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Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2011 – March 2017

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Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: Final Narrative Report

Submitted 30th June 2017

Population Services International (PSI) – Myanmar

I. Summary Information

GRANT INFORMATION (BMGF)

Project Name Containment of Artemisinin Resistance in Eastern Myanmar

Organization Name Population Services International

Grant ID# 1024757 **Foundation Program Officer** Jonathan Cox

Date Grant Awarded October 2011 **Grant Amount** $7,500,000

Project Start Date October 2011 **Project Duration** 66 months

Final Report Period From October 2011 **To** March 2017

Report Due *June 30th 2017*

Has this project been granted a no-cost extension? *Yes, a no-cost extension was approved on 22 Oct 2015, and the contract was amended to extend the duration until 31 March 2017*

GRANT INFORMATION (DFID)

Project Name Replacement of Malaria Monotherapy Drugs in the Private Sector

Organization Name Population Services International

Component #/ Purchase Order # 202759-101/40049299 **Program Officer** Dr. Wai Lwin

Date Grant Awarded October 2011 **Grant Amount** $17,655,000

Project Start Date October 2011 **Project Duration** 66 months

Final Report Period From October 2011 **To** March 2017

Report Due *June 30th 2017*

Has this project been granted a no-cost extension? *Yes, a no-cost extension was approved on 22 Oct 2015, and the contract was amended to extend the duration until 31 March 2017*

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

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Geographic Location(s) of Work		
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		
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. Narrative

1. Goal:

The Artemisinin Monotherapy Replacement (AMTR) Project was developed in conjunction with the Myanmar Artemisinin Containment Strategy (MARC) in 2011[1]. The MARC framework presented a comprehensive set of interventions aimed at malaria control and the growing problem of artemisinin resistance in the GMS, including prevention programs, increased testing and treatment through public sector providers, and the replacement of oral artemisinin-based monotherapy (oAMT) in the private sector with artemisinin-based combination therapies (ACTs).

PSI's AMTR project aimed to work with private sector suppliers and providers throughout Myanmar to rapidly replace sub-standard antimalarials in the private sector (particularly artesunate monotherapy) with government-approved, quality assured ACTs (QAACTs), and to reduce suboptimal dosing among the target population in eastern Myanmar. Supply chain activities were conducted alongside wide-reaching behavior change communications (BCC) targeting both consumers and providers in high risk border areas, emphasizing the importance of malaria testing and treatment compliance. The expected impact of the project was the prevention (or at minimum significantly delay) of the spread of artemisinin resistant Plasmodium falciparum (Pf) malaria parasites within Myanmar and beyond its borders.

To that end, PSI engaged the two major private sector suppliers of oAMT in the country: AA Pharmaceuticals and Polygold, which, after negotiation with PSI, agreed to purchase highly subsidized, pre-packaged, quality-assured ACTs from PSI, rapidly replacing oAMT in at least 70% of all private sector malaria treatment in Myanmar. The quality assured ACT was branded *Supa Arte* and over packaged by PSI. An additional brand, *Artel Plus* was introduced in 2014 to facilitate market competition. The packaging included a quality-assurance lotus leaf for consumer recognition of the brand as a high-quality WHO and nationally recommended medicine. Complementing the private sector distribution of subsidized ACT were a variety of demand creation activities targeting private sector providers and patients. Underserved outlets (pharmacies, general retailers, and itinerant drug vendors) were targeted by PSI in project intervention areas.

The program achieved game-changing success in reducing the availability of monotherapies among targeted outlets, from 67% at baseline in 2012 to only 20% in 2016— a decrease of 47% in just 4 years. The project has continued to expand the availability of first-line, quality-assured ACTs among targeted outlets, from 4% at the beginning of the project to 50% in 2016. In the majority of project areas, a full course of quality-assured ACTs continue to be sold at or below the cost of a single-dose of oAMT (500 Myanmar kyat, approximately $0.37 USD).

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2. Objectives & Results:

The goal of the AMTR project has always been to prevent (or at minimum significantly delay) the spread of artemisinin resistant Pf parasites within Myanmar and beyond its borders.

As mentioned in greater detail in the challenges section, the program has seen three significant contextual shifts: 1) a much faster than expected decline of malaria burden in Myanmar; 2) new evidence indicating artemisinin resistance is not just spreading but emerging spontaneously in Myanmar; and 3) concerning data from market surveys that showed a rise in monotherapy availability in 2015.

[1]The strategy was developed by the Ministry of Health and Sports (MOHS) in collaboration with the World Health Organization (WHO) and other development partners and endorsed in April 2011

Due to the major contextual changes above, the logframe was revised in 2015 to better reflect the evolving context and resulting shifts in the project, in agreement with donors. Some indicators were not measurable or they had to be adjusted.

Primary Outcome[2]

The primary outcome of the project was "increased availability (and appropriate use) of RDTs in the informal private sector as oral artemisinin monotherapy is displaced from the market and replaced with quality-assured ACT (in order to reduce drug wastage, improve case management practices and mitigate the risk of resistance developing to artemisinin partner drugs)".

The 3 primary Outputs under the revised logframe were:

1) Output 1: Increased opportunity, ability and motivation of private providers to effectively test for and appropriately treat Pf Malaria[3].
2) Output 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[4].
3) Output 3: Increased opportunity, ability and motivation of private sector providers to conduct a rapid diagnostic test (RDT) prior to the appropriate prescription and dispensation of nationally approved QAACTs[5].

The section below highlights key achievements and activities under each output.

Output 1: Increased opportunity, ability and motivation of private providers to effectively test for and appropriately treat Pf Malaria

1. Advocacy to the NMCP, MoHS, and FDA

The AMTR project has benefited from the strong support of the Myanmar National Malaria Control Program (NMCP). PSI first negotiated with the Ministry of Health and Sports (MoHS) to allow non-formal outlets to sell first-line quality-assured ACTs in 2012, which was foundational to the goals of the AMTR program. The success of the program's early years allowed PSI to receive approval to scale up RDTs through trained and supervised AMTR providers beginning in 2015. The AMTR program is unique in the region in terms of its support from the Myanmar NMCP/MoHS as none of the other GMS countries allow the same scope of malaria activities to occur in the non-formal private sector.

