
Seasonal malaria chemoprevention with sulfadoxine–pyrimethamine plus amodiaquine in children: a field guide

Second edition



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Following the release of the *WHO guidelines for malaria, 3 June 2022*, which includes updates relating to seasonal malaria chemoprevention (SMC), the WHO Global Malaria Programme and the Special Programme for Research and Training in Tropical Diseases (TDR) convened a technical consultation on 21–23 November 2022 to develop the second edition of the SMC field guide.

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This update also considered the outcomes of a previous meeting (jointly organized by the Global Malaria Programme and TDR) in 2019, following the large-scale implementation of SMC in 13 African countries, as well as an updated performance framework for SMC produced by the Monitoring and Evaluation Subgroup of the SMC Alliance.

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Abbreviations

ACT	artemisinin-based combination therapy
AQ	amodiaquine
CD	community distributor
CHW	community health worker
CI	confidence interval
DOT	directly observed therapy
M&E	monitoring and evaluation
NMP	national malaria programme
SBC	social behaviour change
SMC	seasonal malaria chemoprevention
SP	sulfadoxine–pyrimethamine
TDR	Special Programme for Research and Training in Tropical Diseases
WHO	World Health Organization

Glossary

community distributor (CD)	Community-based worker recruited and trained to administer SP+AQ to eligible children during each SMC distribution cycle. CDs often work in teams of two people, under the direction of field supervisors.
daily summary form	A form completed each day of the distribution period (i.e. the 3–5 days when the CDs are distributing the medicines in the community each cycle) by health facility workers to summarize daily data from all the tally sheets and referral forms in the health facility catchment area. Used to inform the end-of-cycle report.
directly observed therapy (DOT)	It is advisable for a CD to be physically present while the first dose of SP+AQ is administered to a child by a caregiver, to provide advice and reassurance, to see whether the child ingests the medicine or spits it up, and to be sure that at least the first dose has been given to the child tallied in the tally sheet. In most countries, only the first dose is directly observed (DOT1). In some countries, a CD observes each dose on each of the 3 days (DOT3).
door-to-door distribution	A method of delivering SMC by CDs in the child's household.
end-of-cycle report	A report completed at the end of each cycle that summarizes the total number of children administered SMC (by age group), re-dosed and referred to a qualified health worker. Used to provide a summary of SMC medicine reconciliation, medicine wastage and balance of blister packs at the end of each cycle.
enumeration	Determining the number of children of eligible age in SMC targeted areas. Enumeration is part of the planning process. It is critical to refining planning assumptions and planning accurate SMC medicine procurement for the following campaign.
fixed-point distribution	A method of delivering SMC at a central location by CDs or health workers, such as a health facility, school or central community location.
quantification	Determining the quantity of SMC medicines and other commodities required for the SMC round.

seasonal malaria chemoprevention (SMC)	The intermittent administration of full treatment courses of an antimalarial medicine during the malaria season to prevent malarial illness. The objective is to maintain therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk.
SMC campaign	The period when all SMC activities are implemented. Campaign components are planning and enumeration, procurement and supply management, community engagement, training, administration of SMC medicines, case management and pharmacovigilance, supervision, and monitoring and evaluation.
SMC child record card	A card given to the child's caregiver that tracks the total number of SMC tablets given each cycle.
SMC course	The age-dependent recommended dosing regimen of SMC medicines, which is given over a period of 3 days.
SMC cycle	A 28-day interval between each course of SP+AQ.
SMC distribution method	The method or scheme used to reach eligible children and administer SMC at monthly intervals. The distribution method can be door to door, at fixed locations in the community or health facility, or a mixture of methods.
SMC distribution period	The number of days within each SMC cycle when SP+AQ is distributed to eligible children in an area (typically 4–5 days).
SMC implementation plan	A written plan that describes all activities to ensure an effective SMC campaign. It provides an estimate of human, logistics and financial resources required. It also includes aspects related to procurement and supply management, training, supervision, pharmacovigilance, security, risk preparedness, and monitoring and evaluation.
SMC implementers	All individuals involved in delivering SMC, including CDs, supervisors, health workers, town criers, trainers, the health authority, the national malaria control programme and implementing partner staff.
SMC referral form	A form given to a caregiver when a child is referred to a qualified health worker during SMC. The health worker writes in the referral form the evaluation of the child's clinical status and reasons for referral.

SMC supervisor	Person responsible for supervising CDs during SMC cycles. Each SMC supervisor is responsible for several SMC teams, observing the administration of SP+AQ, and providing constructive feedback, mentoring and support. SMC supervisors and health workers are in turn supervised by senior supervisors, often from district or regional health authorities.
SMC tally sheet	A daily log sheet used by CDs to track the number of SP+AQ doses given, re-dosed and wasted. It is also used to track administrative coverage and medicine accountability each day of each distribution period.
SP+AQ co-blister pack	A blister pack containing one full course of SP+AQ, often with pictorial instructions to improve adherence to treatment. The first dose (one tablet of SP and one tablet of AQ dispersed in water) is administered by, or under the supervision of, the CD on day 1 of each course. The other two tablets of AQ are given to the caregiver to disperse and administer at home in single daily doses on days 2 and 3.
SP+AQ dose range	There are at least three child dose ranges (not formulations) of SP+AQ: <ul style="list-style-type: none"> • infant doses for 3 to <12 months • child doses for 12 to 59 months
town crier	Individuals engaged in SMC campaigns to mobilize communities before and during each SMC cycle, providing key messages about SMC.

1. Introduction

According to the *World malaria report 2022*, there were an estimated 247 million malaria cases and 619 000 malaria deaths worldwide in 2021; 76% of the deaths were in children under 5 years of age (1).

In 2021, the World Health Organization (WHO) launched the consolidated *WHO guidelines for malaria* on the online MAGICapp platform (<https://app.magicapp.org/#/guideline/6832>). The consolidated guidelines bring together two previous guideline documents – the *Guidelines for the treatment of malaria, third edition*, and the *Guidelines for malaria vector control* – and include sections on prevention (vector control, preventive chemotherapies and vaccination), case management, elimination and prevention of reintroduction, and surveillance. As new evidence becomes available, the recommendations are reviewed and updated following WHO’s guideline development process, and the content of the platform is updated. The version of the guidelines published on 3 June 2022 provided an update on the recommendations for seasonal malaria chemoprevention (2).

The interventions currently recommended by WHO for the control of malaria include use of insecticide-treated nets and/or indoor residual spraying for vector control, prompt access to diagnostic testing of suspected cases, and treatment of confirmed cases with effective artemisinin-based combination therapy (ACT). In addition, preventive interventions recommended for specific high-risk groups in areas of moderate to high malaria transmission include seasonal malaria chemoprevention (SMC), intermittent preventive treatment in pregnancy and among school children, perennial malaria chemoprevention in children, post-discharge malaria chemoprevention and malaria vaccination.

Following the recommendation to scale up SMC in 2012, WHO published the first edition of the field manual for seasonal malaria chemoprevention, which recommended use of amodiaquine (AQ) plus sulfadoxine–pyrimethamine (SP) in 2013 to support SMC implementation (3). Since then, SMC has been adopted as policy and implemented on a large scale in 13 African countries (Benin, Burkina Faso, Cameroon, Chad, Gambia, Ghana, Guinea, Guinea-Bissau, Mali, Niger, Nigeria, Senegal and Togo), reaching more than 45 million children in 2021. Pilot programmes have been completed in Mozambique and Uganda.

Best practices for SMC implementation based on the experiences of African countries since 2013 have been compiled in this updated field guide. The goal of this guide is to share these best practices to improved SMC implementation, coverage, and monitoring and evaluation. Examples of materials and tools, and links to resources are included to support managers and health workers conduct successful SMC activities and prevent malaria among vulnerable children.

2. Seasonal malaria chemoprevention

In areas of seasonal malaria transmission, children in age groups at high risk of severe malaria should be given antimalarial medicines during peak malaria transmission seasons to reduce malaria burden (strong recommendation, moderate certainty evidence).

2.1 What is SMC?

SMC is the intermittent administration of a curative dose of antimalarial medicine during the malaria season to asymptomatic children, regardless of whether the child is infected with the malaria parasite – that is, asymptomatic children are not tested for malaria before SMC administration. The objective of SMC is to establish antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the period of greatest malaria risk. SMC is recommended in areas of highly seasonal *P. falciparum* malaria transmission.

2.2 Who is eligible for SMC?

Children in age groups at high risk of severe malaria are eligible. Malaria programmes should use local data to determine which age groups are at high risk of severe malaria. In most countries with intense seasonal malaria transmission, these are children below 5 years of age (1).

2.3 Where should SMC be implemented?

The priority target areas for SMC implementation are those where:

- *P. falciparum* malaria transmission is highly seasonal and the majority (>60%) of clinical malaria cases occur within 4 consecutive months – where data on malaria from the health management information system are unreliable, rainfall data could be used as a proxy for seasonality in incidence (at least 60% of annual rainfall in 4 consecutive months); and
- the clinical attack rate of malaria (without SMC) is at least 0.1 episodes per child during the transmission season in the target group.

2.4 When should SMC be implemented?

SMC should be implemented during the peak malaria transmission period, when the incidence of malaria is highest. SMC courses should be given at 28-day intervals, beginning at the start of the transmission season and continuing for 3–5 cycles, depending on the local context.

SMC administration should be chosen to cover the period when children are at greatest risk for malaria infection. The seasonal distribution of malaria (number of confirmed malaria cases per month) should be described by district in each country to define the ideal timing to start and end SMC. Rainfall data can also be used to estimate peak transmission periods. Depending on the seasonal patterns of malaria transmission, the timing and number of SMC cycles (3–5) may vary between countries and in different parts of the same country (see section 3.2).

2.5 Why is SP+AQ recommended?

WHO recommends that medicines used as first- or second-line malaria treatment in a country not be used for chemoprevention in that country.

The combination of SP+AQ is currently recommended for SMC for the following reasons.

- In the clinical trials that provided the evidence base for WHO recommendations, SP+AQ conferred greater protection than other medicine combinations.
- There are no indications that the chemoprevention efficacy of SP+AQ is diminishing in Africa.
- The SP+AQ regimen is well tolerated and relatively inexpensive.
- The SP+AQ regimen confers protection for 28 days.

2.5.1 Dosing schedules for SP+AQ

The combination SP+AQ is available as dispersible tablets in two different blister packs for the following two age groups:

- Infants 3 to <12 months of age: a single dose of a tablet of 250/12.5 mg SP and three 75 mg tablets of AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are given on days 2 and 3, respectively.
- Children aged 12–59 months: a single dose of a tablet of 500/25 mg SP and three tablets of 150 mg AQ base. The tablet of SP and one tablet of AQ is given on day 1; tablets two and three of AQ are given on days 2 and 3, respectively.

As there are currently no specific blister packs for children >60 months of age, countries should ensure that the target dose of SP+AQ based on weight is delivered daily for 3 days: SP – 25/1.25 (25–70/1.25–3.5) mg/kg bw single dose and AQ – 10 (7.5–15)mg/kg bw daily for 3 days.

The packaging clearly indicates that both SP and AQ tablets need to be given on day 1, and only AQ tablets on days 2 and 3. Different manufacturers' packaging may be slightly different, and this should be considered in the development of training materials. The single dose of SP on the first day is given at the same time as the first dose of AQ.

All children eligible to be treated in the first SMC cycle remain eligible throughout the campaign (i.e. children do not "age out" of SMC during a campaign). However, the reverse is not true – children who become eligible in later cycles should receive SMC from that point on.

2.5.2 Contraindications

SMC should not be given to:

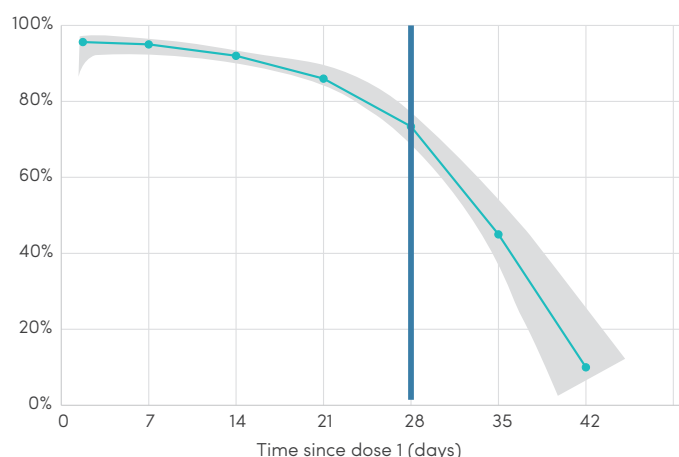
- a child with an acute febrile illness or a severe illness – these children need to be referred to the nearest health facility for appropriate care (or tested and, if positive for malaria, treated on the spot with an antimalarial in countries where rapid diagnostic tests and ACT are available in the community as part of the SMC campaign);
- a child taking co-trimoxazole (e.g. HIV-positive child receiving co-trimoxazole prophylaxis);
- a child who has received a dose of either SP or AQ during the previous 4 weeks; or
- a child who is allergic to either SP or AQ.

Community distributors (CDs) of malaria medicines need to be trained on the contraindications. They should ascertain for each child in each cycle that none of the contraindications apply before administering the medicines.

2.6 Chemoprevention efficacy and drug resistance

SMC with SP+AQ provides a high degree of protection for up to 28 days, and protection decreases rapidly thereafter (**Fig. 1**). A 28-day interval between SMC courses is therefore important to achieve a high level of protection.

Fig. 1. Efficacy of SMC in relation to time since start of treatment



Source: London School of Hygiene and Tropical Medicine (4).

