
# MALARIA CONSORTIUM

# SEASONAL MALARIA CHEMOPREVENTION (SMC) PROJECT
# GRANT NUMBER OPP1053614

# MONITORING AND EVALUATION PLAN

**November 2012 – August 2015**

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## Abbreviations and acronyms

| | |
|---|---|
| AQ | Amodiaquine |
| CCGs | Community Care Givers |
| BCC | Behaviour Change Communication |
| DHS | Demographic and Health Survey |
| HMIS | Health Management Information System |
| M&E | Monitoring and Evaluation |
| MIS | Malaria Indicator Survey |
| MOH | Ministry of Health |
| NMCP | National Malaria Control Program |
| PPS | Probability Proportionate to Size |
| PSU | Primary Sampling Units |
| RDT | Rapid Diagnostic Test for Malaria |
| SMC | Seasonal Malaria Chemoprevention |
| SP | Sulfadoxine–Pyrimethamine |

# 1. Introduction

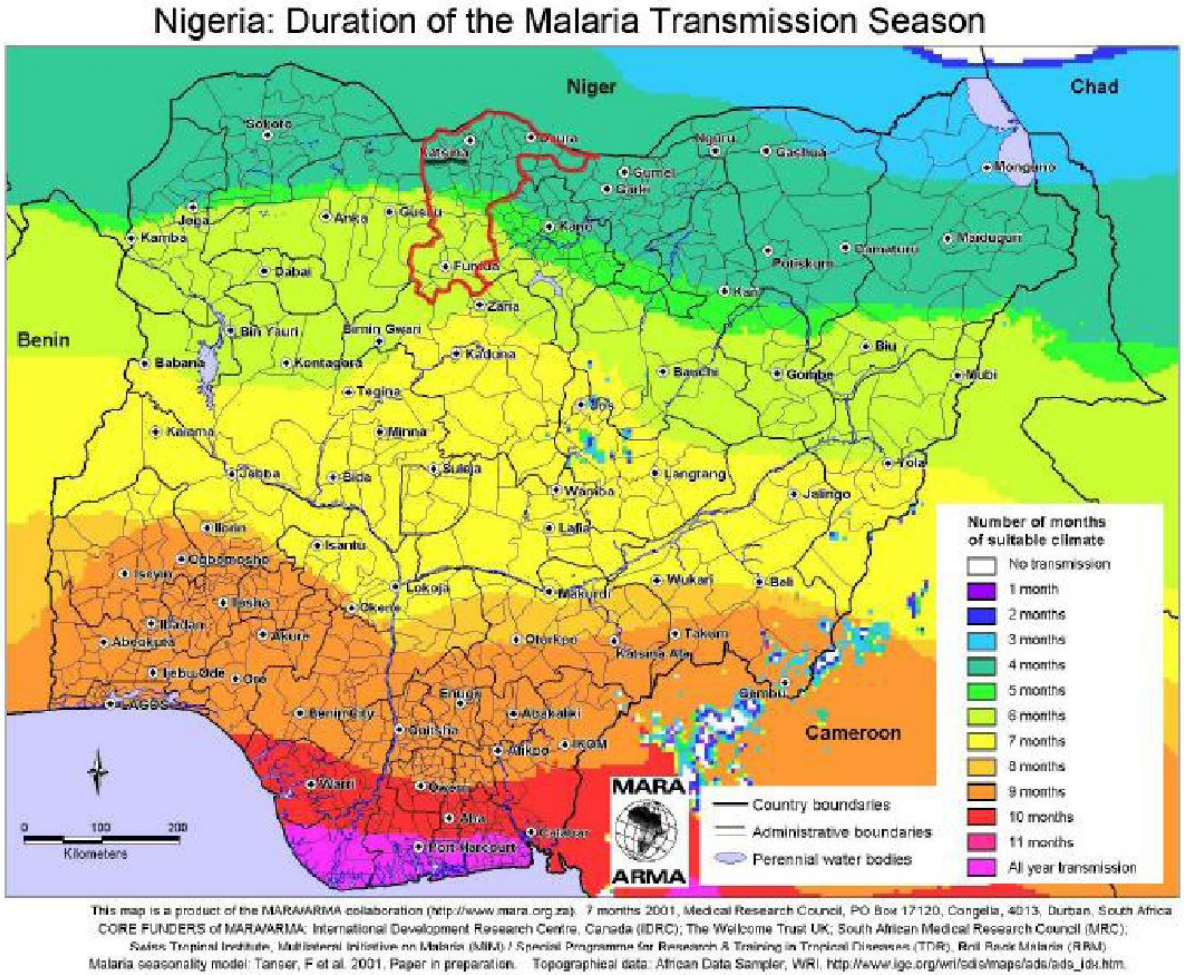
## 1.1. Seasonal Malaria Chemoprevention (SMC)