2. Subsidized QAACT distribution

PSI's rapid market assessment studies in 2012 found oAMT to be the most common antimalarial drug available in the private sector, with the supply chain dominated by a single distributor, AA Pharmaceuticals. The most common treatment practice for suspected malarial fevers in the private sector was to administer two or three tablets of oAMT at a total cost of 500 kyats. Therefore, PSI has partnered with AA (and PolyGold in 2014 to maximize the coverage and to boost market competition) to distribute highly subsidized QAACTs through its existing supply chain. PSI's negotiations have convinced these

[2] Revised in 2015. Original primary outcome was: "Sub-standard antimalarials in the private sector (particularly artesunate monotherapy), replaced with government approved and quality assured ACT, and suboptimal dosing reduced among the target population in eastern Myanmar."
[3] Revised in 2015. Original output (2011): "Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT."
[4] Revised in 2015. Original output (2011): "Increased opportunity, ability and motivation of the target population in eastern Myanmar to promptly and effectively treat suspected malaria with a nationally approved and quality assured ACT."
[5] Revised in 2015. Original output (2011): "Increased opportunity, ability, and motivation of private sector providers to conduct a rapid diagnostic test prior to the appropriate prescription and dispensing of nationally approved, quality assured ACT."

large pharmaceutical wholesalers to distribute subsidized QAACT, with only a minimal margin to cover logistical costs, in order to contribute to the health of communities across Myanmar.

With input from the two distributors, PSI has also designed user-friendly packaging for QAACTs (in four age/weight groups) with full instructions in Myanmar language and pictures that discourage the blister cutting of the drugs, as this is a common practice in Myanmar. Two different brands of QAACT (*Supa Arte* and *Artel Plus*) were developed for two distributors for easy monitoring and tracking of the sales of drugs, but each has been branded with the golden Padonmar (lotus flower) seal to indicate quality and boost brand visibility. Moreover, PSI also set the maximum price for the distributors in such a way that a full course of QAACT is not more than what end-users wouldusually pay for a typical partial course of oAMT to treat a fever case.

The replacement of oAMT with QAACT was not limited to any particular geographical area or population group, but took place nationwide. By March 2017, approximately 3,500 wholesale/mid-wholesale and retail drug shops located in more than 200 townships were stocking QAACT, and more than 2.1 million courses of QAACT have been distributed.

3. Geographic coverage and western expansion

The AMTR project started in 2012 with activities in 85 townships in eastern Myanmar. In response to evidence of the independent emergence of artemisinin resistance in the country, and the persistent presence of oAMT in western Myanmar according to PSI's annual outlet surveys, PSI received approval from the MoHS to expand the geographical coverage of the project to western Myanmar (including Chin, Sagaing, Magway, Rakhine). From 2015 to 2016, PSI expanded program activities to cover an additional 46 western townships, deploying more than 80 new Product Promoters enrolling 7,320 new outlets in the AMTR network. As of March 2017, PSI Product Promoters' BCC activities have reached over 30,000 outlets across 131 townships.

4. QAACT availability

QAACT availability in priority outlets in the intervention area increased from 4% of outlets stocking at baseline to nearly 80% in 2014. 2015-2016 showed a slow decline in QAACT availability with 62% of outlets stocking QAACT in 2015 and only 50% in 2016. The availability of QAACT in AMTR expansion areas (54%) was similar to that in eastern regions (50%) in 2016 (Figure 1).

5. oAMT availability

Outlet surveys from the first three years of the project (2012-2014) showed dramatic declines in the availability of oAMT in parallel with the increase in the availability of QAACT. However, the 2015 outlet survey showed a slight increase in oAMT availability in the private sector over the previous year. Fortunately, the 2016 outlet survey showed that oAMT availability in the eastern intervention area had again decreased: from 27% in 2015 to 20% in 2016 (Figure 2). However in the western expansion area where the 2015 outlet survey found the highest oAMT, oral AMT was still available in 27% of outlets in 2016. Among all outlet types, grocery stores were found to have the highest oAMT in both Eastern and Western areas (30% and 40% respectively), followed by pharmacies (7% in Eastern and 22% in Western) and informal drug vendors (5% in Eastern and 9% in Western).

6. Other Achievements

Pricing: The project continued to achieve the price target for QAACT. In project year 5, 89% of outlets sold PSI distributed QAACTs for less than 500 MMK (0.37 USD), the typical cost of one artemisinin monotherapy dose (79% in 2014 and 92% in 2015).
Supply chain consistency: the proportion of outlets with no reported stock out of PSI distributed QAACT for more than one week also continued to increase from 72% in 2015 to 86% in 2016.
Providers' Knowledge: 47% of target outlet providers in eastern intervention region mentioned QAACT as the most effective antimalarial drug, which increased from 25% of outlets in the previous year 2015.

Figure 1. Percentage of antimalarial-stocking target outlets with nationally approved and quality assured first-line ACT in stock at time of survey, across survey rounds
Among all outlets with at least one antimalarial in stock

