Accelerating the scale-up of intermittent preventive treatment in infants for malaria

Proposed approach for the scoping phase

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malaria consortium
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Abbreviations

BID	Better Immunization Data Initiative
CCM	community case management
CHW	community health worker
DPT	diphtheria, tetanus, pertussis vaccine
DRC	Democratic Republic of Congo
EPI	Expanded Programme on Immunization
HMIS	Health Management Information System
iCCM	integrated community case management
IPTi	intermittent preventive treatment in infants
IPTp	intermittent preventive treatment during pregnancy
LLIN	long-lasting insecticide-treated net
M&E	monitoring and evaluation
MCV	measles containing vaccine
MDA	mass drug administration
MMV	Medicines for Malaria Venture
MOH	ministry of health
NMP	national malaria program
OR	operational research
PMI	President's Malaria Initiative
SMC	seasonal malaria chemoprevention
SP	sulfadoxine-pyrimethamine
USAID	US Agency for International Development
VR	vital registration
WHO	World Health Organization

Overview

In 2010, the World Health Organization (WHO) recommended the use of intermittent preventive treatment in infants (IPTi) with sulfadoxine-pyrimethamine (SP). However, to date only Sierra Leone has adopted IPTi, even though it has been deemed safe and cost-effective and been shown to reduce clinical malaria by approximately 25 to 30 percent in the clinical trials that informed the WHO recommendation.[1] PATH and Malaria Consortium propose to accelerate the scale-up of IPTi in the Democratic Republic of Congo (DRC) and Nigeria by building upon learnings from the Sierra Leone IPTi experience; ongoing IPTi programs funded by the Bill & Melinda Gates Foundation, Unitaid, and the Global Fund to Fight AIDS, Tuberculosis and Malaria; and PATH and Malaria Consortium's experience working with ministries of health across Africa to introduce and scale tools and approaches to reduce malaria.

During a proposed four-month scoping phase, PATH and Malaria Consortium will work together define the pathway to scale for IPTi in DRC and Nigeria. The overall approach for the scoping period will follow our pathway to scale approach (summarized in Figure 1). This will include a **landscaping** of stakeholders and assessment of country demand—including discussions of evidence needed for policy adoption; defining subnational target areas through analysis of epidemiological context and existing delivery platforms that could be leveraged for IPTi delivery; assessing and performing a gap analysis of existing pharmacovigilance, data surveillance platforms, and digital tools; and understanding the potential clinical impact of IPTi as estimated using mathematical modeling. The scoping period will also cover aspects of **launch planning** for scale-up through mapping commodity procurement and distribution channels; assessing the health information system and data quality to inform the development of a monitoring and evaluation (M&E) plan to effectively measure coverage and impact of IPTi; and defining and collecting cost inputs required for delivery.

Figure 1: Pathway to scale for IPTi tailored to each geography.

[1] Aponte JJ, Schellenberg D, Egan A, et al. Efficacy and safety of intermittent preventive treatment with sulfadoxine-pyrimethamine for malaria in African infants: a pooled analysis of six randomised, placebo-controlled trials. *The Lancet.* 2009; 374:1533–1542.

Our intention is that at the end of the scoping phase we will have developed, in close consultation with GiveWell and the ministries of health, a context-specific roadmap for DRC and Nigeria which will include an assessment of the criteria detailed in Table 1, which captures the factors that we believe to be critical for the introduction and scale-up of IPTi. Our focus and deliverables for the scoping phase, detailed in the sections below, include (1) a landscaping report, (2) an M&E plan, (3) a roadmap for scale, including associated risks and mitigation strategies, (4) a costing model, (5) detailed roles and responsibilities for the implementation phase, (6) mathematical modeling to assess potential impact, and (7) an overall notional budget for the implementation of the project.

Critical questions to be answered in the scoping period and our approach to answering them

PATH and Malaria Consortium plan to conduct scoping in DRC and Nigeria using the criteria described in Table 1. Through the scoping process, and in close collaboration with GiveWell, we will develop a country-context-specific plan to enable rapid introduction and scale of IPTi.

