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Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2014 – March 2015



Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: End-of-year Summary of Progress



Submitted 3 July 2015

Population Services International (PSI) – Myanmar

Please refer to the <u>Progress Report Guidelines</u> for instructions on completing this form.

I. Summar	y Information	.:		
GRANT INFOR		SI		
Project Name	Containment of Artemisinin Resistance	e in Easte	e <mark>rn</mark> Myanma	r
Organization Name	Population Services International			
Grant ID#	1024757	Founda Progra	ntion m Officer	Thomas Kanyok
Date Grant Awarded	October 2011	Project	End Date	March 2016
Grant Amount	\$7,500,000	Project	Duration	54 months
Report Period From	October 2014	То	March 201	5
Report Due	June 30 th 2015	Vaa	no cost ov	tension was approved and the
Has this projec	t been granted a no-cost extension?	contra 31 Ma	nt was ame arch 2016	ended to extend the duration until
GRANT INFOR	MATION (DFID)			
Project Name	Replacement of Malaria Monotherapy	Drugs in	the Private	Sector
Organization Name	Population Services International			
Component #/ Purchase Order #	202759-101/40049299	Progra	m Officer	Nan Hom Nwet
Date Grant Awarded	October 2011	Project	End Date	March 2016
Grant Amount	\$17,655,000	Project	Duration	54 months
Report Period From	October 2014	То	March 201	5
Report Due	June 30 th 2015	Ves	no-cost ev	tension was annroved and the
Has this projec	t been granted a no-cost extension?	contra 31 Ma	nct was ame arch 2016	ended to extend the duration until

An additional \$1,000,000 has been awarded by Good Ventures.

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Geographic Location(s) of Wor	k	
Country and Region/State	Amount	Donor
Myanmar (80% coverage)	\$7,500,000	BMGF
Myanmar (80% coverage)	\$17,655,000	DFID
Myanmar (80% coverage)	\$1,000,000	Good Ventures
Total Grant Amount	\$26,155,000	

Geographic Area(s) to be Served	l	
Country/Continent	Amount	Donor
Myanmar (80% coverage)	\$7,500,000	BMGF
Myanmar (80% coverage)	\$17,655,000	DFID
Myanmar (80% coverage)	\$1,000,000	Good Ventures
Total Grant Amount	\$26,155,000	

II. Progress and Results

GENERAL PROGRESS

A priority objective in Myanmar's national plan for artemisinin drug resistance containment (MARC) is the rapid replacement of oral artemisinin monotherapy (oAMT) with a quality-assured artemisinin-based combination therapy (QAACT) in the private sector. This report provides an update on this component of the MARC, implemented by Population Services International (PSI), with support from the UK Department for International Development (UKAID), the Bill & Melinda Gates Foundation (BMGF), and Good Ventures.

Progress made on key activities and achievements during this reporting period include:

- A 2-day project review meeting workshop was carried out in January 2015 with all staff carrying out provider Behavior Change Communication (BCC) activities in the field. The objectives of the meeting were to review project progress to date, including dissemination of key findings/logframe indicators from survey results, share the challenges and lessons learned, and discuss the RDT scale up plan. Participants discussed the areas that need improvement and brought forth ideas to improve the BCC strategy. Performance gaps and remedial action points were discussed and agreed upon using adult-learning approaches. The action items were incorporated in the project workplan, including a monitoring plan to assess their progress.
- 2. Despite PSI's success on the RDT pilot program its scale-up has been delayed due to government approvals. As previously reported, the RDT pilot was successful demon-strating that private sector outlets could administer RDT. PSI conducted a dissemination workshops where all partners reviewed and discussed the pilot results, and collectively recommended RDT scale up. The MOH, however, denied approval. During this reporting period, PSI carried out a series of advocacy meetings with high-level MOH authorities to understand their concerns and reassured them of the quality and feasibility of the pilot. PSI re-submitted the RDT scale up plan in Jan 2015 addressing the MOH's concerns and approval was obtained in late Feb 2015. PSI is working closely with the Ministry of Health to determine exactly what activities/components of the plan are approved/disapproved and to what extent.
- 3. PSI submitted and received final MoH approval for a "Get tested First" communication campaign to support the RDT scale up. Detailed design and communication messages to be used in print and broadcast media were drafted, revised, re-submitted to MoH following their recommendations and comments from initial review. RDT demand creation consumer BCC campaign will be rolled out in the next reporting period, which is well-timed for malaria peak season.
- 4. PSI carried informant interviews with existing ACT distributors, wholesalers and most importantly, with a sample of AMTR outlet providers to identify their perceptions and preferences regarding the packaging/design of the RDT test kits that PSI is planning to distribute. Based on the discussion and recommendations, PSI developed, designed and procured the packaging materials for RDT. This includes materials with the steps to carry out RDT testing, the interpretation of different test results, and the reminder/warning to check if the test kit has enough buffer (recent findings from WHO laboratory study showed that the buffer solution evaporated before the expiry date in the field and RDTs do not have enough buffer which has impact on test results) etc. The materials are designed in a way that a provider with very minimal education can understand and follow (less text and more pictorial).
- 5. Training on RDT administering, how to interpret the test results, how to prescribe/sell

the antimalarial drugs according to test results, recording and reporting on malaria positive cases, and appropriate waste management were provided to all PSI field staff carrying out the provider BCC activities (Product Promoters) in all AMTR townships.

