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ACCESS SMC

Achieving catalytic expansion of seasonal malaria chemoprevention in the Sahel

Monitoring and Evaluation Strategy

November 2015

This M&E Strategy was prepared by Malaria Consortium thanks to funding from UNITAID under the ACCESS-SMC project. The views expressed do not necessarily reflect those of UNITAID.

ACCESS-SMC is a UNITAID-funded project, led by Malaria Consortium in partnership with Catholic Relief Services, which is supporting National Malaria Control Programs to scale up access to seasonal malaria chemoprevention (SMC) to save children's lives across seven countries in the Sahel, by demonstrating the impact of SMC at scale; ACCESS-SMC will promote the intervention's wider adoption.

For further information visit www.access-smc.org and www.unitaid.org

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Abbreviations and Acronyms

ACT	Artemisinin-based Combination Therapy
AQ	Amodiaquine
CHW	Community Health Worker
CRS	Catholic Relief Services
CSSI	Centre de Support en Santé Internationale
DHS	Demographic Health Survey
ERP	Expert Review Panel
HMIS	Health Management Information System
LLIN	Long Lasting Insecticide Nets
LMIS	Logistic Management Information System
LSHTM	London School of Hygiene and Tropical Medicine
M&E	Monitoring and Evaluation
MC	Malaria Consortium
MIS	Malaria Indicator Survey
MMV	Medicines for Malaria Venture
MSH	Management Sciences for Health
NMCP	National Malaria Control Programme
PV	Pharmacovigilance
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
SBCC	Social Mobilization and Behaviour Change Communication
SEA	Speak Up Africa
SMC	Seasonal Malaria Chemoprevention
SP	sulfadoxine/pyrimethamine
SP+AQ	sulfadoxine/pyrimethamine + amodiaquine
SUA	Speak Up Africa
TA	Technical assistance
WARN	West African Regional Network
WHO	World Health Organization

1. Purpose of Monitoring & Evaluation strategy

The document lays down processes and approaches to monitoring and evaluation of the ACCESS-SMC project in the target communities in Africa.

The M&E strategy is aimed at maintaining systematic processes for SMC data collection and management thereby creating opportunities to generate and use quality data for reporting and decision making during the project lifetime. M&E approaches described in this document are aligned with existing data collection and management systems within each of the project countries, as well as the partner organizations, documented best practices, rigor in evidence, integrity and transparency, informed by best thinking and innovations and efficiency in implementation.
Specifically, the document articulates:

- standard indicators (core and additional) that will be measured in the life of the project;
- key roles and responsibilities of each of the partners as it relates to the project M&E framework;
- data flow and reporting responsibilities within the countries, as well as among the consortium partners;
- donor reporting and reporting calendar;
- data quality processes and approaches; and
- data utilization and dissemination.

2. Project overview

Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC) is a UNITAID-funded project, led by Malaria Consortium in partnership with Catholic Relief Services, which is supporting National Malaria Control Programs in the roll out of SMC. This three year project is supported by London School of Hygiene & Tropical Medicine, Centre de Support de Santé International, Management Sciences for Health, Medicines for Malaria Venture, and Speak Up Africa. It will provide up to 30 million SMC treatments annually to 7.5 million children in Burkina Faso, Chad, Guinea, Mali, Niger, Nigeria and The Gambia, potentially averting 36,750 deaths.

In 2012, the World Health Organization endorsed seasonal malaria chemoprevention (SMC) as an important tool in the prevention of malaria. SMC, achieved by administering up to four monthly doses of sulfadoxine-pyrimethamine (SP) plus amodiaquine (AQ), or SP+AQ, is effective in areas with high seasonal variation in malaria transmission and where resistance to SP+AQ is low, with the greatest opportunity for impact being in the Sahel. SMC is targeted at 24 million children aged three to 59 months of age who bear the greatest risk of mortality. SMC is highly effective, and has the potential to prevent 75% of uncomplicated and severe malaria cases.

ACCESS-SMC will aim at reducing the cost of SMC administration and promote its wider adoption by demonstrating its feasibility and impact at-scale. It also aims to increase the global supply of quality assured SMC products by incentivizing an additional manufacturer to join the currently monopolistic market for quality SP+AQ.

It will generate evidence of the safety and efficacy of SMC by strengthening national pharmacovigilance systems and monitoring drug resistance. And finally, ACCESS-SMC will mobilize additional resources so that more children can sustainably benefit from this important intervention both now and into the future.

ACCESS-SMC project will play a critical role in assisting countries in developing strong and sustainable systems to incorporate SMC as a key intervention for malaria control into their strategic plans.

The project will increase SMC coverage in seven target countries, and expand global production of quality SMC products through achievement of five core outputs, namely:

1. SMC product demand forecasting strengthened
2. SMC products efficiently procured and delivered
3. SMC treatments administered to target population within target countries
4. Affordability of SMC delivery improved by increased efficiencies
5. Additional resources for SMC mobilized from other sources

2.1. ACCESS-SMC Program Structure and Operations

ACCESS-SMC is implemented by a consortium of international and national partners in collaboration with the National Malaria Control Programs of targeted countries and existing regional Roll Back Malaria (RBM) networks. Malaria Consortium is the lead partner on the project, with the ultimate accountability to the donor.

The project is being implemented in close partnership with Catholic Relief Services (CRS).

