

# End of Project evaluation for Unitaid's Investments in Perennial Malaria Chemoprevention

#### Unitaid

25 July 2025



#### **FINAL REPORT**



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#### **Contents**

Ex	ECUTIV	E SUN	//MARY		
Ac	RONYM	ıs		<b>V</b> !	
1.	INTRO	DUC	TION, EVALUATION OBJECTIVES AND METHODOLOGY	1	
	1.1.	Ba	ckground to Unitaid's investments in PMC	1	
	1.2.	Eva	aluation objectives	2	
	1.3.	Eva	aluation framework and methodology	2	
	1.4.	Re	port structure	6	
2.	FINDI	NGS .		7	
	2.1.	Re	levance and coherence	7	
	2.2. Effi		ciency		
	2.3.	Effe	ectiveness, sustainability and scale-up	16	
	2.4.	Imp	pact	37	
3.	Conc	CLUSIC	ONS	41	
4.	RECO	MME	NDATIONS	43	
<b>Α</b> P	PENDIX	Α	BIBLIOGRAPHY	45	
ΑP	PENDIX	В	CONSULTATION LIST AND INTERVIEW GUIDE	49	
ΑP	PENDIX	С	Unitaid theory of change for the PMC intervention	55	
ΑP	PENDIX	D	DEDOOSE ANALYSIS AND UNITAID CONTRIBUTION ASSESSMENT	56	
ΑP	PENDIX	E	PROJECT LOGFRAME AND ACHIEVEMENT	59	
ΑP	PENDIX	F	DELAYS IN ETHICAL APPROVAL OF RESEARCH COMPONENT	65	
ΑP	PENDIX	G	PMC ADOPTION IN FOCUS, PLUS-THREE AND NON-PROJECT COUNTRIES	71	
<b>Α</b> P	PENDIX	Н	COMMUNITY AND CIVIL SOCIETY ENGAGEMENT ACTIVITIES	75	
<b>Α</b> Ρ	PENDIX	1	PMC IMPLEMENTATION AND TRACKING TOOLS DEVELOPED	77	
<b>Α</b> P	PENDIX	J	PMC Institutionalisation framework and status reflection tool	79	
<b>Α</b> Ρ	PENDIX	K	PMC INSTITUTIONALISATION IN THE FOUR FOCUS COUNTRIES	85	
ΑP	PENDIX	L	PLUS PROJECT DISSEMINATION ACTIVITIES	89	
Αр	PENDIX	М	IMPACT MODELLING METHODOLOGY	91	



#### **EXECUTIVE SUMMARY**

#### Introduction

Despite being a preventable and treatable disease, malaria remains a leading cause of illness and death globally with the burden felt most strongly by infants and children in sub-Saharan Africa. While Perennial Malaria Chemoprevention (PMC) has been found to be an effective tool, with positive impact on rates of clinical malaria and anaemia in infants and children, uptake had been low with only Sierra Leone adopting Intermittent Preventive Treatment in Infants (IPTi) (now PMC) in 2016. This was due to multiple access and adoption barriers including restrictive country policies, low demand, limited access and insufficient supply. In this context, Unitaid made investments in IPTi/ PMC in 2021 through two complementary projects - The Plus Project and Medicines for Malaria Venture (MMV) Supply Grant, presented in Table E.1.

Table E.1: Summary of Unitaid PMC investments

Grant name	Grantees	Duration	Budget	Key objectives	Focus countries
The Plus Project	Population Services International (PSI) <sup>1</sup>	Aug 2021-Oct 2025, no-cost extension until Mar 2026	US\$35.5m	Generate evidence and promote uptake of PMC for children through co-design of country specific PMC pilots and evaluation	Benin, Cameroon, Côte d'Ivoire, Mozambique (termed 'focus countries') Additional research in DRC, Ghana, and Zambia (termed 'Plus- Three countries')
Supply Grant (Output 4)	Medicines for Malaria Venture (MMV)	Dec 2020 – Sept 2024	US\$1.4m	Improve global supply of quality assured SP for PMC	Sub-Saharan malaria endemic countries Manufacturers supported for WHO PQ in Nigeria

#### Evaluation objectives, framework and methodology

The evaluation objectives were to provide Unitaid with an end of project evaluation for the Plus Project and the MMV Supply Grant (Output 4). The evaluation was theory-based and assessed the success of the projects overall including relevance, coherence, efficiency, effectiveness, sustainability/ scalability and impact, as well as lessons learned with a focus on the extent to which the projects have accelerated and advanced the uptake of PMC. The methods included document review, 52 stakeholder and focus-group interviews, two country case studies (Côte d'Ivoire and Mozambique), impact modelling and workshop/ presentations with Unitaid Secretariat and partners. Key limitations include an incomplete dataset for this evaluation – including the Plus Project's final results and select research results, which will be available after the conclusion of the evaluation. Furthermore, the evaluation has been conducted at a time of much change and uncertainty with regards to the global financing environment.

#### **Evaluation findings and lessons learnt**

#### Relevance and coherence

1. Unitaid's investments in PMC were relevant as they were responsive to the malaria epidemiological context, promoted equity and comprehensively targeted the range of access barriers restricting PMC uptake.

<sup>&</sup>lt;sup>1</sup> PSI had a consortium approach to implementing the project and this included London School of Hygiene and Tropical Medicine, Centre de Recherche Entomologique de Cotonou (Benin), the Fobang Institutes for Innovations in Science and Technology (Cameroon), the Tropical Disease Research Center (Zambia), the University of Kinshasa (DRC), and the Universities of Copenhagen and South Florida.



- 2. The project was 'ahead of the curve' in terms of the new 2022 World Health Organisation (WHO) guidelines on PMC. There were some gaps in its scope in that it did not cover additional research areas highlighted by WHO and donors and what would support an update to the subsequent WHO guidelines, but it has considerable value in providing implementation evidence for the planned 2026 field manual by WHO.
- 3. Though the landscape for malaria prevention interventions has changed during the course of the project, PMC remains relevant within a package of prevention interventions.
- 4. The Plus Project co-design feature with country governments was a real strength and fostered national ownership of the PMC strategy. Select other design features such as the misalignment in timings between research and implementation and limited engagement with the Plus-three countries have been challenging.
- 5. The Plus Project was viewed as highly collaborative, with PSI and London School of Hygiene and Tropical Medicine (LSHTM) supporting coherence with other partners including through the Community of Practice (COP).

#### Efficiency

- 6. Overall, both PSI and MMV managed their investments well.
- 7. With regards to the Plus Project, of 22 research study sites for which information on the ethical approval process is available, 10 were delayed. Noting the longstanding timelines challenges with Ethical Review Committee (ERC) processes (WHO and country), some additional areas of improvement include early agreement on country and research partners and training of local researchers on ERC approval processes.
- 8. With regards to the MMV Supply Grant work, Swipha and Emzor have taken four years to submit dossiers for SP dispersible for WHO Pre-qualification (PQ) since the start of the project, with planned timelines deemed ambitious for manufacturers with no prior expertise in WHO PQ.

#### Effectiveness

- 9. Innovation and availability New SP-PMC products are now available, also due to leveraging of prior Unitaid investments for Intermittent Preventive Treatment in Pregnancy (IPTp) and Seasonal Malaria Chemoprevention (SMC). However, while solid progress has been made, manufacturers supported directly through this project have not yet succeeded with PQ. The work by MMV has been instrumental and the progress achieved would not have been possible in the absence of the grant. Unitaid's support for regional manufacturers is considered to be a valuable investment and expected to provide ongoing benefits beyond the timeframe of the project. Future viability of the supply of the new products may be in question with unclear demand from countries in the wake of the global financing crisis.
- 10. Demand and adoption There has been good progress on addressing the demand and adoption access barrier in a number of countries since the initiation of the Plus Project with PMC being included in national policies. The level of contribution of the project in this regard has varied by country.
- 11. Demand and adoption The project's several research studies are expected to be valuable for supporting countries with evidence base and implementation guidance on PMC, and are currently being finalised. LSHTM's inability to share results until finalised, while prudent, presents a missed opportunity to leverage alongside close out of PSI's implementation support in countries.
- 12. Supply and delivery The Plus Project has helped address the supply and delivery access barrier by expanding the potential approaches to PMC delivery, with the main challenge being with regards to coverage of PMC, especially in the second year of children's lives. Delivery through existing national health programmes has its efficiency benefits but PMC coverage is limited by the reach of the Expanded Programme on Immunisation (EPI) and nutrition programmes and the extent of coordination between these and the malaria programme.



#### Sustainability/ scalability

13. The Plus Project has well supported a number of aspects for the institutionalisation and scalability of PMC in the four focus countries, although not uniformly across countries. There is good political support and a degree of integration within health systems, and while some have included PMC in their Global Fund funding requests, financing is an important issue in light of the current global health financing status – an unexpected factor beyond the control of the project.

#### **Impact**

14. PMC has demonstrated some valuable health and economic impact, although this is lower than initially envisioned. This is primarily due to lower than expected PMC dose delivery, with only 2 doses delivered per eligible child, and lower scale-up due to constraints in the global health funding landscape.

Lessons learnt – (+) denotes positive experience from the projects, (-) negative and (±) mixed

- (+) A consolidated end-to-end approach to investment design in terms of considering the range of access barriers on both the demand and supply side is relevant, appropriate and effective.
- (+) Co-designing interventions with country stakeholders is an effective approach for Unitaid to consider
  across its projects. Ensuring a process whereby all relevant stakeholders are engaged and "learning by
  doing" is incorporated throughout the implementation process can support further optimisation of this
  approach.
- (-) Better or more thoughtful alignment of research and implementation timelines, especially for focus
  countries where considerable investment has been made and stakeholders have been engaged is
  important. So far, as PSI has closed-out in focus countries and LSHTM is finalising research results, it is a
  missed opportunity not to "sell" the research findings to country stakeholders during close-out.
- (-) Timelines for research studies will always be impacted by the complex ERC processes (global and country) and so Unitaid should plan for other aspects to shorten overall research timelines such as early identification of countries and local research partners as well as providing capacity building support to local researchers on ERC processes.
- (±) Supporting local manufacturers achieve WHO PQ for quality products is a complex undertaking, and
  despite best efforts, can be challenging to achieve and is heavily dependent on the manufacturer's
  capacity and prior history with WHO PQ. On the other hand, prior PQ experience can hasten
  manufacturer capacity for future PQs.
- (-) The Plus Project is not showing much linkage with policy adoption in Plus Three countries or non-project African countries. There are good efforts in these countries within available budgets, but impact is more distal. It may be useful to rebalance budgets across countries so Plus Three countries received a little more support. Further support will be needed to accelerate PMC uptake.
- (+) Integration of health programmes is of top priority, is people centred and also extremely relevant in the current global health financing environment. Donor programmes should incorporate approaches that encourage this integration.
- (-) Unitaid's sustainability and scalability model relies predominantly on international donors supporting
  the intervention following the pilot projects. In the current global health international financing situation,
  this assumption is risky and exploring ways to encourage domestic financing or alternative innovative
  financing measures is paramount.

#### Recommendations

The following <u>four recommendations</u> are proposed for Unitaid to ensure effective close out of the project and that the gains from the project are fully maximised. These recommendations do not necessarily suggest Unitaid invest further in PMC – rather, that it engages with project implementers to ensure outstanding activities are completed and objectives are realised. However, should some additional funding become available, then this could potentially be used for discrete activities to facilitate adoption and scale-up.



- 1. Ensure smooth and effective close-out of the Plus Project, particularly in terms of ensuring research results are concluded and made available widely (for focus countries, Plus-Three and other countries (governments, communities) as well as the WHO implementation manual). A no-cost extension is in place with PSI to support dissemination with countries. PSI's engagement with this evaluation is also a testament of their commitment to support effective dissemination. The COP is also a useful modality to support widespread dissemination, a model that Unitaid could consider sustaining for the future.
- 2. Consider select opportunities with the four focus countries and non-project countries to support drivers for scale-up of PMC. This may include direct Unitaid engagement with country governments or additional funding to grantees or other technical partners for technical assistance (TA) to aid countries in accessing funding from the Global Fund or domestic budgets, or to pilot implementation in non-project countries. Another important area for TA is to ensure PMC is integrated into national systems like data systems and supply chains.<sup>2</sup>
- 3. Follow-up with MMV to ensure its continued engagement with the two Nigerian manufacturers on support for WHO PQ and also on their supply viability position. MMV continues to engage with the suppliers beyond Unitaid funding. This value-added commitment from MMV should be followed up upon by Unitaid.
- 4. Advocate that PMC does not get deprioritised by the global community, especially through prioritising strong dissemination of project implementation and research findings at select fora even after the conclusion of the projects. Several stakeholders mentioned that this requires communicating clearly the value add of PMC in terms of its cost-effectiveness and its opportunity to complement and build on the malaria vaccine, which is currently receiving most attention both by malaria and EPI programmes.

The following <u>eight recommendations</u> are proposed for Unitaid in line with its strategy and to foster future results across its portfolio, based on learnings from the PMC investment, including the recent experience of the project in the face of the constrained global health financing situation. Aspects that the projects did well and not so well in this regard are highlighted in italics font.

- 5. Unitaid should increase emphasis on scalability through domestic budgets in the face of the growing financing crisis in global health. The co-design with governments approach employed by PSI is an important strategy in this regard. Other examples may include efforts by grantees to align their work with country planning and budgeting cycles, greater emphasis on country political and policy level engagement, greater engagement with multilateral development banks and country finance ministries to explore additional sources of funds, supporting the development of public private partnerships with faith-based companies or private insurances to support PMC funding; etc. Upfront and ongoing engagement on these aspects is essential (rather than one-off or only as project close).
- 6. Unitaid should reconsider its role within the regional manufacturing agenda in light of the constrained global health financing environment, with key partners supporting regional manufacturing with likely reduced budgets (e.g. Global Fund, US development aid). This implies that Unitaid's own contribution within the context of what other players do might require a re-think. These reductions will impact available funding both for research and development support for manufacturers as well as purchase of commodities, and therefore Unitaid will need to think about its role and added value in this context (e.g. advocating for solidarity of national governments to procure SP-PMC from African PQ-ed manufacturers whilst ensuring development of a healthy competitive market; further emphasising affordability of the products produced by local manufacturers so they are competitive

<sup>&</sup>lt;sup>2</sup> For data integration, this could be through modifying existing data collection tools, adapting DHIS2 modules like the routine immunization or malaria dashboards to include PMC-specific indicators. For supply chain integration, this could be through strengthening supply chain management by linking DHIS2 with the logistic management system to ensure accurate forecasting, procurement, and distribution of PMC commodities; and tracking drug consumption patterns at different levels of the health system to optimize supply chain efficiency and ensure timely replenishment of stocks.



with established global manufacturers; strengthening African pooled procurement mechanisms such as the Southern African Development Community (SADC) Pooled Procurement Mechanism to reduce fragmentation and improve efficiency).

- 7. **Unitaid should emphasise integration across its investments** *with PMC, integration with EPI presented a solid opportunity*, and similar opportunities for other products should also be harnessed, especially noting the constrained global health financing environment. Support for integration needs to be considered carefully noting the pitfalls with combining multiple services without effective planning. For example, future projects should include specific components to assess and mitigate increased workload on health workers when integrating new interventions. This could involve funding for additional temporary staff, incentives, or efficiency-enhancing tools and training to prevent burnout and maintain quality of care across all services.
- 8. Unitaid should carefully think through the optimal management of research and implementation within its projects ensuring the needed synergies between the two to effectively support its work on fostering demand and adoption. This was a missed opportunity in the Plus Project. Potential actions include early planning, timely confirmation of countries and partners (and avoid changing countries midway), and training of local researchers on ERC approvals process. On the point on countries, Unitaid could provide a steer on focus countries during the call for proposals so avoid changing countries later on.
- 9. Unitaid should consider its added value in countries where its investments and engagement (through grantees) is minimal, and whether there might be alternate ways to ensure wider scalability an aspect that worked less than optimally for the Plus Project design. Examples of alternate areas of focus include working closely with WHO to produce guidelines in a timely manner, enhancing work with donors to direct funding in needed areas, enhancing work with partners to ensure the most appropriate TA is provided to countries, supporting advocacy efforts with governments, developing a COP type platform, etc. There may also be a case to rebalance funding across countries to ensure a certain "threshold" of support is received by each country.
- 10. Unitaid should exploit scale-up based on implementation evidence, where feasible. For example, where a WHO recommendation already exists (as is the case for PMC) and countries have champions and have expressed interest. Unitaid should encourage grantees to work with countries and consider scale-up options based on implementation evidence. Approaches may then be course corrected, as needed, when full research results are available. Such an approach also needs support from WHO at both the global and country levels.
- 11. Unitaid's should comprehensively consider demand and supply related access barriers portfolio for innovative health products/ interventions (as was done through the PSI/ MMV work for PMC) and ensure a consolidated approach to funding, reflective of other partner priorities and funding.
- 12. **Unitaid should encourage the iterative co-design process with countries,** *facilitated through the Plus Project*as relevant for other products and portfolios. Engagement with the range of stakeholders should be encouragedbeyond government, also with community stakeholders and frontline health workers. There should also be mechanisms for project course correction and adaptation by learning in countries in an agile yet structured fashion.



#### **ACRONYMS**

Acronym	Definition
API	Active Pharmaceutical Ingredient
ASTMH	American Society of Tropical Medicine & Hygiene
BE	Bioequivalence study
CHW	Community Health Workers
СОР	Community of Practice
DRC	Democratic Republic of Congo
EPI	Expanded Programme on Immunisation
ERC	Ethical Review Committee
EU	European Union
FGD	Focus group discussion
GMP	Good Manufacturing Practices
IPTi	Intermittent Preventive Treatment in Infants (now PMC)
ІРТр	Intermittent Preventive Treatment in Pregnancy
KII	Key informant interviews
LSHTM	London School of Hygiene and Tropical Medicine
MMV	Medicines for Malaria Venture
NMCP	National Malaria Control Programme
PCPI	Parasite Clearance and Protection from Infection study
PMC	Perennial Malaria Chemoprevention
PMI	President's Malaria Initiative
PQ	Pre-qualification
PSI	Population Services International
RBM	RBM Partnership to End Malaria
RCT	Randomised Controlled Trial
SADC	Southern African Development Community
SMC	Seasonal Malaria Chemoprevention
SP	Sulfadoxine-Pyrimethamine
SPAQ	Sulfadoxine-Pyrimethamine and Amodiaquine
ТоС	Theory of Change
UCL	Universal Corporation Ltd
WHO/ WHO AFRO	World Health Organization/ WHO Regional Office for Africa



# 1. INTRODUCTION, METHODOLOGY

#### **EVALUATION**

**OBJECTIVES** 

AND

This report presents Cambridge Economic Policy Associates' (CEPA's) evaluation of Unitaid's investments in Perennial Malaria Chemoprevention (PMC).

This first section provides the investment background (Section 1.1), evaluation objectives and priorities (Section 1.2), the evaluation framework and methodology (Section 1.3) and the structure of the rest of the report (Section 1.4).

#### 1.1. BACKGROUND TO UNITAID'S INVESTMENTS IN PMC

Despite being a preventable and treatable disease, malaria remains a leading cause of illness and death globally with the burden felt most strongly by infants and children in sub-Saharan Africa. According to the latest World Malaria report 2024, there were 263 million cases of malaria in 2023 compared to 252 million in 2022, reflecting the challenge in reducing infections. The estimated number of malaria deaths was 597,000 in 2023 compared to 600,000 in 2022. The World Health Organization (WHO) African Region continues to carry a disproportionately high share of the global malaria burden, including 94% of all malaria cases (246 million) and 95% of all malaria deaths (569,000) in 2023. In 2019, prior to the start of investments, 24 million children are estimated to have been infected with malaria in the WHO African Region – of whom 12 million had moderate anaemia and 1.8 million had severe anaemia. In 2024, the proportion of deaths due to malaria remains high among children (76% of all malaria deaths in the WHO Africa Region still occur in children under 5 years of age).

To reduce malaria morbidity and mortality in infants and children, in 2010, WHO recommended intermittent preventive treatment in infants (IPTi) with sulfadoxine-pyrimethamine (SP) in areas of moderate to high malaria transmission, i.e. where transmission occurs throughout the year. The 2010 recommendation was on the use of SP at three contacts of the Expanded Programme on Immunisation (EPI) during the first year of life, at two, three, and nine months of age timed with the second and third doses of the Diphtheria, Pertussis, and Tetanus (DPT)/ Pentavalent and measles vaccine. WHO also recommended IPTi only in areas where SP resistance was low (defined as a prevalence of the pfdhps 540 mutation below 50%). In 2022, the WHO renamed the IPTi intervention, PMC, and updated its recommendation to be less restrictive, specifically allowing for greater flexibility on the number and frequency of antimalarial doses given and the age of children who can receive them to better suit local contexts. WHO also removed restrictions on the use of SP based on prevalence of pfdhps 540 mutations. The 2022 WHO recommendation for PMC is conditional however, based on moderate certainty of evidence.

Overall, PMC has been found to be an effective tool, with positive impact on rates of clinical malaria and anaemia in infants and children; however uptake had been low with only Sierra Leone adopting IPTi in 2016. This was due to multiple access and adoption barriers including restrictive country policies, low demand, limited access and insufficient supply. Given a shifting landscape around malaria prevention, particularly with progress on malaria vaccines, countries need to make challenging decisions regarding the most appropriate and cost-effective malaria prevention strategies.

Unitaid began its investments in IPTi/ PMC in 2021 through two related projects described in Table 1.1, namely the Plus Project and Medicines for Malaria Venture (MMV) Supply Grant (Output 4). These aimed to be complementary investments, with the Plus Project focusing on expanding access and adoption of PMC through in-country implementation support and research and MMV addressing the need for high-quality supply with a regional manufacturing focus.

Table 1.1: Summary of Unitaid PMC investments

Grant name	Grantees	Duration	Budget	Key objectives	Focus countries
The Plus Project	Population Services	Aug 2021-Oct 2025, no-cost	US\$35.5m	Generate evidence and promote uptake of PMC for	Benin, Cameroon, Côte d'Ivoire, Mozambique



Grant name	Grantees	Duration	Budget	Key objectives	Focus countries
	International extension until (PSI) <sup>3</sup> Mar 2026		children through co-design of	(termed 'focus countries')	
				country specific PMC pilots and evaluation	Additional research in DRC, Ghana, and Zambia (termed 'Plus-Three countries')
Supply Grant (Output 4)	Medicines for Malaria Venture	Dec 2020 – Sept 2024	US\$1.4m	Improve global supply of quality	Sub-Saharan malaria endemic countries
	(MMV)			assured SP for PMC	Manufacturers supported for WHO PQ in Nigeria

#### 1.2. EVALUATION OBJECTIVES

The evaluation objectives were to provide Unitaid with an **end of project evaluation** of the Plus Project and the MMV Supply Grant (Output 4).

The evaluation assessed the success of the projects overall *including relevance, coherence, efficiency, effectiveness, sustainability/ scalability and impact*, as well as *lessons learned* with a focus on the extent to which the projects have accelerated and advanced the uptake of PMC. The findings and lessons learnt from the evaluation will inform Unitaid's future projects in this area.

Select areas for deep-dive on lessons learnt include: (i) impact of the projects on regional manufacturing for equitable access; (ii) WHO's conditional recommendation on PMC linked with expected manual post project; (iii) relevance of the decision support tool delivered as part of the project; (iv) effect of important evidence being available after support for country level activities have ended; (v) product development and approval assumptions and delays that led to extensions/ incomplete deliverables

The evaluation scope covered the life of the two projects. At the time of the evaluation, the Plus Project's in-country implementation work has been completed but the research findings are being collated and finalised. As such, the final PSI progress report to Unitaid has not been available as well as most of the research results. The MMV investments has concluded and the final report to Unitaid has been available.

#### 1.3. EVALUATION FRAMEWORK AND METHODOLOGY

The evaluation framework and methodology is presented in Figure 1.1. This is a theory-based evaluation based on the investment Theory of Change (Appendix C) supported with contribution analysis. The evaluation questions have been structured around the OECD DAC evaluation criteria grouped in four pillars: (i) relevance and coherence; (ii) efficiency; (iii) effectiveness, sustainability/scalability; and (iv) impact, and are mapped to the Unitaid Strategic Objectives. Mixed methods have been employed (described in Section 1.3.1), supported by a robustness assessment framework for findings (described in Section 1.3.2). The evaluation has had a utilisation focus by focusing on lessons learnt and engaging with a wide stakeholder group for information gathering and review of findings.

<sup>&</sup>lt;sup>3</sup> PSI had a consortium approach to implementing the project and this included London School of Hygiene and Tropical Medicine, Centre de Recherche Entomologique de Cotonou (Benin), the Fobang Institutes for Innovations in Science and Technology (Cameroon), the Tropical Disease Research Center (Zambia), the University of Kinshasa (DRC), and the Universities of Copenhagen and South Florida.



Figure 1.1: Evaluation framework and methodology<sup>4</sup>

OECD DAC Evaluation Criteria	Evaluation Questions	Learnings
Relevance, Coherence	<ul><li>1.To what extent are the projects relevant to beneficiary needs and adaptive to changes and context, including being responsive to issues on gender, social inclusion and equity? (SO3)</li><li>2. How well do the projects fit in the context of other malaria interventions and priorities? (SO3)</li></ul>	<ul> <li>Project design &amp; targeting</li> <li>Effective demand driven partnerships</li> <li>Unitaid role and coordination</li> <li>Value add</li> </ul>
Efficiency	3. Have the projects been time and budget efficient and has implementation been collaborative and integrative with countries (Plus Project) and reflective of efficient product development (MMV)?	Reasons for delays, mitigation actions     Factors driving efficient production
Effectiveness, Sustainability/ Scalability	<ol> <li>Is the intervention achieving its objectives as per the access barriers identified (innovation and availability; demand and adoption; supply and delivery) and is the investment catalysing and promoting global policy adoption and country implementation in project and non project countries? (SO1)</li> <li>How sustainable are the gains and what gaps remain? Have the projects primed scale-up at global and country levels and what are key driving factors? What are future prospects under the current complex funding environment? (SO1)</li> <li>What is the impact and value add of supporting regional manufacturing of SP products for PMC? (SO2)</li> <li>How well have the projects disseminated knowledge, evidence and lessons on equitable access and has this contributed to broader awareness/ support for these areas? (SO2)</li> </ol>	Product development and mark shaping results, value Learnings from country experiences on adoption, uptak sustainability and scalability Status/ expectations in current complex funding environment Iffective approach to supporting effective regional manufacturing WHO recommendation context Project tools and dissemination Post project and non project country influence and actions Lessons on systemic conditions driving access
Impact	8. Are the projects' impacts still valid at this end-term and aligned with Unitaid's framework and approach?	•Impact assessment methodolog

#### Approach

- ❖ Overall approach Theory based approach with contribution analysis
- Supporting frameworks assessing robustness, effect, significance
- Utilisation-focused evaluation, with learning emphasis
- Inclusive, community and equity responsive
- Software-supported qualitative data analysis for robustness

#### Methods

- Document review- Grantee, Unitaid, wider literature
- Key stakeholder and focus group interviews – strong focus on external interviews (including remote data collection from non-case study countries)
- ➤ 2 country case studies in Cote d'Ivoire and Mozambique
- > Impact assessment

Overall conclusions and actionable recommendations cognizant of future landscape

<sup>&</sup>lt;sup>4</sup> Unitaid Strategic Objectives reflected in the figure are: SO1 – accelerate the introduction and adoption of key health products, SO2 – create systemic conditions for sustainable, equitable access, SO3 – foster inclusive and demand-driven partnerships for innovation.

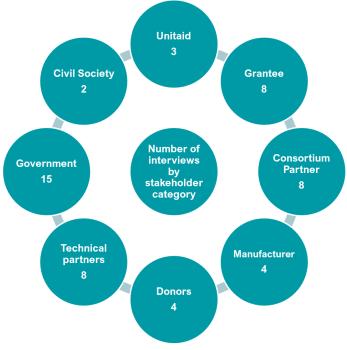


#### 1.3.1. Mixed methods evaluation

Table 1.2 below details the key methods applied for the evaluation.

Table 1.2: Evaluation methods

able 1.2. Evaluation methods				
Method	Detail			
Document review	Includes grant documentation, wider Unitaid documentation, reports from the grantees, and partner documents. A bibliography is provided in Appendix A.			
Key stakeholder and focus-group interviews	Semi structured key informant interviews (KIIs) and focus groups discussions (FGDs) were conducted with a mix of internal (Unitaid, grantees, consortium partners at global and country level) and external stakeholders (including malaria donors (Global Fund, President's Malaria Initiative (PMI), GiveWell), technical partners (WHO – HQ and regional, PATH, RBM Partnership to End Malaria (RBM)), SP-manufacturers, additional country stakeholders beyond country case studies – see below).			
	A total of 52 interviews were conducted (23 at global level, 7 in non-case study countries and 22 in country case studies – see below).			
	Figure 1.2: Number of interviews by stakeholder group			



Interviewee list and guides are provided in Appendix B.

Analysis was supported by the qualitative coding software Dedoose, in order to systematically assess the spread of evidence from KIIs against the evaluation framework (see Section 1.3.2 and Appendix D for further details).

	framework (see Section 1.3.2 and Appendix D for further details).
Country case studies	Two in-person country case studies were conducted in Côte d'Ivoire and Mozambique covering document review and interviews with key stakeholders. Appendix B also includes the interviewee list in both countries.
Impact modelling	The grantee impact model was reviewed. CEPA developed an Excel-based impact model which is closely based on the grantee impact model. Appendix M provides an overview of the impact modelling approach.
Virtual workshops/ presentations	Virtual workshops/ presentations with Unitaid Secretariat and partners on key findings, conclusions and recommendations from the evaluation to validate and ensure the relevance of the findings/ conclusions and usability of the recommendations.



#### 1.3.2. Interview coding using Dedoose

A Dedoose-supported<sup>5</sup> analysis of KIIs, encompassing interviews at both global and country levels, has supported the assessment of the strength of evidence.

From the 52 KIIs reviewed, 1,081 excerpts of data were coded. Table 1.3 demonstrates the distribution of data across a selection of key codes. Data excerpts can be associated with multiple codes. As seen in table, all evaluation questions were based on robust qualitative data with a strong quantity of KII evidence to support triangulation. The highest amount of KII evidence supporting findings related to relevance and effectiveness. A more complete analysis is presented in Appendix D.

Table 1.3: Number of data excerpts by key code

Code	# of excerpts
EQ1 Relevance	385
EQ2 Coherence	215
EQ3 Efficiency	140
EQ4 Effectiveness	462
EQ5 Sustainability/ Institutionalisation & Scalability	228
EQ6 Value-add of regional manufacturing	86
EQ7 Knowledge and evidence dissemination	109
Total	1,625

#### 1.3.3. Robustness assessment framework

Evidence was collated across methods and the strength of evidence was assessed based on the quality and quantity of the evidence. Table 1.4 presents the strength of evidence framework. All robustness rankings are relative robustness rankings, based on careful consideration and are ultimately judgement-based.

