



**Roll Back Malaria – Malaria in Pregnancy Working Group 20th Annual Meeting
Maputo, Mozambique
February 12-14, 2019**

FULL MEETING REPORT

Executive Summary:

The 20th Roll Back Malaria- Malaria in Pregnancy (MiP) Working Group (WG) annual meeting was held from February 12-14, 2019 in Maputo, Mozambique. The meeting was organized in collaboration with the RBM Partnership, PMI, The PMI IMPACT Malaria Project, The Global Fund, Unitaid and the Bill and Melinda Gates Foundation.

Purpose and Objectives: To help countries improve access to and coverage of key interventions, the 20th RBM MiP Working Group meeting focused on the following objectives:

1. Share, disseminate and discuss updates on key recommendations for MiP programming
2. Share, disseminate and discuss key country practices and models of innovation that are helping to improve coverage of MiP interventions
3. Share, disseminate and discuss innovative practices that are or have the potential to contribute to improving MiP coverage
4. Share, disseminate and discuss new MiP research and implications for MiP programming
5. Discuss WG strengths, weaknesses, threats and opportunities to help inform work plan priorities

These objectives were achieved through a range of presentations, technical panels, round table discussions and group brainstorming sessions. Speakers included technical and programmatic leaders, donors, researchers and NMCP and MCH country representatives who shared their country experiences with MiP targets and interventions. A complete meeting agenda is available as Annex 1.

Participants:

The meeting included fifty-three participants, including representation from 11 countries and the donor, academic and implementation communities. A complete list of participants is available as Annex 2.

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Summary of Meeting Takeaways and Priorities:

The MiP WG remains committed to aligning RBM partners on best practices and lessons learned in MiP programming to help achieve higher coverage in MiP interventions globally. The 20th Annual Meeting provided an opportunity for country representatives from both malaria control and reproductive health programs, donors, researchers and implementing partners to share the most up to date information and experiences including best practices and lessons learned. The 20th meeting focused on key areas relevant to the acceleration and scale-up of MiP interventions: comprehensive ANC service delivery, quality of care, community engagement and SP stock management. Through country panel and round table discussions the WG identified existing challenges and new opportunities to help propel MiP programming efforts forward that will contribute to increasing access and coverage. The section below highlights some of the RBM MiP WG 2019 priorities. For a complete understanding of the WG work plan, please visit our website: <https://endmalaria.org/our-work-working-groups/malaria-pregnancy>. The 2019 MiP WG work plan will be posted upon finalization.

Policy- The WG will continue to support country adoption and implementation of the [WHO 2016 Recommendations on antenatal care for a positive pregnancy](#) through the re-dissemination of the WG brief, *Implementing Malaria in Pregnancy Programs in the Context of World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience*, which provides guidance on how countries can implement MiP programming in the context of the new ANC recommendations. Support will include two webinars in collaboration with WHO and sharing lessons learned on the adoption process across countries.

Tools & Products- Effective tools and products are essential to strengthen quality care, increase demand among clients and providers and improve provider knowledge and skills. The MiP WG will support efforts to:

- A one page complementary brief to the *Implementing Malaria in Pregnancy Programs in the Context of World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience* will be developed based on the ANC/ MiP contact schedule and discussing the difference between a contact and visit.
- Finalize the MiP M&E Brief which provides an MiP Monitoring and Evaluation Framework and guidance on MiP Indicators

Advocacy- Prioritization of MiP programming remains highly important recognizing the vulnerability of pregnant women and as countries move from high to low malaria transmission. The MiP WG will continue to advocate for the most optimal care to protect pregnant women from malaria and to support efforts that will give countries the guidance needed for successful implementation of MiP initiatives. The MiP WG will:

- Share best practices for the promotion of community engagement in MiP programming including the dissemination of an SBCC CHW manual
- Support dissemination of brief on the use of ACTs in 1st trimester for uncomplicated malaria pending WHO approval of policy change
- Provide guidance to countries on the development of Global Fund grants in the context of RMNCH services including MiP

Coordination & Collaboration- Continued coordination and collaboration at global and country level is key to achieving MiP WG priorities, focusing on increased IPTp uptake, use of LLINs and effective case management. The MiP WG will support efforts that:

- Strengthen partnerships to engender effective coordination and collaboration. This includes engagement with the RBM-- Country and Regional Support Committee, other RBM Working Groups and sharing best practices across the various WG partners and countries.
- Foster integration of national reproductive health and malaria control programs through national Technical Working Groups and the harmonization of XXXX

Research- Taking research to practice is a core element of the MiP WG's efforts. Moving forward, the MiP WG will support:

- Dissemination of key MiP research findings that include both clinical trials and operational research



Day 1: Tuesday, 12 February

Introduction and Overview of MiP Working Group

In addition to the key themes in our WG work plan (advocacy, policy, products & tools, coordination, research), there are multiple priority efforts and/or considerations that complement these themes for accelerating MiP programming. These include:

- Harmonizing national level documents between MCH and Malaria as well as HIV can reduce provider confusion and improve efficiencies in implementation
- Identifying maternal/reproductive health champions early to move MiP programming forward
- Prioritization of national MiP technical working groups to help provide technical guidance and coordination of program implementation
- Task shifting
- Community engagement and behavior change communication (BCC) are critical for increasing IPTp uptake and early ANC attendance
- Maternal/reproductive health involvement in forecasting for MiP commodities at ANC can help minimize SP stockouts of SP and ITNs at ANC
- Coordination across technical areas (e.g. HIV, MCH, M&E) is key

Discussion:

- Pregnant women may have asymptomatic malaria before they get pregnant and this is something we should look at.
- For prevention of MiP in Asia, bednets should be used; early diagnosis and effective treatment should be available. If the malaria species is not known with certainty, treat as for uncomplicated *P. falciparum* malaria. In areas with chloroquine-susceptible infections, treat adults and children with uncomplicated *P. vivax*, *P. ovale*, *P. malariae* or *P. knowlesi* malaria with either an ACT (except pregnant women in their first trimester) or chloroquine. In areas with chloroquine-resistant infections, treat adults and children with uncomplicated *P. vivax*, *P. ovale*, *P. malariae* or *P. knowlesi* malaria (except pregnant women in their first trimester) with an ACT. Treat pregnant women in their first trimester who have chloroquine-resistant *P. vivax* malaria with quinine. To prevent relapse in *P. vivax* or *P. ovale* malaria, consider weekly

chemoprophylaxis with chloroquine until delivery is completed, then, on the basis of G6PD status, primaquine could be given to prevent future relapse.

- Document development: From WHO perspective, anything that is produced by WHO is on behalf of the countries. When the guidelines are adapted at country level, they belong to the country. The country takes the lead with support of partners.

Panel Discussion: Global Support and Technical Direction for MiP

RBM Summary:

Zero Malaria Starts with Me:

- Campaign is co-led by the African Union Commission and the RBM Partnership to End Malaria
 - Will support grassroots, national, and regional movements in their fight against malaria
 - Keep malaria high on the political agenda
 - Raise funds to support malaria work
 - Engage everyone, from heads of state to community members
- Strategic support for country-led resource mobilization and advocacy through RBM CRSPC
 - Keep malaria high on the political and development agenda to ensure continued commitment and investment to achieve GTS and AIM milestones and targets
 - Technical assistance and limited financial assistance possible
- Platform for sharing best practices and experience:
 - Zero Malaria Toolkit: <http://zeromalaria.africa>

WHO Key Takeaways:

- World Malaria Report (WMR) 2018 shows a continued increase in the number of malaria cases. The achievement of the 2020 goals of the Global Technical Strategy is in danger and more efforts are needed to tackle malaria to get back on track.
- WMR 2018 also shows a continued low coverage of IPTp-3. With the 8 contacts (versus the previous 4 ANC visits) recommended in the updated WHO guidance on antenatal care for a positive pregnancy experience we now have the opportunity to increase IPTp coverage. The inter-agency briefing contains a suggested contact schedule with proposed times of IPTp-SP administration, that can be adapted to country contexts. The briefing “Implementing malaria in pregnancy programs in the context of World Health Organization recommendations on antenatal care for a positive pregnancy experience” is available in three languages at the following link: <https://www.who.int/reproductivehealth/publications/implementing-malaria-pregnancy-programmes-brief/en/>
- WHO Guidelines for the treatment of malaria: An update of the recommendations on 1st trimester use of ACTs is pending.
- WHO Prequalification Programme: SP from Guilin Pharmaceuticals was prequalified by WHO in October 2018. Full information is available at <https://extranet.who.int/prequal/content/prequalified-lists/medicines>
- WHO Model List of Essential Medicines: WHO is working on adding SP for IPTp to the list. The dossier was prepared and submitted in December 2018 for review. The corresponding WHO Expert Committee Meeting will be held early April, 2019.

Global Fund Key Takeaways:

In order to succeed in getting Global Fund grants, it is important to have the following:

- Clear articulation of MIP strategy (e.g., needs, costs, and financing gaps) will give countries the potential to leverage various funding streams to ensure delivery of a comprehensive, integrated intervention package
 - In many countries they are not using national funds to cover the costs of providing SP

- A functioning health system is essential to decrease maternal and neonatal morbidity and mortality due to malaria in pregnancy and global malaria targets overall
 - Programs must address both supply and demand challenges
 - Derive clear lessons from assessment of new approaches to the delivery of preventive and treatment strategies within the context of integrated services delivery.

