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Independent Evaluation of Artemisinin Monotherapy Replacement in the Private Sector to Support the Containment of Artemisinin Resistant Malaria in Burma

Burma AMTR Evaluation - DFID Global Evaluation Framework PO 6073
Final Report

UKaid
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TROPICAL HEALTH

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Myanmar Artemisinin Monotherapy Replacement Malaria Project (AMTR) Independent Evaluation

Is implemented by

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1.1. Acknowledgements

The evaluation team would like to thank all those who have generously given their time, experience and expertise in guiding this assessment; in particular, the staff of DFID and PSI in Yangon. The team would also like to thank all individuals listed in this paper who were interviewed as part of the assessment.

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1.2. Note on Nomenclature

The Republic of the Union of Myanmar is referred to as 'Burma' in UK Government nomenclature. This report uses both names, 'Myanmar' and 'Burma', interchangably. Original UK Government documents and references retain 'Burma', whilst most other references and acronymns retain 'Myanmar'.

CONTENTS

2. EXECUTIVE SUMMARY

This report presents the summary of findings and final assessment of an independent, external evaluation of the DFID co-funded project "Replacement of malaria monotherapy drugs in the private sector to support the containment of drug resistant malaria in eastern Burma" or, in short, the "artemisinin monotherapy replacement" project (AMTR). The AMTR project was launched in 2012 while the evaluation project started with some delay in 2013.

The methodology applied by the evaluation team consisted of a combination of qualitative (key informant interviews, field visits, document review) and quantitative data collections (analysis of routine and survey data), as well as an in-depth Value for Money analysis and construction of a case-management model to explore project impact and project future developments under a defined set of assumptions and scenarios.

The results can be summarised as follows:

Theory of change and logframe

One of the identified weaknesses of the project was that the theory of change was not actively used as a management tool to guide the project until the final project year. This did not negatively impact on outcomes but would possibly have facilitated a more rapid adjustment of activities to the rapidly changing environment of a declining malaria incidence. The logframe initially had some unrealistic indicators and needed multiple revisions in light of the changing epidemiology and socio-economic context, but was ultimately a useful tool for assessing progress and short-comings.

Key evaluation questions

Has the replacement of oral artemisinin monotherapy been achieved?

It can be said that the AMTR project did successfully replace oral artemisinin monotherapy (oAMT) through the formal distribution channels with quality assured artemisinin combination therapy (QA-ACT), but some oAMT returned – mainly through informal channels outside of the project's influence. At the same time, QA-ACT showed overall declining trends due to the changing malaria epidemiology. One concern that can be raised is that of sustainability of the social marketing approach under the assumption that some kind of subsidy or market support for QA-ACT will be needed in the future. An approach that delivers a subsidy directly to distributors and avoids brand ownership by the social marketing organisation could possibly have included more distributors, and hence larger coverage, and would be more sustainable in the future.

Has the proportion of fever cases correctly treated increased?

The evidence suggests that correct treatment of fever cases was quite favourable for those testing negative and those not tested, in part due to the declining malaria incidence and increasing awareness among providers that fevers are much less likely to be malaria. However, for correct treatment of true positive cases, the outcome showed only moderate improvement and the proportion of cases treated in such a way that resistance spread could be encouraged was still high at 40%. This was mostly a function of low testing rates in the face of declining malaria incidence.

Has the need for prior testing been established and are RDT used?

There were significant delays in RDT implementation and roll-out that were due to external factors but resulted essentially in testing rates too low to significantly improve the major intended outcome of increased adequate treatment of *Plasmodium falciparum* cases seen in the private sector. Further increases seem possible in the future with a focus on those outlets that are best suited for testing, but the issue of cost, or rather no-cost, to the consumer will have to be addressed creatively if RDTs are

to be channelled through normal private sector supply chains, which in turn will be essential for sustainability.

What influence did the BCC and promotional activities of AMTR have?
There is evidence of success in promoting awareness and knowledge among both consumers and providers. However, overall, this has been less successful than was hoped for, and falls short of the targets in the logframe. The challenge here seems to be that the type of messages that are most adequate in a situation of rapidly decreasing malaria incidence can no longer focus on malaria as a danger (e.g. test your fever because it may be malaria), but rather acknowledge the increasingly rare character of the disease whilst emphasising that excluding malaria is essential for both individual health and the benefit of the entire society.

What was the contribution of the AMTR project to resistance containment?
This evaluation has highlighted that the proportion of adequately treated *P.falciparum* malaria cases that are seen by private sector providers has increased since the start of the project. This certainly can be seen as a contribution towards resistance containment, even if it was not as high as hoped for and although there were still 40% of true malaria cases that were highly inadequately treated with a potential to worsen resistance (reduced from 60% at the start). However, with the available evidence, it is not possible to say whether this contribution was in fact significant in terms of overall resistance development in Myanmar.

What is the long-term perspective for private sector support in malaria beyond AMTR?
Based on the observations and modelling results, the evaluation makes an attempt to look forward into the potential role of private sector health care providers and malaria commodity markets in Myanmar's attempt to reach malaria elimination by 2030 and ultimately contain spread of resistance. The major conclusion here is that elimination will not be possible without some kind of intervention in private sector case-management. Increasing testing of suspicious fever cases will be critical and, in conjunction with optimal consumer and provider behaviour, the correctly treated malaria cases in the private sector can be increased to 50-60%. Cases with highly inadequate treatments which would enhance resistance selection pressure and spread could be reduced to 9-12%.

Value for Money analysis

Key findings include:

a) Miscalculation of demand and supply, and ACT and RDT commodity losses of over USD 2.5 million, or 47% of total commodities procured, lead us to conclude that AMTR has not promoted positive economy in programme operations.
b) In consideration of the significant unforeseen obstacles faced by AMTR implementation, and the multiple changes in programme focus necessitated by a dynamic operating context, we do not believe that it is useful to make an efficiency assessment at this time. We urge close monitoring of RDT uptake and compliance as a near-term indicator of whether AMTR can efficiently bend the provider curve toward routine testing and appropriate treatment.
c) We do not assess the effectiveness factor at this time. Changes to the logframe do not allow sufficient time to assess outcome or impact data, though concern is expressed at the slow progress with provider use of RDTs and appropriate treatment, as reported in 2016.
d) The equity spread of AMTR is well defined, granular, and well-focused on sales channels, providers, compliance with medical detailing and users across regions. These data disaggregation will continue to add value to AMTR.

The following cross-cutting VFM observations arise from AMTR and are relevant across many DFID-funded programmes.

a) Data upon which to make decisions are often limited, incomplete, or of suspect quality. In such cases, due-diligence, data triangulation (where possible), and aggressive risk management are requisite.
b) DFID's business case process is compromised when the data used in developing the business case are not subjected to data triangulation or other due diligence. Key assumptions in the AMTR Business Case were repeated from other sources, though not verified.

The review has seen little evidence that risk-management documents were translated into active risk-avoidance strategies by project managers.

Conclusion with respect to the OECD Development Assistance Committee evaluation criteria is as follows:

Effectiveness

The AMTR project was effective in delivering the subsidy on QA-ACT to consumers and was largely effective in replacing oAMT with QA-ACT, even though some oAMT returned due to factors beyond the project's control. The project was only marginally effective in increasing the use of RDT for malaria diagnosis in the private sector. This was in part due to delays caused by other stakeholders involved in the process, but to some extent also due to the lack of reviewing the Theory of Change on a regular basis.

Efficiency

The AMTR project was overall efficient with the one exception that risk management in the procurement planning was not as it should have been, resulting in significant amounts of expired medicines.

Relevance

The AMTR project was highly relevant as it was the only effort to address the markets of anti-malarials at a large and national scale. From the analysis of the Myanmar malaria elimination strategy, and confirmed by the modelling by this evaluation, it is clear that without private sector involvement and intervention, elimination will not be possible.

Impact

The AMTR project subsidy on QA-ACT had a significant impact on shaping the markets for anti-malarials in Myanmar. The impact on correct malaria treatment of potentially resistant *Plasmodium falciparum* cases was evident but not as high as it could have been due to low levels of diagnostic testing and availability and use of other anti-malarials. Some impact on the spread of malaria resistance can be assumed, but there is no direct evidence.

Sustainability

Sustainability would normally be a significant factor in the evaluation of a project that applies a subsidy and where the analysis shows that this subsidy will be needed in some form also in the future. However, in the case of malaria elimination, this is different. Once malaria is eradicated, i.e. eliminated from each and every country, the success will be sustainable forever. But until then it is clear – as is

the case in any disease elimination programme – that the marginal cost per additional case detected and correctly treated will increase significantly and that these increasing costs have to be borne if elimination is to be reached.

Lessons learnt

Lessons learnt with respect to the overall target of containing artemisinin resistance:

1. Given the epidemiological situation in Myanmar, elimination of artemisinin-resistant falciparum malaria (and hence its containment) will not be possible without contributions of the private sector.
2. Public sector investments to replace artemisinin monotherapy in the market can be successful, but
    a. require a subsidy that brings down the cost of QA-ACT to that of a partial dose of monotherapy
    b. does need to be coupled with significant increases in fever testing in the private sector
3. Sufficient attention must be paid to external factors such as influx of monotherapy through illegal pathways.

Lessons learnt with respect to the project implementation:

4. A Theory of Change is a powerful tool to guide a project, but only if it is used actively as an element of project management and is adjusted on a regular basis.
5. Timely revisiting the procurement forecasts and adjustment of procurement schedule in combination with short timelines are critical to avoid costly expiry of medicines in a rapidly changing epidemiological environment.

Lessons learnt with respect to the evaluation:

6. Independent evaluations will be less effective if they start after the project they are to evaluate. Similarly, if evaluations are extended to cover the additional time provided to implementers under no-cost extensions with no addition budget for the evaluation, they have to stretch their resources over longer periods and are not able to achieve as much – in this case a full final evaluation visit at the end of the AMTR project was not possible.
7.

Recommendations

1. This evaluation clearly showed that further interventions will be needed in the private sector and markets for diagnostics and QA-ACT

2. It is recommended that donors engage in a way that supports existing market mechanisms with the primary objective being to:

    Maximise the adequate treatment of *Plasmodium falciparum* cases in the private sector in Myanmar and thereby contribute to transmission reduction and containment of Artemisinin resistance.

    A secondary objective would be to:

    Provide value for money in the interventions to achieve the primary objective by optimising the use of ACTs and minimising the amount that goes to patients that do not have malaria.

The changes or steps that need to be achieved on the road to reaching the goal can be divided into three groups of recommended interventions:

- Interventions addressing the consumer or patient
- Interventions that involve consumers as well as providers
- Interventions addressing the markets for anti-malarials

3. ACRONYMS

ACT	Artemisinin Combination Therapy
AMT	Artemisinin Mono-Therapy
AMTR	Artemisinin Mono-Therapy Replacement
API	Annual Parasite Index
BCC	Behaviour Change Communication
CHW	Community Health Worker
DALY	Disability-adjusted Life Years
DFID	Department for International Development
DHS	Demographic and Health Survey
FDA	Food and Drug Administration
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMS	Greater Mekong Sub-region
HMIS	Health Management Information System
KII	Key Informant Interview
LLP	Limited Liability Partnership
MARC	Myanmar Artemisinin Resistance Containment
MIS	Malaria Indicator Survey
MMA	Myanmar Medical Association
MoH	Ministry of Health
oAMT	Oral Artemisinin Mono-Therapy
PR	Principle Recipient
OECD	Organisation for Economic Co-operation and Development
PSI	Population Services International
QA-ACT	Quality assured ACT
RDT	Rapid Diagnostic Test
TBD	To be determined
ToC	Theory of Change
ToR	Terms of Reference
UCSF	University of California – San Francisco
UK	United Kingdom
UNOPS	United Nations Office for Project Services
USAID	United States Agency for International Development
VFM	Value for Money
WHO	World Health Organisation
WMR	World Malaria Report

4. PURPOSE, SCOPE AND RECIPIENT

In the late 1990s, suspicions arose in the scientific community that resistance to artemisinin and its derivatives – the mainstay of malaria treatments today – was developing in the most dangerous human malaria parasite, *Plasmodium falciparum*, in the countries of the Greater Mekong Sub-region (GMS). By 2007, this had become a certainty [Ashley EA, Dhorda M, Fairhurst RM, Amaratunga C, Lim P, Suon S et al.: Spread of Artemisinin resistance in *Plasmodium falciparum* Malaria. *New England Journal of Medicine* 2014, 371:411-423] and resistance had begun to spread in the region in such a way that the international community was alerted to the danger that artemisinin resistance would spread via the Indian sub-continent to Africa South of the Sahara, as resistance to other anti-malarials had previously, with potentially devastating consequences for public health outcomes [White LJ, Lubell Y, Meek S, White NJ, Day NPJ, Nosten FH, Ashley E, Socheat D, Nguon C, Dondorp AM: Malaria in the Asia-Pacific: modelling the current and potential impact of artemisinin resistance and its containment. Working Paper No 4, Saving Lives in the Asia-Pacific conference, Sydney 31 October – 2 November 2012]. This led to country specific plans to contain resistance, such as the strategic framework of the Myanmar Artemisinin Resistance Containment (MARC) [MARC strategic plan 2011-2015, version May 2012], as well as international collaborations and actions coordinated by the World Health Organisation (WHO), such as the global response to resistance emergence [WHO: Global Plan on Artemisinin Resistance Containment, Geneva, 2011, http://www.who.int/entity/malaria/publications/atoz/artemisinin_resistance_containment_2011.pdf] and the regional emergency response for GMS [WHO: Emergency Response to Artemisinin Resistance in the Greater Mekong Sub region. Regional Framework for action 2013-2015, 2013, WHO Geneva.].

Despite increased public sector engagement to contain resistance, it was very clear that in all countries in the GMS, the private sector of health care providers and the markets for malaria commodities played a significant role and had to be involved if containment was to be successful. In the case of Myanmar, this led to a project which aimed to address the most critical issues identified for the malaria case management in the private sector of Myanmar; the high level of use of oral artemisinin mono-therapy (oAMT), mainly with artesunate; application of incomplete doses; and the very low level of availability of quality assured artemisinin combination therapy (QA-ACT). This project was called "Replacement of malaria monotherapy drugs in the private sector to support the containment of drug resistant malaria in eastern Burma" or in short, the "artemisinin monotherapy replacement" project (AMTR). It was co-funded by the UK Department for International Development (DFID), the Bill and Melinda Gates Foundation (BMGF) and Good Ventures. The contract was tendered internationally and

won by Population Services International (PSI). Implementation of the AMTR project started in March 2012 and was initially planned to end in December 2014 but in August 2014 received a first no-cost extension until March 2016, followed by a second no-cost extension until March 2017.

In May 2013, DFID contracted an independent evaluation of its project as part of the Global Evaluation Framework Agreement (GEFA PO 6073) to Montrose International, which was supported by Tropical Health and Innovision. The team was comprised of Albert Kilian, technical team leader, Karen Bulsara, private sector specialist, Rubaiyath Sarwar, supply chain expert, Win Maung, local consultant and health and migration expert, and David Toomey, economist and Value for Money (VFM) expert.

Scope

The overall objective of the independent evaluation was described in the Terms of Reference (ToR) to:

- assess the effectiveness of what was done (for example, (i) the replacement of monotherapy (ii) the introduction of diagnosis and testing in the informal private sector and (iii) behaviour change strategies), whether and to what level the outcome targets have been achieved;
- assess the value for money of the programme in delivering its outputs and outcomes; and
- Identify, document and disseminate lessons learnt for wider interest where results have or have not been achieved.

The ToR (presented in full in Annex 1) also expresses the scope of the evaluation as follows:

- What were the performance, effectiveness and outcome of key components of the programme, importantly (i) the replacement of monotherapy; (ii) the introduction of and adherence to diagnosis and testing in the informal private sector; (iii) ACT uptake and use (completion of treatment); and (iv) behaviour change strategies?
- What was the differential impact of these key interventions on the poor and other vulnerable groups, including in-depth analysis of what works (or doesn't) to reach the hard-to-reach, poorest and most vulnerable?
- What was the cost effectiveness and value for money of the programme (using DFID's VFM framework and approach)?
- Were the assumptions underlying the theory of change valid and what is the IEA's judgment on whether the theory of change remains relevant and feasible at the end of the evaluation period?

The evaluation questions from the ToR were then further revised and specified during the inception period and presented as part of the evaluation framework in the inception report. Changes were especially relevant for the second bullet above as it was already anticipated that data on gender, wealth and age would be very limited in a project that primarily intervenes in markets and the private sector. The proposed changes to the scope and evaluation design from the inception report were reviewed and accepted by the DFID evaluation quality assurance team (see Annex 2).

The following are the final evaluation questions:

Level 1:

The first evaluation question addresses the outcome that can be seen as the primary objective of the project and the outcome that is the most under control of PSI including a critical look at the outputs on which these outcomes are based:

- **Evaluation question 1a: Has the replacement of oral Artemisinin monotherapy with quality-assured ACT in the private sector and particularly in the primary target outlets (pharmacies, itinerant drug vendors and general shops) been achieved?**

Indicators:

1. Proportion of adult-equivalent doses of anti-malaria medicines sold in the past week (7 days) in the primary target outlets being AMT
2. Proportion of adult-equivalent doses of anti-malaria medicines sold in the past week (7 days) in the primary target outlets being QA-ACT
3. Number of annual total doses of QA-ACT sold to distributors and by distributors to outlets

Source: PSI outlet surveys at baseline, midterm and endline (see also Figure 4); PSI routine monitoring data.

The next evaluation questions address the outcome at population level where contributions of both public and private sectors are captured, and the PSI contribution can only be established by disaggregation between the main sources of treatment of the fever cases:

- **Evaluation question 1b: Has the proportion of people with fever who are treated with a full course of QA-ACT increased?**

- **Evaluation question 1c: Conversely, has the proportion treated with AMT declined or even disappeared?**

Indicators:

4. Proportion of people with a fever episode in the last two weeks who received AMT as treatment (disaggregated by public and private sector as primary source)
5. Proportion of people with a fever episode in the last two weeks who received a full course of QA-ACT as treatment (disaggregated by public and private sector as primary source and if possible by the result of the diagnostic test if done)

Source: PSI household surveys at baseline, midterm and endline (see also Figure 2).

The fourth evaluation question addresses the issues around diagnosis:

- **Evaluation question 1d: Has the need for a diagnostic test prior to malaria treatment been established amongst providers (outlets) and amongst clients and are RDT available in the private sector and used?**

Indicators:

6. Proportion of priority outlets that have an RDT available
7. Proportion of priority outlets that offer or recommend a diagnostic test for fever patients
8. Proportion of people with a fever episode in the last two weeks who had a diagnostic test done prior to treatment (disaggregated by public and private sector as primary source)

Source: PSI outlet, mystery client and household surveys at baseline, midterm and endline (see also Figure 2).

The fifth evaluation question looks at the PSI Behaviour Change Communication (BCC) strategy and implementation:

- **Evaluation question 1e: What influence did the BCC activities of PSI have on consumer behaviour?**

Indicators:

9. Proportion of people with a fever episode in the last two weeks who were exposed to any messages regarding QA-ACT (Padonmar quality seal) and RDT
10. Proportion of people with a fever episode in the last two weeks who can recall any messages regarding QA-ACT (Padonmar quality seal) and RDT
11. Difference in use of diagnostic test and QA-ACT by people exposed and not exposed to BCC messages based on propensity score matching.

Source: PSI household surveys at baseline, midterm and endline (see also Figure 2).

Level 2:

The second level of evaluation questions addresses the impact of the project, or rather the contribution to impact, taking into account the two inherent goals:

a) Containment of resistance of *Plasmodium falciparum* to Artemisinin derivatives
b) Reduction in the number of malaria cases and consequent improvement in the health status of the population

- **Evaluation question 2a: Has the pool of potentially Artemisinin-resistant *P.falciparum* strains in tier 1 of the MARC project been reduced?**

- **Evaluation question 2b: Has a spread to other areas been prevented?**

- **Evaluation question 2c: What is the contribution of the AMTR project?**

Indicators:

12. Trend in malaria infection and morbidity indicators such as reported cases per 1,000 population and test positivity rate (disaggregated by tier or region within country)[1]
13. Proportion of patients with uncomplicated *Plasmodium falciparum* infection that have **not** cleared parasites by day three following treatment with QA-ACT (disaggregated by tier 1 and tier 2/3)
14. Proportion of patients with uncomplicated *Plasmodium falciparum* infection that show clinical treatment failure following treatment with Artemisinin-derivative monotherapy (disaggregated by tier 1 and tier 2/3)
15. Proportion of estimated overall malaria cases per annum in the PSI project region (*P.falciparum* and *P.vivax*) that have been adequately treated (compliance with full course according to national treatment guidelines) in the private sector

Source: MoH surveillance of day three clearance times in tier 1, tier 2 and tier 3 and results from therapeutic efficacy studies, MoH malaria HMIS data, resistance surveillance data from neighbouring countries as part of the regional containment efforts, and PSI and AA Medical Products sales data in conjunction with modelling output of expected cases.

- **Evaluation question 2d: How many DALYs have been averted by the PSI project and what proportion can be attributed to the DFID contribution to the project?**

[1] This indicator measures overall trends in malaria epidemiology without a claim that such changes were effected by case management interventions alone

Indicator:

16. DALYs averted

Source: PSI calculations and sensitivity analysis based on variation in assumptions undertaken by evaluation team (see also working papers in annex 3).

Level 3:

The third and final level of evaluation questions concerns the situation and potential development of the private sector after the PSI project has ended.

- **Evaluation question 3a: What is the anticipated development of the private sector malaria treatments after the PSI project in the medium and long-term?**

- **Evaluation question 3b: What will be the potential role of the private sector in malaria control in general?**

In the course of the evaluation two changes were agreed upon with DFID: first, indicator 16 (DALY) was dropped based on the results from the evaluation working paper 1 which suggest that the measure of DALYs averted in this context is not a useful measure of success (a direct link to the paper is given in Annex 3). Second, on request of DFID a modelling exercise addressing the level 3 question of future developments was added to the ToR.

Recipients

The primary recipient of this evaluation is DFID, as well as the co-funder of the AMTR project (the Bill & Melinda Gates Foundation). The secondary recipient is PSI as the implementer, and a tertiary recipient is the public health community in general.

Structure of the report

This final report focuses on the evaluation results for the core evaluation questions agreed upon during the inception phase, with a strong focus on the VFM report. Its structure is in keeping with the DFID Evaluation Quality Assurance (EQUALS) criteria, though the nomenclature deviates slightly from the DFID terms “analysis” and “findings” to follow more general scientific practice. Under “results”, this report presents all data and findings from the evaluation team, as well as the AMTR surveys undertaken by PSI in view of the main evaluation question and cross-cutting issues. This would be equivalent to the “analysis” section of the DFID EQUALS criteria. The inferences from the results are then presented, analysed and discussed based on the main objectives of the evaluation. This section is equivalent to the “findings” section of the DFID EQUALS criteria. This is then followed by a section on key recommendations and lessons from the evaluation.

5. CONTEXT

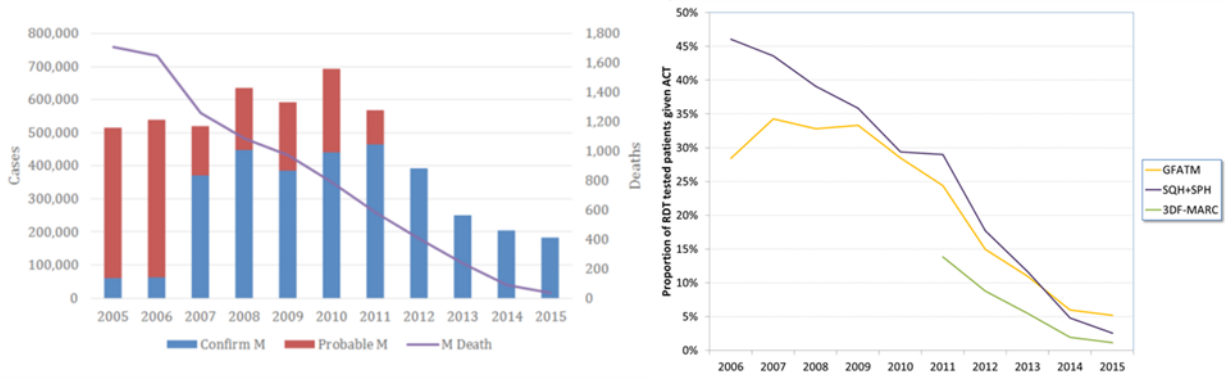
5.1. The changing epidemiology and its consequences for AMTR

At the time of emergence of artemisinin resistance in the GMS around 2007, Myanmar was by far the country with the highest malaria burden in the region and it was assumed that there would be many years of malaria control before the country could consider elimination. However, data from the health management information system (HMIS) in the following years showed a much faster than expected decline in malaria transmission, incidence and prevalence [Mu TT, Sein AA, Kyi TT, Min M, AungNM,

Anstey NM et al. Malaria incidence in Myanmar 2005-2014: steady but fragile progress towards elimination. Malar J, 2016; 15:503]. Although one has to assume that national public-sector data under-reports true cases, the WHO World Malaria Report (WMR) of 2010 estimates that, of the 600,000 officially reported, there were 1.2 million cases in 2009 [WHO: World Malaria Report 2010, http://whqlibdoc.who.int/publications/2010/9789241564106_eng.pdf] (Figure 1, left). Thereafter however, cases sharply declined and the 2014 WMR estimate of malaria cases is slightly less than 600,000 for 2011 and 300,000 for 2013 [WHO: World Malaria Report 2014, http://www.who.int/malaria/publications/world_malaria_report_2014/report/en/]. The Myanmar Ministry of Health (MoH)/WHO estimate that there were slightly fewer than 200,000 cases in 2015. This dramatic reduction in malaria incidence is confirmed by a number of other sources, such as data from NGOs working in remote areas and the data from private sector health clinics and Community Volunteers, which show a consistent decline of RDT test positivity rates from up to 45% in 2006 to 5% or less in 2015 (Figure 1, right). In addition, trend data from the Myanmar-Thailand border region confirms this steep decline in malaria prevalence and incidence [Carrara VI, Lwin KM, Phyo AP, Ashley E, Wiladphaingern J, Sriprawat K, et al. Malaria burden and artemisinin resistance in the mobile and migrant population on the Thai-Myanmar border, 1999–2011: an observational study. PLoS Med. 2013;10:e1001398]. But while prevalence rates are declining to levels below 2% in nationally representative household surveys such as the Malaria Indicator Survey (MIS) [MARC baseline survey 2012], the proportion of asymptomatic infections is significant, reaching 75% of all infections in some areas and, when detected, with a highly sensitive PCR technique [Imwong M, Nguyen TN, Tripura R, Peto TJ, Lee SJ, Lwin KM et al. The epidemiology of sub-clinical malaria infections in South-East Asia: findings from cross-sectional surveys in Thailand-Myanmar border areas, Cambodia, and Vietnam. Malar J, 2015; 14:381].

