



End-of-Grant Evaluation Report

Transforming IPT for Optimal Pregnancy (TIPTOP) Project and Output 1 of the Supply Side Grant

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List of Acronyms

Afi	Area For Intervention
ANC	Antenatal Care
API	Active Pharmaceutical Ingredient
BMGF	Bill & Melinda Gates Foundation
CCM	Country Coordinating Mechanism
CHW	Community Health Worker
C-IPTp	Community Intermittent Preventive Treatment in Pregnancy
DAC	Development Assistance Criteria
DALY	Disability Adjusted Life Years
DHS	Demographic and Health Survey
DRC	Democratic Republic of Congo
ITN	Insecticide-Treated Nets
IPTp	Intermittent Preventive Treatment in Pregnancy
ISGlobal	Barcelona Institute for Global Health
KIIs	Key Informant Interviews
LMICs	Low- and Middle-Income Countries
LRP	Learning Resource Packages
MiP	Malaria In Pregnancy
MMV	Medicines for Malaria Venture
NMCP	National Malaria Control Program
NMSP	National Malaria Strategic Plan
OECD	Organisation for Economic Co-operation and Development
PMI	President's Malaria Initiative
PR	Principal Recipient
QA	Quality Assured
ROI	Return on Investment
SMC	Seasonal Malaria Chemotherapy
SBCC	Social Behaviour Change Communication
SP	Sulfadoxine-Pyrimethamine
TIPTOP	Transforming IPT For Optimal Pregnancy
TWG	Technical Working Group
WHO	World Health Organization

Executive Summary

BroadImpact was contracted by Unitaid to conduct the end of grant evaluation of the Jhpiego-led Transforming IPT for Optimal Pregnancy (TIPTOP) Project, and Output 1 of the Medicines for Malaria Venture (MMV) Supply Side Grant.¹ The evaluation was conducted between December 2021 and June 2022. It assessed the overall performance of the TIPTOP & Supply Side Grant (Output 1) across the following domains: **relevance, coherence, effectiveness, efficiency, impact and sustainability** of the Organisation for Economic Co-operation and Development (OECD), Development Assistance Criteria (DAC).² This evaluation report refers to the Jhpiego-led project as **“TIPTOP”** and the MMV Supply Side Grant as **“Supply Side Grant”**. Where the joint efforts of both projects are described, they are referred to as **“the projects”**.

Unitaid invested USD 52.6 million towards increasing access to Intermittent Preventive Treatment for pregnant women (IPTp). The investment was implemented through two grants awarded in 2017: TIPTOP and the Supply Side Grant. TIPTOP was implemented by a consortium of two organisations, Jhpiego as the lead grantee and Barcelona Institute for Global Health (ISGlobal) as the evaluation and research partner. TIPTOP focused on removing demand-side access barriers by introducing an innovative, ‘no missed opportunities’ community-based approach to increase the number of pregnant women in malaria-affected countries in sub-Saharan Africa receiving IPTp, without detracting from antenatal care utilisation. The Supply Side Grant’s first output focused on overcoming supply-side barriers by improving global availability and supply of quality assured SP for IPTp. This was to be achieved through technical support for the WHO pre-qualification of Sulfadoxine Pyrimethamine (SP) products for IPTp, including an African manufacturer, and the development of user-friendly packaging. TIPTOP was implemented in four target countries, the Democratic Republic of Congo (DRC), Madagascar, Mozambique and Nigeria, from May 2017 to April 2022. The Supply Side Grant was implemented from September 2017 to April 2021. The Supply Side Grant has been extended till December 2022 to attain other deliverables unrelated to IPTp-SP.

The evaluation found that the design of the projects, their objectives and expected results were very relevant to the current needs of global malaria stakeholders, targeted beneficiary countries, and other malaria-endemic countries. The high Malaria in Pregnancy (MiP) burden in these countries; the availability of a proven and effective intervention (IPTp); the need for evidence on alternative delivery models; complementary World Health Organisation (WHO) guidelines on IPTp and ANC (already in place); and a need to introduce prequalified SP products into the market, are all factors that depict the relevance of the projects. Country-level respondents and beneficiaries from all implementation countries highly regarded the TIPTOP project, applauding it for reaching the hardest-to-reach locations and addressing a persistent public health gap. The TIPTOP project also adapted well to contextual changes at global and country levels, as evidenced by its adaptation to different Community Health Worker (CHW) cadres; utilizing modified implementation approaches to adapt to each of the focus country’s context; supporting the implementation of the 2016 WHO Antenatal Care (ANC) guidelines which were just being adopted by countries at the start of the project; as well as navigating COVID-19 and other unexpected natural disasters, health emergencies and insecurity experienced throughout the life of the project.

¹ The Supply Side Grant had two other outputs that are unrelated to IPTp-SP and are therefore not covered by this report. These cover the improving global supply of Sulfadoxine-pyrimethamine and amodiaquine (SP+AQ) for Seasonal Malaria Chemoprevention (SMC) and Rectal artesunate suppositories (RAS) for the pre-referral management of severe malaria.

² <https://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm>.

The projects were also very coherent, with Community IPTp (C-IPTp) well integrated into existing community health systems, leveraging existing personnel (community health workers) and structures (information systems, supply chains, referral mechanisms) for delivery of community health services. The intervention was complementary to existing facility-based IPTp delivery through ANC, as it helped extend IPTp and referral services, and improved the availability of QA-SP at both facility and community levels. The TIPTOP project worked exceptionally well with both global and local stakeholders. There was great alignment within the consortium of Jhpiego and ISGlobal, productive interactions with supportive projects – the Supply Side Grant and WHO’s enabler, and a well-constituted project steering committee comprising of the US Government President’s Malaria Initiative (PMI), the Global Fund, MMV, ISGlobal, WHO, and Jhpiego. There was also effective engagement with PMI and GF as scale-up partners, a series of learning events with a wide variety of stakeholders, active participation in in-country TWGs and extensive networking through CSOs in-country. These interactions were consistent from inception through closeout, creating a high level of coherence for the C-IPTp intervention.

The projects were largely effective and increased coverage of IPTp through a community-based approach, with TIPTOP surpassing its life-of-project targets for the percentage of pregnant women receiving three or more doses of IPTp. IPTp3 coverage increased from baselines of 21% in DRC, 28% in Madagascar, 53% in Mozambique and 11% in Nigeria to endlines of 65% in DRC, 75% in Madagascar, 59% in Mozambique and 63% in Nigeria. The projects also successfully overcame targeted access barriers as follows:

- The Supply Side Grant effectively addressed the limited availability of quality assured manufacturers of SP specifically packaged for IPTp (**quality, innovation and availability barrier**) by supporting the WHO prequalification process of three manufacturers (UCL Kenya, SWIPHA Nigeria and EMZOR Nigeria). UCL Kenya and SWIPHA Nigeria have submitted their dossier for review with an expected approval for the UCL product by mid-2022 and the SWIPHA product by 2023. The dossier for EMZOR was only submitted in mid-2022 with an estimated 18-24 months review period.
- TIPTOP effectively addressed the low demand for IPTp among providers and pregnant women (**demand & adoption barrier**) by creating strong ownership for the project’s interventions through consistent stakeholder engagements; increased sensitisation and awareness of IPTp through CSOs and CHWs; and strengthened linkages between health facilities and community structures. The improved IPTp-SP packaging, branded for pregnant women, also improved the acceptance of the product.
- TIPTOP addressed the insufficient evidence behind alternative service delivery innovations (**demand & adoption barrier**) by generating and disseminating evidence on the effectiveness of C-IPTp through its research and routine monitoring results.
- TIPTOP addressed supply chain inefficiencies (**supply and delivery barrier**) in supported sites by strengthening the community health system through tailored trainings, reinforced supply chains and improved health information systems. These resulted in significant reductions in SP stockouts in project sites.

The projects experienced challenges, especially with the COVID-19 pandemic, as well as extreme weather/natural disasters and insecurity in specific districts in different project countries. These events mildly impacted the project results, with targets unmet in a few locations. The main factors that influenced the effectiveness of the projects were country-level ownership and political support, effective integration into existing health systems, strengthened community-facility linkages, extensive and tailored CHW trainings, supply chain strengthening at supported sites, evidence-based decision-making, adaptability to COVID-19 and related restrictions, as well as MMV’s expertise in deftly navigating the WHO prequalification process with manufacturers who

were new to the process. The projects are described as very successful by stakeholders at all levels, including beneficiaries.

The changes in IPTp3+ coverage potentially translated to improved health outcomes for mothers and newborns, with a third dose of SP increasing the protective efficacy in reducing malaria by 33% - 40%. More specifically, estimates from the modelling exercise show that the project could contribute to 2.9m [829k– 4.6m] malaria infections averted; 100,806 [27,690 - 156,497] deaths averted [9,618 maternal deaths and 91,188 neonatal deaths]; and 7.9m [2.7m – 10.4m] DALYs averted [0.3m maternal DALYs and 7.7m neonatal DALYs] from 2023-2027 across the four project countries and six additional countries in Africa with the highest likelihood for adoption and scale-up. The intervention also has the potential to generate cost-saving by averting treatment costs for the health system of US\$69m [17m, 120m] in the next five years. The intervention will also confer an incremental cost of US\$625m [221m, 768m] to the health system over the next five years, with a Return on Investment (ROI) of 31.9. The intervention is cost-effective; based on the cost-effectiveness threshold typically adopted to inform decisions in health care (up to 30 US\$ per DALY averted being highly cost-effective, and up to 150 US\$ per DALY averted being cost-effective).³

The projects were largely time-efficient, delivering most activities on time; however, external challenges mentioned earlier, delayed or stopped implementation in certain project locations. The projects were also largely cost-efficient, improving their absorptive capacity annually, with TIPTOP and the Supply Side Grant expending 81% and 116% of their project budgets, respectively, by December 2021. The intervention was cost-effective, as determined by the modelled estimates above. Factors considered by the project to achieve value for money included integration of the intervention within existing community health systems, utilizing government's CHWs (these were not remunerated by the project), leveraging funding partners early and transitioning some of the procurement to these funders even before project closeout. The project, though unintentionally, also had significant savings due to the transition to virtual activities per the COVID-19 pandemic.

The intervention is poised to be sustainable, with sustainability factored in at design stage, including its co-creation with Ministries of Health (MoH), involvement of scale-up partners in site selection and implementation through country health systems. The project was implemented through existing MoH structures with extensive support to ensure integration and some support extending to other Maternal, Newborn and Child Health (MNCH) services. Furthermore, C-IPTp has been included in National Malaria Strategic Plans (NMSPs) in DRC, Madagascar and Nigeria, even before inclusion in global policy documents. Also, the comprehensive learning systems set up by the project led to increased interest beyond project countries to take up the intervention. There is tremendous support from PMI and GF, with some funding already made available and expectations of receiving funding in future funding allocations in three countries (DRC, Madagascar and Nigeria). The main sustainability gap is limited funding commitment from domestic sources; however, the low cost of this intervention creates a higher likelihood for inclusion in country budgets. There was also some dissonance between stakeholders at both country and global level, with some stakeholders expecting updated WHO guidelines to signal WHO's support for community delivery as an acceptable method for delivering IPTp, and WHO determining mid-project that the current ANC guidelines do not preclude community delivery. In the updated guidance published in June 2022, WHO affirmed its recommendation for IPTp-SP in moderate to high *P. falciparum* malaria transmission areas, stating

³ WHO. Making choices in health: WHO guide to cost-effectiveness analysis. In: Tan-Torres Edejer T, Baltussen R, Adam T, Hutubessy R, Acharya A, Evans DB, Murray DB, Murray CJL, editors. Geneva: WHO; 2003.

that the recommendation does not limit the delivery of IPT-SP to ANC settings; indicating that the use of community health workers may be explored where inequities exist.⁴

Recommendations from this evaluation for different stakeholder groups include:

To **National Malaria Control Programs, National RMNCH Programs and Ministries of Health:**

- **Baseline needs assessments for country adoption** should include CHWs availability/workload and training needs, registration requirements for SP (plus commodity packaging requirements) and an understanding of supply chain gaps.
- **Create avenues for communication and collaboration between Malaria and RMNCH programs** to strengthen C-IPTp and similar cross-cutting interventions.
- **Conduct tailored trainings for CHWs** per country context and CHW need (may be IPTp focused or more extensive covering MiP or other MNCH themes).
- **Closely monitor SP resistance levels**, as countries scale up the use of IPTp-SP at ANC as well as at community level.
- **Utilise TIPTOP costing and cost-effectiveness estimates** for strategic planning and for further advocacy to funders.
- **Prioritise QA SP for IPTp with improved packaging** and facilitate distribution through all delivery mechanisms. This will also contribute to creating demand for the newly prequalified manufacturers.

To **TIPTOP, Supply Side Grant & other Implementers**, the evaluation recommends:

- **Advocate to country decision-makers on the need to prioritise quality assured SP.** A key enabler to having new prequalified African manufacturers catalyse the market.
- **Provide access to project results for ongoing dissemination** after project closeout, for countries and other stakeholders to further engage.

To **Unitaid, other Donors & Global Policymakers**, the evaluation recommends:

- **Sensitise national stakeholders on the interpretation of the updated WHO guidelines on the provision of C-IPTp.**
- **Prioritise prequalified SP products from local manufacturers in specific regions** for future investments.
- **Explore options for future replacement of SP** including existing drugs, new drug development, or breakthrough technologies. Although there are no reports of resistance, SP has had a track record of resistance in malaria treatment, and C-IPTp is likely to scale the use of SP significantly, with concerns of reduced effectiveness due to resistance in the future.
- **Lead advocacy targeting other funders/potential scale-up partners;** this is essential for the catalytic approach of Unitaid's projects to be successful. *(Unitaid Only)*
- **Consider re-structuring budget allocation** within the first year (especially when less than six months), having a smaller budget dedicated to – consortium and implementation partners' set up, phased personnel recruitment, and research protocol development and approval. This will allow for focused activities and reduced underspend in Y1, and consequently, a seamless implementation in year 2. *(Unitaid Only)*

⁴ WHO Guidelines for malaria, 3 June 2022. Geneva: World Health Organization; 2022 (WHO/UCN/GMP/2022.01 Rev.2). License: CC BY-NC-SA 3.0 IGO.

1. Introduction

1.1 Background

Malaria is one of the leading causes of illness, death, and lost economic productivity in the world. An estimated 241 million malaria cases occurred globally in 2020, increasing from 227 million cases in 2019. This increase is associated with the disruption to services due to the COVID-19 pandemic. The majority of these cases occurred in sub-Saharan Africa, with six countries accounting for 55% of cases globally; these are Nigeria (27%), the Democratic Republic of the Congo (12%), Uganda (5%), Mozambique (4%), Angola (3.4%) and Burkina Faso (3.4%). These countries also accounted for half of the malaria deaths globally, with malaria deaths increasing by 12% in 2020, also due to COVID-19 disruptions.⁵

Pregnant women and children are more vulnerable to malaria infection. In pregnant women, malaria infection causes pregnancy complications such as maternal and perinatal anaemia, which may result in loss of the pregnancy, premature births, low birth weight infants or maternal death. In Africa, 10,000 women and between 75,000 and 200,000 infants are estimated to die annually as a result of malaria infection during pregnancy, and approximately 11% (100,000) of neonatal deaths are due to low birthweight resulting from *Plasmodium falciparum* infections in pregnancy.⁶ In 2020, 33 moderate-to-high transmission countries in sub-Saharan Africa accounted for an estimated 34 million pregnancies, of which 34% (12 million) were exposed to malaria infection during pregnancy. This resulted in 819,000 children with low birthweight. The use of even one dose of intermittent preventive treatment in pregnancy (IPTp) among these women would have averted 45 000 children from being born with low birthweights. Three doses with up to 90% coverage would avert 206,000 low birthweights.⁷

Malaria in pregnancy is highly preventable with consistent use of insecticide-treated nets and uptake of IPTp. In 2020 in Sub-Saharan Africa, only about half of the population, including pregnant women slept under an Insecticide-Treated Net (ITN), 46% of the general population and 52% for pregnant women, with access and utilisation of ITNs declining annually since 2017.⁸ Implementing appropriate prevention and control measures for pregnant women is thus critical. The use of sulfadoxine-pyrimethamine (SP) for IPTp has been recommended by WHO in moderate to high transmission areas for over two decades now. IPTp can reduce the incidence of low birthweight by 29%; severe maternal anaemia by 38%; and neonatal mortality by 31%,^{9,10} however, the uptake of IPTp-SP has been low. IPTp-SP is often delivered through antenatal care at health facilities, and the rates of provision of IPTp-SP first dose (IPTp1-57%) are much lower than first Antenatal Care (ANC) attendance rates (74%), with only 32% receiving a third dose (IPTp3).¹¹

This low uptake of IPTp-SP shows that there are significant gaps in effectively delivering IPTp-SP in sub-Saharan Africa. These include lack of supply of quality assured SP for IPTp, low demand by health workers and pregnant women, doubts among health workers over the efficacy of the drug because of the perception of SP as a failed drug, periodic stockouts of SP, out-of-pocket payments, weak information systems which are unable to track IPTp doses effectively, and client-related

⁵ World malaria report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

⁶ Rollback Malaria Partnership 2014. Progress & Impact Series. The contribution of malaria control to maternal and newborn health

⁷ World malaria report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

⁸ World malaria report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

⁹ Roll Back Malaria. Progress and Impact Series. the contribution of malaria control to maternal and newborn health July 2014. <http://www.rollbackmalaria.org/microsites/wmd2012/report17.html>.

¹⁰ Sicuri E, Bardaji A, Nhampossa T, et al. 2010. Cost-effectiveness of intermittent preventive treatment of malaria in pregnancy in southern Mozambique. *PLoS One*. 5(10):e13407.

