





## 2016 WHO Antenatal Care Guidelines

Malaria in Pregnancy Frequently Asked Questions (FAQ)

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#### Introduction

In 2016, the World Health Organization (WHO) published <u>Recommendations on Antenatal Care for a Positive Pregnancy Experience</u> (WHO 2016), which outlines a new set of evidence-based global guidelines on recommended content and scheduling for antenatal care (ANC). These recommendations are the first set of ANC guidelines created under WHO's current approved process for development of clinical guidelines.

The 2016 ANC guidelines include a significant new recommendation that pregnant women have eight contacts with the health system during each pregnancy. Depending on the country context, the definition of "contact" may include the more familiar model of clinic-based ANC visits, as well as ANC care and/or counseling sessions for pregnant women at the household and community levels. WHO, the Roll Back Malaria - Malaria in Pregnancy Working Group, and the Maternal and Child Survival Program (MCSP) have developed a summary of these guidelines and the implications for delivery of intermittent preventive treatment of malaria in pregnancy (IPTp) with sulfadoxime pyrimethamine (SP), Implementing Malaria in Pregnancy Programs in the Context of World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience (WHO 2017). Table 1 compares the contact schedules of the previously recommended focused ANC (FANC) visit model and the newly recommended ANC model. WHO and partners recommend that countries consider adding a visit between 13 and 16 weeks to ensure early delivery and optimal coverage of IPTp-SP.

Table I. WHO recommended ANC contact schedule

WHO FANC model	2016 WHO ANC model	
First trimester		
Visit 1: 8–12 weeks	Contact 1: up to 12 weeks	
Second trimester		
Visit 2: 24-26 weeks	Contact 2: 20 weeks Contact 3: 26 weeks	
Third trimester		
Visit 3: 32 weeks Visit 4: 36–38 weeks	Contact 4: 30 weeks Contact 5: 34 weeks Contact 6: 36 weeks Contact 7: 38 weeks Contact 8: 40 weeks	
Return for delivery at 41 weeks if not given birth.		

This FAQ addresses commonly asked questions about the implementation of IPTp programs in the context of the 2016 ANC recommendations, as well as reminders about technical considerations for IPTp programs. Readers should also refer to the key underlying documents, specifically the WHO Guidelines for Treatment of Malaria, third edition (WHO 2015a) and the <u>WHO Policy Brief for the Implementation of Intermittent Preventive Treatment of Malaria in Pregnancy Using Sulfadoxine-Pyrimethamine (IPTp-S)</u> (WHO 2014). In addition to IPTp, pregnant women should be encouraged to sleep under an insecticide-treated net (ITN) every night.

#### **Frequently Asked Questions and Answers**

## Q1. WHO now refers to "contact" instead of "visit." What does this difference in terminology mean?

A1. The recommendations use "contact" instead of "visit" to imply an active connection between a pregnant woman and a health care provider that is not implicit with the word "visit." When operationalizing this recommendation, "contact" can be adapted to local contexts through community outreach programs and lay health worker involvement (WHO 2016). Under the new recommendations, a routine ANC visit is considered a contact.

## Q2. WHO recommends eight ANC contacts, although many African countries are still struggling to achieve high coverage of four ANC visits. How can we address barriers to attainment of this new standard?

A2. Focus on tackling the barriers that can be impacted. For example, clinicians should counsel women on the importance of attending all scheduled contacts and help them plan for scheduled clinic-based ANC. At the community level, community health workers should emphasize the importance of attending ANC as early as possible in pregnancy, communicate reported barriers up through the health system to facilitate health systems' attention to these issues, and encourage eight ANC contacts in messaging to community members. Emphasis may be placed on ensuring reports are submitted in a timely manner, resupplying ANC clinics with quality-assured SP and other ANC commodities, and ensuring appropriate staffing to deliver the recommended number of ANC contacts. Remember that the experience of care plays a significant role in a woman's motivation to attend ANC; efforts to provide respectful care and reduce disrespect and abuse in health care settings can greatly enhance ANC uptake and attendance. Furthermore, ANC should be evidence-based and address the information and counseling needs of women. Shorter wait times, emphasis on the benefits of both community-based and clinic-based ANC contacts, and enhanced communication to clients of days and times for ANC can also foster the sense that women's time and effort are well spent on accessing ANC services.

## Q3. How does the suggested schedule of ANC contacts fit with the recommended timing of IPTp?

A3. The schedule of eight contacts outlined in the 2016 WHO ANC recommendations (Table 1) is intended to be adapted to national and regional contexts when it is adopted at country level. As such, countries can modify the proposed schedule of contacts to meet contextual demands and schedules for intervention delivery through the ANC platform. To prevent the irreversible negative consequences of malaria during pregnancy, it is critical to encourage pregnant women to sleep under an ITN during their entire pregnancy, and to start an IPTp regimen as early as possible in the second trimester. Because the period between 13 and 20 weeks—when the placenta is forming and parasite densities are highest—is critical, WHO and partners recommend initiating malaria prevention efforts beginning at 13 weeks to achieve major benefit. For maximum impact, pregnant women should have contact with a health care provider between 13 and 16 weeks gestation to ensure timely access to the first dose of IPTp. Ideally, they will receive a second dose of SP one month later to cover this critical period. The example contact schedule in Table 2 accounts for the recommended timing of each dose of IPTp. Any revisions to national ANC guidelines should include provisions to promote early attendance at ANC to ensure that women complete the recommended contacts during the pregnancy.

