Scaling IPTi-SP in DRC and Nigeria: A scoping report

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PATH

malaria consortium
disease control, better health

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Abbreviations

ACSM	Advocacy Communication and Social Mobilizations
ACT	artemisinin combination therapies
ADR	Adverse Drug Reaction
AEFI	adverse event following immunization
ANC	antenatal care
ANICiis	Agence Nationale d'Ingénierie Clinique d'Information et d'Informatique de Santé
ANRP	National Pharmaceutical Regulatory Authority
BAU	business as usual
BCC	behavior changes communication
BCZS	Bureau Central de Zone de Santé (Health Zone Central Bureau)
BMGF	Bill and Melinda Gates Foundation
CCM	community case management
CDR	Centrale de Distribution Regionale
CHEW	Community Health Extension Workers
CHIPS	Community Health Influencers and Promoters
CHW	community health worker
CMAM	community-based management of malnutrition
CNPV	Centre National de PharmacoVigilance
CORPS	Community Resource Persons
DGLM	Direction Generale de la Lutte contre la Maladie
DGOGSS	Direction Generale d'Organisation et de Gestion des Soins de Sante
DHIS	District Health Information Software
DHS	demographic and health survey
DPM	Direction de la Pharmacie et du Médicament
DPS	provincial health divisions
DPT	diptheria-pertussis-tetanus vaccine
DRC	The Democratic Republic of Congo
DSE	Direction de Surveillance Epidemiologique
DSNIS	Division du Systeme National d'Information Sanitaire
EMOD	Epidemiological Modeling Software
EOC	Emergency Operations Center
EPI	Expanded Programme on Immunization
FCDO	UK Foreign, Commonwealth and Development Office
FEDECAME	Federation des centrales d'approvisionnement en medicaments essentiels
FMOH	Federal Ministry of Health

FY	fiscal year
GF	Global Fund
GHSC-PSM	Global Health Supply Chain Program-Procurement and Supply Management
HBHI	High Burden to High Impact
HMIS	health management information system
HRIS	human resources information system
HZ	health zone
IPTi	intermittent preventive treatment in infants
IPTi-SP	intermittent preventive treatment in infants with sulfadoxine-pyrimethamine
IPTp	intermittent preventive treatment during pregnancy
IRS	indoor residual spraying
IT	information technology
ITN	Insecticide-treated bed nets
LGA	local government area
LLIN	long-lasting insecticide-treated net
LSHTM	London School of Hygiene and Tropical Medicine
M&E	monitoring and evaluation
MCV	measles containing vaccine
MDA	mass drug administration
MEL	monitoring, learning, and evaluation
MICS	Multiple Indicator Cluster Survey
MMV	Medicines for Malaria Venture
MOH	ministry of health
MOP	Malaria Operational Plan
MOU	memorandum of understanding
MPR	Malaria Program Review
M-RITE	MOMENTUM Routine Immunization Transformation and Equity
NAFDAC	National Agency for Food and Drugs Administration Control
NDHS	Nigeria Demographic and Health Survey
NIRPUT	National IPTi Research Policy Uptake Task Team
NMP	national malaria program
NMSP	national malaria strategic plan
NPC	National Pharmacovigilance Centre
NPHCDA	National Primary Health Care Development Agency
OR	operational research
PAAR	Global Fund prioritized above allocation request
PIE	post introduction evaluation

PMI	President’s Malaria Initiative
PNAME	Programme National d’Approvisionnement en Médicaments Essentiels
PNECHOL-MD	Programme National d'Elimination du Cholera et des autres Maladies Diarrheiques
PNSR	Programme National de la Sante de Reproduction
POD	proof of delivery
PPMV	patent and proprietary medicine vendors
PSI	Population Services International
Q1	quarter 1
RBM	Roll Back Malaria
RDT	malaria rapid diagnostic tests
RMNACH	Reproductive Maternal Neonatal Adolescent and Child Health
RPVC	Regional Pharmacovigilance Centers
SANRU	Santé Rurale
SMC	seasonal malaria chemoprevention
SMEP	State Malaria Elimination Programme
SOP	standard operating procedure
SP	sulfadoxine-pyrimethamine
TIPTOP	Transforming IPT for Optimal Pregnancy
TOR	terms of reference
TWG	technical working group
UMC	Uppsala Monitoring Centre
UNICEF	United Nations Children’s Fund
USAID	US Agency for International Development
VHW	Village Health Workers
WHO	World Health Organization
WUENIC	WHO and UNICEF estimates of national immunization coverage
Y1	year 1

Executive Summary

Intermittent preventive treatment in infants with sulfadoxine-pyrimethamine (IPTi-SP) is a safe, effective, and affordable intervention to reduce rates of malaria in children under one year of age. In 2010, the World Health Organization (WHO) recommended the administration of a full therapeutic course of sulfadoxine-pyrimethamine (SP) to infants at risk of malaria at 10 weeks, 14 weeks, and 9 months of age, leveraging the existing vaccination platform for delivery.[1] Many countries with high malaria burden, including the Democratic Republic of Congo (DRC) and Nigeria, have expressed interest in introducing and scaling up IPTi-SP. To date, concerns about SP resistance, funding, and operations research to support implementation have been the biggest obstacles to widespread implementation of IPTi-SP.

Over the last four years, the increasing concern around plateauing or even reversing of progress against malaria, particularly in highly endemic countries in sub-Saharan Africa (SSA), has renewed interest in the potential for IPTI-SP to be a useful tool for malaria prevention. DRC and Nigeria are among the countries that have expressed interest. It is a timely opportunity to introduce and scale up IPTi-SP given:

- The availability of recent data on SP resistance, vaccine coverage, and malaria transmission from national surveys and global reports, enabling donors and country governments to target preferred national and sub-national geographies for IPTi-SP implementation.
- That revised WHO guidelines are in development and will likely recommend a broader approach to chemoprevention that can be tailored to individual country needs and contexts, providing flexibility around number of touchpoints, duration of period of chemoprevention, and delivery platforms
- The approval of the first malaria vaccine, RTS,S, making possible new intervention combinations targeted at preventing malaria transmission and saving infant lives.

Under this investment, PATH and Malaria Consortium conducted a four-month scoping exercise in DRC and Nigeria to gather and analyze the data necessary to engage the national malaria program (NMP) and other key stakeholders in the landscaping and project design process, identify appropriate geographies and delivery methods of IPTi-SP in each country, and identify knowledge gaps to be addressed during implementation. The two organizations also conducted mathematical modeling and costing exercises to assess the impact and cost of IPTi-SP on malaria incidence in infants. The mathematical modeling showed that IPTi-SP could reduce incidence by 13 to 38 percent depending on geography, malaria epidemiology, and coverage assumptions.

In DRC, the landscaping exercise indicated that, since 2013, the Ministry of Health (MOH) has demonstrated interest in adopting and implementing IPTi-SP, which is already part of national policy. However, IPTi-SP has not yet been implemented in the country due to lack of funding. There is a renewed interest in IPTi-SP after the WHO-led High Burden to High Impact stratification included IPTi-SP among the mix of interventions most impactful for specific strata. The NMP has selected ten provinces in the west for potential IPTi-SP implementation based on SP resistance levels (lowest in the western provinces), transmission intensity, and modelled impact. The MOH prefers to start IPTi-SP implementation using the current WHO recommendations but is receptive to implementing alternative approaches if recommended by WHO (e.g., additional touchpoints, alternative delivery platforms, and/or alternative drugs).

As detailed in this scoping report, PATH developed an implementation plan for IPTi-SP scale-up in DRC using inputs from stakeholder discussions, landscaping of the available literature and data, a costing framework, and impact modeling. In the scale-up plan, PATH proposes a five-year implementation period, focusing the first year of project implementation on operations ramp-up in up to two of the ten IPTI-SP

eligible provinces. PATH will work closely with the MOH to expand IPTi-SP to cover the remaining eight IPTI-SP-eligible provinces in years two through five, as well as collaborate with the London School of Hygiene and Tropical Medicine (LSHTM) to identify additional IPTi-SP eligible provinces as supportive data on SP resistance becomes available over the next five years (funded through PSI-LSHTM UNITAID IPTi Plus project).

In Nigeria, IPTi was included in the national malaria strategic plan (NMSP) 2021–2025 as one of the malaria prevention initiatives. Following a National Malaria Stratification Mapping exercise conducted in 2019, 16 states in the southern part of Nigeria were identified for IPTi-SP implementation and 5 states were selected to implement IPTi in certain local government areas (LGAs).

The scale-up plan for Nigeria, through a phased approach, includes 'defining scalable units' by implementing IPTi-SP in select states. Taking into consideration key criteria such as malaria prevalence, incidence rates, infant mortality, and Expanded Programme on Immunization (EPI) coverage – three states were identified: (1) Edo, (2) Ebonyi, and (3) Ekiti. However, to inform strategic plans for like-scalable units, based on heterogeneity factors, including regions with low EPI coverage and regions where some locations are mapped for IPTi and others for seasonal malaria chemoprevention (SMC) (within same state), a fourth state was selected – Adamawa state. IPTi-SP implementation will commence in 2022 and will be scaled in four states: Edo, Ebonyi, Ekiti and eligible LGAs in Adamawa state.

To track the progress of this investment, PATH and Malaria Consortium co-designed a common measurement, evaluation, and learning (MEL) plan. The plan is intended to deliver on three key objectives:

1. Track progress toward stated results.
2. Identify risks prospectively.
3. Support program adaptation and learning.

PATH and Malaria Consortium developed a shared results framework with outputs that are anticipated to contribute to project outcomes, which in turn lead to scale-up and coverage of IPTi-SP, culminating in a reduction of malaria morbidity in infants. This results framework was used to guide the development of the four key components of the MEL plan which will fulfill the above objectives: (1) a monitoring plan to show how progress towards intended program results will be measured routinely; (2) an evaluation plan which identifies areas where supplementary data collection may be needed; (3) a learning agenda which identifies additional exploratory questions of interest to stakeholders; (4) data management and use plan which identifies tools and approaches to ensure the use of collected data to mitigate project risks and guide adaptations to implementation.

PATH and Malaria Consortium will continue to foster the close, collaborative working relationship that has been developed through the scoping process. DRC and Nigeria are both at different stages of IPTi-SP adoption and implementation, and therefore the year one (Y1) activities will be distinct in each country. The functional workstreams from each organization, established during the scoping phase, will meet regularly to share key learnings, challenges, and engage in problem-solving to improve and advance IPTi-SP scale-up in both countries.

Introduction

Intermittent preventive treatment in infants (IPTi) was initially evaluated as a chemoprevention strategy in a proof-of-concept trial in Tanzania in the first few years of the 21st century and showed substantial protective efficacy against clinical malaria and anemia in infants. In addition to the promising impact, the intervention was also appealing as it could be delivered through the existing and highly functional Expanded Programme on Immunization (EPI) platform. Infants received a single dose of SP at already scheduled EPI visits at 10 weeks, 14 weeks, and 9 months of age, leveraging delivery of the intervention through routine immunization visits. SP also had the added advantage of being a single encounter, one-dose treatment regimen, resulting in highly efficient, directly observed therapy. A consortium of researchers (the IPTi-SP Consortium, funded by the Bill and Melinda Gates Foundation [BMGF]) was formed to further explore this promising intervention in different settings in SSA through a series of clinical trials to assess the safety, impact, and cost-effectiveness of this intervention. The robust body of evidence produced subsequently informed the World Health Organization (WHO) policy recommendation on IPTi-SP in 2010.

Current WHO Guidance for IPTi (2010)

1. **Target age group:** infants 2-12 months of age
2. **Delivery:** single dose of SP at already scheduled EPI visits at 2, 3, and 9 months of age
3. **Implementation context:** limited to areas with moderate to high malaria transmission in SSA that have less than 50% prevalence of certain antifolate resistance mutations (Pfdhps 540 mutation in the P. falciparum parasite), since that mutation is associated with SP resistance

IPTi-SP has not been taken up by many national malaria programs (NMPs), largely due to implementation considerations, including drug resistance to SP, narrow target age group, and limited funding. However, over the last four years, the donor community and host countries have expressed a renewed interest in implementing IPTi-SP. In addition, WHO has revisited their approach to policy guidance, with an eye towards adapting recommendations to be more flexible and more suitable for tailoring to individual country contexts. The revised WHO IPTi-SP guidance, expected to be released in the first quarter of 2022, will likely allow for:

- Increased numbers of touch points (rather than limited only to three immunization visits);
- Consideration of alternative delivery platforms (for example community case management programs); and
- Expanded age range (extending the age range into the second year of life).

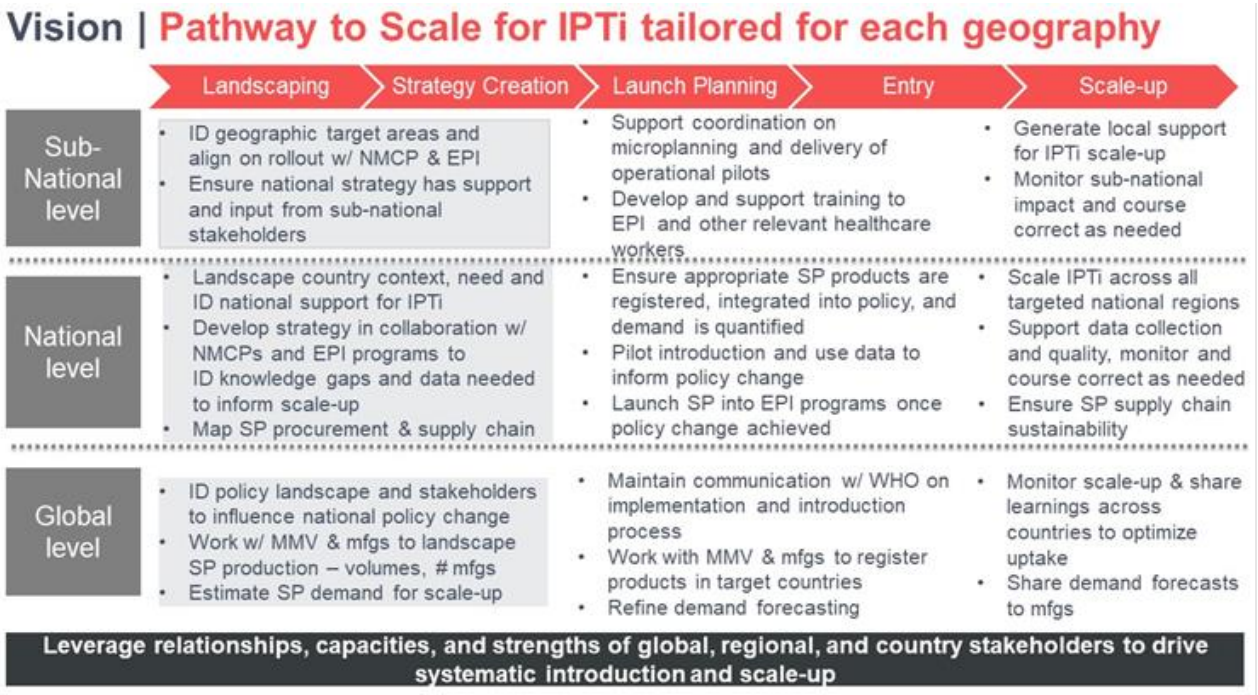
The renewed interest in IPTi-SP, along with these potential program flexibilities, will allow countries to include IPTi-SP in locally tailored intervention packages that are based on epidemiology, entomology, seasonality, and health system considerations.

Under this scoping exercise, PATH and Malaria Consortium completed the landscaping and strategy creation phases of the pathway to scale model illustrated in Figure 1, exploring many of the factors associated with a locally tailored intervention package listed above. The PATH team led the scoping exercise in DRC and the Malaria Consortium team in Nigeria. PATH and Malaria Consortium coordinated closely across six workstreams throughout the scoping period: 1) interviews and stakeholder engagement; 2) desk reviews; 3) costing; 4) modeling; 5) monitoring, evaluation, and learning (MEL); and (6) program design and budget.

In DRC and Nigeria, the team collectively interviewed over 30 stakeholders from key organizations including the NMP, the EPI, ministry of health (MOH) directorates, WHO, Global Fund, and U.S. President's Malaria Initiative (PMI). A detailed list of the stakeholders interviewed is included in Annex A. Following the interviews, a validation workshop was held in both DRC and Nigeria to share preliminary insights with key stakeholders in each country and gain buy-in and support. PATH/Malaria Consortium further substantiated stakeholder interview findings with supporting evidence from a review of over 45 documents from each country. The findings of the landscaping report and stakeholder validation workshop are the foundation of the proposed program design. This report includes a detailed description of the methodology used to develop the mathematical model, costing model, and monitoring and evaluation (M&E) plan in those respective sections.

The findings and deliverables for the scoping phase are detailed in the following sections: (1) landscaping report, (2) mathematical modeling to assess potential impact, (3) costing model, (4) roadmap for scale, including associated risks and mitigation strategies, (5) M&E approach for the implementation phase, (6) roles and responsibilities, and (7) an overall notional budget for the implementation of the project. Each section includes sub-sections with country specific details for DRC and Nigeria.

Figure 1. Pathway to scale for IPTi-SP tailored to each geography.

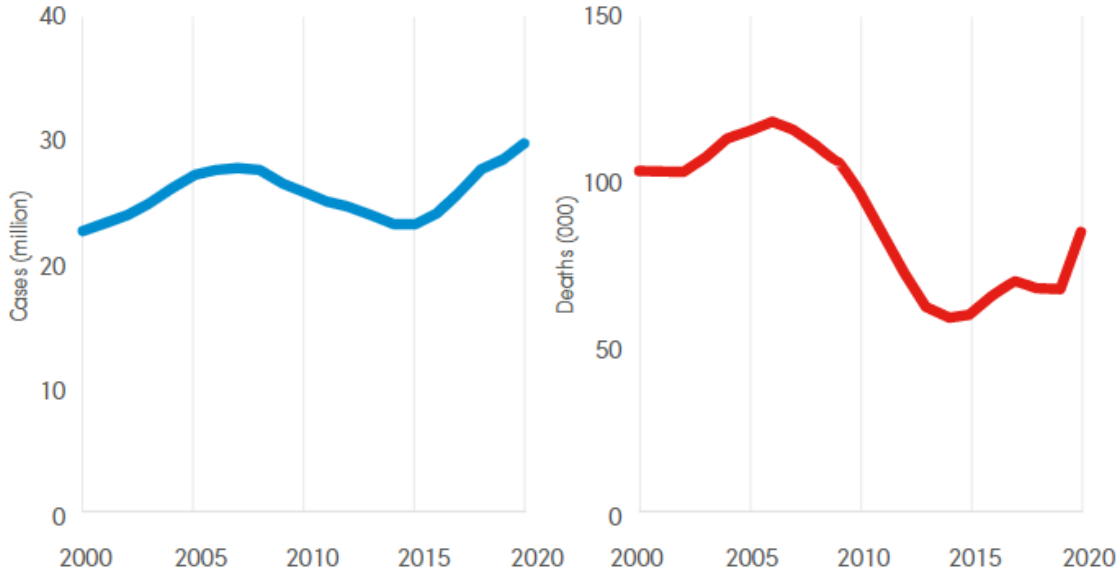


1 Landscaping Report

1.1 DRC

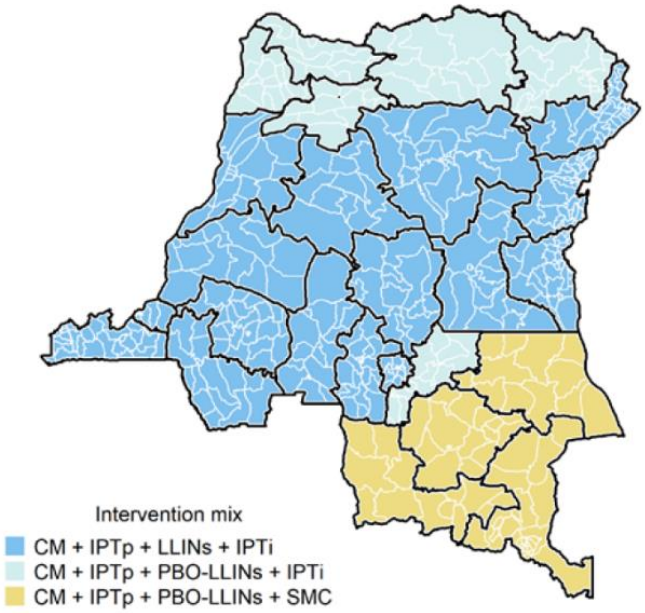
DRC has the second highest burden of malaria in the world, accounting for an estimated 12 percent of cases and 12 percent of deaths globally.[2] In DRC, forty percent of child deaths below age five are attributed to malaria[3] and severe malaria causes 77 percent of hospitalizations among children under five.[4] According to the 2021 World Malaria Report,[2] both the number of cases and deaths have increased in the last five years, following a period of decline (Figure 2).

Figure 2. Estimated malaria cases and deaths in DRC, 2000-2020 (#55).



The current malaria control strategies in DRC rely on case management with artemisinin combination therapies (ACTs), distribution of long-lasting insecticide-treated nets (LLINs), and intermittent preventive treatment in pregnancy (IPTp) with SP. A more targeted approach was developed through the High Burden to High Impact (HBHI) activities supported by WHO and Roll Back Malaria (RBM), with stratification of the health zones based on epidemiological, entomological, health system factors, seasonality, and other characteristics to identify appropriate tailored packages of intervention mixes (Figure 3).[5]

Figure 3. Stratification of interventions in DRC, 2019 (doc 54).



Abbreviations: CM: case management; IPTp: intermittent preventive treatment in pregnant women; LLINs: long-lasting insecticide-treated nets; PBO-LLINs: LLINs treated with piperonyl butoxide; SMC: seasonal malaria chemoprevention; IPTi-SP: intermittent preventive treatment in infants.

Administratively, DRC is divided into 26 provinces. The health system is organized in three levels:

1. National level
2. Provincial level with 26 provincial health divisions
3. Operational level (519 health zones)

Health zones (HZs) represent the operational unit of the system and implement the primary health care strategy. The HZ is an integrated system that provides comprehensive, continuous, and integrated high-quality care.[6] A HZ usually covers a population of 100,000–150,000 inhabitants in rural areas and 200,000–250,000 in urban areas. Each HZ includes a general referral hospital, some health centers, and a dozen lower-level health facilities. Each HZ is led by a chief medical officer and managed by an HZ team. All health services, including antenatal care (ANC) and routine immunizations, are integrated at health facilities. In DRC, health facilities are the point of delivery, unlike the health systems in other countries wherein the EPI system might be responsible for immunization services.

1.1.1 Country demand for IPTi

Since 2013, the MOH in DRC has demonstrated documented interest in adopting and implementing IPTi-SP (see Table 1 for more details); IPTi is also already part of the policy in DRC. The primary limitation to implementation has been identifying sources of funding to support the scale-up.

Table 1. Documented demand for IPTi-SP in DRC.

Document and year	Reference
2013-15 National Malaria Strategic Plan (NMSP)	Included as a potential intervention with the following language: "administer one dose of IPTi-SP to more than 80 percent of infants in targeted areas."[7]
2016-2020 NMSP	Included reference to IPTi-SP, focusing this time on operational research to "ensure delivery of IPTi-SP."[8]
2020-2023 NMSP	Included as follows: "A situation analysis will be conducted to identify eligible areas for IPTi-SP according to WHO criteria. A pilot implementation plan prior to scale-up will be developed and implemented."[5]
Global Fund prioritized above allocation request (PAAR)	The MOH included IPTi-SP in their PAAR for the Global Fund 2020 to 2022 grant, with plans to introduce IPTi-SP in 2022.
U.S. President's Malaria Initiative (PMI) DRC Malaria Operational Plan (MOP) FY 2020	PMI indicated support for DRC's malaria control strategy.[9,10]
High Burden to High Impact (HBHI) risk mapping	During our stakeholder consultations, DRC NMP confirmed their interest in implementing IPTi-SP, especially after the HBHI stratification process that included IPTi-SP in the intervention mixes and led to the development of maps and identification of areas deemed suitable for IPTi-SP (Figure 3 above).

IPTi financing and prioritization

To date, funding has been the primary obstacle to IPTi-SP implementation in DRC. Global Fund and PMI are the two main malaria funders in DRC. IPTi is currently not part of PMI's implementation strategy in DRC. The MOH originally planned to introduce IPTi-SP starting in 2022 with funds from the Global Fund 2020 to 2022 grant. However, it was removed in the latest iteration of the Global Fund grant due to competing priorities, as Global Fund is currently prioritizing maintaining and improving coverage of existing interventions (especially ACTs, LLINs, RDTs). Therefore, IPTi-SP implementation will require funds from a different source. The MOH will cover the salaries of health workers and will facilitate the importation of SP. All other resources will need to come from a donor. No other donor supporting malaria work in DRC is currently funding IPTi-SP.

Potential risks of competition between IPTi and other malaria interventions and opportunity costs

Based on stakeholder discussions, the MOH and WHO do not see any risk of competition between IPTi-SP and other malaria interventions (refer to Annex E for interview documentation). The WHO anticipates synergies across the interventions based on the HBHI modeling, which illustrates the added benefit of IPTi-SP in appropriate geographies. Rather than an opportunity cost, the NMP indicated that IPTi-SP might improve coverage of other interventions, like EPI, by creating an additional draw to routine health service touchpoints (see additional details in section 1.1.3).

This synergistic effect could also potentially be achieved with the combination of the newly recommended RTS,S vaccine and IPTi-SP. Given the overlap of the target population and the use of the same delivery platform (EPI), combining the interventions has the potential to improve coverage overall. Further, initial evidence has shown that combining RTS,S immunization with seasonal malaria chemoprevention (SMC) delivers additional impacts in preventing malaria morbidity and mortality.[11] IPTi-SP offers the potential for

immediate impact while awaiting research evidence on the benefits of co-deployment and expansion in vaccine supply.

MOH preferred implementation strategy for IPTi

The MOH prefers to start implementing IPTi-SP following the current WHO guidance as they have not seen evidence on the effectiveness of alternative approaches (see Annex E for details from stakeholder interviews). The MOH is receptive to implementing alternative approaches if recommended by WHO through updated guidance, which is expected to be available in the first quarter (Q1) of 2022. This investment could serve as a platform to explore other IPTi-SP strategies through operational research activities on topics including increasing the number of IPTi-SP touchpoints, alternative drugs, and other distribution channels such as through community health workers (CHWs).

1.1.2 Defining the appropriate epidemiological context for IPTi in DRC

The MOH has identified ten provinces for IPTi-SP implementation based on data on SP resistance, malaria burden, and modelled impact scenarios (see Table 2 below for details). The ten selected provinces are highlighted in pink in Figure 4 below and the SP resistance profile for all provinces is shown in Figure 5 below. All ten provinces are supported by the Global Fund. In addition, EPI coverage in these provinces is another important criterion to consider in the selection of appropriate contexts for successful IPTi-SP introduction and scale-up.

Figure 4. Ten provinces selected by MOH for potential IPTi-SP implementation.[12]

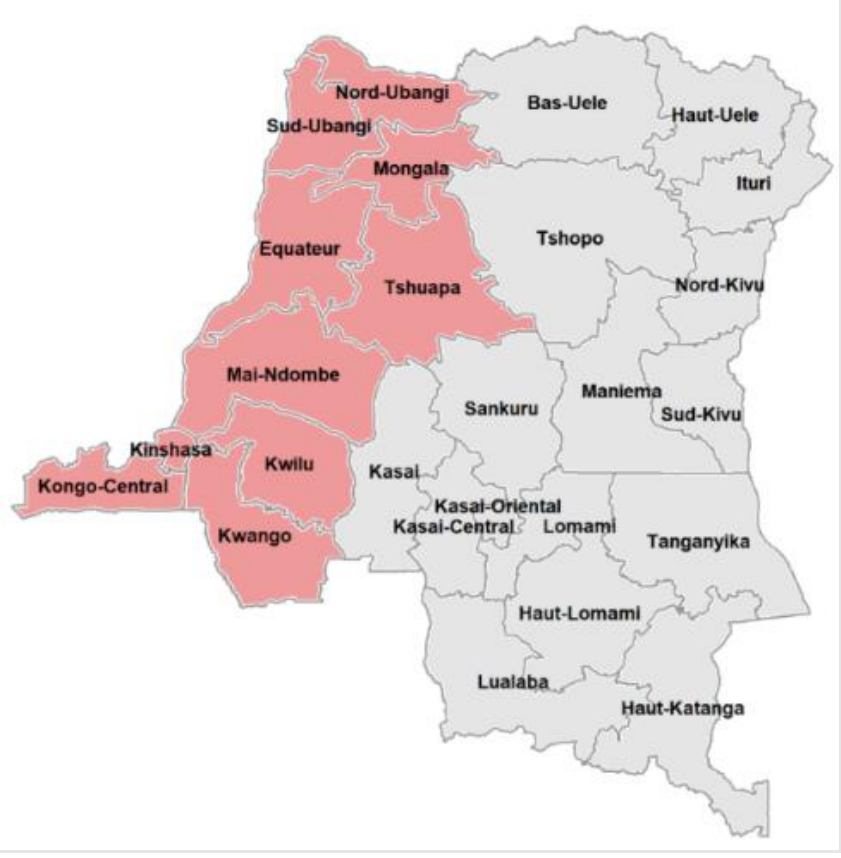
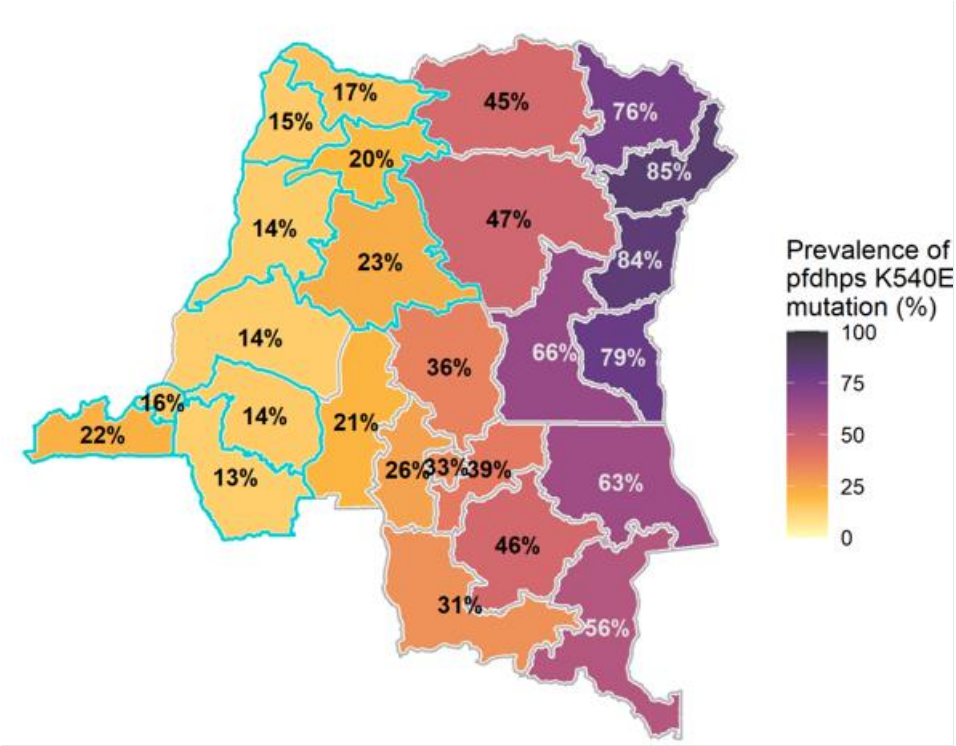


Figure 5. Estimated prevalence of pfdhps mutations (K540) that indicate SP treatment failure.[13]



We have included additional details on the characteristics of each of the provinces in Table 2 below.

Table 2. Relevant indicators for the 10 IPTi-SP targeted provinces.

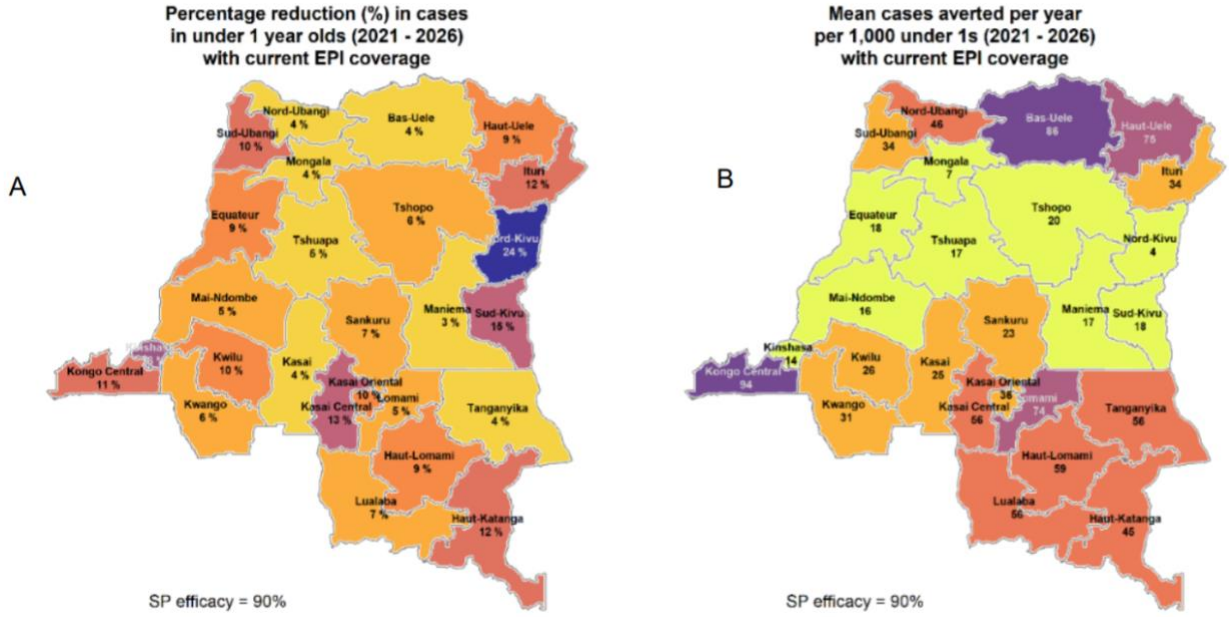
	Population		Malaria					EPI coverage			Socio-economic status		SP resistance	Community care sites
	Total pop[14]	Pop of infants (<12m)[14]	2020 Incidence of clinical malaria per 1000/yr in <5yo[15]	2020 Incidence of severe malaria per 1000/yr in <5yo[15]	2017-18 *P. falciparum* infection prevalence by RDT in children 6-59m[16]	2017-18 % of children <5yo having slept under an ITN the previous night[16]	2017-18 % of children <5yo having had fever in the last 2 weeks who sought care from a health care provider	2017-18[16]/2020[17] Vaccine coverage* of Pentavalent vaccine dose 2 in children 12-23m	2017-18[16]/2020[17] Vaccine coverage* of Pentavalent vaccine dose 3 in children 12-23m	2017-18[16]/2020[17] Vaccine coverage* of Measles vaccine in children 12-23m	2017-18 % of women 15-49yo who are literate[16]	2017-18 % of households in poorest economic quintile	Prevalence of Pfdhps K540E mutation[13]	Coverage of functional community care sites per 1000 pop[15]
Kongo Central	4,183,373	146,000	702	99	40,0%	72%	52%	75% / 87%	69% / 80%	69% / 75%	62%	7%	22%	0.9
Kinshasa	11,477,750	400,573	183	23	11,4%	67%	56%	75% / 96%	60% / 85%	76% / 87%	92%	0%	16%	0.3
Kwango	2,702,910	94,332	706	32	48,0%	42%	49%	37% / 87%	31% / 79%	48% / 85%	47%	27%	13%	0.7
Kwilu	5,672,580	197,973	432	40	46,9%	58%	29%	55% / 92%	25% / 86%	54% / 83%	61%	27%	14%	0.8
Mai Ndombe	2,159,605	75,370	630	53	24,4%	60%	51%	38% / NA	18% / NA	38% / NA	69%	30%	14%	0.9
Equateur	2,828,190	98,704	555	33	39,0%	55%	47%	50% / NA	40% / NA	52% / NA	68%	35%	14%	1.5
Tshuapa	2,254,438	78,680	365	35	49,8%	41%	29%	36% / 57%	27% / 43%	35% / 58%	40%	54%	23%	0.9
Mongala	2,886,050	100,723	734	49	25,8%	60%	36%	22% / 52%	17% / 37%	32% / 50%	46%	37%	20%	0.8
Nord Ubangi	1,693,624	59,107	1015	61	72,6%	52%	26%	34% / NA	28% / NA	39% / NA	30%	41%	17%	0.8
Sud Ubangi	3,351,437	116,965	1122	48	43,3%	76%	49%	48% / NA	37% / NA	43% / NA	37%	30%	15%	1.2

Abbreviations. EPI: Expanded Programme on Immunization; ITN: insecticide-treated bed net; m: months; pop: population; y: year; yo: years old; RDT: malaria rapid diagnostic test; SP: sulfadoxine-pyrimethamine.