- Training on reporting and inventory system for sales/medical representatives of Polygold was conducted by PSI with the purpose of strengthening the data reporting system. This system which will enable PSI to track the distribution of malaria commodities under this project.
- 7. During the annual AMTR project review meeting held with donors in February 2015, PSI requested the log-frame indicators to be updated considering the recent epidemiological changes in Myanmar. The donor agreed to revise some of the language and targets of the indicators and acknowledged the need to conduct a thorough revision of the logframe regularly, especially once the RDT scale up approval is obtained.
- 8. Two papers on RDT pilot study and one paper on 2012 baseline malaria outlet survey were published in peer reviewed journals¹²³.

The findings from the recent resistant gene mapping studies that the association of mutations in a kelch protein on chromosome 13 (K13) with the resistance⁴ and the independent emergence of K13 mutations in multiple geographic locations suggests that elimination of the parasite from the entire GMS region will be the only way to stop the spread of resistance malaria towards Africa⁵. Efforts to eliminate artemisinin-resistant malarial parasites in one region may have a limited impact on the emergence of resistance in neighboring regions, particularly if selection pressure for resistance is sustained by continued availability of artemisinin monotherapies and counterfeit or substandard medicines. Therefore, the entire Greater Mekong Sub-region (GMS) has shifted its strategy from resistance containment to malaria elimination. All GMS political leaders have endorsed this agenda and agreed to eliminate malaria from the region by 2030. This has implication on the AMTR project. PSI discussed the urgent needs for project area expansion outside current AMTR project townships, especially towards the western border of Myanmar. PSI requested and received donor's approval during annual donor review visit to expand the geographic scope of the project. Moreover, to contribute to the regional goal of malaria elimination, PSI will revamp its malaria case management strategy in the private sector to ensure utilization of RDT test results and completion of the treatment course.

CRITICAL MILESTONES

The milestones that were agreed upon when the AMTR project was approved in Sept 2011 are no longer be relevant after Year 3 due to recent epidemiological changes and the strategy

15: 415–21 (Tun et al)

^{1&}lt;sup>™</sup>Motivations and challenges for use of malaria rapid diagnostic tests among informal providers in Myanmar: A qualitative study May Sudhinaraset, Christina Briegleb, Moe Aung, Hnin Su Su Khin, Tin Aung (Accepted by Malaria Journal on 7 November 2014)

 $^{2^{\}mathbb{Z}}$ Improving uptake and use of malaria rapid diagnostic tests in the context of artemisinin drug resistance containment in eastern Myanmar: An evaluation of incentive schemes among informal private healthcare providers : Tin Aung, Christopher White, Dominic Montagu, Willi McFarland, Thaung Hlaing, Hnin Su Su Khin, Aung Kyaw San, Christina Briegleb, Ingrid Chen, May Sudhinaraset (Accepted by Malaria Journal on 7 November 2014)

 $^{3^{\}mathbb{Z}}$ Availability and quality of anti-malarials among private sector outlets in Myanmar in 2012: results from a large, community-based, crosssectional survey before a large-scale intervention: Hnin Su Su Khin; Ingrid Chen, PhD, MS; Chris White; May Sudhinaraset; Willi McFarland; Megan Littrell; Dominic Montagu; Tin Aung (Accepted in Malaria Journal Journal on July 2015)

 $^{4^{\}mathbb{Z}}$ Spread of artemisinin-resistant Plasmodium falciparum in Myanmar: a cross-sectional survey of the K13 molecular marker: Lancet Infect Dis 2015;

 $^{5^{\}mathbb{Z}}$ Independent Emergence of Artemisinin Resistance Mutations Among Plasmodium falciparum in Southeast Asia: Journal of Infectious Diseases Advance Access published September 22, 2014

shifted to P.f elimination in the region. Thus, PSI has developed the key milestones/new activities beyond Year 3 implementation (beyond 2014 through March 2016). The revised milestone/workplan which included the key new activities is summarized below (new milestones are in italic).