Information on treatment efficacy cannot be used as a surrogate for chemoprevention efficacy. Molecular markers of drug resistance are a useful but imperfect tool for predicting the efficacy of chemoprevention strategies. Surveys in seven countries in 2018 indicated that key markers of resistance were uncommon, but the situation could change and should continuously be monitored. WHO has published the *Malaria Chemoprevention efficacy study protocol* for monitoring the protective efficacy of antimalarial medicines used for chemoprevention indication (5).

2.7 Safety

Before SMC was widely implemented, SP and AQ were considered safe and well tolerated when used at the recommended doses and regimens. Both medicines have been used for decades for malaria treatment, and SP is currently used for intermittent preventive treatment of malaria in pregnancy, and in infants and children up to the age of 2 years (perennial malaria chemoprevention). In many countries, AQ is used in combination with artesunate as ACT for the treatment of uncomplicated malaria.

The most frequently reported adverse events associated with AQ are vomiting, weakness, abdominal pain and diarrhoea. Rare adverse events associated with AQ include extrapyramidal symptoms. Rare severe adverse events associated with SP include severe skin reactions (e.g. toxic epidermal necrolysis, Stevens–Johnson syndrome).

Weekly administration of SP or AQ for chemoprophylaxis was discontinued because of the potential for serious adverse drug reactions. As there are limited data on cumulative toxicity of AQ, it is not recommended to shorten the interval between cycles to less than 28 days.

National malaria programmes should not deploy antimalarials containing SP or AQ for first- or second-line treatment in areas implementing SMC. It is important to engage with the private sector to prohibit the sale of medicines containing SP or AQ in areas

implementing SMC. This will prevent potential repeated exposure to SP or AQ at short intervals, which may cause serious toxicity.

In 10 years of SMC implementation, few severe adverse drug reactions have been reported. Pharmacovigilance systems in many countries though weak, along with information from several studies have been used to strengthened surveillance to access SMC safety. A summary of these findings is provided in **Box 1** below.

Box 1. Summary of adverse drug reactions following 10 years of deployment of SMC

Safety measures taken to improve pharmacovigilance during SMC were reviewed by WHO in 2017 (6). Up to the end of 2016, a total of 1721 individual case safety reports related to SMC treatment had been submitted to Vigibase, the WHO international drug safety database managed by the Uppsala Safety Monitoring Centre (7). The reports were from Burkina Faso, Guinea, Mali, Niger, Nigeria, Senegal and Togo, and included 363 reports for children aged 6–10 years from Senegal. The number of reports was similar for males and females. Vomiting and diarrhoea were more common among children under 2 years of age; fever and abdominal pain were more common in children 2–4 years of age. An additional 61 cases in 2015–2016 were notified to ACCESS-SMC, a multi-country SMC initiative (8). A total of 46 were graded serious (requiring or prolonging hospitalization), including two cases of Stevens–Johnson syndrome, one case of Lyell syndrome, two cases of rash, two cases of severe febrile illness and 33 cases of gastrointestinal disorders. In total, there were six cases of extrapyramidal syndrome, only one of which was graded serious. In the 2017 campaign, one child died as a result of suffocation from inhaling SMC medicine following administration when the child was not fully awake. In 2018, one case of Stevens–Johnson syndrome after SMC was reported in Niger (Lamninou, NMCP Niger, personal communication, 2018), and, in 2019, one child aged 43 months died of Stevens–Johnson syndrome in Togo after the third course of SMC (Tchassama Tchadjobo, NMCP Togo, personal communication, 2020).

Analysis of causality was limited by the difficulty in eliminating other aetiologies (e.g. dysentery, malaria). SMC CDs are trained to exclude children who become unwell after receiving SMC, but, where SMC coverage is high, there may be children who become unwell shortly after receiving the SMC medicines as a result of a pre-existing illness (symptoms may not be apparent in the early stages of an illness). A further limitation in assessing case reports has been the lack of biochemical and haematological parameters, which may have led to underdetection of hepatotoxicity and agranulocytosis.

2.8 Expected benefits of SMC

The WHO policy recommendation for SMC in 2012 was based on the results of seven studies conducted in areas of highly seasonal malaria transmission in the Sahel and sub-Saharan regions of sub-Saharan Africa between 2002 and 2011 (9, 10). Evidence from these studies showed that SMC with SP+AQ administered at 28-day intervals to all children under 6 years of age during each malaria transmission season (11):

- prevented approximately 75% of all malaria episodes;
- prevented approximately 75% of severe malaria episodes;
- may decrease child mortality from 3 per 1000 per year to 2 per 1000 per year;
- may reduce by one third the incidence of moderately severe anaemia;

- did not result in an increase in clinical malaria cases in the subsequent malaria transmission season after 1 year of implementation; and
- was rarely associated with serious adverse events, although it may cause vomiting in some children.

In 2015 and 2016, the Achieving Catalytic Expansion of SMC in the Sahel (ACCESS-SMC) project sought to remove barriers to the scale-up of SMC for children younger than 5 years in seven countries (Burkina Faso, Chad, Gambia, Guinea, Mali, Niger and Nigeria).

SMC was administered monthly by community health workers (CHWs) who visited door to door. Medicine administration was monitored via tally sheets and household cluster-sample coverage surveys. Effectiveness of monthly SMC treatments was measured in case-control studies that compared receipt of SMC between patients with confirmed malaria and neighbourhood-matched community controls eligible to receive SMC. Impact on incidence and mortality was assessed from confirmed outpatient cases, hospital admissions and deaths associated with malaria, as reported in national health management information systems in Burkina Faso and Gambia, and data from selected outpatient facilities (all countries).

In 2020, results of an observational study to evaluate the effectiveness of SMC in west and central Africa demonstrated that SMC at scale was effective in preventing morbidity and mortality from malaria (8). SMC was associated with a protective effectiveness of 88.2% (95% confidence interval [CI]: 78.7–93.4) over 28 days in case-control studies (2185 cases of confirmed malaria and 4370 controls). In Burkina Faso and Gambia, implementation of SMC was associated with reductions of 42.4% (95% CI: 5.9–64.7) and 56.6% (95% CI: 28.9–73.5), respectively, in the number of malaria deaths in hospitals during the high-transmission period. During 2015–2016, the estimated reduction in confirmed malaria cases at outpatient clinics during the high-transmission period in the seven countries studied ranged from 25.5% (95% CI: 6.1–40.9) in Nigeria to 55.2% (95% CI: 42.0–65.3) in Gambia. Coverage varied, with some areas consistently achieving high levels via door-to-door campaigns. In 2015, among eligible children, mean coverage per month was 76.4% (95% CI: 74.0–78.8), and 54.5% of children (95% CI: 50.4–58.7) received all four treatments. Similar coverage was achieved in 2016: 74.8% (95% CI: 72.2–77.3) treated per month and 53.0% (95% CI: 48.5–57.4) treated four times.

At the time of writing in 2023, studies were ongoing to assess the impact of SMC in east and southern Africa (including Mozambique and Uganda).

2.9 Considerations for deployment of SMC

The following considerations apply in areas where SMC is deployed.

- The 28-day interval should be respected between cycles – that is, a child who is treated on day 1 of the first SMC cycle needs to be treated on day 1 of the following cycles.
- SP and the first dose of AQ should be taken on the first day of treatment, under directly observed therapy (DOT1). The second and third doses of AQ should be given over the next 2 days by the caregiver. Caregiver adherence to the 3-day regimen can be reinforced through appropriate health communication and community engagement. The delivery of all three doses under directly observed therapy (DOT3) is an option, although cost-effectiveness data for DOT3 are lacking.

- A mechanism is needed for children who are sick at the time of the campaign to be referred to a qualified health worker for testing, and then receive either curative treatment or SMC if they test negative to malaria. This could be at a health facility or, where appropriate, by a CHW.
- Pharmacovigilance should be strengthened where it exists and should be instituted where it does not. Efforts to simplify and expedite reporting of adverse events are important. Systems are also needed to ensure full documentation, as well as resources to review reports and assess causality (for more details on pharmacovigilance applied to SMC, see section 5.3).
- Drug resistance monitoring and systems to evaluate the protective effect of SMC as a complex intervention under programmatic conditions at the population level could be supported or instituted (for more details on monitoring chemoprevention efficacy of SP+AQ for SMC, see section 2.6).
- Existing health management information systems should be strengthened to record uncomplicated and severe malaria cases and deaths attributed to malaria. Records in health facilities of uncomplicated malaria, severe malaria and malaria deaths should systematically document whether the child took SMC (Yes/No/Unknown) during the previous 4 weeks.

SMC complements existing malaria control interventions and should be deployed concurrently with other preventive and curative interventions. However, perennial malaria chemoprevention (formerly known as intermittent preventive treatment in infants), which is used in areas of perennial malaria transmission, should not be deployed in districts or communities that conduct SMC.

2.10 Costs and cost-effectiveness of SMC

In 2016, a cost-effectiveness study of the ACCESS-SMC project in seven countries found that the weighted annual average economic cost of administering four monthly SMC cycles was US\$ 3.63 (in 2016 US\$) per child under the age of 5 years. The incremental economic cost per malaria case averted ranged from \$2.91 to \$30.73 (range: US\$ 2.71–8.20 (12)). Variation was seen between countries, reflecting differences in recurrent costs and the proportion of children covered. As the number of cycles now varies between different areas, a more meaningful unit cost would be the cost per child and cycle. The cost-effectiveness of SMC will become less favourable as programmes expand to age groups at lower risk of severe disease and areas of lower transmission.

3. Updating of national SMC policy

When countries decide to develop, review or update their SMC national policy, they should consider involving all relevant stakeholders, including technical and financial partners. The process should be led by the national malaria programme, with the involvement of its technical advisory committee, regional and district health authorities, research institutions, civil society and community health organizations.

One of two typical policy scenarios applies.

- Countries update their current SMC policy because they are considering extending it to other geographic areas, varying the number of cycles, extending it to older children, or changing the medicine regimen from SP+AQ to another regimen.
- Countries consider introducing a new SMC policy based on positive results from initial trials (e.g. Mozambique, Uganda, United Republic of Tanzania).

In either scenario, a situation analysis is important.

3.1 Situation analysis

A situation analysis should be carried out as the basis for developing or updating the national SMC policy, following publication of the *WHO guidelines for malaria, 3 June 2022 (2)*. SMC is part of a package of interventions that includes effective vector control, case management, prevention services for pregnant women and (in the near future) vaccination. The situation analysis **may include the following components**.

3.1.1 Context

Population characteristics: rural, urban, nomadic, internally displaced, refugees, insecure areas, geographical access barriers, border (potential for collaboration with bordering countries also implementing SMC).

Population data: defining the target population.

- How up to date and reliable are the data?
- What have coverage rates of previous campaigns revealed about the target denominator?
- Methods of calculating denominators include the following.
 - Previous year's total number of SMC-eligible children – if individual children were not tracked or identified, use the number of children per age category treated in the cycle with the highest number of children treated and apply a growth rate (this will vary by country).
 - Household enumeration from other recent campaigns (e.g. long-lasting insecticidal nets, vaccination).
 - Household enumeration during micro-planning, or social mobilization a day or two before the first cycle.
 - National census data with an annual growth rate applied.

3.1.2 Malaria situation

- Monthly incidence of uncomplicated and severe malaria by district, region and country during the previous 3 years.
- Proportion of malaria cases that occur during the high-transmission season.
- Monthly rainfall patterns by region/district to facilitate decisions about location and timing of campaigns.
- Current first-, second- or multiple-line treatment regimens for uncomplicated malaria.
- Medicines containing AQ and SP on the market and available in the private sector.
- Description of major policy changes that may affect treatment-seeking behaviour, especially referral of sick children identified during SMC cycles (e.g. introduction of free care for children under 5 years of age, new cost-recovery schemes in public health facilities).

3.1.3 Health system situation

- Current coordination mechanisms for malaria/public health campaigns.
- Description and timeline of other concurrent activities during the period of SMC implementation that could potentially reduce SMC coverage and implementation (e.g. national or district elections, other health campaigns that will rely on the same cadre of health workers as SMC).
- Current data collection methods for other door-to-door campaigns or activities.
- Supply chain for distribution and management of commodities relevant to SMC campaigns.
- Description of service delivery programmes at the community level (e.g. integrated community case management, malnutrition screening, vitamin A supplementation).
- Functionality of health facilities and of CHWs (where appropriate) for malaria case management.
- Quality and availability of malaria case management services in the community, including referral of sick children who cannot be treated at the community level.
- Whether CHWs are allowed to diagnose and treat malaria cases in the community or if referral of all febrile children is required. If CHWs can diagnose and treat uncomplicated malaria cases, can active detection of cases during a door-to-door SMC campaign be accommodated by the existing workforce and supply chain?
- Description of human resources needed and available for SMC delivery (e.g. CDs, supervisors, managers) at all levels of the health-care system. CDs can either be recruited as volunteers specifically for the campaign (often from a pool of community members known in the health system because they work on many campaigns), or recruited from a recognized, salaried cadre of CHWs if workload allows.
- Existing knowledge, attitudes and care-seeking practices in the community concerning SMC, malaria prevention and malaria treatment.
- Existing strategies and resources for advocacy, community engagement and social mobilization.
- Strengths and weaknesses of the existing pharmacovigilance system.
- Identification of risks for, and barriers to, SMC implementation that may arise before, during or after SMC delivery (e.g. medicine procurement and importation, shortage of SMC medicines at time of distribution, natural disasters, heavy rains, security issues, strikes that could prevent transport and access to communities).

- Chemoprevention landscape in the country. Is perennial malaria chemoprevention being planned, studied, piloted or implemented? What is the status of intermittent preventive treatment in pregnancy in the country? Are there elimination areas conducting mass drug administration activities? Are there concerns about “drug pressure” on SP?

