PERENNIAL MALARIA CHEMOPREVENTION OPERATIONAL HANDBOOK

1ST EDITION – JANUARY 2025

A midwife administers SP for PMC to an infant in her mother's arms in a photoshoot purposed for SBC materials in Abengourou, Côte d'Ivoire.
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PNLP

MINISTÈRE DE LA SANTÉ
RÉPUBLIQUE DU BÉNIN

PNCM

ISGlobal Barcelona Institute for Global Health

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

malaria consortium
disease control, better health

MMV Medicines for Malaria Venture

PATH

psi

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ABBREVIATIONS

ACTs	Artemisinin-based Combination Therapies
AEs	Adverse Events
ANC	Antenatal Care
AS-AQ	Artesunate/Amodiaquine
boPV+IPV1	Bivalent Oral Polio Vaccine and Inactivated Polio Vaccine Type 1
CHWs	Community Health Workers
CSO	Civil Society Organization
DHAP	Dihydroartemisinin-piperaquine
DHIS2	District Health Information Software
DOT	Directly observed therapy
DPT Hib-HB	Diphtheria, pertussis, tetanus, hepatitis B and Hemophilus influenza type B vaccine, also known as Pentavalent vaccine (Penta), 3 doses
EMA	European Medicines Agency
EPI	Expanded Programme on Immunization
FEFO	First Expired, First Out
GAVI	Global Alliance for Vaccines and Immunization
HCC	Healthy Child Consultation
HCD	Human-Centered Design
HCW	Health Care Worker(s)
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
iCCM	Integrated Community Case Management
IEC	Information, Education, and Communication
IPTi	Intermittent Preventive Treatment in Infants
IPTp	Intermittent Preventive Treatment of Malaria in Pregnancy
IPTsc	Intermittent Preventive Treatment in school aged children
IRS	Indoor Residual Spraying
ITNs	Insecticide-Treated Nets
LLINs	Long-Lasting Insecticidal Nets
MDA	Mass Drug Administration
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MR1/MR2	Measles-Rubella Vaccine, 2 doses
NMP	National Malaria Program
NMCP	National Malaria Control Program
PCV13	Pneumococcal Conjugate Vaccine
PDMC	Post-Discharge Malaria Chemoprevention
Pfdhps	Plasmodium falciparum dihydropteroate synthase
PMC	Perennial Malaria Chemoprevention
PMTCT	Prevention of mother-to-child transmission
SBC	Social Behaviour Change
SP	Sulfadoxine-pyrimethamine
SP+AS	Sulfadoxine-pyrimethamine + Artesunate
SMC	Seasonal Malaria Chemoprevention
Vit A	Vitamin A
WHO	World Health Organization

ACKNOWLEDGMENTS

The writing of this PMC Operational Handbook is the result of the collaborative effort of the members of the PMC Community of Practice, chaired by Dr. Williams Houndjo (NMCP Benin) and Dr. Junior Voundi (NMCP Cameroon). Their leadership and vision have been instrumental in guiding the creation of this comprehensive resource.

The Secretariat of the PMC Community of Practice extends its deepest gratitude to the many experts and agencies who contributed their time, expertise, and dedication to the planning, development, and review of the PMC Operational Handbook:

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SPECIAL THANKS

The Secretariat acknowledges the invaluable contributions of all reviewers, planners, and developers whose insights and expertise enriched this handbook. The collective efforts of individuals across multiple organizations and institutions have been pivotal in shaping this document into a practical and impactful resource for implementing PMC strategies worldwide.

1. INTRODUCTION TO THE PMC OPERATIONAL HANDBOOK

Nurse Oda KOUAKOU administers SP to a child in Bouafle, CDI.
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1.1 WHAT IS PMC?

Perennial malaria chemoprevention (PMC) is the administration of a full treatment course of an antimalarial medicine at predefined intervals, to prevent illness in children in moderate to high perennial malaria transmission settings, regardless of malaria infection status. The goal of PMC is to protect young children by establishing preventive antimalarial drug concentrations in the blood that clear existing infections and prevent new ones during the age of greatest risk of severe malaria.

1.2 WHO IS THE PMC OPERATIONAL HANDBOOK FOR?

The PMC Operational Handbook is designed for stakeholders interested in implementing PMC. This includes:

- National malaria programs
- National and subnational technical working groups on PMC
- Regional, district malaria control teams
- Civil society organizations
- Implementing partners

There are separate job aids and training materials for healthcare workers and for community health workers.

1.3 WHAT IS THE PURPOSE OF THE PMC OPERATIONAL HANDBOOK?

The purpose of the PMC Operational Handbook is to support national malaria programs and implementers at different levels to plan and implement PMC interventions. It provides the technical and operational information and tools necessary to help policymakers and implementers at the national level decide how to integrate PMC into their malaria prevention package and describes a step-by-step approach for implementing PMC. It is intended to be a source of practical advice for implementers, as it draws from the experiences of PMC implementation and the lessons learned from Benin, Cameroon, Côte d'Ivoire, Mozambique, Democratic Republic of Congo, Sierra Leone, and Nigeria.

Lead CHW Angelina fills our her health register and follow up notes after a household visit in Nkolbisson, Cameroon.
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Lead CHW Supervisor Gwendolyn shows the health services informational guide that all CHWs carry with them during household visits in Nkolbisson, Cameroon.
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2. BACKGROUND

Parents Jacques and Reine KOUADJA posing with baby Axel in photoshoot for SBC materials in CDI.
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Since 2000, expanded access to WHO-recommended malaria prevention tools and strategies[1] has had a major impact in reducing the global burden of this disease. Some of these essential strategies are **i)** vector control through deployment of insecticide-treated nets (ITNs), larviciding and indoor residual spraying (IRS), **ii)** chemoprevention and chemoprophylaxis including the intermittent preventive treatment of malaria in pregnancy (IPTp), perennial malaria chemoprevention (PMC) (previously known as intermittent preventive treatment in infants (IPTi)), seasonal malaria chemoprevention (SMC), intermittent preventive treatment in school-aged children (IPTsc), and post-discharge malaria chemoprevention (PDMC), **iii)** mass drug administration (MDA) for malaria burden and transmission reduction and mass relapse prevention, and **iv)** the new malaria vaccines (RTS,S and R21).[2]

National malaria programs have adopted and implemented chemoprevention strategies for young children over the past decade, and even longer for pregnant women. In 2020, WHO convened a group of leading malaria experts to consider more than 10 years of evidence and operational experience on these interventions. On June 2022, WHO released updated guidelines focusing on 3 key malaria prevention strategies: SMC, PMC, and IPTp.

PMC, when it was known as IPTi, became a WHO recommended strategy in 2010 and recommended a full therapeutic course of sulfadoxine-pyrimethamine (SP) be co-administered with DTP2, DTP3, and measles1 immunization to infants through routine contacts of the Expanded Program on Immunization (EPI) in countries in sub-Saharan Africa. The recommendation extended to areas with moderate-to-high malaria transmission (annual entomological inoculation rates ≥ 10) and where the Pfdhps K540E mutation was not high (< 50% or less). At that time, Pfdhps K540E mutations were over 50% in east and southern Africa. Between 2010 and 2020 only one country adopted IPTi as policy: Sierra Leone. The low uptake of the strategy was thought to be because of the Pfdhps K540E mutation cut-off, moderate impact of IPTi given that chemoprevention only protected infants and did not protect older children, and that SP was seen as a failing antimalarial drug. Since 2020, the name has changed to PMC, the age range for the intervention now includes older children, and the Pfdhps K540E mutation cut-off has been removed. PMC pilot implementations have since commenced through routine health system delivery supported by the Unitaid-funded and PSI-led Plus Project in Benin, Côte d'Ivoire, Mozambique,[3] and Cameroon. In addition to the Unitaid Plus Project, PMC is being implemented in other districts in Cameroon (supported by the Global Fund),[4] as well as in DRC (supported by PATH with funds from GiveWell) and in Sierra Leone, which was the first country to implement IPTi starting in 2017 (PMC pilot now supported by ISGlobal and funded by EDCTP).

Other countries are also currently considering the possibility of starting PMC implementation and have included it either as part of their research agenda (Ghana), or in their national malaria strategic plan (Burundi, Cameroon, Côte d'Ivoire, Mozambique, Sierra Leone, Togo, and DRC).

1. WHO Guidelines for malaria, 14 March 2023. *iris.who.int/bitstream/handle/10665/366432/WHO-UCN-GMP-2023.01-eng.pdf*

2. Each of these preventive tools is partially effective, and availability of case management as close as possible to the community must be maintained. Layering several interventions have been demonstrated to boost protection levels, e.g. long-lasting insecticide nets (LLINs) plus SMC plus RTS,S (Dicko et al., 2023) and is likely to hold true for PMC plus R21 plus LLINs.

3. Perennial Malaria Chemoprevention : Implementation guide. National Malaria Control Programme Mozambique.

4. Guide de mise en œuvre du traitement préventif intermittent chez le nourrisson. PNLP Cameroun-MINSANTE, septembre 2021.

3.
WHO GUIDELINES

Midwife Desiree showcasing SP for PMC to caregivers at CSU Apoisso, January 2023.
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PERENNIAL MALARIA CHEMOPREVENTION (2022)[5]

In areas of moderate to high perennial malaria transmission, children belonging to age groups at high risk of severe malaria can be given antimalarial medicines at predefined intervals to reduce disease burden.

- Perennial malaria chemoprevention (PMC) schedules should be informed by the age pattern of severe malaria admissions, the duration of protection of the selected drug, and the feasibility and affordability of delivering each additional PMC course.
- Sulfadoxine pyrimethamine (SP) has been widely used for chemoprevention in Africa, including for PMC. Artemisinin-based combination therapies (ACTs) have been effective when used for PMC, but evidence is limited about their safety, efficacy, adherence to multi-day regimens, and cost-effectiveness in the context of PMC.
- Previously, PMC was recommended in infants (<12 months of age) as intermittent preventive treatment in infants (IPTi). Since the initial recommendation, new data have documented the value of malaria chemoprevention in children aged 12 to 24 months.
- The Expanded Programme on Immunization (EPI) platform remains important for delivering PMC. Other methods of delivery can be explored to optimize access to PMC and integration with other health interventions.
- Moderate to high perennial malaria transmission settings are defined as areas with *P. falciparum* parasite prevalence greater than 10% or an annual parasite incidence greater than 250 per 1000. These thresholds are indicative and should not be regarded as absolutes for determining applicability of the PMC recommendation.

In areas of moderate to high malaria transmission, the following benefits and harms of PMC have been demonstrated:

- **Clinical malaria**: PMC probably reduces the risk of clinical malaria compared to placebo or no PMC when using SP (rate ratio: 0.78; 95% CI: 0.69–0.88), AS-AQ (rate ratio: 0.75; 95% CI: 0.61–0.94), DHAP (rate ratio: 0.42; 95% CI: 0.33–0.54) (all moderate-certainty evidence), or SP+AS (rate ratio: 0.78; 95% CI: 0.62–0.97; high-certainty evidence).
- **Severe malaria**: PMC may reduce the risk of severe malaria compared to placebo or no PMC when using SP (rate ratio: 0.92; 95% CI: 0.47–1.81; low-certainty evidence) but may increase the risk of severe malaria when using DHAP (rate ratio: 1.29; 95% CI: 0.28–5.98; low-certainty evidence). There was no reported evidence on the effect of PMC with AS-AQ or SP+AS on severe malaria within the included studies.
- **Anemia**: PMC probably reduces the risk of anemia compared to placebo or no PMC when using SP (rate ratio: 0.82; 95% CI: 0.68–0.98), AS-AQ (rate ratio: 0.77; 95% CI: 0.53–1.12) or SP+AS (rate ratio: 0.72; 95% CI: 0.49–1.07) (all moderate-certainty evidence). No data were available on this outcome for DHAP in the meta-analysis.
- **All-cause hospital admissions**: PMC probably reduces hospital admissions compared to placebo or no PMC when using SP (rate ratio: 0.85; 95% CI: 0.78–0.93; moderate-certainty evidence) and probably has little effect when using AS-AQ (rate ratio: 0.98; 95% CI: 0.76-1.27; moderate-certainty evidence), SP+AS (rate ratio: 0.92; 95% CI: 0.71–1.20; moderate certainty evidence) or DHAP (rate ratio: 1.58; 95% CI: 0.46–5.42; low-certainty evidence). Malaria-specific hospital admissions were not covered by the systematic review.
- **All-cause mortality**: PMC probably reduces the risk of death compared to placebo or no PMC when using SP (risk ratio: 0.93; 95% CI: 0.74–1.15; moderate-certainty evidence) or SP+AS (risk ratio: 0.83; 95% CI: 0.36–1.89; moderate-certainty evidence), and may reduce mortality when using DHAP (risk ratio: 0.33; 95% CI: 0.01–8.08; low-certainty evidence). Although available evidence

5. WHO guidelines for malaria - 16 October 2023. app.magicapp.org/#/guideline/LwRMXj/section/LkgQZL

suggests that AS-AQ probably increases the risk of death (risk ratio: 1.21; 95% CI: 0.58–2.55; moderate-certainty evidence), the actual effect varies, and it is possible that there is little or no difference.

- **Parasitemia**: PMC probably reduces the risk of parasitemia compared to placebo or no PMC when using SP (rate ratio: 0.66; 95% CI: 0.56–0.79; moderate-certainty evidence). No data were available on this outcome for AS-AQ, SP+AS, or DHAP in the meta-analysis.
- **Adverse events**: In one study, the frequency of gastrointestinal symptoms was higher in children who received PMC with SP compared to placebo (risk ratio: 2.25; 95% CI: 1.51–3.35).
- **Potential drug–vaccine interactions and blood transfusions** were outcomes not covered by the systematic review. However, a study done in a subset of children enrolled in five randomized controlled trials in Ghana, Kenya, Mozambique, and the United Republic of Tanzania found that PMC with SP did not affect the serological response to EPI vaccines.

WHO recommends that medicines used for PMC be different from those used as first-line malaria treatment. SP has been widely used for chemoprevention in Africa and has been shown to be efficacious, safe, well tolerated, available, and inexpensive. SP was evaluated in 10 trials for PMC, AS+AQ in one trial, DHAP in one trial, and SP+AS in one trial. All regimens were found to be effective in reducing clinical malaria. Although ACTs have been effective when used for PMC, evidence is limited on their safety (including potential cumulative toxicity), efficacy, adherence to multi day regimens, and cost-effectiveness in the context of PMC in young children. A drug regimen that can be administered as a directly observed single dose, such as SP, is preferable to multi-day regimens.

