



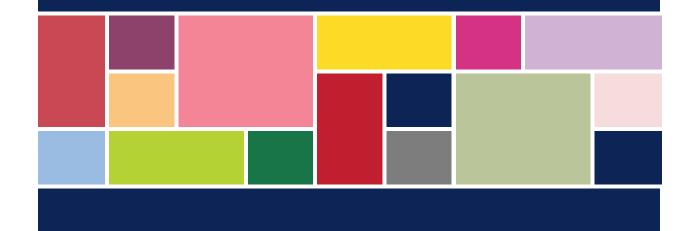


Feasibility Study on Intermittent Preventive Treatment of Malaria in Pregnancy at the Community Level in Burkina Faso

Implementation Research for Testing New Approaches to Improving Prevention of Malaria in Pregnancy

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Abbreviations

ANC antenatal care

CI confidence interval

C-IPTp community-based distribution of intermittent preventive treatment of malaria in pregnancy

CHW community health worker

CSPS Centre de Santé et de Promotion Sociale (Center for Health Care and Social Promotion)

DHS Demographic and Health Survey

DPES Direction de la Promotion et de l'Education pour la Santé (Directorate of Health Promotion)

DSF Direction de la Santé de la Famille (Directorate of Family Health)

DSS Direction des Statistiques Sectorielles (Directorate of Sectoral Statistics)

IMC Improving Malaria Care (USAID/US President's Malaria Initiative Bilateral Project)

IPTp intermittent preventive treatment of malaria in pregnancy

MOH Ministry of Health MiP malaria in pregnancy

NMCP National Malaria Control Program

OR odds ratio

PI principal investigator

PMI US President's Malaria Initiative SMC seasonal malaria chemoprevention

SP sulfadoxine-pyrimethamine WHO World Health Organization

Acknowledgments

The team would like to thank the US President's Malaria Initiative for supporting the study through MCSP and the Improving Malaria Care Program in Burkina Faso. Program implementation by the Ministry of Health in Burkina Faso is appreciated, specifically, the National Malaria Control Program, district health teams, clinic staff, and community members in the three study districts who ensured that the study was implemented with country ownership.

Executive Summary

Burkina Faso's 2016–2020 National Malaria Strategic Plan aims to reduce malaria case incidence using strategies that include the prevention of malaria in pregnant women using intermittent preventive treatment of malaria in pregnancy with sulfadoxine-pyrimethamine (IPTp-SP). The challenge has been achieving the recommended three or more monthly doses starting at week 13 of pregnancy, which was only 22.4%, according to the 2014 Malaria Indicator Survey available at the start of study planning.¹

According to the World Health Organization (WHO), every woman living in moderate- to high-transmission areas should receive at least three doses of IPTp-SP during pregnancy, beginning as early as possible in the second trimester.

In Burkina Faso, IPTp is administered during antenatal care (ANC) by facility-based health workers. As reported in the most recent Demographic and Health Survey, late initiation of the first ANC contact, especially among rural women, and low levels of subsequent ANC attendance² do not enable each woman to receive the number of doses required for optimal protection against malaria for herself and her fetus. In fact, the 2017 annual statistical report of the Ministry of Health (MOH) showed that 81% registered for the first ANC contact, 73% attended twice, and 38% made four visits. Ideally, women should attend ANC for the first time during their first trimester, and 36% who registered did so. At this visit, SP cannot be given, but bednets are recommended. It is on the second visit, therefore, that these women can start IPTp.

To remedy this, the MOH opted to look for alternative approaches to delivering IPTp. In this context, with support from the US President's Malaria Initiative (PMI), the MOH, with technical assistance from MCSP and the Jhpiego-led, PMI-supported Improving Malaria Care (IMC) program, initiated the implementation of a feasibility study on distribution of IPTp at the community level. The quasi-experimental pre-/post-mixed-methods implementation research study aimed to determine the effects of a community intervention on IPTp and ANC coverage in three districts of Burkina Faso. The study was conducted in three phases: baseline assessment, intervention implementation that included ongoing monitoring, and a post-intervention endline evaluation. The intervention involved training existing community health workers (CHWs) to implement community sensitization activities around ANC and malaria in pregnancy for the general population and pregnant women in particular, to refer a pregnant women to ANC for their first dose of IPTp and then to administer subsequent IPTp doses to the woman at the village level.

The intervention ran from May 2017 through August 2018. At the end of the intervention period, data analysis from the baseline and endline assessments and analysis of routine health information system data demonstrated that CHWs were able to work with facility-based health workers to deliver IPTp services at the community level, thus improving ANC attendance and IPTp coverage among pregnant women. This result was facilitated through training and regular monitoring and supervision of CHWs by health workers.

At baseline, women received a median of 2.1 doses; by endline, women received a median of 1.8 doses in the control group and 2.8 doses in the intervention group. There was a nonstatistically significant increase in the proportion of women attending four ANC visits in the intervention compared to the control group. By endline, administration of IPTp was higher in the intervention than control. Community delivery of IPTp is a promising strategy that led to increases in ANC attendance and IPTp coverage, and it should be pursued.

Despite a WHO recommendation for all pregnant women to receive at least three doses of IPTp, coverage in most areas of sub-Saharan Africa remains below international targets. This study shows that CHWs can effectively deliver IPTp, resulting in trends toward improved coverage of IPTp3 and IPTp4, without

¹ Institut National de la Statistique et de la Démographie/Burkina Faso, Programme National de Lutte contre le Paludisme/Burkina Faso, ICF International. 2015. Burkina Faso Enquête sur les Indicateurs du Paludisme (EIPBF) 2014. Rockville, Maryland: Institut National de la Statistique et de la Démographie/Burkina Faso, Programme National de Lutte contre le Paludisme/Burkina Faso, and ICF International.

² MCSP. 2019. Burkina Faso. MCSP website. https://www.mcsprogram.org/where-we-work/burkina-faso/.

adversely affecting ANC attendance. The latter arose in part because the study reinforced the existing CHW tasks in Burkina Faso of promoting maternal health and malaria control. Also of note, no adverse events were reported during CHW delivery of IPTp. In short, CHW involvement in IPTp provision is both safe and feasible, and increases the available options and contacts for pregnant women.

In the intervention arm, routine data from the CHWs and clinics showed two important findings. First, based on the common use of ANC1 attendance as a denominator in health information system calculations of coverage, intervention clinics, with the help of CHWs, achieved higher IPTp3 and IPTp4 coverage than the control area clinics, where CHWs did not have SP for IPTp. Secondly, it appears that CHW provision of IPTp may have replaced some of that provided in the clinic, thus making IPTp more accessible. Considering that CHWs were trained and supervised by clinic staff, one can attribute the combined coverage as an achievement of the clinic as a whole.

Introduction

Malaria Situation

Worldwide, malaria morbidity and mortality have declined considerably since 2000—by 18% (262 million cases in 2000 to 214 million in 2015) and 48% (839,000 deaths in 2000 to 438,000 in 2015), respectively. The majority of cases and deaths occur in Africa (88%). Between 2000- 2015, there was a 66% decline in malaria mortality among all age groups.3 These declines continue as documented in the 2019 World Malaria Report but are threatened by resurgence = and inadequate funding.⁴

Despite the progress made, malaria remains a major public health problem worldwide, especially in sub-Saharan Africa. Children under 5 years old and pregnant women are the most vulnerable. In addition to effective case management, including diagnosis and treatment, use of the following preventive methods is recommended to defeat malaria: indoor residual spraying, long-lasting insecticide-treated nets, seasonal malaria chemoprevention, and IPTp.5

The 2019 World Malaria Report offers both encouragement and caution for the malaria situation in Burkina Faso. Only Burkina Faso and Tanzania were estimated as having more than half of pregnant women receiving three doses of intermittent preventive treatment of malaria in pregnancy (IPTp3) in 2018, while the average across sub-Saharan Africa was only 31%. Burkina Faso is of concern because it is among the 19 highestburden malaria countries in the world for *Plasmodium falciparum* malaria.

Studies in many settings in sub-Saharan Africa, including Burkina Faso, have proven the effectiveness of IPTp with sulfadoxine-pyrimethamine (IPTp-SP) to prevent malaria in pregnancy (MiP). 6,8 Since 2012,9 WHO has recommended that pregnant women receive the first dose of IPTp-SP as early as possible in the second trimester (13th week of pregnancy) and at every antenatal care (ANC) contact up until delivery, with doses spaced at least 1 month apart. 10 Ideally, women should receive at least three doses of SP during pregnancy. The 2019 World Malaria Report states that in 2018, among eligible pregnant women worldwide, 60% received IPTp1, 49% received IPTp2, and 31% received IPTp3.11

At the time of study design (2016), the results from the 2014 Malaria Indicator Survey (MIS) in Burkina Faso showed that 68% of recently pregnant women received the first dose of IPTp (IPTp1), 48% received IPTp2, and 22% received IPTp3. Seventy percent of Burkina Faso's population is rural. 12 According to the 2010 Demographic and Health Survey (DHS), there is a very high initial ANC registration rate of around 95%, but 56% of women in rural areas where the study took place do not attend ANC until their second or even third trimester of pregnancy. The Annual Review of Statistics from the Ministry of Health (MOH) reported in 2017 that 81% of pregnant women registered for ANC, but only 36% did so in the first trimester. The rate for two ANC visits were 73% and for four visits was 38%.13

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³ WHO. 2015. World Malaria Report 2015. Geneva: WHO.

⁴ WHO. 2019. World Malaria Report 2019. Geneva: WHO.

⁵ WHO. 2017. Malaria in pregnant women. WHO website. https://www.who.int/malaria/areas/high_risk_groups/pregnancy/en/.

⁶ Tiono AB, Ouedraogo A, Bougouma EC, Diarra A, Konate AT, Nebie I, Sirima SB. 2009. Placental malaria and low birth weight in pregnant women living in a rural area of Burkina Faso following the use of three preventive treatment regimens. Malar J. 8:224. doi:10.1186/1475-2875-8-224.

⁷ Pell C, Menaca A, Afrah NA, et al. 2013. Prevention and management of malaria during pregnancy: findings from a comparative

qualitative study in Ghana, Kenya and Malawi. *Malar J.* 12:427. doi: 10.1186/1475-2875-12-427.

⁸ Likwela JL, d'Alessandro U, Lokwa BL, Sorongane EM, Gasana G, Kokoma JB, Wilmet MD. 2010. Effet du traitement préventif intermittent (TPI) de la femme enceinte à la sulfadoxine-pyriméthamine (SP) sur le poids de naissance des enfants dans un milieu à résistance élevée du Plasmodium falciparum à la SP à l'Est de la République Démocratique du Congo (RDC). Revue Médicale Rwandaise. 68(40:10-5.

⁹ WHO. 2012. Updated WHO policy recommendation: intermittent preventive treatment of malaria in pregnancy using sulfadoxine-pyrimethamine (IPTp-SP). Geneva: WHO.

¹⁰ WHO. 2014. WHO Policy Brief for the Implementation of Intermittent Preventive Treatment of Malaria in Pregnancy Using Sulfadoxine-Pyrimethamine (IPTp-SP). Geneva: WHO.

¹¹ WHO. 2019. World Malaria Report 2019. Geneva: WHO.

¹² Worldometers. 2019. Burkina Faso Population. Worldometers website. https://www.worldometers.info/world-population/burkina-faso- population/. Accessed December 8.

13 MOH. 2018. Annuaire Statistique 2017. Ouagadougou, Burkina Faso: MOH.

A qualitative study from 2015¹⁴ documented that women in Burkina Faso often were late to begin ANC because they thought "ANC can be postponed ... until the day when time will allow it. Some participants explained their late recourse to their first ANC because they do not want to use antenatal care several times or because of lack of time. It seems that the more flexible conception of time by women goes against the stricter conception of the antenatal care calendar."

At the start of the study, the official approach to IPTp was that only trained providers at health facilities could deliver IPTp as part of standard ANC services for pregnant women. However, since women have trouble accessing ANC, especially those in rural areas, the intensified delivery of IPTp through the existing community health worker (CHW) network has the potential to boost the percentage of women reached for the recommended number of IPTp doses and enhance attendance at ANC for the full range of maternal health services.

Study Context and Objectives

The ongoing gap between high ANC attendance in sub-Saharan Africa and the low proportion of eligible pregnant women receiving at least three doses of IPTp reflects missed opportunities in the health system and the need for innovative approaches to IPTp service delivery. Provision of SP at the community level by trained CHWs is one such approach, yet few studies have been conducted to assess the efficacy of using CHWs to distribute IPTp at the community level.

