

Conversation between Chris White (PSI Myanmar), Cari Tuna (Good Ventures), and Elie Hassenfeld and Natalie Stone (GiveWell) on September 12, 2012

Note: This is a set of notes compiled by GiveWell in order to give an overview of the major points made by Chris White in conversation.

Summary:

- We spoke with PSI Myanmar because Good Ventures gave the organization a \$1 million grant to support a project to fight malaria drug resistance in Myanmar, and we are monitoring how the project progresses, as well as evaluating whether to consider the project for further support.
- PSI Myanmar cannot, at this time, predict how much additional funding the project will require. Due to uncertainty in whether additional funds will be needed for its the monotherapy replacement component of the project, it may to use the funding from Good Ventures to expand the rapid diagnostic text component of the project. This is a change from our previous understanding of how additional funds would be used.
- The Myanmar government had previously told PSI that it had banned artemisinin monotherapies. PSI learned in June 2012 that the government's ban did not cover all brands of artemisinin monotherapy. The government plans to institute a full ban of artemisinin monotherapy soon, but the delay may have caused PSI's partner supplier to lose market share, at least temporarily.

From monotherapy to artemisinin-combination therapies (ACT)

In Myanmar, malaria is often treated with the artemisinin monotherapies (artemisinin given alone, not in combination with other antimalarial drugs). There are signs that the malaria parasite is becoming resistant to artemisinin in the region, so that continuing to use artemisinin alone is likely to lead to a malaria parasite which artemisinin is no longer effective against.

Artemisinin-combination therapies (ACTs) are bundles of antimalarial drugs consisting of artemisinin together with a secondary drug. The advantage of ACT over artemisinin monotherapy is that the secondary drug present in the former kills malaria parasites that are resistant to artemisinin, thereby preventing artemisinin resistant parasites from spreading.

The use of artemisinin monotherapy is explicitly discouraged by the World Health Organization. The malaria control community has placed high priority on replacing artemisinin monotherapy with ACTs.

Historically, there hasn't been so much focus on preventing the spread of resistance to antimalarial drugs because there was always another antimalarial drug that was close to being developed. This is not presently the case, so it's important to delay resistance for as long as possible.

Sources of uncertainty in PSI's monotherapy replacement program

The malaria work that PSI Myanmar is doing is focused on the replacement of artemisinin monotherapy with ACTs. In order to facilitate this, PSI Myanmar is working with an antimalarial drug supplier called

AA.

There are a number of sources of uncertainty as to how much near term funding the project needs:

1. The development landscape in Myanmar changes on a weekly basis. There are frequent changes in restrictions on operations of agencies and in the amounts that different donors are giving to fund aid efforts in the area.
2. It is unclear how quickly the government will be able to expand services into remote, rural areas of the country. This is the most critical factor for the project in the longer-term (i.e. past year three).
3. The Ministry of Health and Federal Drug Administration in Myanmar inadvertently left a type of artemisinin monotherapy out of its ban. The FDA rightly banned Artesunate (the most common AMT at the time), but did not ban the second most prevalent AMT, Artemether. The non-banned type (artemether) gained some market share (although with Artesunate no longer entering the supply chain, the market as a whole has reduced in size). Because PSI's partner AA had previously been supplying artesunate, when artesunate was banned, AA lost market share to suppliers of artemether, and AA's market share has dropped from 70-80% to around 2% over the past 12 months. The government is moving quickly to ban artemether, and PSI notes that the Artemether supply chain is already drying up. However, there is still a possibility that market penetration speed with ACT will be affected by a reluctance to stock new commodity before selling existing stocks of AMT.

This factor represents a new source of project uncertainty, but it remains unclear how important this will be in the medium to long-term.

The project's overall funding gap appears to be unaffected by these factors, but these factors affect *the pace at which money will be required*. Because ACTs have a shelf life of only two years, it's important that PSI Myanmar doesn't order more of the drug than can be moved through the supply chain in a timely manner.

In view of the uncertainty present, it's important that PSI Myanmar be flexible so as to be able to respond to changes.

