Community deployment of intermittent preventive treatment of malaria in pregnancy with sulfadoxine-pyrimethamine: a field guide

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Abbreviations

ANC	antenatal care
CHW	community health worker (at the community level)
c-IPTp	community-based intermittent preventive treatment of malaria in pregnancy
CSO	civil society organization
DOT	directly observed therapy
HMIS	health management information system
IPTp	intermittent preventive treatment of malaria during pregnancy
IPTp-SP	IPTp with sulfadoxine-pyrimethamine
ITN	insecticide-treated net
M&E	monitoring and evaluation
MIP	malaria in pregnancy
MOH	ministry of health
SBCC	social and behaviour change communication
SP	sulfadoxine-pyrimethamine
TIPTOP	Transforming Intermittent Preventive Treatment for Optimal Pregnancy
TWG	technical working group
WHO	World Health Organization

Glossary

antenatal care (ANC)-1	First ANC visit at an ANC facility, ideally as early as possible in pregnancy
ANC-4	Four ANC visits at an ANC facility throughout pregnancy
directly observed treatment (DOT)	Provision or administration of IPTp-SP in the presence of a health worker or community health worker (CHW) to ensure that the correct dose of SP (consisting of three tablets of SP, each tablet containing 500 mg/25 mg SP, for the total required dosage of 1500 mg/75 mg SP) is taken by the pregnant women.
intermittent preventive treatment of malaria in pregnancy (IPTp)	The administration of a treatment course of an antimalarial medicine at predetermined intervals, regardless of whether the pregnant woman is infected with malaria. Malaria infection during pregnancy poses substantial risks not only to the mother, but also to her fetus and the newborn.
IPTp-1	First dose of IPTp-SP
IPTp-2	Second dose of IPTp-SP
IPTp-3	Third dose of IPTp-SP
IPTp-3+	Three or more doses of IPTp-SP (ideally, these should not be lumped but documented as IPTp-4, IPTp-5, IPTp-6, etc.)
IPTp contraindications	IPTp-SP is not recommended for pregnant women before week 13 of pregnancy, or for those with severe acute illness, who are unable to take oral medication, who received a dose of SP during the previous 30 days, or who are allergic to any of the components of SP. IPTp-SP should not be given to individuals receiving a sulfa-containing medicine as treatment or prophylaxis, including co-trimoxazole (trimethoprim and sulfamethoxazole) for HIV. High doses of folic acid (a daily dose of 5 mg or more) have been shown to counteract the efficacy of SP as an antimalarial, and only low-dose formulations (0.4 mg daily) should be co-administered with SP.
IPTp with sulfadoxine-pyrimethamine (IPTp-SP) dosing schedule	IPTp-SP should not be given before week 13 of pregnancy due to an increased risk of fetal malformation. IPTp-SP should start as early as possible in the second trimester. At least three doses of IPTp-SP should be received during pregnancy. Doses can be given until the time of delivery, provided that doses are given at least one month apart.

community-based IPTp (c-IPTp)	The administration of quality-assured SP for IPTp to eligible pregnant women by trained CHWs at the community level. c-IPTp complements the delivery of IPTp-SP at ANC facilities. The c-IPTp approach intends to bridge the gap between ANC attendance and IPTp coverage and allows CHWs to create awareness and sensitize pregnant women on the need to attend an ANC clinic for comprehensive ANC services.
quantification	Quantification in the context of c-IPTp determines volumes of SP and other commodities required for IPTp-SP, considering both services provided at ANC facilities and at the community level through trained CHWs.
pregnancy wheel	A small calendar that can be used to determine both the gestational age and the due date for delivery, based on the last menstrual period.
quickening	The pregnant woman's first awareness of fetal movement; suggests a pregnancy of at least 16 weeks. The practice to give the first dose of IPTp-SP at quickening means that the pregnant woman and fetus can be left unprotected against malaria for an unnecessary long period, as quickening depends on a woman's individual perception and timing of quickening. However, the first dose of IPTp can be given as early as possible in the second trimester (week 13 of pregnancy).
SP dosage	The total required dosage of SP for IPTp is 1500 mg/75 mg. The main commercial products of SP available on the market for IPTp usually contain 500 mg/25 mg SP per tablet, so three tablets of SP are required to make one full dose.

1. Introduction

1.1 Background and purpose

Malaria continues to be a major public health challenge globally, leading to ill health, death and decreased economic productivity. The *World malaria report 2023* estimated that 249 million malaria cases and 608 000 malaria deaths occurred in 85 malaria-endemic countries and territories in 2022. Women and children are often the most vulnerable groups *(1)*.

Malaria infection during pregnancy has substantial risks for the pregnant woman, her fetus and the newborn child. For the pregnant woman, malaria infection can lead to severe disease and death, and to placental sequestration of the parasite, which can lead to maternal anaemia. It puts the mother at increased risk of death before and after childbirth, and is an important contributor to stillbirth and preterm birth. Placental infection can also lead to poor fetal growth and low birth weight, which in turn can lead to retardation of child growth and poor cognitive outcomes. Placental infection can also be a major risk factor in perinatal, neonatal and infant mortality *(2-4)*.

In 2022, in 33 moderate to high transmission countries[1] in the World Health Organization (WHO) African Region, there were an estimated 35.4 million pregnancies, of which 12.7 million (36%) were exposed to malaria infection. By WHO subregion, prevalence of exposure to malaria during pregnancy in 2022 was highest in west Africa, where about 6.4 million (39.3%) of an estimated 16.2 million pregnant women had malaria infections, and in central Africa, where about 3.4 million (40.1%) of the 8.3 million pregnant women were infected with malaria. The prevalence of malaria infection in pregnant women was lower in the subregion of east and southern Africa (27%) than in other subregions in 2022; however, the number of infected women in east and southern Africa (2.9 million) was similar to that in central Africa (3.4 million) *(1)*.

WHO recommends a package of interventions for controlling malaria and its effects during pregnancy. These include the promotion and use of insecticide-treated nets (ITNs), appropriate case management through prompt diagnosis and effective treatment of malaria in pregnant women, and the administration of intermittent preventive treatment of malaria in pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) in malaria-endemic areas.

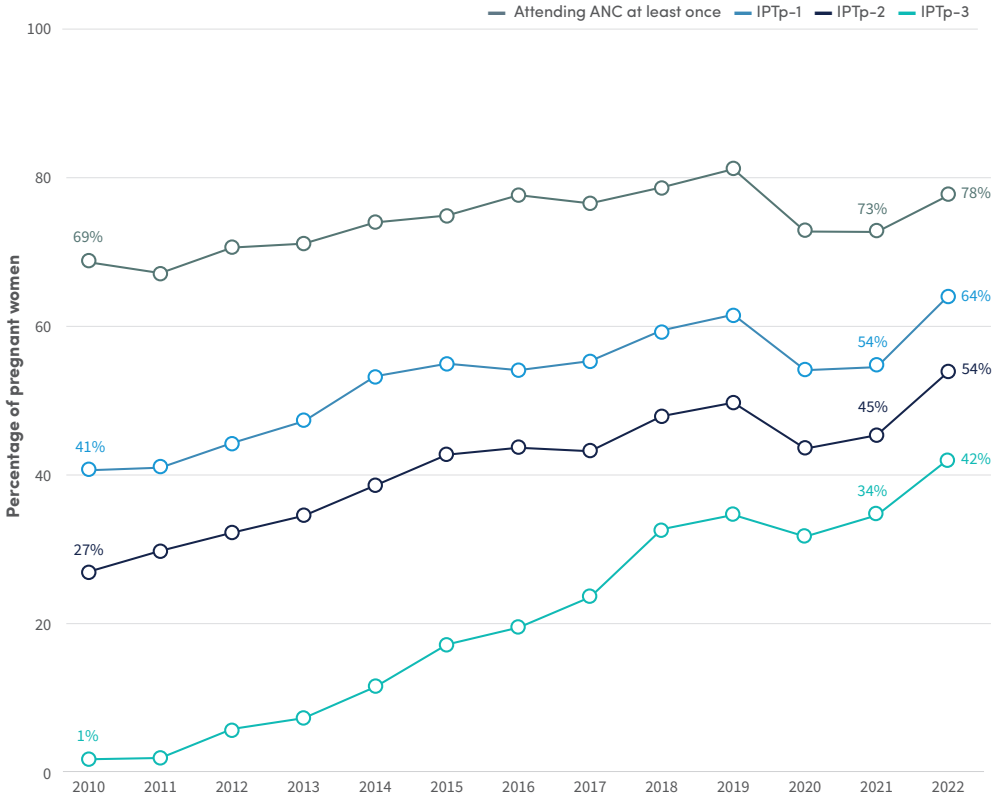
IPTp-SP prevents adverse consequences of malaria on maternal and fetal outcomes *(5,6)*. However, in 2022, coverage of IPTp-3 was 42%, well below the target of at least 80% (Fig. 1) *(1)*. This underscores the substantial number of missed opportunities for IPTp, and the need for innovative approaches to deliver IPTp to protect pregnant mothers and their babies and overcome existing obstacles and barriers.

Low birthweight is a strong risk factor for neonatal and childhood mortality, and averting a substantial number of low birthweights will have a considerable impact on all-cause mortality in children. If there had been no pregnancy-specific malaria chemoprevention, it is estimated that exposure to malaria infection would have resulted in 914 000 neonates with low birthweight in 2022, compared with about 393 000 neonates with low birthweight estimated at the current IPTp coverage levels in the three subregions. The subregion of west Africa carries about half (55.1%) of the burden of low birthweight neonates due to malaria infection during pregnancy.

1 Angola, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Nigeria, Senegal, Sierra Leone, South Sudan, Togo, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

Accounting for the current impact of IPTp, it is estimated that low birthweight was averted in about 512 000 neonates. If all pregnant women visiting ANC clinics at least once during pregnancy received a single dose of IPTp – assuming that they were all eligible, and that the levels of IPTp-2 and IPTp-3 coverage remained the same – an additional 60 000 low birthweights would be averted, reducing the remaining residual low birthweight burden of malaria in pregnancy to 332 000. If IPTp-3 coverage matched the levels of ANC-1 coverage, assuming that subsequent ANC visits were just as high, then an additional 164 000 low birthweights would be averted, reducing the remaining residual low birthweight burden of malaria in pregnancy to 229 000. Finally, if IPTp-3 coverage increased to 90% of all pregnant women, an additional 221 000 low birthweights would be averted, reducing the remaining residual low birthweight burden of malaria in pregnancy to 172 000.

Fig. 1. Percentage of pregnant women attending an antenatal care clinic at least once and receiving IPTp, by number of SP doses, sub-Saharan Africa, 2010–2021



ANC: antenatal care; CDC: United States Centers for Disease Control and Prevention; IPTp: intermittent preventative treatment of malaria in pregnancy; IPTp-1: first dose of IPTp; IPTp-2: second dose of IPTp; IPTp-3: third dose of IPTp; NMP: national malaria programme; SP: sulfadoxine-pyrimethamine; WHO: World Health Organization.

Source: reproduced from the *World malaria report 2023 (1).*

In summary, IPTp-SP is a long-standing WHO recommendation, and while global trends of IPTp-3 coverage have slowly increased over the last decade, 58% of pregnant women still do not benefit from this protective intervention. This field guide focuses on minimizing these missed opportunities by increasing IPTp coverage using a community-based delivery approach (c-IPTp), to complement existing deployment of IPTp-SP at ANC clinics. The approach is well aligned with the recommendations published in the *WHO guidelines for malaria, 3 June 2022 (7,8).*

1.2 Field guide development and target audience

This field guide outlines essential steps and provides guidance to countries on the adoption and deployment of c-IPTp so that it integrates into the existing health system. It was developed based on discussions and findings of the WHO technical consultation to assess evidence on community-based delivery of IPTp, which was held 21–23 June 2022 *(9)*. The evidence assessed at this WHO technical consultation comprised data generated as part of the Transforming Intermittent Preventive Treatment for Optimal Pregnancy (TIPTOP) Unitaid-funded project, as well as evidence and experiences from additional countries where c-IPTp was piloted. It draws upon best practices and lessons learned from pilot implementation experiences in eight African countries: Burkina Faso, Democratic Republic of the Congo, Madagascar, Malawi, Mozambique, Nigeria, Senegal and Sierra Leone.

The initial draft for this field guide was developed by a WHO-commissioned consultant who supported implementation of the TIPTOP project in African pilot countries; for selected sections the draft was developed in collaboration with TIPTOP project partners, all of which attended the June 2022 WHO technical consultation. The draft was then reviewed by expert panel members of the June 2022 WHO technical consultation.[2]

A revised draft of the field guide was thereafter shared as advance copy at the Roll Back Malaria (RBM) Malaria in Pregnancy (MIP) Working Group (WG) meeting in September 2023, and the additional feedback (received by Jhpiego and the WHO Sexual and Reproductive Health and Research Department) was incorporated in the final version.

This field guide targets all stakeholders at a national level that are involved in the provision of maternal and child services, including national and local policymakers and implementers of malaria, maternal health, child health, reproductive health and community health programmes, and nongovernmental and other organizations.