¹¹ World malaria report 2021. Geneva: World Health Organization; 2021. Licence:CC BY-NC-SA 3.0 IGO.

access barriers for follow-up visits.¹² This led motivated actors to explore more innovative delivery models, including community-based services and quality improvement approaches. Unitaid's Afl (Area for Intervention): Increased access for pregnant women to intermittent preventive treatment of malaria, was a response to this gap. The resulting grants aimed to address these gaps by generating evidence on innovative approaches to supply, delivery, demand generation, as well as to support global guidance and scale-up.¹³

1.2 Programme Description

Unitaid invested USD 52.6 million towards increasing access to intermittent preventive treatment for pregnant women. The Afl was designed to address four access barriers: The absence of a WHO prequalified SP product, with countries using non-quality assured SP products (a quality barrier); limited availability of quality assured manufacturers of SP specifically packaged for IPTp (an innovation and availability barrier); low demand for IPTp among providers and pregnant women partly due to perceptions that IPTp is a failed drug and insufficient evidence behind alternative service delivery innovations (a demand & adoption barrier); and ineffective supply chain systems especially distribution to end users, with frequent stockouts experienced (a supply and delivery barrier).

The Afl was implemented through two grants awarded in 2017: The Jhpiego-led TIPTOP and the MMV Supply Side Grant through its first output: Improved global supply of quality assured SP for IPTp. TIPTOP was implemented by a consortium comprising Jhpiego and ISGlobal as lead research and evaluation partner, in three pilot districts, in each of the four target countries (DRC, Madagascar, Mozambique and Nigeria), and ran from May 2017 to April 2022. The Supply Side Grant's first output was implemented from September 2017 to April 2021). The Supply Side Grant had other outputs supporting other Malaria treatment interventions by other Unitaid grantees and not under the scope of this evaluation.

TIPTOP focused on removing IPTp-SP demand and adoption access barriers by demonstrating its effectiveness through community delivery. The evidence generated through the project was expected to support WHO in their review of IPTp guidelines, facilitate policy updates by country governments, and stimulate health provider and end-user demand. Thus, expanding the coverage of IPTp through a community-based distribution strategy, in addition to the existing ANC strategy, in both project countries and other countries with low IPTp-SP uptake. The Supply Side Grant focused on overcoming supply-side barriers; with the absence of a WHO prequalified SP product at project inception, MMV was expected to provide technical support for the prequalification of at least one product by an African manufacturer, as well as the development of user-friendly packaging that branded the commodity for pregnant women. The increase in the availability of more quality assured sulfadoxine and SP sources through MMV's efforts, and the demand created through TIPTOP was expected to increase uptake of IPTp.¹⁴

¹² Thiam, S., Kimotho, V. & Gatonga, P. Why are IPTp coverage targets so elusive in sub-Saharan Africa? A systematic review of health system barriers. *Malar J* 12, 353 (2013). <https://doi.org/10.1186/1475-2875-12-353>

¹³ <https://unitaid.org/news-blog/unitaid-targets-preventative-malaria-therapy-pregnant-women-grant-proposals-call>

¹⁴ Terms of reference Transforming IPT (intermittent preventive treatment) for Optimal Pregnancy [TIPTOP] and MMV SupplySide Grant (for Output 1 only) End-of-Project Evaluation 2021

1.3 Theory of Change¹⁵

TIPTOP & SUPPLY SIDE GRANT (O.1) THEORY OF CHANGE



AFI: INCREASED ACCESS TO INTERMITTENT PREVENTIVE TREATMENT OF MALARIA FOR PREGNANT WOMEN

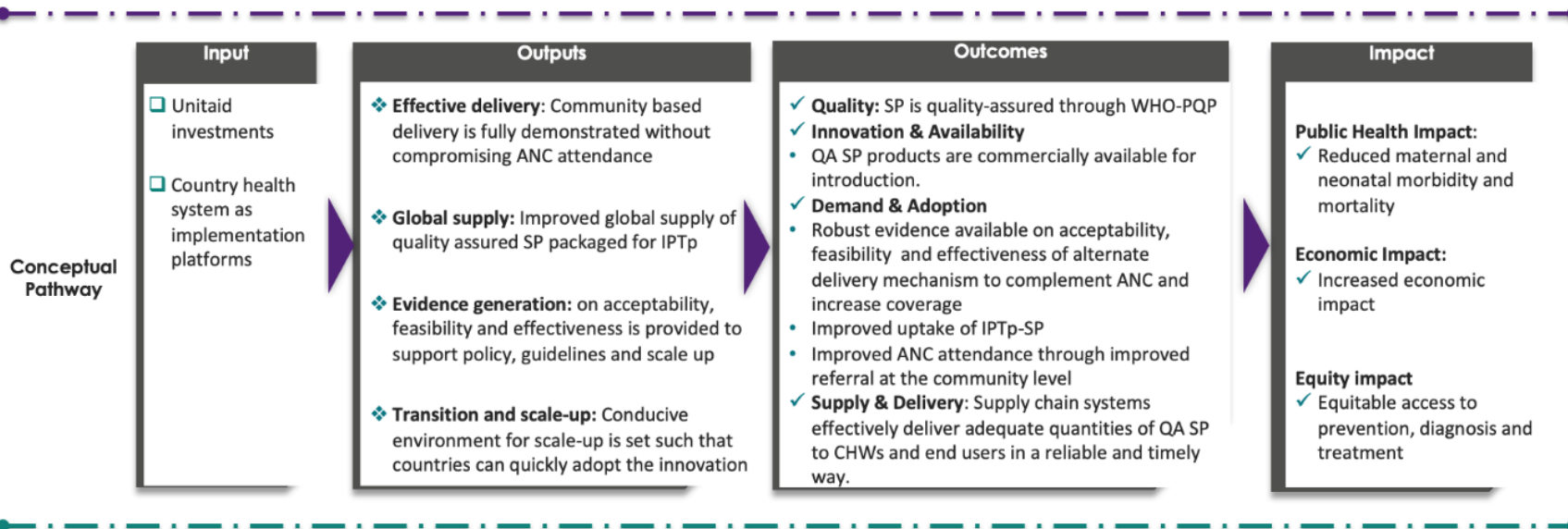
Problem

Public Health Need

- The unacceptably low proportion of pregnant women receiving intermittent preventive treatment of malaria in pregnancy with quality assured sulfadoxine-pyrimethamine (IPTp-SP), only 17% receive 3 doses, leaves millions of pregnant women unprotected with malaria resulting in preventable maternal and neonatal morbidity and mortality.¹

Access Barriers

1. **Quality:** No WHO prequalified product, countries using non-quality assured SP products
2. **Innovation & Availability:** Limited availability of quality assured SP specifically packaged for IPTp
3. **Demand & Adoption:** Low demand for IPTp among providers and pregnant women partly due to perceptions that SP is a failed drug. Insufficient evidence behind alternative service delivery innovations
4. **Supply & Delivery:** Ineffective supply chain systems especially distribution to end users with frequent stockouts



Key Risks

- Strategic Risks:** SP resistance increases to levels that make SP less effective. ANC attendance declines due to women receiving treatment at community
- Implementation Risks:** Weak health system, inhibitive policies or overburdened community health workers limiting the potential for integration
- Transition & Scalability Risks:** Lack of sustainable funding, delays in adoption into country policies and guidelines, low acceptability; limited capacity of governments to expand recommended approaches beyond project areas.

1. The public health need in the ToC represents the context of the projects at inception.

¹⁵ Culled from terms of reference and adapted for the evaluation. The public health need in the ToC represents the context of the projects at inception.

2 Purpose & Scope of the Evaluation

2.1 Purpose

The evaluation assessed the overall performance of the TIPTOP & MMV Supply Side Grant (Output 1) across the following OECD-DAC evaluation domains: **relevance, coherence, effectiveness, efficiency, impact and sustainability**.¹⁶ The evaluation also identified lessons learned across the program activities. The evaluation focused primarily on the project countries but also assessed the catalytic effect of the projects and the potential scale-up in non-project countries.

2.2 Objectives

Specifically, the evaluation objectives were:

- 1. To assess the relevance and the extent of integration of community-based IPTp services into the countries' health systems (Relevance & Coherence)**
 - Integration of IPTp within the community health worker (CHW) system and the ANC platform.
 - Relevance of the projects in the context of other community-based projects and supporting a single intervention vs the entire health system.
 - The added value of the intervention among a range of interventions that CHWs provide.
 - Response and adaptation of the community-based intervention to COVID disruptions.
- 2. To assess grant performance against critical access barriers (Effectiveness)**
 - Innovation and availability.
 - Demand and adoption.
 - Supply and delivery.
- 3. To assess the collective impact of Unitaid's investments in the grants (Impact)¹⁷**
 - Public health impact:
 - Direct impact during grant implementation
 - indirect impact during the 5-year period following grant closure.
 - Expected economic impact.
 - Return on investment.
 - Equity impact.
 - Strategic benefits and positive externalities.
- 4. To review the potential catalytic effect of the grants (Scalability & Sustainability)**
 - Acceleration of the adoption of the community-based approach in non-project countries pending WHO recommendation.
 - Dissemination of the project's evidence widely among relevant scale-up partners.
 - Effectiveness of the project's field data plan in informing evidence review by WHO's Global Malaria Programme (GMP) and Malaria Policy Advisory Group (MPAG).

¹⁶ <https://www.oecd.org/dac/evaluation/dacriteriaforevaluatingdevelopmentassistance.htm>

¹⁷ Modelling outputs will be extracted from ISGlobal C-IPTp Impact Model

3 Findings

The evaluation results are summarised in Fig 1.0 below. Detailed findings thereafter have been structured by evaluation **Criteria** and *evaluation questions*.

Fig 1.0 DAC Assessment Overview

Criteria	<i>Not achieved</i>	<i>Slightly achieved</i>	<i>Moderately achieved</i>	<i>Largely achieved</i>	<i>Fully achieved</i>	Strength of Evidence
Relevance <i>(Did the intervention do the right things?)</i>	[Fully achieved]					Strong
Coherence <i>(How well did the intervention fit with other interventions?)</i>	[Fully achieved]					Strong
Effectiveness <i>(Did the intervention achieve its objectives?)</i>	[Fully achieved]					Strong
Efficiency <i>(How well were the resources used?)</i>	[Largely achieved]					Strong
Impact <i>(Did the intervention show public health & economic benefits?)</i>	[Fully achieved]					Medium
Sustainability <i>(Will the benefits last?)</i>	[Largely achieved]					Strong

Supporting documents for strength of evidence: Medium – document review, and key informant interviews. Strong - document review, key informant interviews and secondary data analysis and/or site visits. *See Evidence Framework in Appendix 7.1 Methodology*

3.1 Relevance

R1. To what extent did the objectives and design of the projects respond to the needs of targeted beneficiaries (among vulnerable populations, including pregnant women, community and civil society organisations, government/national health systems, and scale-up partners)?

Finding 1. The projects were responsive to the needs of the beneficiary countries as well as the global malaria response, as they targeted countries in Sub-Saharan Africa that account for almost half of the global malaria burden.

The projects focused on countries that urgently needed effective approaches to scale up prevention efforts, with high rates of malaria in pregnancy and malaria deaths.¹⁸ The countries selected created a foundation for the intervention to be highly impactful as the four countries contribute to over 40% of the global malaria burden, so improvement in these countries would also improve the global disease profile. Country-level respondents and beneficiaries from all implementation countries highly regarded the project, applauding it for reaching hard-to-reach locations and addressing a persistent gap.

“I benefited a lot this time taking the drugs. During my first pregnancy I was down with malaria and it really affected me and my baby, but this time around during my antenatal I did not experience malaria and at the end of the day I had a very healthy baby.”
Beneficiary

Finding 2. The projects leveraged an existing and proven intervention (IPTp-SP) and an effective strategy (taking services to where people are, using community health workers), thereby creating an alternative delivery model.

The projects were also relevant because they addressed the persistently low uptake of IPTp-SP delivered through antenatal care at health facilities. TIPTOP deployed an already proven, cost-effective and lifesaving intervention (IPTp-SP)^{19,20} even in areas with SP resistance²¹, and delivered it through community health systems; which have been shown to increase uptake and improve health outcomes across different health interventions.²² The Supply Side Grant contributed to the model through ensuring availability of a quality assured and a well branded product for community delivery. As a result, the approach had a very high potential for success by design. Stakeholders at both country and global levels indicated that utilizing community health workers was a good strategy to supplement existing facility-based efforts.

“We have an efficacious drug; it’s safe, it’s available, but we talk an awful lot about the missed opportunities for delivering SP to pregnant women and the challenges that they face, instead of exploring other delivery models.”
Global respondent

Finding 3. The Supply Side Grant addressed the gap in availability of QA SP products packaged for IPTp, which is an important precursor to increasing IPTp coverage.

The Supply Side Grant was also very relevant because there was no WHO-prequalified SP product packaged for IPTp at the start of the project. The closest product to prequalification at the time was the Guilin 500/25mg 3-tablet blister (GSCOPE). However, the prequalification of this one product would be insufficient to cater to the growing demand, with IPTp interventions receiving

¹⁸ World Malaria Report 2020

¹⁹ Roll Back Malaria. Progress and Impact Series. The contribution of malaria control to maternal and newborn health July 2014. <http://www.rollbackmalaria.org/microsites/wmd2012/report17.html>.

²⁰ Sicuri E, Bardaji A, Nhampossa T, et al. 2010. Cost-effectiveness of intermittent preventive treatment of malaria in pregnancy in southern Mozambique. *PLoS One*. 5(10):e13407.

²¹ WHO Global Malaria Program: Recommendations. Intermittent screening and treatment in pregnancy and the safety of ACTs in the first trimester. 2015.

²² Haines A, Sanders D, Lehmann U, et al. 2007. Achieving child survival goals: potential contribution of community health workers. *Lancet*. 369:2121–2131.

more attention globally, mostly WHO-driven. In its design, the Supply Side Grant proactively addressed this envisaged risk of supply shortage, with a plan to support the entry of more manufacturers, and at least one African manufacturer. During the course of implementation, the project supported the registration of three African manufacturers: one in Kenya and two in Nigeria. The registration of Nigerian-based manufacturers was especially important due to the restrictions on importing SP into the country. Although all three manufacturer's products are still in the prequalification process, they are poised to catalyse the West, East and Southern Africa markets. This is discussed in more detail in [Section 3.3 Effectiveness: Quality, Innovation and Availability](#).

R2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context?

Finding 4. The TIPTOP project leveraged the new WHO Antenatal Care guidelines to increase IPTp coverage.

WHO's antenatal care guidelines released in 2016, increasing antenatal care to a minimum of eight ANC contacts, was one of the key contextual changes in the life of the project. Even though the guidelines were released prior to the project's start in 2017, many countries were yet to adopt or begin implementing the guidelines. In addition, the WHO Guideline on Health Policy and System Support to Optimise Community Health Worker Programmes was also released in 2018²³, and this created a real shift in the recognition that community health workers needed to be formalised within health systems, including their remuneration. The project leveraged the new ANC guidelines by supporting countries to make the transition with a focus on updating their service delivery guidance, provide training and documentation tools, to provide and document more IPTp doses.

"We had to negotiate with countries' ministries of health to make certain changes; for instance, the antenatal clinic registers had to be modified to accommodate more than two doses of IPTp because the recommendation was now three doses and amended from four ANC visits to eight contacts. They had to make special adaptations to change to three doses." Global respondent

Finding 5. The TIPTOP project was highly adaptable, incorporating baseline findings into its design, and employing a phased approach that enabled further refinement of its design and implementation processes, ensuring the proof of concept was tested before scaling to additional districts.

The project identified higher values of IPTp coverage and ANC utilisation in Nhamatanda district in Mozambique at baseline. This data informed this district as a learning site to understand the effect of the C-IPTp intervention in more varied settings including locations with higher coverage. The learnings from Phase 1 of the project also saw the introduction of adaptations in the project, including implementing a more family-centred approach in DRC, private sector engagement in Madagascar, utilising midwives to boost ANC attendance in Nigeria and introducing a human-centred design (HCD) strategy to address the challenge of low early ANC attendance.

Finding 6. The TIPTOP project adapted to the different Community Health Worker types and implementation arrangements across focus countries.

Ministries of health have been looking at how to better utilise CHWs to ensure that services reach vulnerable and hard-to-reach populations. The project responded to this identified need by utilising available CHWs in favour of recruiting new ones. For instance, in Nigeria, a formal CHW

²³ WHO guidelines on health policy and system support to optimise community health worker programmes. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO

cadre called Community Health Influencers and Providers (CHIPS) had been recently instated, so these were trained to provide IPTp in addition to other community health services. In Mozambique, there were very few government-certified CHWs known as APEs; here, the project advocated to the government, who engaged Lay Community Counsellors (LCC), a separate cadre in the community to augment the work of the CHWs. The project also assessed the workload of the community health workforce and the implications of including another service into their already very full basket of services versus the risk of not reaching pregnant women or requiring pregnant women to bridge their access to health care gaps themselves, e.g., long distances or prohibitive travel costs amongst others. The workload was found to be higher but not significant when compared to the benefits pregnant women received. The only country where the workload was significantly more challenging due to the low number of APEs (CHWs) was Mozambique, thus the engagement of LCCs. The implementation arrangement was also adapted to the countries' health systems with the delivery model for the first IPTp dose different in Mozambique and Madagascar as it was done at the health facilities; whereas, in Nigeria and DRC, the dose was provided in the community by CHWs. In Mozambique, respondents described the use of APEs (CHWs) to provide the subsequent IPTp doses as an extension of their facility outreach services. The project also adapted to attrition of trained community health workers mainly attributed to Government transfers. This was addressed with an ongoing cycle of training and mentorship of new personnel.

Finding 7. The value of the TIPTOP project was amplified at the onset of the COVID-19 pandemic and other health emergencies. The project adapted almost seamlessly to community networks already established to continue service delivery.

The COVID-19 pandemic was a major disruptor to health services over the past two years, with movement restrictions that reduced access to health services, supply chains and diversion of health services to address COVID-19 and related needs. The project, being a community-based intervention, was only mildly affected, with CHWs continuing to provide services, since they live and work within the communities where their clients are. CHWs also took on additional responsibilities to support COVID-19 information dissemination and services. An area of work that had to be adapted to the pandemic were Social Behaviour Change Communication (SBCC) campaigns, reducing activities to smaller gatherings per COVID-19 protocols and relying more on mass media methods such as radio broadcasts which were developed and aired regularly. COVID-19 disruptions also resulted in closures of some countries' regulatory agencies, with the project experiencing delays in the submission and review of dossiers for registration of QA SP. The project also experienced other health emergencies including LASSA fever and Cholera outbreaks in Nigeria, with the project responding by reallocating some funding towards prevention and reducing the spread of the outbreaks. These did not have a significant effect on project implementation as well.