Table 1: Critical questions to be answered during the scoping period.

Criteria	Question(s)	Why is this question important?	Proposed approach to assessing the criteria
Country demand for IPTi	Has the Ministry of Health (MOH) demonstrated interest in adopting/ implementing IPTi, including barriers using the current WHO recommendation?[2] What are the anticipated timelines for policy adoption/implementation of IPTi? How will the project affect the timelines and pathway to scale-up? Are there any risks of competition between IPTi and other malaria interventions in terms of opportunity cost? Is the MOH receptive to additional touchpoints for IPTi?	National and subnational level buy-in is essential for uptake of any new intervention, especially for matrixed interventions, like IPTi, which require cooperation of multiple parts of the MOH (including, for example, the Expanded Programme on Immunization [EPI] and national malaria programs [NMPs]). Some of the criteria will also support development of a counterfactual scenario to better assess impact.	Review of national strategic plans, Global Fund proposals, and President's Malaria Initiative (PMI) malaria operational plans for documented requests for IPTi. Document discussions with MOH stakeholders at the national and subnational level, including NMPs, EPIs, and other partners delivering malaria or immunization services. Discussions as appropriate with Ministry of Finance for awareness. Document conversations with support from local WHO and UNICEF representatives. Identify and connect with partners that help with essential drug procurement to evaluate current pathway for products and levels of procurement (Global Fund principal recipient and PMI representatives, if possible). Collect letters, emails, and other relevant materials from MOH documenting interest/support.

[2] WHO recommendation for IPTi: Treatment should be given three times during the first year of life at intervals corresponding to routine vaccination schedules.

Criteria	Question(s)	Why is this question important?	Proposed approach to assessing the criteria
Appropriate epidemiological context for subnational targeting and relevant populations[3]	Is the malaria context in the selected subnational geographic areas appropriate for IPTi? For example, is there substantial malaria burden in the first (and potentially the second) year of life? Are there socio-demographic differences within geographic areas, such as urban, rural, or hard-to-reach groups? How seasonal is malaria transmission? What is the coverage of existing proven interventions (e.g., long-lasting insecticide-treated nets [LLINs])? Are there other interventions (currently or planned) targeted at infants (0 to <12 months) and children? What data are available on the prevalence and intensity of resistance of *Plasmodium falciparum* to antifolate drugs?	IPTi distributed based on the EPI schedule is hypothesized to be more effective in areas with perennial transmission as: a) Doses given during a dry season would have limited impact. b) In highly seasonal areas, seasonal malaria chemoprevention (SMC) may be the indicated strategy (and includes the same age group as IPTi). IPTi is a complementary strategy to population-wide interventions, therefore likely to only be implemented programmatically in areas with high coverage of existing highly cost-effective interventions. IPTi with sulfadoxine-pyrimethamine (SP) may be more effective in areas with moderate- to low-level resistance of *P. falciparum* to antifolate drugs.	Collate and overlay data on each of these factors to identify subnational areas where IPTi would be most appropriate. Provide maps and rationale demonstrating the subnational geographies where IPTi would be an effective malaria control strategy. Analyze malaria burden data from routine case incidence, national prevalence surveys, program reports, and modeled prevalence surfaces. Assess coverage of other malaria interventions using national surveys, routine reporting data, and program reports. Collate SP resistance data from existing repositories containing information on therapeutic efficacy studies and studies on molecular markers of resistance. Analyze other complementary data sources that might include inpatient data by age on malaria hospitalizations, severe anemia, and blood transfusions in children under two years of age. Assess laboratory availability, requirements, and costs for conducting SP resistance monitoring. Determine if there are other implementing partners conducting SP resistance monitoring studies in targeted areas.

[3] WHO recommends IPTi to be used in high malaria burden areas (250 malaria cases per 1,000 population per year, or 10% malaria parasite prevalence and above). In 2021, the WHO Global Malaria Programme is conducting a formal external review of their chemoprevention guidance including IPTi. Revised recommendations are expected to offer increased programmatic flexibility in how IPTi could be implemented (e.g., regimens, touchpoints, delivery platforms), with an emphasis on the collection of high-quality evaluation data during implementation to assess the acceptability, feasibility, and impact of local programmatic adaptations.