Table 1.4: Strength of evidence rating for findings

Rating	Assessment
High (4)	The finding is supported by multiple sources of data of generally good quality, allowing for robust triangulation including documents, different stakeholders in different contexts and majority of consultations (both quantitative and qualitative sources)
Medium (3)	The finding is supported by a few data sources of good quality, limited triangulation, where corroborative sources allow for reasonable but evidence coverage not complete.
Low (2)	The finding is supported by very limited evidence (1 or 2 sources) or by multiple sources of lower quality and no triangulation.
Insufficient (1)	The finding is supported by incomplete or unreliable evidence or contradictory consultations. Should not be included in report.

<sup>&</sup>lt;sup>5</sup> Dedoose is a qualitative data analysis application designed for mixed methods research. It supports qualitative coding, the process of systematically categorising and labelling segments of qualitative data (in this case, interview transcripts) to identify patterns. A codebook was developed based on the evaluation framework and applied to the interview transcripts.



#### 1.3.4. Limitations and mitigating actions

Table 1.5: Limitations and mitigation actions

Limitations	Mitigating actions
Incomplete dataset for this evaluation – including the Plus Project's final progress report and majority of the research results. These will be available after the conclusion of the evaluation.	<ul> <li>Comprehensively assessed documents that are available and reviewed documents in addition to grant documents, where available.</li> <li>Use of mixed-methods approach including consultations, country case studies and quantitative analysis to complement and triangulate information and findings across a number of evidence sources.</li> </ul>
The evaluation has been conducted at a time of much change and uncertainty with regards to the global financing environment.	<ul> <li>Where relevant the evaluators have noted the current situation of the global financing environment and its consequences. It is recognised that this may be different in the coming months.</li> </ul>
Key informants selection bias given many stakeholders suggested by grantees and Unitaid Secretariat	<ul> <li>Included some suggestions from evaluation team members in stakeholder list, especially at the country level to compliment informants suggested by grantees</li> <li>All interviewees were encouraged to provide objective data in their responses.</li> </ul>
Generalisation of country findings especially from country case studies to draw overall conclusions especially given the diversity in implementation of PMC approaches at the country level.	<ul> <li>Highlighted where the evidence base is based on select countries only and where there is divergence in experiences across countries.</li> <li>Complemented insights from country case studies with consultations with select non-case study country stakeholders.</li> <li>Used mixed-methods approach of document review and global level stakeholder consultations to add to findings from additional countries and grants as a whole.</li> </ul>

#### 1.4. REPORT STRUCTURE

Following this introduction, the report has been organised in the following sections: Section 2 provides the evaluation findings, including findings on Relevance and Coherence of the investments (Section 2.1); Efficiency (Section 2.2); Effectiveness, Sustainability and scale-up (Section 2.3); and Impact (Section 2.4). Lessons on the select evaluation deep dive areas are included within these sections. Section 3 presents overall conclusions and Section 4 provides recommendations for Unitaid investments in PMC and its wider portfolio.

The main report is supported by the following appendices: Appendix A includes the bibliography; Appendix B provides the list of global and country level consultations and interview guide; Appendix C presents the Unitaid Theory of Change (ToC) for investments in PMC; Appendix D the Dedoose analysis and Unitaid contribution assessment; Appendix E presents the project logframe and achievements reported by grantees; Appendix F presents ethical approval timelines for research protocols; Appendix G presents information on PMC adoption in countries; Appendix H describes community and civil society engagement activities; Appendix I presents PMC implementation and tracking tools developed; Appendix J summarises the PMC Institutionalisation Framework and Status Reflection Tool; Appendix K includes information on PMC institutionalisation in the four Plus Project focus countries; Appendix L lists dissemination activities; and Appendix M outlines the impact modelling methodology.

<sup>&</sup>lt;sup>6</sup> Research results made available for this evaluation include the impact of dhps mutations on SP protective efficacy, implications for malaria chemoprevention and the draft Decision Support Tool. Research results not yet available include the process evaluation, impact monitoring and evaluation, economic evaluation, and policy adoption and receptivity evaluation work packages.



#### 2. FINDINGS

This section of the report provides the findings of the evaluation as per the OECD DAC evaluation criteria.

A summary assessment of performance against the OECD DAC criteria is presented in Figure 2.1. This is based on a 5-point scale adopted by Unitaid as follows: (1) exceeded all expectations; (2) successfully met expectations; (3) met minimum expectations; (4) did not meet all expectations; and (5) did not meet any expectations. As the figure demonstrates, the PMC portfolio of investments did well in terms of being relevant and coherent, and less well on some efficiency parameters. Importantly, outcomes are being achieved in terms of positive progress towards addressing key access barriers, but scalability is at risk, in light of the current constrained global health financing environment and the need to better engage with domestic budgets. This is also one of the key reasons for lower than anticipated impact numbers (based on most realistic assumptions as of today). This assessment and the details behind it are discussed in the subsequent sections.

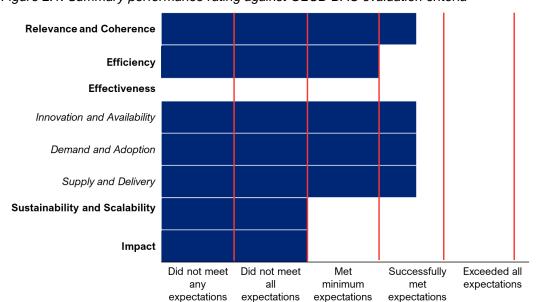


Figure 2.1: Summary performance rating against OECD DAC evaluation criteria

#### 2.1. Relevance and coherence

- 1. To what extent are the projects relevant to beneficiary needs and adaptive to changes and context, including being responsive to issues on gender, social inclusion and equity?
- 2. How well do the projects fit into the context of other malaria interventions and priorities?

Performance rating for the Plus Project and Supply Grant Output 4 – Successfully met expectations (partially)

**Explanation** – Unitaid's investments in PMC were relevant in that they responded well to the malaria epidemiological context, however it is recognised that the intervention is not a panacea in its own right and fits within a broader set of options for malaria prevention. The investment design has been strong and both projects are viewed as highly collaborative, especially PSI's approach on co-designing country implementation and its work on the Community of Practice (COP). There are some gaps in terms of misalignment of the research and implementation components of the Plus Project and the extent of catalytic impact for the Plus-Three countries.



# Finding 1: Unitaid's investments in PMC were relevant as they were responsive to the malaria epidemiological context, promoted equity and comprehensively targeted the range of access barriers restricting PMC uptake.

Strength of evidence rating	Rationale
High (4)	Confirmed through documentation and data, and strong agreement from global and country level stakeholders.

As highlighted in Section 1.1 on the PMC investment background, malaria remains a leading cause of illness and death globally with the burden felt most strongly by infants and children in sub-Saharan Africa. Unitaid's foray into PMC through the investments made to PSI and MMV were thus appropriately targeted at the important issue of preventing malaria amongst children in sub-Saharan Africa, building on its previous investments in Intermittent Preventive Treatment in Pregnancy (IPTp) and Seasonal Malaria Chemoprevention (SMC).

The investments promoted equity in terms of seeking to improve access to malaria prevention tools for children and empowering women to make health-related decisions for their children, given that women tend to engage with the childhood vaccination system which is the main delivery channel for PMC. Box 2.1 provides insights in this regard from the Côte d'Ivoire country case study.

#### Box 2.1. Gender, social inclusion and equity in Côte d'Ivoire through the Plus Project on PMC

Most stakeholders in Côte d'Ivoire agree that the project actively sought to address gender, social inclusion and equity issues in Côte d'Ivoire. With regards to gender, the training of women's groups on PMC provided an additional channel to raise awareness among caregivers, recognising the pivotal role of women in household health decisions and empowering them to disseminate health information. The project also worked with traditional, religious and civil society leaders to promote PMC within communities and foster social inclusion. Leveraging Community Health Workers (CHW) also enabled personalised engagement, addressing specific barriers across diverse social groups. As one country level stakeholder said, "The project successfully addressed issues related to gender, social inclusion, and equity. All children were included in the intervention equally, regardless of their gender. Social inclusion and equity were perfectly considered in the intervention's targeting. All health agents conducted the intervention without discrimination."

As also described in Section 1.1, despite the WHO 2010 recommendation on IPTi, there was virtually no implementation of IPTi. Unitaid's investments in PMC sought to comprehensively address a wide range of access barriers restricting PMC uptake (as outlined in the ToC in Appendix C). In general, the projects were well designed to cover these various access barriers, with some small gaps, summarised briefly below and discussed in more detail further in the report:

- Innovation and availability: There was a lack of quality-approved taste-masked SP formulations with no quality-approved SP-PMC appropriate for children. Instead, non-dispersible adult formulations had to be cut into quarters and were not palatable for children. Support for quality-assured child-friendly SP products through the MMV grant was therefore critical.
- Demand and adoption: The Plus Project aimed to reduce restrictive policy relating to PMC, lack of confidence
  in PMC amongst policy makers and other stakeholders and lack of efficacy evidence. For example, there was
  some data on PMC impact and cost effectiveness (30% decline in malaria cases, 21% decline in anaemia
  cases, cost per Disability Adjusted Life Year (DALY) averted of US\$2.90-40 compared to US\$7-77 for SMC<sup>7</sup>)
  but limited evidence on efficacy at different resistance levels. Some research gaps were identified by some

<sup>&</sup>lt;sup>7</sup> Menendez et al (2024), Avoiding another lost decade. The Lancet and Unitaid (2025): PMC End of Project Evaluation Kick-off



stakeholders, although these do not take away from the overall well-designed research priorities covered through the Plus Project.

Supply and delivery: The guidance was restrictive (the dosing schedule implied gaps in protection and there
was a need to extend the age range). There was also a need for greater implementation experience to help
guide countries on PMC. The Plus Project's approach to trialling different implementation approaches was
positive in aiding focus countries to have experience in these approaches. However some stakeholders have
also noted that variable country contexts may present issues with transferability of learnings.

In sum, the Unitaid PMC portfolio through both demand side interventions from the Plus Project (including a mix of research evidence on key aspects as well as on-ground implementation in countries with local stakeholders) and supply side interventions from MMV on helping suppliers secure WHO-PQ for infant-appropriate SP formulations presented a well-rounded, consolidated approach to tackling the access barriers to PMC.

Finding 2: The project was 'ahead of the curve' in terms of the new 2022 WHO guidelines on PMC. There were some gaps in its scope in that it did not cover additional research areas highlighted by WHO and donors and what would support an update to the subsequent WHO guidelines, but it has considerable value in providing implementation evidence for the planned 2026 field manual by WHO.

Strength of evidence rating	Rationale
Medium (3)	Some mixed feedback from stakeholders on relevance of scope of research priorities.

As outlined in Section 1.1, the 2022 WHO guidelines rebranded the IPTi intervention as PMC, with a much broader recommendation than previously in terms of expanding the contact points and resistance levels for PMC. There was already considerable discussion in terms of broadening PMC use over the years, and therefore the Unitaid PMC investments were in some sense 'ahead of the curve' by already exploring an expansion of the restrictive IPTi approach. This also applies to the research commissioned on PMC by other partners such as Gates, GiveWell and the European Union (EU).8

Once the new 2022 guidelines were issued, we understand the project did not need to revise much given the project already aimed to deliver PMC for children up to two years, in line with EPI schedules. Overall, the project well adapted to the new WHO guidelines (for instance, adapting terminology change from IPTi to PMC).

A few comments were received during the evaluation interviews that the project's research focus should have been adapted further to cover aspects that would support subsequent WHO guidelines for PMC. It was indicated that including a randomised controlled trial (RCT) within the research scope to consider the appropriate number of cycles for PMC would have been beneficial to support an update of the WHO guidelines in the future. However, it was also commented that an RCT would not necessarily have focused on the most important aspects in terms of PMC delivery and would have been "very complicated" to implement. Donor partners interviewed also indicated a number of additional research priorities - e.g. focusing on narrower operational guidelines to help countries decide on specific approaches to choose from (number of doses, SP or SP-amodiaquine (SPAQ) etc), trialling community-based dispersal to a larger extent, provision of PMC to over 2-years old, etc.

<sup>&</sup>lt;sup>8</sup> The Gates Foundation financed a study on the feasibility and effectiveness of PMC in Nigeria led by the Malaria Consortium (2020-2024); GiveWell financed an implementation pilot of PMC in the DRC (2022-2024) led by PATH; and the European and Developing Countries Trials Partnership (EDCTP) financed a study on the impact, operational feasibility and acceptability, and cost and cost-effectiveness of PMC in Togo, Sierra Leone, and Mozambique led by ISGlobal (2021-2025).



We understand that Unitaid, WHO, donors and other partners were in regular touch during the project to ensure coordination and alignment, but some misalignment in agreed priorities were experienced over time, also due to movement of staff within these organisations. Our conclusion is that the additional research priorities would have been "nice to have" but do not take away from the relevance of the range of research conducted under the project. In particular, the range of implementation evidence being generated from the project (additional data on impact, the possible effect of SP resistance, acceptability of the intervention, cost-effectiveness) is expected to be instrumental to drive the development of an operational field manual to be developed by WHO in 2026 as well as a policy framework by WHO Regional Office for Africa (AFRO) to support countries to integrate PMC into national malaria strategies.

Finding 3: Though the landscape for malaria prevention interventions has changed during the course of the project, PMC remains relevant within a package of prevention interventions.

Strength of evidence rating	Rationale
High (4)	Strong agreement from global and country level stakeholders including malaria technical experts and confirmed in documentation.

The malaria prevention toolbox has evolved over time, with an expansion in interventions, however no single intervention is currently regarded as a panacea. A package of interventions is regarded as most useful – tailored to specific country epidemiology and health systems.

Malaria prevention options for young children include: (i) vector control (including insecticide-treated nets and Indoor Residual Sprays); (ii) chemoprevention (including SMC and PMC); and (iii) the malaria vaccine (including RTS,S/A01 and R21/Matrix-M). This landscape has continued to evolve since the start of the PMC investments in 2019, with the malaria vaccine in particular becoming more widely available.<sup>9</sup>

Different challenges impact the various prevention strategies (e.g. insecticide resistance, antimalarial resistance, effect duration and high costs). Technical experts have emphasised therefore that to maximise impact, malaria prevention should be delivered as a package by countries, with PMC remaining a valuable tool within that package particularly given its cost-effectiveness compared to other interventions (discussed under Section 2.3 on Effectiveness). Studies suggest that the combination of bednets, SMC, and the malaria vaccine drives down malaria cases by over 90%, with a similar effect expected to be observed for PMC.<sup>10</sup>

Finding 4: The Plus Project co-design feature with country governments was a real strength and fostered national ownership of the PMC strategy. Select other design features such as the misalignment in timings between research and implementation and limited engagement with the Plus-three countries have been challenging.

Strength of evidence rating	e Rationale	
Medium (3)	Strong agreement from stakeholders on strength of co-design model, mixed views on interplay between research and implementation, and less evidence on catalytic impact	

<sup>&</sup>lt;sup>9</sup> The Plus Project implemented PMC in conjunction with the malaria vaccine schedule where relevant. Some examples include: (i) PMC was co-administered with the malaria vaccine in all four countries in some of the project districts and where relevant, aligning the PMC doses with the malaria vaccine; and (ii) In terms of the research studies, the design studies for the impact evaluation in Cameroon and Côte d'Ivoire, included data collection on the malaria vaccine. Cote d'Ivoire added a piece to their study on PMC to look at coherence with the malaria vaccine.

<sup>&</sup>lt;sup>10</sup> Dicko et al, 2024. Seasonal vaccination with RTS,S/ASO1 vaccine with or without seasonal malaria chemoprevention in children up to the age for 5 years in Burkina Faso and Mali: a double-blind, randomised, controlled phase 3 trial. *The Lancet Infectious Diseases*.



Strength of evidence rating	Rationale		
	of Unitaid funding in non-project countries due to limited consultations with government stakeholders in Plus-Three and non-project countries.		

Relevant and appropriate project design is key to the achievement of objectives. Certain aspects worked well, and others less well, as follows.

**PSI co-design of PMC** with country governments was a real strength of the project fostering national ownership and multisector collaboration. PSI provided an illustrative rather than final design of the project in countries to Unitaid, with the aim to iteratively develop the final design in each country based on the input of government and community stakeholders. This allowed strong levels of country ownership of the strategy, and the development of PMC champions within the National Malaria Control Programme (NMCP). In Mozambique for example, stakeholders stated that the Plus Project was not a PSI project, but rather "an NMCP project that PSI was supporting". A similar view was also expressed by stakeholders in other focus countries, notably Côte d'Ivoire and Cameroon.

The project was also able to bring together stakeholders across the health system, including from the NMCP, Immunisation, Child and Maternal Health, Traditional Medicine as well as communities and civil society to participate in the co-design process. In Côte d'Ivoire, this cross-department collaboration facilitated strong partnerships and integration down the line, including the involvement of 100% of immunisation workers in SP administration within project districts.

However, some challenges were also observed with the co-design model. Some stakeholders commented that engagement with frontline health workers would also be beneficial to help realise the practical realities of delivery. It was also highlighted that while some focus countries adopted a phased approach to expand project implementation over time (e.g. including additional districts over the years), the co-design model was emphasised upfront but with few formal check-ins to adapt the design of the project during implementation. For example, Benin had planned to introduce the second Measles vaccine at 15 months in 2023 but has not yet implemented this and therefore this scheduled contact point was not as convenient as it might have been.

Both the research and implementation components of the Plus Project have their own respective value, but misalignment of their timings impacts relevance for focus countries. There was a misalignment in the timeframes of the implementation and research components of the Plus Project, with in-country implementation concluding in Q2 2025 following which research data would be analysed and final research results will be made available in Q3 2025 and Q2 2026. As a result, PSI has had to close-out the project in the four focus countries without presenting the research results which has curbed timely PMC uptake. Research results dissemination is however planned for later in 2025 and 2026 (facilitated through a no cost extension for the Plus Project), but this would be delivered after project close-out in the focus countries (and closure of PSI staff contracts in country), with the risk that the momentum gained could be partially lost.

There is an inherent tension between the implementation and research components of the project which was highlighted often by stakeholders – implementers want findings on impact to align with project close-out to support countries in decision-making; and researchers are hesitant to share preliminary findings and need time for additional analysis and consolidation to support evidence-based decision-making for policymakers at global and national level.

Stakeholders suggested this has led to a push for policy adoption without all the relevant data available. In Côte d'Ivoire and Cameroon for example, stakeholders are still waiting on evidence from the research to inform scale-up. In Benin, the government has made the decision to support scale-up but largely based on implementation experiences rather than research results.

There is thus a need for a more thoughtful approach to better aligning implementation and research timelines in country, to ensure maximum and timely impact on uptake and scale-up.

Extension of the catalytic impact of Unitaid funding through the model of light-touch support in the Plus-three research countries has been of limited value thus far. While a common feature of most Unitaid projects to ensure



"maximum bang for the buck", the PMC project implementation has thus far shown limited value in DRC, where country stakeholders were unaware of the Unitaid funded work and its results (despite involvement of PSI with PATH on co-designing the PMC work implemented by PATH in the country). This raises a question as to the potential of this light touch support impacting decision making and uptake in the country and whether it is the best use of Unitaid monies.

# Finding 5: The Plus Project was viewed as highly collaborative, with PSI and London School of Hygiene and Tropical Medicine (LSHTM) supporting coherence with other partners including through the COP.

Strength of evidence rating	Rationale
Medium (3)	Strong agreement from stakeholders at country and global level, but based on a fewer number of consultations. Confirmed through documentary evidence.

As noted, at the time that the Plus Project began, three other PMC projects were also being launched funded by Gates (Malaria Consortium), the European and Developing Countries Clinical Trials Partnership (ISGlobal), and GiveWell (PATH). There were many examples of collaboration between the four projects: (i) LSHTM and ISGlobal had important exchanges on the design of the research component to measure impact of PMC; and (ii) PSI fed into the co-design of the PATH project in the DRC.

Further, researchers and implementers across the four projects were involved in the COP – a collaborative platform for NMCPs, EPI implementation partners, researchers and other stakeholders led by PSI – with interest in cross-sharing of results (particularly around SP resistance). The COP was seen as a best practice for sharing lessons learned from implementation and research findings, supporting communication across countries as well as coordination across the different projects and funding streams.

PSI undertook great efforts to facilitate coordination and sharing of results. At the national level, chemoprevention working groups/ project advisory groups were established and hosted by NMCP stakeholders which supported enhanced communication and coordination with national stakeholders. This is discussed in more detail in Section 2.3.4 on Dissemination.

## Lessons Learned: Relevance and Coherence – (+) denotes positive experience from the projects, (-) negative and $(\pm)$ mixed

- (+) A consolidated end-to-end approach to investment design in terms of considering the range of access barriers on both the demand and supply side is relevant, appropriate and effective.
- (+) Unitaid's role in leading the way in terms of new approaches and innovations and providing funding behind its priorities (i.e. both its pathfinder and investor roles) is making a positive contribution to the PMC and malaria prevention landscape.
- (±) Wide consultation and ongoing continuous engagement with WHO and donors is critical to support relevant and coherent design of Unitaid investments, also to keep abreast/ aligned when there is movement of people within these organisations.
- (+) Co-designing interventions with country stakeholders is an effective approach for Unitaid to consider across its projects. Ensuring a process whereby all relevant stakeholders are engaged and "learning by doing" is incorporated throughout the implementation process can support further optimisation of this approach.
- (-) Better or more thoughtful alignment of research and implementation timelines, especially for focus countries where considerable investment has been made and stakeholders have been engaged is important. So far, as PSI has closed-out in focus countries and LSHTM is finalising research results, it is a missed opportunity not to "sell" the research findings to country stakeholders during close-out.



#### 2.2. EFFICIENCY

3. Have the projects been time and budget efficient and has implementation been collaborative and integrative with countries (Plus Project) and reflective of efficient product development (MMV)?

Performance rating for the Plus Project and Supply Grant Output 4 - Met minimum expectations

**Explanation** – The projects have mostly been delivered in an efficient way, especially with regards to budget. Some key outputs have been delayed and are yet to be achieved – finalisation of research results for the Plus Project largely due to delays in receiving ethical approvals and WHO PQ for the manufacturers supported under the MMV Supply Grant.

Finding 6: Overall, both PSI and MMV managed their investments well.

Strength of evidence rating	Rationale
High (4)	As per annual reporting and also strong agreement from global and country level stakeholders.

Investments by both PSI and MMV were efficiently managed, despite their complexity, and were finalised within budget. PSI in particular was praised by stakeholders as having managed a multi-site project with both research and implementation components very effectively. They coordinated well with the appropriate stakeholders, and were highly responsive to requests from Unitaid and other partners as well as clear in their progress reporting. MMV was also viewed as a strong partner, effectively managing a challenging project while staying within budget.

Whilst remaining within budget is a strength, there was a relatively high underspend on the Plus Project. As of the end of project implementation in 2024, there was an 25% underspend. This is on account of a number of reasons including delays in contracting in-country research agencies and external professional services as well as delays in the research approval process and SP procurement (each of which had a compounding effect on the other), reservation of some budget until the finalisation of the research results, some reductions in planned expense items due to inability to share costs with US funding given its decline.<sup>11</sup> These factors reflect the practical challenges of managing budgets for complex projects being delivered in a dynamic environment.

Finding 7: With regards to the Plus Project, of 22 research study sites for which information on the ethical approval process is available, 10 were delayed. Noting the longstanding timelines challenges with ERC processes (WHO and country), some additional areas of improvement include early agreement on country and research partners and training of local researchers on ERC approval processes.

Strength of evidence rating	Rationale	
Medium (3)	Data confirmation on delays. Less evidence on areas for improvement, based on consultations with researchers and implementers.	

<sup>&</sup>lt;sup>11</sup> Plus Project - 2024 Annual Narrative Report Submitted 2025.02.28



Table F.1 in Appendix F summarises timelines for the ethical approval of study protocols (by site), as well as reasons for the delay. Of the 22 studies for which information is available, ten experienced delays due to ethical review processes at both the WHO and country levels, including the following:

- policy adoption package in Ghana (start of study severely delayed, could not start data collection in 2024),
- economic evaluation across sites (6 week delay in baseline data collection),
- impact evaluation across sites (3 month delay across sites, and reduction in timeline from 24 to 18 months to meet project timelines),
- process evaluation in Cameroon (baseline data collection delayed 5-6 months until June 2023),
- evaluation in Mozambique (baseline data collection delayed by around 2 months, and no longer avoided the rainy season and elections causing gaps in data collection),
- Zambia parasite clearance and protection from infection (PCPI) study (delayed by one year from Q2 2023 to Q2 2024),
- Cameroon PCPI study (delayed by two months from Q4 2023, to Q1 2024 impeding ability to capture seasonality).

As a result, PSI (planned for and ultimately) requested an extension until Q2 2026 from the initial project end point in October 2025.

Multiple layers of ethical review were required for each research protocol – that of WHO ERC, LSHTM, and national-level ERCs. Because the Plus Project started in August 2021 when COVID was a public health emergency of international concern, priority was given to COVID related research protocols from ethics review committees (and later also Mpox). Additionally, protocols had to be resubmitted for WHO ERC approval which caused delays. Some researchers suggested that feedback on the research protocols from the WHO ERC was vague and difficult to understand (with Unitaid needing to intervene to support the approval process). At country level, there were also delays due to long processing times of national ERCs (including extensive requests for additional documentation, and gaps when ERCs were not convening). Additionally, there were a few instances when materials were submitted by Unitaid to WHO ERC too late to meet the deadline, delaying review of the protocol until the next month.

The overall delays from plan on the research were also in part because countries for implementation and the research component of the project were confirmed after grantees had made their proposals. This meant that PSI and LSHTM proposed their partnership before being able to select and contract local partners. Given that the contracting process takes some time, the start of the research did not align with the start of project implementation.

Further, stakeholders suggested that ethics review processes were somewhat of a capacity-gap for some local research partners, and difficult to therefore efficiently manage – recommending training to facilitate the process be integrated into future support from Unitaid.

These delays highlight the challenges experienced in commencing and implementing research due to a range of factors, many of which were not within the Plus Project's ability to control. While, by design, research results will be available after project implementation, the additional delays experienced due to the range of issues highlighted above compounded the misalignment of project implementation close out timings with research result availability. This impact is discussed further under Findings 11 and 15.

Finding 8: With regards to the MMV Supply Grant work, Swipha and Emzor have taken four years to submit dossiers for SP dispersible for WHO PQ since the start



## of the project, with planned timelines deemed ambitious for manufacturers with no prior expertise in WHO PQ.

Strength of evidence rating	nce Rationale	
High (4)	Alignment across consultations, and with project documentation.	

The MMV Supply Grant Output 4 aimed at having at least two additional manufacturers, namely Emzor and Swipha, developing a PQ-ed SP dispersible scored tablet formulation, in two dosage strengths (500/25mg for >10kg and 250/12.5 mg for the 5-10kg infants).<sup>12</sup> Both manufacturers had been selected previously by MMV as Nigerian lead candidates for SP for the IPTp project (Output 1 of Unitaid's supply grant to MMV).<sup>13</sup>

Table 2.1 below, shows the initial expected timelines for the key activities to achieve WHO PQ, compared to the actual finish dates. In total, around 2-3 years was anticipated at project start, but currently we are at 4+ years. Most stakeholders suggested that the estimated timeframes that were established for the submission of the dossier for WHO PQ was more or less accurate for manufacturers with prior WHO PQ experience. However, they recommended that in the future Unitaid take into account the differing level of experience of manufacturers with WHO PQ processes and the implications this is likely to have on the timeframes for WHO PQ, and specifically that this timeframe was likely too ambitious for manufacturers with no prior WHO PQ experience. It is important to highlight that this was the first time that Emzor or Swipha had applied for WHO PQ on a product and the first time that a manufacturer in Nigeria had applied for WHO PQ on a product.

Table 2.1: Expected and actual timeframes for key activities to achieve WHO PQ

Activity	Manufacturer	Start of work with manufacturers post- negotiations <sup>14</sup>	Expected end date	Actual end date
Completion of	Swipha	Q2 2021	Q1 2022	Q1 2024
Bioequivalence (BE) study	Emzor			Q4 2024
WHO PQ submission	Swipha	Q2 2021	Q4 2022	Q2 2025
	Emzor			Expected Q2 2025
WHO PQ approval	Swipha	Q4 2022	Q3 2024	Pending
	Emzor			Pending

The delays in the submission of the hard SP tablet for IPTp dossier for both Emzor and Swipha had knock on delays for dispersible SP. This required two amendments extending the timeline of the grant: (i) a no-cost extension extending the project end date from 31 December 2022 to 31 December 2023 to allow MMV to continue to support Swipha in completing the BE study and submitting the dossier for WHO PQ (both the hard tablet SP IPTp product (500/25 mg) approved by WHO PQ in August 2024, and the dispersible SP product for PMC submitted for PQ in 2025); and (ii) an extension of nine months until 30 September 2024 to allow Emzor to complete the dossier for WHO

<sup>&</sup>lt;sup>12</sup> MMV\_Supply Grant\_amendment\_Request \_Output 4\_28082020

<sup>&</sup>lt;sup>13</sup> As per Project Plan approved in 2020MMV\_Supply Grant\_amendment\_Request \_Output 4\_28082020

<sup>&</sup>lt;sup>14</sup> As per the Project Plan approved in 2020 (Reference: MMV Gantt Chart for Supply Grant Extension Output 4 28082020)



PQ (Emzor's hard tablet SP for IPTp was submitted for PQ in December 2024, and dispersible SP product was expected to be submitted for PQ in 2025).<sup>15</sup>

MMV was aware of the complications that might occur, and worked with two manufacturers in Nigeria in part as a risk mitigation strategy in case one was unable to receive WHO PQ. As a further risk mitigation strategy, MMV agreed to devote internal resources to support manufacturers to complete the process of obtaining WHO PQ if necessary after September 2024, and minimised the financial impact of operational delays by keeping down staff costs and cutting down on administrative expenses. These are prudent risk strategy mechanisms. Furthermore, the repeat BE studies were funded by the manufacturers – an indication of commitment and value of MMV and Unitaid support.

Ultimately, the mismatch in timing meant that SP was never procured from regional manufacturers for the Plus Project. However, the project has built competencies with the PQ process at national level in Nigeria which may lead to future efficiency improvements, with further detail in Section 2.3.

Further, in contrast, stakeholders commented that Universal Corporation Limited (UCL), who was supported under the MMV Supply Grant (Output 1) and able to achieve WHO PQ for the hard tablet SP for IPTp on time, was then able to leverage this expertise to achieve WHO PQ the dispersible tablet SP for PMC. This highlights the value of previous experience in achieving WHO PQ – and multiplier effect of Unitaid support in this regard.