Mathematical modeling to inform stratification and intervention mix by strata

The WHO HBHI modeling work, a PATH-led effort in close partnership with the NMP, Global Fund, and WHO, used mathematical modeling to estimate the impact of different packages of interventions in various provinces to support better sub-national targeting of interventions as part of an optimal NMSP.[18] IPTi-SP was modeled in the report assuming the standard WHO recommendations: infants receive a dose of SP at 10 weeks, 14 weeks, and 9 months. The potential IPTi-SP coverage that could be achieved was estimated using EPI data from the 2017/2018 multiple indicator cluster survey (MICS). Data on the estimated percentage reduction in cases in children under one year old and mean cases averted per year in the same age group are included in Figure 6 below. Updated estimates using current EPI coverage, incidence and malaria intervention coverage estimates are presented in section 2.

Figure 6. Malaria cases averted per year in children under one, based on 2017/18 EPI coverage, as presented to the NMP as part of the HBHI work.



Source: Slater H, Siraj A. Modeling the impact of sub-nationally tailored intervention packages in The Democratic Republic of The Congo. Seattle: PATH; 2021.

1.1.3 Existing delivery platforms for IPTi

Current EPI schedule and coverage (DTP2, DTP3, Measles)

The current EPI schedule in DRC is presented in Table 3 below. Immunizations are included as a part of a routine, integrated package of services administered by nurses at health facilities; and not a standalone immunization service. IPTi-SP will be included as a component of this routine package of interventions for infants. Stakeholders from the NMP indicated that nurses are integral to providing these services at health facilities and are perceived by MOH staff to have the capacity to administer IPTi-SP alongside routine immunizations. Currently, no routine health visits occur during a child's second year of life, however senior leadership from the EPI program shared that DRC is considering the introduction of a second dose of Measles vaccine starting in 2022. The introduction of RTS,S could also provide additional touchpoints with infants to leverage for IPTi-SP. EPI coverage data are presented in Table 2 above in section 1.1.2.

Table 3. Current immunization schedule in DRC with touchpoints to layer on IPTi-SP highlighted in green.

Age	At birth	6 weeks	10 weeks*	14 weeks*	9 months*
Immunization provided	• BCG • OPV	• OPV1 • Pentavalent1 (DPT-HepB-HiB1) • PCV1 • Rotavirus1	• OPV2 • Pentavalent2 (DPT-HepB-HiB2) • PCV2 • Rotavirus2	• OPV3, IPV • Pentavalent3 (DTC-HepB-HiB3) • PCV3 • Rotavirus3	• Measles • Yellow fever

BCG: Bacille Calmette-Guérin; OPV: oral polio vaccine: DPT: diptheria-pertussis-tetanus; HepB: hepatitis B; HiB: haemophilus influenzae type b; PCV: pneumococcal conjugate vaccine; IPV: inactivated polio vaccine
*IPTi-SP touchpoints (per current WHO guidance) are highlighted in green.

Immunization coverage at the IPTi-SP timepoints (10 weeks, 14 weeks, 9 months) for 2017-18[16] and 2020[17] are shown in Table 2 (above in section 1.1.2) and below in Figure 7 for 2017-18 and Figure 8 for 2020 with the ten provinces for IPTi-SP consideration outlined in pink (the 2020 Vaccination Coverage Survey did not include all provinces). Coverage estimates for 2020 for provinces not sampled can be generated by scaling up the 2017-18 coverage based on improvements in coverage observed in nearby districts that were sampled in both surveys.

The immunization program is largely donor dependent with 75 percent of immunization funding coming from Gavi and the World Bank.[19] The MOH plans to take action to improve EPI coverage, however this plan depends on external resources for implementation. This will be done through the Mashako 2.0 plan, currently under development by the MOH, which aims to strengthen routine immunization in all DRC provinces with goals to fully vaccinate at least 75 percent of all children by 2023. The Mashako plan is financed by Gavi, WHO, UNICEF, BMGF, and other partners.[20,21]

Figure 7. EPI coverage at 10 weeks, 14 weeks, and 9 months per 2018 MICS survey.[16]

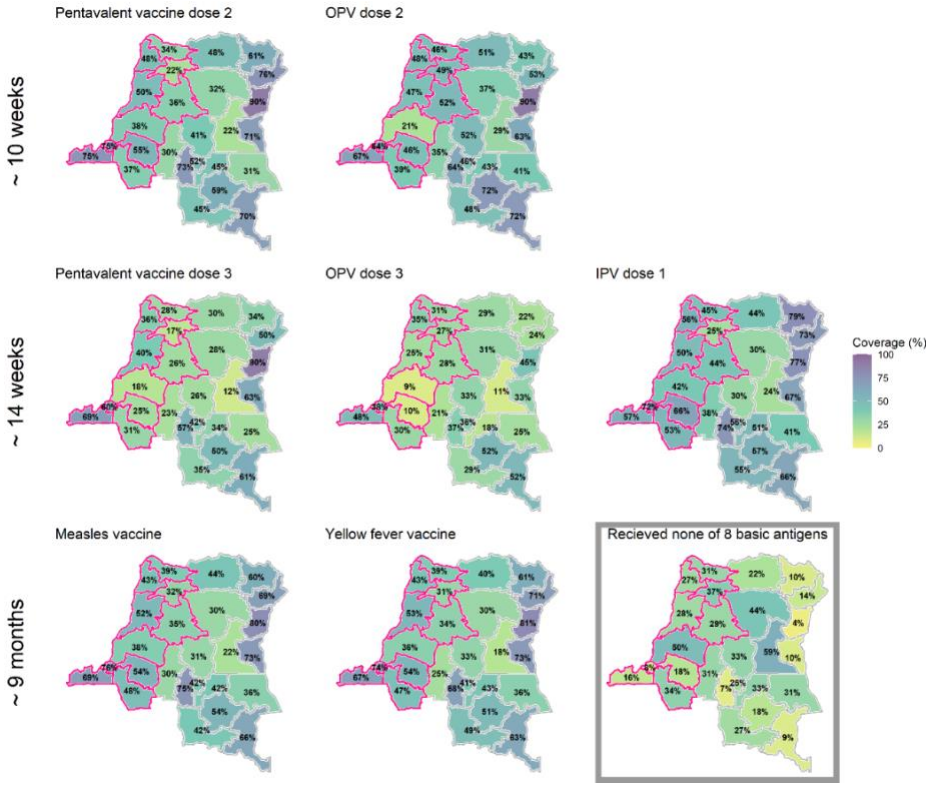
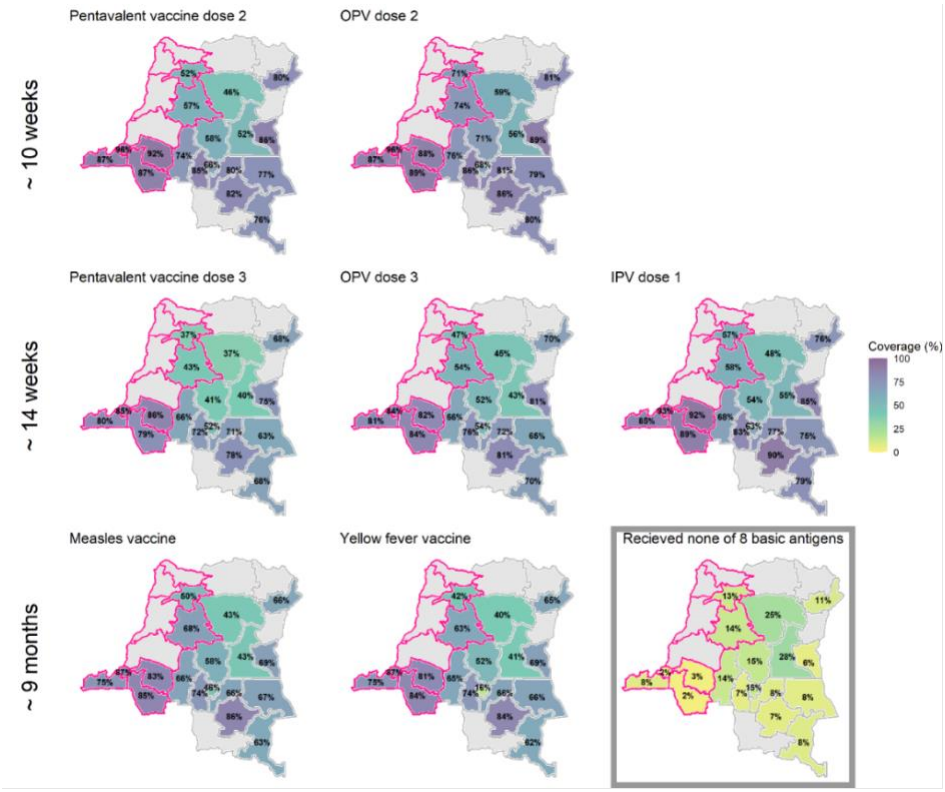


Figure 8. EPI coverage at 10 weeks, 14 weeks, and 9 months per 2020 vaccination coverage survey.[17]



Additional potential IPTi delivery platforms

The updated WHO IPTi guidance is anticipated to be less prescriptive on delivery methods, leaving room to explore other delivery platforms that could achieve greater coverage. For example, there are multiple community-based platforms that could be leveraged for IPTi implementation, including EPI outreach visits, immunization campaigns, and community-based delivery by community health workers (CHW). During the implementation phase of this investment, the team could also map local partners delivering other relevant services, profiling what they currently do in the target areas, and how they could support IPTi delivery. Characteristics of the CHW network in the area selected/eligible for IPTi will also need to be taken into account.

The malaria community case management services are provided by CHWs at community care sites with two CHWs per site. Community care sites are designed to serve hard-to-reach communities residing more than five kilometers from a health center.[22] There are two types of CHWs in DRC: (1) promotional community health workers, and (2) curative community health workers. Curative community health workers are responsible for providing diagnosis, treatment, and referral services. Promotional community health workers focus on health promotion, communication, and community mobilization. Both groups are unpaid volunteers who receive non-financial incentives (phone credit for referrals and data reporting, bicycles, etc.). CHWs receive training every two to three years focused on malaria, pneumonia, and diarrhea diagnosis and treatment, including administration of malaria rapid diagnostic tests (RDTs) and ACTs.[23,24]

In 2020, there were 15,750 CHWs and 7875 community care sites in DRC, covering all provinces and providing services at community care sites in 402 out of 519 health zones. The coverage of community care sites per 1000 in the ten targeted IPTi-SP provinces is shown in Table 2 (section 1.1.2). In stakeholder interviews, MOH officials expressed that, even though coverage is not optimal, CHWs provide an excellent platform to reach communities without access to a health facility. There are plans to expand CHW coverage by adding an additional 1,500 community care cites with an additional 3,000 CHWs (two CHWs per site). In the event of updated WHO guidance, CHW delivery of IPTi-SP at community care sites is another delivery method to consider.

Existing or recent collaborative linkages between the EPI and NMP

IPTi-SP delivery in DRC will require collaboration between two different MOH programs – NMP and EPI. During stakeholder interviews, the NMP confirmed that the NMP and EPI in DRC have a history of collaborating to optimize the delivery of health services. Together, they determine avenues for collaboration at the strategic level that are then implemented at the operational level. The linkages between the EPI and NMP have been mutually beneficial in the past. During the stakeholder interviews, the NMP gave the example of the distribution of LLINs to children who are completely vaccinated at their nine-month visit is a strategy implemented in DRC that is meant to incentivize and increase vaccine coverage. The NMP also uses EPI as an entry point to reach children. For example, children presenting with fever at the immunization visit are systematically screened for malaria using an RDT and treated if positive.

Previous or current operational experience successfully delivering other drug-based interventions for malaria

IPTp, introduced in DRC in 2005, is the only malaria chemoprevention intervention being implemented in DRC currently. It has been delivered successfully for the past 17 years.[25] Currently, IPTp is delivered to pregnant women during routine ANC visits. This strategy is implemented in close collaboration between the NMP and the Maternal, Newborn, and Child Health program. Achieving high coverage has been a challenge

due in part to the low utilization of health services such as ANC. However, the coverage has been improving since 2014.[8] As of 2017, more than 50 percent of pregnant women received their first dose of IPTp and approximately 30 percent received their second dose.[16]

Potential risks associated with integrating SP administration in EPI or other delivery platforms

In general, stakeholders interviewed indicated that IPTi-SP could have a positive impact on EPI performance. The administration of IPTi-SP as a malaria intervention could potentially incentivize the community towards improved EPI attendance, resulting in improved immunization coverage.

The main risk is miscommunication regarding the purpose and potential side effects of SP, especially for infants. To mitigate this risk, it will be important to produce and disseminate communications materials on IPTi-SP and the pharmacovigilance aspects of SP used for IPTi-SP.

MOH program responsible for the implementation of IPTi

The NMP will take the lead on IPTi-SP implementation. Per stakeholder consultations, the NMP and EPI agree that EPI will not play a lead role in IPTi-SP implementation. EPI will, however, be the entry point to reach the target populations as needed and play a role at the strategic coordination level. Other key players include the Maternal, Newborn, and Child Health program which can play an important role in the sensitization of pregnant women during ANC visits, and the Nutrition program delivering nutrition supplementation to children during EPI visits.

At the facility level, all operations are integrated. Health workers at the primary health care level deliver the full package of health services offered at health facilities. The health workers then report the relevant data through the health management information system (HMIS), irrespective of which program is leading the activity at the national level.

1.1.4 Commodity procurement and distribution channels

Current procurement, quantification processes, storage, and distribution channels for malaria-related commodities at the facility and community level

The NMP leads the quantification process for commodities (including for IPTp, SMC, and case management), with support from technical partners and the Programme National d'Approvisionnement en Médicaments Essentiels (PNAME) – the National Essential Medicine Supply Program. The NMP communicates the procurement needs identified through the quantification process[a] to key partners including USAID's Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM), UNICEF, and Santé Rurale (SANRU). The flow of health commodities in the DRC is shown in Figure 9 with the role of each stakeholder involved in this process outlined in Table 4 below.

[a] The quantification process is intended to be bottom up with health facilities quantifying their commodity needs to then be aggregated by BCZS and DPS. In practice, it is a top-down approach with the Central level determining needs based on historical consumption.

The commodity procurement in DRC follows the National Essential Medicine Supply System (Systeme National d'Approvisionnement en Medicaments Essentiels [SNAME]). Depending on the funding source, there are different stakeholders supporting the logistics. For the procurement of malaria commodities, the stakeholders vary depending on whether the province is supported by PMI, Global Fund, or the procurement is funded directly by the government. For all Global Fund supported provinces, SANRU, a local non-governmental organization and one of the Global Fund's principal recipients in DRC, supports all logistics, including procurement and distribution of commodities.[26] Through GHSC-PSM, Chemonics does the same for all PMI-supported provinces.[27] In cases where the government directly procures the commodities, UNICEF manages the logistics and distribution. The Global Fund supports procurement and distribution of commodities in all ten selected IPTi-SP provinces.

Figure 9. Flow of health commodities.

Regardless of the organization supporting the procurement, the commodities are stored at the regional level in distribution centers called Centrale de Distribution Regionales (CDRs). All CDRs are coordinated by FEDECAME (Federation des centrales d'approvisionnement en medicaments essentiels). Each province has one CDR. CDR supplies are then distributed to health zones, where health facilities source their supplies.

Table 4. Stakeholders involved with flow of commodities in DRC.

Name of organization	Role
Programme National d'Approvisionnement en Médicaments Essentiels (PNAME)	Coordinates the national medicine supply chain in the public, private, for-profit, and non-profit sectors.
FEDECAME/ Central Buying Unit (BCAF)	Oversees supplies for the Ministry of Public Health including purchase of medicines and other essential pharmaceutical products nationally and abroad in compliance with price and quality standards; manages the human resources, materials, logistics, medicines, data, distribution, and M&E in the Provinces.
Centrale de Distribution Regionale (CDR)	Stores commodities at provincial level and distributes to health zones.
Provincial health divisions (DPS)	Coordinate interventions for the supply chain at the provincial level, including the management of the supply chains in the health zones.
Bureau Central de Zone de Santé (BCZS)	Estimates the quarterly medicine needs (based on estimates from health facilities) in the Health Zones and makes regular adjustments. Stores and distributes commodities to health facilities.
Health Facility	Estimates need based on consumption and morbidity rates and disperses medicine to patients.[26]

The logistics management information system (LMIS) data is reported through the District Health Information Software (DHIS2); the supply data is reported monthly and visualized through "InfoMed", a logistic data visualization tool managed by PNAME. Health zones and health facilities, however, do not

have a computerized data management system and manually record supply and stock information on multiple paper forms, including the RUMER (drug use and incomes register).[19,26]

Implementation of IPTi-SP would follow the same quantification, procurement, and distribution processes. The cost and storage implications will be discussed with the key partners currently supporting these efforts, including Chemonics GHSC-PSM and SANRU, during Y1 of the implementation of the investment.

Current SP procurement flows

The SP procurement process follows the same flow described above, and procurement of SP for IPTi-SP would align to this same system. This supply chain is already established at health facilities currently delivering IPTp during ANC visits. The tools used by health facilities (and CHWs if they were to distribute IPTi-SP) to track the stock of commodities will need to be updated to incorporate SP for IPTi-SP, along with the HMIS reporting tools.

Brands and dosing formulations of SP currently registered in the country

The tablet formulation of SP (Fansidar® 500mg/25mg) supplied by Iplus solutions is registered in DRC. To date, dispersible formulation of SP is not registered. Given dispersible SP is a new formulation in DRC, it will require an authorization for market distribution, which is issued by the Directorate of Pharmacy and Drugs (Direction de la Pharmacie et du Médicament [DPM]) at the MOH. The authorization for market distribution is an official document designated to approve drugs and authorize the distribution of a product. The approval process for the authorization for market distribution typically takes between 90 and 180 days.[28] Dispersible SP for IPTi will be categorized as necessary for public health interest and will therefore go through an expedited approval process. PATH has the necessary experience to support this process, and this support is included in the implementation plan.

Risks and challenges to SP procurement and distributions

The main challenge will be stock outs. An external review conducted in 2018 showed that 79 percent of Bureau Central de Zone de Santé (BCZS) and 70 percent of health centers experienced shortages in vaccines and/or vaccination consumables.[6] Furthermore, during the 2016-20 period, only 61 percent of health facilities had no stock outs of malaria commodities.[5] The NMP director reported an eight-month stock out of SP in some provinces two years ago and confirmed that proper logistics are now in place to prevent further SP stock outs, including better coordination between the key stakeholders (PNAME, SANRU, GHSC-PSM) and strengthened capacity of operational level staff on quantification and supply management. Partners including GHSC-PSM and SANRU work closely with the MOH to track and manage the proper supply of health commodities. Stakeholders recommend that, during the implementation of IPTi-SP, the team should coordinate with the supply chain partners and the Ministry of Finance to ensure the proper supply of SP and smooth management of the customs process for importing SP.

1.1.5 Assessment of the health information system and data quality for interoperability with other systems and readiness for scale-up

Existing routine surveillance and data collection systems to capture coverage of malaria, immunization, and child health services

Approximately 8,000 health facilities offer immunization services across 519 health zones[22] through fixed services (at heath facilities), outreach, and/or mobile services in DRC. Health facilities and CHWs use a

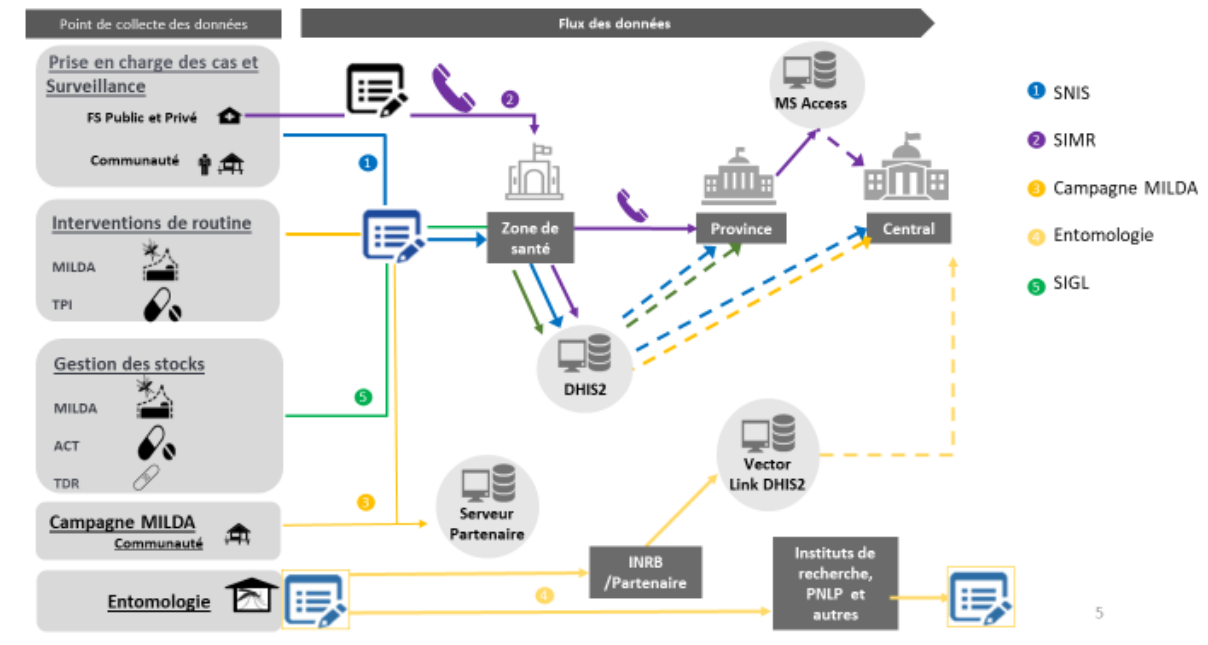
paper-based system to record data in facility immunization registries. Individual vaccines administered are also recorded on Cartes de Consultation Pre-Scolaire, child health cards kept by the mothers/guardians.[22,29] DRC does not have an electronic immunization registry to track individual children, and as a result, only data on the number of vaccine doses administered is reported.[22] The primary method for tracking individual children is by using a "tickler file" which includes detachable coupons from a child's health card which are kept in a file at the facility that corresponds to the month when the child should return, thus enabling health workers to track defaulters.[22] There is no patient reminder or recall system for routine immunizations.

When a child presents for immunization, health facility staff record immunization data in facility paper-based registries. This information is manually aggregated by all doses administered by antigen (vaccine type and dose number) in a paper-based monthly tally sheet that is then sent to data managers at the health zone level. The data managers are responsible for entering the information into theDHIS2. The MOH began the roll out of DHIS2 across all 519 health zones in 2016.[22] Given that service delivery is integrated at the operational level, malaria data follow the same flow as EPI. Information on suspected cases, RDTs performed, confirmed malaria, and severe malaria is recorded on a paper form at the health facilities and by CHWs.

In addition to the monthly reporting, data on cases and death from notifiable diseases, including malaria, are reported weekly under the integrated disease surveillance and response system. The system is paper based until the provincial level where data are entered into DHIS2. Data in the DHIS2 are disaggregated by patients seen by CHWs and those seen at the health facilities, as well as aggregated by under-five or five years and older. Data disaggregated to the first year of life (infancy) is not available. The DHIS2 is used for managing, visualizing, and monitoring routine surveillance data, but not all users have been trained or have laptops and internet access.[22]

The flow of immunization and malaria data in DRC is illustrated in Figure 10 below.

Figure 10. Flow of malaria data in DRC.



PATH just completed an assessment of the malaria surveillance system in DRC,[30] which showed an improvement in data reporting and completeness compared to previous years. However, challenges remain

with data quality, especially data accuracy. Also, DRC's EPI recognizes data quality as a major challenge for improving immunization coverage. Two recent assessments of the EPI surveillance system, including the M-RITE assessment and the 2018 EPI review,[22] found immunization coverage estimates to be inconsistent across data sources due to data quality challenges and population denominators based on outdated census data, as well as recurrent civil conflicts, population mobility, and migration.[22] Additionally, given that the compilation of immunization data is primarily manual, there is room for transcription errors, miscalculations, and inconsistencies in data reporting.

Efforts have been made by EPI to improve the quality of vaccination and surveillance data by providing data collection and reporting tools to all 519 health zones, holding data validation meetings at the national level and in some provincial health divisions (DPS), conducting quarterly DPS program reviews, monitoring for action at the HZ level, and improving utilization of DHIS2.[2] However, M-RITE's assessment identified that sub-national data review meetings were not occurring routinely due to funding gaps.[22]

To successfully track the roll-out and coverage of IPTi-SP, the health reporting tools including child health cards and immunization paper registers will need to be adapted. This investment will need to create data elements to capture and track IPTi-SP implementation (e.g., the number of expected infants; number of infants receiving IPTi-SP1, IPTi-SP2, and IPTi-SP3; stock of SP; and documentation of adverse events). The HMIS Division of the Primary Health Care Directorate manages these tools and will need to be engaged to make the necessary changes, as well as the HMIS Division to incorporate IPTi-SP reporting into the DHIS2.

The successful integration of reporting on IPTi-SP into the HMIS system is a key output (1.4) under the project results framework (section 5.1.1) and completion of integration efforts will be tracked through programmatic reporting. Once IPTi-SP is integrated into HMIS systems, routine reporting on IPTi-SP delivery and SP stock indicators through the HMIS system will be included in program measurement and reported through programmatic dashboards (see section 5.6).

Additional data sources available to triangulate with health system data

In addition to the routine information system, the MOH also uses survey data to complement the EPI and malaria data. These include the vaccination coverage survey, the demographic and health survey (DHS), and the MICS. There is a vaccination coverage survey planned for 2022 to capture immunization coverage in all provinces, and a DHS planned for 2022.

The web-based early warning system in InfoMED (Table 5 below) presents logistics data for 115 medicines (including SP) and vaccines, summarizes health facility stock status by product, and triangulates patient data with logistics data for HIV/AIDS, malaria, and tuberculosis health programs. However, InfoMED does not integrate well with the HMIS and LMIS and can be difficult to use effectively due to limited internet access and electricity and a lack of staff trained on the tool.

There are no additional age-specific data available for all malaria and EPI indicators in children under five. In malaria surveys, prevalence of infection is usually reported for children aged 6-59 months, and in EPI coverage surveys coverage is provided for children aged 12-23 months and, in some cases, also for children aged 6-11 months old.

Current use of digital tools for data recording and reporting and potential to use existing tools to support IPTi-SP data recording and reporting

DRC does not currently use a routine immunization or malaria dashboard to support data analysis and decision making. Various epidemics and more recent efforts to implement COVID-19 vaccination have

accelerated the use of digital tools. For example, during a recent Ebola outbreak, CommCare piloted a project in Kinshasa for electronic payments and registration of staff and CHWs.[26] However, to-date, most digital health tools have only been used in pilot projects in a few provinces and are not disseminated nationally. A few of these tools are described in Table 5 below. With the Agence Nationale d'Ingénierie Clinique d'Information et d'Informatique de Santé (ANICiis), the MOH envisions improving digital health coverage throughout DRC by 2025. Through the USAID-funded Digital Square project, PATH supported the MOH to develop DRC Digital Strategy and Plan for ANICiis and is supporting the implementation of its national plan of public health system digital transformation. The digital tools will also need to be promoted at the community level to gradually replace the paper-based tools.[22]

Of these digital tools, a few are interoperable with the DHIS2, including mHero, CommCare, and OpenClinic. The National Digital Plan for 2025 includes a commitment to leverage digital tools to standardize health information systems.[29] Table 5 describes the digital tools that have been piloted to date in DRC.

Table 5. Digital tools piloted in DRC.

Tool	Current Application
mHero	Combines iHRIS, an open-source human resources information system (HRIS) developed by Intra-Health, and RapidPro, UNICEF's SMS platform that allows users to create SMS messages in a "workflow" through a website. mHero supports one-time messages to health workers or two-way communication between health workers and the MOH. The technology is interoperable with DHIS2.
RapidSMS	DRC is one of five countries supported by UNICEF to implement Rapid SMS, a digital community information system. This free and open-source framework is designed to send and receive data using basic mobile phones, manage complex workflows, automate analysis, and present data in real-time between clinics and CHWs.
GRID3	Uses a participatory mapping approach in which local health workers are trained to collect information on settlements, health facilties, and health boundaries that are combined with population estimates to produce maps to inform micro-planning.
InfoMED	Web-based Early Warning System that provides supply chain information for public health programs to support evidence-based decision making. The dashboard will provide access to stock status and consumption information that will provide forecasting and timely procurement using national and donor resources.
Mashako App	Helps health workers monitor immunization sessions, vaccine stocks, and cold chain performance in real time. The data collected via the app is fed into a national dashboard to help inform rapid, evidence-based decision making at the MOH.

The DHIS2 is designed to securely store sensitive personal data. Hosting for each DHIS2 instance is handled by the owner organization. For example, at the national level, the MOH can define their own parameters for data storage in accordance with local laws and privacy concerns. Whether hosted locally or in the cloud, no outside entity, including DHIS2 software developers, can access patient data unless that access is specifically granted by the owner of the database. Given that IPTi-SP will be implemented through existing systems, the two nationally rolled out digital tools (DHIS2 and InfoMED) will be used to manage routine data and visualize commodity data respectively.

Status of a vital registration system for reporting child deaths

Even though the Ministry of Justice is the official authority in charge of registering a death in DRC into the centralized registry, only a very limited percentage of child deaths are captured through a medical death certificate. Malaria cases and deaths are notified weekly and monthly through the transmission circuit of the national health information system into DHIS2. Currently, the data and quality controls are only performed for internal use. There is no clear process in place to reconcile differences between internal population data and international estimate or survey data.[31] Given the limited nature of these data, they cannot be used to track program impact.

The most recent surveys capturing mortality include the DHS 2013/2014 and MICS 2017/2018. A limitation of the DHS was that only children whose biological mother was available to participate were included in the survey.

Effectiveness of existing national pharmacovigilance system in identifying, reporting, and investigating adverse events and potential safety issues

DRC's National System of Pharmacovigilance, established in 2009, is implemented by the Direction of Pharmacy and Drugs (Direction de la Pharmacie et du Médicament [DPM])/National Pharmaceutical Regulatory Authority (ANRP). ANRP is responsible for identifying, as early as possible, all the adverse effects of health products, especially those that are serious and unexpected. The national pharmacovigilance policy includes ANRP's National Pharmacovigilance Commission, which evaluates the risks incurred by participants in a clinical trial and advises ANRP on the trial's continuation or discontinuation. In addition, the National Pharmacovigilance Center, established within the University of Kinshasa's Unit of Clinical Pharmacology and Pharmacovigilance, receives information on adverse effects of health products and is responsible for establishing accountability and assessing the relative risk. The system is meant to be decentralized, with Regional Pharmacovigilance Centers (RPVCs), which should receive Individual Case Safety Reports from manufacturers, health professionals, and other individuals, and transmit the information to the National Pharmacovigilance Center. Health professionals are trained in pharmacovigilance and have the obligation to notify all suspected adverse effects related to the use of drugs or health products. Pharmacovigilance focal points should ensure the promotion of pharmacovigilance in their health facilities, act as the link between their health facility and the RPVCs, and be responsible for collecting and submitting the Individual Case Safety Reports to the RPVCs.[32]

However, due to lack of funding, the implementation of the RPVCs has not yet started and the National Pharmacovigilance Center is the only functional technical structure.[32] Other weaknesses in DRC's adverse event following immunization (AEFI) reporting system include frequent stockouts of surveillance data collection tools, insufficient training of health personnel in surveillance of vaccine preventable diseases and AEFI, and management of AEFI.[22] Fear of AEFI also contributes to non-vaccination.[22] Overall, pharmacovigilance systems are somewhat limited with low notification rates and timeliness. This investment will support the strengthening of the pharmacovigilance system by training health personnel at implementing health facilities in reporting of medicines adverse reactions.

1.2 Nigeria

Nigeria has the highest burden of malaria in the world, accounting for 27 percent of global malaria cases and 32 percent of the global estimate malaria deaths in 2020.[2] The 2020 World Malaria Report showed the country reported the highest absolute increase in cases of malaria (about 2.4 million) in 2019 compared to

2018. The 2018 Nigeria Demographic and Health Survey (NDHS) showed a nationwide malaria prevalence rate of 23 percent in children under five years of age (microscopy).[33]

The National Malaria Strategic Plan involves adapting multiple prevention strategies which include scale-up of indoor residual spraying (IRS), universal coverage of LLINs, and strategic use of larval source management (larviciding and environmental management), use of IPTp, and strategic deployment of SMC in eligible areas. This aims to provide a universal prompt access to effective case management with emphasis on parasite confirmation before treatment.[34]

The Nigerian Constitution provides the administrative context for the organization of health services. It places health on the Concurrent Legislative List (Section 17(a) of the Part II of the Second Schedule of the Nigerian Constitution, 1999). The public health system of Nigeria is divided into three tiers, each of which is associated with one of the administrative levels of government.

The Federal Government is responsible for tertiary health care and formulates health policies through the Federal Ministry of Health. This level provides specialized services through the Teaching Hospitals, Federal Medical Centers, Specialist Hospitals and Medical Research Institutes.

The State Governments provide secondary health care through the state General Hospitals.

The local governments areas (LGAs) are generally responsible for primary health care services. Both the state and LGAs receive resources from the federation account, a percentage of which is expected to be dedicated to health. The private health sector is registered and supervised by the government. The private sector non-governmental organizations and local communities provide considerable services at all levels of health care.

