Identification, referral and reporting of Adverse Events & Serious Adverse Events (SAE)

Lower level facilities with no capacity for AHA response
What are Adverse Events?

- Adverse Events (AE) are any unfavourable medical occurrence in a patient administered a medicine (not necessarily caused by the medicine).

- Adverse Drug Reactions (ADR) or Suspected Adverse Drug Reactions (SADR) are unfavorable medical occurrences that is possibly caused by a medicine.

- Serious Adverse Events (SAE) and Serious Adverse Drug Reactions (SADR):
  - The term ‘severe’ is used to describe the intensity of an event. But the event itself might be minor e.g. a severe headache.
  - A ‘serious’ event is one that results in death, poses a threat to a patient’s life, results in or prolongs hospitalisation, causes a congenital anomaly or results in permanent disability.

- Adverse Events of Special Interest (AESI) are adverse events specific to a product or program for example haemolytic anaemia with primaquine or tafenoquine.
How severe is an Adverse Event?

Adverse events or adverse Drug Reactions can be categorised into mild, moderate and severe:

- **Mild** – easily tolerated and does not interfere with daily activities

- **Moderate** – sufficiently discomforting so as to interfere with daily activities

- **Severe** – prevents normal everyday activity
# Identification of AHA-suspected cases

After treatment, if a patient returns to your health facility, check for the following signs/symptoms:

<table>
<thead>
<tr>
<th>Symptoms &amp; Signs that may trigger Adverse Events of Special Interest (AESI)</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Fatigue</td>
<td>Keep patient under observation.</td>
</tr>
<tr>
<td>2. Dizziness</td>
<td>Check for increase in severity and/or adverse events combining. Hospitalize if fear of developing AHA.</td>
</tr>
<tr>
<td>3. Breathlessness or shortness of breath (tachypnea)</td>
<td></td>
</tr>
<tr>
<td>4. Dark (red or black) urine</td>
<td></td>
</tr>
<tr>
<td>5. Back pain</td>
<td></td>
</tr>
<tr>
<td>6. Yellowing of the skin and/or sclera (jaundice)</td>
<td></td>
</tr>
<tr>
<td>7. Pallor</td>
<td></td>
</tr>
<tr>
<td>8. Rapid heart rate (tachycardia)</td>
<td></td>
</tr>
<tr>
<td>9. Fever</td>
<td></td>
</tr>
<tr>
<td>10. Nausea and/or vomiting</td>
<td></td>
</tr>
</tbody>
</table>
Response to AHA-suspected cases

Following clinical assessment, the health worker may decide on one of the following actions:

- Send the patient home after educating them to observe AHA signs and symptoms and report to the health facility if they observe ANY signs

- Refer the patient to the hospital for observation OR further critical care management

- If a patient is referred to hospital, ensure they are aware that they may need further critical care management and that they should proceed to the hospital urgently
Current practice for managing / referral of Serious Adverse Events (SAE)

- [to be adapted to country context]
Current practice for reporting of SAE

▪ [to be adapted to country context]
Exercise to complete SAE reporting form

- [Scenario to adapted to country context]
What should you do if a patient presents with an adverse event including AHA at your health facility?

- **In groups of 2-3 discuss and note the following:**
  - Are there procedures in your health facility for managing and reporting adverse drug reactions?
  - What are the procedures for adverse drug reactions?
    - Specifically, what are the tools for diagnosing AHA?
    - What are the clinical management guidelines in your country?
  - What data you need to report about patients with adverse drug reactions?
    - Specific data regarding primaquine or 8-aminoquinolines?

- Be ready to present your notes to the rest of the group.
Key points to remember:

- Explain the signs of haemolysis to patients in simple words
- Ask patients if they have experienced any signs of haemolysis when they come back to the clinic
- Refer any patients who complain of signs of haemolysis for investigation/management to the hospital
- Report any cases of serious adverse event, including AHA, to the national pharmacovigilance centre.

Any questions?