**ToR End-of-Round Survey in Nampula**

**Overview**

Seasonal malaria chemoprevention (SMC) is a highly effective intervention to prevent malaria infection during peak transmission among those most at risk, ie children under age five. SMC involves administering four monthly cycles of two antimalarial drugs to children 3–59 months of age: sulfadoxine-pyrimethamine (SP) and amodiaquine (AQ)-SPAQ. Medicines are usually delivered door-to-door by volunteer community distributors (DC). Recommended by the World Health Organization (WHO), this intervention is safe, affordable, and feasible, and can prevent up to 75 percent of cases of malaria in children under five when accompanied by other interventions to combat malaria.

A pilot, hybrid, phased study was conducted in Mozambique, the first phase of which (2020 and 2021) aimed to assess acceptability, feasibility and therapeutic efficacy and phase II aims to assess effectiveness and impact.

The results of phase I, despite the high levels of resistance to SP observed, led to the conclusion that the SMC was viable, acceptable and confers good therapeutic efficacy.

The SPAQ distribution round, phase II, which started in January 2022 and ended last April, was successful and the administrative coverage data shows that a total of 120,000 children received the SPAQ and that there were no cases of adverse events. serious.

At the same time, the results of the research reveal that the SMC conferred a protective efficacy of 69%.

MC scaled the SMC intervention to the entire province of Nampula, targeting 1,3 million children under 5 years, last round beginning January, 2023. The main goal for this survey was to evaluate coverage and quality of the 2022/23 SMC round implemented across 23 districts in Nampula Province

Based on these results we started implementation SMC at scale targeting all 1,5 million under 5 years across Nampula Province.

It is important to evaluate the SMC implementation process in Mozambique, with attention to intervention coverage (as it relates to doses administered), specifically, SPAQ coverage; and quality (fidelity to the protocol), as the latter relates to age eligibility, directly observed therapy of the Day 1 dose and adherence to the Day 2 and Day 3 doses. The Medical Research Council Process Evaluation Framework for Complex Interventions (Moore et al, 2015) may be adopted to evaluate the SMC implementation process in Mozambique.

***SPAQ Coverage***

For maximum protection, children should receive a full three-day course of SPAQ during all four monthly cycles in a seasonal round of SMC. At the population level, SMC should provide maximum coverage to extend protection as widely as possible among the eligible population in targeted areas.

In general, coverage can be defined as the number of people reached by services offered by a program as a proportion of the eligible target population. In the context of SMC, coverage can therefore be defined as the proportion of children who received SPAQ in each monthly cycle during the transmission season. It should be noted, however, that in each population, SPAQ coverage can be defined in different ways. As receiving the first dose of SP and AQ alone is insufficient to provide full protection for the full duration of the high transmission season, coverage indicators should consider adherence to all relevant components of SMC administration, including proportions of households visited by distributors, administration of Day 2 and 3 AQ by caregivers, and whether caregivers reported adherence to all three doses of SPAQ in all monthly cycles.

To evaluate the coverage provided in the SMC pilot, an End-of Round (EoR) survey will be carried out by an independent research agency in May 2024.

 The objective of the end-or-round survey is to retrospectively determine coverage by surveying caregivers of eligible children and asking them if their children received the full 3-day course of SPAQ during each cycle of the SMC round.

In essence, the End-of-Round surveys aim to assess coverage defined as the proportion of eligible children that received a full 3-day course of SPAQ during each of the four monthly cycles of the 2023/24 SMC campaign. The surveys are designed to meet the following objectives:

* To assess coverage in terms of households visited, Day 1 SPAQ administered and full three-day course of SPAQ received during cycle 4
* To assess coverage in terms of children who received Day 1 SPAQ during all four monthly cycles
* To assess compliance with directly observed administration of Day 1 SPAQ by community distributors
* To assess coverage in terms of adherence to the full three-day course of SPAQ
* To assess the level of receipt of SPAQ by ineligible children aged 60–119 months.
* To assess programme performance across the four monthly SMC cycles.