"With COVID crisis, bringing health closer to the patients through community-based approaches seemed to be a critical move in the right direction."

Global respondent

"To be candid, we first thought that the era of COVID-19 would affect us having access to ANC services but the reverse was the case, as the CHWs were always around in the community. None of them left us; they call, they do follow-up on all our ANC days, and they are always here to receive us."

Beneficiary

3.2 Coherence

C1. To what extent have the projects created synergies between relevant interventions/ integrated in the countries' health systems including Community Health Systems?

Finding 1. TIPTOP project teams worked effectively with in-country stakeholders from project design through implementation.

The project teams worked with national and sub-national level stakeholders in project design (especially site selection and research protocol conceptualisation), to conduct rapid facility readiness assessments, including data quality assessments at MCH service delivery points, to review the national ANC guidelines, to standardise IPT training for health workers which

"We designed the project with ministries of health and the intent was not to introduce parallel systems but build into existing systems." Global respondent

generated generic Learning Resource Packages (LRP), as well as co-creating sustainability plans with country-specific roadmaps and handover processes. The project also engaged consistently with national malaria and RMNCH technical working groups, where MiP efforts were coordinated more broadly with other partners, while ensuring that C-IPTp was kept on the agenda. Respondents, including implementers and in-country MoH personnel, allude to the synergies created with the project. This included coordination between NMCPs, who provided technical oversight for C-IPTp strategically and RMNCH departments responsible for implementation management. This close working relationship also saw the MoH in Nigeria collaborating with TIPTOP to carry out two studies in its national research agenda: on ANC care seeking and knowledge, attitudes, and practices of HCWs, including CHWs, during the COVID 19 pandemic.

Finding 2. The TIPTOP project was well integrated with community health systems in project countries, from commodity supply chains to CHW utilisation, service delivery systems, and health information systems. It became part of the community health system and a well-linked extension of facility-based services, especially ANC.

All the project countries previously relied on health facility-based delivery of IPTp with limited success due to perceptions about the low efficacy of the drug, which resulted in low demand by health workers, pregnant women and their communities. Other factors earlier mentioned were stockouts of SP, out-of-pocket payments, weak information systems and client-related access barriers for follow-up visits. There was need for an intervention that addressed the doubts of both health workers and communities, as well as a more accessible service that was readily available. TIPTOP created a community delivery option, in addition to existing ANC services, providing IPTp free to all pregnant women, in the convenience of their homes. It also provided additional complimentary support, as it also sought to maintain and potentially improve ANC coverage. The project helped increase demand for ANC by reaching out to women in

"APE (CHW) complemented the health facility efforts, using the same cards pregnant women used with the National Health System. Day-to-day supervision and supplying activities took place together between the project's and the health facilities' staff/resources." Country Level respondent

communities, providing them with IPTp and referring them to health facilities for ANC services. It also followed up with women in the community who had received services already to provide further IPTp doses per their eligibility and further referrals to the health facility. In addition, the project's commodity logistics system was embedded with the government's systems, with procurements routed through national distribution systems and buffer stock provided to protect the supported facilities from stockouts. Respondents in Nigeria described the integration of C-IPTp into their ICCM-Integrated Community Case Management and RMNCH (Reproductive Maternal, New-born and Child Health) programs; in Madagascar, they described the alignment

with existing ITN distribution networks, and in Mozambique APEs (CHWs) provision of C-IPTp was aligned with health facility outreach services. To operationalise C-IPTp, the project also strengthened the community health workforce through trainings, developing service delivery processes, improving health information systems, and even embedding personnel in government offices to provide further administrative support and strengthen the collaboration. These are discussed in more detail in [Section 3.3: Effectiveness: Demand and Adoption](#).

C2. How well does the intervention align with priorities/needs identified by partners/the global disease response? +To what extent are the projects' interventions consistent with other initiatives/international and national policies, norms and standards within the same space)?

Finding 3. The TIPTOP project objectives were closely aligned with WHO guidelines and global goals, enabling the project to support countries to implement recent guidelines and better positioning the project to contribute to future guideline updates.

The project was aligned closely with relevant guidelines at their inception, including the 2012 WHO IPTp guidelines which promoted the initiation of IPTp-SP as early as possible in the second trimester²⁴, and the 2015 Global Call to Action²⁵, which also prioritised MiP interventions, and the 2016 WHO ANC guidelines, which promoted eight ANC contacts including support provided by CHWs. This alignment enabled the TIPTOP project to help countries progress towards adopting current guidelines and achieving WHO global targets on IPTp3+ as well as Sustainable Development (SDG) Goal 3. The TIPTOP project was also well positioned to contribute further evidence towards updating the WHO IPTp guidelines towards including a community delivery approach. TIPTOP's interventions and activities were also aligned with project country priorities and national strategic plan objectives. The strong alignment allowed integration of the TIPTOP strategy into community service delivery processes and subsequently integration into national plans and donor funding requests.

Finding 4. The TIPTOP project increased its potential for scale-up funding through very early and focused engagement with funding partners who co-created the project.

The project was designed with sustainability prioritised from inception. This was achieved by involving Ministries of Health, WHO, PMI and GF at both global and country-level in design consultations. These key stakeholders were consulted within the selection of project countries, ensuring that there was political support and ownership from the government of the target countries, and that these were also priority countries for both funders. Both global and country level respondents of these organisations reported that the project did engage early and consistently through the project life.

“First and foremost, we knew that from the conceptualisation of this project that we would not be successful if we weren't working closely with funding partners, starting with the Ministries of Health and other international funders.”
Global respondent

Finding 5: The intervention was also coherent with past and ongoing efforts under Unitaids' Malaria Prevention portfolio.

Many effective malaria prevention interventions, including Indoor residual spraying, preventive malaria drugs, and use of ITNs are underutilised or inconsistently used. As earlier discussed, only

²⁴ WHO policy brief for the implementation of intermittent preventive treatment of malaria in pregnancy using sulfadoxine-pyrimethamine (IPTp-SP). 2014. WHO website. <http://www.who.int/malaria/publications/atoz/iptp-sp-updated-policy-brief-24jan2014.pdf?ua=1>.

²⁵ Roll Back Malaria. 2015. Global call to action: To increase national coverage of intermittent preventive treatment of malaria in pregnancy for immediate impact. Roll Back Malaria website. http://www.rollbackmalaria.org/files/files/resources/call_to_action_report_v5d_EN.pdf.

half of the population in SSA sleep under ITNs, a third of pregnant women receive IPT, and even fewer children receive seasonal malaria chemoprevention. Pregnant women and children under five are disproportionately affected with higher prevalence and mortality due to malaria. Unitaids' projects have focused on improving utilisation of these existing interventions by improving access, affordability, and user-friendliness, through innovative delivery models and/or new formulations. This is done alongside other novel approaches, e.g., the new malaria vaccine trials. The most recently concluded project, "Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS–SMC)", focused on children under five in the Sahel region receiving SMC"; TIPTOP focused on pregnant women receiving IPTp3; while the newest project Intermittent Preventive Treatment in infants – Plus (IPTi+) project focuses on children under two years who are at even greater risk of severe malaria. Each of these projects is unique and complementary, addressing the needs of different high-risk groups.

C3. To what extent is the project adding value (and not duplicating efforts or establishing parallel systems)?

Finding 6: TIPTOP was the only large multi-country study generating evidence on the effectiveness and impact of C-IPTp, so its expected contribution to the evidence base is important to the global malaria response. It also provided multiple references for other countries with similar context looking to replicate the intervention.

There are other similar C-IPTp pilots being implemented in other non-project countries with the same goal of finding alternative service delivery models. These are supported by other researchers (e.g., Liverpool School of Tropical Medicine) and funders (PMI), and though initiated after TIPTOP, but not directly informed by TIPTOP. These pilots are much smaller in geographic coverage compared to TIPTOP and will also contribute to the evidence base but would be more limited in applicability to a variety of settings. TIPTOP is the only large multi-country study that examines the implementation of C-IPTp in a variety of settings and country contexts; this contributed to the uniqueness of the project.

"It's a multi-country study with big players in malaria in pregnancy space involved in one way or another, there's no duplication of efforts with other similar projects."
Global respondent

3.3 Effectiveness

Quality, Innovation & Availability

E1. How successful were the projects in bringing quality assured SP for adoption in LMICs? Has this resulted in the approval (by WHO PQ or another appropriate regulatory authority)?

Finding 1. The Supply Side Grant provided technical support to three manufacturers of QA SP based in Africa (UCL Pharma, SWIPHA and EMZOR pharmaceutical), with UCL Pharma likely to obtain PQ status in 2022, and SWIPHA and EMZOR in 2023. In addition, three other SP products were WHO prequalified during the life of the project, and are now commercially available for in-market consumption. None of these was supported by the Supply Side Grant, but they are contributing to the availability of QA-SP.

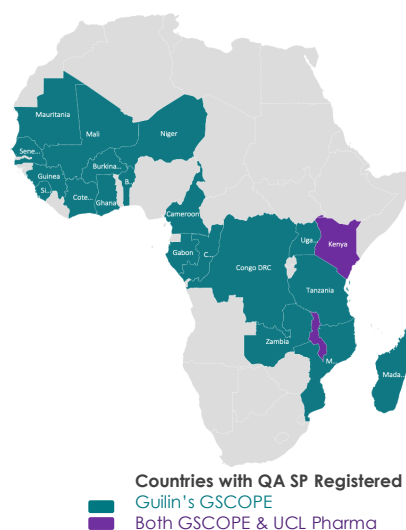
The three African manufacturers are currently at different stages of prequalification. The Kenya-based pharmaceutical, UCL Pharma and SWIPHA Nigeria have their dossiers under WHO-PQ review and are expecting WHO Prequalification at the end of 2022 and 2023, respectively, while the EMZOR dossier was only submitted in May 2022. This was achieved through leveraging MMVs' extensive experience in providing technical support to achieve prequalification. MMV, working hand in hand with manufacturers, provided a set of services including Bioequivalence (BE) studies expertise, risk assessment and mitigation, review of dossier submissions and supporting manufacturers to prepare for WHO PQ Good Manufacturing Practice (GMP) inspections. This support was significant, as these African manufacturers were new to the process. The three prequalified international SP manufacturers with adapted SP packaging for IPTp are S Kant, MacLeod's, and Guilin. Although these were not supported by the project, they are contributing to availability of QA-SP with improved packaging.

"MMV truly is best in class on the supply side of the intervention. We've seen the work that they've done with ACTs and then with chemoprevention drugs, and there has been a significant increase in quality assured SP that is produced locally."
Global respondent

E2. To what extent have the projects contributed to increased availability of quality assured SP that are commercially available for rapid introduction in LMICs? +Have the products supported through the projects been registered for commercial use in relevant project countries or are plans in place for their registration after project closure? +To what extent has the availability of better products increased for the target groups/region?

Finding 2. The Supply Side Grant has contributed to improved availability of quality assured SP for IPTp, with the UCL product already registered in two countries and product dossier approvals pending in 4 others.

The project's target was to have eight countries registering QA-SP with its adapted packaging; this was not achieved due to COVID-related delays. The UCL product is registered in Kenya and Malawi, with the dossier submitted to Rwanda, Tanzania, Uganda, and Zambia. UCL plans to submit the dossier in eleven other African malaria endemic countries before the end of 2022. In addition, through the availability of other prequalified products, QA SP is now registered in 19 countries to date across East, West and Southern Africa. These include Benin, Burkina Faso, Cameroon, Congo, Cote d'Ivoire,



Gabon, Ghana, Guinea, Kenya, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, DRC, Sierra Leone, Tanzania and Senegal.

Finding 3. The branding of SP for pregnant women with new user-friendly packaging was innovative, and it enhanced the perception of the quality of the product, thereby increasing the acceptability of SP for IPTp by pregnant women.

The Supply Side Grant also supported the development of new user-friendly packaging for community delivery of IPTp in collaboration with TIPTOP and WHO to enhance the acceptability of C-IPTp by end-users. The packaging was developed using the GSCOPE product, alongside educational infographics in three languages: English, French and Portuguese. One lesson learnt in this process was the need to understand packaging approval requirements as the new packaging required an authorisation permit update in DRC, resulting in shipment delays. These did not affect commodity availability in-country.

“I remember the days where you'd go to a facility, and there is this giant nearly unlabelled or some random writing on it that would say that this is SP, versus now you've got this really lovely packaging that demonstrates that this is a quality assured medicine.”
Country Level respondent

The packaging was pilot tested in three countries (Democratic Republic of the Congo (DRC), Madagascar, Nigeria) to support IPTp-SP uptake. Qualitative research on the acceptability of the package focused on generating data on CHWs, facility-based health workers, and pregnant women's experience and perceptions of the updated SP packaging and the patient leaflet in DRC and Nigeria. **Results from the study show a preference for the new packaging among pregnant women.**

The research findings are a useful reference for pharmaceutical partners developing new Quality Assurance Surveillance Plans (QASP). Many respondents described the change in acceptability for SP as a result of the new packaging reporting that it increased confidence among beneficiaries because it eases the identification of the product by pregnant women, it is considered to have appropriate dosing, and it contributes to the perception that SP is safe and effective. The packaging with the image of the pregnant woman validated that SP for IPTp is reserved for use in pregnant women. Based on these findings, a reflection should be made on whether the ability of the updated packaging to enhance the acceptability of IPTp-SP among pregnant women could negatively impact end users' perceptions of the SP delivered through different channels if it is packaged differently (or not packaged at all).

“SP was previously perceived as a failing drug and a drug that could be harmful during pregnancy. The adapted packaging ensured compliance and user friendliness and increase uptake. The WHO prequalified product is procured in project countries. In 2019, SP has been included in the WHO essential medicines list for preventive use.”
Global respondent

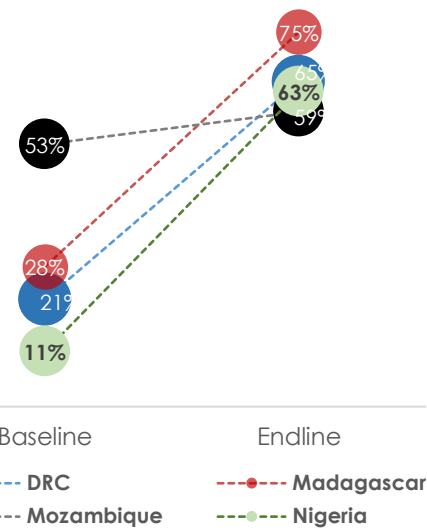
E3. What progress did the projects make in facilitating increased demand and uptake for scale-up of cost-effective SP products within target countries and beyond?

+How effectively has implementation generated demand and the ability to reach the priority/target population

Finding 1. The TIPTOP project increased demand among pregnant women for IPTp through CHW delivery in project locations.

The increased demand was achieved by creating strong ownership for the project’s interventions through consistent stakeholder engagements; increasing sensitisation and awareness of IPTp-SP through CSOs and CHWs who strengthened linkages between health facilities and community structures; and the introduction of the new user-friendly packaging. IPTp3 coverage increased significantly from baselines of 21% in DRC, 28% in Madagascar, 53% in Mozambique and 11% in Nigeria, to endlines of 65% in DRC, 75% in Madagascar, 59% in Mozambique and 63% in Nigeria. The increase was marginal in Mozambique, where baseline levels were already higher.

Proportion of pregnant women who received three or more doses of IPTp: Baseline vs Endline

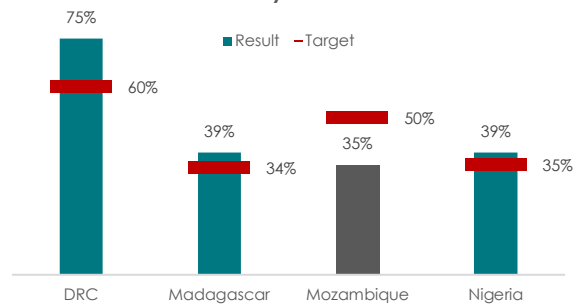


Source: TIPTOP Household Survey Data/ISGlobal Impact Model

Finding 2. The TIPTOP project also increased ANC attendance, including early ANC and a proportion of women completing four or more visits.

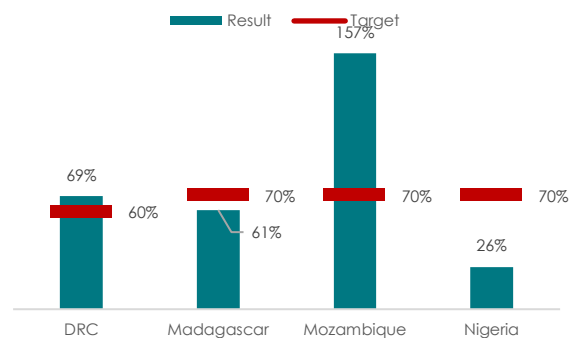
The project achieved its target on early ANC attendance, with the target exceeded in all countries except Mozambique; however, all countries experienced improvements from baseline. The WHO ANC guidelines recommend a first contact within 12 weeks; Mozambique strictly adheres to this, with the other countries utilising more liberal definitions of up to 16 weeks.

Proportion of pregnant women attending early ANC



Source: TIPTOP Annual Report 2021

Proportion of pregnant women with 4 or more antenatal care (ANC) visits

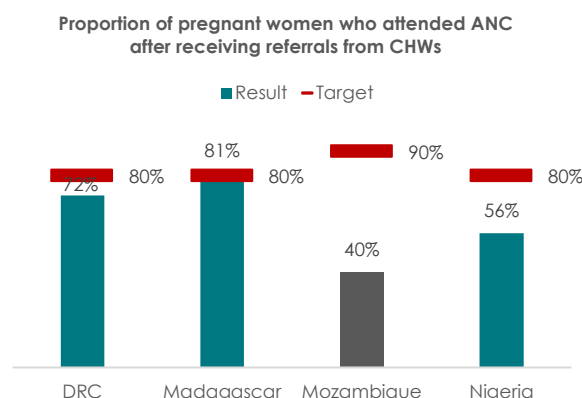


Source: TIPTOP Annual Report 2021

The results on pregnant women attending four or more ANC visits were also on target or above in all countries except Nigeria. The 70% target was very ambitious for Nigeria, which had a much lower baseline at inception. The project site in Nigeria also experienced extenuating circumstances with high levels of

insecurity, resulting in community displacements with services closed throughout 2021.