Criteria	Question(s)	Why is this question important?	Proposed approach to assessing the criteria
Existing delivery platforms	What is current EPI coverage, schedule, and equity nationally/subnationally? What is the existing health worker capacity and approach at primary health care and EPI facilities? Do other potential IPTi platforms exist, both within and outside facility levels? What are the characteristics of the community health worker (CHW) network (e.g., services provided, ratio of workers to catchment population, subnational distribution, training, supervision, and support)? Are there existing or recent collaborative linkages between the EPI and NMP (e.g., through continuous distribution of LLINs)? Is there operational experience successfully delivering other drug-based interventions for malaria (e.g., SMC, mass drug administration [MDA], intermittent preventive treatment during pregnancy [IPTp])? What are the risks (e.g., negative impact on EPI performance, if any) associated with integrating SP administration in EPI, or other delivery platforms? Which MOH program(s) (malaria or EPI, Child	Routine immunization reaches more people than any intervention and is at the core of WHO's approach to strengthening primary health care services. EPI also often serves as the initial (and follow-up) point of contact with children as they receive and have their vaccinations recorded. EPI has traditionally been seen as a potential point of integration with other national programs (e.g., campaigns, outreach, and provision of LLINs). Exploring alternative delivery platforms, such as CHWs, is critical for identifying target populations for optimal coverage, which is key to cost-effectiveness, especially in a context of low/inequitable EPI coverage. In some countries and settings, vaccination, and other drug-based interventions such as IPTp, have been successfully delivered through CHWs. However, in some countries, CHWs are barred from providing those services. Understanding the context and practice standards will be an important aspect of assessing the feasibility of scaling IPTi. Operational experience delivering other drug-based interventions and existing collaborative linkages between the NMP and EPI represent an opportunity to build upon previous experience and an existing	Assess the reach and equity of immunization coverage nationally and subnationally through collection and analysis of joint WHO/UNICEF immunization coverage estimates. Indicators will include: DPTcv3 (diphtheria, tetanus, pertussis vaccine) and measles-containing-vaccine first-dose (MCV1) coverage (nationally) and DPT-2, DPT-3, and MCV1 coverage (in districts with the lowest 20% of coverage). Document any available data on barriers to immunization or health care access. Review of national reports, policies, or standard operating procedures for delivery of immunization services integrated with primary health care. Conduct meetings and discussions with relevant stakeholders (e.g., EPI, UNICEF, WHO, US Agency for International Development [USAID]) to discuss delivery of immunization services and exploration of other potential IPTi platforms within and outside health facility levels, including CHWs. Review of national guidelines, reports, literature on CHWs/community case management (CCM)/integrated community case management (iCCM), highlighting key components such as network, coverage, saturation, target, and scope. Leverage PATH's and Malaria Consortium's previous and ongoing CHWs/CCM/iCCM activities in both countries to inform scoping. Document any nationally relevant experience with the delivery of non-immunization services through, or