PMI Priorities for improving IPTp coverage

- Improving Health Provider Practices & Knowledge
 - Trained 36,000+ health providers in IPTp delivery
- Improving Social Behavior Change Communication
- Standardizing Data Collection and Management
 - For example, MiP M&E Brief
- Strengthening SP Procurement and Supply Chain

Panel Overview:

- Emphasis on coordination and collaboration. The global platform can be a way to help prioritize MiP programming and accelerate the MiP agenda to accelerate MiP control.
- Advancing and helping to disseminate global policy at multiple levels
- Advocacy emphasis on Quality Improvement, ANC and community engagement

Discussion:

While there are still a number of challenges, many countries have done great work to advance their MiP programming and improve outcomes. Country implementation strategies, best practices and lessons learned should be documented and disseminated.

Pre-qualified medicines

- USAID has a different standard of stringent regulatory authorities (SRA) for SP and the registration in Cyprus (one product is listed on the Global Fund procurement list for antimalarial medicines) is not considered a stringent approval by USAID.
 - WHO is revising its definition on stringent regulatory authorities, but this doesn't tackle or change the WHO prequalification of the Guilin product.

Use of ACTs in the first trimester for uncomplicated malaria

- Revision of efficacy of ACT in 1st trimester: The WHO Technical Expert Group (ERG) on Malaria Chemo-therapy, as Guidelines Development Group generated a recommendation in December 2017. The Malaria Policy advisory committee (MPAC) has endorsed the recommendation in July 2018, however, an update of the WHO guidelines is pending.
 - The final decision to include new recommendations in the malaria treatment guidelines is made by the WHO Global Malaria Programme (GMP). The pending 1st trimester guideline update coincided with a revision of the overall GMP policy development process. As mentioned above, the recommendations has gone through ERG, and MPAC has endorsed it, however, translation into an official WHO recommendation in the malaria treatment guidelines is pending. The group will be kept informed about any updates / changes in due course.
- Ghana is currently reviewing its MiP guidelines, and asked whether they can already recommend the use of ACTs in 1st trimester. Is there something tentative that can be used now since we are reviewing our guidelines next week?
- The current WHO guidelines say ACTs can be used for treatment in the 2nd and 3rd trimesters. During the **1st trimester**, 7 days of quinine + clindamycin should be given. However, current

guidelines already suggest an ACT can be used if quinine is not available or adherence to 7 day treatment is not guaranteed.

- If we are going to screen women at first ANC, if it is asymptomatic malaria, is this risk being considered with this recommendation?
 - There is no WHO recommendation for screening or treatment of asymptomatic malaria in pregnant women.

ANC recommendation adoption: Country Round Tables

No adoption: Senegal, DRC, Cote d'Ivoire:

Barriers to adopting ANC recommendations:

- Some countries are not yet achieving 4 contacts so it is not possible to move forward with 8 and be successful.
 - Senegal is counting IPTp-SP, but not the number of ANC visits
- Interpretation of guidelines is still very confusing.
 - It's not clear what each visit [contact] is.
 - What is the difference between contact vs. consultation [visit]?
- Concern: ANC is supposed to be free, but that is not always true in reality, especially for add-on services like lab tests. If you are adding 8 contacts, women will be required to pay more.
- Confusion and concern about how comprehensive ANC can be done if visits are not all with trained health providers.

Discussion:

- Suggestion: In each country there can be a consultative meeting with WHO and then officials can come together to adapt the recommendations within the country context
- Suggestion: countries could start a pilot in one district and see if it is possible to expand
- When providers give SP, the focus is on SP and the other ANC interventions are left out.
 - Advocacy is needed with providers to give comprehensive service

Partial Adoption: Burkina Faso, Tanzania, Uganda, Zambia

What's worked so far:

- Preparation for adoption meetings at national level, then at regional level to refine content of each visit
- Many did a pilot in a selected district
- Roll out has been organized and coordinated between reproductive health and other departments
- Defined clear road map and plan of action
- Support needs:
 - Training
 - Countries are still struggling with increasing minimum number of ANC visits before full adoption

Full adoption: Ghana, Madagascar, Mozambique, Nigeria, Sierra Leone

What's worked so far:

- Ensuring proper stakeholders meeting to discuss why to adopt the recommendations
- Need to harmonize guidelines with national records because data collected is on IPTp3
- 8 contacts are recommended, but for IPTp countries are focusing on 4+
 - WHO: The recommendations are for maximum problems/risk. 4 contacts are not sufficient for addressing all of the risks. In the 8 proposed contacts there are

recommendations on what should be done at each contact. WHO proposed the interventions for each contact, but these can be adapted by each country.

In Ghana:

- They adopted free ANC services and this dramatically increased ANC attendance
 - The cultural barrier in Ghana is decreasing mainly because of the free health insurance.
 - If women are not coming, then it is a big problem of access.
 - They use CHWs to encourage the women to attend.
- Capacity building was very important to give clear instruction to providers on when to begin IPTp
- Client health and MCH records are combined country-wide
 - This was the opportunity to adopt recommendations and provide guidance on how many visits.
 - Recommendations were adapted to say 3 visits in 2nd trimester and a minimum of 4 in the 3rd trimester.

In Sierra Leone:

- ANC card has 8 contacts and one additional visit between 13 and 16 weeks.
- Encouraging women to come to ANC before 12 weeks.
- ANC card was released country-wide.
- Called stakeholders together and had WHO consultant to help with adoption.
- Piloted new recommendations in 4 districts
- Combined client health and MCH records.
- ANC contacts are only at facility and outreach. CHWs do not provide ANC, but refer pregnant women to facilities.

Discussion:

- How have you made sure you are synchronizing ANC visits?
- How are you coping with confusion around women coming more often but only being able to give SP at certain contacts?
 - Service providers know the schedule for giving IPTp.
 - Ghana gave a broad statement: come at least 3 visits in the 2nd trimester so there is flexibility for women to schedule their visits.
 - This is especially important for those that are very ill as we want to get them to come more often.
- Have you seen any impact on mortality yet?
 - We are looking at coverage and that has been the focus rather than looking at stillbirths, low birth weight, etc.
 - Sometimes we rush too much to look at impact. Let's look at it for a while and then see.
- Among countries feeling like they need more support and guidance, there is a MiP ANC Brief developed by the MiP WG in collaboration with WHO on how to apply the ANC recommendations in the context of malaria in pregnancy: ***Implementing Malaria in Pregnancy Programs in the Context of World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience***
 - English: <https://endmalaria.org/sites/default/files/MIP-ANC-BRIEF-English-final-2.pdf>
 - French: <https://endmalaria.org/sites/default/files/MIP-ANC-BRIEF-French-final-1.pdf>
 - Portuguese: <https://endmalaria.org/sites/default/files/MIP-ANC-BRIEF-Portuguese-final-1.pdf>
- Ghana and Sierra Leone both shared their MCH record booklets and electronic copies were shared with the Working Group by email.

Quality of Care Panel
Burkina Faso, Côte d'Ivoire, Nigeria, Senegal



Burkina Faso:

- Need to get pregnant women to ANC earlier by overcoming cultural and educational barriers, such as illiteracy and lack of education.
- Uptake of SP needs to be better controlled. Sometimes CHWs will give SP for the pregnant women to take at home.
- ITN provision is strong, but utilization of ITNs is weak.
 - Need to consider best practices and key actions/strategies such as:
 - Weekly surveillance by health staff and CHWs
 - Maternal and Neonatal Death Surveillance and Response
- Next steps:
 - Expand IPTp at community level
 - Fully adopt WHO 2016 ANC recommendations

Côte d'Ivoire:

Challenges to address:

- Increase SP uptake by pushing pregnant women to come to ANC earlier
- Proper management of SP to ensure ongoing availability
- Improved strategies for the effectiveness of DOT
- Consider Community IPTp

Next Steps:

- Involve 190 new private for-profit facilities
- Continue to administer at least 3 doses of SP given under controlled conditions
- Ensure effective functioning of the Malaria Task Force during pregnancy
- Conduct consultations for operationalization of Community IPTp
- Adoption of 8 ANC contacts and IPTp from the 13th week by 2020

Nigeria:

Lessons Learned:

- Timely submission of distribution plan for movement of SP helps to reduce SP stockouts
- Government investment in procurement and distribution of SP is critical to program success
- Community mobilization is critical to increase ANC coverage, as is provision of respectful maternity care.
- Mixed interventions have been successful in modifying behaviors and misconceptions

Key Takeaways:

- Use of DOT approach and pre-packaged water significantly improved uptake of IPTp
- Distribution of LLINs to pregnant women attending ANC1 is a good motivation.
- Need to ensure effective use of data to plan net distribution campaign.