CHW referral to ANC was challenging, with only Madagascar achieving its target of 80%, and DRC was close at 72%. However, Nigeria only achieved 40% and Mozambique 40%. The project continued to make strides towards early and sustained ANC attendance in addition to IPT uptake, but the motivation to complete referrals was affected by multiple pre-existing barriers (distance and cost being the prominent factors).



Source: TIPTOP Annual Report 2021

“The IPTp 1 to 3 coverage was seen to be increased and access to IPTp 4 to 6 which before the project was thought to be impossible.”
Country Level respondent

“The intervention was so successful that two of the babies born to pregnant women were named TIPTOP.”
Country Level respondent

“It has sparked an increase in demand among pregnant women. For example, regarding the updated packaging of the prequalified commodity, pregnant women prefer the updated packaging compared to going to the ANC clinic and getting tablets out of this big jar of 1000 tablets.”
Country Level respondent

E4. How effective are the delivery models and what best practices can be learned from the process?

Finding 3. The TIPTOP project’s delivery model and its variants were very effective as they successfully increased the coverage of IPTp, improved ANC attendance and were easily integrated into country health systems.

Although the engagement models and service delivery mechanisms of CHWs varied slightly from country to country, they effectively generated demand for IPTp and delivered C-IPTp doses per agreed guidelines. Country-level respondents reported the capacity building efforts towards CHWs as important for the integration of C-IPTp into their scope of work. CHW performance was well demonstrated in the number of IPTp doses distributed to eligible pregnant women, exceeding targets as earlier described. The following paragraphs describe different components of the model and why they were effective.

“We tried as much as possible to select existing health workers, those who have done similar work in the past. If they were still available in the community, they were selected and then retrained on malaria in pregnancy.”
Country Level respondent

+How did the project effectively engage Community Health Workers (CHWs)? How did the low motivation, low incentives and low literacy levels of CHWs affect the project, and how did the project address these issues?

Finding 3a. The community health workforce in project countries were engaged optimally with the project’s robust recruitment process and tailored capacity building support for CHWs.

CHWs were the most critical actors in the project, as they were responsible for both demand creation, referrals to ANC and delivery of C-IPTp. The project’s engagement methods were standard, engaging existing CHWs who live and work in the project communities in consultation with community gatekeepers such as traditional leaders, village heads, religious leaders and political leaders. The project provided extensive trainings for both CHWs and key CSO actors. In Mozambique, community volunteers were trained over a period of four or five months to provide a variety of essential health services. In other countries, they already had Government trained community health workers working within the communities; these were provided additional training specific to MiP and IPTp. CHWs were also trained in data collection and quality and supported monitoring and reporting project activities in the community, with reporting rates over 90% in all four countries. CHWs received basic incentives including T-shirts and backpacks, which increased their visibility in their communities, as well as transportation and communication stipends. Community members also provided in-kind incentives in appreciation of the efforts of these CHWs. In terms of remuneration, the project relied heavily on existing CHW remunerations structures in each country, with a focus on ensuring sustainability.

+How effectively have implementers partnered with/engaged and supported communities and civil society organisations to increase demand, political support and financial commitments?

Finding 3b. The TIPTOP project established strong community involvement and ownership through its extensive civil society networks.

CSOs were not formally contracted but were engaged in mutually beneficial partnerships that allowed the project’s community engagement needs to be included in their portfolio of work. In turn, the CSO would also benefit from capacity strengthening support and funding for their interventions which align with TIPTOP’s planned activities. The project engaged and trained 71 CSOs across project countries, including faith-based organisations, community health committees, women’s groups, community radio groups, grassroots development foundations, and motherhood associations. The CSOs conducted different activities tailored to the country’s context and needs. In the DRC, CSO conducted SBCC campaigns in all project districts and radio broadcasts about C-IPTp and COVID-19 were developed and aired regularly. In Madagascar, the community engagement strategy also included sensitisation during small-group activities. In Mozambique, the project collaborated with traditional birth attendants to mobilise pregnant women to continue to seek ANC services. In Nigeria, CSOs also addressed poor spousal support, which has been identified as one of the barriers to early initiation of ANC. In Madagascar, respondents reported that community participation led to the improvement of other community health indicators in the supported district. Country level stakeholders at sub-national and community levels report the active role the CSOs played in sensitising and creating awareness in their communities.

“Community members gave CHWs in-kind incentives, which included farm produce, chickens, and things like that to thank them for serving the community.” **Country Level respondent**

“The trained CHIPs and CHW for the delivery of the services will continue to render service at the community and facility level.” **Country Level respondent**

+How did the project leverage existing Community HMIS structures successfully to integrate C-IPTp monitoring in to the existing systems in supported countries?

Finding 3c. The project improved Health Management Information Systems and facilitated evidence-based decision-making.

Community health information systems are often linked to facility information systems, with community data feeding into catchment health facility records for both reporting and program decision-making. As a result, data quality improvements need to target the entire HMIS, not just community documentation processes. The project team understood the dynamics around community information systems and therefore supported HMIS capacity strengthening efforts in all the countries, which resulted in a culture of data use at project sites and improved reporting rates. Some activities implemented to achieve this include: HMIS trainings for decision-makers and program managers in Madagascar (the capture of community data in the DHIS2 in Madagascar was made possible for the first time by the project) and conducting supportive supervision visits and data review meetings to monitor facility performance in all project countries.

“TIPTOP project also championed the use of community Health Management Information System (CHMIS) which aided the data collection from the community system to be uploaded in the DHIS.”
Country Level respondent

E5. How was the implementation approach effective in promoting or shaping global policy adoption and country adoption both in the project and non-project countries? +Why has Mozambique not included C-IPTp in its strategic plan? Are there any concerns/reservations that are still unaddressed?

Finding 4. TIPTOP made a significant contribution towards shaping country policy and is expected to inform global guideline updates as well.

The project has made a significantly contributed to shaping country policies and plans, working closely with the Ministry of Health, National Malaria Control Programs and RMNCH departments. The project advocated for the adoption of existing policies, including the 2016 WHO ANC guidelines (only Nigeria has fully adopted the guidelines), and revision of strategic plans to support C-IPTp services. Usually, National Malaria Strategic Plan (NMSP) activities are derived from the National Health Policy document, so ideally, C-IPTp should first be included in the National Health Policy of countries before being translated into the NMSPs. Countries had earlier expressed their decision to await WHO’s MiP policy change recommendations in order to effect changes in local health policies and strategic plans. However, DRC, Nigeria and Madagascar have pre-empted this change by including C-IPTp in their NMSPs and national treatment guidelines, laying the foundation for development partners to support the replication of the positive results from the TIPTOP project. The Nigeria 2021-25 National Malaria Strategic Plan was updated to include C-IPTp in September 2020, the DRC 2020-23 NMSP in January 2020, and the Madagascar’s 2018-2022 NMSP was also revised in 2020. Even though Mozambique has not included C-IPTp in its NMSP, the NMCP is supportive of the intervention and currently awaiting the update of their new Community Health Sub-System policy in 2022; this is a prerequisite for the strategy to be updated. Country-level stakeholders describe the support from

“Given that IPTp is usually not on the radar of Ministries of Health and NMCP, I think TIPTOP has done a remarkable job in terms of engaging Ministry of Health. They’ve engaged PMI, in-country staff, Global Fund, and other partners that are looking at adding community IPTp as part of their approach for malaria in pregnancy”
Country Level respondent

the project towards reviews of their national strategic plans, especially with respect to making data-driven decisions and improving resource allocations towards optimizing community health programming and community health workers within the broader health system.

The project staff (Jhpiego, ISGlobal and MMV) have also closely engaged with key global stakeholders in the Malaria space, including the WHO, the President’s Malaria Initiative, the Global Fund, and the Bill & Melinda Gates Foundation, the projects steering committee, MiP working group and Impact Malaria Policy Advisory Committee, amongst others. These have been carried along throughout the life of the project. When interviewed, these respondents described their active engagement and participation in project activities, especially results dissemination workshops and learning activities.

The project team’s engagement with WHO was also geared towards preparations for WHO’s evidence review group, as this was a precursor to any updates to existing guidelines. However, with respect to IPTp guideline revisions, WHO GMP respondents described the current global guideline as already adequate to support C-IPTp activities since the guidance²⁶ is silent on the delivery model and does not explicitly require facility-based delivery. Other respondents at Global and Country levels felt that updated guidelines were necessary or some statement released by WHO to clarify the inclusion of C-IPTp. This was later resolved through WHO’s guidance update, discussed further in [Section 3.6 Sustainability](#). Other non-project countries such as Malawi, Senegal and Sierra Leone have applied similar community approaches and hope to provide the evidence from these pilots for assessment during the WHO technical consultation in June 2022 as well.

“There has been quite a lot of consistent engagement. There has been more information shared that is of interest to the partners. We’ve been informed about the process and the outcomes of the intervention. I would broaden that not only to the steering committee but to the Malaria in Pregnancy Working Group, which has been receiving regular updates.”

Global respondent

“The WHO has recently said that we should not be expecting some big policy recommendation, that they will be giving some guidelines and that they there are enough guidelines already for countries to be able to make their own decisions to go forward, move forward with community IPTp.”

Global respondent

²⁶ WHO Guidelines for malaria, 18 February 2022. Geneva: World Health Organization; 2022 (WHO/UCN/GMP/2022.01). License: CC BY-NC-SA 3.0 IGO. Pg 65

E6. To what extent did the Afl/grant improve supply and delivery systems to ensure that products reach those in need in a reliable and timely way?

+To what extent did the projects contribute to the establishment (or integration) of functional and sustainable supply chain processes, including forecasting, planning, procurement, storage, and distribution? Probe on challenges with SP procurement in Nigeria.

Finding 1. TIPTOP significantly improved QA SP supply chain processes at supported facilities, with limited episodes of stockouts experienced during the life of the project.

Stakeholders interviewed described stockouts of SP prior to the project due to inconsistencies in the supply chain. TIPTOP worked closely with government partners to maintain SP supply through the existing commodity supply chain systems at supported health facilities, where CHWs received their stock of SP. The project's commodity distribution model was through monthly monitoring meetings at the district level. CHWs stock of TIPTOP SP were refilled at these meetings. If a CHW or their health facility head missed the meeting, they would miss their resupply and be at risk of experiencing a stockout. A few CHWs experienced stockouts during the COVID-19 pandemic, which prompted the creation of a two months buffer stock at each site to ensure that even when a meeting was missed, stocks were still adequate to carry the CHW and their health facility through the next two months. The project also put in a system that allowed a representative to attend meetings and a peer CHW to follow up with those who missed the meeting.²⁷ In terms of storage, the project's procured commodities were also stored with other ANC commodities but with a monitoring system for accountability.

"Our role was more set working with the government to ensure that SP was delivered through existing distribution systems."

Country Level respondent

"The project was able to eliminate SP stockout. Prior to the TIPTOP project, there were lots of SP stockout, and this was evidenced from the baseline health system assessment of several health facilities."

Country Level respondent

At above site level, the project supported transportation of SP from national and sub-national level storage facilities to health facility level when transportation delays were experienced in the government system. The project also built a 10% buffer into its procurements to bridge the gap when government-supplied SP was short at health facilities, as this would invariably affect the CHW's supply. In Mozambique, TIPTOP and the MOH also collaborated with mobile brigades that provide ANC services to pregnant women residing in hard-to-reach areas, inaccessible due to security issues. These mobile brigades helped to distribute SP to CHWs and provide supervision for the continuation of quality C-IPTp services in the affected areas. Overall, TIPTOP-procured SP was effectively stored and distributed throughout the life of the project.

These initiatives put in place by the project were very effective, but some of these may not be sustained post-project. The district delivery meetings are a standard in the countries, and the additional variations put in place, such as having alternates to the facility head attending in their absence, as well as peer follow-up to check with CHWs who missed their pick-up have become quite commonplace and are more likely to be sustained. The buffer stocks put in place to bridge facility shortages and missed attendance to pick-up meetings may, however, not be feasible post-project life since the stocks infused by TIPTOP into the supply chain will no longer be available.

²⁷ TIPTOP Annual Report 2020

However, in locations where PMI or GF continue to provide SP, the buffer initiative may be sustained.

+To what degree have the projects ensured availability and sustainability of adequate supply channels to deliver the products to the vulnerable/underserved populations?

Finding 2. The projects successfully registered QA SP in other countries, beyond the implementation countries, with additional registrations still in progress towards ensuring sustained availability of QA SP. TIPTOP also addressed challenging importation requirements in Nigeria to ensure availability of the commodity in this country throughout the project duration.

The Supply Side Grant supported the registration of the UCL SP product in two countries and is currently awaiting registration approval in 4 others, as earlier described. During the project's life, TIPTOP, in partnership with the Supply Side Grant, already supported the registration of the Guilin product in three of the project countries: DRC, Madagascar and Mozambique. The projects, however, faced challenges registering Guilin's product in Nigeria because SP is on the import ban list in order to protect the Nigerian pharmaceutical companies producing SP. An import waiver was required to procure SP. Though challenging, the project was able to leverage Jhpiego's existing relationships with relevant government agencies in the country to obtain the waiver. The approval process was long and cumbersome, as the project had to engage with four key government offices in-country. The project first engaged with the National Malaria Elimination Program (NMEP), which obtained an approval letter for the Minister of Health, the letter from the Minister of Health was sent to the National Food and Drug Agency (NAFDAC) for import license approval, and thereafter to the Minister of Finance for the Import Duty Exemption Certificate (IDEC) approval. The process lasts anywhere from 6 months to 1 year. After this approval was obtained, there was a further policy update that required all pharmaceutical products coming into the country from India and China to be accompanied by a Clean Report of Inspection and Analysis (CRIA). This policy was introduced after the importation of Guilin's SP; however, the project was still required to obtain CRIA and also signed an undertaking not to deploy the goods until NAFDAC issued a local CRIA certificate. The entire import waiver process has now been digitalised, but this only increases complications with the portal being sometimes down; physical visits and phone calls are then required for progress follow-up, and payments taking several weeks to reflect on the portal.

Due to the extensive networks and relationships of Jhpiego in-country team, the IDEC process was completed in five months. However, this delay in importation did not affect implementation or cause stockouts because it was addressed before the project began to distribute SP. This import ban of SP reinforced the need for MMV to support the pre-qualification of African manufacturers, hence, the support to two Nigerian-based manufacturers. These are expected to not only cover the Nigerian market but also to respond to the SP demand in-the West-Africa region.

Finding 3. TIPTOP had been able to leverage funding partners to commit funds to sustain SP availability in project locations and scale up in two of the project countries. However, scale-up funding is not yet secure in two others. QA SP is also registered in 3 project countries and 16 non-project countries across West, East and Southern Africa, an indication of interest in utilisation.

The allocation of budgets by Ministries of Health to procure these prequalified SP products or the availability of donor funding to continue to support IPTp uptake and scale-up in project countries and beyond is essential for supply security. The project's early engagement with GF and PMI created alignment on areas where funding would be available, with two project countries (DRC and Madagascar) poised to receive maintenance and scale up funding. There has, however, not been any commitment from Ministries of Health in project countries to procure QA SP with

domestic funds. Also, the number of countries where the commodity is now registered is definitely an indication of interest in potentially procuring and utilising the commodity.

E7. How likely is it that the projects will catalyse the global market and supply in terms of volume, diversity and prices, in particular from the African-based manufacturers?

Finding 4. There is a strong potential for a healthy and competitive market on the African continent, with three manufacturers already prequalified and three more likely to be prequalified by 2023.

The number and geographic focus of these manufacturers will create a healthy and competitive market; with the Kenyan manufacturer expected to catalyse the East and Southern Africa region and the Nigerian manufacturers catalysing the West African region. The Supply Side Grant has already begun the process by supporting registration processes in several other countries, as earlier discussed, with pending approvals for UCL's product. The process was delayed by COVID-related disruptions, with some regulatory offices temporarily closed during the pandemic, resulting in registration targets not being met. However, dossiers have now been submitted to countries where registration was planned. Also, with the success rate from Guilin's product, it is expected that UCL's product will also be approved in the target registration countries. Responses from key informants indicate confidence that the African manufacturers will receive their WHO prequalification and will be able to deliver adequate supply volumes. The next hurdle includes getting countries to prioritise quality-approved SP, especially those produced by African manufacturers in their national procurement systems. These manufacturers are going over and beyond their country standards to achieve WHO prequalification, and the context in these countries still includes many non-QA products also in the market. The Supply Side Grant has continued discussions with project countries to increase the likelihood of inclusion of these prequalified products for future procurements; this will, however, be an area for further follow-up post-project.

E8. What were the main factors influencing the achievement or non-achievement of the intended outputs or overall outcomes? +How did COVID-19 impact project results, and how did the project adapt to Covid-19-related restrictions /related implementation challenges?

Factors that positively influenced achieving the project's objectives

1. Integration into Existing Health Systems

The reliance of donor-funded projects on existing health systems and structures is often a rate-limiting step in LMICs, where public health systems are often sub-optimal and require significant investments to strengthen and maintain. TIPTOP, however, successfully navigated the pitfalls associated with leveraging existing systems and successfully integrated the intervention within the Community Health Systems in supported countries. This was achieved through very early engagement with the Ministry of Health and NMCP, who supported the creation of the project. At inception, the project was aligned with existing initiatives, including iCCM and MNCH platforms and data management systems, followed by recruitment of already existing CHW, e.g., CHIPs and APEs (in most cases) who were trained to include IPTp-SP in their package of services, joint supportive supervision meetings, regular data review meetings and very active engagement in TWGs and use of CSOs. Most country-level respondents alluded to the very high level of integration of the project as an indication that it did not duplicate efforts but complimented and extended MiP interventions. The successful integration was, however, mostly attributed to the

early and consistent engagement and the fact that the project was further improving delivery of an existing intervention as opposed to introducing a completely new one.