Criteria	Question(s)	Why is this question important?	Proposed approach to assessing the criteria
	Health) would be responsible for the implementation of IPTi?	system for a smooth introduction process. It will be useful to explore evaluation experience with delivery of and barriers to IPTp as an example of challenges experienced and opportunities identified integrating malaria services with other programs (in this case, Reproductive Health).	integrated with, routine EPI services. Review national guidelines, reports, and literature on other drug-based interventions implemented in the country, looking at their successes, challenges, and lessons learned, especially from any linkages built with EPI programs. Hold meetings and discussions with relevant stakeholders to discuss lessons learned from the implementation of other drug-based interventions that could be useful for IPTi implementation.
Functioning commodity procurement and distribution channels	What are the current procurement, quantification processes, and distribution channels for malaria-related commodities (including IPTp, SMC, and case management) at the facility and community level? How does SP procurement currently flow? What (if any) are the quality assured brands and dosing formulations of SP registered in the country? What do the central procurement and subnational distribution channels look like? How do commodities flow to EPI and the malaria program? Are there any anticipated supply chain risks and challenges with procurement of SP, importation and tariffs, storage, distribution, and stock-outs?	Effective procurement and distribution are critical to ensure SP will be available both in the country and in subnational target areas. Given the linkages between IPTi and EPI, the supply chain and distribution of SP may be tightly linked with how vaccines or injection supplies are distributed in country. Supply chain and distribution issues would be different in each case, but we believe that even in countries where SP is not widely procured yet, we can identify viable supply chain processes by looking at existing systems.	Consult with Medicines for Malaria Venture (MMV) to identify the global and national product pipelines and associated timelines for dispersible SP. Evaluate and document how products are added into national procurement plans, whether SP has received regulatory approval (and what the dosage regimen for infants is), and whether funds have been allocated for SP in existing Global Fund or domestic budgets. This will help assess speed to implementation, current practice, and the counterfactual IPTi scenario. Document national distribution systems (centralized versus decentralized) and, if possible, gather secondary data on stock levels/evidence of stock-outs. Conduct a high-level scoping of IPTp and SMC procurement and distribution channels if ongoing in the country.

Criteria	Question(s)	Why is this question important?	Proposed approach to assessing the criteria
Assessment of the health information system and data quality for interoperability with other systems and readiness for scale-up	What existing routine surveillance and data collection, including quality, accuracy, and reliability of existing systems are in place to capture malaria, immunization, and child health services coverage? What other data are available to triangulate with health system data (Health Management Information System [HMIS]/Logistics Management Information System)? Are there additional age-specific data available for all malaria and EPI indicators in children under five? How are community-level data reported? What is the quality of routine surveillance and data collection in the countries? How is IPTi coverage monitored and reported in Sierra Leone (where IPTi is being implemented)? What is the potential of existing digital tools to support data recording and reporting? What is the existing national pharmacovigilance system, including adverse event and investigation linkages with EPI? How effective is the system in identifying, reporting, and investigating adverse events and potential safety issues? Is the information system designed to be interoperable and able to exchange data with other systems?	The ability of countries to track and provide services is shaped by their ability to track and manage health and health systems data. Understanding the performance of existing routine heath information systems will help design plans to bolster existing M&E approaches and/or design additional/ alternative data collection strategies, if needed, to better estimate coverage and impact. This includes their ability to exchange data with other systems, such as the national HMIS.	Use existing malaria and EPI data to estimate IPTi target population based on epidemiologically relevant areas and other criteria. Assess routine reporting systems and data reported by the NMP, EPI, and other child health programs to WHO, the Global Fund, and Gavi in order to track program coverage. Review HMIS data completeness, promptness, coverage, and representativeness at the national and subnational levels, and ability to exchange data with other information systems. Conduct gap analysis of the availability, usability, and usefulness of existing data quality indicators from the Data Quality Review, including indicators from WHO, Gavi, and the Global Fund that can be used to develop country-specific profiles of routine data quality. Explore applications of digital tools, including tools developed though the Better Immunization Data (BID) Initiative, for tracking coverage of IPTi. Leverage ongoing surveillance assessment under BMGF MACEPA grant in DRC and Nigeria that is evaluating malaria case surveillance at the national and subnational levels including a data quality audit of the HMIS and key informant interviews. Additionally, surveillance systems for commodities and intervention monitoring and evaluation will be assessed. Review national and subnational pharmacovigilance systems, including reporting and case investigation systems. Assess how IPTi would be incorporated and the systems' ability to be interoperable with other information systems.

Monitoring and evaluation approach for the implementation phase

A monitoring and evaluation (M&E) plan for the implementation phase will be developed during the scoping phase. Guiding systematic collection of accessible, high-quality, and timely data and evidence generation is critical to evaluate the project, inform programmatic decision-making, and measure progress toward results. The M&E plan will define (1) how we measure progress toward the intended program results and equip stakeholders with data for program decision-making, (2) which data sources and specific tools will be used to capture indicators and how we will measure their quality, and (3) how we will measure the impact on burden of disease (e.g., incidence of clinical cases and hospitalizations).