Malaria remains a major public health problem, with an estimated burden of 216 million clinical episodes and 655 000 deaths worldwide attributable to malaria in 2010. A significant proportion (91%) of reported deaths from malaria occurs in sub-Saharan Africa, where children under 5 years of age bear most of the burden. In 2010, it is estimated that 86% of all malaria deaths occurred in this age group [1].
Global approaches to malaria control are beginning to shift from a 'one size fits all' approach to the targeting of malaria control strategies to specific populations and/or locations for maximum effectiveness.
In keeping with this approach, WHO is now recommending a new intervention against *Plasmodium falciparum* malaria: Seasonal Malaria Chemoprevention (SMC). This intervention has been shown to be effective, cost-effective, safe, and feasible for the prevention of malaria among children less than 5 years of age in areas with highly seasonal malaria transmission [2].
Seasonal malaria chemoprevention (SMC), previously referred to as Intermittent Preventive Treatment in children (IPTc), is defined as the intermittent administration of full treatment courses of an antimalarial medicine during the malaria season to prevent malarial illness with the objective of maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk[3].

## 1.2. SMC in Nigeria

Nigeria is made up of six geopolitical zones and 37 states including the Federal Capital Territory. Nigeria has a tropical climate with wet and dry seasons. The dry season occurs from October to March and the wet season between April and September.
The geographic location of Nigeria makes the climate suitable for malaria transmission throughout the country. It is estimated that up to 97 percent of the country's more than 150 million people risk getting the disease. The remaining three percent of the population who live in the mountains in southern Jos (the Plateau State), at an altitude ranging from 1,200 to 1,400 metres, are at relatively low risk for malaria (Figure 1)

Figure 1: The duration of the malaria transmission season in Nigeria

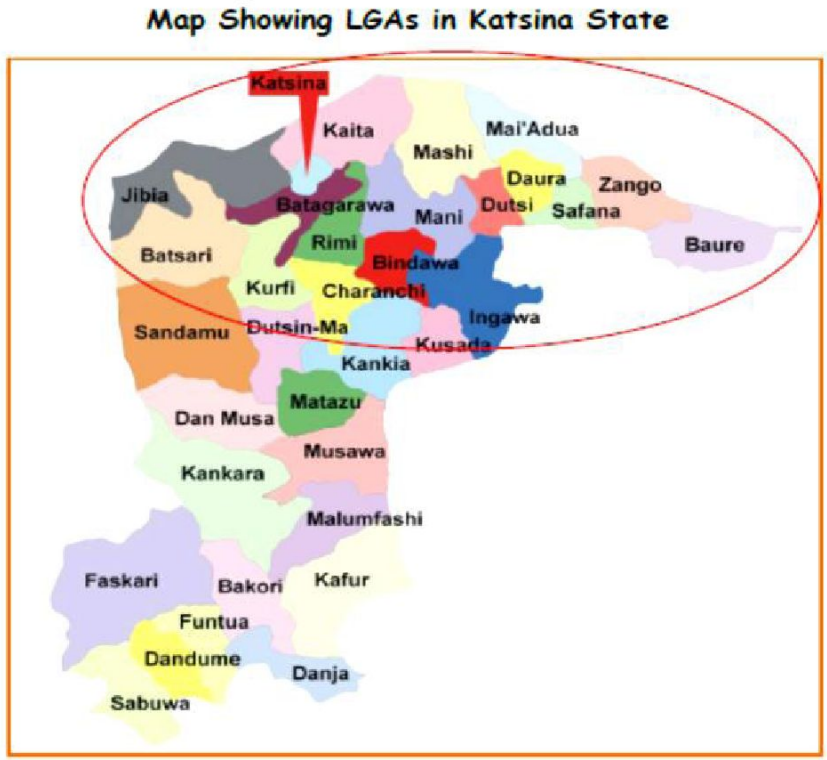


The areas of northern Nigeria where malaria transmission lasts less than four months present an opportunity for those at risk to benefit from the implementation of SMC. Whereas the feasibility and effectiveness of SMC has been demonstrated elsewhere, the approaches to implementation, which require high coverage levels, have to be contextualised to fit the local setting.
Thus there is a need to explore possible approaches in the Nigerian context that will provide effective delivery systems for the eventual scaling up of the intervention to cover areas in northern Nigeria with highly seasonal malaria transmission.

