Module 5. NTD Drug Management

Session 4. Management of SAEs and Surveillance
Role Play
Role Play –
Incidents and rumors during MDA

• Participants split into 2 groups to prepare a role play in the scenario of incidents and rumors during an MDA campaign.
• The role play should include the following parts:
  – Preparation of PC intervention
  – MDA campaign in one school
  – Incidents
  – Rumors
  – Response
  – Consequences
Role Play: Discussion

Situation in District A – Performance of District Team

- Training not given to HWs.
- Communication strategy through the media poorly performed.
- Parents, teachers not actively involved and consent not obtained.
- PZQ given on empty stomach.
- HWs and nearby referral centres unavailable.
- Response to AE weak and delayed.
Role Play: Discussion

**Actions taken by MoH Team**

- Give appropriate training and supervision to HEWs.
- Plan a comprehensive communication and awareness campaign before the start of MDA.
- Inform parents and teachers of the possibility of side effects and of their nature.
- Give PZQ after people eat.
- Make HWs and nearby referral centres available.
- Respond appropriate and promptly to AE on site.
- Approach and communicate rightly to media.
What can be done to best address AEs and SAEs and prevent their negative impact on reaching effective coverage?
Risk Management

Before

MDA

After
BEFORE MDA
PC Preparation (IEC and training)

- Social mobilization, IEC
  - Include information on AEs and the benefits of PC for community
  - Critical to achieving and sustaining high compliance and effective coverage
  - Do not scare stakeholders, influential leaders, and the public about AE/SAEs

- Training of HWs and CDDs
  - To be able to recognize and respond to both AEs and SAEs
Communication Strategy

- Create an atmosphere of trust and participation.
- Mobilization campaigns through the media.
  - Community radio and television programming
- Involving stakeholders of civil society.
  - Change the attitudes and practices of communities
- Interactive broadcasting with phone-ins/SMS for Q&As.
- Involving services such as safe motherhood and hygiene promotion to help gain public trust.
- Educational sessions as part of PHC programmes.
- Community meetings lead by HWs/CDDs.
Prevent/Minimize AEs

Observe contra-indications of administration of the medicines and best practices

• Understand well and stick to the **exclusion criteria**.
• Observe the guidelines for IVM distribution in Loa loa co-endemic areas (section 5.3).
• Ensure that medicines are taken after a meal (even a snack).
• Tablets must be crushed/chewed for the children and whenever possible POS should be given.
• Caution on possible interaction with other treatments.
Preparedness to Respond AEs/SAEs

- AEs are mild and transient and can be managed at the HW level.
- SAEs will need referral to a health center or hospital.
- Before MDA:
  - Prepare guidelines for case management
  - Train CDDs and HWs to recognize, manage, or refer AEs/SAEs
  - Provide guidelines and supplies to HWs and
  - Identify referral facilities to ensure proper care for patients with AEs/SAEs
Communities Before Round 1 of MDA

• Requires special attention due to heavy infections and inexperienced CDDS and HWs.

• Ensure that:
  – Drug dosed and administered appropriately, and exclusion criteria followed
  – Inform patients about possible AEs and subsequent action
  – Care and support available for responding to AE and SAEs (including training of staff and care for young children)
  – Special precaution to pregnant women and communities with high maternal mortality/morbidity
  – Monitoring and reporting system in place to record AEs/SAEs, to MoH, WHO, donation programs, implementation partners
  – Awareness of other concurrent public health intervention that may cause AEs
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AFTER AE OR SAE
Responding to Adverse Events (AE-f-MDA and SAE)

All Adverse Events reported to, presenting at, or occurring in any health facility

- Responding to Patient Needs
  - Treat the patient
  - Determine if it was a Serious Adverse Event (SAE)
  - Communicate with communities
  - Communicate with media
  - Respond to rumors or public enquiries

