Unitaid project evaluation: Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS–SMC)

November 2016 – April 2017

FINAL REPORT

EXECUTIVE SUMMARY

OVERVIEW

Unitaid has made a USD 67 million grant to Malaria Consortium (MC) to implement a malaria prevention program: Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC). To date, various challenges have prevented adoption at scale of Seasonal Malaria Chemoprevention in the Sahel. On the demand side, healthcare systems and funders have not shown demand for expanding the treatment at scale. On the supply side, the global market has historically not supplied treatments at the volume or in the formulations needed. The ACCESS-SMC project aimed to overcome these challenges by (i) providing SMC treatment in seven countries, and; (ii) working with market actors, including potential donors and new manufacturers, to change market dynamics.

This report evaluates programmatic implementation of the project with a particular focus on the overall progress towards the projects' health and market objectives. Unitaid commissioned Dalberg to evaluate ACCESS-SMC. Dalberg has assessed the grant across five dimensions – relevance, effectiveness, sustainability, efficiency, and learning and risk mitigation[1]. We identified issues from this assessment and subsequently provided recommendations to address them. Dalberg did not conduct a data audit per se, but used interviews and document reviews to assess information consistency.

RELEVANCE

ACCESS-SMC's design aligned closely with Unitaid's overall mission and two of its strategic objectives. Its focus on scaling access to a recently approved form of mass drug administration to prevent malaria in children directly supported Unitaid's strategic objective 6 – to increase access to products for the prevention of malaria – and also supported strategic objective 2. In addition, the program aligned well with Unitaid's overall mission due to (i) its global market-based approach to scaling-up the use of anti-malaria drugs and (ii) its emphasis on reaching disadvantaged areas.

The project's intended outcomes were relevant to the challenges facing SMC, but the logframe could have more explicitly linked activities to outputs and intended outcomes.[2] Some of the objectives included at the "output" level would be more appropriate at other levels, and some project activities were not linked to output metrics. This created some difficulty to assess which activities had contributed to changes in outputs and outcomes.

EFFECTIVENESS

[1] Sustainability is assessed as a dimension of effectiveness, since project work streams related directly to changes in the market landscape (output 1) and mobilization of resources (output 5).
[2] Comments refer to the latest logframe. The original logframe was substantially revised in 2015.

The program was largely effective despite challenging conditions. ACCESS-SMC met most of its targets for procuring and delivering treatments directly. Its targets in supporting broader transformation are generally longer-term in range but most appear to be on track.[3]

Public health

Output 2: SMC products efficiently procured

MC secured its targeted procurement volumes.[4] In 2015 there was a global shortage of sulfadoxine-pyrimethamine plus amodiaquine combination (SP+AQ), the drug combination used in SMC. Global supply of the drug was reduced to 16 million treatments. ACCESS-SMC procured 14.8 million of these. In 2016, ACCESS-SMC met its target of procuring 30 million treatments.[5]

There were no substantive delays to drug procurement and delivery in 2015. However, in 2016, delays in placing SP+AQ orders delayed drug delivery, requiring some adjustment to implementation plans. In agreement with Unitaid, Malaria Consortium placed orders for SP+AQ for the 2016 cycles in February 2016, which was two to three months later than planned. This contributed to drug shipment delays in five countries of between two and six weeks. This delay, and poor communication of timelines by the procurement agent, resulted in last-minute changes to drug distribution plans and cost 3% of 2016 commodity costs.

The impact of these procurement-related delays on distribution cycles was limited, nevertheless they compounded delays to four cycles in Chad and Nigeria in 2016, and the third cycle in Guinea in 2016. In Guinea in 2016, the third cycle was delayed by ten days. In Chad, each cycle was delayed by a month due to government related administrative issues outside grantee control. Similarly, there were significant delays in Nigeria due to severe administrative hold-ups but these were outside the control of grantees. There were no procurement-related delays in other countries in 2016.

Country offices report limited problems with stockouts. There were no stockouts at the national level and few stockouts at the district level.[6]

Data are not yet available on the levels of stock left over at the end of 2016; however the grantee consortium reallocated stock as an attempt to reduce the number of treatments that remained unused. The decision to allow a 10% buffer for waste, loss and spoilage made it likely that some stock would be unused at the end of the project. Where there was stock leftover, it has been

[3] S.Kant, a new manufacturer slated to enter the market during the programme has not yet entered the market, however they are expected to begin production in 2018.
[4] For 2016, when left-over stock is taken into account, the target was exceeded.
[5] It is important to note that according to Unitaid, MC should have accounted for 2015 stock when placing orders for 2016.
[6] In Mali, CRS and the Pharmacie Populaire du Mali, the state pharmaceutical distributor, had a dispute over fees which led to some stockouts in some districts. In Niger, there were some district-level stockouts as district supply chain managers did not order new stock when supplies were low, although there was sufficient stock in central stores. There were potentially some stockouts in Chad, but the Dalberg team is awaiting confirmation from the relevant stakeholders in Chad.

donated to NMCPs. MC reallocated treatments procured for 2016 into countries with higher demand based on the amount of stock left over from 2015.[7]

Output 3: SMC treatments administered

ACCESS-SMC has reached its target number of children and six of the seven countries reached their national targets in each year. In 2015, the program administered 12.5 million treatments to at least 3.2 million children. In 2016, it administered 25.0 million treatments to at least 6.9 million eligible children.

The project appears to have achieved its targeted coverage rate despite challenging environments. According to administrative data gathered during the project, in each cycle most countries reached the target of covering 80% of the eligible children in target districts – with the exceptions of Niger in 2015 and Mali in 2016. Household surveys conducted for the 2015 campaigns indicate that over 80% of target populations received at least one treatment across all countries but Nigeria.

ACCESS-SMC set up systems to ensure the safety of treatment and identified few severe adverse reactions. In each country, LSHTM supported development of national pharmacovigilance systems. Out of 12.5 million administrations in 2015, there were 10 serious adverse events; no adverse events have yet been recorded for 2016 but this may change as records are finalized. Of the ten-reported serious adverse events, two resulted in hospitalisation (in Chad and the Gambia), while eight were treated on site. One case resulted in a death (in Niger); whether this can be attributed to SMC is still being investigated.

Market transformation

Output 1: Global production of quality and acceptable SMC increased

No second manufacturer will enter the global SP+AQ market until at least 2018 due to market events outside the grantee's control. The consortium selected a second manufacturer – S Kant – to receive project support to become a WHO-approved provider of dispersible SP+AQ by 2016.[8] MMV provided support in the form of a technical consultant and subsidies for product development. However, S Kant was unable to obtain the necessary active pharmaceutical ingredient (API) after the only global sulfadoxine API supplier was disqualified from WHO's pre-qualification list. It would have been challenging for the grantees to foresee this risk. Since this event, MMV has continued to provide support and S Kant is likely to enter the market by 2018. The previously disqualified global sulfadoxine API supplier has been reinstated to the WHO pre-qualification list.

Global production and production capacity of quality-assured SP+AQ has increased over the course of the project. Global production has increased from 6 million SP+AQ treatments in

[7] A large proportion of stock was reallocated to Burkina Faso, however as of May 2017 this stock has not been used.
[8] SMC Semi Annual Report. 2016.

2014, to 35 million in 2015, to 67 million in 2016.[9,10] In 2015, Guilin invested in both the in-house manufacture of SP API and a blistering machine, to increase annual capacity to approximately 90 million treatments in 2016. This remains the only pre-qualified source SP globally. Since Guilin remains the only manufacturer and estimated global need is 100 to 120 million, global capacity does not yet meet demand but is likely to once S Kant enters the market as is expected in 2018.

ACCESS-SMC has supported development of a market for dispersible SP+AQ formulations. Guilin began developing a dispersible formulation of SP+AQ in 2012 after the WHO's recommendation on use of SMC in the Sahel (prior to commencement of the ACCESS-SMC initiative).[11] Nevertheless, according to Guilin, demand from ACCESS-SMC expedited supply expansion of the dispersible formulation. Production of dispersible tablets began in 2016, and ACCESS-SMC procured 23.5 million dispersible treatments that year.[12]

Output 4: Affordability of SMC delivery improved

ACCESS-SMC maintained the favorable drug prices secured in 2015 for 2016.

The project demonstrated that SMC programs can be conducted cost effectively. MSH's cost effectiveness study found that, on average across all countries in 2015, recurrent costs are equivalent to USD 4.35 per four-cycle annual course of treatments, which is below the project target of USD 5.00.[13,14] Average costs were lower than this target in four of the six countries where data are available.[15] Stakeholders agreed that further substantial cost savings are unlikely for the general ACCESS-SMC model.[16]

The ACCESS-SMC model's cost-effectiveness is comparable to other malaria interventions. A very approximate calculation of the recurrent costs of ACCESS-SMC per disability-adjusted life-year (DALY) suggests cost-effectiveness is similar to insecticide-treated nets and Indoor residual spraying (IRS). These calculations also suggest ACCESS-SMC is highly cost-effective according to the definition of the World Health Organization's Choosing Interventions that are Cost-Effective initiative (WHO CHOICE).

Output 5: Additional resources for SMC mobilized

[9] Email communication from Guilin, 16 December 2016.
[10] Guilin's 35 million production in calendar year 2015 exceeds other stakeholders' assessments of a global production of 16 million for distribution in-year because some of the drugs manufactured by Guilin in 2015 were for use in 2016.
[11] Expert interview
[12] SMC Annual Report 2015.
[13] David Collins. Management Sciences for Health. The cost and Impact of ACCESS-SMC – Transforming the Malaria Landscape in the Sahel: Seasonal Malaria Chemoprevention. June 2016.
[14] Cost effectiveness studies for the 2016 cycles have not been conducted.
[15] Costs exceeded the target in Guinea by USD 0.02 and in the Gambia by USD 1.07. Data were not available for Chad at the time of writing.
[16] However, some further reductions in unit cost may be possible through Integration with other programs delivering at scale in target communities during the rainy season – such as tuberculosis screening, nutrition checks, or other intermittent preventative treatments.

Transition funding from new donors is fully (four countries) or at least partially (two countries) in place for six of seven target countries. In 2017, The Global Fund will replace Unitaid as the largest SMC funder in Guinea, Mali, Niger, and the Gambia. CRS manages ACCESS-SMC in Guinea, Niger and Gambia, where it is also a principal recipient to the Global Fund, and its experience and relationships played an important role in mobilizing those resources.[17] The Global Fund will also take on funding for 14 additional districts in Chad. PMI is likely to provide funding to replace a portion of Unitaid's funding in Burkina Faso in 2018, but this is not confirmed as of February 2017. Unitaid is considering providing further funding for the ACCESS-SMC initiative in Burkina Faso, Nigeria, and Chad. It is likely that SMC will be included in Nigeria's Global Fund concept note in 2017, and possible that it will be included in Chad's and Burkina Faso's. It should be noted that Global Fund resources will not be sufficient to maintain the current levels of pharmacovigilance or drug resistance monitoring, and it is unclear if these activities will continue.

EFFICIENCY

The combination of two separate grant proposals created some project management efficiency gains, but also contributed to some inefficiencies. [18] Stakeholders report that MC and CRS forged a strong relationship, solved problems jointly and shared information when necessary. There were some instances where the relationship was less efficient. For example, the two agencies have different perceptions on the events that led to perceived slow change in distribution strategies in Niger. CRS shared that there was a delay switching distribution models because of the time required for MC's approval. MC noted that CRS asked to change the distribution strategy after the third cycle, when approval was immediately granted.

Grantees perceived Unitaid's administrative processes to be challenging. Unitaid did not approve the grant's final budget until 17 months after the project began, creating administrative burden for the grantee. MC found it difficult to comply with Unitaid's revised reporting requirements. The grantee noted that changes to the required reporting tools and accounting policies increased the administrative and managerial burden.[19]

National level planning was generally efficient, but long-term sustainability could be improved by greater involvement of NMCPs in supply chain planning. Grantee organisations managed implementation planning alongside NMCPs. Grantees report that this process of joint planning was efficient and successful at national and local levels.

In 2015, there were instances where MC did not follow procurement protocol, but these had limited impact on the program, and have since been corrected.[20]

IMPACT

[17] CRS was replaced as Global Fund PR by PSI in Mali

[18] ACCESS-SMC was delivered by a consortium of grantees – led by Malaria Consortium (MC) as prime recipient, subcontracting to five subgrantees, some of which used subsubgrantees.

[19] According to Unitaid the reporting format was revised to accommodate meaningful performance assessment.

[20] Documentation suggests that in some cases of protocol breach, there was agreement from Unitaid. Further detail in main body of report.

Initial estimates suggest that malaria incidence has been substantially reduced in target communities. MSH estimates that the 12.5 million treatments administered in 2015 will avert 1.03 million malaria cases and 5,395 deaths.[21] Interviewees have also reported a reduction in malaria cases in affected communities. Dalberg developed a model to extrapolate this impact over the period 2016-2022. Based on the assumptions used, SMC would avert a cumulative 50 million malaria cases and 260,000 deaths over that period. This translates to USD 117 million in cost savings overall. Additionally, using a SMC approach would transfer the financial costs of malaria from households, to program funders (i.e. donors and governments) because under a SMC program, households and health systems see fewer cases and no longer incur the expense of seeking healthcare.

The grant is on track to achieve the goal of reducing malaria incidence on a national level in the seven target countries. By demonstrating feasibility and effectiveness of SMC at scale across the Sahel, the program has increased donors' commitment to the model. This may in turn enable national-scale adoption. Mali is currently the only SMC country currently adopting the intervention on a national scale.

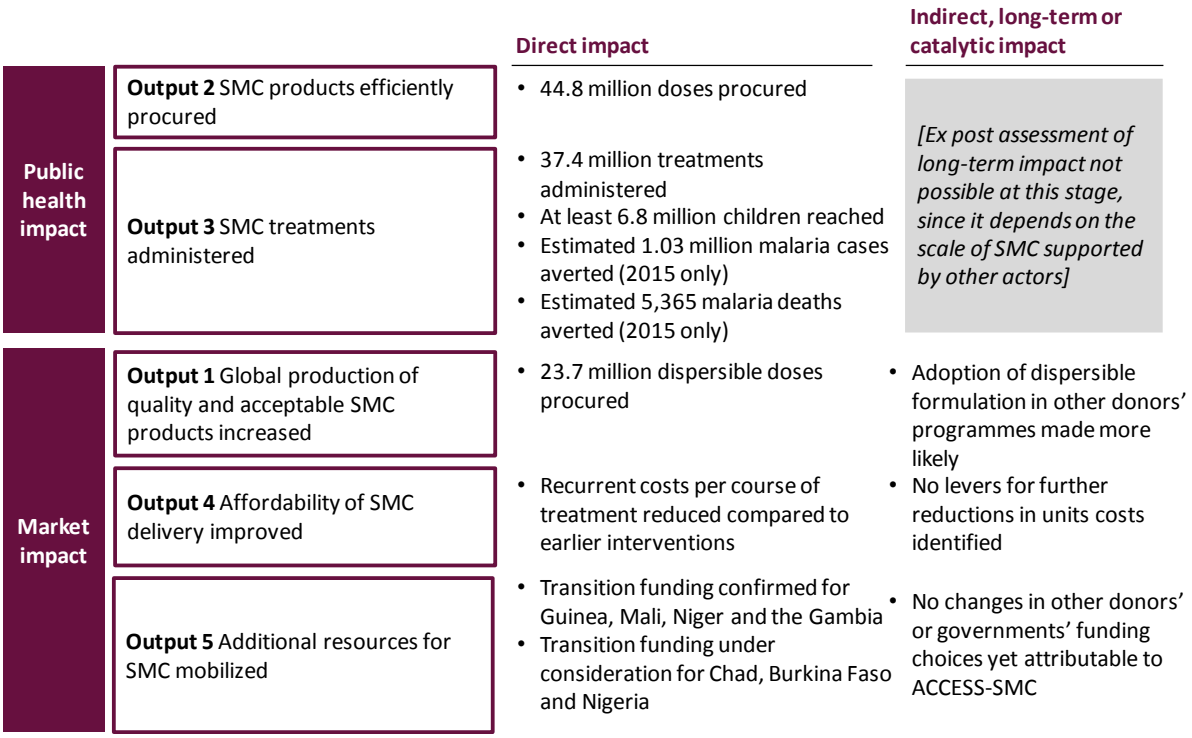
In the long-term, the balance between demand and supply of SMC products is uncertain. ACCESS-SMC has increased demand for products to-date and in the near future. Donors such as the Global Fund and the World Bank will be funding SMC till at least 2018. However, funding beyond 2018 has not been confirmed. On the supply side, S Kant will possibly enter the market in 2018 at the earliest. However, their production capacities remain a forecasted estimate, so is uncertain. The relationship between uncertain demand beyond 2018 and untested supply capacity could lead to a situation where demand and supply do not increase in tandem. Therefore, the market balance is uncertain beyond the end of Unitaid support.

VALUE-FOR-MONEY

The value-for-money assessment is detailed below. The project generated significant direct benefits, including treating almost seven million children whilst introducing a more acceptable treatment formulation in two seasons. The project also secured transition funding for four of the seven target countries. The longer-term impacts relate to the impact of greater supply of the dispersible formulation, and the successful proof-of-concept for SMC in general, which could lead to wider rollout in the future (although this cannot yet be identified or attributed to ACCESS-SMC).

[21] David Collins. Management Sciences for Health. The cost and Impact of ACCESS-SMC – Transforming the Malaria Landscape in the Sahel: Seasonal Malaria Chemoprevention. June 2016.

Figure 1. Ex-post assessment of value generated by ACCESS-SMC grant



LEARNING AND RISK MITIGATION

There are several examples of grantees and sub-grantees demonstrating adaptability and flexibility in response to feedback. Throughout the grant, SMC programs held learning-oriented meetings in each country to allow stakeholders to share lessons learned. Specific adjustments included the following: (i) CRS changed its distribution model from fixed-point to door-to-door based on findings from other countries that door-to-door administration could increase coverage; (ii) In Chad, MC redesigned tally sheets when the country office identified that health workers were making avoidable errors.

MC provided strong oversight of in-country operations to mitigation operational risks, and, introduced new procedures to manage managerial risk in response to Unitaid's review. MC did not initially report and track the risks and mitigating actions. However, beginning with the 2016 semi-annual report MC, identified, assessed, and described mitigation procedures for the risks it identified.

