

Bihar School-based Mass Deworming Programme Adverse Event Protocol

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Bihar School-based Mass Deworming Programme Adverse Event Protocol

1. BACKGROUND

This document is primarily based on the World Health Organization (WHO) guidelines for assuring drug safety during Mass Drug Administration.

An *adverse event* (AE) is any untoward medical occurrence that may present during treatment with a medicine, but that does not necessarily have a causal relationship with the treatment (WHO Guidelines, 2011).

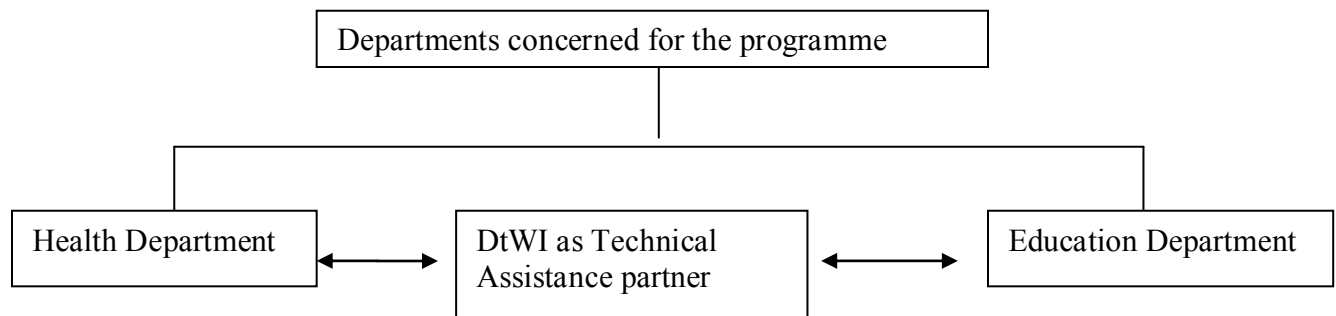
A *serious adverse event* (SAE) is an event that is fatal, life-threatening, disabling or results in hospitalization after drug intake.

The deworming drug (Albendazole -400 mg) used in Bihar School-based Mass Deworming Programme are effective, have an excellent safety record, and are approved by the World Health Organization and the Govt of India for use in treating school-age children.

Cumulative experience of deworming millions of children worldwide confirms that these drugs themselves cause only rare, mild and transient side events or adverse drug reactions (Loukas & Hotez, 2006) and that these reactions are generally related to degeneration of the worms that have been killed. Most of the side-events observed in school Programmes occur during the first 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 frequently reported adverse events, are not serious and do not normally require medical treatment

2. PREPARATORY PHASE TO HANDLE ADVERSE EVENTS:

To effectively deal with any adverse event (AE) during Mass Drug Administration (MDA) during the Deworming Day a coordinated approach should be established with both the Health Department and the Education Department of the Government of Bihar.



2.1 Health Department:

All the officers/offices concerned with the programme should be effectively briefed on dealing with a Serious Adverse Event (SAE). The Civil Surgeon of the concerned district will contact all the concerned officers/personnel in advance of deworming day with the following information:

- i. The date of Deworming Day
- ii. The flow of information about any adverse event
- iii. Prepare a team for **Emergency Response Team** and train them to handle any adverse situation
- iv. Doctors to be deputed to handle tele calls on the emergency helpline for the Deworming Day.
- v. District health officials should be briefed on dealing with SAE and will be expected to be in contact with any school reporting an SAE.
- vi. Civil Surgeons should notify local hospitals/ CHC/Primary Health Centre /ANMs about the dates of Deworming Day and Mop-Up Day no later than January 15, 2014. They should be notified to expect to manage an increased number of children presenting with minor, unspecific symptoms.
- vii. Ambulance services should be on ALERT for handling any SEA case.
- viii. The reporting channels or the “cascade” of information flow for any SAE should be clearly explained to health officials in advance **(Annexure I)**
- ix. Important phone number or Helpline number should be circulated.**(Annexure III)**

2.2 Education Department:

- i. All the Schools/ teachers should be informed about the Deworming and Mop up day
- ii. The flow of information about any adverse effect in the school is attached.**(Annexure I)**
- iii. Teachers should inform the parents of the child ahead of Deworming Day about the following :
 - a. Benefits of Deworming
 - b. Sick child shouldn't be sent to school on Deworming day
 - c. Mild side event may be expected .The side events usually are not serious and would pass by soon.
 - d. Precautions the Education and Health Department are taking to handle adverse situation.
 - e. In case the child shows serious adverse event than the child will be immediately taken to the nearest health centre.
- iv. Schools should prepare a shaded area for children experiencing any side events to rest until recovery.