Federal and State Ministries of Health also have agencies and parastatals under them such as National Primary Health Care Development Agency (NPHCDA), National Agency for Food, Drug Administration and Control (NAFDAC), and State Health Management Boards etc. In the same regard, the LGAs have the Ward Health Committees, Village Health Committees, Private Health Care Providers, and Traditional and Alternative Health Care Providers.[34]

1.2.1 Country demand for IPTi

In 2020, the NMP formally included IPTi with SP to the current 2021-2024 NMSP, signaling a paradigm shift from the previous NMSPs that did not include IPTi (2014-2020 and 2009-2013).[34]

The 2021-2024 NMSP outlines an IPTi evaluation pilot in a carefully selected set of local government areas (LGAs) in non-seasonal malaria chemoprevention (SMC) states in the first three years of the strategic plan to explore the SP resistance profile as well as the impact on reducing malaria burden in infants to inform further decisions.[34] In line with the NMSP and with funding from the Bill and Melinda Gates Foundation (BMGF), Malaria Consortium is conducting implementation research to assess the clinical effectiveness and operational feasibility of IPTi-SP in Ebonyi or Osun State to catalyze decision-making in Nigeria regarding the policy adoption of IPTi-SP.

There is currently no IPTi policy in Nigeria. There have been high level discussions on IPTi policy adoption at the national level. However, subsequent discussions were held following the engagement of BMGF on IPTi-SP through Malaria Consortium. This led to the launch of the BMGF project and IPTi-SP research group, National IPTi-SP Research Policy Uptake Task Team (NIRPUT), by the Honorable Minister for Health in 2021. The IPTi-SP research group, also known as the task team, serves as a central coordinating group with representatives from key stakeholders: Federal Ministry of Health and the National Malaria

Elimination Program (NMP, National Primary Health Care Development Agency [NPHCDA], National Agency for Food and Drug Administration and Control [NAFDAC], WHO, UNICEF, and academia.

The BMGF-funded project (implementation research) on IPTi-SP currently taking place in one of two southern states, Ebonyi or Osun (state selection is ongoing), will be instrumental in providing key information and guidance for IPTi-SP implementation strategies, including:

- Approach for implementation of the intervention.
- The outcome of resistance profile of SP.
- Drug formulations and dosages to be recommended for IPTi-SP.

Anticipated timelines for policy adoption and implementation of IPTi in Nigeria

The BMGF funded project will provide evidence on clinical effectiveness and operational feasibility of IPTi to drive policy adoption and roll out of IPTi in other eligible areas. The tentative timeline for policy adoption is 2023 (interim policy adoption using modeling prediction before the end of the project or in 2024, if research findings support the adoption and scale-up of IPTi-SP).

This investment will contribute to accelerating the scale-up of IPTi-SP through testing scale-up in enough scalable units—reaching four eligible states (Edo, Ekiti, Adamawa, and Ebonyi depending on the state selected) covering factors such as malaria epidemiology/stratification, immunization coverage, and infant mortality in heterogenous implementation settings—before full scale-up to all 21 eligible IPTi-SP states in 2025.

Potential risks of competition between IPTi and other malaria interventions and opportunity costs

There is no anticipated risk of competition between IPTi-SP and other available malaria interventions as IPTi-SP has a distinct population from other existing malaria interventions, utilizes different delivery methods, and is designed to achieve a different outcome in areas of moderate to high malaria transmission in the southern states of the country.

MOH preferred implementation strategy for IPTi

One of the mandates of the NMP is to evaluate malaria programming and review adaptability and applicability of malaria interventions based on context. Although there have been engagements with WHO, NMP notes the need to understand the value proposition of IPTi-SP, as well as other related implications. This was the case for SMC implementation and scale-up following a pilot and assessments. Therefore, NMP doesn't have a preferred implementation strategy at this stage but is very interested in reviewing emerging evidence, in addition to adapting the WHO recommendations for IPTi-SP scale-up in Nigeria.

Malaria Consortium is currently conducting implementation research to assess the clinical effectiveness and operational feasibility outcomes of IPTi-SP for three touchpoints and five touchpoints (in the latter, the additional two touchpoints will be given either in the EPI platform or at the community level) in Ebonyi/Osun State. Evidence from the study will be shared with the NMP to guide the decision-making process regarding the policy adoption of IPTi at the national level.

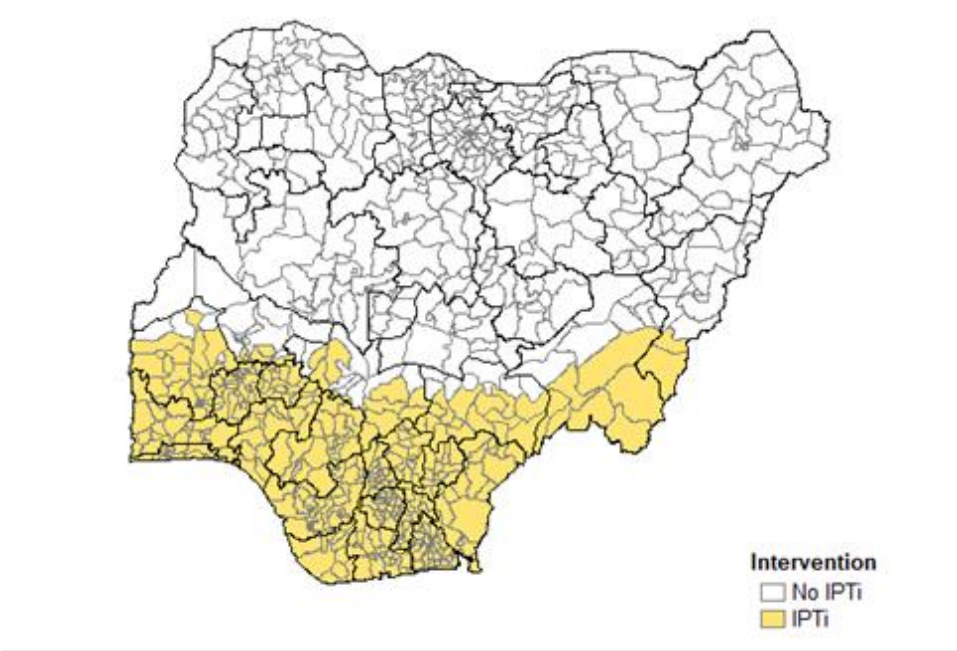
1.2.2 Defining the appropriate epidemiological context for IPTi in Nigeria

In 2019, the WHO/NMP conducted a comprehensive stratification of the malaria context, as part of the HBHI initiative, to provide strategic information to guide a targeted approach to the deployment of malaria

interventions targeted areas according to local disease burden. The epidemiological stratification was based on parasite prevalence (and rainfall covariates), incidence rates (adjusted by reporting rates, health seeking behavior, and testing rates), and all-cause under-five mortality rates and seasonality.[35] The output of this stratification exercise was a Malaria Intervention Stratification Map which identified 15 states, mostly in the Northern region of Nigeria, as having SMC-only eligible areas, while 16 States in the southern parts of the country were deemed eligible for IPTi-SP-only (see Figure 11 below). However, five states (Adamawa, Benue, Kwara, Oyo, and Taraba) have some local government areas (LGAs) eligible for IPTi-SP and others eligible for SMC. The areas mapped for IPTi-SP implementation are therefore:

1. Areas not eligible for SMC;
2. Areas with *Plasmodium falciparum* prevalence rate in children under-five of more than 10 percent in 2018.[35]

Figure 11. IPTi-SP targeted LGAs based on rainfall seasonality and burden (Source: WHO/NMP Stratification).



Malaria Burden (prevalence and incidence)

As detailed in Table 6 below, in the IPTi-SP supported states, malaria parasite prevalence by microscopy in under-five children ranged from above 30 percent in Ekiti (South West region) and Ebonyi (South East region) to 15 percent in Edo (South South region). The prevalence rate for both states was above the 10 percent cut off point used for selecting IPTi-SP targeted areas by the NMP. Analysis of malaria prevalence by place of residence and economic status in the IPTi-SP targeted states was not conducted as these variables/categories were not disaggregated by state. However, at the national level the prevalence of malaria was 2.4 times higher in rural areas as compared to urban areas (31.4 percent versus 12.9 percent). Even more variations were noted based on differences in economic status, malaria prevalence was 6.7 times higher in the poorest quantile as compared to the highest wealth quantile (38.4 percent versus 5.7 percent).[Error! Bookmark not defined.,36]

Table 6. Malaria case incidence and prevalence in the IPTi supported states by population (Source: NDHS 2018, DHIS2).

State	Population			Malaria				
	Total Population [1]	Population of infants (< 12 m)[1]	Population of children <24 months	2019 Incidence of clinical malaria per 1000/year in <5y[2]	2020 Incidence of severe malaria per 1000/year in <5y[2]	2018 *P. falciparum* infection prevalence by microscopy in children 6-59m[3]	2018 % of children <5y having slept under an insecticide-treated bed net the previous night[3]	2018[3] % of children <5y having had fever in the last 2 weeks who sought care from a health care provider
Ekiti	3,683,269	147,331	184,164	14	0.82	32%	54%	62%
Edo	4,764,522	190,581	238,226	32	0.24	15%	54%	78%
Ebonyi	3,213,174	128,527	160,659	287		31%	89%	64%
Osun	5,317,955	212,718	265,898	122		28%	63%	66%
Adamawa^	306,950 ^	15348^	12,278.00 ^			21%	80%	49%

^ Population figures refer to the 2 eligible IPTi LGAs

Analysis of HMIS/DHIS2 2019 data showed that malaria case incidence (cases per 1,000 population at risk) ranged from 287 in Eboni to 14 in Ekiti. Of all the malaria cases in the IPTi-SP targeted areas in Nigeria in 2019, 29 percent were in children under the age of five.[37]

Mortality attributable to malaria

Analysis of Global Burden of Disease (GBD, 2019) estimates for Nigeria shows that malaria accounts for 12.4 percent of all deaths in the under-five children.[38] On the other hand, the 2019 Verbal and Social Autopsy study conducted to estimate the causes and determinants of neonatal and child mortality in Nigeria showed that malaria was the single largest cause of death in children 1-59 months of age (22% in physician-coded diagnosis and 35% in the expert algorithm).[39] The 2019 Verbal and Social Autopsy study data was not disaggregated by state and age distribution (i.e., the proportion of malaria deaths in the first and second years of life are thus not known).

Hospitalizations due to malaria

Analysis of DHIS2 data in Table 6 also shows that a total of 230 under-five children with severe malaria in 2019 and 2020 were admitted for inpatient case management of severe malaria in Edo state. Similarly, 548 and 604 under-five children with severe malaria were admitted for inpatient case management of severe malaria in Ekiti state in 2019 and 2020, respectively. The incidence of severe malaria per 1000 per year in under-five children corresponds to 0.82 and 0.24 in Ekiti and Edo, respectively. Again, the DHIS2 data is not disaggregated by age distribution and thus difficult to know the proportions of hospital admissions associated with malaria in children in the first and second years of life.

Coverage of key malaria interventions

Nigeria uses the “rolling mass campaigns” approach. These campaigns are conducted in different states each year; state selection is staggered for every three years and based on malaria risk, previous malaria

control activities and routine LLIN distribution gaps.40 Nigeria has proven experience and capability implementing programs at scale across the country through mass campaigns. The country distributed a total of 127.9 mililon LLINs through 45 campaigns in 32 states during the implementation of the 2014-2020 NMSP.41 The 2021-2025 NMSP envisages distributing over 282 million LLINs through mass campaigns and routine channels by 2025.34 In the IPTi-SP supported states, a total of 11.6 million LLINs were distributed through mass campaigns between 2014 and 2019 (details in Table 7 below).

Table 7. Number of LLINs distributed in IPTi eligible states from 2014 to 2019 through mass campaigns (adapted from the 2019 MPR report).

State	Total # of LLINs distributed	LLIN mass campaigns (1 net per 2 people per year)					
		2014	2015	2016	2017	2018	2019
Edo	2,110,210	-	-		2,110,210		
Ekiti	1,419,446	1,419,446	-		-	-	
Ebonyi	3,131,357		1,425,748				1,705,609
Osun	2,470,742				2,470,742		
Adamawa	2,511,319				2,511,319		
Total	11,643,074	1,419,446	1,425,748	0	4,982,061	2,110,210	1,705,609

ITN ownership, access, and use

Nationally, the use of ITNs by children less than five years of age was 53 percent in all households and 74 percent in those living in households with at least one ITN.[33] This suggests that ITN accessibility is a key determinant in ITN utilization.Error! Bookmark not defined. In the IPTI-SP targeted states, ITN utilization among under-five children in all households was lower than the NMSP target of 80 percent and national average (53%) in both states. Among households with at least one ITN, the utilization rate in children less than five years of age ranged from 54 percent in Edo and Ekiti states to 89 percent and 90 percent in Ebonyi and Adamawa, respectively (see Table 8 below).[33]

Table 8. ITN ownership, access and use in the IPTi target states and national (Source: NDHS 2018).

States	% of households with at least 1 ITN	% of household population with access to an ITN	% of U5 children who slept under an ITN last night	
			All households	Households with at least one ITN
Edo	57.0	47.7	31.4	53.6
Ekiti	45.3	31.4	26.4	53.6
National	60.1	47.5	52.2	74.3

Nationally, the percentage of children who slept under an ITN decreases with increasing age, from 57 percent among those less than age 12 months to 48 percent among those age 48-59 months. In addition, children under age 5 and pregnant women from households in the lowest wealth quintile (60% and 68%, respectively) were more likely to sleep under an ITN the night before the survey than those from the highest wealth quintile (40% and 38%, respectively).[33] Data on ITN utilization rate in under-five children by economic status was not disaggregated by state in the 2018 NDHS report.

SP resistance

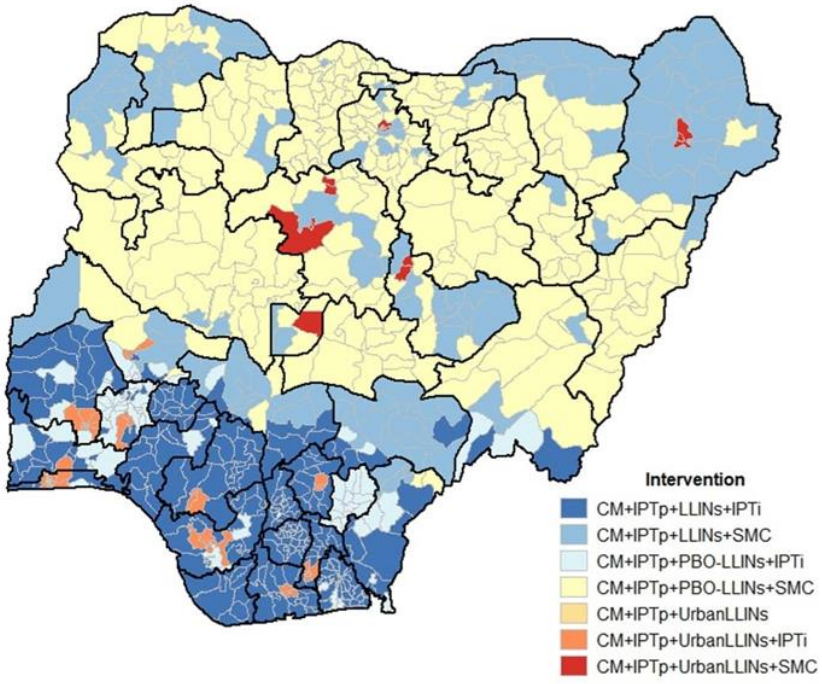
There are limited studies on the molecular markers of SP resistance among infants in the southern part of Nigeria; however, a large-scale observational study by UNITAID-funded Achieving Catalytic Expansion of SMC in the Sahel (ACCESS-SMC) project showed that markers of resistance to SP remained uncommon. The prevalence of the quintuple mutation associated with resistance to SP (triple mutation in pfdhfr with pfdhps-437Gly and pfdhps-540Glu) was 0·4% (0·2–0·8) in 2016 and 0·7% (0·3–1·5) in 2018 (prevalence ratio 1·8 [0·7–5·0).

The BMGF IPTi project is profiling the prevalence of 540E SP resistance in Ebonyi and Osun states. The GiveWell IPTi project will also assess 540E SP resistance in phase 2 eligible states (Edo, Ekiti and Adamawa).

Mathematical modeling to inform stratification and intervention mix by strata

The NMP recently undertook a comprehensive stratification of the malaria context to provide strategic information to guide a targeted approach to the deployment of malaria interventions (see Figure 12). **Error! Bookmark not defined.**

Figure 12. A malaria intervention mix map of Nigeria (Source: WHO/NMP 2019).



A modelling analysis of the impact of four intervention scenarios was implemented:

1. Business as usual (BAU), which is the pre-HBHI approach;
2. A fully funded NMSP updated using the HBHI approach, where 80 percent or more of coverage of core interventions (including IPTi-SP) is achieved in areas where they are targeted;
3. A funding request based on updated NMSPs that limits SMC to five states; and
4. A fund request that increases SMC to an additional five states (Fig. 12).

The analysis showed that the BAU approach will lead to very small reductions in malaria prevalence in Nigeria, whereas full implementation of the sub-nationally tailored NMSP will lead to substantial reductions in malaria prevalence by 2023, infection prevalence in children aged under 5 years will be about 16 percent, a reduction from the estimated prevalence of 28 percent in 2020.[35]

A malaria funding landscape analysis conducted by the NMP shows that current and expected domestic resources and external resources from the Global Fund, PMI, World Bank, and UK Foreign, Commonwealth and Development Office (FCDO) will fund only 50 percent of the total projected budget (about 4.9 billion USD) required to achieve the goal of the NMSP 2021-2025.[34] The government and external resources will fund 44 percent and 6 percent of the NMSP, respectively. However, the government financing for malaria has been inadequate, budgets have not been fully implemented and the funds released are sometimes not managed efficiently.[41]

The Global Fund has allocated $388 million for three malaria grants from 2021 to 2023, whilst the proposed PMI fiscal year (FY) 2022 budget for Nigeria is $68 million.[Error! Bookmark not defined.,36]

1.2.3 Existing delivery platforms

Current EPI schedule and coverage (DTP2, DTP3, Measles)

In Nigeria, the government provides routine immunization services largely through the primary health care system. The National Primary Health Care Development Agency (NPHCDA) is responsible for controlling vaccine-preventable diseases through the provision of vaccines and immunization guidelines. Nigeria has progressively expanded the antigens used in the EPI and currently has 12 vaccine preventable diseases on its EPI schedule (see Table 9).[42]

Table 9. Current EPI schedule for children under two years in Nigeria and opportunities to layer on IPTi-SP (highlighted in green) (Source: NPHCDA).

Ages	At birth	6 weeks	10 weeks*	14 weeks*	6 months**	9 months*	15 months**
Immunization provided	• BCG • OPV • Hep B	• OPV1 • Pentavalent 1 (DPT-HepB-HiB1) • PCV1 • Rotavirus1	• OPV2 • Pentavalent2 (DPT-HepB-HiB2) • PCV2 • Rotavirus2	• OPV3, IPV • Pentavalent3 (DTC-HepB-HiB3) • PCV3	• Vitamin A 1st dose	• MCV1 • Yellow fever • Meningitis	• MCV2 • Vitamin A 2nd dose

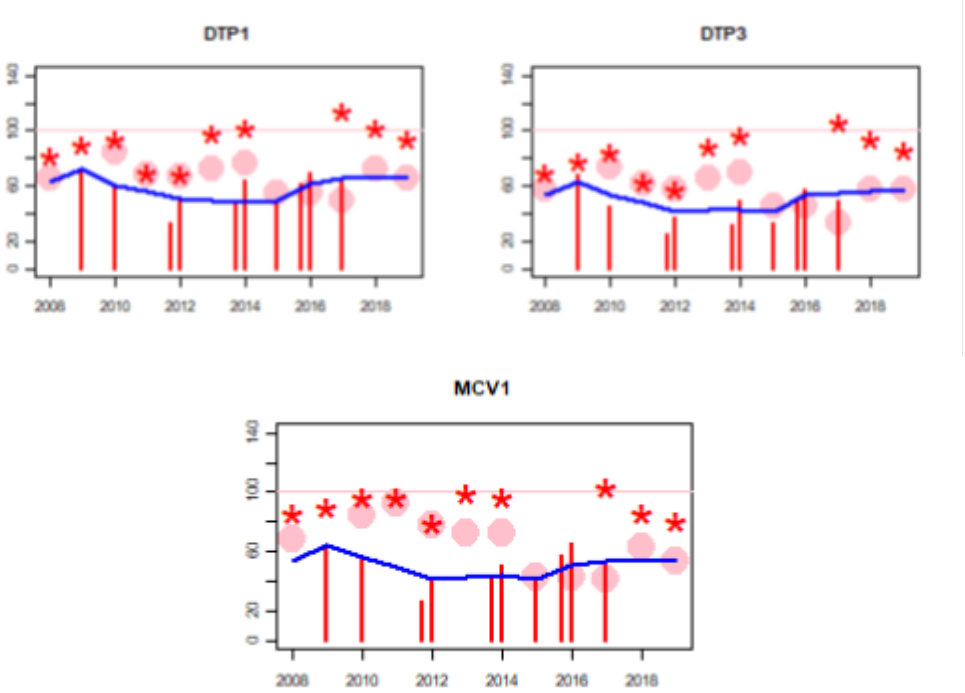
BCG: Bacille Calmette-Guérin; OPV: oral polio vaccine: DPT: diptheria-pertussis-tetanus; HepB: hepatitis B; HiB: haemophilus influenzae type b; PCV: pneumococcal conjugate vaccine; IPV: inactivated polio vaccine, MCV1 measles containing vaccine first dose, MCV2 measles containing 2nd dose (MCV2)

*IPTi-SP touchpoints (per current WHO guidance) are highlighted in green.

** Additional potential IPTI-SP touchpoints are highlighted in gray

Nigeria measures vaccination coverage at state and national levels using three surveys: the Demographic and Health Surveys (DHS), the multiple indicator cluster surveys (MICS), and the National Nutrition & Health Surveys. In recent years, large fluctuations have been observed in Nigeria's survey-based national vaccination coverage estimates.[43] The WHO and UNICEF also review household survey reports annually to calibrate and establish the WHO and UNICEF estimates of national immunization coverage (WUENIC). The latest WUENIC show national immunization coverage for diphtheria-pertussis-tetanus 1 (DPT1), DPT3, and MCV1 standing at 65 percent, 57 percent, and 54 percent, respectively (see Figure 13).[44]

Figure 13. WHO and UNICEF estimates of national immunization coverage of DPT1, DPT3 and MCV1 (2019).



According to the 2018 NDHS, immunization coverage varied widely by zone and state. Penta1 coverage, commonly taken as an indicator of access to vaccination services, was over 80 percent in the three Southern Zones but very low in the northwest and northeastern zones. For penta3 and MCV, however, coverage was well below targets even in southern states. Penta1, penta2, and penta3 coverage was above 86 percent in the IPTi supported states with exception of Adamawa. MCV1 was above 80 percent in two of the IPTi-supported states (Edo and Ekiti) (see Table 10).

Substantial inequalities in vaccination coverage also exist based on differences in economic status, education, and place of residence. Only 24 percent of the children in the poorest quantile received Penta compared with to 54 percent of the children in the richest households. Penta3 coverage is also lower for rural children (38.4 percent) compared to urban children (67.9 percent). Penta3 coverage is also lower in households with no education than those with secondary education (81.2% versus 55.0%).[33,Error! Bookmark not defined.] In addition to socioeconomic and demographic characteristics, other factors seen to have contributed to poor routine immunization performance include ineffective supply chains, poor delivery of services, scarce human resources, low demand for health services, funding gaps, accountability issues and weak governance, and poor data quality. Furthermore, vaccine hesitancy–defined as "a delay in the acceptance or refusal of vaccines despite the availability of vaccine services"–may also play an important role.[45]

Table 10. Vaccination coverage in the IPTi supported states (Adapted from DHS 2018).

State	Penta1 (%)	Penta2 (%)	Penta3 (%)	MCV1 (%)
Edo	86.0	86.0	80.7	80.6
Ekiti	95.0	95.0	93.0	86.4
Ebonyi	95.5	92.1	82.4	64.3

Osun	88.9	88.1	83.5	76.6
Adamawa	80.2	73.0	65.9	65.2

Additional potential IPTi delivery platforms

Other potential IPTi-SP platforms at the health facility level include the well-baby clinic where babies come to the clinic for preventive and promotive healthcare, such as weighing, prophylactic treatments, and immunizations. Additional touchpoints within EPI (at 6 months and 15 months) could also be considered; however, there is currently no evidence demonstrating the clinical effectiveness and feasibility of IPTi-SP within such delivery platform.

Community delivery platforms have been successfully employed to improve the coverage of malaria prevention in some settings. For instance, implementation of community IPTp was associated with an increase in the use of ANC services and uptake of IPTp. As with other public health strategies, community involvement is a key factor in malaria prevention, and it has been shown that CHWs may play a relevant role in promoting public health interventions and in delivering primary health care tools.[46]

Key platforms recommended by stakeholders for consideration include:

- EPI and ANC platforms: Stakeholders interviewed acknowledged that based on the objective of IPTi-SP, which targets infants under one, the best platform to deliver IPTi-SP is through EPI. In addition, ANC visits present an opportunity for pregnant women to be sensitized on IPTi-SP, in order to vaccinate their children when born, especially since it is free. IPTi-SP can serve as motivation for vaccination. Also leveraging on some of the structures set up for IPTp, ANC can support the drive for demand creation.
- Nutrition platform: Another platform to leverage IPTi-SP is through community-based management of malnutrition (CMAM)[b] program offered at nutrition clinics. This could be considered for states where CMAM program is implemented.
- Community health structural platforms: IPTi-SP can also be implemented through the Community Health Influencers and Promoters Services (CHIPS) platforms currently being implemented in a few Nigerian states. However, this would require advocacy to the Executive Director of the NPHCDA (see details below on the CHIPS platform).
- LLIN distribution platform: could be considered but would require engagements with the Advocacy Community and Social Mobilization (ACSM) to create awareness and demand creation.
- Family Health platforms: the TIPTOP[c] project used family health platforms to deliver IPTp. Family Health has a unit known as the Reproductive Maternal Neonatal Adolescent and Child Health (RMNACH), through which it coordinated engagements on IPTp. Though NMP has malaria-RMNACH, it still engages with the Family Health units often.

Characteristics of the CHW network in the area selected/eligible for IPTi

In Nigeria, Community Health Extension Workers (CHEWS) are engaged to support primary health care across the country. CHEWS is a certification program, whereby personnel attend an 18-month course to become qualified and certified. They attend the School of Health Technology and work within the community

[b] Community-based Management of Acute Malnutrition

[c] Jhpiego led IPTp program – Transforming Intermittent Preventive Treatment for Optimal Pregnancy (TIPTOP).

from a health facility. There are also other community-based health workers such as the Community Resource Persons (CORPS) and Village Health Workers (VHWs), and the CHIPS.

The National Public Health Care Development Agency (NPHCDA), which has the mandate to implement community level services, adopted a new community health workers' model called CHIPS. The CHIPS strategy seeks to transition all current community-based workers from programs that are phasing out into a single national program. The CHIPS program is made up of one category of community-based workers – the CHIPS personnel, made up of CHIPS Agents and Community Engagement Focal Persons. A minimum of ten CHIPS agents, preferably females, are trained in each political ward. They are responsible for working at the household level to provide counselling, create demand, and refer household members to primary health care facilities for the uptake of needed services. Also, they provide basic preventive services, case management of fever, cough, and diarrhea in children under five years and first aid services. These CHIPS personnel will work on average for three days per week on a volunteer basis.[47]

As of October 2021, 19 states across the country are currently in the implementation phase with all states in various stages ranging from state training of trainers to full deployment of CHIPS Personnel. Two of the targeted states (Ebonyi and Adamawa) for phase 2 GiveWell IPTi implementation have completed training of selected CHIPS Personnel but are yet to deploy to commence service provision.

Existing or recent collaborative linkages between the EPI and NMP

The NMP/State Malaria Elimination Programs (SMEPs) have collaborative engagement with health facilities for continuous distribution of LLINs through ANC and EPI. At antenatal clinics, one LLIN is given to pregnant women during their first visit. In EPI clinics, children under five years are given one LLIN each during one of their routine vaccination visits to the health facilities. LLINs have been delivered with measles vaccination, which is scheduled at nine months of age or in other settings, with DTP3 at 12–14 weeks.[48]

NPHCDA[d] collaborates with the NMP on IPTp implementation for pregnant women to ensure SP and other IPTp commodities are available during antenatal clinics. NPHCDA also collaborates on SMC campaigns, and for COVID-19 vaccine sensitization in the states.

The collaboration between NMP and NPHCDA was mostly through the TIPTOP/IPTp program. The experience from this engagement witnessed a gradual process to ensure effective collaboration which was facilitated by high-level engagement between heads of both agencies; the National Coordinator of NMP and the Executive Director of the NPHCDA. Subsequently both organizations have conducted joint review meetings on other joint projects such as the SMC program.

Management of primary health care workers and reporting

In Nigeria, primary health care workers are state employees and not employed by the Federal Government. However, management of state health workers is coordinated by the State Primary Health Care Board who currently have autonomy for oversight functions and reporting. There is no direct management of primary health care workers by the NMP; however, service providers have, as part of their routine responsibility, the mandate to complete various registers and patient cards. They should ensure that information on LLINs given out during routine ANC/EPI visits are recorded in the registers/patient cards and are also transferred into the HMIS registers. The health facilities should also endeavor to adhere to data flow mechanism by

[d] The EPI coordinating agency.

sending their data to LGAs, which in turn would send to state and eventually to the national office for aggregation and national reporting.[48]

Previous or current operational experience successfully delivering other drug-based interventions for malaria

The NMSP (2014-2020) recommends SMC in nine states in the Sahel region: Sokoto, Kebbi, Zamfara, Bauchi, Katsina, Kano, Jigawa, Yobe, and Borno.[49] Malaria Consortium has been implementing SMC programs in northern Nigeria since 2013, and currently operates in a total of seven States comprising of three Global Fund (GF)-supported States (Kano, Katsina and Yobe States) and four Global Alliance for Vaccines and Immunization [Gavi]-supported States (Bauchi, Jiagwa, Kebbi and Sokoto States).[50] The remaining two states (Zamfara and Borno) were supported in 2020 by PMI and the Global Fund, respectively.[51]

The IPTp TIPTOP program was also noted to be successful. Preliminary results from the recently concluded endline survey have shown the program was successful compared to baseline. The results and outcomes from the TIPTOP project are expected to be published shortly. The challenge will be to sustain and improve on results. The TIPTOP program was led by Jhpiego and included other stakeholders such as the NPHCDA, NMP, Family Health department.

Potential risks associated with integrating SP administration in EPI, or other delivery platforms

Low EPI coverage could affect the clinical effectiveness and operational feasibility of delivery of SP, as well as the uptake of IPTi-SP. Two of the 16 IPTi-SP eligible states (Bayelsa and Ogun) have low Penta1 and Penta2 coverage (less than 70 percent).[33] There are also a number of demand and adoption barriers that prevent uptake of IPTi-SP by healthcare providers and caregivers. An end user perspective study on IPTi-SP implementation within the EPI delivery platform in Sierra Leone identified workload (with crushing the tablets being the hardest and most time-consuming step of the treatment); limited access to commodities, such as clean water and cups; and the lack of training of staff/nurses due to high turnover rates.[52]

On the other hand, there was no evidence of adverse effects of IPTi-SP on infants' serological response to EPI vaccines (DPT, Polio, Hepatitis B, Hib, yellow fever, and measles).[53] IPTi-SP was also shown to have a positive impact on EPI performance. A cluster randomized control trial in Mali showed an increase in EPI vaccines coverage after one year of implementation of IPTi-SP using routine health services (69.5% in the IPTi-SP intervention zone compared to 53.8 percent rise in the non-intervention IPTi-SP zone).[54]

MOH program responsible for the implementation of IPTi

IPTi-SP implementation should ideally be a collaborative responsibility between (1) NPHCDA, who would lead immunization activities, and (2) the NMP leading of malaria activities. This should be reviewed at policy development stages which will include reviews of responsibilities and targets.

In July 2021, the Federal Ministry of Health (FMOH) inaugurated the NIRPUT to serve as a source of support for knowledge management and engagement with key national and subnational stakeholders to increase the likelihood of uptake and acceptability of the findings from the BMGF-funded IPTi-SP effect research project.

1.2.4 Commodity procurement and distribution channels

The National Supply Chain system for the malaria program is coordinated by the Procurement and Supply Chain Management branch of NMP, which coordinates the forecast and quantification of malaria health product needs of the country. The procurement of malaria health products by Government and

donors/implementing partners, is based on the national quantification outcome and donor commitment to the specific state(s) being supported. The malaria supply chain has three storage levels: National warehouses (Lagos and Abuja), Axial or Zonal warehouses (Lagos-South West; Gombe-North East; Sokoto-North West; Abuja-North central; Cross River-South south and Anambra-South East) and the State warehouses.[34]

Presently, Government of Nigeria and donor-procured commodities flow from two national pharmaceutical grade warehouses (Abuja and Lagos) to regional/axial stores and then directly to health facilities, bypassing state warehouses. The warehouse management and distribution are outsourced to private logistics providers. The regional distribution system is meant to be a medium-term solution. As states upgrade to pharmaceutical grade warehouses, distributions can again take place from the state level to health facilities, coordinated by the state logistic management coordination unit.[36]

At the health facility, the health products are received, and the Proof of Delivery (POD) signed off confirming receipt of quantities issued from the axial warehouses. Each health facility has LMIS tools for reporting and recording transaction. The Bimonthly Facility Stock Report is used to generate logistics report at the health facility every two months. The report is collected by the LGA logistic management coordination unit and transmitted to the state coordination unit for entering into the National Health Logistics Management Information System to generate the malaria logistics dashboard and the Last Mile Delivery plan. The Last Mile Delivery plan drives the bimonthly re-supply of malaria health products to the facilities.[34]

The primary health care facility serves as an operational logistics hub for the distribution of commodities for community- based health services.[41] NMP engages with National Agency for Food and Drug Administration and Control (NAFDAC) for waiver and importation processes.

Current SP Procurement Flows

The procurement of SP follows the same Procurement and Supply Chain Management channel as described in section 1.2.4.

Over the years the Global Fund, PMI/USAID and UK FCDO Foreign, Commonwealth and Development Office (under SuNMaP and SuNMaP2) supported the procurement and distribution of SP to health facilities for IPTp and community-based SMC implementation. Currently, the state governments are expected to provide SP for IPTp as part of co-financing contributions using a portion of their Basic Healthcare Provision Fund. **Error! Bookmark not defined.**

Brands and dosing formulations of SP currently registered in the country

SP with 500mg + 25mg formulations (tablet/oral liquid) is included in the 2020 Nigeria Essential Medicines List.[55] SP is marketed in Nigeria under several brand names including Fansidar, Amalar, Antimal, Astab, Celoxine, Dupridox, Malareich, and Laridox.[56] In Nigeria, Emzor and Swipha are currently in the process of securing WHO prequalification for infant and adult formulation of SP. However, Escant (in India) has received WHO prequalification for infant formulation of SP, and Nigeria would be leveraging this for IPTi-SP implementation.

Dispersible tablets of SP in pediatric formulation are not currently available in the country. However, Malaria Consortium has imported limited quantities of WHO pre-qualified SP dispersible tablets of 250mg + 12.5mg for its BMGF-funded IPTi-SP project in Ebonyi or Osun depending on the state selected. WHO prequalified SP is accessible for procurement in Nigeria.