3.2 Data to guide decisions on number of SMC cycles per district

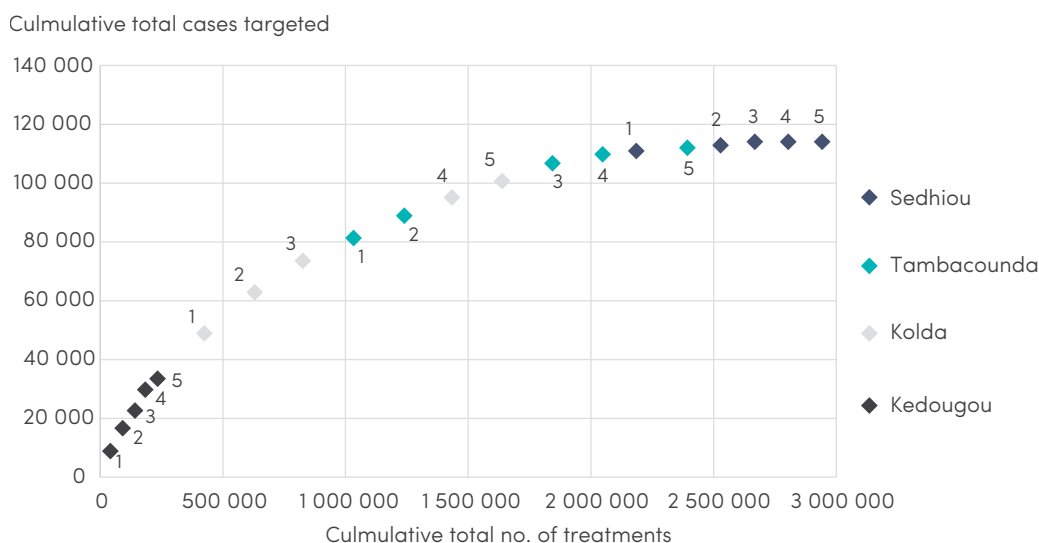
WHO recommends that SMC be implemented in areas with highly seasonal transmission patterns of malaria, defined as areas where at least 60% of annual cases occur within a consecutive 4-month period (3). SMC is expected to be highly cost-effective in areas where malaria incidence in the absence of SMC is above 0.1 per child during a 4-month high-transmission season. However, the start and end of the malaria transmission season is not always abrupt; if a fifth month on either side of the 4-month season contributes more than 10% of the annual burden, it may be cost-effective to add a fifth SMC cycle. Gains from adding a sixth SMC cycle appear to be minimal (13). In some places, three cycles might suffice.

Where SMC has been already implemented, the fraction of cases occurring immediately before or after the main transmission season can be estimated using monthly aggregates of facility-level data for age groups not receiving SMC. The analysis should be limited to facilities with complete data. After identifying the 4-month period when 60% of annual cases occur, review data over several years to assess whether more than 10% of the annual malaria cases consistently fall during a fifth month on either side of the identified high-transmission period. If surveillance data are not reliable, rainfall data can be used as a proxy for estimating seasonal trends. Note that the high burden to high impact initiative uses the criterion of 60% of annual rain falling in 4 consecutive months for the previous 4 years as a reasonable proxy for estimating case data. Guidance on when to stop SMC does not exist because it is difficult to estimate transmission in the absence of SMC once it has been implemented. Seasonality does not need to be updated; it should be based on seasonal disease patterns before SMC was introduced.

If resources are limited, when determining the optimal number of cycles per district, identify where the greatest number of unsuppressed cases is each month during the rainy season. To do this, estimate the number of cases in the absence of SMC in the target age group per 1000 population, in each 28-day period, by district. Next, rank the 28-day periods in order of malaria incidence. Then plot the cumulative total number of cases against the cumulative total treatments available for distribution. To achieve desired outcomes, some districts may require five cycles, others four and others only three. Fewer than three cycles is unlikely to be cost-effective. The process is illustrated in **Fig. 2**.

After identifying the optimal number of cycles by district, identify the optimal start time for the first cycle. SMC cycles should be started approximately 2 weeks before malaria cases start to rise. If rainfall data are being used to estimate the high-transmission period, rainfall data for the year of implementation are not helpful because cycle dates will need to be fixed several months in advance of the campaign; rather, rainfall patterns from previous years should be used. Approval will be needed from the ministry and Director General of health, as well as communication with other ministries and programmes to ensure that the SMC cycle dates are agreed to and there is minimal impact on, or from, other programmes and campaigns.

Fig. 2. Determining the optimal number of SMC cycles per district



Priority order:

1. 5 cycles in Kedougou
2. 5 cycles in Kedougou, 3 cycles in Kolda
3. 5 cycles in Kedougou, 5 cycles in Kolda, 3 cycles in Tambacounda

Source: Jean Louis Ndiaye, University of Thies, personal communication, 2022.

3.3 Data to guide age range expansion

Most research studies have evaluated SMC in children aged 3–59 months, but limited studies among children 60–120 months of age have also demonstrated reduced malaria incidence in this age group. Two studies evaluating the impact of SMC on children aged up to 10 years revealed benefits of extending SMC to older children. In Mali, one year after SMC implementation in Kita district, including in children 5–10 years of age, investigators found a 21% reduction in uncomplicated malaria and a 62% reduction in severe malaria in children 5–10 years of age in the pilot district compared with the control district (14). This was associated with an additional cost of US\$ 0.43 per child compared with children 0–5 years of age (US\$ 2.95 vs 2.52). In Senegal, where SMC has been provided for children 3–120 months of age since its introduction in 2013–2014, investigators found a 43% reduction in hospital malaria deaths among children <10 years of age associated with the introduction of SMC and a 44% reduction among outpatients with confirmed malaria in this age group (Jean Louis Ndiaye, University of Thies, personal communication, 2022). The impact was similar among children aged 3–59 months and 60–120 months.

Local patterns of severe malaria admissions should be reviewed using the available routine data stratified by age group. When age-disaggregated rates of severe malaria are unreliable or unavailable, data on uncomplicated malaria may be used. The definition of a target age group depends on the availability of age-disaggregated routine data, which is often limited to two child age groups: under and over 5 years of age.

Areas where SMC started in children aged 3–59 months may observe a decrease in expected disease incidence in the intervention areas. The decision to expand SMC to older children should be determined by:

- the level of reduction in the percentage of severe disease in children <5 years of age;

- the burden of severe malaria observed in children 5–10 years of age;
- the operational feasibility of expanding to older age groups; and
- the cost-effectiveness of the expansion.

Mathematical modelling may be required to inform some of these thresholds.

3.4 Data to guide spatial targeting

For geographic targeting of SMC, countries should decide on the definition of seasonality and methods used to determine it.

Data for determining seasonality include age-stratified data on routine cases, historical annual incidence and prevalence estimates, and severe malaria indicators. Epidemiological threshold data can also be used to identify areas with historically high transmission. In addition, historical rainfall data can be overlaid on other datasets.

SMC is not recommended in areas where children are receiving perennial malaria chemoprevention (although post-discharge malaria chemoprevention can be used in areas receiving SMC). These data will be available in targeted chemoprevention plans.

3.5 Policy update or development process

Relevant stakeholders, including public health leadership at all levels, and technical and financial partners, should be included in SMC policy reviews. The process should be led by the national malaria programme, with the involvement of its technical advisory committee, regional and district health authorities, research institutions and civil society, including community health organizations.

Policy updates will likely be part of subnational tailoring of malaria interventions, using local data and contextual information to determine the appropriate mix of interventions and delivery strategies for a given area (e.g. district, health facility catchment, village) to achieve optimal impact. Many countries have started stratification – the process of geographically and temporally classifying malaria risk and its determinants into meaningful categories to inform the tailored targeting of the intervention and strategy mixes for each subnational unit. Geospatial analysis and modelling approaches are useful for stratification.

4. Planning and implementation

Countries should begin macro-planning at least a year in advance of the SMC campaign to quantify and procure medicines, and mobilize funds. SMC medicines need to be ordered a year before the campaign.

Micro-plans should be developed at district or regional levels, as appropriate, 4–6 months in advance of the campaign launch, taking into consideration local specificities, opportunities and needs.

4.1 Distribution strategies

SMC can be distributed at fixed points or via door-to-door visits in the community, or through a combination of these. Selection of the most appropriate distribution method depends on context, including population size, distance between households, location of health facilities, and availability of human and financial resources. There may be some health or cultural aspects to consider as well. For example, at the height of the COVID-19 epidemic, fixed-point distribution was discouraged, to limit mass gatherings.

Criteria for selecting the distribution strategy should be evaluated and discussed during the macro- and micro-planning processes, and reviewed after each cycle to make adjustments as needed. **Table 1** presents aspects of implementation that should be considered when selecting the most appropriate distribution strategy to reach children in each context.

Table 1. Distribution strategies

Characteristic	Door to door	Fixed point	Mixed models, including mobile outreach
Accessibility in rural or urban areas	Good option to achieve higher coverage in rural areas, but access may be limited by distances, road conditions and climatic conditions during rainy season (rains/floods)	In urban contexts, may be more efficient to access large populations, and provides rapid access for sick children to be tested and treated	Use of mobile teams in rural areas can increase access to different groups, but outreach can be limited by road and climatic conditions
Accessibility in insecure areas	Access may be difficult, and the delivery strategy should be adapted to the local context to achieve the best possible coverage of eligible children. SMC distribution should avoid mass gatherings in insecure areas.		
Community leaders	Play an essential role in micro-planning phase and social mobilization. In urban areas, they could be more difficult to identify.		
Logistic resources/team	More distribution teams required	Fewer resources required as the setting is already available	Fewer resources required
Human resources/team	More teams required	Fewer teams required than door-to-door distribution, if done in health facilities	Fewer teams required than door-to-door distribution, but more than at a health facility
Supervision requirements	Harder to supervise	Easier to supervise	May be difficult to supervise, depending on the context

Characteristic	Door to door	Fixed point	Mixed models, including mobile outreach
Expected children per team per day	25–80 children/day (based on local capacity, distance, access to households, etc.)	150–300 children/day, depending on capacity and availability of human resources	50–75 children/day
Expected coverage	Better coverage because caregivers can passively accept SMC	Lower coverage because caregivers must actively seek SMC	Lower coverage because caregivers may be afraid to leave the home
Adherence strategy	DOT1 or DOT3	DOT1	DOT1
Rumour management	In rural areas, it may be easier to control and limit dissemination of rumours. If generated in urban settings, rumours can be quickly generated and disseminated.		
Community engagement	Allows richer interpersonal interactions between family members and distributors from within the community	The community can be engaged in a different way as the population is assembled and has waiting time	Essential in a context where people are afraid and may be mistrustful
Concomitant interventions	More difficult to combine multiple interventions (although frequently done, such as for malnutrition screening in Niger and Mali)	Easier to integrate multiple interventions	Often relevant to add other interventions given that the target population may have limited access to health facilities
Relative cost	More expensive than fixed point, as more distribution teams required	Cheaper than door-to-door distribution as fewer teams required	More expensive than 100% fixed point and less expensive than 100% door-to-door distribution

4.1.1 Door-to-door distribution

Door-to-door distribution involves teams of one or two CDs visiting each household. One CD is responsible for registration using the site tally sheet, filling in the child's SMC card and completing other data collection forms (e.g. pharmacovigilance forms, referral forms), as needed.¹ The second CD is responsible for assessing the presence of illness, giving the first dose of SP+AQ to the child's caregiver to administer immediately under DOT, counselling the caregiver on how to complete the treatment course on days 2 and 3, and advising the caregiver on when to seek treatment at health facilities in case of illness. It is possible for one CD to do all this because it is advisable for the CD to wait 30 minutes after administration of the medicine to be sure that the child does not vomit. This is the model used in Cameroon.

Recruitment of CDs should take into consideration sex, literacy and cultural expectations within the community. Other criteria can include previous involvement in mass campaigns, access to a mobile phone, access to a mobile bank account and possession of a form of identification. The recruitment strategy should ensure that CDs are recruited from, and respected within, the community.

¹ An example of referral form is provided by the Malaria Consortium at the following link: <https://www.malariaconsortium.org/gallery-file/11070356-81/10referralform2019.docx> (accessed 17 February 2023).

The number of children to cover per day per CD will be defined by the target population size, the distance between households and plans for delivery of other interventions (e.g. malaria case management, malnutrition screening, tuberculosis screening).

Door-to-door distribution is preferable to cover relatively small villages (i.e. those with fewer than 500 children) and when households are relatively short distances apart. In villages with fewer than 200 children in the target age group, two CDs can be expected to visit and administer SMC to an average of 25–80 children per day. The number may increase to up to 100 children, depending on the distance between households, previous experience of CDs and absence of complementary interventions.

For the door-to-door approach, the distribution plan should include the target households and the specific sequence of household visits for each day of the SMC cycle. To maintain an interval of 28 days between treatments for each child, the same sequence of household visits should be followed each month. In many countries, CDs use chalk to make a mark on the outside of a house or compound to indicate to subsequent CDs that the house has already been visited. A specific mark could also serve as a reminder that the household needs revisiting because at least one of the target children was absent at the time of the first visit.

Developing systems for ensuring timely and transparent payments to the large number of CDs is an important component of the planning process.

4.1.2 Fixed-point distribution

In fixed-point distribution, the SMC medicines are given by CDs at a specific location that is accessible to most of the population. The fixed point should have sufficient shelter from sun and rain, and tables and chairs or mats, as well as a plan for crowd control. Common choices include health facilities or another known point regularly used for campaigns (e.g. a marketplace).

