Training Course for Introducing Pharmacovigilance of HIV Medicines:
November 23-28 at the White Sands Hotel, Dar es Salaam, Tanzania.

TANZANIA PHARMACOVIGILANCE ACTIVITIES AND PLANS:

Henry Irunde
Tanzania Food and Drugs Authority
Map of Tanzania

- 2nd largest lake worldwide
- 2nd deepest lake worldwide
- Highest Mt. in Africa
Country profile I

• Total area of country: 945,000 sq. Km

• Approx. 40 millions population

• Approx. 5000 doctors, 12,000 nurses and 900 pharmacists

• GDP per capita: $800 est.
Country profile II

- Diseases of public health importance include Malaria, HIV/AIDS & TB
- HIV/AIDS prevalence: 7.0% est.
- Life expectancy at birth 44.6yrs est.
- Birth rate 39.5/1000 population est.
- Death rate 17.4/1000 population est.
ART Program:

• By the year 2003 a total of 176,102 AIDS cases were reported to NACP from the 21 regions

• In 2007 about 2 million persons were estimated to be living with HIV and AIDS

• Approximated 600,000 (30%) were in need of ART.

• To date 407,716 are on care and 205,879 on ART (June, 2009) and over 60% are women
1st line treatment regimens

AZT + 3TC + EFV

- d4T or TDF
- peripheral neuropathy
- anaemia

- 3TC or FTC
- women, early pregnancy
- NVP intolerance, severe skin rash, TB

- NVP
First line treatment regimens

- Zidovudine (AZT) + Lamivudine (3TC) + Nevirapine (NVP) / or EFV
- Stavudine (d4T) + Lamivudine (3TC) + Efavirenz (EFV) / or NVP
- Tenofovir (TDF) + Emtricitabine (FTC) + Efavirenz (EFV) / or NVP
- Tenofovir (TDF) + Lamivudine (3TC) + Efavirenz (EFV)
- Tenofovir (TDF) + Lamivudine (3TC) + Nevirapine (NVP)
2ND Line treatment regimens

- TDF plus 3TC or FTC combined with a ritonavir-boosted PI, either LPV/r or ATV/r (TDF+3TC or FTC +LPV/r or ATV/r)

- ABC plus ddl combined with a ritonavir-boosted PI, either LPV/r or ATV/r (ABC + ddl + LPV/r or ATV/r)

- The second line NRTI choice for adults and adolescents depends on the first line regimen

- Note that LPV/r, TDF/3TC and TDF/FTC are currently available as FDC formulations which simplify dosing
Country PV background info

• 1989 A Drug Information Centre (TADATIS) was established at MMC now MNH funded by WHO and DANIDA

• Objectives were to monitor ADRs and promote rational use of medicines,

• A spontaneous (yellow form) system of capturing ADRs was established

• 1993 Tanzania officially became member of WHO International Drug Monitoring program.
Current Country development

- 2003 TFDA was established and empowered by law to ensure quality, safety and effectiveness of drugs.

- TFDA mission statement is to protect the public health by ensuring availability of safe, quality and efficacy of food, drugs, cosmetics and medical devices.

- TFDA is responsible for Marketing Authorization of medicines for use and Post-marketing risk analysis.
Current developments cont....

• Established PV system and implementation of ADR Monitoring is under Clinical trials and pharmacovigilance department

• Zone Drug Information Centers at MNH, Bugando, KCMC and Mbeya referral hospital were established

• Collaboration with stakeholders such as PHPs & NGOs e.g MSH, AIDS Relief/CRS, INESS, IHI.

