Overview of potential 24-month perennial malaria chemoprevention pilot in DRC

April 2023

I. Geographic location/population served

Of the ten provinces in the DRC selected by the Ministry of Health (MOH) for implementation of perennial malaria chemoprevention (PMC), PATH proposes to conduct a pilot in four health zones (and use four health zones as comparators/control areas) in the province of Kongo Central to generate evidence of the impact and operational feasibility of PMC. Kongo Central was selected by the National Malaria Control Program (NMCP) as the priority region for PMC pilot and implementation activities (as documented in their National Strategic Plan).

Figure 1| Eligible Provinces for PMC in DRC

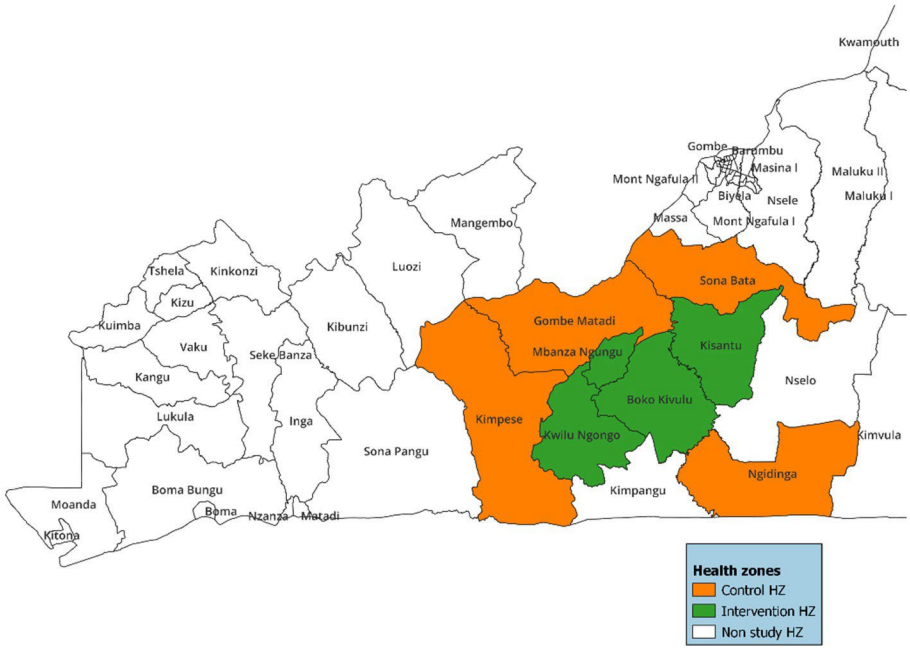
Based on malaria burden, Expanded Program on Immunization (EPI) coverage from Health Management Information System (HMIS) data, and in alignment with the NMCP pilot plan, the initial list of recommended health zones for the pilot are outlined in the table below (from the District Health Information System [DHIS2]; taking into account 3.3% annual population growth).

Table 1 | Recommended health zones for PMI pilot in Kongo-Central

Area	Health zone	Total pop., 2021	Pop. children under 2, 2021	Incidence of confirmed malaria in all ages, 2021 (per 1,000 pop.)	Projected 2023 total pop.	Projected 2023 pop., children under 2
Health zones in PMC intervention area	Boko Kivulu	206,304	16,504	170	220,145	17,612
	Kwilu Ngongo	157,243	12,579	351	167,792	13,423
	Kisantu	214,780	17,182	209	229,189	18,335
	Mbanza Ngungu	155,686	12,455	398	166,131	13,290
Intervention subtotal		**734,013**	**58,720**	**282**	**783,257**	**62,660**
Heath zones in the comparator/control area	Sona Bata	118,168	9,453	245	126,096	10,088
	Kimpese	193,430	15,474	223	206,407	16,513
	Gombe Matadi	110,589	8,847	297	118,008	9,441
	Ngindinga	163,979	13,118	190	174,980	13,998
Control subtotal		**586,166**	**46,892**	**239**	**625,491**	**50,040**

The projected 2023 population of the health zones proposed for the PMC pilot is 783,257 with an estimated population of 62,660 under two years of age.