In Nigeria, a Jhpiego-led study (2007–2012) successfully demonstrated that it was possible to entrust IPTp distribution to community-supported volunteer distributors who were trained and supervised by ANC staff from the nearest health facility. ¹⁵ At the time, the WHO recommendation was to provide at least two doses of IPTp-SP. The effects of the community-directed intervention program included an increase in the percentage of pregnant women taking at least two doses of SP during pregnancy by 35.3 percentage points relative to the control group. Specifically, the intervention area showed a significant increase, from 6% to 65% from baseline to endline, in IPTp2 uptake, compared with 5% to 27% in the control group. The increase in the control group was facilitated in part because the project ensured that ANC clinics in both study arms had SP supplies.

According to national guidelines, only facility-based health providers in Burkina Faso are able to give IPTp during ANC. ¹⁶ The MOH, with technical assistance from MCSP and the US President's Malaria Initiative (PMI)-sponsored Improving Malaria Care (IMC) program, led by Jhpiego, planned to increase the coverage of IPTp in Burkina Faso as part of the prevention of MiP through a feasibility study of community-based IPTp (C-IPTp).

The purpose of the study was to contribute to the identification of an additional channel for IPTp distribution in Burkina Faso. The main research question that the study sought to answer is whether a community-based approach to provision of IPTp is able to increase uptake of three or more doses of IPTp in Burkina Faso, without negatively affecting ANC attendance.

The overall study objective was to determine the effects of a community-based intervention on IPTp and ANC coverage in the target areas of Burkina Faso. Specific study objectives included:

- Document the level of IPTp coverage by distribution channel through assessment of IPTp by CHWs and ANC coverage in the study areas.
- Identify the sociocultural factors that influence the levels of IPTp use and ANC attendance.

 ¹⁴ Quality of Antenatal Care and Obstetrical Coverage in Rural Burkina FasoL. Nikiema I, Y. Kameli 2, G. Capon 3, B. Sondo I, and Y. Martin-Préve J HEALTH POPUL NUTR 2010 Feb;28(1):67-7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2975848/pdf/jhpn0028-0067.pdf
 ¹⁵ Okeibunor JC, Orji BC, Brieger W, at al. 2011. Preventing malaria in pregnancy through community-directed interventions: evidence from Akwa Ibom State, Nigeria. *Malar J.* 10:227. doi: 10.1186/1475-2875-10-227.

¹⁶ MOH. 2014. Directives nationales pour la prise en charge du paludisme dans les formations sanitaires du Burkina Faso.

• Document the implementation process of IPTp distribution by CHWs.

Study Methodology

This was a quasi-experimental pre-/post-mixed-methods implementation research study using a randomized cluster design. The study involved two groups: one intervention group, where pregnant women received IPTp-SP during pregnancy by CHWs in addition to facility-based ANC services, and one comparison group, where pregnant women received IPTp-SP through facility-based ANC services only.

The study was implemented in three phases: baseline assessment, intervention, and endline assessment. Developing the concept note, obtaining study approvals, and study preparation took place between March 2015 and March 2017. During 2016, the study team sought institutional review board approvals and developed supporting documents, such as information, education, and communication materials. Baseline data collection took place in April 2017. The intervention was implemented between May 2017 and August 2018. Monitoring of the intervention also took place between May 2017 and August 2018. The endline evaluation was conducted in August 2018. Dissemination of study results occurred at both national and district levels in September 2018 (Table 1).

Table I. Study phases

Phase	Dates	Activities
Study Preparation and Baseline	March 2015–March 2017	 Protocol developed Collaboration obtained Materials designed Institutional review board approvals sought
	April 2017	 Household survey with 360 women who had given birth in the last 9 months In-depth interviews with community health workers (CHWs) and health staff
Intervention and Monitoring	May 2017–August 2018	 Supervisors and CHWs trained Health education materials and health information forms and printed Sulfadoxine-pyrimethamine obtained and provided at district and clinic levels
	June 2017–July 2018	 Monthly supervisory visit/meetings, CHW reports, Centre de Santé et de Promotion Sociale (Center for Health Care and Social Promotion) data compiled Weekly team review of field activities Monthly review of progress with US President's Malaria Initiative
Endline and Dissemination	August 2018	 Household survey with 360 women who had given birth in the last 9 months In-depth interviews with CHWs and health staff
	September 2018	Data analysis, reporting, and dissemination

The intervention was designed to be in alignment with Burkina Faso's existing national program of CHWs, where every government-designated village selects two CHWs who receive a modest honorarium of around USD 8–10 per month. The training manual for CHWs covers reproductive and maternal health, infectious diseases like malaria, immunization, hygiene, and nutrition. Most of the work in practice is health promotion and education, since the CHWs are yet to be adequately supplied with drugs and materials. For example, although CHWs have been taught to provide appropriate malaria treatment, malaria drugs are only available

in a few pilot communities. Of interest to this study is the fact that CHWs are expected to promote attendance at ANC and efforts to prevent malaria generally and in pregnant women specifically.¹⁷

The normal duties of the CHW include visiting women, educating them about various health issues, and referring them to the local health facility when necessary. Providing IPTp was not among the current duties of CHWs when the study started. Therefore, the intervention sought to build on the existing CHW training to promote attendance at ANC. Based on the WHO recommendation to initiate IPTp dosing at the beginning of the second trimester, CHWs were taught, for this intervention, to bring women to ANC for IPTp1 so that trained health workers could correctly calculate gestational age to ensure that starting IPTp was appropriate. CHWs provided subsequent monthly SP doses.

Due to recent reorganization of the CHW program, some villages had one male and one female CHW, while others had two male CHWs. Due to cultural sensitivities about male CHWs visiting the homes of another man's pregnant wife, in cases where there were no female CHWs, the project recruited an additional woman designated as an *animatrice* (a generic term referring to a community educator or animator/mobilizer) to work with the male CHWs. See Intervention Components and Implementation Process section for more details about the implementation of this intervention.

Study Setting

Burkina Faso is a landlocked Sahelian country located in the heart of West Africa and covers an area of approximately 272,960 kilometers.² It is bordered to the north and west by Mali, northeast by Niger, southeast by Benin, and south by Togo, Ghana, and Côte d'Ivoire. It is divided into 13 regions, 45 provinces, and 70 health districts. In 2016, the resident population of Burkina Faso was estimated at 19,034,397. Women comprise 51.8% of the overall population, while children under 5 years old comprise 18.1%. It is expected that 5.5% of women will be pregnant at any given time. ¹⁸ The general mortality rate is 11.8%, and life expectancy at birth is 56.7 years. The total fertility rate is 6.2. ¹⁹ In 2017, the crude birth rate was estimated at 41.2 births per 1,000 people. ²⁰ According to the World Bank, the infant mortality rate of Burkina Faso was 49 per 1,000 live births in 2018. ²¹ The Government of Burkina Faso reports an average of 341 maternal deaths per 100,000 live births. ²²

The study was implemented in Burkina Faso because it has been among the earliest adopters of malaria chemoprevention in pregnancy, it had an active MiP program supported by PMI, and it is among the highest-burden malaria countries globally. The three regions, South West, Central South, and Central East, were chosen in past because they lie in moderate to high malaria transmission zones and are currently involved in other US Agency for Internation Development (USAID)-supported malaria interventions. One district was purposively selected from each of the three regions, taking into account higher malaria transmission and the presence of active CHWs (Figure 1).

¹⁷ MOH. 2016. Module de Formation des Agents de Sante a Base Communautaire, Cahier du Participant.

¹⁸ MOH. 2018. Annuaire Statistique 2017. Ouagadougou, Burkina Faso: MOH.

¹⁹ MOH. 2018. Annuaire Statistique 2017. Ouagadougou, Burkina Faso: MOH.

²⁰ Central Intelligence Agency (CIA). 2018. World Factbook 2018. Washington, DC: CIA.

²¹ World Bank. 2019. Mortality rate, infant (per 1,000 live births) - Burkina Faso 2018. World Bank website. https://data.worldbank.org/indicator/SP.DYN.IMRT.IN?locations=BF. Accessed December 8.

²² Institut National de la Statistique et de la Démographie - INSD/Burkina Faso, ICF International. 2012. Enquête Démographique et de Santé et à Indicateurs Multiples du Burkina Faso 2010. Calverton, Maryland, USA: INSD and ICF International.

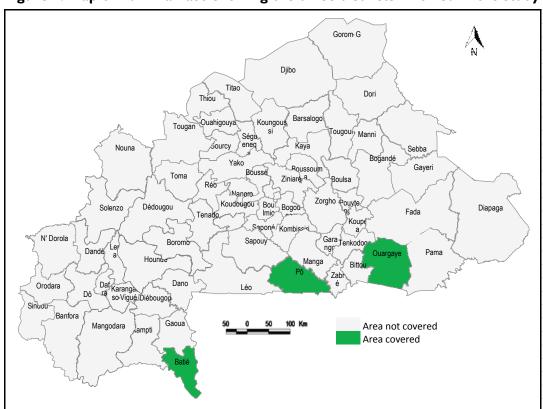


Figure 1. Map of Burkina Faso showing the three districts involved in the study

General characteristics of the districts before the study are presented in Table 2.

Table 2. Characteristics of the districts before the study

District (Region)	Number of Health Centers	Number of ANC Staff	Number of CHWs	Number of Villages	Population	Number of Expected Pregnancie s During Year	IPTp3 Cover age
Batié (South West)	П	11	496	248	91,831	4,996	34.6%
Pô (Central South)	20	19	154	154	202,955	11,052	52.8%
Ouargaye (Central East)	27	29	483	213	341,063	19,725	47.2%
TOTAL	58	59	1,133	615	635,849	35,773	44.9%

Sources: District data 2015, MOH Statistical Yearbook 2014

Study Sampling

Two facilities were selected in the intervention area and two in the control area within each of three selected districts (for a total of 12 facilities). The first facility in each pair was selected randomly, and the second facility in the pair was matched. Each noncontiguous facility pair was matched on characteristics including catchment area size, number of pregnant women registered for ANC, and baseline level of IPTp3 use obtained from the health information system (HIS). Within each pair, one facility was randomly assigned to the intervention arm and the other to the comparison arm.

Table 3. Characteristics of included facilities in 2015

District	Health Center	Population	Number of Villages	Number of Community Health Workers	Number of Expected Births
Intervention	n				
Batié	Dankana	6,991	21	42	379
	Boussoukoula	5,484	16	32	297
Pô	Guiaro	9,001	8	8	490
	Kampala	7,760	8	8	423
Ouargaye	Nabangou	5,770	4	12	334
	Kongloré	3,490	2	6	202
Control					
Batié	Midebdo	7,648	30	60	417
	Tamipar	6,078	16	32	332
Pô	Kaya	8,408	6	6	458
	Guelwongo	8,757	3	3	477
Ouargaye	Salembaore	6,467	2	12	374
	Tensobtenga	4,012	I	8	232

All 111 villages covered by the 12 *Centres de Santé et de Promotion Sociale* (CSPSs, Centers for Health Care and Social Promotion) were included in the study (see Table 3). This was based on the team's own mapping to confirm the catchment area villages. The study intervention targeted all pregnant women living in the selected areas.

Semistructured interviews were held at baseline, and in-depth interviews were done at endline with health workers in the targeted facilities and CHWs serving the targeted facilities. Final in-depth interviews were done to learn about the experiences and opinions of the health staff and CHWs during the intervention. Three providers per facility (the head of the health facility, one ANC provider, one CHW supervisor) were selected for interviews during baseline. The head of the health facility was selected deliberately. The other two providers were also selected deliberately, but when more than one ANC staff was on duty at the time, one was randomly selected from a list prepared previously by the head of the health facility. If the person selected was not there or refused to participate, another provider was randomly selected from the list. For the endline interview, all health workers present the day of the interview were included.

Each village in the catchment area covered by the selected health facilities had at least two CHWs, and at least one of them had been trained on malaria case management by the MOH. One CHW from each village was interviewed for the baseline survey. A mix of female CHWs, male CHWs, and *animatrices* were interviewed in each catchment area. For the endline survey, CHWs and *animatrices* were randomly selected and interviewed from the intervention villages only to learn about their intervention experiences.

Baseline and endline household surveys that included women who had given birth in the 9 months preceding the surveys were used to assess the impact of the intervention. Each village in a catchment area was visited (see Table 3), and a sample was selected based on village size. A key variable of interest was IPTp3 because of its emphasis in the updated WHO guidelines; this was the main focus of sample size calculations. At the time of study preparation (2016–2017), the only available national data on IPTp coverage was the 2014 MIS, which was started only 2 years after WHO introduced the extended IPTp dosing regimen. In that report, only 11% of women nationally had received IPTp3. Regional data were reported (but not district or health center levels), and the three regions where the study was slated had achieved 8%, 11%, and 31% IPTp3 coverage.