Health facility

Health facilities are typically used as fixed-point distribution sites when the size of the community is large and access to health facilities is relatively good. The community will need to actively seek the intervention, so a sensitization campaign should take place ahead of the scheduled distribution date and time. This distribution strategy works well for integration of SMC into the health system. On an identified day, all health workers are available to provide SMC to families who seek it. This method allows symptomatic malaria cases among the target population to be identified and treated immediately. As well, children and families attending a health facility for other reasons (e.g. vaccination, new-born consultation, another illness that is not a contraindication for SMC) can be given SMC.

Known fixed point used for mass campaigns

Established fixed points can be used when there is relatively poor access to health facilities. This allows treatment of 150–300 children per day in densely populated areas (urban or rural), but can also be used as a mobile outreach strategy (e.g. at known gathering points for small groups of nomadic families).

4.1.3 Mixed SMC delivery models

If a combined door-to-door and fixed-point approach is used, quantification exercises must account for the needs of both – for example, the health facility or other fixed point will require a medication allocation. In addition, campaign data will need to be collected from both door-to-door and fixed-point activities.²

² Tools to support budgeting and quantifications are provided by Medicines for Malaria Venture at the following link: https://www.mmv.org/sites/default/files/uploads/docs/access/SMC_Tool_Kit/Planner_SMC_EN.xlsx (accessed 17 February 2023).

Deployment of different strategies in different parts of the country

A country can use fixed-point delivery in urban settings or other densely populated areas (capitals of regions and districts), door-to-door delivery in rural areas, and delivery by mobile outreach teams to nomadic populations to meet local needs. For example, in Mali, SMC has been delivered at fixed points by mobile teams, and using a mixture of door-to-door and fixed-point distribution during a campaign. Mobile teams delivering SMC in Mali have been equipped with malaria rapid diagnostic tests to test febrile children for malaria and ACT medicines to treat those who test positive. Teams also screen for severe acute malnutrition.

Fixed-point delivery at health facilities and door-to-door visits for tracing children lost to follow-up

In Senegal and Ghana, a mixed-model strategy was implemented to increase coverage in the second, third and fourth SMC cycles, to reach children who did not attend the health facility when they were expected to.

Door-to-door visit followed by fixed-point delivery

Door-to-door visits followed by fixed-point delivery to reach children who were absent at the time of the household visit have been implemented in Burkina Faso. To avoid having CDs leave the medicines with caregivers to administer the first dose unobserved when the child returns home, CDs instruct caregivers to bring eligible children to the fixed point by a cut-off date. This is to reduce the likelihood of medicines being kept and given to somebody else in case of suspected malaria later.

Fixed-point delivery with mobile teams at health facilities

Fixed-point delivery with mobile teams at known gathering places in villages is used in Guinea-Bissau.

4.1.4 Delivering SMC in insecure areas

SMC implementation in insecure areas needs specific operational adaptations, including the following.

- Identify who has good relationships with local authorities, community leaders and health system leaders.
- Identify partners successfully operating in areas where access is restricted.
- Determine whether the target population is able and willing to attend a fixed point, or whether CDs need to go door to door, and adapt approaches as needed.
- Track and plan for anticipated population displacement (e.g. population estimates, movement routes).
- Determine referral plans for sick children.
- Estimate capacity and plans for the supply chain.

In insecure areas, the model of implementation could include:

- supply of medicines to CDs who will operate unsupervised and may move with the population; CDs may need to be given supplies for more than one SMC cycle;
- ongoing community leader and caregiver engagement in areas of predicted or existing conflict to ensure acceptability, preparedness and alternatives to the distribution plan;
- plans to maintain curative services provided by CHWs, including a referral system;
- negotiating safe access (corridors) in conflict areas; and

- combined distribution strategies to maximize opportunities to reach target populations.

4.1.5 Payment strategies for SMC campaign workers

SMC campaigns mobilize large numbers of CDs, who are paid a daily fee, sometimes with an additional payment to reimburse them for campaign-related transportation costs. These CDs implement the campaign for 4–5 days each month for 3–5 months, depending on context. Payments can be made in person using paper tools, or digitally. When they are paid in person, CDs are often paid through the local health centre, which sometimes results in a lack of transparency, late payments and delayed submission of supporting documents. Another option, used in Niger, is to contract a microfinance firm as the payment agent. Outsourcing of both payment and initial document review to an entity that already has an existing physical presence in the target areas reduces the need to send finance staff out to the regions to review paper payment justification documents. Instead, a review of documents can be conducted slightly later from the capital without slowing down the payment process.

A general trend across many countries implementing SMC has been to transition to mobile payment systems. Burkina Faso, Chad, Mali, Mozambique, Togo and Uganda have all introduced mobile payment systems. Mobile money transfer increases transparency and accountability, is efficient, and promotes safety because it eliminates the need to move project staff with physical money through sometimes insecure regions. However, the system needs to be planned and mapped out well in advance of the campaign. It requires mobile network coverage in the SMC regions. Ideally, CDs should have their own SIM cards rather than using a neighbour's or relative's, which makes verification harder. In some countries, mobile providers have agreed to provide CDs with a registered SIM card if they do not already have one.

4.2 Preparing an SMC implementation plan

The goal of SMC planning is to determine where, when and how SMC will be implemented. Planning requires completion of the situation analysis as described in section 3.1.

4.2.1 Key activities of SMC planning

Estimating medicine requirements and procurement

The first step in SMC planning is estimating the population of children aged 3–59 months (or older if that is the strategy) in the areas where SMC will be delivered (i.e. village, health zone, district, region or country). Estimates should be done for all the SMC cycles expected in one campaign, taking into account that children will age into the cohort (e.g. reach 3 months of age in time for the second cycle) or advance into a new age group requiring a higher dose of medication (e.g. reach 1 year of age between cycles) (see section 3).

The next step is to calculate medicine, material and tool requirements for that population estimate. These estimates need to be done at least a year in advance of implementation to allow adequate time for procurement – this includes manufacturers' and freight service providers' timelines for delivery to the point of entry, as well as regulatory approvals, and waivers of taxes and tariffs for importation. These days, with more manufacturing capacity than in the early days, the main delays occur during shipment – for example, as a result of limited container and vessel capacity, and port congestion – and have been exacerbated by the COVID-19 pandemic. It is also important to plan the in-country distribution of commodities from the port of entry to the health facility level. For this purpose, planners must identify the people responsible for distribution, quality control and batch testing, import taxes, last-mile distribution and reverse logistics.

Purchase orders for SMC medicines should be completed a year before SMC implementation. Ideally, everything needed should be positioned at the main distribution points at least 2 months before the first SMC cycle.

Dispersible SP+AQ should be procured from WHO prequalified manufacturers in co-blistered packets containing one full course of SMC medicines for each cycle – that is, each blister pack contains one tablet of SP and three tablets of AQ. The packs have pictorial instructions on the packaging to facilitate adherence to treatment. They contain dispersible tablets of different strengths for children of two age groups: 3 to <12 months and ≥12 to 59 months. This grouping was determined to be convenient to reduce the risk of overdosing or underdosing. The number of packets for each age group needs to be quantified and then multiplied by the number of expected cycles.

In the early years of an SMC campaign, it is advisable to add a 15% contingency margin to the quantification to allow for calculation errors, expired or lost medicines, vomited/spat-up doses and unexpected shifts in populations, especially in cross-border areas. (In areas where data from previous campaigns exist and there is no reason to anticipate major changes, such as population movement, a much lower buffer may suffice.) Another strategy, which has the added benefit of minimizing the risk of delays because of late arrival of shipments, is to pre-position stock for the first cycle of the following year – this stock essentially acts as a buffer in the current year as well. There would then be a need to factor in leftover stock from previous years, bearing in mind the shelf life and storage conditions of SP+AQ.

Develop national SMC macro-plan

The national SMC macro-plan will include activities, resources, targets, outputs, responsible officers/agencies, and a timeline incorporating planning and cycle dates to avoid conflicting with other national or subnational campaigns (e.g. SMC CDs may also be involved in other public health programmes and therefore unavailable).

The dates for the cycles should be confirmed within 6 months of implementation, with a letter signed by the minister (or Director General) of health. These dates should be communicated widely across programmes. The campaign should start before the projected start of the high-transmission season.

Preparing SMC micro-plans

The goal of SMC micro-planning is to design the logistics and elements required to ensure that SMC resources, medicines and materials are available in the correct quantities, and in the right place at the right time, to deliver SMC to eligible children in the communities. The micro-plan should be completed 4 months in advance of the first SMC cycle. Micro-planning can take up to 6 weeks to complete. The micro-plan should be specific to the communities where SMC will be implemented and contain detailed information. It should include details of the people responsible for conducting and completing each activity, when each activity will begin and end, detailed logistics for resources needed (people, money, materials) and how success will be measured. Activities within the micro-plan should include how to order, transport, store, distribute and deliver SMC commodities to communities. It also outlines how resources will be allocated, how training and supervision will be done (who, what, when, where), and how and when communities will be informed about the campaign.

Components of a successful micro-plan

A successful micro-plan has the following components.

- SMC team composition according to the delivery system selected. The selection criteria for CDs need to be defined and met. It is recommended that the same staff start and continue all cycles of distribution, if possible.

- An effective plan for training, with clearly defined roles and responsibilities for all levels of staff.
- A detailed plan for supportive supervision.
- A plan for strengthening case management and referral in target districts.
- A comprehensive community mobilization plan.
- An acceptable and context-specific payment plan for all levels of staff.
- Details of adequate and appropriately distributed medicines, supplies, reporting forms and commodities to be pre-positioned in the right quantity at the right time.
- A realistic timetable, including the planned dates for each SMC distribution cycle in the villages plus the time for reporting of monitoring and evaluation summaries afterwards.
- A detailed plan for monitoring and evaluation, including data from CD teams, surveillance data from health facilities, adverse events reports and any coverage surveys in specific districts.

The DHIS2 app store has a microplanning application (15), which allows the user to:

- create catchment areas boundaries for health facilities and publish them to DHIS2;
- create visualizations and maps by combining the catchment areas with DHIS2 reporting data;
- generate target population estimates for each catchment area to calculate coverage estimates;
- see travel time to the health facilities within the catchment area to support outreach and session planning.

Requirements are an account with Crosscut (a third-party application) and internet access.

4.2.2 Training SMC campaign staff (cascade training)

Development or updating of materials

Training materials include training manuals, data collection forms, job aids and social behaviour change (SBC) materials.³ The quantity of these tools and materials needs to be calculated. They then need to be produced and included in the procurement for delivery no later than 2 months before SMC implementation.

Staff training

SMC campaign staff must be trained. All trainers and staff implementing SMC, including health personnel at the district, health facility and community levels, should be trained according to their respective tasks (supervision, delivery or reporting) to ensure that there is clear understanding of roles, responsibilities and materials required.

- Cascade training (at central, regional and district levels) and refresher training, including supervisory oversight, should be planned. Personnel participating in training sessions should be informed of plans well in advance to avoid overlap with other activities.

³ An example of SMC job aid for CHW developed by the Catholic relief Services for Gambia is available at the following link: https://www.crs.org/sites/default/files/job_aid_the_gambia_.pdf (accessed 17 February 2023).

- The training sessions should be completed before the start of the first cycle of SMC. Refresher training during the campaign can be considered as needed. Budgets for this training are needed.
- Job aids, role playing and practical exercises (e.g. simulations of administering medicines, completing forms, counselling caregivers, monitoring for safety, managing crowds and communicating with the community) are important resources for training CDs.
- The training materials should be reviewed annually to maintain relevance and quality (e.g. updated content, organization of training sessions, duration of training sessions, training of trainers, supervision of the training, evaluation of trainee knowledge and skills, evaluation of the training, training reports).
- It is generally good practice to assess training (e.g. using pre- and post-training tests) and determine what to do if people fail the post-training test.

Instructions to CDs, health facility staff and district health staff

Caregivers and the community should receive the following information about SMC.

- SMC medicines can prevent children from becoming sick with malaria but are not 100% effective, so parents still need to seek care for a child who develops a fever, even if they have received SMC.
- SMC medicines should not be used to treat children once they are sick.
- SMC is given to children aged 3–59 months (or 120 months, depending on the location) because they are most at risk from malaria. The medicines do not work if given to older children with malaria symptoms.
- A full SMC course (SP+AQ) is administered 3–5 times (SMC cycles) at 28-day intervals during the rainy season.
- A full SMC course of SP+AQ is given over 3 days.
- At the time of the SMC campaign, any child who is very sick, has a fever or has a suspected adverse drug reaction should be referred to the nearest health facility with a referral form filled in by the CD. In some settings, children with fever would not be referred to health facilities but would be tested and treated in the community by the CHW or CD, or a nearby team (e.g. “the rapid diagnostic test agent” model in Mali).
- Caregivers should not interchange SMC medicines if they have more than one child who should receive SMC.
- Caregivers should keep empty blister packs at the end of each SMC cycle for inspection and verification purposes.
- Caregivers must be informed by CDs of the location of the nearest referral health facility to take their children to if they are unwell.
- Caregivers should be encouraged to report adverse events observed to a qualified health worker.
- If a child vomits or spits up SMC medication, they can be given a second dose after 30 minutes. If this happens on day 2 or 3, the caregiver needs to go to a health facility to receive an extra pill.
- Administration of SMC medications should be recorded on each child’s SMC card and, where it is being used, also in the register.

At the end of each day, CDs should:

- count the number of doses of SP+AQ administered to each age group;
- count the number of eligible children who did not receive medicines because they were sick, or had an allergy to the medication or another contraindication;
- count the number of discarded, dropped or damaged tablets;
- take completed forms to the health centre;
- give a brief report to the head nurse or the supervisor of the SMC campaign; and
- prepare material for the next day (or at the beginning of the following day), with all the items and quantities needed, depending on the expected number of children for the day.

