

Risk Minimization

Patient Counselling & Follow-up

- ***By the end of this session you should be able to:***
 - **Identify ways to reduce risk of adverse events and in particular, haemolysis**
 - **Provide patients with information about side effects that they need to report to health workers**

Goals of risk minimization

- To make you, the health worker, aware of the potential life-threatening risk of severe haemolysis caused by primaquine (PQ) or tafenoquine (TQ) in G6PD deficiency /low activity*
- To ensure that you understand how the risk of haemolysis caused by PQ or TQ can be reduced by using a quantitative G6PD test (before giving PQ or TQ)
- To ensure that you recognise PQ/TQ are contraindicated in pregnancy
- To reinforce how important it is to identify and report suspected adverse reactions to your national pharmacovigilance centre via **[local advice to be provided]**

* G6PD enzyme level ≤ 4.0 U/g Hb (6PD activity in units per gram of haemoglobin)

Risk Minimization for liver-stage treatment

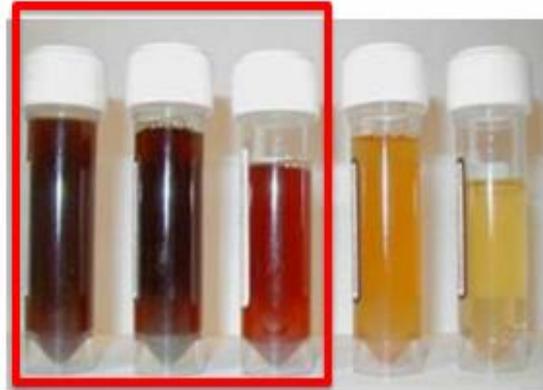
- After *P. vivax* malaria has been confirmed and **always perform quantitative G6PD testing before using TQ or PQ**
 - Semi-quantitative point-of-care test or lab-based spectrophotometric assay
- Verify that the patient's haemoglobin level is greater than 7 g/dL Hb for the G6PD test results to be reliable.
- Never give **daily** primaquine to a patient with known OR suspected G6PD deficiency (i.e. G6PD activity of ≤ 4.0 U/g Hb)
 - e.g. patient has a history of haemolysis following ingestion of fava beans
- Never give TQ to a patient with known OR suspected G6PD deficiency (intermediate or low G6PD activity; <6.1 U/ g Hb)
- Always advise patients to check for clinical signs/symptoms of haemolytic anaemia and to seek medical attention if they occur
 - provide patients with a patient information card
- **Never give PQ or TQ to**
 - a patient who has a medical history of haemolysis
 - to pregnant women. Even if a pregnant woman is not G6PD deficient, the foetus may be G6PD deficient

What is Acute Haemolytic Anemia?

- Acute haemolytic **anaemia** (AHA) occurs when the red blood cells are destroyed faster than they can be made
- AHA can occur when patients who are G6PD deficient (low G6PD activity) or have intermediate /medium G6PD activity are given PQ or TQ treatment
- AHA may lead to life-threatening **anaemia** requiring blood transfusion, dialysis and can lead to kidney failure or death

What are the signs and symptoms you should discuss with patients?

- **The most common sign or symptom of Acute Haemolytic Anaemia is dark urine – with a red or black (coca cola) colour**



Other signs and symptoms of Acute Haemolytic Anaemia are:

- Fatigue
- Breathlessness, or shortness of breath
- Back pain
- Yellowing of the skin or whites of eyes
- Pallor – an unhealthy pale appearance
- Rapid heart rate
- Fever
- Nausea and/or vomiting

Signs and symptoms of acute haemolytic anaemia



Fatigue



Dizziness



Breathlessness or shortness of breath



Dark urine
(Red or black colour)



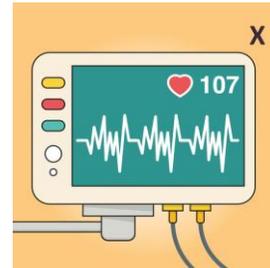
Back pain



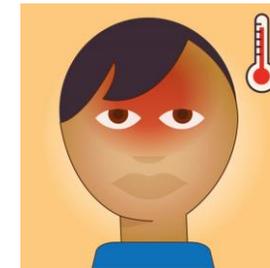
Yellowing of the skin
and/or whites of eyes



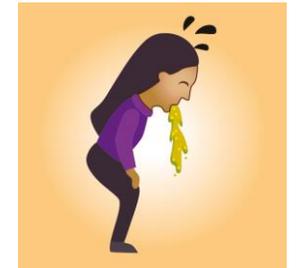
Pallor – unhealthy
pale appearance



Rapid heart rate



Fever



Nausea and/or
vomiting

What steps will you take to ensure patients are aware of the side effects of liver-stage treatment

In addition, to counselling about adherence to treatment, you must take time to explain the potential side effects of the treatment;

- Ensure the patient is aware of all of the signs and symptoms of AHA
- Ask the patient again if they have any concerns or fears that you can help resolve
- Ask patients to describe the signs and symptoms of AHA to you and what steps they plan to take if they notice any of the signs in themselves

Counselling for patients with low or medium G6PD activity

- **[Give them a written record of their G6PD enzyme level]**
- **Advise them not to eat certain foods (e.g. fava beans) and not to take certain drugs to reduce the risk of haemolysis**
- **Tell them about the signs and symptoms of haemolysis**
- **Ensure that the patient understand that they should stop primaquine and seek medical advice immediately they experience a warning sign of haemolysis**
- **Inform them about different treatment options for managing *P. vivax* malaria, if appropriate**

Patient follow-up post-treatment

Patients who receive primaquine or tafenoquine should be followed up during or after their treatment to ensure they are:

- i. adhering to their treatment and/or,**
- ii. suffering any adverse events as a result of either primaquine or tafenoquine**

- **Should be undertaken on days [5, and 14]**
- **Depending on where the facility and patients are located, follow up can either be done by**
 - Telephoning the patient,
 - Requesting the patient to return to the health facility or
 - An in-person visit e.g. by community health worker
- **A record needs to be taken of whether patient was contacted, their current adherence to treatment & whether or not any AE related to primaquine or tafenoquine were reported**
- **If a patient reported an AE, ensure they are requested to return to the facility, or advised to go to a higher level facility**

Key points to remember:

- The goal of risk mitigation is to make you aware of the risk associated with radical cure treatment and the importance of reporting any adverse reactions
- You can minimize risk to patients by ensuring you fully understand the radical cure treatment algorithm
- A quantitative G6PD test **MUST** be done before administering liver-stage treatment
- Remember, liver-stage treatment should not be given to pregnant women
- **Daily PQ** should not be given to a patient with low G6PD activity (less or equal than 4 U/g Hb)
- Report any suspected adverse reactions to the national pharmacovigilance centre

Any questions?