- Responding to Community Needs
  - Debrief national authorities and report SAEs to national and international pharmacovigilance and regulatory agencies, WHO, drug donor companies and donors supporting programmes
  - Investigate to determine causality
  - Debrief and share progress and outcome of investigations with national and international pharmacovigilance and regulatory agencies, WHO, drug donor companies, donors supporting programmes, communities and media
  - Correct the problem
    - Manage risk situations if they arise
    - Improve training of health workers
    - Improve social mobilization
    - Ensure the quality of drugs

- Disseminate and highlight actions taken based on results of investigations

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Reassurance
Rest
Responding to AEs/SAEs

Manage the case
• Prompt case identification and referral and management.
• Free of charge for the patient.

Communication
• With the communities
  – Good links with community leaders and peripheral HWs
• Communicating with the media
  – Important players in addressing community concerns
• Be proactive and designate a respected spokesperson.
• Preparation of spokesperson includes:
  – Understanding the media perspective
  – Holding a media conference
  – Preparing a press release
Reporting SAEs

WHAT?

- SAEs should be reported on standard form (Annex in Preventive Chemotherapy in human helminthiasis).
- Each country should prepare a list of suspected SAEs with their detailed clinical description.
- AEs even mild or moderate occurring in clusters should be reported and investigated.
## Serious Adverse Events That Need to Be Reported

<table>
<thead>
<tr>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any hospitalization or death</td>
</tr>
<tr>
<td>Anaphylactic Reaction</td>
</tr>
<tr>
<td>Mazzotti Reaction (fever, urticaria, swollen and tender lymph nodes,</td>
</tr>
<tr>
<td>Fits, convulsion, and seizures</td>
</tr>
<tr>
<td>Choking</td>
</tr>
</tbody>
</table>
Reporting SAEs

HOW?

• Appropriate form -> District Health Authorities -> National medicine regulatory authority -> Uppsala Monitoring Centre (WHOCC for International Drug Monitoring)

• National Medicines Regulatory Authority <-> Manufacturers (Companies have a legal responsibility, thus it is critical to get the information shared quickly)

• Eliminate barriers to reporting (aim is to find problems and solution, not to blame individuals).
Sample of SAE Reporting Form

Preventive chemotherapy in human helminthiasis

<table>
<thead>
<tr>
<th>Country:</th>
<th>Date of report: / / (day/month/year)</th>
</tr>
</thead>
</table>

1. Patient information
- **Name**
- **Age**
- **Sex**
- **Location**
- **District**
- **Province/State**

2. Pre-existing conditions
- **Health status before treatment with the drugs:**
  - Good
  - Poor
  - Unknown
- **Parasitic infections**
  - 1. Sti (Strongyloides stercoralis)
  - 2. Lymphatic filariasis
  - 3. Cholera
  - 4. Schistosomiasis
- **Other parasitic infections, known or suspected:**
  - Malaria
  - Loa loa
- **Other medications being taken (currently or recently):**
  - Yes
  - No

Preventive Chemotherapy in human helminthiasis, pge 43; WHO Ref: ISBN 92 4 154710
http://www.who.int/neglected_diseases/buffet_pctmanual/en/
Reporting SAEs

WHO?
• Anyone who is able to identify the case and complete the form can report a SAE: HW, teacher, parent, chief.

WHEN?
• Immediately (as soon as anyone come across the SAE <24 hours).
Investigating Reported SAEs

**WHICH?**

- Due to operational error
- Is in the country list of SAE
- Unexplained cause
- Leads to community concern

**WHO?**

- Properly trained Investigator with adequate resources

**WHEN?**

- Urgently – within 2 days
Outline of a SAE Investigation

- Confirm information provided in the report.
- Gather & verify basic information on each case (age, sex, time, relationship).
- Make a direct examination of PC treatment site.
- Gather data on the suspected medicine and obtain a sample.
- Collect information on clinical features of suspected SAE and in non-treated persons.
- Formulate a working hypothesis on the cause.
- Conclude the investigation.
Investigating Reported SAEs Promptly and Completely