The M&E plan will include the following components:

- **Monitoring plan**. The measurement framework will be aligned with the plan for scale and include indicators for (a) inputs, (b) processes, (c) outputs, (d) outcomes, and, where feasible, (e) impact.
- **Evaluation plan** for additional, embedded studies to support routine monitoring activities (see Table 2 potential indicators and approach). The evaluation plan will include studies that (a) estimate program impact, (b) estimate coverage and adherence to IPTi administration, (c) assess the quality and accuracy of the routine data collected, and (d) capture broader contextual lessons and benefits of the program. It will also include a **process evaluation** to understand how well the relationship with the government and other implementing partners is going and identify areas for improvement for greater efficiency and impact.
- **Learning plan** that includes key questions of interest to stakeholders and plans for discussion and dissemination of routine monitoring and evaluation results throughout the implementation period.

The measurement plan will identify potential malaria, immunization, and community health indicators and data sources, and explore potential strengths and limitations of different approaches to measurement. In Table 2 below, we highlight potential outcome and impact measures we will be considering in the development of the M&E plan.

Table 2: Potential monitoring and evaluation indicators and approach.

Illustrative outcome and impact measures for consideration in M&E plan	Potential approach	Data source	Questions to be explored in scoping
IPTi coverage	Routine monitoring	HMIS	What information is currently registered and reported for EPI and IPTp? Are there data quality assurance activities related to these data? What additional digital tools (e.g., tools developed by PATH's BID Initiative to improve reporting and tracking) for data quality

			assessments, surveys, and reviews of information system data should be explored?
	Supplemental evaluation	Population-based cross-sectional survey(s) to assess coverage/receipt of IPTi dose regimens through: (1) review of EPI cards and (2) history as reported by caregiver	What experience is there with conducting such surveys (such as vaccination coverage survey)? Are there planned or ongoing surveys in the study area that could be leveraged for collection of this information?
Impact on morbidity	Routine monitoring	HMIS, with consideration of indicators such as incidence in age group of interest, uncomplicated malaria, hospitalization with malaria and/or malaria-related anemia	What Information is available on recent data quality assurance activities? What demographic and clinical information are routinely available in HMIS including iCCM data? Can information be collected routinely in age group of interest? If not, what methods/changes might be needed to be put in place to collect these data?
	Supplemental evaluation	Infant cohort using a nested case-control design or cohort study design (set up in control cohort in non-IPTi area if possible) to assess morbidity (measured as incidence of infection and/or clinical malaria) through first 12–18 months of life with IPTi receipt as an exposure of interest.	What experience is there with conducting longitudinal cohorts? What is known about incidence rates of clinical malaria and infant/young child mortality in the area and how would this affect needed sample size? What supporting field operation infrastructure would be needed? What partners might be available, and what are the estimates of cost for these supplemental evaluations?
	Supplemental evaluation	Facility-based surveillance to assess hospitalization with	What demographic and clinical information is currently collected on hospitalized children?

		malaria and malaria-related anemia. Use case control methodology to assess exposure to IPTi among cases and controls (Healthy children attending health facilities; community and/or health facility-based controls). Step-wedge or controlled interrupted time series.	What are the incidence rates for malaria hospitalizations? What supplemental data collection activities would need to be implemented to capture desired information (e.g., incidence in infants and under two years of age) and at what cost?
Impact on mortality	Routine monitoring	Vital registration (VR)	What is status of VR reporting? What percentage of child deaths are estimated to be captured? Are there activities that could be implemented to enhance/improve VR reporting to make it a feasible data source?
	Supplemental evaluation	Population-based surveys	What are the child mortality rates in the area of interest? When was the most recent mortality survey(s) and what type was it (e.g., Demographic and Health Survey)? Are there any upcoming surveys to leverage?
	Supplemental evaluation	Village-based mortality reporting	Is there a village health worker system/capacity? If so, do the village health workers have any experience being trained in death reporting? Would such an approach be feasible/locally acceptable?