CONCLUSIONS AND RECOMMENDATIONS

Overall, the ACCESS-SMC initiative was successful in achieving its public health and market shaping outcomes, particularly given the rapid scale-up and level of in-country challenges. The ACCESS-SMC initiative reached its targets at output and outcome level with few, if any, serious delays.

ACCESS-SMC's success can be attributed to several success factors. The introduction of a new approach into several health systems simultaneously incentivized manufacturers and supported systems development on-the-ground. Using a light-touch approach, by providing

guidance and technical assistance to existing structures, helped build capacity for future sustainability. Additionally, providing options for alternative programmatic approaches, and leaving that choice up to grantees, enabled the program to become more effective over time.

There are several recommendations for future grants, emanating from the experience obtained during this grant.

The potential for follow-on funding is likely to be increased by working with partners who already have strong relationships with relevant donors. CRS's relationship with the Global Fund was crucial to attract Global Fund funding beyond the life of the Unitaid grant.

Maintaining consistent financial and programmatic reporting approaches can mitigate administrative and managerial burden. As far as possible, roles and responsibilities between grant maker and recipient should be agreed up front, and any changes should be clearly communicated.

Stakeholders should define policies on how to deal with unused treatments. Without a policy on how to treat leftover stock, it is challenging to assess the extent to which the grantee followed protocol.

Selecting reliable and relevant output indicators is paramount to encourage robust findings. The quality of administrative data varies widely across countries and this could have been considered during project planning, probably lending more focus to household surveys. Furthermore, given the fact children are required to participate in all four cycles to receive protection for the entirety of the rainy season, a more relevant output target would have been the percentage of children who receive all four cycles of treatment. This might also have incentivized follow-up by health workers to ensure ongoing participation.

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS USED

ACCESS-SMC	Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel
API	Active Pharmaceutical Ingredient
AQ	Amodiaquine
CSSI	Centre de Support en Santé International
CRS	Catholic Relief Services
DALY	Disability-Adjusted Life-Year
ERP	Expert Review Panel
LSHTM	London School of Hygiene and Tropical Medicine
MC	Malaria Consortium
MSF	Médecins sans Frontières
MSH	Management Sciences for Health
MMV	Medicines for Malaria Venture
NMCP	National Malaria Control Program
NMEP	National Malaria Elimination Programme, Nigeria
PMI	President's Malaria Initiative, United States Agency for International Development
PNLP	Programme nationale de lutte contre le paludisme (national malaria control program)
PR	Prime recipient
RFI	Request for information
SMC	Seasonal malaria chemoprevention
SP	Sulfadoxine-pyrimethamine
SP+AQ	Sulfadoxine-pyrimethamine plus amodiaquine combination
SUA	Speak Up Africa
WAHO	West African Health Organization
WHO	World Health Organization
WHO CHOICE	World Health Organization, Choosing Interventions that are Cost-Effective initiative

1 INTRODUCTION

1.1 Context

In 2012, the World Health Organization (WHO) recommended seasonal malaria chemotherapy (SMC) as an intervention to reduce malaria incidence. SMC reduces the risk of developing malaria by providing intermittent full treatment courses of anti-malaria medicines during peak malaria transmission seasons. These medicines are a sulfadoxine-pyrimethamine plus amodiaquine combination (SP+AQ), typically at monthly intervals for the four months of the rainy season. Pilot studies showed that administering SMC treatments could prevent up to 75% of malaria episodes.[22,23] Based on studies of seven chemoprevention trials, the WHO recommended adoption of SMC for children under five as a tool for fighting malaria in the Sahel in 2012.

Until 2015, a lack of demand and weak supply, prevented adoption at scale of SMC. This was exacerbated by a lack of examples of SMC administration at scale to prove feasibility. For two years following the WHO's initial recommendation, less than 5% of the 23.7 million children eligible for SMC were benefitting from the intervention.[24] There was weak demand from governments and donors for SMC treatments due to (i) a lack of evidence that it could be successful and safe at scale, (ii) the perception that cost per child reached was high, (iii) the logistical difficulties and expense of reaching sites once per month during the rainy season – often in remote areas, and (iv) weaknesses in national health systems' capacities to deliver the intervention. There have also been constraints on the supply side. There was no manufacturer of SMC treatments quality-approved by the WHO in 2013; global production of quality-assured SMC treatments was 5.6 million in in 2014. Manufacturers were reluctant to invest in increasing this capacity in the absence of proven demand.

In 2014, Unitaid made a grant of USD 67 million to Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC), an initiative aiming to provide SMC treatments to 7 million children under five in the Sahel. Initially, Malaria Consortium (MC) and Catholic Relief Services (CRS) submitted separate bids to Unitaid. Unitaid gave the two organizations the option of combining their bids and delivering SMC intervention jointly, or of competing against each other for the grant.[25] They chose to form a consortium, incorporating most of the sub-grantees included in prior bids.

The consortium includes six members, with MC acting as prime recipient (PR). The six members are MC, CRS, Medicines for Malaria Venture (MMV), Management Sciences for Health (MSH), London School of Hygiene and Tropical Medicine (LSHTM), and Speak Up Africa (SUA). A seventh member, Centre de Support en Santé International (CSSI), previously operated in Chad

[22] World Health Organization. Seasonal Malaria Chemoprevention with Sulfadoxine pyrimethamine plus ammodiaquine in children: A field Guide. July 2013.
[23] World Health Organization. WHO Policy Recommendation: Seasonal Malaria Chemoprevention (SMC) for Plasmodium falciparum malaria control in highly seasonal transmission areas of the Sahel sub-region in Africa. March 2012.
[24] ACCESS-SMC, The Project, www.access-smc.org/pages/the-project/context
[25] MC does not believe an option was provided in this scenario

only but MC did not renew CSSI's contract after the first year of partnership.[26] MC was the prime recipient and retained accountability to Unitaid. CRS also played a management role in the consortium, managing relationships with LSHTM and SUA.[27]

ACCESS-SMC aimed to address the barriers to wide-scale adoption of SMC by providing evidence on the effectiveness and viability of SMC at scale and by shaping the market for the necessary drugs. This included market-shaping activities at the global level and implementation activities in seven target countries. At the global level, activities included:

- Conducting negotiations with drug suppliers, purchasing, and procurement of the drugs required (MC and procurement agents employed by MC)
- Handling international shipping of the treatments (procurement agents)
- Providing market support, such as forecasting demand, supporting manufacturers to develop new products and formulations, and supporting manufacturers to enter the market (MMV)
- Assessing cost effectiveness of the ACCESS-SMC model (MSH)
- Providing advice on supply chain optimization (MSH)

In each country, operations were led by either MC or CRS. MC led the consortium's country activities in Burkina Faso, Chad, and Nigeria. CRS led in Guinea, Mali, Niger, and the Gambia. Gratnees' in-country implementation involved:

- Conducting sensitization and behavior-change campaigns in target areas (MC in MC's countries; SUA in CRS's countries)
- Jointly planning implementation with NMCPs and liaising with other donors and implementers of SMC (MC[28] or CRS)
- Providing technical support during implementation (MC or CRS)
- Supporting development of national pharmacovigilance systems (LSHTM)
- Research, monitoring and evaluation (LSHTM)[29]
- Mobilizing funding from other donors to ensure funding of SMC programs in future years (MC or CRS)

Governments also played a crucial role in delivering ACCESS-SMC. Existing public sector health structures delivered the program. National malaria control programs (NMCPs) jointly developed strategies with MC or CRS ("macroplanning"). At district level, local health authorities jointly developed plans for rollout ("microplanning").

Peer organizations are implementing other SMC programs in the Sahel at smaller scale. The World Bank is implementing SMC in Burkina Faso (20 districts), Mali (13 districts) and Niger (11 districts). The President's Malaria Initiative at the United States Agency for International

[26] During a 2015 partner review, MC concluded that CSSI had weak financial management and insufficiently transparency accounting procedures, and did not renew its one-year contract on expiration in 2015.
[27] According to MC, the relationship between CRS and LSMTH was programmatically difficult and encountered challenges related to financial negotiations.
[28] CSSI in Chad during 2015.
[29] According to MC, MC itself was involved in protocol development, tools development and review, results analysis and interpretation.

Development (PMI) is funding SMC in a few districts in Burkina Faso and Mali. UNICEF is operating at a small scale in Burkina Faso, Mali, and Niger. Elsewhere in the Sahel, a pilot is providing SMC to children under ten in 16 districts in Senegal. In Burkina Faso, Mali, and Niger, where peer organizations implemented parallel SMC programs, these peers also participated in macroplanning and coordination together with ACCESS-SMC grantees and NMCPs.

1.2 Report scope and objectives

Unitaid commissioned Dalberg to undertake a mid-term evaluation of the ACCESS-SMC initiative. The evaluation draws on interviews[30], global health literature, and data provided by grantees and is therefore limited by the data provided. Dalberg's assessment showed that information received was generally consistent (any exceptions are mentioned in the report). However, it was not possible for Dalberg to replicate or independently verify the data supplied. Additionally, some of the consortium's activities in research, monitoring and evaluation were still underway at the time of the evaluation. As a result, some data from 2016 – in particular survey data on reach, the public health impact of SMC campaigns, levels of stock at project closure, and analyses of units costs in 2016 – were not available to inform the evaluation. The methodology and scope of the evaluation is detailed in the annex.

The remainder of the report summarizes the key findings from the evaluation and makes recommendations on how Unitaid can learn from the project. This report assesses in turn the grant's relevance, effectiveness, impact, efficiency, and learning and risk mitigation procedures.[31] As an empirical document, the evaluation is limited in its ability to assess more fundamental questions about programme design. In particular, it is not possible to assess the project performance against a hypothetical alternative project.

[30] Interviewees were proposed by Unitaid, MC and CRS. The evaluation team interviewed stakeholders from grantee consortium members, in-country implementation partners (predominantly in government health authorities) and peer donors.

[31] Sustainability is assessed as a dimension of effectiveness, since project work streams related directly to changes in the market landscape (output 1) and mobilization of resources (output 5).

2 RELEVANCE

Key questions

- *Are the outcomes and impacts of the grant aligned with UNITAID's overall mission to contribute to the scale up of and access to treatment for HIV/AIDS, malaria and TB for the most disadvantaged populations in developing countries using innovative global market based approaches?*
- *How did the grant contribute to one or more of UNITAID's six strategic objectives?*

The goals of ACCESS-SMC align closely with Unitaid's mission. The grant's remit of (i) procuring and distributing SMC treatments, and (ii) working to change market dynamics support Unitaid's mission of promoting price reductions for key medicines and improving their availability. By targeting the Sahel, it supports Unitaid's focus on low-income countries.

ACCESS-SMC directly supports Unitaid's strategic objective 6. By improving access to prophylaxis for populations who would otherwise not have access, ACCESS-SMC contributes to Unitaid's strategic objective of increasing access to products for the prevention of malaria. ACCESS-SMC also supports strategic objective 2 of increasing access to affordable pediatric medicines for malaria.

The grant's intended outcomes addressed the major challenges that constrain scale-up of this high-potential intervention. The grant supported an intervention proven to be effective in pilots but not yet adopted at scale. One set of outputs intended to provided governments with the support they needed to fund, manage, and deliver mass drug administration.[32] Another set of outputs aimed to increase the support of manufacturers and funders for SMC in the longer term through (i) promoting changes in the market, (ii) developing more affordable models of SMC delivery, and (iii) securing the support of other funders for future rounds of SMC.[33]

However, the project activities and outputs included in project planning did not all link logically to the grant's intended outcomes.

- **Some outputs were dependent on completion of other outputs.** Some of the logframe outputs were dependent on others, but this was not explicitly mentioned. For example, SMC administration (output 3) was an important component of the project but relies on stock having been procured (output 2).
- **Some "outputs" were more accurately "outcomes".** Global production (output 1) and resources mobilized (output 5) were not directly within the consortium's control. As a result, where ACCESS-SMC has not been able to achieve the intended change in these areas due to problems outside its control despite extensive work by the consortium,[34]

[32] Output 2 on efficient procurement of SMC products and output 3 on administration of SMC treatments, relating most clearly to the "public health" goals of the grant.
[33] Output 1 on improving global production, output 4 on improved affordability, and output 5 on mobilization of resources, relating most clearly to the "market transformation" goals of the grant.
[34] For instance, as discussed in section 3, S Kant was not able to enter the market because its supplier's prequalification was removed despite the extensive support MMV provided.

the logframe reports the output targets as missed. These outputs could instead have been considered dimensions of the intended outcome of market change.

- Some output metrics did not link logically to intended outcomes. The research outputs tracked under output 4 did not logically support increased production. Their intended audience was instead future funders; these outputs instead supported resource mobilization (as noted above, a dimension of market transformation).
- Some activities were missing relevant output indicators. Some activities were conducted by grantees but were not included in the logframe, such as:
    - Longer-term advocacy and influencing.
    - Training and capacity building of staff in national health systems.
    - Support for regional procurement initiatives.

There are therefore some challenges in understanding the relationships between activities and the project's intended outcomes.

3 EFFECTIVENESS

Key questions

- *Are the outputs of the grant consistent with the objectives and expected outcomes as described in the project plan? If changes have been made, has the UNITAID Secretariat been involved in discussions and decision making on the changes?*
- *Were the outputs of the project for the evaluation period fully achieved within the timeframe and budget specified in the initial project plan?*
- *What are the main factors influencing the achievement or non-achievement of the outputs or overall outcomes across all countries and within each beneficiary country?*
- *What factors have been considered to ensure that value for money has been achieved?*

3.1 Public health

3.1.1 Output 2: SMC products efficiently procured

Procurement volumes met targets. ACCESS-SMC procured 14.8 million treatments in 2015, representing 93% of the worldwide supply of quality-assured SP+AQ.[35] This slightly exceeded the revised annual target of 14.7 million treatments despite challenging market conditions.[36] In 2016, ACCESS-SMC procured its target number of treatments almost exactly: 30 million.[37] Note that MC's procurement in 2016 did not account for excess stock from 2015, thereby increasing the risk of excess stock in 2016 (although MC notes that it was obliged to procure all 30 million treatments, via its agreement with Unitaid).

Table 1. Performance against logframe targets, Output 2

Indicator	Country	2015 target	2015 actuals	2016 target	2016 actuals
O2.1 Volume of quality assured SP+AQ delivered to countries by the project	–	14,700,000	14,766,388	30,000,000	29,999,975
O2.2 % of orders that reach the country at least 30 days before the commencement of the first cycle	–	90%	50%[38]	90%	21%[39]
	Burkina Faso	0%	0%	0%	0%

[35] 93% = 14.8 million / 16.0 million

[36] The 2015 target was reduced from 30 million due to a production shortage, which occurred only after the project began. Only 16 million treatments were available worldwide for the 2015 season. These market challenges are discussed in detail in section 0 on Market transformation.

[37] The volume procured was 25 treatments short of the target due to pack-related rounding and pre/post-shipment withdrawals for inspection purposes.

[38] 79% weighted by number of treatments

[39] 41% weighted by number of treatments

O2.3 Number and percentage of cycle agreed dates that are delayed by more than 2 weeks (by country)	Chad	0%	0%	0%	100%[40]
	Guinea	0%	0%	0%	25%
	Mali	0%	0%	0%	0%
	Niger	0%	0%	0%	0%
	Nigeria	0%	0%	0%	100%
	The Gambia	0%	0%	0%	0%
O2.3 Number and percentage of cycle agreed dates that are delayed by more than 2 weeks (by districts)	Burkina Faso	15%	0%	10%	0%
	Chad	15%	0%	10%	100%[41]
	Guinea	15%	0%	10%	Not available
	Mali	15%	0%	10%	0%
	Niger	15%	0%	10%	0%
	Nigeria	15%	0%	10%	100%
	The Gambia	15%	0%	10%	0%

There were delays in placing orders in both years.

- **There was a minor delay in placing orders for the 2015 campaign, but this had little operational impact.** Unitaid required that MC appoint a procurement agent before making its first order. Running the appointment process from September to November 2014 meant MC placed the order in December 2014, one month later than planned.[42] However, this did not result in delayed manufacturing and did not impact shipment dates.
- **There was a more considerable delay in 2016, which resulted in additional costs for air freighting.** For the 2016 campaign, as Guilin increased its production capacity for dispersible tablets – a new formulation – MC, with agreement from Unitaid, decided to delay placing its order until February 2016 in order to maximize the proportion of its order that was dispersible. This was two to three months later than was originally planned. As a result, MC had to use a faster method of transportation to countries (air freight) rather than less expensive sea freight, incurring USD 300,000 in additional expenses.[43]

Most drugs did not arrive in-country before the originally planned 30-day buffer; in 2016, there were delays in drug delivery that delayed some administration cycles by up to six weeks.

- **In 2015, there were no significant delays in drug shipment but the 30-day buffer was not met; administration cycles were unaffected.** The original objective of ensuring drugs

[40] Refers to delays from the originally planned start dates, rather than the revised planned start dates, which took account of procurement delays.
[41] Refers to delays from the originally planned start dates, rather than the revised start dates.
[42] According to MC i) Unitaid originally wanted to delay the start of the project to November and ii) the timing of order placement was driven by the timing of ERP approval for the product.
[43] MC had previously agreed with Unitaid to send stocks by sea freight to those countries with sea ports, and by air freight only to landlocked countries, however all orders were sent by airfreight due to the shortened timelines caused by late ERP approval.

arrived more than 30 days before the start of the first cycle[44] was not achieved due to the compressed procurement schedule at year-end 2015. Fifty percent of shipments were received before this cut-off, representing 79% of the treatments delivered. However, all of the seven countries received their 2015 drug consignments in sufficient time for the planned campaign start dates. For example in Burkina Faso, a district-level medical officer shared that "there was a delay in the drugs, but a solution was found for us to start administration on time.[45]" Similarly in Mali, a stakeholder shared that "late arrivals did not have much effect on implementation because there was staggered implementation."

- In 2016, ordering delays contributed to more significant delays in drug delivery.[46] Burkina Faso, Chad[47], Guinea, Niger, and the Gambia all received stock more than a week late. Twenty-one percent of shipments (representing 41% of treatments), arrived more than 30 days before the start of the first cycle. The duration of delays ranged from two weeks (in Niger) to six weeks (in Guinea).