The other partners on the project are:

- LSHTM: Responsible for surveillance, public health evaluations, and pharmacovigilance, technically, operationally and contractually responsible for management of a range of country-level research partners. LSHTM also provides technical assistance (TA) to CRS in implementation of SMC in the four CRS-led countries.
- MMV: Responsible for demand forecasting, product development and manufacturer support.
- MSH: Responsible for the costing component of SMC and of providing technical assistance on optimizing the supply chain to deliver SMC interventions.
- SUA: Responsible, in CRS-led countries, for the development of the communication strategy and messages for behaviour change communication; community mobilization and mass communication. Malaria Consortium will lead communications work in the three countries where it leads on program implementation.

The project is led by a Project Director, supported by a Deputy Project Director; steered through a Project Leadership Committee that meets on a quarterly basis; and the technical strategic advice is provided by a Technical Advisory Committee, chaired by LSHTM.

The following table provides a summary of specific M&E roles and responsibilities for each of the partners and supported countries.

Table 1: Roles and responsibilities for partners and supported countries

	Organizations	Overall roles and responsibilities within the partnership	Specific M&E roles and responsibilities
1	Malaria Consortium (MC)	Lead Partner SMC delivery in Burkina Faso, Chad and Nigeria;	Integrate and coordinate all aspects of the project M&E in response to project logical framework, lead M&E QA efforts and reporting to UNITAID. Collate ongoing output level data in all countries (with hands-on responsibility for the countries it directly supports) generated by implementing SMC at scale. Collation will integrate data from CRS on CRS-supported countries.
2	Catholic Relief Service (CRS)	Manage sub-recipient agreements with SUA, LSHTM SMC delivery in Guinea, Mali, Niger and the Gambia.	Collate ongoing output level data in its supported countries generated by implementing SMC at scale. Participate in overall M&E QA activities in its supported countries
3	LSHTM	Design & implement surveillance, public health evaluation, pharmacovigilance, resistance monitoring. Chair of Technical Advisory Committee	Design and implement public health evaluation deliverables across all 7 countries, which include coverage surveys, drug resistance monitoring studies, and effectiveness studies, using case control design and malaria surveillance. Monitoring of severe ADRs across all 7 countries
4	MMV	Design and implement market shaping components, product development and manufacturer support.	Demand forecasting Market intelligence components
5	MSH	Design and implement costing studies related to SMC delivery and provide expert assistance on optimizing the supply chain to deliver SMC interventions	Support to country level SMC gap analysis Costing study
6	Supported countries: (Chad, Burkina Faso, Nigeria, Niger, The Gambia, Guinea, Mali)	Supply Chain Management at country level, Training for SMC delivery, SMC delivery, pharmacovigilance, identification of good and bad practices, lessons learnt on SMC delivery processes, facilitation of research and operational studies.	Generate data from implementation of SMC, including: training of health workers, and support supervision visits, stock inventory and logistic data, social mobilization/social and behavior change communication (SBCC), and reported cases of eligible children who received SMC

2.2. M&E principles of the project

The general guiding principles to be applied in the development of the M&E systems within ACCESS-SMC project are as follows:

i. Work closely with National Malaria Control Programs (NMCPs) & Ministries of Health (MOHs), and WARN, during M&E activities, sharing results in order to support and contribute to national M&E frameworks and plans.

ii. Build upon existing systems and tools, where possible avoiding use of parallel tools, including in drug safety monitoring. If parallel tools are needed for specific organizational policies/practices, they should be able to communicate and interact with what is available in country, as well as inform data management and broader M&E policies as relevant.

iii. In the course of implementing the project M&E strategy, explore opportunities to support NMCPs in capacity strengthening on M&E and in harmonization of malaria M&E indicators across in-country partners implementing SMC.

iv. Support efforts to strengthen routine Logistic Management Information Systems (LMIS) and build capacity in the use of these systems. Part of these efforts will be a rigorous assessment of data quality.

v. Develop or adapt simple and easy to use monitoring tools, where these do not exist, to be used by health staff at community, district and national levels. Facilitate the interpretation and use of data by supporting data processing and analysis where possible.

vi. Closely link M&E efforts to current knowledge gaps to generate scientific evidence and answer the pertinent questions, in order to support decision-making and strategy development.

vii. Measure project log-frame indicators (categorized as “core” contractual indicators and “additional”) through a combination of project monitoring and evaluation sources.

3. M&E Strategy

3.1. Project Monitoring

Based on the results chain as illustrated in figure 1 below, monitoring will concentrate on tracking key outputs and processes derived from project activities. However, where outcome indicators can be derived from routine monitoring, these will also be included in the project monitoring activities.

