Partnership for Vivax Elimination

PAVE

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.**

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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

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

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**

ក្រសួងសុខាភិបាល
នាយកដ្ឋានឱសថ ចំណីអាហារ បរិក្ខារពេទ្យ

ព្រះរាជាណាចក្រកម្ពុជា
ជាតិ សាសនា ព្រះមហាក្សត្រ

CONFIDENTIAL
see reverse side for directions

របាយការណ៍ស្តីអំពីប្រតិកម្មរំខានរបស់ឱសថ
ADVERSE DRUG REACTION REPORT

ជាសំខាន់

ព័ត៌មានអ្នកជំងឺ / PATIENT INFORMATION

ឈ្មោះអក្សរកាត់/Patient Initials :.....ភេទ/Sex: ☐ស្រី/ F ☐ប្រុស/ M អាយុ/ Age :.....(ឆ្នាំ/Y) ទម្ងន់/Weight: .....(គីឡូក្រាម/Kg)
មានផ្ទៃពោះ/Pregnancy: ☐គ្មាន/No ☐មាន/Yes (ខែទី/In which month.....)ទូរស័ព្ទទំនាក់ទំនង/Telephone:

ឱសថសង្ស័យថាមានប្រតិកម្មរំខាន / SUSPECTED DRUGS

ឈ្មោះឱសថ (លេខឡុត និង ថ្ងៃផុតកំណត់) Drug Name (Batch and Expiry date)	ផ្លូវប្រើប្រាស់ Route	កំរិតប្រើ Dosage	គោលបំណងក្នុងការប្រើប្រាស់ Reason for Use	ថ្ងៃចាប់ផ្តើមប្រើ Date Started	ថ្ងៃឈប់ប្រើ Date Stopped

ឱសថប្រើប្រាស់រួមជាមួយឱសថសង្ស័យខាងលើ (រួមទាំងឱសថបុរាណ) / OTHER MEDICINES IN USE (INCLUDING HERBAL MEDICINES)

ប្រតិកម្មរំខានរបស់ឱសថដែលកើតមាន / ADVERSE DRUG REACTIONS

ថ្ងៃចេញរោគសញ្ញា/Onset Date: ..... ថ្ងៃបាត់រោគសញ្ញា/ Stopped : .....

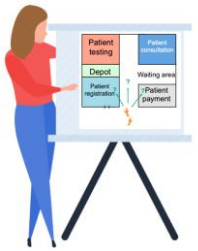
សូមរៀបរាប់ពីរោគសញ្ញា/Description :.....
.....
.....

Serious /ធ្ងន់ធ្ងរឬទេ? ☐បាទ/ចាស/yes ☐ទេ/No
ភាពធ្ងន់ធ្ងរបស់ប្រតិកម្មរំខាន/Seriousness
☐ស្លាប់/ Death ☐គំរាមគំហែងដល់ជីវិត/ Life-threatening
☐សំរាកពេទ្យ/បន្តសំរាកពេទ្យ/ hospitalization/prolonged
☐ពិការភាព/ disabling ☐ទារកកើតមិនគ្រប់លក្ខណៈ/ congenital anomaly
☐ជំងឺផ្សេងៗកើតឡើងដោយសារឱសថ/ other medically important condition

លទ្ធផលនៃផលរំខាន/ outcome of reaction
☐ជាសៈស្បើយ/ recovered ☐មិនជាសៈស្បើយ/ not recovered
☐ជាសឡើមៗ/ recovering ☐ស្លាប់/ fatal
☐ជាសៈស្បើយតែបន្សល់នូវស្លាកស្នាម/ recovered with sequelae
☐មិនដឹង/ unknown

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**

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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?