Other objectives will include:

* To assess the level of the use and retention of SMC cards by parents and caregivers of children.
* To assess the level of SMC awareness, knowledge and perceptions among parents and caregivers of children.
* To assess the level of access to other malaria preventive interventions such as mosquito nets and indoor residual spraying in households.

The key indicators that will be assessed include:

1. Proportion of households with eligible children visited by a community distributor.
2. Proportion of Day 1 SPAQ administered by community distributors to eligible children (in terms of children who received Day 1 SPAQ at least once during 2023/24, and by monthly cycle)
3. Proportion of eligible children who received a full three-day course of SPAQ (including Day 2 and Day 3 AQ) *{among eligible children who received Day 1 SPAQ)*
4. Proportion of SPAQ administered by community distributors by DOT *(among eligible children who received Day 1 SPAQ)*
5. Proportion of Day 1 SPAQ received per eligible child over the course of the SMC round (including proportion of children who received Day 1 SPAQ during all four SMC cycles)
6. Proportion of ineligible children (age 60-119 months) who received SPAQ during the last cycle of the round.

**Quality**

Measuring the quality of SMC implementation is essential to determining the effectiveness of SMC and delivering a safe, robust intervention. Quality SMC delivery ensures the safe administration of SPAQ to eligible children each month during the period of high seasonal malaria transmission. The current SMC treatment course consists of a co-blistered pack of 1 dispersible tablet of sulfadoxine-pyrimethamine (SP) plus 3 dispersible tablets of amodiaquine (AQ) or SPAQ.



**SP AQ**

<https://www.who.int/malaria/publications/atoz/9789241504737/en/>

A full 3-day course of SPAQ^ administered each cycle includes 1 dose of SP and AQ taken together on Day 1 under directly observed therapy (DOT), and one dose of AQ given once each day of Days 2 and 3. There are two dosages of SMC based on the child's age:

* 3 **to <12 months** [SP 250 mg/12.5 mg and AQ76.5 mg] in the orange blister pack



* **12 to 59 months** [SP 500 mg/25 mg and AQ 153 mg] in the red blister pack

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For maximum protection, and to minimize selection of drug resistance, eligible children 3 to 59 months should receive the complete 3-day course of SPAQ each monthly cycle to cover the full duration of the transmission season (SMC round). However, there are logistical, service delivery and uptake challenges that can compromise the coverage, quality and efficacy of SMC. These challenges could ultimately affect the programme's impact, safety, drug resistance and assessment of effectiveness. In order to measure the quality of SMC coverage, three key indicators will be assessed as part of this the End-of-Round survey:

1. **Age eligibility:** only afebrile children aged 3-59 months receive SPAQ. Infants who are under 3 months on Cycle 1 may receive SPAQ once they are 3 months old. Children who are 59 months on Cycle 1 may receive SPAQ for all 4 cycles. However, children who are 60 months or older at Cycle 1 are not eligible for SMC. Community Distributors will be trained to determine a child's age using the following criteria if a birth certificate or vaccine card with the child's date of birth is unavailable:
* Infant between 3 to <12 months: can hold head and neck steady when held upright, can crawl, can sit without help
* Child between 12-59 months: can stand or walk, not able to raise their arm and touch their opposite ear, not able to stand or jump on one foot
1. **Directly observed therapy (DOT):** direct observation by a Community Distributor of the child swallowing all the dispersed medicine. Day 1 dose of SP and AQ for each of the four cycles, and/or a re-dose of SP and AQ given on Day 1 if the child vomits the first dose.
2. **Adherence:** eligible children are administered one dispersed tablet of AQ on Days 2 and 3 of each SMC cycle for all 4 cycles and re-dosed with AQ if they vomit.
3. Due to logistical constraints, it will not be possible to translate the packaging into Portuguese for this round I of implementation at scale. They are color coded and the tablets differ in size for each dose.