#### Lessons Learned: Efficiency – (+) denotes positive experience from the projects, (-) negative and (±) mixed

Research ethical approval

(-) Timelines for research studies will always be impacted by the complex ERC processes (global and country)
and so Unitaid should plan for other aspects to shorten overall research timelines such as early identification
of countries and local research partners as well as providing capacity building support to local researchers on
ERC processes.

Supporting manufacturer WHO PQ

(-) Factor in manufacturer experience and national context when estimating timelines for WHO PQ approval.

#### 2.3. EFFECTIVENESS, SUSTAINABILITY AND SCALE-UP

#### 2.3.1. Access barriers

4. Is the intervention achieving its objectives as per the access barriers identified (innovation and availability; demand and adoption; supply and delivery) and is the investment catalysing and promoting global policy adoption and country implementation in focus and non-project countries?

Performance rating for Innovation and Availability (and regional manufacturing) - Supply Grant Output 4 – Successfully met expectations (partially)

**Explanation** – Objectives only partially achieved as supported manufacturers have not obtained WHO PQ as yet. However, Unitaid's support for regional manufacturers is considered to be a valuable investment and expected to provide ongoing benefits beyond the timeframe of the project

<sup>&</sup>lt;sup>15</sup> Note that this paragraph includes details outside of the scope of this evaluation (not included in MMV Output 4) related to the production of hard tables for IPTp. This has been included for information purposes only, given links between the timing of the SP hard tablet and SP dispersible.



Performance rating for Demand and Adoption (and dissemination) – Plus Project – Successfully met expectations (partially)

Policy adoption in 4 for focus countries (Benin, Cameroon, Cote d'Ivoire and Mozambique), in 1 of 3 Plus-three research countries (DRC), and select other non-project countries (Burundi, Togo, Tanzania, Congo Brazzaville)

**Explanation** – Some key objectives were achieved in terms of policy adoption in focus countries, but not in additional countries. Progress made in terms of research studies which are currently in the process of being finalised.

Performance rating for Supply and Delivery – Plus Project – Successfully met expectations (partially)

**Explanation** – Most of the objectives/ expected results were achieved but with a significant shortcoming of low coverage, especially in the second year of life.

#### 2.3.2. Access barriers: Innovation and availability

Finding 9: New SP-PMC products are now available, also due to leveraging of prior Unitaid investments for IPTp and SMC. However, while solid progress has been made, manufacturers supported directly through this project have not yet succeeded with PQ. The work by MMV has been instrumental and the progress achieved would not have been possible in the absence of the grant. Future viability of the supply of the new products may be in question with unclear demand from countries in the wake of the global financing crisis.

Strength of evidence rating	Rationale
High (4)	Strong agreement from global and country level stakeholders close to the detail and confirmed in documentation.

Of the two manufacturers supported by MMV to secure WHO-PQ for paediatric SP for PMC, neither have secured WHO PQ during the project lifetime, although both have made good progress. Prior Unitaid support for manufacturers for IPTp and SMC has facilitated new product entry for SP-PMC. As discussed previously, at the time of the projects' conception, there was no quality-approved SP formulation suitable for children. Instead IPTp tablets were used (an adult non-dispersible tablet) and this had to be cut into quarters and was not palatable for children. This was a barrier to take up by countries, especially in relation to time required to prepare the dose, acceptability by children and confidence among health care workers and beneficiaries. No manufacturers had WHO PQ for dispersible SP-PMC globally and furthermore Nigeria, which is a large potential market for SP-PMC given its burden from malaria, had an import ban on SP. If a Nigerian manufacturer obtained WHO PQ for SP-PMC, that would make it possible for Global Fund funding to be used for PMC in Nigeria given Global Fund only procures from Expert Review Panel (ERP)/ PQ sources.

Through the MMV Supply Grant Output 4, two manufacturers were supported to obtain WHO PQ for dispersible SP for PMC (250/ 12.5g), as shown above in Table 2.1. At the close of the project in September 2024, neither have received WHO PQ, but Swipha submitted a dossier for WHO PQ in Q2 of 2025 and Emzor was expected to do the same. As of the end of 2024, neither manufacturer had obtained registration in any country.<sup>16</sup>

<sup>&</sup>lt;sup>16</sup> MMV Supply Grant\_Final report 2024 resubmitted 11 March 2025



On the other hand, within the project period, UCL and S Kant who had received MMV support for WHO PQ for hard tablet SP for IPTp (Output 1) and SPAQ (Output 2) respectively and managed to also receive WHO PQ for dispersible SP for PMC. This demonstrates a "multiplier effect" from previous support from MMV for UCL and S Kant to achieve WHO PQ, and there are expectations that this should be the case for Emzor and Swipha in the future as well.

Despite non-achievement, MMV support has been instrumental to manufacturer progress, and this would not have been possible in the absence of MMV and Unitaid support. Whilst Emzor and Swipha have not yet achieved WHO PQ, the progress they have made to date is highly significant, especially given that no other manufacturers in Nigeria (there are around 160 pharmaceutical companies in Nigeria in 2022) have previously received WHO PQ for any products.<sup>17</sup> Without Unitaid and MMV support, stakeholders confirmed this progress is not likely to have been possible. In particular, manufacturers were asked specifically if any different type of support would be useful and they confirmed that the mix of technical and financial support received under this project from MMV was appropriate and valuable.

Based on stakeholder feedback, the **financial support** enabled the manufacturers (Emzor, Swipha) to make necessary investment into new equipment required for WHO PQ.

**Technical support** has been provided by experts in the field to help manufacturers conduct BE studies and navigate the WHO PQ process, including ensuring the product received the WHO GMP certification.

Another area of technical support provided by MMV was on the development of **demand forecasts** for SP which was finalised at the end of 2022 and presented at a symposium at the American Society of Tropical Medicine and Hygiene (ASTMH) in October 2023 and recently published in Malaria Journal which is commendable. Demand forecasts are valuable in terms of providing manufacturers data on demand which is needed for visibility and planning. However, the demand forecast that was developed was based on modelled demand and assumes a certain number of schedule points. Our assessment is that it would have been more beneficial if the demand forecasts had been developed with 'end use' in mind which would have required actively updating them and sharing with manufacturers alongside supporting capacity development in countries to develop their "live" demand forecasts.

We argue that achievement of WHO PQ for the products is not sufficient to fully address the innovation and availability access barrier, and supplier/ market viability is also an important factor that needs to be considered in the round. Figure 2.2 presents the main factors that have supported dispersible SP-PMC supplier success/ progress towards WHO PQ, and in addition also outlines other factors to ensure suppliers remain interested in the market and countries ultimately have the products available. On this latter aspect, the figure highlights some of the ongoing challenges, discussed in more detail after the figure.

<sup>&</sup>lt;sup>17</sup> Unitaid (2022), Domestic Manufacturing in Nigeria. Highlights, lessons and reflections from the visit to Lagos (5-7 Sept 2022)

<sup>&</sup>lt;sup>18</sup> Audibert, C., Hugo, P., Gosling, R. et al. Projected uptake of sulfadoxine–pyrimethamine for perennial malaria chemoprevention in children under 2 years of age in nine sub-Saharan African countries: an epidemiologically-based 5-year forecast analysis. Malar J 24, 124 (2025). https://doi.org/10.1186/s12936-025-05355-0



Figure 2.2: Factors supporting WHO PQ and affecting ultimate product availability and supply security

#### SUPPORTING FACTORS FOR MANUFACTURERS ACHIEVING WHO PQ FOR THEIR PRODUCTS

Supplier capacity/interest –
Attracted and managed through
MMV RFP and selection of suppliers

Financial support – Provided by MMV to pay for WHO PQ submission and undertake bioequivalence studies

**Technical support** – Provided by MMV to prepare dossier submission

**Demand forecasts**– Developed by MMV to guide suppliers

FACTORS DRIVING PRODUCT AVAILABILITY AND SUPPLY SECURITY

Country registrations – Lack of harmonized system and resources at the country level cause delays

Procurement channels – Lack of volume guarantees from global donors (e.g. Global Fund) and shrinking global health funding threatens procurement of WHO PQ products

Market viability, competition and volume of supply – Number of suppliers in relation to demand, WHO PQ products more expensive that non-WHO PQ products and therefore may not be competitive in the private market

Product achieves WHO PQ

Source: CEPA

Three aspects were highlighted in stakeholder consultations as areas for consideration for support in future grants/potential missed opportunities under this grant and include:

- Support for country registration work which is considered to be a key step in the process for making products available but can be a challenge for manufacturers given resource constraints and regulatory complexity.<sup>19</sup>
- Potential need for purchase guarantees to support commercial viability of the suppliers, especially noting the current challenging financing environment for global health and the risk that product orders are not placed once WHO PQ is obtained. Without orders, some manufacturers and stakeholders consider that manufacturers will not be able to recoup their financial outlay. While the current funding climate means that this is an issue that was not previously expected to be so significant, some stakeholders think that Unitaid should consider increasing/ extending the financial support to include initial orders once WHO PQ has been obtained (e.g. through purchase guarantees for six months). The other option is private sector sales, but this is limited for PMC.
- Commercial viability of suppliers becomes even more challenging in the face of multiple suppliers achieving WHO PQ during the project lifetime with Guilin, Macleods, UCL and S Kant securing WHO PQ for SP-PMC. It is not clear if demand levels can be achieved to hold all of these suppliers, although the Nigerian suppliers will have access to the Nigerian market given the import ban. There is also the issue of WHO PQ-ed suppliers not being competitive in private sector markets although we understand UCL has managed to produce SP-PMC at price parity with Indian and Chinese generic manufacturers.

Table 2.2 below presents volume allocations to date by manufacturer and donor.

<sup>&</sup>lt;sup>19</sup> Medicines for Malaria Venture (2025), MMV Supply Side Grant – Final Report



Table 2.2: Volume allocations by manufacturer, donor and current status

Manufacturer	International donor	Country	Volume	Status
UCL	Global Fund	Cameroon	1 million SP dispersible 250mg packs	Completed
Emzor	World Bank and Islamic Development Bank	5 states in Nigeria	3.5 million SP dispersible 250mg packs	Partly delivered, remaining part to be delivered
Swipha	PMI	Nigeria	4.5 million SP dispersible 250mg packs	To be delivered

Box 2.2 provides a summary of the healthy market framework employed by Gavi which considers a well-rounded approach to ensuring product availability and supply security.

#### Box 2.2. Gavi's Healthy Markets Framework

Gavi's Healthy Markets framework was used to develop a clear and consistent definition of market health, including: establishing a common way of thinking about market health, communicating Alliance assessments of individual markets, and improving trade-offs between how different market elements are analysed.

The supply dynamics component is of relevance to the current discussion where Gavi looks at a number of parameters beyond product availability in the market including market sustainability and attractiveness – which is precisely the aspect highlighted in our assessment above. Other key related aspects are "supplier base risk" and "supply meets demand", which we believe should be further incorporated in Unitaid's assessment of addressing the Innovation and Availability access barrier.

A new iteration of the HMF designed in 2024 formalises representation of demand and adds a dimension around regional diversification across suppliers to mitigate geopolitical and health security risks in every market.

XXX	Demand health	Materialisation of demand	The degree to which country introductions and campaigns materialise
		Predictability of demand	The degree to which both the quantity and timing of demand can be accurately predicted and sustained by countries
		Balanced demand of appropriate products & timely uptake of new innovative products	The degree to which country product choices are data-driven, value-based; leading to balanced demand for appropriate products & timely uptake of new innovative products
De la company	Supply dynamics	Market sustainability & attractiveness	The degree to which the market remains sufficiently attractive for incumbent suppliers to remain or for new suppliers to enter
		Regulatory / NRA risk	The magnitude of risk that doses cannot be released or exported from the country of production
		Supplier base risk	The magnitude of risk that a supplier will be unable to supply expected doses
		Meeting country product preference	The degree to which available supplies can meet countries' product choices
		Supply meets demand	The degree to which the overall supply can meet total forecasted demand
	Innovation	Incentivising & scaling up innovations	The degree to which ongoing innovations address countries' unmet needs and may be adopted by countries in the future
(3)	Geopolitical & health security exposure	Geopolitical and regional diversity risk	The degree to which regional diversification across suppliers mitigates geopolitical and health security risks



Lessons Learned: Innovation and availability – (+) denotes positive experience from the projects, (-) negative and  $(\pm)$  mixed

- (±) Supporting local manufacturers achieve WHO PQ for quality products is a complex undertaking, and despite best efforts, can be challenging to achieve and is heavily dependent on the manufacturer's capacity and prior history with WHO PQ. On the other hand, prior PQ experience can hasten manufacturer capacity for future PQs.
- (+) Local manufacturers benefit from expertise in navigating through the process to securing WHO PQ and public/ UN institutional business.
- (-) A healthy market comprises an appropriate number of suppliers in relation to demand, also ensuring future viability of suppliers to stay in the market.
- (-) The situation for supporting regional manufacturing has become more complex in the current constrained climate for global health financing.
- (-) Demand forecasts should be actively shared with the private sector and country capacities to develop forecasts should be enhanced.

#### 2.3.3. Access barriers: Demand and adoption

Finding 10: There has been good progress on addressing the demand and adoption access barrier in a number of countries since the initiation of the Plus Project with PMC being included in national policies. The level of contribution of the project in this regard has varied by country.

Strength of evidence rating	Rationale
High (4)	Based on country policy document/ NSPs/ funding information as well as feedback from PSI and country stakeholders (more detailed for the country case studies, but also from interviews with other countries).

Good progress has been made on policy uptake and implementation by a number of countries during the Plus Project lifetime, although with varying contributions from the Plus Project. Table 2.3 provides a summary with more details in Appendix G.

Table 2.3: Country PMC policy and implementation progress

Country	PMC included in policy	Implementation status	Doses	Contribution of Plus Project
Benin	Yes (in 2024)	3/19 districts + 5 additional districts from 2025	8 doses (previously 5 doses but have decided to increase to 8 due to the Plus Project)	Plus Project was instrumental to policy adoption in Benin and supported the implementation of PMC in Benin
Cameroon	Yes (in 2022, PMC implementation agreed before Plus Project start)	157/157 districts	5 doses currently. Waiting on PSI research study results to evaluate whether to increase to 8	Cameroon was already implementing PMC before the Plus Project, but the Plus Project provided training, supervision, community engagement and the availability of the dispersible paediatric formula in the project districts
Côte d'Ivoire	Yes (in 2021)	3/81 districts	5 doses in the PSI research pilot schedule	The Plus Project supported the implementation of PMC in pilot districts



Country	PMC included in policy	Implementation status	Doses	Contribution of Plus Project
Mozambique	Yes (in 2023 ) <sup>20</sup>	13/81 districts	4 then 5 doses in the national schedule/PSI implementation, 6 in the ISGlobal research pilot schedule	Policy incorporated PMC prior to the Plus Project, but the project supported the implementation of PMC in Mozambique
DRC	Yes (in 2013)	31/383 districts	6 in the GiveWell research pilot schedule	The Plus Project supported PATH in the co-design process of the GiveWell Project in DRC and through the COP
Ghana	No	1 district	Data not provided (research study only)	PMC adoption decision is pending the results of Plus Project research studies
Zambia	No	No implementation	Data not provided (research study only)	PMC adoption decision is pending the results of Plus Project research studies

As can be seen from the table, and additional qualitative information is as follows:

- Policy adoption in focus countries: All four focus countries Benin, Cameroon, Côte d'Ivoire and Mozambique – have incorporated PMC in their national strategic plans for malaria. The Plus Project has been particularly instrumental in Benin where the incorporation of PMC in the national strategic malaria plans occurred during the project period. Moreover, Benin decided to change its dosing schedule from five to eight during the first two years of life based on the project experience where an eight-dose schedule was trialled. In Mozambique, PMC was included in the new malaria strategic plan 2023-2030 following a decision by the NMCP in 2021, prior to the Plus Project start. Therefore, the value add of the Plus Project was to move from a strategy to implementation by providing funding at the right time. The direct impact on policy uptake has been less pronounced in Côte d'Ivoire and Cameroon. In fact, Côte d'Ivoire included PMC in the national malaria strategic plans in 2021, prior to the project start and primarily on the back of the 2022 WHO quidelines. Similarly, Cameroon's policy adoption of PMC pre-dated the project. However, the added value from the Plus Project in these countries was establishing the best means of implementation and providing funding for PMC (see Section 2.3.1.3 on Supply and Delivery for further information). The differing experiences across focus countries underscores the complexity of factors at play for product uptake in countries. We understand Benin also has PMC supportive leadership and the progress in the country reflects the value of having champions drive new product introduction and demand.
- Implementation status in focus countries: In three of the focus countries Benin, Côte d'Ivoire and Mozambique PMC was piloted for the first time through the Plus Project. In Cameroon, there was some prior delivery although coverage was low and the Plus project enabled the delivery of PMC in more districts than would have been possible without the project. Uptake outside of the project districts in all countries has not been significant to date. Further guidance on the implementation approach in countries will also be based on the research evidence (e.g. Cameroon is waiting for the Plus Project research results to determine whether to scale-up to eight doses instead of five, as currently listed in the national policy).
- Demand and adoption in the Plus-Three research countries: The impact on policy adoption for the three research countries – DRC, Ghana and Zambia – has been more limited. At this stage, the three research

<sup>&</sup>lt;sup>20</sup> PMC was included in the Mozambique new malaria strategic plan 2023-2030 following a decision by the NMCP in 2021.



countries have not decided to adopt PMC, although DRC has confirmed their strong interest in implementing PMC.<sup>21</sup> Ghana and Zambia are awaiting the availability of the final research results. DRC has also benefited from additional funding for PMC from GiveWell which is expected to be an important driver for policy adoption in the future. The few stakeholders consulted in these countries were not aware of the Plus Project, indicating that, most likely, the value of the exchange in these countries has been limited to date. However, given the research findings have not yet been shared, this might change following research dissemination. Discussions with PSI indicate that the more limited policy impact in the Plus-Three countries is on account of the newness of PMC and the need for more engagement with countries to support adoption.

• Demand and adoption in non-project countries: A number of other sub-Saharan African countries have occasionally joined the COP (e.g. Burundi, Nigeria, Republic of Congo and Togo) and benefitted from learnings on PMC shared through this platform. However overall contribution towards furthering demand and adoption from the Plus Project for these countries has been relatively distal other than through the COP. We understand PSI was keen to reprogramme its work to cover additional support to these countries but this was not approved by WHO and Unitaid. The main factors driving decision-making and interest in these countries is the 2022 WHO guidelines and other donor funding (e.g. Gates/ Malaria Consortium in Nigeria and EU/ ISGlobal in Togo). That said, many stakeholders have noted that the Plus Project is the largest of all projects, undertook strong efforts to disseminate information, and is the only one which had both a research and an implementation component and hence has good potential for wider impact.

The policy and implementation progress across the four focus countries has been well facilitated by PSI and there has been a lot of value through the Plus Project intentionally supporting the introduction of a new intervention in a country with supporting training, supervision, community engagement, use of the appropriate child-suitable formulation, etc. In particular:

- Healthcare professionals and technicians were provided with extensive training, ensuring that they were well-prepared to deliver PMC. For example, in Mozambique supervision visits and on-the-job training of all people working in Healthy Child Consultations, EPI and nutrition increased SP administration and registration. One stakeholder commented that the Plus Project has paid for the "start-up cost" because continuing the intervention in the Plus Project countries will be easier now thanks to the extensive training which can now be easily transmitted to new health providers. Feedback from country level stakeholders noted that health care workers and beneficiaries felt confident in administering and receiving PMC respectively, supporting ongoing adoption of PMC.
- The community engagement and advocacy efforts were highlighted as a key crucial factor influencing uptake
  in focus countries (Appendix H provides a list of community and civil society engagement activities in the
  focus countries). For example:
  - In Côte d'Ivoire, the project conducted social mobilisation activities in all 22 sub-districts, to gather feedback and adapt communication materials, fostering local buy-in and encouraging PMC uptake. As a respondent highlighted, "the community-based approach was highly successful in this project, largely due to effective awareness campaigns and the engagement of various community leaders".
  - Interviews in Mozambique showed that there was high acceptance of PMC by caregivers and rare cases of hesitation. Any initial hesitation towards PMC by caregivers was linked to lack of knowledge on PMC and its benefits but was overcome with short promotional talks before or during consultations by health providers or in the community by CHWs, health management committees and influential

<sup>&</sup>lt;sup>21</sup> Whilst DRC had included PMC in its 2013-2015 National Malaria Strategic Plan as a potential intervention, it was not yet implementing PMC other than through research projects.



leaders. As caregivers were familiar with SP through IPTp, PMC was framed in the promotional talks as part of the continuum of care and not as a new intervention thereby improving acceptance.<sup>22</sup>

Finding 11: The project's several research studies are expected to be valuable for supporting countries with evidence base and implementation guidance on PMC, and are currently being finalised. LSHTM's inability to share results until finalised, while prudent, presents a missed opportunity to leverage alongside close out of PSI's implementation support in countries.

Strength of evidence rating	Rationale
Medium (3)	Based on a range of stakeholder views and some mixed opinions. Finalisation of research results ongoing, so some aspects of this finding are preliminary.

The Plus Project incorporates a series of important research studies on PMC aimed at improving the evidence base for the adoption and uptake of the intervention. These are summarised in Table 2.4. In particular, despite already existing data on the efficacy of IPTi, the evidence from the project, especially on the feasibility and cost-effectiveness of different schedules of SP delivery is expected to be particularly useful. Both global and country stakeholders also noted that cost effectiveness evidence in particular is likely to be crucial in the current constrained financing environment. Global stakeholders commented that the findings, especially those on the SP resistance, will allow countries to assess in which areas PMC should be implemented and how. That said, as noted in Finding 2, some global stakeholders identified additional research priorities that would have been nice to have covered as well.

Table 2.4: Plus Project research studies across countries

Type of research study	Benin	Cameroon	Côte d'Ivoire	Mozambique	Research countries (DRC, Ghana, Zambia)
Process evaluation	Yes	Yes	Yes	No	No
Impact Monitoring and Evaluation	No	Yes	Yes	No <sup>23</sup>	No
Economic Evaluation	Yes	Yes	Yes	Yes	Yes (modelling)
Policy Adoption and Receptivity Evaluation	Yes	Yes	Yes	No	Yes
SP Suitability Assessment	Yes	Yes	Yes	Yes	Yes

Some implementation guidance and tracking tools are available in draft at present. Appendix I provides a list of these tools and Box 2.3 below provides the mixed feedback to date on the Decision support Tool.

#### **Box 2.3. Decision Support Tool (renamed PMC Compass)**

Knowledge gaps still exist on the epidemiological impact of PMC and its combination with other interventions, such as malaria vaccine, vector control and case management to inform decision makers on its usefulness as an

<sup>&</sup>lt;sup>22</sup> Unitaid Plus Project 2023 Narrative\_Annual Report-Jan-Dec2023

<sup>&</sup>lt;sup>23</sup> Mozambique was removed from the Impact Monitoring and Evaluation because of lack of funding.



intervention in high malaria burden countries. The PMC Decision Support Tool aims to inform national and international policy-makers about the expected impact on malaria morbidity and mortality as well as the cost and efficiency of PMC implementation delivery mechanisms in different areas within a country. It is an interactive webbased tool that is being developed to aid NMCPs to prioritise and rank PMC implementation by administrative areas, thereby allowing effective targeting of resources.

The tool has been modelled for alternative PMC schedules and delivery mechanisms using the Imperial College malaria transmission simulation model and incorporating SP protective efficacy based on local genotype profiles as well as the expected coverage of each target PMC dose, the varying costs and cost savings from averting malaria cases and the potential impact of PMC. It also includes the existing control measures including with/without RTS,S or R21 vaccination. The PMC Decision Tool is to be refined and further extended based on the finalised results of research studies, namely the genotyping, economic studies and process and impact evaluations.

The tool is currently in draft from and not disseminated amongst stakeholders. For example, in Mozambique, government stakeholders had limited knowledge of the Decision Support Tool before the transition workshop in April. Our interviews indicated mixed feedback on the utility of the tool. Some stakeholders flagged that no new information is provided by the tool as it suggests that PMC should be implemented in high burden areas and the NMCP already uses stratification to determine where different interventions should be implemented. On the other hand, some stakeholders stated that the tool could be useful as it shows which provinces to expand PMC to and with what dosing schedule. It is therefore considered to complement existing information.

Moreover, given that the greatest reduction in malaria cases will come from using as many malaria control interventions available and this will require prioritisation in the current financial climate, stakeholders flagged that, in order to be useful, the tool should be able to determine what are the most cost-effective approaches to use and where, looking at PMC in combination with other interventions.

Moving forward, the value of the tool is expected to be around mapping the cost effectiveness of PMC particularly if SP resistance patterns change and it is less effective in reducing parasite burden. The tool will most likely not support demand for PMC, as this will be more likely be driven by WHO guidance, criteria to implement PMC and available funding.

Finding 7 highlighted the delays experienced with some research studies, which ultimately has also impacted the timely availability of research results alongside the implementation in the focus countries (a tension that was highlighted in Finding 4 on challenges with the project design). Analysis of research findings is currently ongoing and it is anticipated that by September 2025, primary outputs from the Plus Project evaluations will be available. Further secondary analyses will then be available by March 2026. It has been a missed opportunity not to have leveraged the research findings alongside project close out in countries (noting that it is prudent to share final research results only). With project close by PSI in countries, teams deployed in these countries will be moving on and the momentum gained with country governments and other stakeholders has the potential to be diluted. Some stakeholders expressed concern that current policy adoption does not take account of the latest evidence and that adoption and scale-up is being encouraged without consolidated and well-articulated research findings and recommendations. A more thought out approach that better harmonised project timings in implementation and research would be instrumental.

In the remaining time for the project until March 2026, PSI has planned a number of dissemination activities alongside availability of these research results including engagement with focus, Plus-Three and non project countries (Congo Brazzaville and Burundi), with the RBM Case Management Working Group as well as Country and Regional Support Partner Committee (latter is planned), and with multiple global donor and research partners. PSI is seeking to leverage both in-person meetings as well as webinars for wider attendance.



Lessons Learned: Demand and adoption – (+) denotes positive experience from the projects, (-) negative and  $(\pm)$  mixed

- (±) There are a range of factors driving policy adoption and uptake in countries, often beyond the direct control of the Unitaid funded projects. Country level leadership, interest and capacity (including having a champion for the intervention) can swing the adoption pendulum swiftly.
- (-) The Plus Project is not showing much linkage with policy adoption in Plus Three countries or non-project
  African countries. There are good efforts in these countries within available budgets, but impact is more distal.
  It may be useful to rebalance budgets across countries so Plus Three countries received a little more support.
  Further support will be needed to accelerate PMC uptake.
- (+) The Plus Project's consolidated approach to PMC implementation in countries including community outreach has been of much value.
- (-) The misalignment of project implementation close out by PSI in countries with availability of final research
  results from LSHTM while somewhat inevitable given research can conclude after project implementation –
  has presented a missed opportunity to leverage country engagement and impact on scalability. A more
  thoughtful approach on how to marry the timings of the two would be instrumental.

#### 2.3.4. Access barriers: Supply and delivery

Finding 12: The Plus Project has helped address the supply and delivery access barrier by expanding the potential approaches to PMC delivery, with the main challenge being with regards to coverage of PMC, especially in the second year of children's lives. Delivery through existing national health programmes has its efficiency benefits but PMC coverage is limited by the reach of the EPI and nutrition programmes and the extent of coordination between these and the malaria programme

Strength of evidence rating	Rationale
Medium (3)	Agreement in most instances between global and country level stakeholders. Some details in documentation only preliminary (e.g. cost-effectiveness data).

Overall, the Plus Project is considered to have demonstrated feasibility of PMC in focus countries. The project has tested a number of aspects in terms of implementation of PMC which had not been trialled before such as (i) the roll out of PMC beyond the first year of life, (ii) different number of doses within the first two years of a child's life, and (iii) how to integrate PMC with existing programmes - mainly EPI and to a lesser extent other programmes, including community based programmes. In addition, it was implemented in some settings alongside SMC to demonstrate subnational approaches to chemoprevention.

While the WHO 2022 guidelines removed the requirements for some aspects to be explored, the project still aimed to provide learnings on feasibility of implementation (e.g. number of contacts, use of alternative programmes to EPI etc). Most stakeholders considered that the project has done this well and this evidence can be used by project country governments in their forward planning and consideration of PMC. The particular added value from the Plus Project in focus countries was enabling countries to introduce and undertake PMC implementation by priming them for introduction through capacity building of health care workers, improving quality data collection etc.

Overall stakeholders were very complimentary of the approach of integrating PMC with existing national health programmes. Use of EPI programmes to distribute PMC has generally worked well, especially countries with relatively strong EPI programmes and where coordination worked well between NMCPs and EPI programmes. Stakeholders really appreciated the approach of integrating PMC with existing programmes because of (i) not introducing parallel systems; (ii) limiting costs of the programme given existing systems were utilised; and (iii) the co-design process with countries to trial the PMC schedule based on what was considered best for individual



country contexts. The cost-effective delivery of PMC through existing programmes was noted by many stakeholders to be a key strength and to increase the likelihood of implementation of PMC going forward. Preliminary findings indicate that cost per PMC dose per child is approximately US\$0.20-US\$0.50 while SMC is approximately US\$1.00-US\$1.60, mostly due to the increase in SMC cost through campaign delivery rather than existing programmes, highlighting the benefits of PMC's integrated approach.<sup>24</sup>

Box 2.4 presents examples from implementation in Côte d'Ivoire and Mozambique and stakeholders' views on the efficiency of the delivery of this approach.

### Box 2.4. Stakeholder views on efficiency of delivery of Plus Project approaches in Côte d'Ivoire and Mozambique

In **Côte d'Ivoire**, the delivery methods primarily leveraged the EPI contact points. SP doses were administered during vaccination clinics, outreach strategies, and special events like World Malaria Day and World Children's Day. This integration aimed for efficiency and cost-effectiveness by utilising established health service infrastructure. One hundred percent of facilities in Côte d'Ivoire received at least one supervision visit in 2023, with data accuracy scores reaching 94.6% in 2023, indicating robust monitoring of delivery quality.<sup>25</sup> The deployment of a dedicated PMC focal point (PSI District Coordinator), in each district also provided strong local support for implementation. Also, the project conducted comprehensive cascade trainings for 278 providers, 594 CHWs, and 96 supervisors in Côte d'Ivoire on PMC implementation and effective communication.<sup>26</sup>

In **Mozambique**, including PMC as part of the EPI schedule at the health facility was recognized by Mozambican stakeholders to be an opportunistic delivery method that required limited resources to implement. The healthy child consultation<sup>27</sup> was the preferred point of entry of PMC as it is the first point of contact of the child with the health provider, and therefore potentially would provide better coverage results, as it can capture any child that have arrived at the health facility.