2. Country Ownership & Political Support

The consistent engagement of TIPTOP with local stakeholders created strong ownership for the project's interventions, and its success in delivering C-IPTp further reinforced the support the project enjoyed. This was well depicted by the government's willingness to revise their NMSPs even before any policy changes were made at global level, and the desire expressed to scale-up this intervention by many country-level stakeholders interviewed.

"One of the biggest factors that is beyond the data and the research findings is really the government's willingness and wanting to be able to continue IPTp in the districts that we are supporting even beyond."

Country Level respondent

3. Early Alignment with Scale-Up Partners

TIPTOP's decision to involve potential scale up funders early has also been a critical factor for pre-positioning countries to receive scaleup funding. As described earlier, project countries are priority countries for funding partners and have previously been supported to procure SP or strengthen SP delivery systems. Funding for continuation and scale-up has been included in funding applications in two of the project countries – Madagascar (GF & PMI) and DRC (GF), with a plan to include C-IPTp in Nigeria's next GF application.

4. Community Participation and Facility Linkages

Being a community-based project, effective community participation was crucial. TIPTOP's utilisation of CSOs and engagement of a wide range of community actors, as detailed earlier, not only increased sensitisation and awareness of IPTp but also strengthened linkages between Health Facilities and Community structures; thus, improving referrals and access to care within communities.

5. Tailored Trainings and Supportive Supervision

TIPTOP trained CHWs in all countries. Trainings were tailored based on the availability of a formal CHW workforce and the CHWs having undergone prior training on other community health interventions. In some cases, the trainings exceeded the IPTp content. The increased coverage of IPTp and related MNCH services reported are also attributed by respondents to these trainings. The trainings were also said to increase the confidence of CHWs, and quality of services at health facilities leading to increased care-seeking behaviour as evidenced by increased facility attendance.

6. Supply Chain Strengthening at Project Sites

TIPTOP's investment in strengthening supply chains primarily focused on ensuring deliveries to project sites, supporting forecasting and quantification efforts and training relevant health workers in commodity management in project locations. Most respondents reported that these efforts did contribute to consistent stocks of SP at project sites, which enabled effective delivery of C-IPTp services.

7. Data-Informed Decision-Making

TIPTOP's support to strengthen information systems also facilitated improved commodity quantification at user points to determine re-order levels. The culture of data-informed decision-making was also built across project sites, with improved community-based reporting modules of C-IPTp, including commodity usage and performance review meetings to review process and

course correct program implementation. Respondents also described the embedding of project staff in government offices as vital to sharing learning and informing decision-making.

8. Evidence Generation on C-IPTp

TIPTOP strengthened the community health system to deliver an existing, proven intervention. It generated and disseminated evidence on the effectiveness of C-IPTp through the life of the project. The level of engagement provided for country and global stakeholders with project results was an essential contributor to the increased country ownership and adoption seen in project countries and the further demand created in non-project countries.

9. Adaptability to COVID-19 and Related Restrictions

The project responded quickly and adapted its plans and processes to risks posed by the COVID-19 pandemic. TIPTOP took key steps to keep service providers, community health workers (CHWs), and pregnant women safe while maintaining quality service provision, ensuring pregnant women continued to receive malaria protection and comprehensive ANC care. Similar approaches were taken during national elections with the risk of political instability, where the project proactively organised sufficient SP stocks for CHW and health facilities in advance to mitigate disruptions in service provision. The community-based nature of the C-IPTp approach helped to ensure continuity of services by affording pregnant women the opportunity to receive IPTp from a trusted community member during periods of limited movement and fear.

10. Expertise of MMV in navigating the WHO Prequalification Process

Manufacturers benefited from MMV's extensive experience in providing technical support to achieve prequalification. Through the supply grant, they provided a set of technical services that not only prepared the manufacturers for dossier submissions but also addressed emerging challenges throughout the process.

Factors that negatively affected the delivery of the project's objectives

1. Human Resource Gaps

The project faced several human resource challenges. This ranged from availability to quality and attrition. These challenges affected the ability of each country to meet specific targets during the period they were experienced.

- The low number of CHWs in Mozambique already highlighted earlier, and the increased responsibility for C-IPTp created a strain on APE's time resulting in the reprioritisation of other activities. The government addressed this issue by introducing LCCs who were hired specifically to support the project – a new introduction to the health system that may prove to be unsustainable if not formalised within the health worker structure. The ongoing process of updating the national guidelines in Mozambique includes this as a critical consideration.
- In DRC, the project experienced a national health workers' strike that lasted six months and resulted in the partial closing of TIPTOP-supported health facilities during the period.
- A labour strike in Niger State, Nigeria, caused temporary disruptions to TIPTOP implementation.
- There were also challenges with low literacy levels among CHWs in one district in Mozambique.
- All countries also experienced personnel attrition, mostly related to government appointments and transfers, especially in post-national elections. One project site in Nigeria

(Ohaukwu Phase I) experienced an unexpected transfer of all TIPTOP trained health care workers (HCWs) in project sites.

2. Other Emergencies

Another unexpected negative factor were emergencies related to health and weather conditions that occurred during the life of the project, including:

- Cyclone Idai hit Nhamatanda in Mozambique, and halted activities for significant periods of time due to infrastructure loss.
- The Lassa fever and Cholera outbreaks in Nigeria diverted MOH staff and resources, thus, leading to cancellations of some project activities.

These also limited or halted the project's progress in these locations during the periods they occurred.

3. Political Instability

Three project countries (DRC, Mozambique, and Nigeria) experienced several cases of insecurity, which caused temporary disruptions to project activities. These include:

- Armed conflict in the initial selected intervention areas in DRC.
- Four TIPTOP-supported health facilities in Nhamatanda District in Mozambique were inaccessible for much of 2021 after being burned down or closed due to insecurity.
- Communal clashes in two of the three zones (Effium and Ngbo) located in the Phase I district of Ohaukwu, Ebonyi State, Nigeria, resulted in the closing of TIPTOP-supported health facilities and suspension of C-IPTp activities, leading to no data reporting from these two zones.
- The Ondo State, Nigeria, response to youth protests on police brutality caused temporary disruptions to TIPTOP implementation.

Although these events affected health care delivery, respondents reported that some CHWs were still actively providing services directly to households during these events.

4. COVID-19 and Related Restrictions

Although the project responded well to the COVID-19 pandemic, it still had some effects on the project, mostly related to minor implementation delays, especially challenges supervising field research teams during endline surveys due to movement restrictions and dossier submissions put on hold due to temporary closure of regulatory authority offices. The delays resulted in underspending of project funds, primarily due to limited travel locally and internationally. The projects effectively reprogrammed the unspent funds in subsequent years.

3.4 Impact

Im1. To what extent has the investment generated, or is expected to generate, global/national-level effects across Unitaid’s four dimensions of impact?

i. Public health impact (4.1 - Increasing public health impact: Number of lives saved (projection). Number of malaria cases averted (projection), Proportion of newborns with low birthweight (project-reports).

ii. Economic impact (4.3 - Delivering positive returns, Return on investment).

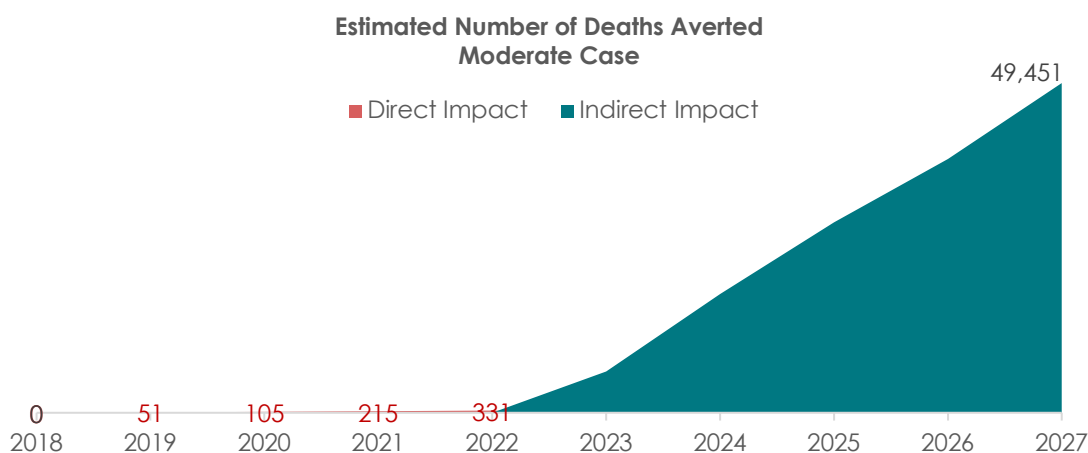
iii. Equity (5.1 – Investing for the poorest.; 5.2 – Investing for the underserved).

iv. Strategic benefits and positive externalities. +Are there any unintended effects of community-based delivery of IPTp?

The goal of the project was to contribute to reducing maternal and neonatal mortality in project areas by expanding access to QA SP for IPTp. The impact of the project was estimated through modelling²⁸. The model utilised expected population growth and estimated number of pregnancies, and projected number of annual malaria cases, utilising World Malaria Report (WMR) trends. It also included six additional non-project countries with the highest likelihood to adopt and scale up the intervention, selected based on community health system capacity and the inclusion of C-IPTp in the most recent GF application.

Public Health Impact

The changes in IPTp3+ coverage potentially translated to improved health outcomes for mothers and newborns, with a third dose of SP increasing the protective efficacy in reducing malaria by 33% - 40%. More specifically, estimates from the modelling exercise show that the project could contribute to 2.9m [829K – 4.6m] malaria infections averted; 100,806 [27,690 -156,497] deaths averted [9,618 maternal deaths and 91,188 neonatal deaths]; and 7.9m [2.7m – 10.4m] DALYs averted [0.3m maternal DALYs and 7.7m neonatal DALYs] from 2023-2027 across the four project countries and six additional countries in Africa with the highest likelihood for adoption and scale-up. The number of deaths averted was estimated using the difference approach between 2 scenarios: Impact Scenario and Counterfactual Scenario. The Impact Scenario used evidence and results from the TIPTOP project and other secondary data sources to model the use of IPTp3 and fatalities in the ten countries. The Counterfactual Scenario was designed to evolve following the indicators from the World Malaria Report (i.e., increase IPTp rate by 13.5% every year).

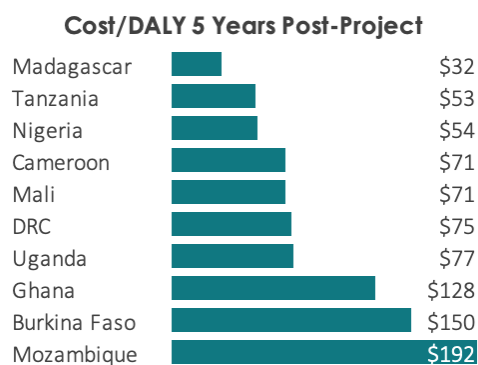


²⁸ TIPTOP impact projections developed by ISGlobal April 2022

Economic Impact

The intervention also has the potential to generate cost-saving by averting treatment costs for the health system of US\$69m [17m, 120m] in the next five years. The intervention will also confer an incremental cost of US\$625m [221m, 768m] to the health system over the next five years, with a Return on Investment (ROI) of US\$ 31.9. The intervention shows a similar cost per DALY as other facility IPTp projects and C-IPTp pilots, these range from USD\$25-\$50 per DALY averted in similar countries.^{29, 30} Based on the cost-effectiveness threshold typically adopted to inform decisions in health care (up to 30 US\$ per DALY averted being highly cost-effective and up to 150 US\$ per DALY averted being cost-effective)^{31,32,33}, the intervention appears to be cost-effective in most countries, except in Mozambique where baseline levels were already quite high and similar resources were invested towards closing the remaining gap.

The Economic Impact of the project was estimated using incremental cost-effectiveness ratios (incremental cost / incremental DALYs averted) from the health care perspective. This is based on estimates of net incremental costs of the intervention, including the cost savings for the health system, but not the cost savings for the households.



Equity

Finding 8. The projects were equitable by design and were implemented accordingly.

The projects targeted pregnant women who are at risk of malaria because they live in malaria-endemic countries with the highest rates of both malaria cases and mortality globally. The project locations were also more remote settings with higher poverty levels, limited formal health facilities and a multitude of access barriers to reaching health care (distance, long travel times, travel cost) all contribute to delays in seeking both preventive and curative services. These factors further emphasise the need for community-delivered services that the project provided.

“It is an equitable approach; it diminishes the indirect cost heavily by allowing women to get access to the medicine near home.”
Country Level respondent

Strategic Benefits and Positive Externalities

What additional benefits has the health system experienced due to the introduction of the project? What unintended effects have been experienced as a result of the project to either beneficiaries or the health system?

Finding 9. The TIPTOP project supported COVID-19 prevention efforts and also addressed health system inadequacies revealed by COVID-19.

²⁹ A.K. Mbonye, K.S. Hansen, I.C. Bygbjerg, P. Magnussen. Intermittent preventive treatment of malaria in pregnancy: the incremental cost effectiveness of a new delivery system in Uganda. *Trans R Soc Trop Med Hyg*, 102 (7) (2008), pp. 685-693

³⁰ E. Sicuri, A. Bardaji, T. Nhampossa, et al. Cost-effectiveness of intermittent preventive treatment of malaria in pregnancy in Southern Mozambique. *PLOS One*, 5 (10) (2010), Article e13407

³¹ WHO. Making choices in health: WHO guide to cost-effectiveness analysis. In: Tan-Torres Edejer T, Baltussen R, Adam T, Hutubessy R, Acharya A, Evans DB, Murray DB, Murray CJL, editors. Geneva: WHO; 2003.

³² Edwards C. Cost-effectiveness analysis in practice. In: Hunter P, Cameron J, Jagals P, Pond K, editors. Valuing water, valuing livelihoods. London: IWA Publishing; 2011. p. 181–197.

³³ Mueller DH, et al. Costs of early detection systems for epidemic malaria in highland areas of Kenya and Uganda. *Malar J*. 2009;8:17. doi: 10.1186/1475-2875-8-17.

The COVID-19 pandemic revealed inadequacies in the health system. The project played a huge role in addressing these inadequacies as well as supporting COVID-19 prevention services. The supported activities included improving client flow with social distancing measures to minimise COVID transmission risks. The project also provided PPE to health care workers and CHWs, supported the development of safety guidelines for delivering services to pregnant women in the COVID-19 context, incorporated COVID-19 prevention measures into SBCC efforts by CHWs, and strengthened infection prevention and control systems. These were not part of the original project scope, but the presence of the project provided an excellent opportunity to provide these additional services. The support was also needed to ensure that the project’s activities were delivered safely.

*“The CHWs are not just talking about malaria and pregnancy, they were also talking about COVID 19, distributing face masks, promoting handwashing, promoting use of hand sanitiser, and social distancing.
“Country Level respondent*

Finding 10. TIPTOP provided targeted quality improvement support as it successfully leveraged the health system for the implementation of its activities.

The project leveraged the existing community health system, and as a result, the project implemented a number of quality improvement efforts at project sites. These needs were identified during baseline assessments, such as:

- Improving data management systems with improved reporting rates of other MNCH services.
- Extensive training of community health workers beyond IPTp services with improvements made to the training curriculum including a module on data reporting.
- Creating a culture of data reviews and use at project sites.
- Improving logistics management system, especially facility level quantification and stock management with minimal stockouts of SP for both community and facility delivery experienced during implementation
- Health facility infrastructure upgrades.

Finding 11. Results on SP resistance monitoring are not yet available, but this is an important area to be closely monitored post-project.

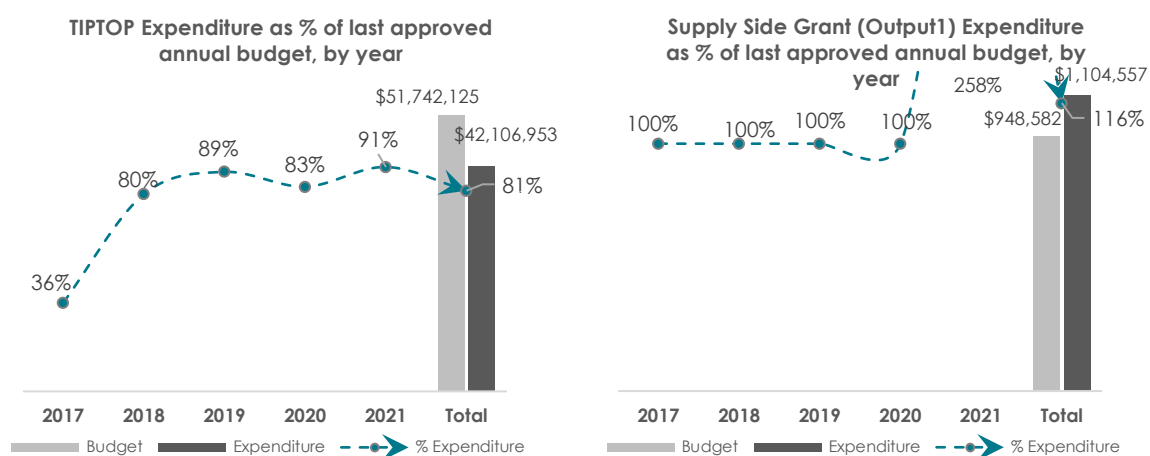
TIPTOP conducted drug resistance monitoring as one of its research areas. ISGlobal worked with NMCPs to develop the SP resistance monitoring (SPRM) protocol, with significant WHO input. Samples were collected for the monitoring of SP resistance via molecular markers at baseline, midline and endline. Baseline samples, due to a change in WHO’s sample analysis laboratory partner, could not be processed till 2021 and after analysis, did not show any evidence of resistance, with the A581G mutation responsible for intensifying resistance absent. In line with the protocol, endline samples are currently being analysed, and midline samples will be analysed only if an increase in resistance markers is shown in endline samples. There is a concern among key global stakeholders that the increased use of SP would lead to an increase in resistance. It would be important to closely monitor the development of resistance further down the road. There is also the need for a more forward-facing approach to drug development and new tools or breakthrough technologies that may replace SP in the future.