These quality indicators are included along with the coverage indicators in the End-of-Round survey tool (see **Appendix 4).**

**End-of-Round survey study area**

The study will aim to achieve representative sample of children aged 3-119 months in households grouped within clusters identified from health facility catchment areas across the 23 intervention districts of the SMC in Nampula Province.

**Study Design**

For this objective, the design will be a cross-sectional cluster randomized survey to evaluate the coverage level and quality of the SMC treatment implemented across Nampula Province.

**Study population**

The study population will be eligible children aged 3-119 months who are, or have been, resident in the Nampula for a minimum of at least one month, during the SMC implementation period. Survey responses will be provided by caregivers.

**Inclusion criteria**

* Primarily, the inclusion criteria are households with children aged 3-119 months, resident in Nampula (at least one month) during the period of the programme implementation.
* A person aged 18 years or older with the primary responsibility for feeding and daily care of at least one child aged 3 months to 10 years of age where the person has been resident prior to the start of the SMC campaign

**Household exclusion criteria**

* Refusal to participate in the survey
* No one aged 18 years or older available at the time of data collection
* No children aged 3-119 months present

Households refusing to participate in the study will be replaced with the next eligible household until the estimated sample size is attained.

**Sample Size and technique**

The End-of-Round (EoR) survey will employ multi-stage random samples of households in areas covered by Malaria Consortium's SMC campaign and will intend to achieve a representative sample of the target population at the district level to estimate coverage of SMC at the level of individual eligible children. The sampling protocol aims to achieve a self-weighted sample with sampling units selected with probability proportional to size (PPS). Only at the last stage of sampling (i.e. at the household level) will a constant number of eligible children (one child per household) be selected.

The survey will be powered to give an estimate of SMC coverage for children aged 3-59 months with a margin of error of 5%, while also providing a representative sample of children aged 60-119 months.

The main sampling frame for the selection process will be a list of villages (*Comunidades)*, obtained from the *postos administrativos.* Villages will then be randomly selected using probability proportional to size (PPS). Villages will be the primary unit of sampling through which households and eligible children will be selected randomly. This may be reviewed once the study starts if this approach is not feasible in practice.

A primary caregiver in this survey refers to any individual, aged 18 years or over, with the primary responsibility for the feeding and daily care of at least one child under the age of five, in a household where he or she has been resident prior to the start of the SMC campaign or one month before the last cycle of the treatment.

**For total survey**

* The assumed intra-cluster correlation (ICC) is 0.2
* 15 eligible children per cluster
* The (design/cluster effect) = 1 + (b-1) \* ICC= 1 + (15-1) \* 0.2 = 3.8
* The coverage rate of SMC in children aged 0-4 years of at least 80% (and in children aged 5-9 years of at most 20%)
* A margin of error of 5%
* Finite population adjustment is applied (1.3 million)
* Non-response rate of 5%
* Assumed ratio of children aged 5-9 years to those aged 0-4 years of 0.88

**Stata output:**

**Estimated sample size needed to survey, assuming the following:**

Population size: 1.300.000

Proportion of sample with the expected outcome: 0.80

Margin of error: +/- 5.0 %

Confidence level: 95.0 %

Design effect: 3.8 (assuming intraclass correlation coefficient of 0.2 and cluster size of 15 households)

Response rate: 95%

Estimated required sample size:

n1 = 246

Sample size adjusted for design effect (3.8) and response rate (95%)

n2 = 983

Sample size multiplied by 1+ratio (0.88) of children aged 0-4 years to those aged 5-9 years (to obtain sample sufficient for estimating coverage in both age groups if obtained through random sampling).

n3 = 1848

**Recommendation on sample size:**

These sample size calculations suggest that a sample of 120 clusters, each comprising 15 households (n=l,800), with approximately 60 households sampled in each of the 23 districts.