Malaria Consortium is also working with the Nigerian pharmaceutical manufacturers to plan for quality-assured infant dose dispersible SP production in Nigeria. If successful, this will ensure the availability of quality assured pediatric formulation of SP for this investment in Edo, Ekiti, Ebonyi and Adamawa states. In addition, Malaria Consortium will work with the NMP/SMEPs' branches on storage and distribution of quality assured dispersible SP to ensure no stock outs at service delivery points in Ekiti and Edo states.

Increasingly, there has been more access for local procurement of SP, as in-country sourcing of SP has proven to be more cost effective compared to importation.

There is a recurring engagement between NMP and NPHCDA since the inception of SMC in 2011. This waiver system has been adapted for the procurement of SPs, which is done annually.

Central procurement and subnational distribution channels

The LMIS is used for commodity procurement, distribution, and tracking. This is used for data extraction and analysis, especially for triangulating commodity and implementation data. On a biannual basis, an LMIS – HMIS triangulation meeting is held. Other analyses conducted for commodity procurement include comparing national level data with data collated from Health Facility monthly forms. This sort of data triangulation started in 2018 on a pilot basis and has been conducted biannually since 2019. This has resulted in a gradual close in variance, as there were huge data gaps previously which affected quantification for state procurement and distribution. This triangulation and data validation occur mostly in the 13 PMI-supported states and need to be scaled up.

The triangulated quantification processes have allowed linkages from procurement to service data to inform decisions; this is aggregated to form fulcrum for requests and quantification done for 3-to-5-year periods. Vaccines are procured by UNICEF with support from various development partners. The government's contribution towards procurement is in the form of co-financing for of GAVI supported vaccines. The vaccine supply chain consists of the National Strategic Cold Store in Abuja and six Zonal cold stores located in the six geopolitical zones of North-Central (Minna), North–West (Kano), North-East (Bauchi), South–West (Lagos), South-East (Enugu) and South–South (Warri). Distribution of vaccines and immunization supplies is mostly by road to all thirty-six states of the federation plus the Federal Capital Territory through the Zonal cold stores. There is a relatively good all-weather road network from the Federal Capital to all state capitals. The distribution system is a push system from the national to the zonal and state stores. Most LGAs make monthly trips to the states to collect vaccines and dry materials for immunization. Health facilities collect vaccines on scheduled immunization days using either cold boxes or vaccine carriers where storage facilities are not available. In health facilities with cold storage capacity, vaccines are collected on a monthly basis and stored for use during sessions.[57]

Risks and challenges to SP procurement and distributions

In the past, there were challenges with SP availability in Nigeria for IPTp. In some areas, there have been other associated challenges resulting in poor commodity management, which has included poor capacity of health workers for data management, which has contributed to SP stock outs, particularly in some northern states. Fewer stock outs were experienced in southern states who received support during the TIPTOP program for IPTp. The TIPTOP program also engaged with the private sector which was instrumental in addressing and mitigating issues of stock outs.

TIPTOP states have not experienced stock out of SP as workers are well trained and documentation is done properly due to training received and support from Jhpiego. Currently there is a national ban on the importation of SP. Malaria Consortium obtained a national import waiver and procured limited quantities of

WHO pre-qualified SP dispersible tablets of 250mg for its BMGF-funded IPTi-SP project in Ebonyi/Osun state.

Malaria Consortium is also working with the Nigerian pharmaceutical manufacturers to plan for quality-assured infant dose dispersible SP production in Nigeria. If successful, this will ensure the availability of quality assured pediatric formulation of SP for this investment in Edo and Ekiti states. In addition, Malaria Consortium will work with the NMP/SMEPs' branches on storage and distribution of quality assured dispersible SP to ensure no stock outs at service delivery points in Ekiti and Edo states.

Current pharmacovigilance system for SP

Pharmacovigilance of SP is NAFDAC's area of engagement, and it is a relatively new process for SP being used for IPTp. There is a standard process which should also be considered for IPTi-SP, especially for event monitoring because of the younger age group (10 weeks). Pharmacovigilance for SP as part of co-blistered SPAQ has been conducted for children as young as 3 months during SMC.

Each year, NAFDAC is responsible for training SMC health workers on a module on pharmacovigilance which Malaria Consortium has helped to develop and facilitate. It is expected that these training materials can be adapted for IPTi-SP. Presently, health facilities have national pharmacovigilance forms and know how to complete them.

Late last year an app called *Medsafety* was launched, with the aim to phase out paper-based forms. The app is free and accessible via android phones. It enables real-time reporting of suspected adverse events to medicines (mild, moderate, and severe). The *Medsafety* app is directly routed to the Uppsala Monitoring Centre (UMC); a conduit between the national information system and UMC. The report to the UMC is transmitted directly and on a daily basis.

A severe adverse event requires immediate reporting, and with the app data is reflected in real time. It is compulsory to have the Adverse Drug Reaction (ADR) system set up for all programs which engage in procurement processes through the waiver systems as they are exempted from going through the standard rigorous processes. The NMP has a pharmacovigilance focal person, as it is a requirement for all the public health programs.

Where there are reports on ADR, the pharmacovigilance unit engages with the programs and manufacturers to conduct reviews and make recommendations, such as adjusting dosages, as applicable.

There are very few cases of severe ADR reported during SMC, but the sulfa derivative of SP has been associated with serious but rare allergic reactions (anaphylaxis), which can include difficulty breathing, chest tightness, or swelling of the face, lips, or tongue, or Stevens-Johnson syndrome—a severe exfoliative body rash which can be life threatening. Therefore, careful consideration should be given to ensuring proper prescription of IPTi-SP and right dosage of SP.

1.2.5 Assessment of the health information system and data quality for interoper ability with other systems and readiness for scale-up

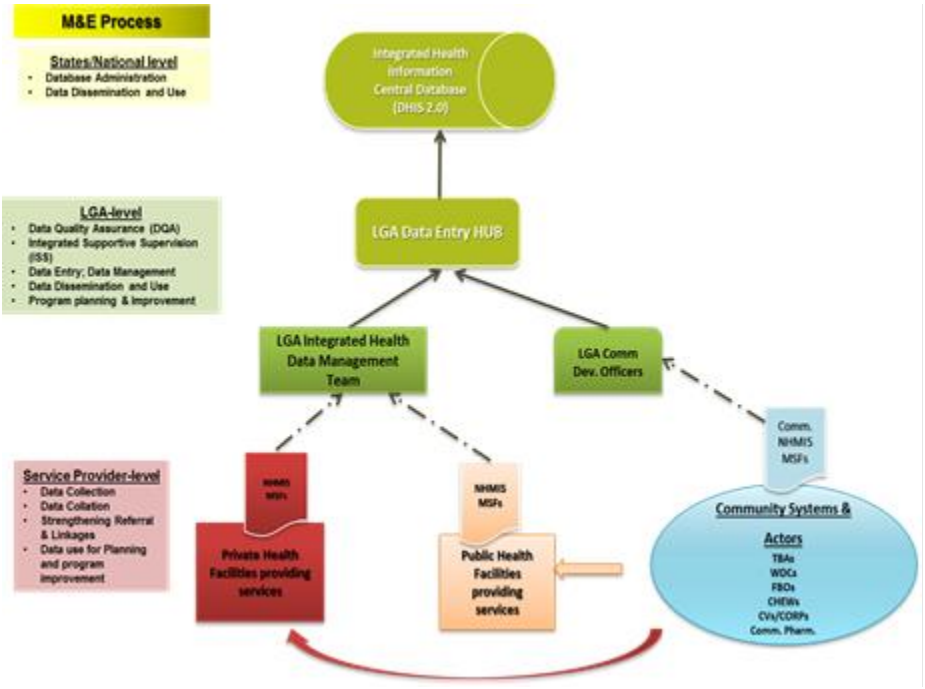
Existing routine surveillance and data collection systems to capture coverage of malaria, immunization, and child health services

Routine malaria data reporting from all HFs is fully integrated into the DHIS2 under the national 'one' health information system (HIS) that also captures other program data such as that from reproductive, maternal,

newborn, child and adolescent health and nutrition; non-communicable diseases; HIV; and TB.[Error! Bookmark not defined.]

As detailed in Figure 14 below, Nigeria's current malaria surveillance landscape begins with paper-based data collection at the facility level, which is aggregated by facilities and reported to the LGA on a monthly basis. LGAs enter HMIS data electronically into the DHIS2 platform. State and National Malaria Elimination Programs have access to view these data and provide quality audits, but they do not generate primary data. LGA, state, and national program members then can analyze and use these data for programmatic decision-making and quality assurance.[58]

Figure 14. Data flow from the health facility level to national level. (Data source: NMP Standard Operating Procedure for data management, Sept 2021)



The DHIS has been fully rolled out nationwide across all LGAs where facility-level (largely primary health care) data are entered into DHIS2.[41] The private sector contributes less than 30 percent of the current HMIS data to the HMIS, although patent and proprietary medicine vendors (PPMVs), community pharmacists, and private clinics are the first resort for malaria treatment for >60 percent of those seeking care. Despite all the efforts and investment in the national DHIS, challenges and gaps still exist in the reporting and availability of data for action across all levels of care. Although 33+1 states are now reporting through the DHIS platform, there are thought to be 1,029 facilities not reporting.[Error! Bookmark not defined.]

Additional data sources available to triangulate with health system data

Population-based household surveys, such as those conducted through DHS, MIS, and MICS provide best estimates for child health outcomes in Nigeria. Such information, including infant mortality, malaria prevalence, coverage of key malaria interventions, and EPI coverage can be used for triangulation with routine health facility data (HMIS/LMIS).

Recently the NMP launched National Malaria Data Repository that captures both routine malaria data synchronized from the national DHIS and non-routine data existing in excel and other third-party applications. It serves as a decision support tool for malaria stakeholders at all levels in the country.[59]

There are certain key data reported by EPI and Routine Immunization, captured on the DHIS. However, there might be other types of data captured by agencies like the NPHCDA that are not transmitted to the DHIS platform.

There are a variety of datasets for child health—immunization, LLIN uptake and other child health and malaria programs.

Additional age-specific data available for all malaria and EPI indicators in children under five

Currently, malaria and EPI indicators and data reported through the routine surveillance system and those captured from DHS and MIS are only available for under-five children and do not include additional age-specific level disaggregation.

Community-level data Reporting

Malaria case data are collected at the community level. CHIPS/Community Oriented Resource Persons (CORPS) and PPMVs collect treatment and commodity use data on children under 5 years old using the Home Management of Malaria Register and summarize data monthly on the community HMIS form. In the public sector, CHIPS/CORPS submit the data forms monthly to designated health facilities. In the private sector (e.g., PPMVs), data are meant to be collected from the PPMVs.

Since public sector community data are mostly tied to health facilities (i.e., their data are submitted to the health facility from which they receive their malaria commodities), a major challenge is that the community data are often either missed or grouped fully with facility data. Furthermore, private sector community (e.g., PPMV) data are usually not collected and/or not included in DHIS2. These gaps in community-level and PPMV data limit an understanding of the full malaria picture nationwide, as these sectors are the source of first care for a substantial share of malaria cases.[58]

Current use of digital tools for data recording and reporting and potential to use existing tools to support IPTi data recording and reporting IPTi

Digital tools are not deployed at scale due to gaps in local capacity, lack of trained personnel, and other infrastructural challenges such as access to computers and internet facilities. However, at state and national level, Kobo Collect (a data collection app) is used to collate and upload summary health facility data. There are discussions on scaling up adaptable software to be used on android phones to enable gathering minimal information for ease in tracking.

Onsite electronic reporting has been rolled out for secondary and tertiary health facilities under the current Global Fund grant with phased implementation also planned at primary health care level to improve reporting rates, timeliness, and data quality.Error! Bookmark not defined. The NMP currently uses electronic tools (Kobo Collect) for supportive supervision and data quality assurance activities. Kobo Collect is a free open-source tool for mobile data collection.

Status of a vital registration system for reporting child deaths

Child mortality is reported on the DHIS platform and collated from routine Health Facility data. There are some issues with reporting causes of death. The Nigeria Demographic and Health Surveys (NDHS), which are carried out every five years, provide information on levels, trends, and differentials in perinatal, neonatal, infant, and under-five mortality rates.[33] Recently, as a follow-up to the 2018 NDHS, the country conducted the Verbal and Social Autopsy Study to estimate the causes and determinants of neonatal and child mortality.[39]

Effectiveness of existing national pharmacovigilance system in identifying, reporting, and investigating adverse events and potential safety issues

Pharmacovigilance activities in Nigeria are coordinated by the National Pharmacovigilance Centre (NPC) situated in the National Agency for Food and Drug Administration and Control (NAFDAC), the drug regulatory agency in Nigeria. NPC serves as a repository for reported ADRs from various stakeholders including patients, health care professionals, health institutions and Marketing Authorization Holders across the country. NPC also liaises with other international groups such as the WHO, US Food and Drug Administration and the European Medicines Agency in improving drug safety in Nigeria.[60] ADRs are reported using ADR forms (also known as yellow forms). NPC also uses a digital tool, *Medsafety*, an app for reporting adverse drug reactions. The BMGF funded IPTi-SP project also intends to use the *Medsafety* app for reporting ADR during the implementation of IPTi-SP. A study conducted to evaluate the pharmacovigilance system performance in South-South Nigeria showed that only 12 percent of the 811 healthcare professionals had ever used the national ADR reporting form and there were few adverse drug reaction reports in the local hospital databases. These were attributed to insufficient awareness of pharmacovigilance on what can be reported, poor reporting processes, wrong beliefs that their reporting will not make a difference and difficulty in determining what to report.[61]

2 Modelling the potential impact of IPTi in DRC and Nigeria

Mathematical modelling can be a useful tool to estimate the potential impact of novel and existing malaria interventions. Models have been used widely to support global decision-making and planning for many malaria interventions, including the RTS,S vaccine, new IRS chemicals, and new LLINs.[62-64] In this section, PATH/Malaria Consortium applied two established models to support decision-making around IPTi-SP strategy. Existing models that had been previously carefully calibrated to capture the transmission dynamics of DRC and Nigeria were used to estimate the potential impact of IPTi-SP on malaria burden. The models can be used to estimate the impact of IPTi-SP as it is currently recommended (i.e., 3 doses of SP at 10, 14 weeks and 9 months), as well as to consider alternative implementation approaches such as additional doses, extending the intervention to older age groups, or increasing coverage. The models also estimate the impact of the intervention on different malaria indicators, including incidence of uncomplicated malaria, incidence of severe malaria, and prevalence of malaria parasite infection.

2.1 Overview of models

Two mathematical models are used in this analysis: (1) DRC outputs are formulated using the Imperial College malaria transmission model; and (2) the Nigeria outputs are formulated using EMOD, a model developed by the Institute for Disease Modeling.[65,66] Both these respective models have been used to support Global Fund applications and sub-national tailoring efforts as part of the WHO-led High Burden to High Impact (HBHI) initiative.[67] The models are individual-based stochastic models, meaning that each individual's variation is explicitly considered in terms of their age, their immunity, the malaria interventions they use, and their propensity to get bitten by mosquitoes that transmit malaria. When an individual receives an infectious mosquito bite, they have a certain probability of developing either symptomatic or asymptomatic malaria depending on their level of immunity. Individuals developing symptomatic malaria will either receive effective diagnosis and treatment or have ongoing infections which eventually become asymptomatic. Once an individual receives treatment it is assumed that they will be protected against subsequent infections for a time period determined by the effective duration of the antimalarial they were treated with before becoming susceptible again. All individuals developing clinical malaria have a probability of developing severe malaria and dying. Asymptomatic individuals can either slowly clear their infections or get re-infected and become symptomatic (or asymptomatic again). All the key parameters in both models that describe the fundamental epidemiological processes (i.e., infectivity, duration of infection, immunity, age-based heterogeneity, mosquito dynamics) have all been extensively fitted to multiple data sources from a large number of endemic countries and have been widely published elsewhere.[68,69]

2.1.1 Model calibration

As part of the HBHI modelling process, both models were calibrated to either prevalence or incidence data from Nigeria and DRC at both the first administrative and second administrative levels. For brevity, this report focuses on outputs at the first administrative (province) level. The calibration process involves collating historical data on intervention scale-up to ensure that the models are able to capture the impact of increasing intervention coverage on changes in malaria incidence and prevalence over time. This typically consists of collating LLIN coverage estimates from national surveys (i.e., DHS/MICS/MIS) and from national distribution data, treatment coverage estimates from national surveys, and IRS coverage estimates from national data, PMI reports, and national surveys. For Nigeria, historical estimates of SMC

scale-up were also collated for provinces in the north. We also collated data on mosquito species composition, insecticide resistance and rainfall patterns to ensure we accurately represented mosquito dynamics. Having a well-calibrated model is essential to ensure accurate capture of transmission intensity and existing intervention mixes as both these factors can have a large impact on the predicted impact of additional interventions.

2.1.2 IPTi assumptions and scenarios considered

Both models assume that the implementation of IPTi-SP is conducted with the provision of SP to infants at 10, 14 weeks and 9 months of age according to current WHO guidance. We assume SP has a 100 percent success rate at initially clearing parasites from infected infants and then provides a period of prophylaxis. This latter assumption differs between the models, and there is a lack of data on this for this population. The Imperial model assumes the drug has a mean duration of prophylaxis of 25 days. In EMOD, the effect of SP is modeled by concentration-dependent killing of asexual parasites, for Sulfadoxine and Pyrimethamine, resulting in a combined mean prophylactic duration of around 28 days. Both models assume some level of maternal immunity is conferred to the infant at birth (which then wanes over a few months) and is dependent on the mother's level of immunity.

IPTi-SP coverage is initially assumed to be based on EPI coverage for vaccinations delivered at the same touchpoints—namely, the second doses of the pentavalent vaccine and OPV for the 10-week dose, third doses of the pentavalent vaccine and OPV for the 14-week dose, and the measles and yellow fever vaccines for the 9-month dose. In instances where the estimates of intervention coverage for a given touchpoint vary, we assume the higher coverage value.

We also consider two alternative scenarios, namely:

- Standard IPTi-SP (3 doses total) at 70, 80, 90, 100% coverage.
- Standard IPTi-SP + 2 additional rounds at 5 and 11 months of age (5 doses total) at 70, 80, 90, 100% coverage.

2.1.3 Analysis of model outcomes and IPTi impact

The model-predicted incidence of clinical malaria and prevalence of infection in infants aged 3 to 12 months, after two years of implementation, is used to describe the likely impact of IPTi-SP in both countries at the first administrative level. In Nigeria, IPTi-SP was only simulated for the Southern provinces that are eligible for IPTi-SP. For DRC, IPTi-SP was simulated for the ten provinces where IPTi-SP is being considered by the NMP.

2.2 Main findings

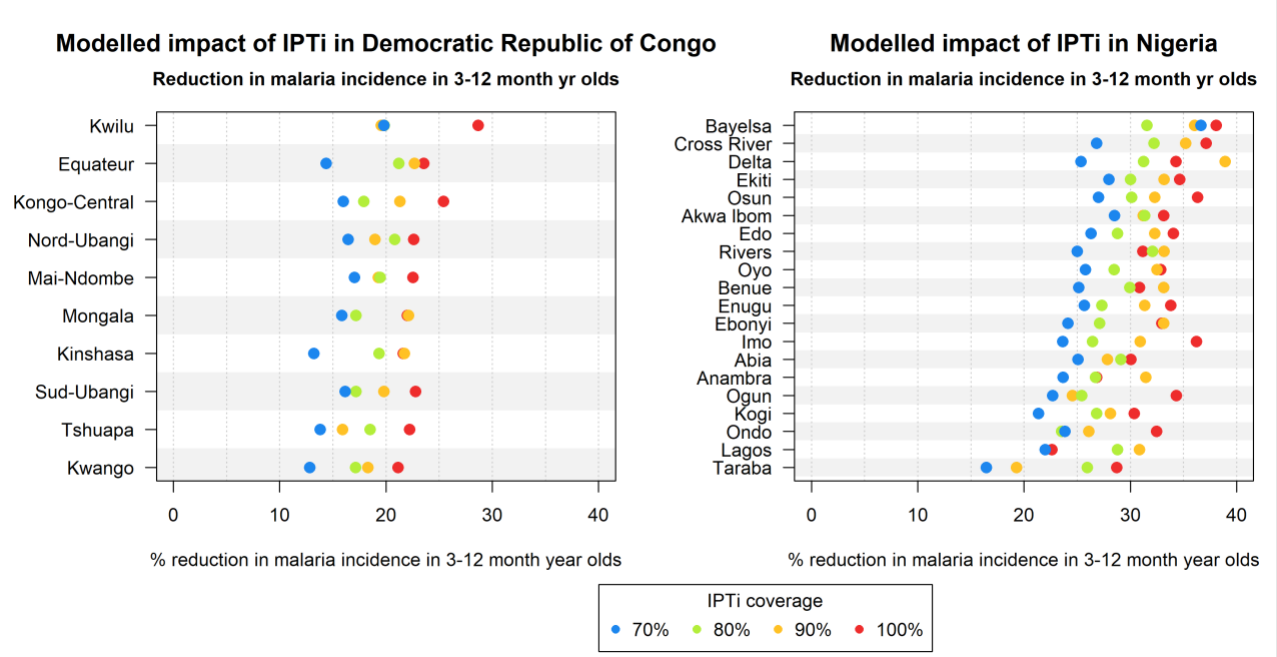
2.2.1 Estimated impact of IPTi with current recommendation of 3 doses in the first year of life

Modelling indicates that with high coverage of IPTi-SP (90%), a 20-30 percent reduction in incidence of clinical malaria in the 3- to 12-month age group could be achieved (Figure 15). Results are broadly consistent between the two mathematical models, with the EMOD model predicting slightly higher effect sizes than the Imperial College model. This could be due to differing assumptions around the duration of SP efficacy or the duration of transferred maternal immunity during the first year of life. Further research

into these key questions will be conducted in collaboration with the other groups conducting IPTi-SP projects to enable us to better quantify and understand these important parameters.

Both models also show the importance of achieving high coverage of the intervention. The Imperial College model predicts a 40 percent difference in impact in DRC by going from 70 percent coverage to 100 percent coverage. Similarly, EMOD predicts a 31 percent difference in impact in Nigeria for the same improvement in coverage.

Figure 15. Modelled estimates of the percentage reduction in incidence of clinical malaria in 3–12-month olds achieved through provision of IPTi with SP at four different coverage levels in all provinces being considered for IPTi.

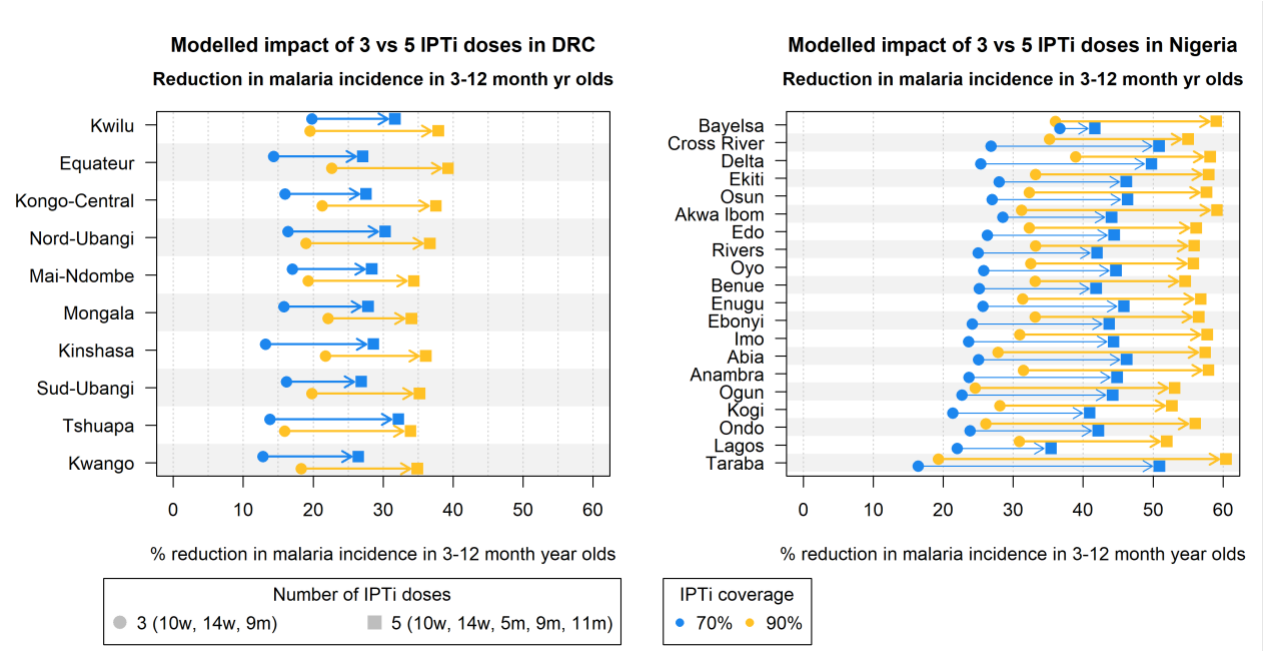


Source: Estimates for DRC are produced by PATH using the Imperial College model and estimates for Nigeria are produced by Northwestern University using the EMOD model.

2.2.2 Estimated impact of IPTi with current recommendation of 3 doses in the first year of life plus two additional touchpoints at 5 months and 11 months

Both models indicate a marked increase in effect size (13-25 percentage points) from adding two additional touchpoints at 5 and 11 months compared the current 3-dose regimen (Figure 16).

Figure 16. Modelled estimates of the percentage reduction in incidence of clinical malaria in 3–12-month olds achieved through provision of IPTi with SP at either the current 3-dose regimen (circles) or extending to add two additional touchpoints at 5 and 11 months (squares) at two coverage levels.



Source: Estimates for DRC are produced by PATH using the Imperial College model and estimates for Nigeria are produced by Northwestern University using the EMOD model.

2.3 Conclusions

The modelled impact of IPTi-SP using the current WHO recommended implementation regimen is consistent with estimates reported in real-world trials.[70] This modeling exercise shows that adding additional touchpoints has the potential to greatly increase the impact of this intervention. However, cost-effectiveness calculations would be needed to assess the added benefit of additional touchpoints as delivery could be more expensive if not occurring at the same time as an already occurring touchpoint (i.e., the current EPI schedule).

3 Costing model to support accelerating the scale-up of IPTi-SP for malaria

This section presents the incremental cost estimates of introducing and delivering IPTi-SP within the routine immunization programs in DRC and Nigeria. The cost estimates are based on existing literature and data sources, with limited new data collection. This section details the costing methodology and discusses the results and cost drivers. An Excel-based generic costing model was developed and used to aid the analysis. The high-level cost estimates generated in this analysis are intended to inform discussions around delivery costs and broad budget needs for IPTi-SP implementation in DRC and Nigeria for planning purposes. This costing model can be used to update the costing analysis with detailed activities and resource use data when available.

The cost estimates should not be used for approximating overall project implementation budgets as the program budget depends on the anticipated implementation partnership for delivery. The cost estimates in this analysis do not include research costs and other possible donor/administrative support costs that are included in program budgets. The specific objective of the costing analysis is to develop a costing model and generate incremental cost estimates (projections) for IPTi-SP implementation within the existing routine EPI platform in Nigeria and DRC to inform planning and decision-making from country and donor perspectives.

3.1 Methods

3.1.1 Scope

The analysis is conducted individually for each country, DRC and Nigeria. The analysis assumes a health facility–based delivery of IPTi-SP, based on current WHO recommendation, where an intermittent 3-dose SP regimen is delivered to the target population through an existing routine immunization platform during three separate visits. Infants were assumed to receive one dose of SP at 10 weeks, 14 weeks, and 9 months during existing routine vaccination contacts.

The analysis considers only the incremental or additional costs of introducing and delivering IPTi-SP within the national immunization programs over a 5-year time period with first introduction beginning in 2022.

3.1.2 Costing approach

Given the limited data on the potential roll out plan and the necessary inputs on resource requirements at the time of analysis, the current analysis builds upon the cost estimates from the existing literature by adapting and applying the estimates from literature to a target population within a given country setting.

IPTi implementation costs from literature

A literature review on IPTi-SP costing studies published between 2005 and 2021 was done to summarize the existing estimates of the cost of delivering IPTi-SP in African country settings. Six publications on IPTi-SP costs and cost effectiveness were identified.[71–76] All six studies used the data from a single source Manzi et al[71] that collected and analyzed primary data on cost of implementing IPTi-SP from Tanzania in 2006. All other studies adapted and used estimates from Tanzania.[71] Specifically, they complemented adjusted program implementation cost from Tanzania with country-specific commodity costs to inform the

respective costing/cost effectiveness analysis. A handful of studies on IPTp, IPT in children, and SMC also reported cost estimates using primary data from several settings, however, the primary delivery strategy and the target group were distinct from that for IPTi-SP and thus were of limited use for this analysis.

Given limited literature on IPTi-SP implementation costs, the analysis was conducted using the Manzi et al. estimates from Tanzania to inform the potential programmatic costs of IPTi-SP implementation in DRC and Nigeria. The unit costs of program implementation from Tanzania were first adjusted and applied to country specific target population and other background information to generate cost estimates for Nigeria and DRC.

The program implementation (non-commodity cost) from Manzi et al[71] were classified into several programmatic components:

- Policy change: included costs of supporting planning and policy consultations at the national level.
- Sensitization: included costs incurred for sensitization of various stakeholders at all levels in preparation for intervention implementation.
- BCC: included costs of developing, printing, and distributing information education and communication materials for parents as well as materials such as posters, training materials, job aids for health workers.
- Training: included costs of training activities at all levels in preparation of intervention implementation and delivery.
- Administration of intervention (or service delivery): included cost of administration of intervention and constitute recurrent costs of intervention implementation such as preparation, and administration of SP doses to infants, recording and reporting of SP coverage, drug reconciliation and wastage as well as value of time for educating mothers about IPTi-SP.
- Strategy management: included costs of a range of additional support from recruitment of public health professionals to support the implementation activities to adaptation of reporting tools and printing those tools.
- Drug distribution: included costs associated with managing the supply chain or distributing the drugs and related supplies from the purchase point to the point of delivery.

Both financial and opportunity unit cost per dose of delivery for each programmatic component were reported. These unit costs were adjusted to inform the current analysis.

Adjustment of unit cost from literature

Cost per dose from the literature Manzi et al[71] were from Tanzania and presented in 2005 USD units. Adjustments of the reported unit costs were done to reflect country-specific costs for Nigeria and DRC. For adjustment, we first converted reported unit costs in 2005 USD units to the local currency units for each country for the same year using the World Bank's official exchange rates.[77] The respective values in local currency units were then inflated to 2020 local currency units using the country specific inflation rates.[78] The 2020 local currency unit values were finally converted to 2020 USD using the World Bank official exchange rates.[77] The adjusted non-commodity unit costs were applied to country specific background data to generate cost projections. Table 11 presents the program costs derived from the literature by cost category and the adjusted unit costs by category for each country.

Table 11. Unit cost per dose of IPTi-SP implementation derived from literature Manzi et al[71] and adjusted for Nigeria and DRC (in USD cents).

Cost category	Estimates for Tanzania in 2005 USD cents		Adjusted estimates for Nigeria in 2020 USD cents		Adjusted estimates for DRC in 2020 USD cents	
	Financial	Opportunity	Financial	Opportunity	Financial	Opportunity
Planning and management (policy change)	0.01	0.02	0.02	0.04	0.01	0.03
Sensitization	0.76	1.12	1.43	2.10	1.00	1.48
Behavior change communication	0.03	0.05	0.06	0.09	0.04	0.07
Training	3.06	2.30	5.75	4.32	4.04	3.04
Administration of intervention (Service delivery)	-	1.25	-	2.35	-	1.65
Strategy management	0.65	0.10	1.22	0.19	0.86	0.13
Drug distribution	1.60	-	3.00	-	2.11	-

Product characteristics, purchase price, and procurement add-on costs

Commodity costs, which includes cost of medicines and other supplies needed for drug administration, were collected from Nigeria. A dispersible formulation of SP 250 mg strength per tablet supplied by S Kant Health Care Limited, India was considered. Supplies necessary for administration include a cup, a spoon, a liquid syringe (only for first dose administration), and a pill cutter (one pill cutter would last 5000 doses administration).

In DRC, only costs of bulk hard tablets (500 mg per tablet) currently used for IPTp (for pregnant women) were available, as IPTi-SP is not implemented in country. Given cost data on dispersible infant formulation of SP was unavailable, we used the commodity cost from Nigeria to inform DRC cost estimates.

In Nigeria, a small-scale implementation research study for IPTi-SP is currently in planning stages in two states funded by BMGF. The characteristics and the unit cost of commodity were based on procurement prices paid by Malaria Consortium.

The procurement add-on costs were collected for each country and added to the product cost as a percent of the product costs. The procurement add-on included costs of shipping, handling, clearance, insurance, and other taxes, as applicable, and were estimated at 38 percent and 32 percent in DRC and Nigeria, respectively. Country specific wastage rate and buffer stock were applied which range from 5-10 percent.

Target population, coverage, and sub-national introduction year

Country specific background information on target population, expected population growth rate, and the expected coverage rates were collected from respective countries.

3.1.3 DRC

Ten provinces in DRC were assumed to be eligible and targeted for IPTi-SP based on the epidemiological stratification.[12] Of the ten provinces, three were assumed to roll out IPTi-SP in 2022, and the rest in 2024, based on current discussions in country. All surviving infants within the eligible areas were considered the target population for the intervention. The target population was taken from DHIS2 2022 population and

attributing four percent of the total population as surviving infant population. Further, a national annual growth rate of 3.3 percent was used to project the target population in the future years. The three-dose schedule of IPTi-SP was assumed to be delivered via EPI using the current coverage rates for DTP2, DTP3, and Measles for doses 1, 2, and 3, respectively. Province specific EPI vaccine coverage for respective vaccination from DHIS2 were used as proxy for coverage of IPTi-SP.[15] The assumed average coverage for SP drug doses 1, 2, and 3 were 91.8 percent, 89.53 percent, and 87.7 percent, respectively.

The key data inputs and assumptions used for cost projections are available in the inputs page of the costing tool.

3.1.4 Nigeria

Fifteen states in Nigeria were assumed to be eligible and targeted for IPTi-SP based on the epidemiological stratification.[34] States with all LGAs identified as being eligible for IPTi-SP implementation were considered within the scope of this costing analysis. Of the 15 states, at the time of the analysis, four states were considered to roll out IPTi-SP in 2022 and the rest in 2024. All surviving infants within the eligible areas were considered the target population for the intervention. The target population was estimated from the National population statistics based on 2006 population census data and attributing a 3.7 percent of total population as surviving infant population. Further, a state specific annual growth rate was used to project the target population in the future years. The three-dose schedule of IPTi-SP was assumed to be delivered via EPI, using the current coverage rate for each state for DTP2, DTP3, and Measles 1 for doses 1, 2, and 3, respectively. State specific EPI vaccine coverage for respective vaccination from NDHS 2018 were used as proxy for the coverage of IPTi-SP. The assumed average coverage for SP drug doses 1, 2, and 3 were 81.6 percent, 75.5 percent, and 72.6 percent, respectively.

3.1.5 Cost analysis and outcomes

We developed an Excel-based costing tool to support cost analysis.

Commodity cost: The country specific commodity costs adjusted for the procurement add-on costs such as shipping, handling, and clearance costs were multiplied by the target population and projected coverage. We assume no opportunity costs outside of the direct financial outlays of expenditure required for commodity purchase.