Next Steps:

- Harmonize malaria program logistic system with national supply chain integrated program
- Strengthen stakeholder coordination between malaria and Mal-RMNCAH integration
- Train more service providers on 2016 WHO ANC recommendations
- Advocate for technical and funding support to scale up C-IPTp and quality of care processes
- Use data effectively to plan net distribution campaigns to ensure ITN availability at ANC

Senegal:

Lessons Learned:

- Engaging CHWs is critical for early and full achievement of ANC
- Taking bottlenecks into account through situational analysis in the districts has improved IPTp2 and IPTp3
- The availability of SP is crucial to the quality of care in any IPTp strategy

Key Takeaways:

- Priority given to improve IPTp coverage in some districts with gaps according to this indicator.
- First, a situational analysis with identification of the determinants of low IPTp coverage was performed.
- Then, 'acceleration plans' for low performing districts were implemented
- These acceleration plans include a set of activities to increase the level of involvement and ownership of actors at all levels

Next Steps:

- Pilot the recently released WHO guidance advocating a minimum of 8 contacts in 3 health districts before scaling up;
- Improve care with the introduction of more sensitive diagnostic tools in all areas of low transmission
- Scale up community IPT model to improve adherence
- Strengthen collaboration with private gynecologists and midwives
- Strengthen advocacy for MiP with national institutions to ensure local funding

Discussion:

Overview:

- Everyone is making a strong effort to improve MiP outcomes, but still ANC4 coverage and IPTp uptake are low.

Care of severe malaria in pregnant women:

- WHO does not recommend pre-referral treatment with rectal artesunate in pregnant women. WHO recommendations for pre-referral treatment with rectal artesunate target children under 6 years of age only. WHO has issued an information note on Rectal artesunate for pre-referral treatment of severe malaria, which is available via the following link:
<https://www.who.int/malaria/publications/atoz/rectal-artesunate-severe-malaria/en/>.
However, injectable artesunate (inj AS) can be used for treatment of severe malaria in both pregnant and lactating women. Treatment then needs to be completed with a full treatment cycle of an adequate medicines once the patient can tolerate oral medication. and this is a gap.

Questions:

IV Artesunate

- Has there been much confusion over IV artesunate or IV quinine?
 - MSF did a survey and found many people were still using IV quinine to treat severe malaria in pregnant women in 1st trimester
 - IV or IM artesunate should be used through all trimesters.
 - Some people use IV quinine which is not a first line drug.
 - The guidelines are there, but the quantity of artesunate is not enough. It is insufficient to treat malaria in children under 5.
 - DRC conducted a study to mobilize this artesunate for use in pregnant women, but with severe malaria we should use the IV artesunate and this is not available.

Health Provider movement

- Movement of health providers around facilities is an issue. PMI supports pre-service training. How many countries have this for ANC and IPTp?
 - Only about half of the countries are doing this.
 - This should be a routine part of ensuring quality MiP services.
- Is there something that the donor communities can do to minimize the shifting of HCWs from facility to facility or from one section of clinic to another section?
 - Most of the smaller facilities in Malawi only provide ANC a couple days a week and it is a single provider that provides everything.

Quality of care standards

- Do countries other than Nigeria use specific quality of care standards/measurements to look at your child and maternal health programming including MiP?
 - Senegal also has a framework working on quality of care. Quality of care is now considered a major priority for the MOH
- WHO has developed standards for quality of care.
 - Nigeria and Côte d'Ivoire are part of that network for maternal, newborn and pediatric care.
 - There is a tool for quality assessment in hospitals and these are available.
 - Burkina Faso has used the tool to assess their hospitals and there are reports showing the major gaps, especially with neonatal care.
 - You can read more about the quality of care network on the WHO website:
https://www.who.int/maternal_child_adolescent/topics/quality-of-care/network/en/
- Patient-centered, equitable care are issues
- In order to have good quality there needs to be good data so there is a good quantification of needs to help mitigate SP stockouts. You also need to ensure distribution to the last mile.

Treatment guidelines

- WHO Guidelines for the Treatment of Malaria (Summary pages 11 and 12:
<https://www.who.int/malaria/publications/atoz/9789241549127/en/>):
 - 1. Treatment of severe malaria: injectable artesunate should be given for at least 24 hours; once the patient can tolerate oral medication treatment should be continued with an appropriate medicine.
 - 2. Pre-referral treatment: the order of preference of medicines is injectable artesunate, if not available then injectable artemether, and then injectable quinine. For children under 5, the order of preference of medicines is Injectable artesunate, then rectal artesunate, then injectable artemether, then injectable quinine recommended for children under 5

Other

- Highly sensitive RDTs have gone through the Evidence Review Group.
- MPAC has reaffirmed that highly sensitive RDTs are not recommended for routine malaria control or elimination programmes (MPAC meeting report October 2018: <https://apps.who.int/iris/bitstream/handle/10665/275762/WHO-CDS-GMP-2018-24-eng.pdf?ua=1>).
- More data is needed.

Research:

An update on the implementation of more doses of IPTp in Ghana, *Nicaise Ndam*

Takeaway message:

The new IPTp policy is well implemented and utilized by pregnant women in Ghana. Our findings also showed that uptake of 3 or more IPTp-SP was associated with increased birth weight as compared to the previous standard 2-dose regimen. At the same time, this study also reveals that, malaria infections remain a threat outside the window of application of IPTp, mainly before women present to antenatal care with clear negative impact on maternal anemia. Therefore, complementing this strategy with an approach that can protect women from infections in the first trimester of pregnancy is still needed.

Discussion:

- There are younger women going into pregnancy already infected. Can we do more to support women to sleep under ITNs?
 - This category of people is less likely to utilize ITNs. We need to think about alternatives/interventions.
- Can the differences observed between the study sites be more related to the interventions we have deployed?
 - We did not have to intervene and we did not make any intervention at facility.
 - This was an observational study simply because the purpose was to observe what happens in the health centers, to collect the data and to analyze them.
 - The differences we observed are related to the interventions implemented in health centers according to their understanding of the national policy and therefore their way of applying those policies.
- Did the study take into account cofactors in the analysis to limit bias? The study seems to show a predominant role of IPTp on birth weight.
 - We took into account the reasoned cofactors that were not developed for this presentation because the goal was to go straight to the main message.
 - Taking into account as adjustment covariates including BMI, treatments, ANC attendance, parity status of women and many others such as the season was effective and the analysis clearly shows a clinical benefit of taking 3 or more doses of IPTp-SP on the improvement of birth weight in the study areas.
- Are there results from the pregnancy register on the use of artemether lumefantrine in pregnant women by?
 - Previous studies have looked at artemether lumefantrine, but not DP and we are specifically looking at DP exposure in first trimester.

Safety of dihydroartemisinin-piperaquine (DP) for the treatment of malaria during first trimester of pregnancy, Indonesian experience, *Rukhsana Ahmed*

Conclusions:

- It is work in progress with a prospective component following women exposed to DP until 8 weeks post-natal period
- Subsequent analysis will compare birth outcomes by drug exposure groups.

Key messages:

- The hospital records are a rich source of retrospective data to collect information on safety of antimalarial exposure in pregnancy
- Overall birth outcomes in women treated for malaria anytime in pregnancy were comparable to women who received treatment in first trimester of pregnancy
- A limitation of retrospective hospital data is that miscarriages maybe missed and surface congenital anomalies are not adequately documented
- Prospective component of this study will enable to provide additional information on miscarriages and surface anomalies.

Discussion:

- Have you made some kind of analysis on statistical difference those in first trimester vs. those outside of the first trimester?
 - We have not yet done more detailed statistical analysis. Hopefully we can provide that by the end of the year.
- What about congenital anomalies?
 - Unfortunately we are still trying to dig more, but up until now we haven't found any documentation on congenital anomalies in the retrospective data.
 - This is why we are doing a prospective study of women exposed to DP.
 - We hope to provide this information by the end of this year as well.
- Do you have any data regarding stillbirth?
 - We are very interested in finding stillbirths in women exposed to DP in 1st trimester because everyone is concerned about potential harm to the fetus.
 - From the WHO perspective, more than ever before, stillbirths are of interest because the data that was used to develop the revised ANC WHO recommendations show that there is an impact; a new model could have an impact on reducing the perinatal deaths, including stillbirths. Stillbirths is one of the indicators that is properly tracked by WHO.

Discussion of brief: ***Performance of ultra-sensitive RDTs in detection of malaria in pregnant women in Indonesia***

- In countries like India where we are not able to use SP this is very disappointing. There is a huge asymptomatic burden and it's too bad the data on the ultra-sensitive RDTs is not positive.
- Are any studies being done on other ACTs besides DHA-PPQ?
 - There is an analysis by Stephanie Dellicour looking into these other ACTs. This study has been published and is available.
- Are you using data on other ACTS?
 - Previous studies have looked at artemether lumefantrine, but not DP and we are specifically looking at DP exposure in first trimester.

Day 2: Wednesday, 13 February

Community Engagement Panel

Ghana, Madagascar, Sierra Leone, Tanzania



Ghana:

Lessons Learned:

- Intensify community level health education on the importance of benefits of SP
- Increase number of auxiliary nurses deployed to CHPS zones
- Regular deployment and streamline career progression of auxiliary nurses
- Increase and standardize allowances given to community volunteers across programs

What's working:

- Strengthening of existing primary health care level
- Task sharing with auxiliary nurses
- Regular supervision by midwives
- Use of standard registers and reporting forms for documentation
- Collaboration with and use of local NGOs and community volunteers

Discussion:

- Not all regions in Ghana perform the same.
 - There are regions that are doing well in uptake, but are not recording their data well.
- Need for better education involving mothers in law: are there specific messages that are effective?
 - Once you take SP these are the benefits to the mother and to the newborn.
 - If you are a mother in law or husband you can encourage the pregnant woman to go get SP and provide the money for her to do this.