The MOH released its 2017 Annual Statistical Report in early 2018—too late for use in study preparation. Earlier reports could not be obtained, but the overall annual statistical reports for the nation for 2015 and 2016 only reported malaria cases, not interventions like IPTp.

Therefore, based on available reports, a sample size of 360 women who had given birth in the last 9 months for each survey (30 women per health facility catchment area) during both baseline and endline surveys. This was planned to achieve 80% power to detect a difference between the group percentages of approximately 19%, from a baseline proportion of 44.7% (average of the proportion in the three districts) to 64.3%, using an unpooled two-sided Z-test at a significance level of 0.05 and assuming an intracluster correlation of 0.03. To ensure that the study team found 360 women who had given birth in the last 9 months, the team estimated it would have a 5% maximum refusal rate and adjusted the planned number of women to 384 women who had delivered within the last 9 months. Based on data from other household surveys, the study team estimated it would need to visit 4.9 households to find one woman who had recently been pregnant, so the team targeted 1,862 households at each time point (see Table 4).

Table 4. Baseline sample size: number of recently pregnant women (who had given birth in the last 9 months to be interviewed for household surveys)

Di	istrict	Number of pregnant women	Baseline third dose IPTp coverage (%)	Expected coverage after intervention (%)	Number of clusters in each arm per district	Number of women per arm per district	Total
Batié	Intervention	1,954	34.6%	54.4%	2	30	60
	Control				2	30	60
Ouargaye	Intervention	1,932	52.8%	71.6%	2	30	60
	Control				2	30	60
Pô	Intervention	2,762	47.2%	66.8%	2	30	60
	Control				2	30	60
Total	Total						360

A list of the data collection tools and methods are presented with the target respondents in Table 5.

Table 5. Data collection tools by method and target

Data Collection Tool	Collection Method	Target Respondent	Content Sought
Household questionnaire	Semistructured interview (baseline or post-intervention)	Women who delivered in the last 9 months from the start date of the survey	Uptake of ANC and intermittent preventive treatment of malaria in pregnancy (IPTp) and basic demographic information
Pre-intervention interview guide	Semistructured interview	Clinic staff	Supervision experiences with CHWs and aspects of CHW work that focus on maternal health and malaria
Post-intervention in- depth interview guide	In-depth interview	Clinic staff	Experiences and opinions about the intervention and performance of CHWs
Community health worker (CHW) pre-intervention interview guide	Semistructured Interview	CHWs	Aspects of CHW work that focus on maternal health and malaria
CHW post-intervention in-depth interview guide	In-depth interview	CHWs	Experiences and opinions about the intervention
Village register maintained by CHWs	Register book	CHWs	Number of IPTp doses provided monthly
Antenatal care (ANC) register at clinic	Register book	Clinic staff	ANC visits and catchment area summary of IPTp doses

Survey Procedures

The baseline and post-intervention surveys took place in March 2017 for baseline (Appendix 1) and July—August 2018, respectively. The implementation of the intervention required that a certain number of tools and materials be made available to study team. Preexisting tools, including data gathering templates (e.g., questionnaires and registers) and learning tools (e.g., flip charts, job aids), were also used. These tools and materials are listed in Appendix 6. The complete tools are available on request. The survey endline implementation timeframe is presented in Appendix 7.

For each district and survey (pre- and post-intervention), 10 interviewers were recruited each from within each district by the district supervisor and then trained over 2 days. Training was performed by a team of IMC and National Malaria Control Program (NMCP) staff. Based on performance during the training, eight interviewers were chosen to collect data in the field. The trainings focused on mastery of data collection tools as well as topics covering compliance of ethical rules by study staff and ensuring data quality.

Interviewers were trained based on a manual containing standard information and procedures. Trainers explained the nature and procedures of survey research. They stressed the importance of comportment, respecting local culture, and ethical issues and practices. The trainers reviewed the technical content of the questionnaire and the intervention, such as IPTp, ANC, malaria, and reproductive health issues, and how these related to study objectives. Practical steps in approaching households and potential interviewees was explained, as were the consent procedures. Supervision, data quality, and completeness were stressed.

Data collection tools were pre-tested during the interviewer training process in the communities for clarity and relevance, then revised accordingly before data collection. Data collection by interviewers was undertaken

pre- and post-intervention and monitored by trained supervisors, including the training team and staff from the district health office. At the village level, the Expanded Programme on Immunization sampling method was identified to select households where women would be interviewed.²³ During each survey, at the center of the village, a direction was chosen by spinning a bottle on the ground. Households along the path indicated were visited, and the questionnaire was administered to women who met the requirements.

The semistructured and in-depth interviews were conducted by the research team consisting of IMC staff and members of the NMCP team. Data collection was followed by data entry using the designed data entry form and data analysis. Quality control began in the field with review of completed questionnaires and interviews.

Analysis Plan

The entire implementation process for the intervention was documented, starting with the orientation and training of team members from national, regional, district, and health facility levels. During the implementation process, routine health facility and CHW data were collected and summarized in Excel to show monthly provision of SP by dose as well as ANC attendance in each study arm.

Quantitative data analysis of the household survey data began with a description of the sociodemographic characteristics of the baseline and post-intervention survey samples by intervention and control areas. ANC and IPTp coverage were also presented as dependent variables in accordance with the objectives of the study. The data were first subjected to bivariate analysis between independent and dependent variables to develop a model to determine the positive or negative influence of social and demographic factors on ANC attendance and IPTp. Final data from the baseline and endline questionnaire data were analyzed in Stata, version 15.1. To compare the baseline and endline data, bivariate data analysis was used. Ultimately, difference in differences analysis was performed to control for clustering.

For qualitative analysis, health worker and CHW baseline semi-structured and post-intervention in-depth interviews were analyzed using the content analysis method. Narrative data were entered in a database for analysis based on major themes relating to ANC, pregnancy, and malaria services. For CHWs, data were also sorted by gender. At baseline, open-ended questions sought the views of ANC providers and CHW supervisors about CHWs' current work and perceptions of the feasibility of CHWs administering IPTp to pregnant women.

Intervention Components and Implementation Process

After a preparation phase, the intervention began on May 1, 2017, with six CSPSs in the intervention area (two CSPSs per district) and ended on August 31, 2018. For the CSPSs in the control area, IPTp activities continued as they were, with specific monitoring of SP availability. An initial concern was to ensure continued availability of SP at both the intervention and control CSPSs so as not to distort findings. During the preparation phase, some districts had SP stock-outs. Stakeholders at the highest level mobilized and advocated for consistent SP supply, ensuring SP availability throughout the intervention phase. The study team negotiated with the district to ensure that SP would be available in both study arms throughout the duration of the implementation. Then, the team ensured that SP availability was monitored on a weekly basis by the field coordinator. Fortunately, no stock-outs occurred during the study period.

Each woman seen at ANC in the intervention CSPSs received information on the C-IPTp implementation process and had the choice to participate or not. Only those who agreed to participate had their personal information recorded on a summary sheet and subsequently reported on the CHW registers to facilitate their follow-up for the intervention.

²³ National Research Council. 1988. Sampling Techniques for Evaluating Health Parameters in Developing Countries: A Working Paper. Washington, DC: The National Academies Press.

Given that the target recipient of IPTp is the pregnant woman, the study had planned from the outset to work with female CHWs for village-level intervention activities. Each village in the catchment area of the health facilities selected for the study was required to have two CHWs (one man and one woman). Although the official training and duties of CHWs did not vary by gender, the fact that the ideal of having one female and one male implied that an informal division of labor in the village would be based on the role gender plays in communicating about health issues, particularly those surrounding reproductive health. This was the standard in Burkina Faso for over 10 years preceding the study.

At the beginning of the study, the study team realized that some villages did not have female CHWs because the MOH reported that, under the new CHW criteria requiring primary school education certificate, some villages did not have women with these. To remedy this, the NMCP obtained approval from the *Direction de la Promotion et de l'Education pour la Santé* (DPES, Directorate of Health Promotion) for the research team to recruit *animatrices* with support from the districts and health centers. The recruitment procedure was the same as that planned for the CHWs. However, while existing CHWs were paid by the government, the project hired and paid the *animatrices* the standard CFA 20,000 (approximately USD 35) per month. These female *animatrices* assisted the male CHWs only in the villages where there were no female CHWs.

The preparation phase also consisted of developing tools and documents to help the stakeholders involved in implementation (see Appendix 3). A field coordinator was designated in each district to monitor activities and act as a liaison between the health facilities and study coordinators. The facility-based health workers had roles in training, supervision, and data management, as described below and outlined in Appendix 4.

Training

Activities were implemented using the cascade training approach. An orientation manual and a training guide were developed to ensure harmonized content.

The first training of trainers oriented central-level staff from the MOH—NMCP, Direction de la Santé de la Famille (DSF, Directorate of Family Health), DPES, Direction des Statistiques Sectorielles (DSS, Directorate of Sectoral Statistics), MCSP, and the Jhpiego-led PMI bilateral IMC—and the field coordinator from each of the district teams on the study procedures. The training taught them how to use the various intervention tools and the procedures for training CSPS staff. Should the ministry decide to continue the process of C-IPTp, this team would be able to provide training of trainers in other districts.

The second training took place at the district level. Health workers from the six intervention CSPSs were oriented by trainers trained in the first training. The orientation sessions were organized in two groups in the capital of each district and were attended by all intervention CSPS health workers. The orientation content focused on organization of the intervention and especially on the CHW training modules.

The third level of the cascade was CSPS staff training CHWs and *animatrices* in their catchment area. The trainings were held in the district capital for each intervention CSPS. No C-IPTp-related training was conducted for the control area CSPS, but the importance of ANC attendance, prevention of MiP, and IPTp were already included as part of the basic training package for CHWs. A total of 56 CHWs (22 women and 34 men) and 33 *animatrices* from 58 villages were trained, as presented in Table 6. The overall roles of CHWs in the program are outlined in Appendix 5.

Table 6. Community health workers and animatrices trained in each district

District	Center for Health Care and Social Promotion	Number of Community Health Workers	Number of Animatrices
Batié	Boussoukoula	18	14
	Dankana	17	9

District	Center for Health Care and Social Promotion	Number of Community Health Workers	Number of Animatrices
Ouargaye	Nabangou	3	2
	Kongloré	2	I
Pô	Guiaro	7	2
	Kampala	9	5
Total		56	33

Supervision

Existing IMC staff on the ground were responsible for overall supervision of implementation. They were assisted at the regional and district level by a central team of MOH staff representing program areas including malaria, child health, reproductive health, essential medicines, community health promotion, and health statistics. The involvement of ministry personnel was aimed at creating ownership of the process and fostering skills to continue such interventions after the project was finished.

Project-specific supervision was organized in four levels and involved all implementation stakeholders as follows:

- Supervision of implementation stakeholders by the co-investigators including the central/national team
- Supervision of district-level stakeholders (field coordinators/CHW supervisors), CSPSs (health workers), and villages (CHWs/animatrices) by the central-level team
- Supervision of health workers and CHWs/animatrices by field coordinators
- Supervision of CHWs/animatrices by CSPS health workers

The frequency of supervision varied from once a quarter (every 3 months) at the central level to once a month for stakeholders in the field. Supervision activities were also used by the central level as an opportunity to provide materials and tools to the districts.

The standard CHW supervisory process was expected to take place in the control areas. This was done by a designated member of the district health team. MCSP did not monitor this process, but since there had been no provision of essential drugs for any CHWs before this intervention, it was realized that CHW activity would be minimal, as would be supervision.

A summary of people involved in implementation is presented in Table 7 below.

Table 7. Supervisory process

Person supervised	Activity	Supervised by
District field coordinator	 Organize supervision. Provide tools to Centers for Health Care and Social Promotion. Monitor stock management. Produce reports. Archive documents and study tools. 	Project team consisting of Improving Malaria Care and Ministry of Health staff
Health worker at health center	 Distribute intermittent preventive treatment of malaria in pregnancy. Complete and maintain study tools and documents. Hold monthly meetings. Organize supervision. Provide tools to community health workers. 	District coordinator

Person supervised	Activity	Supervised by
	Manage sulfadoxine-pyrimethamine stock.Produce reports.	
Community health worker/animatrice	 Conduct sensitization sessions (individual and group). Refer pregnant women to Centers for Health Care and Social Promotion. Distribute intermittent preventive treatment of malaria in pregnancy. Complete and maintain study tools, documents, and materials. Provide tools to Centers for Health Care and Social Promotion. Manage sulfadoxine-pyrimethamine stock. Produce reports. 	Center for Health Care and Social Promotion staff

Coordination Feedback Meetings with the NMCP

During the course of the study's implementation, a steering committee was necessary to ensure coordination of implementation. This body brought together all directorates and organizations of the ministry (NMCP, DSF, DPES, and DSS) involved in the implementation. However, to avoid the duplication of effort, it was decided to entrust coordination to existing bodies. Coordination was therefore ensured by the stakeholders of the PMI-supported IMC project that led the implementation of the study.

