Rolling Out the Tafenoquine Proposition (TQP) for Radical Cure of *Plasmodium vivax* Malaria

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Topics to be covered in the next 15 minutes …

- Haemolytic anaemia risk minimisation
- Practical implications for endemic countries
  - Quantitative G6PD testing
  - Education
  - Pharmaco-vigilance (PV)
- Partnership roll-out plan
- Questions
Primaquine Effectiveness Dependent on Treatment Adherence

- Primaquine treatment compliance can be as low as 25%\(^3\)
- 3- to 4-fold greater risk of *P. vivax* recurrence associated with missed doses\(^1\)

Minimising haemolytic anaemia risk in G6PDd (Ex-US)

- Labelling: Contraindication in G6PDd (or unknown) + lactation
- Packaging will include wording that G6PD pre-test needed
- Point of care *quantitative* G6PD diagnostic to be made available (PATH-led)
- Local adoption of G6PD pre-testing guidelines to be mandatory
- Initial roll-out to be phased
  - Sites with trained health care workers and access to emergency care
  - First country (Brazil) has low G6PDd prevalence
- Education programme (TQ haemolysis/diagnostic/PV reporting)
  - Effectiveness assessed in implementation studies
Practical Implications for Endemic Countries

- Quantitative G6PD testing will need to be adopted
- Guidelines may need to be amended to support quantitative G6PD testing
- Educational materials will need to be adapted
- Training programmes will need to be rolled out & documented
- PV capacity will need to be expanded
Qualitative vs Quantitative G6PD Testing

Qualitative

Quantitative

Read results within specified time. Coloured window = normal. White window = deficient. Light colour (borderline result) = interpret as deficient.
Potential Educational Materials

How to counsel patients

Most patients feel better after taking Coartem or Coartem-Dispensible for one or two days. This means that many patients do not understand why they need to finish the full three-day course of Coartem or Coartem-Dispensible. If they do not complete the course, their malaria may recur.

Here are some ideas from Mary and Ali on the best way to help a mother use Coartem or Coartem-Dispensible is the right way to treat a child with malaria.

- Be kind and friendly – a mother with a sick child will be worried and will have more of what you are trying to understand.
- Polite for coming to take you stuff.
- Talk with the mother, ask her how she is and reassure her, don’t just give her instructions.
- Let the mother hold the pack and point to the dosages as you explain when to give them.
- Ask the mother to repeat what you have told her. If she gets something wrong, do not blame her, but explain it again.
- Ask the mother if she has any questions.
- Do not judge her for anything that you do not agree with. If you do, she may not listen to your advice.
- The mother may not have used Coartem or Coartem-Dispensible before – adults learn best if you show them how to use it, explain the reasons and discuss any questions.

I always try to be friendly. It does not take any longer than taking Coartem. And if I reassure the mother she helps her understand.

Potential Educational Materials

How to Do the Rapid Test to Detect G6PD Deficiency

Potential Educational Materials

TAFENOQUINE

FOR THE TREATMENT AND RELAPSE PREVENTION OF Falciparum Malaria.

HOW IS FALCIPARUM MALARIA CURRENTLY TREATED?

3 DAY COURSE OF CONVENTIONAL TREATMENT

14 DAY COURSE OF PROPHYLACTIC TREATMENT

The Tafenoquine Propository [single dose tafenoquine and G6PD testing] will enable countries to expand access to radical cure throughout national health systems and will provide greatly improved tools to support national efforts to eliminate P. vivax.
Strengthening PV reporting in Endemic Countries

- Active surveillance by sentinel sites
  - 2-3 sites per country/regional model covering different G6PD prevalence
  - All patients followed-up by PV co-ordinator working in close collaboration with local health staff
  - Reporting using local spontaneous reporting form but copy sent direct to GSK and WHO Uppsala
  - Possible WHO support – TQ selected as 1 of 3 PV strengthening pilots

- Roll out of training (± stimulated reporting) for non-sentinel sites
Phased, Bespoke Country Roll-Out

- GSK is committed to introduction of TQP in collaboration with MMV, PATH and wider malaria community stakeholders, particularly in \( P.vivax \) endemic countries
- Introduction of global health products requiring a diagnostic is complex
- Phased approach will be adopted
- Bespoke country-by-country roll-out based on readiness
  - G6PD policy adoption
  - Availability of G6PD test training of health staff
  - Robust PV plan