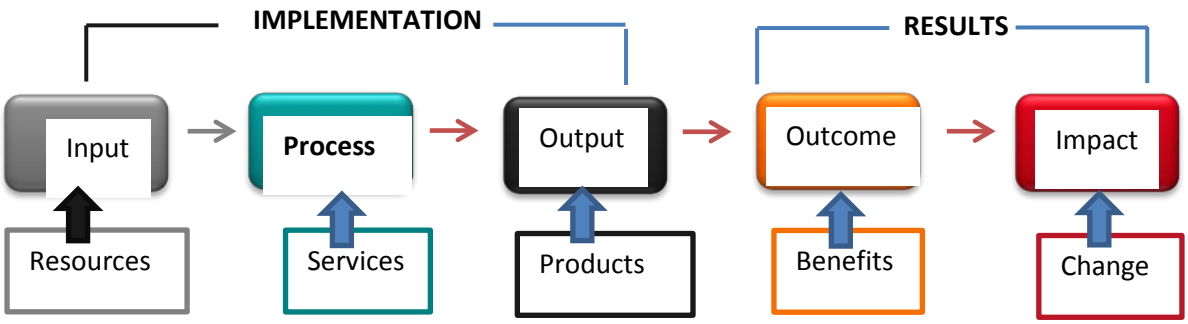


Figure 1: Stages of ACCESS-SMC monitoring data

Proposed project monitoring activities shall be carried out in such a way as to draw from or complement existing NMCP SMC & malaria monitoring activities.

3.2. Monitoring / Assessing the SMC Delivery

Periodic Market Assessments: Global production of quality and acceptable SMC products increased

MMV, as part of its engagement with manufacturers and other intermediaries in the value chain of SMC product, will carry out periodic market assessments to feed into market intelligence reports to be shared on a quarterly basis. The various indicators related to market shaping in the project log-frame are to be drawn from these reports (details of specific indicators can be found in Table 2 below).

Pipeline Monitoring: Production volumes by manufacturers of pre-qualified SP+AQ products

Malaria Consortium, working in close collaboration with the projects procurement agent, will generate periodic commodity pipeline status reports to provide additional insight into the production volumes and quantities of pre-qualified SP + AQ delivered by the project to supported countries. Other indicators to be tracked include commodity pricing, reported stock-outs at national level and lead times for delivery for project supported countries.

Service delivery data on SMC treatments administered

Each of the supported countries will generate service delivery data from implementation of SMC at scale. This includes information on training of health workers and support supervision visits, stock inventory and logistic data, social mobilization/social and behaviour change communication (SBCC), and reported cases of eligible children who received SMC. The process of data collection and aggregation shall be facilitated by Malaria Consortium in Burkina Faso, Chad and Nigeria and by CRS in Guinea, Gambia, Mali and Niger with technical assistance on data management provided by LSHTM as needed. Overall regional data will be collated by Malaria Consortium.

Costing Studies

One of the project's five expected outputs touches on improving the affordability of SMC delivery. This involves learning from large-scale implementation to identify ways to bring down the costs of delivery of SMC. A key element is to understand the service delivery costs in each of the project countries.

MSH is going to lead the SMC costing studies in coordination with the lead implementing partners in each country.

Components of the work will be:

- Developing cost analysis methodology guided by literature reviews;
- Coordinating the work with efforts of the RBM harmonization working groups in the countries to avoid duplication and ensure that the results can be used in the development of strategies and grant proposals;
- Developing instruments for collecting data and tools for analysing and estimating total and additional financial costs of SMC services

- Conducting the SMC costing exercise in each country and use the results for the development of annual and 3-year plans, gap analyses and for cross-country comparisons of efficiency.

For other details including cost modelling, please refer to **Annex II.**

3.3. Monitoring / Assessing the effectiveness of SMC

A series of assessments and surveys led by LSHTM will be conducted to determine the effectiveness and impact of SMC at scale. This section contains a summary of elements of project M&E strategy used to assess the public health impact of the intervention, and a more detailed description can be found in **Annex III**.

The public health evaluations proposed aim at providing scientific evidence in the following aspects:

- SMC coverage at population level, efficacy of SMC treatments, resistance monitoring, impact of SMC scale-up on the malaria burden; and
- Safety of SP+AQ when used for SMC.

SMC coverage surveys

All eligible children in endemic areas are expected to receive SMC every month during the high transmission season. Although output level data will provide information on the number of children who received SMC during each distribution cycle, the real coverage at population level can only be measured through representative household surveys, similar to coverage assessment of the Expanded Programme of Immunization (EPI). Indeed, sampling households at community level will guarantee the inclusion of eligible children potentially missed by the distribution teams and the exclusion of outsiders to the targeted community.

Efficacy studies & resistance monitoring of SMC drugs will be undertaken to ensure local parasites remain sensitive to the drugs used. A major concern for SMC is that its widespread deployment will lead to the selection of drug resistant parasites with progressive loss of efficacy. Thus, it is essential that any large scale SMC program incorporate drug sensitivity monitoring component. This will be done through two different approaches: case-control studies to measure efficacy of a preventive intervention and monitoring of the prevalence of molecular markers associated with resistance to SMC drugs in the circulating parasite population. Detailed methodology for both approaches is articulated in **Annex III.**

Effectiveness of SMC scale-up on disease burden will be assessed across the project countries. The efficacy of SMC against clinical malaria of 75% reduction uncomplicated and severe malaria was demonstrated by eight randomized controlled trials (conducted in several countries in West Africa) in children between 3 to 59 months during the rainy season comparing treatment doses of SP+AQ at monthly or two monthly intervals versus no treatment. However, the protective effect of SMC taken to scale is still to be determined. It is therefore essential to evaluate the impact of SMC implementation and its effectiveness throughout the life of the project. This will be conducted using data from: 1) SMC coverage surveys (see above), 2) sentinel surveillance health facilities, 3) existing data generated by Health Management and Information Systems (HMIS), and 4) secondary analysis of national representative population surveys such as Malaria Indicator Survey (MIS) or Demographic and Health Surveys (DHS).