## 1.3. Katsina State

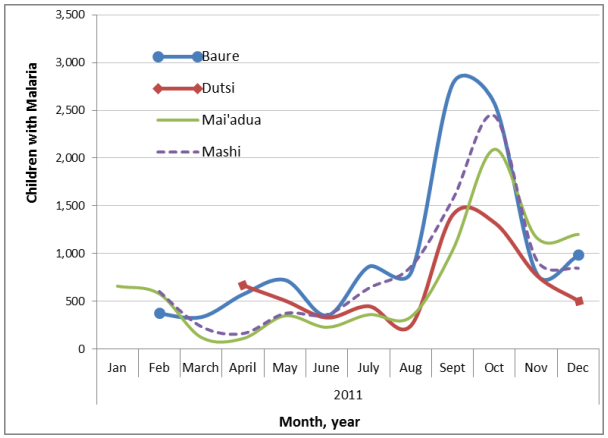
Katsina state was selected because it is within the appropriate malaria transmission zone suitable for conducting an assessment of SMC, it has existing community-based delivery systems on which to develop a SMC delivery system. The state is located in the North West zone of Nigeria, and constitutes 34 Local Government Areas (LGAs) with a total estimated population of 6,916,641 in 2012 (1,383,328 under 5 years). 14 LGAs are in the zone suitable for SMC, as illustrated in Figure 2.

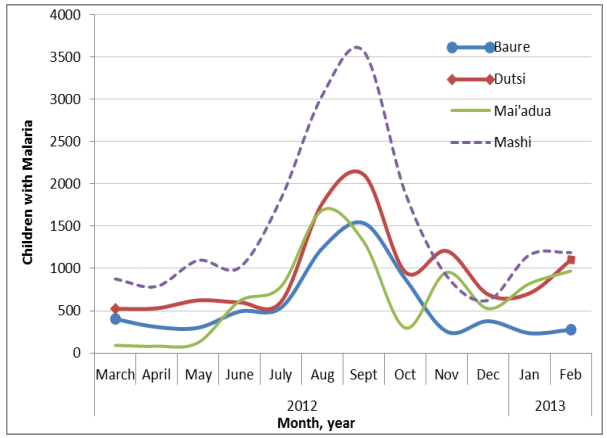
**Figure 2: LGAs in Katsina state**




Malaria is endemic in Katsina state with all year round transmission at levels below national averages, with a seasonal peak between the months of August and November coinciding with the peak of the raining season. Of the 14 Four LGAs, 4 LGA were selected as the site for the assessment of SMC delivery. These all exhibited a seasonal pattern of malaria burden as illustrated in figure 3 below

**Figure 3: Malaria burden in 4 LGAs in Katsina state 2011 and 2012**




## 2. Project Overview

The SMC delivery will be conducted during two rainy seasons over two years. The intervention will be delivered in two phases. In the first phase, the intervention will be rolled out in two of the selected four selected LGAs in the transmission season of 2013 i.e. Baure and Dutsi LGAs, and into all four in the 2014 transmission season. The intention is to allow some learning in the first round to feed into the second round, and also ensure that sufficient human resources are be available by the time of full scale implementation in the four LGAs. In addition, this will also allow for some limited stepped-wedge analysis.

The intervention will be delivered by a combination of community based methods and fixed posts. In the community, Community Care Givers (CCGs) will deliver the intervention where they are existent. These people will receive appropriate training before the intervention begins and be supervised by the appropriate staff within the health system. Additionally, the intervention will also be given at health

facilities. The drug will be given to children in three single doses over three months during the course of the transmission season. It will be important for caregivers to ensure that the drug is taken properly to ensure full protection.

## 2.1. Goal of the project

The goal of the project is to improve child health outcomes in Katsina state, northern Nigeria, through increased access to SMC, exploring the feasibility, acceptability, and costs of community-based SMC delivery systems; and informing the development of guidelines and ongoing implementation, and potentially scale up, plans for SMC within the health system.

## 2.2. Project Objectives

The project has four objectives:

1. To design, in consultation with key local stakeholders, an appropriate community-based delivery system for SMC in Katsina state based on formative research which will review aspects relating to feasibility, community acceptability, effectiveness and cost
2. To launch and execute SMC delivery according to the selected delivery system and collect data on process indicators and costs
3. To evaluate community acceptability, costs and effectiveness of the delivery system for SMC
4. To inform future national and state plans for SMC continuation/scale up by disseminating findings and sharing experiences with key stakeholders