Additional guidance and tools from a country specific example (Nigeria) on training and capacity building for SMC implementation are available online^{4,5}.

4.2.3 Social mobilization and communication

Community engagement should occur throughout the year – before, during and after the SMC campaign. Delivering key messages about SMC should limit the potential for misunderstanding and any negative perceptions about the strategy based on previous campaigns or relevant interventions (e.g. mass drug administration for neglected tropical diseases).

Many countries launch the SMC campaign through an official ceremony and media events. Community leaders should be engaged and consulted on plans to implement the strategy, and will be asked to consent to the launch activities on behalf of their communities to encourage acceptance of the intervention. Community-wide sensitization and mobilization should begin at least 1 month in advance of implementation through radio and television information, posters, and dissemination via religious leaders and public places (e.g. markets). Door-to-door sensitization and mobilization should begin 1 week before the first round of distribution (3 days is sufficient for the subsequent rounds), and household enumeration can be included at this stage.

The communication plan should also target private medicine outlets, to ensure that they change their dispensing practices during the SMC campaign period to avoid dispensing medicines containing SP and AQ to children during the SMC period, to avoid toxicity associated with repeated doses.

Community engagement

The key concepts in community engagement are participatory decision-making, relationship development and capacity-building. Community members are involved throughout the SMC campaign. Some countries, such as Cameroon and Nigeria, involve women's groups (Nigeria has embedded a cadre called "lead mothers" in the SMC platform). Many countries involve religious and community leaders in micro-planning, supervision and community mobilization. See sections 4.4.4 and 4.4.5 for more ideas.

4 A SMC trainer guide and resources toolkit, is provided by Malaria Consortium at the following link: https://www.malariaconsortium.org/gallery-file/06190852-31/smctrainerguideandresource toolkit_nigeria.pdf (accessed 17 February 2023).

5 A training flip book for community health workers on SMC developed by the National Malaria Elimination Programme of the Federal Ministry of Health of Nigeria is provided by Malaria Consortium at the following link: <https://www.malariaconsortium.org/gallery-file/11070411-43/08chwflipbook1stedition.pptx> (accessed 17 February 2023).

Material for advocacy and communication

Material for advocacy and communication should be prepared, field tested and reviewed carefully, with assistance from local experts, and translated into the main local languages. Communication activities should be implemented through a variety of mechanisms, including:

- town criers;
- community-based organizations, including women's groups;
- community leaders, including religious leaders and schoolteachers;
- community and facility-based health workers;
- community volunteers;
- markets and other gathering places; and
- mass media, including radio.

4.2.4 Supply chain management

Developing an effective plan for supply chain management of all SMC commodities is crucial for the success of SMC. This should include how medicines and material will be stored and transported, which medical stores will be used, and where the commodities will be stored before, during and after each SMC cycle. The logistics for distribution of materials and transportation are an important component of micro-planning.

Most countries have an established channel for dispatching health commodities, including antimalarial medicines and long-lasting insecticidal mosquito nets, from the central level to the peripheral level. These channels can be used and, if necessary, strengthened or adapted, to supply districts, health centres and villages with SMC medicines and supplies. It is important to keep in mind that SMC supplies are delivered during the rainy season, when some locations may be difficult to reach because of heavy rainfall.

At each level of the supply chain for SMC medicines, the following should take place.

- Stock record forms should be completed showing the number of supplies received; the supplies dispatched to districts, health centres and villages; and stocks on hand for SMC medicines.
- At the end of each round of SMC implementation, stock levels of medicines should be reported to districts, and compiled for reporting at regional and national levels.
- At the end of the annual round of SMC implementation (i.e. after the third, fourth or fifth cycle, depending on malaria transmission), the stocks of SP+AQ remaining at the health centre or district level should be transferred to the central level for appropriate storage and use in the next malaria transmission season (if the expiry date allows). Stock on hand should be factored in when estimating the amount of SMC medicines required for the following year.

4.3 SMC implementation

4.3.1 Supervision

The role of effective supervision is to support SMC implementation by ensuring that activities are carried out in compliance with agreed procedures. A supervision plan – including appropriate supervision checklists⁶ – should be prepared at central, regional,

6 An example of a supervision checklist from Nigeria is provided by Malaria Consortium at the following link: https://www.malariaconsortium.org/gallery-file/06260222-92/revisedsmcsupervisorchecklistforhfw_nigeria2020.pdf (accessed 17 February 2023).

district and health facility levels, from the national malaria programme to the community. Intensive supportive supervision should be put in place, especially during the early stages of SMC implementation (first cycle and first round) to identify and resolve problems. If required, retraining can be offered on-site to CDs who experience difficulties.

4.3.2 Algorithm for administering SP+AQ

The following process should be used for administering SP+AQ.

1. Determine or confirm the SMC eligibility of each child in the household. If necessary, ask the caregiver to show documentation of a child's age. Determine if the child (or children) have any of the following contraindications to SMC:
 - fever;
 - history of becoming unwell after taking SP or AQ in the past (note that vomiting is not a contraindication);
 - allergies to medicines containing sulfur, such as sulfadoxine or co-trimoxazole;
 - history of taking either SP or AQ (or both) in the previous 28 days; or
 - history of ACT treatment in the previous 28 days.
2. During the first cycle, write the names and ages of all eligible children in the household and the name of their caregiver(s) on the household's SMC card (and in the register, if a register is being used). Give the card to the caregiver after observing the caregiver administer the first dose of SP+AQ to the child or children (see step 3). During subsequent cycles, update the SMC card and the household register.
3. Ask the caregiver for potable water and a cup in which the SP tablet and the first AQ tablet are dissolved as the caregiver observes. Give the medicine solution to the caregiver and ask them to administer it to the child (or children) while the CD observes. If a child vomits, spits up or regurgitates the medicine within 30 minutes, allow the child to rest for 10 minutes and then give a replacement dose.
4. After administration of the dose for the first day, give the remaining two tablets of AQ in the blister pack to the caregiver for treatment on days 2 and 3. Provide instructions for giving treatment at home on days 2 and 3 in each of the cycles.

Training videos have been developed in English, French, Fula, Hausa and Portuguese by the OPT-SMC project (16,17).

4.3.3 Absence of a child during the SMC cycle

CDs should record the names of eligible but absent children or identify the households with eligible but absent children, to facilitate finding these children. Names of these children could be given to community leaders, who might be able to assist with locating them. Most countries use a system of marking the outside of the compound with chalk to indicate whether an SMC visit was completed, which facilitates the work of a follow-up team. Note that missing one cycle of treatment does not prevent a child from receiving subsequent cycles.

4.3.4 Combining SMC with other interventions

It is possible to combine the SMC campaign with other interventions. There are published examples of countries combining SMC with malnutrition screening, malaria testing and treatment (by screening febrile children at the time of SMC distribution and giving them ACT on the spot if they test positive), vitamin A supplementation, and paediatric tuberculosis outreach at community level. Senegal and Gambia have

been combining their campaigns for SMC and insecticide-treated nets as much as possible. Guinea combined SMC with checks of maternal and child immunization, and provided catch-up vaccines for those who were behind. There have been studies delivering SMC in synchrony with the RTS,S malaria vaccine.

Combining SMC with other interventions is possible provided that countries do not reduce the effectiveness of either intervention by doing so, compromise quality or increase cost. Historically, malaria programmes have been better funded than nutrition programmes, for example, so it is more likely that the malaria programme will be subsidizing additional interventions, rather than benefiting from possible cost sharing.

4.3.5 Cross-border collaboration

Cross-border collaboration can provide advantages in areas where populations move freely across borders. Collaboration can include synchronizing the dates of the campaign, harmonizing the target population (e.g. having the same eligible age ranges) and aligning complementary interventions, to avoid populations crossing borders for treatment. These issues can be discussed in various international fora or ad hoc meetings. Some of these issues also apply within borders – for example, where some regions receive four cycles and others five, or have an additional age group included in the target population.

4.4 Roles and responsibilities at various levels

In general, national coordination mechanisms benefit from having roles and responsibilities defined formally. Some examples are provided below by administrative level.

4.4.1 National level

Who

National SMC steering committee or technical working group (create the group if it does not exist, or expand terms of reference of another suitable group that already exists)

Responsibilities

- Undertake overall supervision of SMC implementation.
- Coordinate SMC implementation.
- Undertake monitoring and evaluation after each cycle, to troubleshoot.

Activities

- Incorporate SMC into the national malaria control strategy.
- Secure funding.
- Prepare annual SMC macro-plan and assist in preparation of micro-plans.
- Review and update SMC training, supervision and reporting tools.
- Facilitate training of trainers at central and regional levels.
- Conduct advocacy, information and communication at national level.
- Compile data and prepare progress reports.
- Coordinate the management of serious adverse drug reactions and compile safety reports.
- Identify research questions for data generation to adapt local guidance and match the SMC strategy to the local epidemiology.

For countries targeting children aged 5–10 years with SMC within schools, national malaria programmes are encouraged to work with the ministry of education to facilitate the distribution of SMC in schools.

4.4.2 Regional level

Who

Regional health authorities

Responsibilities

- Supervise the campaign at regional level.
- Facilitate SMC implementation at district level.
- Monitor and evaluate after each cycle to provide feedback on how the strategy has been implemented and areas that could be improved for the following cycle.

Activities

- Organize meetings with stakeholders.
- Ensure adequate supplies of SMC medicines.
- Conduct advocacy at the regional level.
- Facilitate preparation of district micro-plans and budgets.
- Provide managerial and financial supervision.
- Explain the SMC strategy to the district health team.

4.4.3 District level

Who

District health management team

Responsibilities

Supervise SMC implementation at the health facility level.

- Facilitate SMC implementation at the community level.
- Monitor and evaluate after each cycle to provide feedback on how the strategy has been implemented and areas that could be improved for the following cycles.

Activities

- Organize meetings with stakeholders.
- Establish an effective communication system for SMC distribution.
- Prepare the district SMC micro-plan and budget.
- Prepare health facility workers and supervisors for communication with the media, advocacy with the community and social mobilization.
- Train health facility workers and CDs in administering SMC, completing medicine stock cards and identifying any medicine-related serious adverse events.
- Deliver commodities to peripheral health centres.
- Allocate resources to peripheral health centres for SMC implementation.
- Plan and organize supervision of SMC implementation.

- Monitor progress and solve problems (including safety issues).
- Prepare a technical and financial report for approval at the regional level and submission to the national malaria control programme.

4.4.4 Peripheral health facility level

Who

Health facility workers at SMC participating health facilities in each SMC catchment area, and community leaders

Responsibilities

- Supervise SMC implementation at the community level.
- Mobilize communities.
- Diagnose and treat cases of malaria, including referrals when needed.
- Manage any adverse events and report to the national pharmacovigilance agency.

Activities

- Organize meetings with all stakeholders to explain the SMC strategy. Meet communities to explain SMC. Identify the CDs who will administer SMC. Identify community members who will participate in communication activities by making door-to-door visits and delivering messages at suitable gathering places, such as markets, mosques and churches. Train community members to identify and recognize drug-related serious adverse events.
- Prepare a delivery plan for each village and a daily circuit for each CD.
- Manage the stock of SP+AQ. Dispatch medicines, equipment and monitoring forms to the CDs.
- Undertake case management of referred children (for malaria and, in some countries, malnutrition). This includes treatment of children with confirmed malaria, and administration of SMC to children who test negative for malaria.
- Undertake immediate case management of children with serious adverse drug reactions and refer to appropriate health services.
- Supervise the CDs and solve any problems. Two supervisory visits per pair of CDs and cycle of SMC treatment is ideal. Once the team has gained experience, the number of supervisory visits can be reduced. Debrief the CDs at the end of each cycle.
- Complete the SMC tally sheet, SMC referral form, SMC daily summary form and SMC end-of-cycle report. Report serious adverse events to the district medical officer. Track the total number of children reached each day of the campaign and compile the daily reports received from CDs for submission to the district data manager. If feasible, hold evening meetings at the health centres to discuss daily issues from the SMC campaign and prepare for the next day's distribution. Identify, discuss and report community concerns. Prepare reports at the end of each cycle for submission to the district.

4.4.5 Community level

Who

CDs and caregivers of target children

Responsibilities

- Distribute, observe and administer SMC to children.

Activities of CDs

- Distribute and observe administration of SMC to children.
- Promptly refer febrile children for testing and treatment, or test and treat febrile children if applicable in the setting/programme.
- Promptly refer children with suspected drug reactions to health facilities.
- Collect medicines and other material required for SMC at the health centre.
- Complete forms and registers.
- Identify, refer and report adverse events.
- Deliver information, education and communication to caregivers of children on adherence to treatment, how to prevent malaria and when to refer a child to the nearest point of care.
- Report daily to nurses on SMC distribution.

Activities of caregivers

- Ensure that children stay at home until the CD has visited the household.
- Administer SMC to children on the first day of the cycle while being observed by the CD.
- Administer the AQ on the second and third days of each cycle.
- Promptly take febrile children for testing and treatment.
- Promptly take children with suspected adverse drug reactions to health facilities.

5. Monitoring and evaluation

A rigorous monitoring and evaluation (M&E) performance framework is essential to provide confidence that SMC delivery is effective, target populations are reached and operations are having the intended impact. The M&E performance framework includes monitoring and evaluating the quality of distribution, coverage, impact, safety and cost through routine programme data, as well as regular end-of-cycle and end-of-round household surveys.

5.1 Performance framework

The performance framework should guide the collection and analysis of data relating to programme inputs, processes and outputs, with a view to improving quality and use of programme data. It defines how programme coverage and quality of programme implementation can be demonstrated, and how the impact of SMC is assessed. It also allows identification of programmatic bottlenecks, and can inform both logistical and technical decision-making actions.