There were a small number of instances where standard procurement process was not followed. In 2016, Malaria Consortium took responsibility for issuing a purchase order whilst IDA, the procurement agent, handled logistics. This arrangement was employed because Malaria Consortium had a strong existing relationship with Guilin, the manufacturer. This followed the same arrangement from the 2015 season with Crown Agents. However, this presented a few risks. Malaria Consortium assumed payment responsibility (usually reserved for the procurement agent) as well as the risk of defective treatments. On this occasion, none of the risks were realized and stakeholders reported no issues. Further details on procurement irregularities are provided in the Efficiency section below.

The procurement process could be improved by strengthening communication between the procurement agent and MC. MC was dissatisfied with the quality of communication from IDA for the 2016 season. In general interviewees from MC shared that they perceived communications to be long, vague or lacking structure. Though there are no clear links between poor communication and procurement delays, interviewees shared that it added managerial burden for the parties involved. During an interview, a representative of IDA confirmed that communication was not conducted in a structured manner. This did not violate existing terms of agreement, but made communication difficult. Moving forward, IDA has agreed to change the staff responsible for communication and include clear and regular reporting on procurement stages to improve the communication process.

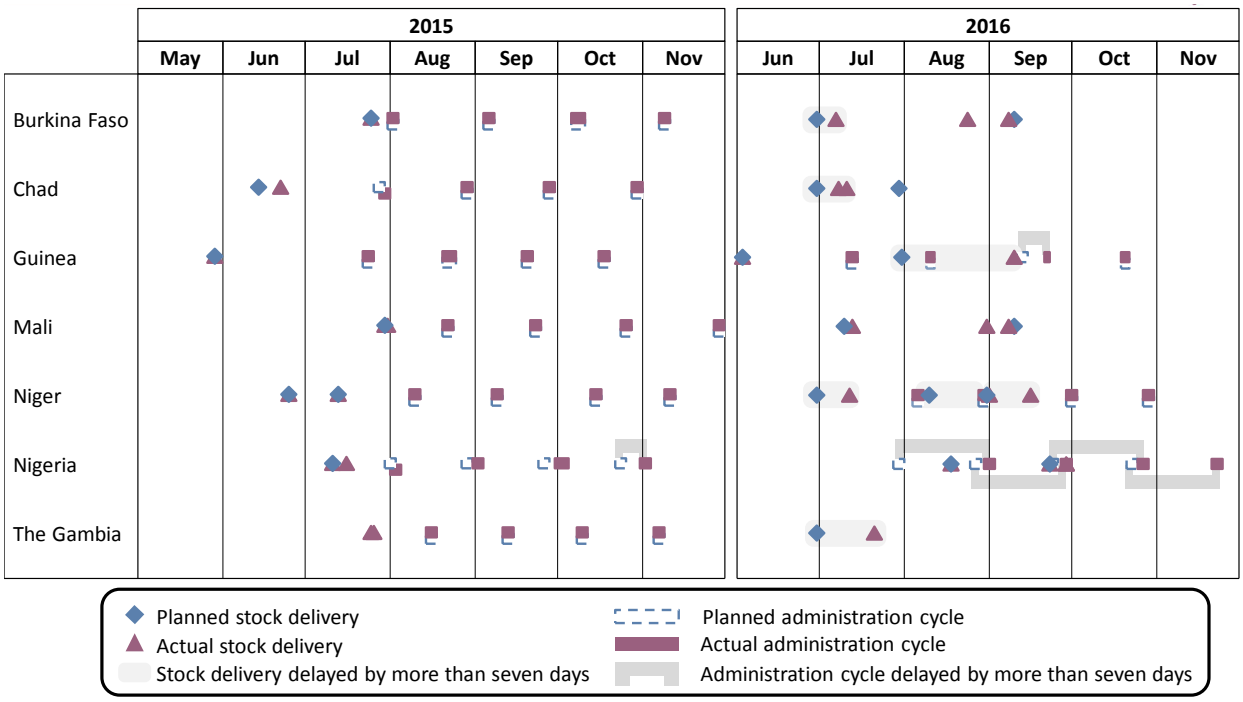
Most administration cycles took place as planned, but there were delays to one cycle in Guinea in 2016 and to all cycles in Chad in 2016.

[44] Noted in the original logframe but not in the 2016 revised logframe.
[45] Cameg, the drug distributor in Burkina Faso, drove through nights to deliver treatments to districts where they were needed before the scheduled administration start date
[46] According to MC, ordering delays were caused by the joint management arrangement of the programme
[47] It is important to note that delays in Chad were mainly due to administrative challenges with the government, and would have persisted even if drug orders were placed according to plan.

- **There were no delays to project delivery at national or district level in 2015.** [48] No country offices report delays in administration at the district level of more than one week due to supply chain issues. There were, however, some delays due to reasons outside the project's control, including security concerns and outbreaks of polio, which required refocusing of health district resources.
- **In 2016, government challenges, delays and poor communication from IDA affected administration schedules in Chad and Guinea; grantees' had to change in-country delivery plans in other countries.** In Chad, all four administration cycles were delayed by one month due to administrative challenges with the government and late arrival of stock. This postponement required WHO approval to ensure the new dates matched malaria peak season. In Guinea, the third cycle of 2016 was delayed by ten days when treatments arrived late. CRS Guinea used leftover stock from previous years during the first two cycles to avoid delays. In most other countries, country offices avoided significant delays in national rollouts by reallocating stock from previous consignments or revising supply chain arrangements, often incurring costs for doing so. For instance, in one case, the government reallocated hard tablets purchased by the World Bank to districts of MC implementation to avoid delays, and later reallocated more expensive dispersible tablets purchased by MC to World Bank districts to cover the initial reallocation.

[48] Defined as delays of over two weeks, in line with indicator O2.3.

Figure 2. Delays in stock delivery and SMC administration by country



NB: 2016 administration dates not provided for Chad, Mali or the Gambia. Interviewees report no delays in Mali and the Gambia. There were delays of one month per cycle in Chad.

In Nigeria, severe delays in stock delivery in 2016 due to a variety of factors eventually reduced the planned four cycles to three in 10 of 27 LGAs. Shipments did not arrive late in Nigeria. However, the new dispersible formulation required regulatory approval.[49] This was not granted for two months as Nigerian authorities determined that the drug registration application submitted by Guilin was not complete, and the key civil servants responsible for granting the approval were absent.[50] As a result of these delays, MC Nigeria had to rotate a reduced amount of stock through its planned number of districts. In effect, for much of the country, the campaign was reduced to three cycles, with the first cancelled.

All treatments procured were delivered intact to the target countries. There were no losses during transit. Country offices report that a small proportion of stock was delivered damaged.

No country experienced national-level stockouts, and there were few at district-level. A few districts in Mali and Niger experienced stockouts, but these were outside the consortium's immediate control.[51],[52]

[49] It is standard practice to obtain certificates of non-objection (NOCs) by NAFDAQ in Nigeria, so it was not unusual to order treatments before approval was granted.

[50] According to MC the absence of civil servants was the key issue and the incomplete registration form was not a major contributor to the delay.

[51] In Mali, CRS and the Pharmacie Populaire du Mali, the state pharmaceutical distributor, had a dispute over fees which led to some stockouts in some districts. In Niger, there were some district-level stockouts as district supply chain managers did not order new stock when supplies were low, although there was sufficient stock in central stores.

[52] The Dalberg team is awaiting information from one stakeholder to confirm if stockouts occurred in Chad.

Data are not yet available on the levels of stock left over at the end of 2016 but it is likely that stock was left over at the end of 2016. Grantees have not yet finalized stocktaking for 2016.[53] However, initial, incomplete reports suggest that approximately 1.8 million of the treatments procured during the course of the project were not used by the end of 2016. Given that waste, loss and spoilage were lower than the 10% buffer, it was very likely that stock would remain unused for the season. This initial estimate represents approximately 4% of the 44.7 million treatments procured over the course of the project – less than the buffer.

MC reallocated planned stock movements and distribution targets to reduce the chance of stock going unused for the season. According to MC, there was an agreement with Unitaid to procure 30 million treatments per year in order to influence the market. In addition, procurement orders were placed in December, before information on left-over stock was available. As a result, the only avenue available to the grantee consortium to avoid overstocking was reallocation of treatments between countries, rather than reduced procurement. MC changed its planned allocation of treatments procured for 2016 based on the amount of stock left over from 2015, and explicit drug needs assessments from countries and CRS among other considerations. MC reduced the stock sent to countries with higher levels of stock left over at end-2015, diverting the remainder to Burkina Faso due to program successes there in 2015.[54] In addition, having been donated to NMCPs as part of the ACCESS-SMC project, there remains the chance SMC treatments will be used by NMCPs in future SMC cycles. It should be noted that Unitaid felt the 30 million treatments target should have been adapted to reflect implementation needs and left-over stock from the 2015 season, to reduce the risk of future leftover stock.

The existing level of in-country expertise determined countries' ability to manage the supply chain. In some countries (notably Burkina Faso) district health workers had a high baseline of previous knowledge, which facilitated smooth supply chain management. In other countries (notably Niger and Mali), prior existing knowledge of supply chain management amongst district health workers was very low. For example, some district supply chain managers waited until their local stocks were almost empty, to order from central stocks, which resulted in local stockouts (as mentioned above).

One of the major tools for improving future procurement, pooled procurement, has been deprioritized. The project plan included support to help countries in the Sahel jointly procure SMC drugs. MSH has developed a document providing guidance to countries in the region on how they might conduct pooled procurement should they choose to. In 2015, MSH held talks with the West African Roll Back Malaria Partnership secretariat to investigate its ability to host such a procurement mechanism. However, interviewees indicate that the consortium has deprioritized support for pooled procurement in 2016 because ACCESS-SMC's activities in this area were not additive to the activities already being pursued by other organizations, notably the West African Health Organization and the Global Fund.

[53] As at March 2017, MC does not have clarity over remaining stocks from the 2016 campaign

[54] Information from May 2017 suggests that the extra stock reallocated to Burkina Faso has not been used.

Evaluator's assessment summary: **For the most part, MC ran a successful procurement process that enabled almost all country administration schedules to proceed as planned.** MC faced logistical complexity to deliver millions of treatments to seven countries as part of a new program. Overall it managed to achieve this with few stock level issues or administration delays. Delays in 2016 were a calculated risk on MC's part, to provide as many dispersible tablets as possible. It was noteworthy that both the manufacturer and procurement agent reported no difficulties working with MC.

3.1.2 Output 3: SMC treatments administered

Figure 3. Performance against logframe targets, Output 3

Indicator	Country	2015 target[55]	2015 actuals[56]	2016 target[57]	2016 actuals[58]
O3.1 Number of treatments administered to eligible children by country	Burkina Faso	2,079,019	2,721,731	7,700,000[59]	5,680,671[60]
	Chad	880,00	1,061,417	2,000,000	2,470,321
	Guinea	672,342	805,131	1,500,000	1,756,298
	Mali	2,590,842	2,752,912	5,100,000	4,648,792
	Niger	1,906,883	1,666,890	3,800,000	3,838,414
	Nigeria	2,534,826	3,149,897	6,900,000	6,275,661
	The Gambia	290,960	308,830	300,000	298,968
	Total	**10,954,873**	**12,467,808**	**27,300,000**	24,969,125
O3.2 Proportion of reported adverse events potentially related to SMC administration that are adequately managed by country	–	100%	All adverse events managed through country systems	100%	All adverse events managed through country systems
O3.3 Minimum administrative coverage per cycle	Burkina Faso	80%	100% (cycle 1)	80%	86% (cycle 1)
	Chad	80%	91% (cycle 1)	80%	83% (cycle 4)
	Guinea	80%	85% (cycle 1)	80%	96% (cycle2)
	Mali	80%	82% (cycle 4)	80%	66% (cycle 1)
	Niger	80%	58% (cycle 1)	80%	82% (cycle 1)
	Nigeria	80%	93% (cycle 1)	80%	55% (cycle 1)[61]

[55] Due to the change in administration targets caused by the global treatment shortage, the target for 2015 has been calculated using target populations from country planning documents multiplied by a target coverage rate of 80%

[56] Sourced from reach and coverage reports provided by country teams after verification with NMCPs.

[57] Targets from Revised Log frame.

[58] Sourced from reach and coverage reports provided by country teams after verification with NMCPs. Note that if each target is multiplied at 80%, to reflect 80% coverage of target population, then all countries except Burkina Faso would exceed the target.

[59] According to MC, the target was misstated in the logframe and should be 7,400,000.

[60] MC in Burkina Faso was responsible for administration of 5.7 million treatments, this figure only accounts for the original target districts i.e. not those added as part of the additional 1.8m allocation to Burkina Faso. In addition, the allocation of additional stock delivered to Burkina Faso should have allowed the MoH jointly with other organizations to administer treatments that would have been counted as ACCESS-SMC contribution within project data – however, these treatments were not distributed during the season (but are likely to be distributed during 2017 season).

[61] During cycle 1 of 2016, most districts in Nigeria were not reached. Nigeria only ran three cycles at full scale in 2016; of these, cycle 2 had the lowest administrative coverage (102%).

	The Gambia	80%	78% (cycle 1)	80%	87% (cycle 4)

Reach

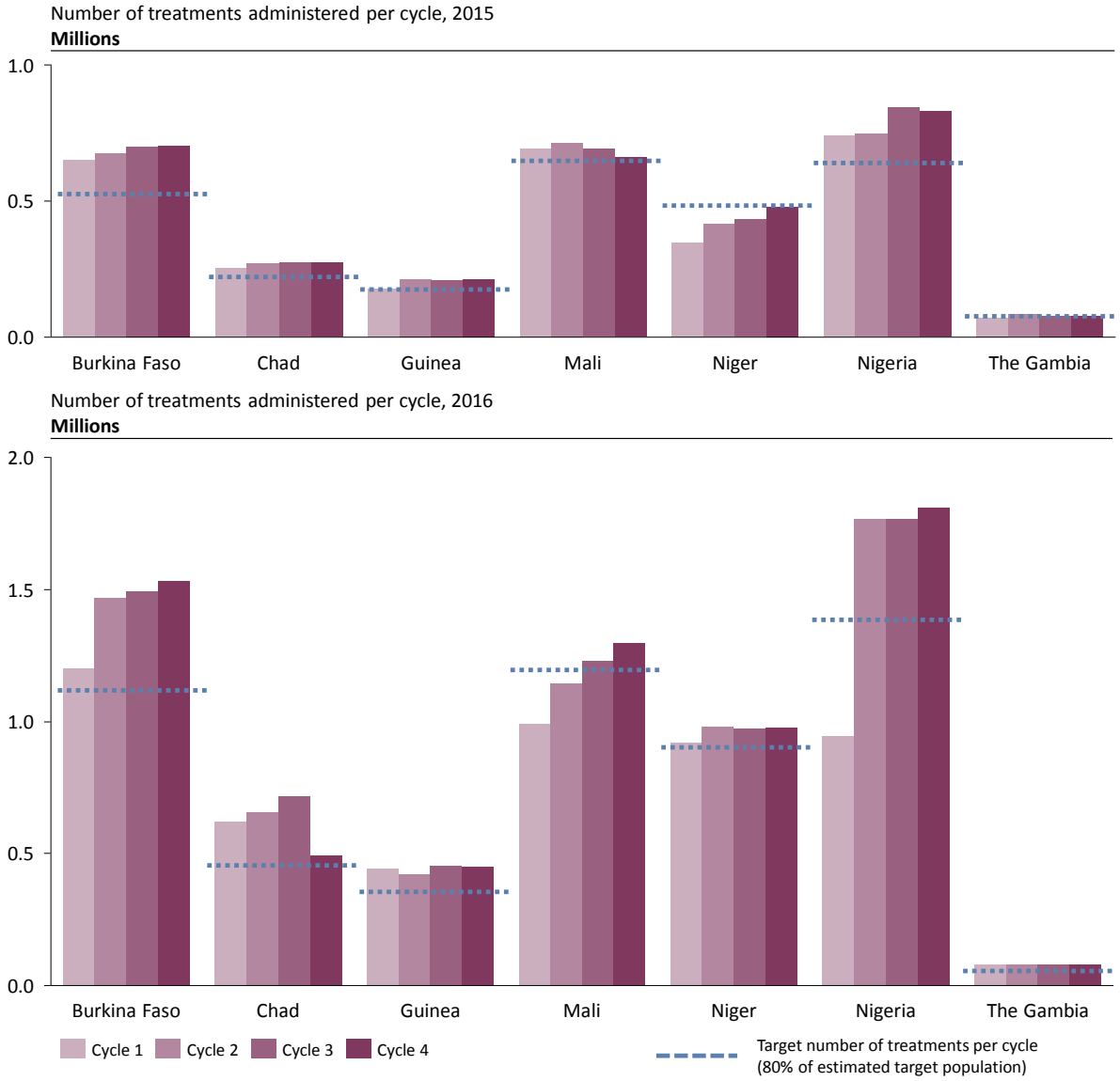
ACCESS-SMC reached its target for the number of treatments administered in both 2015 and 2016.[62] In 2015, the project administered 12.5 million treatments, exceeding the implied target of 11.0 million. ACCESS-SMC also exceeded its target for 2016, administering 25.0 million treatments against a target of 21.9 million. Each country reached its annual target – with the exception of Niger in 2015 and Mali in 2016.

Countries have consistently increased the number of treatments administered per cycle.[63] In both 2015 and 2016, most countries treated more children in the final cycle than the first cycle. According to interviewees, this improvement is due to increased awareness due to ongoing sensitization campaigns, and refinements in distribution models, discussed below.

[62] When assessing achievement against the revised target, which reduced the 2015 target in line with the constraint of the supply of SP+AQ.

[63] The exceptions to this growth in coverage over time are Mali in 2015, and Chad in 2016. In Mali in 2015, where an exclusively fixed-point strategy was used, coverage rates fell during later cycles, as harvesting activity intensified; this was mitigated in 2016 by use of door-to-door and mixed strategies. In Chad in 2016, there was a severe drop for the fourth cycle of 2016 potentially due to stock-outs as a result of inaccurate population estimates, particularly in urban areas, and by up to 40%.

Figure 4. Number of treatments administered per cycle



NB: Implementation in Nigeria was only at full scale in cycles 2 to 4 in Nigeria in 2016 due to delays in administrative approvals

The intervention reached at least 6.9 million children. A Dalberg estimation based on 2016 administrative data suggest that 6.9 million individuals received at least one cycle during 2016, exceeding an implied target of 6.8 million children.[64] This estimation adds together the number of treatments administered during the largest cycle in each country in 2016, once ACCESS-SMC was operating at its largest scale. It is therefore likely be an underestimate, since some children were added to registers at subsequent cycles.[65]

The 2015 treatment targets were reduced from the initial targets due to the global shortage of sulfadoxine API. In late 2014, key input supplier, Shanghai Sanwei, decided to exit the market.