The impact of drug resistance on the protection provided by PMC with SP is currently unclear. Duration of protection of SP has been shown to be 42 days in settings without parasite resistance mutations. This was reduced to 21 days in a setting where 89% of parasites carried the quintuple mutation. In settings with a Pfdhps540 mutation frequency of up to 50%, 3–4 doses of PMC with SP reduced clinical malaria by 30% over the first year of life. However, in the setting where the Pfdhps540 mutation frequency was 89%, no overall protective effect of PMC was observed. The efficacy of SP for treatment is affected by the frequency of mutation-carrying parasites, but there is little evidence that the frequency of molecular markers predicts the efficacy of PMC.

All the ongoing pilots that have fed into this version of the Operational Handbook have used SP. Given the likelihood of increasing SP resistance, particularly in Eastern and Southern Africa, an alternative drug may become relevant at some point. SP and AQ are frequently used for SMC (4-5 doses per year = 8-10 in the first two years of life) so it could be a potential option with a known safety profile. However, AQ has a cumulative effect on the liver so the break between doses in a seasonal context is helpful for flushing out the AQ from the body. ACTs might be another alternative but would require careful thought given concerns about increasing partial resistance to artemisinin and to some partner drugs as well.

In-country studies have shown that, with minimal training, PMC is easy to administer at the time of vaccination, and acceptable to health care workers and communities. WHO, in consultation with other experts, will revise and amend the PMC guidance as a Field Manual in 2026 as the results of the implementation pilots become available to support national malaria programs in the adoption, adaptation, and implementation of updated recommendations.

4.
POLICY DEVELOPMENT

Cameroon co-design, October 2021.
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4.1 PROCESS FOR POLICY DEVELOPMENT AND DECISION-MAKING

When developing a national strategy for PMC, it is crucial to adopt a co-design approach with all stakeholders, and to follow an evidence-based decision-making process that considers the realities of each country. The new WHO recommendations reinforce this autonomy and flexibility for countries to decide on the best PMC model adapted to their contexts, defining a schedule for the administration of SP that considers parameters such as the age pattern of severe malaria admissions, the duration of protection of the selected drug, and the feasibility and affordability of delivering each additional PMC course. Stakeholders to be considered in this process include, but are not limited to, the following:

- The National Malaria Program (NMP)*
- The Expanded Program on Immunization (EPI)
- National Immunization Technical Advisory Group or group that develops national guidelines on immunization
- The maternal and child survival program or the structure in charge of those aspects in the country
- The departments or structures in charge of pharmacovigilance, logistics, and supply chain
- The departments or structures in charge of developing and maintaining the tools used for data collection (i.e. HMIS)
- The departments or structures in charge of communications, such as the department of health promotion at the national level
- The departments or structures in charge of vitamin A supplementation
- The departments or structures in charge of community activities

*National Malaria Programs (NMPs) will serve as lead of PMC implementation because it is a malaria intervention and informs on malaria indicators which should be monitored by NMPs. Since malaria is administered alongside other national programs who direct the platform used to administer PMC (such as EPI), these programs play a significant role in PMC implementation and should be involved in all processes, but NMPs will remain the lead and define core activities.

- Other national decision-makers
- Universities and research institutions
- Donors (particularly the Global Fund, the U.S. President's Malaria Initiative, and others), funders, and implementing partners
- Regional public health delegation and district managers
- Civil society organizations
- Community representatives

To take full account of the influential stakeholders in each country, it is important to conduct a stakeholder mapping to identify all stakeholders and decision-makers to be involved in the decision-making process before defining their roles and responsibilities in PMC.

Many countries already have one or more advisory committees providing technical and/or administrative advice to national malaria and immunization programs. Countries that do not yet have such committees should consider setting one up to help assess the introduction of PMC. Members are generally chosen from scientific circles, program

A regional member of Mozambique's NMCP poses at a health facility in Sofala Province, Mozambique in June 2023.
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managers/executives, and partners. Example Terms of Reference for these advisory committees can be found at the end of this chapter.

The main stages in the decision-making process are as follows:

- Conduct a mapping of stakeholders to be involved in the design and adoption of the PMC strategy.
- Create or strengthen the missions and broaden the terms of reference of an existing committee responsible for bringing all parties together.
- Identify funding sources (public and/or private) and map the potential donors or interested parties.
- Determine the format of the strategy development process (workshop, meeting, etc.) and organize country-level consultations/co-design workshops to decide on the most appropriate PMC model, with participants representing all stakeholders.
- Collect and review available data on policy and programmatic aspects, making use of local data to ensure the PMC strategy is evidence-based and tailored to local settings.
- Design or adapt existing data collection tools, ensuring integration of different approaches (PMC, vaccination, routine consultations) where possible.
- Integrate supervision plans and checklists into the existing system where possible.
- Develop and disseminate strategy recommendations on PMC.
- Ensure that the PMC strategy is integrated and prioritized in national strategic plans.

In situations where a nationwide implementation is not appropriate due to variability in transmission intensity or SP resistance levels, or because of lack of sufficient funding, a political decision may be taken to implement PMC at a smaller scale, in certain regions or districts that can greatly benefit from PMC. In this case, decision-making for sub-national selection of areas for PMC implementation should follow a process informed by evidence, be inclusive of key national and local stakeholders, and consider variations to the PMC strategy for urban, peri-urban, and rural areas.

Once the decision to implement has been taken, the rationale, strategy and activities required for PMC need to be determined and integrated into the national malaria strategy and/or the overall multi-year immunization planning process, either by updating the existing plan (with an addendum, for example), or by developing a new plan if the timeframe of the existing one is coming to an end. In addition, a PMC implementation plan should be developed to provide more details on how PMC will be introduced. In the PMC implementation plan, identify the person(s) and program(s) responsible and the budget and deadlines for PMC introduction. Define all essential activities to be carried out before the start of the intervention. Incorporate into the plan the time and resource requirements for developing training materials, updating notification forms, health information system tools and checklists, and determining the need for staff training and demand creation activities.

4.2 ROLES AND RESPONSIBILITIES AT VARIOUS LEVELS

As the PMC intervention involves several programs (malaria, immunization, nutrition, maternal health, etc.), it is advisable to clearly define from the outset the national coordination mechanisms for this intervention, highlighting the roles and responsibilities of all stakeholders at different levels of the health pyramid, such as the structures in charge of adapting data collection tools, supply chain, and other aspects of implementation. A co-leadership can also be decided depending on country context.

Some examples of these roles by level are defined below:

NATIONAL LEVEL RESPONSIBILITIES

Responsibilities at this level include coordination of the intervention, resource mobilization, and leading the development of implementation strategies. The structure/entity responsible will also have to lead the development and design of training modules, produce

the training cascade plan, develop communication strategies, modify health system data collection tools (e.g. facility registers, patient cards/booklets, and tools used to determine the child's HIV status and any contraindications), and procure drugs. It will also be important to ensure epidemiological surveillance of malaria in target populations and set up the monitoring and evaluation mechanism and the performance framework for the intervention. National level responsibilities also include supervision of the implementation and all implementing partners, sharing progress on implementation. In Cameroon, for example, the National Malaria Control Program (NMCP) has brought together the heads of the departments and programs involved in maternal and child health, civil society leaders, and scientific leaders to design the strategy, from the central level down to the operational level where the intervention will be implemented and the data collected.

REGIONAL LEVEL RESPONSIBILITIES

Depending on how the health system is structured from one country to the other, regional level refers to the intermediate level actor(s) responsible for coordinating the intervention's operationalization. At this level, the lead will be responsible to ensure the availability of drugs needed to implement PMC and delivery of stocks to health districts/facilities, to train district-level management and district-based civil society organizations on coordination of PMC implementation and supervision processes, to support district management teams in implementation and supervise the implementation of activities in the health districts, in reviewing and analyzing data, and to ensure the availability of registers and patient cards to document the administration of PMC.

DISTRICT LEVEL RESPONSIBILITIES

These include the coordination of activities at the health district level, training to healthcare providers and community health workers (CHWs) on PMC administration and use of data collection tools, support to health facilities in implementing the intervention, analysis of health facility reports and feedback provision, supervisions, and supply of drugs to health facilities and CHWs in contexts where CHWs are allowed to administer antimalarials at the community level. They also organize monthly data validation meetings.

IMPLEMENTATION LEVEL

Implementing actors may be health care workers (HCWs) and/or CHWs* who will be responsible for administering PMC to all children in the age group meeting the eligibility criteria, to explain the importance of keeping appointments at the vaccination service, to ensure that data collection tools are filled and kept in good condition, drugs are tracked and stored adequately, adverse effect monitoring notification forms are completed systematically, stock movement records are updated routinely, and PMC data are entered into the national health information system as determined by the country. These responsibilities may take place in health facilities by HCWs, or at the community level through campaigns, event-based administration, or other means of community administration by either HCWs or CHWs (see Chapter 5). District based civil society organizations can play an important role in PMC depending to the country. For example, in Cameroon, they oversee CHWs' activities.

Participants of the Unitaid Plus Project annual meeting visit a health facility in Soa, Cameroon, to see the co-administration of PMC and the malaria vaccine as young children receive their regular vaccinations.
© Unitaid Plus Project

*Community health workers may be allowed to administer PMC in some countries depending on national policy, but not in all settings.

4.3 ROLLOUT OF MALARIA VACCINE AND ITS IMPLICATIONS ON POLICYMAKING FOR PMC

The administration of PMC along with malaria vaccines improved protection against malaria in African countries where the two malaria prevention strategies were implemented. There is evidence demonstrating synergistic improvement in seasonal settings, but a similar observation is not yet proved in perennial settings where a substantial number of malaria vaccine-eligible children live.

In 2015, the European Medicines Agency (EMA) gave to the malaria vaccine RTS,S/AS01 (Mosquirix; GlaxoSmithKline (GSK)) a positive recommendation after reviewing the efficacy data from large phase III trials. Following the EMA recommendation, in October 2021, the WHO recommended the RTS,S/AS01 malaria vaccine (4 doses) for the prevention of Plasmodium falciparum malaria in children living in regions with moderate-to-high malaria transmission. The evaluation confirmed the vaccine's safety and demonstrated the feasibility of implementing it within the existing Expanded Programme on Immunization (EPI) in resource-limited settings. In December 2023, a second malaria vaccine, namely R21/Matrix-M (developed by the University of Oxford, UK) and showing an efficacy in the range of 75-78% (in Phase II trials) was added to the WHO prequalified vaccines list. In view of these findings, the WHO recommends that countries prioritize vaccination with RTS,S/AS01 and/or R21/Matrix-M in moderate and high transmission areas.

The WHO policy has been widely adopted in sub-Saharan Africa with 30 countries expressing interest in rolling out the malaria vaccine; however, only 20 have been approved for support by Gavi, the Vaccine Alliance.

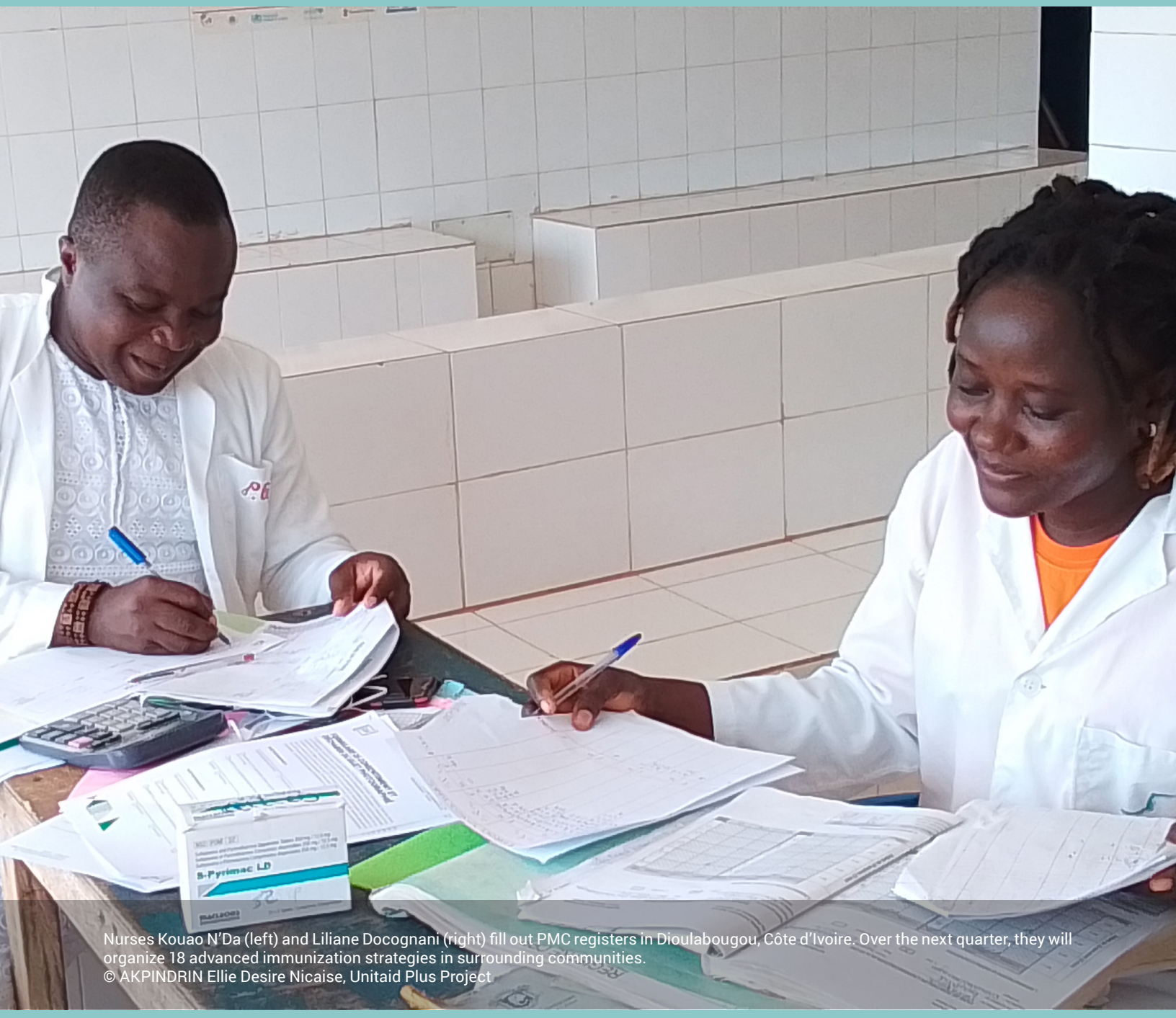
As of October 2024, several African countries have introduced malaria vaccines, either the RTS,S/AS01 or the newer R21/Matrix-M vaccine. Côte d'Ivoire and South Sudan in June 2024 introduced the R21/Matrix-M into their routine immunization programs. These countries joined eight others that had already begun using the RTS,S vaccine, including Kenya, Ghana, Malawi, Cameroon, Burkina Faso, Sierra Leone, Benin, and Liberia.