Use of EPI programmes to distribute PMC has generally worked well, especially in countries with relatively strong EPI programmes and where coordination worked well between NMCPs and EPI programmes. In Mozambique, the process evaluation showed that depending on the size of the health facility and the number of people working in healthy child consultations, PMC and EPI administration was undertaken by the same person in 66% of the cases. On the contrary, in countries where the EPI coverage is not as strong and especially to reach children in their second year of life who are less likely to be brought to EPI contact points, other approaches have been useful such as integrating with Vitamin A programmes and utilising community outreach initiatives (e.g. Cameroon). Cameroon decision makers deemed this approach so successful that PMC will now be integrated through CHW programmes. As one Cameroon stakeholder said, "before the Plus Project were doing 5 doses in some districts but then were able to extend to 8, because of the help of the community approach".

However, some weaknesses in coordination between NMCPs and EPI programmes were noted by stakeholders. This included insufficient engagement between NCMP and EPI programmes which reduced buy-in of EPI programmes and awareness of potential issues with EPI schedules etc. In addition, challenges with reaching children through EPI programmes have also been experienced in PMC roll out. For example, under-immunised children have not been

<sup>&</sup>lt;sup>24</sup> Pitt, C (2025), Using Cost-Effectiveness Analysis to Maximise Health Outcomes. Insights for SMC, PMC, and malaria vaccines, 28 February 2025, Lome - Togo

<sup>&</sup>lt;sup>25</sup> PSI (2023), Plus Project 2023 Annual Report

<sup>&</sup>lt;sup>26</sup> PSI (2023), Plus Project 2023 Annual Report

<sup>&</sup>lt;sup>27</sup> The Healthy Child Consultation (HCC) is a regular health check-up for children, typically provided at health facilities or through community-based programs like mobile brigades. They aim to monitor a child's growth, development, and overall health, identify potential health issues, and provide preventive and curative care. It is the point of entry for a child – a triage for children at the health centre - where children are weighed, given vitamin A and then sent to nutrition, EPI or sick child consultations depending on needs. It is implemented in some other countries, in addition to Mozambique.

<sup>&</sup>lt;sup>28</sup> Project Plus evaluation results – close out meeting presentation 15/04/2025



reached as effectively by PMC as immunised children, compounding inequities in both immunisation and malaria prevention. As one stakeholder noted, "the challenge with implementing IPTi through EPI programmes is that it should be implemented in a functioning EPI programme. So there is a high risk of continuing inequities as children who are most likely not to have nets and need PMC are the ones who are most likely not to get vaccines and PMC". Some mitigation approaches were adopted such as in Cameroon and in Mozambique where PMC was added to scheduled outreach visits in 2024 as both an opportunity to mobilise hard to reach populations and to provide a point of contact for children to receive a dose of SP. Although there is variation in uptake between districts, the use of outreach visits has increased the number of doses given across the province by 8.5%, highlighting some success with this approach.<sup>29</sup>

The implementation of PMC with EPI programmes and other programmes such as vitamin A, improved some existing services and this is discussed further in Section 2.4.

Coverage of PMC was lower than expected in the first and second years of children's lives, particularly decreasing in the second year. Whilst integration with existing health programmes has been complemented, one aspect of the project which has not achieved anticipated success is with regards to PMC coverage levels. In the PSI-supported countries, the levels ranged from 36% to 85% at contact points as can be seen in Figure 2.3 below. Appendix E describes project logframe achievements and includes additional information by country on coverage rates achieved.

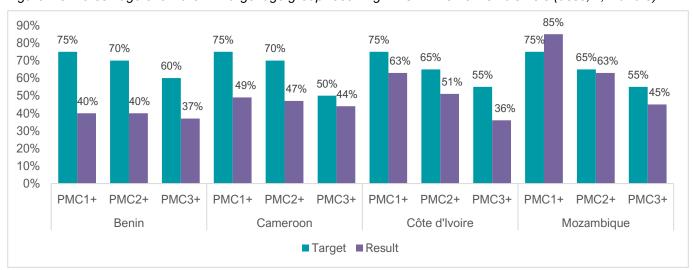


Figure 2.3: Percentage of children in target age group receiving PMC in intervention districts (dose, 1, 2 and 3)30

In particular, the coverage levels were lower than expected in the second year of life. This was mainly due to (i) some expected EPI visits did not occur (as noted above in Benin); (ii) health workers and caregivers incorrectly understood that the EPI schedule ended at nine months with measles 1 and, therefore did not plan for subsequent EPI and PMC visits; and (iii) with children getting heavier over age 1, it made it harder for them to attend appointments.<sup>31</sup> However, this varied by country with Mozambique notably having higher coverage levels than other countries as it leveraged the health child consultation.

Box 2.5 presents specific reasons for the achievement of better and lower coverage levels Mozambique and Côte d'Ivoire respectively.

#### Box 2.5. Mozambique and Côte d'Ivoire PMC coverage levels

<sup>&</sup>lt;sup>29</sup> Project Plus evaluation results – close out meeting presentation 15/04/2025

<sup>30</sup> Project Plus, NMCP. Quimioprevenção Perenal da malária: Implementação e Resultados Presentation 15 April 2025

<sup>31</sup> PSI (2025), The Plus Project 2024 Annual Report



In **Côte d'Ivoire**, while the project achieved its objective of 70% of children in the target age group receiving one or more doses of SP in Côte d'Ivoire in 2023 (71% achieved)<sup>32</sup>, there was a significant deviation from the expectation of children completing the full PMC schedule. In 2022, the initial coverage for 1 or more doses was only 10% against a target of 50%,<sup>33</sup> primarily due to a later implementation start. In subsequent years, reasons for drop off included missed expected EPI visits, misconceptions among health workers and parents that the EPI schedule ended at 9 months (leading to missed later appointments), and logistical challenges for caregivers with older, heavier children or multiple young children.<sup>34</sup> Difficult access to certain health centres, especially during the rainy season, also hindered consistent delivery.

In Mozambique, the Plus Project was conservative in the initial number of contacts points using a 4-dose regimen (4, 9, 12 and 18 months) that aligned with the main vaccination points at 4, 9 and 18 months and the provision of vitamin A at 12 months. In September 2024, a fifth contact at 7 months was added to align with the new malaria vaccine contact. Overall, Mozambique was the only country that met any population dose coverage target and that was for the first dose.<sup>35</sup> There was only one district in Sofala province that reached target number of children for the first three contact points, two districts that reached the target coverage across the first two doses, while four districts that did not reach any coverage target.<sup>36</sup> Uptake was generally seen to decrease after the second dose.<sup>37</sup> Leadership at the district level, particularly of the chief medical officer, and follow-up with health facilities was seen as an important reason for increasing uptake and achieving targets. Other reasons were the degree that PMC was integrated into routine healthy child consultation at the health facility level and provider counselling of caregivers. Coverage of SP-PMC in the second year of life also remains challenging<sup>38</sup>, as fewer caregivers return to the health facility to continue vaccine schedules after the 9-month measles vaccination, which poses a threat for Measles 2 and for the new malaria vaccine booster coverage. Stakeholders stated that this could be attributed to the distance that people had to travel to reach the health facilities, conflict with planting or harvesting times, and that caregivers view the 12-month Vitamin A supplement/deworming contact point, not important as it wasn't against a vaccination/prevention against a life-threatening disease, like measles or malaria. Vitamin A is also delivered by the Nutrition Programme through the outreach programme. A couple of stakeholders also mentioned that initially, some health care providers at the facilities were not registering the PMC doses given, as they had not attended the formal training sessions and were unsure of correct procedure. This was mitigated through supportive supervision and on-the job training.

Importantly, one stakeholder stated that they felt that the intervals between the doses was too long to have any major impact on parasite burden. Taking into account that SP efficacy in Mozambique is reduced to only 16 days (estimated), that results in lower coverage against malaria.

Lessons Learned: Supply and delivery – (+) denotes positive experience from the projects, (-) negative and  $(\pm)$  mixed

• (+) Integration of health programmes is of top priority, is people centred and also extremely relevant in the current global health financing environment. Donor programmes should incorporate approaches that encourage this integration.

<sup>32</sup> PSI (2023), Plus Project 2023 Annual Report

<sup>33</sup> PSI (2022), Plus Project 2022 Annual Report

<sup>&</sup>lt;sup>34</sup> PSI (2024), Plus Project 2024 Annual Report

<sup>&</sup>lt;sup>35</sup> PSI (2024), Plus Project 2024 Annual Report

<sup>&</sup>lt;sup>36</sup> MoH, NMCP(2025), Quimioprevenção Perenal da Malária (QPM) Implementação e Resultados, Presentation

<sup>&</sup>lt;sup>37</sup> PSI (2024), Plus Project 2024 Annual Report

<sup>&</sup>lt;sup>38</sup> PSI (2024), Plus Project 2024 Annual Report



#### 2.3.5. Sustainability and scalability

5. How sustainable are the gains and what gaps remain? Have the projects primed scale-up at global and country levels and what are key driving factors? What are future prospects under the current complex funding environment?

Performance rating for the Plus Project and Supply Grant Output 4 – Did not meet all expectations

**Explanation** – Whilst a number of the programmatic sustainability criteria have been achieved, scale-up is very uncertain in the current financing climate. Whilst the projects could have potentially done more in some instances, this significant challenge is recognised as an external factor.

Finding 13: The Plus Project has well supported a number of aspects for the institutionalisation and scalability of PMC in the four focus countries, although not uniformly across countries. There is good political support and a degree of integration within health systems, and while some have included PMC in their Global Fund funding requests, financing is an important issue in light of the current global health financing status – an unexpected factor beyond the control of the project.

Strength of evidence rating	Rationale
Medium (3)	Strong agreement from global and country level stakeholders close to the detail and confirmed in documentation (e.g. PSI Institutionalisation Report). Strong triangulation for Côte d'Ivoire and Mozambique, less so for Benin and Cameroon.

The project defined institutionalisation as "a process and end state by which an intervention becomes an integral, routine and stable part of a health system. Integration into a health system best positions an intervention to achieve both large scale reach and sustained impact overtime".<sup>39</sup> This closely aligns with the Unitaid Scalability Framework, and particularly the country level factors on securing political and financial support, ensuring programmatic and operational readiness, and creating community-driven demand.

As evidenced by the Plus Project Annual Reports, the institutionalisation meetings and tools developed, the Plus Project has put significant emphasis on institutionalising PMC in the four focus countries which is a very positive step towards sustainability and scalability.

This includes the development of an **Institutionalisation Framework** (see Appendix J) which provides an overview of the institutionalisation drivers and their status. In addition, in order to help countries track progress on institutionalisation, the project also developed a **PMC Institutionalisation Status Reflection Tool** (also see Appendix J). The Reflection Tool provides a guideline to help countries track progress based on parameters of core values (defined as beliefs and values of key stakeholders are sufficiently aligned in support the intervention), leadership, policy and resources. Overall, we consider the framework and tool to be helpful resources, although certain aspects could be further emphasised including coordination between the malaria control and EPI programmes as well as training and capacity building of health care workers in the EPI system to deliver PMC.

Our assessment from the document review and the stakeholder interviews show that good progress has been made in institutionalisation of PMC, although not uniform across the four focus countries. Figure 2.4 illustrates

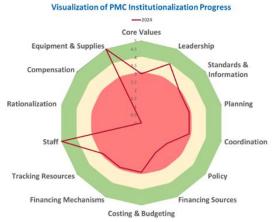
<sup>&</sup>lt;sup>39</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024

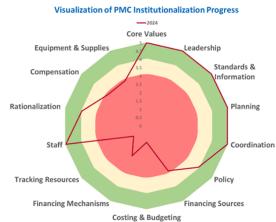


how the countries scored themselves during the Plus Project Annual Meeting in October 2024. Acknowledging that this assessment is based on progress until October 2024, rather than to date, we found, with the exception of the financing and resources assessment, to be in line with the feedback provided during the stakeholder consultations. Appendix K includes more details on the country's status of progress mapped against each institutionalisation driver, including an explanation of all drivers.

Figure 2.4: PMC Institutionalisation in the four focus countries<sup>40</sup>

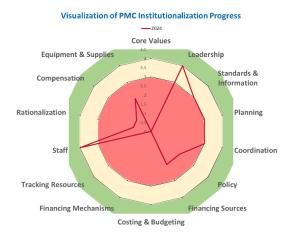
## Benin Cameroon

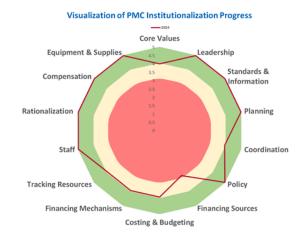




#### Côte d'Ivoire

## Mozambique





#### Legend:

Driver scores falling in the red area show institutionalisation is weak

Driver scores falling in the yellow area show some level of institutionalisation has occurred and should be monitored closely

Driver scores falling in the green area show institutionalisation

As can be seen from the figure, among the four focus countries, Cameroon and Mozambique have achieved greater progress in institutionalising PMC. On the other hand, Benin and Côte d'Ivoire still have gaps which need to be addressed. The following key points of progress are noted for each institutional driver:

<sup>&</sup>lt;sup>40</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024



- Core values: Across the four countries progress has been made in terms of aligning stakeholder's beliefs and values in support of PMC. The stakeholder interviews found that there is generally strong political will among government officials, MoH staff and key stakeholders. Even in Côte d'Ivoire which has not yet integrated PMC in the EPI system, the stakeholder interviews found that there is overall high-level political support for PMC thanks to the Plus Project. The only misalignment is with donors due to the evolving global health financing environment, as further explained in the section below.
- Leadership and governance, including integration with health systems: These are the areas where most progress has been made across all four focus countries. Cameroon and Mozambique show stronger progress, with PMC being fully integrated in the EPI system and planning. For example, in Mozambique, the institutionalisation of PMC is high throughout the national EPI system and implementation benefits from strong leadership from the NMCP. However, when looking at the integration of PMC in the national system of Côte d'Ivoire, the government has decided to keep the PMC data collection register separate from the national DHIS2 tools. Stakeholders highlighted that this fragmentation hindered effective data collection and comprehensive national oversight. Potential stock outs of SP are a significant concern to country stakeholders so there is a high need for embedding of PMC within country supply chains and data systems.
- Policy: As already highlighted in Section 2.3.2 on Demand and Adoption, significant policy progress has been made in Benin, Cameroon and Mozambique. However, during the Plus Project Annual Meeting in October 2024, several countries flagged that a key area of focus remains the adaptation of the results and lessons learned to tools and guides at the national level that can be used by healthcare professionals and other stakeholders to continue implementing PMC. For example, Benin flagged the need to revise the PMC implementation guide and training modules.<sup>41</sup> Similarly, Cameroon highlighted the need for a national guide revision, production and dissemination in health centres.<sup>42</sup>
- Resources: Financing remains a challenge as all countries rely substantially on external funding for PMC. The four countries Benin (August 2024), Cameroon (August 2024), Côte d'Ivoire (June 2024) and Mozambique (July 2024) have confirmed funding for SP procurement, with Cameroon, Côte d'Ivoire, and Mozambique including PMC in their existing Global Fund grants, and Benin committing to procure SP with domestic financing in 2026.<sup>43</sup> This funding is to be used to continue delivery of PMC in existing areas and Benin has committed to including five new districts while Mozambique is planning to cover four new provinces. However, the change of the global health funding landscape threatens this funding. For example, following the abrupt ending of the US government financing to many global health programmes in February 2025, Côte d'Ivoire's NMCP has decided not to scale-up PMC nationally until 2027, opting to maintain it only in the three project-supported districts through the end of 2026, aligning with the Global Fund GC7 grant duration. Moreover, competing malaria priorities, such as the introduction of malaria vaccines, could hinder scalability of PMC. In Côte d'Ivoire, stakeholders highlighted that the significant scale-up of SMC to 13 districts in 2025 and the introduction of the R21 malaria vaccine in Bouaflé in 2024, may divert resources from PMC. All four countries highlighted both in the Plus Project Annual Meeting in October 2024 and in the interviews, the need to secure more diversified and domestic financing.

In pre-2025 global health financing circumstances, the gains made in the focus countries were expected to be sustained and potentially scaled up. However, the current complex global health financing environment substantially threatens the sustainability and scalability of the progress made under the projects. Figure 2.5 below aims to summarise the key factors that are driving sustainability and scalability at present.

<sup>&</sup>lt;sup>41</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024

<sup>&</sup>lt;sup>42</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024

<sup>&</sup>lt;sup>43</sup> Plus Project, 2024 Annual Report, Submitted 2025.03.13



Figure 2.5 Factors driving PMC sustainability and scalability in June 202544

Fact	ors supporting scale-up of PMC	Fact	Factors negatively affecting scale-up of PMC		
<b>+</b>	Supportive country policies	•	WHO guiding principles for prioritising malaria interventions in resource constrained settings, which in effect deprioritises PMC on account of reduced funding for malaria prevention and control.		
<b>+</b>	Low cost of intervention	•	Lack of donor support		
+	Integration in the EPI system	•	Alternative prevention measures (e.g. malaria vaccine)		
<b>+</b>	Trained healthcare professionals		SP resistance		
<b>+</b>	High acceptability by children and caregivers				
<b>+</b>	Availability of dispersible paediatric SP				

Among the factors negatively affecting sustainability and scalability of PMC is the current complex global health financing environment, as unanimously recognised by all stakeholders interviewed. The aim of Unitaid's projects' scale-up is that once the projects have ended, PMC would be scaled-up due to the support by global partners and other external financing, and that SP would be procured from manufacturers who had WHO PQ. This is less likely to be the case for these investments due to the following:

- WHO guidance does not prioritise chemoprevention compared to other malaria prevention strategies (e.g. nets, vaccines), in light of the constrained funding for malaria prevention and control overall. In April 2024, WHO published the Guiding Principles for Prioritising Interventions in Resource-Constrained Country Contexts to Achieve Maximum Impact for National Malaria Control Programmes. The document recommended that, in resource-constrained country contexts and based on the costs of the different drugs and interventions, countries should prioritise treatment strategies through ACTs and insecticide-treated nets in terms of prevention. In terms of chemoprevention, the recommendations highlight that PMC is a new intervention which should not be further scaled up. These guiding principles were published in 2024 and therefore based on assumptions made in a different funding scenario. However, these are still the guidelines currently being followed.
- Key global donors (such as Global Fund, PMI) are undergoing prioritisation exercises and are referring to WHO guidance to aid countries in their decision making. In the case of malaria investments, Global Fund is prioritising access to quality diagnosis and treatment.<sup>46</sup> Prevention interventions, such as vector control and SMC, are next in the prioritisation exercise, while other chemoprevention measures are lower in priority.<sup>47</sup> Specifically, the reprioritisation approach states that "in areas where PMC roll-out has not started, priority should be given to other ongoing interventions".<sup>48</sup> Moreover, Global Fund is pushing for "procurement [of SP for PMC] should be transitioned to the government as soon as this is feasible" and for PMC to be fully integrated in the routine EPI services.<sup>49</sup> Despite this reprioritisation exercise, PSI has supported the four focus

<sup>&</sup>lt;sup>44</sup> Adapted from the Plus Project 2024 Scalability planning and reporting\_Submitted 2022.02.28

<sup>&</sup>lt;sup>45</sup> Guiding principles for prioritizing malaria interventions in resource-constrained country contexts to achieve maximum impact

<sup>&</sup>lt;sup>46</sup> Global Fund (2025) GC7 Programmatic Reprioritisation Approach: Protecting and enabling access to lifesaving services.

<sup>47</sup> Ibid.

<sup>48</sup> Ibid.

<sup>49</sup> Ibid.



countries to include PMC in their Global Fund applications. As highlighted in the stakeholder interviews, the success of securing this funding will also depend on the extend of promotion of PMC by RBM consultants who support the Global Fund malaria funding requests development. Similarly, for PMI, the 2025 Technical Guide reports that PMI is not currently prioritising PMC implementation, although the Guide allows for PMC funding upon country request.

Therefore, in light of the above, **PMC** is expected to need to be financed through national budgets if it is scaled up. Given the apparent cost-effectiveness of PMC, it could be feasible for some countries to utilise their national budgets. However, this requires the willingness of national policymakers and availability of national budgets. For example, Benin has committed to procure SP for expansion districts in 2026 using domestic funds.<sup>50</sup>

In addition, without external donors financing, countries are less likely to pay a premium for the more expensive WHO PQ SP from the supported manufacturers. As reported by manufacturers, the WHO PQ products price is significantly higher than products that do not have WHO PQ, so if PMC is to be supported through national budgets, national policymakers may decide to purchase SP from non-WHO PQ manufacturers as they are cheaper.

Finally, another threat to sustainability and scalability, is the competition of resources and time allocated to PMC versus other malaria prevention strategies, especially the malaria vaccine. One stakeholder mentioned that there is currently a "huge demand for malaria vaccines from ministries of health" and this amount of interest is incomparable to that for PMC.

There has been limited institutionalisation outside of the four focus countries, including in the Plus-Threecountries and non-project countries. This is because there were limited resources diverted to more engaged action in these countries.

Lessons Learned: Sustainability and scalability – (+) denotes positive experience from the projects, (-) negative and  $(\pm)$  mixed

(-) Unitaid's sustainability and scalability model relies predominantly on international donors supporting the
intervention following the pilot projects. In the current global health international financing situation, this
assumption is risky and exploring ways to encourage domestic financing or alternative innovative financing
measures is paramount.

#### 2.3.6. Impact and value-add of regional manufacturing

6. What is the impact and value add of supporting regional manufacturing of SP products for PMC?

Finding 14: Unitaid's support for regional manufacturers is considered to be a valuable investment and expected to provide ongoing benefits beyond the timeframe of the project.

Stakeholders unanimously considered that Unitaid's support for regional manufacturing was valuable. Beyond the direct impact of the project on improving the availability of SP-PMC for malaria chemoprevention for children, the projects have had wider benefits in terms of furthering the regional manufacturing agenda in Africa.

From the perspective of **manufacturers** this relates to:

Improved capacity of manufacturers to be able to obtain WHO PQ. This includes aspects like ability to
obtain GMP certification, undertake BE studies and prepare dossiers for PQ submission. Emzor and Swipha
will be the only two manufacturers in Nigeria with WHO PQ which is testament to the significant impact of the
support from MMV.

<sup>&</sup>lt;sup>50</sup> Plus Project 2024 Scalability planning and reporting\_Submitted 2022.02.28



- Production of higher quality products. This has been aided in part by achieving GMP compliance
  certification because once a facility is deemed compliant, the manufacturer does not have to apply for this
  certification for subsequent regulatory dossier submissions for two years. Therefore, WHO PQ process for
  other products will be less onerous.
- Reputational benefits for manufacturers as it is thought that WHO PQ will provide manufacturers with brand
  recognition for the quality of their products. From the government, regulator and user perspectives, the
  following aspects were highlighted as important value adds from investing in regional manufacturing:
- Development of quality products produced locally which will improve the quality of health products and public health.
- There is more assurance for governments and people in Africa that products required to treat or prevent diseases that disproportionately affect African people (e.g. malaria) are more likely to be available even if there are demands placed on global supply chains for other products and supply chains, i.e. increasing supply chain independence. This has been a significant concern since COVID-19 when many manufacturers prioritised COVID-19 products and deprioritised malaria products. As one stakeholder said "It's great to have manufacturing now close to where people need the drugs. This makes the health environment at the regional level stronger."
- The regulatory and government entities have become more knowledgeable about the WHO PQ process e.g. the Ministry of External Affairs in Nigeria needed to supply documents for the BE studies which they had not previously undertaken and going forward, they will now be aware of these requirements. These efforts also support the aims of the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria to raise the quality of products produced locally which it is trying to do through setting standards and policies and has itself reached Maturity 3 (ML3) in the WHO Global Benchmarking Tool.
- In addition, the examples of Emzor and Swipha being able to obtain WHO PQ may spur other manufacturers
  in Nigeria to aim for WHO PQ. However a significant factor is whether donors will procure these products
  which is now very uncertain.
- The supply time for products is expected to be reduced given the shorter distance for the products to travel
  which is expected to reduce stock outs. In addition, another benefit of local manufacturing is in terms of
  reducing emissions from the reduced travel.
- More widely, there are benefits of increasing regional employment.

There are mixed views regarding pricing with some stakeholders expecting that regional manufacturers will be able to provide products at lower total cost (i.e. product and transport etc) particularly due to the transport cost savings. However, other stakeholders think that cost savings on transport will be very limited on large orders given efficiency gains with economies of scale and often manufacturers from other regions are able to produce products more cheaply. However, the latter has not eventuated in terms of SP-PMC.

# Lessons Learned: Regional manufacturing – (+) denotes positive experience from the projects, (-) negative and $(\pm)$ mixed

- (+) Unitaid's investment in local manufacturers can have wider reaching benefits beyond their specific investment.
- (+) The manufacturer characteristics that aid success include: (i) financial capabilities of a company; (ii) team and their capabilities; (iii) the company's business strategy, including mid to long term investment plans; (iv) regulatory strength capacity and most importantly, (v) a company's maturity and experience undertaking the process for WHO PQ before.



#### 2.3.7. Dissemination

7. How well have the projects disseminated knowledge, evidence and lessons on equitable access and has this contributed to broader awareness/ support for these areas?

Finding 15: Overall, the project has been successful in disseminating knowledge, evidence and lessons learned on PMC to date and has contributed to broader awareness of PMC. It is recognised that further findings from the research are yet to be disseminated.

Strength of evidence rating	Rationale
High (4)	Strong agreement from global and country level stakeholders close to the detail and confirmed in documentation and transition webinars.

Stakeholders at the global level generally found that the project information, implementation experiences and emerging evidence have been proactively and consistently shared with stakeholders. The following dissemination activities were mentioned as effective in developing and disseminating knowledge, lessons learned and advancing PMC implementation. A full list of the dissemination activities can be found in Appendix L.

- COP: PSI instituted a COP on PMC, a collaborative platform for NMCPs, EPI implementation partners, researchers and other stakeholders. The COP is viewed by a wide range of partners as highly effective in disseminating the knowledge, lessons learned and keeping stakeholders involved in the PMC implementation projects and their progress. The COP is led by a Secretariat and there are more than 100 partners involved. NMCPs of the focus countries often join, showing a strong interest in the platform. The COP also included stakeholders from the Multiply Project, the GiveWell project and the Malaria Consortium Project in Nigeria. Despite the inclusiveness of the COP, engagement was sometimes limited due to busy schedules particularly for stakeholders outside of focus countries and global stakeholders. From the interviews, it emerged that further coordination would have been beneficial to ensure global partners received regular updates on the PMC projects. Beyond the project, there is an interest by many stakeholders to continue the COP, highlighting its perceived usefulness. Sa
- **Presentations and events at conferences/webinars:** Knowledge and lessons from the Plus Project and the Supply Grant (Output 4) were disseminated at several conferences, including at the 8th Multilateral Initiative

<sup>&</sup>lt;sup>51</sup> The objectives of the COP are: (i) exchange plans, lessons learnt, and good practices regarding PMC implementation; (ii) discuss PMC implementation research evidence; and (iii) share resources to support PMC implementation. PMC Community of Practice Terms of Reference.

<sup>&</sup>lt;sup>52</sup> The COP Secretariat is composed of the Ministry of Health of Cameroon, the Ministry of Health of Benin, ISGlobal, LSHTM, Malaria Consortium, PATH, PSI, MMV and WHO. Both NMCPs from Cameroon and Benin act as co-chairs. The Secretariat met initially once a week and is currently meeting every other week. Membership is open to all parties interested, provided that their application is seconded by a member of the community and endorsed by at least one of the co-chairs. The COP has been meeting on a quarterly basis and also had an in person meeting in April 2024 on the sides of the 8th Multilateral Initiative for Malaria Society Conference in Kigali, Rwanda.

<sup>&</sup>lt;sup>53</sup> There are ongoing discussions that the COP on PMC could be merged with the SMC Alliance, whose Secretariat is led by MMV, to become the Chemoprevention Alliance or that an umbrella organisation is created to include all chemoprevention strategy initiatives - SMC Alliance, the PMC COP, the IPT school children interest group and the Post-Discharge Malaria Chemoprevention interest group (Reference: Plus Project 2024 Scalability planning and reporting, February 2025). Some stakeholders mentioned that aligning these different communities of practice would be helpful for government stakeholders (given that governments' NMCP focal point is usually the same person for PMC, SMC, IPT-Sc). At the time of the SMC Alliance Annual Meeting in February 2025, it was considered that IPTp would not be part of this merge as there is already a strong Roll Back Malaria Partnership Malaria in Pregnancy Working Group. However, as this working group has been funded by PMI, it is unclear whether the funding will continue and therefore the working group will be able to be sustained given the current withdrawal of PMI from malaria prevention funding.



for Malaria Society Conference, and the ASTMH Annual Meeting in November 2024 in Louisiana, New Orleans. Moreover, some of the preliminary research findings, such as the cost-effectiveness analysis and the PMC Operational Handbook were presented at the SMC Alliance Annual Meeting in Lomé, Togo, in February 2025. Overall, stakeholders found that it was effective to leverage these opportunities to share evidence and lessons learned. There have also been regular webinars and meetings with WHO GMP, countries and other stakeholders to disseminate updates on the project, such as through the phase-out webinars. This was found by stakeholders to be helpful in understanding the different approaches taken by the countries. Dissemination will continue once findings are finalised (e.g. in Côte d'Ivoire, findings will be shared through a meeting with national policymakers, a policy report submitted to the Ministry of Health, and project summary prepared for administrative and political levels of government).

- **Newsletters:** Regular newsletters have been published by PSI. These have been issued in English, French and Portuguese, which was appreciated by some stakeholders.
- Country technical working groups: Within the four countries, technical working groups were formed at a
  central and provincial level, led by the NMCP to discuss lessons learnt and to support planning and
  implementation. Regular progress meeting through these working groups were held at both the central and
  provincial level.

Stakeholders agreed that these dissemination strategies have helped to build broader awareness of PMC among different stakeholders. In particular, the active inclusion of national policymakers, including NCMPs, has been very effective in ensuring their understanding, interest and acceptability of PMC in focus countries. Dissemination also encouraged country exchanges, which was deemed very helpful.

As noted above, one limitation has been the limited research evidence presented given the delays in this aspect of the project, although it is recognised that this should be forthcoming. In addition, **some country stakeholders found that Plus-Three countries could have been more actively involved.** For instance, some national stakeholders in Plus-Three-project countries mentioned they had limited interaction with the Plus Project or were mainly in contact with other PMC projects.

Lessons Learned: Dissemination – (+) denotes positive experience from the projects, (-) negative and (±) mixed

• (+) A COP mechanism, as convened by the Plus Project, brings together multiple partners and countries and is a useful and efficient way to coordinate and disseminate findings and facilitate cross-country learning.

#### **2.4. IMPACT**

8. Are the projects' impacts still valid at this end-term and aligned with Unitaid's framework and approach?

Performance rating for the Plus Project and Supply Grant Output 4 - Did not meet all expectations

**Explanation** – Unitaid's investments in PMC showed a valuable health and economic impact, although lower than envisioned. This is due to lower than expected dose delivery, with an average of only 2 doses delivered per eligible child, an (annualised) protective effectiveness per PMC dose delivered of around 7-8% and lower than expected scale-up due to the global health funding crisis.