[64] This implied target divides the 2016 target population of 27.3 million by four, assuming that the target is to reach each child during each of the four cycles.

[65] However, the higher the number of children reached in a given year, the lower the proportion of those children that would receive all four treatments across all four cycles.

Guilin, the only manufacturer prequalified by the World Health Organization, was therefore only able to produce 16 million treatments for the 2015 season. ACCESS-SMC procured 14.8 million of these treatments, as detailed in the following section. Accordingly, Unitaid and the grantee consortium reduced by half the 2015 targets for the number of treatments to administer; previously the 2015 targets and 2016 targets were identical.

The targets for the 2016 cycle were changed during the course of 2016, complicating the comparison of treatments delivered to targets set. Country offices made amendments to their 2016 plans based on the information gathered during the 2015 campaigns and updated demographic data. Country targets were therefore altered (although we refer to the original targets in the table above, for purposes of performance assessment). However, it was found that some countries had approximately 1.8 million treatments leftover from the previous season, and so needed 1.8 million treatments fewer from the 2016 procurement round. MC was therefore left with 1.8 million treatments without a target destination. It sent these additional treatments to Burkina Faso, due a combination of its strong performance in 2015, and the potential availability of operational financing to administer these additional treatments which it had the highest likelihood of using additional treatments. However, these additional treatments were not administered by other organizations.[66] It should be noted that this decision was not fully discussed and approved with Unitaid, and is discussed later in the report.

Coverage rates

The coverage rate varies greatly by the method used, but both available methods indicate that the project exceeded coverage targets. The methodological differences between each measure is outlined in the table below. The coverage target of 80% per cycle only applies to the administrative approach.[67] No targets were set for the percentage of children that completed all four cycles.

Table 2. Methodologies for calculating ACCESS-SMC coverage rate

Type of data	Description	Strengths	Drawbacks
Administrative data	• Derive coverage rate for each individual cycle from (i) the tally sheets and record cards used during the project, cross checked against stock data, and (ii) government estimates of the number of children of target age in each district.	• Available during planning and campaign administration (and therefore used for target setting) • Allows comparison to other SMC programs using the same methodology	• Estimates of target population in each district often out of date • Reliant on the accuracy of the data recording during administration campaigns
Household surveys	• Estimate coverage by contacting representative samples of the families of	• Not affected by quality of population estimates	• Does not distinguish by cycle; coverage rate is

[66] According to MC, about 1.65 million treatments remain in Burkina, with enough shelf life to be used in 2017. Additionally, the MoH has secured the required funding to distribute these treatments, but these funds were confirmed in November 2016 (and therefore treatments were not distributed during the 2016 season).
[67] Household survey data can show the percentage of individuals in a given area that received one, two, three, or four cycles of treatment.

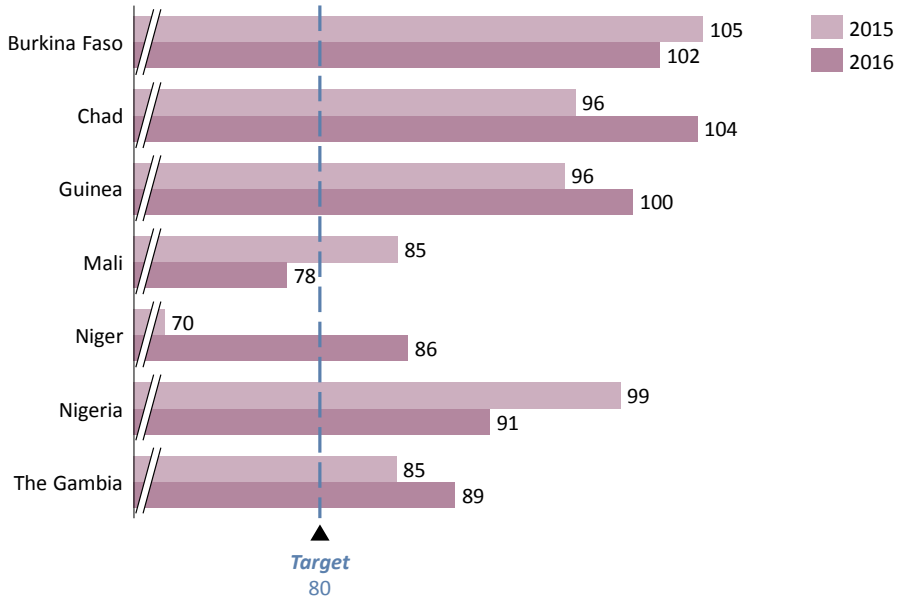
	children in the target age. LSHTM carried out surveys at the end of the transmission season in 2015. • Where possible, respondents' answers are cross-checked against record cards but, where not, are based on recall.		for the whole campaign of four cycles. • Not yet available for 2016 campaigns. • Susceptible to recall bias; caregivers might have difficulty remembering which and exactly how many cycles a child received by the end of the season.[68]

Administrative data show large variations between countries, but indicate that most countries achieved their target of a national average of 80% (with the exception of Niger in 2015 and Mali in 2016). According to these data sets, coverages rates vary widely between countries, from 105% in Burkina Faso in 2015, to 70% in Niger in 2015.[69] Administrative data are also available at the district level and show wide variation between districts and between cycles within the same country. In the Gambia in 2015, coverage rates during the second cycle ranged from 69% to 147% depending on the district. In Zurmi district in Nigeria, coverage varied between 61% and 116% between the first and fourth cycles of 2015. However, the annual national average of administrative coverage rates exceeded the target of 80% in all countries and years, with the exception of Niger in 2015 and Mali in 2016.

[68] According to MC, card and recall provided similar results

[69] Coverage rates of over 100% were possible when using administrative data, for instance if (i) the population data underestimates the number of eligible children in the district, or (ii) children from outside the target district travel to the district to receive treatment. Coverage rates of over 100% were not possible when using household surveys.

Figure 5. ACCESS-SMC coverage rates according to administrative data



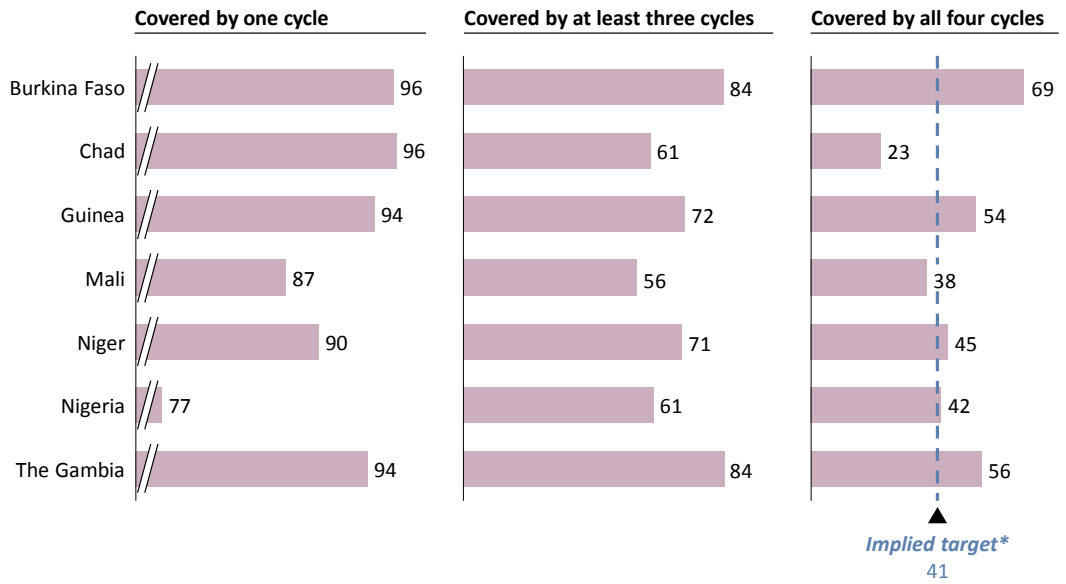
Household data paint a similar picture, indicating that most countries achieved coverage of 80% or more. Surveys find that all countries but one – Nigeria – achieved coverage rates of 80% of the target population in 2015. Data for 2016 are not yet available.

However, household survey data indicate large variations in the number of children participating in all four cycles. These variations are shown in Figure 6. Reasons children might not be included in one cycle include (i) absence from home during visits, (ii) non-attendance at a fixed-point site if no family member is able to accompany the child, or (iii) ineligibility due to a current case of malaria. Children not included in all four cycles did not experience the same level of malaria protection as children who attended all cycles, though some protection above the no-treatment case was obtained. The proportion of children included in all four cycles varied widely by country from 23% in Chad to 69% in Burkina Faso in 2015.[70,71]

[70] Five countries exceeded the target of 41% implied by an average target of 80% compounded over four cycles – with the exception of Chad and Mali. The implied target assumes that the probability of a child participating in one cycle is independent of attendance to other cycles. Though this is an imperfect assumption, the lack of further information makes it impossible to make a more accurate estimate.

[71] In Chad, the survey's finding that a low proportion of children received all four cycles but a high proportion received one may relate to community health workers' difficulties in keeping records. The survey called for verification through patient record cards where available; a higher rate of errors in these cards would have exposed Chad data to a higher risk of inaccuracies due to parent's recall than others. In 2016, Chad's recording cards were redesigned to mitigate this risk.

Figure 6. ACCESS-SMC coverage rates in 2015 according to household survey data



* The target of 80% coverage was set for administrative measures of coverage per cycle, rather than household measures of coverage at any point during the campaign. This implied target for household data is derived from multiplying the 80% per-cycle target over four cycles (80% x 80% x 80% x 80% = 41%). Targets for other rates of coverage used in household surveys cannot be derived from per-cycle targets since they measure coverage at any point during the campaign.

Countries' abilities to reach coverage targets depended on NMCP buy-in and capacity. Where national malaria control programs provided clear strategic direction for implementing agencies, administration was successful. For instance, Burkina Faso benefited from a strong NMCP. By contrast, interviewees report that the political environment in Nigeria was challenging. The central National Malaria Elimination Programme (NMEP) was engaged, but support and capacity were weaker at the local levels that administered the program.

Geographic and demographic constraints also reduced coverage in Mali, Niger, and Nigeria. Some populations were especially difficult to reach: nomadic populations, or those with cultural preferences or practices resistant to drug administration.[72] Mali, Niger and Nigeria had a higher concentration of these populations than other countries. Coverage rates in these countries were lower.

In Mali and Niger, these issues were compounded by the decision to use less effective distribution strategies in 2015. In most countries, SMC administration involved small teams visiting each eligible house in a district – a "door-to-door" strategy. By contrast, a "fixed-point" strategy requires asking families to bring eligible children to one central point in each district. Fixed-point strategies cost less, but often result in lower coverage. Unlike the other countries, in 2015 Mali and Niger planned to use fixed-point strategies nationwide.[73] In Mali, this fixed-point strategy was required by the country's NMCP. It was not possible to ascertain the

[72] These practices include religious prohibitions on women leaving the house to accompany children to fixed-point distribution sites, or receiving visitors such as community health workers.

[73] Burkina Faso and Nigeria used fixed-point distribution in some districts but on a much smaller scale than door-to-door distribution, which was used throughout each country.

underlying rationale for this approach in Niger.[74] All three countries increased their use of door-to-door models and models combining fixed and door-to-door distribution for 2016 and witnessed increases in children reached.

There was also considerable difference within countries. According to interviewees, coverage rates were generally higher:

- **in countries and districts using a door-to-door administration approach**, as discussed above.
- **in rural areas**, where smaller communities are easier to mobilize. The district with the project's lowest coverage rate – 7% in the first cycle – was the town of Maradi in Niger.
- **in non-farming areas**, as families of children in agricultural areas were often needed for work during labor-intensive times on farms, which coincide with the rainy season.
- **in areas without cultural barriers against planned distribution models** such as areas of Nigeria, Niger and Mali, where there is a norm against women travelling outside their home; in others it is culturally inappropriate to receive male visitors, rendering fixed-point and door-to-door strategies ineffective respectively, unless women are used as the distributors.
- **where there was successful behavior change communication, including engagement of religious leaders.** In the Gambia, for instance, some communities across the Upper River Region during 2015 opposed treatment on cultural grounds. Before the 2016 campaigns, community health workers spent time with local religious leaders to explain the treatment, increasing the 2016 coverage.
- **when dispersible tablets are used,** since they are faster to administer and less likely to be rejected.

Countries achieved these treatment totals and coverage rates despite challenging contexts and faced some common challenges. First, public-sector staff did not have experience of managing supply chains or mass drug administration over four cycles. Second, there were logistical challenges due to the remote location of many target districts and the requirement to deliver the drugs during the rainy season. Community health workers in Burkina Faso, for instance, had to reach target districts using bicycles or canoes when roads were flooded. Third, many project areas faced high security risks. For instance, Niono (a target district in Mali), was affected by attacks, requiring changes to distribution plans.

ACCESS-SMC set up systems to ensure the safety of the treatment and identified few severe adverse reactions to refer through these systems. In each country, LSHTM supported development of national pharmacovigilance systems. Out of 12.5 million administrations in 2015, there were 10 serious adverse events; no adverse events have yet been recorded for

[74] According to MC, the rationale was due to centralized planning by CRS in the regional office and by not accepting the approaches suggested by the NMCP.

2016 but this may change as records are finalized. Grantees and national authorities report confidence in systems for pharmacovigilance and treatment of serious adverse reactions.[75] As a notable exception, MC reported that documentation of less serious adverse events in Nigeria in 2015 was weak.

Evaluator's assessment summary: **Grantees successfully guided NMCPs to achieve the targets on overall program reach and participation per cycle, but more should be done to ensure repeat participation by individuals.** It was noteworthy that a new program was able to meet the administration targets, reaching nearly 7 million children after just two years of operation. This was in part due to the i) strong relationship and close alignment on program approach and objectives between government actors and grantees and ii) a clearly defined role for grantees, to support planning, training and program roll-out.

For example, the Ministry of Health in Gambia shared that it has "a positive relationship with CRS" and found CRS to be "very supportive." A similar sentiment was shared by the PNLP in Burkina Faso who described having "a tight relationship that works well with MC." Positive reviews extended to the district level where an officer shared that "there is a good collaboration between MC and the district. MC respect what we do, follow what is going on and have a concern for our activities." Positive views on the work of both MC and CRS were a consistent trend through interviews.

In addition, grantees were responsive to learnings – for example in Mali and Niger – and improved the quality of delivery during the second year of administration. However, coverage of children with all four treatment cycles was low (although this is difficult to judge as there is no formal target). Receiving all four treatment cycles ensures that maximum protections against malaria for each child, and so achieving high coverage across all four cycles is an important objective. Going forward, this should be an explicit target of the program.

Market transformation

3.2.1 Output 1: Global production of quality and acceptable SMC products increased

Table 3. Performance against logframe targets, Output 1

Indicator	2015 target	2015 actuals	2016 target	2016 actuals	2017 target	2017 actuals
O1.1 Number of manufacturers of quality assured SP+AQ	0	1 (Guilin)	1	1 (Guilin)	2	1 (Guilin)

[75] Of the ten-reported serious adverse events, two resulted in hospitalisation (in Chad and the Gambia), while eight were treated on site. There was one death (in Niger), but its attributability to SMC is still being investigated and the Niger government refutes this.

O1.2 Number of sources of pre-qualified API	0	0	–	1 (Anuh Pharma recommended for WHO reapproval in December 2016)	–	Not available
O1.3 Number of supported countries with drug efficacy studies completed	0	0	0	0	7	Publication of final case control studies and molecular marker surveys delayed to December 2017[76]

Attracting new manufacturers

No new quality-assured SP+AQ manufacturer has yet entered the market due to a problem that was likely unforeseeable: the disqualification of the only supplier of a key active pharmaceutical ingredient (API). Therefore, targets to include an additional manufacturer and source of pre-qualified API have not been met.

The consortium aimed to ensure entry of a second manufacturer to the market for SMC treatments by the end of the project in 2017. At the outset of the project, Guilin was the only manufacturer of quality-assured SP+AQ. The consortium planned to increase the supplier base to promote price competition and to reduce the risk of a market exit by Guilin leaving the market without a supplier.

MMV has provided various kinds of support to S Kant and its suppliers to help its entry to the SP+AQ market. Following a tender process, site visits and due diligence from technical experts, in October 2015, the consortium selected S Kant to receive market entry support. Support included a technical consultant and USD 500,000 in subsidies for product development. In February 2016, S Kant agreed to enter the dispersible SP+AQ market. S Kant agreed to work with MMV to perform the required bio-equivalence studies and submit a dossier for approval to the WHO's Expert Review Panel (ERP).[77,78]

However, S Kant will not be able to begin production before the end of the project. S Kant's only sulfadoxine supplier, Anuh Pharma, was disqualified from WHO's list of prequalified API manufacturers because of breaches in best practices in the manufacture of other products not related to sulfadoxine.[79] S Kant could therefore not begin production. As Guilin currently has a monopoly on pre-qualified sulfadoxine (which it started producing in-house in 2015 and does

[76] This note reflects information shared during interviews conducted in November and December 2016. This information differs from the data reported in the SMC semi-annual report 2016.
[77] Interviews with MMV.
[78] ACCESS-SMC semi-annual report, 2016.
[79] An inspection by the French Agence Nationale de Sécurité du Médicament et des Produits de Santé found that Anuh Pharma did not pass supplier details on to customers, used a non-compliant supplier for azithromycin, and did not manage documents according to standard protocol.

not sell), it will remain the only recognized manufacturer of dispersible SP+AQ for the 2017 season.

This shortage was due to reasons outside the control of project actors and could not reasonably have been foreseen. Given that this disqualification related to standards in production of chemicals unrelated to sulfadoxine, it is unlikely that this could have been identified or mitigated beforehand. As there were no other suppliers of the requisite API – indeed, the weakness of the supply market was the problem addressed by this project output – the initial targets for 2015 were impossible to meet.