The SMC performance framework supports an overarching SMC programme aim that can be summarized as “To safely prevent malaria cases in eligible children living in areas targeted by SMC campaigns within the intended period of protection”. SMC programmes aim to ensure that all eligible children receive the full number of SMC treatments they are eligible for.

5.1.1 Indicators

Indicators associated with each objective – all designed to be SMART (specific, measurable, achievable, realistic and timely) – have been identified and categorized as either input, output, outcome or impact indicators. Specifications for each indicator show what is being measured; how, where, when and at what unit of analysis it is measured; and how data will be used. Some of these, listed as “core indicators” (highlighted in grey in the tables below), should be tracked by all malaria programmes implementing SMC. Other indicators are listed for potential use in M&E, as appropriate.

Input indicators

The input indicators (**Table 2**) are those that describe the basic needs for an SMC programme – for example, policy, financing, staffing, infrastructure, medicines and data collection tools. Aspects of the inputs and processes of SMC programme delivery that facilitate the achievement of this overarching goal include:

- supply and demand – ensure provision of appropriate inputs to meet programme demands in relation to the place, time and person;
- readiness – ensure preparedness before implementation;
- timeliness – ensure that the first SMC cycle can start on schedule and subsequent cycles start no later than 28 days after the first dose of the previous cycle;
- acceptability – ensure successful uptake of SMC by well-informed decision-makers and community members, considering the knowledge, attitudes and perceptions of all concerned; and
- safety – ensure safe delivery of SMC, and reporting and management of adverse events following SMC administration.

Table 2. Input indicators

Objective	Indicator	Operational definition	Aggregation level	Frequency
Supply and demand	Proportion of health facilities with sufficient stocks of SMC medicines (core indicator)	Numerator: Number of health facilities with sufficient stocks of SMC medicines at start of SMC round Denominator: Number of health facilities expected to stock SMC medicines at start of SMC round	Facility	Annual
Supply and demand	Number of SP+AQ procured for children aged 3–11 months (core indicator)	Total number of SP+AQ co-blister packs procured for children aged 3–11 months to cover the SMC campaign	Country	Annual
Supply and demand	Number of SP+AQ procured for children aged 12–59 months (core indicator)	Total number of SP+AQ co-blister packs procured for children aged 12–59 months to cover the full SMC round	Country	Annual
Readiness	CDs enrolled for the SMC campaign (core indicator)	Number of CDs of SMC medicines enrolled for the full SMC campaign	District	Annual
Readiness	Proportion of health facilities with adequate SMC reporting tools	Numerator: Number of health facilities supplied with adequate SMC reporting tools at start of SMC round Denominator: Number of health facilities expected to submit SMC reports	Facility	Annual
Readiness	Proportion of health facilities with SMC supervision tools	Numerator: Number of health facilities supplied with adequate supervision tools at start of SMC round Denominator: Number of health facilities expected to submit SMC supervision reports	Facility and district	Annual
Readiness	Proportion of health facilities with logistics management information systems to track SMC medicines	Numerator: Number of health facilities supplied with logistics management information system to track SMC medicines Denominator: Number of health facilities expected to track SMC medicines	Facility and district	Annual

Objective	Indicator	Operational definition	Aggregation level	Frequency
Readiness	Number of field supervisors recruited and active during the whole SMC campaign	Number of field supervisors recruited and active during the whole campaign	District	Annual
Readiness	Proportion of final micro-plans that include data quality plan (including standard operating procedures)	Numerator: Number of micro-plans that include a well-defined data quality plan or strategy Denominator: Number of micro-plans developed	Country	Annual
Readiness	Number of field supervisors per CD	Numerator: Total field supervisors recruited Denominator: Total CDs recruited	District	Annual
Readiness	Ratio of female to male CDs	Number of female CDs Number of male CDs	District	Annual
Readiness	Ratio of CDs to targeted children	Number of CDs of SMC medicines enrolled for the full SMC campaign Number of targeted children	District	Annual
Readiness	Financial resources mobilized for SMC campaigns	Total funds and budget breakdown provided by all stakeholders to supporting planning, procurement, implementation and M&E of the entire SMC campaign	Country	Annual
Supply and demand	Number of SP+AQ procured for children aged 5–10 years	Total number of SP+AQ treatment courses procured for children aged 5–10 years to cover the full SMC round	Country	Annual
Supply and demand	Proportion of the unit cost per course delivered	Numerator: Total costs of SMC programme Denominator: Number of courses delivered	Country and implementing partner	Annual
Timeliness	End-of-round survey started at planned time	End-of-round survey started at planned time	Country	Annual

Notes on readiness

It is recommended that countries assess system readiness before starting the SMC campaign (during the planning phase).

For health facility readiness, a standardized checklist is recommended. The following key elements are important to assess before the SMC campaign begins:

- SMC stocks;
- supervision tools;
- reporting forms;
- human resources readiness;
- personal protective equipment;
- payment process readiness;
- pharmacovigilance forms; and
- IT/communications – power packs, data credits for phones and tablets, as applicable.

At subnational level, the following components should be assessed:

- availability and completeness of micro-plans;
- well-defined data quality strategy or standard operating procedures;
- human resources coverage and readiness;
- current (updated if necessary) training materials;
- supervision tools; and
- payment processes.

Output indicators

The output indicators (**Table 3**) describe what was generated through the planned activities.

Table 3. Output indicators

Objective	Indicator	Operational definition	Aggregation level	Frequency
Readiness	Proportion of CDs who received training on SMC (core indicator)	Numerator: Number of CDs who have been trained on SMC Denominator: Total number of CDs enrolled in the SMC campaign	District	Annual
Readiness	Proportion of health workers or other people trained to supervise SMC campaign (core indicator)	Numerator: Number of health workers or other people trained on SMC supervision Denominator: Total number of supervisors enrolled in the SMC campaign	District	Annual
Readiness	Proportion of health staff trained as focal data entry/management people (core indicator)	Numerator: Number of health staff trained as data entry/management people for SMC Denominator: Total number of health staff enrolled in the SMC campaign for data entry/ management	District or regional	Annual
Supply and demand	Number of co-blisters of SP+AQ distributed at first cycle (core indicator)	Total number of co-blisters distributed at first cycle to target communities	Facility	Monthly
Supply and demand	Number of co-blisters of SP+AQ distributed at second cycle (core indicator)	Total number of co-blisters distributed at second cycle to target communities	Facility	Monthly
Supply and demand	Number of co-blisters of SP+AQ distributed at third cycle (core indicator)	Total number of co-blisters distributed at third cycle to target communities	Facility	Monthly
Supply and demand	Number of co-blisters of SP+AQ distributed at fourth cycle (core indicator)	Total number of co-blisters distributed at fourth cycle to target communities	Facility	Monthly

Objective	Indicator	Operational definition	Aggregation level	Frequency
Supply and demand	Proportion of health facilities reporting stock-out of SMC medicines (SP+AQ) during SMC implementation period (core indicator)	Numerator: Number of health facilities storing SMC medicines that reported stock-outs Denominator: Number of health facilities storing SMC medicines	District	Monthly
Readiness	Proportion of health staff trained on SMC	Numerator: Number of health staff trained on SMC Denominator: Total number of health staff enrolled in the SMC campaign	District	Annual
Readiness	Proportion of sampled households sensitized before each SMC cycle	Numerator: Number of sampled households sensitized on SMC before each cycle Denominator: Number of sampled households in target SMC areas	District or regional	Monthly
Readiness	Number of SMC sensitization materials distributed to health facilities before start of SMC campaign	Total number of printed or electronic SBC materials by type and target audience distributed to health facilities	Facility	Annual
Readiness	Proportion of CDs who received supervision visits during the SMC campaign	Numerator: Number of CDs who received a supervision visit during the SMC campaign Denominator: Number of CDs engaged in SMC implementation	District	Monthly
Readiness	Proportion of eligible children registered at each SMC cycle	Numerator: Number of eligible children registered at each SMC cycle Denominator: Number of eligible children living in the households visited at each SMC cycle	District	Monthly
Timeliness	Proportion of complete SMC reports received on time	Numerator: Number of complete SMC reports received on time at each SMC cycle Denominator: Number of SMC reports expected at each SMC cycle	Facility, district, regional, national	Monthly
Timeliness	SMC started on planned day	SMC campaign started on date ministry of health planned	District	Annual

Objective	Indicator	Operational definition	Aggregation level	Frequency
Acceptability	Proportion of health workers or other personnel trained in SBC	Numerator: Number of health workers or other personnel trained in SBC for the SMC campaign Denominator: Number of health workers or other personnel involved in SBC activities during the SMC campaign	Regional	Annual
Acceptability	Proportion of caregivers who remember key SBC messages about SMC	Numerator: Number of sampled caregivers who remember key SBC messages about SMC Denominator: Number of sampled caregivers interviewed on key SBC messages on SMC	District	Annual
Communications	Number of health areas with documented communication plan with a timeline and budget in place before implementation		Health area	Annual
Communications	Number of health areas where social mobilization activities were initiated before the start of SMC delivery, per cycle		Health area	Annual
Supply and demand	Number of children treated per distributor team per day	Numerator: Number of children treated Denominator: Number of distributor teams	Facility	Monthly

Outcome indicators

Outcome indicators (**Table 4**) are a measure of whether a programme or activity is resulting in the anticipated effect or changes (in the short or medium terms). Children should receive all cycles of SMC and adhere to the daily regimen. Therefore, the two key indicators for the quality of an SMC campaign are:

- the proportion of targeted children who were treated in all cycles; and
- the proportion of targeted children who took their medicines (unobserved) on days 2 and 3.

Number seen, number refused, and number sick and referred are also tallied, and could be reported. However, they are not used in this indicator, which is the number treated as a percentage of the target.

Table 4. Outcome indicators

Indicator	Operational definition	Frequency
Proportion of target children who received first SMC cycle (core indicator)	Numerator: Number of target children who received first SMC cycle Denominator: Total number of target children	Monthly
Proportion of target children who received second SMC cycle (core indicator)	Numerator: Number of target children who received second SMC cycle Denominator: Total number of target children	Monthly
Proportion of target children who received third SMC cycle (core indicator)	Numerator: Number of target children who received third SMC cycle Denominator: Total number of target children	Monthly
Proportion of target children who received fourth SMC cycle (and add similar indicator if a fifth cycle is implemented) (core indicator)	Numerator: Number of target children who received fourth SMC cycle Denominator: Total number of target children	Monthly
Proportion of target children who have received all planned SMC cycles (core indicator)	Numerator: Number of target children who have received all planned SMC cycles Denominator: Total number of target children	Annual

Indicator	Operational definition	Frequency
Proportion of children who were given the full 3 daily doses of SP+AQ at cycle (administrative data) (core indicator)	Numerator: Number of children who were administered all 3 daily doses Denominator: Target number of eligible children	Annual
Number of children reached in a given year (core indicator)	Average number treated over the cycles completed (sum of the number treated, divided by number of completed cycles) (Average within each region according to the number of cycles implemented, and then sum to get the total)	Annual
Proportion of children who experienced an adverse reaction to SMC in the past (core indicator)	Numerator: Number of children excluded due to previous side effects of SMC Denominator: Number of children seen in the cycle	After each cycle
Proportion of communities who know the start date of SMC implementation (core indicator)	Numerator: Number of sampled communities who know the start date of SMC implementation Denominator: Number of sampled communities for the SMC assessment	Annual
Proportion of target children who have received all planned SMC cycles (by survey) (core indicator)	Numerator: Weighted total number of eligible children who received SMC in all planned cycles Denominator: Weighted total number of children eligible for the full number of cycles (Report separately by district according to number of planned cycles)	At end of campaign
Proportion of the first dose supervised by the CD (given as DOT1) (core indicator)	Numerator: Weighted number of children that received the first dose under supervision Denominator: Weighted total number of eligible children	After each cycle or end of campaign
Proportion of children aged 6–7 or 6–8 years who received SMC (in areas where SMC is given to under-5s) (In areas where SMC is given up to age 9, this would be children aged 10–11 or 10–12) (core indicator)	Numerator: Weighted number of children (aged 6–7 or 10–11) who received SMC at least once Denominator: Weighted number of children aged 6–7 or 10–11	After each cycle or end of campaign

Indicator	Operational definition	Frequency
Proportion of children who were given the full 3 daily doses of SP+AQ at last cycle	<p>Numerator: Weighted number of eligible children who took all 3 doses of SP+AQ at last cycle</p> <p>Denominator: Weighed total number of eligible children who received SMC at last cycle</p>	After each cycle or end of campaign
Proportion of households visited	<p>Numerator: Number of households visited with an eligible child</p> <p>Denominator: Total number of households targeted with eligible children</p>	After each cycle
Proportion of caregivers who knew the date of the most recent SMC cycle in advance	<p>Numerator: Weighted number of caregivers aware of SMC date</p> <p>Denominator: Weighted number of caregivers with an eligible child</p>	After each cycle or end of campaign
Number of days between cycle 1 and cycle 2	Mean number of days between first and second cycles among children who received SMC in both cycles	End of campaign
Proportion of children with SMC card during the survey	<p>Numerator: Weighted number of eligible children with SMC card seen in the survey</p> <p>Denominator: Weighted total of eligible children seen in the survey</p>	End of campaign

Impact indicators

The impact of SMC in a programmatic setting is rarely measured, because of challenges with data completeness and timeliness in the national health information system. To address this, countries should use facility-level data from facilities with complete data or sentinel sites, if available. It would be worth considering areas where SMC has recently been implemented to compare before and after the intervention. In areas where SMC has been implemented for many years, it will be difficult to compare the indicators before and after the intervention.