> Cost of commodity = cost per dose of SP drug * number of doses needed adjusted for wastage and buffer stock.

Non-commodity program cost: The adjusted unit costs per dose delivered by activity category derived from the literature were multiplied by the number of doses expected to be delivered in each year.

> Non-commodity cost, by activity = unit cost of delivery, by activity group * number of doses delivered.

Cost across each activity category were summed to generate the total costs of implementation for the period of analysis.

The cost estimates generated from this analysis are presented as an incremental cost per dose of IPTi-SP delivered, and cost per infants receiving 3 doses of SP for IPTi-SP. Total program costs were generated by added cost across all cost categories over the analysis period. The cost per dose was estimated by dividing the total cost of the program by the total number of doses administered during the same time period. For

each output, financial and opportunity costs were estimated separately. Total costs were estimated by adding the financial and the opportunity costs.[e]

All costs are presented in 2020 USD units.

3.1.6 Sensitivity analysis.

In this brief we only summarize the costs estimates generated using the baseline assumptions (described above). The accompanying costing tool can be used to generate cost estimates using alternative input values for each of the model parameters and to evaluate one-way sensitivity of model inputs on cost estimates.

3.2 Findings

Based on population in ten provinces in DRC and 15 states in Nigeria, 6.3 million and 11.3 million infants respectively were projected to be the target for IPTi-SP over a 5-year period (2022-2026). Assuming the state/province level expected EPI coverage, of the total targeted infants, 5.3 million and 8.2 million infants were projected to receive all 3 doses of IPTi-SP (see Table 12).

Table 12. Projected outcomes and total cost estimates over the period of 5 years.

	DRC	Nigeria
Predicted outcomes		
Total target population (infants)	6,309,007	11,294,587
Total number of doses delivered	16,386,418	26,172,793
Total number of infants receiving 3 doses of SP	5,351,641	8,231,569
Predicted incremental cost (in USD)		
Total financial cost	$ 7,163,405	$ 12,080,587
Total opportunity cost	$ 1,048,731	$ 2,379,107
Projected total cost	$ 8,212,136	$ 14,459,694
Predicted incremental unit cost (in USD)		
Cost per dose of SP delivered, financial	$ 0.44	$ 0.46
Cost per dose of SP delivered, opportunity	$ 0.06	$ 0.09
Cost per dose of SP delivered, total	$ 0.50	$ 0.55
Cost per infant receiving 3 doses, total	$ 1.53	$ 1.76

The total incremental costs (financial) of implementing IPTi-SP for the duration of the analysis (5 years) were estimated to be $7.16 million, and $12.08 million in DRC and Nigeria, respectively. The total program cost including the opportunity cost were $8.21 million and $14.45 million respectively. The total cost per dose of IPTi-SP delivered was estimated to be $0.50 in DRC and $0.55 in Nigeria. Of the total unit cost, 87 percent and 83 percent were financial costs in DRC and in Nigeria, respectively. The cost of providing full doses (3 doses of SP) per eligible infant were estimated to be $1.53 in DRC, and $1.76 in Nigeria (Table

[e] Opportunity costs are those costs that are diverted from other use within the system. Financial costs are those that involved direct budget outlays or payment. The sum of financial and opportunity cost is also referred to as economic costs. Typically, costs are represented as financial and economic costs. The term opportunity cost is used in this brief to be consistent with the original article (Manzi et al.)

13). Overall, the commodity procurement costs constitute approximately 71 percent and 63 percent of total cost of program implementation in DRC and Nigeria, respectively (Table 13).

Table 13. Cost distribution by various cost components.

Cost components	DRC		Nigeria	
	In USD	Cost share (%)	In USD	Cost share (%)
Total (across all years)	8,212,136	100%	14,459,694	100%
Procurement	5,842,660	71.1%	9,123,062	63.1%
Planning and management	6,555	0.1%	15,704	0.1%
Sensitization	406,383	4.9%	923,900	6.4%
Behavior change communication	18,025	0.2%	39,259	0.3%
Training	1,160,158	14.1%	2,588,489	17.9%
Administration of intervention (Service delivery)	270,376	3.3%	615,061	4.3%
Strategy management	162,226	2.0%	369,036	2.6%
Drug distribution	345,753	4.2%	785,184	5.4%

3.3 Discussion

The current analysis projects the incremental costs of IPTi implementation within the routine immunization programs in DRC and Nigeria. The cost estimates are informed by the programmatic unit costs derived from existing literature data and limited new data collection, and therefore rely heavily on assumptions. The cost estimates therefore should be interpreted cautiously and may only be useful for a very high-level indication of the potential cost structure in these countries.

Discussions around the feasibility of IPTi-SP implementation in DRC and Nigeria are actively ongoing during the scoping period. Landscaping and development of detailed roadmap for introduction and scale-up expected to be developed during the scoping phase would provide rich contextual information for generating more robust cost estimates. In the next phase once the roadmap and detailed activities are identified, the costing model/tool developed during the scoping period to aid the current analysis can be adapted and refined to generate more robust cost estimates utilizing country specific data, and under alternative delivery scenarios.

Some of the important limitations and caveats are highlighted below:

1. The unit cost estimates on resource use used to inform this analysis were derived from a study which was published about 15 years ago. The implicit assumption in using the data from the literature is that the Tanzania estimates are representative of cost structure in Nigeria and DRC. Attempts were made to adjust the costs to account for inflation using country specific inflation rates over the years, however, the results should be viewed indicative only, as the source data is from over 15 years and from different country context. Further, recent PATH-led immunization cost of delivery studies conducted in similar geographies (e.g., RTS,S cost of delivery) may be adapted to inform the IPTi costs.

2. The unit cost estimates from the literature included both start-up and recurring costs. No distinct unit costs for start-up and recurrent costs were available. Projecting cost of scale-up using such unit costs likely overestimates the scale-up cost particularly as we were not able to distinguish the unit cost of activities/item that do not necessarily vary by number of doses delivered.
3. The IPTi interventions are not currently being implemented in the reference countries at scale or at all. Discussions and deliberations on how the IPTi intervention may be implemented in these countries is in development. The cost estimation is therefore based on many assumptions that have not been vetted or validated with the in-country decision-makers. Further, updated WHO recommendations on IPTi are expected soon. The costing model provides a framework and can be used to generate more robust cost estimates using country specific data on both cost and activities aligned with new global guidance for implementation, when available.

4 Plan for scale

4.1 DRC

PATH envisions a phased approach to IPTi-SP introduction and scale-up in DRC (see scale-up summary in the Gantt chart, Figure 17). Year 1 will consist of start-up and operational planning activities such as key personnel and staff recruitment, procurement planning, subcontract finalization, and refinement of the Year 1 work plan and associated deliverables. PATH will also convene DRC IPTi task force meetings and planning sessions at both the national and provincial levels to align on timelines and stakeholder roles and responsibilities regarding evaluating IPTi coverage, impact, acceptability, SP resistance, operational capacity, and transition planning to MOH counterparts in Year 1. Community engagement, development of operational manuals and technical materials, and subsequently the training of trainers would take place at the national, provincial, and district levels during the first half of Year 1, with supervision visits planned for the latter half of the year.

In terms of plans for scale for this investment in DRC, PATH has put together two scenarios as detailed below. A low-end scenario that will ramp up operations in half the health zones (n=16) in one province in western DRC (Kongo Centrale) and a high-end scenario will include ramp-up in half of the health zones (n=28) of two provinces (Kwilu and Kongo Central). The low-end scenario would provide an opportunity for refining operations prior to expansion, while the higher end would reach be more aggressive to reach a greater number of infants in Year 1. PATH will conduct a midline coverage evaluation in Year 3 of the investment and refine scale-up plans based on findings; including revisiting the 5-year implementation timeline to accommodate new provinces becoming eligible for IPTi given the results from SP resistance studies.

Both the high and low-end scenarios are operationally feasible for PATH; and maximize IPTi-SP coverage of all eligible provinces while allowing a smooth transition to MOH counterparts in Year 5 of this investment. The high-end scenario presents the additional advantage of potentially more lessons learned, as it covers multiple provinces and health zones in Year 1 with different key parameters such as EPI coverage, accessibility, and acceptance. Moreover, in this scenario, all eligible provinces will be covered in Year 3 allowing a high volume of results within a shorter timeframe.

A year-wise summary of the high- and low-end scenarios is provided in Table 14 below.

Table 14. Summary of high-and low-end scenarios for scale-up in DRC, by year.

Scenarios	Y1	Y2	Y3	Y4	Y5
Low end	Ramp up in half (n=16) of the health zones in one province (Kongo Centrale)	Scale to cover the remaining half of health zones in Kongo Central (n=15) Introduce IPTi-SP in 14 health zones in Kwango province	Scale to cover all health zones in the Kwilu, Kinshasa, Mai Ndombe and Tshuapa provinces	Cover all health zones in Equateur, Mongala, Sud Ubangi, and Nord Ubangi, as well as any additional provinces that may have become eligible for IPTi-SP based on new SP resistance data (more details in text below)	Coverage endline assessments Work with MOH counterparts to ensure a transition plan for intervention support
High end	Ramp-up in half of the health zones (n=28) of two provinces (Kwilu and Kongo Central). Assessment of the transition plan based on Year 1 results	Scale to cover all health zones in Kwilu and Kongo Central Introduce IPTi-SP test and scale-up in all HZ in Kwango province (n=14) and half of the health zones in the Kinshasa province (n=18), for a total of 32 additional HZ. Assessment of the transition plan based on Year 1 results	Achieve coverage of all current IPTi-SP eligible provinces by scaling to cover the remaining half of health zones in Kinshasa province (~ 18 HZ) and all HZ in the Mai Ndombe, Tshuapa, Equateur, Mongala, Sud Ubangi, and Nord Ubangi provinces	Asses any additional provinces that may have become eligible for IPTi-SP given scale-up to all currently eligible states would have been completed in Year 3.	

Figure 17. Anticipated scale up activities in DRC.

PHASE FOCUS	Ramp-up				Ramp-up and Maintenance				Ramp-up and Maintenance	Ramp-up and Maintenance	Transition
DRC TASK	Year 1				Year 2				Year 3	Year 4	Year 5
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4			
Start-up											
Recruit and orient new staff											
Finalize subrecipient contracts											
Procure office equipment											
Set-up operational, administrative and accounting systems											
Establish internal controls and donor compliance requirements											
Sensitization & Launch											
IPTi task force meeting national level											
IPTi task force meeting provincial level											
Kick off meeting national											
Kick off meeting provincial											
Community Engagement											
Image-box workshops											
Poster Workshops											
Planning Sessions											
PAO update national level											
PAO update provincial level											
Integrated child health tools update											
Training & Roll-out											
Adaptation of training materials											
Development of operational manual											
Development of supervision checklist											
Induction workshop for PATH staff											
National training of trainers											
Provincial-level training of trainers											
District-level training of health workers											
Procurement											
SP											
Other supplies for SP administration											
Dispersible SP registered											
Ongoing Support and Supervision											
Provincial Support Supervision Visits											
Health Zone Support Supervision Visits											
Provincial IPTI Checklist Supportive Supervision											
Evaluations / Studies											
Reductionin morbidity of malaria in children under 1 year											
Introduce and scale-up coverage and equity of IPTi											
Midline coverage acceptability evaluation											
Endline evaluation											
Transition											
Transition to local partners											

Beginning the investment with the low-end scenario provides additional assurances related to intervention quality. Especially given uncertainty around system readiness and acceptance, the low-end scenario allows for the benefit of time and space for early course corrections to apply in subsequent years of implementation. While the low-end scenario would take more time for ramp-up, should evaluations of this investment demonstrate positive results related to EPI coverage, accessibility, and acceptance, PATH could consider transitioning to the high-end scenario for subsequent years of implementation.

DRC has identified 10 provinces in western DRC as eligible for IPTi-SP (see section 1.1.2 for details on the selection criteria). The MOH is willing to consider additional provinces for IPTi-SP if further supportive data on SP resistance becomes available. Leveraging the ongoing UNITAID funded IPTi Plus project for which DRC is a light-touch country, PATH will collaborate with the LSHTM to generate province level data on SP resistance in all provinces. Per ongoing discussions with the IPTi Plus team, of which the LSHTM team is a core research partner, PATH will be responsible for the design and sample collection, while LSHTM will fund field work and run laboratory analysis in DRC.

4.1.1 Risks to scale-up

There are a number of risks to consider as part of the scale-up plans. We have outlined these risk and potential mitigation strategies in the table below (Table 15). Scale-up risks and mitigation strategies.

Table 15. Potential risks and mitigation strategies

Risk	Mitigation strategy
Stock outs of SP	Strong coordination structures will be established with the supply chain partners and the Ministry of Finance to ensure the proper supply of SP and smooth management of the customs process for importing SP. Additionally, a supply chain manager will be hired at the provincial level to support the province and health zones in quantification and stock tracking and management.
Registration delays for dispersible-SP	To secure the registration of dispersible SP in a timely manner, we will involve and sensitize the key stakeholders (DPM, PNAME) earlier in the activity, start the process of registration as early as possible and work with the NMP to endorse the registration request.
Health worker strike[f]	Potential mitigation strategies include working closely with the MOH and partners to support government actions to address the issue
Health worker turnover	To ensure uninterrupted service delivery, we would train two health workers per health facility who will then provide cascade training to other health workers present at the health facility.
Volatile geopolitical, security, and safety situation in DRC	We will work closely with the relevant stakeholders to stay well informed of the situation and implement appropriate safety and security actions as needed.
COVID-19 or other infectious disease outbreaks	We will work closely with the disease surveillance directorate of the MOH to monitor the situation and respond appropriately to emerging threats. PATH is supporting the strengthening of national and subnational emergency centers (EOC) in DRC for a better outbreak detection and response. PATH also has experience in adjusting implementation plans to minimize COVID risk for staff and beneficiaries.

[f] Since mid-2021, there have been health facility worker (nurses) strikes in all provinces of the country. The government is working on addressing the demands of the workers, however, the potential for future strikes remains, which could present potential delays in not only obtaining project reporting data, but also disrupting IPTi-SP service delivery.

4.2 Nigeria

Pathway to IPTi-SP scale-up in Nigeria

With funding from BMGF, Malaria Consortium is currently conducting implementation research to assess the clinical effectiveness and operational feasibility of SP-IPTi in Ebonyi/Osun State to catalyze decision making in Nigeria regarding the policy adoption of SP-IPTi.

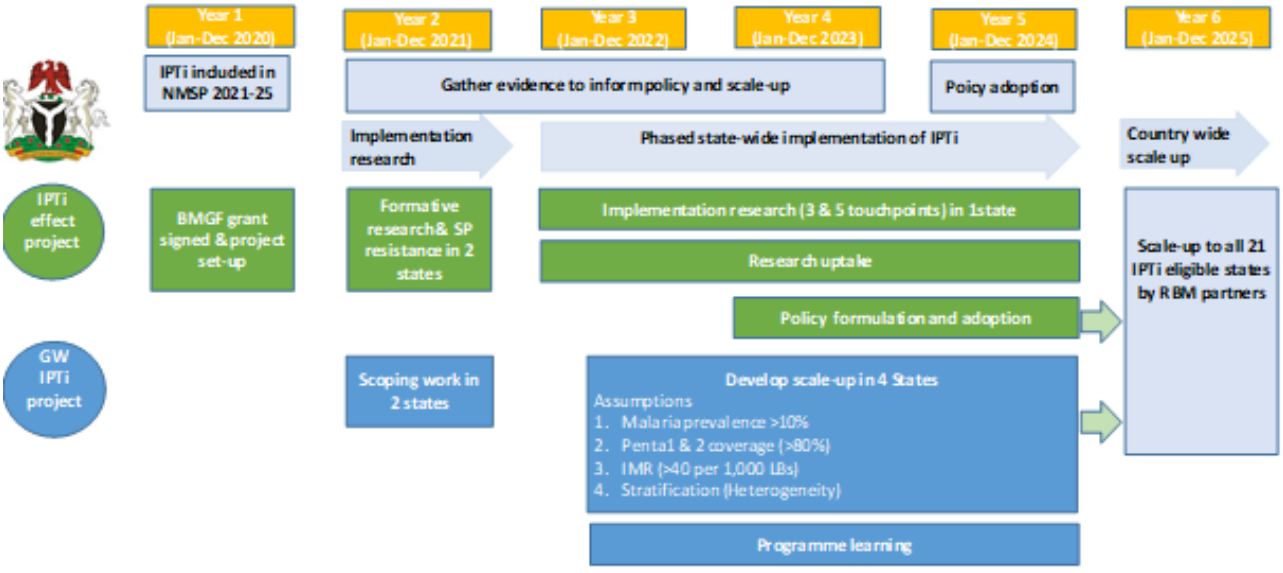
Through the GiveWell IPTi project, the government is working with its partners to define the pathway to scale - up for IPTi in Nigeria through assessment of country demand, defining subnational target areas; and assessing existing delivery platforms, pharmacovigilance, and data surveillance platforms.

In collaboration with the NMP, NPHCDA, and other key partners, IPTi-SP implementation will be scaled through a phased approach taking into consideration contextual factors, and evidence to inform strategies for roll out. This phased approach starts with the implementation of IPTi-SP in the selected four states of Ekiti, Edo, Ebonyi and Adamawa; the minimum cluster of states to generate learnings which guides the wider scale-up to all eligible states in the country.

There are some funds already committed to IPTi scale-up in the country, including (1) BMGF IPTi effect project, and (2) GiveWell IPTi scoping mission project. It is proposed that this investment will fund scale-up in the selected four states with estimated budget of $9.9m over a period of 2.5 years (July 2022 to December 2025). It is projected that all 21 IPTi-SP eligible states will be implementing IPTi by 2025, of which this investment will support implementation in four states Ebonyi, Ekiti, Edo, and Adamawa) and the remaining 17 states to be funded by other partners (PMI, GF, AfDB, and WB). These four states support of GiveWell is estimated to be $11.3m, making the overall investment of GV in IPTi between 2022 and 2025 to be $20.9m.

Figure 18 outlines the country's plan for scaling up IPTi to all eligible 21 states over a six-year period, from 2020-2025.

Figure 18. Schematic diagram of the pathway to IPTI-SP scale-up in Nigeria.



Nigeria IPTi Scale – up Year 1& 2 (2020 and 2021)

Year 1 (2020) marked the formal inclusion of IPTi-SP in the 2021-2025 NMSP. Year 2 (2021) saw the conduct of formative research and SP resistance in two states (Ebonyi and Osun) funded by BMGF. This period also overlapped with scoping work funded by GiveWell in two additional states to define the pathway to scale for IPTi in Nigeria through landscaping of stakeholders and assessment of country demand and health system readiness; and understanding the potential clinical impact of IPTi as estimated using mathematical modelling.

Nigeria IPTi Scale – up Year 3 & 4 (2022 and 2023)

At the national level, this period corresponds to gathering evidence to inform scale up through state-wide implementation of IPTi in selected states. With funding from BMGF, Malaria Consortium is conducting implementation research to assess the clinical effectiveness and operational feasibility outcomes of IPTi-SP for three touchpoints and five-touchpoints (with two additional touchpoints within the EPI platform or at the community level) in Ebonyi/Osun State. During this period, this investment will also introduce IPTi in four states (three IPTi-only eligible states including one state covered by BMGF for the formative research; and another state with partial eligibility of IPTi and low EPI coverage to accommodate heterogeneity of settings).

Nigeria IPTi Scale – up Year 5 (2024)

Nigeria is expected to make decision on implementing IPTI-SP as part of the national policy. The BMGF funded IPTi project will provide evidence about the clinical effectiveness and operational feasibility of IPTi-SP to drive policy adoption and roll out of IPTi-SP in eligible states of the country. This investment will contribute to accelerating the scale up of IPTi through documenting lessons from phased state-wide implementation of IPTi as well as providing contextual details for adapting strategies to maximize impact.

Nigeria IPTi Scale – up Year 6 (2025)

Upon adoption of policy by Year 5, a full scale up to all 21 eligible states (16 full-fledged IPTi states and 5 states with partial IPTi eligibility) will be planned and rolled out by Year 6. The full scale-up implementation will be conducted by RBM partners working in the country with expected funding from domestic and external resources.

4.2.1 Risks to scale up

Some potential risks to the successful roll-out of the project have been identified. In the set-up of this investment, these risks will be discussed with stakeholders and appropriate mitigation actions agreed, implemented, and tracked periodically for other emerging risks. Below is the list of these risks.

- IPTi-SP does not prove to be an effective tool for reducing infant malaria morbidity in Nigeria e.g. does not lead to ≥ 20 percent reduction in infant malaria
- Lack of political to support IPTi-SP implementation
- Lack of local authority to effectively implement large scale IPTi-SP
- EPI not fully functional
- EPI coverage low
- VHWs not active/ no complementary platform for additional touchpoints
- Caregivers do not consent to administering SP to infants
- Infant morbidity and mortality data unavailable
- Unreliable demographic data leads to inadequate ordering of SP for IPTi
- EPI staff are unable to estimate correct dosage of infant SP

- Inclusion of IPTi-SP places unwelcome additional burden on health workers
- VHWs unable to estimate correct dosage of infant SP
- Demographic and clinical data available not reliable for correctly calculation statistically significant sample size
- High turnover of EPI staff or VHWs - lack of institutional memory on IPTi delivery
- Concentration of IPTi in the first 12 months results in measurable rebound of mild and severe cases in second year of life (this should be measured)

Indicative budget and funding gap.

Table 16 below presents the total budget required for scale-up of IPTi-SP in Nigeria for all 21 IPTi-SP eligible states (16 states with full IPTi eligible LGAs and 5 states with partial IPTi eligible LGAs). Parameters employed for the budget assumptions include (1) number of scalable LGAs per eligible state, (2) number of health facilities per LGA, (3) number of eligible infants per state, and (4) number of SP doses and other supplies. Costs for the full scale-up are driven by training of health workers on IPTi and procurement of SP and other supplies required for its administration (cups, spoons, pill cutter). Malaria Consortium used a unit cost of $0.17 per dose of SP based on experience importing limited quantities of WHO pre-qualified SP dispersible tablets of 250mg + 12.5mg for the BMGF-funded IPTi project in Ebonyi or Osun depending on the state selected.

The total projected budget required to achieve full IPTi scale-up in Nigeria is about 46 million USD. Table 16 shows the estimated total cost for IPTi-SP scale-up implementation with regards to personnel, procurement of commodities, and training of services providers for all 21 IPTi eligible states. It also shows an indicative source of funding from domestic and external resources (BMGF, GiveWell, Global Fund, PMI/USAID and World Bank) for full IPTi scale-up implementation. Please note that the estimated budget for 2025 country wide scale-up to all eligible states are yet to be discussed with the partners listed.

Table 16. Estimated costs of IPTi-SP scale-up by state and source of funding.

S/N	Eligible States	Year 2025 Population Projection	Unit Cost per Child per Year			Total	Partners				
			$ 1.36	$ 6.08	$ 1.08						
			Personnel	Service Delivery	Management Oversight		GV	GF	WB	PMI	AfDB
1	Abia	174,160	$ 237,252	$ 1,058,664	$ 188,591	$ 1,484,506			$ 1,484,506		
2	Akwa ibom	268,940	$ 366,368	$ 1,634,801	$ 291,224	$ 2,292,393				$ 2,292,393	
3	Anambra	261,797	$ 356,637	$ 1,591,381	$ 283,489	$ 2,231,507					$2,231,507
4	Bayelsa	108,661	$ 148,025	$ 660,516	$ 117,664	$ 926,206			$ 926,206		
5	Cross river	184,294	$ 251,057	$ 1,120,265	$ 199,564	$ 1,570,887				$ 1,570,887	
6	Delta	276,420	$ 376,557	$ 1,680,270	$ 299,324	$ 2,356,151		$ 2,356,151			
7	Ebonyi	136,062	$ 185,353	$ 827,078	$ 147,336	$ 1,159,766				$ 1,159,766	
8	Edo	197,778	$ 269,426	$ 1,202,230	$ 214,166	$ 1,685,822	$ 1,685,822				
9	Ekiti	157,811	$ 214,980	$ 959,283	$ 170,887	$ 1,345,151	$ 1,345,151				
10	Enugu	211,661	$ 288,338	$ 1,286,620	$ 229,199	$ 1,804,158			$ 1,804,158		
11	Imo	265,394	$ 361,537	$ 1,613,246	$ 287,384	$ 2,262,168			$ 2,262,168		
12	Lagos	256,115	$ 348,897	$ 1,556,842	$ 277,336	$ 2,183,075			$ 2,183,075		
13	Ogun	223,600	$ 304,603	$ 1,359,194	$ 242,127	$ 1,905,924		$ 1,905,924			
14	Ondo	230,905	$ 314,554	$ 1,403,599	$ 250,037	$ 1,968,190					$ 1,968,190
15	Osun	362,839	$ 494,283	$ 2,205,584	$ 392,903	$ 3,092,770	$ 3,092,770				
16	Rivers	273,743	$ 372,911	$ 1,663,997	$ 296,425	$ 2,333,333			$ 2,333,333		
17	Adamawa	13,766	$ 18,753	$ 83,679	$ 14,907	$ 117,339		$ 117,339			
18	Benue	606,752	$ 826,557	$ 3,688,254	$ 657,026	$ 5,171,838	$ 5,171,838				
19	Kwara	29,009	$ 39,518	$ 176,337	$ 31,413	$ 247,267		$ 247,267			
20	Oyo	335,246	$ 456,694	$ 2,037,855	$ 363,024	$ 2,857,573				$ 2,857,573	
21	Taraba	62,048	$ 84,526	$ 377,170	$ 67,189	$ 528,885		$ 528,885			
Totals		4,637,001	$ 6,316,826	$ 28,186,867	$ 5,021,215	$ 39,524,908	$11,295,580	$ 5,155,566	$10,993,445	$ 7,880,619	$ 4,199,697

5 Monitoring, Evaluation and Learning (MEL) Plan for the Implementation Phase

This section describes how PATH and Malaria Consortium will monitor progress against investment goals and contribute to learning in the scale-up of IPTi-SP. The MEL plan is intended to provide a mutual understanding among the investment team and external stakeholders on the measurement processes that will be undertaken during the implementation phase. The objectives of the MEL plan are threefold:

1. Track progress toward stated results.
2. Identify risks prospectively
3. Support program adaptation and learning

To achieve the above goals, the MEL plan is comprised of four key complementary components:

1. Monitoring Plan: the monitoring plan defines a results framework which illustrates the pre-requisites needed to scale delivery of IPTi-SP, how progress toward the intended program results will be measured and stakeholders provided with evidence for program decision-making, and which data sources and specific tools will be used to capture indicators and how quality of the processes and tools will be measured.
2. Evaluation Plan: the evaluation plan identifies area where additional, supplementary data collection may be needed to verify or validate progress towards the scale-up of IPTi-SP, for instance, to evaluate impact of IPTi-SP on burden of disease (e.g., incidence of clinical cases and hospitalizations). Recommendations are included for a combination of evaluation activities to supplement routine monitoring based upon identified stakeholder needs.
3. Learning Agenda: the learning agenda identifies additional exploratory questions of interest to stakeholders; these may be worth exploring concurrent to scale-up of IPTi-SP to identify further opportunities to maximize impact of IPTi-SP.
4. Data Management and Use: a cornerstone of the MEL plan is planning for the use of collected data to identify and mitigate project risks and adapt implementation. The data management and use plan identifies tools and approaches to guide real-time learning and adaptation.

If implementation is undertaken, the MEL plan will be reviewed with all key stakeholders to revise and finalize all components.

5.1 Monitoring Plan

The monitoring plan defines a results framework which illustrates the pre-requisites needed to scale delivery of IPTi-SP and identifies what data will be collected and reviewed routinely to monitor progress and mitigate risks during scale-up. For each component of the results framework, performance indicators are subsequently identified which utilize project reporting, routine data sources, and existing data collection efforts to track scale-up of IPTi-SP. All performance indicators identified in the monitoring plan will be collected and reported to key stakeholders regularly to inform decision-making, mitigate program risks, and inform program adaptation.

The results framework was developed through working sessions with technical leads from PATH and Malaria Consortium to align on common measurement components between both countries. While there are common elements of the results framework, the organization of the results framework, specific data

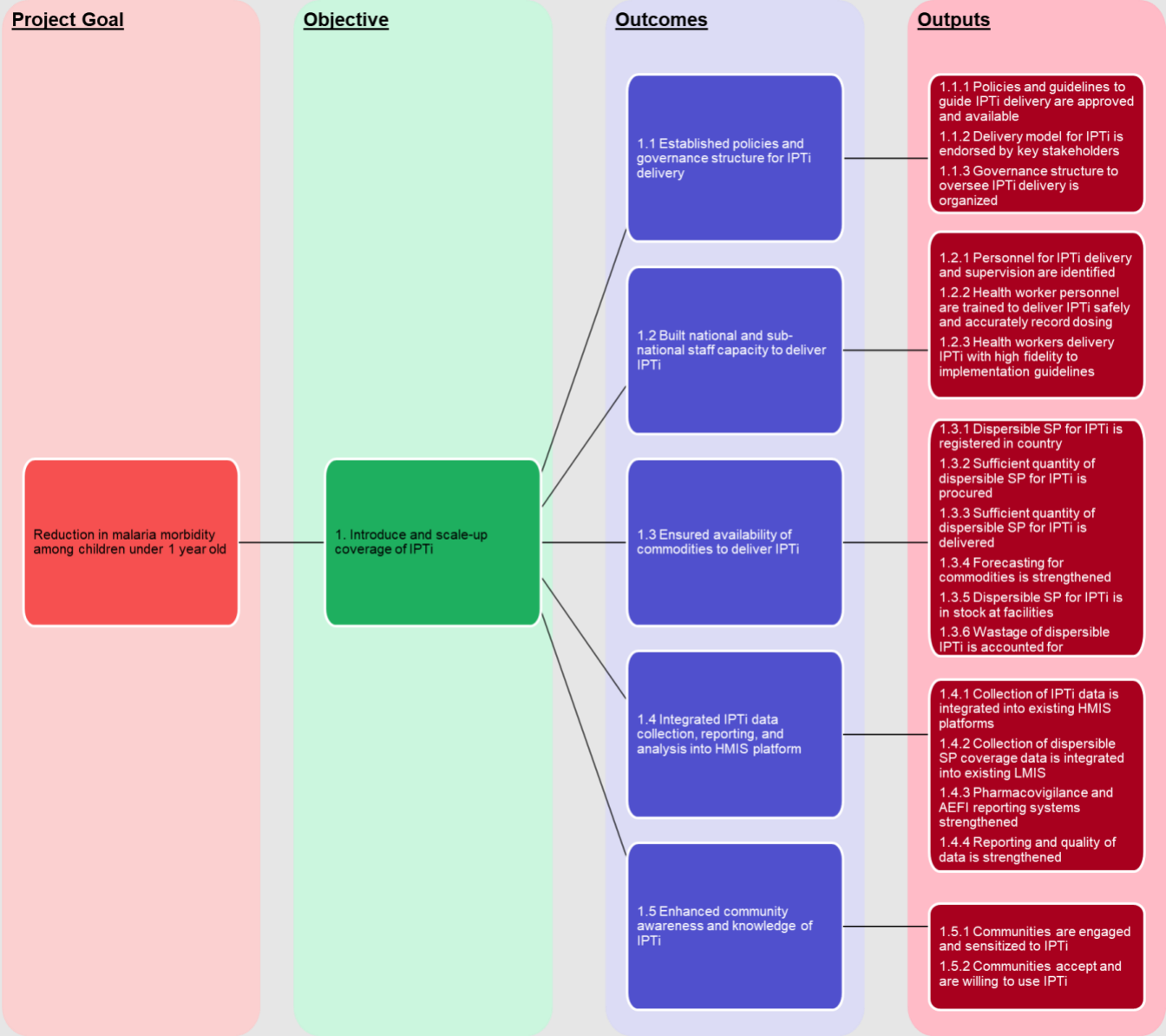
sources, indicators, and evaluations will vary between countries due to the parameters of program design and available data.

Aligned with the results framework, this investment will have a suite of routine performance indicators that will be used to track performance for each component of the results framework in DRC (Table 17) and Nigeria (Table 18). Performance indicators are intended to leverage investment reporting, routine data sources, and existing data collection efforts to track investment progress over time. Recognizing the need for data triangulation, key indicators are also recommended for collection through supplemental evaluation. Elements of the results framework that require additional evaluation are detailed in Section 5.2.

5.1.1 IPTi results framework in DRC

This investment is designed to contribute to a reduction in malaria morbidity among children under one year of age. Figure 19 visualizes the results framework, which illustrates how outputs contribute to investment outcomes, which in turn lead to scale-up and coverage of IPTi-SP, which culminates in a reduction of malaria morbidity in children under one year of age. The components of the results framework are outlined in the subsequent text.

Figure 19. Results framework.



Investment goal: reduction in malaria morbidity among children under 1 year old.

Objective: To introduce and scale-up coverage of IPTi-SP

1.1. Outcome: Established policies and governance structure for IPTi-SP delivery
  1.1.1. Policies and guidelines to guide IPTi-SP delivery are approved and available
  1.1.2. Delivery model for IPTi-SP is endorsed by key stakeholders
  1.1.3. Governance structure to oversee IPTi-SP delivery is organized
1.2. Outcome: Built national and sub-national staff capacity to deliver IPTi-SP
  1.2.1. Personnel for IPTi-SP delivery and supervision are identified
  1.2.2. Health worker personnel are trained to deliver IPTi-SP safely and accurately record dosing
  1.2.3. Health workers deliver IPTi-SP with high fidelity to implementation guidelines
1.3. Outcome: Ensured availability of commodities to deliver IPTi-SP
  1.3.1. Dispersible SP for IPTi is registered in country
  1.3.2. Sufficient quantity of dispersible SP for IPTi is procured
  1.3.3. Sufficient quantity of dispersible SP for IPTi delivered to health facilities
  1.3.4. Forecasting for commodities is strengthened
  1.3.5. Dispersible SP for IPTi is continually in stock at health facilities
  1.3.6. Wastage of dispersible SP is accounted for
1.4. Outcome: Integrated IPTi-SP data collection, reporting, and analysis into national HMIS platform
  1.4.1. Collection of IPTi-SP data is integrated into existing HMIS platforms
  1.4.2. Collection of dispersible SP coverage data is integrated into existing PSCM / LMIS
  1.4.3. Pharmacovigilance and AEFI reporting systems are strengthened
  1.4.4. Reporting and quality of data is strengthened
1.5. Outcome: Enhanced community awareness and knowledge of IPTi-SP
  1.5.1. Communities are engaged and sensitized to IPTi-SP
  1.5.2. Communities accept and are willing to use IPTi-SP

In addition to the above monitoring framework for program activities, we will conduct context monitoring on the following elements which may influence implementation and impact of IPTi-SP:

- SP resistance
- Access to and use of existing immunization services
- Coverage of other malaria control tools (IRS, ITNs)
- Rainfall
- Vegetation index

Further details on how context monitoring will be conducted is included in the performance indicators in section 5.2.

Performance Indicator Table for DRC

Table 17 details the performance indicators that will be used to track performance for each component of the results framework in DRC; elements of the results framework that require additional evaluation are noted in the final column and further information is available in Section 5.2.1.

Table 17. Performance indicators in DRC.