Table 2. WHO recommended ANC contact schedule to include contact for early IPTp initiation#

	iming of Contact	Dose	MiP-related Interventions and Considerations during ANC Contacts
1.	Up to 12 weeks		<ul> <li>Register pregnant women, provide ITNs, and counsel on their use. Screen for HIV.</li> <li>Administer 30 to 60 mg of elemental iron and 400 µg (0.4 mg) of folic acid daily. These supplements should be given as early as possible in pregnancy and continue throughout pregnancy.</li> </ul>
	13–16 weeks	IPTp-SP dose I (additional contact)	<ul> <li>Counsel to return for a visit at 13 to 16 weeks (see contact 1a below) to receive the first dose of IPTp-SP (as directed by national guidelines).*</li> <li>Counsel on prompt diagnosis and effective treatment/malaria case management during pregnancy.</li> </ul>
2.	20 weeks	IPTp-SP dose 2	Remember:  • Do not administer IPTp-SP before week 13 of pregnancy.
3.	26 weeks	IPTp-SP dose 3	<ul> <li>Administer the first IPTp-SP dose as early as possible in the second trimester to fully benefit from the protective capacity in this critical period of</li> </ul>
4.	30 weeks	IPTp-SP dose 4	<ul> <li>pregnancy. †</li> <li>Administer the second dose of IPTp-SP I month later.</li> </ul>
5.	34 weeks	IPTp-SP dose 5	<ul> <li>Administer the following doses of IPTp-SP starting from the scheduled contact at 20 weeks, observing at least 1-month intervals between SP doses.</li> </ul>
6.	36 weeks	No SP (if last	<ul> <li>SP can be safely administered from the beginning of the second trimester until the time of delivery.</li> </ul>
		<1 month ago)	<ul> <li>One full dose of IPTp-SP consists of 1,500 mg/75 mg SP (i.e., three tablets of 500 mg/25 mg SP).</li> </ul>
7.	38 weeks	IPTp-SP dose 6 (if no dose in last month)	<ul> <li>Provide IPTp-SP by directly observed treatment.</li> <li>Pregnant women on co-trimoxazole should not receive IPTp-SP due to an increased risk of adverse events when both drugs are given in parallel.</li> </ul>
8.	40 weeks		<ul> <li>Continue to administer 30 to 60 mg of elemental iron and 400 mcg (0.4 mg) of folic acid.</li> </ul>
			Continue counseling as above.

Pregnant women should receive MiP interventions as appropriate, even when they come at weeks not designated in the contact schedule.

Despite the known side effects associated with sulfonamides, SP for IPTp is 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 side effects tend to decrease with the administration of further doses (Clerk et al. 2008, Tagbor et al. 2006). Side effects should be discussed openly and managed in the ANC.

# This schedule is a suggested adaptation of the WHO ANC schedule for countries implementing IPTp; training should highlight that women attending off-schedule should be attended to appropriately, and that it is the interval, rather than the specific weeks, that are most critical

† Pregnant women should receive their first dose of IPTp-SP as early as possible at the beginning of the second trimester, defined as 13 weeks gestation (i.e., 12 completed weeks or 13 weeks and 0 days).

<sup>\*</sup> It is recommended that the first dose of IPTp-SP be given as early as possible in the second trimester of pregnancy to ensure optimal protection from malaria for the mother and her baby. However, pregnant women who come later in pregnancy can and should receive their first dose anytime (as long as it is not in the first trimester), with following doses being given at least I month apart. When malaria-endemic countries are planning their ANC programming, they may wish to add another contact to allow for monthly dosing of IPTp-SP.

#### Q4. Are all contacts expected to happen at the facility or is contact at the community level included?

A4. This depends on each country's policies and the resources available, especially the existing community health structures. Contacts at the community level may be in the form of outreach by facility-based providers and health worker involvement in person-to-person health promotion activities, with a focus on early ANC attendance, positive health behaviors in pregnancy, and the benefits of birth in a facility setting. Provision of recommended interventions (including iron and folic acid supplementation, IPTp-SP, and ITNs) at the community level will depend on the capacity of the health worker cadre and national policies. Additional information can be found in "Table 2: The 2016 WHO ANC model for a positive pregnancy experience: recommendations mapped to eight scheduled ANC contacts" in the WHO recommendations (WHO 2016, p. 108).

### Q5. If IPTp is provided at both community and facility level, what steps can be taken to ensure it is captured in the facility ANC register for reporting purposes?