As of December 31, 2024, 15 African countries have introduced malaria vaccines into their routine immunization programs, with support from Gavi, the Vaccine Alliance. The rollout of a malaria vaccine is a breakthrough moment, but the highest impact will likely be seen when the vaccine is implemented at scale in countries, in combination with existing malaria control measures, including seasonal malaria chemoprevention (SMC), perennial malaria chemoprevention (PMC), long-lasting insecticidal nets, parasite-based diagnosis, and case management.

4.4 POLICY DEVELOPMENT RESOURCES

Policy development resources
(EN/FR/PT)

5. PLANNING



Nurses Kouao N'Da (left) and Liliane Docognani (right) fill out PMC registers in Dioulabougou, Côte d'Ivoire. Over the next quarter, they will organize 18 advanced immunization strategies in surrounding communities.
© AKPINDRIN Ellie Desire Nicaise, Unitaid Plus Project

5.1 DELIVERY CHANNEL

PMC was developed as an intervention delivered during existing contacts between young children and the health system such as through routine childhood vaccination visits, vitamin A administration, well-child visits, and vaccination outreach campaigns. The EPI platform remains important for delivering PMC due to the alignment in touchpoints in the first and second year of life. For example, in Cameroon, CHWs administer PMC in the community to children aged 6 months and above identified as behind on their appointment during vaccination outreach services. Contextual factors such as preferences of end-users, costs, coverage, and sustainability are considerations in the design of delivery platforms for PMC and integration with existing services such as EPI.

5.2 INTEGRATION OPTIONS

Given the frequency of delivery and the target age group for PMC, countries in the pilot chose to integrate delivery with EPI touchpoints, vitamin A and other child health services. In line with the integration guide for immunization services,[6] key considerations while planning integrated services include: alignment in target age group, timing/frequency, logistical requirements, high levels of acceptability and that the interventions require a similar skill level for health workers. Related to the broader health system it is important that the interventions have supportive political will, national policies, financial support, primary healthcare structures for delivery, monitoring and pharmacovigilance and that the interventions do not disrupt or burden healthcare service delivery. In addition to high-level planning and coordination with the Ministry of Health, implementing partners and civil society in the sectors of malaria and potential integrated platforms such as EPI, co-design workshops inclusive of communities and frontline workers can inform and improve the design and schedule of PMC with other child health initiatives.

5.3 PMC DELIVERY OPTIONS

PMC is often administered at the health facility level as a fixed strategy and can also be administered in other strategies which are present in the health system such as outreach sessions, mobile strategies and health campaigns. Designing the delivery strategy needs to be clearly defined during the macro- and micro-planning processes. During planning and especially in the co-design process, it is essential to understand the health system and consider the best ways of reaching children equitably through existing touchpoints within the health system with tailored strategies identified for hard-to-reach and special populations i.e. missed communities or zero-dose children.

Delivery strategies for PMC include fixed, outreach, mobile and campaigns. These can be integrated with EPI and other health services.[7]

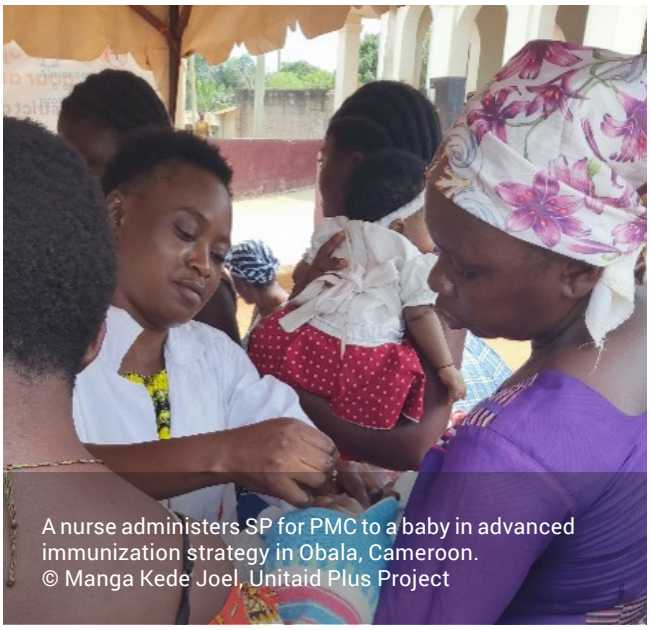
OPTION 1: PMC ADMINISTRATION AS A FIXED STRATEGY IN HEALTH FACILITIES DURING IMMUNIZATION AND AS PART OF WELL-CHILD VISITS

In the pilot studies, PMC was administered to children of the targeted age group during routine immunization sessions and well-child visits in health facilities. These are vaccination sessions organized at a public or private health facility, according to a pre-defined schedule, for the target group who typically live close to the health facility (within a radius of less than 5 km) or who have easy access to it (less than an hour walk). Immunization is offered as an essential service by Ministries of Health and are available free

6. Guide de supervision formative intégrée. Projet d'amélioration des services de santé Primaires (PASSP)- Ministère de la santé de Guinée, juin 2017. *www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi5ufGD_KaFAxWaTaQEHVQfCz8QFnoECCcQAQ&url=https%3A%2F%2Fportail.sante.gov.gn%2Fwp-content%2Fuploads%2F2022%2F08%2FGUIDE-DE-SUPERVISION-FORMATIVE_0306-2017.docx&usg=AOvVaw1D0786_EbVvQ1P020JI4x2&opi=89978449*

7. WHO Guidance March 2024. *www.who.int/publications/i/item/9789240085336*

PMC poster, register, and tools at a health facility in Kpakpame, ZoBoZa, Benin.
© Luc Bankole, Unitaid Plus Project


A nurse administers SP for PMC to a baby in advanced immunization strategy in Obala, Cameroon.
© Manga Kede Joel, Unitaid Plus Project

in public health facilities. The administration of PMC and vaccines to eligible children can be preceded by an educational talk session to provide caregivers with information about vaccinations and PMC.

Well-child visits in some countries, like the healthy child consultation (HCC) in Mozambique (which is the first contact point of every child once at the health facility) take place every month during the first year of life and every two months from the second year onwards. At the well-child visit, the child is typically assessed and directed towards the appropriate services for their age: if healthy, they are kept at the well-child visit for PMC, growth monitoring, routine EPI vaccinations, deworming, vitamin A supplementation, and micronutrient powder supplementation; otherwise, they will be sent to the at-risk child consultation or the sick child consultation.

OPTION 2: PMC ADMINISTRATION ALONGSIDE AN OUTREACH IMMUNIZATION STRATEGY AT A TEMPORARY FIXED SITE

To improve immunization coverage, health facilities are advised to organize regular outreach strategies in remote or hard-to-reach areas between 5 and 15 km from a health facility. PMC can be administered from temporary fixed sites, which involve setting up a vaccination post in the community (e.g. school, bus station, market) for a set period. This brings vaccination and other childhood health services closer to the community. Health facility staff travel to a specific point, following a schedule of visits agreed between the staff in charge of immunization and the communities concerned. Providers can organize vaccination sessions in communities previously identified as having many children of the age group, but which do not always have access to health services. Most often these are day trips with health workers not spending the night in the community. These outreach strategies are opportunities to administer PMC to children under 2 years of age.

OPTION 3: PMC ADMINISTRATION DURING MOBILE STRATEGIES

Mobile immunization sessions involve health workers staying for several days in one or more remote localities (more than 15 km from the health facility), to carry out immunization and other health activities and represent an opportunity to offer PMC. Mobile strategies are generally organized by District Management Team (DMT) in vaccination low coverage areas and requires significant logistical support. In outreach and mobile strategies, PMC is only delivered by HCWs.

OPTION 4: PMC ADMINISTRATION IN THE CONTEXT OF INTENSIFIED CATCH-UP VACCINATION INITIATIVES

Some countries have adopted models of routine immunization catch-up vaccination in the style of a campaign where health workers do not go to a fixed site, but rather travel to missed communities and households in areas where there is a high number of zero-dose. Cooler boxes with vaccines, sharps boxes for waste and SP are brought into communities to administer vaccines and PMC. Health facility registers are also brought directly into communities, although some countries have made a special registry for outreach strategies that is smaller and lighter, and then data is copied later into the facility-based register.

OPTION 5: COMMUNITY ADMINISTRATION OF PMC

Some countries might wish to allow CHWs to administer PMC to children as part of their package of services (cIPTp, iCCM). CHWs in Cameroon, for example, also raise awareness, educate community members about PMC, and verify home-based records like vaccination booklets to remind caregivers of upcoming appointments. For children who have never been to a health facility for their initial EPI contact, CHWs will refer them to the facilities so every child is enrolled for follow-up by the healthcare providers. Given the challenges in reaching children after the first year of life, greater involvement of CHWs is envisaged to find children lost to follow-up in the community.

Lead CHW Angelina administers PMC to a young child during a household visit in Nkolbisson, Cameroon.
© Taylor Prochnow, Unitaid Plus Project

5.4 COMBINING PMC WITH OTHER INTERVENTIONS

PMC is currently combined with immunizations and with other interventions included in the well-child visits including growth monitoring, vitamin A administration, micronutrients and deworming.

In the Soa district of Cameroon, the malaria vaccine RTS,S/AS01 was added to the EPI schedule and is administered in addition to PMC as of 22 January 2024. RTS,S vaccine in areas of perennial transmission is administered in 4 doses: 3 primary doses administered monthly from the age of five months (e.g. 5, 6, 7 months) and a booster dose between 12-24 months after the third dose.

5.5 DOSING SCHEDULES FOR PMC

The PMC schedule should be informed by the length of protective efficacy of the selected drug, as well as the feasibility of delivering each additional PMC course. SP doses should be given at least one month apart. Eight trials have evaluated a range of 3–6 doses of SP for PMC in the first year of life. Four trials have evaluated 1–12 doses of SP for PMC in the second year of life. The safety and impact of PMC programs should be routinely monitored. In some countries where PMC is already implemented, the number of doses ranges from 3 to a maximum of 8 as illustrated in the table below:

EXAMPLE PMC DELIVERY ALIGNED WITH THE EPI SCHEDULE

Child age	10 weeks	14 weeks	6 months	9 months	12 months	15 months	18 months	24 months
Corresponding vaccine*	DTC-hepB2-Hib2 VPO2 Pneumo 13-2 ROTA 2 Rota2 VPO2	DTC-hepB2-Hib2 VPO3 VP1 Pneumo 13-3 ROTA 2	Vit A	MR1 Yellow fever	Vit A	MR2	Vit A	Vit A
Benin	PMC1	PMC2	PMC3	PMC4	PMC5	PMC6	PMC7	PMC8
Cameroon (Plus Project districts)**	PMC1	PMC2	PMC3	PMC4	PMC5	PMC6	PMC7	PMC8
Cameroon (national PMC strategy)**	PMC1	PMC2	PMC3	PMC4		PMC5		
Côte d'Ivoire	PMC1	PMC2		PMC3		PMC4	PMC5	
DRC	PMC1	PMC2	PMC3	PMC4	PMC5	PMC6		
Sierra Leone (national IPTi strategy)***	PMC1	PMC2		PMC3				
Sierra Leone (Multiply PMC pilot)***	PMC1	PMC2	PMC3	PMC4	PMC5	PMC6		
Togo	PMC1	PMC2		PMC3		PMC4		
Nigeria****	PMC1	PMC2	PMC3	PMC4	PMC5	PMC6		
Mozambique*****	PMC1	PMC2	PMC3	PMC4	PMC5		PMC6	

* **Corresponding vaccine**: The corresponding vaccine may differ by country.
** **Cameroon**: Outside of the Unitaid Plus Project districts which use an 8-contact model (facility and community administration of PMC, left column), Cameroon has rolled out a 5-contact PMC strategy nationwide (right column).
*** **Sierra Leone**: In Sierra Leone, IPTi has been implemented nationally since 2017 in a 3-contact model (left). The MULTIPLY project is now also piloting a PMC model in certain districts of Sierra Leone with a new dosing schedule (right).
**** **Nigeria**: Nigeria has a 6 'scheduled' doses linked with EPI and 11 other 'unscheduled' opportunities in-between where caregivers can access PMC for their children so long as the last dose was one month ago.
***** **Mozambique**: In Mozambique, both the Unitaid Plus Project and the MULTIPLY project are piloting PMC in different districts. The MULTIPLY project uses the EPI platform as listed here, whereas the Unitaid Plus Project uses the Healthy Child Consultation (well-child visit) platform listed below with a different model.

EXAMPLE OF HEALTHY CHILD CONSULTATION (WELL-CHILD VISIT) CHANNEL FROM MOZAMBIQUE

Child age	4 months	6 months	9 months	12 months	18 months
PMC dose	PMC1	PMC2	PMC3	PMC4	PMC5
Other interventions provided at this age	boPV+IPV1 and DPT3 Hib-HB	Vit A, dewormer and micronutrient powder	MR1 and PCV13	Vit A, dewormer and micronutrient powder	MR2, Vit A, dewormer and micronutrient powder

CONSIDERATIONS FOR THE SECOND YEAR OF LIFE

With each of the above options but particularly when PMC is administered alongside routine immunizations in the health facility (option 1), PMC pilots have encountered some challenges in reaching children during the second year of life (12 months and beyond). For example, while vitamin A administration is sometimes used as a touchpoint for PMC, in many countries vitamin A administration occurs through community delivery during campaigns rather than routine implementation in health facilities, so the vitamin A touchpoints are not actually health facility contacts and caregivers do not bring their children to health facilities. In Benin, many caregivers believe that routine immunization ends after the child turns nine months old and do not return to health facilities for the measles booster in the child's second year or for vitamin A supplementation contacts. Because of this, many children who are supposed to return for their later PMC doses do not.

To address these challenges, a combination of the above options can be used. Different options for different age groups may also be employed to maximize access to PMC and coverage among the entire target population by leveraging all existing contacts that children have with the health system within the guidance of PMC administration.

5.6 LOGISTICS AND SUPPLY OF SP AND OTHER COMMODITIES

In most countries already implementing PMC, the treatment is administered to the same target groups, at the same time and in the same place as vaccination. To achieve this, it is efficient at the program level to integrate the distribution, delivery, and management of stocks. Most national immunization programs have well-developed and operational logistics systems in place.

5.7 QUANTIFICATION AND SUPPLY CHAIN

The initial estimate of requirements for PMC should be based on the target population, coverage, and wastages. There is often a great deal of uncertainty surrounding these data, so it is better to overestimate rather than underestimate initial requirements (if the shelf life of the SP is long enough to avoid the risk of expiry). Subsequent orders can be adjusted according to actual usage and stock levels. Estimated supply requirements must also be constantly adjusted to account for any new data on population, coverage, or losses.

