

Adverse Event Protocol NDD – At schools and *anganwadi* centers

1. PURPOSE

This document is primarily based on the World Health Organization (WHO) guidelines⁷ for assuring drug safety during mass drug administration (MDA).

The deworming drug (Albendazole 400 mg) used in the Government of India's school and *anganwadi* center – based mass deworming program - NDD - is effective, very safe, and approved by the WHO and the MOHFW of India for treating soil-transmitted helminths in preschool and school-age children. Extensive experience of deworming millions of children worldwide confirms that this drug itself causes only rare, mild and transient side events or adverse drug reactions, and that these reactions are generally related to degeneration of the worms that have been killed. Most of the adverse events observed in school programs occur during initial rounds of implementation of the intervention – a time when children harbor more infections of high intensity. Mild abdominal pain, nausea, vomiting, diarrhea and fatigue are the most commonly reported adverse events in some children with increased worm load, are not serious and do not normally require medical treatment.

An effective 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. Although rare, adverse events can and do occur in programs on a large scale in mass drug administration, and all stakeholders should be well-prepared to ensure safety of all children participating in the program.

2. DEFINITIONS

An **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.

A Severe Adverse Event (SAE): A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- results in death
- results in life-threatening condition
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- causes congenital abnormality
- requires any intervention to prevent the occurrence of any of the above

Note:

- 'Death'- if the patient died due to adverse event, mention the death cause & date in the seriousness of the reaction.
- 'Life-threatening'- if patient was at substantial risk of dying at the time of the adverse event
- 'Hospitalization/prolonged'- if the adverse event caused hospitalization or increased the hospital stay of the patient
- 'Disability'- if adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions
- 'Congenital anomaly'- if exposure of drug prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- 'Required intervention to prevent permanent impairment/damage'- if medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure
- 'Other' -when the event does not fit above conditions, but the event may put the patient at risk and may require medical or surgical intervention to prevent one of the above conditions. Examples include serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization, development of drug dependence or drug abuse

There are a number of key types of SAEs:

- Those caused by the drugs themselves: e.g., an allergic reaction to the drugs

- Those caused by the parasites degeneration when they are killed: e.g., intestinal blockage
- Those caused by operational issues: e.g., choking. Medication Errors leading to choking is major concern while administering this tablet. Proper instructions must be given and should be followed so as to avoid cases of choking
- Those which are coincidental but unrelated: e.g., malaria around the same time as drug administration

3. Preparatory phase for managing adverse events

To effectively deal with any AE or SAE on Deworming Day, a coordinated approach should be established between the Health Department, the Education Department and WCD (ICDS) Department of the respective State Government. The roles and responsibilities of these three primary departments in adverse events management are detailed below.

3.1. Health Department:

Health Department Roles and Responsibilities	
WHO	WHAT
State Nodal Officer	<ol style="list-style-type: none"> 1. Designate official at state level for overall adverse event management 2. Orient the District Civil Surgeon about the flow of information of any AE and SAE 3. Adaptation of adverse event protocol in local language and further dissemination to districts and blocks 4. Orient District Civil Surgeon about the flow of information of any Adverse Events and distribute reporting form to the District Civil Surgeon (Annexure 7)
District Civil Surgeon	<ol style="list-style-type: none"> 1. Inform and orient the Block Medical Officer about Deworming Day and Mop-Up Day. 2. Prepare an Emergency Response Team engaging RBSK and AYUSH doctors and train them to handle any AE or SAE at the Block level 3. Ensure that Ambulance Services other mobility support vehicles i.e. RBSK are available at Block level 4. Distribute the reporting forms and cascade of information diagram to the Block medical officer. 5. Circulate list of important phone numbers of the District health officials to every Block Medical Officer (Annexure 7 Section II)
Block medical officer	<ol style="list-style-type: none"> 1. Inform and orient the PHC/CHC/ANMs about Deworming and Mop-Up Day 2. Depute doctors to handle calls on the emergency helpline for Deworming Day and Mop Up Day 3. Prepare PHCs/CHCs/ANMs to manage an increased number of children presenting with minor, non-specific symptoms 4. Ensure ambulance services and other mobility support are on ALERT for handling any SAE cases 5. Ensure phone numbers of the PHCs/ANMs are circulated to the Block education department for distribution to the school principals, ICDS-CDPO's Supervisors, anganwadi workers, and ASHAs.
ANMs	<p>Should be prepared to accompany sick children to health facilities and ensure they receive appropriate medical attention and care. Visit assigned schools in advance if possible and collect information and phone numbers of the school principal. Provide their phone number to the school principal.</p> <p>Share the information collected with the Civil Surgeon. Also share the phone number of the helpline to all the assigned schools</p>