Madagascar:

Lessons learned:

- Make the training materials as simple as possible
- Train CHW peers to be able to coach other CHWs
- Increase supportive supervision
- Maintain monthly review (capacity building strengthening)
- Initiate collaboration with matrons, private health facility and local CSOs

- Give buffer stock to health facility to avoid facility and community stockouts
- Increase supportive supervision
- District health staff to conduct periodic data quality assessments

Next steps:

- Collaborate with all entities involved in pregnancy services to avoid missed opportunities
- Initiate mobile ANC strategy to increase ANC attendance
- Maintain and optimize the CHW peer system
- Strengthen M&E system
- Capacity building strengthening

Discussion:

- CHW peers system: how does this work?
 - The women who know how to read help the others who are unable to read to fill the management tools in order to improve the quality of data.
- Who is delivering the SP at the community level?
 - The MOH distributes the tools and the TIPTOP project supplies the SP that the CHWs are distributing.

Sierra Leone

Lessons learned:

- Community ownership, when achieved, yields best social change results.
- The use of CHWs/Community Health Club members as mobilisers promoted access and utilization of malaria MiP interventions.
- Community engagement yields ownership and increases utilization of malaria services and products.
- Delivery of C-IPTp by TBAs facilitated access to IPTp 1, 2 & 3 in hard to reach communities.
- Integration of MiP interventions into the basic ANC package improved quality of service.
- Monthly meetings held at Primary Health Units with CHWs/TBAs/CHCs help identify issues and improved on performance.

Key Takeaways:

- Community IPTp implementation by TBAs is essential to increasing IPTp3 uptake.
- Community goal setting is a successful approach to promote MiP interventions.
- Formation of community health clubs/women's support groups help to improve sensitization and mobilization.

Discussion:

- How are the CHWs related to the district plans and the more formal health workforce? How are they supported by the government?
 - CHWs are being paid by donors for now.
 - Initially they were not paid because they all had different responsibilities for different programs.
 - The government then made a plan to harmonize the policy in 2012 so now there is a standardized amount for motivation of CHWs.
 - The Global Fund is saying they should be integrated under the resilience health systems strengthening platform.
 - The CHWs are selected by the communities and should be literate and go through a formal training.
 - There are 4 CHWs attached to each PHU.
- For sustainability, how is the government working to ensure that once the Global Fund support for CHWs is finished that they can continue to support?

- The amount given to CHWs is very small so the government should be able to still give the money.
- They are also given t-shirts, bicycles, etc. to help motivate them.
- In Uganda there have been some negative things that have come up about TBAs and providing SP at 13 weeks is a tricky time so the SP should be given by people who are trained to determine gestational age. How much supervision and training is given to the TBAs to determine gestational age for providing SP?
 - TBAs are experienced women working in the community and they practice with health providers how to deliver babies. Their role has changed from delivery to community sensitization and IPTp.
 - During the training the TBAs are given a manual and can do practical training at the health facilities to learn how to assess gestational age.
 - Supervision is a challenge and the TBAs need supportive supervision.

Tanzania:

Lessons learned:

- Education at the community about importance of SP and use of ITNs in the prevention of malaria is important.
 - Trained CHWs are able to follow up with these populations to reinforce messaging on SP, LLINS and early fever detection.

Key Takeaways:

- Current strategy is mapping of CHWs, providing them with an orientation package for community services, and providing additional training for those that are underperforming
- Currently priority of community malaria interventions in Tanzania is only SBCC (e.g.: cinema shows, Gulio la Afya, Radio talks, provision of IEC materials)

Next Step:

- Develop materials and guidelines for iCCM based on best practices from Rwanda and other countries

Discussion:

- iCCM: Is this iCCM for all ages? Is there a plan to separately document iCCM for pregnant women?
 - The country plan is to do general iCCM, including pregnant women.
- What happened in 2015 where it shows 0% of LLINs were issued to pregnant women?
 - We were in a transition period and no nets were distributed at that time.
 - The solution is education. We spend a lot of money on procuring and distributing the nets, but very little on educating pregnant women. This is why Tanzania is using CHWs for sensitization.
- How have you managed the training for CHWs on MiP when there are so many other technical areas like family planning?
 - There is an intervention package that includes the key messages from all technical areas that CHWs should be delivering. It is an integrated program so that CHWs are well versed on all of the areas.
- There are many issues around cultural norms and you are using radio. Do you have plans to use interpersonal communication? Are you planning on empowering CHWs with talking points targeted toward the social norms identified to change behavior?
 - In Tanzania there is a score card which has messages/key talking points to be given to address the social norms. There is mentoring for this on a quarterly basis.
- In Mozambique they did a study looking at experiences/influences of key behaviors around malaria. Gender was a strong factor. How are you engaging key community stakeholders

especially around gender decision making for ANC utilization? How are you shifting these norms?

- In Tanzania they promote pregnant women to come with their companion/husband/partner and when they do they get priority/fast-tracked in ANC services. Then they can also check on HIV, syphilis, etc.
- In Sierra Leone there are health committees with bylaws that women need to attend ANC. There are also facility management committees with the town chief as the chairperson to link the facilities and the communities. They help promote men to attend ANC with their wives.

Group ANC: Koki Agarwal

Conclusions:

- First study to suggest G-ANC in low-resource settings (Nigeria, Kenya)
 - Improves IPTp-SP coverage
 - May improve ITN use for infants – critical (malaria responsible for 61% <5 mortality in Nasarawa)
- No clear impact on malaria diagnosis
- Results support further study of G-ANC as platform to improve coverage of other interventions

Future Directions for G-ANC:

- Can model be scaled? Can it be further optimized?
- Appears sustainable for now...
 - All 10 intervention sites continue to offer G-ANC after conclusion of study and with no additional financial support
- Phase 2: Postnatal mothers, 1st year of life for infants
 - Post-partum family planning initiation/continuation
 - Breastfeeding
- New settings, including Ethiopia
 - Harvard ENAT study (PI: Lee) – birthweight outcomes

Discussion:

G-ANC vs. current ANC format

- How does G-ANC differ from what we often see at ANC where there is a waiting room where women are getting education and what were they talking about that was different?
 - The biggest difference is looking at this as being centric on the relationship/care between women and care provider. Because things are repeated and discussed and they have an opportunity to reach out to each other they have a much better understanding. The relationship between the woman and the provider is a very key point as it makes the women more comfortable connecting and discussing.
 - They also do nutritional counseling and offer more opportunities to look at other interventions and empower women.
- This is all facility based, correct?
 - Correct.

Study Measurements

- Malaria outcomes: if it is only measuring by RDT, unless you've had SP in last 3 or 4 weeks, it will not show impact, so then maybe in future you should consider other means for measurement. In Phase 2 it would be interesting to consider differences if you are comparing between 2 and 4 doses.
 - Most of the recent data is looking at different drugs or no IPTp vs some IPTp.
- Did the study look at febrile episodes throughout the pregnancy rather than just at the outcome at the end?

- We can look and see if they were measured and see how they compare with individual diagnoses of malaria.
- Were estimates adjusted for any confounding factors?
 - The team is in the process of doing further analysis related to the primary outcome, birth in a health facility, to report findings adjusted for age, parity, education, religion, etc.
- Did the study measure infant survival?
 - The study in Ethiopia will be looking at infant survival.
 - In Rwanda they will be looking at clinical outcomes around preterm birth and 28 day perinatal mortality.
- The study was powered for 15% difference between arms at endline in facility-based deliveries
- IPTp: we need an outcome monitored. Can the study team do placental malaria assessments? Looking at febrile episodes points mainly to use of LLINs.
 - There was a recent study done in Kenya showing that IPTp works. This study is starting from the principle that IPTp works. This is an operational study trying to look at uptake.
 - We have a WHO recommendation to scale up IPTp because it works and should move forward with this information. The interventions included in the study were agreed upon and the question is at what coverage level.
 - For example we want to see better reporting of individual health outcomes: blood pressure, delivery of folic acid, etc.

Government involvement

- What work was done with national governments to ensure they can scale this up outside of a research setting? Is it feasible to implement this model in all facility settings? In some settings there isn't a skilled professional who can organize the group and provide the correct information. Is there a minimum standard criteria on where this can be scaled up?
 - Each of the visits is pre-determined so there are appointments set up so it can be the same midwife doing each visit and it can be optimized for the provider and the woman.
 - The feasibility will be the next phase, looking at how to go out of the research setting and see how it can be implemented. This is one of the things that PMI is hoping to do to expand the coverage and make solid recommendations to the ministry on how it can be done.
- This is a great meeting because it includes implementers, donors and country Ministries of Health are all present. The point about doing the feasibility study next is good to hear. Let's do a study and then see how we can implement it. We need to have the government voice from the beginning about what the minimum necessary package is to support this. In the absence of having a midwife available, is there a CHW who can support this intervention and how does that impact feasibility?
 - The national and sub-national group were involved in these studies and we hope that ministries feel interested in how to expand this approach.