• Integrating Pharmacovigilance in PHPs
WHO Collaborating Centre for Drug Monitoring

Pharmaceutical industry

DRUG SAFETY MONITORING BY THE TFDA

Muhimbili MNH
Mbeya MRH
Bugando BMC
Kilimanjaro KCMC

PATIENT HEALTH PROFESSIONNALS
Integrating PV in PHPs

**PHP**

- opportunity to implement PV activities
- Offer a cohort of patients under controlled conditions to be monitored for safety over a period of time

**PV**

- detect, evaluate, and prevent adverse events
- promote rational use of drugs in mass treatment programmes
- Evaluate the impact of the programmes
- improve acceptability of the programme
INTEGRATING P.H.P AND PV
FUNCTIONAL AND STRUCTURAL RELATIONSHIP

WHO ADVISORY COMMITTEE

WHO-PV (UMC)

DRUG REGULATORY AUTHORITY

Expert Safety Review Panel

PV Coordinator
National PV centre

DISTRICT INVESTIGATION TEAM

PATIENTS

Health workers

PATIENTS

W.H.O PROGRAMMES

Vaccines
Malaria
Tuberculosis
Filarisis
Trachomatis

NATIONAL PUBLIC HEALTH PROGRAMMES

W.H.O PROGRAMMES

Health workers
Current development cont........

• Strengthen previous yellow form system (spontaneous) more HCW sensitization, Swahili version yellow form was produced

• Introducing new innovation methods of monitoring medicine safety such Cohort Event Monitoring (CEM)

• Introducing the use of modern data management tools such as Vigiflow for spontaneous data and CEMflow for CEM data
Reports of Suspected ADRs from ARVs (June 06, to Nov 2009) SOC as per Vigiflow analysis.

<table>
<thead>
<tr>
<th>Category</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin &amp; appendages (eczema, pruritis, rash, rash macular papular, urticaria, fixed eruption, SJs)</td>
<td>60 (37.74%)</td>
</tr>
<tr>
<td>Centr &amp; periph nervous system disorders</td>
<td>35 (22.00%)</td>
</tr>
<tr>
<td>Liver and biliary system disorders</td>
<td>3 (2.00%)</td>
</tr>
<tr>
<td>Gastro-intestinal system disorders</td>
<td>19 (11.90%)</td>
</tr>
<tr>
<td>Metabolic and nutritional disorders</td>
<td>11 (6.90%)</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>5 (3.14%)</td>
</tr>
</tbody>
</table>
Reports of Suspected ADRs from ARVs (June 06, to Nov 2009) SOC as per Vigiflow analysis cont.....

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disorders, general</td>
<td>1</td>
<td>0.63%</td>
</tr>
<tr>
<td>Heart rate and rhythm disorders</td>
<td>2</td>
<td>1.25%</td>
</tr>
<tr>
<td>Respiratory system disorders</td>
<td>5</td>
<td>3.14%</td>
</tr>
<tr>
<td>Platelet, bleeding &amp; clotting disorders</td>
<td>1</td>
<td>0.63%</td>
</tr>
<tr>
<td>Urinary system disorders</td>
<td>1</td>
<td>0.63%</td>
</tr>
<tr>
<td>Reproductive disorders, female</td>
<td>5</td>
<td>3.14%</td>
</tr>
<tr>
<td>Body as a whole - general disorders</td>
<td>11</td>
<td>6.90%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>159</td>
<td>100%</td>
</tr>
</tbody>
</table>

This was almost 50% of all suspected reported cases of ADRs (2006/09)
Current development cont. .......

- CEM of antimalarial already introduced and started this year 2009.

- Proposal for CEM of ARVs was approved and awaiting funds to start.

- Recruiting additional staff in the department

- Staff trainings in using Vigiflow and CEMflow was conducted
Future plans

• Introducing CEM of ARVs

• Introducing a Pregnancy Register

• Recruit additional staff at National PV centre

• Continue with CEM of antimalarial

• Collaboration with AIDS Relief/CRS, MSH and INESS
Challenges:

- Underreporting
- Funding for active surveillances
- Work load to HCW working in PHPs
- Human resources at the National and Zonal PV Centres.
- Making PV an integral part of care
CONCLUSION

• The success of Pharmacovigilance is largely dependent on the participation of all health care professionals countrywide to report ADRs / or AEs.

• Raising awareness and sensitization of on ADR / or AEs reporting to consumers can also contribute to improve reporting rate.

• PV is essential tool to promote the rational and safe use of medicines and the acceptability of mass treatment programmes.
Merci beaucoup !

Mt. Kilimanjaro in Tanzania