The mechanism of coordination was to regularly present the updates of the study and collect the suggestions and recommendations of the key actors during IMC meetings with stakeholders, including PMI and MOH representatives. Beyond the stakeholder meetings, the NMCP could organize meetings with the different MOH directorates as needed to decide on issues related to the implementation of C-IPTp. Decisions made at these meetings were passed on to the regions and districts, and the implementation team ensured follow-up.

Monthly CHW and Health Worker Meetings

Control area health center staff continued their limited and sporadic CHW supervision during the implementation period. In the intervention areas, a monthly meeting was organized between health workers and CHWs/animatrices at each intervention CSPS. The objectives of the monthly meetings were to:

- Systematically collect information on progress achieved and objectives met.
- Have the opportunity to discuss problems faced by stakeholders in the field.
- Create an atmosphere of understanding, open collaboration, and good communication.

The meetings took place between the 26th and 30th of each month and allowed health workers to include IPTp data from CHWs in the overall CSPS monthly report. The monthly meeting agenda included:

- Update on monthly activities by village
- Discussion of challenges and proposed solutions
- Recording of data from the villages (sensitization, household visits, referrals, IPTp)
- Registration of new women attending ANC in the CHW/animatrice registers
- Provision of tools and SP to CHWs/animatrices for the activities in the coming month

Although districts and health facilities had designated CHW supervisors, there were limited funds for village-level supervisory visits as seen during preparation for the study. Thus, the team anticipated that monthly meetings with CHWs and health staff at the health centers could provide a model of CHW

supervision and health information data collation for future supervision of CHW work, and specifically for any potential future extension of C-IPTp delivery.

Monitoring Data Collection, Management, and Reporting

Health workers collected ANC and IPTp data monthly from the CHWs with the existing tools (ANC register, individual ANC client booklet, and monthly summary sheets). CHWs attached a small referral/notice slip to the ANC booklet to facilitate real-time exchange of information to the ANC staff on IPTp administration to each pregnant woman by the CHW. In addition to the existing tools, health workers completed a monthly summary of the new pregnant women from each village seen at the CSPS. The sheet was completed in duplicate so that a copy could be given to the CHW at each monthly meeting. CHWs also completed the second part of each referral sheet they received. This allowed them to reconcile the number of referrals received per month and compare that to the referral total reported by each CHW/animatrice.

Each CHW/animatrice collected the following data monthly:

- Sensitization activities (on the sensitization sheet)
- Administration of each dose of IPTp to pregnant women in the village (specific columns on the CHW register)
- Referrals of pregnant women to the CSPS (on the CHW register)
- SP stock monitoring
 - For CHWs on their stock inventory sheet
 - For health centers and district pharmacy stores, site visit observations and monthly calls to district supervisors by project staff

At the end of the month, all data were compiled in the monthly report and then submitted to health workers during the monthly meeting at each project health facility. The field coordinator was in charge of collecting data from the control area, with help from the workers in charge of managing data at the district level. These data were integrated into the monthly report and the Excel database for each district. Regular reports were produced throughout the implementation period of the intervention. To harmonize the content of the different reports, forms were designed to serve as a basis for drafting each report. These reports included:

- Weekly activity monitoring report: This was used to update the whole study team on the status of the study during the duration of the project.
- CHW report on C-IPTp activities: This was the monthly summary of services provided at the community level.
- CSPS report on IPTp: This was the monthly summary of services at the facility level in both intervention and control provided.
- District report on IPTp: This included all IPTp provided at community and facility levels.
- District Excel database/health management information system data: This provided updates on community- and facility-level data.
- Summary report on IPTp activity implementation in the three districts: This was a summary done by the project coordinator for the project.
- Excel database from the three districts: This was a summary done by the project coordinator for the project.

Preparation of the abovementioned reports is described in Appendix 6 in the table on intervention reporting.

Study Results

The results in this section describe the implementation process, the monitoring process of data collection and the supervision, baseline, and endline process both quantitative and qualitative.

Intervention Processes

Basic processes, such as training, recordkeeping forms and equipment, supervision, and monthly CHW meetings, were put in place to ensure the intervention ran smoothly.

The project trained four levels of people on the implementation of the intervention:

- Core team: The core team comprised seven people. Training resulted in six people from national-level agencies: NMCP (3), DSF (1), DPES (1), and DSS (1). It also included one person from the Jhpiego monitoring and evaluation section.
- District team: Four district coordinators were trained. Each district had a district coordinator chosen by the district health management team. During the project, one had to be replaced (Ouargaye) by the district health management team, which was done immediately. In August 2017, this new coordinator started and was trained on the intervention.
- CSPS staff: Twenty-four CSPS staff (nurses/midwives) were trained; 17 were male and eight female. They were in-charges at their CSPS and were responsible for overseeing the community activities for IPTp.
- CHWs: A total of 90 CHWs/animatrices were trained. When the study team initially inquired about the number of CHWs in the communities, it found 57: 33 male CHWs and 24 female CHWs. The study team brought in 33 animatrices to train for the intervention to work with the male CHWs.

In addition to training, recordkeeping forms and equipment (boxes, bags, pens, registers, first provision of SP) were supplied to intervention CSPSs and CHWs. Before the intervention started, three visits (one to each district) were made to ensure that each had adequate tools and materials. The study team collected ANC and IPTp data from existing health center records. These recordkeeping forms and equipment are included in Appendix 6.

In the intervention area, 24 job aids were given to health workers, four to each CSPS, two of which were placed in the maternity ward and the other two in ANC. Twelve extra were printed just in case these needed to be replaced. One-hundred thirty were printed for the CHWs, meaning each CHW would have received one, and extras were available in case any needed to be replaced. Each CSPS received five extra job aids as replacements for CHWs if they needed them.

Each CHW received a CHW register, for a total of 90 registers. Each of the six intervention CSPSs was given two extra CHW registers to use as replacements for the CHWs. Thus, 102 CHW registers were distributed. Each CHW received a bag, for a total of 90 bags. Each intervention CSPS received two replacement bags for CHWs if they needed them, so 102 bags were distributed. Educational flip charts were distributed to CHWs for use in educating villagers generally about the importance of IPTp as well as for monthly counseling of the pregnant women. Other items handed out were referral slips; reporting forms, which were stocked on each supervision visit; pens, which were also given to coordinators on the ground so they could be replenished; and SP stock.

Before the project was up and running, the study team ensured that the system could provide SP for both intervention and control throughout the duration of the project. Estimated SP needs were assessed based on expected pregnancies in the catchment area and ongoing ANC volume. In May 2017, to verify SP stocks before the intervention began, the CHWs reviewed the number of women in the villages and communicated the number to the CSPSs during outreach. This informed the SP stock they needed for the month of June

2017, when the intervention started. Each village received a small case in which to keep the SP. There were 57 of these cases distributed for CHW use. Cases were locked and stored at CHWs' homes.

SP for each CSPS and the CHWs associated was stocked at the CSPS, and SP was estimated and ordered by CSPS staff on a monthly or quarterly basis from the district pharmacy/medical store. CHWs/animatrices obtained SP from health workers during the monthly meetings. CSPS staff and CHWs/animatrices had a stock card where the inputs and outputs were recorded. The SP needs for each village were calculated on the basis of the women registered for the month, with a surplus of two to three doses to avoid stock-outs. Each month, the study coordinator checked at each level to ensure SP availability and followed stock levels in each of the districts. Each month, the coordinator checked if the stock was low and called the field coordinator (district) if it was to ensure that it was replenished. The field coordinator then called the CSPS. Because of this, the monthly reports from the field coordinator indicated that there was stock throughout the project. At each woman's first ANC contact, if her gestational age did not allow health workers to provide SP, information was given to the CHWs/animatrices through the month's summary sheet. Likewise, for those who received SP, their information was reported in the CHW/animatrice register to facilitate follow-up. This allowed the CHW/animatrice to remind the woman to return to the facility in time for her appointment. If the woman was going back to the CSPS for her appointment and her gestational age at the time meant she could receive her first dose of SP, then the ANC health worker would administer it and write the woman's name on the monthly summary sheet. Then, this woman would be added to the list for follow-up for the second dose at the village level. All first doses of IPTp were administered at the facility.

During the 15-month intervention period, supervision happened at all levels. At the core level before the intervention began, the project coordinator visited or phoned the districts monthly. During site visits to the districts the project coordinator visited each intervention health center together with the district coordinator, who led the process. They then went together with CSPS staff to one or two villages as time allowed. They also participated in the monthly supervisory and data collation meetings at the CSPS. When the project coordinator was unable to visit the district in person, the district coordinator undertook these activities and reported the activities during a phone conversation. The project coordinator produced monthly reports to summarize all supervisory activities. Supervision reports noted any problems found and how these were being addressed. An important 'negative' finding during this supervisory process was that there were no reported severe/adverse events in the use of SP at the community level.

The project coordinator followed up on issues reported from the field to ensure that the appropriate people were taking the necessary actions to resolve the issues. The issues were not so much IPTp-specific as general CHW program management. Through his weekly reports on monitoring and action, the team learned the importance of holding the government stakeholders at all levels to their promise to provide supplies, in this case SP. Although attrition of CHWs was very low, the team learned the importance of prompt response at the village level to identify replacements. A practical issue arose concerning catchment area mapping. Two health centers had included one village each that was on the periphery of their area and, in fact, since no one from those villages attended those health centers for any service, the two villages were not only dropped from the study list but also from the overall health center data.

While Burkina Faso's community health system officially designates personnel at district and health center level to oversee community activities, including CHWs, these people had not been functioning in the absence of higher-level support and encouragement. The project showed that a team from the MOH at national and regional levels, when mobilized, can provide that needed encouragement

Regular monthly CHW meetings were held at each CSPS throughout the intervention period, for a total of 15 meetings for each CSPS in each district across the CSPS. The attendance of CHWs/animatrices was good throughout the intervention period, with few absences (sometimes one to two CHWs per CSPS). These meetings made it possible to gather, review, and ensure the quality of the CHWs'/animatrices' data each month to complete the monthly CSPS report in order to transmit it to the district level.

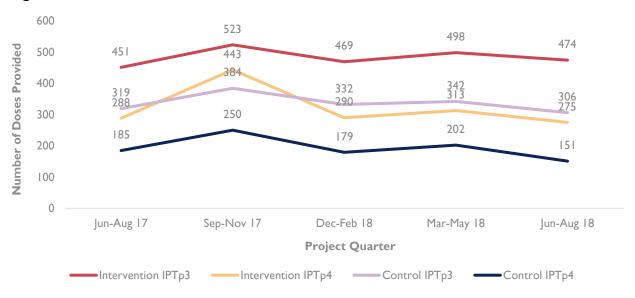
During the intervention, all reports were generated and transmitted. Every 25th of the month, each CHW/animatrice gave a summary of the activities carried out during the month. This was recorded in a monthly report document. This summary focused on the community awareness sessions conducted during the month, referrals, doses of IPTp administered, and total number of pregnant women seen. The report was given to CSPS staff on the day of the monthly CHW meeting to be verified for quality before compilation. CHWs worked with the CHW supervisor at the clinic to reconcile their reports and data. Animatrices who had trouble filling out the reports were assisted by the male CHWs if they could read and write or by health workers on the day of the meeting. The study team found, however, that most animatrices were literate, contrary to expectations. The analysis of the data in these reports allowed the results of the routine collection to be presented at monthly meetings based at the CSPSs. CHW supervisors at health center and district levels addressed any implementation or performance challenges they faced in the field, such as challenges filling out the forms. Any new information about the intervention was passed on to them at the time.

Uptake of IPTp

The figures below show the results of IPTp3, IPTp4, and ANC4 provision analyzed from routine health service statistics collected by health providers and CHWs during the course of the intervention. Data are disaggregated by intervention and control groups. No adverse events were reported from either CHWs or health providers.

