**RBM MIP Working Group meeting, June 13, 2018**

**Meeting Minutes**

Participants:

1. Kristen Vibbert, Jhpiego/MCSP
2. Elaine Roman, Jhpiego/MCSP
3. Erin Ferenchick, The Global Fund
4. Nicholas Furtado, The Global Fund
5. Maud Majeres Lugand, MMV
6. Julie Gutman, CDC
7. Bolanle Olapeju, JHUCCP
8. Prudence Hamade, Malaria Consortium
9. Azucena Bardaji, ISGlobal
10. Raquel Gonzalez, ISGlobal
11. Maddie Marasciulo, Malaria Consortium
12. Lia Florey, PMI/USAID
13. Matt Chico, LSHTM
14. Lisa Nichols, ABT Associates
15. Valentina Buj, UNICEF
16. Mike Toso, CCP
17. Grace Adeya, PSM
18. Mary Nell Wegner, MHTF
19. Andrea Stewart, WWARN

**Agenda Items:**

1. **Update on regional SEARO meeting in New Delhi**

* New Dates: The WHO ANC meeting is now confirmed for July 10-13 in New Delhi.
* New Focus: The original focus was on the new WHO ANC recommendations, similar to the meeting held in Kigali last year. The new focus is ‘across the continuum care’ so ANC, newborn and intrapartum updates.
* MiP session: We had allocated 1-1.5 hrs for a MiP technical update, but this was lost in the agenda revisions.
  + We have gone back to SEARO to get this put back in the program and we are now working with them to readjust the agenda to include the MiP session.

**Discussion:**

* Q: Is there still discussion around prioritizing presentations of specific countries, such as Myanmar, to share their experiences?
* A: The MiP session has been modified to focus on the following:
  + Overview of current epidemiology in region
  + Review of evidence based strategies for MiP in low transmission settings (hopefully GMP can provide updates on this)
  + Sharing of best practices: Due to time constraints, the focus will be on Myanmar and the lessons they have learned from updating their ANC guidelines and incorporation of MiP

**Next Steps:**

* ACTION ITEM: Erin will tweak concept note based on shift in agenda and share with the WG
* ACTION ITEM: Erin to share updated agenda, once confirmed, with the WG

1. **Update on Nutrition/MiP discussions**

**Background:** *There is a need to address the issue of supplementation of iron and folate in areas highly endemic for malaria because this is an intersection of focus for malaria and nutrition programs. There was a teleconference between the WHO Nutrition Department, GMP and The Global Fund about how to update the WHO guidance and how the WG can contribute to this.*

**Update:**

* None of the key partners has come back with any way forward so we will have to find a way to move the discussion along.
  + Once we move to the next stage, we will be able to provide a more comprehensive update.

1. **Presentation: SP Procurement: Challenges, Risks and Opportunities, Grace Adeya, PSM/USAID**

* GHSC/PSM: Global Health Supply Chain Program -(GHSC) Procurement and Supply Management (PSM) Single Award Indefinite Delivery Indefinite Quantity (IDIQ)
* Procurement is on behalf of USAID so for malaria that means procurement is on behalf of PMI
  + ACTs
  + SP for IPTp
  + SPAQ
  + LLINs
  + Severe malaria commodities (injectable Artemisinins, Quinine etc.)
  + Other Malaria Pharma and commodities (lab supplies etc.)
* Forecasting: As we are discussing the scaling up of MiP based on updated WHO ANC guildelines, how do we start planning for this in terms of better quanitifying requirements?
  + IPTp3 vs IPTp6+
    - Key discussion point: How to plan for scale-up to IPTp6+ to meet new WHO guidelines
    - Key issue: Unreliable and inconsistent, consumption monitoring often leads to issues of over procurement
      * Countries are holding huge quantities of SP at central level while we are receiving reports of stockouts at facility level
      * The money being used to procure and hold large quantities of SP means it’s not available to hold other malaria commodities.
* Sourcing:
  + There are no WHO prequalified single-unit dose presentations of SP indicated for IPTp;
  + GHSC-PSM procures non-prequalified SP from wholesalers that meet the PMI sourcing requirements.
    - This limits the number of manufacturers they are able to procure from
  + Market Risks: future API availability concerns
    - The prices for SP are going to increase and the availability is going to decrease
    - Need to be very clear on what quantities of SP are needed and when they are needed
* Product Specifications:
  + Previously many countries ordered 1,000 packs of tablets, but these need to be broken down to send to facilities and this creates risk of contamination
  + Countries are starting to request 100 tablets or blister packs
    - The challenge is that with these smaller presentations there is almost doubling of the prices (33 cents for 1,000 tablet presentations vs. 70 cents for smaller presentations)
* Product Registration:
  + There is no incentive for global manufacturers to register in every country because the market is so small
  + Issue: countries prefer to use in-country sources and are not giving waivers for registration

