRACTICE OF PHARMACOVIGILANCE IN TANZANIA

Alex F. Nkayamba, MD
Officer, Clinical Trials and Pharmacovigilance Department
PHARMACOVIGILANCE MILESTONES

• 1989 - PV program was first introduced (Tanzania Food and Toxicology information Service)
• 1993 - Tanzania officially implemented spontaneous reporting (Joined WHO International Drug Monitoring program)
• 1998 - PV information incorporated in MoHSW
• 2003 - PV as core function of TFDA with its establishments (TFDA, Act 2003).
METHODS OF PHARMACOVIGILANCE

• Two methods
  ➢ Passive reporting
    ✓ Yellow forms (ADR forms) – English version
        – Swahili version
    ✓ Patient reporting forms (Swahili)
    ✓ Poor Quality Products
    ✓ Patient alert cards
  ➢ Active surveillance
    ✓ CEM Artemether Lumefantrine (Coartem) & Dihydroartemisin Piperaquine
    ✓ CEM of ARVs (Fund received and sites have been identified)
COHORT EVENT MONITORING OF COARTEM (1)

- Target 10,000 reports
- Four (4) regions;
  - Dar es Salaam
  - Mwanza,
  - Arusha and
  - Coast Region (Kibaha + Bagamoyo)
- Visits - twice, follow up after 7 days
- Will be closed 2012
- 6200 (62%) reports have been collected
COHORT EVENT MONITORING OF COARTEM (2)

- No major events in majority of reports
- Few events; skin rash, GIT discomforts and no response to treatment
- Data analysis - May 2012
- Publication - National and scientific news letters
COHORT EVENT MONITORING OF DHA + PPQ

• Private health facilities in six regions
  ➢ Dar es Salaam, Tanga, Morogoro, Mbeya, Arusha & Mwanza

• Target 10,000 reports

• 100 health personnel (doctors, pharmacists and nurses) were trained

• Visits - twice (follow up after 10 days)

• 2,000 (20%) reports have been collected
CHALLENGES FROM CEM ACTIVITIES

• Lost to follow up
• Patient fear of monitored medicines (research?)
• More labour intensive than SR
• More costly
• New to health professionals and PV centers
• Training required
PASSIVE REPORTING

• The most common form of ADR reporting.
• Spontaneous’ or ‘voluntary’ reporting.
• Dependent on the initiative and motivation of the reporters.
• Cover the whole Tanzanian population
• Report ADR for all registered medicines
• Causality assessment is done on receipt of ADR
PV TOOLS

• Guidelines for Monitoring of Medicines safety
• Tanzania Pharmacovigilance Training Manual
• They are all found on www.tfda.or.tz

OTHER TOOLS
WHAT IS DONE ON RECEIPT OF ADR REPORTS

- Acknowledgement on receipt of ADRs
- Assessment (Relation btn ADRs vs Susp Medicine)
  - Certain
  - Probably
  - Possibly
  - Not related
- Entering the data into Vigiflow
  - Done by trained officer
  - Manager review and audit the data before commitment
OUTCOME & CHALLENGES OF ADR REPORTING

OUTCOME
• Additional investigations
• Recommend restrictions on usage
• Enhancing educational initiatives on medicine use
• Regulatory action eg withdraw if situation warrant

CHALLENGES
• Only suspected ADRs are reported
• Underreporting
• Reporting bias
• Lack of denominator
• Poor at detecting delayed ADRs
• Deaths poorly reported
WEAK POINTS

• Information sharing with stakeholders!
• Publications!
  ➢ Safety bulletins
  ➢ Newsletters (National and International)
• Capacity of PV Zone officers!
• Interim data analysis!
  eg CEM Artemether Lumefantrine
EFFORTS TO IMPROVE PV SYSTM

• Training of 17 PV officers from PV Zones 10 - 13 April 12.
• Procurement of infrastructure for old and new PV Zone offices
• To conduct regular training and supervision
• Increase number of PV trained health personnel in private and government facilities
• Print more IEC materials
• Increase public awareness by using media (TV, radio, newspaper etc.)
• National Annual PV meeting (recently resolution)
OBVIOUSLY ................

If some one want to walk fast ...........
Walk alone!

But ............
If you want to reach very far... Walk with your friends

TAKE HOME MESSAGE FOR SSA COUNTRIES
THANK YOU