Although a detailed attribution as to the reasons for this steep decline of malaria incidence in Myanmar is beyond the scope of this review, it is very likely that as in neighbouring GMS countries it was not only and maybe not primarily driven by public sector interventions, but rather by ecological changes (e.g. deforestation) and general economic development which has reduced the vectorial capacity in many areas of the country.

Figure 1: Trend in malaria cases from MOH records (left panel) and RDT positivity rates from MMA volunteers and PSI SunHealth clinics (right panel)



With the dramatic decline in malaria incidence in Myanmar and the international efforts to move towards malaria elimination in the GMS, the Myanmar Malaria Programme, in collaboration with their development partners, moved quickly and the National Malaria Strategic Plan 2016-2020 [National Strategic Plan for Intensifying Malaria Control and Accelerating Progress towards Malaria Elimination, 2016-2020, Dept. of Public Health, Ministry of Health and Sports, The Republic or the Union of Myanmar] now proposes a step-wise progress towards elimination until 2030.

The plan explicitly points to the private sector as one of the partners to contribute within its capacity to delivering equitable and universal access to effective preventive and curative services to all at-risk populations. Whilst private sector presence and capacity to deliver is determined by profitability, it still achieves reach into areas of Myanmar where public sector provision is lacking, and is therefore still a highly relevant potential partner. It also highlights the participation of the private sector in adequate treatment, diagnostics and surveillance, and highlights the need for replacement of artemisinin-monotherapy (giving the example of AMTR), but does not outline in great detail how these private sector goals should be achieved.

5.2. The political and social changes in Myanmar

The political and social context of Myanmar has changed greatly since the emergence of artemisinin resistance in 2007, as well as since the start of AMTR in 2012, and has impacted on the project in a number of areas, both epidemiological and in terms of wider context. As mentioned previously, this has meant that the original AMTR Theory of Change (ToC) became obsolete in a number of areas, and better updating of this ToC and use of it as a management tool would have kept the project in line with the changing context.

In 2007, the military government was firmly in place, and the army directly controlled many of the areas of emerging artemisinin resistance on the Thai and Chinese borders. Military run healthcare facilities and military owned drug manufacturing enterprises were also a major part of the health sector context, with the latter producing and distributing oAMTs, thereby potentially contributing to the spread of resistance. Whilst smaller private sector drug vendors were part of the scene, their freedom to operate in many areas was curtailed, especially in conflict zones. By 2011, a new ex-military and nominally civilian government was in place, and a range of political, economic, and social reforms were kick-started. With this opening up, the Ministry of Health (MoH) and Ministry of Defence (MoD)/army became more open to collaboration with donors, NGOs, other organisations, and neighbouring countries in targeting artemisinin resistance. Initiatives such as the WHO Emergency Response to Artemisinin Resistance (ERAR), launched in 2013, were bought into by Myanmar.

This was the context in which AMTR was designed and launched – a more politically and socially open Myanmar, where government was more aligned on malaria control, and civil society and private sector were freer agents to be key actors in this. Notably, the MoH and MoD made commitments to cease military production of oAMTs, and to ensure military hospitals brought in new malaria diagnosis and treatment procedures. Larger private drug companies such as AMTR partners AA Pharmaceuticals and PolyGold, were targeted as newly freed private enterprises. At the same time, civil society and NGOs were freer to bring attention to the scale of the malaria challenge in Myanmar, with national NGOs the Myanmar Health and Development Consortium (MHDC) and Myanmar Business Coalition on Aid (MBCA) playing a major role in mapping malaria burden and bringing attention to government and private sector actors on the risks of the disease, diagnosis and treatment procedures, and the longer-term challenge of control and elimination. The AMTR ToC supposed this context to continue to become more of a positive driver of efforts in targeting artemisinin resistance.

During the life of AMTR, from 2012 to 2017, the political and social context has changed further, notably the victory of the National League for Democracy (NLD) in the November 2015 national elections ushering in a new NLD led government in April 2016, with the resulting changes of ministers and shifting of political emphasis within government. Whilst military influence over government decision making is still strong (due to the army's constitutional position in parliament and the key ministries of Defence, Home Affairs, and Border Affairs), the highly opaque, closed, conservative influence of the generals and their cliques of crony businessmen and supporters has waned. NLD policy is focussed on the poorer and marginalised in society first and foremost, and has heavy

emphasis on the wellbeing of smallholder farmers, small business owners, and ethnic minorities – in the opinion of some to the detriment of economic reforms that would have expanded the private sector quicker than has occurred since the NLD took power. Whilst the NLD has also been criticised for overly-centralised decision making on major policy areas, at local levels society is continuing to become more open, and government continues to improve how it interacts with citizens – meaning that public/private collaboration should be more possible in future health delivery efforts. Society has continued to become more open and liberalised, in particular in urban areas where technology such as smartphones and data connectivity has transformed access to information and social attitudes – and these technologies are now reaching areas of the country previously untouched by external influences, allowing innovations such as maternal health and agricultural market information apps to transform rural people's lives. Such technologies will also further empower local actors in drives towards malaria elimination.

Contextual changes which should have promoted changes to the underlying assumptions of the AMTR ToC through their impact on the project are as follows:

- Political changes within the MoH which led to a delay to RDT rollout prior to 2015, and then post 2015 policy direction changes
- Changing regulation of the private sector – increasing openness of government to private sector solutions and partnerships; new Myanmar Investment Law 2016; liberalisation of the pharmaceuticals market and more potential private sector drug manufacturers and distributers
- Changing thinking of development partners – less emphasis on NGO service delivery, more appetite to work with Myanmar government post-2015, new private sector aid actors
- Economic growth, construction of infrastructure, and subsequent physical changes to the landscape, urbanisation, deforestation, etc. which contribute to changed epidemiology
- Societal opening, dramatic increase in mobile phone technology and data connectivity, ability to apply communication solutions in the health and drugs marketing sectors

These changes have all affected the underlying context of AMTR, and will be key to take into account in future programme design and ToC formulation. They will also be essential to monitor in order to make continuous adjustments to the ToCs of future programmes and keep programming flexible and relevant.

6. METHODOLOGY AND IMPLEMENTATION OF EVALUATION

6.1. Methods of data collection by evaluation team

The primary approach for this work was a mix of quantitative and qualitative methods. The qualitative approach comprised Key Informant Interviews (KIIs), field visits, and a document, survey reports and literature review. The quantitative approach included analysis of routine data from AMTR and other implementers in Myanmar, secondary analysis of survey results from the AMTR project and the construction of a compartmental model of malaria cases and diagnosis and treatment. In addition, financial records of AMTR were analysed for the Value for Money evaluation. Throughout the evaluation, the AMTR project, staff from PSI-Myanmar was very cooperative, supporting all of the evaluation team's activities and data requests, and their effort is highly appreciated.

According to the TOR the evaluation team did not actively collect routine or survey data with the exception of the qualitative survey of knowledge, attitudes and practices of migrant workers which was one of the working papers (see Annex 3). All survey data results came from the AMTR project and the evaluation team only had the PSI reports available for analysis, not the original data.

An assessment by the evaluation team of the methodology of the surveys undertaken by the AMTR project is presented in section 5.4.

The final evaluation assessment, conclusions and recommendations were agreed upon by all evaluation team members and there was no divergent opinion. The evaluation team had access to all survey reports and routine and financial data form the AMTR project and had free access to any interview partner.

6.1.1. Field visits and interviews

Key Informant Interviews
The following people or groups were consulted (some repeatedly) during the three evaluation team visits (see Figure 2):

- PSI-Myanmar (all relevant departments)
- Suppliers of QA-ACT for AMTR (AA and PolyGold)
- Suppliers of RDT (Shwin Chan Trading)
- Ministry of Health (Malaria Programme and OR Department)
- Ministry of Defence (Health Department)
- WHO
- UNICEF
- Myanmar Medical Association (MMA)
- Food and Drug Administration (FDA)
- UNOPS (PR for GFATM Grant)
- Donors (DFID, USAID, JAICA)

Field visits
During the inception period, field visits were undertaken to some of the AMTR supported retail outlets in two townships in Mon State. In addition, exploratory visits were undertaken to major pharmaceutical markets in Yangon and Mandalay during the inception and the final evaluation visits. Additional field visits to typical outlets were not undertaken after the inception visit. While these are standard practice for official DFID project reviews, the evaluation team did not think their purely anecdotal character and lack of representativeness would be helpful to answer the key evaluation questions of the evaluation framework agreed upon with DFID.

6.1.2. Secondary data reviews and analysis

The following data collected by the AMTR project was used. In line with the ToR there was no active data collection by the independent evaluation team.

Routine data

- PSI-AMTR QA-ACT sales to distributor and from distributor to retailers
- PSI-AMTR RDT trainings and distributions
- PSI SunHealth franchise data on RDT use and positivity rates 2012-2016
- MMA community worker RDT use and positivity rates 2006-2015

Survey reports

- PSI AMTR surveys: household surveys 2012-16; mystery client 2013-16; retail outlet surveys 2012-16; RDT pilot surveys, fever follow-up survey 2016
- MOH surveys: MARC baseline 2012 and MIS 2015
- Other: Demographic and Health Survey (DHS) 2015

6.1.3. Malaria case management model

The purpose of the model was to recreate as closely as possible the situation in the public and private sectors during the roll-out of the AMTR project, comparing project to model output, allowing inferences on the impact of the project and then developing projections regarding possible future developments under various assumptions and scenarios. The model was created in Excel using three pillars of populations: 1) the national population by township and district, projected from the 2015 census for the period 2011-2030 and divided into three epidemiological strata (low, medium and high incidence based on MOH/WHO malaria incidence data 2015); 2) the population of fever cases derived from estimates of "two week fever" prevalence from surveys; 3) the population of malaria cases (*Plasmodium falciparum* and *Plasmodium vivax*) estimated from 2015 incidence data based on Annual Parasite Indices (API) and historical trends of test positivity.

This population was then exposed to three steps towards diagnosis and treatment of malaria and their respective probability in each year: 1) **health seeking** through different public and private sector providers; 2) **diagnosis** by microscopy or RDT; 3) **treatment** with various anti-malarials or other medicines.

The major outputs were:

1. The proportion of *P. falciparum* cases that were adequately treated in the sense of control and elimination of Artemisinin resistance
2. Annual estimated number of fever and malaria cases, testing rates per channel and endemicity stratum
3. Annual ACT and RDT use (demand) and need for each sector, stratum and years under various scenarios

Parameterisation of the different model scenarios was informed by the available information from surveys and reports and adjusted to national level where only sub-national data were available. A more detailed description of the model can be found in the annex of working paper 5 (see Annex 3).

6.2. Approach to Value for Money evaluation

The approach to the VFM Evaluation builds upon DFID's "4 E's" framework: Economy, Efficiency, Effectiveness, and Equity. Definitions of the factors in VFM analysis, derived from DFID documentation and experience, are as follows:

- **Economy** relates to the "price at which inputs are purchased…" according to DFID's Guidance Notes[2]. In AMTR, we understand economy primarily as the functions of procurement, risk profiling and mitigation, budget tracking and budget management.

- **Efficiency** relates to "how well inputs are converted to the output…". In AMTR, we understand efficiency to include achievement of output targets, and evidence of concrete planning and programming agility.

- **Effectiveness** is understood as "the extent to which programme outputs… are converted into programme outcomes and impact…"[3]. In AMTR, we understand effectiveness to be the

[2] VFM Guidance Notes, 2011

[3] "Guidance on measuring and maximizing VFM in cash transfers," p. 8, DFID 2013

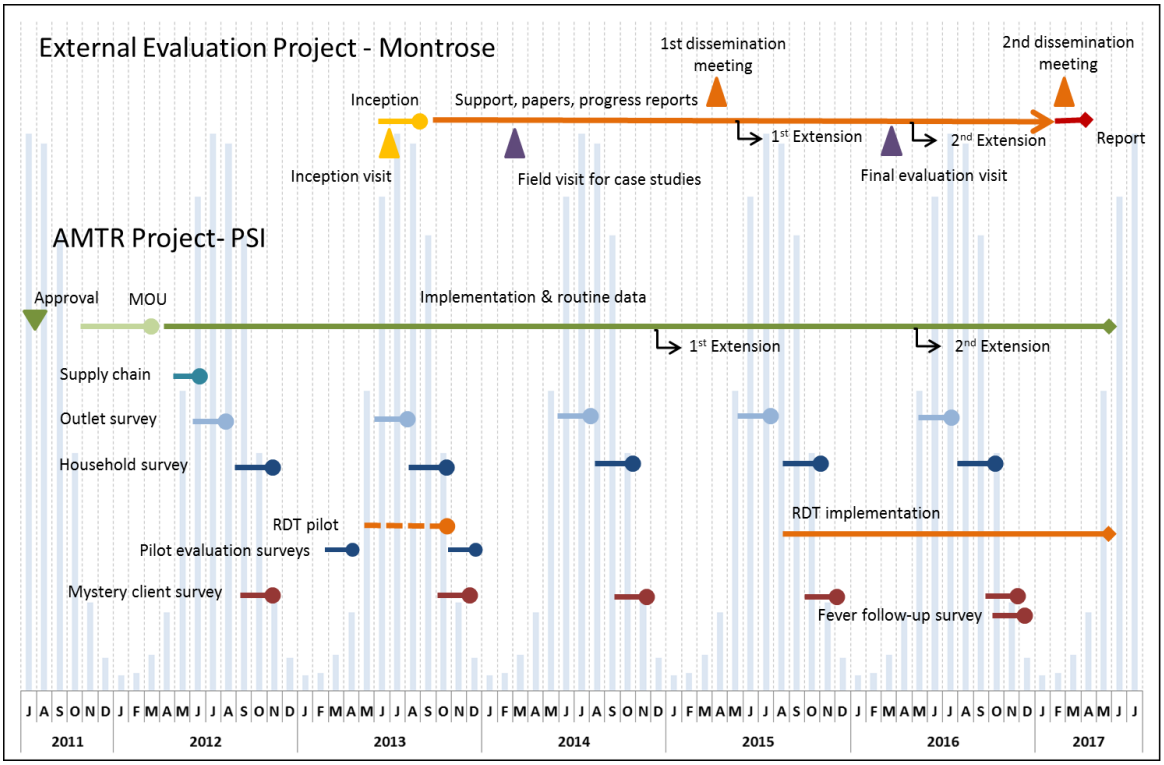
consistency and sustainability of provider and consumer uptake of the intended outputs. The focus has changed over time from driving oAMTs from the market to widespread testing of febrile patients and targeted QA-ACT treatment.

- **Equity** is understood as the spread across beneficiary groupings of the uptake of outputs and the benefits of outcomes and impact. In AMTR, we understand equity as detailed provider, consumer and ACT availability data across regions, outlet types and gender.

6.3. Implementation of evaluation

An overview over the implementation and timing of the evaluation as well as the AMTR project and its data collections are shown in Figure 2 below. Following the first AMTR no-cost extension, the evaluation project was also extended and the final evaluation visit postponed to March 2016. Due to miscommunication, the evaluation team was not informed of the second AMTR no-cost extension in time and although a second no-cost extension was also provided to the evaluation, this did not allow for another in-depth visit before the end of the project. After consultation with DFID, the activities of the evaluation team were therefore restricted to a desk review of data and final documents and the development of the case-management model and a final working paper (see below). Two dissemination meetings were held in Yangon, in March 2015 and March 2017, to present some of the findings of the evaluation and the case studies and working papers to stakeholders.

Figure 2: Overview and timeline of the independent evaluation, AMTR project with data collections and the relevant MARC activities. Light blue vertical bars represent average monthly rains.



In addition to five six-monthly progress reports, the evaluation team produced five working papers and two case studies addressing questions concerning not only the AMTR evaluation itself, but also of wider interest to the public health community, including:

- Sensitivity analysis of the calculation of Disability Adjusted Life Years (DALY) averted in the context of the AMTR project, which suggests that DALYs may not be the best way to summarise project impact.
- Adding primaquine to the standard treatment of uncomplicated *P. falciparum* malaria – perceptions of various providers and options for implementation strategies.
- Challenges of rolling out malaria RDT among private health care providers and what can be learned from the AMTR experience.
- The potential impact of increased private sector investment in Myanmar on malaria control strategies and the potential future role of the private sector in contributing to malaria control.
- Moving forward: The potential future role of the private sector in Myanmar in efforts towards containment of *Plasmodium falciparum* artemisinin resistance and malaria elimination which presents the findings from the case management model and what it implies for future strategies of the public sector to support changes in the private sector.

A complete list of case studies and working papers is given in Annex 3.

6.4. Methods used by AMTR project for data collections and surveys

As shown in Figure 2, the AMTR project undertook annual household, outlet and mystery client surveys. The reports for these surveys were used by the independent evaluation team for their quantitative assessments. The evaluation team did not have access to the original data.

Overall the survey methodology applied for the AMTR project for outlet, household and mystery client surveys closely followed the methodology of the *ACTwatch* project and has been well established and recognised as "state of the art". In this respect, the evaluation team had no concerns with respect to data reliability and quality. However, there are a few aspects that one should be aware of:

Sampling methodology: In order to achieve a good "representation" of accuracy and internal validity, it is generally advisable in population-based surveys to have as few steps in the sampling design as possible, as with each further step a new layer of potential loss of precision through design effects[4] is introduced. This means that usually only two steps are applied to household cluster surveys. However, because the *ACTwatch* methodology relies on larger administrative sub-units to sample all eligible medicine outlets within that unit (in the Myanmar context a township), there were four steps in the sampling process and the number of primary sampling units (townships) was rather low, with 13 compared to the optimum usually recommended to minimise the design effect of about 30. This sampling methodology did not necessarily introduce a bias but is likely to lead to loss of precision in the final estimates due to larger design effect and does imply the assumption that outcomes are reasonably homogeneous between townships within a domain. However, given the need to overlap the sampling domains of outlet and household surveys and using the same design throughout the project to ensure comparability, no changes were recommended by the evaluation team.

Outlet, household and mystery client surveys had different sampling frames (areas targeted for sampling) and these also changed over time. The outlet surveys had two domains: first, the "intervention area" comprising 92 townships where outlet visits by promoters were undertaken and BCC activities targeted consumers; second, the "comparison area" which comprised 46 townships in the centre and East of the country. In 2016 these townships were included in the "intervention area"

[4] The design effect is the ratio between the between and within variance of a specific outcome, or in practical terms the factor by which the confidence interval of an estimate needs to be inflated compared to a sampling where the units of observation are selected directly, without clustering.

and therefore labelled "extension area". The 2016 outlet survey then added a third domain which was the Western border area.

The household surveys were limited to the original "intervention area" and the mystery client surveys were limited to some townships from the outlet survey (sub-sample).

Sample size: Sample sizes for the surveys had been calculated based on anticipated outcomes and their changes across the PSI project area. This implies that any disaggregation of data as recommended by tier 1 versus tiers 2 and 3 would results in a loss of precision (larger confidence intervals). The biggest challenge, however, was the sample size of the household survey. It was sufficient to describe consumer knowledge and treatment seeking, but due to the low incidence of fever and the rapidly declining malaria incidence it was not sufficient to analyse specific malaria cases. The evaluation team discussed with the AMTR project possible alternatives as an extension of the sample size of the household survey did not seem feasible. As a result, the AMTR project undertook a fever follow-up survey.

Questionnaires: The survey tools used by *ACTwatch* and adopted for the Myanmar context were comprehensive enough to allow all analyses that were suggested by the evaluation team in the evaluation framework.

Quality assurance during data collection and entry: Quality assurance procedures during data collections reported by PSI followed the general practice of validating at least 5% of interviews by the supervisors and are therefore sufficient. However, it could not be established to which extent these data validation exercises were also documented by the contracted survey firms.

Data entry was performed with a professional data entry software package using state-of-the-art double entry and validation and there are no concerns regarding data quality.

6.5. Limitations

There were two major limitations for this independent evaluation:

- First, the evaluation contract was awarded two years after the approval of the AMTR project and 14 months after the start of project activities. This made it impossible for the evaluation team to influence the Theory of Change or logframe at an early stage.

- Second, due to the much lower than expected sales of QA-ACT the project had sufficient resources for two no-cost extensions. In contrast, the evaluation team's budget was mainly for staff time for analysis and evaluation visits so that the two no-cost extensions led to a lack of resources. Combined with the miscommunication regarding the second no-cost extension of the AMTR visit the evaluation team had to base its final evaluation on a desk review only.

7. RESULTS

Before the results against the evaluation questions are presented, it is essential to include a brief discussion of the AMTR theory of change and how it was influenced by the changing circumstances, as well as discussions held by the evaluation team. As a consequence, significant changes were also made to the logframe.

It appears also useful to remind the reader that the different interventions of the AMTR project had differing target groups or areas. The main intervention was the replacement of oAMT with QA-ACT in the distribution chain of the private sector using first the distributor with the largest market share in anti-malaria and then adding a second distributor. By nature, this intervention has no specific target area and is applied nation-wide wherever the distribution chains of the distributors reach. In contrast, the intensive promotional activities of the AMTR project with regular visits to outlets and general BCC activities was initially only targeted to 92 townships in the East and South (ties 1 and 2 of MARC) of which some, however, were inaccessible at some time periods due to insecurity. In 2016, the intervention area was expanded into 46 additional townships of the former "comparison area" in the centre and West of the country. Interventions for the RDT were initially only limited to the six townships in Mon and Shan states. The implementation area for RDT then expanded to the original intervention townships for sales promoters. As shown in Figure 16 in Annex 6 RDT sales by the end of the project had not yet reached all the intervention townships.

7.1. Business case and theory of change

The DFID business case (BC) as well as the PSI project proposal both include sections on theory of change which refer to calculations and projections made by PSI but are not really a theory of change in the strict sense of "a comprehensive description and illustration of how and why a desired change is expected to happen in a particular context[5]". Instead, it is the attempt to estimate the initial expected number of fever and malaria cases seen in private sector outlets and project outcome and outputs of the AMTR project. The specific assumptions (detailed in Annex G of the PSI proposal) include the following:

- There are approximately 5 million fever cases in the population of the AMTR target area equivalent to a two-week fever prevalence of 1.8% amongst the general population.
- Of these fever cases, 44% test positive for *P. falciparum* malaria and 78% of all malaria cases are infections with *P. falciparum.*
- The majority of all cases (>70%) are treated in the private sector.
- Of malaria treatments from the private sector, the majority of treatments given are artemisinin monotherapy and most patients only take a partial dose.

Based on these assumptions, the major anticipated output as calculated by the applied formulas (see Annex G of the PSI proposal) was:

- 1.8 million treatment courses of QA-ACTs received, packaged and sold by end of Year 1, 3.6 million in Year 2 and 3.4 million in Year 3, in total: 8.8 million (of which 0.9m; 1.8m and 1.7m and total of 4.4m attributable to DFID).
- 1,900 providers trained in the use of Rapid Diagnostic Tests in Year 2, 7,000 by the end of the project (of which 950 and 3,500 respectively are attributable to DFID).
- 250,000 Rapid Diagnostic Tests correctly used and reported in Year 2, 950,000 in Year 3 (of which 125,000 and 475,000 respectively are attributable to DFID).

This would then lead to the following outcomes and impact:

- 73% of suspected malaria cases will complete a full course of a nationally approved, quality assured artemisinin combination therapy within 24 hours of onset of fever.
- Proportion of malaria cases in the target areas that are treated with artemisinin monotherapies fall to less than 10% by Year 2.
- 161, 000 DALYs gained in Myanmar over the three years (of which 80,500 are attributable to DFID).

[5] See: http://www.theoryofchange.org/what-is-theory-of-change/

The implicit theory of change at the beginning of the AMTR project – as described in the evaluation inception report – can then be described as identifying the artemisinin resistance and its potential spread as the general problem to be addressed. The specific problem was the fact that most fever cases treated in the private health care sector did not receive a recommended ACT but an insufficient dose of an artemisinin derivative alone, mainly artesunate. This low dose artemisinin monotherapy is limited in its ability to reduce malaria transmission and represents a tremendous drug pressure on the malaria parasites, enhancing the likelihood of selecting and spreading resistant strains. Reversing this situation by replacing oral artemisinin monotherapy in the private sector with full treatment courses of QA-ACT in combination with increased use of diagnostic tests through the AMTR project therefore significantly contributes to resistance containment efforts.

The strategy the project developed to achieve its targets was based in principle on a modified social marketing approach. An ACT recommended by the MoH, artemether-lumefantrine, was procured from an Indian manufacturer with WHO-pre-qualifications guaranteeing quality, re-packaged by PSI under a new brand name and introduced into the pharmaceutical markets with a significant subsidy that would match the price of a partial dose of oAMT which was estimated at 500 Kyat (or USD 0.55). This subsidy was considered sufficient to crowd out oAMT (and full cost ACT as a side effect). But instead of PSI distributing the QA-ACT directly into the retail supply chain, the AMTR project used existing pharmaceutical distributors that previously were very active in the market of oAMT. The first distributor was AA-Pharmaceuticals, which had previously held approximately 70% of the artesunate market in Myanmar and in September 2012 started selling the QA-ACT branded as Supa-Arte. Negotiations were also started with a second distributor which had a significant share in the artesunate market, PolyGold, but did not commence sales of the QA-ACT branded as Artel until August 2014. Both brands, Supa-Arte and Artel, are owned by PSI and not the distributors. The AMTR QA-ACT brands were issued with a quality seal called “Padonma” which was meant to be available to any distributor of QA-ACT, including the public sector, and which was used extensively – at least initially – by the AMTR project to promote QA-ACT. While the two distributors marketed the QA-ACT nation-wide within their networks of sales representatives and clients, the AMTR project undertook their own intensive promotion and BCC through their field staff in an “intervention” area that comprised 92 townships in Eastern Myanmar, which were equivalent to the areas initially identified in the MARC strategy as the most exposed to the threat of artemisinin resistance (tiers 1 and 2). The primary target outlets were pharmacies and drug-shops, general retail shops selling some pharmaceuticals and informal providers. Outlets outside the “intervention” areas were initially considered the “comparison” area but from 2015, promotional activities were also provided in this area and it was hence called the “expansion” area.

The efforts of the AMTR project to replace oAMT with QA-ACT in the Myanmar private health care sector were supported by a ban of monotherapy for malaria by the MoH and the Federal Drug Administration (FDA). This comprised a ban of, first, artesunate monotherapy in December 2011, and then artemether in August 2012 (see Figure 1). However, the ban was essentially only a decision not to issue any further licences for these products other than as ACT, and did not affect any licenses already in place. For example, the Ministry of Defence (MoD), which manufactures pharmaceuticals for the armed forces in Myanmar, produced artesunate monotherapy until the license ended in early 2014, and some of this medicine was regularly found in wholesale markets in Yangon and Mandalay.