Figure 2 presents results on IPTp3 and IPTp4 provision. The data collected from the intervention zone are disaggregated to show women who received IPTp3 and IPTp4 from CHWs/animatrices and those who received it from the CSPSs to show the effect CHWs/animatrices had on the number of IPTp doses distributed.

Figure 2. Number of third and fourth doses of intermittent preventive treatment of malaria in pregnancy administered according to study group and by quarter, June 2017–August 2018



The results of the routine data analysis show that the provision of IPTp and attendance at ANC are higher in the intervention area than in the control area. In other words, the number of women who were able to obtain the recommended four ANC contacts in Figure 3 and received at least IPTp4 in the intervention group is higher compared to that of the control. Based on ANC1 registration at each clinic, the percentage of women who registered and received IPTp4 is calculated and seen in Figure 4. Intervention clinics achieved a consistently higher coverage of IPTp4 provision.

Figure 3. Number of women who completed their fourth antenatal care contact according to study group and by quarter, June 2017–August 2018

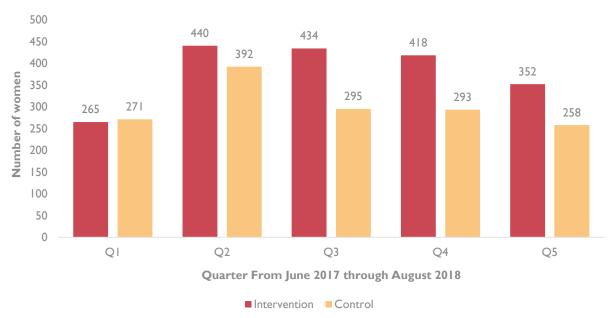
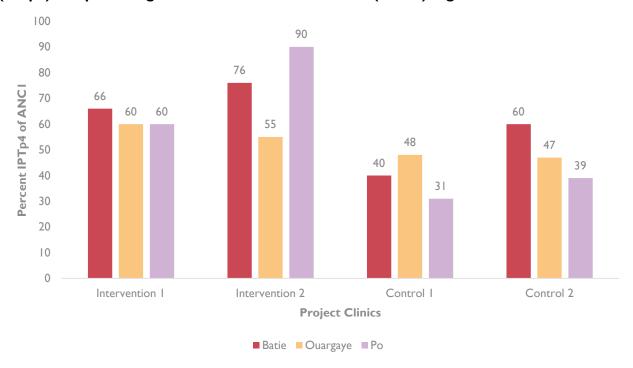


Figure 4. Fourth dose of intermittent preventive treatment of malaria in pregnancy (IPTp4) as a percentage of first antenatal care contact (ANCI) registration



While the coverage found in Figure 4 is not the same as determined through surveys like the DHS and the project's own household surveys, when ANC registration is very high, IPTp coverage based on ANC1 approximates that of coverage in the catchment area. Figure 4 shows data that were collected and used throughout the project to make decisions at all levels but also documents the actual distribution of SP in the study areas.

Analysis of Data from Household Surveys

MCSP interviewed 374 women in the baseline survey and 360 in the endline survey. Sociodemographic characteristics of women in the control and intervention groups were similar both within and between surveys (Table 8). On average, one-quarter of surveyed women had had one pregnancy, one-third had two to three pregnancies, and the rest had four or more.

Table 8. Sociodemographic characteristics of women in household survey at baseline and endline (those who had given birth in the last 9 months)

		Interv	ention	Control		
Basic Demograp	hic Information	Baseline (%) (n = 188)	Endline (%) (n = 180)	Baseline (%) (n = 186)	Endline (%) (n = 180)	
Demographics						
Age	Range	18–44	18–45	18–47	18–48	
	Median	26	27	26.5	28	
	<20	26 (14)	25 (14)	28 (15)	21 (11.7)	
	20–24	47 (25.3)	50 (27.8)	51 (27.1)	45 (25.0)	
	25+	113 (60.8)	105 (58.3)	109 (58)	114 (63.3)	
Formal education	None	131 (70.4)	102 (56.7)	109 (58)	126 (70.0)	
	Primary	43 (23.2)	64 (35.6)	51 (27.1)	33 (18.3)	
	Postprimary	12 (6.5)	14 (7.8)	28 (14.9)	21 (11.7)	
District	Batié	60 (32.3)	60 (33.3)	60 (31.9)	60 (33.3)	
	Ouargaye	64 (34.4)	60 (33.3)	69 (36.7)	60 (33.3)	
	Pô	62 (33.3)	60 (33.3)	59 (31.4)	60 (33.3)	
Number of times	I	44 (23.7)	41 (22.8)	54 (28.7)	39 (21.7)	
pregnant	2	24 (12.9)	37 (20.6)	33 (17.6)	28 (15.6)	
	3	34 (18.3)	25 (13.9)	26 (13.8)	28 (15.6)	
	4	42 (22.6)	20 (11.1)	25 (13.3)	22 (12.2)	
	5	15 (8.1)	26 (14.4)	14 (7.5)	27 (15.0)	
	6+ above	27 (14.5)	31 (17.2)	36 (19.2)	36 (20.0)	
Marital status	Married	180 (96.8)	175 (97.2)	179 (95.2)	169 (93.9)	
	Not married	6 (3.2)	5 (2.8)	7 (3.7)	11 (6.1)	
Religion	Muslim	77 (41.4)	73 (40.6)	73 (38.8)	62 (34.4)	
	Catholic	39 (21)	38 (21.1)	24 (12.8)	24 (13.3)	
	Protestant	15 (8.1)	34 (18.9)	36 (19.2)	42 (23.3)	
	No religion	10 (5.4)	7 (3.9)	4 (2.1)	4 (2.2)	
	Other	45 (24.2)	28 (15.6)	51 (27.1)	48 (26.7)	

Women who had attended at least one ANC contact increased from 90.3% at baseline to 97.8% at endline for the intervention groups. A comparable but smaller increase was seen in the control group: 89.4% and 94.4%. For ANC4+, the coverage rate increased by 15 percentage points for the intervention area between the baseline and endline surveys (61.8% to 77.2%), with only a 3 percentage-point increase in the control group (62.2% to 65.0%). Figure 5 shows endline details for each ANC visit.

Percentage of woman and the second se

ANC₂

ANC sessions attended

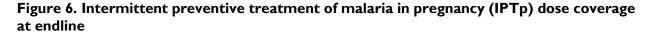
■Intervention (N=180) ■ Control (N=180)

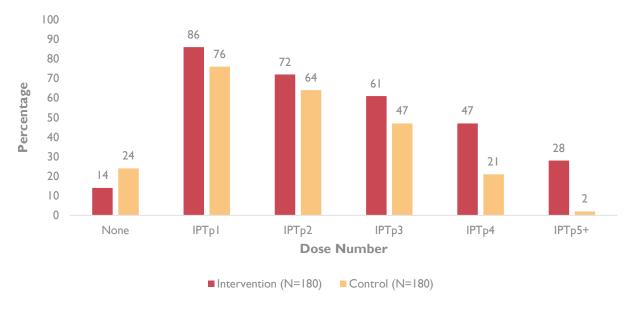
Figure 5. Antenatal care (ANC) session attendance at endline

ANCI

None

At baseline, women received a median of 2.1 doses (range 0–5 doses) across both arms according to documentation on the ANC card and a median of 2.5 doses (range 0–6) according to self-report, with no significant differences across arms. At endline, control group women received a median of 1.8 doses (range 0–5) according to the card and 2.8 doses (range 0–7) per self-report, and women in the intervention group received 2.8 doses (range 0–5) per ANC card and 3.4 (range 0–7) per self-report (p-value <.0001 for difference in arms by both card and self-report; Figure 6).





ANC4

ANC3

ANC4, IPTp3, and IPTp4 coverage were similar at baseline, with ANC4 coverage of 61.8% in the intervention and 62.2% in the control (p-value = 0.96), IPTp3 coverage of 50.5% in the intervention and 54.3% in the control (p-value = 0.74), and IPTp4 coverage of 21.5% in the intervention and 16.0% in the control (p-value = 0.59) (Table 9).

There was a 15.4 percentage-point increase in the proportion of pregnant women who had attended at least four ANC visits in the intervention area and a 2.8 percentage-point increase in ANC4 attendance among women in the control group, for a DiD of 12.6 percentage points (p-value = 0.16). By the endline, administration of IPTp was universally higher in the intervention than control. There was an overall 17.6 percentage-point increase in IPTp3 at endline in the intervention group, after accounting for baseline coverage (DiD p-value = 0.31).

There was a 25.2 percentage-point increase in IPTp4 the intervention area (p-value 0.02 for comparison from baseline to endline) and only a 5.1 percentage-point increase in the control (p-value 0.60 for comparison from baseline to endline), with a difference in differences of 20% (p-value = 0.34). The greatest improvement was seen in IPTp5, which increased from 4.3% at baseline to 27.8% at endline in the intervention arm (DiD = 23.9 percentage points; p = 0.06) (Table 3). Results did not change substantially when adjusted for maternal age and pregnancy (Table 10). The calculated interclass correlation coefficient was 0.095 for IPTp3 and 0.089 for IPTp4. Pregnancy was associated with receipt of IPTp3, but not IPTp4 nor ANC attendance, while age over 20 was associated with ANC attendance (both ANC1 and ANC4), but not receipt of IPTp (Table 11).

At baseline, women reported first presenting to ANC at a mean of 3.1 and 2.8 months gestational age in the control and intervention arms, respectively (p-value = 0.07), while at endline, mean gestational age at first presentation to ANC was reported to be 3.0 and 2.6 months in the control and intervention arms, respectively (p-value = 0.03), controlling for age and pregnancy. Among the 90.1% of women who stated that they told someone about their pregnancy, the vast majority (91.7%) disclosed that they were pregnant before feeling the baby moving/showing, with no significant differences between baseline/endline or control and intervention groups. Two-thirds (65.9%) reported having first told their husbands/the father of the baby, 12.1% first told their mother-in-law, 8.2% first told a health worker, and 4.9% first told their mother; only 1.8% first reported their pregnancy to a CHW.

Adjusting for age and pregnancy, at baseline, 34.4% and 56.7% pregnant women in the control and intervention arms, respectively, reported having spoken to a CHW about their pregnancy; this increased to 54.0% and 77.6% in the control and intervention arms, respectively, at endline. The increase was statistically significant only women in both arms (p-value <0.0001 in control and p-value 0.0028 in the intervention arm; p-value 0.0002 for the difference between arms at endline). Similar percentages reported discussing prevention of MiP with a CHW (26.7% and 57.9% in the control and intervention arms, respectively, at baseline, and 51.3% and 74.3% in the control and intervention arms, respectively, at endline). The increase was statistically significantly different in the control (p-value 0.007), but not the intervention arm (p-value 0.13); however, given the difference at baseline, there was still a statistically significant difference between arms at endline (p-value 0.01).