# 3. Project Monitoring and Evaluation

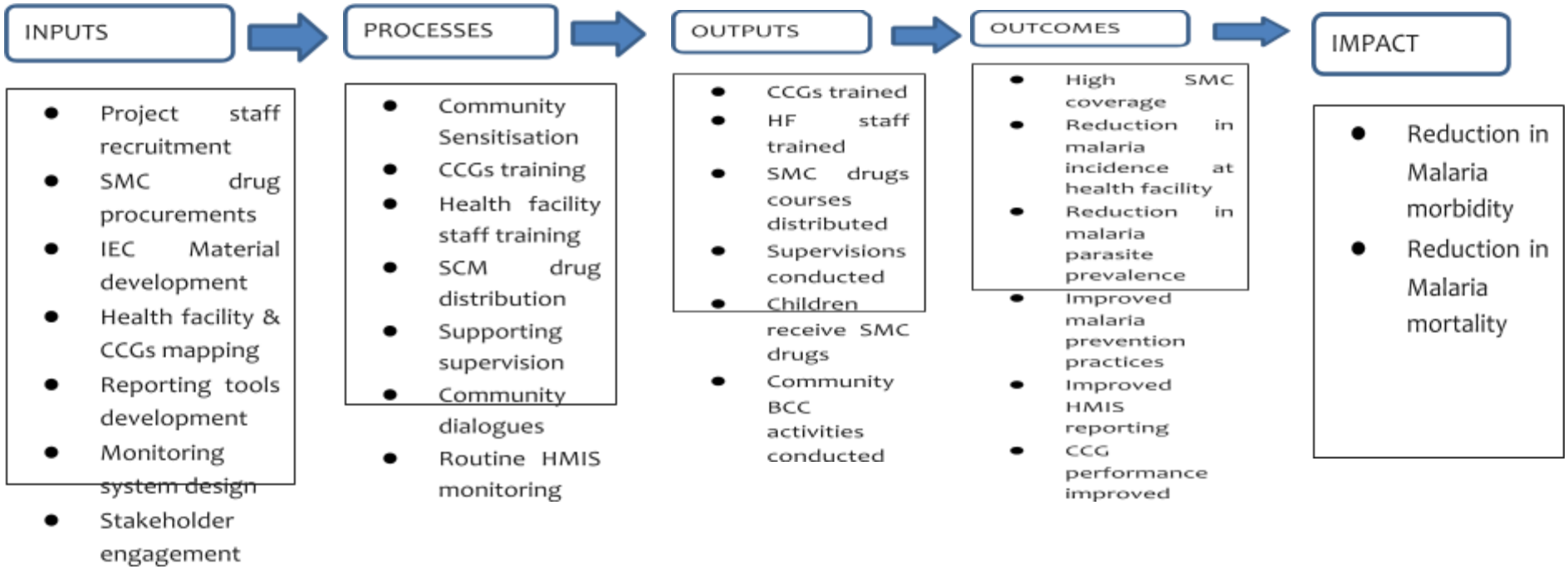
This section describes the scope of how project progress will be monitored and its objectives evaluated. It gives a description of the M&E framework illustrating how the objectives fit into the overarching goal used, the methodologies for the evaluations that will be conducted, the strategies that will be laid to ensure good quality data is collected and stored and the data utilisation and dissemination.

## 3.1. Project M&E framework

The project M&E framework is essential in understanding and analysing the project. It helps in clearly defining key relationships among factors key to the implementation and success of the project. With a framework in place, the implementers, managers and other stake holders' understanding of the project, upon which a good foundation for developing sound M&E indicators is built.

A logic model has been used to illustrate the linear relationships across the different components of the project i.e. the inputs or resources which enable the processes or project activities that produce the immediate results or outputs, ultimately leading to broader results or outcomes and subsequently the longer term impact[4].

**Figure 4: SMC M&E Framework**



## 3.2. Project Monitoring

Monitoring is a continuous internal process, conducted by project staff/managers to check the progress of the interventions. This section describes the processes that will be employed for monitoring project progress. This will enable the project to understand on a regular basis '*to what extent are the planned activities being realized'.* This allows on going learning and feedback throughout the implementation of the project.

### 3.2.1. Routine data and data sources

The project will be routinely monitored by collecting tracking performance on a number of project process and output indicators which are in line with the objectives. Data for these indicators will be regularly collected to help track project progress. The following routine data will be collected from the sources listed below.

**Table 1: Routine data and sources**

| | Main activity area | Data to be routinely collected | Routine data source |
|---|---|---|---|
| 1 | SMC Drug distributions | SMC drugs procured | Project reports |
| | | SCM drugs distributed | CCGs & HF SMC drug registers |
| | | SMC drugs returned after distribution | |
| | | SMC drug stock outs | |
| 2 | Children reached | Children received SMC drug course | CCGs & HF SMC drug registers |
| | | Children not received SMC drug course | |
| 3 | Health Facility data | Malaria outpatient cases | Health facility HMIS forms<br><br>Project forms |
| | | RDT positivity rates (where applicable) | |
| | | Malaria related deaths | |
| | | Adverse events monitoring | |
| | | Referrals made by CCGs | |
| 4 | Communication & advocacy activities | Stakeholder engagement activities conducted | Project reports |

| | | | |
|---|---|---|---|
| | | IEC Materials developed | |
| | | BCC activities implemented | |
| 5 | Trainings and support supervision activities | Trainings conducted | Project reports |
| | | Supervisions conducted | |

It is anticipated that additional data sources and activities that need to be monitored may be added during the course of project implementation.