Project scale

The scale of the project was determined in early conversations with the Bill and Melinda Gates Foundation (BMGF). PSI proposed three levels of involvement and BMGF indicated that it would only be able to support PSI's lowest-intensity proposal, the nationwide monotherapy replacement project with intensified communication activities limited to the eastern part of the country where resistance to artemisinin is indicated.

If PSI had as much money as it wanted, it would scale up sophisticated, high quality case management services with intense supervision and interpersonal communications through an extensive network of community-level field staff, covering the whole country (where feasible, considering memorandum of

understanding permission constraints). That would cost well over 100 million dollars.

PSI Myanmar's future need for funding

The budget for the current project is based on a time frame of three years. If PSI is not able to sell ACTs at the budgeted pace, it may not require additional funding during these three years. In order to reach full scale, it will need additional funding (perhaps even more than budgeted), but the timeline for when it would need this funding remains uncertain for the time being.

Use of funding from Good Ventures

In part because of uncertainty about if/when additional funding for ACTs will be needed, and in part because of an interest from the UCSF Global Health Group in conducting research on how to incentivize drug sellers to use rapid diagnostic tests (RDTs), PSI is considering using part of the funding from Good Ventures to expand the RDT component of the project.

There are serious demand-related constraints associated with distributing and ensuring the use of RDTs among private sector providers. There is virtually no research that addresses RDT demand creation and quality assurance in the private sector. PSI plans to test three methods for creating this demand among providers receiving ACT through private sector channels. It was originally planning a relatively small and qualitative pilot project, but has decided to do a larger pilot project that is more academically robust and thus publishable in peer-reviewed literature. Once PSI Myanmar identifies the best one of the three methods, it hopes to scale up the model.

PSI Myanmar has a need for more funding for the RDT component of its malaria project, both funding for its partnership with the UCSF Global Health Group and also funding for the larger pilot project. The money needed for the partnership with UCSF is in the range of \$180,000-\$190,000. It has not yet estimated the operational costs.

Reasons for including rapid diagnostic tests (RDTs) in the project

Rapid diagnostic tests (RDTs) offer a quick and simple way for health workers to determine whether a given patient has malaria. Their use is important for the following reasons:

1. Minimizes risk of overuse of ACT that might lead to resistance developing to the 'partner' drug
2. Minimizes wastage of ACT that is significantly more expensive than diagnostic tests (which is particularly important in the Myanmar context because transmission is already being reduced by aggressive malaria control scale up efforts, at least in Myanmar Artemisinin Resistance Containment (MARC) priority areas)
3. Helps improve the chances of appropriate non-malaria fever management (assuming policy environment is supportive of the deployment of medications for pneumonia and diarrhea treatment)

In addition, by deploying RDTs at scale and monitoring positivity rates over time and by location, a

clearer picture should emerge regarding changes in transmission risk.

All lessons learned will be relevant to many malaria endemic countries, as the malaria community as a whole is wrestling with the challenge of how best to deploy RDTs in the private sector.

Reporting

PSI Myanmar is happy to provide regular reporting to GiveWell and Good Ventures on how the money donated to the project was spent, for example, exactly what proportion was spent on commodities vs. learning around RDTs in partnership with UCSF. PSI also plans to share all updates and progress reports prepared for BMGF and DFID with Good Ventures and GiveWell.

PSI will share data from the baseline household and outlet surveys shortly. It hopes to be able to share this data publicly and will be discussing this with the government of Myanmar.

PSI is not yet sure whether it will be able to publicly share information about the quantities of products sold by its distribution partners.

Myanmar Artemisinin Resistance Containment (MARC) framework

Myanmar Artemisinin Resistance Containment (MARC) is a strategic framework that describes how partners supporting the Ministry of Health are scaling up multi-intervention malarial control in the east of the country where drug resistance has been indicated. Historically, MARC has been supported by Myanmar's Three Diseases Fund (3DF), with WHO providing technical assistance. MARC has been searching for additional funding to continue operations past year one. PSI believes that the 3DF (now morphing into the so-called 3MDG fund) will continue to support MARC, but it's not clear what funding gap might remain. Key is the current uncertainty around whether or not Myanmar will receive Global Fund resources, and this will have a significant impact on MARC and on malaria control efforts more broadly.