3.2 School Education and Literacy Department:

Department Roles and Responsibilities of School Education & Literacy	
WHO	WHAT
State Education nodal officer	<ol style="list-style-type: none"> 1. Inform all District education officers about Deworming Day and Mop-Up Day. 2. Distribute the reporting form to the District education officer (Annexure I) 3. Distribute the locally adapted Adverse event protocol and reporting format to the District education department.
District Education officer	<ol style="list-style-type: none"> 1. Inform and orient the Block education officer about Deworming Day and Mop-Up Day. 2. Distribute the reporting form to the District education officer or the “cascade”
Block Education officer	<ol style="list-style-type: none"> 1. Inform and orient the principal and school teachers about Deworming Day and Mop-Up Day. 2. The flow of information or the “cascade” on SAE in the school is to be shared with the department officials and school principals. 3. Ensure to circulate important phone numbers of the Block level health officials to the school principal and instruct schools to display the emergency contact numbers in schools before deworming day
Principals and teachers	<ol style="list-style-type: none"> 1. Teachers should inform parents of the children through different forums such as school management committee meetings or parents teachers meeting as appropriate ahead of Deworming Day about the following : <ol style="list-style-type: none"> a. Deworming and Mop-Up Day b. Benefits of deworming on children’s health and education c. Mild side effects in children may be expected to only children with high worm load. The side effects are usually not serious and would pass by soon. d. Preparations undertaken by the Education and Health Department to manage any AE. e. Build confidence that the child will be taken under observation and care if they show any serious side effects. They will be immediately taken to the nearest health centre. 2. Schools should prepare a shaded open area and keep safe drinking water available for children experiencing any side effects to rest until recovery.

3.3 Women and Child Development Department:

Women and Child Development (ICDS) Department Roles and Responsibilities	
WHO	WHAT
State Program Officer (ICDS) - Nodal Officer	<ol style="list-style-type: none"> 1. Inform all District ICDS officers about Deworming Day and Mop-Up Day. 2. Distribute the reporting form to the District ICDS officer (annexure I) 3. Distribute the Adverse Event Protocol and reporting format to the District ICDS department.
District ICDS officer	<ol style="list-style-type: none"> 1. Inform and orient the Child Development Block Officer (ICDS- CDPOs) about Deworming Day and Mop-Up Day. 2. Distribute the reporting form to the District education officer or the “cascade” of information flow to the District civil surgeon (Annexure I)
Child Development Block Officer (CDPO) – ICDS	<ol style="list-style-type: none"> 1. Inform and orient the ICDS Supervisors and anganwadi workers about Deworming Day and Mop-Up Day. 2. The flow of information or the “cascade” on SAE in the anganwadi centers is shared with the department officials and anganwadi workers. (Annexure I) 3. Ensure to circulate important phone numbers of the Block level health officials to the ICDS Supervisors, anganwadi workers and instruct anganwadis to display the emergency contact numbers at anganwadi centers before deworming day
Anganwadi Workers and ASHAs	<ol style="list-style-type: none"> 1. AWWs and ASHA should inform parents of the children through different forums such as VHND, VHSNC meetings, Gram Panchayats, home visit etc. about the following : <ol style="list-style-type: none"> a. Deworming and Mop-Up Day. b. Benefits of deworming on children’s health and education. c. Mild side effects may be experienced in children with high worm load. The side effects are usually not serious and would subside soon. d. Preparations undertaken by the WCD (ICDS), Education and Health Department to manage any Adverse Event. e. Build confidence that the child will be taken under observation and care if they show any serious side effects. In case of a prolonged adversity the child would be taken immediately to the nearest hospital. 2. AWCs should prepare a shady open area for children experiencing any side effects to rest until recovery.
ANMs and ASHAs	<p>Should be prepared to accompany sick children to health facilities and ensure they receive appropriate medical attention and care. Visit assigned AWCs in advance if possible and collect information and phone numbers of the AWWs. Give own phone number to the AWWs.</p> <p>Share the information collected with the Civil Surgeon. Also share the phone number of the helpline with all the assigned AWWs.</p>

