JOB AIDS
for MANAGING ADVERSE EVENTS FOLLOWING MASS DRUG ADMINISTRATION (AEs-f-MDA) and
SERIOUS ADVERSE EVENTS (SAEs)

This Job Aid was developed by RTI International as part of the ENVISION Project funded by the US Agency for International Development under cooperative agreement No. AID-OAA-A-11-00048. The period of performance for ENVISION is September 30, 2011 through September 30, 2019. For more information, go to www.NTDenvision.org.
RESPONDING TO SERIOUS ADVERSE EVENTS (SAEs)

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

Responding to Patient Needs

TREAT THE PATIENT

Responding to Community Needs

Communicate with communities

Communicate with media

Respond to rumours or public enquiries

Decide if this is a Serious Adverse Event (SAE)

Debrief national authorities and report SAEs to
- National pharmacovigilance and regulatory agencies
- WHO
- Drug donor companies
- Donors supporting programmes

Investigate to determine causality

Debrief and share progress and outcome of investigations with
- National pharmacovigilance and regulatory agencies
- WHO
- Drug donor companies
- Donors supporting programmes
- Communities
- Media

Correct the problem

- Improve training of health workers
- Improve social mobilisation
- Ensure the quality of drugs
- Develop crisis management plan

Disseminate and highlight actions taken based on results of investigations

This Job Aid was developed by RTI International as part of the ENVISION Project funded by the US Agency for International Development under cooperative agreement No. AID-OAA-A-11-00048. The period of performance for ENVISION is September 30, 2011 through September 30, 2019. For more information, go to www.NTDenvision.org.
**ADVERSE EVENTS (AEs):** Common symptoms and their treatment

It is rare and usually impossible to predict whether an AE will progress to an SAE, so **always meet the immediate needs of the patient.** Most patients with AEs can be treated at the drug distribution site, at home, or at the primary health clinic. To treat such patients, obtain a clinical history including past illnesses and medications used. Conduct a rapid clinical assessment and record or monitor the patient’s temperature, pulse rate, blood pressure, and respiratory rate. **ANY SUSPECTED SAEs SHOULD BE SENT IMMEDIATELY TO THE NEAREST HOSPITAL, AS NOTED IN THE RED BOX ON THE BACK PAGE.**

Treat at distribution site, home, or primary health clinic

When treating patients with AEs, emphasize that the event is almost certainly **NOT A REACTION TO THE MEDICINE itself but due to the KILLING OF THE PARASITE by the medicine.** The event is a SIGN THAT THE MEDICINE WORKS and was needed.

<table>
<thead>
<tr>
<th>Abdominal pain, vomiting, and diarrhoea</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Rest</td>
</tr>
<tr>
<td>• Traditional remedies for nausea and vomiting</td>
</tr>
<tr>
<td>• Make sure patient can drink water or fruit juices</td>
</tr>
<tr>
<td>• Watch for signs of dehydration: thirst, dry skin, dark coloured urine, dry mouth, fatigue, and weakness</td>
</tr>
<tr>
<td>• Oral/intravenous fluids, if necessary</td>
</tr>
<tr>
<td>• Antispasmodics and antiemetic, if necessary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Malaise (feeling unwell, sleepy, tired, or weak)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Rest, protected from excessive temperature, noise, and light</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fever, headache, aches, pains in the joints or inflammation (inflammation usually in the inguinal area or scrotum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Rest</td>
</tr>
<tr>
<td>• Paracetamol (See dosage guide in Handbook)</td>
</tr>
<tr>
<td>• Cold compress in areas affected with localised inflammation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Photophobia (exposure to light causes discomfort or pain to the eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Protect patient’s eyes from light</td>
</tr>
</tbody>
</table>

(continued on back)
(continued) Treat at distribution site, home, or primary health clinic

**Dizziness**

- Rest
- Check blood pressure to rule out postural hypotension
- Prop the head up with pillows when in bed to reduce the likelihood of orthostatic hypotension when getting up
- Advise the patient to get up slowly from a sitting or lying position

**Wheezing**

- Make sure administered tablet is not choking the patient
- Give antihistamines (Chlorpheniramine or Promethazine)
  - See dosage guide in Handbook
- If symptoms are uncontrolled or worsen, refer patient to health facility

**Mild hives, rashes, or itching**

- For **non-serious** cases, give antihistamines (Chlorphenamine or Promethazine)
  - See dosage guide in Handbook

(for serious cases see below)

**SEND PATIENT TO THE NEAREST HOSPITAL IMMEDIATELY**

**Serious hives, rashes, or itching**

If any signs or symptoms of **serious** conditions are present, such as

- Stevens Johnson Syndrome
- Toxic Epidermal Necrolysis

**Additional potential SAEs**

If

- any of the AE symptoms progresses or persists beyond 24 hours
  
  or

- an unexpected reaction is observed
  
  or

- an SAE is observed

---

**Key resources**


Key messages before MDA

- **Medicine safety**: The medicines you will receive are extraordinarily safe. Many millions of people all over the world have safely received these drugs in similar programmes.