During the inception visit and subsequent report the evaluation team analysed whether the assumptions underlying the initial estimations still held and tried to spell out the implicit theory of change examining whether it was sufficient to achieve the project outcome. This process was continued in the progress reports and the evaluation visit of March 2016. The major points that were raised and discussed can be summarised as follows:

1. At the time of the inception of the evaluation, it was already obvious that some of the estimates used to project AMTR outputs were unrealistic. This included the proportion of fever cases seen in the private sector being less than the 70%, assumed based on the 2012 MARC baseline survey, a proportion of *falciparum* compared to vivax cases among all malaria cases of closer to 50% rather than 70% and – most importantly – a much lower and rapidly declining malaria incidence than expected. This meant that it was already clear that the major outcomes of 8.8 million doses of QA-ACT within three years would not be achieved. However, this did not imply that the outcome of contributing to the containment of resistance could not be achieved. In addition, the under-estimation of occurring changes cannot be seen as a short-coming of the project as, at the time of project design in 2011, information was very limited and PSI had worked with the best data available at the time.

2. More significant was the initial consideration of the evaluation team that the implicit theory of change focusing merely on the replacement of oAMT by a QA-ACT fell short of what was needed to achieve the defined outcome of "73% of suspected malaria cases [seen in the private sector] will complete a full course of QA-ACT within 24 hours of fever-onset", i.e. a treatment that will clear any potentially resistant parasites and stop them for onward transmission.

   Firstly, it had become evident in the first round of AMTR surveys (retail outlet, household and mystery client surveys) that oAMT treatments, while being the most important, were not the only threat to an inadequate treatment of falciparum malaria. There was a significant proportion of "suspected malaria" cases that received other anti-malarias such as quinine or chloroquine, possibly under the assumption of a vivax case, or received only non-malaria medicines such as antibiotics. These treatments in "true" *Plasmodium falciparum* cases would significantly reduce the proportion of adequate treatments, even if oAMT was successfully replaced by QA-ACT. So, unless this issue was addressed, the outcome could not be fully achieved.

   Secondly, with evidence of the start of a decline in malaria incidence, it quickly became clear that equating fever of otherwise unknown causes with "suspected malaria" would no longer be adequate as it would lead to QA-ACT being increasingly given to non-malaria fever cases, and therefore poor value for money or cost-effectiveness. This meant that the importance of rapidly introducing appropriate malaria diagnostics into the private sector was much higher than originally anticipated. It was necessary to address the issue of inadequate malaria treatments other than oAMT mentioned above as well as being more cost-effective with the subsidised QA-ACT.

3. The theory of change was initially not used by the AMTR project as a process to aid in project management as recommended by DFID [Vogel I: Review of the use of 'Theory of Change' in international development http://r4d.dfid.gov.uk/pdf/outputs/mis_spc/DFID_ToC_Review_VogelV7.pdf]. The topic was not picked up on until the end of the DFID funding when, driven by the discussions with the evaluation team as well as requests from the DFID Annual Review, a new theory of change was developed to serve as a template for future project designs. This is not to say that project roll-out would have been significantly different than it was, as many obstacles were beyond project influence (see section 6), but it might have created a more focused discussion on what is needed in the private sector within PSI and partners and stakeholders.

7.2. Changes in logframe indicators

The initial logframe of the AMTR project followed the implicit theory of change by defining the project outcome as the replacement of oAMT by QA-ACT in the private sector outlets, which would then contribute to the containment of artemisinin resistance.

At a lower level, it defined three outputs, the first focusing on private sector providers and particularly the target outlets of the AMTR project. The second output focused on the population as consumers of malaria diagnostics and treatment, and the third on the diagnostic awareness and capacity of providers.

During the project implementation, a number of changes were made to logframe outcome and output definitions, as well as the respective indicators and milestones and targets. This was in part due to the shifting epidemiology and increasing focus on changing the theory of change as described above. But adjustments of indicators that were not measurable as initially formulated (e.g. disaggregation of sales data from the private sector by age and gender is not possible), as well as the increasing difficulty in capturing malaria treatment cases in general household surveys due to the low incidence, also played a role. The major changes were made in 2014, two years into the project, and consisted of a shift from a focus on treatment of suspected fever cases to a focus on diagnostics and the roll-out of RDT among private sector providers outside clinics and general practitioners. A detailed summary of the changes in output and indicator definitions in the logframe are presented in Annex 3, a summary of achievements against each indicator in table 6 of the VFM analysis (section 6.5) and the final logframe with results as submitted by the AMTR project in Annex 5. Below, the impact, outcome and outputs of the final evaluation are presented.

Impact: To prevent (or at minimum significantly delay) the spread of artemisinin resistant *Plasmodium falciparum* parasites within Myanmar and beyond its borders

Outcome: 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).

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

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.

Output 3: 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.

7.3. Results from key informant interviews

During the three country visits of members of the evaluation team (see Figure 2) KII were held with key partners and stakeholders. A list of all interview partners is presented in Annex 7. Some of the key results are presented and summarised here.

Public sector partners and stakeholders

In general, there was a high level of appreciation from public sector partners and stakeholders for the AMTR project, especially from the Ministry of Health, WHO, UNOPS and Save the Children. They all were aware of the importance of the private sector for the overall achievement of the ambitious target of malaria elimination. However, the evaluation team found that most interview partners had no or very little understanding of how markets for anti-malarials work and what interventions can be expected to achieve what effects. As a result, these interviews did not contribute much to the

assessment of the key evaluation questions. The highest level of understanding was found from the Myanmar Medical Association (MMA) which is working with private sector outlets and volunteers in a similar fashion in some difficult to reach areas with funding from the Global Fund. None of the public sector stakeholders expressed any diverse views or opinions.

Private sector partners

Repeated interviews with the main private sector partners showed that they remained committed to the objectives of the project, but also showed that the main interest was not the business perspective or profit expectation but rather to support the public sector malaria elimination goal and to some extent to simply stay in the market for anti-malarials. This was particularly true for AA-Pharmaceuticals which clearly stated that they see the QA-ACT sales primarily as social responsibility as they constitute less than 0.05% of the company's revenue. Both distributors expressed interest in continuing with the activity beyond the AMTR project as long as there would be some kind of subsidy as they were convinced that without subsidy the non-ACT medicines would return to dominate sales. Both partners were also aware that the ownership of the subsidised QA-ACT brands (Supa-Arte and Artel) was not theirs but rather that of PSI which limits their options for the post AMTR era as they would depend on some kind of agreement with PSI.

7.4. Results against Evaluation Questions

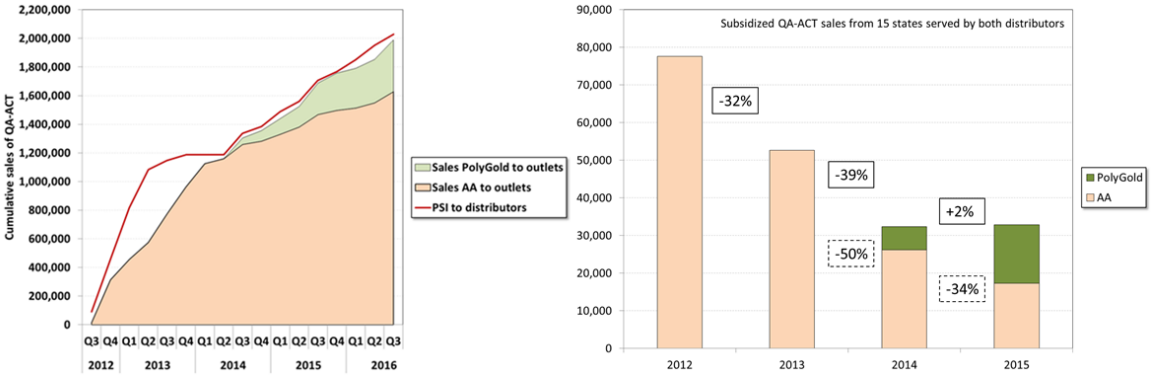
7.4.1. Level 1: Outputs, outcomes and effects at outlet and consumer level attributable to AMTR

7.4.1.1. Has the replacement of oral artemisinin monotherapy been achieved?

Sales of the QA-ACT Supa-Arte started in September 2012 and quickly rose to approximately 78,000 doses per month. As shown in Figure 3 (left panel), the sales of the AMTR project to the distributor initially were too optimistic as they were still based on higher incidence assumptions. By the second quarter of 2013, this was corrected and from then on sales to the distributors matched those from the distributors to their clients. This did not, however, include some issues with expiring medicines that led to a significant recall and exchange of QA-ACT (see VFM section for details).

By early 2014, average sales slowed down further, which can be seen from the reduced slope of the cumulative sales curve in Figure 3. After two years of implementation the total QA-ACT sales by the distributors were 1.2 million, or 22% of what had originally been anticipated at this time, showing the magnitude of the malaria incidence decline in Myanmar. By August 2014, the second distributor started sales of the Artel QA-ACT and quickly picked up sales. This distributor, PolyGold, had initially lost a number of clients when AA-Pharmaceuticals started the subsidised sales of Supa-Arte as they could not compete with the subsidised price, but they quickly regained these clients and as a consequence the gradient of the cumulative sales curve (Figure 3) remained unchanged after the entry of the second distributor. A more detailed analysis of the sales data by state showed that, in the 15 states where both distributors were active, there were significant losses by AA in favour of PolyGold (Figure 13, Annex 3), but overall there also seems to have been a temporary halt in the decline in QA-ACT sales by the addition of PolyGold, as shown in Figure 3 (right panel). This suggests that the sales base was slightly expanded by the addition of the second distributor. An interesting trend was seen in the sales data which reflects the declining malaria incidence and a likely shift from community-based transmission to increasingly occupational transmission in high risk foci: the proportion of adult doses among all QA-ACT sales of the AMTR project steadily increased from 60-70% in 2012 to 90% or more by the end of 2016 (Figure 14, Annex 6).

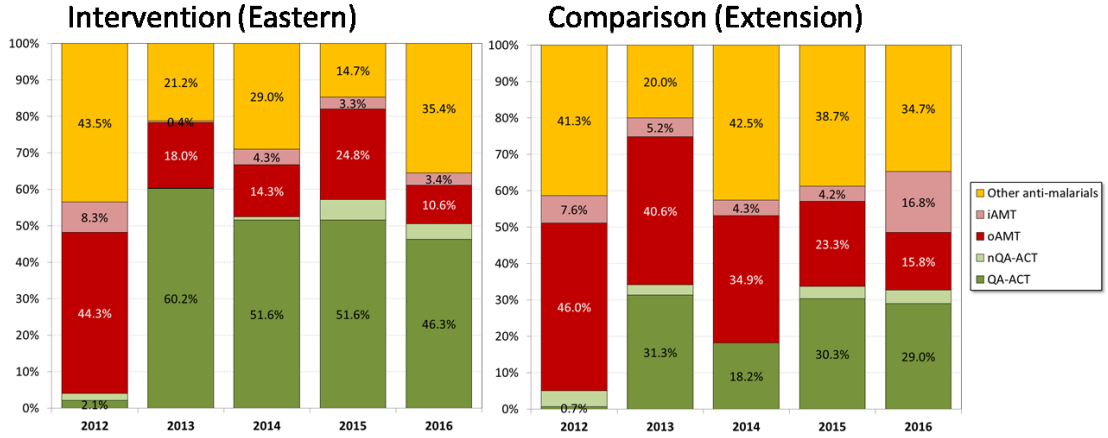
Figure 3: Cumulative quarterly sales of subsidised ACT in the AMTR project (left) and effect of second distributor (right) (Source: PSI routine data)



A critical question for the evaluation is whether or not the subsidy on the QA-ACT was actually delivered to the consumers. This was measured by the annual retail outlet surveys by calculating the average price for the QA-ACT and then determining the proportion of outlets that sold the QA-ACT "at a price less than or equal to the cost of the most common artemisinin monotherapy at baseline" (logframe output indicator 1.3). The initial target was 70% and thereafter 80% and in all years the rate found in the surveys exceeded the target. This strongly suggests that the subsidy was successfully passed on to the consumer and that QA-ACT was able to compete with the oAMT on price as intended.

Availability of oAMT and QA-ACT respectively and their proportionate sale shares were the criteria to assess whether oAMT was reduced and/or disappeared in favour of QA-ACT. The trend for the priority outlets in the intervention and comparison areas is shown in Figure 4 and suggests that initially there was a very favourable development, with QA-ACT increasing from a 2% to a 60% share in the intervention areas while oAMT was reduced to 18% from 44%. However, there was little progress thereafter and even a slightly declining trend in QA-ACT sales, mainly due to high rates of other anti-malaria sales and a stagnant oAMT share.

Figure 4: Sales share of anti-malarials in pharmacies, retail outlets and informal providers from AMTR outlet surveys. Intervention area corresponds to the core target townships with intense promotion. iAMT=injectable AMT, nQA-ACT=non-quality assured ACT.

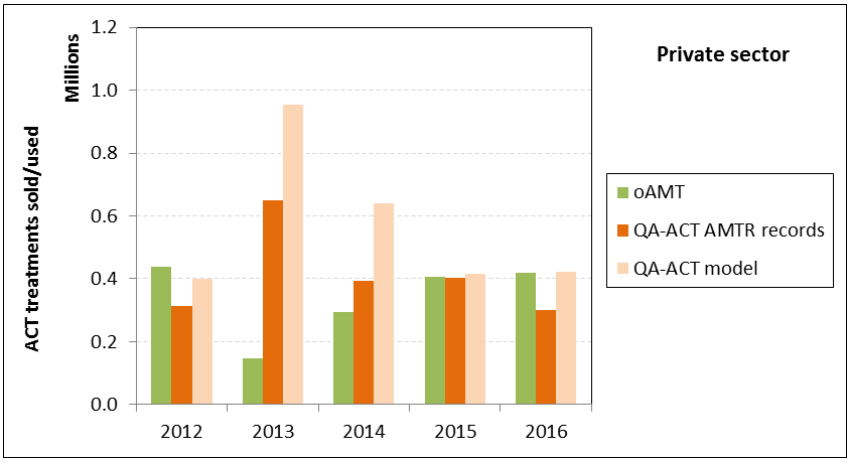


In the comparison areas, the development was similar but the reduction of oAMT from 46% sales share at baseline to 15% in 2016 was more gradual and the QA-ACT share stagnated at about 30%. In the private clinics and among community health workers (CHWs), the situation was more favourable: QA-ACT sale shares were around 60% from the beginning and oAMT fluctuated around 10% share throughout the project implementation (Figure 15, Annex 3).

However, the failure of oAMT to disappear from the markets or bounce back after the initial significant decline was not necessarily a failure of the AMTR project, as the formal channels of oAMT supply did largely disappear after the military stopped production of artesunate and the previously licenced stock had been sold. Explorations by the AMTR team, as well as the evaluation team, found that the continued or even increased availability of oAMT was mainly due to medicines entering the country illegally from China and Vietnam, which went through channels other than the formal distribution channels. It appears that this could not have been stopped, even though from 2015 the FDA and associated township inspectors increased checks on un-licenced AMT.

In the logframe, the replacement is measured by output indicator 1.5 which looks at the ratio in sale shares of QA-ACT vs. oAMT. Overall, this was quite favourable with rations of 0.7:0.3 or 0.8:0.2 in the outlet surveys. Data from the case-management base model confirms the initial favourable shift away from oAMT in 2013 (Figure 5), but also suggests that, thereafter, the annual output of oAMT and QA-ACT in the private sector, while overall reducing due to declining incidence and increasing diagnosis, returned to roughly equal absolute amounts. This was in part due to the declining use of QA-ACT due to the absence of testing resulting from declining malaria incidence overall (see next section).

Figure 5: Private sector annual QA-ACT output from AMTR records and the baseline model in relation to the model output for oAMT.



From KIIs conducted during the evaluation, it became clear that distributors of non-subsidised QA-ACT had mostly left the market – i.e. were crowded out – except for some distributors serving higher end private clinics and hospitals. This is also supported by the outlet survey data, which shows that non AMTR based QA-ACT or other ACT had a sales share of about 2-5%, except in private clinics where it reached up to 30% in some outlet surveys.

The other two logframe indicators regarding the replacement of oAMT showed mixed results. While those outlets that did stock QA-ACT rarely had stock-outs (outlet indicator 1.1), the proportion of outlets that did stock the QA-ACT among those with any anti-malaria in stock (outlet indicator 1.1) consistently reduced from 79% in 2013 to 50% in 2016 compared against a target of 95%. This is an effect of the shrinking market, as well as increasing awareness of the decreasing threat by *falciparum* malaria, and will likely continue.

7.4.1.2. Has the proportion of fever cases correctly treated increased?

The question of whether the project managed to increase correct treatment on fever cases must be separated into two different aspects.

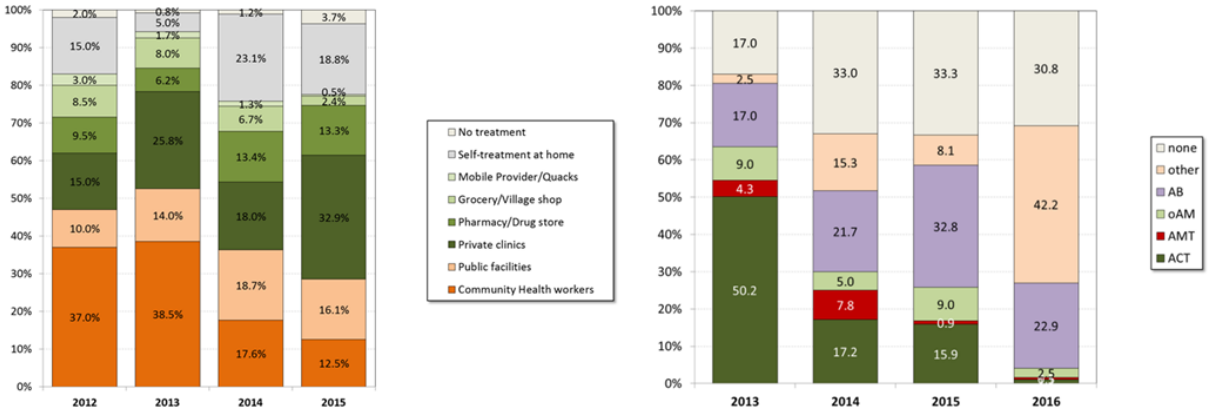
The first aspect concerns fevers that are true negative cases, i.e. they do not have malaria parasites. Their correct treatment primarily depends on whether they are tested, which is discussed in the next

section. However, if they are tested and turn out to be negative, the correct treatment is not to give an antimalarial. This is reflected in the AMTR logframe in outcome indicator 2 and output indicator 3.3; the former measured in the household survey using the population with fevers testing negative, and the latter from the mystery client survey. Unfortunately, the way the data for outcome indicator 2 is presented by the AMTR project is a bit misleading, as the reported value seems to be the "% of population with fever not getting an anti-malarial when negative among all fever cases" rather than among those actually tested negative (the reported values are 3.5% in 2015 and 4.4% in 2016). However, using results from outcome indicator 1, the proportion of fever cases tested, and assuming a positivity rate of 5%, one can estimate that the proportion of fevers tested negative that did not get an anti-malarial was 70% in 2015 and around 80% in 2016. This is more in keeping with the results from the mystery client survey, which showed negative compliance of 96% in both years. It is also in keeping with findings from other countries and suggests a reasonably good outcome.

The second aspect of correct fever treatment is the one most relevant to resistance containment, namely the treatment of true positive cases with a full dose of QA-ACT. This depends not only on the availability of QA-ACT in the outlets but also where people with a febrile illness seek treatment, whether the provider has a diagnostic test available and is willing to use it, what treatment he or she gives if the case is positive and, finally, whether a full course of the right medicine is given. On the patient's side, adequate treatment also depends on whether a full course is completed. The latter is addressed in output indicator 3.4 of the logframe and for 2016 was found to be 61% in the fever follow-up surveys. Earlier estimates made by the evaluation team from household and mystery client surveys suggested a complete dose was taken in approximately 70% of cases; overall not an excellent but certainly a good result.

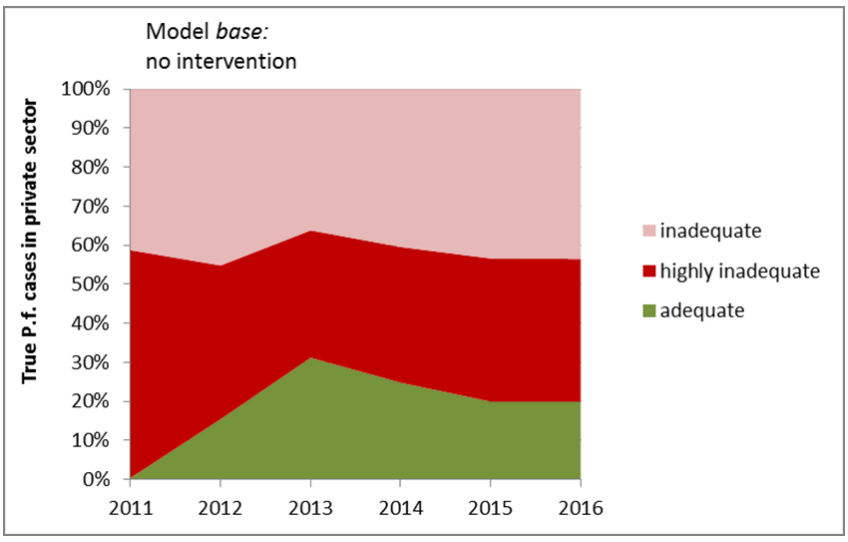
Independent of the availability and use of RDTs discussed in the next section, there were two important trends visible in the survey data from AMTR relevant to the evaluation question at hand. There was an increase in the use of private sector outlets and a corresponding decline in public sector providers in the AMTR household surveys (Figure 6, left). More importantly, the outlets that gained popularity were private clinics, pharmacies and drug shops while mobile providers and general shops declined. This can be seen as a favourable development as QA-ACT availability and testing is better in the formal outlets whilst the quality of care in general shops could be described as questionable. The second trend comes from the mystery client surveys (Figure 6, right) and suggests that, at least in the priority outlets, there was a strong trend away from the use of anti-malarials and an increase in the prescription of antibiotics. This is most likely an effect of an increasing awareness among providers that malaria is rapidly declining and is favourable for the treatment of negative cases and those not tested as they are more likely to get the correct treatment. It once more emphasises, however, the importance of testing fevers for malaria in order to ensure that positive cases are treated correctly.

Figure 6: Trend in health seeking behaviours from AMTR household surveys (left) and changes in the type of treatment offered to mystery clients in priority outlets (right). AB=antibiotic; oAM= other anti-malarial.



Using available survey data from the AMTR project, the evaluation team estimated the proportion of true malaria cases treated with a full dose of QA-ACT twice during the evaluation, in 2014 and again in 2016. At both times the estimate was around 20%, with approximately one third being treated with an incomplete dose that could induce resistance selection pressure on the parasites and the remainder treated with non-malarials. These estimates are based on small numbers from the surveys, but are confirmed by the output of the case-management base scenario that attempts to capture the outcomes of the AMTR project. As shown in Figure 7, the proportion of adequately treated cases of *Plasmodium falciparum* initially increases to 30% and then stabilises at 20% while the proportion of highly inadequately treated cases (oAMT or incomplete dose of QA-ACT) reduces initially from 60% to 35% but then remains at around 40%.

Figure 7: Model output regarding treatment outcome of true *P.f.* cases attending the private sector during the AMTR project phase. Adequate treatment= full dose of QA-ACT; highly inadequate=AMT or incomplete QA-ACT; inadequate= any non-artemisinin-based treatment. "No intervention" refers to the absence of additional interventions in the private sector beyond what was achieved under AMTR.



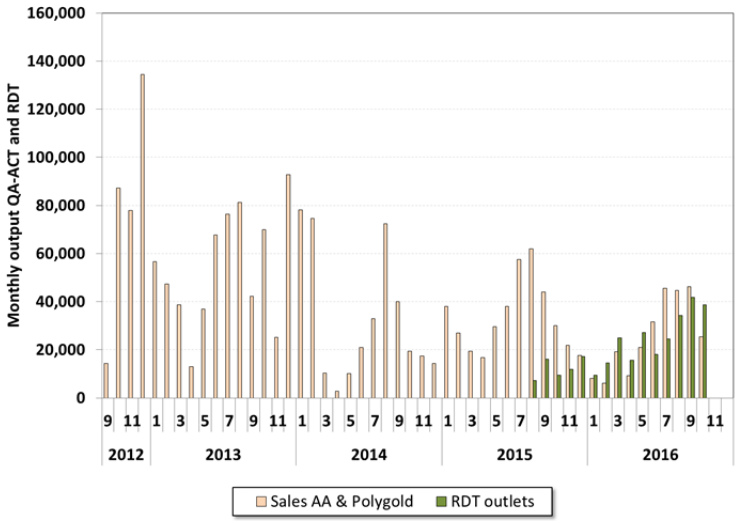
7.4.1.3. Has the need for prior testing been established and are RDT used?

As pointed out previously, testing fever cases for malaria increasingly became the crucial element in the rapidly changing environment in which the AMTR project was implemented. RDT distribution to the private sector did not actually start until September 2015, three years after the start of the project.

However, this cannot really be blamed on the project, as most of the delays were due to external factors. Firstly, after consultation with stakeholders and the MoH, it was decided that a pilot of RDT distribution among private sector providers was needed since so little was known about how best to accomplish it and what incentives would work best.

The pilot was implemented with assistance from the University of California, San Francisco, USA, and took place between October 2012 and October 2013. The design involved three strands, each with different monetary or capacity building incentives. The results have been summarised in Case Study 1 of this evaluation (see Annex 1) and have also been published in peer-reviewed journals [Sudhinaraset M, Briegleb C, Aung M, Khin HSS, Aung T. Motivation and challenges for use of malaria rapid diagnostic tests among informal providers in Myanmar: a qualitative study. Malar J, 2015;14:61,Chen IT, Aung T, Thant HNN, Sudhinaraset M, Kanh JG. Cost-effectiveness analysis of malaria rapid diagnostic test incentive schemes for informal private healthcare providers in Myanmar. Malar J, 2015; 14:55,Aung T, White C, Montagu D, McFarland W, Hlaing T, Khin HSS et al. 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. Malar J, 2015; 14:105]. In short, the use of RDT among providers of AMTR priority outlets was shown to be feasible at a subsidised price and a combination with intensified communication efforts proved to be the best incentive to stimulate use by the provider. By early 2014, the project developed a RDT implementation strategy based on the original concept that the RDT would be channelled through the distributors that were used for the QA-ACT, namely AA-Pharmaceuticals and PolyGold. However, the MoH did not agree with this approach and insisted that the RDT should be free to the consumer. This required a re-planning and direct distribution of RDTs by the AMTR project. As a result, the actual roll-out of intensive training and use of RDT did not start until August 2015 (see Figure 8).

