What is current practice of pharmacovigilance in Uganda?

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Head Drug Information Department
Head National Pharmacovigilance Centre
National Drug Authority, Uganda
**POLICY, LAW, AND REGULATION**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Y/N</th>
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<tbody>
<tr>
<td><strong>Policy</strong></td>
<td>Yes</td>
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<tr>
<td><strong>PV Policy statements in PHPs (n=4)</strong></td>
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<tr>
<td><strong>Legal provision</strong></td>
<td>No</td>
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<tr>
<td><strong>MAH mandatory ADR reporting</strong></td>
<td>No</td>
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<tr>
<td><strong>MAH mandatory PMS</strong></td>
<td>No</td>
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- National Drug Policy and Authority act (CAP.206, 2000 Edition) does not specify pharmacovigilance
- National Drug Policy, 2002 includes pharmacovigilance
- Draft regulation 2011 to be approved
  - Mandatory reporting for Industry, health workers proposed
- Strategic plan 2011-16 includes pharmacovigilance
- None of PHPs have clear statements on pharmacovigilance in their policy.
PHARMACOVIGILANCE

National Pharmacovigilance Centre

The tools

Guidelines to report ADRs
Form for quality of medicines

Member of the WHO Programme since June 2007
THE PEOPLE

NDA Board
COMMITMENT TO PHARMACOVIGILANCE

Phv Funding trends in NDA

- NDA Recurrent Budget
- DID Recurrent Budget
- Pharmacovigilance budget

NDA Organogram

- Executive Secretary
- Inspectorate Dept
- Quality Control Lab
- Drug Information Dept
- Finance & Administration
- Assessment & Registration Dept
- Units
  - Quality Mgt
  - Human Resource
  - Public Relations
  - IT
  - Internal Audit
  - Procurement
  - Food Desk Coordinator

FY 2008/9
FY 2009/10
FY 2010/11
FY 2011/12
Routine surveillance systems in PHPs now being utilized for monitoring, collecting, and reporting ADRs.

- TSR Project of ARVs
- AMFm Project

Pharmaceutical industry

- Complaint handling system

NPC and DGHS rewarding the regional pharmacovigilance centers who are active in reporting ADRs to NPC
REGIONAL PHARMACOVIGILANCE CENTRES

TO THE EXECUTIVE SECRETARY,

NATIONAL DRUG AUTHORITY

Dear Sir,

RE: NOMINATION OF CORE TEAM FOR MANAGEMENT OF PHARMACOVIGILANCE ACTIVITIES IN OUR CATCHMENT AREA

We are humbly sending this list of the staff in our core team for the above activity in our catchment area of Mubende, Mityana, Kiboga and Kyankwanzi districts.

1. Coordinator  Nankoola Dennis
2. Deputy Coordinator  Dr. Wanga Dison
3. Secretary  Mumbi Stella
4. Member  Dr. Musingunzi Patrick
5. Member  Dr. Mwesigye Ismael
6. Member  Kayeny Teopista
7. Member  Kalyesubula Esther
8. Member  Muyeyebwa Gerald

Yours faithfully,

Dr. Nkurunziza Edward
Hospital Director
Mubende RRH
Using the RPC; The Case of Quinine

- 2009, there were increased cases of gluteal fibrosis, quadriceps fibrosis, and post injection paralysis among 1-14yrs children in Kumi RPC
- Media reported these cases and raised the concern on the risks.
- 2009-2010 NPC investigated the cases in Kumi
- Several factors possible
  - injection by unqualified personnel,
  - poor quality of the injection (Quinine counterfeits identified near Ug. Border)
  - irrational use of injection in community
  - unavailability of oral drug (ACTs)
- Discussed during the meeting of national pharmacovigilance committee.
- NPC searched for the cases (patients who received surgical operation with a history of quinine) from the hospital records in other RPCs.
- Recommendations were made to Ministry of Health based on the findings, including public education, restriction on the use of quinine only in Health Centers that can monitor its use, and training of health workers on proper administration of quinine.
- MOH recommended the change of the administration site for quinine injection from gluteus to thigh and it was reflected in the treatment guideline. (2010)
RISK MANAGEMENT AND COMMUNICATION

1. Dear doctor letter distributed on possible interaction between Proton Pump Inhibitors and clopidogrel (from outside sources)
2. Marketing authorization suspended for rosiglitazone (from outside sources)
3. Found Quinine counterfeit (reports from Regional PV coordinator) circulated near the border of Kenya
4. Quinine injection disabilities probably due to medication errors (contributed to change in treatment guideline)
5. Safety of Pethidine injection; Investigations so far revealed no quality problems despite complaints by physicians. CME was conducted to increase knowledge on safe use of drugs.
6. Recall of Amoxiren batch and Aspiren batch (from medicine quality reporting)
7. Veterinary Pharmacovigilance: Withdrawal of Nitrofurans was effected through alerts in mass and electronic media.( possibility of causing cancer and mutagenicity )
POOR QUALITY MEDICINES

TOOLS

- Informers
- GHFK Minilab
- Truscan
- Procedure + form for assessing quality of medicines
- Risk based approach to quality assessment
COUNTERFEITS...

Outcome:
Prosecution
Public display on counterfeits
PRESS CONFERENCE ON SAFETY OF MEDICINES, MARCH 2012

NPC and health consumer groups

The media involved
WAY FORWARD

- Develop a strategy to coordinate stakeholders involved in pharmacovigilance
- Improve communications to stakeholders and information management
- Tap existing capacities in public health programs and other established institutions to strengthen signal generation and risk evaluation (routine surveillance system, reporting line, DHO, DTCs)
- Develop a structured procedure on risk management and risk communication for high risk medicines
ACKNOWLEDGEMENT

• Regional coordinators
  • Core teams of the regional pharmacovigilance Centres
• National Pharmacovigilance centre staff
• National Drug Authority
• Management Sciences for Health
• Securing Ugandans’ right to Essential Medicines (SURE) Project-USAID.