MMV has since provided support to Anuh Pharma in addition to S Kant to mitigate the supply challenges. MMV funded a mock audit for Anuh Pharma and worked with WHO to have a second inspection by the end of 2016, by the European Directorate for Quality of Medicines and WHO prequalification authorities. Anuh Pharma passed the inspection, and WHO has recommended restoration of its sulfadoxine prequalification. MMV and S Kant are ready to restart work and can continue with bio equivalence studies and finalize drug development in 2017 depending on Unitaid's continued funding support.[80]

S Kant is likely to enter the market in 2018. S Kant aims to submit a dossier on its formulation of dispersible SP+AQ to the WHO ERP for approval by October 2017. If this application is accepted, S Kant could begin production in time for the 2018 season, as according to a representative from S Kant, it currently has the capacity to start production on short notice.[81]

Increasing global production capacity

In 2014, Guilin's annual production capacity was 30-35 million treatments, but an API shortage meant it could not deliver at that level for the 2015 season. In 2014-2015, Guilin's production capacity was around 30-35 million treatments per year (two to three million per month). However, Guilin's API supplier (Shanghai Sanwei) ceased production in the autumn of 2014. This restricted Guilin's SP+AQ production to 16 million treatments in 2015 (of which ACCESS-SMC procured 14.8 million).[82,83]

During 2015, Guilin made manufacturing investments to increase annual production capacity to 90 million treatments. Following Shanghai Sanwei's market exit, Guilin obtained WHO prequalification to manufacture its own supply of sulfadoxine. Guilin simultaneously invested in greater blistering capacity, so that by 2016 its annual production capacity was around 90 million treatments (7.5 million treatments per month). Guilin was therefore able to meet market demand for 65 million treatments for 2016.[84]

Demand from the ACCESS-SMC initiative has been a key driver of increased production volumes. ACCESS-SMC, with funding from Unitaid, was the major buyer in the market and placed the

[80] It is possible that the programme will be funded through another project, and not necessarily via extension of this project
[81] Interview with S Kant.
[82] ACCESS-SMC annual report, 2015; verified in conversation with Guilin.
[83] Interview with MC.
[84] ACCESS-SMC annual report, 2015; verified in conversation with Guilin.

largest orders for SP+AQ in 2015 and 2016. Guilin credits ACCESS-SMC with the rapid demand growth.

Global SP+AQ production capacity remains short of total estimated need but S Kant's market entry would meet this demand. Guilin's production capacity of 90 million treatments a year does not meet estimates of a total market size of between 100 and 110 treatments a year.[85] S Kant estimates that its production capacity will be 60 million treatments a year which, added to Guilin's capacity, would create total annual market production capacity of 150 million treatments.[86]

Promoting dispersible formulation

Guilin started manufacturing a dispersible formulation of SP+AQ in February 2016 for the 2016 season. Before development of the new formulation, SMC treatment for children involved grinding down hard tablets with pestles and mortars, dissolving the powder in water, and mixing with sugar. This solution is very bitter and often unpalatable. A stakeholder from the Gambian Ministry described using hard tablets as "one of the biggest challenges faced in the 2015 season." On the other hand, dispersible tablets are easier to administer (simple dissolving in water) and are less likely to be rejected. Guilin began development of a dispersible formulation of SP+AQ in 2012 when the WHO recommended SMC as a method to fight malaria in children. Guilin obtained the WHO ERP's approval in February 2016 and produced 23.5 million dispersible formulation treatments for the 2016 campaigns. ACCESS-SMC initially ordered 30 million hard tablets with an option to switch in case ERP was granted within a reasonable time period. ERP was granted by the end of January, by which time 6 million hard tablets had been produced. So, ACCESS-SMC bought 6 million hard tablets and 23.5 million dispersible tablets.

Guilin has indicated that the rapid scale-up of the dispersible formulation was only possible because of the demand from ACCESS-SMC in 2016. Guilin also report that ACCESS-SMC's use of dispersible formulation at scale is may increase demand from other SMC projects in future years.[87]

Project participants report that use of the dispersible formulation is likely to reduce wastage in the 2016 season as compared to the 2015 season. Distributors reported that administration was easier in areas using dispersible formulation in 2016 than in areas using hard tablets in 2016 and 2015.[88] Though there is no data on falls in rejection by dispersible SP+AQ, changing from hard to dispersible formulations of another malaria drug reduced rejections by 30% to 40%.[89]

[85] Estimate of 100 million assumes four treatments per child for each of the approximately 25 million children aged three to 59 months in target regions of the Sahel. Estimate of 110 million assumes a 10% stock buffer is needed. 25 million estimate derived from WHO, 'Seasonal malaria chemoprevention, http://www.who.int/malaria/areas/preventive_therapies/children/en/

[86] Email communication from S Kant.

[87] Email communication from Guilin, 16 December 2016

[88] Interviews with MC and CRS.

[89] The change to dispersible Coartem reduced rejections by 30 to 40%. Coartem and SP+AQ have different characteristics so this rate may not apply to dispersible SP+AQ.

Supporting future demand growth through research

The ACCESS-SMC project is conducting research into the effectiveness and safety of SMC treatments, to support more widespread adoption of SMC. ACCESS-SMC is conducting case control studies and molecular marker surveys. Case control studies assess the efficacy of SMC doses as the intervention is scaled. Molecular marker surveys assess the development of resistance to SMC treatments as implementation is scaled up. Both sets of studies are being conducted in Burkina Faso, Chad, Mali, Nigeria, and the Gambia.

Both sets of research have been delayed, so results were not available to use in donor discussions – however, MC was able to influence other funders via presentation of efficacy data. Baseline molecular markers surveys were completed in all seven countries in the first quarter of 2016, with the final analysis to be published in 2017.[90] This was later than planned due to delays in contract signature between CRS and LSTHM, which in turn delayed the signing of contracts between LSHTM and the research organizations it chose to subcontract to in each of the four countries. As two years are required between baseline and end-line surveys, the follow-on survey will be delayed until at least December 2017. Therefore, results from these studies were not available for use in discussions with donors. However, MC publicized efficacy results at ASTMH in November 2016, at the WHO and at the Ouagadougou joint meeting (ACCESS-SMC, WHO-GMP and WAHO) in February 2017. MC reports that this boosted the conviction of PMI and the Global Fund.

Evaluator's assessment summary: **ACCESS-SMC has supported the expected entry of a second manufacturer, and helped to accelerate production capacity increases. However, the decision to develop a dispersible formulation was taken before the program began, so it is likely not attributable to ACCESS-SMC.** Without the effort from ACCESS-SMC, S Kant would not currently be a contender to enter the SP+AQ market for 2018. The program placed a call for new suppliers, provided financial and technical assistance and helped navigate unforeseen challenges as described above. It is difficult to draw generalizable lessons from the experience of ACCESS-SMC with regards to introducing new manufacturers. It is possible that more rigorous mock inspection of Anuh Pharma would have uncovered its deficiencies, but the extent to which this is realistic within given budgets is not clear. ACCESS-SMC also played a big role in providing sufficient market incentive for Guilin to increase production capacity of dispersible tablets. However, the program was not responsible for Guilin's development of a dispersible formulation, as this was a strategic decision taken by Guilin's management in response to an updated WHO policy on SMC, prior to the design of ACCESS-SMC. Nevertheless, the program contributed to faster deployment of dispersible tablets.

3.2.2 Output 4: Affordability of SMC delivery improved

Table 4. Performance against logframe targets, Output 4

Indicator	Country	2015 target	2015 actuals	2016 target	2016 actuals

[90] The survey will not strictly be a baseline in the Gambia because the survey will be done in URR, which has already received SMC.

O4.1 Median price of quality-assured SMC products by source	–	Maintain baseline prices: • USD 0.24 for infant formulation • USD 0.27 for child formulation	• USD 0.24 for infant formulation • USD 0.27 for child formulation	Maintain baseline prices • USD 0.24 for infant formulation • USD 0.27 for child formulation	• USD 0.24 for infant formulation in hard tablets • USD 0.26 for infant formulation in dispersible tablets • USD 0.27 for child formulation in hard tablets • USD 0.29 for child formulation in dispersible tablets
O4.2 Cost per child reached with SMC four-cycle annual course of treatments[91]	Burkina Faso	Under USD 5.00	USD 3.93	Under USD 5.00	Costing study for 2016 ACCESS-SMC season not completed
	Chad	Under USD 5.00	USD 4.64	Under USD 5.00	
	Guinea	Under USD 5.00	USD 5.13	Under USD 5.00	
	Mali	Under USD 5.00	USD 4.05	Under USD 5.00	
	Niger	Under USD 5.00	USD 3.48	Under USD 5.00	
	Nigeria	Under USD 5.00	USD 4.61	Under USD 5.00	
	The Gambia	Under USD 5.00	USD 6.58	Under USD 5.00	

SMC drug prices

ACCESS-SMC has achieved its target of maintaining baseline drug prices. The prices of SP+AQ formulations have remained stable since the start of the project. The infant formulation of the hard tablet cost 24 cents per dose and the child formulation cost 27 cents per dose throughout the project.[92] The new dispersible formulation, introduced for the 2016 season, costs 2 cents more than the hard tablets for each formulation type.[93] These prices have been secured (notably, despite Guilin's monopoly position).

The prior relationship between Guilin and Malaria Consortium was important to maintain stable treatment prices. MC's CEO conducted in-person relationship-building with Guilin in autumn 2014 before price negotiations began. During these negotiations, Malaria Consortium secured a price lower than the USD 0.34 per treatment MC had paid Guilin for a previous project in Nigeria.[94] IDA wrote to MC in 2015 that MC had secured lower prices for the 2016 campaign

[91] Average equivalent recurrent cost per child (3-59 months) for four SMC cycles – based on the equivalent number of children (3-59 months) who received four SMC cycles

[92] According to Unitaid the baselines were 25 and 28 cents respectively, but UNTAID requested that the baseline be updated with 2015 actuals.

[93] ACCESS-SMC semi-annual report, 2016

[94] Interview with Malaria Consortium

than IDA had secured recently for other buyers.[95] Guilin also committed not to increase prices until the 2017 season.[96]

Future price reductions for SP+AQ formulations are unlikely, even if a new manufacturer enters the market. Interviews with Guilin suggest that there may be limited scope for future price reductions. Indeed, price rises may be likely after 2018. Guilin expects rising labor and material costs to put upward pressure on prices, although these may be mitigated by S Kant's entry into the market in 2018.

SMC distribution costs

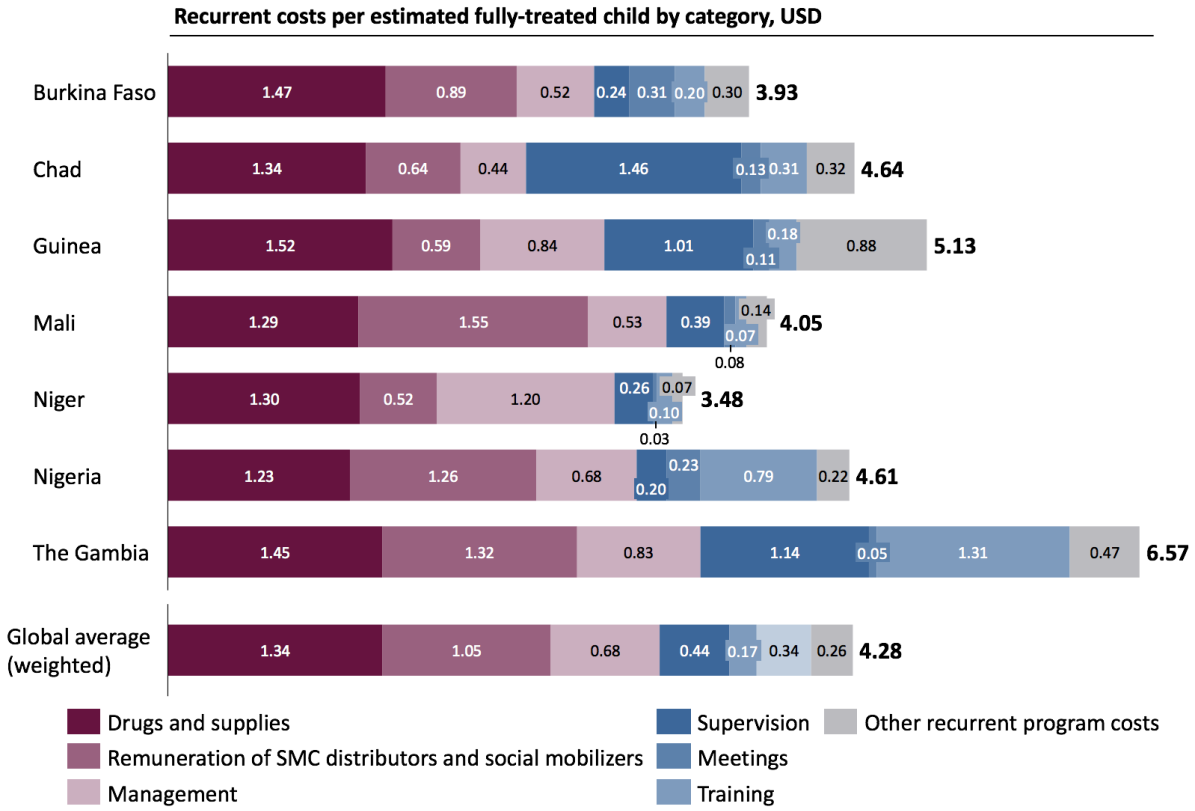
For five of seven countries and in aggregate, ACCESS-SMC achieved the target of spending less than USD 5.00 per child reached in 2015.[97] The total recurrent costs of the program in 2015 were USD 13.3 million across all seven countries.[98] Across the 12.4 million treatments administered in 2015, the cost per treatment was USD 1.07. This implies a cost of USD 4.28 for a four-cycle annual course of treatments across all countries – below the target of USD 5.00.

Beyond the cost of treatments themselves, labor constituted the next largest cost category. The main costs of delivering SMC treatments were (i) drugs and supplies, including taxes customs and transport costs, (ii) remuneration of community health workers and social mobilisers, and (iii) management costs, including salaries of managers in government and implementing partners, and reporting costs. These three cost categories accounted for over 75% of all recurrent expenditures.

There was considerable variation in per-child cost for full treatment between countries at both aggregate and category levels. The aggregate cost per four-cycle treatment in 2015 was estimated to be below the USD 5.00 target in Burkina Faso, Chad, Mali, Niger, and Nigeria. Cost per treatment was lowest in Niger at USD 3.48, but Niger also had the lowest estimated coverage rates for full treatment. By contrast, in Guinea, the cost was narrowly above the target at USD 5.13; in the Gambia, the cost was USD 6.57. In addition, with the exception of drug and supply costs – which were seen to be fairly constant – expenditures by cost category varied significantly across countries. See Figure 7 below for a detailed analysis of recurrent costs by category in each country.

Figure 7. Average equivalent recurrent cost per child (3 to 59 months) for four SMC cycles, by cost category, 2015[99],[100]

[95] Letter from IDA Foundation to Malaria Consortium, 15 December 2015
[96] Interview with Guilin
[97] According to MC, there was no agreed benchmark for this indicator. Targets were set by Unitaid based on 2015 actuals in the 2016 logframe revision.
[98] Management Sciences for Health, 'The costs of Seasonal Malaria Chemoprevention (SMC) implementation in the Sahel sub-region of Africa: a multi-country cost analysis'
[99] Management Sciences for Health, 'The costs of Seasonal Malaria Chemoprevention (SMC) implementation in the Sahel sub-region of Africa: a multi-country cost analysis'
[100] "Other" costs include Distributor and supervisor equipment (t-shirts, cups, spoons, etc.), recurrent monitoring and evaluation activities, social mobilization activities and playing of radio spots, satisfaction surveys, and other miscellaneous recurrent costs.



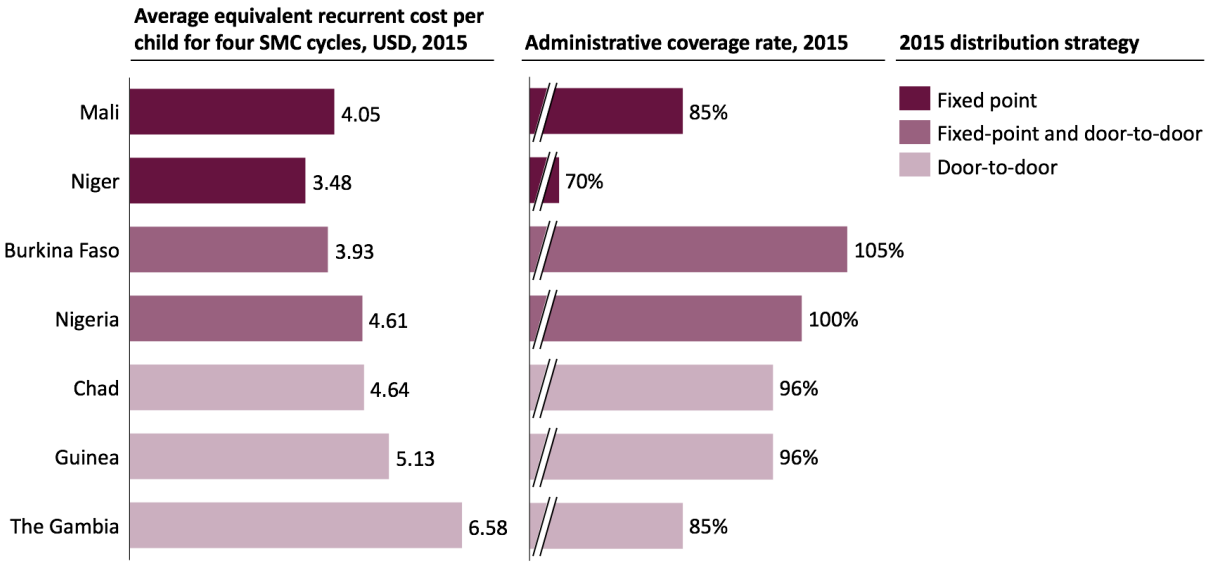
NB: Global average shows Dalberg calculations based on costs reported in MSH's multi-country cost analysis. This average weights the costs per country by the number of treatments distributed per country

Countries using fixed-point distribution strategies tend to have lower costs but also lower coverage rates; countries using both models had the highest coverage. As illustrated in the figure above, Niger, which used fixed-point strategies for most of 2015, had the lowest costs per four cycle- course of treatments at USD 3.48. This was mostly due to lower costs in supervision, trainings, and other costs.[101] Guinea and the Gambia, by contrast, where costs exceeded USD 5.00 per child, were the only countries to use exclusively door-to-door distribution. Burkina Faso and Nigeria, which predominantly used door-to-door administration with fixed-point distribution in some cases, achieved the highest rates of children reached but incurred costs in the middle range.