The Monitoring and Evaluation Subgroup of the SMC Alliance has proposed impact indicators (Table 5) that countries can use, depending on data availability. This might be possible using monthly aggregate data from the national health information system, especially if the aggregate data are available by age group (e.g. 0–4 years, 5–9 years, 10–14 years and 15–19 years, or even smaller age ranges of 0–1, 1–2, 2–4, 5–7 and 8–10 years).

Table 5. Impact indicators

Indicator	Operational definition	Challenges and other considerations
Confirmed uncomplicated malaria incidence in under-5s (or under-10s) in district where SMC has been conducted (per 1000)	Numerator: Number of children under 5 (or under 10) with confirmed uncomplicated malaria Denominator: Population of children under 5 (or under 10) in SMC target areas	Changes in testing and reporting rates Changes in care-seeking behaviour related or unrelated to SMC activities
Severe malaria incidence in under-5s (or under-10s) in district where SMC has been conducted (per 10 000)	Numerator: Number of children under 5 (or under 10) with severe malaria Denominator: Population of children under 5 (or under 10) in SMC target areas	Low quality of care at health facilities Poor referral systems Poor reporting and/or misclassification of severe cases at health facility level
Malaria-attributable hospital deaths in under-5s (or under-10s) (per 10 000)	Numerator: Malaria-attributable hospital deaths in under 5s Denominator: Population of children under 5 in SMC target areas	Low quality of care at health facilities Poor referral systems Overestimation of malaria recorded deaths if children have a malaria infection that is not the cause of death
Monthly ratio of uncomplicated confirmed cases in under-5s to over-5s (or under-10s to over-10s)	Numerator: Number of confirmed uncomplicated malaria cases in under-5s* (or under-10s) Denominator: Number of confirmed uncomplicated cases in over-5s* (or over-10s) *Adapted to the age targets	Potential for SMC to reduce transmission intensity in an area, which would affect the number of cases observed in the untargeted group (over-5s)
Anaemia-attributable hospitalizations in under-5s (or under-10s) (per 10 000)	Numerator: Number of hospitalizations in under-5s due to anaemia Denominator: Population of children in SMC target areas	Changes in comorbidities affecting anaemia

For further details on calculations, see the SMC Alliance M&E Toolkit (18)

5.1.2 Data sources and data collection methods

In all countries, routine administrative data are generated by the CDs. These are supplemented in some countries by post-cycle or post-round household surveys. The data source for the indicators will depend on whether digital or paper-based data tools are used. Data on receipt of SMC medications from all cycles may be available if the campaign has been digitized, or could be tallied from registers if the country is using paper registers. Data on adherence to treatment may be based on household surveys, interviews with caretakers and inspection of empty blister packs or, in research settings, measurement of drug blood levels in children. Adherence can only be known for sure if daily visits are made to supervise administration of medicines (e.g. through the DOT3 approach), although end-of-round or end-of-cycle surveys of caregivers can be used to estimate round or cycle adherence. During the SMC campaign, CDs note how many children they treat daily during each cycle in a standard register. They check each child's SMC record card, when available, but still treat the child even if the card cannot be found. In principle, data on adherence are collected by CDs checking SMC cards during the later cycles for doses given on days 2 and 3 during earlier cycles. In practice, CDs do not always fill in these columns in the registers.

Few countries track each individual child from one cycle to the next. Most national malaria programmes rely on administrative programme data, aggregated from the CDs' records. Administrative data do not give valid estimates of coverage, because of uncertainty about the size of the target population. Coverage estimated from the number of doses administered is generally an overestimate because of the inclusion of treatments administered to children outside the eligible age range.

A child might be treated in one month and not the next for several reasons. For example, the child may not be home during a subsequent cycle, or might have had a fever during one cycle and therefore be excluded until the next one. Infants age into the eligible age group between cycles. This means that, even if the administrative coverage rate remains relatively constant from one cycle to the next, it may not be the same children who are reached in each cycle (or the same children being missed).

Household surveys at the end of the transmission season, conducted shortly after the last SMC cycle, are needed to establish the level of coverage, combined with investigations to understand reasons for suboptimal coverage and steps needed to improve. Data on adherence to treatment can be obtained from specific surveys (see considerations for household surveys as a means of estimating adherence to treatment, below). Ideally, personnel involved in data collection should be independent of the SMC programme.

The target population size may come from census projections or other sources, such as household enumeration. The method or source should be specified. Ideally, counts of children made at the time of the SMC visit should not be used because this will limit the count to the households visited. Another method for determining coverage is to use digital technologies (e.g. MAXAR™ or similar technologies) to make maps of structures in a community. All structures in the SMC-eligible area can be identified, and digital tools (such as phones) can be used to track which structures have been visited and which have not. This method could potentially be used during surveys to check completeness of household visits. Monitoring coverage of an intervention delivered door to door requires that the household visits during the survey are as exhaustive as possible, to avoid overestimating coverage.

Notes on household surveys as a means of estimating SMC coverage and adherence

Household surveys should be conducted after the first cycle, at least, as well as after the last cycle. End-of-cycle surveys are rapid surveys to detect problems. They should be used locally to improve distribution at the next cycle. This means retaining some budget for additional visits, refresher trainings or additional communication efforts, depending on the problems identified by the survey.

Measures should be taken to ensure that the survey is representative of the target population. The survey should use methods that sample children with known probability, and non-response should be minimized by arranging call-back visits if a caregiver is not at home during the survey. The sample size (the number of clusters and number of children per cluster) is chosen to achieve a geographically representative sample and to yield estimates of coverage with the desired level of precision, both overall and in specific geographical strata (cluster sample survey designs are not well suited to producing highly granular estimates of coverage in each local area, as this would require representative sampling of each local area). **Box 2** provides a country survey example. Guidelines on sample size and sample selection for coverage surveys are available (19).

Box 2. SMC household survey in Guinea

As an example, recent surveys in Guinea, where SMC was implemented in 13 districts, used a sample size of about 1700 eligible children in 66 clusters, designed to yield survey estimates of coverage with a precision of $\pm 6\%$ overall and, within each of three geographical zones, $\pm 10\%$. In this survey, children were included up to age 7 years to enable assessment of the amount of treatment outside the target age range.

Some countries, including Benin, Burkina Faso, Cameroon, Mali, Niger and Nigeria, have adapted the lot quality assurance sampling (LQAS) method for SMC surveys. This allows identification of issues in SMC delivery (e.g. low programme coverage) at a local level while providing national-level summaries of key indicators. Examples of questionnaires, and reports of SMC coverage surveys, are available (20).

A protocol detailing the methods and including the survey questionnaire, participant information sheet and consent form should be approved by the local ethics committee before the survey starts. Informed consent should be sought from all survey participants, who should be provided with information on the objectives of the survey, its ethical approval and a point of contact should any issues arise because of the survey.

Note that SMC indicators cannot generally be included in national surveys (Multiple Indicator Cluster Surveys, Malaria Indicator Surveys, Demographic and Health Surveys), because the timing may not be optimal for SMC – surveys need to be undertaken after the last cycle to minimize recall bias.

5.1.3 Digitizing the SMC campaign

Countries often have an overarching country-level digital strategy that goes beyond just SMC. Although most SMC campaigns still use paper-based tools, especially in countries that have a large surface area to cover, countries are increasingly using digital tools to collect their SMC data. Some countries, such as Gambia, have fully digitized their campaign since 2015; a case study illustrates how Gambia is using various mobile platforms (21). Other countries have parts of their campaigns digitized; for example, in Cameroon, digital tools are used from the health facility level and up to regional and central levels, but not at the CHW level.

Digitization of campaigns allows the campaign team to monitor most activities in almost real time, including training of campaign staff, registration of households and children (including location), digitally capturing delivery of medication and tracking campaign worker activities. Datasets resulting from digitization can also be used to support other campaigns (e.g. insecticide-treated nets, neglected tropical diseases) within the country.

As countries opt to digitize either parts or all of their SMC campaigns, we recommend that countries learn from those that have experience using different types of applications, platforms and tools. National malaria programmes from the following countries can be contacted to share their experiences.

- Benin and Nigeria use RedRose.
- Burkina Faso and Niger are piloting DHIS2 Tracker.
- Ghana uses an android-based tool called SiCapp (see **Box 3** for more details).
- Gambia has used iFormBuilder and CommCare, and has piloted DHIS2 Tracker.

Although the digital platforms have been proven and field tested in at least one country, most of the countries listed above have found that it is useful to first pilot them in a smaller geographic area before scaling up, as contextual issues can complicate implementation. Regardless of how the pilot testing is done, countries should factor in time (at least 6 months before the first digital campaign) and resources during the planning phase for use of the tool (involving training and field testing). Availability of resources to sustain the roll-out after the pilot stage, including procurement and repair of mobile devices and accessories, purchase of internet data and technical capacity of in-country staff to troubleshoot system challenges, are also important considerations.

Digitizing an SMC campaign can lead to increased coverage of targeted populations (including vulnerable populations), more equitable campaign outcomes and the ability to respond rapidly based on live data. It also minimizes the number of paper forms required for campaign management and monitoring. For example, paper-based registers do not exist separately from the digital format – as children are registered into the devices during administration of the first dose, they are automatically aggregated to form a list of all children.

As countries implementing SMC are now developing SMC indicators in their DHIS2 systems, they are eager to have SMC digital campaign tools integrate seamlessly with DHIS2. An SMC DHIS2 module was developed in early 2023 in collaboration with Oslo University and is being piloted in collaboration with OPT-SMC in 2023.

Catholic Relief Services has developed a digitization handbook, which is available on its website (22).

Box 3. Ghana's experience integrating SMC data into DHIS2

Ghana's digital data collection tool called SicApp is the primary method for capturing field data on SMC. The national health management information system database (DHIMS2) includes an aggregate form for entering SMC data at facility level. SicApp has a summary form that aggregates these data for easy entry into DHIMS2. There are ongoing discussions to explore linking SicApp to DHIMS2 for seamless transfer of data.

Pros:

- Ensures easy aggregation of data for entry into DHIMS2.
- Data in DHIMS2 allow wider access to SMC data beyond implementing districts and regions.
- Allows easy comparison of SMC implementation data with epidemiological data (case data) from facilities.

Challenges:

- Possible data entry errors while transferring data from SicApp to DHIMS2.
- Late reporting of data due to other competing activities after the SMC season.

5.1.4 Known challenges with monitoring SMC coverage

Administrative data do not give valid estimates of SMC coverage because of uncertainty about the size of the target population (many countries report coverage above 100%). Coverage estimated from the number of doses administered generally overestimates the actual coverage because of the inclusion of treatments administered to children outside the eligible age range.

SMC cards do not generally capture SMC visits in which the child was seen but not treated. The child may have been referred due to illness, or excluded because of intake of other medicines or previous side effects. In this sense, SMC treatment coverage underestimates programme coverage.

Referral and treatment of children who were unwell at the time of the visit, including screening for malnutrition where this is performed, are important aspects of the programme but will be difficult to capture in surveys unless they are recorded on the SMC card.

Several elements may explain why high coverage is not achieved in campaigns, such as:

- limited access to, or shortage of, medicines;
- poor geographical access (roads);
- climate (rains, floods);
- poor access for security reasons;
- type of distribution strategy used;
- lack of community awareness;
- rumours leading to low acceptability of SMC or absence of caregivers;
- supply issues;
- lack of funding or resources;
- child illness on the day of SMC delivery;
- CHW not visiting the household;
- logistics issues (e.g. lack of fuel);
- overlap with other health activities or important events (e.g. Eid, elections); and
- poor quality of denominator data (e.g. outdated population census from which the population of target children is estimated).

5.2 Monitoring adverse drug reactions

The medicines used for SMC are effective and well tolerated, but can be associated with adverse events that can be mild, moderate or severe. Adverse events should be reported as part of the pharmacovigilance system.

Health personnel and CDs should be trained to identify and report adverse events. Caregivers should also be sensitized and informed about adverse events. If CHWs identify a serious adverse event, they should report it to nurses at the health centre, who will complete a referral form and send it to the district medical office for appropriate action. In many locations, routine pharmacovigilance systems will have to be strengthened to ensure effective reporting of drug-related adverse events after implementation of SMC.

There may be an increased risk of serious adverse reactions associated with:

- interactions with other medicines;
- an underlying chronic medical condition;
- a person's genetics;
- dosing errors; and
- substandard quality of medicines.

Key features of a functional pharmacovigilance system include:

- a functional technical committee
- spontaneous reporting of adverse events;
- inclusion of pharmacovigilance in training;
- district investigation teams;
- a crisis communication plan;
- causality assessment;
- reporting to WHO via Vigibase (7) – this includes distinguishing between CD observations of adverse events during administration, solicited caregiver reports when asked about previous adverse events, and adverse events detected by caregivers that lead to a child attending a health facility;
- availability of reporting forms (or electronic reporting); and
- display at health facilities of a job aid describing known SMC adverse drug reactions.

5.2.1 Definitions

An adverse event is any unfavourable or unintended symptom or disease (including laboratory findings temporally associated with use of a medicinal product), which may or may not be related to exposure to a medicinal product. A serious adverse event is a medical occurrence in response to a medicine that at any dose:

- is life-threatening;
- requires or prolongs hospitalization;
- results in disability or incapacity;
- results in a congenital abnormality or birth defect;
- results in death; or
- may require intervention to prevent one of the outcomes listed above.

5.2.2 Recording and reporting adverse events

Occasionally, SP and AQ cause mild to moderate adverse events; in rare cases, serious adverse events can occur. Mild adverse events associated with SP involve the skin and mucous membranes. In rare cases, serious cutaneous toxicity (e.g. Stevens–Johnson syndrome) and hepatotoxicity may be observed.