Because PMC is a new intervention, countries may have difficulties planning for the quantity of SP needed during early PMC introduction. For this reason, PMC coverage will initially be estimated based on the coverage of vaccines administered at the same time (e.g., DTP2, DTP3 and MR1 and MR2). Note that it is common for some children vaccinated with DTP3 to not return for measles at 9 months of age, or the measles booster in the second year of life, though efforts are made to find children lost to follow up who can be given their missed PMC doses at the same time.

It is likely that some tablets will be lost during distribution, or that children will vomit them and need another dose, so a loss rate of 5% of the quantities to be administered must also be included. In addition, to avoid stock-outs due to shipping delays or higher-than-expected coverage, it is recommended to maintain a reserve stock of 10% of the year's needs.

If SP is the selected antimalarial for PMC, for the case of SP dosed with 500 mg sulfadoxine and 25 mg pyrimethamine the result of the calculation should be divided by 2, because some SP tablets are divided in two to provide PMC for 2 children depending on the child's weight and age (see section 8.2).

Once PMC has been successfully introduced, quantity of SP to order can be recalculated based on data from the first year of implementation.

CALCULATION OF THE NUMBER OF SP TO BE ORDERED FOR THE FIRST YEAR OF IMPLEMENTATION

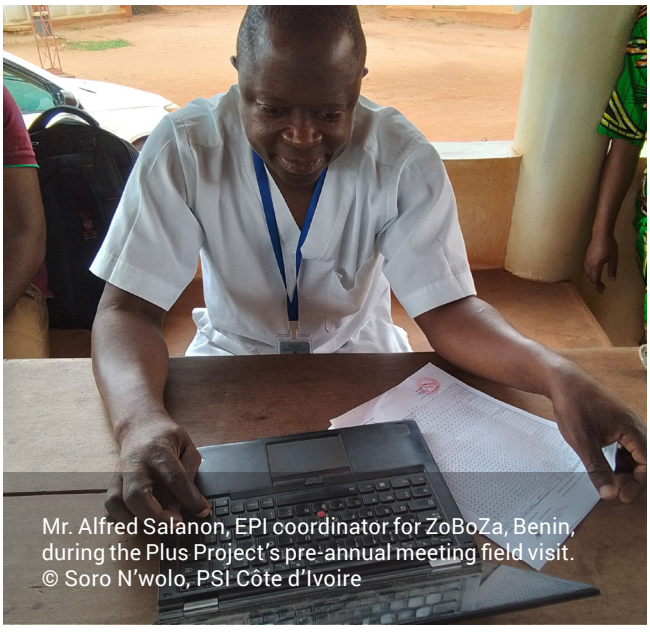
$$\text{DOSES OF SP TO ORDER FOR THE 1ST YEAR} = \frac{\text{DOSES OF SP TO ADMINISTER PER YEAR} \times 1.05\ (5\%\ \text{LOST}) \times 1.10\ (10\%\ \text{RESERVE STOCK})}{\text{DIVIDED BY 2 (IF SP 500/125 MG)}}$$

5.8 STOCK MANAGEMENT

To ensure better stock management, it is important to build the capacity of those involved in the process in terms of conservation, storage conditions, stock reconciliation, tool maintenance and reporting. As already emphasized, tablets for PMC should ideally be kept with the equipment and vaccines used by immunization and preventive child health services. At each level of the health pyramid, a person responsible for the daily monitoring of EPI vaccine and other drugs management must be designated. In addition, the FEFO (First Expired, First Out) principle will be strictly applied at all levels, in line with national guidelines on pharmaceutical product management. Expired or soon-to-be-expired medicines will be systematically withdrawn, then destroyed in accordance with regulations. SP drugs should be stored in the facility away from daylight, in the absence of humidity, on shelves 30 cm away from the wall, and at least 30 cm from the ceiling.

A physical inventory of stocks must be taken at the end of each month at the health facility and district or health zone level, and quarterly at the regional level, and then recorded in the appropriate tools. Inventory management must also be entered into national tools such as DHIS2.

A health provider poses in a pharmaceutical stock room at a health facility in Sofala Province, Mozambique, in June 2023.
© Meredith Center, PSI



Mr. Alfred Salanon, EPI coordinator for ZoBoZa, Benin, during the Plus Project's pre-annual meeting field visit.
© Soro N'wolo, PSI Côte d'Ivoire

6. SOCIAL AND BEHAVIOR CHANGE

A family speaks with a community health worker during a communications campaign in Yaounde, Cameroon, in July 2023.
© Erica Mengue, Association Camerounaise pour le Marketing Social (ACMS)/PSI Cameroon

Social and behavior change (SBC) is a discipline used in the health field that seeks to empower individuals to practice positive behaviors and ultimately achieve positive health outcomes. By understanding the behavioral determinants that promote or hinder the practice of a behavior, health interventions and community engagement strategies can be tailored and designed to facilitate decision-making and the prolonged practice of positive behaviors. Successful administration and uptake of PMC is complex and can be affected by numerous structural, environmental, cultural, interpersonal, and individual factors. The socioecological model, therefore, is an appropriate behavioral framework to understand the interactions of these complex factors and their influence on behavior, and ultimately, administration and uptake of PMC.

6.1 TARGET POPULATIONS AND KEY BEHAVIORS

To effectively design SBC strategies, the target populations should be identified with key stakeholders at the national and sub-national levels. Once target populations are defined, key behaviors to achieve high coverage of PMC should be outlined for each target population.

Example target populations and key behaviors include:

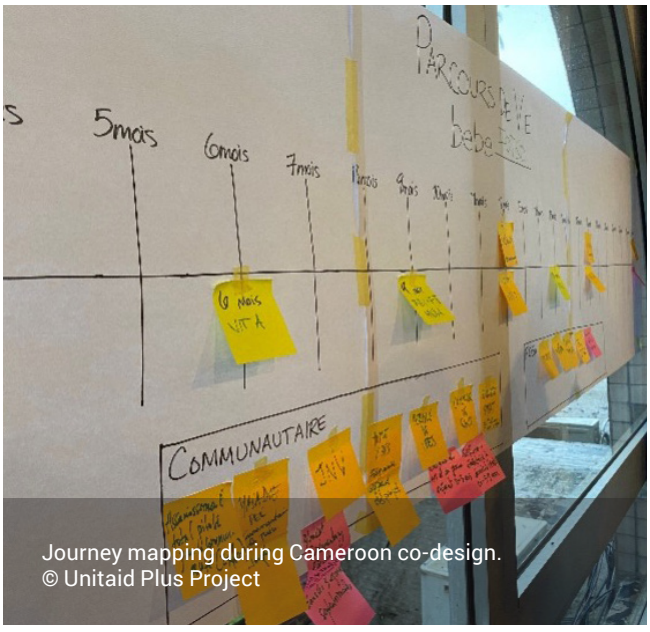
- **Healthcare workers**: Administer doses of PMC according to national guidelines; provide empathetic and compassionate care.
- **Community health workers**: Educate community members on PMC including where and how it is administered in their country; refer caregivers of children eligible for PMC to the health facility for vaccination/PMC; refer caregivers of children eligible for PMC to the health facility if they are late for a vaccination/PMC visit.
- **Caregivers of children eligible for PMC**: Attend vaccination appointments on time; attend vitamin A supplementation appointments on time; seek out information and resources to adopt best practices for the health of their children.

6.2 HUMAN-CENTERED DESIGN TECHNIQUES

Clearly defined target populations and behaviors form the basis of an SBC strategy and are key to achieving PMC coverage. Human-centered design (HCD) techniques can then be utilized to gain a better understanding of behavioral determinants that either promote or hinder the practice of desired behaviors, guided by insights from the target populations themselves. Various activities can be completed with members of each target population to better understand their perceptions, attitudes, existing practices, environmental, and structural factors that influence their service delivery, adherence or health seeking behaviors.

Examples of HCD tools for PMC could include:

- **Journey maps**: Collect and analyze qualitative data about the administration and/or adoption of PMC, depending on the target population whose journey is being mapped. A journey map could outline the interactions that a caregiver has with the health system while a child is eligible for PMC and the barriers faced by that caregiver in attending their vaccination/PMC appointments, or the daily experience of a HCW or CHW providing



Journey mapping during Cameroon co-design.
© Unitaid Plus Project

PMC services. Journey maps help to visualize the target populations' lived experience and can serve as useful tools to identify gaps and prioritize activities.

- **Circle of trust**: Uncover trusted and frequent channels of communication for health information and help to prioritize channels used for key messaging to promote the administration of PMC, knowledge-raising, and demand generation activities.
- **Empathy maps**: Humanize target populations through discussion of what target audience members say, do, think, and feel about malaria prevention and/or childhood vaccination. Empathy maps help to elicit attitudes, perceptions, and practices of the target population and can be used to develop or adapt key messages.

6.3 DEVELOPING A COMMUNICATIONS STRATEGY

Developing a PMC communications strategy is important to identify and track objectives, stakeholder audiences, channels of communication, key messages, and other outputs. The PMC communication strategy is highly context-specific: one generic formula for success does not exist. Nonetheless, some components may be generalized: PMC messages should be adapted to the specific target audience and informed by formative assessments conducted with the target audience. It is important to develop PMC communication strategies in collaboration with as many stakeholders and potential users as possible, such as CHWs, community leaders, regional health officials, national policymakers, etc., as it will allow fine-tuning of PMC communication and maximize its effectiveness. All materials, including but not limited to radio spots, visual tools, and job aids, should be pre-tested with the target audience before being printed or disseminated at-scale. Examples of community engagement and SBC materials for PMC can be found in the appendix of this handbook.

In many countries PMC will be a new malaria intervention. As such, communication strategies should include accurate, consistent messaging and materials for demand creation and should be specific to the country or geographic context. Educating the community and healthcare providers on the availability of PMC (including when and where to get it), associated costs, benefits, and carefully communicating any risks from PMC are critical to generate demand. Using trusted, established, and frequently used channels of health education to pass the appropriate message to the appropriate target population is equally important. Healthcare workers may trust health information from the government, their supervisors, and/or national policies, whereas community health workers may trust health information from their supervising nurses. Community members likely have a variety of trusted and frequent channels for health education, which may include healthcare providers and/or community health workers, but may also include radio and social media, local religious leaders or educational institutions, and other channels.

After a period of time, the communication strategy will shift from awareness raising and education to sustaining coverage and improving routine attendance at vaccination and/or child health visits. This can often be a more difficult phase of community engagement, as barriers to seeking care can be environmental and/or socioeconomic (such as geographic distance from a facility or travel costs) or can be interpersonal and/or sociocultural (such as access to financial resources in the household or cultural beliefs about child health). These barriers require additional resources and strategies to overcome, through outreach services, interpersonal communication strategies, and targeted messaging. Formative assessments can be conducted to expand understanding of underlying drivers of hesitancy, either pertaining to service delivery or care seeking behaviors. Additional outreach strategies may also be required to overcome environmental and/or structural barriers to PMC adoption in some communities (such as geographic distance from a facility or travel costs). Overall, the communications

strategy should take into account and address the phases of PMC from introduction to scale, as well as the underlying causes of hesitancy.

6.4 INTEGRATING PMC COMMUNICATIONS INTO EXISTING CHILD HEALTH INITIATIVES

While PMC is, at least initially, a new intervention, many opportunities exist to simplify messaging and improve understanding among both healthcare providers (including CHWs) and caregivers. Health education campaigns can be costly, but if planned for, resources can be maximized through integration. In many instances, the same providers will administer PMC as well as other childhood vaccinations, including the malaria vaccine if applicable. Similarly, the same caregivers seeking PMC services for their children will also be eligible for multiple child health interventions. Efforts during the introduction and scale-up of PMC to simplify and integrate messaging and community engagement activities with other child health services can improve confidence in and uptake of the interventions. Providers may hesitate to administer PMC if they are unsure of the calendar and how it overlaps with the malaria vaccine, for example, preferring to avoid PMC and/or malaria vaccine administration rather than risk over-medicating a child. Similarly, caregivers may be unsure of why two different interventions are being provided to their child to prevent malaria, and preferences may arise over an injection/vaccination as compared to an oral pill, or vice versa. Even with a plan in place to integrate messaging and community engagement strategies, lessons will be learned during roll out that can help adapt strategies for more effective scale-up.

The following opportunities for integration should be considered when developing a communications strategy:

1. Consultations and health education sessions for pregnant women during Antenatal care (ANC)
2. Health education sessions during vaccination days / child health visits
3. Child health educational materials (including vaccination calendars) at the health facility
4. Educational materials for the malaria vaccine (including calendars)
5. Vaccine & child health reminders during CHW house visits & community events by checking the vaccination booklets
6. Community engagement materials utilized by CHWs for health promotion

6.5 PUTTING THE COMMUNICATIONS STRATEGY INTO PRACTICE

The overarching communication objective is to push out information to different target groups to increase awareness about PMC and encourage them to adopt the intervention, thereby increasing demand for PMC and ultimately contributing to reduction in morbidity and mortality due to malaria and anemia in children aged 0-24 months. In practice, this will include:

LAUNCH/ROLL OUT OF PMC

- Train CHWs to educate the community on PMC (key messages, research and informational talking points to address hesitancy or misinformation [see 6.8 PMC Frequently Asked Questions], interpersonal communication skills, etc.).
- Improve the Information, Education and Communication (IEC) skills of stakeholders (CHWs, women's groups, community leaders, etc.) to enhance the quality and effectiveness of communication.
- Educate and encourage caregivers to adopt PMC as a means of preventing malaria in children aged 0-24 months alongside other effective, proven interventions such as the use of bed nets.
- Educate healthcare providers about the benefits of PMC and encourage them to share information with their patients and to offer the intervention during appointments.

LONGER TERM/SUSTAINED

- Encourage healthcare providers to systematically include PMC in their routine vaccination activities for children 0-24 months.
- Promote the uptake of PMC among communities by equipping CHWs and health care providers with information and resources to support caregivers in adhering to the integrated vaccination schedule year-over-year.
- Promote the scale-up and institutionalization of PMC in national strategies, policies, and guidance as a sustainable, effective prevention method.

6.6 SHAPING KEY MESSAGES TO IMPROVE COVERAGE OF PMC

Insights gathered during the formative HCD stage should be leveraged to adapt key messages to the target populations' specific motivators and barriers for administering, educating about, and/or seeking PMC. For example, if healthcare workers are unsure of the safety and efficacy of PMC for children this young, communication strategies should promote confidence and trust building approaches that reinforce the safety and efficacy of PMC. Coupling these messages with pharmacovigilance training can also help to build HCW confidence in a health system that can identify and detect any side effects should they arise. Similarly, if caregivers are frequently late for their vaccination appointments because they have a hard time reading the appointment date, training CHWs to review home-based vaccination records and give reminders during house visits and community events can help to overcome this obstacle. If caregivers do not attend vaccination appointments because they forget the date or cannot remember the general calendar for PMC and vaccination, or believe children in the second year of life may not need vaccines, CHWs can encourage caregivers to routinely check the home-based vaccination record to remind themselves of the appointments or to better understand the intervention calendar. If mothers have confidence in chemoprevention from their experiences taking IPTp, especially if using SP for PMC, framing PMC as a continuation of care rather than a new intervention can help build confidence and acceptance for PMC.