Finding 16: PMC has demonstrated some valuable health and economic impact, although this is lower than initially envisioned. This is primarily due to lower



# than expected PMC dose delivery, with only 2 doses delivered per eligible child, and lower scale-up due to constraints in the global health funding landscape.

Strength of evidence rating	Rationale
Low (2)	There are a number of limitations regarding the modelled estimates: (i) no access to the final data from the research studies on cost-effectiveness and protective effectiveness of PMC supported through the grants; (ii) high uncertainty in future scale-up of PMC given the recent significant changes to the global health funding landscape and the diminished amount of funding; (iii) lack of district-level data specific to the role out of PMC.

The impact figures have been estimated by developing a bespoke-Excel based model for this evaluation which closely builds on and leverages the PMC impact model which was developed at the start of the grant by the grantees. As noted in the strength of evidence rating and rationale, there are a number of significant limitations, and it is likely that the model will need to be revised with latest data once the research studies are completed and there is some further certainty on the global health funding landscape. Therefore, this model was developed so Unitaid can revise the estimates as needed in the future. Following Unitaid's impact modelling approach, the impact estimates provided state only additional impact achieved through the supported work by Unitaid and, thus, ensure that uptake in PMC that would have also happened in the absence of the Unitaid investment is taken into consideration. The impact is differentiated between direct impact (achieved by Unitaid investment in 2023 and 2024)<sup>54</sup> and indirect impact (expected to be achieved in the five years following grant closure from 2025-29). Appendix M provides a detailed overview of the draft model approach as well as input assumptions that have been varied for the three scenarios modelled: conservative, central and best-case scenario.

Table 2.5 below provides a summary of the public health and economic impacts for PMC against Unitaid's KPIs. The key findings from the impact modelling include the following:

• The health and economic impact of PMC is lower than initially envisioned prior to the project start with the most recent evidence pointing towards lower than expected scale-up and impact. Throughout 2023-24, the Unitaid grants directly led to the additional delivery of 1,378,500 PMC doses across the four focus countries averting 79,700 [60,700 - 98,100] malaria cases and 190 [150 - 230] malaria related deaths. This would be equivalent to 5,500 [4,100 - 6,900] Disability-adjusted life years [DALYs] averted.<sup>55</sup>

The indirect impact to expected to be achieved between 2025-29 includes **1,409,000 [946,100 - 1,976,700]** malaria cases and **3,900 [2,600 - 5,500]** malaria deaths averted. This would be equivalent to **114,200 [75,500 - 162,500]** DALYs averted. This is based on an estimated 26.8 million additional PMC doses delivered across the four focus countries as well as six non-project countries that are likely to use PMC and have benefited from the Unitaid investment. For the year 2029, the model estimates that an additional 8,371,100 [7,396,700 – 9,522,600] PMC doses would be delivered leading to 458,300 [307,900 - 642,400] additional malaria case averted and 1,200 [800 - 1,700] additional lives saved.

While PMC offers valuable health impact and is an important tool to combat malaria, the impact from Unitaid PMC investments is estimated to be lower than originally envisioned based on current data information. Key drivers for this include (i) lower than expected dose delivery with an average of only ~2 doses delivered per

<sup>&</sup>lt;sup>54</sup> The estimates do not account for any additional PMC doses delivered in 2025. This could be included once numbers for 2025 are finalised.

<sup>&</sup>lt;sup>55</sup> The reported DALYs only include the benefits on averting malaria cases and death and not the additional benefits of also averting anemia cases.

<sup>&</sup>lt;sup>56</sup> The model includes impact in Burundi, Congo, DRC, Nigeria, Sierra Leone and Togo.



eligible child<sup>57</sup>, (ii) an (annualised) protective effectiveness per PMC dose delivered of around 7-8% in most settings and (iii) lower than expected scale-up due to constraints in the global health funding landscape with estimates that only a total of ~30% of all 35 million eligible children would be covered in 2029.

There would be significant **public health impact through PMC** if the eleven countries included in the analysis manage to achieve a full scale-up for their eligible populations by 2029. This would lead to a significant impact for the years 2025-29 with **2.2 million malaria cases averted and 6,200 deaths averted** due to an estimated 42.7 million doses of PMC delivered.

• Economic impacts in the form of cost-savings to the health system are significant with quantified cost-savings estimated to be around US\$ 14 million [6.5m – 25.7m]. This is for the full time period from averted treatment costs averted for uncomplicated and severe malaria. This is half as much in cost savings as the additional PMC programmes costs which would be estimated at around US\$ 27.4 million.<sup>58</sup> However, these findings are not robust at this stage with further evidence on the costing of the PMC programmes needed.

Table 2.5: Public health and economic impacts of Unitaid's investments in PMC

		Indicator	Direct (2023-24)	Indirect (2025-29)	Total (2023-29)
Public impacts (KPI 4.1)	health	Cases averted [conservative – best case]	79,700 [60,700 – 98,100]	1,409,000 [946,100 – 1,976,700]	1,488,700 [1,006,800 – 2,074,800]
		Deaths averted [conservative – best case]	190 [150 – 230]	3,900 [2,600 – 5,500]	4,000 [2,700 – 5,700]
		DALYs averted [conservative – best case]	5,500 [4,100 – 6,900]	114,200 [75,500 – 162,500]	119,700 [79,600 – 169,400]
Economic impacts (KPI 4.2)		Treatment costs averted (US\$) [conservative – best case]	782,100 [408,900 – 1,273,700]	13,195,900 [6,137,900 – 24,408,500]	13,978,000 [6,546,800 – 25,682,200]
		Total additional PMC programme costs (US\$)	1,404,000 [1,677,000 – 1,207,100]	27,369,500 [28,887,400 – 26,769,400] <sup>59</sup>	28,773,500 [30,564,400 – 27,976,500]

<sup>&</sup>lt;sup>57</sup> Based on data from the four focus countries that had a coverage of 1.9 PMC doses per eligible child in 2024.

<sup>&</sup>lt;sup>58</sup> The total PMC programme costs only take account of direct costs related to the PMC programmes (e.g., commodity, service delivery and estimates for training needs). It does not take account of wider system costs or support provided under the Unitaid grant. The programme costs currently are estimates and do not take account of the data generated through the funded cost-effectiveness studies under the grant.

<sup>&</sup>lt;sup>59</sup> The ranges for the PMC programme costs are lower in the best case scenario due to assumptions on lower service delivery costs compared to the central scenario.



# Finding 17: There were some wider benefits for other health programmes and systems from PMC being implemented alongside these programmes.

Strength of evidence rating	Rationale
Low (2)	Limited feedback based on select interviews or documentation.

The PMC programme was delivered through the EPI programme and other facility-based visits such as vitamin A supplementation visits, de-worming visits, well-child nutrition weighing visits, child health days, and, where relevant, measles 2 and RTS,S vaccine visits. In addition, there were some community-based contacts (e.g., the EPI's community outreach activities and community health worker visits). Some examples of benefits for other programs highlighted include:

- In Cameroon (the only country who implemented community PMC), stakeholders considered community level PMC through integration with community outreach initiatives to be very useful to address access and equity, including reaching under-immunised children for PMC, immunisations and iron supplements, as well as pregnant women for IPTp and calcium supplements. However one stakeholder noted that a strong benefit of PMC when it is implemented at the facility-based level rather than the community level is its cost-effectiveness therefore raising a question about the benefits versus cost when being implemented in community-based programmes.
- In Cameroon, there was also a slightly higher uptake of the Vitamin A programme when beneficiaries knew that they could receive PMC at the same time as Vitamin A.
- In Mozambique, PMC was seen to have a positive effect on the uptake of EPI, weighing children and Vitamin A, in part due to data quality audits and joint supervision.
- An increase in immunisation coverage and participation in nutrition programmes following implementation of PMC was seen in Benin and Côte d'Ivoire. In Côte d'Ivoire, administering PMC as part of the routine EPI encouraged mothers to bring their children to get vaccinated and weighed, minimising the risks of gaps in children's vaccination schedules and leading to routine measurements of children's growth indicators.
- In DRC, PMC implementation has helped to identify weak points of the immunisation schedule and Vitamin A schedule, and this has led to lessons learned for the dispersal of Vitamin A.



#### 3. CONCLUSIONS

In this section, we outline the conclusions from this evaluation including by Unitaid Strategic Objectives.

With regards to Strategic Objective 3 – Foster inclusive and demand-driven partnerships for innovation, Unitaid's investments in PMC have been relevant and appropriate given the malaria epidemiological context and in keeping with Unitaid's aim to promote equity. The design of the Plus Project and Supply Grant (Output 4) had a well thought out approach that comprehensively targeted the range of access barriers to PMC uptake. Even though the landscape for malaria prevention interventions has changed during the course of projects' implementation, particularly in terms of the introduction of the malaria vaccine, PMC remains relevant within a package of prevention interventions. In addition, the investments were 'ahead of the curve' by trialling expanded implementation approaches for PMC in advance of the 2022 WHO guidelines update that confirmed less restrictive implementation. There were some gaps in its scope in that it did not cover some additional research areas highlighted by WHO and donors, although overall, research priorities were deemed useful and relevant and will have considerable value in providing implementation evidence for the planned 2026 field manual by WHO.

The Plus Project co-design feature with country governments was a real strength and fostered national ownership of the PMC implementation. Select other design features such as the interplay between research and implementation and related timings and the "light touch" approach with Plus-Three countries have been more challenging.

The Plus Project was viewed as highly collaborative, with PSI supporting coherence with other partners including through the COP.

Both PSI and MMV managed the complex projects well, including within budget. But there were **two main issues** with project efficiency:

- For the Plus Project, while both the research and implementation components have had their own respective value, misalignment of their timings has meant that project country close out meetings could not benefit from evidence emerging from the research activities. Research delays were also on account of delays in obtaining ethical approvals where there have been important learnings in terms of the potential of time saving by early confirmation of countries and research partners and also providing some training to local researchers on the ethical approval processes. A more thoughtful approach on how to marry the timings of research and implementation would be instrumental.
- The Supply Grant was impacted by delays from manufacturers in achieving WHO PQ as original targets were ambitious given lack of manufacturers' experience with WHO PQ. The project offers important learnings in terms of the need for more realistic timelines to PQ where manufacturers do not have prior experience, as well as in terms of the value of the additional time to PQ given wider benefits this secures in terms of manufacturer capacity and enhancement of regional manufacturing.

With regards to Unitaid's Strategic Objective 1 to accelerate the introduction and adoption of key health products, the project aimed to overcome the **access barriers** of (i) innovation and availability; (ii) demand and adoption and (iii) supply and delivery. Good progress has been made to overcoming these barriers as follows:

Innovation and availability: The Supply Grant (Output 4) has supported good progress from two manufacturers (Emzor and Swipha of Nigeria) towards WHO PQ of SP-PMC although they have not yet obtained WHO PQ. That said, the work under the grants has been instrumental to progress which would not have been achieved in the absence of the grants. In particular, Unitaid's support for regional manufacturers is considered to be a valuable investment and expected to provide ongoing benefits for the manufacturers beyond the timeframe of the project (as for example has been observed for UCL and S Kant that were supported for WHO PQ of IPTp/SMC products previously by Unitaid). This is an important achievement with regards to Unitaid's Strategic Objective 2 to create systematic conditions for sustainable, equitable access. We raise the issue of commercial viability of the SP-PMC product in the face of multiple PQ suppliers and unclear demand with the global health financing crisis.



- **Demand and adoption:** There has been good progress on addressing the demand and adoption access barrier in focus countries through the Plus Project, although the level of contribution of the project has varied by country. The project's several research studies are expected to be valuable for supporting countries with evidence base and implementation guidance on PMC, and are currently being finalised. Overall, the project has been successful in disseminating knowledge, evidence and lessons learned on PMC, another aspect supporting *Unitaid's Strategic Objective 2*. However, LSHTM's inability to share results until finalised, while prudent, presents a missed opportunity to leverage alongside close out of PSI's implementation support in countries. A more thoughtful approach on how to marry the timings of research and implementation aspects of the projects would be instrumental.
- Supply and delivery: The Plus Project has helped address the supply and delivery access barrier by
  expanding the potential approaches to PMC delivery, with the main challenge being with regards to PMC in
  the second year of children's lives. Delivery of PMC through EPI has its efficiency benefits but is also limited
  by the reach of EPI and extent of coordination between the immunisation and malaria programmes in country.

From a sustainability and **scalability perspective**, the Plus Project has well supported a number of aspects for the institutionalisation and scalability of PMC in the four focus countries, although not uniformly across countries. There is good political support and a degree of integration within health systems, but financing is an important issue especially in light of the current global health financing status – an unexpected factor beyond the control of the project. Current WHO prioritisation recommendations for malaria control in resource constrained environments deprioritises PMC, and as donors are following this guidance, external funding is not likely for PMC. Engagement with national budgets is therefore of high priority to support scale-up of PMC.

PMC has demonstrated some valuable health and economic **impact**, although this is lower than initially envisioned. This is primarily due to lower than expected PMC dose delivery, with only 2 doses delivered per eligible child, and lower scale-up due to constraints in the global health funding landscape.

In sum, the overall conclusion of this evaluation is that the Unitaid investments through the Plus Project and MMV Supply Grant (Output 4) have done well with good gains on PMC policy adoption in countries and manufacturer progress towards WHO PQ of SP-PMC respectively. But the next step in terms of scale-up of PMC does not appear likely in the face of limited donor and WHO prioritisation of SP-PMC, and inadequate engagement with domestic financing where governments also face the complex challenge of prioritising different malaria prevention interventions.



#### 4. **RECOMMENDATIONS**

This final section of the report provides recommendations for Unitaid for this project and wider recommendations for other investments based on learnings from this project.

The following <u>four recommendations</u> are proposed for Unitaid to ensure effective close out of the project and that the gains from the project are fully maximised. These recommendations do not necessarily suggest Unitaid invest further in PMC – rather, that it engages with project implementers to ensure outstanding activities are completed and objectives are realised. However, should some additional funding become available, then this could potentially be used for discrete activities to facilitate adoption and scale-up.

- 1. Ensure smooth and effective close-out of the Plus Project, particularly in terms of ensuring research results are concluded and made available widely (for focus countries, Plus-Three and other countries (governments, communities) as well as the WHO implementation manual). A no-cost extension is in place with PSI to support dissemination with countries. PSI's engagement with this evaluation is also a testament of their commitment to support effective dissemination. The COP is also a useful modality to support widespread dissemination, a model that Unitaid could consider sustaining for the future.
- 2. Consider select opportunities with the four focus countries and non-project countries to support drivers for scale-up of PMC. This may include direct Unitaid engagement with country governments or additional funding to grantees or other technical partners for TA to aid countries in accessing funding from the Global Fund or domestic budgets, or to pilot implementation in non-project countries. Another important area for TA is to ensure PMC is integrated into national systems like data systems and supply chains.<sup>60</sup>
- 3. Follow-up with MMV to ensure its continued engagement with the two Nigerian manufacturers on support for WHO PQ and also on their supply viability position. MMV continues to engage with the suppliers beyond Unitaid funding. This value-added commitment from MMV should be followed up upon by Unitaid.
- 4. Advocate that PMC does not get deprioritised by the global community, especially through prioritising strong dissemination of project implementation and research findings at select fora even after the conclusion of the projects. Several stakeholders mentioned that this requires communicating clearly the value add of PMC in terms of its cost-effectiveness and its opportunity to complement and build on the malaria vaccine, which is currently receiving most attention both by malaria and EPI programmes.

The following <u>eight recommendations</u> are proposed for Unitaid in line with its strategy and to foster future results across its portfolio, based on learnings from the PMC investment, including the recent experience of the project in the face of the constrained global health financing situation. Aspects that the projects did well and not so well in this regard are highlighted in italics font.

5. Unitaid should increase emphasis on scalability through domestic budgets – in the face of the growing financing crisis in global health. The co-design with governments approach employed by PSI is an important strategy in this regard. Other examples may include efforts by grantees to align their work with country planning and budgeting cycles, greater emphasis on country political and policy level engagement, greater engagement with multilateral development banks and country finance ministries to explore additional sources of funds, supporting the development of public private partnerships with faith-based companies or private insurances to support PMC funding; etc. Upfront and ongoing engagement on these aspects is essential (rather than one-off or only as project close).

<sup>&</sup>lt;sup>60</sup> For data integration, this could be through modifying existing data collection tools, adapting DHIS2 modules like the routine immunization or malaria dashboards to include PMC-specific indicators. For supply chain integration, this could be through strengthening supply chain management by linking DHIS2 with the logistic management system to ensure accurate forecasting, procurement, and distribution of PMC commodities; and tracking drug consumption patterns at different levels of the health system to optimize supply chain efficiency and ensure timely replenishment of stocks.



- 6. Unitaid should reconsider its role within the regional manufacturing agenda in light of the constrained global health financing environment, with key partners supporting regional manufacturing with likely reduced budgets (e.g. Global Fund, US development aid). This implies that Unitaid's own contribution within the context of what other players do might require a re-think. These reductions will impact available funding both for R&D support for manufacturers as well as purchase of commodities, and therefore Unitaid will need to think about its role and added value in this context (e.g. advocating for solidarity of national governments to procure SP-PMC from African PQ-ed manufacturers whilst ensuring development of a healthy competitive market; further emphasising affordability of the products produced by local manufacturers so they are competitive with established global manufacturers; strengthening African pooled procurement mechanisms such as the SADC Pooled Procurement Mechanism to reduce fragmentation and improve efficiency).
- 7. **Unitaid should emphasise integration across its investments** *with PMC, integration with EPI presented a solid opportunity*, and similar opportunities for other products should also be harnessed, especially noting the constrained global health financing environment. Support for integration needs to be considered carefully noting the pitfalls with combining multiple services without effective planning. For example, future projects should include specific components to assess and mitigate increased workload on health workers when integrating new interventions. This could involve funding for additional temporary staff, incentives, or efficiency-enhancing tools and training to prevent burnout and maintain quality of care across all services.
- 8. Unitaid should carefully think through the optimal management of research and implementation within its projects ensuring the needed synergies between the two to effectively support its work on fostering demand and adoption. This was a missed opportunity in the Plus Project. Potential actions include early planning, timely confirmation of countries and partners (and avoid changing countries midway), and training of local researchers on ERC approvals process. On the point on countries, Unitaid could provide a steer on focus countries during the call for proposals so avoid changing countries later on.
- 9. Unitaid should consider its added value in countries where its investments and engagement (through grantees) is minimal, and whether there might be alternate ways to ensure wider scalability an aspect that worked less than optimally for the Plus Project design. Examples of alternate areas of focus include working closely with WHO to produce guidelines in a timely manner, enhancing work with donors to direct funding in needed areas, enhancing work with partners to ensure the most appropriate TA is provided to countries, supporting advocacy efforts with governments, developing a COP type platform, etc. There may also be a case to rebalance funding across countries to ensure a certain "threshold" of support is received by each country.
- 10. Unitaid should exploit scale-up based on implementation evidence, where feasible. For example, where a WHO recommendation already exists (as is the case for PMC) and countries have champions and have expressed interest. Unitaid should encourage grantees to work with countries and consider scale-up options based on implementation evidence. Approaches may then be course corrected, as needed, when full research results are available. Such an approach also needs support from WHO at both the global and country levels.
- 11. Unitaid's should comprehensively consider demand and supply related access barriers portfolio for innovative health products/ interventions (as was done through the PSI/ MMV work for PMC) and ensure a consolidated approach to funding, reflective of other partner priorities and funding.
- 12. **Unitaid should encourage the iterative co-design process with countries,** *facilitated through the Plus Project* as relevant for other products and portfolios. Engagement with the range of stakeholders should be encouraged
   beyond government, also with community stakeholders and frontline health workers. There should also be mechanisms for project course correction and adaptation by learning in countries in an agile yet structured fashion.



### Appendix A **BIBLIOGRAPHY**

Appendix A provides the list of documents and references used for this report.

#### A.1. THE PLUS PROJECT

#### **Grant documents**

Unitaid (2021) Intermittent Preventive Treatment In Infants - Plus (Ipti+) Final Budget

Unitaid (2021) Intermittent Preventive Treatment In Infants - Plus (Ipti+) Health Impact Model

Unitaid (2021) Intermittent Preventive Treatment In Infants - Plus (Ipti+) Logframe

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#### **Reprogramming and Extensions**

Unitaid (2025) Plus Project Budget 2025 Reprogramming

Unitaid (2025) Plus Project Extension Request Form Annex 1

Unitaid (2025) Plus Project Gantt Chart 2025 Reprogramming

Unitaid (2025) Plus Project Logframe 2025 Reprogramming

Unitaid (2025) SP-IPTI+ Reporting and Accountability Annex 4

#### Other

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#### A.2. MMV SUPPLY GRANT

#### **Grant documents**

Unitaid (2022) MMV Supply Grant Amendment Request Output 4

Unitaid (2022) MMV Supply Grant Budget Output 4

Unitaid (2022) MMV Supply Grant Gantt Chart Output 4

Unitaid (2022) MMV Supply Grant Logframe Output 4

#### **Progress Reports and Unitaid assessments**

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Unitaid (2023) MMV Supply Grant Annex 1 Project Plan Amendment

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## Appendix B CONSULTATION LIST AND INTERVIEW GUIDE

This appendix provides a list of stakeholders interviewed at the global and country level and the interview guide used.

## **B.1.** STAKEHOLDERS INTERVIEWED

Table B.1: List of global level and non-country case study consultations

Stakeholder group/ Organisation	Name(s)	Position	
Unitaid	Ambachew Medhin	Programme Manager, Programme Division	
	Ademola Osigbesan	Sourcing Lead, Access and Regional Manufacturing, Strategy Unit	
	Dale Halliday	Technical Manager, Strategy Unit	
	Ombeni Mwerinde	Monitoring and Evaluation Manager, Results Unit	
	Ying Chen	Grant Finance Manager, Finance Unit	
Grantees			
Population Services International (PSI)	Charlotte Eddis	Project Director	
Medicines for Malaria Venture (MMV)	Pierre Hugo	Vice President Market Dynamics and Global Supply Security, Access and Product Management	
	Celine Audibert	Senior Director, Market Research, Access and Product Management	
	Andre Marie Tchoatieu	Director, Access and Product Management	
Consortium partners			
LSHTM	Roly Gosling	Plus Project Technical Director	
	Matthew Chico	Impact Evaluation and Parasite Clearance and Protection from Infection	
University of Southern Florida	Gillian Stresman	Impact Evaluation Lead	
Centre de Recherche Entomologique de Cotonou (Benin)	Corinne Ngufor	Professor, Principal Investigator	
University of Kinshasa (DRC)	Mesia Kahunu	Professor, Principal Investigator	
Donors			
The Global Fund	Estrella Lasry	Malaria Technical Advisor	
GiveWell	Sam Aman	Programme Associate	
PMI	Rose Zulliger	Former Chemoprevention Lead	
Technical partners			
WHO Global Malaria Programme	Andrea Bosman	Unit Head, Malaria Diagnostics, Medicines and Resistance Unit	



Stakeholder group/ Organisation	Name(s)	Position	
	Silvia Schwarte	Technical Officer, Malaria Diagnostics, Medicines and Resistance Unit	
	Peter Olumese	Medical Officer, Malaria Diagnostics, Medicines and Resistance Unit	
WHO Immunisation, Vaccines and Biologicals	Mary Hamel	Malaria Vaccine Team Lead	
WHO AFRO	Dorothy Achu	Team Lead for Tropical and Vector Borne Diseases	
PATH	Meredith Centre	Deputy Director for Malaria, former Plus Project Director at PSI (from GAD through October 2023)	
RBM Partnership to End Malaria	Daddi Wayessa	Regional and Country Support Manager	
Manufacturers			
Emzor	Emeka Okoli	Chairman of the Board	
Swipha	Abbas Sambo	Business Development and Licensing Director	
SKant	Kalpesh Shah	Vice President International Marketing	
UCL	Meer Dhanani	Head of Business Development	
Government			
Cameroon	Dr. Dominique Bomba	Health of Prevention, NMCP	
	Junior Voundi Voundi	PMC Community of Practice Chair; Chemoprevention Lead NMCP	
DRC	Dr Aline Maliwani	Head of Case Management, NMCP	
Sierra Leone	Musa Sillah-Kanu	MESME Lead, NMCP	
Civil Society			
СНЕМКА	Gwendoline Ndiomo Shang	Programme Director	

Table B.2: List of country case study consultations

Stakeholder Organisation	group/	Name(s)	Position
Côte d'Ivoire			
Grantees			
Population International (PSI)	Services	Hans Bahibo	Country Lead, Plus Project
Government			
NMCP		Colette Kokrasset	Deputy Director, NMCP
		Serge Assi	Head of Research Development, NMCP
		Paul Valerie Odjohou	Deputy PMC Focal Point
Abengourou District		Kouame Yao	Malaria Focal Point



Stakeholder ground Grganisation	up/	Name(s)	Position
Boufale District		Oba Kouakou Jules	Malaria Focal Point
Seguela District		Djabia Tanoh Julien	Malaria Focal Point
PEV		Fatoumata Kone	Head of Services
Consortium partners			
National Institute of Pul Health	blic	William Yavo	Director General and Principal Investigator
National Advisory Group		Emmanuel Bissagnene	Group President
Technical partners in cou	ıntry		
Save The Children		Jacob Agnima	PMC Focal Point
Mozambique			
Grantees			
Population Service International (Population Mozambique	ces PSI)	Sergio Gomane	Plus Project Country Lead / previously Plus Project M&E Manager
Government			
NMCP		Albertina Chihale	PMC Focal Point
		Sergio Tsabete	SBC Focal Point
Family Health		Nelice Santos Mate	Head of MCH unit
Sofala Provincial Hea	alth	Tomas Almeida Bande	Programa da Malaria/ M&E
Directorate		Neusa Marta Bando	Programa da Malaria / Head
		Branza Amos	PMC Focal Point
Consortium partners			
Manhiça Health Resea	rch	Herminio Cossa	Project Plus Manager
Centre	_	Francisco Saute	CISM Scientific Director/Multiply Project Lead
Technical partners			
PATH		Elsa Nhantumbo	Former Plus Project Country Lead, PSI
Malaria Consortium		Sonia Enosse	Technical Coordinator
Civil Society			
World Vision		Gerito Augusto	Global Fund CSO Grant Manager
Donors			
Confidential <sup>61</sup>			

<sup>&</sup>lt;sup>61</sup> One additional stakeholder was interviewed but given confidentiality purposes their name and position cannot be disclosed.



#### **B.2.** Interview guide

This section presents the interview guide that was used for the stakeholder consultations. It presents the interview questions, and highlights which questions were asked of specific stakeholder groups in italics. Tailored interview guides were then developed for each stakeholder group including Unitaid Secretariat, grantees (PSI and consortium partners, MMV), technical partners, donors, manufacturers and country stakeholders.

#### Relevance

- 1. What is your assessment of the relevance of the projects given the context of the malaria burden, alternative malaria prevention approaches and access barriers to PMC in countries, particularly noting any specifics with regards to targeting issues in relation to gender, social inclusion and equity? (Unitaid, grantees, donors, technical partners, countries)
- 2. Did the selection of partners, countries/ manufacturers, approaches (i.e. specific design in countries for PSI, type of support provided by MMV, design/ scope of research and implementation aspects of the projects) respond well to the needs and project objectives? (grantees, countries)
- 3. How did the projects adapt to the new 2022 guidelines and do you assess this to be well done? Also was adaptation to challenges presented due to COVID-19 well done? (grantees, technical partners)
- 4. What are key learnings in terms of effective project design and appropriate targeting and demand driven partnerships? (*Unitaid, grantees*)

#### Coherence

- 5. How well are the projects aligned with the priorities and work of other stakeholders WHO in terms of requirements for guidelines development, other funders/ partners working on PMC in terms of coordination and added value of Unitaid investment? (grantees, donors, technical partners)
- 6. How well was the project design aligned with your country systems? (countries)
- 7. What do you view as the value of Unitaid's investments in PMC noting the range of other available/ developing malaria preventive strategies? (*Unitaid, grantees, partners, donors, countries*)
- 8. How might Unitaid better improve coherence of its investments vis a vis other donors/ partners and at the country level? (*Unitaid, grantees, partners, donors, countries*)

#### **Efficiency**

9. What, if any, were issues faced by the projects to keep to time and budget? Specifically for PSI, what are key lessons vis a vis timelines for protocol development and approval? For MMV, what are key lessons vis a vis timelines for supporting product development and PQ? (grantees, partners)

#### Effectiveness, sustainability and scalability

- 10. What evidence is there is relation to the project contributing to Unitaid's defined access barrier of innovation and availability? Specifically:
  - a. To what extent did the MMV supply grant accelerate the development of quality-assured SP products fit for children with good manufacturing practice commercial scale manufacturing solution? How well did MMV support adapted packaging for PMC along with credible and timely demand forecasts? (Unitaid, grantees, partners, manufacturers)



- b. To what extent was product development needed given existing products available in the market at the time (including in relation to resistance markers and how that might affect long-term effectiveness of PMC)? (Unitaid, grantees, countries, partners, manufacturers)
- c. In what ways and to what extent did working with regional manufacturers in Africa influence access to PMC? (Unitaid, grantees, manufacturers)
- d. Was the approach used by Unitaid including the market shaping activities fit to addressing the gap (including the choice of capital support or technical assistance provided to manufacturers)? (Unitaid, grantees, manufacturers)
- 11. What evidence is there is relation to the project contributing to Unitaid's defined access barrier of demand and adoption? Specifically:
  - a. To what extent did the investments facilitate increased demand and adoption within target countries and beyond? (*Unitaid, grantees, partners, donors, countries*)
  - b. What have been the main factors influencing readiness for adoption and scale-up and how have the investments contributed to overcoming these including (i) restrictive policy guidance for implementation;
     (ii) lack of confidence in PMC amongst policymakers, healthcare providers and caregivers and (iii) lack of evidence of efficacy at different resistance levels and for children above age one? (Unitaid, grantees, partners, donors, countries)
  - c. What is WHO's position on need for further evidence to support a strong recommendation for PMC? Have the project studies contributed to developing the evidence to support WHO guidelines updates? (Unitaid, grantees, partners)
- 12. What evidence is there is relation to the project contributing to Unitaid's defined access barrier of supply and delivery? Specifically:
  - a. How effective are the delivery methods in efficiently and cost-effectively reaching infants within the project to ensure there aren't gaps in delivery schedules leaving children unprotected in their first two years of life (e.g. what approaches were used to do mop-ups, how effective were approaches in capturing zero-dose children)? (grantees, partners, countries)
  - b. What lessons can be learnt from partnering with different child-focused health programmes, especially in relation to PMC coverage achieved? Were there any positive or negative affects to other child-focused health programmes (e.g. Vitamin A, EPI, weighing children) because of PMC? (grantees, partners, countries)
  - c. How applicable are the delivery methods beyond the project (e.g. in other countries with different EPI programmes)? (grantees, partners, donors, countries)
  - d. What successes or challenges have there been in terms of using EPI contact points? What are the reasons for the coverage levels attained in different countries and what lessons are there in relation to these in terms of number of contact points, use of EPI versus other contacts such as Vitamin A programs, how the communication strategy was employed, country specific success factors etc. What more could have been done to mitigate reductions in coverage levels? (Unitaid, grantees, partners, countries)
  - e. In what ways and to what extent did working with regional manufacturers in Africa influence supply and delivery? (*Unitaid, grantees, manufacturers*)
- 13. How likely are the benefits from the projects likely to be sustained and what are key risks to their sustainability? (Unitaid, grantees, partners, donors, manufacturers, countries)



- 14. What is the potential for scale-up? Aspects to be discussed include creating sustainable access conditions (e.g. generating evidence, normative guidance, increasing the supply base etc.), competing malaria priorities especially other prevention interventions, donor support and country readiness for scale-up including securing of political and financial support, ensuring programmatic and operational readiness, creation of community-driven demand. (Unitaid, grantees, partners, donors, manufacturers, countries)
- 15. How impactful, and what is the value add of Unitaid's support for regional manufacturing of SP products? Is access to SP better off with the regional manufacturers? How did this investment impact and influence manufacturers? Have manufacturers proceeded to produce/ qualify other essential medicines? Is there any impact on the company's brand perception in the market place? (Unitaid, grantees, manufacturers)
- 16. What efforts have been undertaken by Unitaid and the grantees in disseminating knowledge, evidence and lessons from the evidence generated from the project? How effective have these been? (Unitaid, grantees. partners, donors, countries)

#### Recommendations

17. What key recommendations and learnings do you have for Unitaid for future investments? *(Unitaid, grantees. partners, donors, countries)* 



# Appendix C UNITAID THEORY OF CHANGE FOR THE PMC INTERVENTION

Figure C.1. present the theory of change (ToC) for the PMC intervention as outlined in project documents. Innovation and availability (and the causal pathway for this) relates to Output 4 of the Supply grant whilst the other aspects relate to the Plus Project. The TOC remains valid for use for this evaluation, noting the change in terminology from IPTi to PMC following the 2022 WHO guidelines.