- v. Schools should ensure that IEC materials provided by the Programme are clearly posted at schools. These materials emphasize that sick children should not be given the drug, and that drugs should not be given to children on an empty stomach.
- vi. Necessary or important phone number should be exchanged before Deworming Day. (**Annexure III**).

3. Handling Adverse Event on Deworming Day:

- i. Any children who are not well on deworming day (or immediately before) should not be given the deworming drug.
- ii. Headmasters, teachers, and other school personnel should be provided with the Adverse Events Protocol in advance and understand the process to be followed should any adverse or severe adverse events occur.

3.1 Mild Adverse event

MILD ADVERSE EVENTS

WHAT ARE THEY?

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

WHAT SHOULD WE DO WHEN WE OBSERVE SUCH INSTANCES?

1. Children with side events should be taken to a quiet, shaded place and allowed to lie down and rest. They should also be provided with some clean drinking water.
2. Teachers and parents should be prepared for these reactions and take immediate action in case that they occur.
3. Children should not leave school till at least 2 hours after treatment.

3.2 Management of Serious Adverse Events on Deworming Day

Serious adverse events are very unlikely to be due to the deworming medication. Teachers and health officials should ensure this message is conveyed to community members/parents immediately and consistently.

Serious Adverse Event

- i. Separate the affected child from the other children and stop deworming activities.
- ii. Be calm and communicate that the adverse event is likely not due to the deworming medicine.
- iii. If any control room/helpline is set up the Principal should immediately call the Helpline number.
- iv. The Principal should inform the ANM/ MOIC of the area. The ANM should direct the principal to take the child to the nearest Health Center.
- v. If Ambulances are available immediate ALERT to the ambulance should be given for transport of the child to the nearest PHC/CHC.
- vi. The child's parents should be informed immediately.
- vii. Immediate treatment should be provided to the child (Guidelines for Emergency Response Team) as **Annexure VI**)
- viii. The ANM should inform the Medical officer who should complete an incident report form (**ANNEXUR IV**) and submit it to the Civil Surgeon immediately.
- ix. Once the report form is received it should be immediately notified to the next level as per the cascade of information flow as per **ANNEXURE I**
- x. The Executive Director of SHSB should sign /confirm the report(s), determine if further investigation is needed and should submit the report to the Programme immediately. The Executive Director, SHSB or his designated Officer will be the spokesperson to the media

MEDIA HANDLING:

The Executive Director/Civil Surgeon or the designated person will be the spokesperson to the Media.

Maintain calm messaging that the adverse event is very likely not due to Deworming medicine.

If the teacher is unable to manage deworming day after a serious adverse event they should do the following:

- a. Principal should suspend deworming temporarily until the Health officials reach the school and make a decision about how to proceed.
- b. Immediately elevate the situation via the information cascade (**Annexure I**)

4. Management of Serious Adverse Events after Deworming Day

- i. It is possible that an adverse event may occur after deworming day and may still be attributed to the deworming drugs. Teachers, Parents, health facilities and all health officials including ANMs must be vigilant for such occasions and elevate immediately through the information cascade.
- ii. Parents should be informed that though side events are expected and serious events are likely to be unrelated to the drugs they are encouraged to report early to ANM or Principal if they are very worried about the health of their child.
- iii. Teachers should investigate absenteeism more carefully after deworming day and encourage any sick children to seek treatment or inform an ANM if they are worried.
- iv. ANM should be prepared to accompany sick children to health facilities and ensure they receive appropriate medical attention and care.
- v. By becoming involved early in any potential serious event, the Principals and ANM will reduce the chances that serious adverse events are incorrectly attributed to deworming drugs and will be able to undertake good and accurate community sensitization ahead of any media coverage.

Information Cascade: If there is any Serious Adverse Event at School or Home the Information Cascade should be followed as per **Annexure I**

ANNEXURE: I

INFORMATION CASCADE:

HOME:

To fill the reporting form (Annexure II)

Parent → Principal or ANM → Medical Officer → Medical Officer in Charge → Civil Surgeon → State Programme Officer/ Nodal Officer → Executive Director

SCHOOL and Health:

Inform Parent

To fill the reporting form (Annexure II)

Principal → ANM → Medical Officer → Medical Officer in Charge → Civil Surgeon → State Programme Officer/ Nodal officer → Executive Director

Information to DtWI team:

State Programme Manager Officer/ Nodal Officer will inform the DtWI team.

