Managing Adverse Events
Emergency Response System

National Deworming Day
Background

- The deworming drug (Albendazole 400 mg) is considered to be **effective and safe**. The drug is **approved** by World Health Organization (WHO), and is in the list of essential medicines (2011) by Ministry of Health & Family Welfare (MoHFW).

- The drug have been through extensive safety testing and used in millions of people worldwide for treating Soil Transmitted Helminths (STH).

- Worldwide experience of administering deworming confirms that the drugs themselves cause only rare, mild and transient side events which are generally related to degeneration of the worms that have been killed.
Purpose and Definitions of Adverse Event Protocol

• **Provide clear instruction to manage:** Adverse Event Protocol is intended to protect the program, and those who administer the program, by providing clear instructions on the management of adverse events.

• **Preparation for ensuring safety of children:** Although rare, adverse events can and do happen in programs on large scale. All stakeholders should be well-prepared to ensure safety of all children participating in the program.

**Terms and Definitions**

*Adverse Event (AE)* is a medical incident that takes place after a preventive chemotherapy intervention and is suspected to be but is not necessarily caused by the medicines used in the intervention. Some AE, after investigation, may be found to have been caused by the medicine. Such AE will also be referred to as adverse drug reactions or side effects.

• **Serious Adverse Event (SAE)** is fatal, life-threatening, disabling, or incapacitating or that results in hospitalization after drug intake.

• **Mild Adverse Event:** are transient and usually do not require hospitalization. These include nausea, mild abdominal pain, vomiting, diarrhoea and fatigue which may occur in a few children especially those with high worm infestation.
Managing Adverse Event

- A coordinated approach should be established between the Health Department, the Education Department and WCD (ICDS) Department of the respective State/UT Government.
- All functionaries to be geared up with clear understanding of their roles and responsibilities prior to deworming day to respond effectively and timely in case of adverse events on both the days i.e 10th Feb and 13th Feb, 2015.
- The phases for managing adverse event are:
  - Preparatory phase
  - Managing adverse event on Deworming Day
  - Managing adverse event after Deworming Day
## Preparatory Phase - Roles and Responsibilities

### a) Health Department

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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</table>
| State Nodal Officer         | • Inform state and district officials about the date of Deworming Day and Mop-Up Day  
                              • Orient the District Civil Surgeon about the flow of information of any AE and SAE  
                              • Share Adverse Events Protocol and reporting form to the District Civil Surgeon ([Annexure I](#)) |
| District Civil Surgeon      | • Inform and orient Block Medical Officers about Deworming Day and Mop-Up Day  
                              • Prepare an Emergency Response Team and train them to handle any AE or SAE at the block level  
                              • Ensure that Ambulance Services are available at block level  
                              • Block Medical Officer must have reporting format ([Annexure I](#))  
                              • Phone number of health officials to be shared ([Annexure II](#)) |
| Block Medical Officer       | • Depute doctors to handle calls on the emergency helpline for Deworming Day and Mop Up Day  
                              • Prepare PHCs/CHCs/ANMs of handling emergency in mass  
                              • Ensure ambulance services are on ALERT for handling any SAE cases  
                              • Phone number to be shared with education department Anganwadi workers, ASHAs, ICDS Supervisors ([Annexure III](#)) |
| ANMs                        | • Accompany sick children to health facilities and ensure they receive appropriate medical attention and care  
                              • Keep the phone number of school principal handy  
                              • Share helpline number to all schools of the area  
                              • Share the information collected with the Civil Surgeon |

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[Annexure I](#): Adverse Events Protocol and reporting form.  
[Annexure II](#): Phone number of health officials.  
[Annexure III](#): Phone number to be shared with education department workers.
Preparatory Phase - Roles and Responsibilities

b) Education Department

- **State Nodal Officer**
  - Distribute reporting form to the District Education Officer (Annexure I)
  - Distribute adverse event protocol and reporting format with district education department

- **District Education Officer**
  - Inform and orient block education officer about Deworming Day and Mop-Up Day
  - Distribute reporting form to the District Education Officer or the “cascade” of information flow to the district Civil Surgeon (Annexure I)

- **Block Education Officer**
  - Share flow of information or the “cascade” on SAE with school Principals (Annexure)
  - Circulate important phone numbers of the block level health officials to the school principal

- **Principals and Teachers**
  - Inform parents on dates for deworming & Mop Up Day, benefits of deworming, mild side effects expected
  - Schools should prepare a shaded open area for children experiencing any side effects to rest until recovery
### Preparatory Phase - Roles and Responsibilities