Table 9. Antenatal care (ANC) and intermittent preventive treatment of malaria in pregnancy (IPTp) coverage at baseline and endline, by study arm

	Baseline		Endline		Difference	P-value for	
	Control	Intervention	Control	Intervention	in	difference in	
	N = 188	N = 186	N = 180	N = 180	differences	differences	
IPTp doses (mean, 95% CI)	2.3 (1.9, 2.8)	2.3 (1.8, 2.9)	2.1 (1.53, 2.9)	2.9 (2.3, 3.8)	0.89%	0.18	
IPTpI+ (percentage, 95% CI)	86.2 (73.5, 93.4)	80.7 (65.4, 90.2)	75.6 (54.6, 88.8)	86.1 (74.9, 92.8)	16.1%	0.18	

	Baseline		Endline		Difference	P-value for
	Control	Intervention	Control	Intervention	in	difference in
	N = 188	N = 186	N = 180	N = 180	differences	differences
IPTp2+ (percentage, 95% CI)	73.4 (55.2, 86.1)	69.9 (57.1, 80.2)	64.4 (41.3, 82.3)	72.2 (50.3, 87.0)	11.3%	0.57
IPTp3+ (percentage, 95% CI)	54.3 (39.3, 68.5)	50.5 (35.0, 66.0)	47.2 (28.6, 66.7)	61.1 (40.6, 78.4)	17.6%	0.31
IPTp4+ (percentage, 95% CI)	16.0 (8.4, 28.3)	21.5 (8.3, 45.3)	21.1 (12, 34.5)	46.7 (29.6, 64.6)	20.0%	0.33
IPTp5+ (percentage, 95% CI)	2.7 (1.0, 6.8)	4.3 (1.1, 15.4)	2.2 (0.6, 8.1)	27.8 (17.3, 41.4)	23.9%	0.06
ANC visits (mean, 95% CI)	3.2 (2.9, 3.6)	3.23 (2.9, 3.6)	3.4 (3.0, 3.7)	3.6 (3.6, 3.7)	0.22%	0.47
ANCI+ (percentage, 95% CI)	89.4 (80.4, 94.5)	90.3 (76.8, 96.4)	94.4 (84.7, 98.1)	97.8 (94.6, 99.1)	2.4%	0.43
ANC4+ (percentage, 95% CI)	62.2 (49.4, 73.5)	61.8 (50.5, 72.0)	65.0 (48.5, 78.6)	77.2 (73.1, 80.9)	12.6%	0.16

^{*}DiD = Difference in differences

Table 10. Antenatal care (ANC) and intermittent preventive treatment of malaria in pregnancy (IPTp) coverage at baseline and endline, by study arm, adjusted for pregnancy and maternal age

	Base	eline	Endline		Difference	P-value for
	Control	Intervention	Control	Intervention	in	difference in
	N = 188	N = 186	N = 180	N = 180	differences	differences
IPTp doses (mean, 95% CI)	2.4 (2.0, 2.9)	2.3 (1.8, 3.0)	2.2 (1.6, 3.0)	3.0 (2.4, 3.8)	0.92	0.17
IPTp3+ (percentage, 95% CI)	57.7 (41.6, 72.3)	53.6 (37.3, 69.1)	50.1 (30.9, 69.2)	64.2 (45.1, 79.7)	18.3%	0.29
IPTp4+ (percentage, 95% CI)	16.6 (8.6, 30.7)	22.7 (8.6, 47.8)	22.2 (12.8, 35.8)	48.5 (30.9, 66.4)	20.2%	0.34
ANC visits (percentage, 95% CI)	3.3 (2.9, 3.6)	3.3 (2.9, 3.7)	3.4 (3.1, 3.8)	3.7 (3.6, 3.8)	0.25	0.42
ANCI+ (percentage, 95% CI)	91.5 (83.2, 95.9)	92.2 (80.0, 97.2)	95.5 (87.3, 98.4)	98.3 (95.9, 98.5)	2.2%	0.39
ANC4+ (percentage, 95% CI)	65.3 (51.4, 77.0)	64.9 (53.1, 75.1)	67.6 (50.3, 81.2)	80.2 (75.5, 84.1)	13.0%	0.12

^{*}DiD = Difference in differences

Table II. Effects of pregnancy and maternal age on uptake of intermittent preventive treatment of malaria in pregnancy (IPTp) and antenatal care (ANC)

		OR	Confidence Limits	p-value
IPTp doses	PTp doses Pregnancy, Primi vs multi		(0.76, 0.94)	0.002
	Age <20	1.02	(0.86, 1.21)	0.78
IPT _P 3	Pregnancy, Primi vs multi	0.62	(0.39, 0.99)	0.05

		OR	Confidence Limits	p-value
	Age <20	0.93	(0.49, 1.77)	0.83
IPT _P 4	Pregnancy, Primi vs multi	0.71	(0.43, 1.17)	0.18
	Age <20	1.02	(0.65, 1.59)	0.94
ANC visits	Pregnancy, Primi vs multi	0.98	(0.9, 1.06)	0.64
	Age <20	0.92	(0.87, 0.99)	0.02
ANCI	Pregnancy, Primi vs multi	0.73	(0.36, 1.46)	0.37
	Age <20	0.58	(0.36, 0.94)	0.03
ANC4	Pregnancy, Primi vs multi	0.91	(0.51, 1.61)	0.75
	Age <20	0.61	(0.4, 0.93)	0.02

Qualitative Interviews with Health Workers and CHWs

Findings from Interviews with Health Workers

Interviews with health workers at baseline and endline focused on the frequency of ANC contacts at the health center level, the existence of CHWs and their activities at the village level, the possibility of using CHWs to provide IPTp, and the information and tools used by CHWs to implement activities.

The interviews indicated that there were CHWs from all of the villages in the study. The national community health promotion directorate reorganized the CHW program in 2016, with a goal of ensuring that all CHWs had a primary school certificate. This meant that many current CHWs were relatively new to the job, as those without the primary school certificate were let go. CHWs were trained to implement a package of activities, including:

- Community sensitization on health topics
- Case management of uncomplicated malaria, diarrhea, and acute respiratory infections
- Standalone activities tied to mass distribution campaigns
- Dissemination of messages related to health center activities
- Support for advanced strategies on immunization and screening for malnutrition

All health workers interviewed noted that the C-IPTp approach was a new concept. Some, though not most, even expressed reservations about the ability of CHWs to carry out activities related to this approach. Others indicated that the approach is feasible if CHWs are trained and monitored regularly, and people are well informed about the activity implementation process for this approach.

In terms of the tools used by CHWs, the baseline interviews revealed that only a few existing CHWs who were involved had tools for their work. The new CHWs were still waiting to receive tools. Twenty-three health workers from the six intervention CSPSs took part in the endline interviews after completion of the intervention activities. The endline interviews allowed the health workers to highlight the relevance of the approach and how the work was organized with the CHWs and the communities. Overall, health workers at endline found that the work of CHWs in the intervention was a good thing for the health of the communities and, at the same time, contributed to reducing the health workers' workload. A health worker from the Kongloré CSPS said: "CHWs are very useful for our work. With CHWs, ANC contacts have increased, and women respect appointments. We hope that continues. CHWs are good but need to be monitored and supervised."

For activity implementation, it appears that the health workers set up a system to allow for contact between women and CHWs at the village level. One health worker said: "From the beginning of the study, we put pregnant women in contact with CHWs. When they come for ANC after getting IPTp1, we explain to them that the CHW will come to their home to give them the other doses. At the end of each month, the CHWs

are informed of pregnant women in their village who should receive SP. This is how they contact them and provide SP at home."

For the health workers, the success of the CHWs' work is a result of raising community awareness, particularly among pregnant women. For them, sensitization has led to a better understanding among pregnant women of the usefulness of ANC and taking SP regularly. The health workers also appreciated the fact that CHWs referred women to the health center. They found that overall, CHWs had a good command of the tools available to them for the job. Some health workers indicated that there were difficulties for certain CHWs who could not read or write.

Some health workers believed that either a man or a woman is able to perform the work of a CHW. They justified this by the fact that all CHWs receive the same training, and tasks are not differentiated in the official CHW documents. Others found there are advantages and limitations related to the gender of the CHW. A health worker from Batié District said:

- About a male CHW: "The tasks are no different for men than for women. They do sensitization, referrals, malaria treatment, and prevention of malaria in pregnant women. Men are busy with other activities. Men share information more often about their work as a CHW. They carry more weight when doing sensitization with other men. It's easy for them."
- About a female CHW: "She performs the same tasks. A female CHW can communicate better with women. She goes to the same places (wells, market, etc.), and that facilitates sharing information. Men do not listen very well to a female CHW."

Findings from Interviews with CHWs and Animatrices

All CHWs had a positive view on implementation of the broader community health promotion program of the MOH. Being from the communities themselves, they found that they are in a position to help these communities be healthier. However, they recognized that CHWs were not always available due to their personal activities and travel. Some CHWs noted that they had not yet been paid by 6 months into their employment. All CHWs said that they could administer SP to pregnant women if they were trained in this area by health workers. They reported they would be prepared to give SP tablets and sensitize communities on adopting new behaviors for malaria control and attending ANC.

A CHW stressed that their support could reduce the workload of CSPS-level health workers. Because some villages only had male CHWs, some female CHWs felt that it was necessary to also have women in the CHW role because some clients may be ashamed to speak in front of men, or a husband could complain if he sees a man interacting with his wife. As for men, the majority thought that a CHW, whether male or female, could do the job as long as the person is well trained and the community accepts them as a CHW.

Baseline semistructured interviews numbered 139. At endline, 50 in-depth interviews were conducted with 29 CHWs (11 female CHWs, eight *animatrices*, and 10 male CHWs) and 21 health clinic providers, as seen in Table 12 below.

Table 12. Interviews with community health workers (CHWs) and animatrices at baseline and endline

Phase	Number of Female Chws	Number of Animatrices	Number of male CHWs	Number of Female Antenatal Care Providers	Number of Male Antenatal Care Providers	Total
Baseline	62	N/A	42	12	23	139
Endline	П	8	10	6	15	50

CHWs' views at endline did not change on the topics discussed before the intervention. The CHWs and *animatrices* interviewed reaffirmed their appreciation of the existing community health program. Through implementation of the C-IPTp activities, they were able to demonstrate that they could do the work and that communities appreciated their work. Some of them said:

- "I am happy to help the community. People have really accepted the work that I do. Women listen to us and respect our advice. Husbands often get involved to help women understand the work that we do."
- "Once I meet with a pregnant woman, I first give her a referral sheet. She goes to the CSPS to take the first dose, and then I give the other doses to her at home."
- "The community adheres to our activities and accepts my advice during sensitization sessions and when it
 is necessary to refer severe cases. Pregnant women no longer deliver at home. They agree to follow
 weighing programs."

Some CHWs/animatrices found that using tools for C-IPTp activities was easy, while others found it difficult. One animatrice from Batié District said: "I use referral sheets, a monthly report, a stock inventory sheet, a register, and there is also a bag and a flip chart. The referral sheet is the easiest tool to use. The register is the most difficult." Such suggestions led to reviews of forms and procedures at monthly meetings.

The CHWs/animatrices indicated that a mechanism exists for them to be in contact with health workers. A CHW from Ouargaye District said: "I go to see them once a month, or more if there is something. For example, the last time I went back before the expected date. When I go to the CSPS, we go over what I have done during the month, and I get more SP. That's what I've come for today. The health workers visit me to see what I'm doing. They come each month. After they have seen what I do, they give me work advice."

Discussion

Coverage of IPTp by CHWs and ANC in the Areas Covered by the Study

Despite a WHO recommendation for all pregnant women to receive at least three doses of IPTp, coverage in most areas of sub-Saharan Africa remains below international targets. This study shows that CHWs can effectively deliver IPTp, resulting in trends toward improved coverage of IPTp3 and IPTp4, without adversely affecting ANC attendance. The latter arose in part because the study reinforced the existing CHW tasks in Burkina Faso of promoting maternal health and malaria control. Also, of note, no adverse events were reported during CHW delivery of IPTp. In short, CHW involvement in IPTp provision is both safe and feasible, and increases the available options and contacts for pregnant women.

In the intervention arm, routine data from the CHWs and clinics showed two important findings. First, based on the common use of ANC1 attendance as a denominator in HIS calculations of coverage, intervention clinics, with the help of CHWs, achieved higher IPTp3 and IPTp4 coverage than the control area clinics, where CHWs did not have SP for IPTp. Secondly, it appears that CHW provision of IPTp may have replaced some of that provided in the clinic, thus making IPTp more accessible. Considering that the CHWs were trained and supervised by clinic staff, one can attribute the combined coverage as an achievement of the clinic as a whole.

The CHW role in recording and reporting needs to be stressed. CHWs can learn to keep community records on IPTp, make appointments, and easily contact pregnant women in their communities to ensure they receive the next IPTp dose. The study team observed CHWs using their job aids and flip charts to educate/advise pregnant women, giving the correct doses, and keeping accurate records in their villages. The role of monthly meetings to review and summarize CHW data at the health center not only demonstrated a way to ensure data quality from CHWs but also exemplified a good way to conduct regular supervision when health centers lack adequate transportation resources.

The increase in coverage of both ANC1 and ANC4 further highlights the important community outreach/sensitization role of these workers. Yet despite the increases in IPTp coverage, the study was unable to demonstrate a statistically significant difference overall for any of the IPTp coverage and ANC attendance measures. This was likely due to the small sample size and insufficient power, as the team powered the study on prior population sample-based estimates (2014 MIS) of IPTp coverage that were available at the time but turned out to be lower than what existed when the study began. The year 2014 was only 2 years after WHO introduced the updated IPTp dosing guidelines, so it was not surprising that coverage levels were low. As noted, no other national data, either in the form of surveys or annual statistical reports, were available until sometime after the study started. Later reports after the study was underway reflected increases in IPTp dosing that could occur if a country vigorously implemented the new guidelines.

Indirectly, the intervention may have had a positive effect overcoming some of the factors that may have inhibited ANC attendance. In the end, there was no conclusive evidence that sociodemographic factors influence IPTp uptake and ANC attendance. Age and number of times a woman had been pregnant were significant only to ANC4 attendance in the intervention group at baseline. However, at endline, these sociodemographic factors were no longer significant. It may be possible that CHW intervention overcame some of the barriers. Overall, there was no significant sociodemographic influence on the key outcomes at either baseline or endline.