The commonest mild adverse events associated with AQ intake are vomiting (for more than 2 hours), abdominal pain, fever, diarrhoea, itching, headaches, movement disorders, weakness for more than 2 days and rash. Agranulocytosis, aplastic anaemia and severe, even fatal, hepatotoxicity are rare serious adverse events associated with weekly prophylactic use of AQ; such events have not been reported with use of monthly AQ as part of SMC.

Clear guidelines must be in place for effective monitoring of medicine safety at all levels. These should include:

- definition of the roles and responsibilities of staff;
- standard definitions of “adverse event” and “serious adverse event” for use by all staff;
- use of standard forms for notification of referral/counter-referral and serious adverse event investigation;
- guidelines for recording, reporting and investigating serious adverse events;
- criteria for assessing the association of the event with SMC medicines;
- documentation of action taken;
- clear indications regarding criteria for immediate referral following adverse events; and
- use of a standard national pharmacovigilance database to record all serious adverse events.

Guidance should be provided on identifying and reporting serious adverse events to ensure that adequate information is available for proper assessment of reported events. The information could include the patient’s name, age, sex and weight; brief description of the event, including severity, date and time of onset after medicine intake; duration of symptoms; treatment given and response to treatment; dates of onset and termination of administration of SMC and concomitant medicines; batch number and expiry date of SMC medications; and outcome.

Serious adverse events can lead to negative perceptions in the community and jeopardize the success of SMC. Therefore, whether an adverse event appears to be related to the SMC medicines should be documented. An excellent communication strategy is required to explain the risks and benefits of the intervention and any issue that might affect community acceptance of SMC.

Once an adverse event has been identified and referred with a referral form, prompt action must be taken by the medical team to minimize the risk to children’s health and ensure a positive outcome.

5.2.3 Potential difficulties in reporting adverse events

The perceptions of CDs and health staff about the importance of pharmacovigilance can lead to underreporting of adverse events. Some adverse events may be missed for various reasons, including an assumption that the event is not related to SMC medicines. Some may need further investigation (e.g. vomiting versus regurgitation). Staff in charge of reporting adverse events should be encouraged to report any such factors. Refresher training, training of supervisors and regular discussions with personnel involved in reporting adverse events are recommended to minimize the risk of underreporting. Where available, flyers about adverse events should be made available to CDs and nurses at health centres. Communication and notification of adverse events should also be reinforced at the country level. After notification, it is important to have a system in place to manage all pharmacovigilance data. This could be WHO Vigibase or an equivalent national pharmacovigilance database (7).

5.3 Monitoring and reporting of costs

Two aspects of the economics of SMC are of interest to national malaria programmes. First, it is important to determine the financial cost of delivering SMC, which is helpful for planning and budgeting purposes – that is, what is the total cost and/or unit cost of

providing a complete dose of SMC to each child? Financial costs reflect the value of goods and services. This information is useful in helping programmes know, ahead of time, the financial resources that will be required to effectively deliver SMC to target populations. A useful guide to estimating the budget for SMC is available as an Excel spreadsheet.⁷ Note that country-specific price data are required to complete this sheet.

Second, the economic cost of delivering SMC, which reflects the full value of all resources used, is useful in determining the economic viability of investments in SMC. The economic cost considers the financial resources, as well as the donations and time of key stakeholders invested in SMC. This information will clarify the total cost of implementation and whether the investment in SMC is cost-effective, bearing in mind the limited resources that countries have available to allocate. Economic costs are useful because they help justify prioritization decisions of countries. To enable an economic assessment of the benefits of SMC, it is important to track resource use and administrative coverage as part of SMC implementation. The following serves as a guide to the economic indicators that could be tracked.

For each broad activity as part of SMC (e.g. planning, payment and training of field staff and volunteers, social mobilization, administration of SMC, monitoring and supervision, reporting, adverse event monitoring), it is useful to track and record the following categories of resource use (most of these are often available but must be systematically recorded):

- cadres and number of personnel involved in the activity (including paid and volunteer personnel);
- salaries and/or allowances for paid staff and volunteer allowances, if any;
- time (total minutes or hours) that personnel are involved in the activity;
- quantity and unit cost/price (in appropriate units, such as cartons) of recurrent items (e.g. medicines, other medical and non-medical supplies such as rapid diagnostic tests, hand sanitizer, cloth face coverings) and operational costs (e.g. fuel for vehicle operation, storage and transport of medicines and supplies, maintenance, rental cost of venues for training and other activities, meals, communication); and
- quantity and unit cost of equipment (e.g. registers, mobile phones, distributor equipment such as boots or t-shirts) and capital items (e.g. motorcycles, other vehicles, personal computers).

Where different strategies of SMC distribution (e.g. door to door, fixed point, mobile) are used, it is important to track resource use by strategy as well as administrative coverage, if possible.

5.4 Final end-of-campaign report

At the end of the campaign, when the SMC data have been cleaned and validated, a summary report should be prepared. An ideal outline has been developed by the SMC Alliance as part of the M&E Toolkit, as follows.

1. SMC campaign objectives

2. Macro-planning and micro-planning

- 2.1. Planning parameters: personnel needed (by cadre), days needed for each activity (training, delivery, supervision, monitoring and evaluation), number of events for each activity

⁷ An example of budgeting and quantification tools, is provided by Malaria Consortium at the following link: https://www.mmv.org/sites/default/files/uploads/docs/access/SMC_Tool_Kit/Planner_SMC_EN.xlsx (accessed 17 February 2023).

- 2.2. Intervention zones
- 2.3. Map of selected health districts
- 2.4. Mapping of facilities
- 2.5. Inclusion criteria

3. Preparatory activities

- 3.1. Preparatory meeting
- 3.2. Collaboration and partnership
- 3.3. Planning and tool review meeting
- 3.4. Warehouse identification and assessment
- 3.5. Selection of mobilizers and distributors

4. Procurement and supply management

- 4.1. SP+AQ storage conditions at the central medical store
- 4.2. Commodity management at the central medical store and health facilities
- 4.3. Acquisition and distribution of all SMC tools and materials
- 4.4. Proper use of stock management tools
- 4.5. SP+AQ procurement and lead times
- 4.6. SP+AQ in-country distribution
- 4.7. Stock movement analysis
- 4.8. Medicine allocation on the distribution plan by cycles
- 4.9. SP+AQ reconciliation methods (administrative data and stock reconciliation data)
- 4.10. End-of-cycle logistics report

5. Community engagement

- 5.1. Programme engagement with local authorities on SMC delivery in selected districts
- 5.2. Advocacy visits
- 5.3. Media engagement
- 5.4. Community mobilization and SMC promotion activities
- 5.5. Household mobilization
- 5.6. State/province campaign approval

6. Training

- 6.1. Training of supervisors at central level
- 6.2. Training of regional and health district supervisors
- 6.3. Training of local supervisors
- 6.4. Training of mobilizers and CDs
- 6.5. Training of data entry staff and pharmacovigilance focal points
- 6.6. Training of community criers
- 6.7. Refresher training of CHWs

7. SP+AQ administration

- 7.1. SMC delivery methodology
- 7.2. Adaptations to delivery methodology due to COVID-19

7.3. Non-administration of SP+AQ to eligible children

8. Case management and pharmacovigilance

8.1. Management and referral of sick children

8.2. Pharmacovigilance monitoring

9. Supervision

9.1. Supervisors at central level

9.2. Regional and health district supervisors

9.3. Debriefing and reporting of supervision visits during SMC cycles

10. Monitoring and evaluation⁸

10.1. Administrative data collected during SMC cycles 1–5

10.2. End-of-cycle surveys

10.3. End-of-round coverage survey

10.4. Health facility surveys

10.5. Household surveys

10.6. Limitations of administrative data, surveys and study methods

11. Results

11.1. Health district performance during the campaign

11.2. Characteristics of households and targeted children

11.3. Characteristics of targeted children

11.4. Distribution of treatment to targeted children during the campaign

11.5. Children treated

11.6. Person in charge of administering treatment to the treated children

11.7. Reasons for which children were not treated

11.8. Adverse effects after treating children

11.9. Difficulties filling out SMC cards or administering the medicines to children

11.10. Knowledge, awareness raising and appreciation for the campaign

12. Conclusions

12.1. Achievements against work plan

12.2. Adjustments to work plan

12.3. Good practices

12.4. Success stories

12.5. Debriefing meetings at health district and regional levels

12.6. Lessons learned

12.7. Challenges and opportunities

12.8. Recommendations

⁸ For each survey, note the choice of health districts and health areas for the surveys, sample size and accuracy, and methods of data analysis (data input, processing and tabulation).

References

1. World malaria report 2022. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. (<https://apps.who.int/iris/handle/10665/365169>, accessed 17 February 2023).
2. WHO guidelines for malaria, 3 June 2022. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/354781>, accessed 17 February 2023).
3. Seasonal malaria chemoprevention with sulfadoxine–pyrimethamine plus amodiaquine in children: a field guide. Geneva: World Health Organization; 2013 (<https://apps.who.int/iris/handle/10665/85726>, accessed 18 February 2023).
4. Milligan P. Age-based dosing, duration of protection, and predicted cost effectiveness, of IPTc (SMC). Technical report. London: London School of Hygiene and Tropical Medicine; 2011 (<https://researchonline.lshtm.ac.uk/id/eprint/4647454>, accessed 18 February 2023).
5. Malaria chemoprevention efficacy study protocol. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. (<https://apps.who.int/iris/handle/10665/360908>, accessed 17 February 2023).
6. Safety monitoring in seasonal malaria chemoprevention (SMC) in the Sahel region. WHO Pharmaceuticals Newsletter No. 4, 2017:30–31 (<https://apps.who.int/iris/handle/10665/258800>, accessed 17 February 2023).
7. Vigibase [online tool]. Uppsala Safety Monitoring Centre, Sweden (<https://who-umc.org/pv-products/vigiflow/>, accessed 17 February 2023).
8. ACCESS-SMC Partnership. Effectiveness of seasonal malaria chemoprevention at scale in west and central Africa: an observational study. *Lancet*. 2020;396(10265):1829–40. doi:10.1016/S0140-6736(20)32227-3.
9. WHO Policy recommendation: seasonal malaria chemoprevention (SMC) for plasmodium falciparum malaria control in highly seasonal transmission areas of the Sahel sub-region in Africa. Geneva: World Health Organization; 2012 (<https://apps.who.int/iris/handle/10665/337978>, accessed 17 February 2023).
10. WHO/GMP technical expert group meeting on preventive chemotherapy: report of the technical consultation on seasonal malaria chemoprevention (SMC), chimio-prévention saisonnière du paludisme (CSP), Geneva 4–6 May 2011. Geneva: World Health Organization; 2011 (<http://apps.who.int/iris/handle/10665/367268>, accessed 17 February 2023).
11. Meremikwu MM, Donegan S, Sinclair D, Esu E, Oringanje C. Intermittent preventive treatment for malaria in children living in areas with seasonal transmission. *Cochrane Database Systemat Rev* 2012;2:CD003756. doi:10.1002/14651858.CD003756.pub4.
12. Gilmartin C, Nonvignon J, Cairns M, Milligan P, Bocoum F, Winskill P, et al. Seasonal malaria chemoprevention in the Sahel subregion of Africa: a cost-effectiveness and cost-savings analysis. *The Lancet Global Health*, Volume 9, Issue 2, e199 – e208. doi.org/10.1016/S2214-109X(20)30475-7.

13. Cairns M. Criteria for seasonality, implications for the number of SMC cycles, and data to guide national decisions. Technical report. London: London School of Hygiene and Tropical Medicine; 2022.
14. Diawara SI. Expansion of the age range for seasonal malaria chemoprevention in Mali [PowerPoint slides]. University of Sciences, Techniques and Technologies of Bamako, Mali; 2019 (<https://mesamalaria.org/resource-hub/astmh-2019-sory-i-diawara-expansion-age-range-seasonal-malaria-chemoprevention-mali-0>).
15. Crosscut. Microplanning [app]. DHIS2, version 1.0.1, 22 June 2022 (<https://apps.dhis2.org/app/de19ff76-3459-4ec1-a881-5b8644cd6c51>, accessed 17 February 2023).
16. Delivering seasonal malaria chemoprevention 2012 [videos]. London School of Hygiene & Tropical Medicine; 2021 (<https://www.lshtm.ac.uk/research/centres-projects-groups/opt-smc#smc-training-videos>, accessed 17 February 2023).
17. "Introducing Seasonal Malaria Chemoprevention." Malaria Consortium, uploaded by YouTube, 11 Sept. 2015, www.youtube.com/watch?v=ZHjTsAWSb8w.
18. Seasonal Malaria Chemoprevention Monitoring & Evaluation Toolkit. SMC Alliance, 2021 (<https://www.smc-alliance.org/resources/seasonal-malaria-chemoprevention-monitoring-evaluation-toolkit>, accessed 17 February 2023).
19. World Health Organization vaccination coverage cluster surveys: reference manual. Geneva: World Health Organization, 2018 (<https://apps.who.int/iris/handle/10665/272820>, accessed 17 February 2023).
20. Loua KM, Milligan P. Seasonal malaria chemoprevention coverage survey Guinea, 2018. Project report. London: London School of Hygiene and Tropical Medicine; 2019. doi:10.17037/PUBS.04654302.
21. Factors contributing to success for digital malaria campaigns. Baltimore; Catholic Relief Services, 2023 (<https://www.crs.org/our-work-overseas/research-publications/11-success-factors-digital-malaria-campaigns>, accessed 17 February 2023).
22. Digitalizing malaria campaigns: ITN and SMC handbook. Baltimore; Catholic Relief Services, 2023 (<https://www.crs.org/our-work-overseas/research-publications/digitalizing-malaria-campaigns-itn-and-smc-handbook>, accessed 8 March 2023).

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