Sentinel surveillance health facilities

Malaria incidence will be the primary indicator for the assessment of SMC impact on morbidity. Routinely collected data on malaria cases at health facilities through national HMIS systems would be the best source of information. However, weaknesses in these systems often result in data of insufficient quality to generate solid evidence. Therefore, it will be necessary to identify health facilities that will receive appropriate project support to ensure high data quality and generate reliable information on malaria cases. These sentinel sites will benefit from adequate supplies of RDTs for malaria diagnosis, and of ACTs for treatment of malaria. Project staff will visit each of these facilities on a regular basis.

HMIS data

In addition to data collected through sentinel surveillance sites, it will be important to compare trends in malaria incidence in surveillance sites and in real life setting to assess how generalizable these results are. As such ACCESS-SMC will strengthen efforts toward accurate recording and analysis of HMIS data on malaria morbidity in each of the program countries, in the districts where SMC is implemented.

Secondary analysis of HMIS and DHS data

Although measurement of impact of SMC on malaria mortality is not the primary focus of ACCESS-SMC, considering the short project life, efforts will be made to derive some impact-related measurements from select secondary sources. In addition to tracking case fatality rate from malaria using HMIS data, surveys approaches to measure all-cause child mortality can also be used. In the scope of this project, data generated through existing national surveys such as DHS surveys and malaria indicator surveys, will be used for secondary analysis. Where possible, supplementary sampling will be provided by the project to adequately monitor changes in child survival in the areas where SMC is implemented, as long as funds are available.

3.4. Safety of SMC drugs / Pharmacovigilance

Pharmacovigilance reporting forms will be made available at all health facilities in SMC areas before the start of SMC and additional forms distributed with the SMC drugs. A database of names and phone numbers of the head of each health facility in the SMC areas will be compiled and automated SMC messages sent to each number shortly before each SMC cycle, to thank and remind about pharmacovigilance and to remind to submit a report, 10 days after each cycle.

Each facility will be asked to submit a report on SMC delivery each month, which will include a checklist for reporting adverse drug reactions seen and a set of key system strengthening indicators. Any suspected case of serious adverse event (SAE) will be referred immediately to the nearest hospital. All severe adverse events will be reported immediately to the district medical officer. All serious adverse events will be reported within 15 days to the regulatory authority. All completed pharmacovigilance reporting forms will be collected after each cycle and entered into a database before being forwarded to the regulatory authority.

A review panel will assess each event for severity and relatedness to SMC drugs, and will be responsible for monitoring that any children with severe adverse reactions were provided with appropriate clinical care. Pharmacovigilance monitoring activities will be led by LSHTM.

For details regarding methodology and data management, please refer to **Annex III.**

4. Project progress indicators by source

At the project design stage, eighteen core project indicators were defined and agreed to by the donor. These indicators consist in those for which the project has the contractual obligation to report to the funder on a regular basis.

In addition to these core indicators, a set of additional indicators have been identified at project start up, in order to provide additional information related to the core indicators and further explain how progress has been attained. These indicators are described in detail in the logical framework and in the indicator reference sheet that can be found in **Annex VII.**

Table 2 below highlights the various indicators that feed into programmatic reporting to the donor, ordered by partner source.

Table 2: Project indicators

Type	Area of work	Indicator	Data source	Responsible partner
		Goal		
Core	Population coverage	Percentage coverage of eligible children who received full course of SMC in project sites according to national policies	Patient cards	LSHTM
Extra	Population coverage	Percentage coverage of eligible children who received full course of SMC for at least 3 cycles	Patient cards	LSHTM
Extra	Malaria burden	Malaria incidence amongst all age groups	Sentinel Surveillance and HMIS	LSHTM
Extra	Malaria burden	Malaria prevalence amongst children	Case control studies & molecular marker studies	LSHTM
Extra	Malaria burden	All-cause mortality rate amongst population (all age categories)	Sentinel surveillance	LSHTM
Extra	Malaria burden	Percentage of eligible children who reported a recent episode of fever (within the past 2 weeks) at the time of the survey	Coverage survey	LSHTM & MC
Extra	Efficacy of SMC treatment	Prevalence of molecular markers associated with resistance to SMC drugs	Molecular marker studies	LSHTM
Extra	Efficacy of SMC treatment	Percentage of suspected malaria cases tested with an RDT or microscopy	Sentinel Surveillance and HMIS	LSHTM
		Outcome		
Core	Global supply	Production volumes by manufacturers of pre-qualified SP+AQ products	Market research	MMV