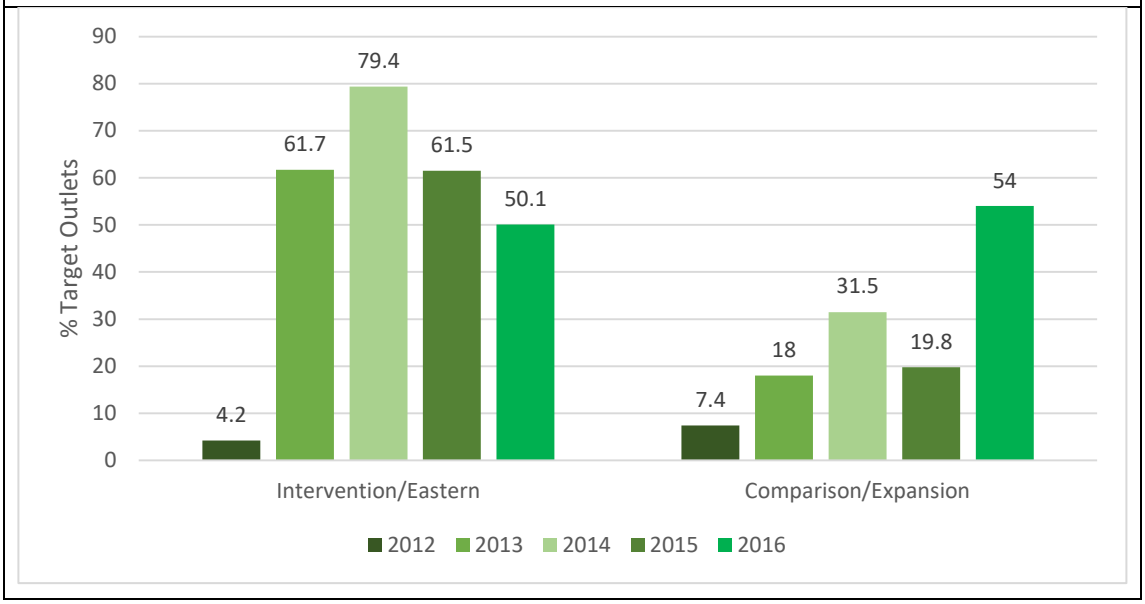
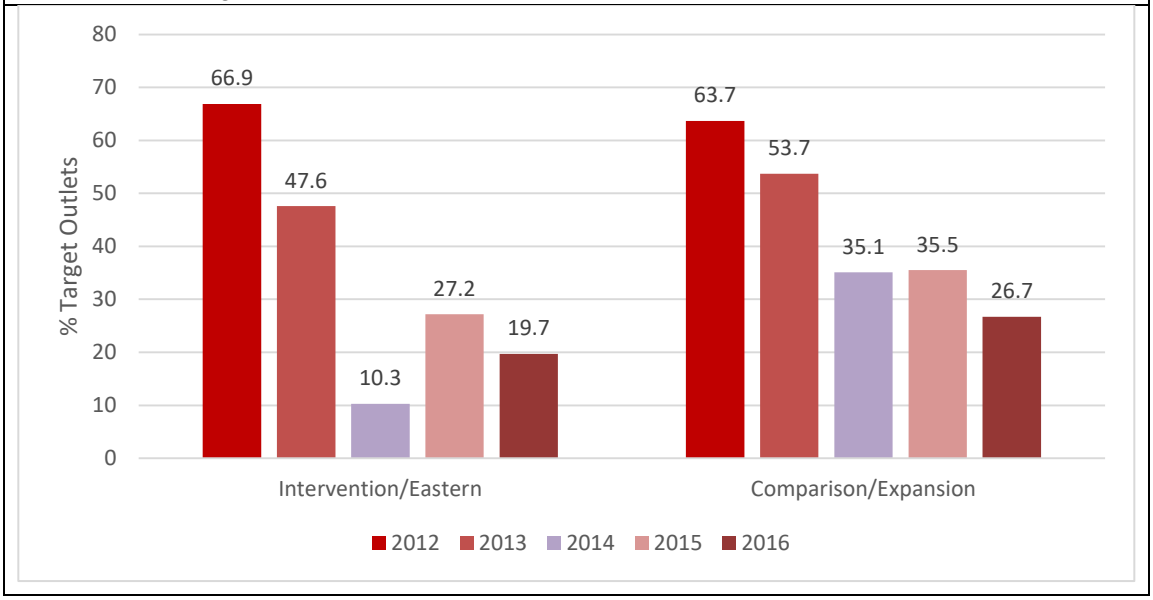


Figure 2. Percentage of antimalarial-stocking target outlets with oral artemisinin mono-therapy in stock at time of survey, across survey rounds
Among all outlets with at least one antimalarial in stock



Output 2: Increased opportunity, ability and motivation of the target population in eastern My-

anmar to request an RDT before accepting malaria treatment and to know where such tests are offered.

1. Consumer targeted behavior change communication campaign

PSI has been implementing a consumer targeted BCC campaign with a two-phase approach. The objective of the first phase was to promote the use of quality assured ACT with the Padonmar quality seal and to encourage the full course of treatment; the objective of phase two was to encourage demand for RDTs before receiving treatment and deter the use of antimalarial drugs if the test showed negative.

PSI developed television and radio advertisements for both ACT and RDT demand creation campaigns featuring high risk groups including forest and mobile workers, and these ads were aired through different television and radio stations covering most of the malaria endemic townships in the program area before and during the rainy season since 2012. Some adjustments were made in the phase-two campaign including (a) translation of the radio spots into four additional ethnic languages, (b) TV air time on a range of channels to cover the majority of the country, (c) a reduction in text and an increase in picture messaging. The phase-one campaign started to air in August 2012, and phase-two in 2015.

The campaign was supported by RDT mini-billboards in more than 60 high malaria prevalence townships, planted in high traffic areas such as bus terminals. Marketing strategies and designs for alternate communication channels such as merchandising in public transport vehicles, traditional opera, edutainment road show, etc., were also implemented in 2016. To complement the mass media communication campaign, Product Promoters conducted 60,423 inter-personal communication sessions in the period of August 2014 to March 2017 in 120 townships. These BCC messages were delivered to a total of 765,293 participants in rural communities.

2. National Communication Campaign for NMCP

In 2016, the NMCP reallocated their savings fund for the development of national communication campaigns for malaria elimination to PSI, making PSI Myanmar a key partner in the government's BCC strategy for elimination, which is highlighted in the National Strategic Plan. PSI is leading the development of the national campaign and has worked closely with the NMCP with technical support from WHO on the final design, including television advertisements and radio spots. Alternative communications strategies, such as billboards, job-aid materials for volunteers and other communication materials (e.g. pamphlets) have been developed and distributed to state and regional vector-borne disease control teams in 2017. The key messages and design of all materials have been completed with NMCP approval, and PSI has begun airing messages through five TV stations and seven radio stations since February 2017.