The ASPIRE Trial (Zambia), Matthew Chico

Key Takeaways:

- IPTp-SP is protective against adverse pregnancy outcomes attributable to malaria and curable sexually transmitted and reproductive tract infections (STIs/RTIs).
- Among HIV-uninfected women in Zambia, 37% were co-infected with malaria and curable STIs/RTIs, 25% had curable STIs/RTIs only, and 19% had malaria only.
- The leading curable STIs/RTIs are trichomoniasis and bacterial vaginosis, for which metronidazole is indicated in pregnancy.
- In Zambia, the 'ASPIRE Trial' (*Aiming for Safe Pregnancies: Reducing Malaria and Infections of the Reproductive Tract*) is designed to reduce the burden of malaria, trichomoniasis and

bacterial vaginosis by comparing IPTp-SP versus IPTp-SP plus metronidazole versus IPTp-DP plus metronidazole. The trial will enrol 5,436 women HIV-negative pregnant women (all gravaidae) between 16-28 weeks-gestation.

Discussion:

- How frequently do you give DP? We're now talking about up to 8 doses of SP during pregnancy.
 - Under WHO guidelines for IPTp-SP, 8 doses of SP is too many. IPTp should be administered during the second and third trimesters at no less than monthly intervals. DP would be no different. In the ASPIRE Trial, we will enroll women at ANC booking who are between 16 and 28 gestational weeks and provide as many doses as the gestational age will permit. We expect women to receive on average 4 doses.
- Are you looking at microbiome structure before you introduce the antibiotic?
 - Yes. We will collect the first swab before any treatment administration and then take swabs at each ANC visit thereafter to observe changes.
- With efforts to increase women taking more doses of SP, do you think this will lead to an increase in drug pressure and drug resistance against SP?
 - That is possible and surveillance is needed, but increasing the provision of SP will NOT likely result in greater drug resistance because over all use in the population at large would still be relatively small
- One word of caution on resistance discussion with DP, in Cambodia they developed resistance quickly. This is something that needs to be considered as well.
 - The example from Cambodia
- What if SP use promotes drug resistance to other sulpha-based drugs?
 - Until there is a vaccine that protects against placental parasitemia, we need to scale up the use of SP. There is always a theoretical chance that SP will select for resistance against other sulpha-based compounds, but there is no evidence that has occurred in the 15 years since the WHO has recommended IPTp-SP.
- For areas where we don't use SP would we be able to draw any conclusions for RTIs/STIs?
 - Those who are working in non-malarious areas where there are RTIs, the primary point of entry would be trying to work out of syndromic management of the RTIs and towards point of care testing. Even though there is evidence that SP is protective against adverse pregnancy outcomes attributable to STIs, I don't know if governments would welcome IPTp-SP for STI control. I think they would opt first for screen and treat.
 - This is a new pattern/frontier we should collectively consider. If SP is something we are championing, IPTi is a natural segue.
- What do you consider the potential of this study [the ASPIRE Trial] for informing policy change?
 - Given the high burden of co-infection in sub-Saharan Africa, we are hopeful our research will inform policy change. We need to show effectiveness first, that SP plus metronidazole or DP plus metronidazole is superior to SP alone. We have built in cost benefit analyses in the trial, along with discrete choice experiments that will involve health care providers and pregnant women that will quantify the degree to which the standard of care or the alternatives are preferable. This sort of information will inform the potential scalability. In these ways, we have built into the trial key sub-studies that will inform policy and implementation.
- Are you going to study the impact of SP on bacteria causing asymptomatic infections?
 - We have sub-studies built into the trial that will investigate the in vivo and in vitro sensitivity of non-malarial infections to sulphadoxine.

MiP M&E, Julie Gutman

Overview of MiP M&E Brief:

- MiP Monitoring and Evaluation Framework and MiP Indicators
 - Routine indicators- collected from the health facility/ routine data
 - Reflect what happens at facility level (uptake); depending on access to care may provide a biased view of coverage, but if access is very high, then uptake may approximate coverage
 - Periodic indicators- collected from household cross sectional surveys
 - Provide a better indication of unbiased community level coverage, but are expensive and only conducted periodically
 - Understanding different data sources/ denominators
 - **WMR- Modelled coverage**; Denominator for IPTp & ANC coverage = Total number of pregnant women **eligible** for IPTp, calculated by adding total live births from UN population data + spontaneous pregnancy loss after 1st trimester
 - **DHS/ MIS**: Denominator for IPTp & ANC coverage = Total number of surveyed women **with a live birth** in the past 3 or 5 years (Excludes women with pregnancy loss who may be less likely to attend ANC/ take IPTp)
 - **HMIS**: Denominator for IPTp & ANC coverage = EITHER estimated number of pregnant women in facility catchment area OR pregnant women presenting for ANC1
- Core Routine Programmatic MiP Indicators
 - Percentage pregnant women attending 1 or more ANC visits
 - Percentage pregnant women attending 4 or more ANC visits
 - ANC attendance in the first trimester
 - Percentage of pregnant women attending ANC who received IPTp1, IPTp2, IPTp3 under direct observation
 - Percentage of pregnant women attending ANC who received an ITN
 - Percentage of pregnant women tested for malaria who tested positive
 - Percentage of pregnant women testing positive for malaria who were treated
- Data Visualization and Data Use
- Practical Tips for M&E of MiP Programs and Services

Discussion:

ANC Indicators

- Denominator for indicator of ANC attendance: this should be the estimated number of pregnant women in catchment area.
 - NOTE that the estimated denominator should give a better idea of overall coverage similar to DHIS, but it is an estimation, and may be quite far off depending on how long it has been since last census and how much in/out migration there has been.
 - The WHO list has a different denominator: Total # of women aged between 15-49 who have a live birth in the same period.
 - It seems both of these are the same estimations—the words are different, but the point is the same.

IPTp Indicators

- The M&E brief recommends using ANC1 as a denominator, while WHO M&E manual recommends estimated # pregnant women. Using ANC1 provides a better estimate of uptake at the facility level, while the estimated # pregnant women estimates coverage.
- Not all countries record IPTp1, 2 and 3 in HMIS.
 - Some have dropped IPTp2 as they take on IPTp3.

- In Senegal we have the files, but severe cases are hospitalized.
 - We have information regarding diagnosis, but we do not have the proper information about how to treat severe malaria in pregnant women so the case should be referred and the treatment will take place at the hospital and there's no duplication.
- In Mozambique the MiP data is part of the HMIS.
- Question to consider: Is this (tracking completion of the referral) something CHWs could assist with or will that overburden CHWs?
 - We know pregnant women are especially vulnerable and this would be good data for advocacy around MiP.

***C-IPTp Panel, Elaine Roman & Baltazar Candrinho
Burkina Faso, Mozambique, Nigeria, Senegal, Sierra Leone***



Overview:

C-IPTp presents an opportunity to:

- Increase coverage and reach of pregnant women
- Bend the curve on malaria in pregnancy
- Improve maternal and newborn health outcomes
- Build the evidence base for WHO and countries

Transforming Intermittent Preventive Treatment for Optimal Pregnancy (TIPTOP) Project:

- Aims:
 - Drive impact in target countries and regionally to help countries significantly increase coverage
 - Bend the curve: reaching the hardest to reach
 - Steer global, regional and country level advancement in malaria in pregnancy
- Phase 1 Achievements:
 - Baseline research conducted
 - Implementation commenced
 - Quality Assured SP procured in all countries
 - Data collection underway
 - Engagement with key stakeholders at all levels

Mozambique:

- In Mozambique the first dose of SP must be at the health facility.
- There are only 42 CHWs in the Phase 1 district so they are working closely with the lay community counselors who help to refer the pregnant women to the CHW.

- The tools being used are based on existing tools with a few adapted columns specific to the community level data.
- Each month there are supervision visits with MOH and Jhpiego to ensure quality of implementation and data.
- They are also doing a lot of SBCC to sensitize pregnant women and community leaders for the project.
- Implementation recently started so there is no data to share at this time, but next year we will be able to do this.

Sierra Leone:

- In Sierra Leone, C-IPTp began in 2013 because IPTp is part of documented essential care.
 - There are many hard to reach areas and they had to ensure the missed opportunities were being covered. This is why C-IPTp is important in Sierra Leone.
- They did consultative meetings with stakeholders and community sensitization meetings to commence IPTp.
- They selected TBAs who have been doing deliveries at community level to distribute the IPTp.
- TBAs do a three day training at the health facility and it includes practical administration of SP.
 - They did a refresher training in 2018 to continue the administration of IPTp to communities.
- At the end of the month the TBA reports to the PHU and submits the monthly data.
 - The PHU staff assess the data and distributes additional SP.
 - The PHU staff also performs monthly supervision visits to observe the work of the TBAs in the community.

Senegal:

- In Senegal we noticed there was a problem with IPTp. The health districts looked at the data points and they wanted to improve the coverage rate in the country.
- They started C-IPTp in 3 districts as a pilot.
- The first dose is taken at the health facility under supervision of qualified staff.
 - All women taking the first dose are registered.
 - If women have not yet had their first dose, then they are referred to the health facility for ANC and IPTp1.
 - Then the following doses can be given by a volunteer chosen by the community
- Volunteers need to be able to read/write in French.
 - After being selected the volunteers are trained for 3 days to provide services of care and sensitization.
 - The volunteers make home visits and discuss SP/ANC with pregnant women, husbands and mothers in law.
 - The data the volunteers collect is shared with the health facility providers.
 - There are places in the tools where the IPTp doses are listed.
 - Every month the nurse/midwife meet with the community volunteers.