Supply issues have challenged traditional clinic-based IPTp delivery and coverage, which is why the study team obtained the commitment of the MOH to guarantee SP supplies for the study districts, both intervention and control, and monitored this throughout. Any IPTp effort based in community and/or clinic must take supply into account. The study therefore documented that the MOH can demonstrate the will to ensure access to essential medicines.

Also, the C-IPTp study suggests that it is feasible for CHWs to increase the percentage of pregnant women receiving multiple doses of IPTp and shows the potential of this community intervention approach as a mechanism to enhance uptake of other aspects of MiP. For example, the same community approach in Akwa Ibom State, Nigeria, showed that in addition to a significant increase in IPTp coverage, CHWs were able to promote higher levels of sleeping under insecticide-treated bed nets in the intervention areas.

The fact that there was an improvement in retention in ANC should alleviate many of the concerns around community delivery of IPTp. In fact, the MOH's standard CHW training does emphasize the need to promote ANC and other maternal and reproductive health services. This was reinforced with the intervention area CHWs, and the referral to the health center for first ANC visit and first IPTp dose made this an intrinsic component of the intervention.

While larger studies are warranted to confirm that this method of delivery results in significant improvements, this study suggests that there is no disadvantage to C-IPTp distribution. This approach builds on the intrinsic value of CHW programs. Using the Lives Saved Tool (LiST), Chou and colleagues found that: "Scaling up CHW programming to increase population-level coverage of lifesaving interventions represents a very promising strategy to achieve universal health coverage and end preventable maternal and child deaths by 2030."²⁴ Also using LiST in Mozambique, Macicame et al. found that IPTp itself contributed to 8.7% of the lives saved through maternal health interventions in Mozambique between 2011 and 2015. Thus, the additional IPTp doses contributed through CHWs in Burkina Faso have lifesaving value.²⁵

Concerns have been raised that providing IPTp in the community could lead to women receiving more IPTp doses than recommended and at wrong intervals. By requiring that women received the first dose of IPTp-SP at the health facility, this study ensured that women were not started on IPTp until they were deemed eligible,

²⁴ Chou VB, Friberg IK, Christian M, Walker N, Perry HB. 2017. Expanding the population coverage of evidence–based interventions with community health workers to save the lives of mothers and children: an analysis of potential global impact using the Lives Saved Tool (LiST). *J Glob Health*. 7(2):020401. doi: 10.7189/jogh.07.020401.

²⁵ Macicame I, Magaço A, Cassocera M, et al. 2018. Intervention heroes of Mozambique from 1997 to 2015: estimates of maternal and child lives saved using the Lives Saved Tool. J Glob Health. 8(2):021202. doi: 10.7189/jogh.08.021202.

at least 13 weeks pregnant as determined by a midwife at the health center. Subsequently, the setup of the village register stressed appointment making with the CHW for specific dates 1 month apart. If the date passed without the woman seeing the CHW, the CHW would look for her. It was these same registers that the staff at the health center reviewed for completeness and accuracy. Thus, the study was designed specifically to ensure communication between CHWs, health staff, and pregnant women.

A key takeaway lesson is that CHWs can improve IPTp coverage when given an adequate supply of SP for the estimated number of pregnant women in an area and with appropriate training and supportive supervision. The implication appears to be that the intervention area CHWs were able to encourage better ANC4 attendance and overcome the access barriers because they had a more detailed focus on ANC than "regular" CHWs who did not have the extra training.

Another lesson is that the supply of SP cannot be forecast based on past ANC participation. C-IPTp involves reaching out to the community to serve all pregnant women. Therefore, a combination of SP provision data from communities and health facilities must be used to provide a complete estimate of the number of pregnant women in the community to accurately forecast SP needed. This means any future intervention must take into account the procurement and supply chain management of basic commodities and other malaria control products.

While the study team provided technical assistance, guided problem-solving, and ensured standard implementation across districts, it was the Burkina Faso MOH, district health teams, health center teams, and CHWs who actually implemented the program. The study therefore not only shows that these existing health personnel can implement and manage community-based IPTp but also that they are capable of more broadly managing community interventions. This is an important foundation for additional CHW interventions that the NMCP and the MOH wish to deliver through their community health system.

Finally, it is important to recall that the intervention was designed to add a new skill to the CHW job description. While their basic training included promoting malaria control and maternal health, the distribution of SP was not among the core tasks. The addition of this task came with increased supervision to allay concerns about CHWs handling SP correctly. While this provided more contact between health staff and CHWs in the intervention areas, it should be noted that the CHW training and community health activities in the control areas reflected the current "standard of care" or service delivery in the country.

Limitations

While positive trends were observed, this study was powered to detect changes in IPTp3. Similar trends in IPTp4 provision were observed and provide an impetus for further study. The provision of IPTp5 and higher was minimal, since most women had delivered by the date that they were due for IPTp5.

The initial assumptions and decisions for household survey sample size focused on the study area as a unit but calculated numbers needed for each of the 12 clinic catchment areas (six intervention and six control) as clusters. This was done using available national survey data on IPTp coverage and ANC attendance to guide the number of recently pregnant women (within 9 months preceding the interview) needed to determine a significance level of 5%. It turns out that the initial calculation of sample size did not provide the power needed to enable the effect of the intervention to be seen using a difference in differences analysis. Although there had been initial discussion concerning using four clinic catchment areas per district per study arm with separate districts for intervention and control, as was done in the Jhpiego-led Nigerian study on C-IPTp that preceded this, ²⁶ this option was not pursued for cost reasons.

²⁶ Okeibunor JC, Orji BC, Brieger W, at al. 2011. Preventing malaria in pregnancy through community-directed interventions: evidence from Akwa Ibom State, Nigeria. *Malar J.* 10:227. doi: 10.1186/1475-2875-10-227.

Dissemination of Results

The first dissemination activities were organized as soon as the preliminary analysis of the final results were obtained. These activities were divided into three parts: meetings with each head of the organizations and directorates that took part in the implementation of the study, a national meeting presenting the results, and meetings with stakeholders of the districts concerned.

The officials came from USAID and the US Centers for Disease Control and Prevention in Burkina Faso, the NMCP, the DSF, the DPES, and the DSS. The objectives of these meetings were to present the results, gather officials' points of view, and find out what they could contribute if C-IPTp were to be adopted as an approach in other districts. All officials had a positive assessment of the results of the study. They also discussed their availability to support a possible extension of the approach.

The national meeting was held under the auspices of the General Directorate of Public Health. In addition to organization and directorate heads, attendees included heads of the regions and districts involved in the study and partners, such as PMI, WHO, the Procurement and Supply Management project, Malaria Consortium, and Jhpiego. After presentation of the results, participants asked questions to better understand the study's implementation process.

Meetings were also held in each district involved in the study. Attendees included the district chief medical officer, the study's field coordinator, the leaders and officers responsible for the CSPSs involved (intervention and control), and two CHW representatives from intervention CSPSs. These meetings were facilitated by an NMCP representative and the study coordinator. The results were presented and discussed. All participants expressed pride in having contributed to these results. They hoped that the approach could continue and, if possible, scaled up to the district level.

Specific recommendations put forth at the meeting included:

- Pending WHO approval of this intervention, continue pilot studies to provide more evidence on the effectiveness of this intervention.
- Develop a C-IPTp extension plan for all three health districts (Batié, Ouargaye, Pô).
- Make a plea for respect for number of births (one man and one woman) in the recruitment of CHWs for each village.
- Advocate to make SP available at all times.
- Support studies on the effectiveness of SP.

In addition, the table below highlights follow-up issues.

Table 13. Next steps from dissemination meeting

	Next Steps/Action	Responsible	Date
1.	Continue in-depth data analysis to get the most out of lessons.	Study Coordinator	October 2018
2.	Carry out missions in the three districts for sharing the results of the pilot study.	Study Coordinator	October 2018
3.	Organize a meeting of partners to advocate for the extension of the community IPTp in Burkina Faso.	NMCP Coordinator	November 2018
4.	Finalize the implementation plan of the extension to other health facilities in study districts.	NMCP Coordinator	December 2018

Of note, the NMCP was involved in all study processes and participated in all field activities. It had created a place holder in the National Malaria Strategic Plan for such community activities. Since the workshop on dissemination of project results, the NMCP has continued discussions with partners on how to sustain current gains in IPTp coverage in intervention areas and possibly expand the C-IPTp efforts throughout the three districts while awaiting official policy change from WHO, which will give a green light to governments to roll out such programs.

Conclusion and Recommendations

The analysis of routine data and surveys show the CHWs were able to support the health workers in health facilities to increase the coverage of IPTp in pregnant women in Burkina Faso without negatively affecting ANC coverage. The study shows evidence of impact and feasibility in the Burkina Faso context.

Exploration of the sociocultural factors that could influence levels of IPTp use and ANC attendance did not show clear results. More research is necessary to better clarify these factors.

This intervention depends on CHWs' and health workers' commitment and the participation of the populations in the intervention areas. It is also important to note the study team's organization and implementation of the C-IPTp process.

Encouraged by the results, the malaria control authorities in Burkina Faso at the study dissemination meeting committed to:

- Maintaining implementation of the intervention in CSPSs that participated in the pilot intervention
- Developing a C-IPTp extension plan for scale-up in all three health districts (Batié, Ouargaye, Pô)
- Simplifying the C-IPTp tools used by CHWs
- Advocating for at least one female CHW to every one male CHW in the recruitment of CHWs for each village
- Advocating for CHW recruitment for villages that do not yet have CHWs
- Advocating to make SP available at all times so that there are no missed opportunities to provide SP to pregnant women
- Supporting studies on the effectiveness of SP in Burkina Faso

Beyond Burkina Faso's commitment to continuing the implementation of C-IPTp, the study team recommends that:

- The Roll Back Malaria MiP Working Group should ensure that the approach is disseminated to all relevant stakeholders in Burkina Faso and the other countries that need innovation to fight malaria, particularly with high-transmission countries where a CHW program is already in place.
- The NMCP should organize to scale up the approach in other parts of Burkina Faso with higher malaria burden and ensure it is well documented.
- Partners in this study and the MiP Working Group should advocate with WHO to ensure that C-IPTp is considered in the policies for the prevention of malaria in pregnant women.

Appendixes

Appendix I. Survey training agenda

Topics covered in data collector training

Day	Topic/Content			
ı	Survey sites, target, and organization in the field			
	Survey organization			
	How the interviewer should conduct herself/himself			
	What is research: human subject research, fundamental principles of ethics in human research			
	Ethical issues in conducting research: research process, ethical interaction with human subjects, data integrity			
	Quality control and quality assurance in research			
	Concept of malaria			
	Antenatal care and intermittent preventive treatment of malaria in pregnancy			
	Administering the questionnaire			
	Selection of households to visit			
	Household introduction and use of the selection form			
	Review of consent process and questionnaire			
2	Components of data quality			
	How to assure data quality			
	Role-plays			
	Field simulation			

Appendix 2. Training Content

Overview of community health worker training modules

Module I: Overview of malaria in pregnancy (MiP)
Objective: Explain the cause of malaria, prevention measures, and MiP consequences.

Content

Definition of malaria

Signs of malaria

Malaria transmission

MiP consequences

MiP prevention

MiP case management: prompt referral to the Centre de Santé et de Promotion Sociale (CSPS; Center for Health Care and Social Promotion)

Module 2: Antenatal care (ANC) Objective: Describe the services and care provided during ANC visits and their importance.

Content

Definition of ANC

The goal and importance of ANC visits

Description of services and care provided during ANC

Benefits of attending ANC for pregnant women

Schedule of ANC visits

Danger signs in pregnancy

Description of the community health worker (CHW)'s role in providing ANC

Module 3: Overview of community-based intermittent preventive treatment of malaria in pregnancy (C-IPTp)

Objective: Describe the implementation process of C-IPTp activities.

Content

Introduction to the study and C-IPTp study objectives

Introduction to the main aspects of CHW work in implementation of the C-IPTp study

Introduction to ethics and informed consent

Techniques of group sensitization and individual interviews

Module 4: Community sensitization and education on health and C-IPTp Objective: Use methods adapted for educating and sensitizing pregnant women and other community members to adopt C-IPTp.

Content

Introduction to sensitization and community eduction methods

How to include village leaders in C-IPTp promotion

How to involve husbands and other influential people in the household in IPTp promotion

How to conduct an individual interview with a pregnant woman on adopting IPTp (interpersonal communication)

Demonstration on the correct use of sensitization tools

Module 5: Administration of C-IPTp by CHWs Objective: Administer IPTp at the village level.