- **Do NOT take the drugs if you are sick now, pregnant, under 2 years of age or older than 60 years.**

- **Possible mild side effects** include mild fever, nausea, vomiting, diarrhoea, or fatigue for some people.
  - Do not worry. **These are signs that the drugs are killing the parasites and getting rid of the infection.**
  - Any side effects would start a few hours after taking the drugs and last a few days at most.

- ______________________ is available to treat any side effects and can be found at _____________________.

- **If you have questions**: Do not listen to rumours. Contact [your health facility/volunteer/distributor] who will be able to answer your questions.

- **Remember that the medicines are very beneficial**. The medicines kills the parasites and bacteria to prevent further disease or spread of infection. By taking the medicines you are keeping yourself and members of your community from getting the disease, and you are allowing the children to grow up free of infection.

Key messages following a potential SAE

- **We have heard about [event or rumoured event], but we do not know what caused [event].**

- It is very rare for the medicine to cause a serious adverse event. Remember that the medicine is extraordinarily safe. Many millions of people all over the world have received these medicines in similar programmes with no events. **Operational errors** or a **coincidental illness** are much more likely causes.

- We are doing everything possible to **investigate** what happened. [Speak about the specific actions being taken to investigate, correct, and eliminate every possibility of error].

- We will provide an **update** as soon as we have more information [provide date, if possible].

- **Remember that the medicines are very beneficial**. The medicines kills the parasites and bacteria to prevent further disease or spread of infection. By taking the medicines you are keeping yourself and members of your community from getting the disease, and you are allowing the children to grow up free of infection.

Following SAE investigation

Inform communities at every stage of an investigation. For more information and key messages, see pages 13–14 of the SAE Handbook.
COMMUNICATING WITH THE MEDIA

See pages 14–17 of the SAE Handbook for tips on communicating with the media.

Always designate a SPOKESPERSON to communicate with the media.

Key messages before MDA

Please help us prevent and treat ________________ in your area by communicating the following:

• Extensive experience after treating several million people has shown that the medicines given during MDA have excellent safety records, regardless of whether or not someone is infected with [disease].

• As an extra precaution, we will not treat:
  • people who are sick now
  • pregnant women
  • children under 2 years old
  • adults older than 60 years

• Some people may experience nausea, vomiting, diarrhoea, or fatigue. These are most often the effect of the medicines killing the parasite and can be managed easily with simple remedies.

• ________________ are available to treat any side effects and can be found at ________________

• Given that MDA targets millions of individuals, coincidental deaths and hospitalization for serious illness unrelated to the drugs may occur. Such events can happen any day and are not related to the MDA.

• Remember that the medicines are very beneficial. The medicines kill the parasites and bacteria to prevent further disease or spread of infection. By taking the medicines you are keeping yourself and members of your community from getting the disease, and you are allowing the children to grow up free of infection.

Key messages following a potential SAE

• Describe the events and their context (e.g. isolated event, coincidental event, etc.)

• Describe whether or not the adverse event is still ongoing (i.e. new cases are still appearing)

• Explain the cause of the event (when identified with reasonable certainty)

• Describe actions taken or planned (i.e. plan of action through completion of the investigation)

• Reemphasize the benefits of MDA and the safety of the medicine (see Key Messages before MDA above)

Press releases and press conferences following a potential SAE

For press releases or press conferences, you should provide media with an information kit that includes:

• All essential facts and key messages (see above)

• Background information on the targeted disease and the benefits of MDA

• A list of possible questions (from journalists and the public) and prepared answers
SAE REPORTING PATHWAYS

Below is an example of a communications tree for reporting SAEs and AEs of concern.

Provide phone numbers and/or emails for the important contacts below. A few useful contacts have been indicated. Add additional contacts as needed.

National Program Manager: ____________________________
District Health Officer: ________________________________
District Hospital: ________________________________
_________________:
_________________:
_________________:

CONTACT INFORMATION

In the space below, create a communications tree for your country, including the time frame by which each entity will be contacted.

SAE REPORTING PATHWAYS AND CONTACT INFORMATION

This Job Aid was developed by RTI International as part of the ENVISION Project funded by the US Agency for International Development under cooperative agreement No. AID-OAA-A-11-00048. The period of performance for ENVISION is September 30, 2011 through September 30, 2019. For more information, go to www.NTDenvision.org.