However, it is too early to conclude on the best balance between fixed-point, door-to-door, and mixed strategies. Given the significant contextual variations between countries and the lack of rigorous cost-effectiveness data, there is not enough information to draw links between number of children reached, cost per child reached, and mechanism of delivery.

Figure 8. Comparison of delivery mechanism, cost per child, and children reached by country

[101] "Other" costs include Distributor and supervisor equipment (t-shirts, cups, spoons, etc.), recurrent monitoring and evaluation activities, social mobilization activities and playing of radio spots, satisfaction surveys, and other miscellaneous recurrent costs.



NB: Niger introduced door-to-door distribution in some districts for the fourth and final cycle of 2015

There are few further opportunities to reduce the costs of the ACCESS-SMC model. As discussed above, the price for SP+AQ is unlikely to see significant decreases. Procurement costs for the project to move medicines from the manufacturer to the different countries were at the industry standard of 1.83% of the value of the goods.[102] In-country distribution is slightly more expensive, at approximately 5%, but the rates are standard for the local pharmaceutical distribution companies that handle in-country supply chain management. It is also unlikely that savings can be made from reduced labor costs when scaling up. The workers involved were paid standard rates determined by the national health system, and sometimes below these standard rates. That said, integration with other programs delivering at scale in target communities during the rainy season – such as nutrition checks, or other intermittent preventative treatments – may increase cost effectiveness by allowing for cost sharing.

These initial cost-effectiveness estimates of SMC treatment appear favorable, but further study is needed to draw firm conclusions. MSH estimates of deaths averted indicate that recurrent program costs equate to a cost per death averted of USD 2,301.[103] The data do not yet exist to conduct a detailed cost-effectiveness analysis. However, Dalberg has estimated the approximate cost of SMC per life-year saved to be between USD 32 and 60, varying by country, with most falling into the range USD 39-48. At this unit cost, SMC would be highly effective according the World Health Organization's Choosing Interventions that are Cost-Effective initiative (WHO CHOICE) benchmarks.[104] Indeed, in most countries, the estimated recurrent

[102] Dalberg expert interview

[103] David Collins. Management Sciences for Health. The Cost and Impact of ACCESS-SMC – Transforming the Malaria Landscape in the Sahel: Seasonal Malaria Chemoprevention. June 2016.

[104] Defined as less than one time the national annual GDP per capita per DALY avoided (as presented in the right-hand column of Table 6).

cost per life-year is approximately one-tenth the total cost per DALY that forms the threshold for WHO CHOICE's definition of highly effective.[105]

Table 5. Analysis of recurrent costs per DALY averted by ACCESS-SMC, excluding Chad (lives-saved data not available)

Country	2013 life expectancy at birth (Years)	Recurrent costs per death averted (USD)	Average life expectancy increase per malaria death averted by SMC[106] (Life-years)	Estimated recurrent costs per life-year[107] (USD)	WHO CHOICE benchmark for "highly cost effective" interventions per DALY, (2015 USD)[108]
Burkina Faso	59.0	2,079	56.4	37	590
Chad	52.2	-	-	-	776
Guinea	58.8	2,716	56.2	48	531
Mali	57.3	2,144	54.7	39	724
Niger	60.9	1,843	58.3	32	359
Nigeria	53.2	2,428	50.6	48	2,640
Gambia	60.6	3,482	58.0	60	472
Source	*WHO*	*MSH*	*Dalberg analysis*	*Dalberg analysis*	*World Bank*

[105] However, the estimates of recurrent costs per life-year for SMC exclude some of the set-up costs included in the unit costs per DALY benchmark.
[106] Derived from life expectancy of an average child in the target population minus average age of child in the target population. Assumes an even age distribution of children between three and 60 months in (i) the target population and (ii) deaths averted. Also assumes (iii) negligible difference between age of treatment and potential age of death, given short half-life of SMC treatment. This column is therefore life expectancy of a child born in 2013 minus 2.625 years, 2.625 years being the halfway point between three and 60 months.
[107] Divides recurrent costs per death averted by estimated minimum DALYs averted per death averted.
[108] WHO CHOICES defines interventions costing less than national GDP per capita per DALY averted as "highly cost effective". This column therefore shows national GDP per capita.

A high-level comparison shows that ACCESS-SMC is slightly less cost-effective than the most common malaria interventions. As described above, Dalberg estimates that ACCESS-SMC experienced a cost-effectiveness of approximately USD 32-60/DALY saved. According to WHO benchmarks, treatment-based malaria responses usually show the best rates of cost-effectiveness, such as case management with ACT (USD 9/DALY) or sulfadoxine-pyrimethamine (USD 13/DALY). However, ACCESS-SMC performed better against other preventative interventions, which commonly show relatively lower rates of cost-effectiveness, such as the provision of bed nets (USD 29/DALY) and indoor residual spraying (31 USD/DALY). See Table 6 below for a comparison of common antimalarial cost-effectiveness benchmarks.

Table 6. Comparison of ACCESS-SMC recurrent costs per DALY averted with other malaria interventions

Type of intervention	Intervention	Coverage level under consideration	Estimated recurrent costs per life year saved (USD)	Comparison to SMC
Prevention	ACCESS-SMC	80%	32-60	N/A
Type of intervention	**Intervention**	**Coverage level under consideration**	**Average cost per DALY saved (USD)**	**Comparison to SMC**
Treatment	Case management with artemisinin-based combination therapy (ACT)	80%	9	More cost-effective
Treatment	Case management with non-artemisinin-based combination therapy (Comb)	80%	12	More cost-effective
Treatment	Case management with sulfadoxine-pyrimethamine (SP)	80%	13	More cost-effective
Prevention	Insecticide-treated bed nets (ITN)	80%	29	Comparable
Prevention	Indoor residual spraying (IRS)	80%	31	Comparable
Prevention	Intermittent presumptive treatment in pregnancy (IPTP)	80%	237	Less cost-effective

Evaluator's assessment summary: **The strength of MC's relationship with Guilin contributed to stable drug prices, and overall delivery costs remained within expectations. However, more data are required to assess what more can be done to improve the cost-effectiveness of distribution approaches.** Drug prices remained stable throughout the program and it was clear that this was in large part due to the existing relationship between MC and Guilin. (In fact, it was found that the procurement agent was not able to secure prices as low as those obtained by MC). Overall delivery costs remained around the USD 5 per child level, as targeted, and there seemed to be few, if any, suggestions from stakeholders of ways to improve efficiency. Initial data suggest that ACCESS-SMC was comparable in cost-effectiveness to other malaria interventions, but final project data, and a detailed comparison-analysis, would be required to make firm conclusions here.

3.2.3 Output 5: Additional resources for SMC mobilized

Table 7. Performance against logframe targets, Output 5

Indicator	2015 target	2015 actuals	2016 target	2016 actuals	Commentary
O5.1 Financial gaps in supported countries identified and reported	–	Baseline funding gap assessment not conducted	–	Gap assessment conducted by MSH	Malaria Consortium has also completed a donor mapping for the seven target countries in 2016
O5.2 Percentage funding for procurement for SMC products and delivery in supported countries by each funder/donor other than Unitaid	Over 12.5%[109]	12.5%	Over 50%[110]	Not available	Six of seven countries have secured additional donor funding for 2017 and 2018

Partners have conducted the planned research into countries' financing needs. MMV finalized its analysis of funding gaps in 2016, rather than 2015 as originally planned. As planned, MSH completed a gap assessment of the unmet SMC coverage and costs as part of its cost analysis published in late 2016. In addition, Malaria Consortium completed a donor mapping of the seven countries.

The Global Fund and PMI plan to provide transition funding for six of seven target countries; transition targets therefore appear to be on track. In 2017, The Global Fund will fully replace Unitaid as the largest SMC funder in Guinea, Mali, Niger, and the Gambia – the CRS-supported countries. Unitaid is considering an application by MC for additional funding for the ACCESS-SMC initiative in Burkina Faso, Nigeria, and Chad in 2017. The Global Fund will also take on funding for 14 additional districts in Chad. PMI will provide funding to replace a portion of Unitaid's funding in Burkina Faso in 2018, however this is not confirmed as of February 2017. It is likely that SMC will be included in Nigeria's Global Fund concept note in 2017. Data are not available on the resources committed by other donors in 2016. However, other donors' willingness to provide support past the project end date indicates that ACCESS-SMC has been successful in attracting longer-term funding.

The project has strengthened M&E and pharmacovigilance systems, but future funding sources are not yet known. Monitoring and evaluation and pharmacovigilance are not yet included in the funding secured from other donors for 2017, and it is not clear what data gathering and reporting systems will be established in these areas.

CRS' proactive approach and strong relationship with the Global Fund helped it successfully transition its grant countries towards Global Fund funding. CRS is a principal recipient of the

[109] Dalberg rephrased the target stated in the log-frame from "under 50%" to "over 50%" to make clear that the objective was to secure 50% of alternative donor funding, which is not aligned with the intention of the output.
[110] Dalberg rephrased the target stated in the log-frame from "under 50%" to "over 50%" to make clear that the objective was to secure 50% of alternative donor funding, which is not aligned with the intention of the output.

Global Fund in several countries. CRS ACCESS-SMC country teams were therefore able to work with CRS teams to understand how to support governments in making applications to the Global Fund. Based on their experience with the multi-year application process, CRS country teams report preparing this process from the beginning of the grant in early 2015.

Malaria Consortium has been less successful in helping countries to transition out of Unitaid funding. MC worked to attract the interest of other donors in SMC by presenting the current results of the SMC campaign in regional and global fora, and by holding bilateral discussions with Unicef and PMI. However, stakeholders within the consortium and in-country implementing agencies expressed disappointment with MC's work towards ensuring the program's sustainability.[111] For example when asked about sustainability of SMC, a government stakeholder shared that "one challenge we have faced is that MC has not made it clear how this will be sustainable." Other stakeholder interviews shared the view that MC begun donor discussions too late, and were not sufficiently targeted when approaching potential donors.

Evaluator's assessment summary: **CRS was able to leverage its position as incumbent Global Fund prime recipient to successfully secure transition funding. MC was less successful (and was not inherently as well positioned as CRS) but could have begun this process earlier, and in a more targeted fashion, by engaging sooner with the Global Fund and relevant country coordinating mechanisms.** Overall, transition of funding to other donors was achieved in CRS-managed countries (with the important exception that funding for ongoing monitoring is not yet secured). Two key success factors were i) CRS started the transition process from the beginning of the engagement and ii) CRS leveraged its position and knowledge of the Global Fund's processes (including the relevant country coordinating mechanisms) to include SMC in country concept notes (i.e. funding proposals). MC was less successful with transitioning, and could have been more strategic to achieve this output. MC might also have seen greater success by prioritizing this output from the beginning of the grant. Its approach of sharing outcomes in international fora and engaging in informal dialogue with donors was not sufficient to fully achieve transition funding.

[111] Evidence from several interviews anonymized

4 EFFICIENCY

Key questions

- *Have the grant implementer and co-implementers ensured project planning, implementation and assessment in collaboration with the national authorities? Can the grant implementers and their partners demonstrate that national authorities were aware and participating in grant activities at the national level?*
- *How cost efficient and cost effective was grant implementation?*
- *Were challenges raised with the UNITAID Secretariat in a timely manner and did the Secretariat participate in resolving these challenges?*
- *Was the grant's procurement model designed to identify and solve procurement-related problems (where applicable)?*
- *Were there any concerns or reported instances related to potential diversion of products, counterfeit products or poor quality products?*
- *Is the grantee implementation arrangement and coordination with co-implementers and national and sub-national authorities efficient?*

The combination of two separate grant proposals made strategic sense. The consortium structure simplified communication for Unitaid, and also limited duplication of activities at the central level (e.g. procurement). Stakeholders report that MC and CRS forged a productive relationship (despite some relationship tension as a result of previously being competitors for the same grant). MC and CRS collaboratively solved problems, for example when deciding how to adjust the project plan to account for lower-than-expected production in 2015. In this instance, the project steering group[112] decided to continue operating in all seven countries but to reduce the administration targets for each country, allocating targets and stock according to need.[113] The collaborative manner in which MC and CRS reallocated the reduced stock contrasts with the competitive relationship with other SMC funders in 2015, who were also seeking Guilin's stock.

However, the specific structures of the consortium – involving one prime recipient and five subgrantees, some of whom subcontracted to each other – resulted in some inefficiencies, including delays in decision making. For example, CRS had to postpone switching its operating model from fixed-point to door-to-door distribution in Niger for two months while it obtained approval from MC. CRS and the Nigerien PNLP noticed that the coverage rate was extremely low in these two districts after the first administration cycle, but could only change the distribution strategy for the fourth cycle as a result of management approval delays. An interviewee from the Niger PNLP noted: "I noticed that administration was simpler in MC countries. When there isn't another unit managing, there is more room for the implementation on the field. It was very complicated; CRS said they had no decision making authority. This makes it very difficult to discuss anything." In addition, not all activity duplication was avoided

[112] Comprising representatives of MC and CRS.

[113] Alternatives included (i) reducing the number of countries or (ii) reducing the number of cycles per country. Together with Unitaid, the consortium decided not to pursue either of these alternatives and to roll out a four-cycle campaign in all seven target countries to ensure the maximum number of countries had experience implementing a full cycle in 2015..

due to the complex variations in subgrantee responsibilities by country. For instance, MC had originally planned to develop communications materials for health workers for its countries, while CRS subcontracted SUA for its countries. However, by the end of the project, MC was using some SUA tools rather than those it had developed in-house.

Delays in finalizing and approving the grant's budget caused operational challenges for country offices. The project began in September 2014 but the budget was not finalized and approved until May 2016. This delayed contracting with some subcontractors, including LSHTM, which could not sign its contract with CRS until May 2015. Grantees worked from provisional budgets during 2015, requiring them to answer for deviations from interim budgets, including out-of-date revisions, which increased the administrative burden they faced.

National-level planning efficiently coordinated a range of stakeholders. In the seven target countries, grantee organisations supported NMCPs' and local health authorities' implementation of the program. Where relevant, other donors funding SMC programmes also participated. Grantees in all countries report that this process of joint planning was efficient and successful at the national level ("macro-planning") and at the local level ("micro-planning").

Grantees report that the phased scale-up that was forced on country offices by supply-side constraints, but commencing with smaller procurement volumes may have improved efficiency. Country offices could build relationships and improve management capacity while delivering at half the anticipated scale. Some interviewees believe that the first year of full-scale implementation was more efficient than it would have been without this ramp-up.

MC shared that Unitaid's administrative requirements were inconsistent and difficult to comply with. Unitaid had to amend its procurement requirements for MC to meet its 2014 deadline. In 2014, Unitaid required MC to conduct competitive appointment processes for both the procurement agent and the manufacturer. [114] Conducting both processes would have made it impossible to place the order by year-end 2014. As a result, MC proposed to appoint Crown Agents for the 2015 season without a full tender process; this was approved by a procurement officer at Unitaid. MC also found Unitaid's accounting guidance unclear and the expectations of Unitaid finance focal points variable over time. Grantees referred to changes in accounting expectations from Unitaid finance focal points changed.[115] In addition, the grantees report that the financial reporting formats expected by Unitaid were unclear and changed between reporting periods, requiring additional effort in order to change accounting taxonomies and repeat reporting for prior periods in line with new formats.[116] That said, the grantee also noted that, once approved, financial disbursements were made quickly and efficiently.

[114] Despite Guilin's monopoly position in the market.

[115] According to MC, following a 2016 meeting, a new Unitaid team asked grantees to include the costs of amortisation in reporting directly to ACCESS-SMC, which was different from the expectations of a previous Unitaid team. This unexpected inclusion of amortisation resulted in country projects showing a loss where none was expected.

[116] No financial reporting template was provided to grantees for the period September to December 2014, resulting in MC constructing its own reporting template based on materials from previous Unitaid grants. For

A lack of stock arrival information from IDA resulted in managerial frustration and, in some cases, increased expenses – IDA has since assigned additional staff to avoid this issue going forward. Country offices report that they were not informed about the expected arrival dates of delayed stock outline in section 3.1, making it difficult for supply chain staff to revise distribution plans. Delays were exacerbated by a lack of detail from IDA Foundation on when stocks could be expected. Country staff report having to make expensive arrangements such as sending out distribution trucks that were not full, in order to meet planned distribution dates. In Niger, CRS had planned to allocate hard tablets only to districts that had used them in 2015, to reduce the number of districts requiring mortars, pestles, and bags of sugar. However, to avoid stock-outs, this plan was changed and stocks were pushed out as they arrived, requiring procurement of extra accessories to crush and mix with the hard tablets. IDA has since assigned a staff member in Amsterdam to be responsible for communication with the grantee on SMC procurement matters. IDA aims to ensure frequent reporting to MC going forward.

Early in the project, there were instances where MC did not follow the procurement procedures expected by Unitaid. For the 2015 campaign, MC conducted negotiations with Guilin directly, rather than through a procurement agent.[117] In addition, MC used a payment process whereby it would pay the manufacturer directly, once the procurement agent had finalized the procurement contract. Unitaid policy recommends that the procurement agent should make payment directly to the manufacturer. The process was reformed for 2016 when a new Unitaid management team took over the project. Unitaid interviewees report that MC did not keep Unitaid abreast of the changes in timelines that led to the decision to send all stocks by air freight for 2016, and Unitaid only approved this decision retrospectively through the budget review.

During the first year of the program, some of MC's management practices did not meet Unitaid's expectations. Malaria Consortium introduced a range of new review procedures following recommendations from a Unitaid management review in 2016. A management review by Unitaid found that partner financial reports were only signed by staff from Malaria Consortium's finance department. It recommended that partner financial reports should also be signed off by staff involved in project management. This recommendation was adopted for the 2016 report. The review also found that partner expenditure documents for 2015 were not reviewed during in-person visits by MC staff but instead were checked online. From June 2016, Malaria Consortium made monthly country visits and requested detailed transaction lists. It is important to note that there was a change in Unitaid management which may have contributed to some differences in expectation. For example, according to MC, Unitaid's previous approach was to fully evaluate key partners themselves which changed, as new management expected MC to evaluate key partners.

---

the 2015 semi-annual report, Unitaid requested MC to report on finances by output. For the 2015 end-of-year report, Unitaid introduced a reporting tool including reporting by activity, which required a repeat of the financial analysis with an increased level of detail.

[117] According to MC, this structure and process was pre-agreed with Unitaid.