4. MANAGING ADVERSE EVENTS ON DEWORMING DAY

On National Deworming Day, school principals, teachers and anganwadi workers should be prepared for any AE or SAE by having read through the Adverse Events Protocol/Guidelines in advance, and ensuring that the protocol and emergency numbers are on hand. All teachers and AWWs should clearly understand that children who are not well on deworming day should not be given the deworming drug.

The teacher and *anganwadi* workers MUST administer albendazole tablet under their direct supervision in Schools and *Angawadi* on Deworming and Mop-Up Day. The tablet must not be handed over to the child or their family member for consumption later at home.

4.1 Mild Adverse Events

What are they?

Events such as nausea, mild abdominal pain, vomiting, diarrhea and fatigue may occur among children especially those with high worm infestation. These side effects are transient and usually do not require hospitalization.

What should the teacher/principal/awws do when mild adverse event at school or anganwadi centers happens?

- 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 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 center for at least 2 hours after treatment

DO NOT PANIC AND FOLLOW GUIDELINES

4.2 Severe Adverse Events (SAE)

A Severe Adverse Event (SAE)

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- results in death
- results in life-threatening condition
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- causes congenital abnormality
- requires any intervention to prevent the occurrence of any of the.

Choking hazard/asphyxia causes a medication error which needs to be responded to immediately.

- 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.
- Manage the AE as per protocol and also provide the Toll Free Number of Pharmacovigilance Programme of India 1800 180 3024 for reporting the AE. You may also contact the nearby ADR Monitoring Centre (see Annex for list of AMC's under the Pharmacovigilance Programme of India)
- 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 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 by medical/health personnel (See Annexure 7 Section VI: Guidelines for Emergency Response Team). Medical treatment for adverse event should only be administered by medical/health personnel
- The ANM should inform the Medical officer who should complete an incident report form and submit it to the Civil Surgeon within the same day.
- Once the reporting form is received, further notification to the next level must be made as per "cascade" of information flow.
- The Mission Director (NHM) or the designated officer will sign/confirm the report(s), and determine if further investigation is needed and submit the report to the Mission Director immediately. The Mission Director or the designated officer will be the spokesperson to the media

5. MEDIA HANDLING

MEDIA HANDLING:

The designated officer at state level will be the spokesperson to the media. In all cases, it is important to maintain calm messaging and indicate that the adverse event is very likely not due to deworming medicine.

Before any media contact it is vital to prepare:

- Key messages;
- Answers for the likely and awkward questions;
- List of issues not to respond to (e.g. blaming an individual or speculating on the cause before the investigation is complete) etc.

If the teacher or AWWs is unable to manage Deworming Day after a SAE they should do the following:

1. Principal / AWW should suspend deworming temporarily until the health officials reach the school/ AWC and make a decision about how to proceed.
2. Immediately elevate the situation via the information cascade.

6. MANAGEMENT OF SAE AFTER DEWORMING DAY

It is possible that an adverse event may occur after deworming day and 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. By becoming involved early in any potential SAE, the principals and ANM will reduce the chances that SAEs are incorrectly attributed to deworming drugs and will be able to undertake good and accurate community sensitization ahead of any media coverage.