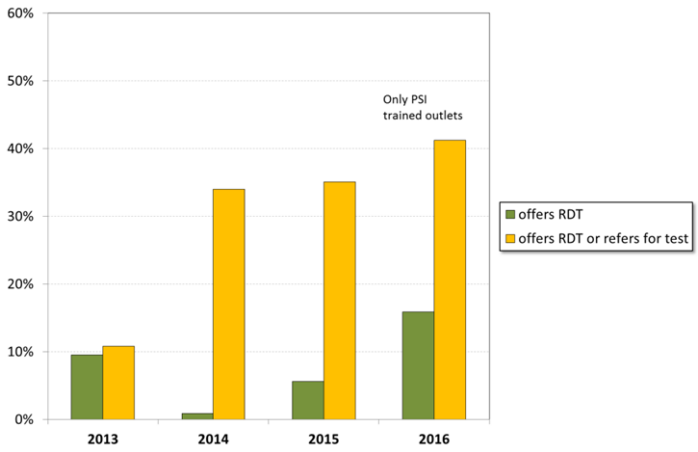
Figure 8: Monthly output of RDT tests over the project period in comparison to QA-ACT sales (Source: PSI routine data)



As the number of trainings increased, the use of RDTs slowly picked up in these areas (Figure 16, Annex 3) and by October 2016, the monthly RDT output had reached 40,000 – approximately the same amount as the monthly QA-ACT output. By that time, the cumulative number of RDTs distributed was 311,000, which is slightly more than the 250,000 that were originally anticipated for Year 2 of the project. By project end, the total might reach 500-550,000, or 46% of the planned total of 1.2 million, based on the project proposal and business case.

As was to be expected from the results of the RDT pilot, the quality of RDT use was very good among the private sector providers with 90-95% of them being able to consistently demonstrate the five key steps of test performance in the mystery client surveys (output indicators 3.2).

Figure 9: Private sector provider use or recommendation for a malaria RDT from mystery client surveys



However, despite the intensive training and RDT distribution roll-out of the AMTR project, actual testing rates increased very slowly. By 2015, the proportion of providers that at least offered an RDT or referred the client to an outlet where a test could be done had increased to 30-40%, but actual testing remained at 5-10% and 15% for those outlets already trained and supplied by the project. The corresponding indicator in the logframe (output indicator 3.1) for 2016 was estimated at 11% compared to a target that had already been adjusted to 30%. Use of RDTs proved to be particularly difficult in general shops, which rarely have the time necessary for testing given that this is only a very small part of their business.

7.4.1.4. What influence did the BCC and promotional activities of AMTR have?

The evaluation of the question of impact of behavioural change communication (BCC) and promotion needs to be divided into effects on the consumer or fever patient and the health care providers.

The first question regarding consumers is whether they have an increased understanding that fevers should be tested for malaria. This aspect is captured by outcome indicator 2.1 and, while for 2015 the target of 50% was indeed reached, the results for 2016 fell short of the 70% target with only a slight increase to 36%. This is most likely an effect of the decreasing malaria incidence and awareness that there is increasingly less malaria in the communities.

As shown in Figure 10, the proportion of consumer respondents from the household surveys exposed to BCC messages regarding the Padonma quality associated with testing and QA-ACT treatment for malaria increased over time, reaching a high of 46% in 2015 and, associated with this, the number of respondents with knowledge of a place where testing can be done increased to 34% in 2015. However, this logframe indicator (output indicator 2.2) also decreased again in 2016 to 28% with a target of 50%. Nonetheless, there was good evidence that BCC in principle was effective in increasing awareness. When the question of knowing a place for a malaria testing was disaggregated by those that had been exposed to the “Padonma” messages and compared to those without exposure, there was a clear and statistically significant impact in 2014 and 2015 (Figure 11). However, this did not translate into a difference in actual use of RDT in cases of fever.

Figure 10: Consumer exposure to QA-ACT related messages (Padonma seal of quality) and RDT awareness from household surveys

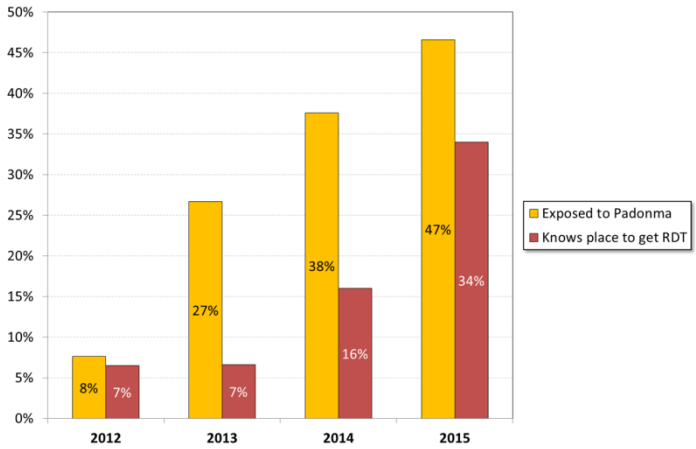
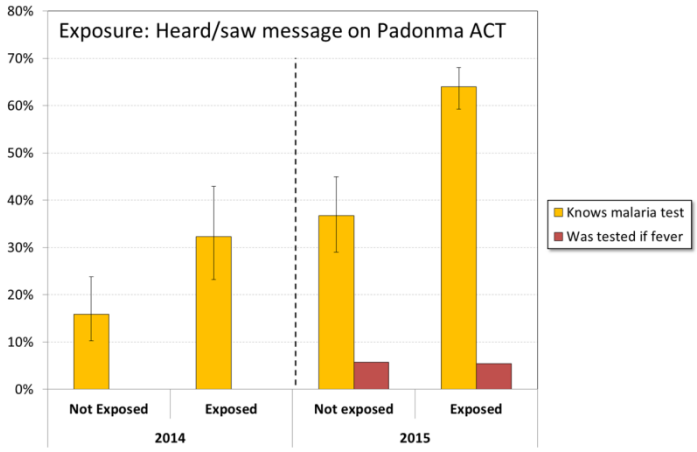


Figure 11: Impact of BCC on consumer knowledge about testing and use of RDTs from household surveys



The effect of BCC and promotional activities by AMTR field staff can, on the one hand, be judged from the comparison between intervention and comparison areas up to 2016, when the promotional activities were extended into 46 townships in the former comparison area. For all years, the difference in QA-ACT availability and reduction of oAMT was significantly better in intervention vs. comparison areas (Figure 4) which can at least be assumed to be associated with the promotional activities, even though the data does not permit the conclusion of a direct cause and effect. Provider awareness of the most adequate treatment for *falciparum* malaria is captured in logframe outcome indicator 1.4 and showed some improvement, increasing from 25% in 2015 to 47% in 2016, but in both cases remained below the target of 50% and 60% respectively.

Household survey data of the AMTR project does not allow disaggregation by gender as only one respondent per household was interviewed. However, all household surveys included the standard wealth quintiles developed from the household assets using a principle component analysis approach. This data suggests that there was no major gradient by wealth quintile of access to treatment, the markets or diagnostic tests.

7.4.2. Level 2: Impact on artemisinin resistance

7.4.2.1. Recent developments in the understanding of artemisinin resistance

In order to discuss the potential influence of the AMTR project on the artemisinin resistance of *Plasmodium falciparum* parasites, it is necessary to briefly review the significant changes that occurred in the understanding of artemisinin resistance since the start of the project.

1. A new test and indicator was introduced which can capture artemisinin resistance even when an ACT is given. This is the parasite clearance curve and half-life, i.e. the time until 50% of parasites are cleared [White NJ. The parasite clearance curve. Malar J, 2011; 10:278,Flegg JA, Guerin PJ, White NJ, Stepniewska K. Standardizing the measurement of parasite clearance in falciparum malaria: the parasite clearance estimator. Malar J. 2011;10:339.]. If it is increased beyond five hours, an artemisinin-resistant strain can be suspected.
2. In 2015, a major breakthrough was achieved with the detection of a genetic marker associated with artemisinin resistance, K13-kelch, [Ariey F, Witkowski B, Amaratunga C, Beghain J, Langlois AC, Khim N, et al. A molecular marker of artemisinin-resistant Plasmodium falciparum malaria. Nature. 2014;505:50–55] which enables malaria mapping of resistance markers in the Greater Mekong Sub-region.
3. A study published in 2015 dramatically changed the perception that artemisinin resistance can only spread continuously. The authors looked at these resistance markers from Myanmar, Laos, Bangladesh, Vietnam and Cambodia and compared these to the reported parasite clearance half-lives following artemisinin treatment [Takala-Harrison S, Jacob CG, Arze C, Cummings MP, Silva JC, Dondorp AM, et al. Independent emergence of artemisinin resistance mutations among Plasmodium falciparum in Southeast Asia. J Infect Dis. 2015;211:670–9.]. The results strongly suggested that artemisinin resistance can appear independently, i.e. “pop up” anywhere in the region from spontaneous mutations.

From the most recent literature and reports, the current situation of artemisinin resistance in Myanmar can be summarised as follows:

- Mutations associated with artemisinin resistance (K13-kelch) are prevalent in all parts of Myanmar, including the western borders with Bangladesh, and different mutations are dominant in the various parts of the country [Tun KM, Imwong M, Lwin KM, Win AA, Hlaing TM, Hlaing T, et al. Spread of artemisinin-resistant Plasmodium falciparum in Myanmar: a cross-sectional survey of the K13 molecular marker. Lancet Infect Dis. 2015;15:415–21]. There is a clearly increasing trend over time in resistance associated mutations [Wang Z, Shrestha S, Li X, Miao J, Yuan L, Cabrera M, et al. Prevalence of K13-propeller polymorphisms in Plasmodium falciparum from China–Myanmar border in 2007–2012. Malar J. 2015;14:168,Win AA, Imwong M, Kyaw MP, Woodrow CJ, Chotinavich K, Hanboonkunupakarn B et al. K13 mutations and *pmfdr1* copy number variation in *Plasmodium falciparum* malaria in Myanmar. Malar J, 2016; 15:110].
- Treatment efficacy of ACTs was initially high [Smithuis F, Kyaw MK, Phe O, Win T, Aung PP, Oo APP et al. Effectiveness of five artemisinin combination regimens with or without primaquine in uncomplicated falciparum malaria: an open-label randomized trial. The Lancet, 2010; 10:673-681] and they remain effective to date in spite of the observed increase in resistance markers [Kyaw MP, Nyunt MH, Chit K, Aye MM, Aye KH, Aye MM, et al. Reduced susceptibility of Plasmodium falciparum to artesunate in southern Myanmar. PLoS One. 2013;8:e57689.]. However, an increasing trend in clearance time has been found recently in upper Myanmar, suggesting that actual treatment failures may be immanent [Tun KM, Jeeyapant A, Imwong M, Thein M, Aung SSM, Hlaing TM et al. Parasite clearance rates in Upper Myanmar indicate a distinctive artemisinin phenotype: e therapeutic efficacy study. Malar J, 2016; 15:185].

7.4.2.2. Has the pool of potentially resistant *plasmodium falciparum* strains been reduced?

There certainly has been a reduction in the pool of malaria parasites and, with it, resistant strains purely by the reduction of transmission. However, no information is available to date to show whether

the share of resistant parasites is increasing within the shrinking parasite pool or not. This is possible if the resistant parasites have a survival advantage.

7.4.2.3. Has the spread of resistance to other areas been prevented?

The answer to the question of whether the spread of resistance to other areas has been prevented is both yes and no. On one hand, the genetic markers for artemisinin resistance of malaria parasites have been screened in a good number of areas in Africa South of the Sahara as well as on the Indian sub-continent, and no mutations associated with resistance in the GMS have so far been detected. This means that resistance has not spread outside of the GMS. However, the evidence cited above also shows that resistance markers continue to spread within the region.

7.4.2.4. What was the contribution of the AMTR project?

This evaluation has highlighted that the proportion of adequately treated *falciparum* malaria cases that are seen by private sector providers has increased since before the start of the project. This certainly can be seen as a contribution towards resistance containment, even if this was not as high as had been hoped for, and there were 40% of true malaria cases still remaining that were highly inadequately treated with a potential to worsen resistance (reduced from 60% at the start). However, with the available evidence it is not possible to identify whether this contribution was in fact significant to overall resistance development in Myanmar or the GMS.

7.4.3. Level 3: Long-term perspective beyond AMTR

7.4.3.1. What is the anticipated development of malaria treatments in the private sector?

The question of what can be anticipated for the private sector health care providers and the markets of malaria related commodities is assessed and discussed in detail in the final working paper 5 (see Annex 3). Therefore, only a brief summary is given here.

7.4.3.2. Results from the evaluation

7.4.3.3.

As malaria transmission and incidence decrease further, two developments can be foreseen that will impact health care providers and commodity markets. First, the proportion of positive results among all tested for malaria will decrease further while the number tested will have to increase. For the private sector this implies that, on the one hand, demand for RDT will increase and demand for anti-malarials and particularly ACT will decrease. On the other hand, the spatial density of malaria cases will become so low in many areas that not all outlets currently stocking ACT will be able to do so because there simply is not enough demand. A reduction in the number of outlets stocking anti-malarials is already visible in the last two outlet surveys of the AMTR project (and ACTWatch). Because testing rates will need to be increased at the same time, this also means that diagnosis and treatment availability will be unlinked, i.e. all outlets that sell ACT will or should also have RDT available, but not every outlet with RDT can be expected to also carry anti-malarials. This will result in shifts in the contribution of specific types of private sector outlets to malaria case management as general retail outlets are less inclined to take up testing if they cannot at the same time sell medicines.

Second, the decline in malaria incidence and positive test results will result in a changed perception of the urgency of the disease among health care providers as well as patients. This could be detrimental to the promotion of testing and may require a rethinking of the way testing is encouraged. It will also make it less likely that fevers not tested for malaria will receive anti-malarials, which is positive for the value for money aspect as less QA-ACT is spent on non-malaria cases, but negative for

adequate treatment of true malaria cases if testing rates remain low. Again, this is a trend already visible in the data from the AMTR project (see Figure 6).

Finally, future developments in the markets for anti-malarials can be anticipated in the absence of the current subsidy for quality-assured ACT. Currently there is some evidence of leakage from the public sector but it has very little impact due to the existing subsidy and the fact that distributors of full price ACT have been crowded out. If the ACT subsidy is no longer available, leakage will increase and the influx of illegal AMT will also increase, unless the public sector can implement more successful measures against these trends than they do at the moment.

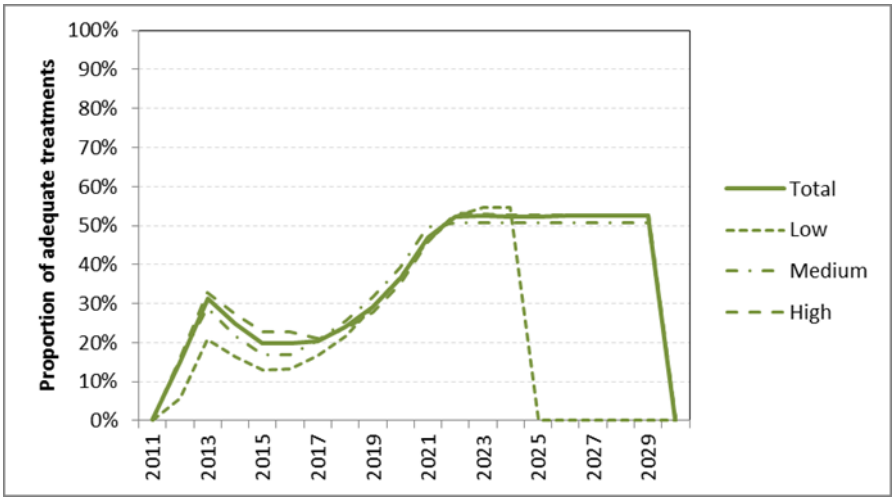
7.4.3.4. Results from modelling

The major findings from the modelling[6] suggest that:

- without changing consumer behaviour and decreasing the proportion of suspicious fevers not seeking any care, and hence avoiding diagnosis and treatment, malaria elimination and resistance containment will be difficult;
- without intervention in the private sector, resistance containment and malaria elimination will not be possible as long as people seek treatment through the private sector;
- given optimal consumer and provider behaviour in the private sector, increasing testing to 50% in pharmacies and drug shops and 70% in private clinics adequate treatment of cases of *Plasmodium falciparum* can reach 50% (Figure 12) and with increases of testing to 70% and 90% respectively can reach up to 65%;
- with decreasing malaria incidence, the demand for QA-ACT will increasingly go to false positive cases if testing is high and this can only be reduced if the effective testing specificity is increased to above 99.5%;
- density of QA-ACT need may decrease to as low as 12 treatments per 10,000 of the population per year in the low endemicity areas, and 35 in the high endemicity stratum. In contrast, RDT demand will be five times higher than that for QA-ACT, reaching 1 million per year even under the moderate testing scenario of 30/50% for drug shops and private facilities;
- under the assumption that QA-ACT cannot be maintained without a price subsidy or some other kind of market intervention, an increase in testing has no effect on the proportion of adequately treated malaria cases in the absence of such a subsidy.

[6] Details of the modelling approach can be found in the annex of Working Paper 5: The potential role of the private sector in Myanmar in efforts towards containment of Plasmodium falciparum artemisinin resistance and malaria elimination

Figure 12: Model output for increases in adequate treatment of true *P.f.* cases in the private sector under optimal consumer and provider behaviour and increase of testing rates to 50-70%. Results are shown by the three levels of endemicity in the country.



7.5. Value for Money Report

7.5.1. Risk assessment changes over project life

The business case noted that "this project is high risk and therefore, even though it is only a three year project, several milestone reviews are programmed, including a mid-term review at 18 months. This gives the opportunity to review progress and make programmatic changes as necessary."[7]

Early on in the independent external evaluation of AMTR, it became evident that risks associated with procurement and sales volumes were serious and that the financial losses due to expired drugs were substantial. To understand when and how the project understood these and other risks, and any mitigating actions taken, we reviewed AMTR risk assessment documents.

No consistent risk assessment document was used for each revision. Each document appears to stand alone. The language describing the risks varies across documents. To assist the reader, where possible this review has grouped similar risks in the same rows for different years.

High level findings from the risk assessment review include:

a. A single consistent risk assessment matrix with annual updates and resolution of prior issues does not appear to have been used in the AMTR. The implications of this finding may include:
   i. a lack of risk and resolution tracking over time;
   ii. an indication that risk assessments in AMTR were not used to guide project operations consistently;
   iii. the actions to mitigate risk are not possible to track or verify;
   iv. valuable learning for AMTR and for future projects is not captured in any systematic way.
b. The governance environment has contributed to difficult private sector operations which has delayed, raised costs, and hindered efficient AMTR operations.
c. The most significant operational risk of AMTR – expired QA-ACTs – was not anticipated in the Business Case; the 2013 risk assessment stated the opposite procurement risk to that which occurred (inability to meet demand rather than dramatically decreased demand).
d. Though the risk of significant value loss due to expired drugs was identified in the VFM review of March 2014 using data available to the project in the last two quarter of 2013, it was not until November 2014 that the risk was identified and included in a risk management plan.
e. In late November 2014, the risk of expired drugs (and value losses) was recognised as medium risk, even though more than USD 925,000 had already been lost through expiry by that date.

Project risks were identified in the Business Case in 2011, and revised and updated by PSI in 2013, 2014, and 2016. Table 1 summarises changes to the risk matrix.

Table 1: Risk assessments and change during AMTR project

	Business Case Risk Summary 2011	2013 Revision	2014 Revision (draft)	2016 revision
1	A restrictive operating environment	ACT registration issues with FDA	Restrictive operating environment	Updated to reflect current conditions
			Commodity registration and endorsement by FDA	

[7] Ibid, pg. 2

	Business Case Risk Summary 2011	2013 Revision	2014 Revision (draft)	2016 revision
2	Market issues and the potential for inappropriate sales in the private sector	Market Competition	Competition risk	
3	Negative environmental conditions		Negative environmental conditions	Updated to reflect current conditions
4	NGOs that are operating on single year MOU agreements	MOU Status		
5	Exchange rate fluctuation		Exchange rate fluctuation	Updated to reflect current conditions
6	Funding shortfalls			
7	Breach of EU rules on aid to Myanmar		Breach of EU rules on aid to Myanmar.	
		Research results acceptance for policy dialogue (baseline)	Research results acceptance for policy dialogue	
8		Decentralisation	Government re-structuring and decentralisation of authority to lower levels	Government re-structuring and decentralisation of authority to lower levels
9		• Bureaucracy	• Importation duty for Drugs	• Importation duty for Drugs
		• Sales Tax	• Sale Tax for AMTR drugs	•
		Packaging License Requirements		
10		Product Sales to border Groups	Products not reach to targeted (border group)	Products not reach to targeted (border group)
11			Continued import/sales of oral AMT in the market	Continued import/sales of oral AMT in the market
12		Resistance to RDT deployment in Phase 2	Uncertainty of RDT scale up	Uncertainty of sustainable RDT scale up in private sector
13		Project sustainability	Sustainability of the project and funding gap	Sustainability of the project
		Global ACT Price Fluctuation		
14				Independent emergence of resistance parasite in multiple places of GMS including India Myanmar border
15		Procurement and high demand	Commodity Management (Risk of expiring drugs Vs Stock out)	Commodity Management (Risk of expiring drugs vs Stock out)
			Budget forecasting (linked to commodity supply)	
16				Increasing risk of antibiotic resistance
17		Non-AA related drug leakage to military (retail)	Drug leakage to military through retailers	Drug leakage to military through distributors

	Business Case Risk Summary 2011	2013 Revision	2014 Revision (draft)	2016 revision
		Drug Leakage to Military (AA)	Drug leakage to military through distributors	
18				Reduced efficacy of AL
19			Fraud/misuse of Promo materials by distributors	Fraud/misuse of Promo materials by distributors
20				Fraud/misuse of incentives by field staff and providers
			Bulk selling of AMTR drugs to other already-funded INGO/NGOs	
			Adopting the quality (Padonma) seal for QA-ACT by all partners and its sustainability	
			Theory of Change Model not improved	

Sources: Business Case Risk assessment, 2011; Risk Assessment March 2013; Risk Assessment November 2014; Risk Matrix for AMTR 2016

While it may not be possible to fully understand the factors that led to ACT oversupply, falling demand and lost value from expired drug losses, some factors stand out:

a. The business case project design used seriously flawed demand projections for commodities.
b. Rigorous analysis in the business case was undermined by inaccurate secondary data on malaria prevalence, primarily drawn from MARC documents prior to 2010. Headline statements in the business case make the point that "Burma has the greatest burden of malaria in Southeast Asia with around 35 million people at risk and an estimated 870,000 - 8.5 million (midpoint 4.2 million) malaria cases in the country in 2006 (the wide range in the estimate reflects the paucity of data in the country)."[8]
c. The acknowledged data gap on prevalence was not identified or operationalised as a risk factor. The statement was accepted as fact, and the statement likely drove project approval and project implementation.
d. The selection of PSI was presupposed in the business case for a number or reasons:
    i. The project's "approach to replace monotherapy in the private sector has been designed by Population Services International (PSI)…"[9]
    ii. PSI's operational strengths in Myanmar were identified in the business case: "PSI is the only NGO in Myanmar which works in health at scale with the private sector. PSI support over 1,200 franchised clinics with private sector doctors, with supporting community health workers; and national social marketing…"[10]
    iii. PSI's comparative advantage was significant, reducing competition and eliminating contrarian project narratives that might have increased risk awareness.
    iv. The business case promotes the excellence of PSI's procurement structures stating that, "PSI has procured more products worldwide than any other private entity engaged in social marketing."[11]

In this instance, DFID's business case model did not fully serve the needs for rigorous partner selection and consequently led to the support of a potentially valuable project without sufficient due diligence, or competition. Certainly, this is easier to say in hindsight than at the time of programming when there

[8] Business Case 2011 p. 5
[9] Business Case 2011 p. 33
[10] Business Case p. 34
[11] Business Case p. 34

was a seeming urgency to slow the spread of resistant malaria. With that caveat, it is still appropriate to consider that the value for money of AMTR was compromised by the close relationship between DFID and PSI in the business case and project award stage, which undermined a rigorous assessment of the actual demand data, and as a consequence unknowingly increased project risk.

Procurement risks were not anticipated by the project, and resultant commodity and value losses totalled over USD 2,500,000[12]. Quantified losses and the implication of such losses are detailed in the following financial profile.

7.5.2. Financial profile

From the first VFM analyses, the independent external evaluation has requested specific activity-based financial data. The evaluation team has identified that the financial framework used by the project does not report financial data in formats that are easily aligned to project processes and outputs or outcomes. Evidently, with DFID agreement at inception, project managers primarily track and report expenditure-to-budget status at a high-level disaggregated by objectives. By combining activity coding into objectives 1-5 (detailed in table 2), it is not fully possible to track expenditures to specific activities. In this project, which has seen a number of significant changes in focus and activity, it would have been useful if financial data provided by PSI were more closely coded to project logframe and work plan activity.

With the above caveat, financial tracking within the project is robust in the finance office. For operational management, there may be less financial data granularity that would be useful to actively manage project implementation. Table 2 defines each programme objective for the purposes of budget aggregation. No budget for objective 4 was set for 2016; a surprising planning omission.

Of note are the changes to the objective definitions. These changes reflect the shift in programme priorities over time. Where changes in the objectives have been made, the original is delineated by an "a" and the change "b", and both the original test and the change are italicised.

Table 2: Project objective descriptions used in financial disaggregation.

	Description of expenses*
Objective 1a	Increased opportunity, ability and motivation of private sector providers to effectively *prescribe and dispense nationally approved, quality assured ACT*
Objective 1b	Increased opportunity, ability, and motivation of private providers to effectively *test for and appropriately treat Pf malaria*
Objective 2a	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*
Objective 2b	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*
Objective 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
Objective 4	Objective 4 (PM) is related with programme management such as Int'l staff salary, Int'l travel, allowances, local support staff salary, consultant, distributor events, ACT Watch

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	outlet survey, Mystery Client survey, Household survey, offices rental, other direct costs (communication, office supplies, utilities, postage, bank charges), programme related meeting/conference.

Source: Descriptions provided by PSI

AMTR financial data are provided by year, disaggregated by objective. The macro-level disaggregation of expenditure by objective does not facilitate cost efficiency analysis by activity or output. Alignment of budget and expenditure data to relevant outputs is made cumbersome, and sometimes impossible, by this data aggregation. This limitation has been communicated to PSI, and it remains a limitation in this analysis.