As illustrated above, the main data sources for routine project monitoring data will be 1) Health facility data (HMIS) 2) Community Care Givers records and 3) Project reports. Each of described in detail below

**Health facility routine HMIS data**

Routine HMIS data will be a major data source for the project. Katsina state maintains a functional HMIS system through which all the health facilities in the state report. At state level, an electronic data (DHISs) is kept, where all monthly data is entered and quick summaries run.

At health facility level, a compendium of HMIS forms is completed routinely. The existing system collects a wealth of information within the public health facilities on malaria. This includes all malaria cases suspected, diagnosed and treated, severe cases and malaria related deaths.

Measurement of malaria incidence will be monitored from both the outpatient and inpatient malaria cases at the health facilities. Since confirmation of presenting fever cases as malaria is not consistent across the facilities, incidence will be measured through both suspected cases (reported as malaria or fever) and confirmed cases (by RDT or microscopy) among children under five reported at health facilities, over the two delivery phases

In facilities where confirmation of malaria cases is done, RDT positivity rates data will also be monitored to assess trends pre and post SMC delivery.

The project will work closely with the LGA and facility level HMIS focal persons in liaison with the State HMIS focal person to support and strengthen so as to enable effective monitoring of clinical malaria cases and the drugs dispensed during the study period. In doing so, the project will be working within and strengthening the existing structures as opposed to setting up parallel systems.

**Project records**

Project progress will also be monitored through project records collected during the course of project implementation. These will include, but not limited to the following

1. Drug procurement records for SMC drugs
2. Training reports for all trainings conducted by the project
3. SMC delivery registers from both facility and community based agents (CCGs)
4. Health facility adverse events monitoring forms
5. ACSM monitoring forms

The research officer will ensure that data from these project records is routinely compiled and entered into an electronic database for analysis and reporting. Results from these data will be used to track project progress and performance.

### 3.2.2. Data management and Quality assurance of routine data

**Data management system**

The project will set up a data management system to track all indicators both routine and non-routine. All data collected by the project from the different data sources mentioned above will systematically be entered into a database resident at the project offices in Katsina. The system will have in built data cleaning, validation and reporting modules to allow timely extraction of performance reports based on the data submitted. Under the management of project research officer, the data management system will be routinely used for the following purposes:

i. Produce reports for feedback to providers of the data on project progress e.g. SMC coverage, trends in malaria presentation
ii. Produce indicator performance statistics to aid project management and decision making regarding project implementation.

**Quality assurance**

The current limitations of the HMIS are recognised. These relate to the quality and completeness of the data. A data quality assurance mechanism will be put in place to address issues of quality of data collected at community, facility and project levels. At community level, CCG supervision mechanisms will be strengthened before and during SMC delivery. The CCG trainings that will be conducted before

intervention will include several sessions on quality data collection. In addition, selected supervisors will routinely conduct data quality audits to CCGs.
At facility level, a similar data verification and validation exercise will be routinely conducted by the project team in company of the LGA HMIS focal person. The results will be shared with the HMIS focal person and reasons for the discrepancies and their impact on the overall HMIS report discussed. These visits are hoped to improve the quality of the data as well as improve the capacity of the data collectors.

## 3.3. Project Evaluation

Evaluations will be conducted to assess whether the project will have achieved its objectives and highlight the benefits/value of the project in a wider context. Summative evaluations undertaken by the project will employ both quantitative and qualitative methods.

### 3.3.1. Surveys

Two cross sectional surveys will be conducted to assess the effectiveness, coverage and acceptability of SMC. The surveys will be conducted at two time intervals, at baseline i.e. before SMC delivery and at the end of the second transmission season.
Objectives of the survey will be to establish the following indicators among children under five

i. The reported Incidence of malaria in the community in the previous two weeks
ii. The Malaria parasite prevalence
iii. Treatment seeking behaviour of the caregivers of febrile children
iv. Coverage of malaria prevention mechanisms in the households
v. Knowledge of malaria prevention by caretakers of febrile children