Objective/Output 3: Increased opportunity, ability and motivation of private sector providers to conduct a rapid diagnostic test (RDT) prior to the appropriate prescription and dispensation of nationally approved QAACTs.

1. RDT training and availability

Since August 2015, Product Promoters have used a medical detailing approach to carry out provider BCC promoting RDT testing by non-formal private providers. The outlets who have committed to providing RDT testing services have been trained on correct RDT use, results interpretation and treatment, case reporting, and waste management. PSI equips trained providers with job-aids (sharp disposal boxes, gloves, timers, etc.); Information, Education and Communication (IEC) materials (testing procedure flowcharts, treatment guidelines, etc.); and product/service reminders and signage (posters, banners, leaflets, etc.).

March 2017 marked 20 months of RDT scale up in which a total of 11,284 outlets were trained for RDT testing and over 500,000 RDTs were distributed across the 131 AMTR townships. PSI greatly exceeded the target for the proportion of outlets stocking RDT with the number of RDT-stocking outlets rising from 13% in 2015 to 37% in 2016.

2. RDT testing and reporting

The three-fold increase in RDT availability in the non-formal private sector has increased access to appropriate case management in some of the most remote areas of Myanmar: from August 2015 to March 2017, AMTR outlets tested 283,550 suspected cases for malaria and diagnosed and reported 6,760 positive cases (55% Pf, 35% Pv, 10% mixed infections).

A performance-based incentive system to encourage RDT use was launched in October 2016. 5,000 kyat (~USD3.70) is given to each RDT-trained AMTR provider who meets two requirements each month: 1) the provider tests at least five fever cases with RDTs, and 2) the provider completes and submits malaria case record forms for all suspected cases. While the average number of outlets who conducted at least five tests per month was 1,000 before the roll out of the incentive scheme, it tripled to an average of 3,000 with the incentive scheme. The average monthly testing rate of these trained private sector outlets increased from 1 at the start of 2016 to 3.6 at the end of that year. Similarly, the proportion of providers who reported monthly caseload data increased from 28% to 60%.

3. Mystery Client Survey

Between 2014 and 2016 the proportion of mystery clients tested by an RDT increased from 0.8% to 11%, a more than ten-fold increase (the mystery client approaches the provider as a patient describing recent malaria symptoms; any RDT tests performed typically result in negatives). Alongside increasing RDT use, malaria-specific presumptive treatment practices also improved greatly[6]. The proportion of clients receiving a quality-assured ACT as a presumptive treatment declined from 17% to 1%, and the use of oAMT, which has been banned nationwide, declined from 8% to 0.6% from 2014-2016.

Furthermore, the quality of services and treatment adherence to national guidelines among those providers who performed RDT testing is extremely encouraging. The 2016 survey found that 93% of providers who performed RDTs correctly described or demonstrated the five essential steps to perform RDT testing correctly and that 96% of those who performed an RDT did not provide any antimalarial drug to the patients who tested negative. The very small number of providers in the survey who recommended an antimalarial to the mystery client as presumptive treatment is a success for the program's training strategy and the national goal of decreasing presumptive malaria treatment.

4. Treatment Compliance by End-users

Following the annual review recommendations, PSI carried out a febrile patient follow up study to assess the treatment completion and compliance of end-users. From the 64 outlets selected, 153 clients (138 with Plasmodium falciparum positives and 15 with mixed infection positives) were reported within two months and these 153 clients were followed up for the study. Of the 153 clients reported, only 103 clients (67%) were interviewed and the remaining (50, 33%) were lost to follow up. Among 84 clients who received QAACT out of 103 interviewees, 51 clients (61%) reported completing the full course of QAACT provided. Although indicators regarding RDT knowledge were not achieved, it is encouraging that a considerable proportion of end-users from AMTR outlets completed the full course of prescribed QAACT.

Other achievements:

Increased Evidence Base

The AMTR project has provided tremendous insights into the non-formal private sector in Myanmar, which has been a major source of substandard drugs and other practices that increase the risk of drug resistance, through the collection of routine data and large-scale research studies. Over the course of the project PSI has conducted:

[6] Given the perilous antibiotic resistance situation in Myanmar and across the world, the number of providers who offered presumptive antibiotic treatment is of interest and concern. In the 2016 mystery client survey, a total of 140 (24%) of providers offered the mystery client antibiotics, including 118 (34%) of the 347 who proposed any treatment without testing.

Five Outlet surveys (annually 2012-2016) to provide a clear picture of the antimalarial drug market across the country.

Three Household surveys (annually, 2014-2016) to give insights into malaria knowledge, attitudes, practices of communities across Myanmar.

Four Mystery client surveys (annually, 2013-2016) to illustrate malaria case management practices in the non-formal private sector in order to inform program strategies

A Fever follow-up study (baseline in 2016) to understand common malaria treatment and patient compliance with drug regimens, which can be critical to preventing resistance.

A Qualitative Study on oAMT Resurgence (2016)
After the 2015 outlet survey revealed a resurgence of oAMT, a follow up qualitative study was carried out to identify the factors driving providers to stock, sell, or prescribe monotherapy. This investigation provided many insights about why providers continue to stock oAMT, which are discussed further in the next section. The study revealed promising potential avenues for future interventions to improve provider knowledge around anti-malarial drugs.

Provider Mapping
Throughout the project period, PSI carried out an extensive mapping exercise to locate all antimalarial stocking outlets in project areas, collecting information on the type of outlet/provider, GPS coordinates of individual outlets, types of treatment provided, etc. This work has brought to the attention of the NMCP areas where oAMT availability is high and additional intervention and regulation is required, helping shape national strategies as Myanmar moves toward elimination.