A community health worker gives a community sensitization session in Sofala Province, Mozambique.
© Mwangi Kirubi for the Unitaid Plus Project

6.7 INTEGRATED MESSAGING & INTEGRATED PLATFORMS / CHANNELS

Communication strategies should utilize social and behavior change (SBC) approaches, and can be deployed through a range of channels, including but not limited to mass media, community activities, social mobilization, interpersonal communication, and advocacy. Communications channels should be selected in collaboration with members from target populations to ensure that information about PMC comes from reliable sources.

MASS MEDIA COMMUNICATION

Mass media includes print media, radio, TV, and the internet. As PMC is a relatively new strategy, including mass media communication in a communications strategy may have several advantages depending on the scale at which PMC is being implemented. Through mass media, a large

Alberto Maquita, a clinical psychologist at Chibabava Hospital in Sofala province, gives a educational session about PMC on his local radio station.
© Luis Mahumane, Unitaid Plus Project

population can be reached relatively quickly, and the message can be controlled. The geographic coverage of PMC may affect which mass media sources are selected for demand generation and awareness raising campaigns. For example, if the entire country is eligible for PMC, a TV spot may be an effective channel if it is a frequent and trusted source of health information for the target population. If only a few districts are eligible, a TV spot may have too broad of a range, but a local radio spot may cover the right geographies and be more cost effective. Social media may also be included under this strategy depending on the penetration of internet in the community.

INTERPERSONAL COMMUNICATION

Interpersonal communication[8] is the process of exchanging information, ideas, and feelings between two or more people using verbal or non-verbal methods. It is intended to promote the behaviors desired, with effective involvement of partners in the process. It includes 1-on-1 discussion and group educational talks and is often done by CHWs as they conduct house visits. Interpersonal communication strategies are also useful during immunization or well-child visits with providers. Instant messaging applications are also valuable options to use between mobile devices. For example, men in Cameroon cited WhatsApp as a trusted communication source for health information.

ADVOCACY

In the context of Social and Behavior Change (SBC), advocacy refers to the strategic process of influencing decision-makers, stakeholders, and communities to adopt policies, practices, or behaviors that promote positive social and health outcomes. In Côte d'Ivoire, as part of Unitaid Plus Project, advocacy meetings were held with administrative authorities (Prefects and Sub-Prefects) in PMC implementing districts.

6.8 PMC FREQUENTLY ASKED QUESTIONS

These FAQs are specific to PMC using SP given the experience of PMC pilots contributing to this handbook which only used SP. However, if other drugs are used for PMC, these FAQs should be adapted or changed according to the drug and should inform key messages.

Q. ***If my child has malaria, can PMC treat it?***
A. *MC is an intervention to prevent malaria, not a substitute for malaria treatment. If your child has symptoms of malaria, go to the nearest health center for treatment.*

Q. ***Is PMC safe?***
A. *PMC is safe. It uses the same drug as you took to prevent malaria in pregnancy, and it helps protect your child against malaria but your child still needs to sleep under a bed net at night.*

Q. ***Why does my child need to take PMC?***
A. *PMC reduces the risk of malaria in children but does not guarantee complete protection. Children still need to sleep under a bednet and be vaccinated.*

8. Xardel D. La communication. Paris : Dunod ; 2010 p.11. *www.cairn.info/la-communication--9782804159740-page-11.htm*

Q. *Is it any different from what is given to pregnant women to prevent malaria?*

A. *PMC is similar to intermittent preventive treatment of malaria in pregnancy (IPTp): SP is used in both cases to protect against malaria. PMC is intended for children, while IPTp is intended for pregnant women. Although the drug is the same, the dosage is different.*

Q. ***Why does PMC only target children aged 10 weeks to 24 months? Why not other children?***

A. *It is an intervention that targets the most at-risk children and also tries to use the existing contacts that the children have with the health system, such as EPI.*

Q. *Is SP effective? What about SP resistance?*

A. *The impact of drug resistance on the protection provided by PMC with SP is currently unclear. The duration of protection of SP has been shown to be 42 days in settings without parasite resistance mutations. This was reduced to 21 days in a setting where 89% of parasites carried the quintuple mutation.*

Q. *Does SP have side effects?*

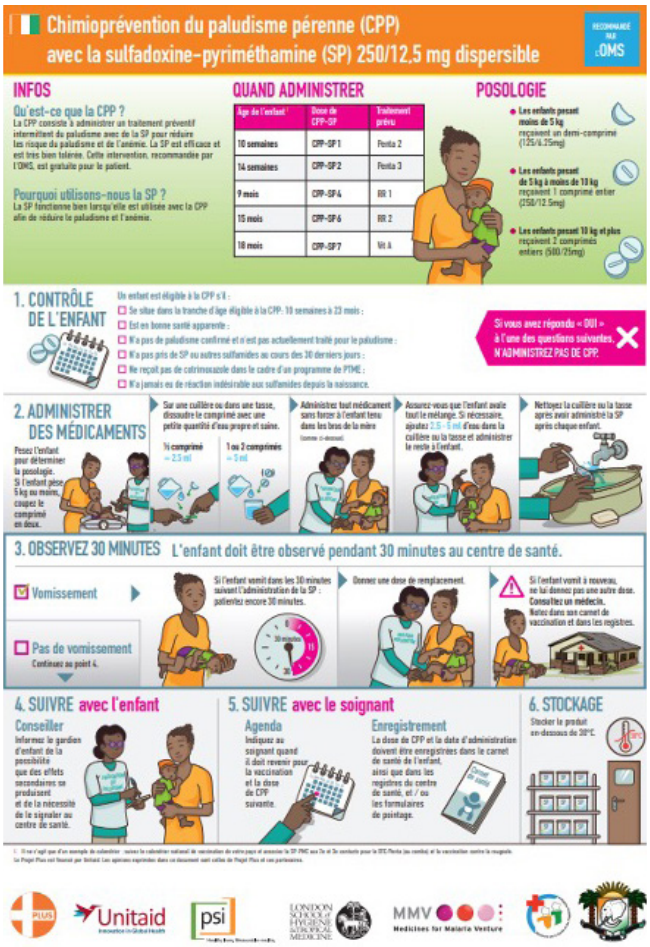
A. *Like any medication, SP can have side effects, but these are minimal. As a result, the risk of these side effects occurring is very low.*

Q. *How long does PMC protect the body?*

A. *Each dose of PMC protects the body against malaria for 21-42 days depending on the parasites in each location.*

6.9 COMMUNITY ENGAGEMENT AND SBC RESOURCES

- *Image box for community health workers* (FR)
- *Flyers, posters, and imagery for awareness-raising* (EN/FR)
- *Administration of SP visual aid for Benin* (FR/PT)
- *Administration of SP visual aid for Côte d'Ivoire* (FR/PT) (see visual below)
- *Administration of SP visual air for Mozambique* (FR/PT)



7. TRAINING

A community health worker in ZoBoZa gives a group educational session during the Plus Project's pre-annual meeting field visit.
© Soro N'wolo, PSI Côte d'Ivoire

Training all providers and implementers at various levels before the start of PMC implementation is crucial to the intervention's success. This training can take place over several days and should cover general information, operational aspects, and include practical work. Above all, it should not be held too long before the start of the intervention, as this could result in participants forgetting certain key aspects of the training. Where possible, rather than organizing a special training course on PMC, it should be planned as part of another regular annual training or refresher course.

7.1 TRAINING CONTENT

PMC training content should cover the following points:

- Brief overview of the national malaria strategy and rationale for introducing PMC.
- Overview of the national PMC strategy and context.
- Background to the link between PMC and vaccination (experiences of combining other interventions, such as vitamin A or deworming treatments, how the vaccination program works, etc.).

Community health worker Marcel showcasing job aid at training session in Abengourou, January 2023.
© Malika Kounkourou, PSI/Princeton in Africa

- General information on PMC, eligibility and players' roles.
- Approved PMC distribution platform(s).
- PMC in practice: drug recommended, administration schedule and dosage.
- Communication, social mobilization, and community engagement on PMC for communities and caregivers.
- Pharmacovigilance (adverse effects of SP and their management).
- Practical exercises on the administration of PMC, administration schedule, dosage and preparation of the solution to be administered to children. Depending on the country, practical exercises can be adapted to the chosen model and platform (e.g. PMC administered in a vaccination context or during well-child visits).
- Monitoring and evaluation (filling in data collection tools, data analysis, and reporting).
- Commodity management.
- Drug supply system.

7.2 METHODS OF TRAINING

Summary reference materials and visual aids should be prepared for distribution to training participants, so that they can review the information on their own and with their colleagues when they return to their workstations. Studies show that, for effective learning, interactive, hands-on training methods – field visits, videos, small-group discussions, demonstrations and hands-on practice – are more successful than classroom lectures.

Cascade training is a widely used approach allowing countries to rapidly achieve scale in programming. However, the content and understanding are inevitably diluted at each stage of the cascade. Countries should pay a particular attention to the selection of trainers, limit as much as possible the length of the cascade and strengthen this approach by adding post training follow visits at the health facilities to address any early issues with implementation.

For a sustained integration, Countries may also wish to integrate PMC into e-learning platforms to enable new health care providers to have access to relevant information on PMC. This can help address the turnover of health personnel. Decision makers may make this course compulsory to any new staff before starting PMC administration in their health facility and advise for the course to be taken every year as a refresher.

7.3 TRAINING EXPERIENCE FROM PMC PILOTS

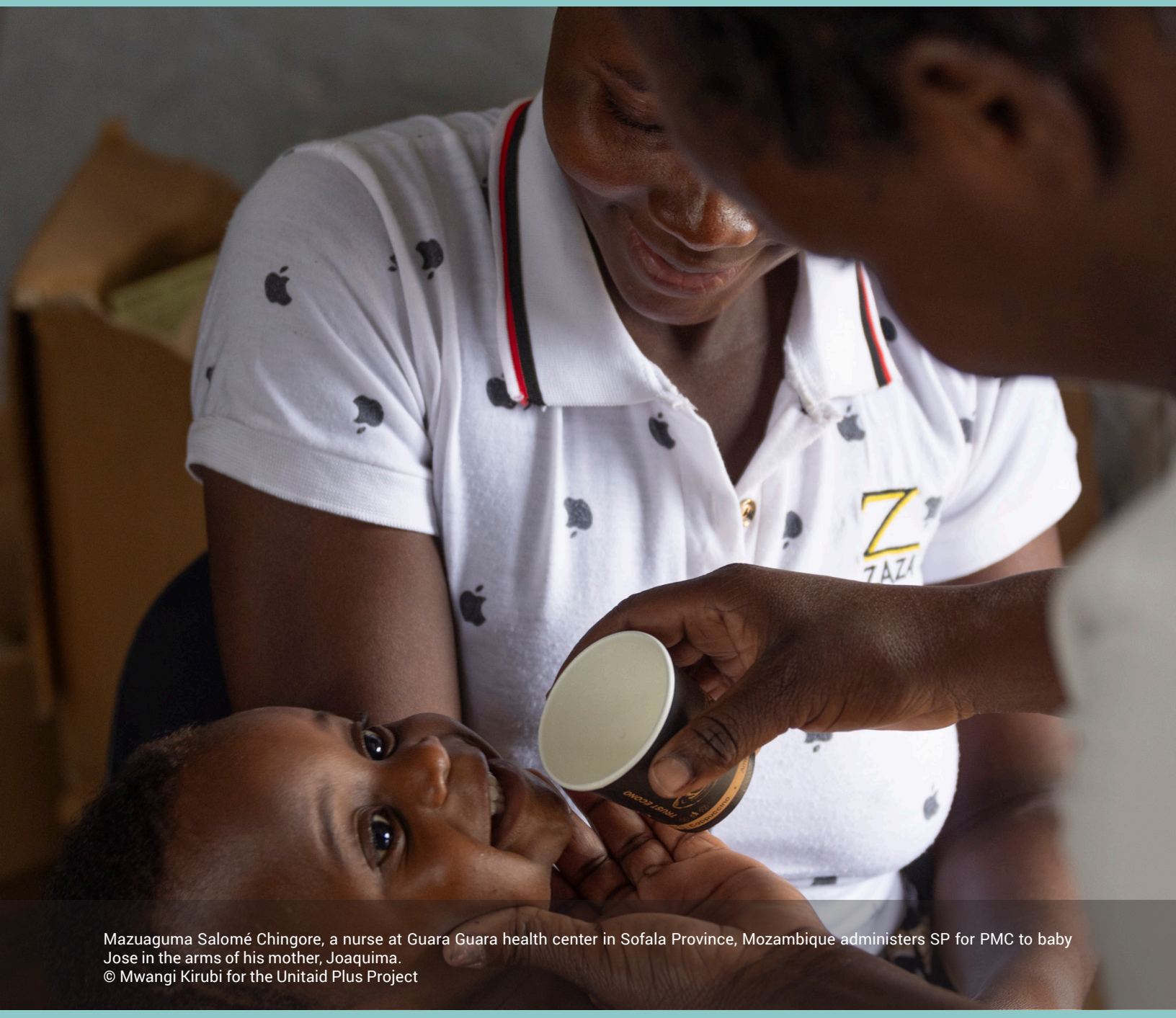
Standard training modules are available and minor adaptations to country context can be made. Cascade training was conducted in all countries and trainees included staff from programs such as NMCP, EPI, Nutrition, and MNCH, as well as focal points for supply chain, pharmacovigilance, and M&E. Community health workers must also be included in trainings with a key focus on IEC. Inclusion of all these stakeholders promotes ownership of the intervention. Whenever possible and particularly when considering PMC expansion, it's helpful to include site visits to observe SP administration and get feedback from trainees in plenary.

Lead CHW Supervisor Gwendolyn checks in with a CHW during household visits in Nkolbisson, Cameroon.
© Taylor Prochnow, Unitaid Plus Project

7.4 TRAINING RESOURCES

Training resources from Cameroon and Mozambique (EN/FR)

8. PMC ADMINISTRATION USING SP



Mazuaguma Salomé Chingore, a nurse at Guara Guara health center in Sofala Province, Mozambique administers SP for PMC to baby Jose in the arms of his mother, Joaquima.

8.1 SP ELIGIBILITY

In areas of moderate to high perennial malaria transmission, children belonging to age groups at high risk of severe malaria are eligible so long as they are healthy and:

- Have not taken any SP or another sulfonamide (such as cotrimoxazole) in the previous 4 weeks.
- Have no symptoms of malaria (fever).
- Have no history of allergy or adverse reactions to a sulfonamide.