Table 3: Percent of total expenditure by objective

PROGRAMME YR.	2013	2014	2015	2016
OBJECTIVE 1	28%	13%	22%	20%
OBJECTIVE 2	20%	69%	15%	25%
OBJECTIVE 3		5%	9%	5%
OBJECTIVE 4	52%	13%	54%	51%
TOTAL	100%	100%	100%	100%

Source: PSI financial data provided February 2017

The striking details of the financial profile are the very high expenditures in year 2 for objective 2, which reflects substantial procurement of QA-ACTs – half the value of which was subsequently lost.

The lack of regular financial reporting that is directly linked to programme outputs (and outcomes) increases the difficulty of cost efficient and cost effectiveness analysis.

Table 5 profiles the percentage of annual budget expended by objective. The drop in objective 3 expenditure in year 3 is related to the programme's change in focus toward testing and targeted treatment, as well as the fact that existing supplies of commodities were sufficient for programming in that year.

Table 4: Percentage expenditure by objective

Objective	Year 1	Year 2	Year 3	Year 4
1	1.15	1.10	1.00	0.89
2	1.14	1.13	1.01	1.11
3	NA	1.20	0.52	0.92
4	1.14	1.05	1.00	NA[13]
Total Direct Costs	1,035,915	5,511,963	2,216,091	2,531,646
Total Indirect Costs	72,514	385,837	155,126	177,215
Total	1,108,429	5,897,801	2,371,218	2,708,862

Source: PSI Financial Report: AMTR through September 2016

7.5.3. Results analysis from VFM perspective

Results have been presented in detail in section 6 above and are here summarised only within the scope of the VFM analysis. Key outcome and output results vs. targets are summarised in Table 6.

[13] No budget was established. The External Review asked for clarification from AMTR who said they would follow up with PSI HQ. No update has been received.

Readers should be aware that results are analysed as the percentage of target achieved (i.e. actual result as percentage of the target value). Thus, if an indicator is the % of population exhibiting a certain behaviour, the analysis shown is the % of the target achieved by the project, not the actual % of the population in the indicator.

There are some differences between the data reported in the logframe and reports made to donors in the 2016 review, "Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2015 – September 2016", which may reflect some lag in data updating. We use the logframe data as our default results source. The results also show that in some cases the achievements consistently exceed the target (values above 100%) suggesting that the targets were selected very conservatively and might have been adjusted in the course of the project.

Table 5: Programme results vs. targets analysis

	Indicator	2013	2014	2015	2016	VFM Notes
Outcome 1	% target population with fever in the last two weeks who received a diagnostic test for malaria…			37.3%	18.6%	Concern is expressed at the lack of traction gained by RDT testing in year 1 of the revised programme. Decrease may be related to programme expansion and incomplete RDT coverage or need to incentivise use of RDT to compensate for potential loss of retailer profit, as noted in 2016 AMTR review.
Outcome 2	% target population with fever in the last two weeks who received a negative diagnostic test result did not receive any antimalaria treatment			46.6%	29.6%	See above and section 6.1.2
Outcome 3	Estimated number of P.f malaria cases with QAACT through DFID funding					No target set. 2015 results: 21,960; 2016 results: 11,098. Reflects lower malaria incidence.
Output[a] 1.1	% target outlets with nationally approved and quality assured first-line ACT in stock at time of survey	100%	105.3%	72.4%	52.7%	2013-14 results affirm efficiency of market flooding activity; declines in 2015 and 2016 may reflect commercial sensitivity to greatly reduced demand.
Output[a] 1.2	% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months	32.7%	100.7%	84.8%	95.6%	Expected, considering initial heavy distribution and limited demand
Output[a] 1.3	% target outlets selling nationally approved, quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline	129.8%	113.3%	114.7%	112.5%	The ACT subsidy works and sticks.
Output[a] 1.4	% target outlet providers that mentioned QAACT as the most effective treatment for uncomplicated malaria	86.4%	184.0%	49.4%	77.6%	
Output[b] 1.5	Ratio of ACT to OMT sold in past seven days	.73 vs. .27	.79 vs .21	.68 vs. .32	.81 vs .19	Across years, the majority of consumers and retailers prefer QAACTs. It is unclear if there is a resurgence of OMTs; reducing the final quarter of OM in the market proves difficult.
Output 1.6	% target outlets with RDTs in stock at time of survey			89.3%	121.6%	Coverage approaching and above targets shows successful early RDT roll out to retail outlets
Output 2.1[c]	% of target population who know that a person with fever should receive a diagnostic test for malaria			100.4%	51.9%	Lesser results (50.2% in 2015 and 36.3% in 2016 are reported in the 2016 Annual report to donors noted below
Output 2.2	% of target population who can identify an outlet who can perform a malaria RDT			136%	56.6%	Lesser success vs. targets as beneficiary spread expands.
Output 3.1	% of outlet providers who offer/carry out RDT testing			37.3%	36%	Retail outlets show RDT reluctance vs. targets. Is this due to profit loss when no treatment offered upon negative tests?
Output 3.2	% 'priority' outlet providers that correctly describe and demonstrate the 5 key steps in			320.6%	159.7%	Medical detailing is effective

	Indicator	2013	2014	2015	2016	VFM Notes
	the process of conducting and interpreting a rapid diagnostic test for malaria					
Output 3.3	% of outlet providers who did not provide any AM treatment if the test result showed negative			320.6%	159.7%	Medical detailing is effective.

Sources: Updated AMTR Logframe Indicators_2016_final for VFM; Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2015 – September 2016 Annual Review

[a] Data and narrative in the 2016 review Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2015 – September 2016 (p.7) highlights differences in outlet measurement in 2016 from prior surveys.
[b] Indicator data does not include 27% OMT availability in in 2016 in the project expansion area data and narrative in the 2016 review Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2015 – September 2016 (p.9)
[c] Lesser results for this indicator are noted in the 2016 review Artemisinin Monotherapy Replacement in the Private Sector in Myanmar: October 2015 – September 2016 (p.11)

7.5.4. Procurement analysis

Commodity procurement and distribution is the highest risk primary cost-driver of AMTR. Table 7 tracks the expiry volume and value of QA-ACTS and RDTs across the period 2014-2016. The total value of all commodities procured through April 2016 is USD 5,423,456. The total value lost through expired drugs is USD 2,506,186 or 46.2% of all expenditures for commodities.

Table 6: Expired QA-ACTs by volume, value, and date

Artemether+Lumefantrine (20mg/120mg) (6's Blister)	16,853	0.465	7,837	14-Apr
Artemether+Lumefantrine (20mg/120mg) (12's Blister)	21,634	0.900	19,471	14-Apr
Artemether+Lumefantrine (20mg/120mg) (18's Blister)	46,037	1.324	60,953	14-Mar
Artemether+Lumefantrine (20mg/120mg) (24's Blister)	505,760	1.673	846,136	14-Mar
Artemether+Lumefantrine (20mg/120mg) (6's Blister)	32,724	0.453	14,824	15-Feb
Artemether+Lumefantrine (20mg/120mg) (12's Blister)	35,086	0.875	30,700	15-Feb
Artemether+Lumefantrine (20mg/120mg) (18's Blister)	85,492	0.875	74,806	15-Jan
Artemether+Lumefantrine (20mg/120mg) (24's Blister)	698,870	1.627	1,137,061	15-Feb
Malaria RDT Combo Test, Pf and Pan	684,007	0.41	280,443	14-Dec
				15-Jan
Artemether+Lumefantrine (20mg/120mg) (6's Blister)	6,943	0.453	3,145	Jun-16
				Sep-16
Artemether+Lumefantrine (20mg/120mg) (12's Blister)	6,648	0.875	5,817	Jun-16
				Sep-16
Artemether+Lumefantrine (20mg/120mg) (18's Blister)	8,327	1.287	10,717	Jun-16
				Sep-16
Artemether+Lumefantrine (20mg/120mg) (24's Blister)	1,319	1.627	2,146	Jun-16
				Sep-16
Malaria RDT Combo Test, Pf and Pan	29,585	0.41	12,130	16-Mar
Total Value Loss			**2,506,186**	

Source: PSI procurement reports 2012,2013, 2014,2015,2016

[+]Unit-cost data provided by PSI includes shipping to FOB, packaging, and drug.

Miscalculation of expected demand for QA-ACTs throughout the project life (early oversupply and current undersupply) have caused significant value losses. Recently predicted stock-outs[14] may now jeopardise ACT and RDT availability and provider confidence in the supply chain.

[14] AMTR annual Review, 2016

How did such a substantial miscalculation of commodity need occur, and what were the factors that caused repeated miscalculation throughout project life?

Several factors contributed to the loss:

1. The business case noted incomplete data to assess *P.f.* malaria prevalence, prevalence trends over time and treatment demand and practice, so assumptions had to be made about these factors in order to ensure timely delivery of the project, given the urgency of start-up.[15]
2. The business case noted the experience of PSI as a skilled procurement management entity, and the only entity of its type with approval to operate widely in Myanmar. There is little evidence that the procurement assumptions or plans were subject to any due diligence internally or by DFID in business case approval.
3. Multiple risk assessment matrices have been created by PSI. No procurement risk was mentioned in the first risk assessment (2011). The second risk assessment noted the potential for high treatment demand and inability to meet demand (2013). The third (2014) and fourth (2016) risk assessments noted the risk of oversupply and expired drugs. Mitigation measures were noted as close monitoring of the supply chain. There is no follow-up on potential commodity risks in reports we have been able to access.
4. An external supply chain analysis commissioned by PSI noted that the supply chain required an average of 44 weeks from order to receipt of commodity "Free on Board" (FOB). Operating in a dynamic environment of uncertain demand, a lengthy supply chain creates inflexibility in which commodity loss is inevitable if demand is lower than expected.
5. During the project planning phase, it appears that PSI and DFID both assumed that PSI's internal procurement expertise was the most cost-efficient mechanism for procurement of QA-ACTs. Factors including PSI experience, quality assurance, MOH approval, packaging and branding, lower unit costs and PSI margins on procured products may all have influenced the procurement decision.
    a. The decision to procure through PSI's global structures increased risk of loss by shifting risk toward PSI (and DFID). PSI was "doing it all", from planning, demand estimation and distribution to marketing and monitoring provider sales and treatment.
    b. In hindsight, it is easy to see that there were wholesalers in Bangkok who could have provided QA-ACTs in smaller volumes, much closer to on-demand. Had PSI prequalified more than one regional wholesaler, the project would have been able to maintain supplier competition, dramatically reduce the procurement time-lag enabling closer-to just-in-time procurement, and reduce risk of commodity loss.
    c. While this step would have decreased risk, it is noted that proprietary packaging and branding that PSI considered essential to user acceptance would have been less likely.

7.6. Cross cutting issues

7.6.1. Wealth

The primary intervention of the AMTR project addresses the private sector and specifically the market for anti-malarials. It is in the nature of market operations that they do not easily allow disaggregation by wealth nor does it make much sense. QA-Act is sold by PSI to the distributor who feeds the product into the supply chain. There is no record of which consumer ends up buying the medicine. Similarly, the outlet surveys of the AMTR project – while being state of the art – do not collect data on wealth and one can only assume that certain outlets such as mobile agents or general stores are more frequently visited by poorer people. Wealth quintiles were only available for the household surveys

[15] Business Case p. 5

and here the low incidence of malaria fever did not allow an assessment of malaria treatment access by wealth. However, there is little evidence that wealth was a significant factor in the project outcome as the subsidy was calculated to be lower than the average cost of a partial dose of oAMT. The evidence suggests that the subsidy was, indeed, passed on to the consumer and the price was well in the reach of even the lowest wealth quintile.

7.6.2. Gender

Though Myanmar is recognised by the Committee on the Elimination of Discrimination Against Women as a country in which "women enjoy social, political, economic, and judicial equality with men", it is also acknowledged that there are longstanding cultural and social norms promoting beliefs that men are innately superior to women. It is very likely that specific gender roles also affect the purchase of malaria medicines. However, as explained above there is no record in the sales data of the gender of the ultimate purchaser or even the person treated with the medicine. Household survey data also have only very limited data on gender and does not suggest a specific disadvantage of women in access to diagnosis and treatment. In contrast, some epidemiological data suggests the with declining malaria incidence and a shift in vector populations the risk of malaria is now higher in young men who seek work on rubber plantations or in mines, where they have to work outside during the night.

7.6.3. Age

In contrast to wealth and gender some information on age pattern can be obtained from the sales records as data is disaggregated by age specific packages. This shows that over the implementation period of the AMTR project the relative sales of adult packages has continuously increased from initially around 70% to above 90% at the end of the project (see also Figure 14, Annex 6). This age shift is in line with the observation that transmission of malaria in Myanmar no longer occurs in the communities where all ages would be affected, but rather as an occupational health of male and to some extent female workers that work during the night in areas with on-going transmission (rubber plantations, forest workers, minors, security guards etc.).

8. INTERPRETATION AND CONCLUSIONS

8.1. Interpreting the results of the evaluation

Considering the results presented above the following major inferences can be drawn:

It can be said that the AMTR project did successfully replace oAMT through the formal distribution channels with QA-ACT, which was made affordable to end users through a subsidised price. However, there is evidence that some oAMT returned – mainly through informal channels outside of the project's influence. At the same time, there was an overall decline in QA-ACT due to the changing malaria epidemiology. One concern that can be raised is that of sustainability of the social marketing approach under the assumption that some kind of subsidy or market support for QA-ACT will be needed in the future (see section 6.3). An approach that delivers a subsidy directly to distributors and avoids brand ownership by the social marketing organisation could possibly have included more distributors, and hence larger coverage, and would be more sustainable in the future. However, at this point this is merely a suggestion and there is no hard evidence that results would be better.

The evidence suggests that correct treatment of fever cases was quite favourable for those testing negative and those not tested, in part due to the declining malaria incidence and increasing awareness

among providers that fevers are much less likely to be malaria. However, for correct treatment of true positive cases the outcome showed only moderate improvement and the proportion of cases treated in such a way that resistance spread could be encouraged was still high at 40%. This was mostly a function of low testing rates in the face of declining malaria incidence.

There were significant delays in RDT implementation and roll-out which were due to external factors but resulted essentially in testing rates too low to significantly improve the major intended outcome of increased adequate treatment of *Plasmodium falciparum* cases seen in the private sector. Further increases seem possible in the future with a focus on those outlets that are best suited for testing, but the issue of cost, or rather no-cost, to the consumer will have to be addressed creatively if RDTs are to be channelled through normal private sector supply chains which in turn will be essential for sustainability.

There is evidence of success in consumer as well as provider awareness and knowledge. However, overall this was less than was hoped for and below the targets set in the logframe. The challenge here seems to be that the types of messages that are most adequate in a situation of rapidly decreasing malaria incidence can no longer focus on malaria as a danger (i.e. test your fever because it may be malaria) but rather must acknowledge the increasingly rare character of the disease whilst emphasising that excluding malaria is essential for both individual health and the benefit of the entire society.

The evaluation team did not find evidence of unintended effects of the AMTR project.

8.1.1. VFM summary

Overall, the programme has had success in progressing toward goals set out in the Business Case, specifically, "of replacing artemisinin monotherapy with quality assured QA-ACTs in the private sector where the majority of people currently seek malaria treatment."[16] While there is evidence of a resurgence of oAMT in the market, it is also clear that AMTR has bent the market toward QA-ACTs as the preferred treatment as evidenced in outlet surveys and logframe indicator data. See data for outputs 1.2, 1.3, 1.4 and 1.5 showing reduced ACT stock outs, stable pricing, providers recommending QAACTs as a preferred treatment and increasing ratios of QA-ACTs to oAMTs sold.

We summarise an assessment of the VFM factors of economy, efficiency, effectiveness and equity as follows:

VFM-Economy
The VFM assessment defines economy as "…the price at which inputs are purchased…" and include the functions of procurement, risk profiling and mitigation, unit cost analyses, budget tracking and management.

Specifically, nearly half of all procured commodities have been lost due to expiry, a loss totalling over USD 2.5 million.

Project planning and risk mitigation were difficult at the beginning of the project due to lack of information on potential demand and the urgency with which programme start-up was required. However subsequent supply chain management, monitoring the supply chain, and shifting risk away from PSI and DFID by acting on oversupply data with agility to stop losses could have been improved later in the project.

[16] AMTR Business Case, Executive summary, 2011

The project has also shown some agility in adapting implementation strategies to a changing context, though commodity losses are continuing at a smaller scale.

Despite progress toward the overall programme objectives, we do not find that AMTR has promoted positive economy in programme operations.

VFM-Efficiency

The VFM assessment defines efficiency as "how well inputs are converted to the output…". In AMTR, we understand efficiency to include and evidence of planning and programming agility.

The efficiency assessment considers the dynamic operating conditions in Myanmar, governance obstacles that delayed critical MOH approvals, changing demand data and the need to re-focus behaviour change communication.

The assessment also notes the reliance on poor data on malarial incidence in programme design and the relatively slow response to such data due to the lengthy procurement chain, which added to losses. Undue reliance on PSI's experience and procurement strengths gave programme managers a false sense of security in the procurement projection and management in the first two years of programme operations.

Also noted is the need to re-tool early behaviour change communication away from consumers to retail outlets, and the slower than hoped for progress engaging retail outlets as treatment partners providing a consistent message of ACT treatment and testing of all febrile patients.

Multiple logframe changes highlight many programming changes and re-targeting that are part of the AMTR project implementation.

We do not believe that it is useful to make an efficiency assessment now. AMTR has faced considerable obstacles in this project, not all of which are PSI's responsibility, and these obstacles have undermined project efficiency. Nonetheless, AMTR has the potential to have a positive impact in promoting targeted use of testing and appropriate treatment compliance, which will contribute to combating the spread of drug resistant malaria.

We urge a close review of testing data and RDT uptake and compliance as a near-term indicator of whether AMTR can efficiently bend the provider curve toward routine testing and appropriate treatment.

VFM-Effectiveness

The VFM assessment defines effectiveness as "the extent to which programme outputs… are converted into project outcomes and impacts…"[17] and the sustainability of outcomes over time.

AMTR outcome and impact measures have changed during the project (see Annex 4).

AMTR's initial outcomes were related to flooding the treatment market with QA-ACT to drive out oAMT, along with protocols and interventions to promote and monitor sales and treatment. There is evidence of movement toward QA-ACT as the primary treatment, though the persistence of some oAMT in the market and continued preference for oAMT were noted, even in the early stages of market flooding.

[17] VFM guidance Notes, 2011

As prevalence decreased and treatment demand fell, AMTR focused on testing and treatment. Targeted rather than mass treatment became the project focus, supporting testing protocols and patient compliance. The data on consistent provider use of testing and of patient compliance with the results of testing are not encouraging to date (outcomes 1 and 2).

Year 1 of RDT roll out concluded in September 2016. There is not yet sufficient evidence to state that RDT roll-out is effective or that either providers or patients are fully engaged with the testing and treatment modality. Providers may constrain testing to preserve profits from sales of malaria treatment that would be lost by negative tests. Subsidies to promote testing are being considered. At the same time, febrile patients may be resorting to blister split doses of oAMT as a more familiar treatment, encouraged by providers who profit more from blister-cut dosing upon demand.[18]

Generally, there should be concern about the sustainability of interventions that rely upon subsidies to drive providers away from easily obtained alternative remedies. However, in the case of the elimination efforts for malaria these concerns are less relevant.

VFM-Equity

The assessment defines equity as the spread across beneficiary groupings (gender, wealth quintile, and ethnicity, etc.) of the uptake of outputs and the benefits of outcomes and impact. As presented previously (section 6.6) the available data on gender and wealth was limited in part due to the nature of the project being primarily a market intervention and in part to the limited data in this respect presented in the PSI survey reports.

In the context of driving oAMTs from the market and promoting RDTs and compliance, data in AMTR are well defined and granular. Outlet surveys and behaviour change data are comprehensive, regionalised, and detailed to the outlet type (pharmacy, retailer, itinerant vendor, private facility and health worker).

Sales data are disaggregated by state or region, type of QA-ACT and monthly sales. Mystery client data were disaggregated by target vendor type and region.

Based on regional sales data and the spatial distribution of malaria incidence there is no strong evidence of significant pro-rich effects. It is likely that malaria is higher in some parts of the country where there is not only high transmission but also social conflict. But here the insecurity is the driver of poverty and hence the effect cannot directly be associated with wealth. The data from the AMTR project surveys also does not show any significant gradients by wealth, region or gender for access to diagnosis and treatment in the AMTR project.

8.2. DAC evaluation Criteria

Our conclusion with respect to the OECD Development Assistance Committee evaluation criteria is as follows:

8.2.1. Effectiveness

The AMTR project was effective in delivering the subsidy on QA-ACT to consumer and was largely effective in replacing oAMT with QA-ACT even though some oAMT returned but this was beyond the project's control. The project was only marginally effective in increasing the use of RDT for malaria diagnosis in the private sector. This was in part due to delays caused by other stakeholders involved

[18] AMTR Annual Report 2016

in the process, but to some extent also due to the lack of reviewing the Theory of Change on a regular basis.

8.2.2. Efficiency

The AMTR project was overall efficient with the one exception that risk management in the procurement planning was not as it should have been resulting in significant amounts of expired medicines.

8.2.3. Relevance

The AMTR project was highly relevant as it was the only effort to address the markets of ant-malarials at a large and national scale. From the analysis of the Myanmar malaria elimination strategy and confirmed by the modelling by this evaluation it is clear that without private sector involvement and intervention elimination will not be possible.

8.2.4. Impact

The AMTR project subsidy on QA-ACT had a significant impact on shaping the markets for anti-malarials in Myanmar. The impact on correct malaria treatment of potentially resistant *Plasmodium falciparum* cases was evident but not as high as it could have been due to low levels of diagnostic testing and availability and use of other anti-malarials. Some impact on the spread of malaria resistance can be assumed, but there is no direct evidence.

8.2.5. Sustainability

Sustainability would normally be a significant factor in the evaluation of a project that applies a subsidy and where the analysis shows that this subsidy will be needed in some form also in the future. However, it the case of malaria elimination, this is different. Once malaria is eradicated, i.e. eliminated from each and every country, the success will be sustainable forever. But until then it is clear – as is the case in any disease elimination programme – that the marginal cost per additional case detected and correctly treated will increase significantly and that these increasing cost have to be borne if elimination is to be reached.

9. LESSONS LEARNT AND RECOMMENDATIONS

9.1. Lessons learnt

Lessons learnt with respect to the overall target of containing artemisinin resistance:

1. Given the epidemiological situation in Myanmar, elimination of artemisinin-resistant falciparum malaria (and hence its containment) will not be possible without contributions of the private sector.
2. Public sector investments to replace artemisinin monotherapy in the market can be successful, but
    a. require a subsidy that brings down the cost of QA-ACT to that of a partial dose of monotherapy
    b. does need to be coupled with significant increases in fever testing in the private sector

3. Sufficient attention must be paid to external factors such as influx of monotherapy through illegal pathways.

Lessons learnt with respect to the project implementation:

4. A Theory of Change is a powerful tool to guide a project, but only if it is used actively as an element of project management and is adjusted on a regular basis.
5. Timely revisiting the procurement forecasts and adjustment of procurement schedule in combination with short timelines are critical to avoid costly expiry of medicines in a rapidly changing epidemiological environment.

Lessons learnt with respect to the evaluation:

6. Independent evaluations will be less effective if they start after the project they are to evaluate. Similarly, if evaluations are extended to cover the additional time provided to implementers under no-cost extensions with no addition budget for the evaluation, they have to stretch their resources over longer periods and are not able to achieve as much – in this case a full final evaluation visit at the end of the AMTR project was not possible.

9.2. Recommendations

Given the fact that the project has already ended, the recommendations only refer to DFID and potentially other donors that intend to invest in malaria control in Myanmar in the future and with respect to the containment of artemisinin resistance in particular.

9.2.1. VFM in future programming

The following recommendations arise from DFID's AMTR project VFM analysis, but are also relevant as cross-cutting commentary for most DFID-funded projects and programmes:

1. Data upon which to make decisions are often limited, incomplete, or of suspect quality. In such cases, both due diligence and aggressive risk management are requisite and should be emphasised during all project phases.
2. Identifying and actively managing the primary cost driver(s) of projects is especially recommended where there is a high risk of external factors causing risk to DFID investments.

9.2.2. Recommendation to DFID and other donors

7. This evaluation clearly showed that further interventions will be needed in the private sector and markets for diagnostics and QA-ACT
8. It is recommended that donors engage in a way that supports existing market mechanisms with the primary goal to:

   Maximise the adequate treatment of *Plasmodium falciparum* cases in the private sector in Myanmar and thereby contribute to transmission reduction and containment of Artemisinin resistance.

   A secondary objective is recommended to:

   Provide value for money in the interventions to achieve the primary objective by optimising the use of ACTs and minimising the amount that goes to patients that do not have malaria.

The changes or steps that need to be achieved on the road to reaching the goal can be divided into three groups of recommended interventions:

1. **Interventions addressing the consumer or patient**
   Reduce as much as possible the number of suspicious fevers that do not see a provider but rather self-treat or do nothing at all. This is equivalent to an increased awareness that any fever that does not have an obvious cause (abscess etc.) needs to checked for malaria not only out of concern for the patient possibly suffering from malaria (which will be increasingly rare) but as a responsibility to help eliminate the disease. It is not so important where these people end up going, the public or private sector, as long as they can then receive the next step which is proper diagnosis and adequate treatment.
   The experience on BCC from this project is positive but it is recommended that in new investments a detailed qualitative and formative data collection is undertaken in the targeted population on which then the design of BCC activities is based.

2. **Interventions that involve consumers as well as providers**
   Here we can distinguish three main changes
   a) Phase out general retail shops as malaria treatment and diagnosis providers. These outlets are already showing a declining trend in fever patient's preference but are also are undesirable in the new scenario of primary diagnosis with RDT and relatively few actual ACT treatments with a need of high compliance.
   b) Increase the proportion of suspicious fevers tested. This may be the most difficult part to achieve, but it is also a very critical change without which neither the primary objective (transmission reduction and resistance containment) nor the secondary objective (value for money) can be reached. It will require innovative thinking and piloting of various approaches to best accomplish this change. It will also involve a significant increase of the volume of RDT turned over.
   c) Introduce comprehensive case reporting among private sector providers and feed this information into the HMIS system so that immediate action can be taken to address local transmission foci. This change will gain importance as the goal of elimination is approached.

3. **Interventions addressing the markets for anti-malarials**
   Increase the availability and use of affordable QA-ACT while minimising availability of oral AMT in the private sector. The starting point here should be a comprehensive market analysis that helps to outline the most promising actions. These will have to involve both the public and the private sector and regulatory and economic interventions:
   a) Determine, through market analysis, the most appropriate way to deliver a subsidy for quality-assured ACT that works with the market (rather than against it)
   b) Continue to provide a subsidy for quality-assured ACT (the level of the subsidy may have to be newly evaluated)
   c) Enforce the ban of oral AMT and implement measures that minimize import of non-licenced AMT as well as fake ACT and also minimize the leakage of ACT from the private sector

9.2.3. Recommendations for indicators and logframe

The major purpose of the logframe is to provide some selected indicators that will show whether the different steps in the ToC have been achieved. The logframe is not to replace a comprehensive performance monitoring and evaluation plan and, therefore, does not need to cover all aspects of the project activities.