Figure 2| PMC selected health zones in Kongo Centrale province, DRC



II. Potential PMC touchpoints extending through second year of life

Given the change in WHO guidelines for PMC and expansion to include additional touchpoints in the second year of life, PATH proposes the following schedule.

Age	10 weeks	14 weeks	6 months	9 months	12 months	15 months
Other interventions @touchpoint	OPV2 Pentavalent 2 PCV2 Rotavirus 2	OPV3, IPV Pentavalent 3 PCV3 Rotavirus 3	Vit A Child development visit	Measles Yellow fever	Mebendazole	Potential MCV2

IPV: inactivated polio vaccine; MCV; measles containing vaccine; OPV: oral polio vaccine; PCV: pneumococcal conjugate vaccine

PATH convened a planning session with the MOH to discuss PMC at the end of November 2022 and confirmed agreement with the proposed expanded touchpoints. Mathematical modeling around the potential additional impact of the added touchpoints was also shared with MOH at the meeting.

III. Proposed evaluation approach

To generate evidence on the impact and operational feasibility of PMC in DRC when delivered through EPI at the proposed touchpoints, a mixed evaluation approach is proposed.

To assess impact, a quasi-experimental design with comparison health zones will be used. This will include a health facility case control component complemented with routine surveillance data. To assess the operational feasibility objectives, community household surveys and health facility surveys will be used. Below are further details on the specific endpoints that will be assessed under each component.

In addition to the proposed evaluations below, the pilot will retain the framework of the monitoring plan described in our scoping proposal, though certain indicators may need to be revised or updated based on the narrower scope of the pilot.

Health facility case control study

To assess the impact of PMC on malaria in children under two years of age, a health facility-based case-control study will be conducted, with malaria test-positives (cases) and test-negatives (controls) presenting to selected health facilities. The primary outcome of interest is malaria cases, though severe anemia will also be recorded as a secondary endpoint. During the case control study, blood samples will also be collected from malaria-positive cases for pre-implementation sulfadoxine-pyrimethamine (SP) resistance monitoring.

This case-control study will be layered with a quasi-experimental design that utilizes routine surveillance data in implementation health zones and comparison health zones to examine malaria incidence. Utilizing existing health facility surveillance data substantially reduces the cost and need for additional personnel while still providing a comparator with non-implementing health facilities. Data quality audits will be conducted in both implementation and control health zones to ensure high quality of routine data.

Cross sectional surveys (health facility and household)

Cross sectional health facility and household surveys will be conducted to assess the coverage, scale-up, acceptability, and operational feasibility of PMC in DRC.

Household surveys will include measurement of the following domains:

- Coverage of PMC (e.g., number of SP doses administered per child, and coverage of PMC).
- Access to and use of existing services (e.g., coverage of EPI services as measured by receipt of DTP2, DTP3, and MCV doses).
- Awareness of PMC among caregivers.

- Acceptability of PMC by caregivers.

Health facility surveys will include measurement of the following domains:

- Acceptability of PMC by health workers.
- Perceptions of the feasibility of PMC delivery among health workers.
- Operational challenges encountered in the delivery of PMC.
- SP resistance (e.g., blood samples collected for post implementation SP resistance monitoring).

If needed, health facility surveys will be augmented with key informant interviews of health workers to understand specific operational and feasibility challenges in the delivery of PMC.

IV. Proposed budget for PMC pilot (in USD)

Cost category	Year 1	Year 2	Total
Personnel	1,149,000	1,317,000	2,466,000
Consultants	32,000	-	32,000
Travel	38,000	40,000	78,000
Equipment	165,000	-	165,000
Commodity procurement	157,000	164,000	321,000
Other direct costs	1,054,000	1,027,000	2,081,000
Sub-awards	66,000	70,000	136,000
Total direct	2,661,000	2,618,000	5,279,000
Indirect costs	467,000	480,000	947,000
Total	**3,128,000**	**3,098,000**	**6,226,000**