Antiparasite Rollout Group Meeting
The Mary Ward House Conference Centre, London, England
March 30-31, 2017

MEETING SUMMARY

The Global Health Group at the University of California, San Francisco and the Malaria Centre at the London School of Hygiene & Tropical Medicine hosted the first two-day Antiparasite Rollout Group meeting in London, England on March 30th and 31st, 2017. These notes represent highlights from presentations and discussions and are not intended to be comprehensive.

**Meeting Objective:** To establish key programmatic considerations and knowledge gaps to promote the efficient targeting of parasite reservoirs for malaria elimination.

**Session 1. Welcome and Overview | Session Chairs:** Roly Gosling (University of California, San Francisco) and Chris Drakeley (London School of Hygiene and Tropical Medicine)

- The goal of the new Antiparasite Rollout Group is to harmonize ongoing discussions across national malaria programs, funders, researchers, and industry representatives. This forum aims to streamline information sharing between stakeholders in order to improve targeting and effectiveness of antiparasite strategies.
- The focus of this meeting was on program considerations for implementing screen and treat (SAT) and presumptive treatment approaches and within this specifically: how do we achieve and optimize coverage, with our options spanning from highly focal screen and treat approaches, such as reactive case detection (RACD) to wider deployment of test and treat (TAT)? What is the benefit of foregoing testing, as with the deployment of presumptive treatment approaches, such as mass drug administration (MDA), which can be conducted focally or more widely across populations?
- Vector control is an essential component to any malaria intervention package. This forum is focused on optimizing drug-based approaches with the assumption that these approaches must be integrated with the most locally appropriate effective vector control methods.

**Session 2. WHO guidance on Screen and Treat (SAT) and Mass Drug Administration (MDA) for malaria elimination | Presenter:** Andrea Bosman (Global Malaria Programme)

- The WHO currently recommends the use of mass drug administration (MDA) during epidemics, complex emergencies, and in low transmission areas approaching malaria elimination. The WHO recommendations are based on: meeting of the WHO Evidence Review Group, GRADE tables, consensus evidence from the Malaria Modelling Consortium, a review of delivery costs of MDA for malaria, and a review by the Malaria Policy Advisory Committee.
- In elimination settings, MDA can be considered for use in two scenarios:
  - P. falciparum elimination in areas with good access to treatment, vector control, surveillance, and minimal risk of re-introduction.
  - As a component of malaria elimination efforts in the Greater Mekong Subregion (GMS).
- Mass screening and treatment (MSAT) and focal screening and treatment (fSAT) are not recommended as interventions to interrupt malaria transmission.
• From the modelling analysis it is predicted that MDA is effective with long-lasting artemisinin-based combination therapy (ACTs). The percentage reduction in transmission will be greater and last longer in low transmission settings. Treating a large proportion of the population in a single year in at least one round is a key determinant of MDA effectiveness. Varying the time between rounds from 4 to 6 weeks and the addition of primaquine (PQ) has little additional impact on transmission.

• The WHO will issue a practical field manual on MDA for malaria in May 2017. This will include guidance considering the human resources required for deployment.

• A recent WHO Evidence Review Group (ERG) provided guidance on cardiotoxicity caused by antimalarial drugs. With the exception of halofantrine, antimalarials including quinine, chloroquine, artesunate-amodiaquine (ASAQ) and dihydroartemisinin-piperquine (DP), have been associated with a low risk of cardiotoxicity at the current recommended doses. The risks of cardiotoxicity of piperquine is likely similar for healthy volunteers and malaria patients; however, repeat dosing must consider the potential increased risks of cardiotoxicity.

Session Discussion:

• A better method for measuring adherence levels is needed. Current best practice involves counting pills.

• Directly observed therapy (DOT) is expensive and demanding and measuring coverage is challenging. Coverage is generally determined based on the amount of drugs dispensed and the number of households or individuals targeted. By using this method it can be unclear which portions of the population are missed, such as mobile and migrant populations.

• Pharmacovigilance mechanisms are needed to measure drug tolerability and acceptability at the household and patient levels.

Session 3. Programmatic experience with SAT and MDA | Session Chair: Effie Espino (Asia Pacific Malaria Elimination Network [APMEN])

• Nine country programs presented on their varied experiences implementing SAT and MDA interventions. The information presented is outlined in Table 1. Country Program Experiences with SAT and MDA on page 3.