In line with the recommended new ToC the following indicators should be considered:

- The proportion of suspected fever cases not seeking care from a qualified provider where "qualified" can be defined as a provider who can provide a diagnostic test (source: household or targeted fever surveys)
- The proportion of fever cases that attend private sector providers and receive a diagnostic test. A sub-category could be added of being tested or referred for testing (source: mystery client and targeted fever surveys).
- The proportion of private outlets that undertake testing and/or malaria treatment and which report results into the HMIS (source: outlet surveys)
- Proportion of outlets stocking quality assured ACT and their sales share and the same for oral AMT (source: outlet surveys)
- The proportion of positive tested patients that receive a full course of ACT and complete the treatment (source: outlet and fever surveys)
- The proportion of negative tested patients that do not receive an ACT or other antimalarial (source: outlet and fever surveys)
- The proportion of fever cases not tested that receive an ACT (source: outlet and fever surveys)

From this information and some data on test positivity rates the indicator for the overall goal can be estimated:

- The proportion of *P. falciparum* cases that are adequately treated to reduce transmission and contain Artemisinin resistance.

Building on the experience from this project the following is recommended for indicators that refer to sales of private market players:

- Indicators of sales or other activities should not be disaggregated by gender and/or wealth quintile as such data is usually not available or not reliable.

10. REFERENCES

1. Ashley EA, Dhorda M, Fairhurst RM, Amaratunga C, Lim P, Suon S et al.: Spread of Artemisinin resistance in *Plasmodium falciparum* Malaria. *New England Journal of Medicine* 2014, 371:411-423
2. White LJ, Lubell Y, Meek S, White NJ, Day NPJ, Nosten FH, Ashley E, Socheat D, Nguon C, Dondorp AM: Malaria in the Asia-Pacific: modelling the current and potential impact of artemisinin resistance and its containment. Working Paper No 4, Saving Lives in the Asia-Pacific conference, Sydney 31 October – 2 November 2012
3. MARC strategic plan 2011-2015, version May 2012
4. WHO: Global Plan on Artemisinin Resistance Containment, Geneva, 2011, http://www.who.int/entity/malaria/publications/atoz/artemisinin_resistance_containment_2011.pdf
5. WHO: Emergency Response to Artemisinin Resistance in the Greater Mekong Sub region. Regional Framework for action 2013-2015, 2013, WHO Geneva.
6. Vogel I: Review of the use of 'Theory of Change' in international development http://r4d.dfid.gov.uk/pdf/outputs/mis_spc/DFID_ToC_Review_VogelV7.pdf
7. Mu TT, Sein AA, Kyi TT, Min M, AungNM, Anstey NM et al. Malaria incidence in Myanmar 2005-2014: steady but fragile progress towards elimination. Malar J, 2016; 15:503

8. WHO: World Malaria Report 2010, http://whqlibdoc.who.int/publications/2010/9789241564106_eng.pdf
9. WHO: World Malaria Report 2014, http://www.who.int/malaria/publications/world_malaria_report_2014/report/en/
10. Carrara VI, Lwin KM, Phyo AP, Ashley E, Wiladphaingern J, Sriprawat K, et al. Malaria burden and artemisinin resistance in the mobile and migrant population on the Thai-Myanmar border, 1999–2011: an observational study. PLoS Med. 2013;10:e1001398
11. MARC baseline survey 2012
12. Imwong M, Nguyen TN, Tripura R, Peto TJ, Lee SJ, Lwin KM et al. The epidemiology of sub-clinical malaria infections in South-East Asia: findings from cross-sectional surveys in Thailand-Myanmar border areas, Cambodia, and Vietnam. Malar J, 2015; 14:381
13. National Strategic Plan for Intensifying Malaria Control and Accelerating Progress towards Malaria Elimination, 2016-2020, Dept. of Public Health, Ministry of Health and Sports, The Republic or the Union of Myanmar
14. Sudhinaraset M, Briegleb C, Aung M, Khin HSS, Aung T. Motivation and challenges for use of malaria rapid diagnostic tests among informal providers in Myanmar: a qualitative study. Malar J, 2015;14:61
15. Chen IT, Aung T, Thant HNN, Sudhinaraset M, Kanh JG. Cost-effectiveness analysis of malaria rapid diagnostic test incentive schemes for informal private healthcare providers in Myanmar. Malar J, 2015; 14:55
16. Aung T, White C, Montagu D, McFarland W, Hlaing T, Khin HSS et al. 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. Malar J, 2015; 14:105
17. White NJ. The parasite clearance curve. Malar J, 2011; 10:278
18. Flegg JA, Guerin PJ, White NJ, Stepniewska K. Standardizing the measurement of parasite clearance in falciparum malaria: the parasite clearance estimator. Malar J. 2011;10:339.
19. Ariey F, Witkowski B, Amaratunga C, Beghain J, Langlois AC, Khim N, et al. A molecular marker of artemisinin-resistant Plasmodium falciparum malaria. Nature. 2014;505:50–55
20. Takala-Harrison S, Jacob CG, Arze C, Cummings MP, Silva JC, Dondorp AM, et al. Independent emergence of artemisinin resistance mutations among Plasmodium falciparum in Southeast Asia. J Infect Dis. 2015;211:670–9.
21. Tun KM, Imwong M, Lwin KM, Win AA, Hlaing TM, Hlaing T, et al. Spread of artemisinin-resistant Plasmodium falciparum in Myanmar: a cross-sectional survey of the K13 molecular marker. Lancet Infect Dis. 2015;15:415–21
22. Wang Z, Shrestha S, Li X, Miao J, Yuan L, Cabrera M, et al. Prevalence of K13-propeller polymorphisms in Plasmodium falciparum from China–Myanmar border in 2007–2012. Malar J. 2015;14:168
23. Win AA, Imwong M, Kyaw MP, Woodrow CJ, Chotinavich K, Hanboonkunupakarn B et al. K13 mutations and *pmfdr1* copy number variation in *Plasmodium falciparum* malaria in Myanmar. Malar J, 2016; 15:110
24. Smithuis F, Kyaw MK, Phe O, Win T, Aung PP, Oo APP et al. Effectiveness of five artemisinin combination regimens with or without primaquine in uncomplicated falciparum malaria: an open-label randomized trial. The Lancet, 2010; 10:673-681
25. Kyaw MP, Nyunt MH, Chit K, Aye MM, Aye KH, Aye MM, et al. Reduced susceptibility of Plasmodium falciparum to artesunate in southern Myanmar. PLoS One. 2013;8:e57689.
26. Tun KM, Jeeyapant A, Imwong M, Thein M, Aung SSM, Hlaing TM et al. Parasite clearance rates in Upper Myanmar indicate a distinctive artemisinin phenotype: e therapeutic efficacy study. Malar J, 2016; 15:185

11. ANNEXES

11.1. Annex 1: Original TOR

Call-down Contract

Terms of Reference

Independent Evaluation of the replacement of malaria monotherapy drugs in the private sector to support the containment of drug resistant malaria in Burma

List of Abbreviations

ACTs artemesinin combination therapies

MARC Myanmar Artemesinin Resistance Containment Framework

AMT oral artemesinin monotherapy

GPARC Global Plan for Artemesinin Resistance Containment

BMGF Bill and Melinda Gates Foundation

PSI Population Services International

IEA Independent Evaluation Agency

OECD Organisation for Economic Co-operation and Development

DAC Development Assistance Committee

SG Steering Group

WHO World Health Organisation

MOH Ministry of Health (Burma)

Introduction

1. The new generation of malaria drugs, artemisinin combination therapies (ACTs) provide a highly effective cure for the most dangerous malaria in most countries; helping to reduce the global burden of malaria by more than half in 43 countries over the past 10 years. This global progress is now threatened by the emergence of malaria that shows resistance to artemisinin. Artemisinin resistant malaria, first detected on the Thai-Cambodia border and then Vietnam, now occurs in eastern Burma.

2. In response, Burma has developed the Myanmar Artemisinin Resistance Containment Framework (referred to as 'MARC'), with support from the Ministry of Health and key non-governmental implementing partners of malaria control. The MARC comprises a comprehensive set of interventions from prevention of malaria and testing and treatment with ACTs. The MARC prioritises five complementary areas for interventions: community-based malaria diagnosis and treatment; replacement of oral artemisinin monotherapy (AMT) in the private sector; a legal ban of AMT; insecticide treated bed nets and screening and malaria treatment for mobile populations. This strategy

is in line with the World Health Organization's Global Plan for Artemisinin Resistance Containment (GPARC)[19].

3. Overall the MARC strategy will lead to reductions in all cause and malaria specific mortality and, in collaboration with regional and global GPARC activities, containment of artemisinin resistance in Burma.

4. The UK (DFID) and Bill and Melinda Gates Foundation (BMGF) are supporting a three-year programme to replace oral malaria drugs containing only artemisinin (monotherapy) with those containing artemisinin with other effective malaria drugs (artemisinin combination therapies, or ACTs) in the private sector, as part of the MARC strategy. This programme will seek to address the root cause of the development of artemisinin resistance: the use of incomplete courses of oral artemisinin monotherapies for the treatment of the majority of cases of malaria in Burma. In Burma most people access care through the private sector through which they receive incomplete courses of oral AMTs without being tested for malaria. AMTs are purchased in preference to ACTs predominantly because they are cheaper. These practices are significant drivers for the development of resistance.

5. The DFID/BMGF funded programme will be implemented by the international non-governmental organisation Population Services International (PSI). This programme will provide quality approved ACT's at a subsidised price to the private sector to replace the AMTs that are currently being used. Given that it is already involved in the treatment of most malaria cases and wide geographical coverage, the private sector is well placed to address the issue of artemisinin resistance. This rapid 'switch' from AMT to ACT using an existing market channel will ensure immediate effect.

6. This programme will support the national ban on the sale of monotherapy in the private sector which will start to come into effect 2011 and 2012. It will be supplemented by communication campaigns to encourage the public to demand a quality assured ACT from the drug sellers as well as training private drug sellers to use rapid diagnostic tests so that it can be determined whether or not the person has malaria and treat them correctly.

7. The specific outcomes of this project by then end of 2014 include:

- 73% of suspected malaria cases will complete a full course of a nationally approved, quality assured artemisinin combination therapy within 24 hours of onset of fever
- Reduce the proportion of malaria cases in the target areas that are treated with artemisinin monotherapies to less than 10% by year 2
- 161 000 Disability Adjusted Life Years gained in Burma over the three years

8. This programme will **contribute the achievement of the MARC** at the impact level. It is important to note that **this programme intervention is necessary but not sufficient for drug resistance containment.** It is also complementary to the DFID supported Three Diseases Fund which will support the scale up of free malaria diagnosis and treatment at community level and through formal public and private health providers in high risk areas.

[19] Global Plan for Artemisinin Resistance Containment. WHO 2010. http://www.who.int/malaria/publications/atoz/9789241500838/en/

Objective

9. Given the global significance of containing drug resistant malaria and since this programme is highly innovative, DFID and BMGF are commissioning an independent rigorous evaluation.

10. The Independent Evaluation Agency (IEA) selected through this process will design and implement an evaluation framework which will:

- assess the effectiveness of what was done (for example, the replacement of monotherapy (ii) the introduction of diagnosis and testing in the informal private sector and (iii) behaviour change strategies), whether and to what level the outcome targets have been achieved;
- assess the value for money of the programme in delivering its outputs and outcomes; and
- Identify, document and disseminate lessons learnt for wider interest where results have or have not been achieved.

11. Assessing the impact of the programme on artemisinin resistance containment would be highly complex, particularly as it is only one component of the wider MARC strategy and would require a range of surveillance activities. However, the IEA will make a judgement, based on the performance against the outcomes, as to whether the programme has contributed to artemisinin resistance containment in Burma.

12. The Evaluation Framework will also consider options for longitudinal studies to assess the long-term impact of replacement of monotherapy in the private sector beyond the project time frame.

13. DFID uses the definition of evaluation agreed by the OECD's Development Assistance Committee (DAC):"The systematic and objective assessment of an on-going or completed project, programme or policy, its design, implementation, and results in relation to specified evaluation criteria." The evaluation should be in line with OECD DAC guidance particularly relating to partnership and transparency. It will be published and is intended to contribute to the global evidence base to help understand what works and what does not work in achieving malaria outcomes.

Recipient

14. The recipient of this evaluation will be DFID and the BMGF**.**

Scope of work

15. Routine monitoring is outside the scope of the services required from the IEA. PSI have included the full costs of monitoring in their programme. They will establish clear baseline data, monitor progress against milestones and targets in the Log Frame and provide progress and annual reports. This includes the use of routine data collection systems and surveys to monitor the programme. The Independent Evaluation Agency will be required to assess that the baseline data is relevant and adequate and that data collection tools and methods (particularly surveys) to ensure this routine information can support data requirements for programme evaluation.

16. The IEA will also design and implement an evaluation framework that outlines how the IEA will:

- assess the effectiveness of what was done (see the range of questions below), whether and to what level the outcome targets have been achieved;
- assess the value for money of the programme in delivering its outputs and outcomes;
- and identify, document and disseminate lessons learnt for wider interest and where results have or have not been achieved.

17. The evaluation will be expected to answer a range of questions that include, but are not limited to:
    - What were the performance, effectiveness and outcome of key components of the programme, importantly (i) the replacement of monotherapy (ii) the introduction of and adherence to diagnosis and testing in the informal private sector; (iii) ACT uptake and use (completion of treatment) and (iv) behaviour change strategies?[20]
    - What was the differential impact of these key interventions on the poor and other vulnerable groups, including in-depth analysis of what works (or doesn't) to reach the hard-to-reach, poorest and most vulnerable?
    - What was the cost effectiveness and value for money of the programme (using DFID's VFM framework and approach)?
    - Were the assumptions underlying the theory of change valid and what is the IEA's judgment on whether the theory of change remains relevant and feasible at the end of the evaluation period?

18. Additional indicative evaluation questions can be found in Annex 1. The IEA will be expected to present evaluation questions in their inception report.

19. The IEA will be expected to provide a draft Evaluation Framework for approval by the evaluation Steering Group (SG) within the first 3 months. This inception report should contain:
    - evaluation strategy;
    - the key questions for evaluation.
    - risk management plan;
    - quality assurance plan;
    - an outline of the proposed methods for assessing core indicators with reference to the target groups;
    - reference to appropriate counterfactuals.
    - outline of proposed approach to assessing the relevance of the theory of change ;
    - outline of proposed approach to assessing the level of attainment of the outcomes and contribution to the overall impact level goals;
    - outline of proposed approach to measuring and evaluating value for money and cost effectiveness of the programme ;
    - outlines opportunities for detailed case studies/ comparative analyses
    - draft strategy for stakeholder and partner engagement ;
    - draft communication and dissemination strategy;
    - detailed costed workplan for implementation, indicating key milestones and deliverables.

[20] It is understood that these components are interrelated and mutually supportive. The Evaluation framework will assess the feasibility of testing the effects of each.

- assessment of PSI baselines; data collection systems, and proposed data collection tools and methods (particularly surveys), and fit with wider MARC monitoring systems, so that data supports required information for evaluation.
- assessment of evaluation design options and recommendations for possible comparators to support the specific areas of comparative analyses and the overall assessment as to whether the programme has contributed to artemisinin resistance containment in Burma.

20. Each of the four specific areas of comparative analyses will be written up as stand-alone papers which will be annexes to the Final Evaluation report. The areas for these papers can be outlined in the Inception Report. In addition, the IEA will document a number of case studies and/or short papers/briefs on key lessons learned. These are aimed at a wide, non-technical audience. The focus, scope and number will be agreed with the SG but is likely to be not more than 4.

The Requirements/Core Deliverables

21. The IEA will submit the following reports, with other deliverables outlined in the Evaluation Framework:

A) **Inception report including the Evaluation Framework** as outlined above with detailed methodology and budget; the foreseen degree of difficulties in collecting data; detailed methodology, programme of work and staff mobilisation; assessment of PSI routine data. The Evaluation Framework will be submitted not more than three months from contract start.

B) At least four **stand alone papers** each addressing specific areas of comparative analyses, **plus** lessons learned and/or detailed case study **short papers/briefs** suitable for wide external dissemination. These stand-alone reports will use academic rigour to report methodology, findings and conclusion.

C) **Final Evaluation report** (of maximum 30 pages + annexes). Besides answering the evaluation questions, the final report should also synthesise findings and conclusions to form an overall assessment of the programme. The report will contain the stand alone reports as annexes. The final report will include (i) an Executive Summary of 2-5 pages, in clear terms for an informed lay reader (ii) a Synopsis of no more than 1 page in plain English which can be used for external communications to the general public. The Final Evaluation report will have excellent analytical quality and writing, but will be written in clear, crisp language, understandable to an informed lay reader. The text of the report and annexes should be illustrated, as appropriate, with maps, graphs and tables. The draft final report will be submitted at least within two months ahead of contract end.

D) Short six monthly progress reports, and regular updates. The format of these will be agreed with DFID, based on consultation with the evaluation SG.

Eligibility

22. Organisations are eligible provided they are independent of PSI and the routine monitoring of the programme including the logframe.

Governance

23. An evaluation Steering Group (SG) consisting of representatives from BMGF, DFID, MOH, WHO will be set up to oversee the evaluation process, the technical review of eligible applications, approval of the evaluation products/reports. The SG will be supported by independent quality assurance experts (to be appointed by the SG as required).

24. The DFID Evaluation Adviser will be the key contact point for the IEA and the SG. The Evaluation Adviser will be supported by the DFID Project Officer.

25. This evaluation package will have two phases: the first phase for the design of an evaluation framework, and the second for implementation of the approved design. Based on quality of the design the SG will decide whether the selected consultant team can continue to implement the framework.

DFID contract coordination

26. The DFID Evaluation Adviser, supported by the DFID Project Officer will have the day-to-day oversight and management of the contact with the IEA. The DFID EvD Team will provide strategic advice as required; ensuring that the evaluation aligns with wider DFID policy and guidelines.

27. The DFID Project Officer will monitor operational and financial progress on an on-going basis and raise any issue that require attention to the SG as necessary.

28. The IEA will be expected to report to the SG six monthly, through the DFID Evaluation Adviser.

Reporting

29. DFID intend to manage the providers performance through a suite of Key Performance Indicators (KPIs). The draft suite of indicators is contained in Annex 3 and tenderers are welcome to comment. Comments will form part of the evaluation process and ultimately be incorporated into the contract. The final KPIs will be agreed with DFID. These will ensure that the management of the contract is undertaken as transparently as possible and to ensure that there is clarity of roles and responsibilities between DFID, the SG, PSI and the IEA.

30. The SG will evaluate the performance of the IEA throughout the life of the programme and as part of the standard review of the programme.

31. The IEA will be expected to submit progress reports six monthly supported by oral or informal updates as appropriate in line with the programme cycle and as outlined in the requirements section of this ToR. It is expected that IEA will take a proactive approach to notifying DFID and the SG of any matters which may require immediate attention.

32. The inception report should be finalized within the first 3 months as detailed in the scope of work and requirements section. The inception report should outline details of timelines for the various components identified in the scope of work.

33. The reports should be sent to the DFID Evaluation Officer with a copy to the DFID Project Officer.

Timeframe

34. The contract for the IEA will be awarded from January 2013 – March 2015. The contract is designed to end after the completion of the programme to allow a final evaluation of components if necessary and time for presentation and finalisation of the Evaluation Report.

35. There will be a 3-month inception period at the end of which the IEA will present their inception report (as outlined in the scope of work) to the SG for discussion and final approval.

36. The first draft of the Final Evaluation report must be submitted by 15th January 2015 and the final draft by 15th March 2015.

37. The SG will provide feedback to IEA on clarifications on draft core deliverable through the DFID Evaluation Adviser. SG will approve reports and other deliverables. The IEA will liaise with the PSI Myanmar for practical arrangements such as meetings, communications, data, site visits etc.

Bidding Documents

DFID will provide templates for bidding documents for technical and financial proposals. The SG supported by independent quality assurance experts (if requested) will make the technical assessment of eligible bids.

Requirements

Skills

The successful service provider for the IEA contract should command the following skills:

Mandatory: demonstrable record of

- Evaluation or research on malaria programmes
- Undertaking evaluations of major donor interventions focussed on non-state providers
- Evaluation of supply chain and market analysis and private sector service delivery;
- Monitoring and evaluation of development programmes (quantitative and qualitative methods)
- Work with health programmes (including measurement of health outcomes)
- Social research management
- Management of impact evaluations

Desirable: demonstrable record of

- Malaria epidemiology in South East Asia, in particular drug resistant malaria

Team Composition

An overall Team Leader with demonstrated skills and experience in leading rigorous evaluation of complex programmes and excellent management, negotiation and communication skills.

Team members with skill areas covering:

- malaria epidemiology in SE Asia (with experience on drug resistant malaria highly desirable);
- supply chain and market analysis; private sector service delivery;
- health economics, including cost and value for money analysis;
- gender and poverty analysis, and equity issues in health; and
- knowledge of the operational context in Burma.

All members of the Team must not have participated in the design or implementation of the PSI programme or its monitoring including the logframe and wider MARC strategy.

Proposals should take account of DFID's vision for women and girls through mainstreaming the principles of gender within this work.

Other requirements

The IEA will have responsibility for:

- Ensuring the evaluations adhere to OECD/DAC evaluation principles and standards and assess the criteria of relevance, effectiveness, efficiency, sustainability and impact.
- Maintaining ethical standards in implementing the evaluation and seeking ethical clearance as required.
- Timely production of evidence-based conclusions, lessons and recommendations to demanding quality standards.
- Managing logistics during in-country visits with limited support from PSI.

Duty of Care

The Supplier is responsible for the safety and well-being of their Personnel (as defined in Section 2 of the Framework Agreement) and Third Parties affected by their activities under this Call-down Contract, including appropriate security arrangements. They will also be responsible for the provision of suitable security arrangements for their domestic and business property.

DFID will share available information with the Supplier on security status and developments in-country where appropriate.

The Supplier is responsible for ensuring appropriate safety and security briefings for all of their Personnel working under this Call-down Contract and ensuring that their Personnel register and receive briefing as outlined above. Travel advice is also available on the FCO website and the Supplier must ensure they (and their Personnel) are up to date with the latest position.

Tenderers must develop their Tender on the basis of being fully responsible for Duty of Care in line with the details provided above and the initial risk assessment matrix developed by DFID (see Annex E of this ToR). They must confirm in their Tender that:

- They fully accept responsibility for Security and Duty of Care.
- They understand the potential risks and have the knowledge and experience to develop an effective risk plan.

- They have the capability to manage their Duty of Care responsibilities throughout the life of the contract.

  Acceptance of responsibility must be supported with evidence of capability (no more than [2] A4 pages) and DFID reserves the right to clarify any aspect of this evidence. In providing evidence Tenderers should consider the following questions:

  a) Have you completed an initial assessment of potential risks that demonstrates your knowledge and understanding, and are you satisfied that you understand the risk management implications (not solely relying on information provided by DFID)?

  b) Have you prepared an outline plan that you consider appropriate to manage these risks at this stage (or will you do so if you are awarded the contract) and are you confident/comfortable that you can implement this effectively?

  c) Have you ensured or will you ensure that your staff are appropriately trained (including specialist training where required) before they are deployed and will you ensure that on-going training is provided where necessary?

  d) Have you an appropriate mechanism in place to monitor risk on a live / on-going basis (or will you put one in place if you are awarded the contract)?

  e) Have you ensured or will you ensure that your staff are provided with and have access to suitable equipment and will you ensure that this is reviewed and provided on an on-going basis?

  f) Have you appropriate systems in place to manage an emergency / incident if one arises?

  Further information on Duty of Care is provided in the Supplier Instructions (Volume 1 of the Mini-Competition Invitation to Tender Pack).

Annex 1. Additional indicative questions

Planning

To what extent were the assumptions and theory of change appropriate?

To what extent was our theory of change validated/ proven/on track?

Implementation

What did we do?

Did we do what we said we would?

What happened as a result and why?

Was the approach the right ones to achieve the objective and contribute to the overarching goal?

To what extent were we guided by the core principles?

What has contributed to successful outcomes and what hindered progress? What have we learnt about ensuring interventions reach the most vulnerable groups?

Impact and results

To what extent have the outcomes and objectives been met?

To what extent are results achieved sustainable?

How cost effective / efficient was our approach?

Were the causal mechanisms correctly identified and what were the conditions necessary for them to work to achieve the high level results?

Learning

What evidence has been generated?

What did we learn about the effectiveness and the cost effectiveness of approaches and interventions that did work?

To what extent did the existing evidence base inform and contribute to achieving results at country level?

What did we learn about how to reach the most poor and vulnerable? What worked, what didn't and why?

What interventions and approaches contributed most to the overall outcome and impact?

Were the assumptions and causal mechanisms correctly identified in the Theory of Change?

What are the lessons learnt?

11.2. Annex 2: Evaluation results of DFID QA for inception report and final evaluation questions

Evaluation Department

DFID Department for International Development

Quality Assurance Template: Entry level evaluation product

Name of Project / Programme	***Independent Evaluation of Artemisinin Monotherapy Replacement in the Private Sector to Support the Containment of Artemisinin Resistant Malaria in Burma***
Department / Country Office	DFID/Burma (Health Sector)
Name of Evaluation Product	Inception Report and Draft Evaluation Framework

Entry level QA Questions		**Y / N**	**Comments and Recommendations**
Sub-questions are intended as a prompt for overall judgement on the headline questions: individual responses are not mandatory for each sub-question.			**Please provide detailed comments against each headline question.** **All recommendations should be underlined.**
Q1	**STRUCTURE AND CLARITY:** **Is the product logically structured, is it clearly written, and does it contain all the relevant elements?** 1.1 Is the product accessible to the intended audience (e.g. free of jargon, written in plain English, logical use of chapters, appropriate use of tables, graphs and diagrams)? 1.2 Is it clear who has carried out the work?	**Y**	Very clear and well written report – and plan for evaluation, that appears to well address the requirements in the TOR. Excellent graphics. The Executive Summary is quite short, but manages to cover the essential aspects, quite remarkable and noteworthy. Given the subject matter, there is some use of medical language and acronyms, but this seems appropriate and indeed helps to indicate the evaluation team's understanding or the programme and the context.