ANNEXURE: II

Dos and Don'ts to avoid any Serious Adverse Event:

DO's	Don'ts
<ul style="list-style-type: none">• Inform parents not to send sick children on Deworming Day to school.• Keep telephone numbers for helpline and the nearest health center handy.• Always direct the children to CHEW the medicine to avoid choking.	<ul style="list-style-type: none">• Never administer medicine to a sick child• Do not swallow the medicine

ANNEXURE III

STATE HEALTH SOCIETY BIHAR,PATNA			
Dist Wise Name & Contact No.DPM, DAM & District M & E Officer			
S.No.	District	D.P.M	CUG No.
1	Araria	Mr. Rehan Asraf	9473191865
2	Arwal	Miss Mukta Bharti	9473191866
3	Aurangabad	Mr. Kumar Manoj	9473191867
4	Banka	Mr. Phabhat Kumar	9473191868
5	Begusarai	Mr. Shailesh Chandra	9473191869
6	Bhagalpur	Mr. Faizan Alam	9473191870
7	Bhojpur	Mr. Sagar Ojha	9473191871
8	Buxar	Mr. Dhananjay Kumar	9473191872
9	Cham.(E)	Mr. Amit Achal	9473191873
10	Cham.(W)	Md. Salim Javed	9473191874
11	Darbhanga	Mr. S. Vishal	9473191875
12	Gaya	Mr. Manish Kumar	9473191876
13	Gopalganj	Mr. Vishal K. Singh	9473191877
12	Jahanabad	Md. Anwar Alam	9473191879
15	Jamui	Mr. suddhansh narayan Das	9473191878
16	Kaimur	Mr. Sahid Kamala	9473191880
17	Katihar		9473191881
18	Khagaria	Mr. G. Shekhar	9473191882
19	Kishanganj	Mr. Ajay	9473191883
20	Lakhisarai	Md.Khalid Husain	9473191884
21	Madhepura	Md. Imran	9473191885
22	Madhubani	Mr. Daya Shankar Nidhi	9473191886
23	Munger	Md. Nasim	9473191887
24	Muzaffarpur	Mr. Ashish Ranjan	9473191888
25	Nalanda	Nagendra	9473191889
26	Nawada		9473191890
27	Patna	Ranjeet Kumar	9473191891
28	Purnia	Mr. Brajesh Kumar Singh	9473191892
29	Rohtas		9473191893
30	Saharsa	Asik	9473191894
31	Samastipur	Mr. N k das	9473191895
32	Saran	Mr. Alok Kumar	9473191896
33	Sheikhpura	Mr. Acharya Mamat	9473191897
34	Sheohar	Mr. Shyam Kumar Nirmal	9473191898
35	Sitamarhi	Mr. Durgesh Kumar	9473191899
36	Siwan	Mr. T. Bishwa Mohan	9473191900
37	Supaul	Mr. P. P Chakariyar	9473191933
38	Vaishali	Mr.Mani Bhusan Jha	9473191934

ANNEXURE: IV

MILD ADVERSE EVENT REPORT FORM

(Event that can be handled at School Level) To be filled up by the Principal

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

Medicine 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 recovered:
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ANNEXURE: V

SERIOUS ADVERSE AFFECT REPORTING FORM: From the Hospital / Health Centre

Date of Report:

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):

Deworming tablet 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 Albendazole:

Clinical sign 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 reporter

Annexure: VI

Emergency Response System

An Emergency Response System has been put in place by the Health & Family Welfare Dept. Government of Bihar to manage any adverse events.

In case of any such adverse events, don't panic, as these side effects are usually very mild in nature and 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 remove all apprehensions.

Step 2. Call District Programme Manager (DPM) if required (Telephone No. Annexure III) for medical advice about adverse events. 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 staff arrival at the site. They assess the condition of the child, note down the vitals, carry the adequate amount of the following medicines:

Medicine Kit:

Susp/Tab Domperidonone /Ondasterone

Susp/Tab Dicyclomine

ORS Packets

Susp/Pack Paracetamol

Administer the drugs if the symptoms warrant for intervention and shift to the nearest health facility if required.

Step 4. In case child is very sick inform DPM and call Ambulance to transport child to the nearest Govt. Hospital/ health facility for further management.

Functional Guidelines for Doctors/ ANMs on Emergency Response Duty.

1. Learn about the area of school assigned to you on Deworming Day. Also collect medicines for use against any side events.
2. Collect the kit from the CMO office and know about assigned schools.
3. Kit will include medicines which may be required in case of any exigency. Visit assigned schools in advance. Collect information and phone numbers about the Principal and Nodal Teachers assigned from the Schools. Give your phone number to the Principal/ Nodal Officers.
4. Share the information collected with the DPM / CMO. Distribute the phone number of the control room to all the assigned schools.
5. In case of reporting of any exigency follow the guidelines circulated to resolve the issue.