Figure C.1: Theory of Change for the PMC intervention

	Public Health Need In su nutri Abou	b-Saharan Africa malaria occurs in childr tional deficiencies; poverty leading to di	ed to 409,000 deaths, 67% of which were amo en who are already weakened by other parasi sproportionate higher levels of child mortality in the region) were estimated to be infected;	tic, viral and bacterial infections;
Problem	Access Barriers  21% the r Supp Dem	PE against anaemia in the first year of lif elevant countries (except Sierra Leone) Ily and delivery: Gaps in delivery schedu and and adoption: Restrictive policy gui hcare providers and caregivers; lack of e	commended by WHO since 2010. It has 30% of e and is highly cost effective. However there he due to barriers related to: les leaving the child unprotected for several in dance for implementation, lack of confidence evidence of efficacy at different resistance leve pproved taste-masked SP formulations for infi-	nas been virtually no implementation in nonths during the first two years of life. in SP-IPTi amongst policymakers, els, and for children above age one.
	Input	Outputs	Outcome	Impact
Conceptual pathway	Unitaid funding     Country health     system human     resources and in-kind     resources	Co-design and pilot test SP-IPTi+ platforms adapted to focus countries.  Demonstration of the impact, operational feasibility, efficacy, effectiveness, and cost-effectiveness of SP-IPTi+  Evidence dissemination and guidance to support transition, wide adoption and scale up  Improved global supply of high-quality SP for SP-IPTi+	Increased access to high-quality SP-IPTi+ services among the target group by addressing:  Supply and delivery: IPTi+ delivered through EPI and other platforms suited to country health systems - including into the 2nd year of life  Demand and adoption: policy guidance and evidence on efficacy, impact, feasibility & effectiveness Innovation and availability: Introducing SP drug and packaging appropriately adapted for pediatric use and supported by in-country registration	Lives saved due to malaria (KPI 4.1) Malaria and anemia cases averted (KPI 4.1) Estimated net cost to the health system (KPI 4.2) Household financial savings from malaria treatment costs averted. Reduced chemoprevention inequity in LMICs (KPI 5.1, KPI 5.2) Positive externalities linked to improved child health (e.g., educational attainment) and health system coordination (e.g., efficiencies)
Key risks / assumptions	Implementation Risks:     Sustainability/Scalabili     Assumption: Receptivi     Assumption: Willingne	ty Risks: Lack of domestic financing and/	forms, limits ability to integrate and expand Si for committed funding from major funding par ess and strong political willingness among targ pate in evaluation components.	rtners limits ability to scale SP-IPTi+.



# Appendix D DEDOOSE ANALYSIS AND UNITAID CONTRIBUTION ASSESSMENT

#### **D.1. DEDOOSE ANALYSIS**

Feeding into the assessment of strength of evidence, was a Dedoose-supported analysis of KIIs encompassing interviews at the global level and those conducted as part of country case studies in Mozambique and Côte d'Ivoire. Dedoose is a qualitative data analysis application designed for mixed methods research. It supports qualitative coding, the process of systematically categorising and labelling segments of qualitative data (in this case, interview transcripts) to identify patterns. A codebook was developed based on the evaluation framework and applied to the interview transcripts. Each code represented a different evaluation question. Additionally, participant information was integrated into the analysis in order to understand the breakdown of excerpts by stakeholder category (e.g. Unitaid, grantee, consortium partner, government, donors, technical partners and manufacturers). This section presents results from the coding of KIIs.

From the 52 KIIs reviewed, 1,081 excerpts of data were coded. Table D.1 demonstrates the distribution of data across a selection of key codes. Data excerpts can be associated with multiple codes. As seen in Table D.1., all evaluation questions were based on robust qualitative data with a strong quantity of KII evidence to support triangulation. The highest amount of KII evidence supporting findings related to relevance and effectiveness.

Table D.1: Number of data excerpts by key code

Code	# of excerpts
EQ1 Relevance	385
EQ2 Coherence	215
EQ3 Efficiency	140
EQ4 Effectiveness	462
EQ5 Sustainability/ Institutionalisation & Scalability	228
EQ6 Value-add of regional manufacturing	86
EQ7 Knowledge and evidence dissemination	109
Total	1,625

Table D.2 disaggregates the 1,081 excerpts of data across seven stakeholder categories. We note that a lower code count is associated with a lower number of interviews per stakeholder category (e.g. only three interviews were carried out with Unitaid Secretariat for example). Additionally, some questions were mainly relevant for certain stakeholders (e.g. more data excerpts on the value-add of regional manufacturing from manufacturers themselves). However, for the most part Table D.2 demonstrates that perspectives from the Secretariat, grantees, and consortium partners, governments, donors, technical partners, manufacturers and civil society were incorporated across most questions. The colour scale is light orange to brown, with high values highlighted in brown and low values in light orange.



Legend: 0-19 code counts, 20-39 code counts, 40-59 code counts, 60-79 code counts, 80< code counts

Table D.2: Code count by stakeholder category

Code	Unitaid	Grantee	Consorti um partners	Govt.	Donors	Technic al partners	Manufac turer	Civil society
EQ1 Relevance	23	71	86	67	33	52	48	5
EQ2 Coherence	7	43	31	54	29	47	0	4
EQ3 Efficiency	13	27	60	13	3	7	16	1
EQ4 Access barriers (Effectiveness)	24	84	65	119	27	67	60	16
EQ5 Sustainability/ Institutionalisation & Scalability	9	45	25	52	27	43	19	8
EQ6 Value-add of regional manufacturing	9	11	0	10	9	9	37	1
EQ7 Knowledge and evidence dissemination	3	27	25	30	7	17	0	0

#### D.2. Unitaid contribution assessment

As part of an overall assessment of the investments, we assessed Unitaid's contribution as a pathfinder, investor and influencer in keeping with the Unitaid contribution assessment checklist in Figure D.1. The evaluators assigned a value between 1 to 10 as per the scoring criteria and have presented our assessment in Table D.4.

Figure D.1. Unitaid contribution assessment checklist

Unitaid's role	Framing Question	Scoring Criteria				
Pathfinder	Was Unitaid critical in identifying high-priority health challenges that lacked solutions?	High (10): Unitaid was the first or only major actor in framing the opportunity space. Evidence that Unitaid's work was influential in crowding in investment by other partners  Medium (5): Unitaid contributed but was not the main driver of identifying the opportunity space.  Low (1): The opportunity space was already identified and widely recognized by other partners, so Unitaid's Pathfinder role was minimal				
Investor	To what extent has Unitaid's investment created added value, both in comparison to the contributions of other partners and in alignment with Unitaid's core mandate (Additionality)	High (10): Clear, systematic evidence of additionality, supported by a range of credible sources.  Medium (5): Some evidence of additionality, but may not be supported by many sources, or there may also be evidence of other partners role in securing progress. Unitaid played a role but was not the main driver to address access barriers.  Low (1): Limited evidence of additionality and/or a lack of evidence to substantiate Unitaid's role. Evidence that other partners played important role in securing access to the health product. The change would have happened without Unitaid.				
Influencer	To what extent did Unitaid, rather than the grantee, take the lead in coalition-building and stakeholder convening on the topic? How was Unitaid positioned relative to other key partners?	High (10): Unitaid led coalitions, and its work directly influenced national/global policy.  Medium (5): Unitaid participated but was not the main driver in coalition-building.  Low (1): Unitaid had limited or no role in stakeholder engagement.				



Table D.4: Evaluator's assessment of Unitaid's contribution

Unitaid investment	Unitaid's role	Scoring criteria	Rationale	Relevant findings
Plus Project	Pathfinder	8	Unitaid has been the major actor in framing the opportunity space, even with some other PMC research projects being supported by other donors. Evidence from the project has been influential and is expected to be even more so once more research studies are available.	Findings 1, 2, 4, 5, 10, 11 and 12
	Investor	8	There is evidence of additionality from Unitaid, and relevant access barriers were addressed mainly due to Unitaid (e.g. supply and delivery supporting implementation, some policy adoption and expanding of PMC within project countries).	
	Influencer	7	Unitaid has been actively involved, especially in liaising with WHO and other global partners. The COP has been very useful in coordinating stakeholders and exchanging information. Once research results are available, there is scope to influence countries further as well as inform WHO implementation guidelines.	
Supply Grant (Output 4)	Pathfinder	7	Unitaid was one of the few actors framing the opportunity space (a few other manufacturers have now entered the market but most of these are not regional).	Findings 1, 9 and 14
	Investor	8	Market has been changed due to having more manufacturers, although this is limited to date given manufacturers supported under Output 4 have not yet achieved WHO PQ. However, strong progress has been made and WHO PQ is expected soon. In addition, Unitaid is the only investor for regional manufacturing of PMC. Financial investment by Unitaid has been invaluable for the manufacturers.	
	Influencer	5	Unitaid has thus far had a limited role in influencing availability and supply of SP-PMC.	



## Appendix E PROJECT LOGFRAME AND ACHIEVEMENT

This appendix presents achievement of MMV's Supply Grant Output 4 (Table E.1) and achievement of the Plus Project (Table E.2) against their respective logframes.

Data on progress - including targets, total progress to date (Q4 2024), percent achievement against targets, and indicator notes - is taken directly from grantee reporting. Sources for this data are the Plus Project 2024 Annual Report and the MMV Supply Grant March 2025 Final Report. The Plus Project final report was not available at the time of this analysis in June 2025.

Regarding Output P7 in Table E.2 (Number of project countries where PMC funding has been secured by grant closure) grantee reporting states 100% achieved in terms of securing funding through Global Fund grants or domestic financing. However this evaluation notes that this funding is not confirmed and at risk given constraints in overall global health financing.

Table E.1: Supply Grant Output 4: Project logframe and progress to-date<sup>62</sup>

Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes				
Goal	Increased access to malaria chemoprevention commodities (measured in number of people)								
G1	Number and % of need that is met by the supply capacity of QA products (disaggregated by SP for IPTp and IPTi)	Total in PMC catchment zone is 3.3 million children	545 children reached (1.3 million doses- Plus Project)	N/A	For information only, not tied to MMV performance				
Outcome	Increased availability of quality assured malaria chemoprevention products								
P1	Submission of dossier to WHO PQ for at least 1 IPTi manufacturer	1	0	0	Targets missed for EMZOR/ Swipha (although submitted dossier in 2025)				
P2	Number of SP tablets procured for IPTi/PMC globally	3.3 million tablets	1.3 million <sup>63</sup>	40%	Reflects Plus Project procurement Nov 2024				
Output 4	Improved global supply of quality assured SP for intermittent preventive treatment for infants (IPTi/PMC)								
O4.1	Number of manufacturers including adapted SP packaging for IPTi/PMC into their dossiers and submitting to WHO prequalification	2	3	>100%	UCL, Emzor and Swipha directly supported by Supply Grant				

 $<sup>^{\</sup>rm 62}$  Results have been interpreted based on Unitaid updates to final reporting.

<sup>&</sup>lt;sup>63</sup> According to the latest data submitted by PSI to the evaluators on the 14<sup>th</sup> July 2025, 3,375,450 tablets of SP have been procured total including in 2025. This suggests an updated % achievement of 102%.



Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes
O4.2	Number of key milestones achieved towards ensuring increased access of QA, adapted packaged SP for IPTi/PMC		3	50%	

Table E.2: Plus Project: Project logframe and progress to-date

Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes			
Goal	Reduced malaria morbidity and mortality in low- and middle-income countries, in particular the high burden to high impact (HBHI) countries							
G1	Malaria deaths averted	476	N/A	N/A	Results will be reported end of full grant period			
G2	Malaria and anemia cases averted	239,481	N/A	N/A	Results will be reported end of full grant period			
G3	Total financial savings to households due to treatment costs avoided	US\$284,996	N/A	N/A	Results will be reported end of full grant period			
Outcome	Increased equitable access to high-quality S	P-IPTi+ services among the	target group					
P1	Percentage of children in the target age grou	up in focus countries receivi	ing 1 or more doses of SP t	through PMC				
	Benin	80%	47%	59%				
	Cameroon	80%	60%	76%				
	Côte d'Ivoire	80%	64%	79%				
	Mozambique	80%	70%	87%				
P2	Percentage of children in the target age grou	up in focus countries receivi	ing 2 or more doses of SP t	through PMC				
	Benin	75%	38%	51%				
	Cameroon	75%	49%	66%				
	Côte d'Ivoire	70%	42%	59%				
	Mozambique	70%	42%	60%				
P3	Percentage of children in the target age grou	up in focus countries receivi	ing 3 or more doses of SP t	through PMC				
	Benin	65%	30%	46%				
	Cameroon	65%	37%	58%				
	Côte d'Ivoire	60%	23%	38%				
	Mozambique	60%	27%	45%				



Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes
P4	Number of focus countries registering appropriate SP products for PMC	4	2	50%	Macleods have been approved in Mozambique (2023) and Cameroon (2024)
P5	Number of focus countries that have developed policy to reflect PMC delivery	4	4	100%	All countries have included PMC in National Malaria Strategic Plans (Benin [2024], Cameroon [2022], Côte d'Ivoire [2021], and Mozambique [2023])
P6	Percentage of caregivers in target areas of fo	ocus countries with a favora	ble attitude to PMC		
	Benin	60%		N/A	Benin conducted client experience of care study and found that:
					89.6% of caregivers would return to the health facility for future PMC doses and other interventions
					82.5% of caregivers expressed trust in SP
					87% of caregivers are satisfied with the care they received during the vaccination/PMC appointment
					44.8% would recommend PMC/vaccination services to their peers while 13.3% would not
	Cameroon	60%		N/A	No client experience of care study due to ERC approval timelines- qualitative information available from process evaluation June 2025
	Côte d'Ivoire	60%		N/A	No client experience of care study due to ERC approval timelines- qualitative information available from process evaluation June 2025
	Mozambique	N/A		N/A	Only qualitative data has been collected on caregiver favorability. Preliminary results indicate that most caregivers expressed positive acceptance of PMC and feel it is important for malaria prevention. Many said they have no doubts or fears. Acceptance was influenced by trust in health professionals, visible results and community mobilisation.
P7	Number of project countries where PMC funding has been secured by grant closure	4	4	100%	All countries (Benin [August 2024], Cameroon [August 2024], Côte d'Ivoire [June 2024], and Mozambique [July 2024]) have confirmed funding for PMC procurement. Cameroon, Côte d'Ivoire, and Mozambique included continuing PMC in their existing Global Fund grants, and Benin committed to procure SP with domestic financing in 2026.



Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes
Output 1	Co-design and implement PMC models adap	ted to focus countries.			
01.1	Number of SP doses issued to eligible children through PMC approaches	2,442,712	1,389,302	57%	
	Benin	1,056,706	403,619	38%	
	Cameroon	362,477	180,887	50%	
	Côte d'Ivoire	477,032	258,413	54%	
	Mozambique	546,497	546,383	100%	
01.2	Percentage of submitted reports with all PMC elements completed				
	Benin	90%	98.3%	109%	
	Cameroon	90%	95%	105%	
	Côte d'Ivoire	90%	99.5%	111%	
	Mozambique	90%	99.8%	111%	
O1.3	Percentage of PMC health facilities targeted	for supervision that are visi	ited		
	Benin	100%	86%	86%	
	Cameroon	100%	88%	88%	
	Côte d'Ivoire	100%	100%	100%	
	Mozambique	100%	87%	87%	
Output 2	Demonstration of the impact, operational fea	sibility, efficacy, effectiven	ess, and cost-effectiveness	s of PMC	
02.1	Number of key milestones completed for the process evaluation	9	9	100%	
	Benin	3	3	100%	
	Cameroon	3	3	100%	
	Côte d'Ivoire	3	3	100%	
	Mozambique	0	0	N/A	



Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes			
O2.2	Number of key milestones completed for the impact evaluation	6	4 <sup>64</sup>	67%				
	Benin	0	0	N/A				
	Cameroon	3	2	67%				
	Côte d'Ivoire	3	2	67%				
	Mozambique	0	0	N/A				
O2.3	Number of key milestones completed for the economic evaluation	26 <sup>65</sup>	25	96%				
	Benin	6	6	100%				
	Cameroon	7	6	86%				
	Côte d'Ivoire	7	7	100%				
	Mozambique	6	6	100%				
O2.4	Number of key milestones completed for policy adoption receptivity evaluation	26	16 <sup>66</sup>	61.5%				
	Benin	5	4	80%				
	Cameroon	5	3	60%				
	Côte d'Ivoire	5	4	80%				
	Mozambique	0	0	N/A				
	Plus-three	11	5	45%				
Output 3	Evidence dissemination and guidance to support transition, wide adoption and scale-up							
O3.1	Number of project countries with updated SP resistance profiles, geo-mapped to subnational level	7	5	71%				

<sup>&</sup>lt;sup>64</sup> Discrepancy in annual report between total results, and in-country results. Adjusted in table.

<sup>&</sup>lt;sup>65</sup> See above.

<sup>&</sup>lt;sup>66</sup> See above.



Result level	Description	Grant start to end target	Total to date (Q4 2024)	% Achievement	Notes
O3.2	Number of national and international evidence dissemination events	31	21	68%	
O3.3	Number of peer-reviewed publications produced from project-funded data collection activities	15	4	27%	4 additional manuscripts submitted for publication
O3.4	Number of national level tools developed or updated to support the introduction of PMC	29	19	66%	
	Benin	7	4	57%	
	Cameroon	7	5	71%	
	Côte d'Ivoire	7	4	57%	
	Mozambique	7	5	71%	
	Global	1	1	100%	
Output 4	Ensure country-level supply of quality-assure	ed SP for SP-IPTi+			
O4.1	Number of key milestones completed towards establishing the supply of quality-assured SP for PMC in focus countries	8	7	88%	
	Benin	2	1	50%	
	Cameroon	2	2	100%	
	Côte d'Ivoire	2	2	100%	
	Mozambique	2	2	100%	



# Appendix F DELAYS IN ETHICAL APPROVAL OF RESEARCH COMPONENT

Appendix F presents the timeline for ethical approval across study topics and by country, including institution, whether grantees consider that there was an institutional delay in receiving approval, and any follow-on effects on the study start. Table F.1 is derived from materials shared directly by grantees, which document all issues with ethical approvals which led to a delay in studies starting. This documentation does not provide data on the initial expected timeline for ethical approval, as such this is not provided in the table below. However, expected timelines for ethical approval are around three to six months on average (corroborated by annual reporting).

Legend: Study delayed (beyond one week)

Table F.1: Ethical approval of research timelines

Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
Policy adoption						
Master protocol	10 December 2021	WHO ERC	No	13 January, 2022 1 month		N/A
Côte d'Ivoire (site- specific protocol)	3 February 2022	WHO ERC	No	10 March, 2022 1 month		N/A
Benin (site- specific protocol)	16 June 2022	WHO ERC	No	24 June, 2022 1 week		N/A
Zambia	Q2 2022	TDRC/ NHRA (national ERC)	Yes	September 2022, 6 months		N/A
	6 February 2023 to Unitaid Final version submitted to WHO ERC 5 May 2023	WHO ERC	Yes	20 June 2023, 4 months	Received feedback on 6 February 2023 that WHO required additional elements not previously requested for site-specific protocols, and that requirements for DOI (Declaration of Interest) forms had changed. Documents were resubmitted to Unitaid on 31 March 2023 after some back and forth, and to ERC shortly after. WHO ERC accepted the protocol on 4 May but requested a typo be fixed and another copy of the local approval letter. The updated documents were submitted on 5 May and approval was received about 6 weeks later on 20 June 2023.	N/A
DRC	Q2 2022	University of Kinshasa Public Health School Ethics Committee		31 October 2022, 4 months		N/A



Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
	6 February 2023 to Unitaid Final version submitted to WHO ERC 31 March 2023	WHO ERC	Yes	4 May 2023, 3 months	Additional information and documents requested, similarly to Zambia. Documents were resubmitted on 31 March 2023 and approved by ERC on 4 May 2023.	N/A
Cameroon	Q1 2022	CNERSH (national ERC)	Yes	March 2023, 1 year	The protocol was submitted to CNERSH, in Q1 2022 but wasn't approved until July 2022. There were further delays getting an amendment to change the PI and approval was received in March 2023.	N/A
	April 2023	WHO ERC	No	5 May 2023, 1 month		N/A
Ghana	Q2 2022	Ghana Health Service Ethics Review Committee	Yes	13 September 2023, 18 months		Start of study very delayed
	Submission 28 July 2024	WHO ERC	No	13 August 2024, 3 weeks		
Economic evaluat	ion					
Multi-country protocol	April 2022	WHO ERC	Yes	10 February 2023, 10 months	Pre-review feedback received 14 June, resubmitted 30 June Protocol reviewed 11 August and additional information requested and revised documents were submitted to ERC on 21 September.	Baseline data collection delayed for 6 weeks until February 2023
					Protocol reviewed again 13 October and received conditional approval 7 November 2022, and full ERC acceptance 21 December (pending local approvals). Final approval received 10 February 2023.	
Benin	13 April 2022	N/A, no delay	No	13 June 2022, 2 months		See above
Cameroon	August 2022	CNRESH (national ERC)	Yes	18 January 2023, 5 months	Economic evaluation jointly submitted with Process and Impact in August 2022, and then resubmitted in October 2022. CNRESH had difficulty finding quorum and couldn't meet until January. Received local approval 18 January 2023.	See above
Côte d'Ivoire	August 2022	CNESVS (national ERC)	Yes	17 January, 5 months	Economic evaluation jointly submitted with Impact in August 2022. Resubmitted response December 2022, and received local approval 17 January.	See above



Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
Impact evaluation						
Multi-country protocol	10 June 2022	WHO ERC	Yes	10 February 2023, 8 months	Submitted to WHO ERC on 10 June 2022. Received pre-review feedback over 2 months later on the 16 August, resubmitted 25 August. Conditional approval received 11 October, submitted revised documents on 14 November and received full approval received 21 December subject to local approval. Received final approval 10 February.	3 month delay in baseline data collection until April 2023, reduction in research timeline to 18 months from 24 months
Cameroon	August 2022	CNRESH (national ERC)	Yes	18 January 2023, 5 months	See economic evaluation	See above
Côte d'Ivoire	August 2022	CNESVS (national ERC)	Yes	17 January, 5 months	See economic evaluation	See above
Process evaluation	- Cameroon					
Cameroon	June 2022	WHO ERC	Yes	22 March 2023, 9 months	Submitted to WHO ERC in June 2022. Shared proof of submission to local IRB with WHO on 13 July. ERC secretariat pre-review feedback was received 4 months later on 12 October. Submitted updated documents on 19 October. ERC reviewed the protocol at the 11 November meeting. On 1 December, received memo from ERC that protocol was not approved and required rewriting. Updated documents were submitted to ERC on 21 December. Received conditional approval from ERC two months later on 24 February 2023 and updated documents were submitted shortly after. Received final approval from WHO ERC one month later on 22 March 2023.	Baseline data collection delayed from Q1 2023 to June 2023, endline data has to be collected May/ June 2025
	August 2022	CNRESH (national ERC)	Yes	18 January 2023, 5 months	See economic evaluation	See above
Process evaluation	- Benin and Côte d'I	lvoire				
Multi-country	October 2023	WHO ERC	No	24 May 2024, 7 months	Received conditional approval from ERC 29 November, pending local approvals. Submitted-site specific approvals for CDI in March 2024 and received 8 April, Benin submitted 17 May and received 24 May. Delay in final approval from WHO due to local approval timelines.	N/A



Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
Côte d'Ivoire	February 2024	CNESVS (national ERC)	No	13 March 2024, 1 month		
Benin	1 February 2024	CNERS (national ERC)	Yes	16 May 2024, 3 months	CNERS closed for 3 months and did not meet	
Mozambique eva	aluation					
Mozambique	14 February 2023 (to Unitaid) 9 March 2023 to WHO ERC	WHO ERC	Yes	3 October 2023, 8 months	Package submitted to Unitaid 14th February was missing DOI and CV, resubmitted 22nd February. Unitaid submitted on March 9th missing the March deadline. Received ERC secretariat pre-review feedback 13th April, same day as ERC meeting. Resubmitted updated documents 2nd May. On 26 May received a letter from the secretariat saying the protocol underwent an expedited review but that review deemed the protocol needed a full ERC meeting review. Study team was given a 4 day turn around time to respond before the June meeting and submitted updated documents in time. Conditional approval received 23 June. Updated documents were submitted to ERC on 18 August. ERC sent several memos between 25 August and 21 September asking for additional clarifications, and then final approval received 3rd October after significant back and forth.	Intended to start data collection July/ August 2023 to avoid elections and rainy season. Had to delay start until October due to delay in approvals. Meant that study teams had to avoid sensitive areas during elections and rainy season.
	14 February 2023	CISM (national ERC)	Yes	1 September 2023, 7 months		See above
Zambia PCPI						
Zambia	14 February 2023 to Unitaid Submitted to WHO 23 March	WHO ERC	Yes	18 July 2024, 17 months	PCPI Zambia protocol was submitted to Unitaid on 14 February 2023. There was some back and forth related to DOI memos as well as a request from LSHTM IRB that resulted in changing the sponsor from PSI to LSHTM. Documents were submitted to WHO ERC on 23 March in time for April meeting deadline. Received secretariat pre-review feedback on 5 April. Study team submitted responses on 14 April, too late for consideration at April meeting. The protocol was reviewed at the 11 May ERC meeting and was conditionally approved on 23 May. Submitted a response package to ERC on 18 August and received a memo from ERC on 31 August requesting additional information and a new peer review due to changes in number of	Had to conduct study a year later than planned in Q2 2024 rather than Q2 2023



Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
					arms. After receiving last of local approvals, updated documents were submitting to WHO ERC on 15 July 2024. Final approval was received promptly on 18 July 2024.	
	9 February 2023	Required approval from 3 local ERCs in Zambia- TDRC, NHRA, and ZAMRA	Yes	TDRA approved August 2023, ZAMBRA 31 May 2024, and NHRA mid-June; 16 months	Extensive requests for documentation between August 2023 – May 2024 from NHRA and ZAMRA	See above
Cameroon PCPI						
Cameroon PCPI	20 December 2023 to Unitaid Late January, early February submitted to WHO	WHO ERC	No	19 May 2024, 5 months	Study team submitted materials to Unitaid on 20 December, but focal point was on leave. Dossier submitted to WHO ERC late Jan/ early Feb, and received pre-review feedback 1 March. Study team submitted response to Unitaid 8 March 2024, but documents submitted to WHO ERC on 15 March after meeting date. Protocol was reviewed 11 April ERC meeting, received conditional approval 26 April and full approval 10 May 2024 following updated submission	Activity scheduled to start Q4 2023, but start date moved to Q1 2024. Start delayed by about 2 months, impeding ability to capture seasonality as intended.
	Information not available	CNRESH (national ERC)	No	Received approval 7 December 2023		
SP Suitability						
Multi-country	20 April 2023 to Unitaid Early May to WHO	WHO ERC	No	3 months	Submitted documents to Unitaid on 20 April 2023 and they were submitted to ERC in time for May meeting deadline. Promptly received secretariat pre-review feedback on 28 April but given 5 day turn around time to respond. Study team submitted documents in time (2 May). Received conditional approval on 25 May. Submitted conditional approval responses on 26 June along with CDI local approval. Received site specific approval for CDI on 26 July. Quickly received rest of site-specific approvals after getting local IRB approvals (5 day turnaround time for Benin, 2 day turnaround for DRC, 2 day turnaround for Cameroon which was the last local approval letter submitted to Unitaid on 24 December 6 2024 and approved by WHO ERC December 6 2024.)	1 week delay in starting sample analysis



Site	Submitted	Institution	Institutional delay?	Length of approval time	Notes	Effect on study start
Local approval- Côte d'Ivoire, Benin, DRC, Cameroon		No major delays in getting approvals from local IRB for CIV, Benin, DRC. Information not available for Cameroon.	No			See above
Client experience	of care- Benin					
Benin	17 July 2023 to Unitaid 10 August 2023 to WHO ERC	WHO ERC	No	11 December, 4 months	This study was added during reprogramming in 2023. Documents were submitted to Unitaid on 17 July 2023 but there were delays in getting the DOI memo signed. Unitaid submitted the documents to WHO ERC on 10 August. Received pre-review feedback from WHO ERC on 30 August and submitted response on 5 September. The protocol underwent expedited review and received conditional approval on 2 October. Updated documents, including local approval letter, submitted to ERC on 17 November. Received final approval on 11 December.	Slightly delayed study by about one week
	13 July 2023 to CER- ISBA, local IRB	N/A, no delays	No	30 October, 3 months	3 months	See above



# Appendix G PMC ADOPTION IN FOCUS, PLUS-THREE AND NON-PROJECT COUNTRIES

Appendix G provides an overview of PMC adoption in both focus, Plus-Three and non-project countries.