This sample will provide estimates of coverage for children aged 3-59 months

60-119 months and 3-119 months with margins of error of 5.0%, 5.4% and 3.5% respectively.

**Sampling procedure**

The sampling methodology will achieve, as far as possible, a self-weighted sample with sampling units selected with probability proportional to size, and only at the last stage of sampling (i.e. at the compound level) select a constant number of eligible children (one child per household).

This will be accomplished using existing data on population estimates (e.g., using Target population calculated reach in each SMC cycle) to construct a sampling frame accounting for the size of each health facility catchment area (or divisions of health facility catchment areas) and select with a probability proportional to their size (PPS).

Based on the estimated sample size,160 clusters based on health facility catchment areas, or divisions of health facility catchment areas if needed to reach the needed number of clusters, will be randomly selected from the sampling frame of existing clusters in all 23 districts using PPS.

Within each selected cluster, a constant number of households (15) will be randomly sampled. One eligible child will be sampled from each compound using a household-level sampling frame of children aged 3-119 months.

**Data collection methods and procedures**

**Study tools**

The data will be collected using a survey questionnaire developed by Malaria Consortium (see **Appendix 4).** The survey questionnaire will be uploaded into the SurveyTCO software application that will enable direct, field-based Computer Aided Personal Interview (CAPI) and remote capture of the data and transfer to a netbook computer.

Whilst the coverage surveys will be the main method to determine coverage, two additional data sources will be analyzed and compared with survey results:

1. Administrative data: based on SMC Tally Sheets completed by distributors and data compiled via daily summary forms and end-of-cycle reports

(coverage = doses delivered/target population)

1. Stock-consumption data

(coverage = SPAQ. blisters received before the campaign - blisters left at the end)

Nevertheless, the two data sources are not being solely relied upon as there are associated limitations in terms of accuracy, such as low literacy levels resulting in faulty completion of the forms, inaccurate target population estimations, meaning the denominator can be unreliable and stock management systems not being digitalized, therefore can be prone to error. Moreover, blister packs may need to be excluded for re-dosing due to a child vomiting a dose, and those that are wasted due to contamination or breakage of the blister.

**Interviewer recruitment and training**

Research assistants with competent skills and expertise who are also conversant in the local language and familiar with the study location will be recruited locally from Nampula province and trained at a central location. The requirements for all data collectors is that they have completed at least secondary level education and are fluent in at least one local language. The training sessions will cover the project background, aims and objectives, field manual, and questionnaires through a combination of lectures, role play using typical field scenarios and pilot exercises. The training will also include modules on how to safely conduct research activities considering CO\/ID-19 (see **Appendix 2).**

**Informed consent**

As part of the process, the interviewers will be trained on the consent procedure. A written informed consent form (see **Appendix** 5) will be explained to all participants in the local language. These forms, to be read out loud to participants, will include a full description of voluntary participation, the right to withdraw from the study at any time, and the right to not answer any question. The forms will also address the risks, benefits, and purpose of the study and what we hope to learn. Interviewees will be requested to provide written consent to be interviewed. Each consent form will be signed by the participant and interviewer and verified by the supervisor to ensure all participants have provided consent.

**Pre-testing of the study tools**

The adapted study tools will be pretested with research assistants as part of training to test the validity of the instrument and the time it will take to complete a questionnaire. The feedback from the pre-test will be used to refine and finalize the tools.

**Data collection**

The SMC End-of-Round coverage survey will involve the collection of a series of essential indicators (both treatment, coverage and quality indicators). Questions and indicators have been adapted to be specific to the implemented SMC campaign. The research team will be trained on inclusion and exclusion criteria and will check these on entering each compound, after requesting permission to conduct research with the caregiver and/or the head of household.