For each objective, describe the critical milestones for the reporting period and whether they were achieved or delayed	If achieved: what source of evidence do you have to support the result? If delayed: what was the cause of the de- lay?
Objective 1: Increased opportunity, ability, and m test for and appropriately treat Pf malaria	notivation of private providers to effectively
Activity 1.1: Baseline Research	
Milestone 1: Baseline Studies complete by end of Q2	Achieved see section following this table for summary results
Milestone 2: Target price points agreed by end of Q2	Achieved A second distributor, PolyGold, has been engaged and prices set at the same level of subsidy as the initial distributor
Activity 1.2: Replace Monotherapy Distribution w	vith Branded ACT Distribution
Milestone 1: Treatment formulations agreed upon, drugs ordered	Achieved
Milestone 2: Contract with distributor(s) signed and first ACTs sold by end of Q2	<u>Achieved</u> Contract with a second distributor, PolyGold, was signed during this reporting pe- riod
Milestone 3: Expand the distribution of QAACT and provider BCC activities to the western part of the country by end of 2015	Request for approval letter for expansion sub- mitted to MOH and waiting approval.
Activity 1.3: Develop a provider-targeted behavio	or change communications campaign
Milestone 1: Communication plan developed for health providers by end of Q2, including medical detailing support materials	Achieved
Milestone 2: Communications campaign launched and approximately 130 "product pro- moters" deployed and active by Q2	<u>Achieved</u> With the exception of some active conflict areas (notably in Kachin State), a total of 148 field staff for BCC activities were deployed (including newly recruited IPCs)
Milestone 3: Communication campaign for RDT testing behavior among providers devel- oped and obtain approval from MOH by end of June 2015	Provider BCC campaign developed, existing materials reviewed and revised. ToT on PBCC carried out, and training to all field staffs com- pleted.
Activity 1.4: Undertake advocacy activities to pre	event the renewal of FDA regulation of oAMT
Milestone 1: New registrations and license renewals of oral monotherapies are stopped by FDA once the replacement of oAMT with ACT is underway	Achieved One particular oAMT has been seen in the market with a June 2013 manufacturing date. The product is being imported from Vietnam. It is not being distributed by AA or Polygold. PSI has made both the DOH and FDA aware, including in- formation regarding the manufacturer and in- country distributor. It is worth noting that institu- tional support for the FDA is included in the re- cently completed Global Fund RAI Concept Note for Myanmar.

Milestone 2: Undertake advocacy activities to ban the sales and distribution of oAMT to FDA and de- velop action plans to work with FDA on this by end of Dec 2015	Initial discussions started with support from RAI and ERAR. Plan to form a drug monitoring Inter- pol task force with all stake holders including po- lice force and custom.
Objective 2: Increased opportunity, ability, and m ern Myanmar to request an RDT before accepting such tests are offered	notivation of the target population in east- g malaria treatment and to know where
Activity 2.1: Develop a user-targeted behavior ch	ange communications campaign
Milestone 1: Communications plan developed for users by end of Q2	Achieved detailed in 2013 progress report
Milestone 2: Communication materials produced and tested, campaign placed and aired from Q3	Achieved detailed in 2013 progress report
Milestone 3: Communication campaign for RDT demand creating targeting to end users developed and obtain approval from MOH by end of June 2015.	Mass media TVC and Radio spots obtained approval and already on air, while print and other materials such as pamphlets, posters re- vised and resubmitted for approval
Additional Activities: Product Packaging	
Milestone 1: Packaging of ACT	Achieved samples available upon request
Milestone 2: Packaging insert and overall de- sign	Achieved samples available upon request
Milestone 3: Packaging options designed and market research conducted	<u>Achieved</u> A new brand of QA_ACT specific to the 2nd distributor PoloGold was developed, and tested for acceptability by the distributor, wholesalers/retailers and end-users.
Milestone 4: Key informant interview carried out to design the packaging for RDT and the packaging materials designed, developed and procured for RDT by end of June 2015	Completed.
Additional Activities: Human Resources	
Milestone 1: International Technical Advisor re- cruitment	Achieved
Milestone 2: Project Manager recruitment	Achieved
Milestone 3: Project staffing restructure and additional recruitment	<u>Achieved</u> Additional research capacity is currently being sourced due to increasing malaria program complexity and workload (costs to be shared across multiple malaria funding streams)
Milestone 4: Carry out HR analysis to assess the additional HR needed for RDT demand creating in the community and HR (IPC chan- nel) recruited by end of March 2015	Completed.
Objective 3: Increased opportunity, ability, and m duct a rapid diagnostic test prior to appropriately proved, quality assured ACT.	notivation of private sector providers to con- y prescribing and dispensing nationally ap-
Activity 3.1: Develop plan, and gain no-objection bution in the private sector (plan to cover BCC/d structure, protocols for non-Pf treatment, and res	from policy makers for scale-up of RDT distri- etailing approach and incentives, pricing sponse to negative tests)
Milestone 1: Pilot RDTs with informal providers in year 1	<u>Achieved</u> Phase 1 pilot successfully conducted. Report submitted.