Countries that decide to introduce c-IPTp are encouraged to adapt the guidance given in this document to their national and local contexts.

2 All expert members attending the WHO technical consultation submitted their declarations of interest, which were assessed by the WHO Secretariat. One member reported a conflict of interests, which was deemed to be not relevant to topics for decision on the agenda. A due diligence search was undertaken and found nothing significant that was not already declared by the expert members.

2. WHO recommendations

The implementation of community-based IPTp (c-IPTp) should be guided by three main WHO documents.

- WHO released the *WHO guidelines for malaria, 3 June 2022 (7)* to improve the prevention and control of MIP. Section 2.1 of this field guide summarizes the key aspects of the updated recommendations for IPTp, presenting how to increase IPTp coverage beyond ANC visits through delivery at the community level by community health workers (CHWs).
- Section 2.2 focuses on the need to increase the number of contacts to reach pregnant women, following the 2016 *WHO recommendations on antenatal care for a positive pregnancy experience (10)*. These recommendations introduced an eight contacts model that superseded the previous four ANC visits model.
- Section 2.3 focuses on the 2018 *WHO guideline on health policy and system support to optimize community health worker programmes (11)*, including essential guiding principles relevant to c-IPTp.

In addition, Sections 2.4 and 2.5 present the medicines used for IPTp, the need for resistance monitoring and chemoprevention efficacy monitoring, and the need to source quality-approved commodities.

2.1 WHO recommendations on IPTp

IPTp is the administration of a treatment course of an antimalarial medicine at predetermined intervals, regardless of whether the pregnant woman is infected with malaria. The aim is to prevent the consequences of a malaria infection during pregnancy to the mother, her fetus and the newborn. Box 1 shows the updated WHO guidance on IPTp (as of June 2022), including a new recommendation that addresses inequities in ANC access. Sociodemographic factors, such as age, marital status, religion and urban/rural residence, can influence access to IPTp. Moreover, health system barriers and socioeconomic factors, such as education, employment and wealth index, have been reported as strong influencers of IPTp-SP uptake *(12)*.

Box 1. June 2022 update of the WHO guidelines for malaria for IPTp *(7)*

In malaria-endemic areas, pregnant women of all gravidities should be given antimalarial medicine at predetermined intervals to reduce disease burden in pregnancy and adverse pregnancy and birth outcomes.

- SP has been widely used for malaria chemoprevention during pregnancy and remains effective in improving key pregnancy outcomes.
- IPTp-SP should start as early as possible in the second trimester and not before week 13 of pregnancy.
- Doses should be given at least one month apart, with the objective of ensuring that at least three doses are received.
- ANC contacts remain an important platform for delivering IPTp. Where inequities in ANC service and reach exist, other delivery methods (such as the use of CHWs) may be explored, ensuring that ANC attendance is maintained and underlying inequities in ANC delivery are addressed.
- IPTp is generally highly cost-effective, widely accepted, feasible for delivery and justified by a large body of evidence generated over several decades.

To facilitate the deployment of IPTp, several practical aspects must be considered.[3]

- SP should be made available at ANC clinics so that pregnant women have immediate access to IPTp-SP during routine care.
- One full dose of IPTp-SP consists of 1500 mg/75 mg SP (i.e. three tablets of 500 mg/25 mg SP).
- SP should ideally be administered as a directly observed treatment (DOT) to ensure that pregnant women take the full required dose.
- IPTp-SP can be given until the time of delivery, provided that doses are at least one month apart.
- If a woman presents to an ANC clinic with symptoms of malaria, these symptoms should be investigated before administering IPTp-SP. If the woman tests positive for malaria – either by microscopy or a rapid diagnostic test – she should be treated in accordance with national malaria case management guidelines. If the woman is negative, she should receive IPTp-SP.
- IPTp-SP is not recommended for pregnant women:
  - before week 13 of pregnancy due to an increased risk of fetal malformation,
  - with severe acute illness,
  - who are unable to take oral medication,
  - who, during the last 30 days, received a dose of any of the medicines being used for IPTp,
  - who are allergic to any of the components of SP.
- IPTp-SP should not be given to individuals receiving a sulfa-containing medicine as treatment or prophylaxis, including co-trimoxazole (trimethoprim and sulfamethoxazole) for HIV. High doses of folic acid (a daily dose of 5 mg or more) have been shown to counteract the efficacy of SP as an antimalarial, and only low-dose formulations (0.4 mg daily) should be co-administered with SP.
- SP for IPTp remains generally very well tolerated. Mild and transient side-effects, including nausea, vomiting, weakness and dizziness, have been reported by some women, particularly with the first dose of SP. Studies have demonstrated that the side-effects tend to decrease with the administration of further doses. *(13, 14)*. Side-effects should be discussed openly with the pregnant women and managed in the ANC.
- Information about IPTp should be fully accessible to pregnant women. As with all health interventions, consent should be obtained from the pregnant woman before administering IPTp.

2.2 WHO recommendations on ANC for a positive pregnancy experience

ANC is the platform for the delivery of many preventive and curative interventions during pregnancy, including interventions for the prevention and control of MIP. *The WHO recommendations on antenatal care for a positive pregnancy experience*, published in 2016, include 39 recommendations related to five types of interventions: nutritional interventions, maternal and fetal assessment, preventive measures, interventions for common physiological symptoms, and health systems interventions to improve the utilization and quality of ANC *(10)*.

3 The practical information for the IPTp recommendation summarized above is detailed in the *WHO guidelines for malaria, 3 June 2022 (7)*.

Of relevance to malaria and IPTp are the recommendations compiled in Table 1, particularly recommendation E.7 on ANC contact schedules that recommends a minimum of eight ANC contacts. These antenatal contacts can be at the health facility or in the community, provided that some essential services are delivered to the pregnant woman during the encounter. As the eight-contact model supersedes the previously recommended four-ANC-visits model, this offers an increased number of opportunities to provide IPTp-SP to pregnant women.

Table 1. Selected ANC recommendations relevant to MIP

Intervention	Recommendation	Type of recommendation
Woman-held case notes	**E.1:** It is recommended that each pregnant woman carries her own case notes during pregnancy to improve continuity, quality of care and her pregnancy experience.	Recommended
Midwifery-led continuity of care	**E.2:** Midwife-led continuity-of-care models, in which a known midwife or small group of known midwives supports a woman throughout the antenatal, intrapartum and postnatal continuum, are recommended for pregnant women in settings with well-functioning midwifery programmes.	Context-specific recommendation
Community-based interventions to improve communication and support	**E.4.2:** Packages of interventions that include household and community mobilization and antenatal home visits are recommended to improve ANC utilization and perinatal health outcomes, particularly in rural settings with low access to health services.	Context-specific recommendation
ANC contact schedules	**E.7:** ANC models with a minimum of eight contacts are recommended to reduce perinatal mortality and improve women's experience of care.	Recommended

Source: reproduced from the *WHO recommendations on antenatal care for a positive pregnancy experience (10).*

2.3 WHO recommendations on CHW programmes

The c-IPTp approach falls within the overall guidelines of WHO to promote delivery of interventions closer to the community, as a way of ensuring equity as well as early prompt services. Detailed information can be found in the 2018 *WHO guideline on health policy and system support to optimize community health worker programmes (11),* which elaborates on 15 recommendations addressing the following areas:

- selection for pre-service training
- duration of pre-service training
- competencies in the curriculum for pre-service training
- modalities of pre-service training
- competency-based certification
- supportive supervision
- remuneration
- contracting agreements
- career ladder
- target population size

- data collection and use
- types of CHWs
- community engagement
- mobilization of community resources
- availability of supplies.

This c-IPTp field guide provides several particularly relevant cross-references to the CHW guideline with regards to remuneration and contracting of CHWs, supportive supervision, selection of CHW and target population size (see Boxes 2, 3, 4 and 5).

Further information on community engagement can be found in the WHO health promotion guide for universal health coverage in the hands of the people *(15)*, and the WHO news feature on using behavioural sciences to support community engagement in Africa *(16)*.

2.4 Medicine of choice for IPTp, resistance and efficacy monitoring

SP is the medicine of choice for IPTp. SP has been widely used for IPTp and has been shown to be efficacious, safe, well tolerated, available and inexpensive. It can easily be administered as a directly observed single dose and should continue to be used in areas of high SP resistance.[4] WHO recommends that the medicine used for IPTp be different from those used as first-line malaria treatment.

IPTp-SP appears to select for antifolate resistance mutations associated with low to moderate increases in drug resistance. However, there is no convincing evidence of selection favouring key mutations, such as dhpsA581G (a mutation in the *P. falciparum* genes that encodes *P. falciparum* dihydropteroate synthase enzyme), which is associated with the loss of IPTp-SP efficacy *(17)*. There is also insufficient evidence to withhold IPTp-SP in areas where the prevalence of dhpsA581G exceeds a threshold of 10% *(18)*. Although the ability of IPTp-SP to clear existing infections and prevent new ones is compromised in areas of high to very high resistance, the intervention still reduces low birth weight and maternal anaemia. Consequently, IPTp-SP should continue to be used in areas of high SP resistance until more effective alternatives for malaria chemoprevention are found *(7)*.

Countries should monitor SP resistance and the preventive efficacy of SP. In 2022, WHO released a *Malaria chemoprevention efficacy study protocol (19)* to evaluate the protective efficacy of SP for IPTp and other chemoprevention interventions. The protocol adapts some of the principles and practices underlying treatment efficacy monitoring to provide standardized approaches for monitoring and evaluating the efficacy of medicines used for malaria chemoprevention.

2.5 Sourcing of quality-approved SP for IPTp

WHO recommends that only SP of proven quality (that is, in line with international standards such as the International Pharmacopoeia) should be used for IPTp. The list of WHO-prequalified products is regularly updated and can be accessed online *(20)*. Complementary information is available on the Global Fund's *List of malaria pharmaceutical products classified according to the Quality Assurance Policy*, which is also periodically updated and accessible online *(21)*.

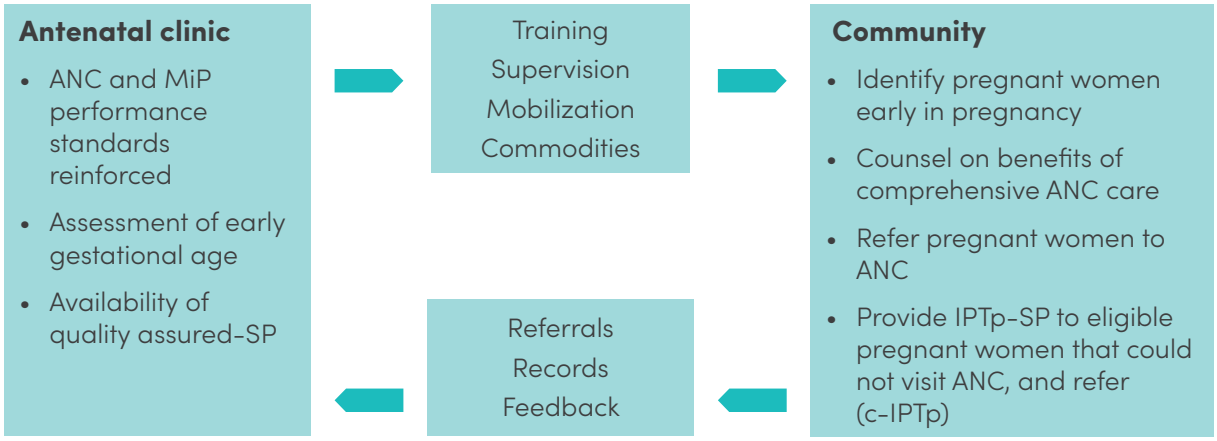
4 IPTp with SP also remains effective in areas where **quintuple-mutant** haplotypes of *Plasmodium falciparum* to SP are highly prevalent. Further research on the relationship of SP resistance markers and IPTp effectiveness should be done, particularly in areas where transmission and thus maternal immunity have declined substantially in recent years. An association between **sextuple mutant** haplotypes of *P. falciparum* and decreased birth weight has been reported in observational studies in a few sites in east Africa. Further studies are required to assess this and to devise the best and most cost-effective prevention strategies in areas of very high SP resistance *(17)*.

3. c-IPTp

3.1 What is c-IPTp?

C-IPTp is the administration of quality-assured SP for IPTp to eligible pregnant women by trained CHWs at the community level. It complements delivery of IPTp-SP at ANC facilities. The c-IPTp approach intends to bridge the gap between ANC attendance and IPTp coverage (see Fig. 1), and allows CHWs to create awareness and sensitize pregnant women on the need to attend an ANC clinic for comprehensive ANC services. Fig. 2 illustrates the community-to-ANC-clinic approach to continuum of care.

Fig. 2. Community-to-ANC-clinic continuum of care



ANC: antenatal care; MiP: malaria in pregnancy; SP: sulfadoxine-pyrimethamine; IPTp-SP: intermittent preventive treatment of malaria in pregnancy with SP; c-IPTp: community-based IPTp.

Source: Community intermittent preventive treatment for malaria in pregnancy implementation handbook (22).