Table 1. Country Program Experiences with SAT and MDA Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACD</td>
<td>Active case detection</td>
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<tr>
<td>AL</td>
<td>Artemether/Lumefantrine</td>
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<td>ACT</td>
<td>Artemisinin-based combination therapy</td>
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<td>DP</td>
<td>Dihydroartemisin/piperquine</td>
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<td>DOT</td>
<td>Directly observed therapy</td>
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<td>fMDA</td>
<td>Focal mass drug administration</td>
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<td>FSAT</td>
<td>Focal screen and treat</td>
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<td>IRS</td>
<td>Indoor residual spraying</td>
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<td>LLIN</td>
<td>Long-lasting insecticide treated bednets</td>
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<td>MDA</td>
<td>Mass drug administration</td>
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<td>MSAT</td>
<td>Mass screen and treat</td>
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<td>PCR</td>
<td>Polymerase chain reaction</td>
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<td>Pf</td>
<td>Plasmodium falciparum</td>
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<td>Pk</td>
<td>Plasmodium knowlesi</td>
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<td>Pv</td>
<td>Plasmodium vivax</td>
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<tr>
<td>(SLD) PQ</td>
<td>(Single low dose) Primaquine</td>
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<tr>
<td>RDT</td>
<td>Rapid diagnostic test</td>
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<td>RACD</td>
<td>Reactive case detection</td>
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<td>SAT</td>
<td>Screen and treat</td>
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<td>Country</td>
<td>Epidemiology</td>
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<tr>
<td>Mozambique, predominantly P. falciparum</td>
<td>Heterogeneous, seasonal transmission</td>
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<tr>
<td>Namibia, Davis Mumbengegwi, University of Namibia</td>
<td>Seasonal transmission along northern border; High rates of parasite importation into border regions</td>
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<td>South Africa, Jaishree Raman, National Institute for Communicable Diseases</td>
<td>Seasonal, heterogeneous transmission limited to border regions of three northeastern provinces; High percentage of cases are imported</td>
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<tr>
<td>Swaziland, Malambe Calsile, National Malaria Control Program</td>
<td>Low transmission with some seasonality; Eastern half of country considered receptive</td>
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<tr>
<td>Zambia, Anthony Yetta, National Malaria Control Program</td>
<td>Seasonal, heterogeneous transmission</td>
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<tr>
<td>Country</td>
<td>Summary</td>
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<tr>
<td>Zanzibar</td>
<td>Transmission is low and focal</td>
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<td>Cambodia</td>
<td>Seasonal, heterogeneous transmission</td>
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<td>Indonesia</td>
<td>Highly heterogeneous transmission</td>
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<td>China</td>
<td>Limited focal transmission, frequent importation</td>
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<td>Asia Pacific, predominantly P. vivax and P. falciparum</td>
<td>seasonal with high levels of transmission, heterogeneous transmission</td>
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<tr>
<td>MDA v. standard of care (control) is being evaluated in randomized control trial in three low transmission districts</td>
<td>PV detected by ACD: Village malaria worker conducts household fever screening by microscopy or RDT; conducts treatment and weekly follow-up until day 90</td>
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<td>Cambodia</td>
<td>Seasonal, heterogeneous transmission</td>
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New national strategy will use 1-2-5 formula for surveillance and response activities in elimination districts.
Session 3. Programmatic experience with SAT and MDA (continued) | Session Chair: Effie Espino (APMEN)