Entry level QA Questions		Y / N	Comments and Recommendations
	1.3 Is an executive summary included, and can it stand alone as an accurate summary of the main product? 1.4 Do the annexes contain – at the least – the original TORs, the evaluation framework (including evaluation questions), and a bibliography? 1.5 Do annexes increase the usefulness of the product? 1.6 Have any departures from the original TOR been adequately explained and justified?		
Q2	**CONTEXT, PURPOSE, SCOPE AND OBJECTIVES:** **Is there a sufficiently detailed description of the background to the evaluation, including the context, purpose, scope and objectives?** 2.1 Does the product provide a sufficient description of the intervention to be evaluated? At the least, this should include detail on the intervention's anticipated impact, outcomes and outputs, target groups, timescale, geographical coverage, and the extent to which the intervention aimed to address issues of equity, poverty and exclusion. 2.2 Is the inception process clearly explained? Have key stakeholders been identified and involved? 2.3 Does the product provide a relevant and sufficient description of whether and how contextual factors (local, national and/or international) have influenced evaluation design? 2.4 Does the product identify key linkages between the intervention and other relevant projects / programmes / donors? If no linkages are identified, does the product justify why other projects / programmes / donors will not be relevant to the evaluation?	**Y**	Excellent description and discussion of the background and the intervention itself, and implications for evaluation. Good consideration of the various (and numerous) complexities at play that will influence any approach to evaluation. The programme assumptions and theory of change developed by PSI are presented. The Inception Report does not especially critique this, although it does, later in the report, indicate how some initial assumptions behind this Theory of Change, such as incident rates of malaria), may affect results that can reasonably be expected, but that the overall logic is still okay. Stakeholder groups consulted thus far (based upon lists of contacts in the annexes, and according to the Inception Report, identified in conjunction with DFID) include mainly PSI staff, government, and various donors, along with a couple of suppliers of medicine (AA and Polygold). This is a rather conventional contact list for medical interventions of this type and is consistent with the TOR, but is focused almost exclusively on the supply side. What seems to be missing are contacts with civil society and with direct AMT private sector providers, who seem to be treated mainly as subjects in the research/evaluation; given that this is where the major problem seems to lie, and where data about the reasons for past behaviours and openness to changes arise, it would seem helpful to provide for at least some involvement at these levels (while acknowledging the challenges of engaging with civil society in Burma). The four identified case studies all propose contact at this level, but at least some advance discussion of these might help provide for increased buy-in and cooperation, and minimise some potential surprises.

Entry level QA Questions		Y / N	Comments and Recommendations
	2.5 Does the product describe what information is needed through the evaluation, and how that information will be used? Does the product describe the target audience(s) for the evaluation? 2.6 Does the product describe whether the evaluation is for accountability and/or learning purposes? 2.7 Does the product justify the timing of the evaluation? 2.8 Does the product clearly outline what aspects of the intervention are and are not to be covered by the evaluation? 2.9 Does the product confirm whether and how the evaluation purpose, scope and objectives were altered during the inception phase?		There is reference to various other relevant projects, within Burma and in other jurisdictions, and to using some data from these projects (e.g. as a counterfactual). Quite good, in my view.
Q3	**EVALUATION FRAMEWORK:** **Is the proposed evaluation framework sufficiently focused and capable of addressing the purpose, scope and objectives of the evaluation?** 3.1 Does the product describe the intervention logic and/or theory of change? If this was developed during the inception phase, does the product describe the development process? 3.2 Have high level evaluation questions been identified? Are they sufficiently clear and specific? Are they clearly related to the evaluation purpose, scope and objectives? Are appropriate and relevant criteria (e.g. OECD DAC) adequately reflected in the evaluation framework? 3.3 Are evaluation questions relevant to the intervention logic and/or theory of change? 3.4 Can the evaluation questions be answered within the evaluation timeframe?	**Y**	The inception report/proposed evaluation framework makes good use of the theory of change, such as In specifying evaluation questions and designing the overall evaluation process. Admirably, the focus of the evaluation will be at the levels of outcomes, impacts, and long-term perspective, with primary focus at the outcome level. This level of focus is very appropriate, indeed necessary in order to maximise the value of the evaluation. Nevertheless, in order to provide for attribution (e.g. 'what can be attributed to the DFID contribution?'), it is essential to have data not just on outcomes, but also on the intervention itself, as actually implemented. Much of this information would come from monitoring data that falls under the responsibility of PSI, and to be sure, many of the proposed evaluation methods will also pick up on this, at least to some extent. Thus while the focus on outcome (and beyond) is very appropriate, I would suggest that the evaluation also not neglect to confirm the actual nature of the intervention and how this might have contributed to documented outcomes. As need be, DFID should ensure that PSI, with primary responsibility for monitoring, will clearly document what was done and deviations from initial expectations. The inception report makes specific reference to cross-cutting issues of poverty, gender, and VfM. There seems to be scant explicit attention to other issues such as human rights, power relations, and capacity building which may be problematic in

Entry level QA Questions		Y / N	Comments and Recommendations
	3.5 Will the evaluation framework be able to address the cross-cutting issues of gender, poverty, human rights, HIV/AIDS, environment, anti-corruption, capacity building, and power relations?		Burma at the moment and in any case would seem to fit better under the programme itself rather than the evaluation.
Q4	**METHODOLOGY AND DATA:** **Is the proposed methodology appropriate and capable of adequately addressing the evaluation questions? Are proposed data sources appropriate and sufficiently robust?** 4.1 Is the proposed evaluation methodology described and justified in sufficient detail? 4.2 Are these methods appropriate for addressing the evaluation questions? 4.3 Is the sampling strategy described, and is it appropriate? Are primary and secondary data sources appropriate, adequate and reliable? Are sample sizes adequate? 4.4 Are there adequate plans to consult with different stakeholders at all levels? 4.5 Is there an appropriate mix of qualitative and quantitative data collection? If not, is it adequately explained why not? 4.6 Are the evaluation principles of accuracy and credibility addressed? 4.7 Does the design provide for multiple lines of inquiry and/or triangulation of data? If not, is there a clear rationale for doing otherwise?	**Y**	Overall, in my view a very sound methodological approach has been developed, involving a good mixed method strategy with complementary use of both quantitative and qualitative data. This evaluation faces severe challenges (e.g. impossibility of the evaluation to influence the quantitative data that are being collected by PSI, inability to influence the project design itself, which was already at the midpoint of it implementation when the evaluation was contracted). I find it refreshing how these, and other methodological challenges, are identified at this stage, along with ways in which they will be addressed. The basic design (before-after comparison with plausibility arguments with respect to attribution) may appear theoretically weak. But it is all that is practically possible and is consistent with good practice, and the design used can avoid many of the implementation and validity challenges inherent in attempts to keep RCT designs pure). There is good use of case studies and other qualitative data. Another nice touch is use of 'control sites" from outside the PSI site that can act as a counterfactual and will provide for triangulation in various ways. My minor quibble is that this more appropriately should be referred to as *comparison* rather that *control* groups – this is not a problem as long as appropriate qualifications are used with respect to quasi-experimental designs such as these when later analysing and interpreting the data. There seem to be various steps identified to check for and enhance the accuracy and validity of various sources of data that will be collected/used. Along the above lines, there is good, explicit attention to both internal and to external validity. This will greatly enhance the value of this evaluation, both in the Burma context and also elsewhere.

Entry level QA Questions		Y / N	Comments and Recommendations
	4.8 Will the methodology enable the collection and analysis of disaggregated data to show difference between groups? 4.9 Are any methodological limitations acknowledged and their impact on evaluation design discussed? Are the limitations acceptable and/or are they adequately addressed? 4.10 Will the proposed methods be appropriate for assessing the cross-cutting issues of gender, poverty, human rights, HIV/AIDS, environment, anti-corruption, capacity building, and power relations? 4.11 Does the framework allow for an appropriate exploration of Paris Declaration principles within the context of this intervention?		Responsibility for most of the statistical analysis falls under PSI, but the evaluation framework calls for this to supplemented where needed by the evaluation team. The analysis plan at this point calls for examining such covariates as gender, age, wealth quintiles, etc.
Q5	**INCLUSION AND ETHICS:** **Will the methods address issues of impartiality, propriety and inclusion? Is the proposal ethically sound?** 5.1 Does the methodology respect concerns around gender, age, ethnicity, caste, religion, geographic location, ability, socio-economic status and hard to reach groups? If not, why not? 5.2 Does the evaluation design include consideration of DFID's commitment to human rights based approaches? If not, why not? 5.3 Will the governance structures for the evaluation include diverse perspectives, and will such perspectives be free of control from organisational influence and political pressure?	**Y**	The evaluation plan does seem to be appropriately impartial and ethically sound. There is, however, a necessarily close relationship with PSI, responsible for the programme implementation (and provision of data required for the evaluation). There perhaps, depending upon findings, could be issues arising later, in particular if findings are unexpected or viewed as negative. In such an unlikely event, I would suggest that DFID play a mediating role, if necessary, to support the evaluation team in remaining objective. The quality assurance (QA) approach described in the report does seem appropriate, and can also if need be help counter any undue pressure. There is no reference in the report to adherence to evaluation quality standards (e.g. the DAC EQS); I would suggest that this be added in, and form part of basis for the QA assessment. In other respects, there is little discussion in the Inception Report itself about governance structures for the evaluation, although based upon what is discussed, I do not see any particular reason to have concerns in this area.

Entry level QA Questions		Y / N	Comments and Recommendations
Q6	**PLANNING, MANAGEMENT AND GOVERNANCE:** **Is the evaluation plan coherent, supported by clear management and governance arrangements? To what extent does the evaluation design take into account Paris Declaration principles?** 6.1 Are management and governance arrangements clearly described? Are these arrangements appropriate? 6.2 Are accountabilities, responsibilities and lines of communication absolutely clear? 6.3 Are expectations realistic, given the available time and resources? 6.4 Have any risks and challenges identified within the original TOR been adequately addressed? 6.5 Are issues of leadership capacity and institutional capacity adequately addressed? 6.6 Is the evaluation team composition appropriate in terms of both sectoral and methodological expertise? Does the Team Leader have financial and human resource management skills, and a proven track record of timely high quality evaluations? 6.7 Does the Evaluation Team include local or national consultants? Is there scope within the methodology to build the capacity of national evaluators? 6.8 To what extent have partner countries participated in, or led, the design, and will they participate in the evaluation process? 6.9 Has coordination with the policies and evaluations of other donors been considered in evaluation design in order to minimise burdens and transaction costs on the partner country?	**Y** (partly qualified by information available to me to assess all these criteria)	The overall evaluation plan, as suggested above, is very coherent. Discussion of risks (including inclusion of a comprehensive risk management plan as a separate document) of various forms, as well as challenges to data availability and how these will be addressed, the implementation work plan, etc. all see to suggest that this plan should be workable. Six month formal interim reporting seems sufficient to ensure that the evaluation is on track, and to identify corrective action and changes as need be. The evaluation team will not have direct control over much of data essential for the evaluation, there will be possible/likely changes in other respects that may have implications for the evaluation and the potential of interim evaluation findings raising other important questions/possibilities worth pursuing. Thus I would suggest that the evaluation team remain flexible and be open to potential modifications to the evaluation approach as need be. As indicated above, there is limited discussion of governance structure in the Inception Report. There is reference to an evaluation steering committee and to the Monrose management team, but no information about composition, roles, etc. (although the TOR indicates this for the steering committee) I do not have enough information about the composition of the evaluation team, including its leadership, to comment, other than to observe that the high quality of the Inception Report, at a minimum, suggests good understanding by at least whoever contributed to it. Other donors, the Myanmar government, and some other key stakeholders, as discussed above, are involved in the evaluation. The work plan does provide for on going and regular contact and feedback to DFID, PSI, and stakeholders.' Additionally, if not implied by the above, I would suggest at least some more formal discussions at key interim steps. There is a plan for a dissemination workshop at the very end of the evaluation. This can help very much. It would be helpful as well, when most of the data are available and prior to drafting of the final evaluation report, to have a perhaps smaller workshop (e.g. expanded evaluation steering committee) to provide an opportunity for discussion of emerging findings, and the identification of possible implications. While this should not constrain the evaluation team from drawing its own conclusions, discussion at this earlier stage can help provide for increased buy-in to the evaluation and to subsequent action, as well as provide an opportunity for stakeholders to identify, at the earliest opportunity, an possible errors or conclusions requiring

Entry level QA Questions		Y / N	Comments and Recommendations
			explanation. A workshop just at the end runs the risk of being seen as one-way communications. I suspect that this evaluation will be weak with respect to at least many of the Paris Declaration principles. But given the way it was contracted, with the programme already at its midpoint, I find it hard to fault the evaluation team for this.
Q7	**USEFULNESS:** **Is the evaluation designed to meet the information and decision-making needs of the intended users and other stakeholders?** 7.1 Have the potential users and stakeholders, and the ways in which the evaluation could be used, been identified? 7.2 Have issues of equity and gender been considered in selection of stakeholders? 7.3 Is there any evidence that the key users and stakeholders feel that priority questions and issues have been identified in the plan for the evaluation? 7.4 Is there a Communications and Dissemination Plan and will it enable a transparent process that engages and meets the needs of all users, including primary stakeholders? 7.5 Will stakeholders affected by the intervention have access to evaluation-related information in forms that respect confidentiality? 7.6 Is there clarity around the final ownership / copyright of findings and evaluation products? Does this include a description of the arrangements for storage and accessibility of any data generated through the work? 7.7 Are the methods for communication appropriate to meet the diverse needs of stakeholders, including gender concerns, and	**Y**	The Inception Report does include a communication and dissemination plan. This is not very detailed at this stage, probably still premature, later on when the emerging findings and issues arising become clearer, it may be helpful for the evaluation team, together with DFID, to specify this further. The current plan does call for engagement of the key identified stakeholders, and sharing of evaluation findings within the Greater Mekong Sub region and internationally, as well as with stakeholders in-country. I would suggest that in addition to the specific evaluation products identified (e.g. case study and working reports along with the evaluation report), consideration be given to alternative forms or communication, that *inter alia* may include: one or more 'briefs' or summary fact sheets, presentations and presentation kits, podcasts and/or other forms of electronic dissemination, engagement with the media in-country, in the region, in the UK and internationally to seek broader publicity. I would think that the topic and the evaluation findings could have broad international significance and interest. Such communication would appear to go beyond the scope of the current evaluation contract, and it might be appropriate to engage appropriate communication experts to aid with this. WHO (who does appear to be engaged in the evaluation) may also be able to assist with this.

Entry level QA Questions		Y / N	Comments and Recommendations
	access for marginalised or non-literate groups affected by the intervention?		

Summary Assessment / Overall Ranking		Rank	Comments and Recommendations
Q8	**Based on your responses to all the above questions, provide an overall rank and commentary summarising the overall quality of the product. Include and underline all essential recommendations within your commentary.**	**Green**	As my comments above indicate, I consider this a well-thought out, indeed exemplary evaluation plan, and except as for the very few points identified above for the evaluation team to remain aware of (as I believe they already are). The background, purpose, approach, and challenges (to the programme, and to the evaluation) are clearly identified. This will be a challenging evaluation, with restrictions placed upon possible design options and data availability, as well as ongoing changes (e.g. a rapid reduction in the incidence of malaria as well as private sector practices). The evaluation team, however, seems very well aware of these, and of other challenges, and has proposed a variety of complementary methods and strategies to address these. Given this context, it may well be that some changes in evaluation approach and methods may be appropriate over the course of this evaluation. As I have indicated above, both the evaluation team and DFID should be open to these, as appropriate, to maximise the responsiveness and appropriateness of this evaluation.

Overall Ranking Guidance:

Green	The evaluation product is **acceptable**
Amber	The evaluation product is **acceptable, but would benefit from additional detail or clarifications**
Red	The evaluation product is **not acceptable, requiring substantial amendments followed by re-submission for QA**

11.3. Annex 3: Evaluation project case studies and working papers

Type and number	Title	Release date	Link
Case study 1	Lessons learnt from the RDT incentives pilot programme for scale-up	July 2016	Not yet available
Case study 2	The role of pharmaceutical distributors and private health care providers in containing artemisinin resistance in Myanmar	June 2014	http://www.montroseint.com/wp-content/uploads/2015/05/Myanmar-AMTR-Independent-Evaluation-Case-Study-2-Private-Providers-....pdf
Working Paper 1	Sensitivity analysis of the calculation of Disability Adjusted Life Years (DALY) averted in the context of the AMTR project	March 2015	http://www.montroseint.com/wp-content/uploads/2015/05/Myanmar-AMTR-Independent-Evaluation-Working-Paper-1-DALYs-v2.pdf
Working Paper 2	Adding primaquine to the standard treatment of uncomplicated P. falciparum malaria – perceptions of various providers and options for implementation strategies	June 2014	http://www.montroseint.com/wp-content/uploads/2015/05/Myanmar-AMTR-Independent-Evaluation-Working-Paper-2-Primaquine-v2.pdf
Working Paper 3	The situation of mobile migrant workers and malaria at vulnerable sites in Myanmar: A qualitative research paper	January 2015	http://www.montroseint.com/wp-content/uploads/2015/05/Myanmar-AMTR-Independent-Evaluation-Working-Paper-3-Migratory-Worker....pdf
Working Paper 4	The potential impact of increased private sector investment in Myanmar on malaria control strategies and the potential future role of the private sector in contributing to malaria control	June 2014	http://www.montroseint.com/wp-content/uploads/2015/05/Myanmar-AMTR-Independent-Evaluation-Working-Paper-4-Corporate-Role-....pdf
Working Paper 5	The potential role of the private sector in Myanmar in efforts towards containment of *Plasmodium falciparum* artemisinin resistance and malaria elimination	March 2017	Not yet available

11.4. Annex 4: Changes in AMTR logframe definitions and indicators

Impact	**Definition**	**-.-**	**To prevent (or at minimum significantly delay) the spread of artemisinin resistant Plasmodium falciparum parasites within Myanmar and beyond its borders**	**No changes**
Impact	Indicator 1	Nov 2014	Parasite clearance rates in eastern Myanmar	Parasite clearance rates in eastern Myanmar. Indicator related to the genetic marker mapping across the region (language TBD later).
Outcome	**Definition**	**Nov 2014**	**Sub-standard antimalarials in the private sector (particularly artesunate monotherapy), replaced with government approved and quality assured ACT, and sub-optimal dosing reduced among the target population in eastern Myanmar.**	**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).**
Outcome	(Indicator 1)	Nov 2014	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who received a nationally approved, quality-assured artemisinin-based combination therapy (ACT) within 24 hours of the onset of fever	Dropped
Outcome	Indicator 1	Nov 2014	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who received a full course of a nationally approved, quality-assured ACT within 24 hours of the onset of fever	% target population with fever in the last two weeks who received a diagnostic test for malaria (within 24 hours of the onset of fever)
Outcome	Indicator 2	Nov 2014	% target population (disaggregated by age and gender) with suspected malaria in the last two weeks who completed a full course of a nationally approved, quality-assured ACT within 24 hours	% target population with fever in the last two weeks who received a diagnostic test for malaria and who did not receive any antimalaria treatment if the test showed negative
Outcome	Indicator 3	Nov 2014	None	Estimated number of P.f malaria cases (disaggregated by age and gender) treated nationwide with QA-ACT through DFID funding of this project.
Output 1	**Definition**	**Nov 2014**	**Increased opportunity, ability and motivation of private sector providers to effectively prescribe and dispense nationally approved, quality assured ACT.**	**Increased opportunity, ability and motivation of private providers to effectively test for and appropriately treat Pf malaria.**
Output 1	Indicator 1.1	-.-	% target outlets with nationally approved and quality assured first-line ACT in stock at time of survey	No changes
	Indicator 1.2	Jul 2016	% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months	% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months (**among those outlets that stock PSI distributed QA-ACT at the time of the survey**)

Output 1	Indicator 1.3	-.-	% target outlets selling nationally approved, quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline	No changes
Output 1	Indicator 1.4	Jul 2016	% target outlet providers that correctly state the recommended first line ACT treatment for uncomplicated malaria	% target outlet providers that mention QA-ACT as the most effective treatment for uncomplicated malaria
Output 1	Indicator 1.5	Jan 2014	Volumes of antimalarials sold/distributed to consumers in the past 7 days (Volume data will include: quality assured (QA) ACTs; non-QA ACTs; artemisinin monotherapies; and non-artemisinin monotherapies.	Relative ratio of volume of ACT to oAMT (sold in the past 7 days)
Output 1	Indicator 1.6	Aug 2015	% target outlet providers who treat a ""mystery client"" with suspected malaria using a full course of ACT and providing instructions for correct use.	% target outlets with RDTs in stock at time of survey
Output 2	**Definition**	**Nov 2014**	**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**	**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.**
Output 2	Indicator 2.1	Nov 2014	% target population (disaggregated by age and gender) who name a nationally approved and quality assured first-line ACT as the most effective treatment for malaria	% of target population who know that a person with fever should receive a diagnostic test for malaria within 24 hours of the onset of fever
Output 2	Indicator 2.2	Nov 2014	% target population (disaggregated by age and gender) who can correctly state the treatment regimen for a nationally approved and quality assured ACT	% of target population who can identify an outlet who can perform a malaria RDT.
Output 2	Indicator 2.3	Nov 2014	% target population (disaggregated by age and gender) who can name a source where a nationally approved and quality assured first-line ACT can be purchased	Dropped
Output 3	**Definition**	**-.-**	**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.**	**No changes**
Output 3	Indicator 3.1	Jul 2016	% target outlets with nationally approved and quality assured RDTs in stock at time of survey	% of outlet providers who offer/carry out RDT testing to the MC (**among priority outlets who received RDT training**)
Output 3	Indicator 3.2		% target outlet providers that correctly state the 5 key steps in conducting a rapid diagnostic test for malaria	% 'priority' outlet providers that correctly describe and demonstrate the 5 key steps in the process of conducting and interpreting a rapid diagnostic test for malaria (denominator = total number of priority outlet providers who offer/carry out RDT testing to MC)

Output 3	Indicator 3.3	Jan 2016	Not initially included	% of outlet providers who did not provide any AM treatment if the test result showed negative (**priority outlets providers who offer/carry out RDT testing to MC**)
Output 3	Indicator 3.4	Jul 2016	Not initially included	% of clients of PSI trained AMTR outlet providers who completed a full course of QA-ACT (**among outlets who received QA-ACT**)

11.5. Annex 5: Final log-frame with results

	Myanmar Arteminsinin Resistance Containment Plan (Private sector component: Rapid monotherapy replacement)							
IMPACT	**Impact Indicator 1**		**Baseline/Milestone (Y1 -2012)**	**Milestone 1 (Y2-2013)**	**Target (date) (Y3-2014)**	**Y4-2015**	**Y5 -2016**	**Assumptions**
To prevent (or at minimum significantly delay) the spread of artemisinin resistant Plasmodium falciparum parasites within Myanmar and beyond its borders [1]	Parasite clearance rates in eastern Myanmar [2] Indicator related to the genetic marker mapping across the region (language TBD later).	**Planned**	25% (artesunate) on China border; 10-20% (one ACT) on Thai border; ACT treatment failure rate currently <10% [3]	**No target is set. PSI will monitor the studies carried out by MOH in Myanmar and will report.**	**No target is set. PSI will monitor the studies carried out by MOH in Myanmar and will report.**	**No target is set. PSI will monitor the studies carried out by MOH in Myanmar and will report.**	**No target is set. PSI will monitor the studies carried out by MOH in Myanmar and will report.**	Assumptions: Sentinel site surveillance (and genetic marker mapping) within Myanmar is allowed by GoM and completed in a timely manner (with results disseminated to MARC partners); Spread of resistant P.falciparum parasites follows previous patterns observed with antimalarials such as chloroquine (i.e. SE Asia westwards to South Asia and then to sub-Saharan Africa)
		Achieved		**The three first-line ACTs used in the country are still effective as treatment for uncomplicated falciparum malaria, with high cure rates.***	**No decrease in parasite clearance rate from baseline has been detected in the sentinel studies carried out.**			
		Source						
		Sentinel site surveillance (and genetic marker mapping), collected by WHO within the MARC framework, indicating the extent of artemisinin resistance in eastern Myanmar (and other regional sites in Asia and sub-Saharan Africa as appropriate.) [4] ***Status update on artemisinin resistance, WHO, January 2014.** Therapeutic efficacy studies routinely carried out at sentinel sites in Myanmar.						

OUTCOME	Outcome Indicator 1		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date)[6](Y3-2014)	Y4-2015	Y5 -2016	Assumptions
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).	% target population with fever in the last two weeks who received a diagnostic test for malaria (within 24 hours of the onset of fever)			5.2% (12%)	Baseline = 2.7%	15% (7.5%)	30% (15%)	
		Achieved			Indicator have not commenced yet.	5.6% (3.9%)		
		Source						
		Source: Annual Household Surveys - 2013, 2014. **TBD for 2015 and 2016 depending on the avialbility of resourses.**						
	Outcome Indicator 2		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2-2013)**	**Target (date) (Y3-2014)**	**Y4-2015**	**Y5 -2016**	**Assumptions**
	% target population with fever in the last two weeks who received a diagnostic test for malaria and who did not receive any antimalaria treatment if the test showed negative			n/a	Baseline = 5.7%	7.5%	15%	it is expected that half of the clients among those who received RDT, which is 15% in above, do not receive any AM treatment for negative result.
		Achieved			Indicator have not commenced yet.	3.5%		
		Source						
		Source: Annual Household Survey. **TBD for 2015 and 2016 depending on the avialbility of resourses.**						
	Outcome Indicator 3 (DFID only) amended/final		**Baseline/Milestone (Y1-2012)**	**Milestone 1 (Y2-2013)**	**Target (date) (Y3-2014)**	**Y4-2015**	**Y5 -2016**	**Assumptions**
	Estimated number of P.f malaria cases (disaggregated by age and gender) treated nationwide with QAACT through DFID funding of this project.	Planned	N/A	**This indicator was added to be in line with other DFID funded malaria programs in Myanmar. The program does not treat malaria cases directly. The figures presented are estimates derived from sale figure. No target is set.**		TBD	TBD	Total estimated # of P.f cases treated nationwide with QAACT under this grant - 191,637. BMGF contribution (20%) - 38,327
		Achieved		153,309	30,914	25,097		
		Source						
		Calculated as follows: **Year 2 (2013):** Number of QAACT courses distributed in Myanmar under AMTR project (including free samples) from Sept 2012 to Oct 2013 is 1,277,579; of them - 80% is funded by DFID (1,022,063); of them, after applying National average RDT positive rate of 25%, those who are actually treated for malaria (255,519); of them, after applying Pf to P.V ratio of 60:40 based on the data from PSI SUN channel, those treated for P.F cases are (153,309); male to female ratio is 70:30 (107,317 cases are male while the rest are female). **Year 3 (2014):** Total # of QAACT distributed (from Nov 2013 to Sep 2014) is 257,612 . Among them - 80% is funded by DFID (206,090). Applying the average national RDT positive rate of 25%, those who are actually treated for malaria (51,523). Pf to Pv ratio is 60:40. Therefore, among those who are malaria cases, P.F cases are 30,914. Male to female ratio is 70:30 (21,640 cases are male while the rest 9,274 are female). **Year 4 (2015):** Total # of QAACT distributed (from Oct 2014 to Sep 2015) is 402,201 . Among them - 80% is funded by DFID (321,761). Applying the average national RDT positive rate of 13% in 2014 (mentioned in National Strategic Plan), those who are actually treated for malaria (41,829). Pf to Pv ratio is 60:40. Therefore, among those who are malaria cases, P.F cases are 25,097. Male to female ratio is 70:30 (17,568 cases are male while the rest 7,529 are female).						