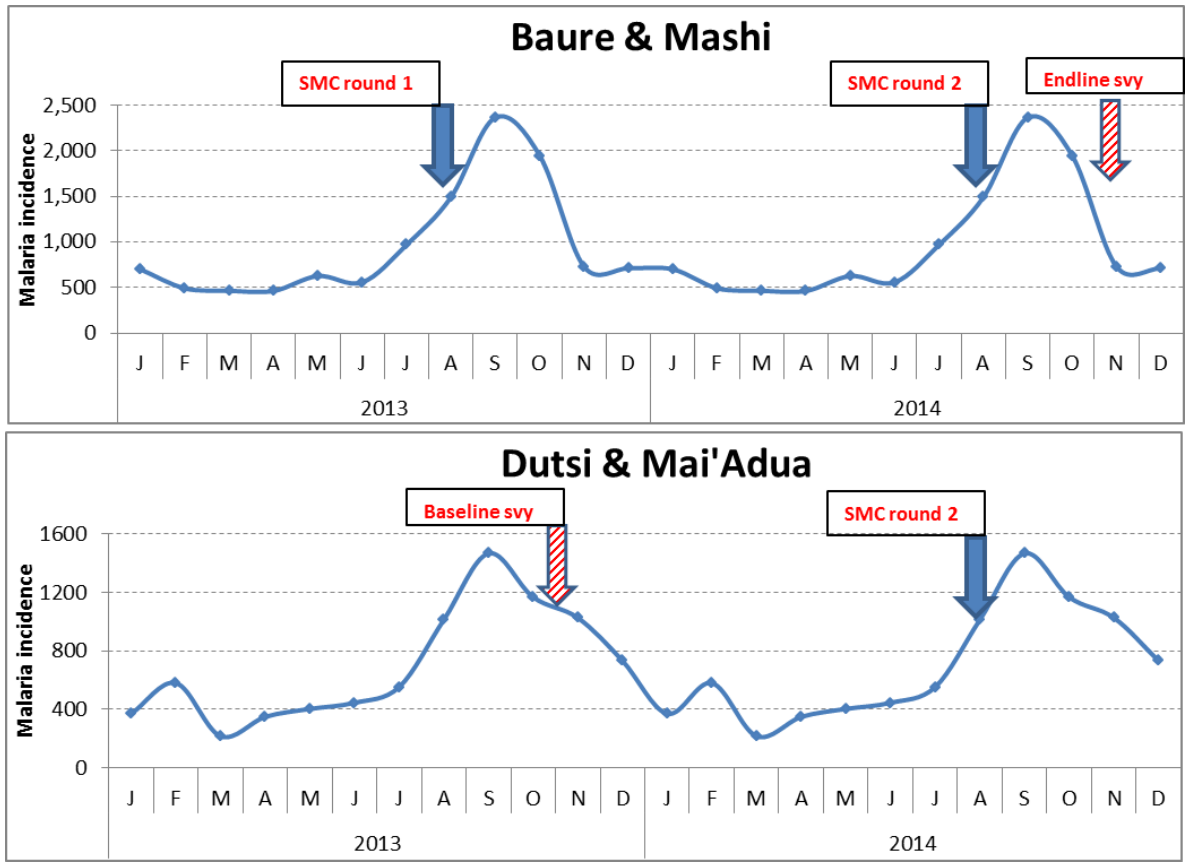
A baseline survey will be conducted to establish the indicator estimates before the intervention, on which performance targets and implementation scale can be based. To ensure the indicators obtained are pre implementation, the baseline survey will be only in the pre implementation two LGAs (Dutsi and Mai'Adua) at the peak of the transmission season.

It is expected that the baseline estimates from the pre-implementation LGAs will be comparable to the 1st SMC delivery LGAs (Baure & Mashi) since all four LGAs exhibit similar rainfall patterns and malaria burden [5].

At end line, all four LGAs will have had the intervention (SMC delivery) though Baure & Mashi will have had it for two transmission seasons whereas Dutsi & Mai'Adua will have had the intervention for one transmission season. Since the aim of the end line survey is to evaluate the effects of SMC, it will be conducted where SMC delivery has been longest i.e. in Baure & Mashi.

The end line survey will be timed at one month following the end of the rainy season to avoid the immediate prophylactic effect of the last round of drug ingestion, while remaining close to the usual period of highest prevalence. Figure 5 illustrates the timing of the surveys.

**Figure 5: Timing of the surveys**



**Design and Conduct of the Household Surveys**

Both the baseline and end line surveys will follow a two stage cluster sampling methodology. At the first stage, Primary sampling units (PSU), which will be defined as settlements will be selected from a sampling frame of all settlements in the two LGAs with probability of settlement selection proportionate to it its size (PPS) . At the second stage, an equal number of households per settlement will be randomly selected from a frame of all mapped households in each sampled settlement.

The sample size of children under five that would give 95% power to detect a difference between 10% and 15% in malaria prevalence would be 634 in each survey. In other words, a sample of 634 children would give a 95% probability of getting a statistically significant result if a 10% prevalence difference truly exists in the population.