Session Discussion:
- Reoccurring themes from Session 3 are as follows:
  - **Current practices:** Many programs are utilizing or planning to utilize one form of SAT or another as they approach low transmission. RACD is the most popular SAT strategy. MDA is only being used in research trials with at least some external funding available for programming.
  - **Delivery Methods:** SAT delivery methods vary considerably across programs. Programs adapt activities to fit their context, transmission levels and available program resources. For example, while many programs are utilizing RACD, the radius and number of households targeted, the triggers, response time and diagnostics differ across and within programs. This variation makes comparisons on the cost and effectiveness of these approaches difficult to analyze. Alternatively, there are several similarities spanning across the different MDA programs including the use of multiple rounds (2-4 rounds), the timing (low transmission point), and ACT administered (DP).
  - **Challenges:** Several challenges were identified that delay or impede SAT and MDA activities. The most common include: issues related to limited human and financial resources, drug procurement and registration issues, timely surveillance and response, and achieving optimal coverage (especially of mobile populations).
  - **Impact:** Impact data was more readily available from MDA trials than any of the SAT activities. Still, questions on how to measure the specific impact of MDA or SAT remain, especially as these strategies are generally deployed within a package of interventions including vector control. Evidence of impact is key to decision making.
  - MDA is primarily carried out as randomized control trials where financial and operational resources exist to conduct the research. What programmatic considerations are required in order to launch a country-led MDA programs?
  - Many programs report the use of SAT interventions, primarily RACD. However, RACD is labor intensive and programs noted the challenges of limited resources. Is the continued use of RACD the most effective strategy? Are certain settings more appropriate for RACD, and if so what are the characteristics?

Session 4. Deploying antiparasite strategies: evidence | Chair: Kim Lindblade (Global Malaria Programme, World Health Organization)

4.1 Target Settings: Malaria Typologies presented by Jackie Cook (LSHTM)
- A malaria typology is a way of stratifying malaria settings that have common elements with regard to malaria endemicity, local ecology, and anthropic factors.
- By characterizing settings by typology, national malaria programs may improve targeting through a more nuanced definition of transmission settings, particularly in areas of low transmission.
- A typology for elimination includes considering the following:
  - Historical endemicity including seasonality, infection sources and surveillance systems.
  - Ecological factors, such as the presence and abundance of vectors, efficiency of species, biting behavior, and breeding sites.
Anthropic factors considering population density, socio-economic status, population movements (especially between sources and sinks), high risk populations, and intervention coverage health systems and population characteristics including.

- Typologies can assist with knowing where to prioritize certain strategies for greatest impact through gaining a better understanding of malaria receptivity and vulnerability (i.e., identifying parasite sources and sinks).
  - For example, some human population movements will matter more than others in elimination settings, such as those contributing to sink-imported cases whereby an individual may travel between areas of little to no transmission and areas of active transmission, posing a risk of reintroduction. Programs may consider targeting these scenarios in their elimination malaria strategies.

- It is important to note that a typology can be a changing state. For example, while it is unlikely that receptivity will change drastically, changing patterns of human movement may affect vulnerability.

4.2 Current empirical evidence for screen and treat (and mass drug administration) presented by Michelle Hsiang (UT Southwestern) and Gretchen Newby (UCSF)

- To consolidate the empirical evidence for SAT strategies, UCSF is conducting a literature review. To date, 1,500 papers have been screened:
  - 93 papers are currently included in the review: Diagnostics/characteristics and detecting asymptomatic cases (n=37 papers), modeling (n=12) intervention studies (n=27), opinion/review (n=10), other (n=7).
  - The 27 intervention studies provide some empirical evidence on antiparasite strategies; 3 of those papers focus on MDA and 24 papers focused on SAT including MSAT (n=4), fSAT (n=3), RACD (n=17, with 2 examining proactive case detection).

- The review has so far revealed several gaps and limitations in available empirical evidence. This includes minimal data from low transmission settings, non-\emph{P. falciparum} species, and identification of cases using more sensitive diagnostic methods beyond rapid diagnostic tests (RDT) or microscopy. Only four studies measured effects on transmission: one in Burkina Faso (high transmission) two in Zambia (in both high transmission regions and those of moderate transmission, and one in Zanzibar (low transmission)
  - Of the four MSAT studies, MSAT using RDTs was demonstrated to be ineffective, having little to no impact on transmission reduction. This is likely due to the limited sensitivity of RDTs that are unable to capture low-density infections that are chronic and afebrile.