RESPONSIBILITIES AFTER DEWORMING DAY

WHO	WHAT
Parents	Should be informed that though mild AEs are expected and severe events are likely to be unrelated to the drugs, they are encouraged to report the incident at the earliest to ANM, ASHA or school principal if they are very worried about the health of their child.
Teachers / AWWs / ASHAs	Should investigate absenteeism more carefully after deworming day and encourage any sick children to seek treatment or inform an ANM if they are worried.
ANMs	To report any case brought into notice to the District Civil Surgeon or Chief Medical Officer through Block Medical Officer or directly as feasible . Toll Free Number of Pharmacovigilance Programme of India 1800 180 3024 for reporting the AE should be used. ADR Monitoring Centre under the Pharmacovigilance Programme of India (see list) should be contacted for ADR management and reporting of AE.

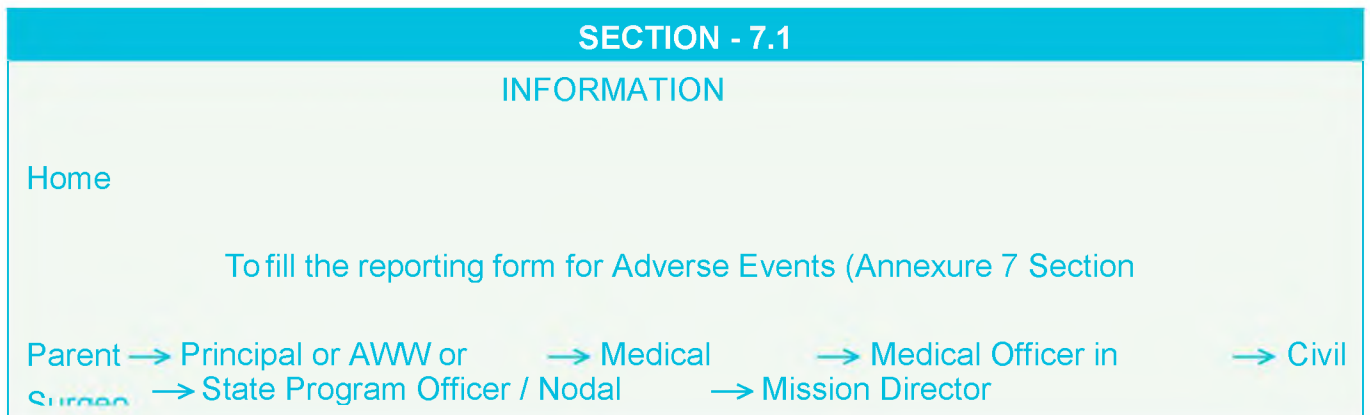
7. DO'S AND DON'TS FOR SCHOOL AND ANGANWADI TO AVOID ANY SAE:

DO	DON'T
<ul style="list-style-type: none">• Keep telephone numbers for helpline and the nearest health center and / or provider such as ANM and MOIC handy.• Always direct the children to CHEW the medicine to avoid choking.• Administer the tablet under your direct supervision• For younger children at anganwadi, crush the table first and then administer.	<ul style="list-style-type: none">• Do not administer medicine to a sick child.• Do not instruct children to swallow the medicine without chewing first.• Do not hand over medicine to parents/children for consumption at home

Annexure 7

INFORMATION CASCADE

Information Cascade: If there is any SAE at the school or home the information cascade should be followed:



ADR Reporting to VigiFlow

AWW/ANM (Consumer Forms) & Medical Officer (Suspected ADR Forms) (Via VigiFlow) → AMC → PVPI

SECTION - 7.2

CONTACT LIST OF DISTRICT MEDICAL OFFICERS

The form is to be filled by the State Civil Surgeon and given to the State Education Officer for dissemination to schools and AWCs

STATE HEALTH SOCIETY CONTACT DETAILS

District wise Name & Contact No.

S.No.	District	District medical officer	Mobile No.
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
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20			

SECTION - 7.3

CONTACT LIST OF BLOCK MEDICAL OFFICERS

The form is to be filled by the District Medical officer and given to the District Education Officer and District Program Officer (ICDS) for dissemination to schools and AWCs

DISTRICT STATE HEALTH SOCIETY CONTACT DETAILS

Block wise Name & Contact No.