Nigeria:

- In Nigeria, IPTp is very low.
- They have CHWs who mobilize pregnant women to attend ANC where they get a package of services, including IPTp.
- CHWs mobilize pregnant women and encourage them to attend ANC.
- Through TIPTOP, CHWs can give the first dose of SP.
- Health providers are conducting monitoring and supervision visits to see the work of the CHWs to ensure quality.

Burkina Faso:

- In Burkina Faso the distribution of IPTp at community level was pilot tested as a feasible study.
 - The intervention was done in 3 districts in 70 health facilities.
 - In each district we had control and intervention areas.
- The study has gone through various stages:
 - First there was a baseline survey.
 - In villages where they didn't have CHWs they recruited animateurs.
 - Then they did the training and implemented the C-IPTp
 - Then there was an endline survey.
- Approach: CHWs identify the pregnant women in the communities and sensitize them to go for the first ANC visit.
 - In this first ANC visit the health facility worker provides the first dose of SP if the woman is eligible.
 - After this work the CHW can provide the other doses in the community.
 - They had monthly meetings to review the data collected by the CHWs and to resupply the SP to the CHWs.
- Results: The results showed that women would go to the health facilities for their first ANC and they are aware that there are CHWs in the villages with whom they can discuss their health problems.
 - The coverage of ANC 4 has improved from 62% to 77%.
 - IPTp4 also improved from 24% to 47%.
- There were favorable factors:
 - The health system used health agents who benefitted from a monetary incentive so the study paid the health providers.
 - There was also permanent availability of SP and no stockouts so good conditions for this study.
- Conclusion: IPTp at community level is doable and we are doing it and extending it to the control areas where the study was conducted.
 - We want to lobby WHO to make a recommendation allowing the country to extend the intervention to the whole country.

Discussion:

- In Sierra Leone where CHWs are trained for 3 days, are they able to correctly determine gestational age?
 - The TBAs are experienced with deliveries and they know how to palpate the pregnant women, however, they are using fetal movement to determine eligibility for SP.
 - In Nigeria and DRC through TIPTOP they also can give the first dose of SP. The idea is to try to identify pregnant woman earlier in pregnancy to refer her to ANC, but in the case where quickening has already occurred she will be given SP and then still be referred to ANC.
- Are CHWs trained to give ITNs as well?
 - In Sierra Leone the CHWs do not distribute ITNs. These are only given at ANC to reinforce ANC visits and during mass campaigns. CHWs promote the use of ITNs.
- What specific actions were put in place to sensitize pregnant women to go to ANC?
 - In Senegal, at the village level they do sensitization with discussion groups and they group husbands and talk to them about encouraging women to go to ANC and get IPTp.

- In countries where CHWs provide the first SP dose, does this have a secondary effect on other medicines they are taking? Is there a checklist when you refer pregnant women to ANC.? Is there any checklist to confirm if the pregnant woman is sick?
 - The midwife makes a list of pregnant women in their village and the date of taking the doses and then indicate when they need to get the subsequent doses.
 - The CHW then follows this calendar to provide the other doses and during this time they look at secondary effects of SP and other illnesses. If there are doubts they will transfer this woman to the facility. All women who have been referred by CHWs to ANC do not have to pay a consultation fee.
 - In Nigeria, if a woman is sick she will be referred to the health facility by the CHW.
 - If there is a woman who didn't take the second dose because she is not feeling well or because of secondary effects we transfer the woman to the health facility. In case of doubt she is referred to the facility.

SWOT Analysis:

WG Mission:

- Provides strategic advice on best practices for scaling up interventions for the prevention and control of MiP towards the achievement of global targets
- Promotes and supports WHO strategy to control MiP:
 - Insecticide treated bed net use (ITN)
 - Effective case management
 - Intermittent preventive treatment (IPTp) in areas of moderate to high malaria transmission
- Priority areas:
 - Alignment of RBM partners on best practices and lessons learned in MiP programming to help achieve higher coverage in MiP interventions globally
 - Advocacy through the development of key tools and products targeting policy makers and program managers with the most up to date information in MiP programming
 - Supporting research and documentation of best practices and lessons learned
 - Coordination and collaboration with other RBM mechanisms
 - Promoting partnership between reproductive health and malaria control programs

Discussion:

Strengths:

- Engagement from a variety of MiP partners with technical depth in MiP; Depth and breadth of expertise among members
- Strong commitment to MiP
- In Tanzania, the MiP WG has been very good because the chair is from RH and most stakeholders make the time to attend the meetings. Jhpiego is the Secretariat getting people come to the meeting and who will take that role if Jhpiego leaves?
- In Uganda there is a MiP WG and there is a terms of reference to guide stakeholders on what should be done. They help share stock status and discuss progress on different indicators.
- In Nigeria, the MiPTWG was revived through TIPTOP.

Weaknesses

- Not enough focus on other forms of prevention aside from IPTp (bednets, vector control, etc.) and also case management for MiP.
- Lack of power to initiate change: There have been many changes in recent years to WHO policy and this is through collective efforts like these MiP WG meetings. Yet despite all of the policy

changes there have not been big changes in uptake so there's still a real need to engage pregnant women.

- The change in the RBM structure has made WGs less important. The mechanisms that WGs used to coordinate in the past are gone and now there are no mechanisms.
 - The harmonization WG was replaced by the CRSPC and all WGs participate in this.
 - There are two yearly meetings each year. There is no funding for participation, but the information will be sent as soon as the dates are confirmed so those who are on the mailing list can plan accordingly.
- We are approaching the new cycle for GF replenishment in 2020. Countries need to include language to provide funding for the activities of the MiP technical working group within their GF grants.
 - There needs to be a MiP Person within the TWG. RBM will want someone from that MiP core group represented.
 - Within the GF proposal there needs to be a justification/argument to include it.
 - RBM can provide a consultant to help with a gap analysis which will strengthen proposals.
- How do the findings from all of the regional/WG meetings feed upwards into the RBM Secretariat for influencing policy?
 - All the proceedings from the meetings are published on the RBM website and are shared with the RBM board.
 - Issues regarding MiP need to be brought up during the CRSPC so that they can come to the attention of RBM.
 - Elaine and Viviana have been participating in the CRSPC meetings, especially on the advocacy side.
 - What we need to think about moving forward is how do we better foster/better engage across WGs?

Opportunities

Support creation/revitalization of MiP Technical Working Groups

- MiP WGs in Countries:
 - Make country WG in country with formal scope of work
 - How can RBM help to get these WGs started?
 - Representation of MiP WG via RBM process to support to GF new cycle proposal
 - Share MiP WG TORs
 - Gap analysis for Global Fund proposals
- The Nigerian MiP WG is trying to coordinate with the RH department to work on adopting the ANC WHO recommendations and the RH department has adopted the recommendations, but the NMCP is not yet on board. So the NMCP is hoping the RH can share some policy documents with them.
 - We've seen in the past with IPTp that when there are different policy documents put forth with different wording by the NMCP and the RH departments then there is a lot of confusion.
 - This ANC adoption really needs to be driven by RH, but with support from the NMCP to ensure early administration of IPTp.
- In Sierra Leone they have a technical management committee where all NGOs and stakeholders meet quarterly to try to harmonize policies/documents.
 - Sierra Leone did have a WG and there were no resources to provide refreshments/transportation so the WG has died out.

- PMI always works with the national malaria control program and RH when they do the Malaria Operational Planning (MOP). They always ask if there is an MiP or ANC WG that brings the two groups together and how PMI can support them.
 - So for countries working with the PMI Team, this is something to consider during the MOP planning to request that this type of WG is supported by PMI or PMI partners.
- Operations research: can this WG play a role in helping countries think through important research priorities/opportunities? Perhaps we can help with the topic/content development and the importance/relevance to the global community.

Threats

- Keeping the focus on MiP
 - We have to demonstrate we can make the change happen at the field level.
 - If we continue to see IPTp and ITN at such low levels the focus on MiP will be lost.
- WHO is supporting a number of countries to adopt and adapt the new ANC recommendations and in one country they were discussing the situational analysis with stakeholders and MiP came up as an important issue because the providers were saying why can't we use SP? The Minister was chairing the meeting and they had to call the malaria person and the response was that they thought it was about resistance.
 - Integration should be at all levels, definitely at service delivery level, but also at national level to have this as part of the package that needs to be considered for the country.
 - We should advocate for MiP to be part of the package, but also to have the integration in terms of implementation.
- Suggestion: We should have countries share their experiences in coming meetings in terms of integrated service delivery.
- What is the scenario for WGs after the RBM restructuring in terms of having funding support for different activities, including participation from key countries?
 - Roll Back Malaria has fewer and fewer resources and these are reserved for very specific activities in their work plan.
 - It is up to the MiP WG to determine our SOW and energy and support ourselves financially.
 - Other organizations have picked up funding support for the WG to hold the meeting, to produce things, to have country representation at meetings.
 - The Global Fund, PMI, Unitaid supported this meeting and country participation. Everyone else is traveling on their own resources.
 - RBM has southeast/east African meeting and a central/west African meeting
 - Money for groups is limited (5 people per program)

Low transmission

- The changing epidemiology in malaria is also a threat/opportunity. When you're looking at the prevention of malaria we need to have some items for when prevalence becomes very low, etc. What policies will we advocate for around MiP in these countries around IPTp, case detection, case management, etc.? WHO has an elimination framework, but it doesn't include information specific to MiP.
 - The reason WHO hasn't commented further on MiP in elimination settings is because we tried to determine a level at which IPTp is not effective. Down to 1% data shows IPTp still offers some protection.
 - There was a meeting In June, 2018 in New Delhi there was a meeting focusing on low transmission and elimination with a specific session on MiP in countries outside of Africa.