- Of the 17 RACD studies (6 = descriptive and 11 = observation) reviewed, the locations spanned: Cambodia, China, India, Indonesia, Thailand, Vanuatu; Botswana, Rwanda, Senegal, Swaziland, Zambia; and Brazil. The radius of response varied throughout these studies. Ten of the studies examined the use of RDTs, with seven comparing RDTs with PCR.
  - A study in Swaziland showed benefits to using the highly sensitive diagnostic loop-mediated isothermal amplification (LAMP), which led to a three-fold increase in foci detection (from 11.9% to 29.7%). RACD using LAMP also increased detection of infections by 48% compared to number of passively identified cases that triggered RACD.
  - In Aceh, Indonesia, RACD provided the program with data to improve targeting, revealing that workers staying overnight in the forest are at greatest risk. This study also revealed a need for improved methods to distinguish \emph{P. knowlesi} infections from those of \emph{P. falciparum}. Aceh is also preparing to publish data on the costs of RACD (Zelman, in prep), showing the cost is $2,482 USD per malaria event (or $47/person screened) and
that the average cost per additional infection found ranges from $35,536 (microscopy only) to $14,743 (LAMP only).

- In summary, the evidence-based benefits of MSAT using RDTs are limited. When considered more focally as RACD, highly sensitive diagnostics such as LAMP proved to benefit case identification in Swaziland, where infections tend to be clustered. In Aceh Indonesia, RACD provided the program epidemiological information to improve targeting.
- Compared to SAT methods, presumptive treatment may provide the benefit of targeting low-density infections missed by the diagnostic tests. Data on MDA has been reviewed; in summary, a Cochrane review from 2013 as well as an MEI background paper (2015) confirmed that while MDA reduces the initial risk of malaria-specific outcomes, often these gains are not sustained.
- Most of the data on MDA are in lower transmission settings and/or highlands and/or small island settings, as well as in moderate transmission settings where vector control is co-deployed.

4.3 What are the evidence gaps and how do we fill them? The role of modeling for SAT and MDA presented by Thomas Smith (Swiss Tropical and Public Health Institute)

- An overview of modeling results from the Malaria Modeling Consortium (MMC) shows that when modeling the infectious reservoir, transmission is characterized by the presence of gametocytes, as well as vectorial capacity. Current results suggest that most very low density infections are irrelevant, even though onward transmission is possible. Thus the benefits of using highly sensitive RDTs are unclear. In these models, the addition SLD-PQ has little impact on transmission.
- In the Zambian context, modeling provides insight into the impact and limited sustainability of nationwide MDA on P. falciparum endemicity, showing a substantial short-term impact where infection levels bounce back.
- MDA does have a prophylactic effect.
- One of the most important considerations for the effectiveness of MDA is coverage. Coverage is most impactful when reaching a wide number of people as opposed to repeatedly reaching the same people.
- Models can support operational research: how widely or focally should infections be targeted? How important is promptness of reaction? What is the benefit of testing for malaria vs presumptive treatment? Should failed drugs be used as f-MDA in Cambodia; what would the potential impact or consequences of this? Which metrics should be used to measure impact?

Session Discussion:

- RACD seems to be the standard strategy utilized by programs once they reach low transmission, but empirical and modeling evidence indicates that RACD may not have a significant effect on transmission. Therefore, it is very important for malaria programs to clarify the goal or motivation behind using these strategies.
- One option for determining priority settings for drug-based strategies would be to characterize settings as malaria typologies. While promising, one anticipated challenge is that data available to characterize settings may be limited by that provided through existing surveillance systems.
- Modeling can provide critical insight for predicting the effectiveness of intervention combinations, particularly those not yet considered for deployment, and to better understand what is likely to work. This can be used as insight for operational and conventional research studies and programmatic activities during planning phases.
5.1 Available toolbox: Landscaping tools for integrated use – antimalarial drugs presented by David Wesche (Great Lakes Drug Development / Bill and Melinda Gates Foundation)

- The ideal characteristics of antimalarial drugs include high levels of efficacy and safety across populations. Some drugs may be of limited use across specific populations, which may be due to inherent genetic polymorphisms (e.g. G6PD deficiency), or external situations such as pregnancy, extremes of age, or chronic disease. Drugs must also be easy to administer operationally; minimal food effects and long shelf life are also ideal characteristics.