3.5 Efficiency

Ef1. How timely, cost-efficient and cost-effective was implementation? +What factors have been considered to ensure that value for money has been achieved from an efficiency standpoint?

Finding 1. The TIPTOP project was largely time-efficient, delivering most activities on time; however, it experienced some external challenges that delayed implementation in certain project locations. The Supply Side Grant was also largely efficient, with the only implementation delays experienced due to COVID-19 restrictions.

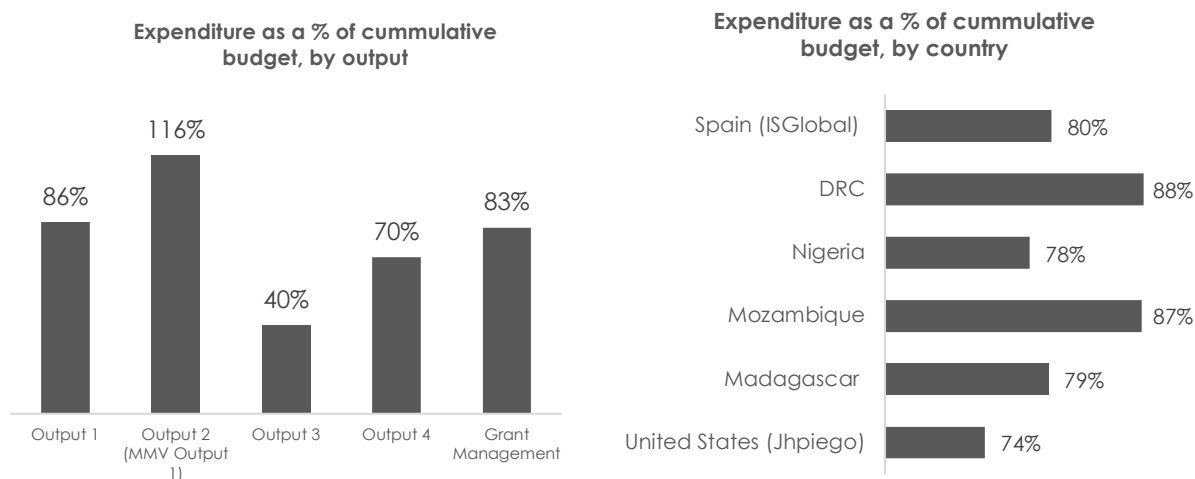
The TIPTOP project kicked off on time, with key personnel hired, final country operating plans and the global project launch held within the first year of the project. A review of project activities by output showed that most planned activities were on track in the project’s first year, except for unexpected delays related to the introduction of the WHO ERC process by Unitaid following grant approval; this affected the study timeline and corresponding activities, as well as the cumbersome process to obtain the import waiver in Nigeria. The project was integrated within existing community health structures; as such required less time to start up activities. Usually, leveraging health systems in LMICs often introduces inefficiencies in delivery; however, this was not the case on this project as the C-IPTp intervention was complimentary and was seen as an additional option for pregnant women to receive IPTp, not a completely new intervention. The factors that impacted time efficiency significantly were the COVID-19 pandemic, extreme weather, political conflict and health worker strikes. These created temporary disruptions to implementation, significantly affecting specific locations but did not set back the entire project. The Supply Side Grant also experienced delays with registering UCLs products in non-project countries due to COVID-19-related closures of registration bodies.



Finding 2. The TIPTOP project was largely cost-efficient, improving its absorptive capacity annually and expending 81% of its budget as at December 2021. The Supply Side Grant also expended 116% of its first output.

The TIPTOP project’s absorptive capacity increased annually from a 36% burn rate in 2017 to 91% in 2021. The lower budget consumption in its first year was due to moving some activities planned in Year one to Year two, a lengthy recruitment process with notice period required by most of the professional staff. Also, ISGlobal experienced delays in selecting their in-country research institutions, leaving these funds unspent. Through the life of the project, the annual budget consumption increased in tandem with the scale-up of project activities and the project team proactively adjusted and realigned budgets each year, rolling over unspent funds. A review of expenditure by country and output as at the end of the project showed over 70% expenditure by

country and by output, with the largest underspend on Output 3 at only 40% expenditure. This resulted from international travel cancellations and a switch to virtual conferences due to COVID-19, as well as savings through negotiated rates for accommodation and the meeting venues for the project’s annual meetings. In addition, Output 3 represents less than 1% of the budget; hence, it represented only a USD 157,096 variance. The project, however, completely delivered most of its planned activities and the unspent funds are not an indication of outstanding activities. There was also an initial underspend on the Supply Side Grant mainly due to COVID-19 travel restrictions, and this was effectively addressed through reprogramming efforts with the entire budget expended at project closeout.



Finding 3. The intervention was cost-effective as determined by the modelled estimates.

The consortium partner ISGlobal conducted a cost-effectiveness analysis as part of the impact model. Modelled estimates reported earlier under [Section 3.4 Impact](#) show that the intervention was cost-effective. Respondents also describe the commodity as well as the community-based approach as an inexpensive solution to a large problem. IPTp is a life-saving intervention that has been proven to be cost-effective for the prevention of malaria in pregnant women; more so, this project contributes additional evidence on its cost-effectiveness via a community-based model. The factors the project considered to achieve value for money included integration of the intervention within existing community health systems, utilising government’s CHWs (these were not remunerated by the project), leveraging funding partners early and transitioning some of the procurement to these funders even before project closeout. The project, though unintentionally, also had significant savings due to the transition to virtual activities due to the COVID-19 pandemic.

*“This was a low-cost intervention to a big problem of malaria in pregnancy”
Country Level respondent*

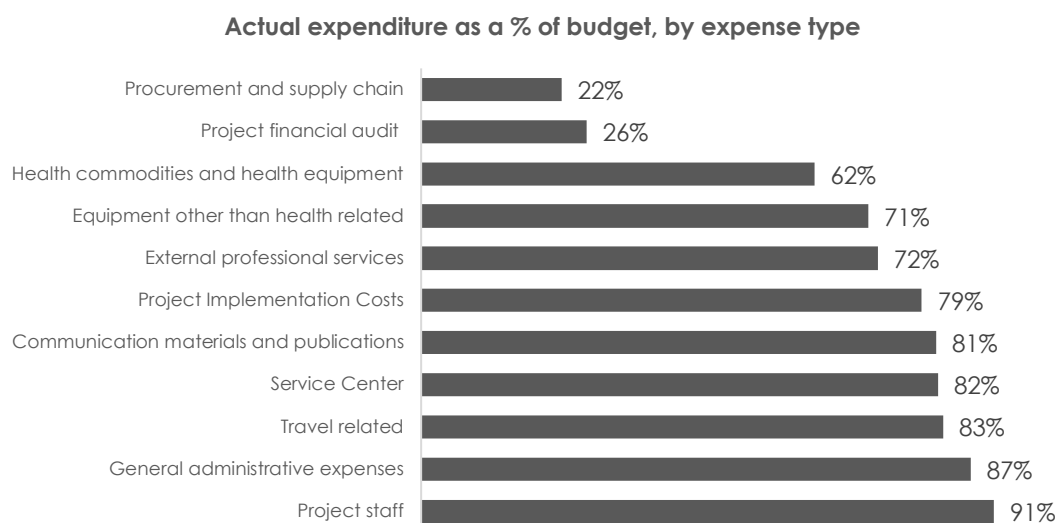
Ef2. Was the funding allocation/split to cover commodities/supplies versus other costs efficient to achieve project objectives?

Finding 4. The funding size for the TIPTOP project was quite large compared to similar projects, and the allocation across outputs was sufficient to achieve its objectives.

The funding allocation across outputs was sufficient to complete activities per the program design. Implementers were satisfied with the budget allocations, with most expense areas underspent at the close of the project and corresponding activities completed. The budget of the C-IPTp intervention was sizeable compared to other similar Unitaaid community-based malaria interventions, e.g., the introduction of rectal artesunate, which was just over a third of the funding

here. It was also markedly more in comparison to other Unitaid implementation projects spanning more than double the number of project countries and interventions with large operational research components.

Ef3. How well did the grant implementers collaborate with national authorities in project planning,



implementation, and assessment to promote integration into existing health systems?

Finding 5: Consistent and effective participation in MiP Technical Working Groups and Program Steering Committees improved coordination and collaboration.

The TIPTOP project staff actively participated in Malaria and MiP technical working groups at country-level, championing the C-IPTp cause, coordinating with other partners and implementers and sharing results periodically through the life of the project. The team also coordinated the TIPTOP program steering committee, which included funding partners, WHO and MoH personnel.

“The project was building on existing health systems; the project did not spend money setting up a parallel service but integrated services within the health systems. This was a very efficient way of increasing coverage of IPT without necessarily incurring extraordinary costs.”
Country Level respondent

Finding 6. Co-working with Ministries of Health (National Malaria Control Programs and RMNCH Programs) was an important factor in fostering integration.

The project also engaged both NMCPs and RMNCH departments at the Ministries of Health, consistently ensuring co-working (joint site selection consultations, joint planning, joint trainings and collaboration for systems improvement), as earlier described, allowing for effective integration of project interventions, joint monitoring of progress and forging the path for government ownership of the C-IPTp approach beyond the project life.

Finding 7. Engagement with Civil Society Organisations and CHWs led to normalising the intervention within communities.

The engagement with CSOs and working through government CHWs also ensured that trainings and the program delivery model is embedded within the ways of working of these actors. These actors have made the intervention a norm in project communities and have created a very high level of acceptability for the intervention and community ownership, as described in earlier sections. CSOs also report that they have also benefited from the project through increased recognition in their communities.

3.6 Sustainability

S1. How have the projects built an enabling global environment for scale-up?

Finding 1. TIPTOP created an enabling environment through evidence generation and dissemination via national and global platforms as well as project developed learning systems.

Evidence generation and learning were built into the project's design and implementation approaches, targeting stakeholders at country, regional and global levels. This learning focus was an important factor in how the projects built an enabling global environment. The project's communication plan included: utilising existing in-country and regional platforms such as TWGs, Steering Committees, Conferences, etcetera, to disseminate results, engaging with key stakeholders (including Governments, WHO, UNICEF, International Funders, CSOs and other implementers) on a fairly regular basis, towards influencing the adoption of the C-IPTp-SP approach. The Gates Foundation joined the steering committee mid-way through the project and became a key contributor, especially supporting efforts to expand learning dissemination. The project organised large-scale learning events, and utilised a variety of dissemination tools, which included publications, impact stories, social media, multimedia communication packages, digital learning platforms and conference presentations. The project dissemination efforts increased understanding of the project's results and research evidence, across local and global actors, including those in non-project countries.

Finding 2. Although TIPTOP was designed to inform normative guidance, it seems the guidance is already supportive of C-IPTp per WHO interpretation. This current interpretation needs to be widely disseminated and cascaded to global and local malaria response stakeholders.

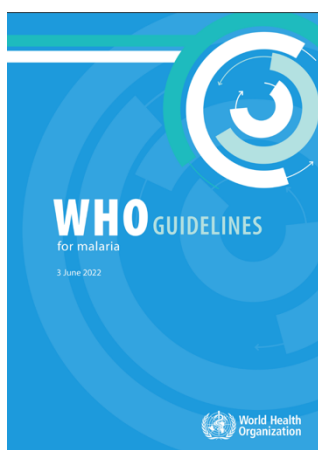
The WHO guidelines are regarded by most stakeholders as a prerequisite for country-level policy change and adoption of new interventions, treatments or models of care. As a result, the project engaged and worked with WHO, sharing progress and learnings regularly with the GMP, and subsequently final results from its studies to inform expected revisions to WHO's guidelines development process. There was also some dissonance between WHO and stakeholders at both country and global level, with many stakeholders expecting updated WHO guidelines to signal WHO's support for community delivery as an acceptable method for delivering

IPTp, and WHO determining mid-project that the current ANC guidelines did not preclude community delivery. TIPTOP and its steering committee engaged in

multiple consultations to address this issue, with a final resolution reached towards the release of updated guidance published June 2022. In the updated guidance, WHO re-affirmed its recommendation for IPTp-SP in moderate to high *P. falciparum* malaria transmission areas, stating that the recommendation does not limit the delivery of IPT-SP to ANC settings and indicating that the use of community health workers may be explored where inequities exist. WHO respondents also alluded to the fact that countries are entirely in the lead on their

"WHO is shifting a little bit more away from dictating any specific delivery approach and really thinking a bit more about providing guidance but countries are making their own decisions." **Global respondent**

"It'll be interesting to see how Mozambique, Madagascar, Nigeria and DRC scale those activities up further beyond the pilot districts. We know where they are in that process, I think part of it hinges on WHO support and endorsement. They're kind of waiting for that signal that they can go ahead with it." **Global respondent**



decision-making when it comes to the delivery channels for these evidence-based interventions, indicating that they have a better sense of what's going on epidemiologically, better visibility into national resources, and systems (community health worker footprint, locally available supply of quality assured SP) and should make an informed decision based more on these factors not just as a result of WHO's guidance.

S2. To what extent have the projects helped establish country readiness for scale-up, including securing ongoing political and financial commitments by national governments and other partners, supportive policies and enhanced health system capacity for delivery, and partnering with communities and civil society to mobilise ongoing community demand and engagement?

Finding 3: Countries now have a variety of supportive tools to guide country adoption.

The four project countries under TIPTOP have piloted this approach, and through the project, a host of resources have been developed, including training curricula and learning resource packages, community health management and information system (CHMIS), communication plans and tools, monitoring and evaluation tools and supply chain processes. Most of these countries have also revised their national strategic plans and the national malaria treatment guidelines, and developed sustainability plans and road maps with the support of the MiP TWG, WHO and TIPTOP. The project countries have also conducted a couple of country readiness assessments each, with adequate readiness improvements reported, with C-IPTp transitions plans signed in two (Madagascar and Nigeria) of the four project countries.

“We’re hoping to work closely with JHPIEGO and the TIPTOP project in terms of adopting these tools and guidelines and resources that have been generated by TIPTOP.”
Country Level respondent

S3. To what extent have core elements of the intervention been transitioned to ensure that the benefits of the intervention will continue beyond the life of the investment?

Finding 4: Most project countries have already adapted the approach to their contexts during the implementation of TIPTOP and are poised to continue implementation as funding becomes available.

TIPTOP is described by its implementers as a project driven by country governments. This is corroborated by country stakeholders, as countries actively participated in the design of the projects making decisions on how best to implement them in their different contexts. The Ministry of Health in Mozambique indicated the need to include lay community counsellors. Mozambique and Madagascar insisted that the first dose of IPTp had to be delivered in the health facility for quality assurance reasons. Closeout discussions for Mozambique are also very different, as the gains experienced with C-IPTp are marginal compared to the other countries. Also, with its somewhat smaller landscape of community health workers and higher IPTp levels than other countries, there will be a need to determine how and where community IPTp is prioritised. There are also concerns that the LCCs will not be sustained after the close of the project since these are not a formal part of the CHW structure. The Mozambique MoH has, however, pledged to prioritise IPTp and is currently planning to include it in their NMST, to be reviewed in late 2022. The Community Health programme in Mozambique is also currently being restructured, and the new Community Health Sub-system intends to recruit additional CHWs, potentially LCCs.

+To what extent are potential scale-up and sustainability partners prepared to fund C-IPTp?

Finding 5. Scale-up and sustainability partners are supportive of the intervention and are interested in funding project countries.

PMI and GF are highly likely to support the scale-up of C-IPTp as they have been well engaged by TIPTOP through the life of the project at both global and country levels. Also, PMI is already conducting similar community pilots in other countries, as earlier described. Countries have not made domestic commitments for continuity, so the support of these partners is pertinent. The recent update of the WHO guidelines further reinforces the support from these partners and will create momentum amongst country actors who have been awaiting the updated guidelines as an endorsement of the community-based approach.

“With all the sustainability parameters that we have worked on over the last four and a half years, financing has been the most challenging where countries have not made that huge commitment to indicate their readiness to go on their own.”

Global respondent

Finding 6. Two project countries have submitted funding applications to both scale-up funders. A third country is targeting the next funding cycle, and the fourth is actively advocating for support.

Prior to the start of the project, PMI was already procuring and distributing SP for IPTp in DRC and Madagascar, with funding support for MNCH training and quality improvement initiatives in Nigeria and Mozambique, respectively. Global Fund was also supporting IPTp in DRC and Madagascar. It is clear that these countries were already priority countries for MNCH and MiP interventions. DRC and Madagascar seem more likely to be funded as the current funding applications include a proposal to Global Fund to support C-IPTp scale up to 136 districts in DRC and 41 districts in Madagascar. Nigeria and Mozambique do not have confirmed funding, but there are expectations that Nigeria’s next funding cycle, 2024-2027, will include C-IPTp. There is also ongoing advocacy for PMI to support the scale-up of C-IPTp in Mozambique.

Finding 7. Non-project countries are including C-IPTp in their funding applications.

There have been other similar pilots in Malawi, Burkina Faso, Senegal and Sierra Leone. These are not as a result of TIPTOP but will add to the evidence base for the C-IPTp intervention. Global respondents, including scale-up funders, report increasing interest among other countries. In terms of non-project countries, six additional countries included C-IPTp rollout in their Global Fund proposal for 2021-2023 funding (Benin, Burkina Faso, Cameroon, Central African Republic, Congo Brazzaville and Senegal). These are not directly attributed to TIPTOP but have benefitted from the experiences and evidence shared with GF, who actively participated in the TIPTOP steering committee.

“It’s good to see other countries, beyond the targeted countries are interested, so there is future momentum around this approach.”

Global respondent

3.7 Learning

L1. What have been the lessons learned and how have they been incorporated in the lifetime of the grants or across other interventions? Have lessons learnt been widely disseminated by grantees and Unitaid?

About the Intervention

1. C-IPTp is Effective, Cost-Effective and Equitable.

IPTp is a low-cost solution to a large-scale problem and it's a proven and effective intervention. The project has also demonstrated the cost-effectiveness of C-IPTp, which also delivered the intervention to women in their homes.