A map of the AMTR Network can be found here:
https://www.google.com/maps/d/viewer?mid=1JizKy8zwcNBjcN0IfVvdGumlImA&ll=21.364352522893299%2C95.6019099253125&z=7

PSI's District Health Information Software 2 (DHIS2)

In order to implement real-time data reporting and analysis within the private sector during the pre-elimination and elimination phase, PSI is rolling out mobile data collection using the DHIS2 platform, which will make data easily accessible and analyzable for stakeholders at all levels. Mobile data collection will reduce lag time in the data collection chain and improve data quality and validation, through the reduction of manual entry of data, and built-in automated feedback loops. PSI has also developed dashboards to display key malaria indicators and conducted pilot testing and Training of Trainer training for data entry and analysis that will flow to all staff levels. These dashboards support data-driven decision-making from the field to management levels, enabling more responsive programming. DHIS2 training for PSI field staff began in the last quarter of 2016 and DHIS2 had been rolled out to the AMTR network beginning in 2017.

Quality Assurance (HNQIS)

PSI will begin rolling out a standardized quality assurance (QA) tool, the Health Network Quality Improvement System (HNQIS) in 2017. HNQIS is a tablet-based standardized checklist that assesses the quality of malaria case management services from diagnosis to reporting based on WHO best practices. PSI will use HNQIS to track quality of care scores across the AMTR network, provide immediate feedback to providers during QA assessments, and to determine the frequency of supervisory visits required, based on quality and patient load. In early 2017, standardized checklists were finalized in accordance with National Treatment Guidelines and the tool has been translated into Myanmar language. DHIS2 configuration has been finalized and training of Product Promoters has begun. The tool will be rolled out tentatively in August 2017 across the network after one-month pilot testing.

Measurements of indicators for the three outputs over the life of the project can be found in the log-frame.

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3. Output indicators not completely achieved

Ongoing availability of oAMT

The primary goal for the AMTR project was for subsidized ACTs to pass down the supply chain, reaching private sector outlets throughout Myanmar, and effectively squeeze oAMTs out of the private sector via price competition. The baseline outlet survey in 2012 revealed oAMT availability in 67% of target outlets in the original eastern intervention areas of the project, with a subsequent annual decline to only 10% of outlets in 2014. However, the 2015 outlet survey saw a slight resurgence in oAMT, which was found at 27% of outlets in 2015, but went down again to 20% in 2016.

To address the slight but surprising reversal in the decline of oAMT availability found in 2015, PSI conducted a qualitative study with outlets stocking oAMT in the nine townships with highest oAMT availability and found that providers' reasons for stocking oAMT were influenced by longstanding perceptions of oAMT effectiveness, including the fast action of the drug and the need for few tablets to relieve symptoms (as opposed to the three-day course of ACTs). Brand familiarity, limited knowledge of antimalarial drugs, and demand from clients also played an important role for continued stocking of oAMT. The 2016 qualitative study, alongside the outlet survey results, highlighted that there is still room for strengthening antimalarial drug regulation, as few providers interviewed were aware of the ban on oAMT, and in fact, many reported its use to be standard practice in their communities.

In response to the continued availability of oAMT in the country, PSI has taken several actions:

- PSI disseminated ACTWatch findings in a government meeting in Nay Pyi Taw in October, 2016, prompting the WHO to take action to work with MoHS to put together a national action plan on substandard / falsified medications in collaboration with enforcement agencies.
- The 2015 outlet survey found that 68-84% of oAMT in the private sector was *Artesunate*, manufactured by Mediplantex in Vietnam and previously distributed by Liberty pharmaceutical company. In 2016, PSI held a meeting with Liberty to stop the importation/distribution of oAMT, and the company has been warned twice by the FDA to stop importation since 2014. Liberty reported stopping oAMT imports in early 2014, importing 20,000 adult equivalent treatment doses that year with final sales in June 2014. Although the Mediplantex oAMT found in the 2015 outlet surveys market had exactly the same packaging design and even included an FDA registration number, the company believes these must be newly imported illegally through border trade by other wholesalers.

In addition, the PSI field team has organized advocacy meetings in five townships with high oAMT including Hpa Kant township, where the highest oAMT availability was found in 2015. In the meetings, local health authorities, including township medical officer and the FDA focal person, gave speeches and presentations to owners and sellers in the regions to educate them on the importance of artemisinin resistance and to discourage stocking, selling and prescribing oAMT.

QAACT availability

Although QAACT availability slowly decreased from its peak in 2014, the lower availability may be due in part to declining caseloads as well as a stock out of ACT in the central supply chain.

Decrease in community knowledge

In the most recent household survey, the percentage of the population who knows that a person with a fever should receive a diagnostic test for malaria had declined to 36%, from a high of 50% in 2015. The percentage of people who could identify an outlet that can perform RDTs also declined: from 34% in 2015 to 28% in 2016. Possible reasons for the lower level of knowledge may be related to the rapid de-

cline of malaria caseload in Myanmar since 2012[7]. In other countries, malaria endemicity has been shown to be a potential factor in community malaria knowledge and perceptions of transmission risk[8]. Communities that experience low rates of transmission and subsequently perceive little malaria risk may not see communication messages on malaria as relevant for them and may not make associations with malaria at the onset of fever. The factors underlying community knowledge, such as local malaria endemicity, individual education levels and socioeconomic status, etc. are important areas of future study as the epidemiological landscape continues to evolve and transmission becomes increasingly stratified between geographic areas and among demographic groups.

Providers' RDT performance in mystery client survey

Although the 2016 outlet survey found RDTs available at 37% of outlets, only 14% of the providers offered a mystery client reporting potential malaria symptoms a rapid diagnostic test. Thus, although RDTs are available among the trained outlets, many providers appear to be reluctant to conduct RDT testing. Among 590 providers, only 94 proposed RDT testing to the mystery client, 149 referred the patient to other health facilities and 347 prescribed medicines without proposing RDT testing. These results suggest several possible reasons for provider reluctance to conduct RDT testing and avenues for improvement. The providers who referred patients may have less confidence in their ability to conduct and RDT, which more frequent trainings and stronger supervision may strengthen. Providers' preference for prescribing medication without proposing RDT testing may be due to either a limitation in resources such as time and man-power or because the possibility of Pf negative or Pv positive RDT results disincentives them, as these results cannot currently be treated, resulting in loss of sale and profit from these cases. These potential barriers have been addressed by the roll out of a performance-based positive incentive system and additional supervisory visits for providers committed to performing RDTs.