- Key considerations for the use of ACTs and 8-aminoquinolines, the choice of drug for SAT and MDA strategies, include:
  - Firstly, the predictability of safety. Cardiotoxicity of piperaquine in DP can be unpredictable because its food effect is affected by the exact dose administered. Thus both food intake and dose will impact potential cardiotoxicity. Additionally, piperaquine dosing is affected by age; young children require higher doses of piperaquine than is currently recommended to achieve clinical efficacy (Tarning et al).
  - Secondly, the limitations of 8-aminoquinolines, such as PQ, must be considered. The efficacy of SLD-PQ is under debate; however, studies may not be looking ahead for long enough duration. A drug with efficacy against mature falciparum gametocytes, but with a longer half-life than PQ, and without the safety restrictions posed by 8-aminoquinolines, would be a valuable addition to the malaria elimination toolbox.
  - Thirdly, antimalarial drug selection must be methodical and fit for purpose. A separate risk/benefit analysis should be completed for standard treatment as well as MDA programs.

- The most recently developed ACT on the market, Pyramax®, contains artesunate-pyronaridine. Evidence to date suggests that this drug combination fits the desirable attributes for antimalarial drugs described above.

5.2 Diagnostic tests presented by Iveth Gonzalez (FIND)

- In malaria endemic areas, access to diagnostic methods for febrile illnesses are limited. Microscopy remains the gold standard for malaria diagnosis mainly in areas were P. vivax is prevalent, such as Latin America, India and South East Asia.

- RDTs are widely used in Sub-Saharan Africa, although HRP2 and HRP3 deletions threaten the effectiveness of these tests. The sensitivity of these tests for non-falciparum species is also limited.

- Nucleic acid amplification techniques, such as PCR and LAMP, are currently widely used in research settings for detection of asymptomatic/sub-microscopic infections and results demonstrate an increased detection of infections when compared to microscopy and RDTs.

- A number of highly sensitive rapid diagnostic tests (HSRDTs) are under development, and the WHO is developing guidelines for the use of HSRDTs. A product by Alere recently launched in April 2017.

- The configuration of next-generation highly sensitive RDTs is still to be defined. Consideration should be given to improved detection of all species, species differentiation between P. vivax and P. ovale infections to target hypnozoites, the implications of HRP2 and HRP3 deletions, heat stability of devices in tropical climates, and the detection of low parasite densities.

- Serology is currently considered as a potential tool for population screening and treatment as a proxy for identification of hypnozoite carriers.
In low transmission settings, the use of fever panels may also be of particular value.

5.3 Ensuring effective rollout: community mobilization presented by Thom Eisele (Tulane University)

- To examine community mobilization in different contexts, two studies on MDA were reviewed: an ongoing study in Zambia where transmission is high, and a study planned in Haiti where transmission is low.
- In Zambia, a two-year mass treatment study involving four rounds of MDA improved access and treatment-seeking. A variety of community engagement strategies were deployed including radio broadcasts, meetings with community leaders, village meetings, and information sharing with community health workers. Efforts were also made to target people who were not covered. These methods were effective; high household coverage (65.6-80.8%), high acceptability rates (<1% refusals among eligible participants), and high levels of adherence (80.6-84.9%) were achieved. A qualitative assessment showed that most people participated in MDA because they were concerned with protecting their family and community from malaria.
- In Haiti, where malaria transmission is very low and people do not perceive malaria as a leading public health issue, community mobilization is expected to be more difficult. Additional challenges in Haiti include its pluralistic health system with widespread mistrust at the institutional and individual levels. Elimination strategies in Haiti will require innovative forms of community involvement, including the inclusion of key community members such as traditional healers and local health officials.
- These two case studies show that community mobilization is context-specific. A qualitative assessment on the risks and opportunities within a community may prove to be helpful during the planning and design process, and specific efforts should be made to understand what motivates the community prior to implementing a new intervention or health program.

5.4 How can rollout be ensured and approached by NMCPs: program management tools presented by Deepika Kandula (CHAI)

- Good program management, at all levels of the health system, is critical to the efficient and effective use of resources in deploying antiparasite strategies. Program management includes the management of people, processes and resources to achieve a strategic goal.
- Important aspects of program management include ensuring accountability, developing strategic partnerships to fill gaps, promoting the use of data at all levels of the program, and monitoring and evaluation.
- The following steps may be required when rolling out a new strategy or intervention: update the strategic plan, develop and follow the microplan/operational plan; resolve bottlenecks, adjust the work plan as necessary, coordinate with partners, and document the lessons learned.
- Microplanning may prove to be a useful tool. Microplanning involves answering the “what,” “how,” “who,” “when,” and “where” related to implementation. This in turn will support adequate planning of financial and human resources, areas identified by programs as current limitations to the efficient use of antiparasite strategies.