Children with confirmed malaria should be treated with the appropriate ACT, in line with national policy, and the SP dose for PMC should be administered at the child's next visit (immunization visit or well-child visit depending on the PMC delivery platform). This should be noted on the child's home-based record (i.e. child health booklet/card) or the health facility's register book, according to the country's context and practices on record-keeping.

8.2 SP DOSAGE BY WEIGHT OR AGE

In most countries currently implementing PMC, the tablet used for PMC is SP which comes in two forms:

- Dispersible scored tablets (pediatric SP) containing 250 mg sulfadoxine and 12.5 mg pyrimethamine (recommended because it is dedicated to pediatric populations).
- Scored tablets containing 500 mg sulfadoxine and 25 mg pyrimethamine (can be used if dispersible 250/12,5 mg tablets are stocked out). Dispersible scored tablets of SP 500/25mg is also available.

Other formulations of SP are under development; MA191, MA192, and MA193 have just been prequalified in April and May 2024. MA191 and MA192 are dispersible tablet formulations. SP can be stored in a dry place at room temperature below 30 degrees Celsius. Tablets for SP should always be kept separate from the equipment and vaccines used by immunization services. SP is usually available in containers of 1000 tablets. If this volume is too large for a health center or outreach service, SP tablets can be divided into smaller containers or packages (e.g. snap-closure or ziplock bags). In the original hermetically sealed container, SP generally has a shelf-life of 3 to 5 years.

Dosage depends on the child's weight as described in the table below.

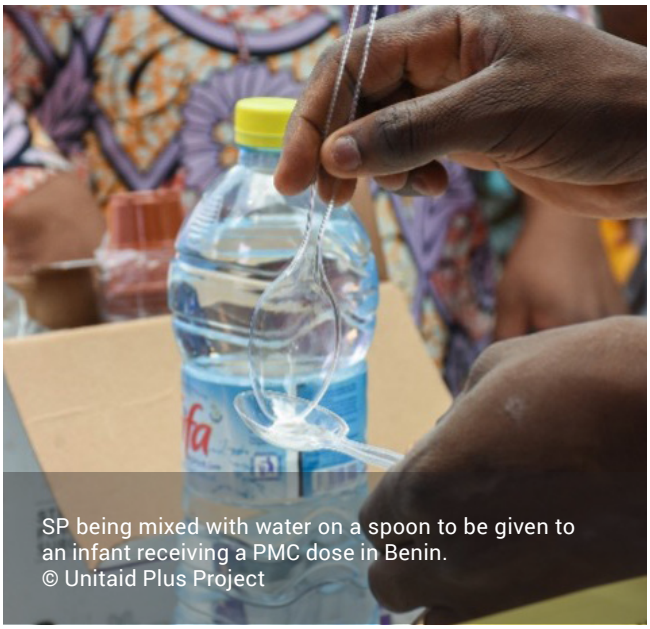
Most infants weigh more than 5 kg at 12 weeks (3 months), but this may not be the case in areas where malnutrition is rife. Children should be weighed to determine the correct dose of SP to administer. In many countries, growth monitoring typically occurs during the same appointment as routine immunizations; thus, where SP for PMC is administered alongside routine immunizations, the need to weigh the child is fulfilled. However, if scales are not available dosage can also be determined by the child's age.

If SP for PMC is being co-administered alongside routine EPI vaccinations, it is best that the child takes

Weight and age*	SP 250/12,5mg dispersible tablet (recommended)	SP 500/25 mg scored tablet
< 5 Kg *or* 10-14 weeks	½ tablet	½ tablet
5 to10 Kg *or* 6-9 months	1 tablet	½ tablet
≥ 10 Kg *or* 12-24 months	2 tablets	1 tablet

* Dosage can be provided by age in settings where no scale is available such as during community outreach.

A scale at a health facility in Sofala Province, Mozambique, used to weigh children to determine adequate dosage of SP for PMC.
© Meredith Center for the Unitaid Plus Project



SP being mixed with water on a spoon to be given to an infant receiving a PMC dose in Benin.
© Unitaid Plus Project

SP first before receiving routine EPI vaccinations, which often make the children cry and therefore less inclined to swallow the SP.

Before administering SP, wash hands with clean water and soap or rub them with a hydroalcoholic solution. Once the right dosage of SP has been determined depending on weight, the pediatric tablet should be dispersed in a spoon with a small amount of drinking water. For exclusively breast-fed infants, breast milk can be used to disperse the tablet instead of water. If important SP residue remains in the cup, add a little more water (or breast milk) and readminister to the child.

Depending on the context, health facilities can provide cups, spoons, water, and other supplies;[9] however, if not available then parents or caregivers can be encouraged to bring these supplies (cups) when coming to the appointment. However, this is not a requirement, and caregivers should not be discouraged from coming to health facilities or receiving PMC for their child if they do not bring these supplies. For outreach campaigns, drinking water should be taken along with other supplies. For community administration by CHWs, those materials can be used directly from the household visited. Whether administration occurs in the health facility or in communities, directly observed therapy (DOT) is mandatory to ensure the child has consumed the whole dose of SP, does not vomit the SP, and has no adverse effects (AEs).

The dispersible form of SP should be prioritized for PMC because it is formulated for pediatric populations. However, if there is a stockout of dispersible SP 250/12,5 mg, the adult 500/25 mg scored SP tablet may be used by grinding it between two spoons or in folded paper before dispersing with a small amount of water. If this is the case, parents or caregivers should be encouraged to bring two teaspoons with them to the appointment.

Injectable vaccines can be administered following administration of SP. WHO guidelines do not stipulate a waiting period between SP and vaccine administration, but a short break may be beneficial since vaccination can generate cries and potentially vomiting. The child should be observed for 30 minutes to ensure they do not vomit the SP solution.

9. Countries implementing PMC employ different solutions to the need for supplies, including disposable cups/spoons, sterilizing cups/spoons, or having caregivers bring their own. In Mozambique, for example, health facilities use cups and spoons they already have and wash these reusable supplies in chlorinated water between children.

In Mozambique, reusable cups from health facilities (lower image) are washed in tubs of chlorinated water (upper image) between children
© Charlotte Eddis, Unitaid Plus Project

If nothing happens, the child can be given vaccines and the caregiver can then be allowed to go home with the child and encouraged to come back for the next appointment or if any adverse events are observed at home. However, if the child vomits within 30 minutes of SP administration, let the child rest for 30 minutes before trying again. If the child vomits a second time, no third attempt should be made. In this case, it should be noted on the child's home-based record and health facility registers that two attempts were made, but that the child did not take the treatment. If the child vomits only partially or rejects ingestion of SP, the provider can decide whether SP should be readministered or not. Before the caregiver leaves, the health care worker should tell them when to return for the next appointment and the next dose of SP for PMC.

If EPI vaccines are out of stock when a child arrives for a scheduled vaccination, SP should still be administered. Similarly, if the opposite occurs, the child must be vaccinated, even if there is no SP available.

8.3 ADMINISTRATION GUIDANCE FOR HEALTHCARE WORKERS

When the healthy child arrives at the health facility for preventive care:

- Explain to the parent or caregiver that: SP for PMC is the intermittent administration of a treatment to protect children from malaria and anemia. This can be given at the same time as they receive their vaccine for routine immunization or during their well-child visit depending on the administration model and dosing schedule approved by their country at predefined intervals.
- Thoroughly wash hands with clean water and soap or a sterilizing solution, before touching any supplies or the child.
- Check the eligibility criteria of the child before administering the treatment:
  - Take the child's temperature. If the child has a fever indicating potential symptoms of malaria, the child should not be given SP.
  - Has the child ever had an adverse drug reaction since birth? If yes, which drugs? If the reaction was caused by SP (e.g. Fansidar) or other sulfonamide-containing drugs, e.g. co-trimoxazole (Bactrim) and Metakelfin, the child should not be given SP.
  - Has the child taken SP or another sulfonamide in the last 4 weeks (SP is found in the following drugs: Novidar SP, Fansidar, Malafan and Suldox)? If yes, the child should not be given SP.

  - » Is the child currently taking ACTs? If yes, the child should not be given SP. However, if the child has recently finished a course of ACTs, SP may be given immediately after the ACT course is finished, regardless of the time elapsed.
  - » Check the home-based record (i.e. vaccination booklet/card) for a code about mother's HIV status to determine if the child was born to an HIV-positive mother. Do not ask the mother about her HIV status directly to avoid stigma. If the mother's HIV status is unclear from the booklet, pull the mother aside before asking questions to preserve confidentiality. If the mother is HIV-positive, is the child taking part in a prevention of mother-to-child transmission (PMTCT) program? If the child is taking part in a PMTCT program and is taking co-trimoxazole, SP should not be administered.
- Prepare the right dosage according to instructions.
- Administer SP to the child following instructions from the manufacturer for the preparation of the solution. Make sure the child is in a semi-seated position in the caregiver's arms when administering the solution.
- Make sure the child swallows all the SP solution. If there is SP solution remaining in the spoon or cup, a little more water/breast milk should be added and given to the child to ensure the child receives the full dose.
- Apply infection control measures by cleaning (preferably sterilizing, but at least washing with soap and water) the spoon (or cup) after administering SP to each child.
- Monitor the child after administration. Advise the caregiver about the possibility of adverse events and the need to return to the health facility.
- Give the date of the next dose of SP alongside the next vaccination or appointment following the model approved in the country.
- Record the dose of SP and the date of administration on the child's health record, health center registers and tally forms.
- Discard all unused split SP tablets (adult formulation and dispersible tablets) at the end of the day (quarters and halves).
- In the event of a vaccine shortage, when a child presents for vaccination, SP should be administered alone and recorded on the child's health record. Similarly, if SP is out of stock, the child must receive the vaccinations that were scheduled.

8.4 ADMINISTRATION GUIDANCE FOR COMMUNITY HEALTH WORKERS

DO

- Always wash hands before administering SP
- Check SP expiration dates before administration
- Use drinking water or breast milk to administer SP
- Refer all children with adverse reactions to health facilities
- Fill in data collection forms correctly

DON'T

- Ignore the concerns of caregivers
- Administer SP to children without following the eligibility criteria
- Prescribe medication for SP side effects
- Give SP to a sick child; however, the child can still receive vaccinations
- Give SP to a child already taking a malaria or sulfonamide-based treatment (e.g. cotrimoxazole / Bactrim); however, the child can still receive immunizations

8.5 ADMINISTRATION RESOURCES

PMC administration resources
(FR/EN)

9. SUPERVISION

Community health worker Claudine completes her workbook after leading a group sensitization session in ZoBoZa, Benin.
© Luc Bankole, L'Association Béninoise pour le Marketing Social et la Communication pour la Santé (ABMS)/PSI Benin

When PMC is first deployed in a country, implementation must be regularly monitored through supervision. National supervision schedules and tools must be adapted to include PMC. Joint supervisions involving the various stakeholders should be organized. Depending on the actors to be supervised, this can be weekly, monthly, quarterly, or bi-annually. Supervision can be carried out in person with observation, remotely, or both, depending on contexts, budgets, and track record of performance.

9.1 INTEGRATED SUPERVISION AND SUPERVISION TECHNIQUES

Supervision is an activity that supports the implementation of a program, and consists, among other things, of supporting the implementing partners involved in carrying out the program. It involves periodic field visits by technically competent senior managers to lower levels, to ensure that interventions are carried out in accordance with established procedures. Supervision offers several opportunities, including:

- It allows the monitoring of personnel in the performance of their tasks, to ensure that they are carried out in accordance with established procedures.
- It is an excellent opportunity to provide further training, improve results and solve other systemic problems.

PMC focused supervision can provide room for more nuanced quality checks, covering more data elements especially at the early stage of implementation, but this approach can be resource-intensive. As much as possible, where PMC delivery is integrated within an existing delivery platform, supervision should be integrated to avoid duplication of efforts and frequent disruption of services due to multiple visits, and to facilitate efficiencies and coherence of implementation. In the Nigerian example of PMC delivery, supervision is integrated with EPI. The EPI supervision checklist and aide memoire were expanded to include indicators on PMC, so, as routine immunization delivery is supervised, PMC also receives appropriate attention by the local, state and national supervisors. The team is usually comprised of managers from both programs (malaria and EPI), who are knowledgeable about PMC. Supervision can be formative or facilitative. Formative supervision focuses on training staff on site during the visit, while facilitative supervision emphasizes joint problem-solving, two-way communication and staff coaching. In practice, supervision must be both formative and facilitative.

9.2 ORGANIZATION OF ROUTINE PROGRAM SUPERVISION

Supervision at the program level is organized in a cascade from the central level to the health areas and communities. Terms of reference, objectives and expected results are defined for the different levels of program supervision (see 9.5 Resources). The specific needs of each level of the system, and additional activities linked to the context of that level, can be integrated during the implementation of the activity, while respecting the previously defined objectives. The higher level is required to supervise all lower-level structures over a given period. Where PMC intervention is leveraging an existing health delivery platform, e.g. EPI, supervision should be integrated to avoid multiple visits and promote program coherence and efficiency. Priority is given to those structures with the lowest scores on performance indicators. However, it is also important to supervise those with good implementation results. This is carried out using tools such as supervision checklists that have been previously developed or adapted as appropriate. The checklist should cover availability of commodities, supplies that facilitate administration of PMC e.g. cup and water for dissolving the SP tablets, PMC administration – determination of eligibility, dosing etc., information given to caregivers, dealing with side effects etc.

9.2.1 ROLES OF THE SUPERVISEE

- Gather all necessary documents.
- Ensure the availability of resource persons.
- Draw up and update the current situation (EPI, district).
- Participate in the visit to the health facility.
- Give feedback on supervision to absent staff.

9.2.2 ROLES OF THE SUPERVISOR

- Ensure the effectiveness of PMC in the target population.
- Evaluate compliance with the SP distribution strategy in the health facility.
- Provide feedback to staff on findings about compliance with SP distribution strategy.
- Create a plan with health facility staff to target weak areas if necessary.
- Ensure the proper collection and reporting of quality data and their management.
- Conduct the visit to the health facility.
- Draw up and share the supervision report.

9.3 PMC SUPERVISION TECHNIQUES DURING ROUTINE IMMUNIZATION

Supervision is best carried out on the days of the vaccination session or well-child visit (depending on the platform chosen in-country for PMC administration) in the chosen health facility, or during community home visits. It consists of three essential stages, in no order:

OBSERVATION

- Are drugs available and how are they stocked in the pharmacy?
- Do the health workers determine eligibility for SP appropriately?
- Is SP available and how is it administered to children?
- Does the facility have other supplies to facilitate SP administration e.g. cup and water for dissolving SP?
- Do staff educate parents about PMC?

DOCUMENT REVIEW

- Do all PMC implementation guideline documents exist in the health facilities?
- How are management tools completed?
- How complete is the data?