	OUTPUT 1	Output 1		
Core	Global production	Updated listing of manufacturers of quality assured SP+AQ	Market research	MMV
Core	Global production	Updated listing of sources of prequalified API	Market research	MMV
Core	Global production	Number of supported countries with drug efficacy studies completed	Project Reports	LSHTM
Core	Global production	List of new and alternative products developed	Market research	MMV
		Output 2		
Core	Procurement	Volume of quality assured SP+AQ delivered to countries	Orders and procurement reports	MC
Core	Procurement	Value of SMC treatments delivered by country	Orders and procurement reports	MC/CRS country IP
Core	Procurement	Median lead time in days from date of order to date of delivery in country	Orders and procurement reports	MC
Core	Procurement	Median duration in days of stock out at national stores at central level during SMC implementation months	Project Reports	MC/CRS country IP
		Output 3		
Core	Service delivery	Number of treatments administered to eligible children per cycle	LMIS	MC/CRS country IP
Core	Pharmacovigilance	Proportion of AE (Serious Adverse Events) potentially related to SMC administration that were effectively managed by country by site	Project Reports	LSHTM
		Training and Supervision		
Extra	Training/supervision	Number HWs trained (by category) as evidenced by certificate by country	Training report	MC/CRS country IP
Extra	Training/supervision	Percentage of distribution teams that were supervised at least once per cycle	Supervision report	MC/CRS country IP
		Social Mobilization and BCC		
Extra	SBCC	Proportion of people who recall hearing /being informed about SMC distribution campaign, incl. source/channel	Coverage survey	LSHTM
Extra	SBCC	Percentage of eligible children who were present at the distribution site during the last SMC cycle by type of site (for fixed site and door to door distribution)	Coverage survey	LSHTM
Extra	SBCC	Percentage of caretakers of eligible children who remembered the key BCC messages about SMC	Project Reports	MC/CRS country IP
Extra	SBCC	Number of materials distributed by type of material and target audience	Project Reports	MC/CRS country IP
Extra	SBCC	Percentage of planned radio / TV spots aired, by country	Project Reports	MC/CRS country IP
		SMC delivery		
Extra	SMC delivery	Percentage of eligible children who received the first dose of SMC treatment course (DOT) at the distribution site, per cycle.	Coverage survey	LSHTM
Extra	SMC delivery	Percentage of eligible children who did complete the treatment course at home, during the last SMC administration before the survey	Coverage survey	LSHTM

Extra	SMC delivery	Administrative coverage of eligible children that received SMC treatment, per cycle	Tally sheets/ Registers	MC/CRS country IP
Extra	SMC delivery	Percentage of eligible children with evidence of completion SMC drug administration for 1 /2 /3 & 4 cycles	Tally sheets/ Registers	MC/CRS country IP
Extra	SMC delivery	Percentage of children that were not given SMC drug because of non-eligibility	Tally sheets/ Registers	MC/CRS country IP
		Pharmacovigilance		
Extra	Pharmacovigilance	Percentage of eligible children who took SMC and reported any adverse event reaction (self-reporting)	Periodic household survey	LSHTM
Extra	Pharmacovigilance	Number of serious adverse events (SAE) reported & confirmed	AE Reporting form	LSHTM
Extra	Pharmacovigilance	Percentage of countries with PV focal point at national level	Project Reports	LSHTM
Extra	Pharmacovigilance	Percentage of HF with up-to-date PV guidelines available	Supervision report	LSHTM
Extra	Pharmacovigilance	Proportion of targeted HW trained in PV (disaggregate data by category of health workers)	Training report	LSHTM
Extra	Pharmacovigilance	Number of cohort event monitoring effectively conducted by country	Tbc	LSHTM
Extra	Pharmacovigilance	Percentage of sampled health workers reporting to have seen a suspected AE (by District/ Country & by cycle)	Supervision report	LSHTM
		Supply chain		
	Supply chain	Proportion of designated storage facilities that have adequate SMC drug supplies at designated time as per their planning document by level (health facility / central store)	LMIS	MC/CRS country IP
	Supply chain	Percentage of forecasted needs of quality assured SP+AQ supplied to districts	Logistic report	MC/CRS country IP
	Supply chain	Median duration in days of stock out at medical stores at district level during SMC implementation months	LMIS	MC/CRS country IP
		Output 4		
Core	Cost	Median price of quality assured SMC products (ex works) by source	Procurement reports	MC
Core	Cost	Cost per child reached with SMC per annum in supported countries	Costing survey	MSH
Core	Cost	Cost per dose delivered by country by type of delivery (fixed point, house to house)	Costing survey	MSH
		Output 5		
Core	Resource mobilization	Financial gaps in each supported country identified and reported	Gap analysis	MSH
Core	Resource mobilization	Percentage funding for procurement for SMC products and delivery in supported countries by each funder/donor other than UNITAID	Gap analysis	MSH
Core	Resource mobilization	Transition funding for SMC per country by amount and timing of transition reported	Project Reports	MC/CRS country IP
		Process Indicators		
		Procurement		
	Procurement	Volume of quality assured SP+AQ accurately quantified by country	Project Reports	MC/CRS country IP