Milestone 2: Plan agreed to by MoH	Delayed MoH denied approval for RDT scale- up. New leadership at the Ministry has not yet concurred with previous leadership's favorable view of this intervention. Advocacy on ongoing to achieve agreement which is hoped for in early 2015.
Milestone 3: Develop RDT distribution model, shared with MOH/donors by end of June 2015	Completed and shared to MOH.
Milestone 5:Develop training manual and plan for RDT and roll out ToT to field staffs by end of March 2015	Completed.
Milestone 6: Roll out RDT training to AMTR outlets started in July 2015	Will be rolled out in July in current AMTR townships in the eastern part of the country.
Milestone 7: Develop quality assurance sys- tem, pilot in 2 townships by end of Dec 2015	Tools from Cambodia reviewed and adapted.
Milestone 8: Roll out QA system to improve/monitor malaria case management in the private sector in all project townships by June 2016	To pilot in Oct to Dec 2015.

Objective 1: Increased opportunity, ability, and motivation of private providers to effectively test for and appropriately treat Pf malaria.

Indicators of success during this project period include:

- 1. Unlike AA who works with its own sales force (of over 100 staff) throughout the country, the new ACT distributor PolyGold (PG) works on a different distribution model. PG has only 2 offices (Yangon and Mandalay) and its distribution relies solely on the network of its sub-distributors (they are regional level wholesalers). This means that once the drugs were issued from PG's warehouse, the products became the property of sub-distributors and there is no reporting/tracking mechanism on what quantity of the drugs actually go where. Therefore, PSI provided additional support including setting up the sales/inventory system at PG offices, establishing the unique outlet identifier codes for easy tracking, providing training to sub-distributors sales persons on proper recording and reporting using the tools developed by PSI. Psi conducted these trainings in the last quarter of 2014 and in 10 cities from different States and Divisions. This will help PSI to effectively monitor the distribution of QAACT and ensure that the project is in compliance with donors' rules and regulations. This also helps to complete the monthly QAACT distribution report in a timely manner.
- 2. Since the AMTR project townships are hard to reach/border areas, recruitment and retention of the right people is challenging. This has resulted in high staff turnover, which forces PSI to repeat trainings for the new comers. "Recruiting better people or the right people with good communication skills, who can speak local language" and "provide better induction and training to all field staff carrying out PBCC to AMTR outlets" were identified as key areas for improvement from AMTR annual project review meeting with field staff. To address this PSI a) has decentralized the recruitment to the respective field offices in order to get the staff who can speak ethnic/local language and has necessary communication skills to perform their function; and b) recruited a short term consultant to develop a digital training package (induction and follow up) to be used on

tablets using visual aids, videos and audios. PSI hopes that with this package, the field officer/managers can provide training to every new field staff easier and faster.

- 3. PSI carried out an internal exercise to estimate additional resources needed for additional activities required to further the malaria elimination agenda. These activities include processing approval requests from MOH to conduct field work, addressing the recent findings of the independent emergence of K13 mutations in western part of the Myanmar, particularly Myanmar India border, and continued availability of oAMT outside AMTR project townships. This strongly suggests the need for AMTR to expand outside current intervention area. PSI discussed this with donors during annual project review visit in February 2015 and continues to seek donors' guidance and approval to review and update project activities and workplan.
- 4. While managing a project at scale, continuous monitoring and analysis of the data for effective allocation of the resources is critical to increase value for money and to achieve high impact. The data on address, type, availability of QAACT and oAMT for all outlets visited by Product Promoters (PPs) for provider BCC were recorded in PSI's MIS system. The analysis showed that a relatively large proportion of outlets are inactive, never restock any AM/QAACT in the past year. PPs are putting efforts on monitoring/supervising those outlets. The reasons many outlets have become inactive and the action items to address this problem were discussed in AMTR review workshop in January 2015. Follow-up actions were identified, such as MIS unit carrying out further analysis to identify patterns (e.g., what type of outlets became inactive more than other types, in what particular region, is there any difference between the different states and regions etc), field operation team developing an improved territory management plan to dissociate inactive outlets from the system/project, maintaining a minimal outlet stocking QAACT in each village/village tract, and ensuring more frequent visits to active outlets while dedicating less efforts on low performers. The progress and outcome of these activities will be included in the next programmatic report.
- 5. Apart from QAACT distribution through the distributors' (private sector) supply chain, PSI also supported other organizations working in the conflict affected and border areas to improve access to quality malaria medicines to the community living in those areas. PSI provided both the materials and the design for communication materials such as malaria educational pamphlets, flipcharts for Interpersonal Communicators (IPC) and the short malaria education videos to IOM to use/distribute in their project townships in Tier 1 area (list of townships and details in attached AR document in Annex 1). Two partners (Community Health and Development –CHAD based in Myitkyina and implementing health related activities in 4 townships in Tier 1 area) have also requested PSI to provide malaria commodities and PSI is now planning to seek donors' approval (please see the details in attached AR document Annex 1). This is also one of the recommendation from annual review report.