Timeline and proposed list of deliverables for scoping period

PATH and Malaria Consortium plan to conduct the scoping phase in DRC and Nigeria over a four-month period in close consultation with GiveWell to produce the deliverables listed in Table 3 that will lay the groundwork for the introduction and scale-up of IPTi in the two countries.

Table 3: Deliverables for scoping period

Deliverables	Description
Scoping report for DRC and Nigeria	The scoping report will include an assessment against the criteria detailed in Table 1 (country demand for IPTi, epidemiological context, existing delivery platforms, SP efficacy, functioning commodity procurement and distribution channels, potential for impact and cost-effectiveness, potential for scale-up) together with key gaps and opportunities identified for each country. The report will also identify subnational target areas for implementation within each country based on discussions with MOH and a review of available evidence, including malaria burden, mapping, coverage by key interventions (e.g., partner platforms such as EPI), surveillance data quality assessments, and SP resistance information, prioritized by potential cost-effectiveness and feasibility. Potential subnational operational areas for IPTi introduction will be aligned with administrative areas so that scale-up is programmatically feasible.
Stakeholder mapping and partnership matrix and engagement plan	The stakeholder mapping and partner engagement plan will capture global, national, and local in-country partners, as well as cross-programmatic coordinating structures (e.g., Interagency Coordinating Committees for primary health care) and national policies/standard operating procedures for integrated health service provision that will be critical to successful introduction and scale-up. Partner mapping will identify other partners that may be useful to facilitate introduction and scale-up of IPTi and potential mechanisms for collaboration (e.g., formation of an IPTi Community of Practice). To date, MMV has expressed an interest in working with PATH and Malaria Consortium to support the SP global supply chain and pipeline, ensuring availability and communication with manufacturers as well as tailoring products for country specifications (e.g., labeling and trainings). PATH has a historically strong working relationship with MMV through partnerships on grants funded by both the Bill & Melinda Gates Foundation and Unitaid targeting introduction and scale-up of tools for *P. vivax* case management. Malaria Consortium is in communication with MMV for their Gates Foundation-funded work in Nigeria and Global Fund- and GiveWell-directed SMC programs.

Deliverables	Description
Plan for scale	The team views scale-up through a stepwise approach that includes close collaboration and partnership with national and subnational partners. Landscaping (i.e., understanding current country contexts, identifying critical stakeholders, and framing the problem) and development of a working roadmap for introduction will be critical first steps. Working with the NMP and partners and in close collaboration with GiveWell, a roadmap for evidence generation, introduction, and scale-up (if applicable given country context) will be developed in collaboration with each country. The roadmap will include proposed activities to be conducted, costed by year during the implementation phase. The roadmap will focus on close collaboration with national and subnational stakeholders and create an initial pathway for the project to eventually achieve policy adaption (if not yet national policy), IPTi introduction, and scale-up. The roadmap will highlight near-term objectives, including meeting country evidence requirements through operational research (OR), and will include details about the study design and sample sizes needed. The OR research plan will be refined and finalized during Year 1 of the implementation phase. It will include descriptions of study sites, key objectives, and training and data collection tools to be developed, and may include a qualitative assessment of feasibility, acceptability, and impact on EPI performance, with primary outcomes including number of children reached, budget, and timelines. Our plan for scale will also include a clear RACI of roles and responsibilities between the two institutions and across both geographies and programmatic components. Lastly, all plans will be developed with initial risk and confidence intervals to help GiveWell assess the risk to timelines and potential impacts to project effectiveness.
Monitoring and evaluation framework and approach for capturing coverage and impact data	During the proposed scoping phase, PATH and Malaria Consortium will develop a monitoring and evaluation strategy for the implementation phase. See details in the “Monitoring and evaluation approach for the implementation phase” section above.
Mathematical modeling to assess potential impact	Using an established mathematical model of malaria transmission, we will conduct a modeling exercise to estimate the potential impact of IPTi on the clinical incidence of malaria in infants. We will also extend the model to consider alternative dosing schedules (e.g., the impact of adding extra doses), different assumptions around the level of SP resistance, and varying coverage levels. Leveraging a previous modeling exercise conducted by PATH in collaboration with the Global Fund and WHO in DRC, we will produce provincial-level estimates of the potential impact of this intervention in this geography. For Nigeria, we will produce estimates of the potential impact of this intervention using a limited range of illustrative scenarios. We will also collaborate with other modeling groups supporting ongoing IPTi projects to generate a short summary of the key knowledge gaps underpinning the modeling estimates of the impact of this intervention—for example, how the underlying transmission intensity in a