In some countries, national policies allow CHWs to administer the first dose of IPTp (IPTp-1), while in other countries, IPTp-1 needs to be given by a healthcare worker during an ANC visit and CHWs can only give subsequent doses (IPTp-2+).

3.2 Who is eligible for c-IPTp?

IPTp-SP should be administered to all pregnant women in malaria-endemic areas, regardless of how many pregnancies they have had *(7)*. This WHO recommendation issued in June 2022 facilitates the implementation of c-IPTp by trained CHWs, as the pregnant woman does not need to be assessed for her number of pregnancies. The trained CHW determines the eligibility of the pregnant woman to receive c-IPTp-SP in line with national policies and based on the pregnant woman's gestational age, history of allergies and adverse reactions, co-medications, and when the last dose of SP was received. The following inclusion and exclusion criteria apply for c-IPTp with SP.

Inclusion criteria (the pregnant woman can receive a dose of SP from a CHW)

- **Gestational age:** the woman needs to be 13 or more weeks pregnant to be eligible to receive SP. The CHW can derive the gestational age from the woman's pregnancy documents, or the CHW can determine the gestational age based on the date of the first day of her last menstrual period using a pregnancy wheel (Fig. 3). If the pregnant woman is unsure about the date of her last normal menstrual period or the gestational age is unclear, the CHW can inquire whether quickening (the mother's first awareness of fetal movement; the baby has started to move in the womb) has occurred; quickening would suggest a pregnancy of 16 or more weeks. Note that while the standard practice in some countries is to give the first dose of IPTp-SP at quickening, this can leave both the pregnant woman and fetus unprotected for an unnecessary long period, depending on variations in a woman's perception and timing of quickening. The period between 13 and 20 weeks is critical for irreversible negative consequences of MIP, when parasite densities are highest and major benefit can be achieved from malaria prevention *(23)*.
- **Sulfa-containing medicines:** the CHW needs to verify that the pregnant woman has not taken a sulfa-containing medicine in the last four weeks; this includes any previous dose of SP for IPTp. The CHW also needs to verify that the pregnant woman has no allergies to sulfa-containing medicines and has not had an adverse reaction to any sulfa-containing medicine.[5]

Exclusion criteria (the pregnant woman should not receive a dose of SP from a CHW)

- **Gestational age:** the woman is less than 13 weeks pregnant, the last normal menstrual period is unknown or the pregnant woman has not yet felt the baby moving in the womb (quickening).
- **Sulfa-containing medicines:** the pregnant woman has received a sulfa-containing medicine in the last four weeks (this includes any previous dose of SP for IPTp), she has an allergy to any of the components of SP or sulfa-containing medicines, or she has experienced an adverse reaction to a sulfa-containing medicine.

  IPTp-SP should not be given to individuals receiving a sulfa-containing medicine as treatment or prophylaxis, including co-trimoxazole (trimethoprim and sulfamethoxazole) for HIV.
- **Other medication:** the pregnant woman has experienced a severe adverse reaction to any previous medication.

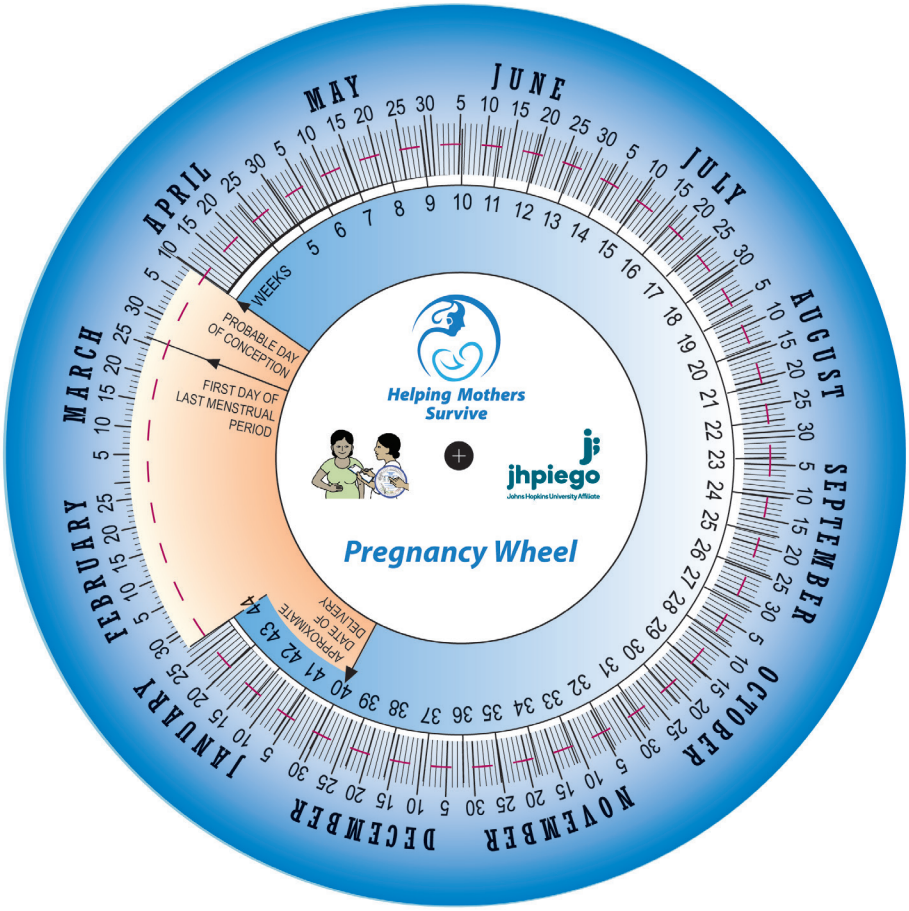
  High doses of folic acid (a daily dose of 5 mg or more) have been shown to counteract the efficacy of SP as an antimalarial, and only low-dose formulations (0.4 mg daily) should be co-administered with SP.
- **Further considerations:** IPTp-SP is not recommended for pregnant women with uncomplicated malaria or severe acute illness or for those who are unable to take oral medication.

The CHW should refer the pregnant woman to an ANC clinic for comprehensive assessment and care.

Detailed guidance for CHW activities is provided in Section 5.6.5. An example job aid for CHWs to determine c-IPTp-SP eligibility is provided in Annex 1.

5 Examples of sulfa-containing medicines include sulfadoxine-pyrimethamine (e.g. Fansidar, G-Cospe) and trimethoprim/sulfamethoxazole (e.g. Bactrim, Septrin).

Fig. 3. Example pregnancy wheel



Source: Jhpiego/TIPTOP, 2018. Adapted from USAID-funded, Jhpiego-led maternal and child survival programme.

3.3 Where should c-IPTp be implemented?

The implementation of c-IPTp can help increase IPTp-SP coverage in malaria-endemic countries. C-IPTp should be considered in areas where the coverage of IPTp in health facilities is low and the ANC attendance high (therefore, where there is a high proportion of missed opportunities), and where policy and programmatic factors are favourable to c-IPTp introduction. Consideration should also be given to contextual factors such as the values and preferences of end users, and the costs, coverage and sustainability of alternative delivery platforms.

C-IPTp pilot studies (see Annex 2) identified several factors that favour c-IPTp and can serve as guiding principles for the selection of implementation areas. These include:

- an existing national health policy that includes the prevention of MIP;
- an existing CHW programme with an adequate number of CHWs that can be deployed within their catchment areas;
- functional CHW networks, integrated into health systems to absorb new activities such as community-based deployment of IPTp;
- a national task-shifting and sharing policy that enables CHWs to dispense medicines, including SP for c-IPTp;

- areas with low IPTp coverage despite functioning ANC services – experiences from the TIPTOP pilot project suggest that a c-IPTp delivery approach is more likely to be successful when it is implemented in areas with an initial low IPTp coverage (see TIPTOP experiences in Annex 2);
- feasible integration of c-IPTp with ANC services, government-led community-based programmes, supply chain management, and monitoring and evaluation (M&E) systems;
- functional supply chain management to ensure uninterrupted availability of SP to ANC facilities and CHWs where c-IPTp will be implemented;
- acceptability of the approach by the beneficiary communities, and strong community ownership; and
- good collaboration among all stakeholders at different levels, especially strong involvement from malaria, reproductive health, maternal health, child health and CHW programmes.

4. Planning

4.1 Inclusion of c-IPTp in national malaria strategic plans

In most countries, c-IPTp will be a new delivery approach for an existing intervention (IPTp-SP) that is already included in national guidelines and documents. To receive international and domestic funds, c-IPTp should be adopted as a new delivery strategy at the policy level and be included in the national malaria strategic plan, the malaria annual operational plans, and in the national policy and guidelines for reproductive health and primary health care programmes.

The policy adoption of c-IPTp should involve the ministry of health (MOH) programmes responsible for reproductive, maternal, newborn, child and adolescent health and nutrition, as well as those responsible for community services. Once it is endorsed by the reproductive health and primary health care programmes, c-IPTp should be included in the national malaria strategic plan.

To ensure successful implementation, no effort should be spared in planning for coordination, integration of services and collaboration at all levels of the existing health care system, including the community health system. The two critical government programmes for MIP are the national malaria programme and the reproductive health division of the MOH that is responsible for maternal and newborn health programming in the country. All relevant technical, implementation and financing partners need to be informed of and involved in the formation or reactivation of a government-led national technical working group focused primarily on MIP (MIP TWG). Such a body can be replicated at subnational levels in countries where health care delivery has been appropriately decentralized. In most countries, TWGs already exist and can be mobilized or expended to work specifically on MIP, with the involvement of relevant MOH programmes and stakeholders.

4.2 Situational analysis

A situational analysis should be undertaken at national and subnational levels to assess health facility and community readiness to deliver quality MIP services. A functional ANC platform is essential for the delivery of recommended interventions for the prevention and control of MIP.

The situational analysis should aim to determine the following parameters:

- evaluation of ongoing MIP activities, including which MIP interventions are implemented and where, who the target beneficiaries are and what the expected outcomes are; which development partners are involved and what their level of support is; and what demand creation activities are ongoing;
- functionality of the existing community health system on which c-IPTp should be built; the situational analysis should map out available CHWs who may be recruited for c-IPTp, with the involvement of the communities (see Section 5.6);
- gender and sociocultural barriers to IPTp uptake at the facility level as well as to community-based services in general;

- knowledge and skills of the healthcare workers at the ANC clinic/facility level, which involves:
  - conducting a baseline rapid health facility assessment, to understand the knowledge, attitude and skills of the healthcare providers about MIP and how available interventions are implemented to reduce the MIP burden;
  - reviewing skills and practices in record-keeping processes and M&E, as well as the records and effectiveness of past training of facility-based healthcare workers who can be trained as trainers and supervisors of CHWs; and
  - mapping healthcare workers in the target areas for c-IPTp, which is very important given the global shortages of human resources for health; findings can influence recruitment or re-deployment of staff;
- availability of quality-assured SP, as the uninterrupted availability of quality-assured SP is critical to c-IPTp implementation; the situational analysis needs to identify gaps and solutions that aim for guaranteed uninterrupted supplies for IPTp and c-IPTp, which involves:
  - an understanding of the SP procurement process, including who procures SP and when, the supply chain management system, storage conditions in the health facilities, how the medicines will be given to CHWs for community distribution, and the status of pharmacovigilance in the target areas;
  - sourcing of quality-assured SP (information is provided in Section 2.5); and
  - ensuring that medicines are put through public supply management systems, to guarantee the last mile distribution to end-user health facilities/ANC clinics;
- existing health management information systems (HMIS), including whether data collection tools are present (such as ANC and labour/delivery registers, monthly summary reporting forms, community HMIS and patient referral forms) and HMIS registers are up to date, what the level of underreporting and overreporting is, and whether there is an existing community HMIS that can be updated to accommodate ANC and IPTp reporting; the situational analysis needs to identify gaps and solutions to update all required forms and templates so that data are captured at the community level (for proper analysis).

Where possible, for example, for the burden of malaria or IPTp coverage, data should already be available to the country and the utilization of the most up-to-data data should be ensured. Further useful information, including on facility assessment, ANC provider knowledge assessment and CHW supervisor interviews, can be derived from the *WHO Service availability and readiness assessment (SARA) (24)*.

4.3 Budgeting for c-IPTp and resource mobilization

A costed c-IPTp implementation plan should be developed and used for resource mobilization in case funding gaps are identified. Table 2 shows example budget lines (non-exhaustive) that should be considered and listed with their corresponding unit costs, the total line cost and their funding source.