#	Level	Component	Proposed indicator	Proposed data source	Requires supplemental evaluation?
	Goal	Reduction in malaria morbidity among children under 1 year old	Incidence of clinical malaria in children under 5 years old Prevalence of malaria in children under 5 years old	Clinical malaria incidence can be captured through DHIS2, but only available as aggregated total for under 5. Additional data collection would be needed to report under 1-specific numbers. Prevalence of malaria in implementation and control areas can be captured through surveys such as MIS, MICS, or DHS. In DRC, the last DHS was 2014; MICS was 2017-18. The next DHS is planned for 2022. DHIS2 and national surveys will need to be updated to include indicators for IPTi-SP. There is a risk that national surveys would not have adequate power at sub-national levels for target population, and would require oversampling in those areas. National surveys may also not be aligned with the timing of evaluation	Yes
1	Objective	Introduce and scale-up coverage of IPTi-SP	Number of IPTi-SP 1 doses given Number of IPTi-SP 2 doses given Number of IPTi-SP 3 doses given Coverage of IPTi-SP	DHIS2 DHIS2 Tracker data collected through PATH staff coaching visits; this can then be compared with national DHIS2 data Population estimates available from several possible sources: NMP population estimates; EPI population estimates; enumeration done for bed net campaigns National surveys such as MIS, MICS, or DHS, with the addition of oversampling of infants-, or study-specific community surveys. DHIS2 and national surveys will need to be updated to include indicators for IPTi-SP. In DRC, the last DHS was 2014; MICS was 2017-18. The next DHS is planned for 2022.	Yes
1.1	Outcome	Established policies and governance structure for IPTi-SP delivery	IPTi-SP operational manual developed Publication of IPTi-SP operational manuals on government portals Policies updated based on revised WHO guidance Established sustainability and transition plan for IPTi-SP	Investment reporting	No
1.1.1	Output	Policies to guide IPTi-SP available and approved	Operational manuals for delivery of IPTi-SP developed Job aids for delivery of IPTi-SP developed	Investment reporting	No

#	Level	Component	Proposed indicator	Proposed data source	Requires supplemental evaluation?
1.1.2	Output	Delivery model for IPTi-SP endorsed by key stakeholders	MOU signed with all key implementing partners	Investment reporting	No
1.1.3	Output	Governance structure to oversee IPTi-SP delivery is organized	TOR established for TWG to govern IPTi-SP delivery External TWG / task force established comprising stakeholders from NMP, EPI, WHO, and UNICEF	Investment reporting	No
1.2	Outcome	Built national and sub-national staff capacity to deliver IPTi-SP	IPTi-SP training curriculum developed TOR for health care workers updated to include IPTi-SP responsibilities	Investment reporting	No
1.2.1	Output	Personnel for IPTi-SP delivery and supervision are identified	Number of health workers identified for delivery of IPTi-SP Health care workers per capita of target population Number of supervisors recruited for supervision of IPTi-SP Supervisors per IPTi-SP health facility	Investment reporting	No
1.2.2	Output	Health worker personnel are trained to deliver IPTi-SP safely and accurately record dosing	Number of health workers trained in delivery of IPTi-SP Number of supervisors trained in supervision of IPTi-SP Proportion of health workers who passed written post-exam training Proportion of supervisors who passed written post-exam training	Investment reporting	No
1.2.3	Output	Health workers deliver IPTi-SP with high fidelity to implementation guidelines	Proportion of health facilities that received a supervision visit in the past quarter Correspondence between EPI (DPT and MCV) coverage rates and IPTi-SP coverage rates	Investment reporting DHIS2	Yes

#	Level	Component	Proposed indicator	Proposed data source	Requires supplemental evaluation?
			Further indicators to be developed based upon the supportive supervision checklist Health worker attrition		
1.3	Outcome	Ensured availability of commodities to deliver IPTi-SP	Dispersible SP is integrated into the InfoMed dashboards	Investment reporting	No
1.3.1	Output	Dispersible SP for IPTi-SP is registered in country	Dispersible SP registered in DRC	Investment reporting	No
1.3.2	Output	Sufficient quantity of dispersible SP for IPTi is procured to meet demand	Order quantities of dispersible SP and demand forecasts	InfoMed	No
1.3.3	Output	Sufficient quantity of dispersible SP for IPTi-SP delivered to health facilities	Expected deliveries of SP	InfoMed	No
1.3.4	Output	Forecasting for commodities is strengthened	Summary reports for SP are displayed in InfoMed dashboard and available for measuring supply chain KPIs and decision making	InfoMed	No
1.3.5	Output	Dispersible SP for IPTi is continually in stock at health facilities	Health facility stock status for dispersible SP	InfoMed	No
1.3.6	Output	Wastage of dispersible SP is accounted for	Indicators to be determined, but likely include examining drug expiry or damaged packaging to determine wastage rates; vaccine wastage is currently tracked through LMIS	Investment reporting	No
1.4	Outcome	Integrated IPTi-SP data collection, reporting, and analysis into national HMIS platform	Developed SOPs for integration of IPTi-SP data collection into existing systems Adoption of an interoperability model (such as OpenHIE) in the National Health Information Architecture to facilitate integration of IPTi-SP data	Investment reporting	No

#	Level	Component	Proposed indicator	Proposed data source	Requires supplemental evaluation?
			IPTi-SP data is available through DHIS2		
1.4.1	Output	Collection of IPTi-SP data is integrated into existing HMIS platforms	Updated tally sheets to include IPTi-SP Updated HF register to include IPTi-SP Updated HMIS forms to include IPTi-SP	Investment reporting	No
1.4.2	Output	Collection of dispersible SP data is integrated into existing PSCM/LMIS	Updated tally sheets to include dispersible SP Updated LMIS forms to include dispersible SP	Investment reporting	No
1.4.3	Output	Pharmacovigilance and AEFI reporting systems are strengthened	Number of health workers trained on use of pharmacovigilance reporting system Number of AEFI reports	Investment reporting	No
1.4.4	Output	Reporting and quality of data is strengthened	Accuracy of routine data Completeness of routine data Timeliness of routine data	Data quality audits on DHIS2 data	Yes
1.5	Outcome	Enhanced community awareness and knowledge of IPTi-SP	Exact indicators to be determined	National surveys such as MICS or DHS	Yes
1.5.1	Output	Communities are engaged and sensitized to IPTi-SP	Number of CHS/CHW's trained on mobilizing and tracing defaulters for IPTi-SP Number of community sensitization sessions conducted	Investment reporting	No
1.5.2	Output	Communities accept and are willing to use IPTi-SP	Yes		
NA	Context	SP resistance	Yes		
NA	Context	Access and use of existing services	Coverage of DTP2 Coverage of DTP3	DHIS2	Yes

#	Level	Component	Proposed indicator	Proposed data source	Requires supplemental evaluation?
			Coverage of MCV	Population estimates available from several possible sources: NMP population estimates; EPI population estimates; enumeration done for bed net campaigns National surveys such as EPI coverage survey, MICS, or DHS. An immunization coverage survey is planned for early 2022. An EPI coverage survey is ongoing in 2022; DHS survey is scheduled for 2022 but there is no planning underway now.	
NA	Context	Coverage of other malaria control tools	Coverage of IRS Coverage of ITN's	Data collected through NMP program delivery	No
NA	Context	Rainfall			No
NA	Context	Vegetation index			No

Data Quality Limitations in DRC

While the performance indicators (Table 17) rely on the use of routine data and program records to track progress, it is critical to acknowledge that there are multiple challenges with the current system of recording and reporting immunization and malaria data that impact the useability of routine data for program monitoring and adaptation. The following section outline data quality challenges in DRC; to address these data quality concerns, key indicators have supplemental evaluation proposed (Section 5.2.1), and periodic data quality assurance will be conducted to ensure the viability of data (Section 5.1.4).

Broadly, there is insufficient coverage of child health cards with only 71 percent of children ever receiving a card and low retention with 26 percent of children still possessing the card at the time of follow up. As a result, tracking and reporting of children immunization information is incomplete and the use of routine data may pose challenges for program implementation. The following section details specific known data quality concerns with the available routine data sources.

DHIS2

There are several known data quality issues with DHIS2 data including poor validity, accuracy, completeness, and quality. The lack of available trained health workers, computers, internet connection, energy, registers, and forms also pose a challenge to routine DHIS2 data entry.[79] The analysis of DHIS data is complicated by the lack of a comprehensive list of all health facilities in DRC. Most recently, ongoing health worker strikes have also compromised DHIS2 reporting with health workers abstaining from completing forms.

Data verification and quality control remain weak with limited ownership and engagement in data quality activities by health zones and health areas. Due to the incompleteness and the lack of accuracy of some indicators encoded in DHIS2 during certain periods, it is often necessary for projects to refer back to the health facility to perform additional data collection or validation using the paper form.[80]

InfoMed

USAID and Chemonics are integrating LMIS systems with DHIS2 into a dashboard with visualizations, known as InfoMed. While it has facilitated better visibility into logistics systems, there are still many challenges in the system, notably:

- Limited access to internet, electricity, and IT equipment
- Uncoordinated and slow integration of HMIS and LMIS platforms in health facilities
- Poor availability of inventory management tools at the health facility level
- Fragmented reporting systems with multiple data collection tools for upstream reporting
- Poor data quality
- Lack of trained staff for data entry and analysis.

National surveys (DHS, MICS)

National surveys are not conducted regularly in DRC which means that survey data is often outdated or irregular. The last DHS was 2014 and the last MICS was 2017-18. The next DHS is planned for 2022. Compounding this, national survey samples are based on assumed population growth projections which undermine the quality and accuracy of national survey statistics from all sources as population denominators may be inaccurate. There are also concerns that respondents are underreporting significant health challenges due to the nature of self-report.

5.1.2 IPTi Results Framework in Nigeria

The phased introduction and scale-up of IPTi-SP is designed to contribute to the reduction in malaria morbidity and mortality among children under 1-year-old. The phased introduction and scale-up for this investment has two intermediate results feeding into one objective as follows:

Objective: To implement phased IPTi-SP delivery, test scalability, and gather lessons to inform scale-up of IPTi-SP.

Intermediate Result (IR1): Phased IPTi-SP delivery implemented

Output 1.1: Stakeholders engaged on the IPTi-SP delivery model

Activities

- Hold stakeholder engagement meetings
- Co-design IPTi-SP delivery model
- Work with key stakeholders to endorse delivery model for IPTi-SP
- Avail state-level coordination platforms for IPTi-SP
- Hold Coordination meetings

Output 1.2: Policy makers' and health workers' capacity developed on IPTi-SP delivery and scale-up

Activities

- Develop and adapt training manuals for IPTi-SP roll out
- Develop job aids for delivery of IPTi-SP
- Sensitize policy makers on IPTi-SP intervention delivery and scale-up
- Train HWs and data clerks on IPTi delivery

Output 1.3: Dispersible SP procured, distributed, and monitored.

Activities:

- Procure SP for IPTi and deliver to HFs
- Establish post-marketing surveillance monitoring for dispersible SP
- Train HWs on adverse event monitoring and reporting
- Establish LMIS system for dispersible SP
- Train HWs on LMIS for dispersible SP

Output 1.4: Community awareness and demand for IPTi-SP catalyzed.

Activities

- Adapt advocacy and communication strategy for IPTi-SP
- Develop advocacy briefs
- Print advocacy briefs
- Develop IEC materials on IPTi-SP
- Print IEC materials for IPTi-SP

Output 1.5: Integrated tools for IPTi-SP implementation and reporting tools developed, printed, and distributed.

Activities:

- Integrate EPI register that incorporates IPTi-S indicators
- Engage stakeholders on inclusion of IPTi-SP indicators in the DHIS2 platform
- Train data clerks on revised tools
- Conduct data quality assurance visits

Intermediate Result 2 (IR2): IPTi-SP scalability tested and lessons generated to inform guidance on scale-up

Output 2.1: Evidence and lessons learned from IPTi-SP scale up available and shared

Activities:

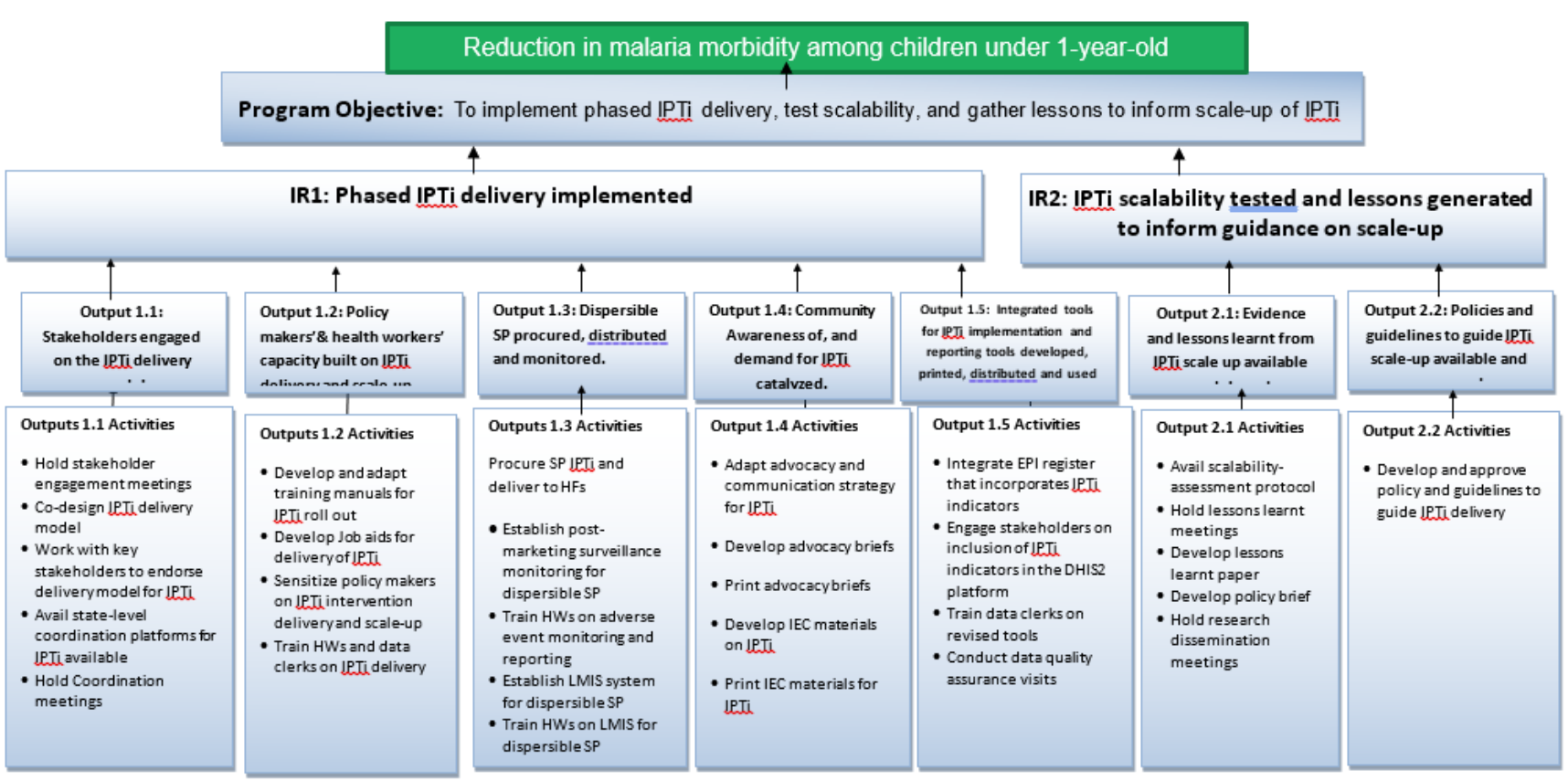
- Avail scalability-assessment protocol
- Hold lessons learned meetings
- Develop lessons learned paper
- Develop policy brief
- Hold research dissemination meetings

Output 2.2: Policies and guidelines to guide IPTi-SP delivery available and approved

Activities

- Develop and approve policy and guidelines to guide IPTi-SP delivery

Figure 20. Nigeria results framework.



Performance indicators for Nigeria

The project has indicators, as detailed in Table 18, that will be used to track project performance and will be tracked with a robust internal M&E plan.

Table 18. Performance indicators for Nigeria.

#	Level	Component	Proposed indicator	Proposed data source	Known risks or data quality issues	Requires supplemental evaluation?
	Goal	Reduction in malaria morbidity among children under 1-year-old	Incidence of clinical malaria in children under 5-years-old Prevalence of malaria in children under 5-years-old	Clinical malaria incidence can be captured through DHIS2, but only available as aggregated total for under 5. Additional data collection would be needed to report under 1-specific numbers. Prevalence of malaria in implementation and control areas can be captured through surveys such as MIS, MICS, or DHS, with oversampling of infants in sub-national areas of interest	Currently ongoing health workers strike that can affect data reporting Poor quality, accuracy and completeness are a concern for routine DHIS2 data DHIS2 and national surveys will need to be updated to include indicators for IPTi National surveys would not have adequate power at sub-national levels for target population, so would need oversampling in those areas National surveys might not be aligned with the timing of evaluation In Nigeria, the last DHS was 2018; MICS was 2016-17. The next DHS is planned for 2022.	Yes
	Objective	To introduce IPTi-SP, test scalability, and gather lessons to inform scale-up of IPTi-SP using a phased implementation approach.	Number of states implementing IPTi-SP Coverage of IPTi-SP	Program report National surveys such as MIS, MICS, or DHS, with the addition of oversampling of infants-, or study-specific community surveys.	DHIS2 and national surveys will need to be updated to include indicators for IPTi-SP	Yes

#	Level	Component	Proposed indicator	Proposed data source	Known risks or data quality issues	Requires supplemental evaluation?
1.0	Intermediate Result 1:	Phased IPTi-SP delivery implemented	IPTi-SP operational manual developed IPTi-SP operational manual adapted Number of states implementing IPTi-SP in Nigeria Number of IPTi-SP doses (1,2 and 3) given Number of infants receiving IPTi-SP (1,2 and 3)	Project reporting Program report Program report HMIS HMIS	Poor data quality (accuracy and completeness) are a concern for routine DHIS2 data	No
1.1	Output	Stakeholders engaged on IPTi-SP delivery model	Number of stakeholder engagement meetings held Availability of co-designed IPTi-SP delivery model Delivery model for IPTi-SP endorsed by key stakeholders Availability of state-level coordination platforms for IPTi -SP Number of coordination meetings held	Project reporting Signed MOU		No
1.2	Output	Policy makers' and health workers' capacity built on IPTi-SP delivery and scale-up	Training manuals developed and adapted for IPTi-SP roll out Job aids for delivery of IPTi-SP developed Number of policy makers trained on IPTi-SP intervention delivery and scale-up Number of HWs and data clerks trained on IPTi-SP delivery	Project reporting		No

#	Level	Component	Proposed indicator	Proposed data source	Known risks or data quality issues	Requires supplemental evaluation?
1.3	Output	Dispersible SP procured, distributed and monitored.	Quantity of SP for IPTi procured and delivered to HFs Post-marketing surveillance monitoring established for dispersible SP Number of HWs trained on adverse event monitoring and reporting LMIS system established for dispersible SP Number of HWs trained on LMIS for dispersible SP	Project reporting	There is currently no locally approved dispersible SP	No
1.4	Output	Community awareness and demand for IPTi-SP catalyzed.	Availability of adapted advocacy and communication strategies for IPTi-SP Number of advocacy briefs developed Number of advocacy briefs printed Number of IEC materials on IPTi-SP developed Number of IEC materials for IPTi-SP printed	Program report		
1.5	Output	Integrated tools for IPTi implementation and reporting tools developed, printed, distributed, and used.	Availability of integrated EPI register that incorporates IPTi-SP indicators Stakeholders engaged on inclusion of IPTi-SP indicators in the DHIS2 platform Number of Data clerks trained on revised tools Number of data quality assurance visits conducted	Program data HMIS	IPTi not on current HMIS registers Poor data quality (accuracy and completeness) are a concern for routine DHIS2 data	

#	Level	Component	Proposed indicator	Proposed data source	Known risks or data quality issues	Requires supplemental evaluation?
			Number of infants receiving IPTi (1,2 and 3 doses)			
2.0	Intermediate Result 2	IPTi–SP scalability tested and lessons generated to inform guidance on scale-up	Availability of lessons learned from scalability testing to inform large-scale implementation of IPTi-SP Availability of approved policies and guidelines to guide IPTi-SP scale-up are available and approved	Assessment report Updated IPTi-SP recommendation in NSP		No
2.1	Output	Evidence and lessons learned from IPTi-SP scale up available and shared	Availability of scalability assessment protocol Number of lessons learned meetings held Number of lessons learned papers developed Number of policy briefs developed Number of research dissemination meetings held	Project reporting		Yes
2.2	Output	Policies and guidelines to guide IPTi-SP delivery are available and approved	Number of policy update/guideline development meetings held Availability of approved policies and guidelines to guide IPTi-SP scale-up are available and approved	Project reporting		No

For reporting on reduction in malaria morbidity, data from HMIS registers is disaggregated for all children under five and submitted to DHIS2; which creates a gap for analyzing outcomes among the target IPTi-SP age group (0-11 months). As a solution, data on HF attendances for children aged 0–11 months (inclusive) will be extracted from health facility registers as full line listings. These will be extracted monthly by the field teams by photographing the relevant pages of the registers and entered using SurveyCTO or directly into Excel tables as appropriate. Names of HF attendees will be covered by a piece of card, and observations will be anonymous and assigned a generic identity number.

Observations for suspected malaria cases only for children aged 0–11 months will be entered into the dataset based on line listings, with variables entered including date of HF attendance, sex, date of birth (or closest estimate of age in months as a preference, if this cannot be confirmed from an identity document, previous HF record or vaccination/medical card), whether a malaria test was performed, type of test performed (RDT or microscopy), results of tests (confirmed malaria or negative test), and any other variables collected routinely for all child attendees (e.g. nutrition status), and malaria mortality.

These data obtained from HF registers will be analyzed regularly to inform progress towards project objectives and evaluate the effectiveness of IPTI implementation. Observations from registers will be categorized by the child's age according to the smallest-possible increments (preferably by month of age). Incidence curves for suspected and confirmed malaria cases by age will be modelled from this data (with use of offset terms to adjust for estimated numbers of children in each age category by district). Incidence curves by age will be either fitted with quadratic or cubic regression terms in STATA 16 or using a thin plate spline term in R (version 3.6.2).

Data Quality Limitations in Nigeria

Routine HMIS data

The quality of routine HMIS data varies across states in Nigeria. The HMIS data is affected by a myriad of data quality issues, including completeness, validity, and consistency. Aside from the structural and data process issues, the utility of malaria surveillance depends on reliable case definitions. Therefore, the quality of parasite-based diagnosis should be assured, which is often not the case for routine microscopy and RDTs. Moreover, access to parasite-based diagnosis is sub-optimal, which further reduces the reliability of the data. This double constraint in both the public and the private healthcare sector grossly reduces the utility of malaria surveillance for decision making at all levels of the information chain.

Available routine malaria data underrepresent the true burden of malaria in the country. Public primary healthcare centers report a large proportion of the data, but they represent only 25 percent of the population seeking care. The malaria surveillance system currently does not capture data from the private sector or secondary and tertiary public health facilities. Expanding routine reporting of health information to the private sector poses unique challenges, but without their involvement, it is difficult to develop and validate tailored packages which respond to the changing epidemiology of malaria in Nigeria. All suspected malaria cases should receive a parasite-based test and should be registered in the routine HMIS, irrespective of where they seek care. There is also still a disconnect between the community HMIS and the national HMIS, as community data is yet to feed into the facility level data in the national HMIS.

Although the reporting rate on the DHIS2 platform has increased over time, the consistency and validity of the data remain sub-optimal. Forms for regular reporting are often unavailable and staff are poorly trained, inadequate, ill-motivated, and overloaded. Despite the availability of data quality assessment (DQA) guidelines and processes, DQAs do not happen regularly and when they do, the activities are donor-driven, poorly coordinated, and rarely provide feedback to the system. The NMP makes some attempt to analyze

the malaria related indicators in the DHIS2 platform on a monthly basis and provide feedback to the states. However, the poor quality and lack of representativeness of the data make it difficult to effectively use them for decision making.

LMIS

The LMIS is still problematic in Nigeria, particularly the quality of reports from service delivery points across the states. The NMP is attempting to bridge the gap between HMIS capturing service delivery, and LMIS, which records commodity utilization. Also, other programs such as family planning and maternal health still suffer from inadequate LMIS reporting from service delivery points characterized by low reporting rates. The LMIS problem is also closely linked to lack of well-trained supply chain staff responsible for the management of public health commodities.

In order to effectively manage the public health supply chain system, there is a need for an adequate number of trained staff with requisite knowledge and skills for the effective management of public health commodities.[81]

5.1.3 Critical assumptions in DRC and Nigeria

In order for scale-up of IPTi-SP to follow the results framework as expected, it is assumed that the following assumptions will be met in both countries:

- The policy on IPTi is adopted (Nigeria).
- The EPI structure and system is ready and adequate for delivering IPTi-SP.
- The country has an adequate supply of SP for IPTi. While the project will work on improving performance and strengthening systems, achieving certain targets such as the proportion of infants receiving IPTi-SP will greatly depend on constant availability of SP in the health facilities, through the national supply chain.
- Appropriate data management tools are available in the health facilities to capture relevant data for measurement of national and investment indicators.
- Staffing levels at health facilities are sufficient and health facility staff are well trained, and motivated to meet the demand for services.

The extent that these assumptions are invalid will compromise this investment's ability to achieve all results described in this framework.

5.1.4 Data Quality Audits in DRC and Nigeria

In recognition of the limited existing DQAs, project-led data quality assessments are typically conducted periodically for routinely collected indicators to ensure information generated from this investment are of adequate quality for programmatic decision making.

For example, in DRC, to bolster quality and usability of DHIS2 data, MEASURE Evaluation (PMI/USAID) conducts routine DQAs of malaria data in the nine PMI-supported provinces through centers of excellence. At this time, there is no overlap between PMI-supported provinces and the proposed IPTi targeted areas in DRC, but this model of DQAs will be adopted in intervention areas. In both Nigeria and DRC, DQAs will be conducted quarterly in conjunction with ministry staff.

The key data quality standards to be measured will include:

- Validity: Data collected will clearly and adequately represent the intended result through developing standard data collection tools and training individuals in the use of the tools before data is collected.
- Integrity: Systems will be put in place to ensure that data collected is safeguarded to minimize the risk of transcription error or data manipulation through automating the data collection processes.
- Precision: Data will have sufficient level of detail and precision to permit management decision-making.
- Reliability: Data collection methods will be well documented to reflect stable and consistent data collection processes and analysis methods over time.
- Timeliness: Data will be captured real time using the electronic data capture systems, making it available at a useful frequency, current, and timely enough to influence management decision-making.

To assess HMIS data quality during quarterly DQAs, data will be collected from health facility registers and compared to data that was submitted in DHIS2. Summary scores for accuracy-reliability and completeness will be calculated for each data point and then aggregated for each health facility for an overall score. These will also be tested using Cohen's kappa coefficient. Further stratification within each health facility by month and variable will also be conducted for more targeted improvements.

- Accuracy–reliability will be calculated using:

$$\textbf{Percentage Error} = \left(\frac{(Value\ in\ Register - Value\ in\ HMIS)}{Value\ in\ Register}\right) X\ 100$$

- Completeness will be calculated by:

$$\textbf{Percent Completeness} = \left(\frac{Number\ of\ Observations\ Recorded}{Number\ of\ Observations\ Expected}\right) X\ 100$$

5.2 Investment Evaluations

Given the data limitations noted above, and to triangulate data on the performance indicators which is collected through routine monitoring, supplementary evaluations are proposed. Evaluations of this investment are intended to collect high-quality, validated primary data that can reliably measure key indicators around (a) program impact, (b) coverage and adherence to IPTi-SP administration, and (c) broader contextual lessons and benefits of the program. The following sections present a menu of potential evaluation approaches for each country; selection of the appropriate combination of evaluation approaches will be done in conjunction with GiveWell and national stakeholders. Recommendations for the minimum evaluation activities included in this investment are described following Table 19.

5.2.1 Evaluation Plan in DRC

Several evaluations are recommended for inclusion based upon various stakeholder needs. The following segments detail the rationale for inclusion of each of the recommendation evaluations:

- Step-wedge or quasi-experimental infant cohort study design with control cohort in non-intervention health zones or other comparator province. We recommend the inclusion of a quasi-experimental infant cohort study to estimate the impact of IPTi-SP on infant morbidity in DRC. While morbidity estimates may not have significant impacts on the cost-effectiveness model, knowing the impact on child morbidity will be important for national stakeholders and donors to inform decisions about future scale and support of IPTi-SP. Estimating impact of IPTi-SP will be used to inform national

decisions about sustaining and scaling IPTi-SP and will be used to advocate for further support from donors such as Global Fund.

- Household surveys to report IPTi-SP doses administered per child and coverage. We recommend inclusion of household surveys to accurately estimate coverage of IPTi. This will allow validation and triangulation of coverage obtained through HMIS data. Validated coverage estimates will be important for identifying bottlenecks in scale-up and informing ministry decisions for future scaling; they will also be critical to estimating impact and updating the cost-effectiveness model for reporting to GiveWell. In addition, the household surveys present an opportunity to assess factors associated with compliance with IPTi-SP and to collect other data on awareness of IPTi-SP, and the feasibility and acceptability of IPTi-SP to community which can help identify possible bottlenecks to coverage that will not be evident through routine HMIS data.
- Facility based cross-sectional study of SP resistance markers in DRC in collaboration with PSI. We recommend inclusion of a study of SP resistance given the importance of SP resistance (or lack of) as a pre-condition for effective coverage of IPTi-SP in DRC. A recent and thorough estimation of SP resistance will also help to update modeled estimates of impact to better understand the probable cost-effectiveness of the intervention, as well as identify and target further geographies that would be appropriate for introduction.

Table 19. Menu of supplemental evaluation activities in DRC.

Component	Potential evaluation design	Potential end point measures	Proposed data source	Pros	Cons	Parameters which may influence cost
Reduction in morbidity of malaria in children under 1 year	Step-wedge or quasi-experimental infant cohort study design with control cohort in non-intervention health zones or other comparator province	Incidence of clinical malaria Prevalence of anemia at 12 months of age (secondary endpoint; not powered to detect impact) Prevalence of malaria infection at 12 months of age (secondary endpoint; not powered to detect impact) Hospitalized malaria (secondary endpoint; not powered to detect impact) Note: in the proposed intervention area, the estimated number of deaths from malaria in under 1s would be small in both intervention and control areas, therefore making it very difficult to determine impact effectiveness from this indicator.	Passive [facility register] and active [monthly household visit] case detection of community cohort	Improved quality of data on outcomes of interest. There are several appropriate control comparators (health zones within the same province).	The cohort needed to feasibly measure the outcome of interest is potentially quite large, particularly if it is desired to be powered for detection of the secondary outcomes. Personnel, time, and resources needed to conduct cohort tracking and data collection	Conducted in Y1. The same study could be conducted in subsequent years pending donor interest or could be supplemented with lighter-touch evaluation such as the case-control approach identified below. A rough sample size calculation based on incidence of 350 cases per 1,000 infants per year in control areas and IPTi-SP having a 20% effect size for reduction in clinical malaria indicate that for 95% significance and 90% power, ~350 infants per arm would need to be followed, or ~440 if we assumed a 20% drop-out rate.
	Case control study to assess exposure to IPTi-SP	Among malaria test-positive (cases) and test-negative controls presenting to health facilities Among cases of severe anemia in hospitalized children and non-cases of severe anemia secondary endpoint; not powered to detect impact)	Health-facility based case-control study	This would require fewer personnel, time, and resources to conduct.	Need to better understand the health facility distribution in each area and the referral of cases to ensure validity.	This could be conducted in Y1 and Y5, or used to supplement a cohort evaluation in interim years (e.g., Y3 and Y5). Sample is to be determined, but based upon the prior assumptions, assumed 400 cases of malaria with a 1:2 ratio of cases: controls (e.g., 800 controls)

Component	Potential evaluation design	Potential end point measures	Proposed data source	Pros	Cons	Parameters which may influence cost
	Step-wedge or quasi-experimental design with comparison health zones	Incidence of clinical malaria Incidence of severe malaria Incidence of confirmed malaria in hospitalized children Incidence of severe anemia in hospitalized children Prevalence of malaria infection Prevalence of anemia	Health facility-based surveillance	Since this would utilize existing health facility surveillance data, the cost and additional personnel needed is substantially less than if using an infant cohort.	Using facility-based surveillance data presents additional data quality risks, given the concerns about routine reporting.	Conducted in Y1. The same study could be conducted in subsequent years pending donor interest, could be supplemented with other evaluation approaches, or used to supplement the above evaluation approaches.
Introduce and scale-up coverage and equity of IPTi-SP	Household surveys to report IPTi-SP doses administered per child and coverage	• Number of IPTi-SP 1 doses given • Number of IPTi-SP 2 doses given • Number of IPTi-SP 3 doses given • Coverage of IPTi-SP	Household surveys	Improved quality of data on the outcomes of interest.	Personnel, time, and resources needed to conduct cohort tracking and data collection	Conducted in Y1, Y3, and Y5. Scope of coverage surveys in each year could be either to only new geographies, or all geographies receiving IPTi-SP. Sample is to be determined, but based upon assumptions of 60% coverage +/- 5%, we estimate we would need around 400 respondents at the level of estimation of coverage (e.g., if coverage is to be estimated at the HZ level, this would require 400 respondents per health zone). Household surveys could be timed to be conducted alongside cohort data collection in order to reduce budget.
Health workers performance	Post introduction evaluation (PIE) of IPTi-SP	This might also require health facility surveys with direct observations to evaluate the		Could be done during mentoring	Knowing they are being observed,	Conducted in Y1 only.

Component	Potential evaluation design	Potential end point measures	Proposed data source	Pros	Cons	Parameters which may influence cost
and fidelity to IPTi-SP delivery		procedures followed by the health workers (eg proportion that administer the IPTi-SP dose correctly, that report the IPTi-SP dose correctly and that document it correctly on the health card)		visits to health facilities	health workers could change their attitude leading to a biased observation	
	Cross-sectional study of feasibility and acceptability of IPTi-SP among health workers	Exact indicators to be determined	Health facility surveys Health facility observation FGD's and KII's			Conducted in Y1, Y3, and Y5.
Reporting and quality of data is strengthened	Data quality audits of IPTi-SP		Health facility data collection	We can leverage IPTi-SP audits to evaluate HMIS data quality at that same time		Conducted annually
Enhanced community awareness and knowledge of IPTi-SP	Cross-sectional study of knowledge and acceptance of IPTi-SP	Exact indicators to be determined	Household surveys FGD's			This would not require a separate survey activity but these indicators could be included in an IPTi-SP coverage survey.
	Cross-sectional study of acceptability and feasibility of IPTi-SP among caregivers	Exact indicators to be determined	Household surveys FGD's and KII's			This would not require a separate survey activity but these indicators could be included in an IPTi-SP coverage survey.
SP resistance	Facility based cross-sectional study of SP resistance markers in DRC in collaboration with PATH		PSI study of SP resistance in DRC in collaboration with PATH Facility-based sample collection			Conducted in Y1 only. 200 samples are anticipated to be collected per province.
Access and use of existing services (EPI)	Cross-sectional study	• Coverage of DTP2 • Coverage of DTP3 • Coverage of MCV	Household surveys			This would not be a separate survey activity but these indicators could be included in an IPTi-SP coverage survey.

5.2.2 Evaluation Plan in Nigeria

Table 20. Plan for supplemental evaluation in Nigeria.