Data will be collected by administering the questionnaires to the identified respondents in the sampled compound within the communities. The survey questionnaires will be administered by the trained research team. All surveys will be administered using SurveyCTO, an electronic data collection platform for smartphones, and data were uploaded to a remote server after each day of data collection. Interviews will be conducted in local languages using the questionnaires provided by Malaria Consortium, with data collectors translating from the Portuguese questionnaire on the spot and assign responses to pre-defined answer categories in SurveyCTO. For the age eligibility indicator, survey respondents may be asked to present a birth certificate or vaccination card to the data collector to verify the child's date of birth.

The duration of the data collection is expected to last for seven days during the first week of May 2024.

**Data management**

Using CAPI, which allows for in-field data entry and server synchronization, data collected will be verified for quality assurance purposes by the quality assurance officer in field and uploaded daily to the SurveyCTO platform. The uploaded files will undergo additional consistency checks, cleaned, and saved into Stata. Extensive data cleaning will be done at the end of the fieldwork.

**Data quality assurance**

Data capture will be performed using software prepared for the survey using the SurveyCTO software application. During fieldwork, daily quality assurance checks will be carried out using Stata 16 and the power-BI to flag inconsistencies in the tabulations of each question for each tool.

**Data protection**

The electronic data collection using SurveyCTO will be kept confidential and anonymous as each study participant will only be Identified by a unique ID in the database and the data will be secured and will be saved on a password-protected encrypted server or on a password-protected encrypted computer for the purposes of analysis. The collected data will only be used for the intended purpose of the research and for possible further analysis by researchers.

**Data analysis**

The data analysis will be carried out using Stata 16. Coverage will be calculated using the proportion command, with 95% confidence intervals calculated using a logit transform. Population size weights will be applied using the svy: command as appropriate for estimates of coverage indicators in the event that it was not possible to achieve a self-weighting sample. All indicators of interest will be calculated in proportion by district and an average across all districts. The confidence interval (Cl) of 95% will be used to provide a range of values around the estimate within which selected result will be expected to fall.

**Risk to subjects and protection**

This study carries minimal risk to all participants. No biomedical interventions will take place as part of this study component. We will take the following actions to mitigate the risk: (a) we will conduct the interviews in a private location as much as possible within the home, and (b) we will analyze and report only aggregate data and (c) we will not release any personally identifiable information.

**Strengths and limitations**

The use of independent coverage surveys will allow for evaluation of the campaign performance and coverage of its target population by data collectors who were not involved in the implementation. This will reduce bias and allow for external resources to be utilized to ensure that the surveys will be implemented in a timely manner. The reliability of the data will be improved by implementing automatic data validation during surveys using question restrictions.

The EoR survey study may face several limitations. A primary limitation of coverage surveys is that they rely on self-reporting, and findings based on survey responses could be subject to recall and social desirability bias. Time will have elapsed from date of SMC administration to the date of the survey. Length of time between administration of SMC and coverage surveys may influence the severity of recall bias. Second, target populations used for calculation of administrative coverage will be estimated based on official population figures, which may be based on outdated national census data and adjusted for projected population growth. At the same time, while the population growth factors employed may be inaccurate, estimates of population sizes may not adequately reflect population movements, for example due to migration. Administration of SPAQ to ineligible children above the targeted age range may also lead to an overestimation of the proportion of children within the eligible age range who will receive SPAQ. The age eligibility quality indicator will aim to provide an idea of the scale of SPAQ administration to children aged 5-10 years. Lastly, data collectors will be trained thoroughly on how to determine a child's age. Caregivers may be asked for proof of a child's date of birth, for example as stated on a vaccination card to confirm age.

**Output:** An evaluation of the coverage and quality of SPAQ administration.

**Implementation;** The coverage survey will be conducted by an Independent Research Firm, with technical oversight by Malaria Consortium. Lead researchers from Independent Research Firm will be briefed on the study and methods by Malaria Consortium staff. They will subsequently recruit and train data collectors, oversee data collection and analysis, and submit a final report to Malaria Consortium.

26th February, 2024