Pharmacovigilance in Kenya

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ARV PV TRAINING TZ
ART program.

• Over 300,000 patients on ARVs: Over 60% female
• About 30,000 children on ARVs in total
• Over 800 health facilities offering ART
Pharmacovigilance in Kenya

• Increased collaboration and joint working and planning between PPB and public Health programs-ATM
• Jointly developed the PV guidelines and reporting tools.
• Jointly developed the PV training curriculum and implementation guide.
Pharmacovigilance in Kenya

• Currently rolling out country wide – spontaneous reporting
• Planning for sentinel sites to boost ADR reporting
• WHO drug monitoring centre associate member
Pharmacovigilance in Kenya

- Guidelines for the National PV System in Kenya developed- ver 2.0 (2009)

- Tools developed:
  - Suspected ADR Reporting Form
  - Alert Card
  - Form for Reporting Poor Quality Medicinal Products
Pharmacovigilance in Kenya

- ‘Field testing’ of PV guidelines and tools completed
- Training material developed: training curricula, guides and manuals
Pharmacovigilance in Kenya

• Formal launch of the National Pharmacovigilance System in Kenya: 9th June 2009, Nairobi
  – Representatives from the ministries of health.
  – Provincial representatives of health
  – ATM program representatives
  – Stakeholders

• 1st and 2nd PV Facilitators training
  (22nd-26th June and 13th-17th July 2009)
  – From all 8 provinces
  – Clinicians, clinical officers, nurses, pharmacists, pharm-techs
Guidelines for the National Pharmacovigilance System in Kenya
What to report?

• Report all suspected adverse reactions to allopathic (modern) medicines, traditional / alternative / herbal medicines, x-ray contrast media, medical devices and cosmetics.

• Report product quality problems, e.g.
  - Suspected contamination, moulding, colour change
  - Poor packaging / poor labeling
  - Therapeutic failures
  - Counterfeit medicine
  - Receiving expired medicines
Pharmacovigilance tools
More space to fill in more information and list more drugs

Severity assessment scale

Causality assessment scale
FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS
PPB Post-Market Surveillance activities

- Past:
  - Surveys of medicines to evaluate:
  - Range and availability, Registration status with PPB and Quality analysis
  - Antimalarials (baseline pre-ACT, QAMSA), cough and colds, ARV, Anti-TB
  - Routine PV and PMS of all pharmaceutical products
PPB Post-Market Surveillance activities

- Present:
  - Pro-active and reactive surveillance
  - Similar sounding / spelt medicines
  - Drug interactions highlights – (PV e-shot)
  - PMS strategy (developed)

- September 2009-Jointly with NASCOP conducted a countrywide PMS of ARVs.
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
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ADVERSE DRUG REACTION ALERT CARD

PATIENT NAME: .................................................................................................................................

AGE: .................................................. GENDER: .....................................................................................

DATE ISSUED: ........................................ ADDRESS: ..........................................................................

SUSPECTED DRUG(S): ............................................................................................................................

DESCRIPTION OF REACTION: ..............................................................................................................

Other comments (if any): .........................................................................................................................

Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.

Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha mhudumu wa afya kadi hii unapo pata matibabu
Alert card
(back side)

CRITERIA FOR ISSUE OF A PATIENT ALERT CARD

The criteria for issue of the Patient Alert Card is as follows:

*The alert card is given to:*

- Patients who are hypersensitive / allergic / intolerant to a particular drug
- Patients who develop a ‘near-fatal’ reaction to any particular drug
- Patients who had a drug- induced morbidity to any drug
- Patients who had hospital admission due to an ADR to any drug
- Patients who developed an ADR which caused increase in the health care expenditure
Pharmacovigilance
Curriculum and Implementation Guide

Republic of Kenya
MINISTRY OF PUBLIC HEALTH AND SANITATION & MINISTRY OF MEDICAL SERVICES, KENYA

PHARMACOVIGILANCE: QUALITY, SAFETY AND EFFICACY OF MEDICINES FOR BETTER HEALTH CARE
CURRICULUM AND IMPLEMENTATION GUIDE

February 2009
Pharmacovigilance
Trainers Manual and Participants Manual
Other Achievements...

- Developed job aids and IEC materials in preparation of national PV roll-out
- Sensitized and trained field staff across all provinces
- Collaboration with KMA, NC, professional associations, stakeholders to encourage reporting of suspected cases
- Include course on PV at University, Schools and Training Institutions
- Stakeholders meeting to combat counterfeiting
Strengthening the PV System—our challenges

- Legal backing
- Personnel
- Dedicated confirmed financial support - routine
- Software - drug interactions, potential ADRs, drug info
- Advocacy - within healthcare fraternity
- Advocacy and awareness - Media for POSITIVE coverage to nation
- Training of data collectors, reporters (ADRs)
Strengthening the PV System—our challenges

• Roll out nationwide

• Inventory systems, database - vigiflow

• Encouraging detection and reporting of ADRs and PQMP

• Publication- info materials, communiqué, updates, e-shots

• Strengthening Pharmaceutical & GMP Inspectors and the link with Pharmacovigilance

• Sentinel site work important
THANK YOU

Asante sana...

“You need not be certain...

Just be suspicious”