Respondents for the household survey will be the heads of the household, from whom information relating to the household will be obtained. Caretakers of children age under 5 years will be interviewed to provide information on knowledge of malaria prevention and health seeking behaviour for febrile children. Both household and child health questionnaires will be based on the respective DHS/ Multiple Indicator Cluster Survey (MICS)/Malaria Indicator Survey (MIS) modules to ensure a standard approach [6,7]. A household will be defined as a group of people who usually take their meals together. The data collection will be conducted by a trained team of research data collectors who will have undergone training prior to the survey

**Data Management and Analysis of Household Surveys**

Upon completion of field data collection, data cleaning, coding and entry by trained data entry clerks under the supervision of the project M&E officer into a pre-prepared computer database use Epi-Data 3.1. All the data will be double entered to minimize data entry level errors. Data analysis will be conducted using STATA 11 software (Stata Corp) by the country M&E Specialist together with the research officer. Further details about the surveys can be obtained from the survey protocol.

### 3.3.2. Case Control study

One of the objectives of the project is to assess the effectiveness of SMC in the context of the implementation area. This objective will be assessed through a case-control study. The study will be conducted at one selected health facility within the implementation area to check effectiveness of the treatment courses during the transmission season and for a short follow up period post transmission.

**Study design and methods**

The study will follow a matched case-control design where protective efficacy (PE) will be approximated using an odds ratio (OR) with concurrent sampling of controls.
The study will be embedded into the main project implementation. This will be a health facility based study where both cases and controls are identified from children age 3-59 months presenting at the health facility.
A case will defined as a child age 3-59 months on the date of recruitment, presenting at selected health facility during the study period with an axillary temperature greater than or equal to 37.5 degrees Celsius or a history of fever in the previous 48 hours and has malaria parasitaemia with a parasite density >=5000/ul on initial reading [8].

A control will defined as a child age 3-59 months on the date of recruitment, presenting at selected health facility during the study period with an axillary temperature greater than or equal to 37.5 degrees Celsius or a history of fever in the previous 48 hours but with negative Malaria microscopy test.

Two matched controls will be recruited per case. Matching will be based on 1) age (under 12 months and 13-39 months) and 2) presenting to the health facility within 7 day from case recruitment.
Children who have not been inhabitants of the catchment area over the last three months will not be included in the study.

**Exposure, Outcome and sample size**

Exposure of interest is receipt of an SMC dose in the four weeks prior to the case being ill and the primary outcome is the protective efficacy (PE) of an SMC dose in reducing malaria incidence. PE will be measured as (1-1/Odds Ratio)*100 [9], where the Odds Ratio(0R) is the ratio of the odds of receiving an SMC dose in the case group to the odds of receiving an SMC dose in the control group.

A precision based sample size was determined using the formula proposed by O'Neill for a case-control study. The sample size required to obtain a precision of 5% for a protective efficacy of 87%, assuming 2 controls per case and 80% prevalence of vaccine exposure amongst controls is 190 cases and 380 controls

Due to operational feasibility and cost implications, one health facility will be selected where the cases and controls will be recruited until the designed sample size is required or one month after the SMC cycle. The selected health facility for the study will be one that;

1. Has a large catchment area, where
2. A high annual febrile case load of children under five years
3. An on-site laboratory which does microscopy based malaria testing
4. Receives children referred from the community agents

The case control study will commence approximately one month after the first round of SMC is deployed in the study area.

**Participant recruitment**

At the selected facility, caretakers of children 3-59 months presenting at the outpatient department with a fever or recent history of fever will be asked to see a study nurse, also stationed at the outpatient clinic, who will inform them about the study and inquire about residence status in the facility's catchment area. If they are eligible, consent to join the study and to take a blood sample by finger prick for both malaria and anaemia testing will be sought. If not granted, the child will be tested and treated according to the normal procedures at the health facility e.g. malaria testing will still be done using an RDT if the procedures dictate so. If the consent is granted, a malaria and haemoglobin test will be conducted using a microscope and a HemoCue machine (HemoCue AB) respectively. As the microscopy results are being processed, the study nurse will also conduct an interview with the caretaker of the child and take anthropometric measures of the child. Once results are available, the child will be classified as a case or a control according to the criteria listed above. The laboratory staff will be given refresher training on both Microscopy and heamoglobin testing and incentivized to conduct these tests on behalf of the study. The study who will have been nominated by the hospital management will be fully be paid by the study for its duration.

## 3.4. Project progress reporting plan

At the end of each month, the research officer will submit a brief report to the project coordinator on the progress of all M&E related activities. These will feed into the compilation of the quarterly report to the donor.

At the end of each SMC distribution cycle, the research officer will compile a list of related indicators providing statistics for targeted and achieved. Discussions will then be held by the project team and country office team members on the way forward.