Table 2. Example budget for c-IPTp implementation

Activity	Unit cost	Total cost	Funding source	Comments
Procurement				
Commodities (SP; lockable storage boxes for CHW; CHW T-shirts, backpacks and other attire; drinking-water; bed nets, etc., as applicable)	...	...	...	...
Procurement and transport (including cost for insurance and freight)	...	...	...	...
In-country distribution	...	...	...	...
Training				
Development, printing and dissemination of training materials and job aids	...	...	...	...
Training of trainers, district training/ANC focal points training, CHW training	...	...	...	...
Refresher training by level	...	...	...	...
Supervision				
Development, printing and dissemination of supervisor materials	...	...	...	...
Training of supervisors at the different levels	...	...	...	...
Refresher training of supervisors at the different levels	...	...	...	...
Cost to cover supervision visits, transport, accommodation, stipends, etc.	...	...	...	...
CHW remuneration/incentives				
CHW remuneration/salaries/stipends	...	...	...	...
Transport costs, phone costs and other compensations	...	...	...	...
Advocacy, and social and behaviour change communication (SBCC)				
Development and dissemination of adequate SBCC materials (include an adequate budget for review meetings, photo shoots, printing, travel/transport, distribution in catchment areas, etc.)	...	...	...	...
Community sensitization campaigns	...	...	...	...
M&E and surveillance				
Revision/development and dissemination of M&E and surveillance forms (include an adequate budget for review meetings, printing, travel/transport, distribution in catchment areas, etc.)	...	...	...	...
Digital tools for data processing (for example tablets for data transfer)	...	...	...	...
Trainings on data entry, processing, analysis and interpretation	...	...	...	...
Supervision	...	...	...	...

4.4 Coordination and cooperation: roles and responsibilities at various levels

The successful implementation of c-IPTp requires optimal coordination and collaboration of the different players across all levels of the health care system. The c-IPTp should be well integrated into existing systems – such as community delivery, procurement and supply chain, and reporting systems, and M&E – to ensure synergies and sustainability of the programme.

Coordination across different levels is facilitated by clearly defining and communicating complementary roles and responsibilities for the different players along the continuum for the implementation of c-IPTp. Table 3 illustrates responsibilities and tasks by administrative level.

4.5 c-IPTp implementation plan

The goal of c-IPTp planning is to determine where, when and how c-IPTp will be implemented. Planning requires the completion of the situational analysis as described in Section 4.2; its results will feed into the development of the c-IPTp implementation plan. In countries with no previous experience with c-IPTp, implementation may begin in a few pilot areas, and lessons learned from pilot implementation can then be used to guide a more widespread, country-specific implementation of c-IPTp.

An implementation plan should cover the following minimum areas:

- coordination of implementation at national, regional, district and community levels (see Section 4.4);
- costing and budgeting, including payment plans for CHW (see Sections 4.3 and 5.2);
- a comprehensive advocacy and community sensitization/mobilization/ engagement plan (see Section 5.3);
- a plan for cascade training, with clearly defined roles and responsibilities for all levels (see Section 5.1);
- a detailed plan for supportive supervision (see Section 5.5);
- an integrated supply chain management plan, including adequate planning for the distribution of medicines and other required supplies, training materials, reporting forms, etc. (see Sections 5.4 and 6.3);
- a detailed M&E plan (see Chapter 6);
- pharmacovigilance; and
- molecular markers of drug resistance and chemopreventive efficacy monitoring for SP (see Section 2.4).

Table 3. Example responsibilities and activities by administrative level

Level	Who	Responsibility	Examples for related activities
National	National MIP TWG	• Overall oversight, coordination and supervision of c-IPTp implementation • Resource mobilization • M&E for continuous improvement of c-IPTp implementation	• Identify and engage key stakeholders • Incorporate c-IPTp into relevant national policies and documents • Budget and secure funding for all required activities and commodities • Conduct the situational analysis and prepare the c-IPTp implementation plan • Oversee supply chain management, including quantification and procurement/ dissemination of all required commodities • Review and update or develop c-IPTp training materials, job aids, and tools for supervision, recording and reporting • Facilitate training of trainers at (sub)national levels • Provide supportive supervision • Conduct advocacy and provide information and communication at the national level, and conduct SBCC • Regularly monitor and evaluate data and use the information to update c-IPTp implementation (based on lessons learned) • Coordinate resistance monitoring/preventive efficacy monitoring • Oversee pharmacovigilance and the management of (serious) adverse drug reactions
Subnational	Regional/ state health authorities	• Provision of training and refresher training • Supervision and facilitation of c-IPTp implementation at the regional/state level	• Provide managerial and financial oversight and supervision • Ensure availability of adequate supplies of commodities required for c-IPTp implementation • Conduct advocacy at the regional level, and conduct SBCC • Organize meetings with stakeholders • Conduct training and refresher training • Explain the c-IPTp approach to the district health team
	District health management team	• Facilitation of c-IPTp implementation at the community level • Supervision of c-IPTp implementation at the ANC-clinic level	• Organize meetings with stakeholders • Train/retrain ANC providers/healthcare workers • Distribute quality-assured SP and other related commodities and forms to ANC clinics/ health facilities in catchment areas • Conduct SBCC • Plan and organize supervision of c-IPTp implementation • Monitor progress of c-IPTp and solve problems • Prepare technical and financial reports as required

Level	Who	Responsibility	Examples for related activities
ANC clinic/ health facility	ANC healthcare workers at ANC clinics/ health facilities participating in c-IPTp implementation in the catchment area	• Supervision of c-IPTp implementation at the community level • Contact with and mobilization of communities • Provision of comprehensive ANC services, including IPTp-SP • Diagnosis and treatment of malaria cases • Management of adverse events, including reporting to feed into the national pharmacovigilance system	• Organize meetings with all stakeholders, including communities, to explain c-IPTp implementation and rollout • Support identification of CHWs for c-IPTp-SP • Train and provide refresher training to CHWs • Provide supportive supervision to CHWs and solve any issues that may arise • Manage stocks of SP for both the ANC and CHW levels, and manage (re)supply of SP and other relevant equipment to CHWs • Collect and analyse reporting forms completed by CHWs • Report adverse events to the district medical officer • Identify, discuss and report community concerns
Community	Community leaders/ members	• Community ownership of c-IPTp • Mobilization and engagement of the community	• Select CHWs (see Section 5.6.3) • Engage civil society organizations • Undertake community self-monitoring
	CHWs	• Provision of services around MIP and IPTp to community members	• Complete CHW activities (see Section 5.6.5 for details): – Provide education and information to pregnant women and their families – Identify newly pregnant women – Refer pregnant women to ANC – Administer SP by DOT to eligible pregnant women – Monitor and manage SP stocks – Record and report

5. Implementation

5.1 Training

5.1.1 Training materials

Representatives from maternal and child health/reproductive health, malaria and CHW programmes should be involved in the development of new MIP and CHW training materials. In addition to the technical elements of MIP, ANC and IPTp-SP administration, recording and reporting, the training curriculum should include interpersonal communication skills, and community mobilization to create demand, increase community awareness and sensitize women of childbearing age/pregnant women and their families, to reach optimal coverage with IPTp-SP and ANC. Required materials include training manuals for trainers and trainees, job aids, data collection forms and social behaviour change materials. An adequate quantity of required materials based on the level of the cascade training (see Section 5.1.2) and the intended audience needs to be calculated well in advance of the training, to allow for production, printing, timely procurement and dissemination to the required training locations. Translation of materials into local languages and validated pictograms for low-literacy levels also need to be considered. All materials should be reviewed and amended at regular intervals based on lessons learned from previous training rounds. The curriculum should also include identification of gender and sociocultural barriers to IPTp uptake and uptake of community health services, and provide knowledge, attitude and skills to help pregnant women overcome these barriers.

5.1.2 Cascade training

Training should be organized as cascade training (in line with other training strategies in the country) that considers the respective tasks required from different staff involved in the implementation of c-IPTp at each level of the system. For example, at the:

- national and subnational levels: training of trainers and master trainers;
- ANC-facility level: training of focal healthcare workers (facility-based ANC providers) and training of CHW supervisors, selected from the best-performing ANC providers based on pre-test and post-test scores; and
- community level: training of CHWs.

The duration of CHW training will vary from country to country depending on the existing CHW training curriculum, which may or may not already have modules on MIP (for an example of a detailed overview of learning objectives for c-IPTp, see Annex 1). The last two or three days of CHW training should be used for community resource mapping (see Section 5.6.2). With the community register, population of catchment areas can be easily determined and compared to the census figures or population projections; this is important for coverage indicators (for example, the percentage of pregnant women in the catchment area who received three doses of IPTp). At the end of their training, CHWs should be able to:

- provide health education and counselling on prevention and control of MIP, correct hanging and use of bed nets, and the benefits of ANC and IPTp;
- know that SP prevents MIP but is not always 100% effective, so the pregnant woman should seek care when she has fever or symptoms, even if IPTp-SP was received;

- know that SP is for MIP prevention only, and is not recommended for the treatment of malaria;
- correctly dispense IPTp-SP and counsel the pregnant women on ANC attendance, how to seek early diagnosis and treatment, and when to return for repeat IPTp-SP uptake;
- know that ANC is essential for additional services that are required during pregnancy;
- identify existing and newly pregnant women in the community and conduct home visits;
- screen pregnant women for eligibility to receive SP and administer SP by DOT;
- correctly identify and apply reasons for referring pregnant women to ANC (for example, refer pregnant women with fever to the health facility for assessment and potential treatment of malaria and other illnesses, recognize adverse drug reactions and the need for comprehensive ANC, etc.);
- complete forms and record information (for example, the CHW register, patient's ANC card, referral forms, appointment cards, data entry in community HMIS tools); and
- manage stocks of all required commodities, including SP and materials supplied to them for use in the community.

It is generally good practice to assess training at all levels (for example, using pre- and post-training tests) and determine what to do if trainees should fail the post-training test. All CHWs should attend regular refresher training.

5.2 Retention of CHWs

Of particular concern for programme effectiveness is the retention of CHWs and the financial resources to sustain the c-IPTp approach. Countries should put measures in place at the community level to enhance the retention of CHWs. Where possible, CHWs should be integrated into the government payroll and receive a monthly salary.

Countries can find detailed recommendations on compensating and motivating CHWs in the *WHO guideline on health policy and system support to optimize CHW programmes* (see Box 2).

Box 2. CHW remuneration and contracting agreements *(11)*

Recommendation 7A: WHO recommends remunerating practising CHWs for their work with a financial package commensurate with the job demands, complexity, number of hours, training and roles that they undertake.

Recommendation 7B: WHO suggests not paying CHWs exclusively or predominantly according to performance-based incentives.

Recommendation 8: WHO recommends providing paid CHWs with a written agreement specifying role and responsibilities, working conditions, remuneration and workers' rights.

If a regular payment is not feasible, a subsidy is needed to ensure availability of CHWs to perform their tasks. Payment of transport fees/facilitation to attend regular working sessions at the linked ANC facility for (re)supply with SP, data reporting and coordination should be considered.

Furthermore, CHW compensation can include – but is not limited to – payment of a monthly stipend; reimbursement of transportation costs and mobile phone expenses; social recognition through branded materials such as T-shirts, caps and backpacks; and provision of rain boots and raincoats during the wet season; etc.

5.3 Social behaviour change communication

Several community social actions and participation models show that the community's active involvement in the distribution of health commodities and scale-up of interventions (in collaboration with the health system) can strengthen linkages between health workers in clinics and the community. Communities are known to play a critical role in malaria disease surveillance and can be empowered to reduce the burden of malaria through culturally appropriate social behaviour change communication (SBCC) activities. SBCC is more than just information, education and communication; behaviour change communication; and health promotion – SBCC includes social mobilization and recognizes that behaviour requires a supportive social environment.

Information, beliefs and experience play a significant role in health-seeking behaviour, and it is important to ensure that pregnant women, their families and the community are well informed about both the adverse consequences of the burden of MIP and the available, low-cost solutions to mitigate it. Pregnant women, their families and the community should learn a set of skills and behaviours to prevent malaria, as well as how to access appropriate diagnostics, medicines, ITNs, and curative and preventive services, and perceive their environment to be supportive.

5.3.1 Stakeholder collaboration and generic messages

Malaria and reproductive health programmes should lead the communication efforts, collaborating closely with the primary health care programmes that heavily rely on community participation. Other stakeholders to involve may include the local district health authorities, service providers at the health facilities, and the community development committee or equivalent. C-IPTp programmes should consider the following aspects when planning for community engagement and SBCC programmes:

- increase knowledge and stimulate community dialogue;
- identify gender and sociocultural barriers to MIP services, and provide strategies to overcome these;
- promote essential changes in attitudes;
- create a demand for information and services, and advocate for appropriate health-seeking behaviours;
- promote services for prevention, care and support, and improve community members' skills and sense of self-reliance.

The social mobilization and SBCC plan should be developed and implemented before and during c-IPTp rollout and implementation. The generic messages should cover the following minimum aspects:

- benefits of both early and subsequent ANC attendance, sleeping inside long-lasting ITNs, and using SP for IPTp as a low-cost, high-impact intervention;
- the safety of SP use by pregnant women after the first trimester, whether given at a ANC facility or in the community;
- that SP has preventive capacity and is not recommended to treat malaria;
- that SP is generally very well tolerated and protects both mother and baby, that there is, however, the potential for adverse reactions to SP – which are usually

mild and transitory – and what should be done if this happens; this includes developing a plan for rumour management;

- timing and schedule of SP dosing for IPTp;
- reasons for administering SP by DOT, whether at an ANC facility or in the community;
- community knowledge that CHWs have specifically been trained for c-IPTp-SP and that they are equipped with quality-assured preventive medicines;
- benefit of community-to-clinic referrals in increasing ANC and IPTp coverage;
- importance of referral compliance by pregnant women; and
- national policy on who should or should not receive IPTp-SP at the community level; some countries' policies make it mandatory that the first SP dose is provided in ANC facilities, while others allow CHWs to initiate SP dosing in the community for eligible pregnant women. Follow-up doses may, thereafter, be given in the community (see Sections 3.1 and 3.2).