Component	Potential evaluation design	Potential end point measures	Proposed data source	Pros	Cons
Reduction in morbidity of malaria in children under 1 year	Step-wedge or quasi-experimental design with comparison health zones	• Incidence of clinical malaria • Incidence of severe malaria • Incidence of confirmed malaria in hospitalized children • Incidence of severe anemia in hospitalized children • Prevalence of malaria infection Prevalence of anemia	DHIS2 data +/- cohort of infants Household surveys Health facility surveys	Using only DHIS2 data would be cheaper, but would require DQAs and infant-specific data reporting	Data quality is weaker in DHIS2 data Personnel, time, and resources needed to conduct cohort and household surveys
Health workers performance and fidelity to IPTi delivery	Post introduction evaluation (PIE) of IPTi-SP				
	Cross-sectional study of feasibility and acceptability of IPTi-SP among health workers	*Exact indicators to be determined*	Health facility surveys Health facility observation FGD's and KII's		
Reporting and quality of data is strengthened	Data quality audits of IPTi		Health facility data collection	We can leverage IPTi-SP audits to evaluate HMIS data quality at that same time	
Enhanced community awareness and knowledge of IPTi-SP	Cross-sectional study of knowledge and acceptance of IPTi-SP	*Exact indicators to be determined*	Household surveys FGD's		

Component	Potential evaluation design	Potential end point measures	Proposed data source	Pros	Cons
	Cross-sectional study of acceptability and feasibility of IPTi among caregivers	*Exact indicators to be determined*	Household surveys FGD's and KII's		
SP resistance	Cross-sectional study of SP resistance in DRC in collaboration with PATH		PSI study of SP resistance in DRC in collaboration with PATH Facility-based sample collection		
Access and use of existing services (EPI)	Cross-sectional study	• Coverage of DTP2 • Coverage of DTP3 • Coverage of MCV	Household surveys		

Secondary analysis of MIS and DHS data

Although measurement of impact of IPTi-SP on malaria related mortality among infants may not be fully possible in the lifespan of the project, efforts will be made to derive some impact-related measurements from existing national surveys. In addition to tracking malaria-related case fatality among infants using HMIS data, surveys approaches to measure all-cause child mortality will be used. Data generated through existing national surveys such as DHS and MIS surveys will be used for secondary analysis. Where possible, stratified analysis will be done for the project focus areas to adequately monitor changes in child survival in these areas where the project is implemented. Modelling of impact will be done concurrently and as actual data is generated from phased implementation, and experiential learning is documented, information should feed into mathematical models on the impact of IPTi-SP.

5.3 Learning Agenda

The learning agenda will focus on answering exploratory questions that can inform and shape continuing scale-up and improvement of IPTi-SP delivery. The learning agenda will center on identifying adaptations to improve program efficiencies, identifying opportunities for integration of innovative IPTi approaches, and generating learnings to support replication of program approaches to advance the malaria program.

With these goals in mind, key learning questions will be defined at the outset of this investment and prioritized for exploration in conjunction with global and national stakeholders. Dependent on stakeholder priorities and the identified learning questions, appropriate operations research methods will be applied to answer the identified questions. The learning generated from investment activities will be published through learning papers, research briefs, and other documentation highlighting key findings. Evidence generated to help answer key learning questions will be shared with malaria stakeholders, including GiveWell and other donors, the National Malaria Program and other relevant MOH bodies through technical working groups and other coordination meetings as appropriate.

The questions below include preliminarily identified learning questions of interest in each country; further questions will be added and refined in the first year of investment implementation. The learning agenda is a living document which will be revisited annually to be updated and refined as needed.

Learning agenda in DRC:

- What is the potential impact on malaria morbidity of delivering IPTi-SP through other platforms (e.g., delivery through CHW's)?
- What is the feasibility and acceptability of delivering IPTi-SP through other platforms (e.g., delivery through CHW's)?
- What is the potential impact on malaria morbidity of adding additional touchpoints to IPTi-SP (e.g., extended dosing into the second year of life)?
- What is the feasibility and acceptability of adding additional touchpoints to IPTi-SP (e.g., extended dosing into the second year of life)?
- What is the potential impact on malaria morbidity of co-delivery of IPTi-SP and RTS,S?
- How can the effect of health worker strikes on high-quality delivery of IPTi-SP services be mitigated?

Learning agenda in Nigeria:

- What is a scalable unit for IPTi-SP in Nigeria?
- What is the best approach for delivery of IPTi-SP at scale through EPI platforms?
- What are the key considerations for scaling up IPTi-SP in Nigeria, considering the heterogeneity of settings?

The research methodologies employed to answer learning agenda questions will be defined on an as needed basis and will prioritize providing actionable and timely insights to inform design and implementation questions.

5.4 Data Management and Use

A critical component is the application of evidence collected through the MEL plan to inform adaptations in program strategy and implementation. The data collected through the MEL plan will be used in three main ways, as described previously:

1. Track progress toward stated results
2. Identify risks prospectively
3. Support program adaptation and learning

To enable timely, actionable use of data, we will develop a user-friendly results dashboard as a cornerstone of the MEL workstream. The dashboard will include all performance indicators identified in the monitoring plan and will be updated monthly with project reporting data and HMIS data. All technical staff will be granted access the dashboard and trained on dashboard use to enable real-time use of performance indicators.

Leveraging expertise and experience in designing and developing dashboards for users, we will work with stakeholders to craft a dashboard that is responsive to user needs and is equipped to enable decision support. If necessary, multiple dashboards will be designed to be responsive to the needs of different user-groups (e.g., global, national, and sub-national stakeholders). As feasible, decision-support cues will be built into the dashboard to prompt appropriate action. Examples of decision-support cues could include automated alerts when a risk is identified (e.g., low stock notifications in facilities), or SMS messages that prompt users to review newly updated data in the dashboards.

In addition to availability of the monitoring dashboards, we will routinely analyze monitoring data at various levels to enhance evidence-based decision making. The results obtained will be summarized using different descriptive statistics and used to assess progress and performance. The focus of data analysis will be on comparing expected results against achieved, understanding reasons for variances, and comparing performance at different intervals (quarterly, semi-annually, and annually) as well as across regions/states and districts. As much as possible, data will be disaggregated by gender, age, and district. On both the dashboards and additional analysis, investment staff will work directly with MOH counterparts to enhance local analytic capacity.

5.4.1 IPTi Data use and dissemination

The progress of this investment and successes and challenges will be shared with stakeholders through the GiveWell, PATH, and Malaria Consortium websites. Programmatic findings will be published in both English and French to ensure accessibility of findings.

Results from the MEL plan will be shared through periodic quarterly and annual reports to key stakeholders. At the national level, findings will be shared through quarterly regional and annual investment review meetings (with investment staff, MOH officials, implementing partners, and other key stakeholders). At the regional/state level, knowledge and data sharing will be done through regional coordination meetings, implementing partners' meetings, and investment performance review meetings. Dissemination will entail presenting lessons learned, successes, and identifying emerging issues/challenges from implementation based on both the routine monitoring data, as well as evaluation findings. The workshops will be designed to be a participatory review of the data, in order to facilitate brainstorming on strategies for addressing the challenges and stimulate adaptive programming. Learnings from these dissemination sessions will guide investment-related internal decision making such as targeting patients with certain characteristics, identifying implementation areas, and adjusting implementation strategies. All these events are aimed at keeping the stakeholders apprised of the investment's progress, provide opportunities for program learning and adaptation, and provide accountability for the investment's performance in the implementation areas.

Lastly, findings from evaluations conducted by the program will be disseminated through national and international conferences as well as publication in peer reviewed journals.

6 Roles and Responsibilities for the Implementation Phase

For the implementation phase, PATH and Malaria Consortium propose to continue to leverage the synergy and momentum built between both organizations during the scoping phase. During the scoping phase, we created cross-organizational thematic workstreams co-led by both organizations. The workstreams (stakeholder engagement, desk reviews, costing model, mathematical modeling for impact, project design and budget, and MEL) met weekly or biweekly to develop the approach, share learnings across both countries, and update on progress. We also convened a monthly all-team check-in between both organizations to talk through the status of each workstream workplan and the overall progress.

During the implementation phase, it would be beneficial to have a similar model bringing together both organizations in specific functional workstreams to develop implementation plans, share learning, and problem solve as challenges arise. Given that DRC and Nigeria are both at different stages of IPTi adoption and implementation, PATH/Malaria Consortium expect distinct Year 1 activities in each country, however, the organizations believe there is a lot to be learned from the cross-organizational exchange of information and coordination. This coordination will be above and beyond the regular interactions at other international fora for IPTi, including the global IPTi Community of Practice being coordinated by the WHO.

7 Notional Budget

7.1 Introduction

The following section summarizes the design of the proposed program for this investment, the assumptions PATH/Malaria Consortium used to develop a notional budget, and the key activities and drivers of costs, including the inputs to be provided via our two organizations. The proposed budget is distinct from the cost estimates presented in section 3 of this report. The costing exercise presented in section 3 estimates the incremental, annualized cost of introducing and delivering IPTi informed by a combination of data inputs from the literature and other data sources. Significantly, it does not consider the expenses of technical assistance support incurred by the implementing partner organizations. In contrast, the budget described in this section is based on a detailed plan for the set of activities our organizations are proposing to undertake with funding from this investment.

For DRC, we have prepared high-end and low-end scenarios, starting with a detailed plan for roll-out and one year of implementation, and scenarios for rolling out and supporting implementation of the intervention in additional provinces to be added in years 2–4. For Nigeria, we have developed a detailed plan including evaluative work and planning and scale-up in four states over a three-year period, which could be followed by a full plan to scale in the country in the following year. We would like to note that plans (and the corresponding budget) for both countries are based on what we have learned and developed during the scoping period. PATH and Malaria Consortium have a high level of confidence in the accuracy of the costs presented in the budget and in the inputs required for this program as designed. However, we would like to note that the underlying assumptions are subject to change based on several factors, including:

- The level of funding that GiveWell can invest and the timing at which the funding is available.
- What we will learn in these two countries as we develop detailed work plans and work with the governments to launch the intervention.
- Possible changes to the intervention model and approach to implementation that may result from experience in the first year.
- Evaluations conducted early in the program.
- Potential changes in IPTi guidance from WHO.

7.2 Democratic Republic of Congo

7.2.1 High level assumptions

Scenarios

For DRC, PATH has prepared high-end and low-end scenarios, starting with a detailed plan for roll-out and one year of implementation, and has extrapolated costs based on those detailed plans for covering an expanded set of geography and population in Years 2–4. Costs will be highest in the first year of implementation in each health zone, driven by training and other costs related to the roll-out of the intervention, including planning meetings, and development and distribution of job aids and materials. Costs will come down in each implementing area in subsequent years, as intervention coverage continues in implementation mode, without the added cost of roll-out. Roll-out costs are spread across Years 1–3 in the high-end scenario, and Years 1–4 in the low-end scenario, following their respective scale-up scenarios. In addition, looking at this investment as a whole, costs per infant treated will be highest in the first year as

we build the structure for the program while initially covering a smaller total geography and population. Costs per infant treated will come down as we scale the intervention across a larger population and scale back the support provided by PATH as an increasing number of provinces continue in implementation mode over Years 2–5. See Table 21 for a visual representation of areas in scale-up versus continuing implementation over the life of the investment, in the high-end and low-end scenarios. Most roll-out and implementation costs scale by the number of provinces, health zones, health facilities, health workers engaged, or infants treated.

High-end scenario

In the high-end scenario, as outlined in section 4.1, Plan to Scale, the program would introduce the intervention in two provinces in Year 1, covering 28 health zones, including 1,192 health facilities, and treating an estimated 197,526 infants. In years 2 and 3, the program would expand, reaching coverage of all health zones in the 10 eligible provinces and would continue covering this area and population through Year 5. During Years 3 through 5, the program would be implementing in 187 health zones, including 6,349 health facilities, and reaching an estimated 1,529,957 infants per year.

Low-end scenario

In the low-end scenario, the program would roll out the intervention in one province in the first year covering 16 health zones, including 721 health facilities, and treating an estimated 83,292 infants. The area of implementation would expand more slowly to reach coverage of the ten eligible provinces by Year 4. By the end of Year 4, the low-end scenario would cover the same areas, facilities, and number of infants covered in the high-end scenario. Planning, sensitization, and roll-out costs would still be required for the same set of geography, but the low-end scenario starts smaller and spreads these costs over a longer period.

Intervention model and assumptions

Costs are based on the intervention model described in section 4 above. Significant elements and assumptions that shape the budget are:

- IPTi-SP will be delivered at government health facilities, by existing health workers, using the existing routine immunization platform, and using the existing touch points for childhood vaccination.
- IPTi-SP will be delivered at three visits per infant during the first year of life, using Dispersible SP.
- Quantification of infants that will receive the intervention is based on population data and reported coverage levels of the routine immunization platform in each province.[15]

Table 21. Geography and coverage in scale-up and continuing implementation phases by year for both scenarios.

	Year 1	Year 2			Year 3			Year 4			Year 5		
	New areas in scale-up phase	New areas in scale-up phase	Continuing implementation	Total	New areas in scale-up phase	Continuing implementation	Total	New areas in scale-up phase	Continuing implementation	Total	New areas in scale-up phase	Continuing implementation	Total
High-end scenario													
Provinces	2	2	2	4	6	4	10	-	10	10	-	10	10
Health zones	28	59	28	87	101	87	187	-	187	187	-	187	187
Health facilities	1,192	2,285	1,192	3,477	2,873	3,477	6,349	-	6,349	6,349	-	6,349	6,349
Health workers engaged	2,383	4,570	2,383	6,953	5,745	6,953	12,698	-	12,698	12,698	-	12,698	12,698
Est. # infants receiving IPTi in new & continuing areas	197,526	453,214	197,526	650,739	783,028	650,739	1,433,767	-	1,481,081	1,481,081	-	1,529,957	1,529,957
Low-end scenario													
Provinces	2	2	2	4	6	4	10	-	10	10	-	10	10
Health zones	16	30	16	45	85	45	130	57	130	187	-	187	187
Health facilities	721	1,292	721	2,012	2,788	2,012	4,800	-	4,800	4,800	-	4,800	4,800
Health workers engaged	1,441	2,583	1,441	4,024	5,576	4,024	9,600	-	9,600	9,600	-	9,600	9,600
Est. # infants receiving IPTi in new & continuing areas	83,292	197,625	83,292	280,916	698,332	280,916	979,248	501,833	979,248	1,481,081	-	1,529,957	1,529,957

Given that the intervention will be administered by government health staff, PATH's inputs for implementation of IPTi will be in planning, stakeholder engagement, roll-out, procurement of the drug and other supplies required for administration, providing support to government coaching and supervision of the health workers, and monitoring and evaluation. Specific activities in these areas are listed in Table 22 below.

Evaluations and studies

PATH will conduct studies and evaluations to measure key indicators reliably using high quality data in addition to data collected through routine monitoring. Details of these activities are provided in the section investment evaluations above. For budgeting purposes, we have included the costs of the two highest priority activities:

- Cohort study: budgeted based on a sample size of 880 infants (440 in the cohort and 440 in the control arm). The cost is based on the cost of similar studies implemented by PATH and scaled to the cohort sample size.
- Household surveys: budgeted in years 1, 3, and 5, for baseline, mid-term, and endline evaluations. The cost is based on the cost of similar surveys implemented by PATH and scaled to the survey sample size. For budgeting purposes, we have used a sample size of 400 households per province. In the low-end scenario, this would be one province in Year 1, six in Year 3, and ten in Year 5; in the high-end scenario it would be two provinces in Year 1, and ten in years 3 and 5.

Timeline

Implementation in DRC is budgeted based on a five-year period.

Activities

Major activities required to initiate, roll-out, and support implementation of IPTi-SP include:

- Sensitization and launch activities.
- Community engagement.
- Planning activities, including sessions with the government starting at the national level down to the health workers in the implementing facilities.
- Development of IPTi-SP tools and materials.
- Intervention roll-out to the provinces, health zones, and health facilities, including training of the participating nurses.
- Procurement of the SP doses and the other supplies needed to administer the drug.
- Ongoing supportive supervision of the participating health workers.
- Monitoring and evaluation activities.

The set of planned activities are shown in Table 22 below.

Table 22. Planned activities in DRC.

Activity group	Activities	Yr 1 high-end scenario	Yr 1 low-end scenario
Sensitization & Launch	IPTi-SP task force meeting national level	1 meeting	1 meeting
	IPTi-SP task force meeting provincial level	1 meeting	1 meeting
	Kick off meeting national	1 meeting	1 meeting
	Kick off meeting provincial	2 meetings	1 meeting
Community Engagement	Workshop - Image box update (Flyers)	1 workshop	1 workshop
	Workshop - development of posters for health facilities	1 workshop	1 workshop
	Production and dissemination of image box and posters	Materials to 2,382 HW	Materials to 1,442 HW
	Radio/TV spots; IPTi-SP listening group (1 radio with solar panel by village)	To 1,192 HF	To 721 HF
	Flyers (image box) for CHW to use for education/meetings with communities (involving community leaders)	To 2,385 CHW	To 1,442 CHW
	Posters for health facilities	To 1192 HF	To 721 HF
Planning Sessions	Workshop - develop/update PAO to include IPTi-SP national	1 workshop	1 workshop
	Workshop - develop/update PAO to include-IPTi-SP provincial	2 workshops	1 workshop
	Workshop - develop/update PAO to include- IPTi-SP HZ	28 workshops	16 workshops
	Workshop - integrated child health tools update /IPTi-SP; Printing and distribution of updated tools	1 workshop	1 workshop
Training & roll-out	Adapt Nigeria's training materials		
	Develop Job aids and training materials for nurses and CHWs, paper dashboard, IPTi-SP supervision checklist	1 workshop	1 workshop
	Develop Operational manual		
	Induction workshop for PATH staff	1 workshop	1 workshop
	National-level training of trainers (NMP and EPI representatives for national level)	1 training	1 training
	Provincial-level training of trainers (DPS: NMP and EPI representatives, including districts representatives)	2 trainings (1 per prov)	1 training
	District-level training of trainers (for health care workers)	97 trainings	57 trainings

Procurement	SP; other supplies for SP administration	3 doses to 197,526 infants	3 doses to 83,292 infants
Ongoing support & supervision	Support to joint visits supervision (National to Prov) - PATH & Ministry staff **[For each implementing province; 1 week each, 2 times/year]**;	2 provinces	1 province
	Support to supervision visits (Province to HZ) - PATH & Ministry staff **[For each implementing Health Zone; 3 days, 4 times/year]**	28 HZs	16 HZs
	Support to supervision visits (HZ to Health facilities) [For each implementing Health Zone; 1 week each, 4 times / year]	28 HZs	16 HZs
	Supervision checklist specific to IPTi-SP (coaching /mentoring), provincial staff, PATH HZ Supervisor and Focal Point's visit all health facilities **[Visit all implementing health facilities]**	1192 health facilities	721 health facilities
M&E and supplemental reporting	DHIS2 tracker development, hosting, and maintenance Data quality audits [Quarterly: visit 2 health facilities per implementing province]	16 HF visits	8 HF visits
Evaluations/ studies / Studies	Infant cohort study	880 infants	880 infants
	Baseline household survey	800 HH	400 HH

Table 23. Budget summary for the high-end scenario in DRC.

DRC: High-end scenario	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Total
Personnel	**1,749,115**	**2,668,709**	**4,333,194**	**1,076,259**	**856,029**	**10,683,306**
Planning and Community Engagement	**296,746**	**440,155**	**685,307**	**18,644**	**19,578**	**1,460,430**
Planning	161,850	165,900	289,217	18,644	19,578	655,188
Community engagement	134,896	274,255	396,090	0	0	805,241
Intervention Roll-out / Scale-up	**115,110**	**131,745**	**182,987**	**0**	**0**	**429,841**
Training	115,110	131,745	182,987	0	0	429,841
Implementation Support	**351,782**	**1,150,394**	**2,567,327**	**1,924,955**	**2,081,442**	**8,075,901**
Commodities: SP	138,346	479,496	1,109,795	1,203,583	1,305,574	4,236,793
Commodities: Other Supplies for SP Administration	60,917	211,132	488,667	529,963	574,872	1,865,551
Supervision	152,520	459,766	968,866	191,409	200,996	1,973,557
M&E and Operations Research	**365,960**	**93,006**	**676,933**	**147,622**	**492,075**	**1,775,597**
Monitoring & Evaluation	55,960	93,006	235,733	147,622	5,675	537,997
Cohort Study	230,000	0	0	0	0	230,000
Household Surveys	80,000	0	441,200	0	486,400	1,007,600
Cross-cutting Operational Costs	**1,825,008**	**2,862,010**	**5,568,372**	**1,263,229**	**1,183,226**	**12,701,845**
Travel	20,020	21,021	22,399	15,842	32,403	111,685
Supplies and Equipment	371,800	375,417	735,767	0	0	1,482,984
Other Operating Costs	542,845	1,061,054	2,132,009	407,343	275,239	4,418,490
Indirect Costs	890,343	1,404,518	2,678,197	840,044	875,584	6,688,686
Total	**4,703,721**	**7,346,019**	**14,014,120**	**4,430,709**	**4,632,350**	**35,126,919**

Table 24. Budget summary for the low-end scenario in DRC.

DRC: Low-end scenario	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Total
Personnel	**1,350,149**	**2,014,053**	**3,022,618**	**2,794,992**	**808,970**	**9,990,781**
Planning and Community Engagement	**207,333**	**203,921**	**538,103**	**283,449**	**151,428**	**1,384,234**
Planning	129,015	69,526	201,770	180,714	19,578	600,603
Community engagement	78,318	134,395	336,333	102,735	131,851	783,632
Intervention Roll-out / Scale-up	**68,750**	**42,170**	**130,367**	**97,537**	**0**	**338,824**
Training	68,750	42,170	130,367	97,537	0	338,824
Implementation Support	**163,386**	**525,120**	**1,710,153**	**2,129,909**	**2,081,442**	**6,610,009**
Commodities: SP	58,451	206,992	757,978	1,203,583	1,305,574	3,532,578
Commodities: Other Supplies for SP	25,737	91,143	333,754	529,963	574,872	1,555,470
Administration						
Supervision	79,198	226,984	618,420	396,363	200,996	1,521,961
M&E and Operations Research	**305,080**	**49,158**	**408,331**	**195,980**	**593,635**	**1,552,184**
Monitoring & Evaluation	35,080	49,158	143,611	195,980	107,235	531,064
Cohort Study	230,000	0	0	0	0	230,000
Household Surveys	40,000	0	264,720	0	486,400	791,120
Cross-cutting Operational Costs	**1,280,056**	**1,855,825**	**3,942,381**	**3,183,634**	**1,330,903**	**11,592,798**
Travel	20,020	21,021	22,399	15,842	32,403	111,685
Supplies and Equipment	230,860	263,571	598,422	424,083	0	1,516,935
Other Operating Costs	379,884	672,264	1,477,537	1,111,632	353,990	3,995,307
Indirect Costs	649,292	898,969	1,844,023	1,632,077	944,510	5,968,871
Total	**3,374,755**	**4,690,246**	**9,751,952**	**8,685,501**	**4,966,378**	**31,468,832**

Description of costs

Personnel

We have budgeted for teams in Kinshasa and the implementing provinces as well as support from our global malaria team.

Kinshasa

The team in Kinshasa will be maintained for the life of the program and will coordinate as the intervention is scaled to additional provinces. Positions include:

- PATH DRC Malaria Program Lead (25% Years 1–5).

- Technical Director (100% Years 1–5).
- Operations Lead (100% Years 1–5).
- Supply Chain Officer (100%).
- M&E Officer (100% Years 1–5).
- Project Administrator (100% Years 1–5).
- Finance Associate (100% Years 1–5).
- Program Assistant (100% Years 1–5).

Provinces

We have budgeted for provincial teams using a phased approach for each province. These teams will be in place during the roll-out and first year of implementation in each province, and then will be transitioned off the program or to another implementing province as implementation is handed over to the Ministry of Health. These teams include:

- Provincial Coordinator (to work with the NMP) (100%).
- M&E Officer (100%).
- Site Supervisor (100%).
- Finance Officer/Administrator (50%).
- Driver (100%).

Health zones

We have budgeted junior officers to be based in the health zones—one officer per health zone during the first three years of the program. In the low-end scenario, junior officers are also budgeted in the newly added health zones in Year 4. These officers will transition off the program as implementation is handed over to the MOH.

Global

We have also budgeted for technical and management support from global staff based outside of DRC, including:

- Program Manager (100% years Years 1–5).
- Project Administrator (100% Years 1–5).
- Program Assistant (100% Years 1–5).

Table 25. Staff contributing to the project in DRC.

Position/role	Responsibilities/contribution to the program
Country office	
PATH DRC Malaria Program Lead	Provide oversight, management support, and linkages with the overall PATH Malaria DRC portfolio.
Technical Deputy Program Lead	Provide technical direction and expertise. Lead work plan development for the project and for implementing studies and evaluations, overseeing the implementation of these studies, and executing daily management of the award.
Deputy Director, Operations	Lead operational planning and oversee operations, administration, and financial management for the program, including DRC-based administrators, finance officers, and assistants. Establish operations in the provinces, and manage the processes for recruiting,

	procurements, field disbursements, establishing and closing out operations for the provincial teams.
M&E Manager	Provide technical leadership and support for monitoring and evaluation and knowledge management across the project.
Supply Chain Officer	Responsible for working with the MOH and SANRU for quantification, procurement planning, and addressing supply chain issues.
Project Administrator	Responsible for budgeting, financial management, and administration for in-country activities. Manage financial transactions and procurement processes, under the supervision of the operations lead.
Finance Associate	Will be responsible for processing day-to-day financial transactions by compiling required documentation and obtaining approvals and supporting the preparation of financial reports.
Program Assistant	Provide general administrative support to the country office team. They will schedule and plan meetings, coordinate travel, compile and organize relevant background materials for meetings, monitor follow-up activities, and coordinate logistics for workshops and meetings.
Provincial office	
Operations Lead	Responsible for province-level operations and administration. Review, monitor, and report on the provincial-level activities. Approve provincial financial transactions, coordinate the PATH procurement review committee for high threshold procurements and contracts and provide review, guidance, and input on drafting and managing agreements with provincial partners.
M&E Officer	Responsible for coordinating the management of data in the provincial health facilities, training and follow-up in IPTi-SP immunization and malaria reporting, and ensuring high-quality data is maintained.
Project Administrator	Provide budgeting and financial management, contract management, procurement, and implementation support for provincial activities. They will be responsible for reviewing financial transactions before they are approved by the Operations Lead, reviewing program advances, and sending reminders to staff. They will help the Operations Lead by reviewing procurement documents.
Finance Associate	Will be responsible for processing day-to-day financial transactions of the provincial office by compiling required documentation and obtaining approvals.
Senior Program Assistant	Provide operational and administrative support to the provincial office team. They will support provincial procurement, schedule and plan meetings, coordinate travel, compile and organize relevant background materials for meetings, monitor follow-up activities, and coordinate logistics for workshops and meetings.
Health zone-based staff	
Junior Officer	Support health facility level supervision and data collection. Provide operational and administrative support to the health zone office in coordination with MOH counterparts, serving as the primary liaison between health facility-based HWs and PATH provincial offices.
Global staff	
Technical Director	Work closely with the PATH DRC Malaria Program Lead, Project Manager, GiveWell and other partners to support the development, implementation, and coordination of program evaluation activities.
Program Manager	Work closely with the PATH DRC Malaria Program Lead, and Deputies, GiveWell and other partners to support the development, implementation, and coordination of program evaluation activities. Coordinate project timelines, deliverables, and provide relationship management.

Project Administrator	Provide overall leadership across administration, finance, and operation functions including work planning, reporting, budget management, and compliance with GiveWell award requirements.
Program Assistant	Provide overall support and coordination to the project.

Program launch, planning, community sensitization

Costs in this area are driven by planning meetings with the MOH, including provincial and zonal levels, and design and production of materials.

Intervention roll-out

Costs in this area are driven by the production and distribution of materials and job aids, and the series of trainings that will be supported to build capacity in the provinces, health zones, and health facilities to implement the intervention. The full set of trainings is outlined in Table 22 above. Most roll-out costs scale based on the number of provinces, health zones, health facilities, and/or health workers engaged. Tables 23 and 24 show the numbers of these drivers of cost by year, for each scenario.

Implementation support

Procurement costs include the cost of the drug used for IPTi-SP and its administration, as well as program vehicles, motorbikes, and other supplies and equipment.

- Sulfadoxine-Pyrimethamine and other supplies required for its administration (cups, spoons, pill cutter, and liquid syringe). We have used a unit cost of $0.23 per dose of SP, based on the costing workstream, which includes the cost of procurement, shipping, as well as wastage. We have used a unit cost of $0.10 per treatment for the other supplies required for SP administration (cups, spoons, pill cutter, and liquid syringe), based on the costing workstream. Note that for budgeting purposes, we have used the cost of the dispersible formulation of SP (Malakant [Dispersible Junior], from S KANT Healthcare Limited) with the assumption that disbursable SP will receive approval from the Directorate of Pharmacy and Drugs (DPM - Direction de la Pharmacie et du Médicament) at the MOH by the time procurement starts for the implementation of IPTi-SP under the proposed program. The quantities for these items are based on the estimated number of infants to be treated each year, which is shown in Table 21.
- Project vehicles. Project vehicles are budgeted at $63,000 each. The unit cost is based on a recent purchase of project vehicles for work in DRC. We propose purchasing three in Year 1; two in Year 2, and three in Year 3 in the high-end scenario; and two in Year 1, one in Year 2, and four in Year 3 in the low-end scenario. This would provide a dedicated vehicle in each province during the first year of implementation in health zones in the province. After the first year of implementation, as requirements for roll-out and PATH involvement in supervision declines in the province, the vehicle can be moved to a new province for its first year of implementation.
- Motorbikes. Motorbikes are budgeted at $5,500 each. The unit cost is based on a recent purchase of motorbikes for work in DRC. We propose purchasing one motorbike for the provincial level in each implementing province, and one motorbike for each implementing health zone. For the high-end scenario described above, this will be 30 motorbikes in Year 1, 59 in Year 2, and 107 in Year 3. For the low-end scenario, the program would purchase 17 in Year 1, 31 in Year 2, 89 in Year 3, and 61 in Year 4.
- Radio with solar panel. We have budgeted for a radio with solar panel for village-based IPTi-SP listening groups. These are budgeted at an estimated unit cost of $70 and quantity based on one per health facility.

Aside from the cost of procurement of the drug and supplies required for administration of the drug, implementation costs are driven by ongoing support and supervision. Costs are primarily transport and allowances for ministry staff that will visit, meet with, and provide refresher sessions with the health workers administering the intervention. This is one of the largest cost drivers in the budget, as the program will support transport and allowances for health zone staff to visit, support, and coach health workers in each participating health facility, starting with 1,192 in Year 1 in the high-end scenario or 721 in the low-end scenario, and reaching 6,349 when scaled to all ten provinces. In the first year of implementation in each health zone, a PATH staff member will participate in the supervision activities. In subsequent years, supervision will continue with only Ministry of Health staff.

Monitoring and Evaluation and Operations Research

A range of studies will be considered and are listed in the M&E Approach section (reference Table 19. Menu of supplemental evaluation activities). For budgeting purposes, we have selected the following subset of evaluation activities:

- Infant cohort study with control cohort in non-intervention health zones. This study would be implemented in Year 1 and would have a sample of 440 infants in the cohort and 440 in control arm.
- Household surveys to report IPTi-SP doses administered and coverage. We have budgeted for a baseline, mid-term, and end line survey. We have budgeted for a household survey reaching 400 households per implementing province in Years 1, 3, and 5.

Cross-cutting operational costs

Cross-cutting operational costs include International Travel, Other direct project costs, and Overhead.

For travel, we have budgeted trips from the US and Geneva for a program advisor and M&E officer each year for technical and management support. We have also budgeted for internal audit visits by a member of our internal audit team based in Kenya in Years 3 and 5.

Other direct project costs include:

- Costs driven by labor, including a technology charge that PATH applies to program labor to cover the cost of laptops, peripherals, software, and IT services for program-dedicated staff.
- Staff cell phones and plans.
- A facilities allocation to cover the cost of office space for staff sitting in PATH offices.
- Costs related to staffing and recruitment.
- Fuel and operating costs for program vehicles for PATH staff in Kinshasa and in the first year in each implementing province and for the motorbikes for focal points in each implementing health zone.

Overhead costs are indirect program costs. They include a share of the organization's costs that are required for implementation of a program but are not easily itemized to each program. PATH applies overhead at a consistent rate across all program base expenditures. PATH's overhead rate is negotiated with and approved by the US government and is audited annually. PATH uses its current approved overhead rate of 26% for budgeting purposes. The actual rate is updated at the end of each fiscal year, and adjustments are applied retroactively to match the actual ratio of overhead to program base spending for the year.

7.3 Nigeria

7.3.1 High level assumptions

- We have defined the state as the scalable unit because the decision-making for the introduction and oversight for IPTi resides at the state level between the two main stakeholders, the State Malaria Elimination Programme (SMEP) and State Primary Health Care Development Agency (SPHCDA). We are looking to prototype IPTi (three touchpoints) in selected states, whereby the intervention will be institutionalized from the outset.
- A scale-up plan for the whole country can be developed through lessons learned from these scalable units (i.e., four eligible states in years 2022, 2023 and 2024) because these units cover heterogeneous implementation settings such as malaria epidemiology/stratification, immunization coverage, and infant mortality.
- Administration of IPTi-SP will be delivered through the EPI platform at three touch points (10 weeks, 14 weeks and 9 months) in line with current WHO IPTi policy recommendations.

This investment will introduce IPTi in four states (three IPTi-only eligible states including one state covered by BMGF for the formative research, and another state with partial eligibility of IPTi and low EPI coverage- to accommodate heterogeneity of settings). This investment will be implemented for two and a half years; with an initial three months (or the third quarter of 2022) dedicated to the project set-up. The third quarter of 2024 is planned for the exit of the project. This investment will implement the roll-out of the intervention in four states covering all IPTi eligible LGAs in Ebonyi/Osun (13), Edo (18), and Ekiti (16), and Adamawa (2). A total of 3,437 health facilities in the four states will be covered and an estimated 3.46 million doses of SP will be administered during project implementation. Learnings from the phased state-wide implementation approach would present data and contextual details for adaptation strategies to maximize impact as well as contribute to accelerating the scale-up of IPTi through testing scale-up in enough scalable units.

Evaluations and studies

This investment will have research and service delivery components. Malaria Consortium will carry out formative research to understand existing platforms and potential for additional touchpoints, systems, and operational dynamics. In addition, we will assess the IPTi-SP scale-up strategy in implementing states among caregivers and health providers including the cost of adding administration of SP to the EPI schedule.

Timeline

Implementation in Nigeria is budgeted based on a two-and-a-half-year period.

Activities

As detailed in Table 26, major activities of the project include:

- Coordination and stakeholder engagements.
- A formative assessment for IPTi scale-up.
- An SP resistance assessment.
- Tool development, surveillance, routine supervision, and a costing analysis.
- Training of health workers on integrated delivery of IPTi through EPI and other channels.
- Procurement and distribution of quality assured and other supplies.
- Demand creation through multimodal SBC.
- Pharmacovigilance.

Table 26. Activities planned for Nigeria.