5 IMPACT

Key questions

- *Has the grantee been able to report on impact as originally framed in the project plan and Log-Frame? If not, has the grant impact been measured in another way?*
- *Where relevant, can the grantee attribute UNITAID's financial support for medicines, diagnostics or preventive products purchased to patients tested or treated in each beneficiary country?*

This section assesses progress towards the project's intended outcomes and overall impact in mostly qualitative terms. As discussed in section 2, some of the data gathered in the logframe as output indicators are applicable to the projects intended outcomes. However, much of this has not been reported – especially for 2016. In terms of public health, data on malaria cases or deaths averted have not yet been modelled. In terms of market transformation, the near-term future global production capacity and other funders' transition funding has not yet been finalized. The project has not yet generated data on the outcomes it has achieved. This inhibits the calculation of quantitative measures of value for money.

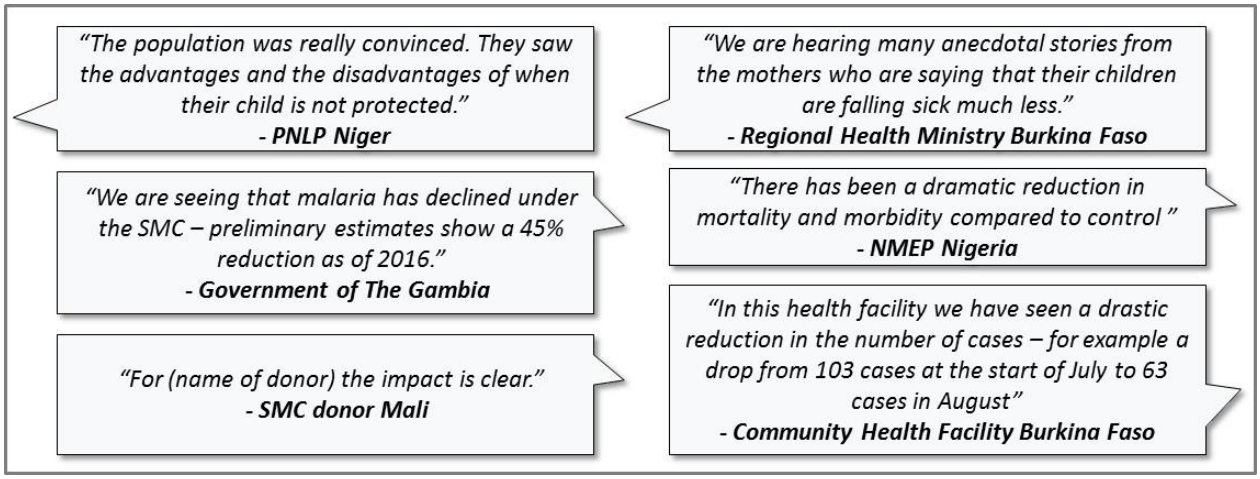
5.1 Public health

Theory of change outcome: *"To reduce the incidence of malaria cases in the regions targeted by the project"*[118]

Anecdotal evidence from interviewees and initial LSHTM analysis suggests that target communities have witnessed drastic reductions in the incidence of malaria among children. Data from LSHTM analysis show that SMC districts experienced reductions in malaria incidence during 2015. Within the under-5 years age group, compared to a modeled counterfactual, the number of malaria cases fell by the following amounts: Burkina Faso – 45%; The Gambia 60%; Mali – 49%; Chad – 24%; Senegal – 54%.[119] Government and donor stakeholders in Burkina Faso, the Gambia, Mali, Niger and Nigeria also shared anecdotal evidence of a reduction in malaria incidence in project areas. MSH reports that its partner clinics on other project no longer receive malaria cases in substantial numbers, and that is planning its work in the Sahel with this reduction in mind. In addition, government officials praised the impact of the intervention and perceived it as adding value to their fight against malaria.

[118] Quoted from revised ACCESS-SMC logframe.
[119] Sagara, Issaka "Progress in scale-up of SMC in the Sahel", ASTMH Atlanta 2016.

Figure 9. Sample of anecdotal quotes on effect on SMC from interviewees.



Though incidence rates are falling, it has so far been difficult to separate the effects of ACCESS-SMC from other malaria interventions. None of the seven country governments have yet made causal claims about reductions in malaria incidence and the ACCESS-SMC program. Though the malaria incidence rate has fallen in each of the seven countries over the last five years, the contribution of one program to this ongoing fall is unclear. ACCESS-SMC was one of several malaria programs conducted in West Africa, which complicates attribution of changes in malaria incidence to ACCESS-SMC.

A reduction in malaria incidence would reduce the burden on health systems. LSHTM's 2015 impact summary finds that ACCESS-SMC had a significant impact on in-patient and out-patient visits.[120,121] Pressure in health systems in target countries is a significant problem. A reduction in malaria incidence would free health care resources to be reallocated to other priorities. ACCESS-SMC may also improve the health system by building health worker capacity – notably community health workers, supply chain managers and those in pharmacovigilance.

ACCESS-SMC has had some success catalyzing support for SMC from governments and other donors. In the future, government and donor funding may increase, enabling expansion of this intervention into new areas and further reducing malaria incidence. As outlined in section 3.2.3 on resource mobilization, the program led to increased support from some donors. Donor funding may, in time, increase SMC program scale – either to national scale in ACCESS-SMC countries, or in other countries in the Sahel.

Initial estimates suggest that expanding SMC will avert millions of cases and thousands of deaths over the next six years, and is likely to contribute to millions of dollars in cost savings. Table 8 below, projects the impact of SMC expansion until 2022. The analysis builds on MSH's analysis

[120] LSHTM, 2015 Impact summary

[121] The impact summary found there had been a 45% reduction among outpatients for malaria in project areas in Burkina Faso in 2015. It found a 66% reduction in inpatients in project areas in the Gambia. Data were not available for other countries.

of cost and impact of ACCESS-SMC from 2015.[122] The analysis models the next seven years such that SMC expands to reach almost 25 million children per year. Based on this expansion, SMC would avert a cumulative 50 million malaria cases and 260,000 deaths. Based on the current cost burden profile of malaria from Ghana[123], the overall cost savings due to SMC will be a cumulative USD 117 million between 2016 and 2022.

The model shows how SMC might transfer the costs of malaria from households, towards program funders (i.e. donors and governments). This is essentially because under a SMC program, households and the health system see fewer malaria cases so incur lower expenses for malaria treatment. This leaves households better off, and frees up resources in the health system. Donors' expenditure clearly increases due to SMC costs, but treatment of future cases is averted.

[122] David Collins. Management Sciences for Health. 'The cost and Impact of ACCESS-SMC – Transforming the Malaria Landscape in the Sahel: Seasonal Malaria Chemoprevention. June 2016.'
[123] Elisa Sicuri et al. The economic costs of malaria in children in three sub-Saharan countries: Ghana, Tanzania and Kenya. Malaria Journal. 2013.

Table 8. Projected impact of SMC expansion[124,125,]

	2015[126]	2016[127]	2017	2018	2019	2020	2021	2022
Number of children reached	***2,724,170***	***5,475,574***	***8,599,759***	***12,824,716***	***16,499,139***	***20,582,971***	***22,770,155***	***24,482,568***
Number of cases averted	*1,229,963*	*2,472,221*	*3,882,791*	*5,790,359*	*7,449,361*	*9,293,212*	*10,280,725*	*11,053,880*
Number of deaths averted	*6,436*	*12,936*	*20,317*	*30,298*	*38,979*	*48,627*	*53,794*	*57,840*
Direct cost savings due to SMC expansion[128]	*2,874,360*	*5,777,454*	*9,073,883*	*13,531,771*	*17,408,774*	*21,717,757*	*24,025,525*	*25,832,347*
Cost of SMC program	*11,850,140*	*23,818,745*	*37,408,951*	*55,787,514*	*71,771,256*	*89,535,925*	*99,050,176*	*106,499,172*
Estimated health system savings	*5,006,330*	*10,062,708*	*15,804,163*	*23,568,557*	*30,321,210*	*37,826,252*	*41,845,739*	*44,992,717*
Estimated household savings	*9,718,170*	*19,533,492*	*30,678,670*	*45,750,728*	*58,858,820*	*73,427,430*	*81,229,963*	*87,338,803*

[124] The expansion to 25 million children reached by 2022 assumes starting SMC administration to 40% of eligible children in Benin, Cameroon and Senegal for 2018; Ghana, Guinea and Mauritania for 2019; and Sierra Leone and South Sudan for 2020. Additionally, the figures assume that the proportion of children reached will increase by 20 percentage points annually in all eligible countries till a target of 80% of all eligible children is reached.

[125] Full explanation of methodology provided in Annex.

[126] David Collins. Management Sciences for Health. 'The cost and Impact of ACCESS-SMC – Transforming the Malaria Landscape in the Sahel: Seasonal Malaria Chemoprevention. June 2016.'

[127] The figures presented from the years 2016 through 2022 are from Dalberg analysis based on the same assumptions as MSH study and figures on eligible SMC population from Cairns et. Al. Estimating the potential public health impact of seasonal malaria chemoprevention in African children. 2012.

[128] Cost of SMC programme – (Estimated health system savings + Estimated household savings)

5.2 Market transformation

Theory of change outcome: *"To improve the existing global SMC product market in terms of demand, supply and quality both within and beyond the life of this project."*[129]

ACCESS-SMC led to improvements in demand, supply, and quality of SP+AQ. ACCESS-SMC has increased demand for SMC drugs from donors, at least in the short term; has supported the availability of a new dispersible formulation; and has contributed to the possible entry of a new supplier into the market from 2018. Given the number of factors outside the control of implementers in shaping the market, these are considerable achievements.

Future market balance is uncertain. ACCESS-SMC has increased demand for products to-date and in the near future, but longer-term demand beyond 2017 is unclear. On the supply side, S Kant will possibly enter the market in 2018 at the earliest, barring any additional delays. To ensure high utilization of the additional production capacity, demand and supply should increase in tandem. However, given the uncertainty over demand and supply expansion, market balance is uncertain beyond the end of Unitaid support.

[129] Not included in project planning but derived by Dalberg from project documentation.

6 LEARNING AND RISK MITIGATION

Key questions

- *Have lessons learnt been documented and widely disseminated by grantees and UNITAID?*
- *Have programmatic and financial risks been identified and tracked over the course of grant implementation?*
- *Have the findings and recommendations of audits (where relevant) been used to improve grant performance?*

Learning

There are examples of individual grantees changing course based on their learning during the project.

- CRS changed its distribution model based on evidence that the chosen strategy was not working. CRS reacted to low coverage rates in Mali and Niger, which used fixed-point distribution strategies, by changing its approach.[130] In two districts of Niger with the lowest coverage,[131] implementers introduced a door-to-door strategy. In the remainder of Nigerien districts and across Mali, CRS introduced the "advanced" strategy, in which delivery teams begin in one fixed point and move to outlying areas once attendance slows down. In Niger, coverage rates increased drastically after the new strategies were introduced.
- In Chad, MC redesigned tally sheets. The country office identified that health workers were making avoidable errors and redesigned the tally sheets to make them more useable for those with lower literacy.
- SMC programs held learning-oriented restitution meetings in each country. These allowed stakeholders from ACCESS-SMC and peer organizations to share lessons learned.
- Project-wide, MC and LSHTM introduced rapid assessment surveys. To supplement the data from household surveys, LSHTM introduced rapid assessment surveys of community health workers at the end of each cycle. These provide an additional data point to triangulate findings on coverage and beneficiary experience. In addition, quick collection of data mitigates the effects of recall bias and missing record cards.

The results of MSH's cost effectiveness study and LSHTM's case control and molecular marker studies were not available during the project period, and so these lessons were not incorporated into project planning. MSH's costing study provides valuable information on the major costs of the model and opportunities (or lack of opportunities) to further reduce costs.[132] The report

[130] According to MC, the change in approach was not instigated by CRS but came about because of a visit by the project director who communicated to NMCP that fixed distribution points were experiencing limited demand; MC also noted that formalization of a more effective distribution strategy in Mali is not finalised

[131] Maradi district and Zinder district.

[132] Gilmartin, C. and D. Collins. The costs of Seasonal Malaria Chemoprevention (SMC) implementation in the Sahel sub-region of Africa: a multi-country cost analysis. 2016. Prepared by Management Sciences for Health for the ACCESS-SMC project

into 2015 was published at the end of 2016. As a result, information from the costing study was not integrated into decision making processes for 2016 cycles. Similarly, the delays in case control and molecular market studies mean they will not be available before the end of ACCESS-SMC. They will not be able to influence project learnings, or provide lessons for donors taking on SMC immediately in 2017.

An iPad and Android system used in the Gambia was an effective tool for increasing the reliability of reporting but, due to low connectivity, could not be used not for mid-project learning or course correction.

Risk mitigation

In-country grantees mitigated risk in each of the seven countries by keeping detailed records and conducting oversight. There were risks inherent to the distribution and management of large quantities of stock in new environments with local staff of varying experience and capacity. Community health workers kept tallies of children treated and tablets distributed; district health supervisors checked and reconciled these and observed community health workers' work to correct any immediate problems

To reduce the chance of loss or wastage during delivery, supply chain managers in country offices monitored stock reports and regularly visited sites. Although there were frequent discrepancies, these related mostly to errors in recording and were reconciled by supply chain managers. None of the seven countries reported any incidents of loss or spoilage of stock in-country.

As mentioned above, the Gambia used an electronic system on iPads and Android devices keep these records. Unlike the paper-based systems that all countries used, the electronic system automatically reconciled in-the-field reporting and stock management reporting. This increased transparency and reduced the burden of reconciliation for supply chain managers.

MC introduced new procedures to manage risk in 2016 in response to Unitaid's review. MC did not systematically report and track the steps it took to mitigate risk as the prime recipient. Starting in the 2016 semi-annual report MC, identified, assessed, and described mitigation procedures for the risks it identified. In addition, as noted above, MC increased its level of financial oversight over subgrantees starting in 2016.

Malaria Consortium mitigated project risk by investigating CSSI's financial capacity and not taking up a renewal of CSSI's contract. CSSI was an in-country implementing partner for SMC in Chad. MC discovered that CSSI lacked the financial management capabilities required of partners and that its accounting was not sufficiently transparent.[133] MC investigated and did not renew the contract with CSSI after it ended in 2015.

Grantees have mitigated any risks from donating SMC drugs to the government through successful relationship management. When SMC treatments enter a country, the implementing

[133] For example, money from different donors became mixed into the same pool.

partners sign a donation contract to hand ownership of the drugs over to the country government. However, grantees remain accountable to Unitaid for the drugs. This poses a dilemma of being accountable for drugs which are not within direct control of implementing partners. This has had an operational impact. For instance, in Niger, when some districts outside ACCESS-SMC ran out of stock in 2016, the government required CRS to channel some of its spare stock outside target districts. However, country offices report that they have been kept abreast of all of these decisions due to good communication, and have been able to account for Unitaid donated stock at all times.

7 CONCLUSIONS AND CONSIDERATIONS FOR FUTURE PROGRAMS

Conclusions

Overall, the ACCESS-SMC initiative was largely successful in achieving its public health and market shaping outcomes. Given the challenging timeline, large size of the grant, level of in-country challenges, and sheer number of stakeholders involved, the ACCESS-SMC initiative was impressive in successfully reaching its targets at output and outcome level[134], and especially for managing a complex procurement and distribution exercise with very few, if any, serious delays.

There are inherently trade-offs between shaping markets and efficiently achieving public health improvements. This will be reflected in all other Unitaid grants given their dual objectives. This grant prioritized market shaping (in line with Unitaid's mission) in its approach in the following ways:

- The steering group's decision to allocate the reduced stock among seven countries. This may have been costlier than focusing on a smaller number of countries; nevertheless given the aim of long-term sustainability via promoting transition funding, it was rational to start the project in more countries to increase the number of places where transition funding could be secured.
- MC's decision to delay procurement to maximize its order for dispersible tablets. This led to additional logistics costs in the 2016 campaigns, delays in Chad and Guinea, and led to some implementation challenges (e.g. the need to use dispersible and hard tablets in the same district). Nevertheless, the use of dispersible tablets improved administration efficiency in some places, and Guilin believes it has supported the expansion of the dispersible market, which over time will improve public health by reducing rejection.

Considerations for future programs

The project achieved many of its output targets, despite working in challenging environments.[135] Several factors contributed to the success of this project, and Unitaid should consider replicating them going forward where relevant and possible:

- **Introducing new health products at scale into the health systems of several countries simultaneously** can incentivize manufacturers to scale-up production capacity whilst also supporting the development of systems on-the-ground to handle greater supply in the future.
- **Using a light-touch approach**, by providing guidance and technical assistance to existing structures, can build capacity where necessary whilst avoiding unnecessary systems redesign. Working through existing health-system distribution networks as opposed to

[134][134] It is important to note that one of the impact level targets (to catalyse market entry of a new supplier) was not met during the programme lifespan; however a new suuplier , S.Kant, are likely to enter the market in 2018.
[135] Country teams in the seven target countries were typically smaller than ten people, as compared to approximately 29,000 health workers, supply chain workers, and volunteers trained and involved in delivery.

creating parallel networks was a notable feature of SMC which should be replicated for future projects.

- Providing options for alternative programmatic approaches (e.g. fixed-point versus door-to-door), and leaving that choice up to grantees, can allow teams on the ground to adapt to specific contexts and react quickly.

Beyond these success factors, there are several broadly applicable recommendations that emanate from the experience during this grant.