SBCC activities should be planned and implemented within the overall national SBCC plan of the malaria programme.

5.3.2 Material for advocacy and communication

Material for advocacy and communication should be prepared in culturally appropriate, easy-to-understand language and field tested and reviewed carefully, with assistance from local experts. The material should be translated into the main local languages as applicable. Communication activities should be implemented through addressing a variety of stakeholders, such as political, traditional and religious leaders; community-based organizations, including women's groups; traditional birth attendants and healers; and community- and facility-based health workers and volunteers. Plan all advocacy activities, such as community visits and gatherings, when and where it is relevant and likely to be the most impactful. Further channels of communication include radio, television and print media, as well as markets and other gatherings. The use of social media should be explored, considering their effectiveness and potential reach. Moreover, community-level meetings, talks and other health education activities, such as village drama sessions and puppet shows, should include discussion on malaria prevention.

5.4 Integrated supply chain management

5.4.1 Supply chain management plan

Proper quantification of commodities, timely procurement and distribution to all catchment areas, correct storage across different levels of the system (including the CHW level) and timely resupply of CHWs are all key elements for successful implementation of c-IPTp programmes. The national malaria control programme, in collaboration with the central medical store, should plan for all required activities so that they are well integrated into the existing national medicine supply chain system, from procurement down to the last-mile distribution to end-user facilities. This should involve the development of a supply chain management plan, with the aim to ensure uninterrupted availability of quality-assured SP (for information on the sourcing of quality-assured SP, see Section 2.5) and other required commodities at both the ANC facility and community level. Particular attention should be paid to supplies required in hard-to-reach areas, considering specific geographical, infrastructural, meteorological and seasonal challenges (for example, heavy rainfalls and unusable roads/unpassable rivers during the rainy season) in the areas planned for c-IPTp implementation. Where the baseline situational analysis has revealed gaps in the flow of much-needed commodities to end-user facilities, the root

causes of the delays and barriers should be determined so that corrective actions can be taken. Health managers should ensure that quality-assured SP (potentially specifically packaged for pregnant women[6]) is listed in the country's procurement list and ordered in a timely manner, to avoid stockouts in the ANC facility that would translate into stockouts at the community level.

5.4.2 Quantification of commodities

Accurate quantification should include the required amounts of commodities at both the ANC facility and the community level, for integrated procurement and dissemination. Several quality-assured SP products are available on the market (see Section 2.5), with different formulations and packaging to enhance patient compliance, including dispersible tablets, taste-masked tablets and blisters packs of three tablets. The following factors should be considered for SP quantification:

- estimated number of pregnant women in the areas selected for c-IPTp implementation/catchment areas (community/village, health zone, district, region);
- target dose per pregnant women, with IPTp-3 (three doses of SP per pregnant woman, consisting of three tablets of 500 mg/25 mg SP per dose to reach the recommended 1500 mg/75 mg SP per dose) considered to be the minimum; the country-specific target dose can be higher as IPTp-SP can be administered up to the time of delivery, provided that doses are given at least one month apart;
- SP requirements per CHW for c-IPTp-SP (initial supply) in each catchment area;
- SP requirements at ANC facilities, considering both ANC IPTp and the resupply of CHWs with SP for c-IPTp;
- stock already available from the country's regular IPTp-SP administration at ANC facilities, including leftover stock from the previous year; note that the shelf life of WHO-prequalified SP varies between 24 and 36 months, depending on the chosen supplier (see Section 2.5); and
- buffer stock of 10% (to account for calculation errors, wastage, expiry, loss, theft, lead time, etc.).

Proper quantification of the requirements for associated commodities (such as water sachets, bed nets, lockable boxes for storage of SP at the CHW level, backpacks, T-shirts, caps, etc.) should also be considered and planned in a timely manner.

Quantification and procurement cycles need to be started well in advance of the planned c-IPTp implementation and rollout (at least one year in advance), to allow for proper planning, procurement and dissemination (including manufacturing of commodities/ lead time, transport/delivery to the point of entry, and regulatory approvals/waivers as applicable, considering taxes and tariffs for importation). Sufficient time needs to be allowed for quality control, batch testing, and in-country and last mile distribution. Potential obstacles should also be considered, such as limited container availability, congested ports and staff shortages (as experienced during and after the COVID-19 pandemic).

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6 The TIPTOP project assessed the impact of an SP product with an adapted packaging specifically designed in the context of the project. The existing blister packaging for three tablets of SP was updated with an image of a pregnant woman and the IPTp indication for use on the blister pack itself. In addition, the revised box containing the individual blister packs had more colour, an image of a pregnant woman, and a dosing schedule indicating pregnancy months and when it is safe to swallow the tablets. The evaluation of this modified packaging suggested an increased acceptability of SP for IPTp. The imagery indicated that the product is specifically for pregnant women and contributed to its perceived safety. However, the study also revealed that pregnant women may have a preference for SP with such updated packaging, which could affect the perception of SP with different or no packaging (e.g. at a health facility where SP from large jars is used), or the perceptions of, and confidence in, other medicines provided at ANC visits *(1)*. Additional information on the adapted packaging is available online *(25)*.

5.4.3 Storage of SP

Health managers should pay attention to the storage conditions of SP at both the ANC facility and community level. In general, the following storage criteria apply to SP:[7]

- Do not store above 30 °C.
- Store the tablets in blisters in the provided box or carton.
- Protect from light and moisture.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton or blister card.[8]
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

CHWs should be equipped with suitable and lockable storage boxes to keep the medicines safe from heat, humidity, and unauthorized access and use. This includes keeping the medicines well protected from children and pets.

5.5 Supportive supervision

The role of effective supervision is to support c-IPTp implementation by ensuring that activities are carried out in compliance with agreed procedures. Box 3 details WHO's recommended general guiding principles on supportive supervision for CHW programmes. A supervision plan that includes appropriate supervision checklists should be prepared.

Box 3. Supportive supervision for CHW programmes *(11)*

Recommendation 6: WHO suggests using the following supportive supervision strategies in the context of CHW programmes:

- appropriate supervisor–supervisee ratio, allowing meaningful and regular support
- adequate training of supervisors
- coaching and mentoring of CHWs
- use of observation of service delivery, performance data and community feedback
- prioritization of improving the quality of supervision.

An adequate training of supervisors should also include information on the role of gender, gender sensitive supportive supervision, and power dynamics in supervision.

Post-training supervision is best performed by the facilitators (including the focal c-IPTp persons) who conducted the training (see Section 5.1.2). Intensive supportive supervision should be put in place, especially during the early stages of c-IPTp implementation so that problems can be identified and resolved early. At the community level, retraining (if required) can be offered on-site to CHWs who experience difficulties.

C-IPTp supportive supervision should be part of an existing integrated supportive supervision system. Table 4 lists different types of c-IPTp supportive supervision; countries should adapt and adopt these supervision approaches in the context of their integrated supportive supervision system.

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7 The patient information leaflet of specific WHO-prequalified products can be accessed via the web page of the WHO Prequalification Programme *(20)*.

8 The shelf life of the current WHO-prequalified products varies between 24 and 36 months.

Table 4. Illustrative types of supervision in a c-IPTp programme

Type of supervision	Purpose	Supervision site	Frequency	Required tools
C-IPTp healthcare worker at the ANC clinic/CHW supervisor meets all CHWs from the health facility catchment areas	• Review CHW reporting of service delivery and referral data • Collect the list of pregnant women in the community who missed their ANC visits. Develop a plan to visit them at home to encourage them to go to the ANC clinic and, where appropriate, assess them for eligibility to receive the next dose of IPTp • Replenish CHWs with a stock of quality-assured SP, based on the consumption in the previous month (number of empty SP blister packs), and other required materials • Discuss challenges and mitigation measures • In some countries, the health facility's c-IPTp focal person is also empowered to reimburse the CHW travel expenses or provide a monthly stipend during the supportive supervision meeting	Health facility	Monthly	• Community HMIS register • SP stock card (see Annex 3) • Checklist for monthly supportive supervision of CHWs (see Annex 1)
CHW peer-to-peer supervision[a]	• Review c-IPTp data before submission at the health facility • Review provision of SP by DOT	CHW's home or community meeting	Monthly	• Community HMIS register • SP stock card (see Annex 3)
C-IPTp healthcare worker at the ANC clinic/CHW supervisor visits CHW at their place of work or service provision[b]	• Review CHW SP storage and maintenance of SP stock card • Observe SP provision by DOT to eligible pregnant women • Review data and recording of service data • Provide on-the-job training to the CHW as needed	CHW's home or community	Monthly (starting as soon as possible after the CHW training)	• Community HMIS register • SP stock card (see Annex 3) • SP provision checklist

Type of supervision	Purpose	Supervision site	Frequency	Required tools
CHW supervisors from the district health office visits the c-IPTp healthcare worker at the ANC clinic/ CHW supervisor	• Review project status at the health facility • Review project status in the community	First at the health facility, then joint visit of CHWs in the community	Regularly	• Example checklist for prevention of MIP in health facilities (see Annex 1)
District health office data review meetings	• Review data • Review SP stock • Discuss challenges and mitigation measures	District health office	Quarterly	• Summary ANC register review
Joint supervision visits to the health facility by MIP TWG members (MOH and partners)	• Review SP stock • Observe ANC clinical skills (health education, estimation of gestational age, screening for SP eligibility, provision of SP by DOT, etc.) • Assess data quality	Health facility	Quarterly	• External supervision checklist • Data quality assessment checklist • SP stock card (see Annex 3) • Clinical skills observation checklist
Remote supervision during the COVID-19 pandemic	• Remind healthcare workers and CHWs about essential tasks and data reporting	Mobile networks	Weekly or monthly	• SMS or Skype messaging • Mobile mentoring

a Some countries have adapted CHW peer-to-peer supervision as a strategy for strengthening the quality of CHW data submitted at the monthly meetings. The CHW peer supervisors are usually selected from the list of literate, high-performing CHWs, and thereafter given some additional training to support other CHWs in the performance of their duties.

b External supervision visits by the facility-based trainers are led by the c-IPTp focal person(s).

5.6 Community-based activities

The main goal of the c-IPTp planning process is to build a partnership between community members and healthcare workers in the ANC clinic/local health facility. The key concepts for community engagement are relationship development, participatory decision-making, and capacity-building. Community members need to be fully involved in the planning and rollout of c-IPTp activities. C-IPTp benefits the health system by reducing the workload of healthcare workers, as communities take responsibility for the intervention. Increased contact between community members and healthcare workers improves human relations and increases utilization of health services.

C-IPTp focal healthcare workers at ANC clinics are trained to nurture this relationship. They will hold informal meetings or contact community leaders and health personnel to gather basic and unbiased knowledge of the community and its characteristics, which helps determine how to successfully implement c-IPTp. To get to know the community and its members' outlook, focal healthcare workers should, if necessary, ask for assistance from a respected community leader based at the district headquarters. Such information gathering may help to facilitate community entry, or alert c-IPTp implementers to potential barriers or resistance to c-IPTp that will need to be addressed. Examples of potential community leaders to approach for entry are the village chief or head, CHWs and healers, leaders of civil society organizations (CSOs), the community secretary, teachers, school heads, religious and opinion leaders, women leaders and other gatekeepers.

5.6.1 Community action plans for c-IPTp implementation

Developing a plan for c-IPTp implementation requires defining the problem of MIP (with input from the community) and identifying available services for the prevention and control of MIP. This includes identifying the community roles in accessing the available services. Community representatives should be requested to meet with all community members, to ensure participation of all segments of the community and to discuss the community action plan.

Information on the status, strengths and weaknesses of malaria control activities in the community should be collected. To obtain more in-depth knowledge about a specific community, it is helpful to review and discuss results of previous community-directed interventions in the catchment area, and the reasons why these succeeded or failed. In addition, community members should be reminded that it is not enough that an individual has received SP, but that the pregnant women has used it as recommended for malaria prevention. It is also important to emphasize and ensure that the satisfied pregnant woman becomes an advocate for the identification of other eligible pregnant women in the community, and refers them to the CHW for similar benefits.

The community and health service personnel should decide on convenient days, times and means for distributing health commodities. For c-IPTp administration, the CHW could either go from house to house or hold a c-IPTp distribution meeting in a central place for all identified pregnant women. Alternatively, pregnant women could seek c-IPTp services when needed and go to the CHW's home to receive the commodities. Planned activities should be documented in the community action plan.

The c-IPTp focal healthcare workers at the ANC clinic should follow up with communities to ensure that the community action plan is being implemented, resolve any conflicts or problems that may have arisen, agree on interventions to address identified challenges, and discuss any challenges and success stories (see Table 3 and Table 4 for more details on responsibilities and supervision).