Cluster of adverse events

- **Yes**
  - All cases from one site and same medicine batch used elsewhere?
    - **No**
      - All cases received same medicine batch?
        - **No**
          - Similar illness in untreated people?
            - **Yes**
              - Operational error
            - **No**
              - Coincidental event
        - **Yes**
          - Known AE?
            - **Yes**
              - AE with expected rate?
                - **Yes**
                  - Coincidental event
                - **No**
                  - Operational error
            - **No**
              - Similar illness in untreated people?
                - **Yes**
                  - Coincidental event
                - **No**
                  - Expected event

- **No**
  - More investigation, new adverse drug reaction?
    - **Yes**
      - Investigating Reported SAEs Promptly and Completely
    - **No**
Cluster of adverse events

All cases from one site and same medicine batch used elsewhere?

Operational error

Fix the underlying problem(s)

Lack of dose poles
Untrained/poorly trained CDD/HW
DOT not being implemented

Supportive supervision implementation to ensure that these errors are corrected and not repeated.
Investigating Reported SAEs

Assessing causality
- Certain/Probable/Possible (known medicine reaction, drug interaction, operational error)
- Unlikely (coincidental event)
- Conditional (investigation not yet completed)
- Unassessable (insufficient evidence available)

Variables
- Clinical judgment
- Nature of the event
- Temporal relationship
- Dose-response relationship
- Exclusion of confounding factors
Is there a system for AE and SAE case management, reporting, and investigation in your country?

How is it working?
Establishing PC Safety Surveillance

• Built on an existing pharmaco-vigilance (PV) system.
  – Collaboration between the national NTD PM and the National Pharmaco-vigilance service/the Medicines Regulatory Authority
  – to ensure early detection, appropriate and quick response to SAEs to mitigate their negative impact on the health of the individuals and on PC programme.

• Before the MDAs, agree on roles and responsibilities of parties involved in PC safety surveillance, including teaching hospitals, quality control laboratory. Train all parties involved.

• During MDA, conduct a country-wide minimum surveillance for operational error and a more intensive one in a few health facilities.
Steps for Establishing PC Safety Surveillance 1

• Seek cooperation and define role of the Pharmacovigilance/medicine regulator authority and all interested parties, and agree on the objectives for the surveillance system.
• Identify the resources available and needed; obtain political commitment to implement safety surveillance.
• Designate focal points for NTD PC safety and establish the national NTD PC safety committee.
Steps for Establishing PC Safety Surveillance 2

- Develop and disseminate a list of SAEs to be reported and a standard investigation procedure and reporting.
- Designate and train HWs at peripheral, district, regional level.
- Inform all CDDs/HWs/clinicians of the need to report SAEs.
PC Safety Surveillance Evaluation

**Criteria should include**

- Timeliness, completeness and accuracy of AE/SAE reporting.
- Timeliness and completeness of investigation(s).
- Audit of corrective action.

**Annual report**

- Number of AE/SAE reports.
- Causality assessment results.
- Good for feedback to HWs, media, leaders, and communities.
What are the key messages from this session?
Key Messages 1

Preparedness includes:

- Collaborate with the pharmacovigilance system and other partners.
- Training to minimize operational errors, facilitate prompt identification and competent management of SAEs, and promote reliable and effective communication in endemic communities.
- Intense social mobilization to sensitize the population on AEs/SAEs.

Management of SAE includes:

- Treatment free of charge for the patients.
- Good communication with the community and the media.
- Reporting of the SAEs.
- Investigate the reported SAEs.
- Prompt reporting of SAEs to the drug companies, WHO, donors, and implementing partners is of paramount importance.
Key Messages 2

Aims of the Safety surveillance:

- Early detection of the cases
- Quick and appropriate response to SAEs

in order to mitigate their negative impact on the health of the individuals and on PC campaigns.