Objective 2: Increased opportunity, ability, and motivation of the target population in eastern Myanmar to request an RDT before accepting malaria treatment and to know where such tests are offered

The primary objective of the project to rapidly replace oAMT drugs with QAACT in the private sector outlets has been achieved in the first phase of the project, PSI's strategy has evolved to focus on improved case management using malaria RDT testing for all fever cases before

dispensing QAACTs. This will not only help improve value for money by increasing the rationalized use of QAACTs, the main cost driver of the project, it will also reduce the likelihood of development of parasite resistance to the partner drug. This is also in line with the GMS's (and Myanmar NMCP's) malaria elimination strategy. Thus, the new logframe indicators that are relevant to RDT scale up phase have been proposed and approved by donors during annual review visit in February 2015. Aiming towards this shift on RDT scale up, the following are summarized indicators of success and key activities carried out during this project period:

- 1. In order to address the lower than expected performance to date against the consumer BCC indicators (2014 malaria household survey showed that although about 37.6% of target population was aware of Padonmar seal/logo, only 6.2% could associate it with quality antimalarial drug), during AMTR review workshop in January 2015, a brainstorming exercise on how to improve communication materials (IEC/print/TVCs) was carried with the field team. Based on the meeting results, PSI developed a consumer targeted BCC campaign to create demand for RDT among end-users: "Get Tested First" (before taking any antimalarial medicine because not all fever are malaria). PSI is ensuring that the materials are right on point for the target audience, are in ethnic languages, include more pictures and less words (IEC). PSI has also recruited a consumer insight manager to focus on this.
- 2. A phase two communication campaign encouraging demand for RDT testing before receiving treatment (and not to take antimalarial drug if the test showed negative) was approved by the MoH. Radio and TV airing will be started in May 2015. However, some materials to be used for billboards, posters and pamphlets had to be revised to address MOH's comments. PSI will re-submit the materials to MOH at the end of April 2015.
- 3. Measuring the end-users' behavior on completing the treatment (provided that RDT test was performed and showed malaria positive) has been a challenge as the disease trends have declined over the past year. PSI plans to carry out a follow-up study to the malaria positive clients who received QAACT from PSI trained AMTR outlets in December 2015. As a first step, in order to carry out a follow up study, PSI has developed malaria case load data collection tools to be filled out by AMTR outlets on a monthly basis. This form now includes the address of individual patients. The tools are now being reviewed and revised by PSI Regional M & E advisor. Roll out is planned by September 2015. The study design and the questions of interest to be included in the study were already drafted by PSI Myanmar research team. The timing of the study is subject to change depending on how easily the AMTR outlet providers can fill out the forms, and how quickly the case load data can be retrieved. Moreover, Malaria Consortium is planning to carry out Malaria Indicator Survey this year. PSI has discussed and reviewed their tools to ensure that the data on health seeking behavior for fever/malaria was included. PSI will use this as an alternative source of data.

Output 3: Increased opportunity, ability, and motivation of private sector providers to conduct a RDT prior to the appropriate prescription and dispensing of nationally approved, QAACTs

Under this output, PSI is expected to increase the availability and correct use of RDTs in the private sector. This includes ensuring that all patients receive a (positive) test for malaria before purchasing QAACTs in the private sector. This will help improved case management of both malaria and non-malaria fever, reduce ACT drug wastage, and reduce the threat of resistance emerging to the partner drug. There is an end-of-project coverage and correct usage target of 18% (among target outlets).

Achievements and indicators of success for this reporting period include:

- 1. The approval for RDT scale up had been denied during the transition in the structure and key personnel of MoH. PSI revised the approval letter of RDT scale up to be more comprehensive and resubmitted to MoH. Approval for RDT scale up was attained in this second time submission, but the detailed way forward for rolling out RDT deployment in private sector was not explicit. The advocacy meeting with the higher level MOH personnel was carried out by PSI's Country Director and along with free distribution of RDT in the private sector (at all level of supply chain), training on RDT testing to private providers by PSI's product promoters and mass media RDT communication campaign were approved at the central level. PSI will carry out advocacy visits to all States and Divisional level health authorities during April to May 2015 to obtain approvals from them.
- 2. Since RDT distribution was recommended to be free, PSI will not be able to use existing distributors' supply chain due to lack of incentives at all level of supply chain. Acknowledging that this is not the best scenario that PSI hopes for, and the speed and efficiency of the RDT scale up will not be as comparable to what was done with QAACT distribution, PSI has carried out an operational planning meeting internally with for key persons involved. Anticipated challenges and risks associated, actions/strategies to overcome/mitigate this, and PSI's sales team's existing coverage and HR, and the additional resources needed for RDT scale up were discussed. Based on the discussions, the distribution model was developed to be shared with donors by July 2015.
- 3. One important anticipated challenge was that not all AMTR outlets that currently stocking QAACT will be interested to participate in RDT scale up for a number of reasons including a) declining epidemiology and not enough incentive for RDT business; b) not enough resources at the outlet/facility (time, space, HR); c) provision of malaria treatment is not their primary business etc. Therefore, what to do with those outlets, how to manage them, and what will be the estimated total number of potential RDT outlets were discussed for activity planning. PSI estimated that only about 50-60% (9000) of current AMTR outlets (15,000)⁶ will be participated in RDT scale up, and majority of general stores or grocery stores will opt out from the program. Thus, better territory management plan and outlet prioritization is essential when rolling out RDT deployment. The plan is not to invest too much time and resources towards inactive outlets or those that do not have the capacity for RDT administration, but at the same time to recruit at least one outlet that can perform RDT in a village.
- 4. PSI MIS unit analyzed outlet visited data, cleaned duplications, and then disseminated to operation team for better territory management. Moreover, PSI has also collected GPS coordinates of majority of outlets visited by PP and stocked QAACT (except in some regions of conflict zones where carrying GPS device is sensitive to ethnic armed forces). Thus, for visualization of the QAACT availability and coverage, all outlets were uploaded onto the map (link below) and this will help improve territory management and planning. This is the first version of the QAACT stocking AMTR outlets on the GIS map, and we are trying to map them by township level (which will be useful for field level staffs to make programmatic decisions) overlaying the layers of relevance such as epidemiology, altitude, forest, population density etc provided that those information