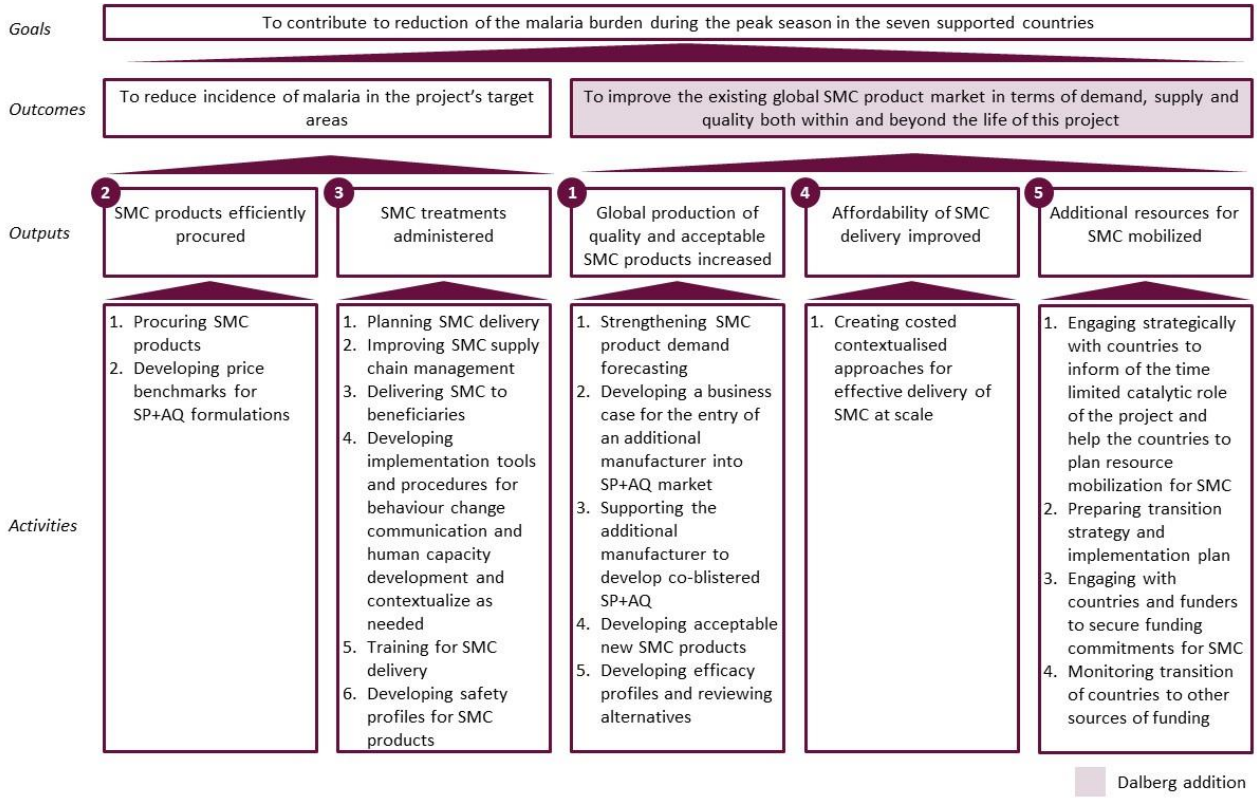
Working with partners who already have strong relationships with relevant donors increases the potential for follow-on funding. CRS's experience as a recipient of Global Fund funding was valuable in securing funding beyond the life of the Unitaid grant. Given Unitaid's focus on time-limited funding, it will be important for Unitaid to continue to evaluate future grantees' donor relationships to support transitioning wherever possible. However, it is important to note that organisations with strong donor ties do not necessarily also exhibit the skills required to implement innovative programmes.

Maintaining consistent financial and programmatic reporting approaches can avoid additional administrative and managerial burden. As far as possible, roles and responsibilities between grant maker and recipient should be agreed up front, and any changes should be clearly communicated. This refers specifically to administrative procedures such as financial and program reporting.

Defining policies on how to deal with unused treatments can avoid potential issues. The grantee's understanding on how to treat leftover stock, and the process to follow in those circumstances, differed from Unitaid's. Regardless of the outcome, the purpose of the 10% buffer stock could have been better defined in the grant's planning stages, to avoid any potential for misunderstandings around its use. Without that policy, it is challenging to assess the extent to which the grantee followed protocol.

Selecting reliable and relevant output indicators is paramount to encourage robust findings. Whilst coverage was clearly high and the program was successful, the quality of administrative data varies widely across countries and this could have been considered during project planning. To address this, more focus could have been given to the household survey targets. Furthermore, given the fact children are required to participate in all four cycles to receive protection for the entirety of the rainy season, a more relevant output target would have been the percentage of children who receive all four cycles of treatment. This might also have incentivized follow-up by health workers where possible, to ensure ongoing participation.

ANNEX THEORY OF CHANGE



his report evaluates the grantee's implementation of the grant

ANNEX EVALUATION METHODOLOGY

The evaluation combined desk research using documents provided by Unitaid and members of the grantee consortium, stakeholder interviews, and visits to Burkina Faso and Niger.

SCOPE

Unitaid contracted Dalberg to assess progress against the goals of the grant. Specifically, Dalberg assessed (i) progress towards the output indicators specified in the revised logframe, (ii) progress towards other objectives implicit in original project plans and the initial logframe, (iii) successes of the project and challenges encountered, (iv) factors for these, and (iv) the extent to which the results of the project are attributable to grantees and to Unitaid.

The evaluation is based on empirical observations – whether from primary research (including interviews with stakeholders on the ground and analysis of reporting documents) or secondary research (including interviews with headquarter staff and annual reports). It is therefore limited in its ability to assess many of the fundamental questions about program design and the extent to which the original project plan optimized effectiveness or efficiency. While Dalberg can assess project achievements against a counterfactual of no intervention, the evaluation does not assess project achievements against the counterfactual of all possible alternative interventions. Instead, Dalberg assesses empirically the criteria and the data on which these decisions were made. Additionally, the evaluation is inherently limited by the quality of data provided as Dalberg could not independently audit all data sources.

Dalberg drew on data provided by grantees, interviews, and a review of relevant literature. (Data sources are detailed in the following section on data gathering methodology.) Dalberg assessed the strength of this evidence by evaluating research methodologies and comparing data points and interviewees' perceptions where possible. However, this evaluation does not attempt to replicate the grantee consortium's data gathering or to otherwise independently verify the data collected.

The timing of the evaluation before completion of project research activities reduced the availability of data for assessing the reach and the public health impact of SMC campaigns. Dalberg's evaluation began in 2016, while the final cycles were still being administered in some countries. Routine project data on the number of doses procured, treatments administered, and campaign cycles delivered on time were available. However, much of the data that will inform assessments of project outputs and outcomes for the 2016 season – notably household surveys of coverage rates, assessments of unit costs in 2016, estimates of the malaria burden and incidence, and final stock levels at project closure – was not available to the evaluation team.

DATA GATHERING

Research was undertaken as follows:

- **Desk review of documents shared by Unitaid and the grantee consortium.** The evaluation team analysed the following documents:
    - MC's original ACCESS-SMC application and its application for SMC Plus
    - Stock reports
    - Semi-annual and annual reports to Unitaid
    - The 2016 revised logframe
    - Results summaries produced by MC and CRS
    - Procurement and shipping documentation
    - Research reports developed by grantee organisations, including MSH's cost effectiveness analysis and LSHTM's household surveys
    - Learning documentation, codifying the lessons learned and summarising project achievements.
- **Additional desk review.** The evaluation team also consulted additional materials, including the World Malaria Report and policy literature on market development in global health.
- **Interviews with 74 stakeholders.** Interviewees were suggested by Unitaid, MC and CRS. The evaluation team interviewed stakeholders from grantee consortium members, in-country implementation partners (predominantly in government health authorities) and peer donors. Country teams identified a shortlist of in-country targets for interviews for each country, including internal staff. Evaluation contact points at MC and CRS identified global-

level interviewees, including managerial staff and staff working on global aspects of the grant. The interviewees are listed in Table 9.

- **For Burkina Faso and Niger, interviews were conducted in person.** The evaluation team interviewed 11 and 12 stakeholders respectively.
- **For the other five countries, interviews were conducted remotely.** Between one and five interviews were held per country, depending on subjects' availability.
- **For global-level interviewees, interviews were also conducted remotely.** Interviews were held with 23 managerial staff and staff working on global rather than country implementation.

- **Visits to an administration site in Burkina Faso.** One member of the evaluation team conducted a visit to Koudougou to speak with stakeholders involved in all aspects of program implementation.
- **Ad hoc data requests and clarifications.** In addition to interviews and document submission, country teams, Unitaid, grantee organisations provided information ad hoc in response to Dalberg's questions.

As with any evaluation exercise, there were practical constraints on Dalberg's data gathering. Due to time limitations, the number of interviews possible in each country was limited. Not all interview targets were available to speak, and some interviews were limited in range or were abandoned due to technological constraints on communication. Dalberg did not conduct an audit of data sources, so are relying on accuracy of primary data sent by various stakeholders. Consistency of information was assessed via triangulation of sources.

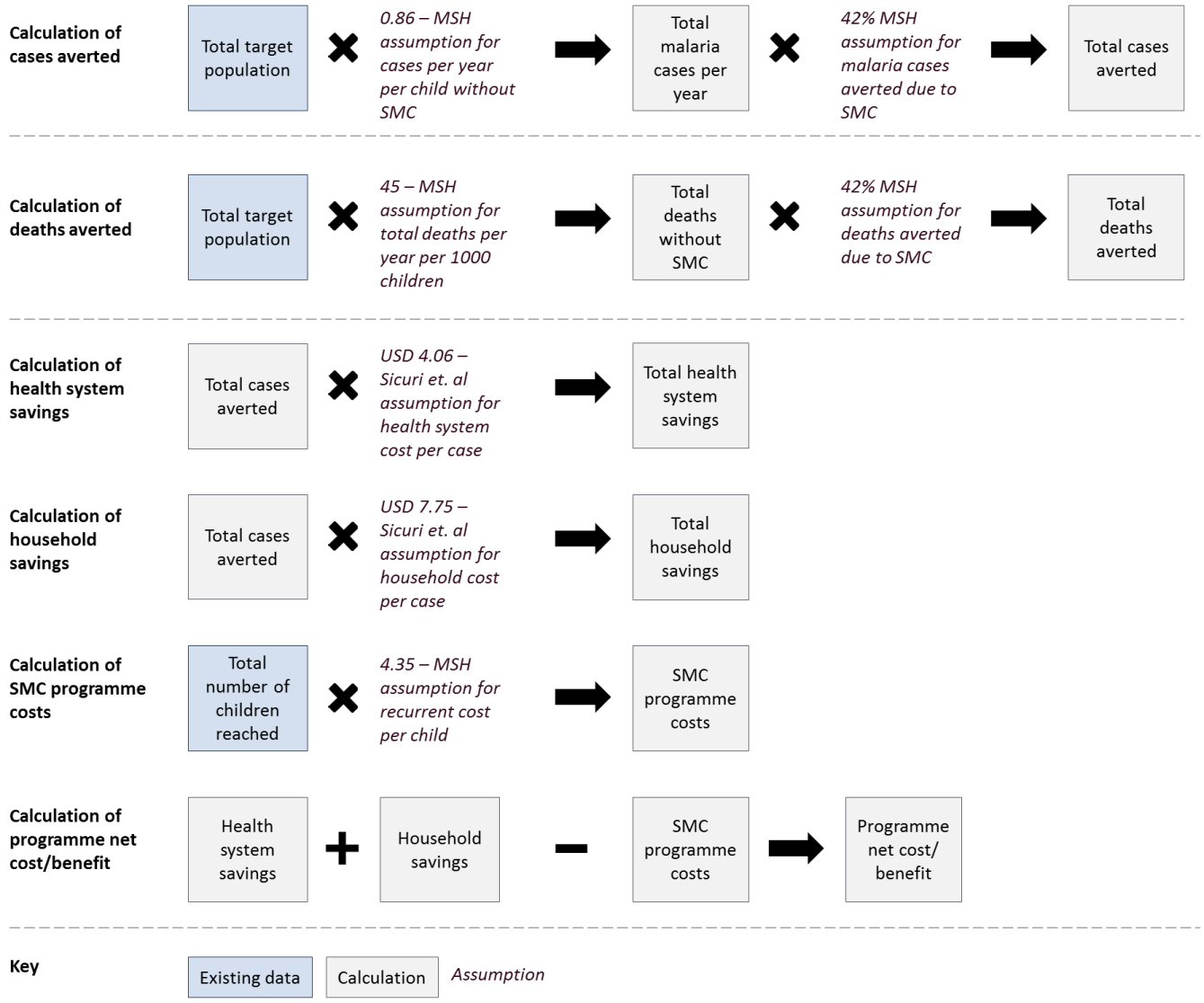
Table 9. List of interviewees

Interviewee	Organisation	Country (if applicable)	Position or title
Rahila Abdoulaye	Catholic Relief Services (CRS)	Niger	Program manager
Abdoulraoufou Alkassane	CRS	Niger	Monitoring, evaluation, accountability and learning officer
Zaratou Ankourao	CRS	Niger	Assistant program manager
Ebenezer Sheshi Baba	Malaria Consortium (MC)	–	Technical director, Africa
M. Baro	Ministry of Health	Burkina Faso	Director general, Koudougou region
Cristine Betters	MC	–	Programs director, Africa
Kodbesse Boulotigam	Programme national de lutte contre le paludisme (PNLP)	Chad	Seasonal malaria chemoprevention (SMC) focal point
Hamadou Boureïma	Unicef	Niger	Nutrition specialist
Robert Camara	Ministry of Health	Guinea	National director
Siriman Camara	WHO	Guinea	HIV/AIDS, TB and malaria prevention
Alexandra Cameron	Unitaid	–	Technical officer
Lamin Ceesay	Ministry of Health	The Gambia	Regional director, Upper River Region
David Collins	Management Sciences for Health (MSH)	–	Global health advisor
Patrice Coulibaly	CRS	Mali	Project manager
Eric Coulibaly	MSH	Niger	-

Interviewee	Organisation	Country (if applicable)	Position or title
Donald Dama	MC	–	Project finance manager
Jean Dieudonne Damiba	MC	Burkina Faso	Monitoring and evaluation manager
Kone Diakalia	Ministry of Health	Mali	Head of national malaria control program
Yacine Djibo	Speak Up Africa	–	President
Seydou Fomba	PNLP	Mali	SMC Focal Point
Katerina Galluzzo	Unitaid	–	Technical officer
Ntadom Godwin	National Malaria Elimination Programme (NMEP)	Nigeria	Head case management branch
Timothee Guilavogui	Ministry of Health	Guinea	Deputy national coordinator
Eric Habbard	CRS	–	Monitoring, evaluation and learning coordinator
Jabar Hamid	Ministry of Health	Chad	General secretary
Suzanne Van Hulle	CRS	–	Senior malaria advisor
Huja Jah	CRS	The Gambia	ACCESS-SMC country project manager
Hadizou Jakou	Ministry of Health	Niger	National coordinator
Baba Galleh Jallow	Ministry of Health	The Gambia	Regional director, Central River Region
Johanna Johansson	MC	Burkina Faso	Acting project director (former), Acting country director (current)
Musa Kana	ERIC (Research agency subcontracted by LSHTM)	Nigeria	Principal investigator
Balla Kandeh	Ministry of Health	The Gambia	Program manager
Maxwell Kawole	MC	Nigeria	Country director
Hamit Kessely	Centre de Support en Santé Internationale	Chad	Research manager
Menno Krijger	IDA Foundation (Procurement agent subcontracted by MC)	–	Director of sales and marketing
Eugene Kaman Lama	CRS	Guinea	Project manager
Yonli Lamoudi	Centre de Support en Santé Internationale	Chad	Head, Public health department
Ross Hamilton Leach	Unitaid	–	Manager, Value for money
Soumana Maiga	PNLP	Niger	Communications officer
Idrissa Maiga	Ministry of Health	Niger	Secretary general
Marie Marcos	Unicef	Niger	Maternal and child health specialist
Aziz Martin	CRS	Niger	Supply chain manager
Jules Mihigo	President's Malaria Initiative	Mali	Health representative
Paul Milligan	London School of Hygeine and Tropical Medicine (LSHTM)	–	Principal investigator
Chada Mohammed	CRS	–	Grant manager
Bala Mohammed	NMEP	Nigeria	Coordinator
Diego Moroso	MC	–	Project director
Daugla Doumagoum Moto	Centre de Support de Santé International	Chad	Director
Ombeni Mwerinde	Unitaid	–	Monitoring and evaluation officer
Victor Nana	MC	Burkina Faso	Program manager

Interviewee	Organisation	Country (if applicable)	Position or title
Charles Nelson	MC	–	Chief executive officer
Ana Alvarez Nieto	Unitaid	–	Program officer
Johnbull Ogboi	Jedima International (Research agency subcontracted by LSHTM)	Nigeria	Principal Investigator
Ines Ouedraogo	Centrale d'Achat des Médicaments Essentiels Génériques et des Consommables Médicaux (State pharmaceutical distributor)	Burkina Faso	Pharmacist in charge of distibution
Jean Bosco Ouedraogo	Institut de Recherche en Sciences de la Santé (Research agency subcontracted by LSHTM)	Burkina Faso	Principal investigator
Ouedrago Ousmane	Ministry of Health	Burkina Faso	Health facility head
Haidara Ousmane	World Bank	Burkina Faso	Public health specialist
Andrew Parkes	MC	–	Global operations manager
Ganesh Ramachandran	Unitaid	–	Grant manager
Timothy Rubashembusya	MC	–	Consultant
Lantonirina Razafindralambo	CRS	Niger	Deputy project director
Arantxa Roca-Feltrer	MC	–	Epidemiologist and monitoring and evaluation function head
Issaka Sagara	Malaria Research and Training Center (Research agency subcontracted by LSHTM)	Mali	Co-investigator
Adama Sanogo	MC	Chad	Country director
Yacouba Savadogo	PNLP	Burkina Faso	Coordinator
Kalpesh Shah	S Kant	–	Vice president, International marketing
M. Sidikou	Office National des Produits Pharmaceutiques et Chimiques (State pharmaceutical distributor)	Niger	Stock manager
Paul Snell	LSHTM	–	Data manager, ACCESS-SMC
Lily Su	Guilin	–	Managing director
André-Marie Tchouatieu	Medicines for Malaria Venture	–	Associate director, Access and product management
Gladys Tetteh	MSH	–	Senior principal technical advisor
Lorenzo Witherspoon	Unitaid	–	Procurement officer
Sourabie Yaya	Ministry of Health	Burkina Faso	District chief medical officer
Ambachew Yohannes	Unitaid	–	Technical officer

IMPACT ANALYSIS METHODOLOGY[136,137]



[136] The existing data on total number of children reached is based on 80% coverage of the eligible U5 population as estimated by Cairns et. Al. Estimating the potential public health impact of seasonal malaria chemoprevention in African children. 2012.

[137] Dalberg's assumption for the average cost per case is from a weighted average of the combined household and health system costs of uncomplicated malaria and malaria hospitalization from Ghana. These figures were calculated by Elisa Sicuri et al. The economic costs of malaria in children in three sub-Saharan countries: Ghana, Tanzania and Kenya. Malaria Journal. 2013.