The large proportion of providers (347 or 59%) who prescribed medication without proposing RDT testing may be explained in part by the limitations of the mystery client methodology, which requires a healthy actor to describe malaria symptoms despite presumably normal vital signs such as pallor and temperature, which providers are trained to use to assess potential malaria cases. This hypothesis is supported by the finding that the majority of providers prescribed non-malarial medications, with very few (25, 4%) recommending anti-malarial treatment of any kind. Thus, the limitations of the mystery client methodology may account in part for the number of providers who did not offer RDT testing as it suggests malaria may not have been suspected in the vast majority of these visits. Factors underlying providers' decisions to offer RDT tests may be an important area of future study, and the importance of RDT testing for patients with normal temperature but a self-reported recent fever can be addressed in future training and supervisory visits.

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4. Accomplishments: List your top 5 results for this project

1. **Increased QAACT availability:** Significantly increased the number of private outlets stocking quality assured ACT from 4% in 2012 to 50% in 2016.
2. **Decreased oAMT availability:** Decreased the number of outlets stocking oAMT from 67% in 2012 to 20% in 2016.
3. **Increased RDT availability:** Nearly tripled the use of diagnostic tests in the AMTR network in only one year, from 13% in 2015 to 37% in 2016, as a result of increased RDT availability in the private sector and training 11,284 outlets on RDT use, contributing to the objective of increasing access to appropriate case management in the private sector.
4. **Increased caseload data availability:** For the first time in Myanmar, malaria caseload data began coming in from the non-formal private sector, and in just over one year, more than

[7] World Health Organization. *World malaria report 2015*. World Health Organization, 2016.
[8] Shimaponda-Mataa, Nzooma M., et al. "Knowledge, attitudes and practices in the control and prevention of malaria in four endemic provinces of Zambia." *Southern African Journal of Infectious Diseases* 32.1 (2017): 29-39.

283,000 fever cases were tested and over 6,700 malaria cases were identified – which is only an early indicator of the network's potential.

5. **Strong evidence base created:** Created an unprecedented base of evidence about the anti-malarial market landscape and the non-formal private healthcare sector in Myanmar, by carrying out rigorous research studies and through continuous monitoring of the project. For example, the annual outlet survey under the AMTR project has been conducted since 2012 and has provided crucial data on the private sector antimalarial market in eastern and western Myanmar.

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5. Lessons Learned:

Importance of the non-formal private sector as Myanmar moves towards elimination

Evidence from this project demonstrates the feasibility of non-formal outlets to play a key role in reducing onward transmission of malaria as the country moves towards elimination. The early years of the AMTR project showed that non-formal private sector interventions can substantially change the antimalarial market landscape. It is also clear that non-formal providers can form a widespread network for malaria case management, including testing and treatment, and serve as an important source of surveillance data. From September 2015 to March 2017, the AMTR network tested over 283,000 febrile cases and detected more than 6,700 positive cases, of which 55% were Pf infections.

The Myanmar National Strategic Plan for 2016-2020 calls for an integrated community case management strategy to ensure that malaria care providers remain motivated and visible to their communities as caseloads decline. There may be a role for high-performing non-formal private sector providers to play in future integrated community case management provider networks given their ubiquity in communities across Myanmar, and their access to remote and marginalized at-risk groups.

"Test and scale up" approach for new interventions

To roll out RDTs in this network, PSI conducted pilot research to establish the most effective incentive model and supervision monitoring system, and worked carefully to select existing AMTR providers who were committed to performing RDTs and reporting caseload data. Learnings from this pilot were used to scale up RDTs throughout the network. Over 11,000 providers have now been trained on RDTs, and mystery client data shows that over 90% of those who perform them do so correctly and offer no presumptive antimalarial treatment when results are negative. Further research is needed to understand provider behavior around RDTs, including pilot programs to increase motivation for testing, such as PSI's current monthly RDT incentive program.

Strong support and supervision is critical in the non-formal private sector

The use of RDTs among non-formal private sector outlets represents a tremendous opportunity to improve malaria case management and malaria surveillance data in Myanmar – particularly in remote areas. Given that performing RDTs and reporting cases are new behaviors for non-formal providers, strong supportive supervision visits are needed to increase the confidence and motivation of providers to perform an RDT for every fever case, record and report the results monthly, and ensure a consistently high quality of care is provided to patients.

Program Flexibility in a Fast-Changing Epidemiological Landscape

During implementation of the AMTR project, it quickly became evident that changes in the malaria landscape in Myanmar were much more rapid than anticipated; the epidemiology, market situation and consumer behavior all saw significant shifts over the course of the project, in ways that have impacted performance and challenged the assumptions made in the initial theory of change. The project has operated in a dynamic, evolving environment by quickly adapting to these contextual and epidemiological changes. Although these changes have constrained progress against some indicators, the continued

versatility and adaptability of the project as well as the support and flexibility of donors was crucial to ensure that the project could achieve its overall goal.

For example, the project was designed to address the emergence of resistance against oAMT in the eastern borders of the country. The independent emergence of artemisinin resistance in western Myanmar in 2015[9] required a strategic pivot in the program strategy, with a new geographic focus on the western border areas and the development of electronic surveillance mechanisms (currently being piloted) to improve the monitoring of RDT testing quality. The project provides an important example of the value of programming flexibility in response to new evidence and contextual changes, which can arise frequently in the malaria landscape of the GMS.

Leveraging the Existing Supply Chain

PSI uses the combination of its own supply chain and two private distributors (AA and Polygold) to supply RDTs and ACTs respectively. Using two private sector pharmaceutical distributors with proven reach across the country, including in non-state actor areas, has been critical to the success of this project. In 2016, 86% and 84% of outlets in the eastern and western regions reported no disruption of QAACT stock, figures which can be improved on but nonetheless indicate the system is working well given the vast size of the network. Given the success of using commercial supply chains for commodity distribution, further advocacy is needed to permit the distribution of subsidized RDTs through distributors such as AA and Polygold. PSI has already conducted dissemination meetings both at state/regional as well as central level with MoHS officials and partners to share these findings.