^{6&}lt;sup>®</sup>Please note that this does not taken into account the expansion into western part of the country.

are available. The managers can see the performance of their staffs in one click – what type of outlets, how many visited, where they are located and what drugs are available etc, and can track the changes over time. <u>https://www.google.com/maps/d/viewer?</u> <u>mid=z6NoAorNPr58.kPVydv7LWhe4</u>

https://www.google.com/maps/d/viewer?mid=zpkq-zv-DOnk.k9_UH5tp7Wqk&usp=sharing

- 5. Based on the results from AMTR review workshop, PBCC was identified as a good starting place to address issues such as improved field communication field resources. A focus group of Product Promoters was held in March to further expand on the AMTR field experience and needs, and ultimately, PBCC materials for ACT and RDTs were developed based on these meetings. In June, the new PBCC materials, along with a communication skills-building training were rolled-out to select PPs and supervisors as a Training-of-Trainers workshop. Having successfully participated in the workshop and practiced for cascade trainings, these new Trainers will facilitate PBCC resources and skills workshops to all of their peers within the month of July.
- 6. As an initial step to mobile data collection aiming to establish real-time, mobile devicederived monitoring of ACT and RDT availability and to provide malaria caseload data from private sector integrated into NMCP database, the manual data collection and monthly monitoring forms were developed and planned to use once the RDT distribution start. The forms are currently being reviewed and revised by PSI Regional M & E advisor. After the initial 3-4 months of the manual forms/data collection has been rolled out, the tools will be revised to adapt into DHIS2 to roll out mobile data collection based on the feedback from the field. DHIS2 consultant has been recruited and started working for PSI – reviewing the existing data base system and tools, current infrastructure etc.

UPDATED APPENDIX A: RESULTS AND CRITICAL MILESTONES TABLE

A new critical milestones table has been developed that takes into account the results of the RDT pilot and approval on RDT scale up from MOH, budget remaining, no-cost extension discussions, and technical updates related to epidemiology (Annex 2).

When AMTR project was designed in 2010/2011, logframe (LF) indicator was developed with inputs from the technical experts to be in line with RBM and other standard malaria indicators of relevant by that time. However, due to changes in the epidemiology and recent strategic shifts in GMS malaria elimination strategy, some of the LF indicators are no longer relevant. RBM has also revised their indicators. Therefore, PSI is currently reviewing AMTR LF indicators by reviewing RBM, MIS (Malaria Indicator Survey that is planning to carry out in Myanmar this year) and other relevant indicators to check if they are in line, and how they are or should be consistently measured across all surveys. PSI has also seeks TA from Malaria and Child Survival Technical Team and ACTwatch team. The revised LF with proposed changes in the language will be submitted by end of July as recommended in annual project review report.

Context and Rationale

The major changes in context relevant to the AMTR project that have emerged are: 1) the steep slope of declining malaria prevalence; and 2) the independence emergence of falciparum resistance parasite gene (K13) mutations in multiple geographic locations that has shifted the whole GMS towards Pf malaria elimination by 2030; 3) thus the involvement of private sector in improved case management, surveillance and elimination become critical (where AMTR project will play a central role); and 4) persistence presence of oral artemisinin monotherapy outside current AMTR intervention area.

The decline in malaria prevalence in the region places much greater emphasis on improved case management, which the project has already made progress on with plan to roll out RDT scale up in 2015.

A cross sectional survey of the K13 molecular marker conducted at 55 sites in ten administrative regions in Myanmar and in relevant border regions in Thailand and Bangladesh, between January 2013 and September 2014, revealed that artemisinin resistance extends across much of Myanmar and parasites carrying K13-propeller mutations had reached at high prevalence next to the northwestern border with India. This study also describe that resistance strains are emerging independently. This has implication on resistance containment strategies – resistance tiers has now been revised (and in Myanmar, all Kayah and East Bago townships became Tier 1 while the rest of the country became Tier 2), and the elimination of Pf parasite from the whole region was considered as the only option to fight the resistance malaria problem as the firewall approach will no longer work.