Among the four focus countries, the Plus Project has facilitated policy adoption in Benin. Moreover, Benin decided to change its dosing schedule from five to eight during the first two years of life based on the project experience where an eight dose schedule was trialled. In the other three countries – Cameroon, Côte d'Ivoire and Mozambique, the Plus Project enabled the implementation of PMC by ensuring the launch of pilot projects soon after PMC was included in national malaria plans. In Mozambique, PMC was included in the new malaria strategic plan 2023-2030 following a decision by the NMCP in 2021, prior to the Plus Project start. Therefore, the value add of the Plus Project was to move from a strategy to implementation by providing funding at the right time. In Cameroon, PMC was already being implemented prior to the Plus Project, but coverage was limited. The Plus Project introduced extensive training and capacity building which ensured higher coverage in the Plus Project districts and introduced dispersible paediatric SP. Moreover, Cameroon is currently considering whether to increase the dose schedule from five to eight doses as trialled by the Plus Project. In Côte d'Ivoire, PMC was included in the national malaria strategic plans in 2021, prior to the project start and primarily on the back of the 2022 WHO guidelines. Côte d'Ivoire, the NMCP has decided not to scale-up PMC nationally until 2027, opting to maintain it only in the three project-supported districts through the end of 2026, aligning with the Global Fund GC7 grant duration.

For the Plus-Three Project countries and non-project countries, the Plus Project has indirectly supported adoption in some cases through the dissemination of PMC through the COP, but adoption has been largely facilitated by other PMC implementation and research projects that were ongoing in the respective countries.<sup>67</sup> Among the Plus-Three Project countries, Ghana and Zambia are still waiting on the research studies results before deciding whether to adopt PMC.

Table G.1 provides an overview of PMC adoption in project, Plus-Three and non-project countries. The last column "Adoption attributed to Unitaid investment" is based on data provided by PSI triangulated with some of the interviews with stakeholders from Plus Project and Plus-Three countries.

<sup>&</sup>lt;sup>67</sup> These include PMC project in DRC led by PATH and funded by GiveWell, the Multiply Project in Mozambique, Sierra Leone and Togo led by ISGlobal and funded by The European & Developing Countries Clinical Trials Partnership (EDCTP) and the PMC project in Nigeria led by Malaria Consortium and funded by Gates Foundation.



### Legend:

**Blue = Focus Countries** 

Orange= Plus-Three Countries
Green= non-project countries

Table G.1: Overview of PMC Adoption in focus, Plus-Three, and non-project countries

Country	Implementation			District information			Health system information		
	PMC included in national malaria strategy	PMC implemented in 2024	PMC planned for implementation in 2025 (post Plus Project)	of districts in	Total number of PMC eligible districts in the country	Total number of districts implementing PMC (2024)	Dose schedules (2024)	Routine delivery platform used	Adoption attributed to Unitaid investment
Benin	Yes (in 2024)	Yes (through Plus Project)	Yes	34	19	3 + 5 additional districts from 2025	8 doses in the PSI pilot schedule (previously 5 doses but have decided to increase to 8 due to the Plus Project)	EPI and Vitamin A administration	Strongly attributable to PSI-PMC project
Cameroon	Yes (in 2022)	Yes (through government and Plus Project in 23 districts)	Yes	205	157	157	5 doses main national, 8 doses in the PSI pilot	EPI	Partially attributable to PSI-PMC project - National adoption would have most likely happened without the Unitaid investment. However, uptake outside the Plus Project districts was significantly lower and the Plus Project demonstrated the importance of supporting the introduction of a new intervention like PMC through training, supervision, community engagement and the availability of the appropriate commodity. The government is now waiting on the Plus Project results to decide whether to scale-up to 8 doses instead of 5 doses,



Country	Implementation			District informa	ation		Health system in	formation	
									which are currently in the national PMC policy.
Côte d'Ivoire	Yes (in 2021)	Yes (through Plus Project)	Yes	113	81	3	5 doses in the PSI pilot schedule	EPI	Partially attributable to PSI-PMC project - Côte d'Ivoire NMCP has decided not to scale-up PMC nationally until 2027, opting to maintain it only in the three project-supported districts through the end of 2026, aligning with the Global Fund GC7 grant duration
Mozambique	Yes (in 2023)	Yes (through Plus Project and ISGlobal research project)	Yes	128	81	13	4 then 5 doses main national, 6 in the ISGlobal research pilot schedule	Healthy Child Consultation in main national, EPI in research pilot	Partially attributable to PSI-PMC project – Mozambique had already decided in 2021 to include PMC in the national malaria plans for 2023-2030.
DRC (in 2013)	Yes	Yes (through GiveWell Project and only research study through Plus Project)	Yes	519 (26 provinces)	383 (20 provinces)	31 (1 provinces)	6 doses in research pilot schedule	EPI and Vitamin A administration	Not directly attributable to PSI-PMC project - potentially only influenced adoption indirectly. PSI supported PATH in the co-design process of the GiveWell Project and through the COP
Ghana	No	No (only research study through Project)	No	261	69 are implementing SMC (Potentially all the remaining 192 districts are eligible for PMC)	1 Atebubu-Amantin Municipality	Experimental study assessing the efficacy of combining the RTS,S/AS01E vaccine with PMC	N/A	Adoption decision is pending the results of the Unitaid research studies
Zambia	No	No (only research study through Plus Project)	No	NA	NA	NA	Experimental study assessing the Parasite Clearance and Protection from Infection. Only 1 dose of SP.	NA	Adoption decision is pending the results of the Unitaid research studies



Country	Implementation			District inform	ation		Health system in	formation	
Burundi	Yes (in 2025)	No	Yes	117	117	0 5 districts started in 2025	NA	No information	Not directly attributable to PSI-PMC project - potentially only influenced adoption indirectly through the COP and dissemination activities (e.g. conferences, tools).
Congo Republic	Yes (in 2023)	Yes	Yes	52	52	0 The 52 districts started in Feb 2025	No information	No information	Not directly attributable to PSI-PMC project - potentially only influenced adoption indirectly through the COP and dissemination activities (e.g. conferences, tools).
Nigeria	No	Yes (through Malaria Consortium project)	Yes	774	381	8	6 doses + 12 additional optional opportunities in the research pilot schedule	EPI	Not attributable to PSI-PMC project - Gates Foundation supported Malaria Consortium pilot in Nigeria
Sierra Leone	Yes (in 2016)	Yes (through government and EDCTP)	Yes	16	16	16	3 doses main national, 6 doses research pilot	EPI	Not attributable to PSI-PMC project - Sierra Leone had already adopted IPTi+ in 2018 and EDCTP supported PMC afterwards
Tanzania	Yes	No	No	NA	No information	NA	NA	No information	NA
Togo	Yes (in 2024)	Yes (through EDCTP project)	Yes	39	16	16	4 doses main national, 9 doses research pilot from October 2025	EPI	Not directly attributable to PSI-PMC project - potentially only influenced adoption indirectly through the COP.



# Appendix H COMMUNITY AND CIVIL SOCIETY ENGAGEMENT ACTIVITIES

Table H.1. presents the community and civil society engagement activities undertaken by the Plus Project up to June 2025 in the four focus countries. As can be seen, the project has organised a wide range of outreach activities including activities for CHWs, house visits, community education sessions, radio spots, community group meetings, and events.

Table H.1: Community and civil society engagement activities<sup>68</sup>

Country	Community and civil society engagement activities
Benin	<ul> <li>23,839 house visits and 1,635 community education sessions raised awareness about PMC</li> </ul>
	<ul> <li>1,620 radio spots were played in different local languages</li> </ul>
	<ul> <li>20 community groups (model husbands, women's groups) raised awareness and mobilized community members to seek PMC, identifying over 350 children for PMC</li> </ul>
	<ul> <li>Advocacy was conducted with religious leaders to request engagement in PMC awareness and outreach strategies</li> </ul>
	<ul> <li>84 outreach strategies reached 41,148 children between 12-24 months old</li> </ul>
Cameroon	<ul> <li>Advocacy and outreach with caregivers, local, religious, and traditional leaders, and other community influencers helped promote PMC and vaccination</li> </ul>
	593 radio spots and 234 TV spots were played
	• 17 large outreach events were organised around World Malaria Day, International Day of the Child, and International Women's Day during which 1,089 PMC doses were administered at the community level, 2,376 households were visited, and 2,438 referrals were made to health facilities for vaccination services.
	• In 2024, community-based PMC administration and outreach strategies reached 21,265 children with PMC services between 9-24 months old
Côte d'Ivoire	5,315 house visits conducted
	999 radio spots played across the three project districts
	• 2,856 integrated immunisation/ PMC outreach strategies conducted, in which at least 50 zero dose children were found and vaccinated
Mozambique	Finalisation of the PMC job aids and flip charts for CHWs
	<ul> <li>Adjustment of the PMC healthcare worker job aids, including additional dose in National Strategy (5-doses total)</li> </ul>
	<ul> <li>791 Radio broadcasts, including radio spots, debates, and talk shows with health technicians</li> </ul>

<sup>&</sup>lt;sup>68</sup> Plus Project, 2024 Annual Report, Submitted 2025.03.13



### Country

### Community and civil society engagement activities

- 1,038 PMC referrals to health facilities
- 159 CHWs trained in expansion districts
- Mobile brigades have been operating throughout 2024 and began reporting PMC administration in September. The brigades administered anywhere between 6-11% of PMC between September and December 2024

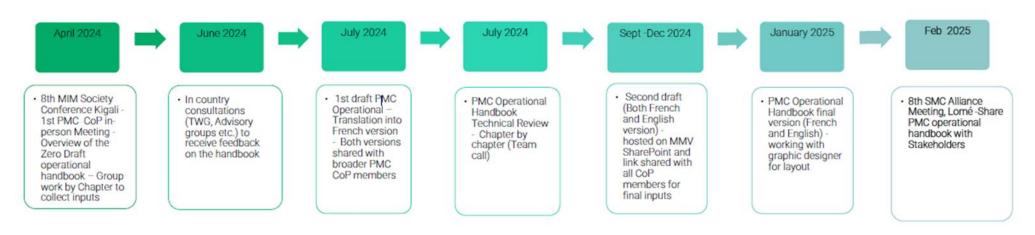


# Appendix I PMC IMPLEMENTATION AND TRACKING TOOLS DEVELOPED

In this appendix, the main tools developed by the Plus Project to support PMC implementation experiences and encourage PMC uptake and scale-up and their objectives are presented.

- **PMC Institutionalisation Status Reflection Tool:** This was developed during the co-design phase to support countries to institutionalise PMC. The tool can be used to categorise status of institutionalisation across the different drivers, including values, leadership and governance, policy and resources. The status of the drivers awareness, experimentation, expansion, consolidation and maturity can be updated over time to track progress. This is described in more detail in Appendix J.
- PMC Operational Handbook: The PMC COP has developed an operational guide for PMC planning, implementation, monitoring, and integration into national health programs, based on experiences and lessons learned from ongoing PMC projects and programs across countries. The operational handbook was developed in consultation with many stakeholders as highlighted in the handbook development timeline below (Figure I.1). The guide provides a detailed overview of the policy development strategies and resources, how to plan for PMC implementation and integrate PMC with other malaria interventions, communicate about PMC with communities and engage them, train healthcare professionals, administer SP and avoid stock-outs, describe PMC supervision techniques, monitor and evaluate PMC implementation and carry out pharmacovigilance to monitor adverse events.

Figure I.1. Handbook development timeline



• WHO-AFRO PMC Policy Framework: WHO-AFRO has been working with PSI to leverage the lessons learned of the Plus Project to develop a Framework for adaptation of PMC guidelines for national and sub-national policy at the African regional level (different from the WHO Field Guide which is meant to be a global level



tool). The document aims to build on the PMC Operational Framework to provide policy guidance on how to adapt PMC implementation in countries. For example, what age group to focus on, which schedule of doses, and how to plan for PMC implementation, including which country stakeholders to consult and involve. This policy framework is currently under development.

- SP Demand Forecasting Model: MMV developed a 5-year epidemiologically-based forecasting model by the end of 2022 to estimate SP volumes required for nine sub-Saharan countries based on seven different scenarios considering the EPI, vitamin A or CHW delivery channels, alone or in combination. The forecasting period was 2023 to 2027. The findings of the forecasting model were presented at the ASTMH annual conference in October 2023, in an event organised by PSI and were published this year in the Malaria Journal. <sup>69</sup> In addition to Unitaid, the model was also shared with the CHAI team working on commodity forecast. Due to lack of additional budget, the demand forecasting model has not been updated with the actual Plus Project PMC implemented schedules. However, the model is built in a way that the assumptions can be modified on a country basis to reflect any changes in schedules implemented by countries.
- Decision support tool: A Decision Support Tool is in the process of being finalised. It is an interactive web-based tool which aims to show the ranked prioritisation of PMC according to its cost-effectiveness for each area in sub-Saharan Africa. It is modelled for alternative PMC schedules and delivery methods using the Imperial malaria simulation model. It aims to use the research findings to incorporate: (i) SP protective efficacy based on local genotype profiles; (ii) expected coverage of each target PMC dose; (iii) costs and cost savings from averting malaria cases; (iv) potential impact of PMC in addition to existing core control measures with/without RTS,S or R21.

<sup>&</sup>lt;sup>69</sup> Audibert, C., Hugo, P., Gosling, R. et al. Projected uptake of sulfadoxine–pyrimethamine for perennial malaria chemoprevention in children under 2 years of age in nine sub-Saharan African countries: an epidemiologically-based 5-year forecast analysis. Malar J 24, 124 (2025). <a href="https://doi.org/10.1186/s12936-025-05355-0">https://doi.org/10.1186/s12936-025-05355-0</a>

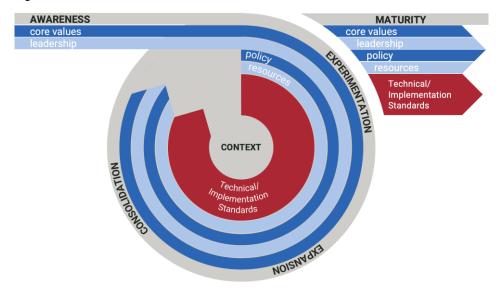


# Appendix J PMC INSTITUTIONALISATION FRAMEWORK AND STATUS REFLECTION TOOL

In this appendix, we describe: (i) the Institutionalisation Framework adopted by the Plus Project and key aspects that it covered; (ii) the PMC Institutionalisation Status Reflection Tool adopted by the Plus Project and key aspects that it covered.

The Institutionalisation Framework adopted by the project was developed through a collaboration between the U.S. President's Malaria Initiative (PMI) Impact Malaria Project and the global Child Health Task Force<sup>70</sup> and is informed by state-of-the-art technical guidance on scale-up, sustainability and institutionalisation of public health interventions, such as WHO's Practical Guidance for Scaling up Health Interventions.<sup>71</sup> Figure J.1and Figure J.2.below outline the institutionalisation framework and the phases of the institutionalisation process, respectively.<sup>72</sup>

Figure J.1. Institutionalisation Framework



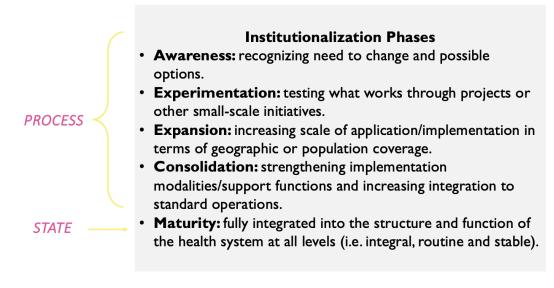
<sup>70</sup> https://www.childhealthtaskforce.org/hubs/iccm/toolkit

<sup>71</sup> https://www.who.int/publications/i/item/9789241598521

<sup>&</sup>lt;sup>72</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024



Figure J.2. Phases of Institutionalisation Process



In order to support countries in institutionalising PMC, PSI developed a PMC Institutionalisation Status Reflection Tool to categorise the status of the institutionalisation across the key drivers:

- 1. Core Values: beliefs and values of key stakeholders are sufficiently aligned in support the intervention.
- 2. Leadership: government/MOH owns and governs delivery of the intervention at strategic and management levels.
- 3. Policy: policies, strategies, and implementation guidance for the intervention are in place.
- 4. Resources: support and delivery of the intervention are integrated into the country's health financing, human resources, and supply chain systems.

Figure J.3. below outlines the PMC Institutionalisation Status Reflection Tool.<sup>73</sup> It shows the various questions that were used by government stakeholders to assess and track progress against the drivers of the PMC institutionalisation. This tool was used during the Plus Project 2024 Annual Meeting.

<sup>&</sup>lt;sup>73</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024



Figure J.3. PMC Institutionalisation Status Reflection Tool

Element		Key question	Illustrative descriptions of pl	nase			
			Awareness (1)	Experimentation (2)	Expansion (3)	Consolidation (4)	Maturity (5)
CORE VALUES	Core values	Are beliefs and values of key stakeholders sufficiently aligned in support of PMC?	Some key stakeholders (govt, donors, technical partners, others) recognise the potential of PMC to address a need or issue they care about, but how beliefs and values of most key stakeholders relate to support for PMC is largely unknown.	How the beliefs and values of key stakeholders (govt, donors, technical partners, others) relate to support of PMC and where conflicting views exist is increasingly known, and a growing number recognise alignment of PMC with their core values.	Conflicting views between key stakeholders (govt, donors, technical partners, others) are increasingly resolved; core values that support PMC are increasingly sensitised with relevant MoH staff at all levels of the health system as well as across other key stakeholders.	Conflicting views between key (govt, donors, technical partners, others) stakeholders are sufficiently resolved. Core values that support PMC are increasingly integrated and expressed in the way relevant government officials, Ministry of Health staff, and other stakeholders make decisions at all levels of the health system.	Core values that support PMC are fully embedded into the way relevant government officials, MoH staff and other key stakeholders do business and continue to perpetuate support and improvements in the implementation of PMC at all levels of the health system.
	Leadership	Is there leadership for PMC at strategic and management levels?	Some leaders within the MoH/government are interested in exploring the viability of the PMC approach within their health system context.	There is one or more leading champion(s) at senior levels of MOH/government, but broad support not yet realised.	There are prominent champions at the political and technical levels of MOH/government as well as key stakeholders actively advocating for support for PMC; key stakeholders are increasingly aligned in support of govt leadership of PMC.	Leaders across MOH/government support the institutionalisation of PMC; key stakeholders are aligned in support of govt leadership of PMC; national health system staff feel accountable for PMC and provide leadership for PMC activities.	PMC is supported throughout the health system at all levels; national health system staff feel ownership of results and empowered to make improvements in collaboration with the aligned support of key stakeholders.
30VERNANCE	Planning	Has the MOH included PMC in national and subnational plans?	Discussions held on the potential piloting of PMC.	Plans for piloting of PMC are developed and implemented.	PMC is included in the subnational health plan where it is implemented, or it is in the national health plan with the aim of expansion across the country.	PMC is included in all relevant national health plans for delivery of services across the country.	PMC is included in national health plans for delivery of services across the country; plans are routinely reviewed and updated to improve delivery of services.
LEADERSHIP & GOVERNANCE	Coordination	Is PMC a regular topic of discussion in appropriate national and sub-national coordinating bodies?	No structure, person or process to coordinate PMC implementation is in place.	Temporary structure, person or process responsible to coordinate PMC implementation is in place.	Long-term/permanent structure, person, or process with authority, resources, and information to coordinate PMC implementation is in place.	Structure, person, or process firmly established within the MOH/government with authority, resources, and information to coordinate in place.	Effective coordination system firmly established within the MOH/government and integrated into standard ways of working.



Element		Key question	Illustrative descriptions of phase				
			Awareness (1)	Experimentation (2)	Expansion (3)	Consolidation (4)	Maturity (5)
	Standards & Information	Are monitoring and reporting systems for PMC in place?	Discussions held on need for data collection and reporting forms for PMC implementation.	A pilot and/or readiness assessment conducted to test indicators and/or reporting forms for PMC implementation.	Appropriate indicators for PMC are used in some, but not all geographic areas and/or standard indicators are measured, but not reported through regular national health information systems.	Appropriate indicators for PMC are increasingly integrated into relevant service delivery operational standards and national health Information systems.	Appropriate indicators for PMC are fully integrated into national health information systems and routinely used for decision-making to ensure coverage and quality of services.
Do policies, strategies		Do policies, strategies and implementation guidance for PMC exist?	No national policies, strategies or technical guidance explicitly refers to PMC. There is no defined PMC model for the country.	echnical for PMC exist, but the PMC has been defined; PMC is efers to defined being defined through major policy and strategy		A PMC model for the country has been defined and continues to be refined; PMC is included across multiple policy and strategy documents; national implementation guidance, standards and regulations are in place.	A PMC model for the country has been defined; PMC is included across all relevant policy and strategy documents; national implementation guidance, standards and regulations are in place, routinely applied and improved.
	Financing Sources	Does the government fund PMC services?	There is no routine funding available for PMC services from government sources or external partners; discussions are underway on merit of investment	External partner(s) and/or government funds the costs associated with pilot activities covering a small geographic area.	External partner(s) and/or government fund the expansion of PMC services; a formal investment case might be developed to advance discussion of the merit of investment.	The government funds a portion of the costs of PMC services and external support is increasingly diversified and coordinated to ensure continuity; merit of investment is increasingly acknowledged across government	Government funds a large portion of PMC services and any ongoing external support is diversified and coordinated to ensure continuity; merit of investment is understood and consistently demonstrated across MOH and relevant government institutions.
nancing	Costing & Budgeting	Does the government include PMC services in its costing and budgeting processes?	There are no data on PMC intervention costs to inform budgeting and planning and it is not clear who is responsible to generate such data.	Some data on PMC intervention costs exist, but they are of questionable quality and/or outdated.	Recent data on PMC invention costs are available, but they are of questionable quality and/or inadequate for budgeting at scale.	Recent data of reasonable quality on PMC intervention costs are available, but they are not routinely used to inform costing and budgeting.	Cost data of good quality are periodically updated and used to inform planning and budgeting, and there is an institutional mandate within MOH to lead work on costing.
RESOURCES: Financing	Financing Mechanisms	Is there a national health financing strategy and financing mechanisms that include PMC services?	There is no health financing strategy in place, no institution responsible for financing of PMC, and financing mechanisms for PMC are fragmented.	There is no health financing strategy in place, financing mechanisms are fragmented, but there is an institution responsible for financing of PMC.	There is a health financing strategy in place, financing mechanisms are better managed and coordinated, but PMC is not sufficiently prioritised.	There is a health financing strategy in place, financing mechanisms are better managed and coordinated, and PMC is more prioritised.	There is a health financing strategy in place that considers PMC financing, and appropriate financing mechanisms are used and regularly evaluated.



Element		Key question Illustrative descriptions of phase					
			Awareness (1)	Experimentation (2)	Expansion (3)	Consolidation (4)	Maturity (5)
Tracking Finances		Does the government have the capacity to generate health spending data of good quality on a regular basis?	There are no data on expenditure for PMC interventions.	There are data on PMC expenditure, but the data are not systematically produced.	There are reliable data on PMC expenditure, but production is ad-hoc without a clear institutional mandate.	There are reliable data on PMC expenditure and data are used increasingly systematically to inform decision-making around budgeting and monitoring.	There is a solid understanding of why resource tracking is important, there are recent and reliable data on PMC expenditure, and data are systematically used to inform decision-making.
	Recognition	Are particular health worker(s) recognized for their role in providing PMC services within the national health system?	No health worker(s) are authorised/designated to provide PMC services and recognized for this role within the national health system.	Particular health worker(s) are authorised/designated to provide PMC services on a pilot basis and/or at small geographic scale; this role and their status within the national health system might still be unclear.	Particular health worker(s) are authorised/designated to provide PMC services across the country; this role and their status within the national health system is increasingly clarified.	Particular health worker(s) are authorised to deliver PMC services across the country; this role and their status within the national health system is recognised and increasingly reinforced through supervision and performance management.	Particular health worker(s) are authorized to deliver PMC services across the country; this role and their status within the national health system is recognised and continually reinforced through supervision and performance management.
RESOUCSE: Human	Rationalisation	How are health worker(s) delivering PMC services recruited and distributed across the country?	There is no standard practice for recruitment or training of health worker(s) to provide PMC. Distribution across the country is largely unknown.	Defined processes for recruitment and training are developed and applied in some areas of the country. Distribution across the country is increasingly known and optimisation considered.	Standard processes for recruitment and training are defined and increasingly applied across the country. Government led processes to rationalise distribution are underway.	Standard processes for recruitment and training are applied across the country and periodically reviewed for improvement. Distribution of across the country is known and managed for increasing optimisation.	Standard processes for recruitment and training are routinely applied across the country and a stable, optimised distribution is maintained.
	Compensation	How are the health worker(s) delivering PMC services compensated?	Health worker(s) providing PMC services receive no consistent financial and/or non-financial compensation; compensation may depend solely on projects of limited timeframes; discussions are underway to consider compensation options.	Various models of compensation are trialled on a pilot basis and/or at small geographic scale, often exclusively with external donor and implementation partner support; discussion of compensation options continue.	Health worker(s) providing PMC services receive some consistent financial and nonfinancial compensation, primarily with external donor and implementation partner support; discussion of compensation options continues with consideration of harmonisation and government adoption.	Government has harmonised partner support of financial and non-financial compensation for health worker(s) providing PMC services; compensation is increasingly provided on a consistent basis and increasingly commensurate with the health worker(s) job demands, complexity, number of hours, training and roles.	Financial and non-financial compensation is commensurate with the health worker(s) job demands, complexity, number of hours, training and roles; it is provided on a routine, consistent basis and managed through government systems.



Element Key question		Illustrative descriptions of phase						
		Awareness (1)	Experimentation (2)	Expansion (3)	Consolidation (4)	Maturity (5)		
	RESOURCES: Supplies	Equipment & Supplies	Does the MOH purchase and distribute the necessary PMC products in sufficient quantities as part of its national supply chain system?	Equipment, supplies and other materials needed for health worker(s) to deliver PMC services are not known; discussions are underway to define supply needs.	Various packages of equipment, supplies and other materials are provided to health worker(s) delivering PMC services on a pilot and/or small geographic scale, often through project-based procurement systems and supply chains managed by implementing partners with external donor support.	Appropriate equipment, supplies and other materials available in several geographical areas, but procurement and/or logistics often managed by external partners; equipment, supplies and other materials often differ based on implementing partner and external donor support; insufficient supplies and stock-outs are common.	Appropriate equipment, supplies and other materials are consistently provided at scale; external donor and implementing partner support coordinated and harmonised; increasingly integrated and managed through government procurement and supply chain systems.	Procurement and logistics for appropriate equipment, supplies and other materials fully integrated into government procurement and supply chain systems, including forecasting, procurement, distribution and monitoring; insufficient supplies and stock-outs are rare.



# Appendix K PMC INSTITUTIONALISATION IN THE FOUR FOCUS COUNTRIES

This appendix provides an overview of the assessment conducted by government stakeholders on the PMC institutionalisation progress in their countries. This assessment was conducted by government stakeholders and key stakeholders who attended the Plus Project Annual Meeting in October 2024 and the traffic light colouring reflects their assessments. Table K.1. provides an overview of their assessment that was prepared by PSI. It is recognised that at the time of drafting this report, eight months have passed with significant efforts to support sustainability and as such, some of these assessments may be outdated.

Legend	
	Driver scores falling in the red area show institutionalisation is weak
	Driver scores falling in the yellow area show some level of institutionalisation has occurred and should be monitored closely
	Driver scores falling in the green area show institutionalisation.

Table K.1: PMC institutionnalisation progress in projet countries<sup>74</sup>

Institutionalisation Drivers		Benin	Cameroon	Côte d'Ivoire	Mozambique
Core values	Core values	Beliefs and values of key stakeholders are relatively aligned on the value of PMC.	Core values that support PMC are fully integrated into the decision-making process of relevant government officials, MoH staff, and other key stakeholders. Strong political will and alignment with national health objectives.	direction and partner support to expand PMC beyond initial	MOH alignment is evidenced by integration of PMC into the NSP 2023-2030.
Leadership and governance	Leadership	· · · · · · · · · · · · · · · · · · ·	Leadership is evident across all levels of the MoH, with national health system staff feeling accountable for PMC. The intervention is led by the NMCP in close collaboration	Leadership for PMC is provided by the NMCP at the national level with engagement at sub-national level limited to the existing pilot district.	NMCP leads implementation at all levels.

<sup>&</sup>lt;sup>74</sup> The Plus Project 2024 Annual Meeting, Institutionalisation Report, Final 22 October 2024; PMC Status\_Visualisation by Country\_23 September 2024



Institutionalisation Drivers		Benin	Cameroon	Côte d'Ivoire	Mozambique
			with the Expanded Program on Immunisation (EPI) and Directorate of Health Promotion (DPS).		
	Standards and information	Monitoring and reporting systems are in place with integration of digitised tools into DHIS2.	Data collection tools have been revised to incorporate PMC at all levels; indicators for PMC are integrated into the DHIS2 system.	Monitoring and reporting systems for PMC exist in pilot districts, but PMC is not yet fully integrated into the national health information system.	Monitoring and reporting systems for PMC are in place, with data collected through health facility records and supervision tools, but not yet reflected in DHIS2.
	Planning	PMC is included in the national strategic plan for disease elimination (INSP 2024-2030) and there is a need to integrate PMC into regional and district annual work plans for 2025.	PMC is integrated into the 2019-2023 and 2024-2028 national malaria control plans, reflecting its inclusion in both national and sub-national health strategies.	PMC is included the NMCP strategic plan; there is a need to integrate PMC into regional and district plans	PMC is included in the NSP 2023-2030, which prioritises vector control and chemoprevention interventions in eligible districts.
	Coordination	Coordination exists at the national level, regional and district health system levels.	A coordination system is well- established within the MOH with PMC regularly discussed in coordinating bodies, including quarterly technical working group and bi-annual advisory group meetings.	Coordination structures for PMC include quarterly National Advisory Group reviews as well as regional and district coordination meetings; coordination will need to be integrated into existing structures after the Plus Project ends.	A permanent PMC Technical Working Group (TWG) coordinates PMC activities across health programs and partners.
Policy	Policy	PMC is included in the national strategic plan for disease elimination (INSP 2024-2030) and there is a need to identify other policy	PMC is included across multiple policy and strategy documents, with national guidelines and regulations in place for implementation (e.g. 2021 PMC guide, checklist	PMC is included in the national implementation guide, but there is a need to refine the implementation model with consideration to vitamin A and EPI schedules	PMC policies and strategies are included in the NSP 2023-2030; there are field guidelines for implementation



Institutionalisation Drivers		Benin	Cameroon	Côte d'Ivoire	Mozambique
		areas where PMC could be integrated.	and Integrated Service Delivery Cascade manual incorporating PMC).	and reflect in guidance documents accordingly.	and training modules for health workers.
Resources	Financing sources	The government will be co- financing the extension phase of PMC alongside Unitaid and other partners.	PMC services are funded by a combination of government resources and partners, but there is still a need to diversify and secure additional funding sources.	PMC is partially funded by the government, with indirect support for personnel, premises, and equipment. However, external funding is still necessary to cover service delivery costs.	PMC services are covered by a combination of government funding and external sources, the Plus Project has planned for the Global Fund to support in the future
	Costing and budgeting	Limited data on PMC costs exist, but PMC activities are included in the NMCP annual work plan.	PMC is included in the government costing and budgeting processes, but funds allocated are sometimes insufficient.	PMC services are included in national budgeting processes, but additional work is needed to align cost data with budgeting for scale-up.	Costing and budgeting for PMC are included in the NSP and Global Fund grants (however this is now under threat).
	Financing mechanisms	PMC funding is included in the national strategy for the NMCP.	No national health financing strategy exists, but there are multiple types of financing mechanism including support from technical and financial partners.	No health financing strategy specifically includes PMC.	NSP 2023-2020 includes financing strategies.
	Tracking resources	Expenditures are tracked through management of the NMCP.	Efforts are being made to improve healthcare expenditure data on PMC.	National health accounts and annual health district reports exist, but do not routinely include PMC expenditures.	Government has the capacity to generate and use health spending data.
	Staff	Health workers are recognised for delivering PMC services, with integration into vaccination services, which are supervised by the district management team.	CHWs responsible for integrated service delivery including PMC are recognised within the national health system.	Healthcare workers administering PMC are recognised within the national health system as civil servants.	Health workers responsible for delivering PMC are recognised and supported by the MoH with regular supervision and training in place.