	Procurement	Number of countries where the agreed quantity was supplied within schedule	Project Reports	MC/CRS
	Procurement	Number of countries with documented procurement plan with a timeline and budget in place before the start of procurement	Project Reports	MC/CRS
	Procurement	Number of countries with an SMC demand forecast in place	Project Reports	MC/CRS
	Procurement	Proportion of project budget utilized for the procurement of SMC drugs, per country	Project Reports	MC/CRS country IP
		Training and supervision		
	Training/supervision	Number of countries with documented training plan with a timeline and budget in place before implementation of training	Training plan	MC/CRS
	Training/supervision	Proportion of training materials produced in local language, per country	Training report	MC/CRS country IP
	Training/supervision	Number of countries where training was completed before the start of SMC delivery	Training report	MC/CRS
	Training/supervision	Proportion of SMC Training Reports received from Master Trainers and National Trainers after each training, per country	Training report	MC/CRS country IP
	Training/supervision	Proportion of budget utilized for training implementation, per country	Training report	MC/CRS country IP
	Training/supervision	Proportion of supervisors submitting End-of-Cycle report	Supervision report	MC/CRS country IP
	Training/supervision	Proportion of health facilities submitting End-of-Cycle report	Supervision report	MC/CRS country IP
		Social Mobilization/Behaviour Change Communication		
	SBCC	Number of materials produced by type of material and target audience	Project Reports	MC/CRS country IP
	SBCC	Number of people trained or oriented in communication for SMC, by people type, per country	Project Reports	MC/CRS country IP
	SBCC	Number of countries with documented communication plan with a timeline and budget in place before implementation	Project Reports	MC/CRS
	SBCC	Number of countries where social mobilization activities were initiated before the start of SMC delivery, per cycle, per country	Project Reports	MC/CRS
	SBCC	Proportion of budget utilized for social mobilization and BCC	Project Reports	MC/CRS country IP
		SMC delivery		
	SMC delivery	Number of distribution team by delivery method (fixed, mobile or h2h), per country, per target pop	Project Reports	MC/CRS country IP
	SMC delivery	Average number of children seen per day by delivery method (fixed, mobile or h2h)	Project Reports	MC/CRS country IP
	SMC delivery	Number of countries with micro plan validated with a timeline and budget in place before SMC implementation	Project Reports	MC/CRS
	SMC delivery	Proportion of budget utilized for service delivery, per country	Project Reports	MC/CRS country IP
	SMC delivery	Proportion of distribution teams reporting on activity, per cycle, per country	Project Reports	MC/CRS country IP
		Pharmacovigilance		
	Pharmacovigilance	Number of PV reporting forms produced, per country	Project Reports	LSHTM
	Pharmacovigilance	Number of training material developed, per country	Project Reports	LSHTM

	Pharmacovigilance	Number of countries with documented PV plan with a timeline and budget in place before training implementation	Project Reports	LSHTM
	Pharmacovigilance	Number of countries where PV forms were supplied and staff trained before the start of SMC delivery, per country	Project Reports	LSHTM
	Pharmacovigilance	Proportion of budget utilized for PV, per country	Project Reports	LSHTM
		Supply Chain		
	Supply chain	Volume of quality assured SP+AQ used/leftover/lost per cycle	Project Reports	MC/CRS country IP
	Supply chain	Proportion of districts submitting the LMIS data per country	Project Reports	MC/CRS country IP
	Supply chain	Proportion of budget utilized for supply chain strengthening	Project Reports	MSH

* This list of indicators will be revised during the first year of project implementation.

* Details regarding tools and sources of data for each of the indicators are described in the Indicator Reference Sheet

Core *Indicates donor contractual indicator reporting*

5. Reporting

A centrally managed log-frame indicator database, managed by Malaria Consortium, will be populated from the multiple sources of data and project databases managed within the project using M&E reporting templates filled in by project at designated reporting periods. Each partner is to observe timely submission of the data required for monitoring and reporting purposes to Malaria Consortium according to these designated deadlines, and Malaria Consortium will in turn use this information to prepare and submit project reports to the donor. In addition to project results/data, an update on progress achieved, challenges encountered and any potential delay in activity will be submitted by each partner to Malaria Consortium and synthetized into one M&E report for submission to UNITAID. For the reporting schedule, kindly refer to Annex E of the partner agreement.

- Partners should provide reporting in the templates provided. The template for M&E reporting will be provided.
- All M&E reports should be sent to the Project Director and M&E Specialist for UNITAID Projects (M&E Report).
- Details of the project final report will be shared with partners when the format and content are confirmed with UNITAID.