The GMS malaria elimination agenda presents an opportunity for full engagement of the private sector in improved case management (especially in Myanmar context where >50% of people seek care in the private sector⁷), delivering data from the private sector to NMCP, and, crucially, real-time monitoring and surveillance in the pre-elimination and elimination phases. PSI's plan to use mobile data collection and DHIS2 to be able to link directly with the public health data system can be a major asset during these phases. PSI is also poised to play an expanded role across the GMS in antimalarial market monitoring through ACTwatch, as well as K13 mapping in partnership with the University of Maryland, Baltimore and the Department of Medical Research, to better understand pattern of drug resistance in Myanmar.

Considering the resistance emergence in western part of the country (Myanmar India border), new Tier stratification and persistence presence of oAMT outside AMTR intervention area, there is an urgent need of AMTR expand beyond current intervention areas especially to the western border of Myanmar. Thus, PSI has proposed to scale up provider BCC activities through Product Promoters in 50 additional townships in 4 States/Divisions (Rakhine, Chin, Sagaing and West Magwe) to the donors and to MOH for approval. Re-aligned budget was also submitted to the donors.

A good news is that all 3 ACTs included in the national treatment guideline are still effective in Myanmar according to TES studies carried out in 2014. Thus, PSI will continue using current ACT – AL combination.

Challenges, Threats and Opportunities

The central immediate threats to AMTR are: 1) PSI's ability to scale up RDT distribution in the private sector; 2) guidance on treatment of non-malaria fevers by private providers; 3) Supply chain management under conditions of declining malaria prevalence; and 4) the potential for political unrest surrounding the planned elections in late 2015 and the potential limitations for carrying out field activities particularly big population level studies.

Successful RDT scale-up is the key to improved case management in the private sector. Moreover, it will largely determine the value for money of the project, and will also have implications on sustainability. The specific challenges associated with RDT scale up are

• the limitations on the distribution model from MOH (to distribute free at all levels of supply chain) will have negative impact on the speed, reach and efficiency of the

^{7&}lt;sup>®</sup>2014 Malaria Household survey in Myanmar.

project (additional HR recruited)

- declining total number of outlets that remain in the malaria service provision business as the disease burden declines (better territory management plan)
- negative incentives for the providers when the test result turned out negative (PSI is now developing incentive system for providers that will include both the quality aspect and reporting/recording the case load)
- anticipated persistent demand for antimalarial drugs by end-users regardless of the RDT test result (RDT demand creation consumer BCC campaign developed and roll out);
- unclear or no guidance/protocol for treatment of non-malaria fevers (continued advocacy to NMCP and at TSG meetings)
- even for malaria positive cases, MOH concerns re: the private providers dispensing Primaquine for single dose treatment of Pf and radical treatment of Pv cases (and thus recommended to refer to nearest public health facility for follow up PQ treatment which is impractical)
- no G6PD deficiency testing tool to be used at scale at the community level (PSI is exploring the tools on this to pilot)
- reliability of RDT test results and the quality of RDT tests in the field setting (need a tool for QA of RDT in the field at point of care) (PSI plans to test Positive Control Wells QA test for RDT in 2016).

As referenced in the Montrose Assessment, commodity and supply chain management have been major challenges for the AMTR project. PSI continues to strive to maintain a balance between the risk of drug expiry and the risk of drug stock out. A detailed description on the risks, challenges and mitigation actions taken by PSI has already been submitted (Annex 3).

Considering the sustainability of the project, PSI has requested an additional twelve month nocost extension until March 2016 during the annual donor review visit in February 2015 and it has been approved now. PSI has also secured \$3 million funding from Global Fund Regional Artemisinin Initiative grant to support AMTR project from April to December 2016, and also expected that GF (NFM and RAI) will continue its support to AMTR in the next round to Myanmar from 2017 to 2020.

With technical assistance from Program Analytic team from HQ in Washington DC, PSI Myanmar is now trying to develop a "revised theory of change," incorporating the changing epidemiology, public sector scale-up, and the trends of antimalarial market in private sector due to AMTR project, and helath seeking behavior over time etc based on all the available data from a number of sources including annual outlet survey and household survey, the case load and village health volunteer data from GF and 3MDG/NMCP (public sector). Tom Drake, a Myanmar focal person from Oxford Mehidol Mathematical Modeling group was also involved in this exercise by sharing his experience from other countries and sharing the data. The first draft was shared internally for review and comments, and will finalize to share with donors (tentatively in last quarter of 2015). This revised theory of change will also help PSI to assess if AMTR needs support beyond 2017.