Content

Starting IPTp administration

Explanation of why the first dose of IPTp should be given during ANC

IPTp administration by CHWs: number of doses, when to administer

Identification of pregnant women who should receive IPTp from a CHW and how to determine the timing of the next contact for SP administration

Precautions before administering SP: information on allergies and history of taking SP or other sulfonamides

Precautions before administering SP: importance and procedure

Module 6: Management of sulfadoxine-pyrimethamine (SP) stocks Objective: Manage SP tablets correctly at the village level.

Content

How SP is re-stocked

Description of SP storage conditions at the village level and the CHW's home

How to check the SP expiration date and what to do if the date has passed

Module 7: Monitoring, evaluation, and reporting Objective: Complete work documents and submit monthly reports to the CSPS.

Content

When and how to complete a referral form for a women

How to complete an SP stock inventory sheet: during procurement, after administering SP to women at the village level

How to complete the CHW IPTp register: new women, harmonization of IPTp and ANC data with the CSPS, contacts with women, SP administration

When and how to complete the form on side effects for a woman taking SP

How to complete and submit the monthly report form

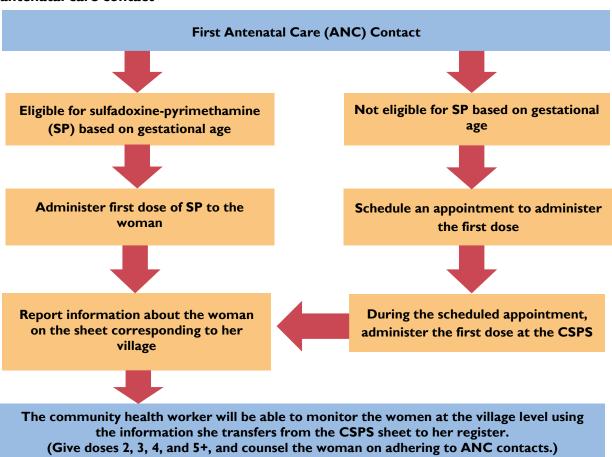
Appendix 3. Stakeholders involved in implementation of the intervention

Stakeholder	Role
US President's Malaria Initiative-US Agency for International Development/US Centers for Disease Control and Prevention	Provide funding for the study and technical input on the study design and protocol. Review data and findings.
National Malaria Control Program Directorate of Family Health Directorate of Sectoral Statistics Directorate of Health Promotion	Monitor implementation.
Jhpiego	Provide technical support for implementation.
Principal investigator	Ensure the terms of the protocol are followed and quality of study implementation.
Three co-investigators	Support the principal investigator with implementation.
Study coordinator	Organize and coordinate study implementation activities with all stakeholders, and report on implementation progress.
Regional health directorates involved in the study	Monitor and supervise study implementation activities in the field.
Health districts involved in the study	Monitor and supervise study implementation activities in the field.
District-level field coordinators	Coordinate study implementation activities in the field with district-level workers, Centres de Santé et de Promotion Sociale (Centers for Health Care and Social Promotion), and community health workers.

Appendix 4. Role of facility-based health workers in the intervention areas

In addition to training the community health workers (CHWs), health workers were responsible for initiating the first dose of intermittent preventive treatment of malaria in pregnancy (IPTp), providing a monthly list of new wo men that CHWs/animatrices should monitor, providing supervision, and facilitating monthly meetings. They also continued to provide the other doses of IPTp for women who could not get them from the CHWs/animatrices at the village level for a variety of reasons. Figure 8 shows the interaction of pregnant women and health workers.

Figure 8. Collaboration between the Centres de Santé et de Promotion Sociale (CSPSs; Centers for Health Care and Social Promotion) and community health workers: first antenatal care contact



Appendix 5. Role of community health workers/animatrices during implementation of the intervention

Community health workers (CHWs)/animatrices were the centerpiece of the intervention. They carried out the following activities at the village level:

- Sensitizing communities and women
- Prompting women to attend antenatal care (ANC) early at a *Centre de Santé et de Promotion Sociale* (CSPS; Center for Health Care and Social Promotion)
- Referring pregnant women to the CSPS
- Administering sulfadoxine-pyrimethamine (SP) to pregnant women
- Managing SP stock
- Following up with women who had not yet received the first SP dose
- Preparing monthly community-based IPTp (C-IPTp) activity report

In addition to the activities mentioned above, CHWs/animatrices participate in monthly meetings with health workers at their referral CSPS.

Sensitization

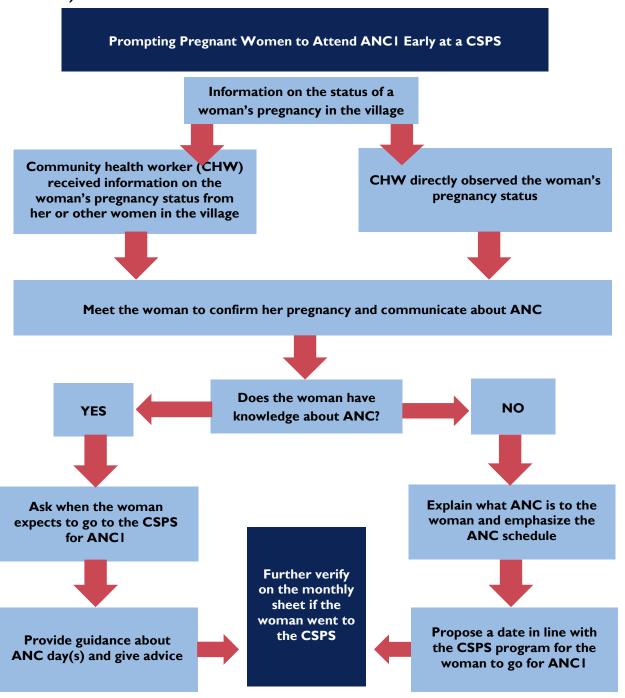
Sensitization sessions were organized regularly at the village level for leaders, communities, and pregnant women. The sessions were organized as group or individual depending upon the topic covered. The topics included:

- Overview of malaria (transmission, prevention, consequences on pregnancy)
- Overview of ANC (benefits and schedule)
- C-IPTp (implementation process)

Prompting Pregnant Women to Attend ANCI Early at a CSPS

A CHW/animatrice living in a community can stay informed about the status of a woman's pregnancy or observe that a woman is pregnant. The purpose here was to seize every opportunity to communicate with women about monitoring their pregnancies at the CSPS level. Figure 9 illustrates this approach.

Figure 9. Prompting pregnant women to attend the first antenatal care contact (ANCI) early at a Centre de Santé et de Promotion Sociale (CSPS; Center for Health Care and Social Promotion)



Referral of Pregnant Women to the CSPS Level

During the intervention, each time that the CHW/animatrice wanted a women to go to a health center, he or she gave her a referral sheet. The referral sheet included information about the woman's identity and the reason for her referral. The reasons for referral were:

- ANC1
- ANC2, 3, 4, 5+
- Signs/symptoms of malaria
- Other pregnancy-related reasons
- Reaction to a drug
- Other reasons

The referral sheet was issued in duplicate. Once the woman was seen at the health center level, part of the sheet was returned to the woman, and the other was kept at the health center to report on those who were seen at the CSPS during the monthly meeting.

SP Administration to Pregnant Women

The CHWs/animatrices used their registers to identify women who already took their first dose of SP (IPTp1). Based on the appointment dates indicated by the health workers for IPTp2, the CHW/animatrice set the date for administration of IPTp2 with each woman. He or she went to the woman's house on the scheduled day to give the dose through direct observation. The CHW/animatrice then reported on his/her register and included the date of the current IPTp dose and the date for the next dose on a sheet attached to the ANC booklet. He/she reminded the woman of the date for her next ANC contact and urged her to adhere. The procedure was the same for all IPTp doses (3, 4, 5+).

To ensure the quality of SP administration, the CHW/animatrice had a job aid that he/she could consult. The section of the job aid on SP is illustrated in Figure 10.

Administration of SP at the Village Level The community The CHW verifies that the The CHW asks the health worker woman has not taken SP or other (CHW) must pregnant woman if sulfonamides within the last 4 she is allergic to SP or meet the weeks or that she is on coother sulfonamides. If pregnant woman trimoxazole prophylaxis. If yes, yes, do not give SP. at the place and do not give her SP. time specified. Remind the woman Reassure the woman Ensure that clean that she can take the drinking water is that she must swallow tablets even if she has available for the woman the SP tablets in front to take SP. not eaten. of you. Write the date of SP administration in the Ensure that the Give the tablets to the register, thank the woman's hands are woman and observe woman, and provide the clean before taking SP. her swallowing them. date for her next appointment.

Figure 10. Administration of sulfadoxine-pyrimethamine at the village level

SP Stock Management

CSPS health workers estimated their SP needs from the district distribution depot based on expected pregnancies and ongoing ANC. At the CSPS, SP was stocked with essential generic drugs. CHWs/animatrices obtained SP from health workers during monthly meetings. They had a stock card where the entries and removals were recorded. SP needs for each village were calculated based on women registered for the month, with a surplus of two to three doses to guard against potential losses and others. At the village level, SP stocks were stored in a specified box. The box was locked and kept at the CHW's home.

Follow-up of Women Who Have Not Received the First SP Dose

If the woman was not eligible for SP during her first ANC contact based on her gestational age, the information was given to the CHW/animatrice through the monthly summary sheet. Like those who received SP, this information was reported in the CHW's/animatrice's registry to facilitate follow-up. This allowed the CHW/animatrice to pay close attention to the appointment scheduled by the health worker to remind the woman in time to return to the CSPS. If, based on her gestational age, the woman was eligible for the first SP dose at her follow-up appointment, the ANC health worker would administer the dose and write the woman's name on the monthly summary sheet. As such, the woman was entered into the system for follow-up for the second dose at the village level.

Development of the Monthly C-IPTp Activity Report

On the 25th of each month, each CHW/animatrice prepared a summary of activities implemented during the month. This was recorded in a monthly report sheet. The summary included monthly sensitization sessions, referrals, IPTp administered, and total number of pregnant women reached. The report was submitted to health workers the day of the monthly meeting to be checked before compiling the report. Those who had difficulty completing the information were helped by the male CHW, if the latter was literate, or by health workers during the meeting.

Appendix 6. Tools and materials

The implementation of the intervention required that a certain number of tools and materials be made available to stakeholders. Pre-existing tools were also used. Such tools included both data gathering templates (e.g. questionnaires and registers) as well as learning tools (e.g. flip charts, job aids). These tools and materials are presented below. The complete tools are available on request.

Tools and Materials Used by Stakeholders to Implement Activities

Stakeholder	Tool	Material
Community health worker (CHW)	 CHW register Flip chart Job aid Sensitization sheet Referral sheet Sulfadoxine-pyrimethamine (SP) inventory stock sheet Monthly report sheet 	CHW medicine boxCHW bagBlue pen
Health worker	 Antenatal care (ANC) register* ANC booklet* Job aid Monthly summary sheet CHW supervision matrix Community-based intermittent preventive treatment of malaria in pregnancy (C-IPTp) monthly report form (Centre de Santé et de Promotion Sociale [CSPS; Center for Health Care and Social Promotion]) Monthly report form (CSPS)* 	Mechanism for direct observation of SP* Blue and red pens
Field coordinator	 Health worker supervision matrix C-IPTp monthly report form (district) 	Blue pen

^{*}Pre-existing tools or materials

Intervention Reporting

Report type	Person responsible	Frequency	Submission deadline
Weekly activity monitoring report	Study coordinator	Weekly	By Monday of the following week
CHW report on C-IPTp activities	CHW in charge of the study in the village	Monthly	By the 30th of the month
CSPS report on IPTp	Head nurse	Monthly	By the 5th of the following month
District report on IPTp	Field coordinator	Monthly	By the 10th of the following month
District Excel database	Field coordinator	Monthly	By the 10th of the following month
Summary report on IPTp activity implementation in the three districts	Study coordinator	Monthly	By the 15th of the following month
Excel database from the three districts	Study coordinator	Monthly	By the 15th of the following month

Appendix 7. Timeframe for endline survey

Phase	Date/Period	Activity	Rponsible
Endline	August 2018	 Survey of 360 women In-depth interviews with health workers at health centers and community health workers 	National Malaria Control ProgramDistrictJhpiego
Activities at the end of the study	September– October 2018	Data analysis, report writing, and dissemination of results	National Malaria Control ProgramJhpiego