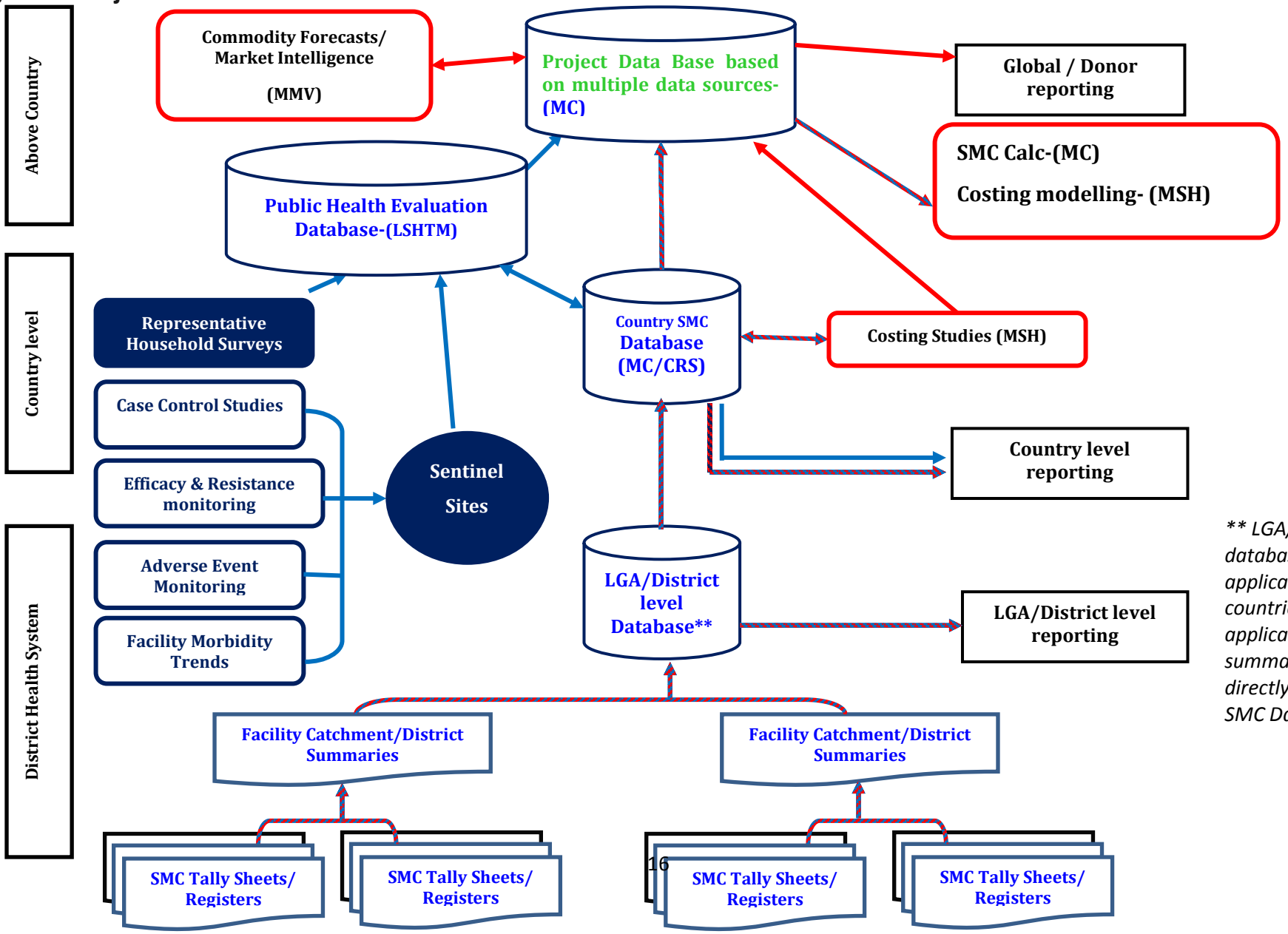
Regardless of donor reporting, Malaria Consortium may need to request ad-hoc submission of specific data from partners and countries, for instance in response to specific requests by donors or in the event of international events where information and results about the project may be shared.

6. Project data flow

In order to ensure consistent reporting and use of data, Standard Operating Procedures (SOPs) will be formulated to inform how data is collected, cleaned and shared with the public by the partners. Databases will be created and updated to address various components of the data flow, and a process put in place for periodic data quality audits. Focal points and mechanisms are to be put in place at country and partner levels to ensure seams access to data collected. Country level databases will be maintained to allow the development of feedback reports NMCPs and MoHs, as well as among the partners. LSHTM shall house and maintain the public health evaluation database on behalf of the project. Beyond the periodic reporting requirements, the Project Management Team may require periodic ad-hoc updates. In these circumstances, care shall be taken to provide adequate notice period. Data will be validated before it is shared with UNITAID or other stakeholders. Additional details regarding data sharing and use by different partners and global platforms will be included in SOPs.

Further details on project data flow are illustrated in Figure 2 below.

Figure 2: Project data flow



*** LGA/ District level database, not applicable in all countries, were not applicable district summaries feed directly into country SMC Database*

7. Data utilization and information dissemination plan

7.1. Results dissemination

The ACCESS-SMC Communications and Publications Framework (Annex IV) has been developed which provides a framework for the project's communication and advocacy, with a particular focus on achievement of Output 5, mobilization of additional resources for SMC. The goal of the Communications Plan is to provide the knowledge base for mobilization of donor and host government commitments to maintain SMC coverage achieved through ACCESS-SMC, and create momentum towards ensuring SMC coverage for all 25 million eligible children aged three to 59 months. All communications activities will highlight the vital limited time and the catalytic role of UNITAID in expanding SMC coverage and shaping the market for SMC products. Further communication activities will increase awareness among key stakeholders on the safety, feasibility, long-term efficacy and cost-effectiveness of at-scale SMC delivery through sharing learning and experiences; and will mobilize donor and host government support for resources to sustain coverage increases achieved in ACCESS-SMC- supported countries and expand to other eligible countries.

7.2. Modelling tools

SMC Calc

MC will develop a user-friendly, customizable tool to be called 'SMC Calc', which will model the effects of increased SMC coverage in combination with other malaria control interventions on malaria morbidity. This will build on a similar tool developed by Malaria Consortium related to LLINs, called 'NetCALC'. As SMC fits into a set of proven malaria control interventions, understanding the complementarity of SMC as a preventive intervention with others such as LLINs or IRS will require modelling the effects in the various settings where SMC is implemented alongside those other interventions. Data derived from SMC Calc would be essential for national planning and budgeting exercises, particularly as eligible countries increasingly incorporate SMC into their five year malaria control strategic plans. SMC Calc would allow countries to understand what effect that choice would have on other aspects of their health system. **Annex VI presents SMC Calc concept note.**

Costing model

MSH will develop a costing model for SMC delivery, based on different implementation strategies, which will be used in costing annual operational plans. The model will be a Microsoft Excel® tool. Given that complete costing of supply chains is expensive, time consuming and data is heavily dependent on accurate data from country, current and future SMC countries and donors will benefit from a simple methodology/tool to better plan and update budgets periodically. The costing model will allow a country implementing SMC to cost and monitor the cost of SMC delivery. The model will be designed to allow countries without significant costing experience and analysis to better estimate the cost of SMC delivery. Its parameters will include the costs incurred at each level of the supply chain: Central Medical Store, Regional Medical Stores, Health Facility and Community. Aspects include costs for tender, quality control, distribution, storage, labour, insurance security, and IT.