#### b) Women & Child Department

<table>
<thead>
<tr>
<th>State Program Officer (ICDS) - Nodal Officer</th>
<th>District ICDS officer</th>
<th>CDPO</th>
<th>Anganwadi Workers and ASHAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Distribute reporting form with district ICDS officer (Annexure I)</td>
<td>• Inform and orient ICDS-CDPOs about Deworming Day and Mop-Up Day</td>
<td>• The flow of information or the “cascade” on SAE shared with Anganwadi workers (Annexure I)</td>
<td>• Inform parents through about deworming benefits</td>
</tr>
<tr>
<td>• Distribute adverse event protocol and reporting format to the district ICDS department</td>
<td>• Distribute reporting form to the district education officer or the “cascade” of information flow to the district civil surgeon (Annexure I)</td>
<td>• Circulate important phone numbers of the block level health officials to the CDPOs, ICDS Supervisors, Anganwadi workers</td>
<td>• AWCs should prepare a shaded open area for children experiencing any side effects to rest until recovery</td>
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Management of Adverse Events on Deworming Day

School principals, teachers and AWW should be:

i) Prepared and be thorough with Adverse Events Protocol in advance

ii) Ensure that emergency numbers or MO-PHC/ANM are available with them in advance (preferably stuck on wall/door of school and anganwadi center)

Medical officer should ensure

i) Availability of necessary medicines at the health center as per Adverse Event Management Protocol (see Annexure) on National Deworming Day (10th February, 2015) as well as on Mop-Up Day (13th February, 2015).

ii) Functional referral services ready for any prompt actions
Management of Adverse Event on Deworming Day

In case of mild adverse event—What to do?

NOT TO PANIC and FOLLOW GUIDELINES

• Children with ANY side effects should be taken to an open and shaded place and allowed to lie down and rest. They should be provided with clean potable drinking water

• Teachers, AWWs and parents should be prepared for these events and take immediate action in case that they occur

• Children should remain at school or Anganwadi centres till at least 2 hours after treatment
Management of Adverse Event on Deworming Day

In case of Severe Adverse Event-What to do?

• Separate the affected child from other children and stop deworming activities
• Stay calm and communicate that the SAE is likely not due to the deworming drug
• School principal should immediately call the Helpline number as per shared details. The school principal should use the information cascade
• If ambulance services are available, immediate ALERT to the ambulance should be given for transport of the child to the nearest PHC/CHC
• The child’s parents should be informed immediately
• Immediate treatment should be provided to the child (See Annexure VI: Guidelines for Emergency Response Team)
• The ANM should inform the Medical officer who should complete an incident report form (ANNEXUR IV) and submit it to the Civil Surgeon within the same day

Management of Adverse Event after Deworming Day

- Possibility of an adverse event to occur after deworming day that may still be attributed to the administration of deworming drugs
- Teachers, AWWs, parents, health facilities and all health officials and providers, including ANMs must be vigilant for such incidents in their area and elevate immediately through the information Cascade

<table>
<thead>
<tr>
<th>WHO</th>
<th>WHAT</th>
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<tbody>
<tr>
<td>Parents</td>
<td>Should be informed that though mild AEs are expected and serious events are likely to be unrelated to the drugs, they are <strong>encouraged to report the incident</strong> at the earliest to ANM, ASHA or school principal if they are very worried about the health of their child</td>
</tr>
<tr>
<td>Teachers / AWWs / ASHAs</td>
<td>Should investigate absenteeism more carefully after deworming day and <strong>encourage any sick children to seek treatment</strong> or inform an ANM if they are worried</td>
</tr>
<tr>
<td>ANMs</td>
<td>To report any case into notice to the District Civil Surgeon</td>
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Media Handling

• ONE designated spokesperson to calmly convey message that adverse event are not likely to be due to deworming medicine
• Before any media contact prepare for key messages, well framed answers to crucial questions
• **Key messages** to be centered around
  - Benefits of deworming
  - Safety of worming is of paramount importance, and any suspicion of a problem is investigated through a well established system
  - AE is currently being investigated, but the medicines' quality is guaranteed
## Do’s and Don’ts to avoid SAE

<table>
<thead>
<tr>
<th>DO</th>
<th>DON’T</th>
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<tbody>
<tr>
<td>Keep telephone numbers for helpline and the nearest health center and / or provider such as ANM and MO-handly</td>
<td>Never administer medicine to a sick child</td>
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<tr>
<td>Appropriate administration of tablet to children is important. During intake, children should chew the tablet and if required should consume some water. Clean drinking-water should be available at the school/ AWC on the deworming day</td>
<td>Do not instruct children to swallow the medicine without chewing first</td>
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<tr>
<td>For young children the tablet should be broken and crushed (between two spoons) and then to be administered with water</td>
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<tr>
<td>Always direct the children to CHEW the medicine to avoid choking</td>
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<tr>
<td>Provide water during SAE</td>
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Information of Annexures

- **ANNEXURE I** - Information Cascade
- **ANNEXURE II** - Contact List Of District Medical Officer
- **ANNEXURE III** - Contact List Of Block Medical Officer
- **ANNEXURE IV** - Mild Adverse Event Reporting Form
- **ANNEXURE V** - Serious Adverse Event Reporting Form
- **ANNEXURE VI** - Emergency Response Team