Partnerships, Coordination, and Advocacy

Intensive advocacy with health authorities at both the state and district levels as well as the central government has contributed to critical successes, most notably the ban on oAMT. The National Malaria Control Program has been closely involved throughout the project and its support has been critical for the success of this project, allowing it to expand into the western region following the results of the 2015 outlet survey, and allowing the roll out of RDTs in the non-formal private sector, which came after intensive advocacy and negotiations with the government.

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6. Data Access:

Throughout the project period, PSI has generated evidence and shared lessons learned around the role of the non-formal private sector in malaria case management as well as providing timely surveillance data for malaria elimination. PSI continues to collect malaria case reports from AMTR providers, and caseload data from the entire network is reported to the NMCP's national surveillance system every 6 months. PSI has also regularly shared the progress of the AMTR project by disseminating the results of the surveys with country-level stakeholders such as the MoHS and the WHO via stakeholder meetings and workshops, including Technical Sector Group meetings.

PSI has disseminated project information through international conferences, peer-reviewed journals and other channels. PSI Myanmar had also organized and participated in national and international forums to present the program and lessons learned, including:

- Five oral presentations at international conferences: 61st ASTMH conference, Atlanta, Georgia, 2012; 6th Multilateral Initiative on Malaria Conference, Durban, 2013; Private Sector Symposium at the 62nd ASTMH conference, 2014, New Orleans; 65th ASTMH conference in 2015 in Philadelphia; a symposium for the Greater Mekong Subregion at the 66th ASTMH Conference, Atlanta, November 2016, and a poster "Oral Artemisinin monotherapy market still maintains a foothold in Myanmar, 2015" at the same ASTMH Conference in 2016 (link here).

[9] Takala-Harrison, Shannon, et al. "Independent emergence of artemisinin resistance mutations among Plasmodium falciparum in Southeast Asia." *The Journal of infectious diseases* 211.5 (2014): 670-679.

- Workshop on Improving Malaria Case Management in Private Sector through Scale up of Diagnostics (RDT Pilot Dissemination) in Yangon on 12th June 2014 (see the full report at this link)
- Dissemination of the Outlet Survey 2015 results at the "Malaria Survey Dissemination Workshop" on 25-26 May 2016 in Nay Pyi Taw (link here)
- ACTWatch 2015 Results Dissemination Workshop in Nay Pyi Taw on 9th November 2016 (see the presentation and full report at this link)
- AMTR project-end dissemination workshop in Nay Pyi Taw on 3rd April 2017 and at the regional level in ten states and regions during February and March 2017 (see the presentations presented at the central level at this link)

Three peer reviewed papers were also published in *Malaria Journal* (link below).

1) *Motivations and challenges for use of malaria rapid diagnostic tests among informal providers in Myanmar: A qualitative study (*http://www.malariajournal.com/content/14/1/61)
2) *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 (*http://www.malariajournal.com/content/14/1/105)
3) *Availability and quality of anti-malarials among private sector outlets in Myanmar in 2012: results from a large, community-based, cross-sectional survey before a large-scale intervention (http://www.malariajournal.com/content/14/1/269)*

PSI Myanmar was also in three featured publications for World Malaria Day 2017 in *Malaria Journal*. These publications are based on the results of the ACTWatch research project conducted throughout the project. The titles of publications are as follows:

- Antimalarial landscape in Myanmar: Results from a nationally representative survey among community health workers and the private sector outlets in 2015-2016 (Link here)
- Insights into the availability and distribution of oral artemisinin monotherapy in Myanmar: Evidence from a nationally representative outlet survey (Link here)
- Private sector opportunities and threats to achieving malaria elimination in Greater Mekong Subregion (Link here)

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7. Challenges

Changing Epidemiological Landscape

The AMTR program was initiated just prior to an unexpectedly steep decline in malaria transmission and prevalence throughout Myanmar. The decreasing malaria burden and international efforts to move towards malaria elimination in the GMS prompted the creation of a malaria National Strategic Plan 2016-2020 that for the first time envisioned step-wise progress towards elimination by 2030. This goal was a significant change in the disease context compared to the start of the AMTR project when sustained control was the target. Furthermore, emerging artemisinin resistance, exacerbated by years of presumptive treatment across the GMS, has made reliable confirmation of malaria through diagnostic testing a necessity in order to reduce drug use practices driving resistance. Furthermore, in the context of this project, which works primarily through the non-formal private sector, there has been a need to re-strategize as small private vendors/providers will see the profitability of stocking antimalarials decrease in line with prevalence. The program responded by advocating to the MoHS to allow the use of RDTs in the non-formal private sector, which was approved in March of 2015.

In early 2015, new evidence[10] revealed a spontaneous emergence of drug-resistant falciparum malaria near the western borders, requiring a reevaluation of the project scope and strategy to expand into western townships and increase surveillance of malaria case management in the private sector.

Delays in the Roll Out of RDTs

Testing before treatment is critical to program goals of reducing to drug wastage, improving case management practices and mitigating the risk of resistance developing to ACTs (which is increased by presumptive treatment[11]). Thus, PSI requested the MoHS to approve RDT roll out in the non-formal private sector beginning in 2014. However, a lengthy approval process meant that permission was not received until March 2015, with RDT distribution beginning in August 2015.

Slow RDT uptake

While training and provider behavior change appears to have influenced prescription practices, RDT uptake has been slower than expected among AMTR providers, who average 1-2 tests per month compared to PSI's community provider network average of around 20 tests per month per provider. Low test rates may be related to factors such as providers' lack of confidence. Although AMTR providers are often the only source of care for febrile cases in remote communities, many do not have a healthcare background and have limited access to updated technical information and on-the-job training. Performing an RDT is a new behavior for them and it takes time to ensure they have the skills and confidence to administer RDTs to every fever case. Some AMTR providers are also shop owners with concerns about profit. In a context where malaria cases are declining, providers may prefer to sell presumptive ACT treatment rather than treating according to RDT results, which may be negative or Pv malaria (which must be referred) in the majority of fever cases in most areas.