2. Community delivery of IPTp is safe and does not disrupt ANC attendance.

CHWs were able to distribute SP safely to women in the community with no reports of side effects or pregnant women receiving excessive doses of SP. The project's results have shown that it is not only possible to prevent a decline in ANC attendance during community delivery of IPTp, but the intervention also increased ANC attendance.

"One of the concerns that our maternal health colleagues had, was the impact on ANC visits, and whether there might be a decline. That has not been the case, instead it has increased proportionally with the additional reach to pregnant women."
Country level respondent

3. C-IPTp also doubles as additional outreach services.

The project's approach to providing both IPTp in communities and aiding referral to health facilities created a dual effect, increasing both C-IPTp and facilitating access to facility-based IPTp and ANC. This reinforces the need to strengthen community-facility linkages and coordination between programs across disease areas, in this case, Malaria prevention and the RMNCH programmes in countries.

4. IPTp-specific packaging and branding for target beneficiaries increased the perception of quality and acceptability of the intervention.

The updated packaging of SP promoting IPTp had a positive effect on uptake of the commodity/impact of the project. It is an important part of the intervention that should also be adopted and scaled up in order to achieve similar results.

About the Implementation Context

5. Early gathering of information on requirements for product registration and import waivers is critical.

The challenges encountered with product registration or receipt of import waivers by the project did not significantly affect the delivery of results but created delays and additional hurdles for project teams to overcome. Country baseline assessments for introducing SP or other products should include registration/importation requirements gathering.

6. Community services are critical in navigating emergencies.

The project proactively organised sufficient SP stocks for CHW and health facilities in advance to mitigate disruptions in the supply chain due to emergencies (COVID-19, riots, adverse weather). Implementing during the pandemic was also somewhat easier due to the community-based nature of the intervention.

"One key lesson is that the community health workers can be trained to provide services, you don't need to have healthcare workers doing the community distribution."
Country level respondent

About the Actors

7. CHWs can be trained to deliver IPTp.

The project provided extensive and tailored trainings for CHWs, as earlier discussed. CHWs have successfully distributed IPTp in the communities, supported referrals to health facilities and

further supported program monitoring and data collection towards the achieving the project's results. As also described earlier, no adverse events were reported due to the delivery of C-IPTp-SP by CHWs. Many respondents described the value of delivering C-IPTp through CHWs, saying that community model created a high level of acceptability of the intervention.

8. CSOs play a crucial role in increasing acceptance and coverage.

It is already well-documented and established that strong community involvement and stakeholder coordination is essential to increase acceptance and uptake of any health intervention, especially for community-based interventions. The project leveraged this principle using existing CSOs to extend its networks in the communities. CSOs were not formally contracted but were engaged in mutually beneficial partnerships that fostered their inherent objectives and those of the project. They conducted a host of BCC activities ranging from community meetings, village dramas, puppetry, etcetera to create awareness for the intervention. CSOs were also useful for engaging communities to troubleshoot and resolve challenges related to service delivery.

9. Embedding project staff in Government offices fosters ownership.

The project had a close working relationship with many key stakeholders through several collaboration avenues and meetings. However, Country-level respondents reported that embedding project staff in government offices was a very effective initiative to increase ownership of the project's interventions with activities, results and decisions being discussed real-time with MoH teams.

About Program Management

10. Focus on program learning, improved delivery and adaptation.

The project had a strong learning focus and leveraged its learning for program adaptations as needed: including family decision dynamics in DRC, private sector engagement in Madagascar, and the role of midwives in boosting ANC attendance in Nigeria. The project has also shared widely evidence generated from its studies through several conferences, project dissemination workshops, and annual meetings, pivoting many of these to virtual platforms due to COVID-19 in the past two years.

11. Utilisation of virtual approaches increased cost savings, with limited or no decline in program effectiveness, in the context of already well-established implementation arrangements.

COVID-19 pandemic restrictions changed the ways of working, allowing many activities to be done virtually and funds utilised differently; less local travel and even fewer international trips. These created savings for the project without significantly comprising the quality of the interventions. It is, however, important to note that the project already had two years of established relationships and implementation arrangements prior to the pandemic. Adaptation to the pandemic was also somewhat easier due to the community-based nature of the intervention.

12. Structure of year-one critical to budget performance.

Most projects tend to have a slower start-off phase in the first year with time-consuming inception activities. TIPTOP had the same experience and moved multiple activities from its first to the second year. It is essential that future budgets are tailored for the start-up phase in Y1, especially when it is not a full calendar year, with budget allocations focused on contract signing with funders and consortium members, phased personnel recruitment and research protocol development. This will allow for optimal expenditure in Y1, and seamless implementation in Y2.

3.8 Risk Mitigation

L2. How effectively have strategic, implementation and sustainability/scalability risks been identified and managed over the course of implementation?

Strategic Risks

The projects identified several strategic risks at design stage, including the perception of SP as a failed drug negatively affecting demand for quality-assured SP for IPTp, the possibility of increased SP resistance, policy barriers inhibiting C-IPTp uptake, and availability of sufficient manufacturers. The only risk experienced related to policy is the dissonance between country stakeholder expectations for global policy endorsement for C-IPTp through WHO guidance, and WHO's insistence that there was no need for additional guidance as the current guidance does not preclude community delivery. This evaluation has included recommendations to further address this risk. Another risk that was addressed was the potential of having only one WHO prequalified SP manufacturer. This was well resolved, with two manufacturers prequalified during the life of the project and another two in progress. There is also an SP resistance monitoring study to be released by the project to confirm the absence or presence of resistance. This was not available at the point of this evaluation.

Implementation Risks

The implementation risks identified in the project's design included CHWs being overburdened with additional C-IPTp responsibility, community distribution of SP negatively impacting ANC attendance, and concerns about the availability of quality-assured SP at project start-up and stockouts during implementation. The project experienced an increased burden of CHWs, especially in Mozambique, due to the limited CHW workforce, which was addressed by the engagement of LCCs to support CHWs. CHWs were, however, incentivised through supportive supervision, mentorship, and provision of work kits and stipends. More so, the communities' appreciation and in-kind incentives were reported by CHWs as the most important motivational factor. The project did not experience any of the other risks earlier identified. The Supply Side Grant also effectively managed the support to manufacturers towards prequalification, and TIPTOP supported commodity logistics for IPTp-SP, ensuring consistent commodity availability in project sites. As earlier discussed, ANC attendance was not negatively impacted; it improved in most districts during the implementation of the project. There were, however, many unanticipated events that posed serious risks to implementation and interrupted C-IPTp provision. These have already been discussed in detail; however, the insecurity in Nigeria and Mozambique were the most impactful as they caused closure of health facilities for protracted periods and affected the ability of the project to achieve targets in the implementation sites in these countries.

Sustainability/Scalability Risks

The identified sustainability risks were the potential shortage of global quality assured SP and scale-up partner support following the life of the project to ensure scale-up. The project proactively addressed both issues from inception, supporting the prequalification of more manufacturers and engaging major partners, especially PMI and Global Fund, working with MoHs and NMCPs to prepare funding applications. Project countries have not yet secured funding but are likely to secure funding to support project locations and scale up to additional districts in project countries. Another sustainability risk was country decisions to await WHO evidence review findings before committing funds to the scale-up of C-IPTp. This risk has, however, been addressed through the recent guideline update in June 2022, where WHO re-affirmed its recommendation for IPTp-SP in moderate to high *P. falciparum* malaria transmission areas, indicating that the use of community health workers may be explored where inequities exist.

4. Conclusions

The main conclusions of the evaluation are as follows:

The design of the projects, their objectives and expected results were very relevant and timely in response to the current needs of malaria stakeholders and targeted beneficiary countries and other malaria-endemic countries. With the high MiP burden in these countries, the availability of a proven and effective intervention (IPTp), the need for evidence on alternative delivery models, and a need to introduce quality assured SP into the market; the need for evidence on alternative delivery models; complementary WHO guidelines on IPTp and ANC (already in place); and a need to introduce prequalified SP products into the market, the projects addressed the most critical access barriers to IPTp coverage. The TIPTOP project also adapted well to contextual changes at global and country levels, as evidenced by its adaptation to different CHW cadres; utilising modified implementation approaches to adapt to each of the focus country's contexts; as well as navigating COVID-19 and other unexpected natural disasters, health emergencies and insecurity experienced throughout the life of the project.

The projects were also very coherent, with C-IPTp well integrated into existing community health systems, leveraging existing personnel (community health workers) and structures (information systems, supply chains, referral mechanisms) for delivery of community health services. The intervention was complementary to existing facility-based IPTp delivery through ANC, as it helped extend IPTp and referral services, and improved the availability of QA-SP at both facility and community levels. The TIPTOP project worked exceptionally well with both global and local stakeholders. There was great alignment within the consortium of Jhpiego and ISGlobal, productive interactions with supportive projects – the Supply Side Grant and WHO's enabler, and a well-constituted project steering committee, comprising US Government President's Malaria Initiative (PMI), the Global Fund, MMV, ISGlobal, WHO, and Jhpiego. These interactions were consistent from inception through close out, creating a high level of coherence for the C-IPTp intervention.

The projects were largely effective and increased coverage of IPTp through the utilisation of a community-based approach, with all project countries surpassing their life-of-project targets for the percentage of pregnant women receiving three or more doses of IPTp. IPTp3 coverage increased from baselines of 21% in DRC, 28% in Madagascar, 53% in Mozambique and 11% in Nigeria; to endlines of 65% in DRC, 75% in Madagascar, 59% in Mozambique and 63% in Nigeria.

The projects also successfully overcame targeted access barriers as follows:

- The Supply Side Grant effectively addressed the limited availability of quality assured manufacturers of SP specifically packaged for IPTp (*quality, innovation and availability barrier*) by supporting the WHO prequalification process of three manufacturers (UCL Kenya, SWIPHA Nigeria and EMZOR Nigeria). UCL Kenya and SWIPHA Nigeria have submitted their dossier for review with an expected approval for the UCL product by mid-2022 and the SWIPHA product by 2023. The dossier for EMZOR was submitted in mid-2022 with an estimated 18-24 months review period.
- TIPTOP effectively addressed the low demand for IPTp among providers and pregnant women (*demand & adoption barrier*) by creating strong ownership for the project's interventions through consistent stakeholder engagements; increased sensitisation and awareness of IPTp through CSOs and CHWs; and strengthened linkages between health facilities and community

structures. The improved IPTp-SP packaging, branded for pregnant women, also improved the acceptance of the product.

- TIPTOP addressed the insufficient evidence behind alternative service delivery innovations (*demand & adoption barrier*) by generating and disseminating evidence on the effectiveness of C-IPTp through its research and routine monitoring results.
- TIPTOP addressed supply chain inefficiencies (*supply and delivery barrier*) in supported sites by strengthening the community health system through tailored trainings, reinforced supply chains and improved health information systems. These resulted in significant reductions in SP stockouts in project sites.

The changes in IPTp3+ coverage potentially translated to improved health outcomes for mothers and newborns, with a third dose of SP increasing the protective efficacy in reducing malaria by 33% - 40%. More specifically, estimates from the modelling exercise show that the project could contribute to 2.9m [829K – 4.6m] malaria infections averted; 100,806 [27,690 – 156,497] deaths averted [9,618 maternal deaths and 91,188 neonatal deaths]; and 7.9m [2.7m – 10.4m] DALYs averted [0.3m maternal DALYs and 7.7m neonatal DALYs] from 2023-2027 across the four project countries and six additional countries in Africa with the highest likelihood for adoption and scale-up. The intervention also has the potential to generate cost-saving by averting treatment costs for the health system of US\$69m [17m, 120m] in the next five years. The intervention will also confer an incremental cost of US\$625m [221m, 768m] to the health system over the next five years, with a Return on Investment (ROI) of 31.9. The intervention is cost-effective, based on the cost-effectiveness threshold typically adopted to inform decisions in health care (up to 30 US\$ per DALY averted being highly cost-effective, and up to 150 US\$ per DALY averted being cost-effective).³⁴

The projects were largely time-efficient, delivering most activities on time. However, external challenges mentioned earlier, delayed or stopped implementation in certain project locations. The projects were also largely cost-efficient, improving their absorptive capacity annually, with TIPTOP and the Supply Side Grant expending 81% and 116% of their project budgets, respectively, by December 2021. The intervention was cost-effective as determined by the modelled estimates above. The project, also had significant savings due to transition to virtual activities per the COVID-19 pandemic.

Lastly, the intervention is poised to be sustainable, with sustainability factored in at design stage, including its co-creation with MoHs, involvement of scale-up partners in site selection and implementation through country health systems. The project was integrated into existing MoH structures. Furthermore, C-IPTp has been included in NMSPs in DRC, Madagascar and Nigeria, even before its inclusion in global policy documents. Also, the comprehensive learning systems set up by the project led to increased interest beyond project countries to take up the intervention. There is tremendous support from PMI and GF, with some funding already made available but limited funding commitment from domestic sources; however, the low cost of this intervention creates a higher likelihood for inclusion in country budgets. There was also some dissonance between WHO and stakeholders, with stakeholders expecting updated WHO guidelines to signal WHO's support for community delivery was acceptable and WHO determining mid-project that the current ANC guidelines do not preclude community delivery. In the updated guidance published in June 2022, WHO re-affirmed its recommendation for IPTp-SP in moderate to high *P. falciparum* malaria transmission areas, stating that the recommendation does not limit

³⁴ WHO. Making choices in health: WHO guide to cost-effectiveness analysis. In: Tan-Torres Edejer T, Baltussen R, Adam T, Hutubessy R, Acharya A, Evans DB, Murray DB, Murray CJL, editors. Geneva: WHO; 2003.

the delivery of IPT-SP to ANC settings; indicating that the use of community health workers may be explored where inequities exist. “Notwithstanding the impending guidance from WHO, the level of interest amongst country stakeholders, support by funders and current guidelines all indicate that the C-IPTp intervention is poised for successful scale-up in sub-Saharan Africa, contributing to higher coverage of SP during pregnancy.

5. Recommendations

This section presents recommendations for different stakeholder categories based on lessons learnt under the projects.

5.1 National Malaria Control Programs and National RMNCH Programs in Ministries of Health

5.1.1 **Ensure baseline needs assessments** cover CHWs availability, workload and training needs; ANC sites and provider readiness to incorporate C-IPTp; registration/ importation requirements for SP (including contextual requirements for commodity packaging and leaflets) and understanding supply chain gaps.

5.1.2 **Create avenues for communication and collaboration between Malaria and RMNCH programs** to strengthen C-IPTp and similar cross-cutting interventions.

5.1.3 **Conduct tailored trainings for CHWs** per country context, ranging from a focused IPTp curriculum using the project's LRP or an extensive CHW training covering wider IMCI or MNCH scope, depending on baseline findings.

5.1.4 **Closely monitor SP resistance levels** as countries scale up the use of IPTp-SP at ANC as well as at community level.

5.1.5 **Utilise costing estimates and cost-effectiveness report** developed by TIPTOP for strategic planning and advocating for funders to fill the supply gap.

5.1.6 **Prioritise QA SP for IPTp with improved packaging**, and facilitate distribution through all delivery mechanisms. This will also contribute to creating demand for the newly prequalified manufacturers.

5.1.7 **Strengthen commodity supply holistically** with a focus on both health facilities and CHW supplies. The availability of stock at health facilities is critical for CHWs to have adequate stock for QA SP since they are resupplied through the facility.

5.1.8 **Reinforce the project-initiated data quality improvement and learning processes.** The culture of data use created by the project needs to be maintained as it contributed to many program adaptations in the course of the project and can be utilised to further strengthen C-IPTp and other service delivery efforts. *(Project countries only)*

5.2 TIPTOP, Supply Side Grant & Other Implementers

5.2.1 **Advocate to country decision-makers on the need to prioritise quality assured SP.** This will be a key enabler to having new prequalified African manufacturers catalyse the market.

5.3.2 **Provide access to project results for ongoing dissemination** after project close out, for countries and other stakeholders to further engage.

5.3 Unitaid, Donors & Global Policy Makers

5.3.1 **Sensitise national stakeholders on the interpretation of current WHO guidelines on the provision of C-IPTp.** This has already been started by the project implementers but can be addressed by global stakeholders in the malaria response with more clout and convening power.

5.3.2 **Prioritise prequalified SP products from local manufacturers in specific regions** for future investments. This will motivate local manufacturers to value prequalification and condition countries in the regions to prioritise these prequalified products.

5.3.3 **Explore options for future replacement of SP,** including existing drugs, new drug development, or breakthrough technologies. Although there are no reports of resistance, SP has had a track record of resistance in malaria treatment, C-IPTp is likely to scale the use of SP significantly, with concerns of reduced effectiveness due to resistance in the future.

5.3.4 **Lead advocacy towards other funders/potential scale-up partners;** this is essential for the catalytic approach of Unitaid's projects to be successful. *(Unitaid Only)*

5.3.5 **Consider restructuring budget allocation** within the first year (especially when less than six months), having a smaller budget dedicated to consortium and implementation partners set-up, personnel recruitment and research protocol development and approval. This will allow for focused activities and reduced underspend in Y1, thus, allowing for a seamless implementation in year 2. *(Unitaid Only)*

6. Risks, Limitations & Mitigation

6.1 Unavailability of Household Survey Data

The evaluators were not able to gain access to the full household survey dataset, as a result several indicators presented in effectiveness are based on the routine data utilized in the projects annual reports which is not as accurate as the rigorous research data. Where appropriate survey data from the impact model produced by ISGlobal has been included in the report.

6.2 COVID-19 Prevention Considerations

This evaluation was conducted during the COVID-19 pandemic, and as a result, contingencies and safety measures were put in place. The safety of participants and interviewers throughout the data collection phase was assured by limiting the number of in-person engagements to a bare minimum and utilising more virtual interviews/group discussions with key informants. Where necessary and absolutely unavoidable, one on one in-person interviews were conducted adhering to the Ministry of Health COVID-19 prevention guidelines in each country, using face masks, sanitising hands, tools and surfaces and practising social distancing.