SMC product demand forecasting

MMV will employ its recently created tool, modified as necessary to fit the needs of this project. The tool will be employed consistently across all countries eligible for SMC. MMV will provide a web-based forecasting and quantification model aiming to provide the visibility on the potential drug demand (based on planning) for SMC and actual drug demand (based on confirmed available

funding) and historical data. While MMV will initially manage the data collection and population, this will eventually be transferred to country leadership. At the beginning, different levels of access and visibility on data will be granted to different stakeholders. With time, the implementing countries/partners will gain access, allowing them to populate their data, contributing to securing the global production capacities. Donors will have visibility of the potential countries' needs. A better understanding of the overall market size will be crucial to convince another manufacturer to come on board and to secure the global production capacities.

8. Data Quality Assurance

The basic components of quality assurance system for ACCESS-SMC are described below:

QA for project monitoring data by CHW

Each of the ACCESS-SMC project country teams will develop a data quality assurance (DQA) plan. Some of the activities to be included will be data validation exercises whereby sample data points will be selected, data from which will be analysed along a pre-determined set of QA criteria on a regular basis. The teams will also plan and conduct feedback sessions aimed at addressing any identified discrepancies and improving overall quality of the data.

QA for Evaluation data

ACCESS-SMC project collects data majorly using paper-based forms and Tablet PCs in some of the countries. Data is collected by Community Health Workers and other trained field enumerators. Each data collector has a responsibility to share the completed forms to the field supervisor. Detailed Standard operating procedures for QA will be developed and used across the project countries.

Data screen preparation

Since the ACCESS-SMC project is conducting some specific studies with common protocols in multiple countries, the preparation of screen for these studies should be centrally coordinated. A designated data manager will be responsible coordinating respective studies in consultation with the statistician and M&E responsible persons.

At country level, personnel responsible for data processing and management should receive data capture screen and test it with the data and provide feedback for improvement if necessary. Any changes made on the data capture screen at facility or district level should be approved by the statistician or M&E responsible person. The data manager at the site may be involved for developing the screen but will not modify the screen at facility or district level without approval from the statistician.

Data entry

During the data entry, the data managers will perform validation of the data to assess completeness and consistency of data each day. Each data entry clerk will tick and sign all forms successfully entered with a red pen. Any form that is queried by checks from the system is reported back to the field supervisor through the Data Manager (this must be documented on a specific query log book). Queries generated during data entry are filled in the query log book with indications of the form number, date, and problem and logged out to the field supervisor (field office) for the necessary corrections to be effected.

When double entry in carried out on specific data sets, the data manager will run validation and consistency tests on the two files entered by the entry clerks. Where found to be inaccurate,

incomplete and other error records found during validation, the hard copy questionnaire is used to make the necessary corrections on the dataset. Once validation is complete, the data manager must document and file all hard copies of validation outputs conducted at the site. The validated files must be saved.

Data cleaning will be conducted by the data manager and statistician after validation to check for other ambiguities, inconsistencies, missing values or cases and errors in the database. Changes to be made on the saved dataset must be confirmed with the hard copy questionnaire and discussed. Any changes made on the hard copy questionnaire must be signed against (initialled) and dated by the person making those changes.

Procedures for data backup

At each data entry site, backup of data is done once a day by the data manager. All screens will be on an external drive to be kept off-site for backup. Back up file should be in EPIDATA format at the site level and data manager should have both EPIDATA and STATA file backup for all datasets.

9. Data Ownership and Sharing

Data sharing among ACCESS-SMC partners and wider access to both routine and survey/research data will be essential in promoting successful collaboration efforts and increasing ability to demonstrate project results (and overall value for money) to donors and other stakeholders.

MC as a lead agency will develop and circulate a data sharing policy, in close consultation with other partners and in line with best practice. This policy will be designed to fulfil three main objectives: (1) facilitate data sharing within the partnership, (2) facilitate data sharing between ACCESS-SMC and other partners, organizations and research consortia, and (3) make the ACCESS-SMC data widely available to the scientific community as required by the funders of the project. Practical tools will be developed to support data sharing including data submission systems, sample availability systems and standard data access agreements (DAA) for the sharing of individual-level data.

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Annex I: Project Recommendations for M&E Tools

Annex II: Cost Analysis of Seasonal Malaria Chemoprevention

Annex III: Evaluation of Seasonal Malaria Chemoprevention

Annex IV: ACCESS-SMC Communications and Communications Framework

Annex V: SMC Calc Concept note

Annex VI: Indicator reference sheet

Annex VII: M&E reporting schedule

Annex VIII: Data Sharing Policy