THE INTERVIEW

- Is there a malaria focal point?
- Are the HWs that are providing routine immunization trained on PMC?

9.4 FEEDBACK AND FILLING IN THE SUPERVISION LOGBOOK

At the end of supervision within a structure, recommendations are formulated depicting essential actions to be undertaken accompanied by a plan for their implementation and follow-up in order to:

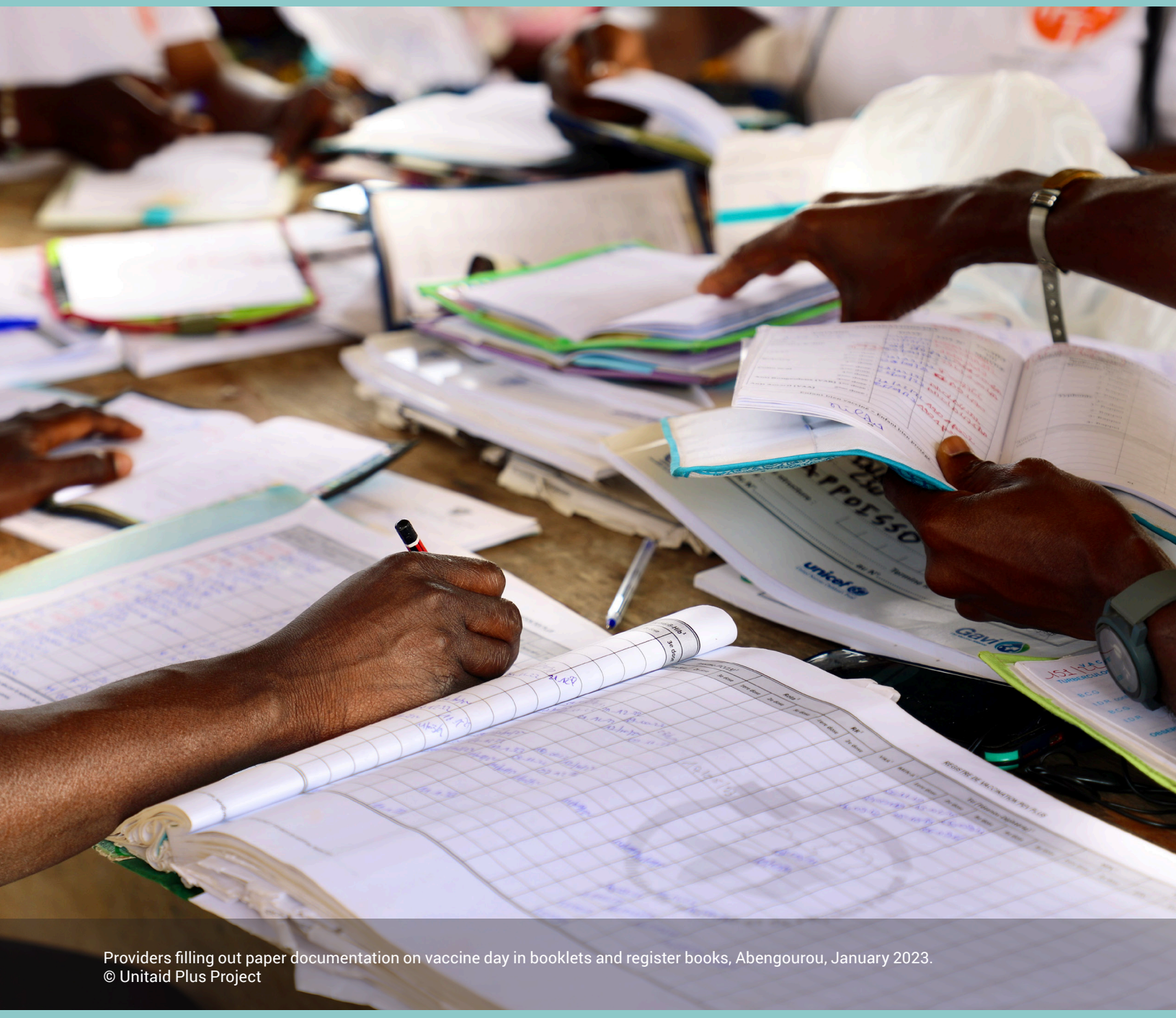
- Agree on corrective actions and how they will be implemented.
- Assess progress made by the supervisee.
- Communicate recommendations to all stakeholders.
- Promptly initiate corrective actions, considering identified problems and objectives.

Supervision of PMC implementation during routine immunization is intended to be an integrated part of routine supervision of EPI and NMCP programs. Given that it is the same health worker providing the two interventions to clients and at the same clinic, addressing issues identified during supervision should be holistic and use a comprehensive approach.

9.5 SUPERVISION RESOURCES

Supervision checklists
(FR/PT)
Supportive supervision guide
(EN/FR)

10. MONITORING & EVALUATION



Providers filling out paper documentation on vaccine day in booklets and register books, Abengourou, January 2023.

10.1 DEFINITION AND PURPOSE OF MONITORING & EVALUATION

Monitoring & evaluation (M&E) of an intervention's activities are essential to the optimal performance of the intervention and to assess progress towards objectives.

- Monitoring the implementation of PMC involves the routine collection and analysis of data on administration, adherence, and adverse events, as well as complementary activities such as supervision and training. Routine use of these data helps to improve the smooth running of activities and implementation. This is an ongoing process.
- Evaluation of PMC's effectiveness may leverage various forms of data sources, such as routine surveillance systems to provide coverage estimates and malaria incidence or surveys to estimate the intervention's impact on malaria-related incidence and mortality in targeted populations within the targeted geographies.

A typical M&E strategy may take the following steps:

1. Define monitoring and evaluation objectives and needs.
2. Define indicators related to each objective.
3. Identify the relevant data flow and actors for collection, reporting, validation, and use.
4. Create data collection, reporting, and quality assurance tools.
5. Train actors on the data flow and collection, reporting, and validation tools.
6. Routinely supervise the actors and use of the collection, reporting, and validation tools.
7. Routinely analyze progress towards objectives, taking action as needed.

This section provides:

- a template indicator log frame,
- recommended PMC-related indicators, definitions, level of disaggregation, and frequency of data collection,
- recommended data sources and data collection methods, and
- recommended responsibilities of actors at different levels.

10.2 TEMPLATE INDICATOR LOG FRAME

The indicator log frame provides the relevant indicators organized by the intervention's theory of changes, which should dictate the inputs and outputs and are expected to result in the expected intermediate outcomes, outcomes, and impact. An indicator log frame is critical to ensure transparency and consistent measurement of relevant indicators and, ultimately, be able to monitor progress and identify areas for improvement.

Objective	Indicator	Baseline		Targets			Frequency	Source	Responsible
		Value	Source	Year 1	Year 2	Year 3			
Impact Indicators									
Outcome Indicators									
Intermediate Outcome Indicators									
Output Indicators									
Input Indicators									

A Theory of change should inform indicators choice

10.3 INDICATORS

To monitor progress at the different levels of the theory of change, indicators to measure each component are required. Each indicator should have a clear objective (why), name and definition (what), source (how), aggregation level (where), and frequency of reporting (when). Some indicators, referred to as "core indicators" (highlighted in grey in the tables below) should be monitored by all malaria programs that implement PMC. Other indicators are listed for potential use in monitoring and evaluation, as appropriate.

Theme	Input	Process	Output	Intermediate Outcome	Outcome
Funding	# budget needed	# funding available			
Supply	# SP tables procured	# SP tablets delivered to HFs	% SDPs with no stockout of PMC		
Demand	SBC plan for PMC administration in place	# PMC-related SBC activities conducted	# of people reached with PMC-related SBC activities # children referred by CHWs for PMC	# SP doses administered # PMC-related adverse events	% targeted children receiving PMC 1, 2, 3, etc. % loss to follow-up
Quality improvement (training)	QI plan for PMC administration in place and includes training	# trainings held	# health workers trained	% of applicable EPI visits with PMC administered	
Quality improvement (supervision)	QI plan for PMC administration in place and includes supervision	# supervision visits integrating PMC conducted	# SDPs receiving PMC-related supervision	% SDPs ready for PMC implementation % HWs competent on PMC implementation	

10.3.1 SAMPLE INPUT INDICATORS

Objective	Indicator	Definition	Source	Aggregation	Frequency
Funding	Budget needed for the implementation of PMC	Amount of budgeted needed for the implementation of PMC	Program records	Country	Annual
Supply	Number of PMC tablets procured	Number of PMC tablets procured	Logistics MIS	Country	Annual
Demand	SBC plan for PMC administration in place	SBC plan for PMC administration in place (Yes / No)	Program records	Country	Annual
Quality improvement (training)	QI plan for PMC administration in place and includes training	QI plan for PMC administration in place and includes training (Yes / No)	Program records	Country	Annual
Quality improvement (supervision)	QI plan for PMC administration in place and includes supervision	QI plan for PMC administration in place and includes supervision (Yes / No)	Program records	Country	Annual

10.3.2 SAMPLE PROCESS INDICATORS

Objective	Indicator	Definition	Source	Aggregation	Frequency
Funding	Funding available for the implementation of PMC	Funding available for the implementation of PMC	Program records	Country	Annual
Supply	Number of PMC tablets delivered to service delivery points	Number of PMC tablets delivered to service delivery points (health facilities, CHWs, etc.)	Logistics MIS	District	Quarterly
Demand	Number of PMC-related SBC activities conducted or material developed	Number of people reached through PMC-related SBC activities, including community outreach and advocacy to improve awareness and attitudes about PMC	Program records	District	Quarterly
Quality improvement (training)	Number of trainings held for service delivery points for the implementation of PMC	Number of trainings held for service delivery points (health facilities, CHWs, etc.) for the implementation of PMC	Program records	District	Quarterly
Quality improvement (supervision)	Number of supervision visits integrating PMC conducted	Number of supervision visits integrating PMC conducted (Observational or non observational)	Program records	District	Quarterly

10.3.3 SAMPLE OUTPUT INDICATORS

Objective	Indicator	Definition	Source	Aggregation	Frequency
Supply	Proportion of targeted service delivery points that did not report a stockout of PMC	**Numerator**: Number of targeted service delivery points (health facilities, CHWs, etc) expected to administer PMC that did not report a stockout of PMC (follow national definition of stock out) **Denominator**: Number of service delivery points (health facilities, CHWs, etc) expected to administer PMC	Logistics MIS	Facility	Monthly
Demand	Number of people reached through PMC-related SBC activities	Number of people reached through PMC-related SBC activities, including community outreach and advocacy to improve awareness and attitudes about PMC	Program records	Facility, Sex, Age	Monthly
Demand	Number of children referred by CHWs for PMC	Number of children referred by CHWs for PMC	HMIS	Facility, Sex, Age	Monthly
Quality improvement (training)	Number of health workers trained	Number of health workers (facility-based, community-based) trained for implementation of PMC	Program records	Facility, Sex, Cadre	Quarterly
Quality improvement (supervision)	Number of service delivery points implementing PMC that received supervision	Number of service delivery points (health facilities, CHWs, etc.) implementing PMC that received supervision	Program records	Facility	Quarterly

10.3.4 INTERMEDIATE OUTCOME INDICATORS

Objective	Indicator	Definition	Source	Aggregation	Frequency
Demand	Number of PMC doses administered	Number of PMC doses administered	HMIS	Facility, Sex, Age	Monthly
Demand	Number of adverse events reported which included PMC as one of the antigens given	Number of adverse events reported which included PMC as one of the antigens given	HMIS	Facility, Sex, Age	Monthly
Quality improvement (training)	Proportion of applicable EPI visits with PMC administered	**Numerator**: Number of EPI visits during which PMC was administered * **Denominator**: Number of EPI visits (applicable vaccine and/or Vit A administered)	HMIS	Facility, Sex, Age	Monthly
Quality improvement (supervision)	Proportion of supervised service delivery points demonstrating readiness for PMC implementation	**Numerator**: Number of supervised service delivery points (health facilities, CHWs, etc) implementing PMC that received supervision achieving at least 80% on PMC-related readiness checklists **Denominator**: Number of supervised service delivery points (health facilities, CHWs, etc) implementing PMC	Program records	Facility	Quarterly
Quality improvement (supervision)	Proportion of supervised health workers demonstrating competence on PMC implementation	**Numerator:** Number of health workers (facility-based, community-based) supervised for PMC implementation achieving at least 80% on PMC-related supervision checklists **Denominator:** Number of health workers (facility-based, community-based) supervised for PMC implementation	Program records	Facility, Sex, Cadre	Quarterly

** "Number of EPI visits during which PMC was administered" can be most easily proxied as "Number of PMC-SP doses administered" (i.e., the total of all PMC doses during the month).*

10.3.5 OUTCOME INDICATORS

Objective	Indicator	Definition*	Source	Aggregation	Frequency
Demand	Proportion of targeted children who received 1st dose of PMC-SP	**Numerator**: Number of children 0-11 months who received 1st dose of PMC **Denominator**: Number of estimated children 0-11 months	HMIS	Facility, Sex, Age	Monthly
Demand	Proportion of targeted children who received 2nd dose of PMC-SP	**Numerator**: Number of children 0-11 months who received 2nd dose of PMC **Denominator**: Number of estimated children 0-11 months	HMIS	Facility, Sex, Age	Monthly

Objective	Indicator	Definition*	Source	Aggregation	Frequency
Demand	Proportion of targeted children who received 3rd dose of PMC	**Numerator**: Number of children 0-11 months who received 3rd dose of PMC **Denominator**: Number of estimated children 0-11 months	HMIS	Facility, Sex, Age	Monthly
Demand	Proportion of targeted children lost to follow-up	**Numerator**: Number of children who had received at least 1 dose of PMC lost to follow-up **Denominator**: Number of children who had received at least 1 dose of PMC	HMIS	Facility, Sex, Age	Monthly

**Although the target population for PMC is children under 2 years, the denominator for each dose should correlate to the year of life for that dose. For example, the 1st dose of PMC is expected to be given around 4 months, so the target population is children under 1 year. In addition, counting children that receive doses "late" per the schedule should be done with caution and follow the existing procedures for monitoring late vaccinations. For example, children who received PMC1 in their 2nd year of life should not be counted in the numerator for coverage of PMC1.*

10.4 DATA SOURCES AND TOOLS

Typically, administrative data is collected using existing Ministry of Health data collection tools, such as the EPI register. Tally sheets can be helpful to simplify the counting process for daily or monthly aggregations. Then, the data are compiled in the monthly report with other health-related indicators. These reports are entered into the national HMIS, typically DHIS2 and typically by the health district, although some facilities may have the infrastructure and equipment to enter data themselves.

Thus, data for PMC delivered during routine immunization in both fixed and advanced strategies, e.g., with a community-based component, should be collected according to standard EPI formats to streamline reporting.