Institutionalisation Drivers		Benin	Cameroon	Côte d'Ivoire	Mozambique
	Rationalisation	Health workers are recruited by the Ministry of Civil Service and assigned to health facilities by the MOH.	Standardised recruitment and training processes are applied nationwide by the MOH with the support of technical and financial partners.	Healthcare workers are distributed based on the national health map, and efforts are underway to standardise training processes.	Health workers delivering PMC services are recruited and trained according to national health system protocols
	Compensation	Compensation is guided by the standards of the Ministry of Civil Service.	Staff providing PMC services receive salaries through government systems; CHWs receive incentives through the MOH with support from technical and financial partners.	Compensation is provided by the government according to civil service standards.	Health workers are compensated according to government standards, though there is no additional compensation specifically for PMC services.
	Equipment and supplies	Supplies are currently purchased with Unitaid funds, but PMC supply chains are integrated into the MOH's national supply chain systems.	The MoH procures and distributes necessary PMC supplies, but occasional stock-outs and dependence on external partners remain challenges. Efforts are underway to improve supply chain integration.	Supplies for PMC are distributed through the national supply chain, but paediatric SP is currently purchased by the Plus Project and there is a need to integrate it within the country's M-supply.	PMC supplies are purchased by the Plus Project; distribution is through the national supply chain systems.



# Appendix L PLUS PROJECT DISSEMINATION ACTIVITIES

Table L.1. presents the national and international dissemination activities, including events, workshops and formal meetings, undertaken by the Plus Project prior to the evaluation team's analysis in June 2025. This list is based on Plus Project annual reporting for 2022-2024.

Table L.1: National and international dissemination activities undertaken by Plus Project<sup>75</sup>

Date	National and international dissemination activities undertaken by Plus Project
2022	LSHTM-led webinar on PMC including speakers from the Plus Project
September 2022	Presentation on PMC and the Plus Project at the annual RBM Malaria in Pregnancy (MiP) meeting
November 2022	Presentation of a poster on co-design at ASTMH
December 2022	NMCP Cameroon's presentation at the PMC COP meeting
February 2023	Presentation at the annual SMC alliance meeting
April 2023	Presentation (by invitation) at the Civil Society for Malaria Elimination (CS4ME) Annual Forum
April 2023	NMCP Benin's presentation at the PMC COP Meeting
June 2023	Plus Project webinar on supervision and catch-up strategy
October 2023	Presentation of posters and symposium at ASTMH in Chicago
November 2023	Virtual presentation at RBM Malaria in Pregnancy (MiP) working group teleconference
February 2024	One presentation at the SMC Alliance Annual Meeting
April 2024	Four events at the Multilateral Initiative on Malaria (MIM) in April (two symposia and other oral presentations, a side event on PMC and the malaria vaccine, and the PMC COP face-to-face meeting)
June 2024	Fobang Institute in Cameroon held a research dissemination meeting
June 2024	Transition workshop for Côte d'Ivoire
July 2024	Transition workshop for Mozambique
August 2024	Transition workshops for Benin and Cameroon

<sup>&</sup>lt;sup>75</sup> Plus Project, 2024 Annual Report, Submitted 2025.03.13; Plus Project, 2023 Annual Report, Submitted 2024.02.28; Plus Project, 2022 Annual Report, Submitted 2023.03.28.



Date	National and international dissemination activities undertaken by Plus Project			
September 2024	Plus Project annual meeting in Cameroon			
February, June, and November 2024	enin held three quarterly TWG meetings			
November 2024	Dissemination presentation at ASTMH in New Orleans			
December 2024	PMC COP webinar			
December 2024	Benin second consultative committee meeting			



# Appendix M IMPACT MODELLING METHODOLOGY

This appendix provides an overview of the modelling approach to estimate the public health and economic impacts of Unitaid's investment in PMC. Section M.1 provides an overview of the modelling plan and approach, including the key limitations, calculations and steps; Section M.2 provides an overview of the key assumptions of the model and the source.

#### M.1. OVERVIEW OF MODEL AND KEY CALCULATION STEPS

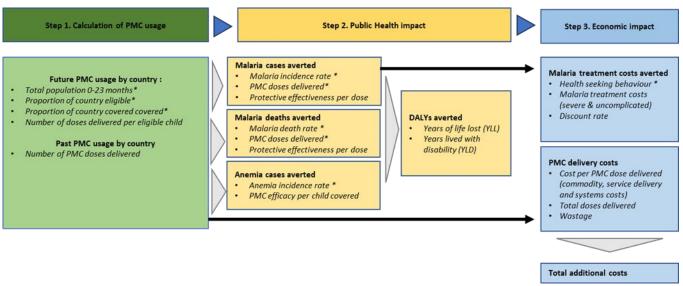
### M.1.1. Model approach

The Excel-based impact model used for this evaluation has been developed by CEPA but is closely based on the existing impact model that was developed at the start of the PMC project and has been periodically updated by LSHTM and PSI. The logic of the original modelling approach was maintained<sup>76</sup> but a new Excel-based model has been developed in order to (i) ease updating with new available data and to run sensitivities – for this evaluation and for further updates as additional data becomes available; (ii) allow for a more accurate calculation of the counterfactual scenario and (iii) ease addition of countries to the analysis.

Figure M.1 below provides an overview of the modelling approach which can be differentiated into three distinct steps: (i) calculation of PMC coverage; (ii) calculation of public health impact and (iii) calculation of economic impact. These steps are explained in more detail below.

To determine the public health and economic impact of Unitaid's investment, the model compares the health and economic outcomes in the **factual scenario** (e.g. with Unitaid grants) against the **counterfactual scenario** (e.g., expected usage of PMC in the absence of Unitaid grant).

Figure M.1: Modelling approach (conducted for factual and counterfactual scenario)



The modelling approach will differentiate the impact by:

• **Country** – e.g., Unitaid project countries as well as those countries with current or expected PMC uptake (with specific focus on high burden malaria countries).

<sup>&</sup>lt;sup>76</sup> SP-IPT+ Impact Assessment Models. Project Plan Annex (submitted April 28 2021)



• **Direct / indirect impact** – e.g., following Unitaid's impact methodology, the direct impact will cover the achieved impact from the grant in years 2023-24 while the indirect impact will cover the five years after grant closure across 2025-29 (and also explore potential scale-up in non-project countries)

#### Limitations

While the model provides a useful framework for estimating the potential impact of PMC, several limitations must be acknowledged in the data that is currently fed to the model. The key limitations are:

- Lack of final data from the research studies: The model relies on preliminary data from the ongoing research studies. In particular, we did not have access to the final findings on the SP resistance in the project countries and protective effectiveness and cost-effectiveness of PMC. As final results become available, key parameters—such as protective effectiveness and cost—may change significantly, affecting the model's outputs. Moreover, the research studies' findings will also influence the decision of countries to adopt and scale-up PMC. For example, Ghana and Zambia are waiting for the research findings to decide whether to implement PMC, and Cameroon is waiting to decide whether to increase the dose schedule from 5 to 8. Therefore, the final research studies results will also change the assumptions on the uptake of PMC scenarios.
- Uncertainty in global health financing: There is considerable uncertainty surrounding the future of global health financing, including for malaria prevention. As previously explained in Section 3.3.2 on Sustainability and Scalability, this makes it difficult to project the feasibility and scale of intervention rollouts, particularly in low-resource settings where external funding is critical.
- Lack of district-level data: The incidence data used in the model reflects national averages rather than
  district-level figures. This limits the model's ability to accurately represent the malaria burden in districts
  specifically eligible for PMC, potentially skewing estimates of impact and cost-effectiveness.
- Static malaria incidence assumptions: The model currently assumes a constant malaria incidence rate across years.

Despite these limitations, the model is built to allow for it to be easily updated in due course as the final findings of the research studies become available and there is further clarity on the future of the global health financing.

## M.1.2. Model calculation steps

### Step 1 - PMC uptake

The key step within the PMC uptake calculation per country is the achieved and expected number of PMC doses delivered across the country. The number of PMC doses delivered was considered one of the most robust data points which has been captured through the Unitaid supported project and is likely to also be captured and reported by countries in the future.

For the past impact, the model is then directly using the reported PMC doses delivered. For expected future use, the number of PMC doses delivered is calculated by multiplying: (i) the total population 0-23 months; (ii) the proportion of the country eligible for PMC (based on districts); (iii) the proportion of eligible districts covered by PMC and (iv) the average number of doses delivered per child.

PMC uptake is currently estimated for the four focus countries as well as seven non-project countries that are likely to use PMC and have benefited from the Unitaid investment.<sup>77</sup>

To calculate uptake, the model has considered the districts currently covered by PMC and used the best evidence from the qualitative data provided to identify the potential scale-up districts in each country. Four scenarios were used to determine the timing and extent of PMC rollout beyond existing project areas from 2026 onward. Table M.2. provides further details about each scenario.

<sup>&</sup>lt;sup>77</sup> The model includes impact in Burundi, Congo, DRC, Nigeria, Sierra Leone and Togo



- In the central scenario, given the complex global health financing situation, the model assumes that most
  countries will not be able to expand PMC to other districts at least until 2027, except in cases where countries
  have already allocated budget for scale-up and expressed strong commitment in 2025. From 2027, we
  assume a modest increase in countries that indicated an interest of expanding PMC (but that currently don't
  have firm commitments for domestic or external fundings).
- In the conservative scenario, given the complex global health financing landscape and the potential for further deterioration, we assume that countries will struggle to maintain PMC in the current districts. The withdrawal of Global Fund support in other health areas may prompt governments to reallocate domestic budgets away from PMC. Additionally, the WHO's 2024 guiding principles<sup>78</sup> deprioritise PMC in fragile settings, reinforcing this trend. As a result, countries might begin scaling back PMC coverage from 2026, when Global Fund GC7 financing ends in the currently supported districts. Overall, we estimate a 25% reduction in the number of districts implementing PMC from 2026 onward.
- In the high scenario, the model estimates a moderate or gradual increase of PMC as indicated in the 10. IPTi health impact model v5 May 2025 New Spectrum Data document developed by PSI
- In the full funding scenario, the model estimates a gradual increase to reach full coverage of all PMC eligible districts as if countries had the required funding for PMC.

### Step 2 - Health impact

The model estimates the public health impact of PMC uptake by calculating malaria cases, anaemia cases, and malaria-related deaths averted, as well as the number of DALYs averted.

To estimate malaria cases averted, the model applies the estimated number of PMC doses delivered to the baseline malaria incidence rates for children under five using Spectrum data and then multiplies this with the protective effectiveness per dose delivered (adjusted to annual timeframe). Anaemia cases averted will be estimated using a similar approach. Malaria deaths averted will be calculated using baseline malaria mortality rates for children under five.

DALYs averted will be calculated by summing years of life lost due to premature mortality (YLLs) and years lived with disability (YLDs). YLLs will be computed by multiplying deaths averted by the life expectancy at birth. YLDs will be calculated for malaria by multiplying the duration of illness by the relevant disability weight and the number of cases averted. The final DALY estimate will be the total of YLLs and YLDs across all conditions.

As outlined above, the total impact of Unitaid investment will be determined by taking the difference between the health outcomes of the factual and counterfactual scenarios.

#### Step 3 - Economic impact

The economic impact estimate (i) the treatment costs averted and (ii) the costs needed for PMC uptake. The total cost impact is then calculated based on the difference between these.

The averted treatment costs are calculated for uncomplicated malaria and severe malaria, based on the health impacts described above.

 For uncomplicated malaria, the model multiplies the number of cases averted by the proportion of cases classified as uncomplicated, the proportion seeking treatment, and the average treatment cost. This cost includes outpatient department expenses, the cost of rapid diagnostic tests (RDTs), and first-line ACT treatment.

<sup>&</sup>lt;sup>78</sup> WHO (2024) Guiding principles for prioritizing malaria interventions in resource constrained country contexts to achieve maximum impact



• For severe malaria, the model uses the estimated number of severe cases averted—derived from the proportion of deaths averted that would otherwise result from severe disease. This is then multiplied by the treatment-seeking rate and the cost of inpatient care, including hospitalisation, RDTs, and treatment.

The costs for the PMC uptake us calculated based on the number of doses provided and the cost per dose (including commodity cost, the service delivery costs and the systems costs). This also takes into account an estimated wastage of 5%.

Lastly, the additional economic cost is then calculated by applying and combining the treatment cost savings and PMC delivery costs (again taken the difference between the factual and counterfactual scenario in both cases).

#### M.2. KEY ASSUMPTIONS

Table M.1. in this section sets out the key model assumptions for the low, central and high scenario. The assumptions can be categorised as follows: (i) on uptake of PMC, (ii) on the counterfactual scenario, namely what uptake and scale-up would have happened in the absence of Unitaid's investments in PMC; (iii) on the health impacts of PMC; and (iv) on the cost-effectiveness of PMC. The last column in the table provides the sources for the data used in the model and the reasoning behind the choice of the data points.

Table M.2. provides an overview of the eligible population for PMC in each country.

Table M.3. provides the key assumptions for the uptake scenarios (central, conservative, high and full funding scenarios) of PMC among eligible districts in each country.

These input assumptions are still in draft form and CEPA would welcome any feedback and further data to further refine the final estimates



Table M.1: Impact model assumptions

Area	Specific input	Sub-input	Low Scenario	Central Scenario	High Scenario	Source/justification
Uptake	Number of doses delivered per eligible child		1.67	1.89	2.15	Based on data from the four focus countries provided by PSI, namely average from 2024 for central scenario, highest country value for high scenario and lowest for low scenario.
	Proportion of children covered by at least 1 dose of SP		70%	80%	90%	This is based on preliminary data from Cote Ivoire (shared by PSI via email). Existing programmes have a range mostly around 70-75%.
	Eligible population in each country		Dependent on each country (see Table M.2)	Dependent on each country (see Table M.2)	Dependent on each country (see Table M.2)	Information shared from PSI (including only areas with >10% PfR and excluding areas with SMC coverage)
	Uptake of PMC among eligible districts	Countries	Dependent on each country (see Table M.3)	Dependent on each country (see Table M.3)	Dependent on each country (see Table M.3)	In the central scenario, given the complex financing situation, we assume that most countries will not be able to expand PMC to other districts at least until 2027, except in cases where they have already allocated budget and expressed strong commitment in 2025. Global Fund's GC7 Programmatic Reprioritisation Approach (6 June 2025) indicates they will not fund expansion of PMC in new districts. From 2027, we assume a modest increase hoping that the funding scenario will improve.
						In the low, given the complex financing situation, we assume countries will not be able to sustain PMC in the current districts. The withdrawal of Global Fund financing in other health areas, may force the government to also



						reprioritise domestic budgets. Given the WHO 2024 Guidance on PMC in fragile settings deprioritises PMC, we expect countries to reduce the number of districts receiving PMC from 2026 when the Global Fund funding for PMC terminates in the countries currently receiving the funding. Generally, estimate a reduction of 25% in the districts implementing PMC from 2026.
						In the High Scenario, we estimate a moderate or gradual increase of PMC as indicated in the 10. IPTi health impact model - v5 May 2025 - New Spectrum Data document developed by PSI
						In the Full Funding Scenario, we estimate a gradual increase of PMC as if countries had the required funding for PMC.
	Population 0-23 months year old	Countries	Dependent on each country	Dependent on each country	Dependent on each country	UN Population Data, 2023
Counterfactual	Proportion PMC doses delivered taken place in	Focus countries (except Cameroon)	0%	0%	0%	Unitaid grant critical for uptake
	absence of Unitaid after grant closure	Focus countries (Cameroon)	50%	50%	50%	National adoption would have most likely happened without the Unitaid investment. However, uptake outside the Plus Project districts was significantly lower and the Plus Project demonstrated the importance of supporting the introduction of a new intervention like PMC through training, supervision, community engagement



						and the availability of the appropriate commodity.
		Countries with other support / existing programmes (Nigeria, Sierra Leone and Togo)	90%	90%	90%	Unitaid potentially only influenced adoption indirectly through implementation tools developed, costeffectiveness studies and WHO guideline support
		Other countries	70%	70%	70%	Unitaid potentially only influenced adoption indirectly through the COP, dissemination, implementation tools developed, cost-effectiveness studies and WHO guideline support
Health impacts	Incidence rate of malaria in children between 0 to 4 years old per 1,000 people	Countries	Dependent on each country	Dependent on each country	Dependent on each country	Spectrum Malaria, 2024
	Death rate in children between 0 to 4 years old per 100,000 people due to malaria	children between 0 to 4 years old per 100,000 people due		Dependent on each country	Dependent on each country	Spectrum Malaria, 2024
	Percentage of children with severe anaemia		Dependent on each country	Dependent on each country	Dependent on each country	National DHS
	Percentage of children with moderate anaemia	Countries	Dependent on each country	Dependent on each country	Dependent on each country	National DHS
	Protective effectiveness from malaria per dose		6.3%	7.1%	7.6%	This was calculated by dividing the length of protective effect per dose in days (30 days) by the protective effect per dose delivered. The source for the



	delivered (adjusted to annual timeframe)					protective effect per dose delivered is the Plus DT / MalariaSimulation from the PSI Unitaid logframe.
	Protective effectiveness from anaemia per dose delivered		7.0%	7.0%	7.0%	This was calculated by dividing the protective effectiveness per child covered (annual) and the average number of doses delivered to achieved affect. This data was sourced from the WHO 2010 IPTi Recommendations, taken from the grantee model.
	Life expectancy	Countries	Dependent on each country	Dependent on each country	Dependent on each country	WHO, 2024
	Proportion of severe malaria cases	Countries	Dependent on each country	Dependent on each country	Dependent on each country	Grantee Model
	Disability weight (malaria, acute episode, severe)		0.13	0.13	0.13	Grantee Model
	Length of severe malaria episode (years)		0.01	0.01	0.01	Grantee Model
	Disability weight (anaemia, severe)		0.15	0.15	0.15	Grantee Model
	Disability weight (anaemia, moderate)		0.05	0.05	0.05	Grantee Model
	Length of anaemia illness		0.06	0.06	0.06	Grantee Model
	Discount Rate		3%	3%	3%	
Economic impact figures	PMC Costs	Commodity costs per dose	0.13	0.13	0.13	Maria Martínez on behalf of the MULTIPLY consortium EDCTP Forum 2025, Kigali, Rwanda, 16th June, 2025



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	Service delivery costs	0.61	0.53	0.44	Maria Martínez on behalf of the MULTIPLY consortium EDCTP Forum 2025, Kigali, Rwanda, 16th June, 2025 - Central uses average of Sierra .Leone and Togo, Hihgh uses lower estimates from SL, Low uses higher estimates from Togo
	Systems costs (training, guidelines etc.)	0.37	0.32	0.26	Maria Martínez on behalf of the MULTIPLY consortium EDCTP Forum 2025, Kigali, Rwanda, 16th June, 2025; training & M&E costs set at 60% of service delivery (assuming 5 years delivery)
Percentage of malaria cases that are uncomplicate		Dependent on each country	Dependent on each country	Dependent on each country	Spectrum
Percentage of uncomplicated malaria cases seeking treatmen	Countries	Dependent on each country	Dependent on each country	Dependent on each country	National DHS
Treatment cost p uncomplicated	er OPD Cost	Dependent on each country	Dependent on each country	Dependent on each country	WHO-CHOICE
malaria cases.	RDT cost	0.42	0.47	0.48	Global Fund Pooled Procurement price list, 2020
	Firstline ACT cost	0.25	0.28	0.30	Global Fund Pooled Procurement price list, 2020
Percentage of malaria cases that are severe	Countries	Dependent on each country	Dependent on each country	13%	Spectrum was used to determine the lower bound
Percentage of severe malaria cases seeking treatment	Countries	Dependent on each country	95%	100%	World Malaria Report 2020



Treatment cost of severe malaria per	Daily cost per patient	Dependent on each country	Dependent on each country	Dependent on each country	WHO-CHOICE
patient	Number of treatment days	3	5	7	Grantee model (reduced days to ensure closer alignment of costs in other Unitaid models)
	Firstline Tx	2.61	1.45	1.45	Grantee model
	RDT cost	0.42	0.47	0.48	Grantee model
Wastage		10%	5%	5%	PMC Operational guideline planning

Table M.2: Proportion of population eligible for PMC (excluding areas with SMC coverage and only including areas with >10% PfR)

Country	Proportion of population eligible for PMC
Angola	98%
Benin	83%
Burkina Faso	0%
Burundi	97%
Cameroon	72%
Congo	100%
Cote d'Ivoire	86%
DRC	100%
Ghana	28%
Malawi	100%
Mali	0%
Mozambique	81%
Niger	0%
Nigeria	42%



Country	Proportion of population eligible for PMC
Sierra Leone	100%
Tanzania	41%
Togo	65%
Uganda	94%
Zambia	100%

Table M.3: Expected uptake scenarios of PMC among eligible districts in each country

	<u> </u>							
Countries	2023	2024	2025	2026	2027	2028	2029	Justification
Central Scena	rio							
Benin	16%	16%	42%	42%	53%	53%	53%	Benin has agreed to scale-up the districts implementing PMC from 3 to 8 in 2025. PMC is currently included in the Global Fund proposal and from 2026 the government has committed to implementing PMC through domestic financing. In 2027, we expect a moderate increase.
Burundi	0%	0%	4%	4%	10%	10%	10%	Implementation in Burundi started in 5 districts in 2025 thanks to MSF Belgium and Global Fund (from Charlotte's email on the 29 May). In 2027, we expect a moderate increase to 10%
Cameroon	100%	100%	100%	100%	100%	100%	100%	PMC will be continued to be delivered in all eligible Cameroon districts.
Congo	0%	0%	100%	100%	100%	100%	100%	Data from 250529 WMR data collection tool for PMC_ JK CE document provided by PSI.



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
								Implementation in 52 districts started in 2025.
Cote d'Ivoire	4%	4%	4%	4%	10%	10%	10%	Cote d'Ivoire is receiving GC7 Global Fund for PMC until 2026. However, it is has agreed not to scale-up PMC until 2027 due to the international health funding situation. In 2027, we expect a moderate increase.
DRC	8%	8%	8%	8%	10%	10%	10%	In the central scenario, given the complex financing situation, we assume the country will not be able to expand PMC to other districts until 2027. In 2027, we expect a moderate increase.
Ghana	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC
Mozambique	14%	16%	16%	16%	35%	35%	35%	Mozambique has included PMC in its GC7 Global Fund proposal. Mozambique has also been considering expanding PMC to 4 new provinces (Tete 15 districts, Zambezia 22 districts, Cabo Delgado 17 districts and Manica 12 districts). However, due to the international health funding situation, we expect only a slight increase in one province in 2027
Nigeria	2%	2%	2%	5%	10%	10%	15%	AFDB and WB have shown interest in funding PMC in Nigeria. We assume that Nigeria, given its larger domestic financing budget, will be able to scale up PMC to 10% by 2027.



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
Sierra Leone	100%	100%	100%	100%	100%	100%	100%	PMC will be continued to be delivered in all eligible Sierra Leone districts.
Togo	100%	100%	100%	100%	100%	100%	100%	PMC will be continued to be delivered in all eligible Togo districts.
Zambia	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC
Low Scenario								
Benin	16%	16%	42%	26%	26%	26%	26%	Due to the complex international financing situation, the government of Benin decides to divert funding from PMC to other areas. Benin is able to scale up PMC only in 2 of the 5 identified districts.
Burundi	0%	0%	4%	4%	3%	3%	3%	Due to the complex international financing situation, the government of Burundi decides to divert funding to PMC to other areas. Burundi is only able to deliver PMC in 75% of the districts already receiving PMC.
Cameroon	100%	100%	100%	75%	75%	75%	75%	Due to the complex international financing situation, the government of Cameroon decides to divert funding from PMC to other areas. Cameroon is only able to deliver PMC in 75% of the districts.
Congo	0%	0%	100%	75%	75%	75%	75%	Due to the complex international financing situation, the government of Congo decides to divert funding to PMC to other areas. Congo is only



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
								able to deliver PMC in 75% of the districts already receiving PMC.
Cote d'Ivoire	4%	4%	4%	3%	3%	3%	3%	Due to the complex international financing situation, the government of CDI decides to divert funding from PMC to other areas. CDI is only able to deliver PMC in 75% of the districts.
DRC	8%	8%	8%	8%	6%	6%	6%	Due to the complex international financing situation, the government of DRC decides to divert funding from PMC to other areas. DRC is only able to deliver PMC in 75% of the districts.
Ghana	0%	0%	0%	0%	0%	0%	0%	In the low scenario, we do not expect Ghana to be starting to implement PMC given that Global Fund's GC7 Programmatic Reprioritisation Approach (6 June 2025) indicates they will not fund expansion of PMC in new districts
Mozambique	14%	16%	16%	16%	12%	12%	12%	Due to the complex international financing situation, the government of Mozambique decides to divert funding from PMC to other areas. Mozambique is only able to deliver PMC in 75% of the districts.
Nigeria	2%	2%	2%	2%	2%	2%	2%	Due to the complex international financing situation, the government of Nigeria decides to divert funding from PMC to other areas. Nigeria is only able to deliver PMC in 75% of the districts.



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
Sierra Leone	100%	100%	100%	75%	75%	75%	75%	Due to the complex international financing situation, the government of Sierra Leone decides to divert funding from PMC to other areas. Sierra Leone is only able to deliver PMC in 75% of the districts.
Togo	100%	100%	100%	75%	75%	75%	75%	Due to the complex international financing situation, the government of Togo decides to divert funding from PMC to other areas. Togo is only able to deliver PMC in 75% of the districts.
Zambia	0%	0%	0%	0%	0%	0%	0%	In the low scenario, we do not expect Zambia to be starting to implement PMC given that Global Fund's GC7 Programmatic Reprioritisation Approach (6 June 2025) indicates they will not fund expansion of PMC in new districts
High Scenario								
Benin	16%	16%	42%	42%	53%	68%	84%	Benin has agreed to scale-up the districts implementing PMC 3 to 8 in 2025. In the high scenario, we expect a moderate increase as estimated by PSI in the 10. IPTi health impact model - v5 May 2025 - New Spectrum Data document
Burundi	0%	0%	4%	4%	10%	15%	20%	Burundi is starting to implement PMC in 5 districts in 2025. In the high scenario, we expect a gradual increase from 2027 as estimated by PSI in the 10. IPTi health impact model



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
								<ul> <li>v5 May 2025 - New Spectrum Data document</li> </ul>
Cameroon	100%	100%	100%	100%	100%	100%	100%	Cameroon continues to deliver PMC in all districts
Congo	0%	0%	100%	100%	100%	100%	100%	Congo continues to deliver PMC in all districts
Cote d'Ivoire	4%	4%	4%	4%	10%	15%	20%	Cote d'Ivoire has decided not to scale- up PMC until 2027. In the high scenario, we expect a gradual increase as estimated by PSI in the 10. IPTi health impact model - v5 May 2025 - New Spectrum Data document
DRC	8%	8%	8%	8%	10%	15%	20%	In the high scenario, we expect DRC to have gradual increase as estimated by PSI in the 10. IPTi health impact model - v5 May 2025 - New Spectrum Data document
Ghana	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC
Mozambique	14%	16%	16%	16%	35%	62%	83%	Mozambique has expressed interest scaling up PMC to 4 new provinces Tete 15 districts, Zambezia 22 districts, Cabo Delgado 17 districts and Manica 12 districts. In the high scenario, we estimate that from 2027 Mozambique will be able to scale-up progressively to these districts
Nigeria	2%	2%	2%	10%	15%	20%	25%	In the high scenario, we expect Nigeria to have gradual increase. AFDB and WB have already shown interest in



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
								funding PMC and we expect Nigeria to allocate domestic funding to PMC.
Sierra Leone	100%	100%	100%	100%	100%	100%	100%	Sierra Leone continues to deliver PMC in all districts
Togo	100%	100%	100%	100%	100%	100%	100%	Togo continues to deliver PMC in all districts
Zambia	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC
Full funding sco	enario							
Benin	16%	16%	100%	100%	100%	100%	100%	Benin has agreed that all eligible districts should get PMC.
Burundi	0%	0%	4%	4%	100%	100%	100%	Burundi is starting to implement PMC in 5 districts in 2025. In the full funding scenario, we assume that after two years of pilot they would gradually scale PMC to all eligible districts.
Cameroon	100%	100%	100%	100%	100%	100%	100%	Cameroon continues to deliver PMC in all districts
Congo	0%	0%	100%	100%	100%	100%	100%	Congo continues to deliver PMC in all districts
Cote d'Ivoire	4%	4%	16%	41%	65%	90%	100%	In the full funding scenario, we assume that CDI would gradually scale up PMC to all eligible districts
DRC	8%	8%	16%	32%	55%	79%	100%	In the full funding scenario, we assume that DRC would gradually scale up PMC to all eligible districts. Given the current fragile setting, we expect



Countries	2023	2024	2025	2026	2027	2028	2029	Justification
								uptake to be slower than other countries.
Ghana	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC
Mozambique	14%	16%	100%	100%	100%	100%	100%	Mozambique has expressed interest scaling up PMC to 4 new provinces Tete 15 districts, Zambezia 22 districts, Cabo Delgado 17 districts and Manica 12 districts. In the full funding scenario, we assume that Mozambique would scale-up to all these districts.
Nigeria	2%	2%	10%	26%	49%	73%	100%	In the full funding scenario, we expect Nigeria to have a rapid increase in PMC.
Sierra Leone	100%	100%	100%	100%	100%	100%	100%	Sierra Leone continues to deliver PMC in all districts
Togo	100%	100%	100%	100%	100%	100%	100%	Togo continues to deliver PMC in all districts
Zambia	0%	0%	0%	0%	0%	0%	0%	Waiting for final research results to understand interest of government in PMC



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