**Discussion:**

* One of the things the WG has had on our list, in coordination with WHO, is to push for and advocate to get SP on the Essential Medicines List. This will be an important step.
* MMV is working with manufacturers to produce QA SP per WHO standards. This will help to open the market up more and give countries a better choice and an incentive to procure QA SP.
  + MMV has received funding to bring at least 2 new manufacturers to submit a dossier for SP prequalification review.
  + One manufacturer has been identified in Kenya and a contract will soon be signed with them.
  + Through the TIPTOP program, we learned that Nigeria is not allowing SP to be imported so there is no possibility of procuring quality SP. The only way to overcome this is to work with a Nigerian manufacturer and currently MMV is doing site inspections to identify one or two Nigerian manufacturers to submit dossiers for SP prequalification.
  + Next steps:
    - Completion of bioequivalence studies
    - Then MMV is looking to sumbit at least one dossier for prequalification next year.
    - If successful, there could be three more manufactuers producing QA SP.
    - MMV is also working to get products on the GF ERP list for use in the meantime.
* Q: If the Nigerian government is not allowing importation of SP, does this mean there is no longer quality SP available for SMC?
  + A: TIPTOP received an import waiver so the SP is QA from Guillin.
* Q: What is the long-term impact of this policy in Nigeria? If there is not a QA SP manufacturer and the country won’t allow importation, there are major implications for long-term sustainability for any project.
  + A: The U.S. government has a bit more flexibility with product quality, but with WHO/Unitaid supported projects, procurement must be based on WHO standards.
  + A: Updates on Nigeria from PSM:
    - Current stock status shows that they are overstocked on SP so there are no concerns about immediate availability of SP.
    - A recent respondent to a USAID bid seems to be close to meeting standards and is able to provide SP, but their product is much more expensive.
* Q: Are blister packs currently available on the market?
  + A: There are three suppliers that are supplying blister packs and three countries that specifically requested them. In some cases they received specific waivers to procure this presentation of SP.
    - Burkina Faso, Ghana and Nigeria are the countries that requested the blister packs.

**Conclusions:**

* This conversation around QA SP is something that we have had our eye on for a while within the WG. It is that classic issue where there are global pieces with the manufacturers as well as country realities and making sure SP is actually at point of care.
* This is something that as a WG need to continue to work together and dialogue on, especially now that we have a frequent dosing policy from WHO. There will be competing needs across countries to procure SP from presently limited manufacturing groups.

1. **Annual Meeting:**

* Viviana and Elaine, with a small group of WG members, have initiated discussions around the framing and priorities for the next WG annual meeting
  + Decided to shift from the September time period due to a number of constraints with the planning and execution of the meeting
    - Looking at sometime early in the new year
  + Will be able to share more information soon

***ACTION ITEM: If anyone is interested in joining the planning committee, please let Elaine & Viviana know***

1. **Partner Updates**

***LSHTM:***

* LSHTM has started recruitment for trial in East Africa comparing SP to DHA-PPQ and also DHA-Azithromycin

***Abt Associates:***

* Abt has started implementation of DRC bilateral USAID funded project. They will be reaching out to different partners to discuss coordination in country.

***CCP:***

* The RBM SBCC WG annual meeting will be in Lusaka, Zambia September 25-27. The agenda is currently under development.

***TIPTOP:***

* TIPTOP is about to launch implementation of C-IPTp within the next one to two months in DRC, Madagascar, Mozambique and Nigeria
* Two research studies are underway, supported by IS Global: Household survey and SP resistance monitoring
  + Implementation will start following the completion of these studies

***ISGlobal:***

* MAMAH project will be carried out in Mozambique and Gabon to study IPTp-DP vs IPTp-placebo in HIV infected women on cotrimoxazole and ARV drugs
* Grant was signed in March and now they are preparing for trials and expect to start early next year