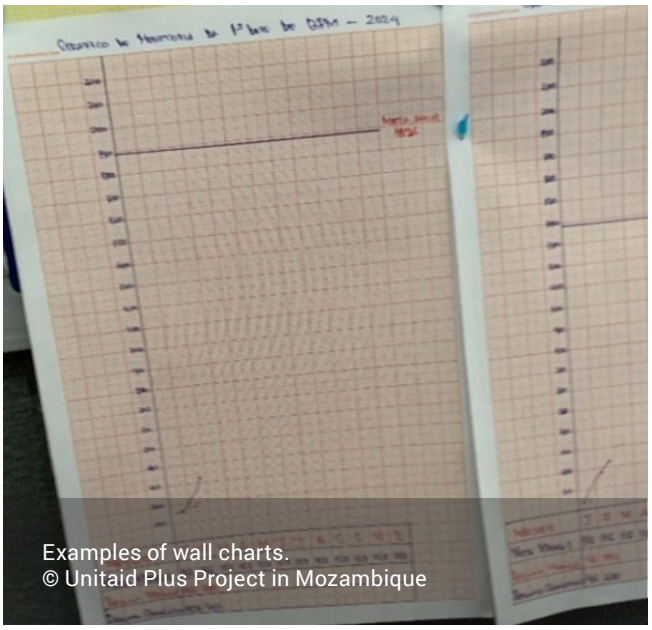
To avoid double counting PMC doses, children's home-based records and longitudinal registers are helpful to track the number of doses a child has received. Even if the dose number does not correlate with the schedule, the correct dose number of what the child has received should be recorded (e.g., for a child who receives their 1st dose of PMC alongside measles, this should be captured as PMC1 and not as PMC3). This process is the same whether administration is done in the community and at a health facility and even if the child switches health facilities.

The minimum tools for PMC M&E include the following.

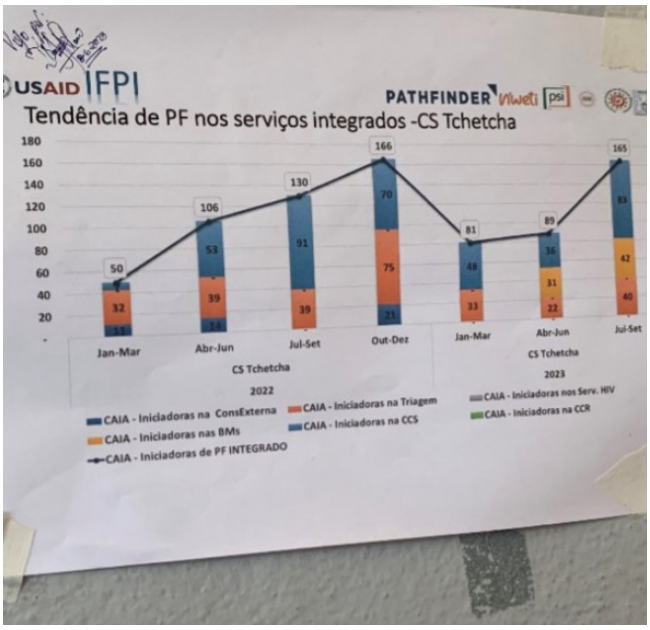
- Child's home-based record
- EPI register
- Tally sheet/book
- Monthly report
- Inventory sheets

It is strongly recommended that malaria programs use the existing national HMIS, especially if it is DHIS2, for data management and not a separate or parallel system. This allows for sustainability, as it is a multi-health system, well-funded, and already understood and maintained as it pertains to data entry and management. Additional data can be collected through household surveys after a certain period of time, especially for coverage and impact assessments.

In addition, wall charts can be useful for health facilities to monitor indicators assessing administration of services and the health of the population in their catchment areas. These can be done manually (as shown on the left below) or printed out using automated DHIS2 or Excel visuals, which may be brought to the facility by the district during visits (as shown on the right, on the following page).



Examples of wall charts.
© Unitaid Plus Project in Mozambique



10.5 M&E-RELATED RESPONSIBILITIES OF ACTORS AT DIFFERENT LEVELS

Level	Roles
Central (national)	• Monthly monitoring of PMC-related indicators, including malaria cases and deaths • Decision-making based on results analyzed at the central level
Region	• Monthly monitoring of PMC-related indicators, including malaria cases and deaths • Decision-making based on results analyzed at the regional level
District	• Validation/quality assurance of facility reports, including feedback to facilities • Data entry into national HMIS • Monthly monitoring of PMC-related indicators, including malaria cases and deaths • Decision-making based on results analyzed at the district level
Facility	• Validation/quality assurance of CHW reports, including feedback to CHWs • Data collection, validation, and reporting by health facilities • Monthly monitoring of PMC-related indicators, including malaria cases and deaths • Decision-making based on results analyzed at the facility level
Community	• Data collection, validation, and reporting by Community Health Workers • Monthly monitoring of PMC-related indicators, including malaria cases and deaths • Decision-making based on results analyzed at the community level

11. PHARMACOVIGILANCE

Zuamuze walks the four-hour journey with her friends and their children from her village to Guara Guara Health Facility in Sofala Province, Mozambique.

11.1 DEFINITION OF PHARMACOVIGILANCE

The WHO defines pharmacovigilance[10] as the "science and activities relating to the detection, assessment, understanding and prevention of adverse events (AEs) or any other possible drug-related problems." It encompasses risk management and the prevention of medication errors, the dissemination of information on medicines, action to promote the rational use of medicines and preparedness for crisis situations.

The principal aims of pharmacovigilance programs are to:

- Improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions.
- Improve public health and safety in relation to the use of medicines.
- Contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use.
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.

When introducing a new intervention like PMC, it is necessary to:

- Ensure the existing national monitoring system is aware of the new intervention and prepared to detect and report all AEs occurring during or after administration of any medicines.
- Organize the system for prompt management of detected AEs.
- Investigate all serious AEs.
- Assist healthcare providers at all levels to ensure better collection and reporting of AEs notification and investigation forms, as well as better communication about them.

11.2 ADVERSE EFFECTS/ EVENTS OF SP

Adverse event (AE): The term "adverse event", unlike "adverse reaction", does not prejudge a causal link with exposure, particularly to a drug. An adverse event is any noxious and unintended occurrence in a person during treatment, whether considered to be drug related or not. Depending on the degree of seriousness, an adverse event may be minor or serious.

A **minor AE** is considered to be an adverse event or effect:

- Not life-threatening.
- Not requiring hospitalization.
- Occurring within 30 days of SP administration.

The most frequently encountered minor adverse events or reactions associated with the administration of SP are:

- Skin rash
- Cutaneous vascularity
- Pruritus
- Urticaria
- Sore throat
- Fever
- Photosensitivity

A **Serious AE** is any medical event occurring within 30 days of SP administration and which causes or leads to:

- A life-threatening illness for the child
- Hospitalization of the child
- Significant or persistent disability
- Death

Clinical signs potentially associated with severe AEs include Lyell syndrome and Steven Johnson syndrome.

10. WHO: Pharmacovigilance: ensuring the safe use of medicines. Geneva, WHO, October 2004. *iris.who.int/bitstream/handle/10665/68782/WHO_EDM_2004.8.pdf?sequence=1*

11.3 RECORDING AND REPORTING ADVERSE EVENTS

For SP, monitoring of adverse events begins on the 1st day of administration and ends 30 days later. The following documents are required for the investigation and reporting of AEs:

CHILD'S HOME-BASED RECORD (I.E. CHILD HEALTH CARD/BOOKLET):

The child's home-based record is an important element for reporting and investigating an AE. In the case of SP administration alongside vaccination, the record of SP administration is the same as the record for vaccination. Health workers can therefore check that the patient's administration/vaccination record is available if they suspect an AE. Only the information on the duly completed administration/vaccination record will enable identification of the drugs involved (manufacturer, batch number, date of manufacture and expiry date), the precise location and the date of administration of the SP.

ADVERSE EVENT REPORTING FORM:

Most countries have a national AE reporting form (pharmacovigilance form issued by the Ministry of Health) used for general pharmacovigilance of all administered medications. This form must be completed in full by the healthcare provider, or the CHW if permitted.

11.4 PHARMACOVIGILANCE ACTIVITIES

The table below provides a non-exhaustive list of these activities which may or may not apply in each country.

11.5 PHARMACOVIGILANCE TOOLS

The tools used in pharmacovigilance are as follows:

- The AE notification form
- AE investigation form
- Investigation report
- National Pharmacovigilance Guide

Notification must be made no later than 48 hours after admission of the case. If a patient has been notified by both the CHWs and the heath care provider, the latter will put the two forms together before forwarding them to the district. In the case of a severe AE, the healthcare provider will also have to complete an investigation form, which will be forwarded to the district. In addition, a team must carry out the investigation and forward the report within 24 hours.

Responsible	Activities to be carried out
District health services	• Oversee the detection, notification, investigation and management of serious AEs occurring in the districts. • Organize feedback on AEs.
Health areas	• Oversee the detection, reporting and management of serious AEs occurring in the districts. • Investigate serious adverse events observed in health facilities. • Organize feedback on AEs. • Compile and transmit data to district level.
Health facilities	• Report all AEs. • Investigate all serious AEs observed. • Promptly manage all suspected cases of serious and minor AEs. • Organize reporting of AEs.
Community	• Detect all cases of adverse reactions observed in households. • Report cases of AEs observed in the community requiring management. • Refer AEs occurring in the community and requiring management to health facilities.

REFERENCES AND LINKS

1. Community Intermittent Preventive Treatment for Malaria in Pregnancy Implementation Handbook. TIP TOP, Advancing prevention of malaria in pregnancy- Jhpiego, April 2022. *www.jhpiego.org/wp-content/uploads/2022/04/TIPTOP-C-IPTp-Implementation-Handbook.pdf*
2. Directives Nationales pour la Prise en charge du paludisme dans les formations sanitaires du Burkina Faso, Ministère de la santé du Burkina Faso, mars 2014. *www.severemalaria.org/sites/mmv-smo/files/content/attachments/2017-03-13/burkina%20faso%20treatment%20guidelines.pdf*
3. Directives Nationales de prise en charge des cas de paludisme. Programme National de lutte contre le paludisme République Centrafricaine, janvier 2013. *www.severemalaria.org/sites/mmv-smo/files/content/attachments/2017-0724/DIRECTIVES%20DE%20PRISE%20EN%20CHARGE%20PALUDISME%20Final_PDF.pdf*
4. Global Immunization Vision and Strategy 2006-2015. WHO/UNICEF, 2005. *www.afro.who.int/sites/default/files/2017-06/ivd%20-%20Global%20Immunisation%20Vision%20and%20Strategy%20GIVS_0.pdf*
5. Guide de mise en œuvre du traitement préventif intermittent chez le nourrisson. PNLP Cameroun-MINSANTE, septembre 2021.
6. Guide de supervision formative intégrée. Projet d'amélioration des services de santé Primaires (PASSP) - Ministère de la santé de Guinée, juin 2017. *www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi5ufGD_KaFAxWaTaQEHVQfCz8QFnoECCcQAQ&url=https%3A%2F%2Fportail.sante.gov.gn%2Fwp-content%2Fuploads%2F2022%2F08%2FGUIDE-DE-SUPERVISION-FORMATIVE_0306-2017.docx&usg=AOvVaw1D0786_EbVvQ1P020JI4x2&opi=89978449*
7. Le paludisme pendant la petite enfance : chimioprophylaxie pérenne du paludisme. Une intervention rentable pour réduire les maladies et les hospitalisations. MULTIPLY, juin 2022. *multiplyipti.net/wpcontent/uploads/2022/06/MULTIPLY-Fact-Sheet-June-2022-French-Interactive.pdf*
8. Monitoring and reporting of essential immunization catch up in the context of the Big Catch Up, January 2024.
9. New WHO recommendations for perennial malaria chemoprevention in young children (PMC). WHO, 29 July 2023. *mesamalaria.org/resource/new-who-recommendations-perennial-malaria-chemoprevention-young-children-pmc*
10. Manuel de formation sur le Chimio prévention saisionnière du paludisme. Medecines for Malaria Venture, 2013. *www.mmv.org/sites/default/files/uploads/docs/access/SMC_Tool_Kit/francais/CPS_MANUEL_DE_FORMATION.pdf*
11. Perennial Malaria Chemoprevention : Implementation guide. National Malaria Control Programme Mozambique.
12. Seasonal malaria chemoprevention with sulfadoxine–pyrimethamine plus amodiaquine in children: a field guide. Second edition, 26 May 2023.
13. "Seasonal vaccination with RTS,S/AS01E vaccine with or without seasonal malaria chemoprevention in children up to the age of 5 years in Burkina Faso and Mali: a double-blind,randomised, controlled, phase 3 trial." Dicko, Alassane et al. The Lancet. Infectious diseases vol. 24,1 (2024): 75-86. doi:10.1016/S1473-3099(23)00368-7.
14. Traitement préventif intermittent du nourrisson à la sulfadoxinepyriméthamine (TPIn-SP) pour lutter contre le paludisme en Afrique: Guide de la mise en oeuvre sur le terrain. Programme mondial de lutte antipaludique (GMP) et département Vaccination, vaccins et produits biologiques (IVB) et UNICEF. WHO/IVB/11.07F 2011. *iris.who.int/bitstream/handle/10665/70807/WHO_IVB_11.07_fre.pdf?sequence=1*

15. WHO guidelines for malaria. WHO, 16 October 2023. *iris.who.int/bitstream/handle/10665/373339/WHO-UCN-GMP-2023.01-Rev.1-eng.pdf?sequence=1*
16. Updated WHO recommendations for malaria chemoprevention among children and pregnant women. WHO, 3 June 2022. *www.who.int/news/item/03-06-2022-Updated-WHO-recommendations-for-malaria-chemoprevention-among-children-and-pregnant-women*
17. World Malaria Report 2023, WHO. *www.who.int/teams/global-malaria-programme/reports/world-malaria-report-2023*
18. WHO Guidelines for malaria. WHO, 14 March 2023. *iris.who.int/bitstream/handle/10665/366432/WHO-UCN-GMP-2023.01-eng.pdf*
19. WHO: Pharmacovigilance: ensuring the safe use of medicines. Geneva, WHO, October 2004. *iris.who.int/bitstream/handle/10665/68782/WHO_EDM_2004.8.pdf?sequence=1*
20. WHO minimum Requirements for a functional Pharmacovigilance System. *cdn.who.int/media/docs/defaultsource/medicines/pharmacovigilance/pv_minimum_requirements_2010_2.pdf?sfvrsn=8bfdc82a_1*
21. Xardel D. La communication. Paris : Dunod ; 2010 p.11. *www.cairn.info/la-communication--9782804159740-page-11.htm*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