Deliverables	Description
	region may impact the level of maternal immunity conferred to an infant, and how this then corresponds to a lower risk of developing clinical malaria during the first months of life.
Identification of potential risk and mitigation strategies	The programmatic risks at each phase of scale in each country and potential mitigation strategies based on stakeholder consultations and in-country project implementation experience from both PATH and Malaria Consortium will be articulated. The categories of risks that will be identified will include security risks, lack of political will, lack of interest in IPTi implementation, issues with registration and procurement of drug, regulatory issues, biological risks including drug resistance, and other health emergencies that might impede implementation.
Costing model	We will develop a costing model design and inputs that capture fixed and variable costs of delivery of IPTi in targeted areas and delivery modalities within each country. The model will include costs specific to country implementation and costs associated with broader learning and evaluation. Costs will take into account both GiveWell project costs as well as government and other funded support for IPTi. Factors that will be assessed include drugs, associated supplies, and their distribution; healthcare worker renumeration costs (e.g., salaries, per diems, travel costs) that are incremental costs of IPTi on top of the EPI program; program management costs that are incremental costs of IPTi on top of EPI; training costs (including training of trainers); communication, socialization, behavior change communication; costs to patients to access care (e.g., health care fees, transportation); expected project implementation costs. Many of these factors will be variable or semi-variable and depend on the geographic reach and number of children reached.
Roles and responsibility for the implementation phase	Agreed upon arrangement for each organization's roles and areas of responsibility during the implementation phase.
Overall notional budget	Estimated cost of the proposed implementation work per country with the best guess timelines and budget that includes the 25th and 75th percentile timelines for each.

Budget for scoping phase

We are requesting $120,000 in total costs for the scoping phase for both organizations. The proposed costs of the scoping phase are primarily driven by labor. Non-labor costs are budgeted for consultants, data collectors, local travel, and meeting costs to conduct stakeholder engagement, assessments, and reviews in DRC and Nigeria. Additionally, PATH will contribute funds to cover additional technical and management labor required for the development of a robust scoping report.

Personnel

We have budgeted labor for the scoping phase for a senior technical advisor from both organizations; a technical lead for the project who will also serve as lead writer; a senior project manager to coordinate the scoping efforts and provide relationship management; a monitoring, evaluation, and learning officer to lead development of the M&E plan; a research scientist with expertise in mathematical modeling to assess potential impact; a health economist to develop the costing model; budget and finance staff members from both organizations who will develop the budget for the implementation phase; technical staff in DRC and Nigeria to lead stakeholder engagement and assessments; and support and operations staff in DRC and Nigeria to help with convening, coordinating stakeholder interviews and workshops, and planning the operations for the implementation phase of the project.

Travel

Travel costs consist of travel within the DRC and Nigeria for country-based project staff as well as transport and per diems for government health staff being engaged in the stakeholder meetings.

Consultants

Local consultants will be engaged in Nigeria for assessments, desk reviews, and development of scoping deliverables.

Other direct costs

Other direct costs include meeting costs for the stakeholder meetings in both countries, costs for data collectors, and transport for the assessments in Nigeria. Other direct costs also include operating costs that are not part of the organizations' indirect cost rates.

Indirect costs

Indirect costs are budgeted according to each organization's indirect cost policies.