Technical Review Meeting of country experiences in surveillance for ARV toxicity

MOH, KENYA
Outline

• Introduction
• PV activities in Kenya HIV program
• Kenya ADR data up to September 2013
• Opportunities and Challenges
• Next steps
Introduction

• PV for ARV use rides on the existing national PV framework i.e. use of existing guidelines, tools and reporting mechanisms

• Partnership for PV between HIV program and national PV center peaked in 2009 with establishment of sentinel sites for surveillance of ADRs to ART

• Close working relationship since then
PV activities in Kenya HIV program

ADR monitoring and reporting
- Spontaneous reporting
- Sentinel surveillance
- Cohort Event Monitoring
- Targeted Spontaneous reporting

Monitoring for poor quality ARV and OI medicines
- Post Market Surveillance
- Routine QA
PV activities in Kenya HIV program

Monitoring for poor quality ARV and OI medicines

• Post Market Surveillance
• Routine QA

Capacity building

• PV sessions during ART guidelines and LMIS tools disseminations done countrywide in 2012
• PV in pharmaceutical care module of the National Integrated HIV training curriculum
• HIV-PV handbook.
PV activities in Kenya HIV program

Use of PV data for decision making

• Routine analysis of ADR and PQ meds data at national, county and facility level proposed

• HIV PV indicators at different levels proposed

• Quarterly national HIV PV report for dissemination to stakeholders especially MOH head office under preparation

• Facilities trained on use of data for decision making
ADRs by class of drugs

ADRs by drug class – Jan 2013 (n=4893)

- ARVs: 92% (4518/4893)
- Antibiotics: 3% (145/4893)
- AntiTB: 3% (145/4893)

Number of suspected ADRs:
- Anti Asthmatics: 4
- Anticancer: 5
- NSAIDs: 8
- Antimalarials: 10
- Local Anaesthetics: 11
- Antihypertensives: 15
- Anti TBs: 27
- Antimalarials: 28
- Antibiotics: 116
- ARVs: 3311

Ministry of Health
ADRs by County_Jan 2013

Number of Suspected ADRs by County

- Uasin Gishu: 555
- Migori: 447
- Narok: 411
- Kisumu: 358
- Kiambu: 262
- Murang'a: 257
- Meru: 160
- Kirinyaga: 138
- Nyeri: 126
- Kitui: 112
- Baringo: 102
- Samburu: 90
- Bungoma: 85
- Kisii: 83
- Bungoma: 80
- Nyeri: 77
- Kakamega: 75
- Homabay: 60
- Siaya: 43
- Kajiado: 42
- Nakuru: 30
- Taita Taveta: 24
- Tharaka Nithi: 22
- Baringo: 16
- Kajiado: 15
- Nyeri: 10
- Meru: 8
- Embu: 6
- Samburu: 6
- Garissa: 5
- Isiolo: 4
- Kwale: 2
- Nyandarua: 2
- Bomet: 1
ADR burden

ADR burden by drug as at end Jan 2013 (n=4893)

Number of Reports

- Stavudine: 2334, 56%
- Zidovudine: 433, 13%
- Nevirapine: 309, 9%
- Efavirenz: 107, 3%
- Cotrimoxazole: 80, 2%
- Enalapril: 49, 2%
- Nevirapine: 12, 1%
- Tenofovir: 11, 0%
- Lamivudine: 11, 0%
- Lamivudine w/nevirapine/stavudine: 9, 0%
- Abacavir: 9, 0%
- Quinine: 9, 0%
- Zidovudine w/lamivudine: 9, 0%

Frequency
Reported ADRs as at January 2013

- Lipodystrophy: 47%
- Lipoatrophy: 13%
- Neuropathy peripheral: 11%
- Anaemia: 8%
- Rash: 7%
- 2%

Leading suspected ADRs:
- Lipodystrophy: 1436, 45%
- Lipoatrophy: 33, 1%
- Neuropathy peripheral: 60, 2%
- Anaemia: 31, 1%
- Rash: 19, 1%
- Stevens Johnson Syndrome: 17, 1%
- Numbness: 31, 1%
- Itching: 222, 7%
- Dizziness: 24, 1%
- Gynaecomastia: 24, 1%
- Rash maculo-papular: 45, 1%
- Headache: 490, 15%
- Vomiting: 471, 15%
- Renal failure: 260, 8%
- Hyperpigmentation skin: 15, 0%
Opportunities

• Devolution – long term
• Technical support – MSH, PPB
• Funding support – CDD, GF
• Partnerships – USAID KP project
Challenges

• Commitment to PV at different levels and by different cadres – PV viewed as nice to do and not a must do and also as additional work

• Data management – filling of forms, transmission of forms, entry into Vigiflow, analysis and use of information

• Evidence of patient safety hard to demonstrate especially for ADR data

• Capacity at national PV center and at NASCOP – staffing, facilities, funding

• Devolution – transition phase
Next steps

• Treatment outcome monitoring plan (2014 – 2018) – HIV DR, PV
• Capacity building – scale up sentinel sites, finalize and disseminate PV handbook
• Generate quarterly HIV PV report (tracking of PV indicators)