PSI has rolled out an incentive scheme to encourage RDT testing, combined with supportive visits by field staff to ensure providers are stocked with RDTs and know how to use them. Encouragingly, the performance-based incentive has proven to be effective in improving providers' performance, as mentioned under Output 3.

Supply chains and commodity management

The MoHS approved the roll out of RDTs through the non-formal private sector in March 2015 with the condition that RDTs be provided free of charge. However, the provision of free RDTs has significant implications in terms of sustainability of the project as it relies on PSI's network of Product Promoters rather than the commercial supply chains of AA and Polygold, which have a broader reach. PSI has made every effort to ensure a smooth supply of RDTs and to avoid any stock outs, but this task has been difficult given the unprecedented scale of the network, which must be stocked during individual outlet visits by Product Promoters, typically on a quarterly basis.

Commodity management has been affected by slower-than-expected RDT uptake: ACT sales were expected to decline with increasing RDT use and have instead stayed consistent from 2015 to 2016. Consequently, PSI may have to contend with both the expiration of RDT stocks and possible stock outs of QAACTs.

Continuing market for oAMT

Oral artemisinin monotherapy availability has decreased across the country but remains high on the western border, which presents an area of concern due to oAMT's role in propagating artemisinin-resistance and the risk of resistance spreading across the India or Bangladesh borders.

In support of improved case management, the government of Myanmar introduced a "ban" on Artemisinin-based monotherapy, which prevented any further licenses from being issued for the oAMT drugs Artesunate (in December 2011) and then for Artemether (in October 2012). The ban did not have an

[10] Takala-Harrison, Shannon, et al. "Independent emergence of artemisinin resistance mutations among Plasmodium falciparum in Southeast Asia." *The Journal of infectious diseases* 211.5 (2014): 670-679.
[11] Bloland, Peter B., and World Health Organization. "Drug resistance in malaria." (2001).

effect on medicines already in the market or on importers with existing licenses for those drugs, though under the ban these licenses cannot be renewed when they expire.

The continued availability of oAMT is also thought to be a result of illegal imports of these drugs, which have not stopped in spite of increased efforts by the FDA to strengthen township drug inspectors. PSI has continued to conduct advocacy at central as well as townships level with the FDA and the NMCP.

A qualitative study found that providers continuing to use oAMT believed it to be effective and superior to ACTs and were not aware of the ban on oAMT. External analysis predicts that oAMT use in Myanmar can resurge if oAMT continues to be available in the antimalarial market and providers lack access to a reliable supply chain of subsidized first-line treatment and strong supervisory support.

Security Issues

Conflicts in Kachin and northern Shan state have affected PSI operations in those areas due to security concerns and increasingly difficult access. For instance, in 2015, a PSI Product Promoter was detained for a night by an ethnic armed group in one township for using a GPS as he was mistaken for a military spy. The staff member was released but resigned and his position could not be filled, so program activities in that township ceased. Conflicts have impacted the consistency of the supply chain and impacted PSI's ability to recruit field staff, in addition to affecting providers who may have to interrupt operations or move due to security concerns. In 2016, armed conflicts forced the halt of program activities in townships in Northern Shan and Kachin. Unfortunately, armed conflicts often occur in areas with high endemicity, affecting the program's ability to reach those who most need malaria services.

Funding Gap

Although the AMTR project will be funded by the Global Fund until December 2017, there is an alarming lack of funding to support continuation beyond 2017. An external evaluation of the AMTR project concluded that without a supported and supervised non-formal private sector (AMTR), Myanmar's elimination agenda will be delayed at best, and severely compromised at worst. PSI predicts four negative impacts should the network close prematurely:

i) A significant rise in the availability of oAMT.
ii) Inappropriate case management of patients and the associated risks, as people continue to seek fever care, but from unknowledgeable and ill-equipped providers.
iii) Misuse of antimalarial drugs increasing risk of emergence and spread of resistance.
iv) Incomplete data in the national surveillance system to inform an appropriate national strategy and response.

Continued national and global advocacy for the engagement of the non-formal private sector in malaria elimination activities is a necessity.

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8. Sustainability

PSI Myanmar received additional funding for the AMTR from January 2016 up to the end of 2017 from the Global Fund, under the regional funding mechanism (RAI). As the role of the AMTR shifts and as the funding environment becomes more strained beyond 2017, PSI proactively planning a strategic scale-down of the network to focus on high risk areas and in underserved areas that are moving towards elimination. Between 2018 and 2020, this will result in reducing the number of target townships from 131 to 39, and reducing the number of outlets from approximately 20,000 to 7,000 individual outlets. However, given the critical role of the non-formal providers in the elimination agenda, PSI is seeking to secure continued funding from its traditional as well as new donors beyond 2017 to maintain high coverage.

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9. Other Sources of Project Support

Report all amounts in U.S. dollars.

Donor	Amount	Received or Potential	Duration
Global Fund (RAI)	$8,154,746	Received	1 January 2016 to 31 December 2017
BMGF (GEMS)	$334,413	Received	1 January 2017 to 31 December 2017

Key Terms

Activities: The processes or actions taken to achieve outputs and move toward outcomes.

Critical Milestone: The most important project results (activities, outputs, and outcomes) that are considered in relation to funding and may be listed in the grant agreement.

Goal: the conceptual aim of the project; the condition that will exist when the project has been successfully completed.

Impact: Ultimate sustainable changes, sometimes attributable to action.

Milestone: Sequential signs of progress during a project or initiative, usually tied to estimated completion dates.

Objectives: The major components of the project required to achieve results.

Outcomes: Intermediate observable and measureable changes that may serve as steps toward impact for a population community, country, or other category of beneficiary.

Outputs: The direct and early results of a grant or intervention's activities. Outputs refer to the most immediate sets of accomplishments necessary, but not sufficient, to produce outcomes and impacts.

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