## 3.5. Data utilisation and information dissemination plan

The progress of the project and its success stories will be shared with stakeholders through information dissemination workshops and seminars at state level and country level and through annual review meetings. These events are aimed at keeping the project's stakeholders aware of the project's progress and provide accountability for the project's performance in the LGAs and the state at large. A detailed information dissemination plan will be developed after mapping out the key project stakeholders and assessing which information is to be disseminated.

# 4. References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# Annexes

## 4.1. M&E Activity schedule

Table below shows the major M&E activities and when they will be implemented.

| Activity Description | Year 1 (2013) | | | | Year 2 (2014) | | | |
|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Conduct baseline qualitative assessment | | | | | | | | |
| Monitoring system setup | | | | | | | | |
| Implementation of case control study | | | | | | | | |
| Baseline study | | | | | | | | |
| Routine Health facility data collection | | | | | | | | |
| End line study | | | | | | | | |

## 4.2. Indicator Matrix

The indicator definition table shows the conceptual understanding of the indicators identified by the project to illustrate results and measure performance. This defines indicators in terms of numerator and denominator and data sources.

| | Indicator | Indicator definition/Measure | Data source | Disaggregation | Frequency of collection/ reporting | Baseline | Target |
|---|---|---|---|---|---|---|---|
| **Impact/Outcome level Indicators** | | | | | | | |
| 1 | Malaria Incidence | Number of confirmed and suspected cases of Malaria in children under five years per 1000 <5 population of children under five years. Measured over the transmission season. | Ward HMIS & sentinel HF records | Tests done | Weekly and Monthly | TBD | 40% reduction |
| 2 | Malaria Parasite prevalence | **Numerator:** total number of children 3-59 months for whom malaria tests were done & parasites present<br>**Denominator:** total number 3-59 months of children for whom malaria tests were done | Surveys & sentinel HF records | Age group | Biennial | TBD | 10% reduction |
| 3 | Percentage of children 3-59 months who received SMC per cycle during the transmission season | **Numerator:** total number of children 3-59 months for who received SMC per cycle<br>**Denominator:** total expected number 3-59 months of children in catchment population | Project reports | Age group & SMC cycle | Transmission season | 0 | 85% |
| 4 | Percentage of children 3–59 months who received four courses of SMC per transmission Season | **Numerator:** total number of children 3–59 months who received four courses of SMC during transmission season<br>**Denominator:** Total number of children given SMC delivered at each SMC cycle | Surveys | Age group and SMC cycle | Transmission season | 0 | TBD |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5 | Rate of adverse reaction in children 3-59 months | Number of children 3-59 months with reported adverse reactions per 10,000 <population of children 3-59 months who received SMC. Measured over the transmission season | Sentinel HF records | Age group and | Transmission season | 0 | TBD |
| **Output Level Indicators** | | | | | | | |
| 6 | Number of SMC drug doses distributed | Total SMC drugs during each month of the distribution cycle. Less SMC drugs returned after distribution cycle | Project reports | Distribution point and drug type | Distribution round | 0 | TBD |
| 7 | Number of SCM stakeholders trained | Number of SCM stakeholders (HF staff, CCGs etc.) trained during the reporting period | Project reports | Trainee cadre | Bi annual | 0 | TBD |
| **Process Level Indicators** | | | | | | | |
| 8 | Number of SCM stakeholder trainings conducted | Number of SCM stakeholder trainings conducted during the reporting period | Project reports | Cadre of SCM stakeholder | Bi annual | 0 | TBD |
| 9 | Number of ACSM activities conducted | Number of ACSM activities that are conducted during the reporting period e.g. community dialogue meetings, advocacy visits, etc | Project reports | Type of activity | Bi annual | 0 | TBD |
| 10 | Number of SCM related supervisory visits conducted | Number of SCM related supervisory visits conducted during the reporting period | Project reports | Type of supervision | Bi annual | 0 | TBD |
| 11 | Sentinel Health facilities[1] reporting rate | **Numerator:** total sentinel health facilities that submitted HMIS forms during the month **Denominator:** All health facilities in the catchment area that are reporting | HMIS & Sentinel HF records | Facility level | Monthly | TBD | TBD |
| **Input Level Indicators** | | | | | | | |

[1] These are the selected health facilities where HMIS strengthening activities will be conducted and where monitoring of malaria incidence, adverse events and RDT/Slide positivity rates will conducted

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 12 | Number of SMC drugs procured | Number of IEC materials developed up until the reporting | Project reports | Drug type | Bi annual | 0 | TBD |
| 13 | Number of SMC related IEC materials developed | Number of SMC related IEC materials developed during the reporting period | Project reports | Category of IEC materials | Bi annual | 0 | TBD |