5.6.2 Community mapping

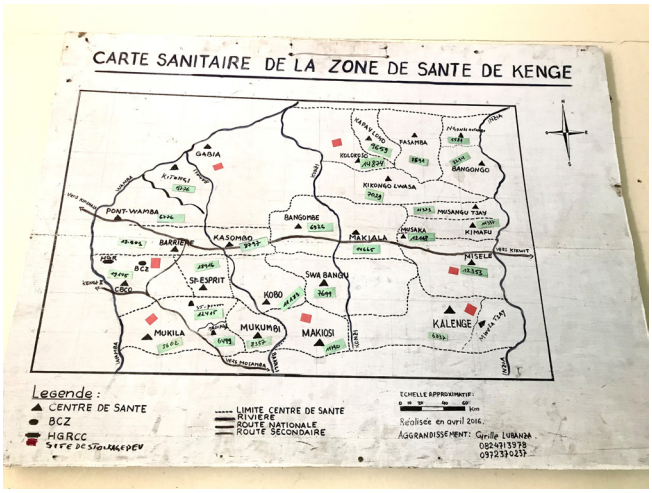
Community mapping allows an understanding of where people live and where pregnant women are, where problem or hard-to-reach areas are, which community resources exist, and which other organizations might be carrying out similar interventions. The mapping is not just about locations: it is a joint activity with the community where all members can learn more about their community, particularly regarding problems and resources such as service quality, access and equity.

Mapping of a community should help identify:

- the location of key health and development resources that the community values, such as health facilities, traditional healers, traditional birth attendants, medicine shops, schools, police posts, markets and churches/mosques;
- key persons and organizations in the community that can help promote c-IPTp activities, such as community leaders, religious leaders, local opinion leaders, local CSOs, etc. – likewise, identify potential opposing people/groups or roadblocks;
- major subdivisions of the community, such as wards and clans;
- resources (both people and organizations) that women, especially pregnant women, go to for advice and help (that is, where or from whom do they get financial, emotional and other support); and
- women's associations and support groups.

Results of the mapping activities should be documented. Ideally, an actual map of the community should be drawn (see the example in Fig. 4) and kept in the community.

Fig. 4. Completed community map showing geographical features and community resources in a village in Kenge District of the Democratic Republic of the Congo



Courtesy of Silvia Schwarte

5.6.3 Selection of CHWs in line with the target population size

Communities should select their CHWs either from an existing pool of CHWs or by identifying new volunteers who should then be trained as CHWs. Community members decide on criteria for CHW selection with guidance from c-IPTp focal persons at the ANC facility and district health office representatives, taking into consideration the target population size (expected number of pregnant women in a catchment area/pregnancy registries). Information generated from community mapping should be used to help identify the types of people best suited to serve as CHWs for MIP programming and c-IPTp. Community mapping can also help identify subcommunities (wards, clans, families, neighbourhoods) from which, and for which, CHWs could be selected.

Communities should select people they can rely on and respect. Selection criteria may consider factors such as age, gender, duration of residence, ability to read and write in the local language, and personality traits (for example, trustworthiness). Communities may also decide on gender requirements, for example that they prefer female CHWs to deliver MIP interventions, while male CHWs could distribute bed nets or other supplies. If the training is held close to the villages where CHWs live, the costs of training will be minimal, regardless of the number of CHWs trained.

The c-IPTp focal person of the linked ANC facility compiles the list of the selected CHWs, and then checks with them to ensure that they are interested in, and accept, serving as CHW to cover c-IPTp activities.

The target population size should also be considered when selecting CHWs, in line with the overarching principles of the *WHO guideline on health policy and system support to optimize community health worker programmes* (see Boxes 4 and 5).

Box 4. Selection of CHWs for pre-service training *(11)*

Recommendation 1A: WHO suggests using the following criteria for selecting CHWs for pre-service training:

- minimum educational level that is appropriate to the task(s) under consideration;
- membership of and acceptance by the target community;
- gender equity appropriate to the context (considering affirmative action to preferentially select women to empower them and, where culturally relevant, to ensure acceptability of services by the population or target group); and
- personal attributes, capacities, values, and life and professional experiences of the candidates (e.g. cognitive abilities, integrity, motivation, interpersonal skills, demonstrated commitment to community service, and a public service ethos).

Box 5. Target population size and CHW programmes *(11)*

Recommendation 10: WHO suggests using the following criteria in determining a target population size in the context of CHW programmes.

Criteria to be adopted in most settings:

- expected workload based on epidemiology and anticipated demand for services;
- frequency of contact required;
- nature and time requirements of the services provided;
- expected weekly time commitment of CHWs (factoring in time away from service
- provision for training, administrative duties and other requirements); and
- local geography (including proximity of households, distance to clinic and population density).

Criteria that might be of relevance in some settings:

- weather and climate
- transport availability and cost
- health worker safety
- mobility of population
- available human and financial resource.

5.6.4 The role of CSOs

CSOs are critical stakeholders in the community's efforts to prevent and control MIP. While some of the existing CSOs may already be playing important roles in disease prevention and control, it is highly advisable to reach out to them for partnerships related to c-IPTp. In addition to health-focused CSOs, it is important to reach out to other types of CSOs that may work closely with pregnant women, such as women's rights organizations, or women's economic empowerment groups. Illustrative roles of CSOs in the implementation of c-IPTp may include the following:

- dissemination of culturally appropriate malaria behaviour-change communication using grassroots platforms and in collaboration with CHWs;
- distribution of malaria information, education and communication materials among pregnant women and households, in collaboration with the CHWs and facility-based health care providers;
- identification and the provision of support to hard-to-reach communities, and subsequent linkage to health facilities and the c-IPTp programme;
- identification, strengthening and/or revitalization of existing community development committees; where non-existent, work with community/service providers to establish one;
- mobilization and education of women of childbearing age to track and record their last normal menstrual periods, to make estimation of gestational age easier;
- advocacy for community ownership of the c-IPTp programme;
- identification of barriers to the implementation of community management of malaria and sharing with the community to proffer solutions; and
- training of CHWs in follow-up and referral services to health facilities.

Plan to provide orientation for the CSOs on c-IPTp as part of the integrated malaria delivery system to complete comprehensive ANC services. Train the CSOs using the adapted national training tools and learning resource packages for CHWs, including supportive supervision modules so that they can ensure that CHWs work within the scope of their training. It is important to ensure that all CSOs are treated equally with regard to compensation or other benefits for their participation in c-IPTp activities.

5.6.5 CHW activities

CHWs who are members of their communities regularly visit households within their catchment areas. With the community register, the members of each household are listed by age, sex and pregnancy status. Thereafter, pregnant women can be followed up with counselling and health education sessions on ANC, MIP, IPTp, determination of gestational age in weeks using a pregnancy wheel, screening for eligibility to receive a dose of SP, provision of SP (if eligible), referral of all pregnant women to an ANC facility, and recording of the services provided in the register.

Before CHWs conduct home visits of pregnant women, they should review the community map and the register of pregnant women, including the addition of names and addresses of newly identified pregnant women, as well as crossing out the names of those who have already given birth. If applicable, they should also review the records of previous visits to the area for required follow-up activities. The CHW should wear branded attire as applicable (T-shirt, cap, etc.) so that she/he is easily identifiable as a trained and authorized CHW.

The CHW should also check her/his bag or backpack to ensure that it contains all required c-IPTp materials, such as job aids (for example, a counselling flip chart), patient education handouts, blister packs of quality-assured SP tablets, the CHW or community

HMIS register, ANC cards, appointment cards, referral forms, a pregnancy wheel, notebook and pen, and optional (depending on country context and catchment area) sachets of drinkable water, paper cups and bed nets.

The actual visit should then be conducted following the six steps outlined below which includes the trained CHW determining the eligibility of the pregnant woman to receive c-IPTp-SP (see Section 3.2 for detailed inclusion and exclusion criteria). Community leaders and members should be notified about the recurrent visits and distribution of SP.

Step 1. Counselling on MIP, IPTp and ANC

- Educate the pregnant woman and her family about the effects of MIP and the benefits of IPTp-SP, ideally using a counselling flip chart. Emphasize the importance of both early ANC and regular ANC visits throughout pregnancy, as well as the importance of regular doses of IPTp-SP up to the time of delivery, to protect both the mother and the baby. Emphasize that pregnant women are particularly vulnerable for irreversible negative consequences of MIP in the period between 13 and 20 weeks, when parasite densities are highest and major benefit can be achieved from malaria prevention *(23,26–27)*. Provide patient education handouts on MIP and IPTp (an example is provided in Annex 1) to the pregnant woman and her family.
- Counsel about the benefits of ANC attendance for all women. All pregnant women, irrespective of age of pregnancy, should be referred to the health facility for comprehensive ANC assessment and care. Ideally, every pregnant woman should visit the health facility in the first trimester (before 13 weeks gestation) for early care.
- Counsel about the importance of early detection of clinical malaria, and prompt treatment with appropriate antimalarial medicines in accordance with the national guidelines.
- Listen to any concerns the woman may have about her ability to attend ANC or other MiP services, and help her to develop strategies to address these concerns.

Step 2. Provision of ITNs (as and where applicable)

- Inquire if the pregnant woman has received an ITN and if she sleeps inside it every night. If she has not received a net and you know a stock of nets is available at the health facility, inform and refer the pregnant woman and her children to the ITN distribution point.
- Listen to any concerns the woman may have about her ability to use an ITN in her home, and help her to develop strategies to address these concerns.
- Educate the household members on how to set up and maintain an ITN according to the type of sleeping arrangement the pregnant woman and/or other household members have (bed, mat, other).
- Help the pregnant woman to hang her own net and advise her to sleep inside the net every night.
- Plan to visit the woman again in 4 weeks' time to check whether she has been sleeping inside the net every night.

Step 3. Determination of eligibility to receive SP

- The woman needs to be 13 or more weeks pregnant to be eligible to receive SP. Check the woman´s pregnancy records; if not available, ask her about the date of the first day of her last menstrual period and use a pregnancy wheel (see Fig. 3) to determine the gestational age.

  If the pregnant woman is unsure about the date of her last normal menstrual period or her gestational age, ask her if quickening (the mother's first awareness of fetal movement) has occurred. Quickening would suggest a pregnancy of 16 or more weeks, indicating that SP can be given. However, note that while the standard practice in many countries is to give the first dose of IPTp-SP at quickening, this practice can leave both the pregnant woman and fetus unprotected for a long period, depending on variations in a woman's perception and timing of quickening *(21)*.

  If the pregnant woman is unsure about the date of her last menstrual period and quickening has not yet occurred, refer her to ANC for comprehensive assessment and care.

- Check for sulfa-containing medicines and other medications the woman may receive (see Section 3.2). Ask the pregnant women to verify which medicines she is taking and that she has not taken a sulfa-containing medicine in the last four weeks; this includes any previous dose of SP for IPTp. For the latter, also review the pregnancy documentation of the woman to confirm the time of administration of any previous doses of SP for IPTp. Double-check with the pregnant woman that she has no allergies to sulfa-containing medicines and has not had an adverse reaction to any sulfa-containing medicine or other medicines.

  Do not administer SP for IPTp if the pregnant woman:

  - is allergic to any of the components of SP or has an allergy to sulfa-containing medicines;
  - has received a sulfa-containing medicine in the last four weeks – this includes any previous dose of SP for IPTp and other sulfa-containing medicines as treatment or prophylaxis, including co-trimoxazole (trimethoprim and sulfamethoxazole) for HIV;
  - has experienced an adverse reaction to a sulfa-containing medicine; or
  - has experienced a severe adverse reaction to any previous medication.

  Ask the pregnant women about folic acid: High doses of folic acid (a daily dose of 5 mg or more) have been shown to counteract the efficacy of SP as an antimalarial, so only low-dose formulations (0.4 mg daily) should be co-administered with SP.

  If the pregnant woman meets any of the above criteria, refer her to ANC for comprehensive assessment and care.

- If the pregnant woman suffers from a febrile illness or is unable to take oral medication, refer her to an ANC facility for comprehensive assessment and care.

An example job aid to help CHWs determine c-IPTp-SP eligibility is provided in Annex 1.

Step 4. Provision of SP to eligible pregnant women by DOT

- You have determined that the pregnant woman is eligible to receive a dose of quality-assured SP. Inform the pregnant woman that she has a right to refuse any medication and request her verbal consent to receive SP for IPTp.
- Listen to any concerns the woman may have about taking SP and respond to these concerns with compassion and empathy.
- Have a cup of clean, drinkable water available (see Box 6).
- Give a dose of SP to the pregnant woman by DOT (that is, watch the woman swallow the correct dose of SP with the water. Note that one full dose of SP for IPTp consists of three tablets of SP, with each tablet containing 500 mg/25 mg SP, for a total required dosage of 1500 mg/75 mg SP).
- Keep the blister pack of the consumed SP and safely store it for recording purposes and resupply at your linked health facility/ANC clinic during your next supervisory visits with your focal point.