Activity group	Activities	Cost category	2022–2024
Coordination and stakeholder engagements	Project office set-up and staff recruitment	Delivery	Secure and equip office accommodation in project states
			Recruit and orientate project staff
	National and state level engagement and mobilization of key stakeholders		Seek and secure stakeholders' consensus on IPTi roll-out and scale-up plans
			Engage and build consensus with stakeholders at national, state, LGA, and community levels
			Sensitize and mobilize project communities on project objectives
Monitoring, evaluation, accountability, and learning (MEAL)	Formative assessment for IPTi scale-up testing	Research	Develop protocol and questionnaires
			Obtain ethical approval for protocol
			Load questionnaires on electronic data collection devices and set up servers
			Recruit and train data collectors in protocol and data collection tools in all states
			Translate questionnaires to local languages; field test, finalize, and conduct data collection.
			Conduct rapid SP resistance assessment
			Quality assured data collection
			Carry out formative research to understand existing platforms and potential for additional touchpoints, systems, and operational dynamics, including a rapid state medical store assessment
			Synthesize key findings from formative research and situation analysis and disseminate to stakeholders
	Routine supervision	Delivery	Conduct routine supportive supervision visits to health facilities implementing IPTi-EPI using existing platforms
			Support adaptation of supervision checklists to incorporate IPTi; print and distribute supervision checklists to project LGAs for health facility workers
	Monitoring implementation	Delivery	Field visits twice per year for national and state level decision-makers
			Monitor implementation and reporting. Biannual monitoring by national program officers (NMEP and NPHCDA)

Activity group	Activities	Cost category	2022–2024
	Surveillance	Delivery	Support routine data quality assurance visits to HFs monthly
			Ensure facilities have constant supply of reporting tools and testing kits
			Train HF data officers on new/adapted tools for HMIS reporting on IPTi-EPI
	Adaptive management through learning review workshops, production, and dissemination of learning papers	Research	Prepare learning papers and policy briefs
			Print learning papers and policy briefs
			Organize periodic learning workshops at state level
			Organize biannual national lessons learning meetings in Y2023 and Y2024
	Costing: collect costing data and carry out budget impact analysis	Research	Develop costing assumptions and tools for data collection.
			Collect routine project implementation costing data
			Budget impact analysis in Y2024
	Assess SP-IPTi scale-up strategy in implementing state among caregivers and health providers	Research	Develop and field test data collections tools for scale-up assessment
			Finalize data collection tools with feedback from field testing
			Roll out printing of final tools for scale-up assessment
			Recruit and train interviewers and note takers for FGDs and KIIs
			Conduct FGDs and KIIs among caregivers and health providers. 10-12 FGDs among HWs across 4 LGAs and another set of 10–12 FGDs among caregivers of children receiving 3 touchpoints while 10 KI will be identified at national, state and LGA levels.
	Tool development: Develop, revise, and validate integrated tools including printing of paper-based reporting tools (HMIS and LMIS) and IEC materials to support implementation through EPI and other	Delivery	Adapt integrated data collections tools for implementation through EPI and other complementary platforms using human-centered design approach
			Field test and finalize integrated data collection tools on electronic HMIS platform and LMIS tools
			Field test and finalize IEC materials on IPTi through EPI at health facility and community levels
			Reach consensus with policymakers and implementers on tools and materials

Activity group	Activities	Cost category	2022–2024
	complementary platforms		Print and distribute final integrated tools (including LMIS tools and treatment algorithms)
			Customize DHIS2 platform for IPTi-EPI reporting
Health workforce capacity development	Training of health workers force on integrated delivery of IPTi (including pharmacovigilance) through EPI and other channels	Delivery	Develop integrated training curriculum/manual/job aids and training plan for health facility and community delivery platforms
			Print and distribute training manual/job aids, provide training materials and equipment at training sites
			Train master trainers on integrated IPTi-EPI delivery and pharmacovigilance
			Train health workers at state level and keep a database of trained personnel
			Train HF data officers on new/adapted tools for HMIS reporting on IPTi-EPI
			Train supervisors at state and LGA levels on revised supervision checklists for IPTi-EPI
Procurement and supply chain management	Quantify, procure, and supply correct quantity of SP to EPI programs and relevant complementary platforms	Delivery	Quantify and procure SP
			Distribute SP from State Medical Stores to health facilities and communities for the study
			Support provision supplies to facilitate delivery of IPTi at HFs (e.g., cup and spoon, water etc.)
			Orientate state LMCUs on logistics management for IPTi-EPI
		Delivery	National review meeting
Demand Creation	BCC	Delivery	Adapt social behavior change communication strategy for IPTi-EPI and organize community sensitization and awareness creation meetings, activities, and use of mass media
			Develop mass media messages and air through jingles to create awareness
Pharmacovigilance	Incorporate pharmacovigilance for IPTi within the existing pharmacovigilance system	Delivery	Support training of health workers in project LGAs on pharmacovigilance
			Support printing and distribution of pharmacovigilance forms to HFs

Budget

The budget is aligned to outputs and cross cutting activities. Under each output, activities are detailed and budgeted. Details of the proposed activity costs and the major cost drivers per output are captured under the other direct costs section of the budget and budget narrative. The summary of the specific activities that drive cost under each output is described below in Table 27.

Table 27. Budget summary for Nigeria.

Details	Year			Total
	2022	2023	2034	
Personnel	$ 288,688	$ 608,423	$ 638,844	$ 1,535,954
Planning and community engagement	$ 166,784	$ 46,515	$ 65,606	$ 278,906
Coordination and stakeholder engagements				
Operations research/prospective Evaluation				
Monitoring and evaluation	$ 669,449	$ 874,197	$ 1,040,722	$ 2,584,368
Intervention roll-out/scale-up				
Health workforce capacity development & supervision	$ 1,319,348	$ 50,746	$ 53,283	$ 1,423,378
Implementation support				
Commodities: SP	$ 138,359	$ 515,625	$ 402,665	$ 1,056,650
Commodities: Other supplies for SP administration				
Demand creation				
SBCC activities	$ 1,034,941	$ 218,156	$ 105,114	$ 1,358,210
Pharmacovigilance	$ -	$ 5,658	$ 5,940	$ 11,598
Cross-cutting operational costs				
Travel				
Supplies and equipment	$ 168,075	$ -	$ -	$ 168,075
Other operating costs	$ 42,161	$ 78,646	$ 70,409	$ 191,216
Indirect costs	$ 459,337	$ 287,756	$ 285,910	$ 1,033,003
Total	**$ 4,287,143**	**$ 2,685,721**	**$ 2,668,494**	**$ 9,641,358**

Description of costs

Personnel

Staff costs are calculated by taking the annual proposed salary and multiplying it by the level of effort (LoE) for each role. LoE for all non-full-time roles is calculated by estimating the number of days for each activity to which the role will contribute. An inflation rate of 5 percent is applied to all national roles and 2 percent for international roles. For Nigeria-based staff, contracts are denominated in NGN for national roles and USD for global national roles. For all UK-based staff, contracts are denominated in GBP.

All salaries proposed are in line with Malaria Consortium's salary and reward policy. All roles are evaluated against a grade and a corresponding salary is applied. The salary levels are based on the median of the benchmark against other similar organizations. The roles included in the project are detailed below in Table 28:

Table 28. Staffing summary for Nigeria.

Position/role	Responsibilities/contribution to the program
Country office	
Senior Project Manager	The overall head of this investment in country and will be responsible for the smooth running of the project including the management of the human resources, stakeholders' engagement, budget, and key liaison for the Givewell iPTI Nigeria office. The role will also oversee all project activities.
Research Specialist	The role will lead the conceptualization, adaptation of all the project research, and ensure buy-in by relevant stakeholders and compliance with all the relevant regulation guiding research in the country and according to the project proposal.
M&E Specialist	The role will take the lead in set-up and ensure data collation, quality, analysis, dissemination, and sharing with broader stakeholders as required.
SBCC/Demand Specialist	This role provides SBC support to the project.
Country Director	This role will take the lead in engaging with high level in-country stakeholders including NMEP, NPHCDA, and FMOH to ensure their buy-in prior, during, and after implementation of this investment. The role will be key in supporting stakeholders to adopt the findings and learning from this investment.
Country Program Manager	This role is the direct line manager for the senior project manager and will provide quality assurance and backstop roll-out of project management tools and processes in support of this investment.
Senior Country Technical Coordinator	This role is the technical lead for the project in the country and is specifically required to ensure this project meets global and national quality standards. They will support the senior project manager to draft, train, and roll out technical quality assurance processes and procedures.
Malaria Specialist	The role will work to ensure this investment is able to capture relevant routine surveillance data, which are gender- and age-disaggregated. Working closely with the PI, the role will help oversee the research integrity aspects of the project.
Country Finance Manager	The Country Finance Manager is the senior most finance staff in the country with the overall responsibility for financial management of the project. This role maintains an oversight function, ensures segregation of duties, and signs off on all financial

	documents in excess of the delegated finance limit of the Finance Officer and the Country Accountant. The role will provide country review and sign-off for budgets, forecasts, and reporting.
Country Accountant	This role will review the financial documents, providing support to the Finance Officer, reviewing, and signing off the payments physically and through online banking, approving expenditure in line with the financial delegation of authority for this role. The role will ensure segregation of duties, manage the risk of fraud and collusion, and support the reporting and budgeting needs.
Finance Officer	This role will be responsible for day-to-day processing of financial transactions, scrutiny of documents for payment of invoices, staff advances, expense claims, activity advances, maintaining petty cash, entering transactions in the accounting system, approving expenditure in line with the financial delegation of authority for this role.
Country Human Resources Manager	This role takes the lead in planning and maintenance of human resources of the program in accordance with the donor, Malaria Consortium, and national regulation and procedures.
Project Accountant (100%)	This role will be reviewing the financial documents, providing support to the Finance Officer, reviewing and signing off the payments physically and through online banking, approving expenditure in line with the financial delegation of authority for this role. The role will ensure segregation of duties, manage the risk of fraud and collusion, and support reporting and budgeting needs.
Supply Chain/Commodity Manager	This role oversees the supply chain of the QA dispersible SP to ensure no stock-outs at all service outlets.
Country Office Manager	This role oversees country office support staff and provides administrative support.
Operations Officer	This role supports operations and logistics.
State office	
State Technical Officer	This role is the lead in the management, engagement, and smooth day-to-day running of the project at the state level.
M&E Officer	This role supports the smooth roll-out of project activities in the state, especially at the service delivery points including direct support to frontline service providers.
Admin/Operation	This role oversees the logistics, administration, and procurement activities of the project at the state level.
Finance Officer	This role will be responsible for processing payments, as well as reviewing and validating any supporting documentation, ensuring compliance with Malaria Consortium's policies and processes. It will also involve supporting the Country Accountant with monitoring and reporting.
London HQ office	
ER team	This role takes the lead in engagement with global stakeholders of the project and will oversee and provide input in the development of publications and learning materials.

Head of Surveillance, Monitoring and Evaluation	This role supports the project in all its surveillance, monitoring, and evaluation activities to ensure they meet global standards.
Senior Research Advisor	The role takes the lead in ensuring that project research methodologies are sound and meet global standards. The role is also responsible for building research capacity of the project team.
Senior Technical Advisor	
Technical Director	This role is the overall lead globally for the project and is responsible for the project.
Global Operations	This role supports the in-country operations team on procurement, logistics, and administration. They will be responsible for procuring the quality assured SPAC from manufacturers.
Global Finance Director	The Global Finance Director provides an overall finance oversight function on all project portfolios in ensuring compliance with the donor and other strategic duties.
Regional Finance Manager	The Regional Finance Manager has responsibility for a portfolio of projects with a view to ensuring donor compliance, training finance staff, reviewing and signing off on documents and expenditure as per delegated financial authority as well as working with the project manager to sign off budget, forecasts, and reporting to the donor.

Coordination and stakeholder engagements

Printing advocacy briefs for all health facilities is the main diver of cost in this area.

Monitoring, evaluation, accountability, and learning (MEAL)

Costs in this area are driven by surveillance, monitoring of implementation, routine supervision, and assessment of IPTi-SP scale-up strategy in implementing among caregivers and health providers.

Health workforce capacity development

The provision of training to about 7,000 health workers is the main cost driver for this area. The bulk of the training will be conducted in Year 1, followed by the provision of targeted refresher training in 2023.

Procurement and supply chain management

SP and other supplies required for its administration (e.g., cups, spoons, and pill cutter). We have used a unit cost of $0.17 per dose of SP based on Malaria Consortium's experience of importing limited quantities of WHO pre-qualified SP dispersible tablets of 250mg + 12.5mg for its BMGF-funded IPTi project in Osun.

Demand creation

Demand creation entails social behavioral change communication and community engagement. Community sensitization and awareness creation meetings are the main cost drivers for this area.

Pharmacovigilance

Pharmacovigilance activities will be conducted in 2022 and 2023. In 2022, training of health workers in the project LGAs on pharmacovigilance will be delivered with broader training on IPTi, with no cost incurred for this activity. Costs in this area are driven by printing and distribution of pharmacovigilance forms/booklets to 50 LGAs in the four states.

Operational costs

Nigeria Country Office Recharge. Members of the investment team as well as non-dedicated staff will be based in the Abuja office and therefore this cost is required for this investment. The recharge methodology is in line with Malaria Consortium's finance policy and is consistent with other projects implemented by Malaria Consortium. The calculation is the cost per day per person multiplied by the numbers of days budgeted in that period. The daily cost of the office is $19.84, which includes rent, utilities, IT services, and security. The quantity per period represents the number of working days' budget for the project team in that period.

State Office Recharge. Same cost principles as above but for the state office. As the office is based at state level, costs are cheaper, which is represented in the lower cost per day per person amount of **$19.84**.

Abuja Vehicle Recharge. Project staff will use an existing project vehicle to attend meetings, training, and conferences. Vehicle costs will be recharged to this investment based on distance of travel. A logbook for all Malaria Consortium vehicles records the purpose and distance of each journey, a cost per km is calculated every quarter, and, based on the distance traveled, an amount is charged to the project. For Abuja, the cost per km equates to **$2**/km, and the "quantity per period" represents the number of kms budgeted.

State Vehicle Recharge: Same cost methodology as above but the state office project vehicle will be used. Cost per km is $2/km.

Laptop and Office Furniture. Required for 20 new investment staff (4 staff in Abuja and 16 staff in state office). We will only budget a laptop and office furniture for full-time project staff. The cost of the laptop covers the software required to perform day-to-day activities.

8 Annexes

8.1 Annex A: Stakeholders Interviewed

8.1.1 DRC Stakeholders Interviewed

Organization	Name	Role
DGLM	Dr. Mwamba	General Director
DGOGSS	Dr. Welo	General Director
DES	Dr. Aruna	Director
PNLP	Prof Dr. Mukomena	Director
EPI	Dr. Cikomola	Deputy Director
PNAME	Dr. Biayi	Director
PNSR	Dr. Tumba	Director
PNECHOL-MD	Dr. Welo	Director
PMI Measure Malaria	Dr. Karemere	Resident Advisor
PMI Impact Malaria	Dr. Landela	COP
WHO	Dr. Sambou	Malaria Focal Point
WHO	Dr. Bahizi	Malaria National Professional Officer
SANRU	Dr. Mongala	Malaria Project lead
Global Fund	Dr. Mwabi	Malaria Project Manager, MOH PR
University of Kinshasa	Prof Dr. Matangila	Professor/Researcher

Abbreviations: DGLM, Direction Generale de la Lutte contre la Maladie; DGOGSS, Direction Generale d'Organisation et de Gestion des Soins de Sante; DSE, Direction de Surveillance Epidemiologique; EPI, Expanded Programme on Immunization; PMI, U.S. President's Malaria Initiative; PNAME, Programme National d'Approvisionnement en Médicaments Essentiels; PNECHOL-MD, Programme National d'Elimination du Cholera et des autres Maladies Diarrheiques; PNLP, Programme National de Lutte contre le Paludisme; PNSR, Programme National de la Sante de Reproduction; SANRU, Santé Rurale; WHO, World Health Organization

8.1.2 Nigeria Stakeholders Interviewed

Organization	Name	Role
NMP	Dr. Perpetua Uhomoibhi	National Coordinator
NMP	Dr. Nnenna Ogbulafor	Head, CM branch
NMP	Mary Nyong/Owoya Samuel	ACSM officers
NMP	Mr. Chukwu Okoronkwo	Head, SMEOR branch
NMP	Mrs. Talatu Kassim/ Pharm Karimu	Head, Procurement and Supply Chain Management branch
NMP	Prof. Olugbenga Mokuolu	NMP Technical adviser,
NMP	Dr. Aishat Gubio	RMNCAH focal person
WHO	Dr. Lynda Ozor	Programme Manager
NPHCDA	Dr. Garba Rufai	Disease control and immunization dept
GF	Dr. James Ssekeetoleko	Technical & M&E Specialist
NAFDAC	Dr. Jennifer Chukwumerije	Malaria focal person
NMP	Dr. Nelson Eze	Case Management
PMI	Dr. Uwem/ Dr Momoh	Program Managers
UNICEF	Fatima Chechi	Malaria focal person

Abbreviations: GF, Global Fund; NPHCDA, National Agency for Food and Drugs Administration Control; NMP, national malaria program; NPHCDA, National Primary Health Care Development Agency; PMI, U.S. President's Malaria Initiative; UNICEF, United Nations Children's Fund; WHO, World Health Organization

8.2 Annex B: Validation Workshop Participants

8.2.1 DRC Validation Workshop Participants

Organization	Name	Designation/Department
PATH	Trad Hatton	DRC Country Director
PATH	Dr. Henry Ntuku	Operational Research Lead
PATH	Dr. Jimmy Anzolo	Malaria Technical Program Manager
PATH	Jicko Bondole	Sr Data Officer
PATH	Edna Harimenshi	Director of Programs, DRC office
PATH	Audry Tshipamba	Program Assistant
NMP	Dr. Eric Mukomena	National Director
NMP	Dr. Edwige Kanyeba	Deputy Director
NMP	Dr. Chris Muteba	Surveillance Division
NMP	Dr. Charlene Kabongo	Head of prevention Division
EPI	Dr. Cikomola	Deputy Director
PNAME	PhD. Nanga	Pharmacist
PNECHOL-MD	Dr .Welo	National Director
PMI Measure Malaria	Dr. Karemere	Resident Advisor
PMI Impact Malaria	Dr. Landela	Chief of Party
WHO	Dr. Bahizi	Malaria National Professional Officer
SANRU	Dr. Phanzu	Malaria Project manager
SANRU	Dr. Musiti	Head M&E
DSE	Dr. Aruna	National Director
DGOGSS	Dr. Bobanga	Community health specialist
University of Kinshasa	Prof Matangila	Professor/Researcher

Abbreviations: DGOGSS, Direction Generale d'Organisation et de Gestion des Soins de Sante; DSE, Direction de Surveillance Epidemiologique; EPI, Expanded Programme on Immunization; NMP, national malaria program; NPHCDA, National Primary Health Care Development Agency; PMI, U.S. President's Malaria Initiative; PNAME, Programme National d'Approvisionnement en Médicaments Essentiels; PNECHOL-MD, Programme National d'Elimination du Cholera et des autres Maladies Diarrheiques; SANRU, Santé Rurale; WHO, World Health Organization

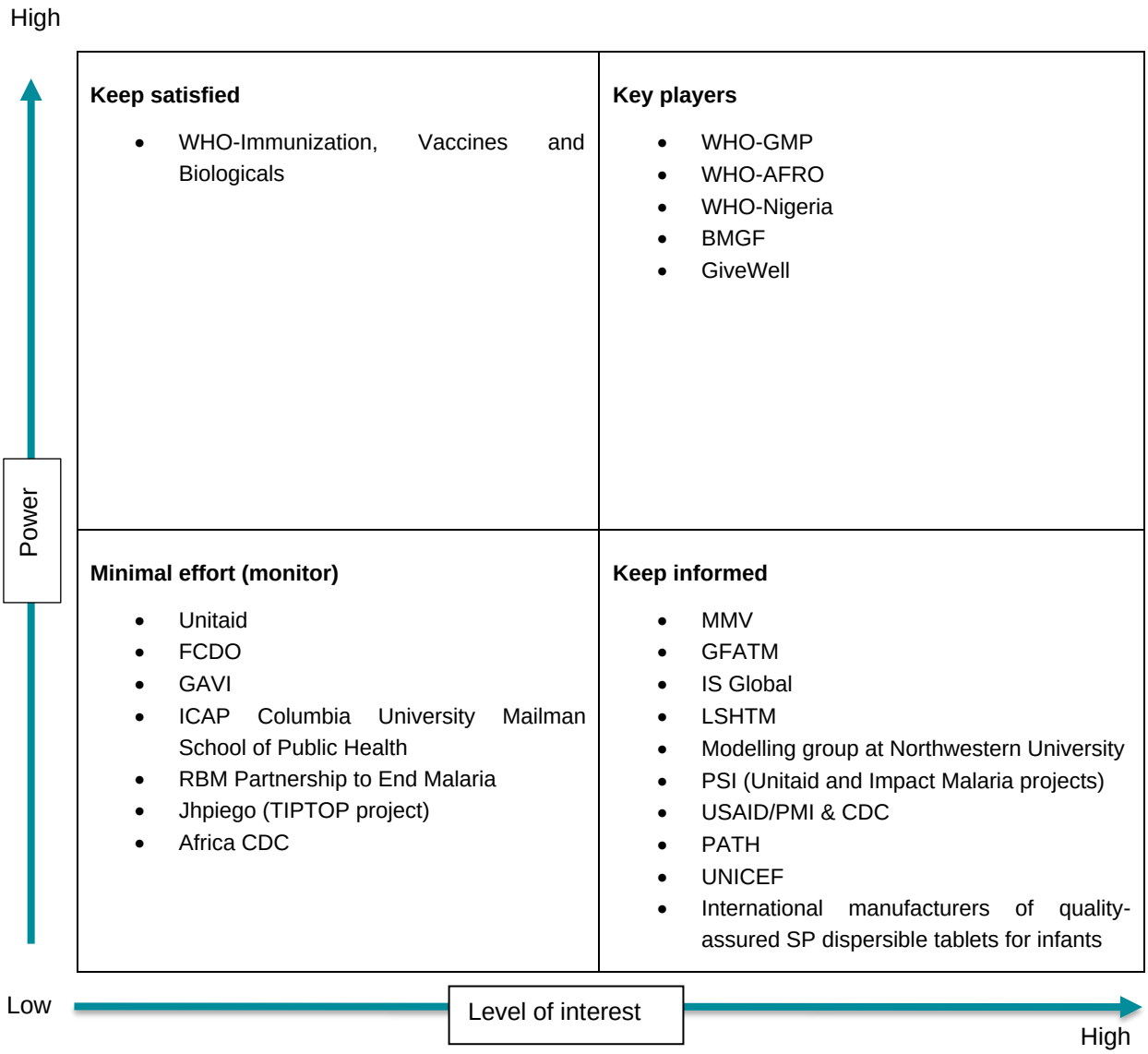
8.2.2 Nigeria Validation Workshop Participants

Organization	Name	Designation/Department
NMP	Bassey Grace Mfon	Deputy Director
NMP	Bilikisu Mukhtar	Advocacy Communication and Social Mobilization (ACSM) unit
NMP	Abonyi Emelda	Case Management unit
NMP	Olanpeleke Olufunke	ACSM unit
NMP	Chukwu Okoronkwo	Monitoring Evaluation and Operations Research
NMP	Ameh Victor 0.	M&E unit
NMP	Salihu Abdullahi Bagobir	Procurement and Supply chain Management
NMP	Wakil Yagara	Procurement and Supply chain Management
NMP	Dr Tony Udoh	Head, Health Services Delivery
FMOH	Ajuzie Chioma	Health Services
FMOH	Otuama Martins	Health Services
FMOH	Anaba Adamu Grace Faith	Case Management
NMP	Fasogbon Olasoji	Member National Emergency Routine Emergency Coordination Centre (NERICC)
AFENET	Oluwafunmi Olanpeleke	ACSM
NMP	Ekandem Anthony	PPO
FMOH	Godstime Akhuem	Medical Laboratory Services
FMOH	Faparusi Folashade	Hospital Services
FMOH	Olusola Oresanya	Snr Country Technical Coordinator
Malaria Consortium	Mary Adeboye	Prorgam Assistant
Malaria Consortium	Ujuju Chinazo	BMGF IPTi-SP MEL Specialist
Malaria Consortium	Dawit Bekele	Senior Malaria Specialist
Malaria Consortium	Ozioma Nwagwu-Unyi	Consultant

Abbreviations: ACSM, Advocacy Communication and Social Mobilizations; AFENET, African Field Epidemiology Network; FMOH, Federal Ministry of Health; IPTi-SP, intermittent preventive treatment in infants with sulfadoxine-pyrimethamine; M&E, monitoring and evaluation; NMP, national malaria program

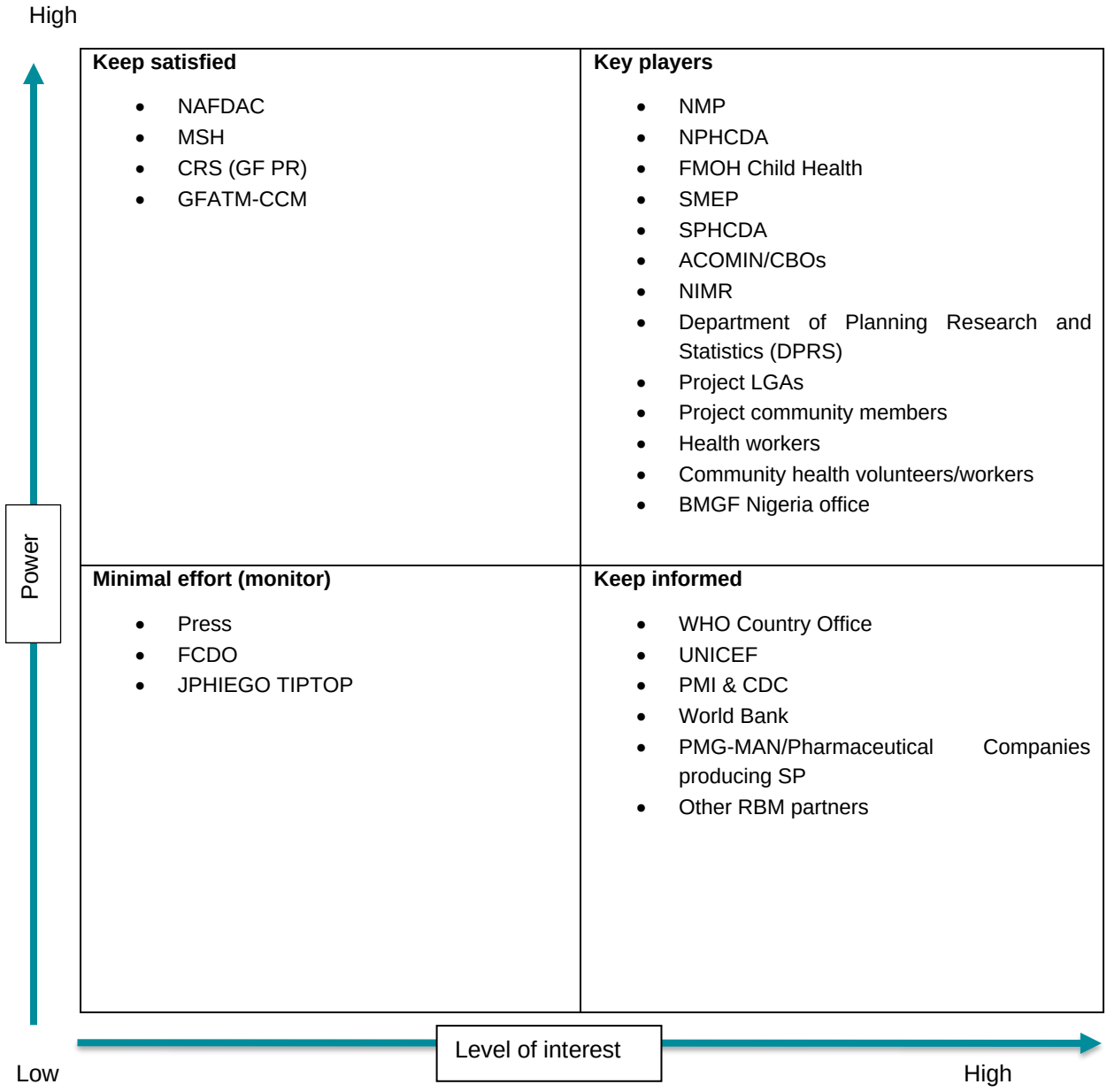
8.3 Annex C: Stakeholder Power-Interest Matrix

8.3.1 International stakeholders for the success of IPTi-SP scale-up in Nigeria



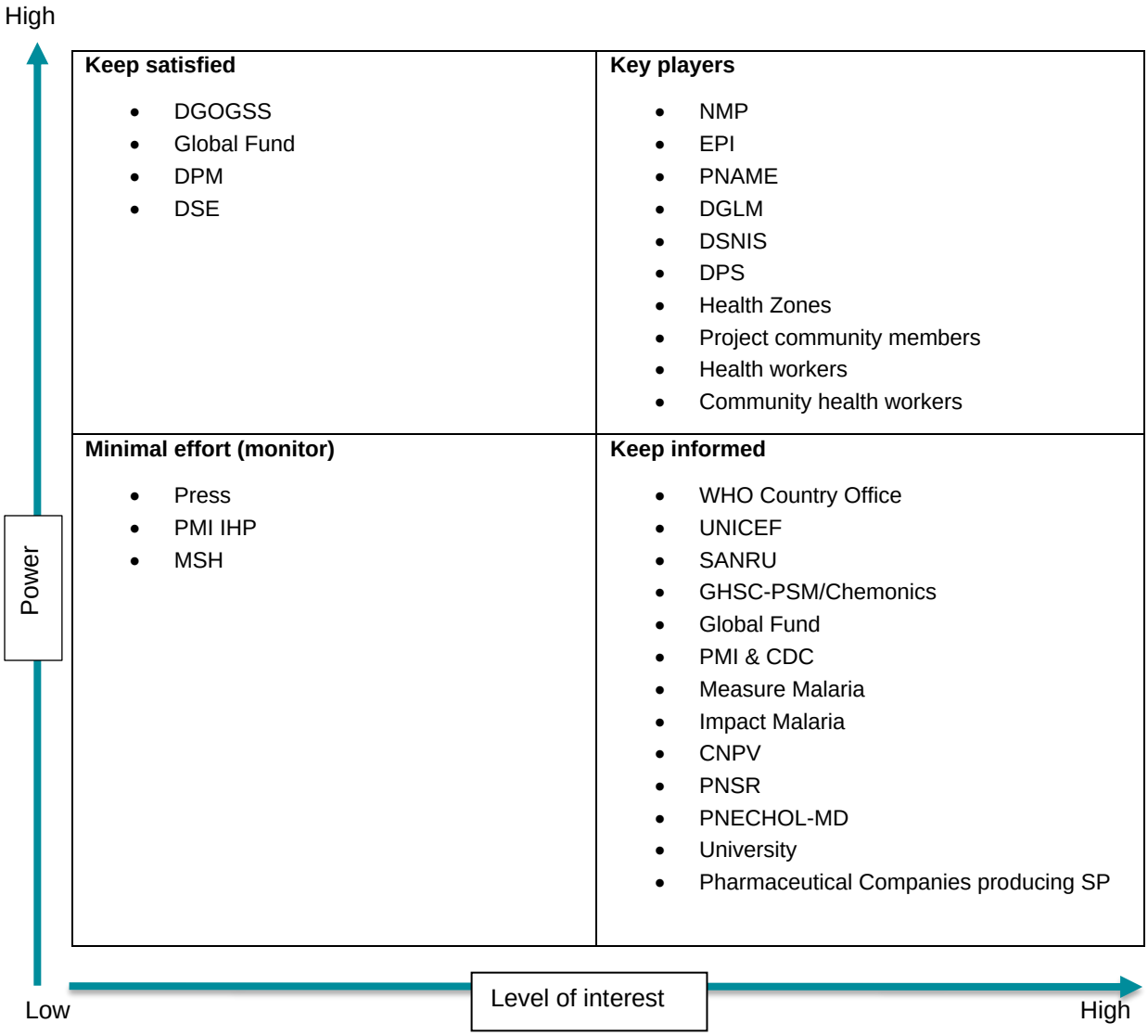
Abbreviations: BMGF, Bill & Melinda Gates Foundation; CDC Centers for Disease Control and Prevention; FCDO, UK Foreign, Commonwealth and Development Office; GFATM, Global Fund to Fight AIDS, Tuberculosis and Malaria; LSHTM, London School of Hygiene and Tropical Medicine; MMV, Medicines for Malaria Venture; SP, sulfadoxine-pyrimethamine; UNICEF, United Nations Children's Fund; WHO, World Health Organization; WHO-AFRO, World Health Organization Regional Office for Africa; WHO-GMP, World Health Organization Global Malaria Programme

8.3.2 National and sub-national stakeholders for IPTi-SP scale-up in Nigeria.



Abbreviations: ACOMIN, Civil Society for Malaria Control, Immunization and Nutrition; BMGF, Bill & Melinda Gates Foundation; CBO, community-based organization; CDC, Centers for Disease Control and Prevention; CRS, Catholic Relief Services; FCDO, UK Foreign, Commonwealth and Development Office; FMOH, Federal Ministry of Health; GFATM-CCM, Global Fund to Fight AIDS, Tuberculosis and Malaria Country Coordinating Mechanism; GF PR, Global Fund Principal Recipient; LGA, local government area; MSH, Management Sciences for Health; NAFDAC, National Agency for Food and Drugs Administration Control; NIMR, Nigerian Institute of Medical Research; NMP, national malaria program; NPHCDA, National Primary Health Care Development Agency; PMI, U.S. President's Malaria Initiative; SMEP, State Malaria Elimination Programme; SP, sulfadoxine-pyrimethamine; SPHCDA, State Primary Health Care Development Agency; UNICEF, United Nations Children's Fund; WHO, World Health Organization

8.3.3 National and sub-national stakeholders for IPTi-SP scale-up in DRC



Abbreviations: CDC, Centers for Disease Control and Prevention; CNPV, Centre National de PharmacoVigilance; DGLM, Direction Generale de la Lutte contre la Maladie; DGOGSS, Direction Generale d'Organisation et de Gestion des Soins de Sante; DPM, Direction de la Pharmacie et du Médicament; DPS, provincial health divisions; DSE, Direction de Surveillance Epidemiologique; DSNIS, Division du Systeme National d'Information Sanitaire; EPI, Expanded Programme on Immunization; GHSC-PSM, Global Health Supply Chain Program-Procurement and Supply Management; NMP, national malaria program; PMI, U.S. President's Malaria Initiative; PNAME, Programme National d'Approvisionnement en Médicaments Essentiels; PNECHOL-MD, Programme National d'Elimination du Cholera et des autres Maladies Diarrheiques; PNSR, Programme National de la Sante de Reproduction; SANRU, Santé Rurale; UNICEF, United Nations Children's Fund

8.4 Annex D: Slides from validation workshops

8.4.1 DRC Validation Workshop Slides on Box

8.4.2 Nigeria Validation Workshop Slides on Box

8.5 Annex E: Question Banks with Stakeholder Interview Notes

8.5.1 DRC Question Bank on Box

8.5.2 Nigeria Question Bank on Box

8.6 Annex F: Costing Models

8.6.1 DRC Costing Model

8.6.2 Nigeria Costing Model

8.7 Annex G. Bibliography

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