- Some countries have moved towards elimination, but then have experienced resurgences.
 - There were Evidence Review Groups on the threshold to discontinue IPTp, but there are instances where countries stopped IPTp and then cases have since increased again. This is why WHO recommends countries should not discontinue IPTp until they have complete disruption of malaria.
- For IPTp, Indonesia is a very specific case. In the meeting there was a recommendation that they could not recommend IPTp outside Africa. Overall they are using a screen and treat policy at every first ANC visit.
 - If you screen and treat you will always miss tomorrow's infection so this is why the screen and treat strategy has not been better than a sub-optimal SP strategy. There's a two prong objective to clear infections now and protect against infections.
 - The treatment is part of it, but there is the gravidae associated epidemiology. Primagravidae may have fewer infected bites, but when they become pregnant again they will have acquired less immunity to carry into their next infection. We would be observing over a 5, 10 year period where the semi-immunity that women would normally be acquiring aren't, so multigravidae are like primagravidae at elevated risk.

Day 3: Thursday, 14 February

***Country Panel: SP Supply
DRC, Mozambique, Uganda, Zambia***



DRC:

Lessons Learned:

- Strong coordination with PTF (Financial and Technical partners) limit risk of stock ruptures in district/ZS (Health Zone)
- Rigorous CMM (Monthly Average Consumption) tracking can reduce the number of days of SP stockout

- Good management of the supply chain with well estimated quantities may reduce the risk of ruptures
- Coaching and supportive supervision improve team drug management skills

Key Takeaways:

- Need to master drug requirement estimations at all levels (a general census may be necessary)
- Assure regular and timely drug supply
- Train providers in drug management and ensure formative supervisions
- Implement a strong SP stockout alert system
- Provide necessary logistics means for drugs deployment in provinces
- Reinforce advocacy for MoH/Government contribution into MiP activities
- Reinforce supportive supervision of providers
- Perform regular follow up of drug stock and management

Discussion:

- In DRC we conducted an analysis and they said there are a lot of drugs at central level, but then the drugs are not in the districts and at the health facilities. We have to give them money to procure drugs directly and when we went there things did not improve. We want women to be cared for and this lack of harmony is with our central policy. The orders should go to the central offices where the orders are validated and then they send the drugs to the province. Then the province will take the drugs directly to the health facilities and send proof to the central offices.
- What is the relationship with RH and NMCP? Is it moving forward in terms of funds and distribution of funds, planning of activities, etc.?
 - The relationship is good. I work for malaria control and the representative of RH could not come. We have WGs with malaria and RH and we have a Director in charge of specific groups—women, children and adolescents. That is the Directorate that deals with malaria affairs. We work under the authority of this Director and he manages all groups so we work together.
- Do you believe the models of the projects that are being done in DRC, Global Fund, TIPTOP, etc. can be expanded? Are there advantages from the MOH side—what do you think about these projects?
 - There is a project running with the support of the World Bank. It brought a significant amount of experience—the focus is on quality, not quantity. Quality takes a long time to achieve, but we agree with the results that were shared and we want to try to move forward.

Mozambique:

Lessons Learned:

- Implementation of a new distribution system where we reduced the number of levels from 4 levels to 3 levels increased and decentralized warehouse capacity
- Development of integrated systems and tools helped to ensure visibility, accountability and product integrity through the supply chain through the use of SIGLUS
- Improvement of routes and volumes of cargo and of transport costing is achieved through Last Mile Project
- It is possible to improve the quantification at central level

Key Takeaways:

- Improve data visibility especially at HF level – this will facilitate data analysis and triangulation, creation of early warning mechanism and optimization of stocks
- Operationalization of the PELF (Pharmaceutical logistics Strategic Plan) should help bring about improvements in warehousing and in the transportation system

- Improved coordination is needed as is the regular monitoring of distribution plans, orders and shipments and available funding
- Supervision and the implementation of on-the-job training, especially for the clinical staff involved in SP management is key.

Discussion:

- What is the factor contributing to the decrease of ANC attendance from ANC1 to ANC4?
 - ANC1 coverage is quite high because women come to receive their cards and a certain package of services. However health facilities are often long distances away and it is hard to motivate women to come back for additional ANC visits. We are trying to introduce waiting rooms where women can wait and stay there until delivery and can receive visitors.
 - A strong component of TIPTOP is to encourage women to go to ANC and we believe we will get better coverage moving forward.
- What is the contribution of the Mozambique government to SP provision?
 - SP is one of the drugs that the Mozambique government procures. ACTs and other drugs for treatment are procured through the Global Fund.
 - The government has a budget that is distributed at the provincial level and the districts have their own budgets which should be used to pay for distribution from the central level, but the issue is the transportation of those drugs. Often the only car at health facilities is an ambulance.
- How does SP supply work within the private sector?
 - Most of the care in Mozambique takes place in the public sector except for in the major cities like Maputo where there are more options for private care.
 - The private sector does not have much weight when it comes to ANC and SP availability

Uganda:

Lessons Learned:

- Health Facility Managers prioritize SP procurement better when they appreciate the significance of IPTp.
- Lack of a tracking system results in frequent stockouts
- SP supplies for especially the higher level facilities is not based on consumption but available funds.
- Making SP a free commodity will increase its availability to pregnant women.
- Stockout levels are not alarmingly high, but what exists are overstocks in some facilities (lower level) and understocks (high level)

Key Takeaways:

- At a district level, weekly “malaria favorite folders” have been created in DHIS2 accounts with SP stock balances as one of the variables.
- Weekly desk data review is performed to track SP stock balances by ANC site.
 - The platform is used to monitor sites “having” and “not having” SP and redistributions are done to avert stockouts

Discussion:

- How are the supplies of ACTs and RDTs managed? Are they managed similarly to the SP?
 - ACTs and RDTs are monitored the same way by the Case Management WG.
 - The stock status is presented to the CMWG and the procurement supply chain officer provides updates.

- We have had challenges with the iCCM commodities, but on the malaria side we have put in place strong monitoring systems for the iCCM commodities at the community level and we hope to replicate this for community IPTp when it happens in Uganda.

Zambia:

Lessons Learned:

- Encourage Districts to use the 4% monthly GRZ drug grant during the period of stockout.
- Prioritize purchase of SP from 4%GRZ Monthly grant.
- Improve record keeping so as to trigger the pull system by training health providers in timely, completeness, and accuracy in the capture and use of data
- Provide technical support supervision, mentorship
- Provide in-service training
- Make LMIS electronic

Key Takeaways:

- Zambia ensures that SP for IPTp is available at health facilities. This builds confidence in the community and encourages them to attend ANC services, thus improving uptake of IPTp.
- Zambia provides IPTp-SP at ANC contacts
- IPTp-SP is part of an integrated package of ANC services which are provided free of charge

Overall Discussion:

Coordination on SP across departments

- It's been helpful to hear the limitations and many of you are doing a lot to address the challenges. What are we doing to address the issues of getting SP into the country? What can you do to help coordination with other sectors of the government (finance, customs, etc.) that sometimes delay the process for 6 months or more?
 - In Uganda the government supports the procurement of SP and they need to work together with other departments. We need to apply what we applied for the LLINs to work together with finance, national medical stores, etc. The issue is identifying a supplier and they want to get several funders. They have a Uganda malaria fund and this will go a long way to support getting a supplier and the supply.
 - In DRC the departments that fight against malaria are not that big. The pharmacy department is the one that updates the policies. We quantify under the guidance of the Pharmacy department and we work together in quantifying with the department of medicine. The quantification should start at the district level and then it moves to the provincial level and then finally to the national level. What is happening is that we do not have a good understanding of the denominators. This is the bottleneck. Currently we are holding meetings to avoid stockouts. I wrote to the national director for help and he asked the Minister and they agreed to support us. We also identified the medicines we needed and the Global Fund helped us to get these medicines up to 2020.

Quantification of SP

- Ghana also gets the stocks from the central level and try to move it to other regions when there are surpluses. We do trainings on quantification, but what else can we do because it is very frustrating that central medical stores have SP, but they don't prioritize it because it is free and they are more interested in drugs that they can charge for. We need facilities to request the quantities they need.
 - In DRC we face the same situation. SP is not prioritized and neither are vaccines and the service providers prefer to give attention to medicines that are more profitable. I believe that if we find a method to solve this problem we can have good quantification. Are we paying attention to all of the factors for quantification? The central stores does the quantification for SP and all other medicine so if we work with the central level to

- solve this problem we might identify other factors that have an influence on the quantification. I think that SP is a concern now because we always have stockouts.
- Uganda has trained and trained people on supply chain management---over 80% of health care providers. They have the knowledge but they are reluctant to adapt and adopt. Uganda created an indicator and targeted districts on testing rates and they saw an improvement on this because districts don't want to appear as low performing.
 - What Uganda is planning to do is to create an indicator that monitors the utilization of data to track stock status of SP and other commodities. Once we have that indicator and districts know their performance will be based on that, they will put pressure on providers to make sure they track quantities right.
 - Do the RH and MCH drugs face similar challenges or are these challenges specific to SP or malaria drugs? If it is specific to malaria drugs and SP, then how can we learn from the other departments?
 - These issues are not unique to SP.
 - How are you quantifying the additional doses of SP? Are you increasing quantification? It sounds like every country is using a different calculation/estimate.
 - Uganda uses the estimates for number of pregnant women and then bases stocks on 4 doses of IPTp.