A5. Some countries are currently piloting delivery of IPTp at the community level in addition to delivery at ANC. The evidence from these countries will help to determine if this approach will increase IPTp coverage without detracting from ANC. For countries considering this approach, **providers doing community-level outreach should note on the woman's ANC card any care or medications,** including the estimated gestational age at time of intervention, and include this information in routine reports to be entered in facility clinic records and registers. To the extent possible, stakeholders should stay engaged in periodic processes to update health information systems that can capture MIP interventions to ensure inclusion of both facility-and community-delivered interventions.

# Q6. WHO recommends IPTp in sub-Saharan African countries with moderate to high transmission. Should countries that reduce transmission to low levels as a result of successful control strategies discontinue IPTp?

A6. The threshold level of malaria transmission below which IPTp is no longer cost-effective has not been identified to date. Therefore, in areas where IPTp has been implemented and control strategies have successfully reduced transmission to low levels, WHO recommends continuing to provide IPTp until the area approaches interruption of transmission (WHO 2015b). Because of natural fluctuations in the incidence of malaria from year to year, the low cost of IPTp, and the operational challenges of reintroducing IPTp after withdrawal, countries should continue to provide IPTp until information is available that would support more specific guidelines (WHO 2014).

#### Q7. What is recommended for African countries that experience SP resistance while still being highly and moderately malaria-endemic?

A7. **SP** is the only medicine currently recommended for IPTp, and it is recommended even in areas with high-level SP resistance. IPTp-SP is highly cost-effective in preventing the adverse consequences of malaria on maternal and fetal outcomes, and remains effective in areas where quintuple-mutant haplotypes of *Plasmodium falciparum* to SP are highly prevalent (WHO 2015b). Although alternative medicines are under investigation, none have yet proven superior to SP (Desai et al. 2015, Kakuru et al. 2016). Further research in this area is ongoing, particularly with regard to the impact of sextuple mutations.

## Q8. Many women coming to ANC are already infected with malaria. Is screening for infection recommended at first contact so a fully effective medicine can be given to clear parasitemia?

A8. Because intermittent screening and treatment has not been shown to be superior to IPTp-SP, and there have been no studies evaluating the added benefit of screening at first antenatal visit in conjunction with IPTp-SP, WHO does not currently recommend screening asymptomatic pregnant women (WHO 2015b). Nonetheless, some countries have policies advocating screening for malaria at first ANC, particularly in Southeast Asia where IPTp is not implemented. In line with the recommended three-pronged WHO intervention package (WHO 2014), all suspected cases of malaria among women seeking ANC should be promptly tested, and those confirmed via rapid diagnostic test (RDT) or microscopy should be treated with an effective antimalarial based on national policies and guidelines.

In areas with sextuple-mutant haplotypes of *P. falciparum*, decreased birthweight has been reported. In these areas, one potential strategy, which requires piloting, is to provide a single RDT screening and artemisinin-based combination therapy (ACT) treatment at the first ANC visit in addition to the continued delivery of IPTp-SP (WHO 2015b).

#### Q9. Which dose of folic acid can be given together with IPTp?

A9. Folic acid requirements increase in pregnancy because of the rapidly dividing cells in the fetus and elevated urinary losses. **WHO** recommends iron and folic acid supplementation in pregnant women at a dose of 30–60 mg of elemental iron plus 0.4 mg of folic acid daily. Every effort should be made to ensure that low dose folic acid (0.4 mg or 400 micrograms) is available and provided as part of routine ANC (WHO 2014), as this dose does not interfere with the antimalarial effect of SP, and can be given concomitantly with IPTp. In some countries, folic acid is manufactured in 5 mg tablets. Although this dose might be required for special medical indications, folic acid doses at or above 5 mg should not be given together with SP, as this counteracts the antimalarial efficacy of SP.

More information is available in MCSP's brief Controlling Maternal Anemia and Malaria (MCSP 2015).

## Q10. What is the recommendation for SP in pregnant women who have sickle cell disease and are already on high dose folic acid?

A10. The term "sickle cell disease" (SCD) describes a group of inherited red blood cell disorders. Pregnancy can worsen SCD manifestations, and SCD can worsen pregnancy outcomes. Daily folic acid supplementation (1 mg or 5 mg oral dose) is often prescribed for women with SCD before and during pregnancy to help them replenish stores lost due to the hemolysis (destruction of red blood cells) caused by SCD.

Malaria prevention is important for people living with SCD, since malaria can trigger sickle cell crisis. However, high dose folic acid regimens (5 mg daily) may decrease the effectiveness of IPTp-SP. Unfortunately, there is no global consensus on the optimal regimen for malaria prophylaxis or folic acid supplementation for pregnant women living with SCD in areas with moderate to high malaria transmission, due to a lack of research. However, **daily folic acid doses of 1 mg have not been shown to interfere with the efficacy of SP**. Therefore, an argument can be made in favor of using 1 mg of folic acid daily in women with SCD (Mbaye et al. 2006). Because these women are at higher risk for pregnancy complications, they should receive access to specialty care in both obstetrics and hematology, as available, so that specialists can make clinical decisions that consider each woman's risks and clinical care needs. Pregnant women with SCD should be encouraged to sleep under an ITN every night.

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