7. Appendices

7.1 Methodology

The evaluation framework and methodology were based on elements of Unitaid's evaluation framework, strategic Key Performance Indicators (KPIs) and scalability framework applicable to the TIPTOP and MMV supply grants as well as TOR requirements. The approach comprised a rapid portfolio mapping for each country, followed by a mixed-methods approach that comprised:

- Desk reviews of existing project documents (plan, logframes, reports, datasets, publications, conference presentations and other information products) to harness qualitative and quantitative data on project outcomes, including modelling outputs.
- Virtual and in-person qualitative interviews (key informant interviews, focus group discussions/workshops).
- Site visits combined with qualitative interviews.
- Triangulation of data from different sources/stakeholders to establish the strength of evidence and level of contribution to achieved results.
- Lastly, the evaluation employed utilisation-focused and participatory approaches.

Portfolio Mapping: Early mapping and portfolio analysis were conducted at inception and data collection phases to ensure that the whole portfolio was unpacked to the largest extent possible through an extensive desk review process. Our team of resident technical area experts also provided an in-depth analysis of each country's Malaria prevention and treatment landscape and navigated key stakeholders' identification and engagement to initiate qualitative interviews, working closely with the lead grantee's in-country staff.

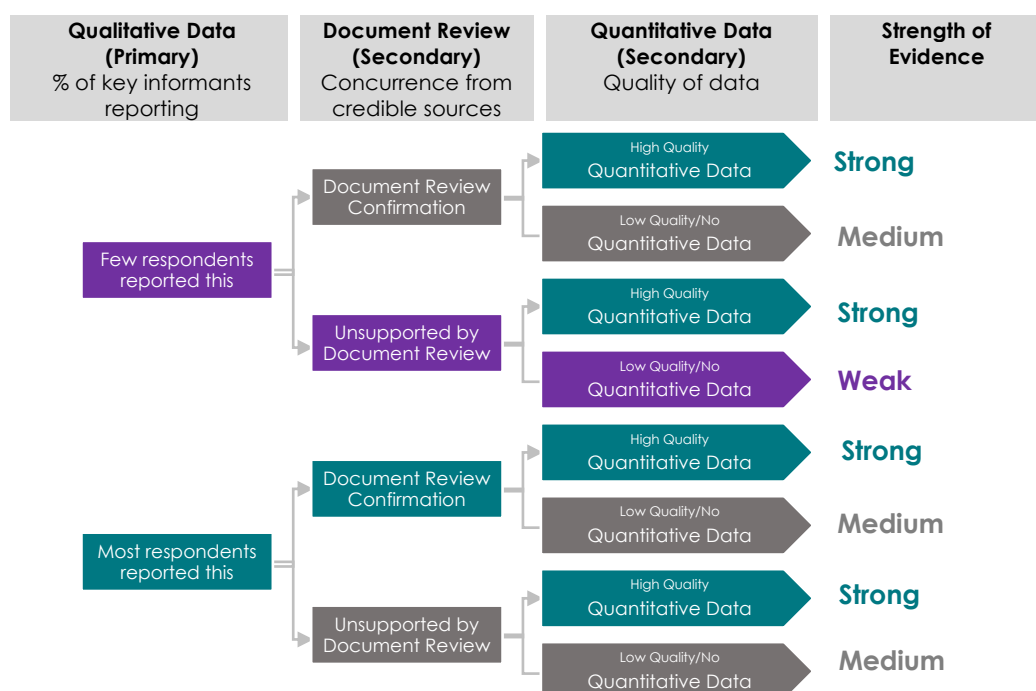
Mixed Methods: The evaluation collected primary qualitative data through key informant in-person/ virtual interviews with a wide variety of stakeholders from community health workers to community groups and civil society organisations, Ministries/coordinating bodies, implementers, national and global technical working groups/fora, other donors, relevant Unitaid grantees and Unitaid staff. Other qualitative data were extracted from project documents such as Work Plans, Theory of Change, Annual Reports, Conference Abstracts, Manuscripts, Publications, Tools, and Guidelines developed. Quantitative data was mainly secondary data extracted from project reports and modelling outputs.

Site Visits: Qualitative interviews with key stakeholders at the sub-national level were conducted alongside site visits as these enabled the evaluation team to validate the reported findings and access stakeholders who may have limited teleconferencing capabilities. In line with Unitaid's effort to reduce carbon footprints related to procurement activities, our teams did not travel internationally as team members were already residents in the TIPTOP project countries, except Madagascar, which was assessed virtually.

Impact Modelling: The scope of this evaluation did not include Impact modelling; however, modelling outputs³⁵ of the public health and economic impact of the project developed by Consortium partner ISGlobal, were reviewed and included in this report.

³⁵ ISGlobal C-IPTp Impact Model

Strength of Evidence Pathway



We consider high-quality quantitative data sources to be objective; consequently, any result backed with verifiable quantitative data is considered strong, irrespective of the presence of qualitative interview feedback or document review confirmation. Qualitative data is often more subjective and prone to a number of biases from both the interviewer and responder, thereby affecting the validity and reliability of findings. The strength of qualitative interview data increased where a large volume of respondents provided the same feedback, complemented by the document review with quantitative data findings. Our framework emphasises this. This framework guided the final compilation of evaluation findings and recommendations.

Sampling & Sample Size

The sampling for the qualitative interviews was purposive and took into consideration representativeness of all key stakeholders in target countries and globally, variation by including a range of stakeholders with different dimensions of interest and optimising cost by limiting the number of operational areas from which respondents were selected. A total of 66 participants were interviewed one on one or in groups; these included 49 country-level participants and 17 global respondents. This sample was deemed sufficient with a high potential to achieve saturation based on our past experience with similar evaluations.

Project Countries

The evaluation covered all four countries of implementation Democratic Republic of Congo (DRC), Nigeria, Madagascar and Mozambique. With in-country experts in DRC, Nigeria and Mozambique, these countries were targeted for field visits. All interaction with Madagascar was virtual through desk review and teleconference interviews.

7.2 Evaluation Matrix

Questions and sub-questions (+) are listed by DAC criteria, culled out from Annex 1 of the Evaluation Terms of Reference and adapted where necessary.

Criteria, Questions & Indicators	Methods & Respondents
Relevance	
<p>1. To what extent did the objectives and design of the projects respond to the needs of targeted beneficiaries (among vulnerable populations, including pregnant women, community and civil society organisations, government/national health systems, and scale-up partners)?</p> <p>2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context (for example, at the policy level – globally or within a national context, emerging and competing technologies/products/approaches)?</p>	<p>Methods: Document Review, KIIs, Group Discussions Respondents: Unitaid Staff, Grantees & Consortium Members, MoH (National Level – Govt NMCP focal points), CSOs, Community Groups, other relevant Unitaid grantees and Malaria technical working groups/global stakeholders</p> <p>Methods: KIIs, Group Discussions, Document Review Respondents: Unitaid Staff, Grantees & Consortium Members</p>
Coherence	
<p>1. To what extent have the projects created synergies between relevant interventions/integrated into the countries' health systems, including Community Health Systems?</p> <p>2. How well does the intervention align with priorities/needs identified by partners/the global disease response? +To what extent are the projects' interventions consistent with other initiatives/international and national policies, norms and standards within the same space)?</p> <p>3. To what extent is the project adding value (and not duplicating efforts or establishing parallel systems)? E.g., working within existing health facilities for service delivery, utilising government personnel (CHWs), utilising the same supply chain management processes and health</p>	<p>Methods: KIIs, Group Discussions Respondents: Other Donors, Unitaid Staff, Grantees & Consortium Members, MoH (National Level – Govt NMCP focal points).</p> <p>Methods: KIIs, Group Discussions Respondents: Other Donors, Unitaid Staff, Grantees & Consortium Members, MoH (National Level – Govt NMCP focal points)</p> <p>Methods: KIIs, Group Discussions Respondents: Other Donors, Unitaid Staff, Grantees & Consortium Members, MoH (National & Sub-national</p>

Criteria, Questions & Indicators	Methods & Respondents
<p>information management system. Or leveraging other structures set up by other international partners in-country.</p>	<p>Level – Govt.), CSOs</p>
<p>Effectiveness</p>	
<p>1. To what extent did the two projects achieve their objectives and expected outcomes in addressing targeted access barriers within the specified timeframe and budget?</p>	<p>Methods: Document Review, KIIs, Group Discussions Respondents: Unitaid Staff, Grantees & Consortium Members</p>
<p>Innovation & Availability <i>(Products that are better (new, adapted, superior); are commercially available for rapid introduction in LMICs)</i></p> <p>2. To what extent have the projects contributed to increased availability of quality assured SP that are commercially available for rapid introduction in LMICs?</p> <p>+To what extent have the projects contributed to development or access to innovative products (better, new, adapted, superior) in resource-limited settings?</p> <p>+To what extent has the availability of better products increased for the target groups/region?</p> <p>+Have the products supported through the projects been registered for commercial use in relevant project countries, or are plans in place for their registration after project closure? How did the inability to register Guilin QA-SP in Nigeria impact project results?</p> <p><i>KPI 1- Total number of Unitaid-supported products for which product development activities have been successfully completed</i></p>	<p>Methods: Document Review, KIIs, Group Discussion Respondents: Unitaid Staff, Grantees & Consortium Members, Other Donors, Grantees, and Malaria technical working groups/global stakeholders</p>

Criteria, Questions & Indicators	Methods & Respondents
<p>Demand & Adoption (<i>Countries, programs, and end users introduce and adopt the most cost-effective products within their local context. Proven service delivery models for LMIC settings exist.</i>)</p> <p>3. What progress did the projects make in facilitating increased demand and uptake for scale-up of cost-effective SP products within target countries and beyond?</p> <p>+How effectively have implementers partnered with/engaged and supported communities and civil society organisations to increase demand, political support and financial commitments?</p> <p>How did the late CHW selection and training affect project results?</p> <p>+To what extent do the piloted delivery systems reach underserved/ vulnerable populations?</p> <p>+How effectively has implementation generated demand and the ability to reach the priority/target population?</p> <p><i>Indicator P1.1-Proportion of women who received three or more doses of IPTp during their last pregnancy (project-specific areas and countrywide)</i></p> <p><i>Indicator P1.2-Proportion of women who received two or more doses of IPTp during their last pregnancy (project-specific areas and countrywide)</i></p> <p><i>Indicator P1.4-Proportion of pregnant women attending ANC four times (project-specific areas and countrywide)</i></p> <p><i>Indicator P1.5-Proportion of pregnant women attending first ANC before or by week 14 (project-specific areas and countrywide)</i></p>	<p>Methods: Document Review, KIIs, Group Discussion</p> <p>Respondents: Unitaid Staff, Grantees & Consortium Members, MoH (National & Sub-national Level – Govt.), CSOs, Community Groups.</p>
<p>4. How was the implementation approach effective in promoting or shaping global policy adoption and country adoption both in project and non-project countries? +Why has Mozambique not included C-IPTp in its strategic plan? Are there any concerns/reservations that are still unaddressed?</p> <p><i>Indicator P2.1- Number of countries updating policy to reflect C-IPTp-SP delivery</i></p>	<p>Methods: KIIs, Group Discussions, Document Review</p> <p>Respondents: Other Donors, Manufacturers, Unitaid Staff, Grantees & Consortium Members, Research Partners. MOH Mozambique</p>

Criteria, Questions & Indicators	Methods & Respondents
<p>5. How effective are the delivery models, and what best practices can be learned from the process? +How did the project effectively engage Community Health Workers (CHWs)? How did the low motivation, low incentives and low literacy levels of CHWs affect the project, and how did the project address these issues? +How did the project leverage existing Community HMIS structures/successfully integrate C-IPTp monitoring into the existing systems in supported countries?</p>	<p>Methods: KIIs, Group Discussions, Document Review Respondents: Unitaid Staff, Grantees & Consortium Members, MoH (National & Sub-national Level – Govt.), Health Workers</p>
<p>Supply & Delivery <i>(Supply chain systems, including quantification, procurement, storage, and distribution, function effectively to ensure that products reach end users in a reliable and timely way. Adequate and sustainable supply exists to meet global needs.)</i></p> <p>6. To what extent did the Afl/grant improve supply and delivery systems to ensure that products reach those in need in a reliable and timely way? +To what extent did the projects contribute to establishment (or integration) of functional and sustainable supply chain processes, including forecasting, planning, procurement, storage, and distribution? Probe on challenges with SP procurement in Nigeria. +To what degree have the projects ensured availability and sustainability of adequate supply channels to deliver the products to the vulnerable/underserved populations? +How effectively have the projects leveraged procurement and supply chain to overcome other access barriers such as quality or affordability (with examples)? +To what degree have the projects ensured that systems are put in place to mitigate diversion, wastages, expiries and other forms of losses due to supply and delivery inefficiencies?</p>	<p>Methods: Document Review, KIIs, Group Discussion Respondents: Unitaid Staff, Grantees & Consortium Members, MoH (National & Sub-national Level – Govt.), Health Workers</p>
<p>7. How likely is it that the projects will catalyse the global market and supply in terms of volume, diversity and prices, in particular from the African-based manufacturers?</p>	<p>Methods: KIIs, Group Discussions, Document Review Respondents: Other Donors, Manufacturers, Unitaid Staff, Grantees & Consortium Members</p>
<p>8. What were the main factors influencing the achievement or non-achievement of the intended outputs or overall outcomes? +How did COVID-19 impact project results, and how did the project adapt to Covid-19-related restrictions/related implementation challenges?</p>	<p>Methods: KIIs, Group Discussions, Document Review Respondents: Unitaid Staff, Grantees & Consortium Members.</p>

Criteria, Questions & Indicators	Methods & Respondents
Impact	
<p>1. To what extent has the investment generated, or is expected to generate, global/national-level effects across Unitaids' four dimensions of impact:</p> <ul style="list-style-type: none"> i. Public health impact <i>(4.1 – Increasing public health impact: Number of lives saved (projection) Number of malaria cases averted (projection), Proportion of newborns with low birthweight (project-reports))</i> ii. Economic impact <i>(4.3 – Delivering positive returns, Return on investment)</i> iii. Equity <i>(5.1 – Investing for the poorest.; 5.2 – Investing for the underserved)</i> iv. Strategic benefits and positive externalities. +Are there any unintended effects of community-based delivery of IPTp? 	<p>Methods: Document Review, KIIs, Group Discussion Respondents: Unitaids Staff, Grantees & Consortium Members, MoH (National & Sub-national Level – Govt.), CSOs, Community Groups, Health Workers</p>
Efficiency	
<p>1. How timely, cost-efficient and cost-effective was implementation (consider both allocative efficiency and technical efficiency)? +What factors have been considered to ensure that value for money has been achieved from an efficiency standpoint? Deliverables vs Expenditure. +What might have been done differently to improve efficiency?</p> <p>2. Was the funding allocation/split to cover commodities/supplies versus other costs efficient to achieve project objectives? What best practices, if any, could be learned for similar grants in the future? <i>(4.2 – Generating efficiencies & savings, financial savings and health system efficiencies)</i></p> <p>3. How well did the grant implementers collaborate with national authorities in project planning, implementation, and assessment to promote integration into existing health systems?</p>	<p>Methods: Document Review, KIIs, Group Discussion Respondents: Unitaids Staff, Grantees & Consortium Members, MoH (National & Sub-national Level – Govt.)</p>
Sustainability	

Criteria, Questions & Indicators	Methods & Respondents
<p>1. How have the projects built an enabling global environment for scale-up, including generating evidence, normative guidance, product supply capacity, tools to support country adoption/adaptation and uptake and advocacy, and stronger partnerships among global actors? +How did the project create ownership among MOH stakeholders, especially with major personnel changes in three project countries and transfers of all TIPTOP trained HCWs in Nigeria? <i>(3.2 – Scaling-up coverage, Additional number of people who benefit from a better health product)</i></p> <p>2. To what extent have the projects helped establish country readiness for scale-up, including securing ongoing political and financial commitments by national governments and other partners, supportive policies and enhanced health system capacity for delivery, and partnering with communities and civil society to mobilise ongoing community demand and engagement? <i>(3.1 – Securing funding, Proportion of project countries where future funding has been secured at grant closure through partners and countries)</i></p> <p>+To what extent are potential scale-up and sustainability partners prepared to fund C-IPTp under the current WHO guidelines?</p> <p><i>Indicator O3.1 – Number of targeted countries with Global Funds (GFATM) submissions that include C-IPTp-SP</i></p> <p><i>Indicator O3.2 – Number of targeted countries with Malaria Operational Plans that include C-IPTp-SP</i></p> <p>3. To what extent have core elements of the intervention been transitioned to ensure that the benefits of the intervention will continue beyond the life of the investment?</p>	<p>Methods: Document Review, KIIs, Group Discussion</p> <p>Respondents: Unitaid Staff, Grantees & Consortium Members, MoH (National Level – Govt-NMCP), Other Donors & Global Stakeholders</p>
<p>Learning & Risk Mitigation</p>	
<p>1. What have been the lessons learnt, and how have they been incorporated in the lifetime of the grants or across other interventions? Have lessons learnt been widely disseminated by grantees and Unitaid?</p> <p>2. How effectively have strategic, implementation and sustainability/scalability risks been identified and managed over the course of implementation?</p>	<p>Methods: Document Review, KIIs, Group Discussion</p> <p>Respondents: Other Donors, Unitaid Staff, Grantees & Consortium Members, Research Partners, MoH (National & Sub-national Level – Govt.), CSOs</p>

7.3 Documents Reviewed

The evaluation team reviewed the following documents including grant specific document and other general documentation.

TIPTOP

Grant agreements, amendments and reprogramming reports

Unitaid (2018) Grant Amendment to increase funding ceiling

Unitaid (2017) Grant Agreement (original)

Reports

2021 Annual Report

2020 Annual Report

2019 Annual Report

2018 Annual Report

Logframe

Impact models/estimations

Jhpiego IPTp Impact Assessment 2017

Reports/Research/Investment cases

ASTMH Abstracts (2021)

MMV Supply Side Grant

2021 Grant Amendments

2018 MMV Supply Grant Logframe

2017 MMV Project Plan

2017 MMV SG Grant Agreement

Other Relevant Documentation

WHO (2021) World Malaria report

The Global Fund Results Report (2021)