INPUTS ($)	DFID ($)	BMGF	Good Ventures	Other (PI) ($)	Total ($)			DFID SHARE (%)
	$17,655,000	$7,500,000	$ 1,000,000	$0	$26,155,000			68%

OUTPUT 1	Output Indicator 1.1		Baseline[10]/Milestone (Y1)	Milestone 1[11] (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	Assumptions
Increased opportunity, ability and motivation of private providers to effectively test for and appropriately treat Pf malaria.	% target outlets with nationally approved and quality assured first-line ACT in stock at time of survey [9]	Planned or baseline	Priority outlets = 4.47 %	Priority outlets target = 50%;	Priority outlets target = 75%;	85%	95%	Supply chain not interrupted by conflict, currency or constitutional changes. Initial estimated volume of ACTs inserted at the top of the supply chain is sufficient. Import regulations do not change significantly, affecting procurement planning and supply chain management. Mystery client methodology appropriate for more rural communities. Outlet survey data is cross-referenced with household survey data (as per ACTwatch methodology). Fluctuations anticipated in ACT stocking behavior and associated knowledge regarding the recommended drug due to decline in fever prevalance and increase in RDT use.
		Achieved		Priority outlets = 50.4 % (61.7%)^	79.0%	59.5%		
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						
	Output Indicator 1.2		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	
	% target outlets with no reported stock-out of nationally approved and quality assured first-line ACT lasting more than 1 week within the past 3 months (denominator = those outlets that normally stock ACT)	Planned or baseline	Priority outlets = 99 %	Priority outlets target = 100%	Priority outlets = 80%	85%	90%	
		Achieved		Priority outlets = 32.7%* (34.4%)	80.6%	74.0%		
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						
	Output Indicator 1.3		Baseline[10]/Milestone (Y1)	Milestone 1 (Y2)	Target (date) (Y3)	Y4-2015	Y5 -2016	
	% target outlets selling nationally approved, quality assured ACT at a price less than or equal to the cost of a typical dose of the most common artemisinin monotherapy at baseline [12]	Planned or baseline	n/a[¥]	Priority outlets target = 70%	Priority outlets = 70%	80%	80%	
		Achieved		Priority outlets = 90.9% (90.0%)	79.3%	91.9%		Fluctuations anticipated in ACT stocking behavior and associated knowledge regarding the recommended drug due to decline in fever prevalance and increase in RDT use.
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						
	Output Indicator 1.4		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	
	% target outlet providers that correctly state the recommended first line ACT treatment for uncomplicated malaria	Planned or baseline	Priority outlets = 5.5%	Priority outlets target = 25%	Priority outlets = 20%	50%	60%	
		Achieved		Priority outlets = 21.6%* (26.1%)	36.8%	24.4%		
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						

	Output Indicator 1.5		**Baseline/Milestone (Y1)**	**Milestone 1 (Y2-2013)**	**Target (date) (Y3-2014)**	**Y4-2015**	**Y5 -2016**	This is the single most important indicator in the logframe as it succinctly reflects the relative sales volume of ACT versus the oAMT product it is displacing.
	Output Indicator 1.5 Relative ratio of volume of ACT to Oral Aremisinin Monotherapy (sold in the past 7 days) **€** 1) quality assured (QA) ACTs; 2) oral artemisinin monotherapies	**Planned or baseline**	For Priority Outlets ACT = 3% Oral Artemisinin Monotherapy = 97%	For Priority Outlets ACT target = 50% Oral Artemisinin Monotherapy target = 50%	For Priority Outlets ACT target = 95% Oral Artemisinin Monotherapy target = 5%	**For Priority Outlets ACT target = 85% Oral Artemisinin Monotherapy target = 15%**	**For Priority Outlets ACT target = 90% Oral Artemisinin Monotherapy target = 10%**	
		Achieved		For Priority Outlets ACT = 73% oAMT = 27% (ACT = 77% oAMT = 23%)	**ACT = 79% oAMT =21%**	**ACT = 74.4% oAMT = 25.6%**		
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						
IMPACT WEIGHTING (%)	**Output Indicator 1.6**		**Milestone (Y1)**	**Milestone 1 (Y2-2013)**	**Target (date) (Y3-2014)**	**Y4-2015**	**Y5 -2016**	
40% [14]	% target outlets with RDTs in stock at time of survey	**Planned or baseline**	Priority outlets = 3.5%	Priority outlets target = 5%;	**10%**	**15%**	**30%**	
		Achieved		**Priority outlets = 5.4%**	**Priority outlets target = 10%**	**13.1%**		
		Source						
		Source: Baseline Outlet Survey - 2012 Target: Annual Outlet Surveys at 2013 , 2014, 2015 and 2016.						
INPUTS (HR)	**DFID ($)**	**BMGF ($)**	**Govt ($)**	**Other (PI) ($)**	**Total ($)**			**DFID SHARE (%)**
	$2,454,483	**$987,242**	**$-**	**$0**	**$3,441,725**			**70%**

OUTPUT 2	Output Indicator 2.1		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	Assumptions
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.	% of target population who know that a person with fever should receive a diagnostic test for malaria	Planned or baseline	NA	43%	Baseline = 38%	50%	70%	Concumer targeted behavior change communication campaign creating demand for RDT (mass media and IPC) has been started to roll out.
		Achieved			Indicator have not commenced yet.	50.2%		
		Source						
		Source: Annual Household Surveys - 2013, 2014. TBD for 2015 and 2016 depending on the avialbility of resourses.						
IMPACT WEIGHTING (%)	Output Indicator 2.2		Baseline/Milestone (Y1)	Milestone 1 (Y2)	Target (date) (Y3)	Y4-2015	Y5 -2016	
20%	% of target population who can identify an outlet who can perform a malaria RDT.	Planned or baseline	NA	NA	Baseline = 16%	25%	50%	
		Achieved			Indicator have not commenced yet.	34%		RISK RATING
		Source						
		Source: Annual Household Surveys - 2014. TBD for 2015 and 2016 depending on the avialbility of resourses.						High
INPUTS ($)	DFID ($)	BMGF	Govt ($)	Other (PI) ($)	Total ($)			DFID SHARE (%)
	$13,996,890	$5,904,649	$ -	$0	$19,901,539			70%
INPUTS (HR)	DFID (FTEs)							

OUTPUT 3	Output Indicator 3.1		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	Assumptions
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.	% of outlet providers who offer/carry out RDT testing to the MC (among priority outlets only)		NA±	NA	Baseline = 0.83%	15%	30%	
		Achieved			Indicator have not commenced yet.	5.6%		
		Source						
		Baseline: Baseline mystery client survey 2013, 2014. Milestones and Target: Annual mystery client surveys to be cross referenced with household and outlet surveys.						
IMPACT WEIGHTING (%)	Output Indicator 3.2		NA£	Baseline/Milestone 1 (Y2)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	
40%	% 'priority' outlet providers that correctly describe and demonstrate the 5 key steps in the process of conducting and interpreting a rapid diagnostic test for malaria (denominator = total number of priority outlet providers who offer/carry out RDT testing to MC)	Planned or baseline	NA[f]	43.9% (RDT pilot townships)	Baseline = 0.83%	30%	60%	
		Achieved			Indicator have not commenced yet.	96.2%		RISK RATING
		Source						
		Mystery Client Surveys						High
	Output Indicator 3.3		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	
	% of outlet providers who did not provide any AM treatment if the test result showed negative (priority outlets only) (denominator = total number of priority outlet providers who offer/carry out RDT testing to MC)		NA±	NA	Baseline = 0.83%	30%	60%	
		Achieved			Indicator have not commenced yet.	96.2%		
		Source						
		Baseline: Baseline mystery client survey 2013, 2014. Milestones and Target: Annual mystery client surveys to be cross referenced with household and outlet surveys.						
	Output Indicator 3.4		Baseline/Milestone (Y1)	Milestone 1 (Y2-2013)	Target (date) (Y3-2014)	Y4-2015	Y5 -2016	
	% of clients of PSI trained AMTR outlet providers who completed a full course of QAACT (denominator = total number of clients of PSI trained AMTR outlet providers who received QAACT numerator = number of clients of PSI trained AMTR outlet providers who completed the full course of QAACT)		NA	NA	NA	TBD	TBD	
		Achieved						Our estimated time line to carry out the follow up study is Jan-Feb 2016, and thus the results may not be available for annual AMTR progress report (due on 31 Dec 2015) and until next annual review (in Feb 2016), and the target will be determined later.
		Source						
		Baseline: Baseline Patient Follow Up Study (Jan 2016) Milestones and Target: Annual Patient Follow Up Study						
INPUTS ($)	DFID ($)	BMGF	Govt ($)	Other (PI) ($)	Total ($)			DFID SHARE (%)
	$1,203,627	$608,109	$ -	$0	$1,811,736			70%
INPUTS (HR)	DFID (FTEs)							

End Notes

[1] MARC Impact Goal

[2] WHO working definition: (1) An increase in parasite clearance time, as evidenced by 10% of cases with parasites detectable on day 3 after treatment with an ACT (suspected resistance); or (2) Treatment failure after treatment with an oral artemisinin-based monotherapy with adequate antimalarial blood concentration, as evidenced by the persistence of parasites for 7 days, or the presence of parasites at day 3 and recrudescence within 28-42 days (confirmed resistance).

[3] Within the MARC framework, WHO is reviewing current sentinel surveillance data for Myanmar and is in the process of expanding and improving surveillance. PSI anticipates having an improved baseline with standardized methodology before drugs are deployed, and annual data with which to monitor this indicator.

[4] As described in MARC section 8.7.1."Monitoring and surveillance to assess Artemisinin resistance" WHO will conduct Therapeutic Efficacy Studies annually in 9 sites nationwide, and establish a further 20 sites using microscopy to monitor Day 3 parasite loads
[5] Quality assured refers to ACTs that meet stringent regulatory authority approval and WHO pre-qualified status.

[6] An additional 7% are treated with CQ (for P.vivax malaria).

[7] Ngasala, B.E., et al. (2011). Effectiveness of artemether-lumefantrine provided by community health workers in under-five children with uncomplicated malaria in rural Tanzania: an open label prospective study. Malaria Journal 2011, 10:64, Smithuis, F. et al. (2006). Efficacy and effectiveness of dihydroartemisinin-piperaquine versus artesunate-mefloquine in falciparum malaria: an open-label randomized comparison. Lancet 2006; 367: 2075–85.

[8] The relatively large number of indicators associated with this output reflect international best practice for pharmaceutical outlet/audit surveys (see notes re: M&E in narrative and appendices) and mirror those used for the BMGF-funded ACTwatch project. Combined, they also relate to the DFID Malaria Framework for Results [output] Indicator (f); Average availability of 14 selected essential medicines in public and private health facilities, plus a first-line ACT for the treatment of uncomplicated malaria.
[9] Target outlets arepriority outltes and providers (Pharmacies, Retail stores and drug vendors) in the private sector able to stock and dispense antimalarials.
[10] Number of target outlets to be determined. Estimates range from 10-50,000.

[11] This particular milestone could differ significantly from that stated here due to the predicted rapidity of the "switch" once ACT is available, monotherapies are banned and old stocks of monotherapies are sold (typically only 3 months of stock are carried).
[12] This will be inflation linked. Influence over this will be limited.
[13] Not applicable as no outlets currently sell ACT at the same price as a typical monotherapy.

[14]Published data suggests that treatment compliance is significantly improved when interventions focus on providing effective treatment, provider knowledge and behavior, packaging and provision of correct dosages. Yeung and White (2005) Trop. Med. Int. Health. vol 10, no.2: pp 121-138.
[15] Target population defined as total population within target townships (risk associated primarily with proximity to forest cover).

Out of 5 private outlet types, the 3 outlets (pharmacy/drug stores, itinerant drug vendors and general stores) are defined as "Priority Outlets" for AMTR project as these outlets are the main sources of AMT.

^ Data reported in 2013 were for combined intervention and comparison areas. This decision was made because the program had only been operational for ~8 months at the time of survey and it was not believed that large differences between intervention and comparison areas would be captured by the Outlet Survey. For 2014, only intervention areas are reported in the logframe, since these are the figures that best reflect the impact of the program. For comparison, PSI has gone back and calculated the intervention-only results for 2013. These are presented in parentheses for each indicator for which the results are available.

* This indicator was incorrectly calculated in 2013 and the logframe has been corrected for the back period. The indicator is calculated as the percentage of outlets with no reported disruption of stock of Supa Arte 4 within the past 3 months, among outlets with Supa Arte 4 in stock on the day of the survey or within the past 3 months.

¥ This indicator was not able to measure in baseline OS survey because no ACT is available in priority outlets (purely private outlets), and in the private/public mixed outlets (Private GP and Health Workers), responded reported as ACT was provided as free of charge although service fee was charged.

€ This indicator was derived from market share data of all anti malaria drugs.

± This indicator was not measured at baseline (Year 1) as the availability of ACT was almost 0% in private sector particularly at priority outlets.

£ This indicator was not measured at baseline OS survey because PSI has not started RDT deployment in the private sector, and no RDT were available in priority outlets.

Output	DFID	BMGF	PI	Total By output
Output 1 - Providers	£ 2,800,101	£ 861,458	£ 219,634	£ 3,881,194
Output 2 - Users	£ 11,539,487	£ 3,550,152	£ 905,133	£ 15,994,773
Output 3 - Testing	£ 896,756	£ 275,889	£ 70,340	£ 1,242,985
Total	£ 15,236,345	£ 4,687,500	£ 1,195,107	£ 21,118,952

11.6. Annex 6: Additional graphs of evaluation outcomes

Figure 13: Average monthly sales by AA-Pharmaceuticals before and after the start of the second distributor in the 15 states where both operated.

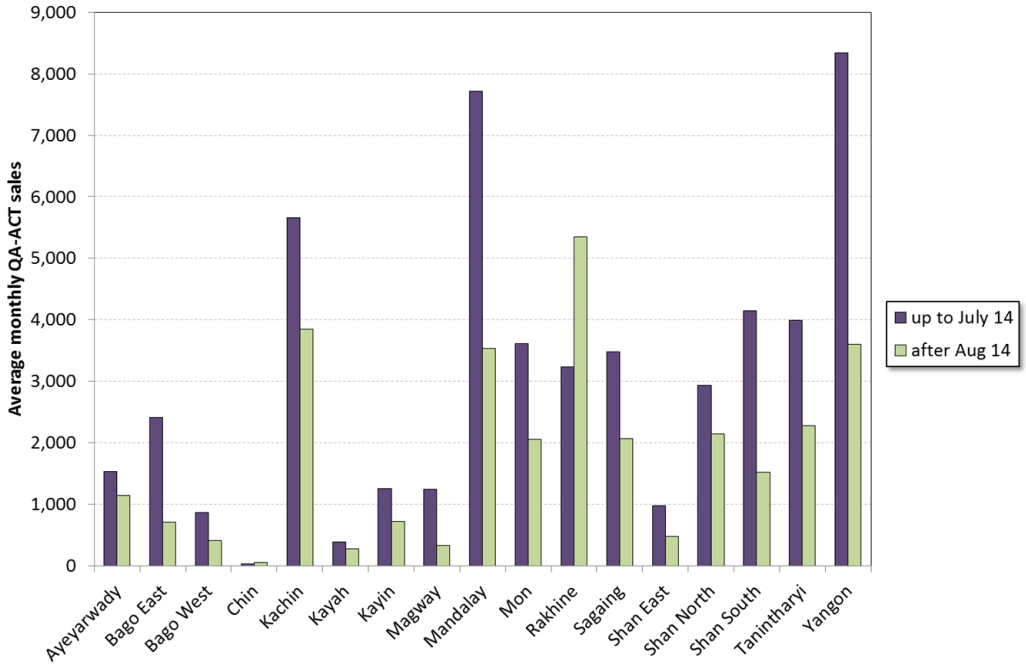


Figure 14: Monthly QA-ACT sales by the AMTR project compared to the proportion of adult doses and the malaria test positivity from SunHealth franchise clinics.

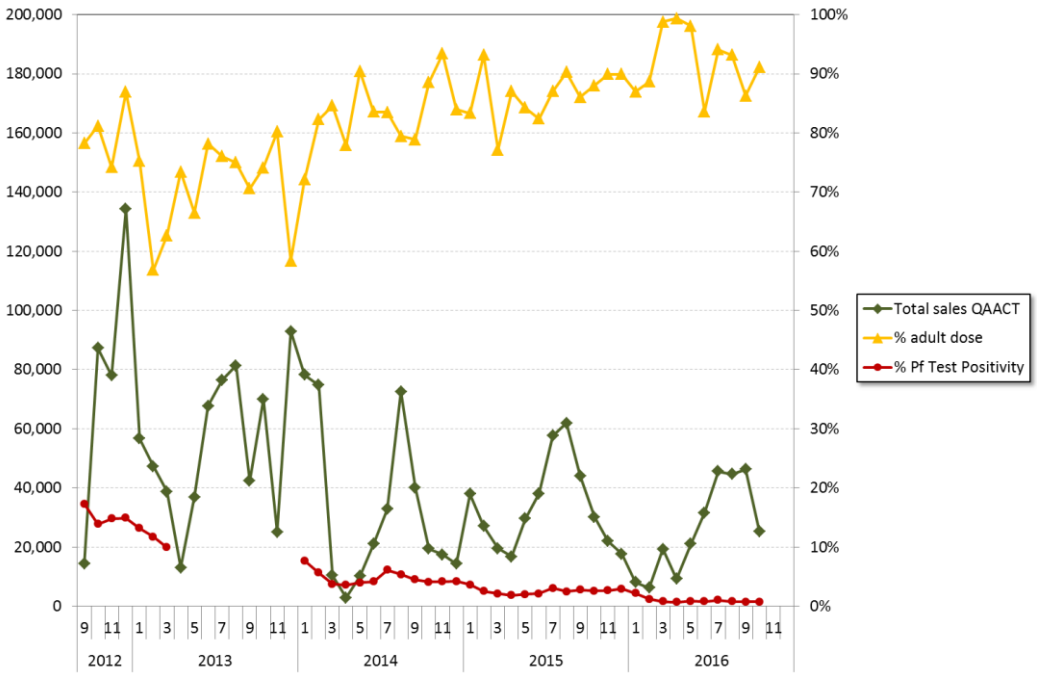


Figure 15: Sales share of antimalarials private clinics and among CHW from AMTR outlet surveys. Intervention area corresponds to the core target townships with intense promotion. iAMT=injectable AMT, nQA-ACT=non-quality assured ACT.

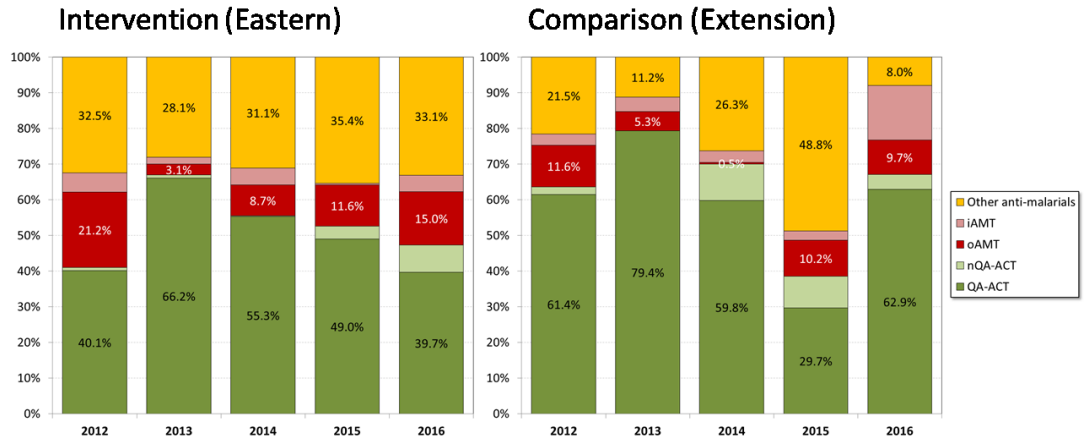
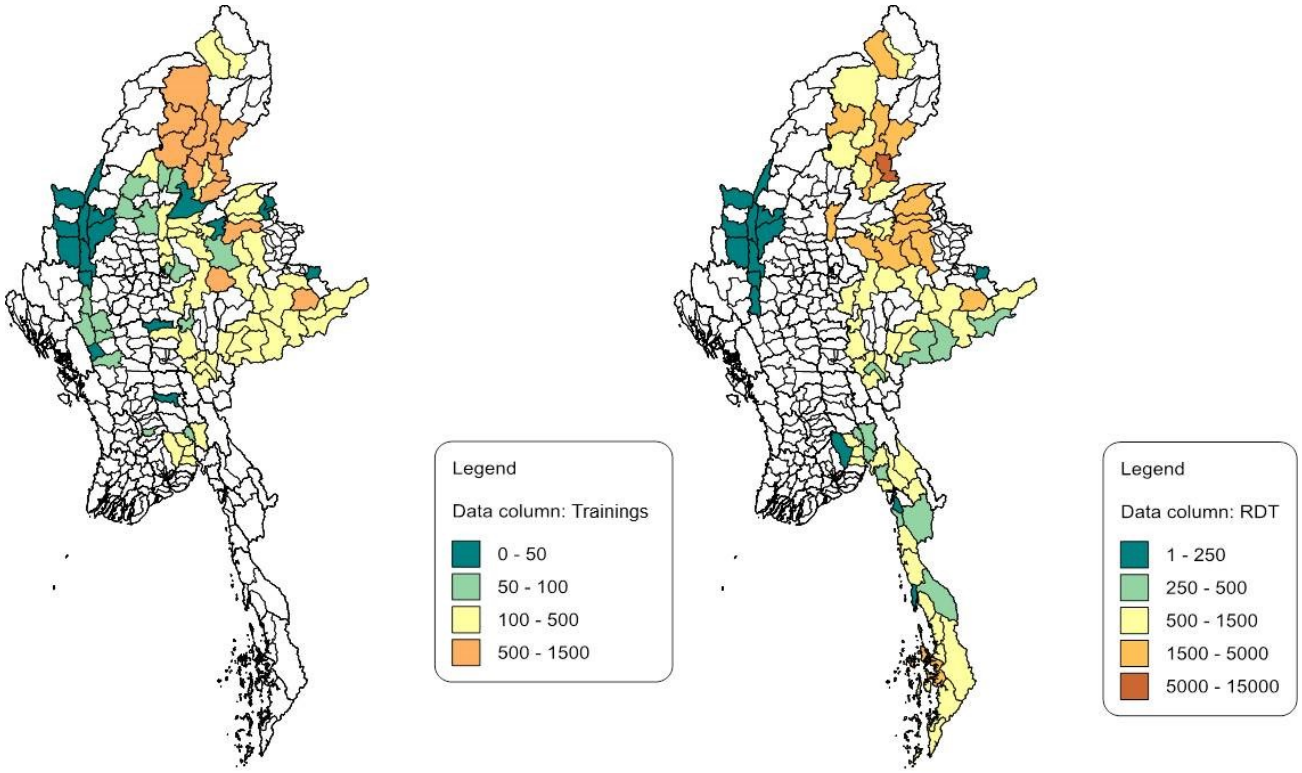


Figure 16: Map of roll-out of RDT training and RDT use by March 2016



11.7. Annex 7: List of people interviewed

Organization	Name	Position
DFID	Nan Hom Nwet	Programme Officer
	Nichola Cadge	Steering Committee AMTR evaluation
	Billy Stewart	Head of Human Development and Senior Health Adviser
Gates Foundation	Thomas Kanyok	Steering Committee AMTR evaluation
PSI	David Valentine	Deputy Country Director
	Daniel Crapper	Senior Strategy Director
	Dr Aung Kyaw Linn	Director Health Services
	Dr Tin Aung	Director Strategic Information
	Dr Si Thu Thein	Dep. Director Strategic Information
	Dr Hnin Su Su Khin (Ma Su)	Deputy Director (Malaria and Child Survival)
	Dr Aung Kyaw San	Deputy Director – Operations Health Services
	Dr Nay Min Tun	Deputy Director Communication
	Zaw Win	Research Manager
	George Aung Aung	Partnership Manager, AMTR Project
USAID	Mya Sapal Ngon	Health Program Manager
	Feliciano Monti	PMI Senior Malaria Advisor
JICA	Matsatoshi Nakamura	Advisor Health
Save the Children	Min Min Thein	Head of Malaria
John Snow International (JSI)	Chris Warren	Senior Advisor supply chain and procurement
University Research Company (URC)	Dr Saw Lwin	Country Director (CAP Malaria)
Malaria Consortium	Ruth Dixon	Country Director
Ministry of Health	Dr Thar Tun Kyaw	Director (Disease Control), Dept. Health
	Dr Than Win	Dep. Director (Disease Control), Dept. Health
	Dr Thaung Hlaing	Deputy Director (Malaria), Dept. Health
	Dr Myat Phone Kyaw	Dep. Dir. General Dept. of Medical Research
	Dr Aung Thi	Malaria Programme Manager
Myanmar Federal Drug Administration	Dr Thinzar Htike	Assistant Director
Ministry of Defence	Col. Tin Maung Hlaing	Commandant, Defence Services Research Centre
	Lt Col. Khin Phyu Pyar	Ass Prof. /Consultant Physician, Defence Services Medical Academy
WHO	Dr Gawrie N.L. Galappaththy	Technical Officer (Malaria Unit)
	Dr Krongthong Thimasarn	Medical Officer, Malaria
	Dr Md. Mushfiqur Rahman	Technical Officer Malaria
UNOPS	Dr Eisa Hamid	M&E Specialist
Myanmar Medical Association (MMA)	Dr Myo Min	Project Manager
AA Medical Products Ltd	Zaw Moe Khine	Chairman & CEO

Organization	Name	Position
	Dr Saw Nay Nwe	Executive Director
	Dr Thin Nwe Win	Director Sales
Polygold Ltd	Kyaw Kyaw	Marketing Manager Lower Myanmar
	Kyaw Lin Han	PA to Managing Director
Shwin Chan Trading (SD Diagnostics)	Han Min Shein	Director
	Aung Than Oo	Business Development Executive
Myanmar Health Development Consortium (MHDC)	Sandii Lwin	Managing Director