**RBM MIP Working Group meeting, November 2, 2020**

**Meeting Minutes**

Participants:

1. Kristen Vibbert, Jhpiego/IMPACT
2. Elaine Roman, Jhpiego
3. Maurice Bucagu, WHO
4. Julie Gutman, CDC/PMI
5. Peter Olumese, WHO
6. Andrea Bosman, WHO
7. Patricia Gomez, Jhpiego
8. Emmanuel Otolorin, Jhpiego
9. Erin Ferenchick, The Global Fund
10. Matt Chico, LSHTM
11. Dale Halliday, Unitaid
12. Raquel Gonzalez, ISGlobal
13. Prudence Hamade, Malaria Consortium
14. Tabitha Kibuka, PSI
15. Ashley Malpass, USAID/PMI
16. Abigail Pratt, BMGF
17. Silvia Schwarte, WHO
18. Jenny Hill, LSTM
19. Estrella Lasry, Global Fund Malaria Team
20. Marie Rose Kayirangwa, Jhpiego Rwanda
21. Abena Poku-Awuku, MMV
22. Valentina Buj, UNICEF
23. Tamar Chitashvili
24. Maud Majeres Lugand, MMV
25. Noella Umulisa, Jhpiego
26. Lisa Nichols, Abt Associates
27. Emmanuel Otolorin, Jhpiego
28. Dr. Aishatu Gubio, MOH Nigeria
29. Deborah Freitas, URC
30. Catherine Dentinger, USAID Madagascar
31. Susan Youll, USAID/PMI

**Agenda Items:**

1. **Presentation: *Process for guideline development at WHO and expected timelines for 1st trimester ACT policy,* Andrea Bosman, Peter Olumese, WHO**

Discussion:

* Q: Will the entire WHO guidelines for treatment of malaria from 2015 be updated?
  + A: The entire document has not been updated, but WHO is updating sections of it based on available data and needs. When the current review is finished, WHO is not going to wait for a 4th edition before the recommendation is released. Each recommendation will stand on it’s own.
* Q: Are there any countries on a fast track for adoption?
  + A: The current recommendation in the 2015 guidelines was clear. In situations where you cannot guarantee a full 7-day course of quinine or a patient cannot tolerate quinine, ACTs should be used. Many countries are already doing this or have already included this in their national guidelines.
* Q: What are the next steps for the systematic review? Is new evidence going to be evaluated?
  + A: If there is a recommendation with very strong evidence behind it, most of the new evidence will support it. As evidence becomes available, there is an ongoing review, wanting to use the most up to date evidence for the recommendation.
  + A: At the ERG meeting in 2015, there was a firm view that the analysis should not pool different classes of ACTs due to the different partner drugs. Most of the data at that time was on AL. An online search in August 2019 did not find any new data however the search will be repeated in the coming months in addition to sourcing data through direct contacts with colleagues working in this field. Apart from AL it is very unlikely that there will be sufficient data on any particular ACT class for analysis by class.
  + A: Most countries have guidelines for quinine and many are still procuring it. However, sometimes there is a difference between what is included in national policies and what is being practiced.
* Q: If evidence was available in 2015 and new guidance developed in 2017, please explain barriers that prevented change in 2017.
  + Legal discussion around off-label use took one full year. This was covering medicines for all diseases and medicines on the Essential Medicines List. Back and forth with guidance review committee has taken time as well. Not a matter of new evidence that moved WHO in a different area, but more the realization that for certain ACTs, like AL even a stringent regulatory authority like the U.S. FDA has now removed all language around restrictions for use in pregnancy so this is a big step forward. There was also the realization that quinine + clindamycin is operationally not suitable for compliance, adherence to treatment and side effects so the lack of visibility in what is the current option recommended in the guidelines. Also specifically for AL there are different formulations which are prequalified by WHO, there is no restriction on the labeling on the WHO prequalified website and some are now in adult sized tablets so you can take one tablet instead of 4, so an adult treatment is just 6 tablets (one in morning, one in evening for 3 days), making the regimen much easier to implement.
* Comment: If this is approved for implementation by WHO, early ultrasound opportunities will help to determine gestational age to help make a decision on treatment based on the recommendation.
* Q: Is WHO going to provide a clear recommendation or will there be a continued caveat deferring to country programs to make the decision?
  + WHO will have a clear recommendation on use in 1st trimester. Countries use the guidelines to develop national policies. This disclaimer is already inside the front cover of any WHO publication, but doesn’t prevent any malaria program to look at what the recommendation is saying. It doesn’t have a major impact on uptake of WHO recommendations.
* How do the 2 different departments in WHO link to each other (Prequalification and GMP)?
  + In the prequalified AL, the specific wording is very different. There are specific products of AL that carry a strict label not to use in the first trimester. However there are others that can be used if no effective antimalarial is available. Is quinine an effective treatment? Probably not because compliance/adherence is so poor so you can always refer back and use the AL. The Novartis coartem on the prequal list is very restrictive, but if you look at the same drug approved by the U.S. FDA, there is no language restricting use for human pregnancies. They can have different labels for the same medicines applied by two different regulatory authorities. What regulators look at is the data and the use of medicines for their own population and what else is available on the market. So it doesn’t necessarily align with WHO recommendations for use in the population irrespective of the specific brand because WHO looks at the finished pharmaceutical product and how it is going to be used in the population.
  + A: Andrea’s response is a great example of regulatory vs. guidelines. Prequalification is more on the regulatory side: It is what the manufacturers want to register that goes before the regulatory board. Guidelines are about public health use: The guidelines use evidence to evaluate the use of medicine in the public health space. WHO would not consider including something in the guidelines that has not been registered by a regulatory authority. Even from the same manufacturer you can have different labels registered in different countries for different settings.
* Comment: GF will look at where quinine + clindamycin are still being ordered. Need to be sure they are not using this as continuation for management of severe malaria. Presume quinine is primarily for MiP, but it’s not clear how it’s being used at facilities if they have it in stock.
* Q: There isn’t that much more evidence so will we run into the same situation again where the process gets stalled?
  + A: The issue with off-label use is now out of the picture so WHO doesn’t expect additional delays. WHO is hopeful that this time around they can accelerate the process and things will not be stalled.
* Comment: As this process goes on, Peter may reach out to some of the WG members to serve in various capacities and hopes for good cooperation.

1. **Events:** 
   * **Media Briefing**, Oct. 6th
     1. Served as launch of Global Call to Action
     2. Huge thank you to RBM, Grayling, MMV and the moderator/speakers
        1. Moderator: Mildred Komey, Malaria in Pregnancy Focal Person, National Malaria Control Programme, Ghana Health Service
        2. Speakers:
           1. Dr. Anshu Banerjee, Director Department of Maternal, Newborn, Child, Adolescent Health & Ageing,
           2. Pedro Alonso, Director Global Malaria Programme, WHO
           3. Dr. Aminata Cisse ep. Traore, Director, Direction Générale de la Santé et de l’Hygiène Publique, Ministére de la Santé et de l’Hygiène Publique, Mali
     3. 255 participants
     4. Next steps for Call to Action: Technical webinar in January, 2021
   * **ASTMH:**
     1. MiP symposium with Kate Wolf and Maurice Bucagu as facilitators: A Fundamental Way to Prevent Malaria in Pregnancy: Improving Health Outcomes for Pregnant Women and Their Babies One Nurse and Midwife at a Time
     2. Dr. Pedro Alonso will make opening remarks
     3. Table of MiP-related presentations will be circulated

*ACTION ITEM: Please send any additional presentation/poster information to Kristen to add to table*

* + **RBMMiPWG Special Edition: Workplanning**
    1. Dec. 9th, 9:00-10:30am EST