Box 6. Drinkable water

Availability of safe, drinkable water is critical for the provision of SP doses by DOT. Unfortunately, many health facilities and households in low- and middle-income countries lack such basic infrastructure. Deep well and borehole water are only safe for drinking if they have been treated (for example, by filtering and boiling, purification and safe storage). Here are some options that can be considered to have safe, drinkable water available:

- Educate pregnant women during antenatal health talks on how to make water safe through boiling and filtration, and ask them to have a bottle of treated water with them when they visit the ANC clinic or are preparing for the CHW visit to receive SP.
- Provide access to commercially available water sachets where pregnant women can buy from a vendor who will also be responsible for disposing of the empty plastic or biodegradable sachets.
- Invest in safe water dispensers or commercially available water purifiers and procurement of small paper cups in health facilities (however, this may be difficult to sustain given widespread inadequate funding of health facilities and financial accountability issues).

Where financial resources are scarce, health managers can leverage support from the community, CSOs or development partners. Corporate organizations, churches and mosques can also be approached to support efforts to provide safe drinking-water in health facilities.

Where SP doses are provided by CHWs during home visits, pregnant women can, where possible, use their usual source of drinkable water at home without the need for any special interventions.

Step 5. Documentation and referral

- Update the pregnant woman's ANC card to indicate the number of IPTp-SP dose given.
- Update the CHW register to include the name of the woman, her ANC card number, and the number of the IPTp-SP dose given.
- Complete an ANC appointment card for the pregnant woman and refer her to the nearest facility. Reasons for referral can include:
  - to receive IPTp-1 or follow-up SP doses (as regulated in the country's policy);

- to receive comprehensive ANC services;
- to receive required appropriate assessment and care for an observed illness;
- to receive an insecticidal net if the pregnant woman has not already received one and national policy supports the provision of free nets to all pregnant women;
- an unclear gestational age; and
- a previous adverse reaction or allergy to a sulfa-containing medicine.

- Remind the pregnant woman to get her next dose of SP in four weeks' time at the nearest ANC facility; inform her of – and ideally, write down or mark – the date when she should get her next dose of SP. Plan for the next visit to the pregnant woman to be in four weeks' time, to follow up on her health-seeking behaviour (find out if she went to the health facility for ANC and IPTp and check on her bed net use).

Step 6. Post-IPTp counselling

- Ask the pregnant woman whether she has any questions, and if she does, provide her the answers. If you do not know the answer, advise the pregnant woman to ask the healthcare worker at the ANC clinic. Also, take a note and report back the issue to your ANC focal person so that you can clarify the issue and have an answer readily available next time the question comes up.
- Take the visit as an opportunity to invite the pregnant woman and her family to any upcoming community activities on MIP (for example, village drama or talks), as applicable.

An example of a detailed checklist for CHWs providing c-IPTp-SP is provided in Annex 1.

6. Monitoring and evaluation

6.1 M&E performance framework

A robust M&E performance framework is essential to assess and confirm that the c-IPTp approach is effective at increasing IPTp coverage while maintaining ANC attendance.

Programme M&E activities start before implementation and continue throughout the life of the project. Baseline assessment findings (see Section 4.2) should inform the design and planning of M&E activities. Routine monitoring continues with implementation, and tracks progress against key performance indicators (see Section 6.2) through record-keeping and regular reporting of results. A good M&E system for c-IPTp utilizes both the routine health information systems and periodic household surveys. Moreover, data audits or verification during routine supervision of CHWs need to be conducted. Supervision is key to ensuring and improving the quality of the data and consistency of reporting.

The M&E performance framework should guide the collection and analysis of data related to programme inputs, processes, outputs, outcomes and impacts, with a focus on improving the quality and use of the data to improve programme implementation and outcomes. The framework defines how programme coverage and the quality of programme implementation is demonstrated, and how the impact of c-IPTp is assessed. It also allows for the identification of programmatic bottlenecks, and can inform both logistical and technical corrective actions as necessary.

6.2 Indicators and data collection

As c-IPTp programmes involve a community–clinic continuum of care and related services, c-IPTp indicators include both community-level and facility-level indicators. These indicators do not need to be newly developed; they can be selected from existing HMIS data elements or previous similar programmes. This allows for comparison across regions and countries. A useful source of information is the interagency document *Monitoring and evaluation of malaria in pregnancy services: practical tips and recommended indicators (28).*

Indicators to monitor the implementation of c-IPTp programmes are categorized as input, process, output, outcome and impact (see Table 5). Their design should be SMART; that is, the indicators must be specific, measurable, achievable, realistic and timely. C-IPTp data sources include communities and facilities, as part of the routine HMIS in some countries (see Table 6).

Table 5. Illustrative indicators for c-IPTp

Illustrative indicators	Data collection
Input indicators	
• Number of CHWs in the programme catchment area	Programme level tracking
• Ratio of CHWs to expected number of pregnant women in the programme catchment area	Programme level tracking
• Number of functional ANC facilities in the programme catchment area	Programme level tracking
• Number of SP doses procured for distribution	Programme level tracking
Process indicators	
• Number of trainings including c-IPTp conducted for CHWs	Programme level tracking
• Number of trainings including c-IPTp conducted for health workers	Programme level tracking
• Number of advocacy and SBCC campaigns conducted on c-IPTp	Programme level tracking
Output indicators	
• Number of health workers trained on c-IPTp delivery	Programme level tracking
• Number of trained CHWs who are actively submitting reports	Routine CHW data collection
• Number of pregnant women referred to ANC by a CHW	Routine CHW data collection
• Number / Percent of pregnant women who attended ANC after receiving referrals from CHWs	Routine ANC data collection
• Number of women who received IPTp at the community level disaggregated by dose (for example: 1, 2, 3, 4+)	Routine CHW data collection
• Number of women of childbearing age who know about the IPTp service provided by CHWs	Periodic household survey
• Number of CHWs with adequate stock of SP	Routine CHW data collection
• Number of ANC clinics with adequate stock of SP	Routine ANC data collection
Outcome indicators	
• Percentage of pregnant women who received IPTp, disaggregated by dose (for example: 1, 2, 3, 4+) and disaggregated by where doses were received (ANC or community)	Periodic household survey
• Percentage of pregnant women with four or more antenatal care (ANC4+) visits	Periodic household survey
• Percentage of pregnant women with a minimum of eight ANC contacts	Periodic household survey
• Percentage of pregnant women initiating ANC early (as defined by country)	Periodic household survey
• Percentage of expected pregnant women attending ANC (disaggregated by visit)	Routine ANC data collection, population estimates
• Percentage of expected pregnant women initiating ANC early	Routine ANC data collection, population estimates
Impact indicators	
• Percentage of newborns with low birth weight (less than 2500 grams)	Routine maternity data collection
• Number of malaria cases averted	Modelled
• Number of lives saved	Modelled

Table 6. Data elements and sources for c-IPTp indicators

Data element	Data source(s)	Who is responsible/user
c-IPTp by dose	• Community register (see Annex 4) • Pictorial CHW tally card (see Annex 5) • Sample patient card (see Annex 6) • CHW monthly summary form	CHW CHW ANC provider/CHW CHW
IPTp at health facility by dose	• HMIS ANC register	ANC provider
ANC attendance by number of visits	• HMIS ANC register	ANC provider
Births by sex and weight	• HMIS labour and delivery register	ANC provider
Pregnant women referred to ANC by CHWs	• Patient referral form • Community register (see Annex 4) • HMIS ANC register	CHW/ANC provider CHW ANC provider
Pregnant women completing CHW referral for ANC	• Referral form • Community register (see Annex 4) • HMIS ANC register	CHW/ANC provider CHW ANC provider
Trained CHWs	• Training report • Training database (for example, Excel)	Trainer MOH M&E officer
Trained CHWs submitting monthly report	• CHW monthly summary form	CHW supervisor
CHW stock of SP for c-IPTp	• CHW stock card (see Annex 3)	CHW
Facility stock of SP for IPTp	• Facility stock card	ANC provider

Trained CHWs visit households and should use the following tools:

- community registers (see Annex 4), to document and update a census of household members, including pregnant women in their village, and services received by date;
- pictorial CHW tally cards (see Annex 5), as an alternative to a community register; these tally cards are meant for non-literate CHWs to tally pregnant women and services received, including referral, MIP counselling, SP administration and commodity stock status, and SBCC messages (note that pictorial CHW tally cards have the limitation of unverifiable clients, and field experience has shown that, sometimes, CHWs can tally and report imaginary clients just to have something to report – this can be prevented by introducing a community register with verifiable household members);
- referral forms, to help document the referral of pregnant women to a health facility for comprehensive ANC and feedback; and
- stock cards (see Annex 3), for keeping track of SP inventory.

Facility health workers document MIP services and commodities provided in health facilities using the following tools:

- a national HMIS ANC register;
- ANC appointment cards, to document appointment schedules and the number of the SP dose received;

- an SP stock card, to document supply, distribution and the stock balance of SP; and
- completed referral forms from CHWs.

6.3 Data collection tools: revision, printing, dissemination and training

Before implementation starts, the existing data collection tools should be reviewed to ensure they can capture the selected c-IPTp indicators, or whether a revision of the tools is needed. Changes should be undertaken and well integrated into the existing system. As applicable, the revised tools should be pilot tested in a sample of CHWs and ANC clinics, and feedback should guide the finalization of the tools.

The next step is to plan for printing and distribution of the tools. This first requires quantification, taking into consideration the number of CHWs/population of pregnant women, number of health facilities/ANC clinics, and the anticipated next printing cycle. Once the number of tools required for printing is determined, the national procurement process should be followed to print and disseminate the tools and user manuals.

Once the tools are ready for use, the next important step is to train the focal M&E officers, data entry clerks and CHWs on the structure and use of the tools. For CHWs, it is recommended to hold the training in locations within the community, so that community members are aware; this can boost the future acceptance of the CHWs in the communities where they will be serving.

6.4 Data collection, analysis and use

At the end of each month, CHWs use their monthly summary form to report services provided, SP distribution and SP stock status. The report is submitted to the CHW supervisor of their supervising health facility during the monthly data validation meeting of all CHWs. The meeting is used for joint verification of the CHW reports with their records.

At the health-facility level, ANC providers document ANC attendance and services provided, including the number of pregnant women attending ANC with referral from CHWs. At the end of each month, these services are reported in the monthly HMIS summary form.

Data is analysed and interpreted at both the district and national level, and feedback and retrospective information should be made available to ANC facilities and CHWs. Facility data and c-IPTp data are analysed using tables, simple bar charts and graphs on a data visualization wall chart, provided as part of the tools to use. Alternatively, cardboard paper can be used to draw the tables, charts and graphs. The analysis of results should be communicated and discussed with ANC providers, CHWs, and community representatives such as the Chairperson or Secretary of Ward Development Committees.

The results of the data analysis should be presented and discussed during a routine scheduled meeting of facility and community participants. The discussions can reveal trends, patterns, or communities with unmet needs, and this can inform decisions for programme improvement.

To inform decisions, data must be of good quality, defined by completeness, validity, timeliness, reliability, integrity and precision. Periodic (for example, quarterly) data quality assessment is a process of verifying data quality, assessing the system that produces that data, and developing action plans to improve both data quality and the M&E system.

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Annex 1. Relevant documents from the TIPTOP implementation handbook

The following documents and appendices can be found in the *Community intermittent preventive treatment for malaria in pregnancy implementation handbook (1)*:

- Checklists for CHWs providing IPTp-SP: Appendix A, page 52; these include:
  - Checklist 1: For CHW interaction with pregnant women to give first IPTp dose
  - Checklist 2: For CHW to conduct a follow-up visit with a registered pregnant woman
- Learning objectives for the c-IPTp implementation handbook: Appendix B, page 59
- Patient education handout: Appendix C, page 65
- Job aids for providing IPTp-SP: Appendix D, page 67
- Checklist for monthly supportive supervision of CHWs: Appendix E, page 69
- Supervision checklist for the prevention of MIP in health facilities: Appendix F, page 71

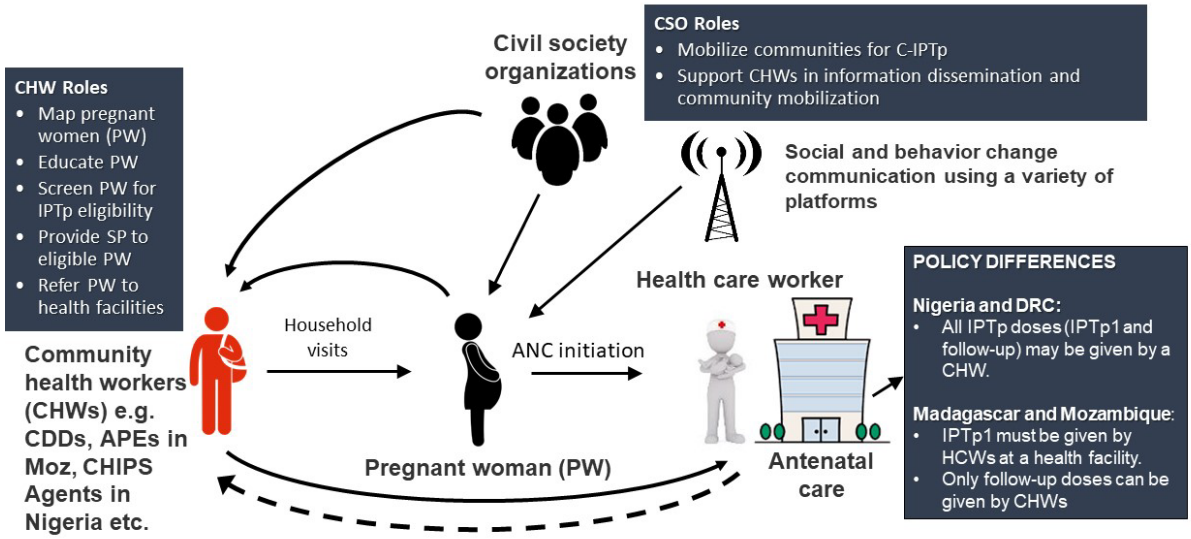
Reference

1. Community intermittent preventive treatment for malaria in pregnancy implementation handbook. Baltimore: Jhpiego; 2022 (https://www.jhpiego.org/wp-content/uploads/2022/04/TIPTOP-C-IPTp-Implementation-Handbook.pdf, accessed 23 August 2023).