Session Discussion:

- The forthcoming HSRDTs being produced by Alere, currently estimated to cost <$1/test, are more costly than the current generation of RDTs. How to best use HSRDTs in low transmission settings is still to be determined. The new HSRDTs are not intended to be a case management tool.
Community mobilization should be differentiated from community engagement. Community mobilization was defined as “catalyzing the collective power of communities to actively promote adoption of malaria elimination strategies” (Lippman et al. 2013). Community mobilization and community engagement exist on the same continuum by which community engagement can be considered as one of several activities or processes by which to achieve community mobilization.

To promote the development of program management tools, it may be useful to document programmatic experiences with MDA and SAT for other countries to review and use. Particularly, information pertaining to program management, such as sharing the management and operational strategies used, and the necessary financial and human resources required, would be helpful. Program management tools will need to be adapted according to the health system (i.e. centralized v. decentralized) but the most important part of the process is to identify the correct people to engage with and work through.

Session 7. Breakout group discussion: Identifying programmatic barriers to the efficient use of antiparasite strategies | Chairs: Roly Gosling (UCSF) and Chris Drakeley (LSHTM)

- Programs discussed areas that could further increase the efficient use of antiparasite strategies. The outputs of these discussions were collated and grouped thematically. Please see Table 2.

| Block 1. | Policy and finance |
| Block 2. | Cost effectiveness of test and treat (TAT) / MDA |
| Block 3. | Operational Guidance |
| Block 4. | Access to commodities |
| Block 5. | Human resources and community mobilization |

Session 8. Breakout group discussion: Identifying pathways to overcoming programmatic barriers to the efficient use of antiparasite strategies | Chairs: Roly Gosling (UCSF) and Chris Drakeley (LSHTM)

- The group discussed pathways to address the blocks identified in the previous session (Table 2). These robust discussions were synthesized in a live document during the report back and a preliminary roadmap to promote the efficient use of antiparasite strategies was populated.
- This preliminary roadmap was refined following the conclusion of the meeting. Gaps and pathways identified at the meeting were prioritized based on the Antiparasite Rollout Group’s intended role, purpose, and objectives.
- The roadmap (Figure 1. Antiparasite Rollout Group: Draft Roadmap) reflects the major outcomes of the meeting.
Figure 1: Antiparasite Rollout Group: Draft Roadmap

**Theme**

**Evidence**
- Lack of knowledge about what works best where, how to improve delivery and assess impact.

**Policy & Financing**
- Countries and funding institutions require policy guidelines to drive implementation.
- WHO to provide policy guidance
- Facilitate national-level drug policy changes
- Develop a framework for programs that detail when to add antimalarial drugs to national policies and/or treatment guidelines.

**Access to Commodities**
- Challenges preventing access to drugs and diagnostic tests in target settings
- Address regulatory barriers
- Identify non-registered commodities and commodities facing registration delays, such as multiple ACTs for different use scenarios.
- Establish pathways to accelerate registration and/or procurement methods (e.g., the use of centralized networks).
- Optimize supply chain
- Ensure access of commodities to remote and rural areas.

**Pathways**
- Characterize target settings
  - Describe settings based on transmission, ecology, and human movement patterns. This group will focus on moderate and low transmission settings.
  - Determine key evidence gaps
    - Determine settings where empirical and modeling evidence is needed.
- Establish cost-effective scenarios in target settings
  - Establish the benefits of MDA & SAT in target settings, including cross-border regions and outbreak scenarios.
  - Determine best interventions and drugs for target settings:
    - Drugs (e.g., DP, AS-Pyridine, SLD-PC, RTS, S)
    - Diagnostic tools (e.g., HBVRm, LAMP, serology)
    - Co-interventions (e.g., reactive vector control, LUM)
    - Surveillance (e.g., how locally to target)
  - Improving delivery:
    - Ensuring coverage within target populations
    - Community mobilization to encourage adherence and acceptance
  - Build consensus on costing methods, measurements of impact, and trial endpoints, include MAE for program implementation and pharmacovigilance.

**Goal**
- Generate evidence to support policy
- Countries implement appropriate antiparasitic measures
- Improve access to needed tools