S.No.	District	District medical officer	Mobile No.
1			
2			
3			
4			
5			
6			
7			
8			
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SECTION - 7.4

MILD ADVERSE EVENT REPORTING FORM

(Event that can be handled at school/AWC level) to be filled up by the school principal / AWW/

Name and Address of Child:	
School Address:	Contact details of parent:
Treatment Site:	
Reported By:	
Contact Details of the person reporting:	

Drug Name (generic name)	Dose	Brand & Manufacturer	Batch Number

Date/Time Deworming tablet given	Date and Time AE started

Action taken to treat AE :

Past Medical history if any :

Nearest Hospital / Health Centre to where the child was taken in case he/she has not
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SECTION - 7.5**SERIOUS ADVERSE EVENT REPORTING FORM**

From the Hospital / Health Centre

Date of Report:

Patient Name :	Age:	Sex:
Patient Height and Weight:		
Location	District	Block:

Pre-existing conditions if any :			
Health status of the child during Deworming:	Good	Poor	Unknown
Other Medicine being taken (concurrently or recently):			

Drug name (generic name):	Batch Number :	Date of treatment:
How many tablets did The child take:	Did the child chew the tablet:	Was this the first time the child took deworming drugs:

Clinical signs and symptoms:	
Date of onset of symptoms	How long after deworming the symptoms showed
Was the patient hospitalised? : Y or N	If Yes : Date of Admission Reason for Admission
Conclusion:	

Sign and Seal of the Reporting Official

- Additionally, physicians must fill PVPI suspected ADR reporting form for all the ADRs (for proper analysis of ADRs) (Annexure A).
- *Anganwadi* and ANM workers to fill the Consumer PVPI forms, provided in local languages also such as Hindi, Assamese, Oriya, Bengali, Kannada, Tamil, Telegu, Malayalam and Marathi for any kind of ADR (Annexure B)
- List of Adverse drug reaction Monitoring Centres (AMCs) for all the states is provided for support to fill in the above-mentioned forms (Annexure C).
- Use toll free number of PVPI for reporting ADRs
- Indian Pharmacopoeia Commission, National Coordination Centre (NCC) for Pharmacovigilance Programme of India has launched Helpline facility (toll free) i.e. 1800 180 3024 along with SMS acknowledgement facility, to provide the assistance in reporting of adverse drug reactions with the use of medicines and to ensure patient safety.

SECTION - 7.6 EMERGENCY RESPONSE SYSTEM

An Emergency Response System has been put in place by the Health and Family Welfare Department of the State Government to manage any adverse events, mild and/or severe. In case of any such adverse events, don't panic, as these adverse events are usually very mild in nature and likely to subside soon.

Step 1. Make the child lie down on a flat surface and give the child a glass of water to drink. Talk to

the child and address all apprehensions.

Step 2. The doctor on call will give you some telephonic instructions before his/her arrival. Follow the instructions and wait for arrival of health team.

Step 3. Doctor/Paramedical/RBSK team/AYUSH doctors staff arrival at the site. They assess the condition of the child, note down the vitals, and carry the adequate amount of the following medicines:

Medicine Kit:

Susp/Tab Domperidone/Ondansetron Susp/Tab Dicyclomine

ORS Packets Susp/Pack Paracetamol

Step 4. In case child is very sick, inform District Civil Surgeon and call an ambulance to transport child to the nearest Government Hospital/health facility for further management.

After the ADR is managed, fill PVPI Suspected ADR reporting form and/or report ADR through Toll free number 1800-180-3024 to PVPI.

Guidelines for Block level Doctors / ANMs on Emergency Response Duty

1. Learn about the location of school and anganwadi centre in your area where deworming will be undertaken. Also collect medicine kit for management of SAE.
2. Visit assigned schools and *anganwadi* centres in advance if possible and collect information and phone numbers of the school principal and AWWs. Give your phone number to the school principal.
3. Share the information collected with the District Civil Surgeon. Also share the phone number of the helpline to all the assigned schools and *anganwadi* centers. After the ADR is managed, fill PVPI Consumer ADR reporting form and/or report ADR through Toll free number 1800-180-3024 to PVPI.
4. In case of reporting of any emergency follow the protocols circulated to resolve the issue.