Annex 2. Findings from c-IPTp pilot projects

The Unitaid-funded TIPTOP project was a large multicountry study to evaluate community-based delivery of IPTp in four malaria high-burden countries in Africa, based on health system strengthening, capacity-building and community engagement. The project was implemented between 2017 and 2022 and assessed two key outcomes: IPTp coverage and ANC attendance. The TIPTOP project aimed to increase the uptake of IPTp-3 among eligible pregnant women in designated districts in each country without reducing the number of ANC visits, and to generate evidence to determine the feasibility, acceptability and cost–effectiveness of c-IPTp. The TIPTOP project used a "no missed opportunities" approach that afforded all eligible pregnant women access to IPTp-SP, both in their communities and at ANC. The project focused on harnessing partnerships, from community to facility to national level; increasing equitable access to quality-assured SP; increasing demand among communities, health providers and governments; and utilizing data to steer the direction of the project. Fig. A2.1 summarizes the role of the different players, including CHWs and CSOs, in the implementation of c-IPTp. The TIPTOP project concluded that c-IPTp has helped to increase total IPTp coverage significantly without negatively affecting ANC attendance (see Fig. A2.2). More information on the TIPTOP project and its findings and results can be found in the TIPTOP implementation handbook, the end-of-grant evaluation report and on the TIPTOP legacy webpage (the Measurement and Learning section lists all published research articles resulting from the TIPTOP project) (1–3).

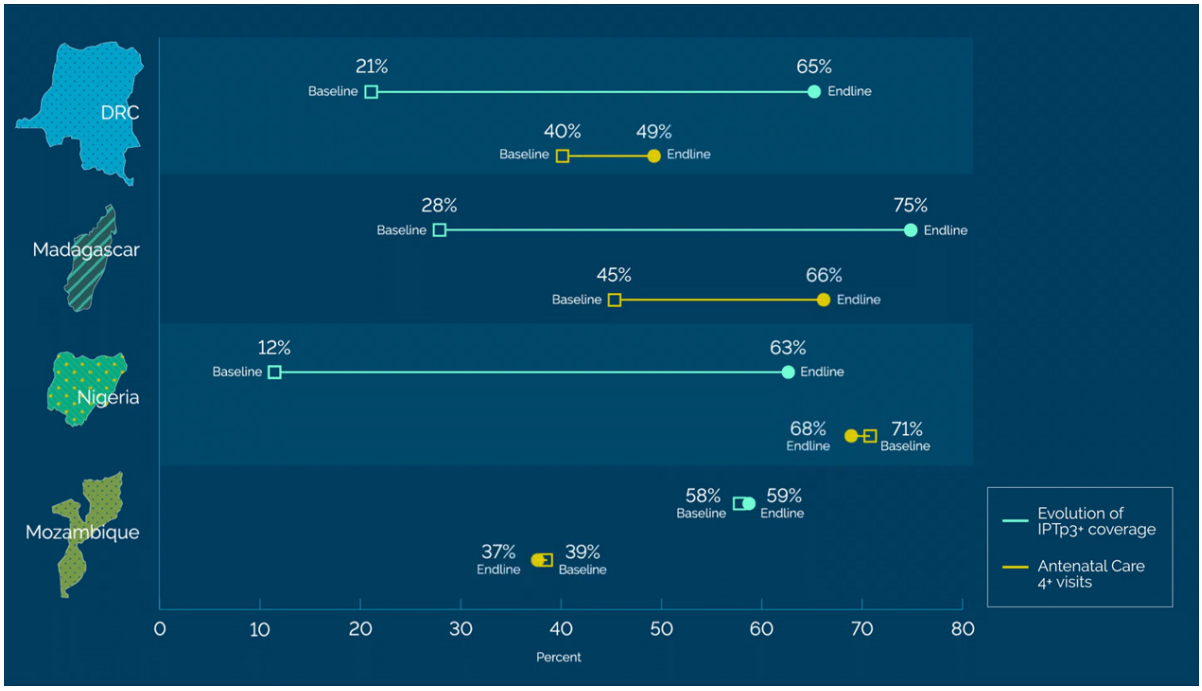
Fig. A2.1. Overview of the TIPTOP project's "no missed opportunities" approach



C-IPTp: community-based intermittent preventive treatment of malaria during pregnancy; SP: sulfadoxine-pyrimethamine; ANC: antenatal care; CDD: community-directed distributor; APE: agentes polivalentes elementaires; Moz: Mozambique; CHIPS: community health influencers, promotors and service; DRC: Democratic Republic of the Congo; IPTp1: first dose of IPTp-SP; HCW: healthcare worker.

Source: adapted from the *Community intermittent preventive treatment for malaria in pregnancy implementation handbook (1).*

Fig. A2.1. TIPTOP baseline and endline comparison of IPTp-3+ coverage and ANC-4+ attendance



DRC: Democratic Republic of the Congo; IPTp3+: three and more doses of SP for IPTp; ANC4+: four and more ANC visits.

Source: Jhpiego *(3)*.

Further studies have shown that the inclusion of community-based programmes can substantially increase effective access to malaria prevention and increase access to primary health care in general. It can also improve ANC attendance, particularly when combined with supply side interventions *(4–6)*. Additional details on experiences made in Burkina Faso, Malawi, Senegal and Sierra Leone are available in the *Technical consultation to assess evidence on community-based delivery of intermittent preventive treatment in pregnancy for malaria (7–9)*.

References

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Annex 3. Sample CHW stock card

Community Directed Distributors' (CDDs) Stock Card

State_____LGA_____Health Facility_____

Village_____ Name of CDD _____

[SP(SULFADOXINE 500 mg + PYRIMETHAMINE 25 mg)] : Packaging (Strip of_1x3_ tablets = 1 Dose); (Quantity = # Doses)

S/N	Date	From/To	Quantity Received	Quantity Issued	Losses	Balance	Signature/ Remarks

LGA: local government area; S/N: Serial number.

Source: adapted from Nigeria's national HMIS (not available online).

Annex 4. Sample community/village register

State _____ LGA _____ Ward _____ Supervisory health facility _____

Community _____ Village _____ Name of CDD _____ Reporting year _____ Month _____

Serial no.	Date of registration/visit *(dd/mm/yyyy)*	Household ID *(number, name of head, or whatever ID agreed upon)*	Name of individual	Phone number	Age in years *(write months for children under 1 year)*	Sex *(Write male or female)*	For female only		New pregnant women	Referral		Date of visits to a pregnant woman before her delivery							*IPTp-SP received						Delivery	
							Is she pregnant?		IF she is newly identified as pregnant in this reporting month, write date	Referred for ANC? (YES/NO)	Write date she returned referral form signed by ANC provider	Record each date you re-visited a pregnant woman after registration *(please insert date)*							Please insert date						Date	Sex
							If YES, tick (√) under YES and insert date					2nd visit	3rd visit	4th visit	5th visit	6th visit	7th visit	8th visit	IPTp-1	IPTp-2	IPTp-3	IPTp-4	IPTp-5	IPTp-6		
							Yes	Date																		

LGA: local government area; PW: pregnant woman; CDD: community directed distributor.

Name of reporting CDD: _____ Signature/date: _____ / _____ Name of verifying officer _____

Source: TIPTOP project/Jhpiego.

Annex 5. Community care of pregnant women tally card

Community care of Pregnant women Tally Card

Page 1 of 4

Volunteer health worker activity tally card

Date.....

Month.....

Year.....

Volunteer health worker's Name.....

Community/Village.....

Facility volunteer is assigned.....

Ward name.....

LGA.....

State.....

Volunteer's Unique ID Number.....

Community Care of Pregnant Women and Deliveries

Ante-natal care		Age Category		TBA	FBM	SBA	CBHVs	Mothers who deliver independently at home	Total
B1  Pregnant women	New identified	Adolescent Girls							
		Adult Women							
	Follow up	Adolescent Girls							
		Adult Women							
B2  Deliveries		Adolescent Girls							
		Adult Women							
B3  Live Births		Boys							
		Girls							

Community care of Pregnant women Tally Card

Page 2 of 4

Community Care of Pregnant Women and Deliveries

	Age Category		TBA	FBM	SBA	CBHVs	Mothers who deliver independently at home	Total
B4  Still Births								
B5  Premature babies/small babies seen and referred (Low birth Weight <2.5kg)	Boys							
	Girls							
B6  Babies placed in skin to skin/ Kangaroo position & referred	Male							
	Female							
B7  Clients that received Family Planning services	Adolescent Girls							
	Adult Women							
B8  Pregnant women referred for ANC for the first time by Community Volunteer	Adolescent Girls							
	Adult Women							

Community care of Pregnant women Tally Card

Page 3 of 4

Community Care of Pregnant Women and Deliveries

	Age Category		TBA	FBM	SBA	CBHVs	Mothers who deliver independently at home	Total
B9  Pregnant women referred for ANC for the follow up by Community Volunteer	Adolescent Girls							
	Adult Women							
B10  Pregnant women referred for tetanus toxoid	Adolescent Girls							
	Adult Women							
B11  Number of women seeking care and treatment for Urine/Stool incontinence referred	Adolescent Girls							
	Adult Women							
B12  Pregnant women referred for IPT	Adolescent Girls							
	Adult Women							
B13  Pregnant women who took CIPT1	Adolescent Girls							
	Adult Women							

Community care of Pregnant women Tally Card

Page 4 of 4

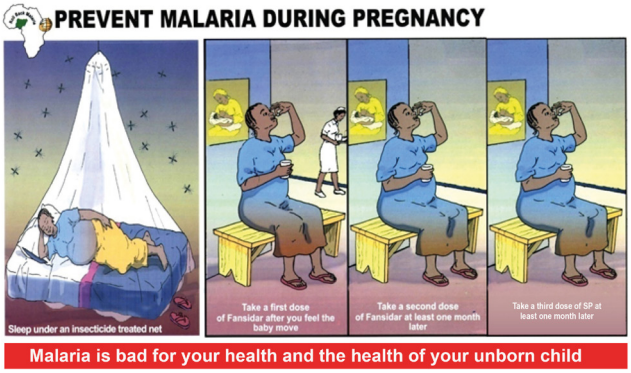
Community Care of Pregnant Women and Deliveries

	Age Category		TBA	FBM	SBA	CBHVs	Mothers who deliver independently at home	Total
B14  Pregnant women who took CIPT2	Adolescent Girls							
	Adult Women							
B15  Pregnant women who took CIPT3+	Adolescent Girls							
	Adult Women							
B16  Pregnant women given Misoprostol	Adolescent Girls							
	Adult Women							
B17  Pregnant women referred for postnatal care within 2 days after delivery	Adolescent Girls							
	Adult Women							
B18  Babies referred for postnatal care within 2 days after delivery	Adolescent Girls							
	Adult Women							

LGA: local government area; TBA: traditional birth attendant; FBM: Faith Based Mission facility or workers; SBA: skilled birth attendant; CBHV: community-based health volunteer; ANC: antenatal care; IPT: intermittent preventive treatment; CIPT1: first dose of community-based IPT; CIPT2: second dose of CIPT; CIPT3+: three or more doses of CIPT.

Source: reproduced by permission of Nigeria's national HMIS (not available online).

Annex 6. Sample patient card



Name of Health Facility:

MINISTRY OF HEALTH

PATIENT'S REFERENCE CARD

Name:_____

Hospital No:_____

Date:_____

Date of patient contact	**Referred from CHW** (✓)	**Service received** Write (IPTp-1, IPTp-2, IPTp-3, IPTp-4, etc. or other service given)	**Where?** Write A (ANC) or H (Home)	**Next ANC appointment**		
				Date	**Time**	**Signature**

Note: **Total IPTp doses** given as at the time of childbirth: _____

Total no. of patients contacts at the time of childbirth: _____

CHW: community health worker; IPTp-1: first dose of intermittent preventive treatment of malaria in pregnancy; IPTp-2: second dose of IPTp; IPTp-3: third dose of IPTp; IPTp-4: fourth dose of IPTp; ANC: antenatal care.

Source: reproduced by permission of TIPTOP Nigeria (not available online).

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