The Need for Assessing the Safety and Tolerability of Primaquine for Radical Cure of *P.vivax* in Ethiopia

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Introduction – common malaria variants in Ethiopia

- In Ethiopia, both P. falciparum and *P. vivax* are co-endemic. (Woyessa et al., 2012)
- *P. vivax* has a dormant liver stages (hypnozoite), which can cause relapses of infections weeks to months after initial attack.

Introduction – primaquine for radical treatment

- WHO recommends primaquine for radical cure of *P. vivax*. (WHO, 2016)
- Ethiopia adopted WHO recommendation to use Primaquine for radical cure of *P. vivax* to prevent relapses. (FMoH, 2018)
- However, clinicians fear of hemolytic anemia associated with Primaquine use in G6PD deficient patients is a challenge to scale-up Primaquine use in Ethiopia

Introduction – the need for additional evidence

- Previously, a nationwide Study have demonstrated low G6PD deficiency prevalence in Ethiopia. (Assefa et al., 2018)
- However, there is a need for active evaluation of the safety and tolerability of Primaquine used for radical cure in routine health care.

Purpose of the Assessment

- Additional research is needed to assess the safety and tolerability of primaquine, used for radical cure of *P. vivax* malaria
  - Assessment should include adverse events monitoring; clinical assessment, and monitoring laboratory indices such as hemoglobin and urine color change
- Determining the prevalence of G6PD deficiency in the population utilizing the drug.

Study population for assessment

- Patients diagnosed with uncomplicated p. vivax malaria or mixed infection at the recruiting health facility.
- Eligibility
  - Age ≥ 6 months
  - Not currently taking any drugs likely to cause hemolysis
  - No evidence of severe malaria, hypersensitivity to study drugs and previous history of hemolysis
  - Hemoglobin measurement ≥ 8gm/dl
  - Pregnant or women breastfeeding a child ≤ 6 months of age are excluded from the study

Data collection procedure

- Data collection on days 0 (treatment initiation), 3, 7, 13 and 27.

Lab tests and adverse event monitoring	D0	D3	D7	D13	D27
Hb testing	X	X	X	X	X
Urine testing	X	X	X	X	X
Pregnancy testing (women)	X				
DBS collected	X				
G6PD testing					X
Adverse event monitoring		X	X	X	X
Assess adherence (pill count)	X	X	X	X	

Indicators for analysis

- Absolute and proportional within person reduction in Hb from day 0 to 3, 7, and 13.
- Proportion of patients with > 25% drop in Hb at each point of follow up.
- The proportion of adverse events and serious adverse events
- Prevalence of G6PD deficient patients

Potential challenges in conducting the assessment

- Achieving sufficient sample size in a short period of time, because of low *P. vivax* load in some regions
- Choosing the correct G6PD test kit

Summary

- Assessing the Safety and Tolerability of Primaquine for radical cure of *P.vivax* in Ethiopia is important to implment the MOH guidelines; and contribute to the malaria elimination endeavor in Ethiopia.
- Such information is critical for providers to confidently administer primaquine in radical cure of *P. vivax*.
- Currently, a study is under way to provide this critical evidence for scale up of the MOH latest guidelines on radical cure of of *P.vivax* in Ethiopia

Thank you!