NMCP is now trying to revise the National Malaria Treatment Guideline and PSI is a member in this the technical working group for treatment guideline revision. In the existing guideline, oral artemisinin monotherapy (oAMT) was recommended as a second line drug to treat P.f malaria in some conditions such as suspected treatment failure with ACT. Moreover oral Artesunate plus Mefloquine was also recommended as first line treatment for P.f. All of this allows room for continued importation/distribution of oAMT in the market in Myanmar. Therefore, with support from other members of the working group, PSI has suggested to delete oAMT from the treatment guideline (second line treatment for suspected treatment failure with one ACT replaced with another ACT combination, and no co-blister formulation should be allowed to imported) and it was agreed by all partners at a wider group workshop carried out in May 2015. Thus, NMCP has approved the decision and the treatment guideline is now being finalized to share all partners in late 2016.

III. Plans for the Next Reporting Period

For the next reporting period (April 2015 to September 2015), PSI anticipates implementing the following key activities:

- 1. Revision of the theory of change and its timeline for the reminder of the project and development of project sustainability plan beyond 2016 with support from donor
- Expansion of AMTR in 50 additional townships in the western border of Myanmar in Rakhine, Chin, West Magwe and Sagaing region with deployment of PSI's product promoters to carry out provider BCC activities
- 3. RDT distribution and training to AMTR outlets (in the eastern region only) started
- 4. Consumer targeted RDT demand creation BCC campaign "Get Test First" fully launched nationally through all channels
- 5. Roll out of ACTwatch expanding to 4 domains (AMTR intervention area, comparison area that is the townships proximity to AMTR with similar endemicity, Myanmar Bangladesh border and Myanmar India Border). This will be the first nationally representative antimalarial market data for private sector.
- 6. Finalize the manual case load data collection tools and roll out to all AMTR outlets.
- 7. Develop and finalize the QA tools to monitor the quality of malaria case management in the private sector that can be linked with DHIS2 database enabling real-time data analysis.
- 8. Participate in National Strategic Planning workshop for 2017-2020; participate in malaria village stratification workshop; and to take a leading position in the Interpol Taskforce forming workshop to tackle/track oAMT and counterfeit and substandard antimalarial drugs across GMS that will be organized by ERAR.

List of documents attached with this progress report are:

Annex 1: Follow up on Annual Review Recommendations Annex 2: Revised Milestone Summary Table for AMTR Annex 3: Risks, Challenges and Actions taken to Improve Commodity Management Annex 4: Updated Risk Matrix

IV. Financial Update for the Reporting Period

BUDGET NARRATIVE – Reports previously provided under separate cover.

Sub-grantees and Subcontractors

Report all amounts in U.S. dollars.

Organization Name	Location (city, country)	Total contracted amount	Actual disbursement for this reporting period

Other Sources of Project Support

Report all amounts in U.S. dollars.

Donor	Amount	Received or Potential
Bill & Melinda Gates Foundation	\$7,500,000	Received
DFID	\$17,655,000	Received
Good Ventures	\$1,000,000	Received

Description of in-kind support, if any: This project is jointly funded by the Bill & Melinda Gates Foundation, the United Kingdom"s Department for International Development (DFID) and Good Ventures Foundation.

V. Optional Attachments

CLINICAL STUDIES AND REGULATED RESEARCH QUESTIONS

Question	Yes or No
Will the project involve a clinical trial ¹ ?	
According to the definition provided, what phase(s) will the projectinclude (Phase I, II, III, or IV)?	No Phase
Does your project involve research using human subjects ² and/or vertebrate animals?	No
Does your project involve the use of recombinant DNA?	No
Does your project involve the use of biohazards or genetically modified organisms or plants?	No
Will the project involve the use of pathogens/toxins identified as select agents ³ by U.S. law?	No

²human subjects

http://www.selectagents.gov/Select Agents and Toxins List.html ³ select agents

If you answered "yes" to <u>any</u> of the questions above, you must complete the <u>Clinical Studies</u> <u>and</u> <u>Regulated Research Assurances Attachment</u> and submit it along with your progress report.

TECHNOLOGY AND INFORMATION MANAGEMENT QUESTIONS

Please provide a response to the following questions using the definition of terms provided below. If you have submitted an annual report previously and nothing has changed from your previous submis-

sion, please indicate "no change".

	Yes/No/No Change
Question	Νο
Do any Third Parties ¹ have Rights ² to Background Technology ³ ?	No
Do any Third Parties have Rights in Project Technology ⁴ ?	No
Have you filed any copyright registrations for or patent applications claiming any Project Technology?	

¹**Third Parties**: All individuals, organizations or companies that have not executed a foundation approved collabora - tion agreement associate with the project.

²**Rights:** (i) Any interest in patents, patent applications and copyrights (e.g. license, ownership, option, security interest and (ii) the rights to use any technologies, information, data or materials.

³Background Technology: All technologies and materials, and all associated Rights, used as part of your project that were created prior to or outside of the project.

⁴Project Technology: All technologies and materials created, conceived or reduced to practice as part of your project and all associated Rights.

If you answered "yes" to <u>any</u> of the questions above, you must complete the <u>Technology and Informa-</u> tion <u>Management Attachment</u> and submit it along with your progress report.

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