MMV Current and Potential Future Contributions, *Maud Majeres Lugand and Myriam El Galool*

Current Contributions:

- Generating Safety Data in Pregnant Women
 - MMV is supporting a study in Indonesia with the Liverpool School of Tropical Medicine in conjunction with the Timika Research Facility, Indonesia, to enrich the growing body of safety data on pregnancy outcomes associated with DHA-PQP exposure in first trimester
- Post-Marketing DHA-PQP studies in malaria in pregnancy
 - Cardio-safety of DHA-PQP and PK of PQP amongst pregnant women in Tanzania – LSHTM
 - Safety and efficacy of DHA-PQP for IPTp of malaria in HIV-infected pregnant women in Gabon and Mozambique (MAMAH study) - ISGlobal
- Unitaid supply grant– filling QA SP Gap
 - Objective 1: secure QA SP market by bringing 2 new manufacturers of finished products to WHO prequalification
 - Objective 2: development of packaging promoting IPTp, in the context of community IPTp

Future Contributions:

- Consider Developing PYR-PQP
- Pre-requisites to administer new investigational drugs in pregnant women in pre-marketing setting, as per FDA draft guidance:
 - 1st Pre-Requisite: Frontload Reprotox Studies to Prioritize the Development of Drugs Safe for Use in WOCBP and Pregnant Women
 - Strategy to Address 2nd Pre-Requisite: To be discussed with HAs in the Countries
- Proposed Clinical Strategy to Inform Drug Label in Pregnancy

Discussion:

- These advances are going to change the space for pregnant women.
- Leaflets:

- If you set IPTp6 as your target, maybe countries will achieve 3 or 4. It's great this leaflet is showing 6 doses.
- Are these leaflets available?
 - This was done in collaboration with TIPTOP so some of the tools are being used within the project.
 - MMV is going to organize some follow up assessments. The purpose is to validate the content and then share the results with Universal and SwissPharm which may produce new information.
- Registration:
 - Is this leaflet supposed to be enclosed in the package because that changes the product and requires new registration and increases the cost?
 - In some cases, Guilin in the past developed patient cards for SMC and it was inserted in the box. I don't know where they are now in terms of adding the leaflet within the box. It could be available separately but there is a high chance that the commodities are there, but not the information so ideally it would be great to have it included in the box.
 - Originally they were thinking of having the drug packaged individually, but there is a lot of cost associated with that.
 - The registration process needs to be factored in. If this is not cross cutting across all manufacturers then this is going to be a challenge with registration.
 - MMV is working with the national drug authority in Nigeria and has been engaging with them throughout the process.
 - In BF they had an issue with SMC drugs because the instructions were on the box, but the thought was that this was too promotional.
- Other manufacturers:
 - In Nigeria, we have more companies that produce SP locally. WHO requested Jhpiego to import the prequalified SP for TIPTOP which meant they couldn't use the locally manufactured SP. We requested Jhpiego to find 1 or 2 local companies producing SP so by the end of the project they can produce prequalified SP.
 - This project is within TIPTOP and MMV invited 12 local manufacturers in Nigeria to participate in the proposal process for producing SP.
- Tablets/Effects:
 - For a pregnant woman it is difficult to take drugs because they are worried about the effects. Is there a way to make SP into one tablet instead of 3? This would help with uptake.
 - It is quite a challenge to reduce the number of tablets as the current SP tablets are already quite large.
- Validation:
 - Has this been validated?
 - Validation is a communication instrument. The work is about what are the key messages that should be present, particularly when it comes to community distribution. We know literacy levels are very low so we want to validate the content in countries and after usage in the field we may refine it.

Proposed Clinical Strategy:

- It is good to see MMV is thinking proactively about adjusting the doses for pregnant women.
 - PYR-PQP is generally safe based on the available database. We don't have sufficient number of pregnant women exposed to that drug already.
 - It would be great if you have funds to do this simultaneously, but we would want to see a bit of individual data in the target population.

- It's not one or the other. We are considering both, but we still have to run proper studies in the general population to identify the correct dose and then extend it to pregnant women.
 - The original thinking is that these drugs are clean so they would be fantastic for pregnant women, but they could also be used for SMC or MDA.
- Would you need additional data before you can validate that this product can go into a medical trial for pregnant women?
 - The full package has been conducted for both drugs and I'm not sure we will need to do combination DOT studies. At this time, MMV is not envisaging increasing the currently marketed dose so from a CMC formulation perspective we do not consider the viability of this is to increase the doses.

Consent:

- It's very important to include pregnant women and children in clinical trials, but how do you obtain proper informed consent for testing drugs in pregnant women? How do you explain to pregnant women the risks from being included in the study?
 - In all clinical trials MMV does there are clear clinical practices to get informed consent and to ensure it is understood by people with no medical knowledge and there is a medical professional who takes time to explain the risks.
 - We also have clinical research partner organizations that monitor this and make sure people are properly screened and the proper consent is given. This is pretty standard practice. MMV is constantly monitored and audited on this.
 - They are in a biased context because it is a clinical trial and it is much more controlled than real life use.

Work planning

Advocacy:

- With WHO to make recommendation on ACTs in 1st trimester. We want to fast track the process!
- For donor support of more community engagement in MiP promotion/services
- Strengthen/establish MiP TWGs (share TORs, best practices)
- Combined folic acid & iron for MiP

Discussion:

- MiP prevention for special groups (ex: people who have sickle cell anemia): There are no WHO guidelines on this. Access to vector control and prompt and effective case management should be ensured.
- Community engagement should include task-shifting policies at the facility level because if these policies are in place, then there can be more health workers to provide services.

Coordination & Collaboration:

- Strengthen integration of MiP into RMNCH platform
- Strengthen coordination and collaboration with other partners/stakeholders within the WG
- Share best practices for coordination
- Effective coordination with other WGs involved in malaria programming
- Integrate capacity building at all levels

Discussion:

- What specific activity can we do to strengthen integration MiP and RMNCH?

- Most countries have very strong coordination platform for RMNCH, but we feel if malaria programming is also integrated and we have to scale up interventions like IPTp uptake, if we fully integrate into RMNCH we also have to address children under 5
- In Uganda MiP WG updates the MCH WG whenever they meet

Policy:

- Support countries to adopt new ANC guidelines
- Share again and more broadly the briefer on schedule of ANC and IPTp
- Keep in touch with countries to see how far they've moved forward with ANC recommendation adoption
- Provide guidance/policy on management on non falciparum malaria (i.e.: vivax) – see above page 2 on existing WHO recommendations.
- Provide guidance for MiP in special populations (i.e.: MiP treatment and prevention for refugees/mobile populations)
- Identify MiP policy gaps and communicate them to WHO and countries
- Improve communication between the country WGs and the RBM MiP WG on policy issues
 - (For ex: country WG co-chairs can be invited to participate in MiP WG teleconferences)
- Translate research findings into implementation science/policy reviews

Discussion:

- We should add policy guidelines for iCCM adoption for pregnant women. The TIPTOP project is currently exploring community-based delivery approaches
- The ANC briefer on the new guidelines has already been shared, but we can re-disseminate

Research:

This Year:

- We know there is substantial impact of pre-existing infections on MiP and we need to think about potential interventions for this. Until we have vaccines the only practical strategy is BCC research on net usage of women of RHA.
- Help provide info on the non-contraindication of G6PD to giving SP
- Utility/sensitivity of field friendly diagnostics, especially in 1st trimester

Long-term:

- Better understanding of correct interventions for low-transmission settings
- Mapping of VAR2CSA
- Need for better strategies to address vivax
- Improve taste of SP to help reduce vomiting and side effects
- Need to better address sickle cell anemia in MiP
- Ongoing work with various vaccines which can hopefully eventually be used to address MiP

Discussion:

- In Uganda they have a challenge with a significant number of mothers who do not do IPTp because they get a rash, but they are included in the nominator.
 - We need better training of health providers to deal with this and push women to get IPTp, but a rash, vomiting, etc. are truly not a contraindication of SP so more education is needed to prepare health providers for this.
 - MSF did a similar analysis and found the numbers to be very small in terms of who got preventive treatment. The number of women on cotrimoxazole makes a bigger impact and if you are treated for malaria and you don't get SP, this has a significant impact in

certain areas. How do you include them so they are still counted in the numbers so they don't skew the data?

- When there is an allergy to SP it is quite a serious allergy and we should collect this data. It's not zero risk, but it does appear to be a bit lower in pregnant women and children in the data seen.

Products & Tools:

- Compile country feedback on key tools to harmonize/simplify messaging
- Re-organize topics on the website so it is easier to find tools by category
- Sent monthly or bi-monthly messages to group to remind everyone of specific new/existing tools available

Discussion:

None