CURRENT EFFICACY OF SULPHADOXINE-PYRIMETHAMINE FOR INTERMITTENT PREVENTIVE TREATMENT OF MALARIA DURING PREGNANCY IN DAR ES SALAAM

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MSc. Clinical Pharmacology Dissertation
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By

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A Dissertation Submitted in (Partial) fulfillment of the requirement for the Degree of Master of Science in Clinical Pharmacology of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that they have read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation titled: **Current Efficacy of SP for Intermittent Preventive Treatment of Malaria During Pregnancy in Dar es salaam,** in (Partial) fulfillment of the requirement for degree of Master of Science in Clinical Pharmacology of the Muhimbili University of Health and Allied Sciences.

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Date: ……

DECLARATION AND COPYRIGHT

I, **Amiri Rajabu Iddi**, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature……. Date……..

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DEDICATION

This dissertation is dedicated to my mother, Zainabu Mbwana, my wife Mwanaisha A. Sampat and my children, Kaleya, Kasana and Karingo. You are the reason why I keep on trying hard. May God bless you

ABSTRACT

Background

Intermittent preventive treatment of malaria in pregnancy with Sulphadoxine-Pyrimethamine (IPTp-SP) reduces incidence of malaria, asymptomatic parasitaemia and anaemia, thus improving pregnancy outcome particularly by increasing birth weight. The strategy is widely used in malaria endemic countries. Currently, SP is probably the best available drug for IPTp and is reserved for the purpose in many countries. This reduces sustained drug pressure to *P.falciparum*, which may increase the level of SP resistance. However, there are anecdote reports that SP continues to be used in non-pregnant patients in Tanzania. Indeed, at least one meta-analysis has indicated that the benefit of SP for IPTp may be declining.

Objective: To determine the current efficacy of SP for intermittent preventive treatment of malaria during pregnancy in Dar es Salaam.

Methodology

Two doses of SP were given to 310 pregnant women according to national guidelines. All participants were followed up and evaluated at least once at week 28 onwards and at delivery.

Results

A total of 310 pregnant women with a mean age (±SD) 26.4 (±0.3) years were enrolled. The proportion of low birth weight was not different from previous studies (6.5%versus 7.3 %; P = 0.721). The proportion of subjects with peripheral parasitemia at delivery was 2% (6/296). None had severe anemia or clinical malaria at delivery, and only six women (2%) had clinical malaria during follow up.

Conclusions

Efficacy of SP for IPTp seems to be at a level similar to what it was about ten years ago. Our data are reassuring that the efficacy of IPTP-SP is still high and the Ministry of Health and Social Welfare may not need to change the policy for treatment of malaria in pregnancy at the moment. However, regular monitoring is essential for timely corrective measures when the need arises.

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LIST OF ABBREVIATIONS

AL	Artemether-lumefantrine
ANC	Antenatal care
Bs	Blood smear
Dhfr	Dihydrofolate reductase
Dhps	Dihydroptoriate synthase
DOT	Direct observed therapy
FANC	Focused antenatal care
Hb	Haemoglobin
HIV	Human immunodeficiency virus
IPTp	Intermittent preventive treatment during pregnancy
LBW	Low birth weight
ITNs	Insecticide treated nets
LLITN	Long lasting insecticide treated nets
LMP	Last menstrual period
MoHSW	Ministry of health and social welfare
NMCP	National malaria control program
SP	Sulphadoxine-pyrimethamine
WHO	World health organization

CHAPTER ONE

1.0 INTRODUCTION

Malaria infection during pregnancy is a major public health problem in tropical and subtropical regions throughout the world (1). In most malaria endemic areas of the world, pregnant women are the main adult risk group for malaria (2). Malaria during pregnancy has been most widely evaluated in the sub-Saharan Africa where 90% of the global malaria burden occurs (2). The burden of malaria infection during pregnancy is caused chiefly by *Plasmodium falciparum,* the most common malaria species in Africa (2). The impact of the other three human malaria parasites (P. *vivax, P. malariae,* and *P. ovale)* is less clear. Every year at least 30 million pregnancies occur among women in malaria endemic areas of Africa, most of whom reside in areas of relatively stable malaria transmission (2).

The symptoms and complications of malaria during pregnancy differ with the intensity of malaria transmission and thus with the level of immunity the pregnant woman has acquired (2). While these settings are presented as two distinct epidemiologic conditions, in reality the intensity of transmission and immunity in pregnant women occurs on a continuum, with potentially diverse conditions occurring within a country (3,4).

In areas of epidemic or low (unstable) malaria transmission**,** women have not acquired any significant level of immunity and usually become ill when infected with *P. falciparum* malaria (5). Pregnant women resident in areas of low or unstable malaria transmission are at a two-or threefold higher risk of developing severe disease as a result of malaria infection than are non-pregnant adults living in the same area (5). In these areas maternal death may result either directly from severe malaria or indirectly from malaria-related severe anemia. In addition, malaria infection of the mother may result in

a range of adverse pregnancy outcomes, including low birth weight (LBW), spontaneous abortion and neonatal death (1).

In areas of high and moderate (stable) malaria transmission, most adult women have developed enough immunity that, even during pregnancy, *P. falciparum* infection does not usually result in fever or other clinical symptoms. In these areas, the principal impact of malaria infection is associated with malaria-related anaemia in the mother and with the presence of parasites in the placenta (5). The resultant impairment of fetal nutrition contributing to low birth weight is a leading cause of poor infant survival and development. In areas of Africa with stable malaria transmission, *P. falciparum* infection during pregnancy is estimated to cause as many as 10 000 maternal deaths each year, 8% to 14% of all low birth weight babies, and 3% to 8% of all infant deaths (3)

Despite the toll that malaria exerts on pregnant women and their infants, until recently this was a relatively neglected problem, with less than 5% of pregnant women having access to effective interventions (1).

The promising news is that during the past decade potentially more effective strategies for the prevention and control of malaria in pregnancy have been developed and demonstrated to have a remarkable impact on improving the health of mothers and infants. Malaria prevention and control during pregnancy has a three-pronged approach: (6) Apart from IPTp-SP the use of ITN and residual spraying also prevent mosquito bite and hence reduce malaria transmission in pregnant women and the effects of malaria in pregnancy.

1.1 **Prevention of malaria in pregnancy**

Currently, IPTp-SP has been rated as having the most favorable cost–benefit profile because of its relatively low cost, high compliance, and efficacy in reducing maternal anemia and LBW. However, implementation of IPTp in most settings is limited by

social, cultural, economic and operational challenges despite good coverage of antenatal services.

In addition, the spread of resistance in some areas has raised questions as to whether this was the most appropriate approach for malaria prevention in African pregnant women (5).

WHO defined IPTp as the delivery of two doses of an effective anti-malarial drug to pregnant women at the beginning of the second and third trimester irrespective of the presence of signs for malaria infection.

IPTp with SP reduces the incidence of LBW, pre-term delivery, intrauterine growth-retardation and maternal anemia. However, the public health benefits of IPTp may be declining due to SP resistance (4).

The usual practice involves providing all pregnant women with at least two preventive treatment doses of an effective ant malarial drug during routine antenatal clinic visits. This approach has been shown to be safe, inexpensive and effective. A study in Malawi evaluating IPT showed a decline in placental infection (32% to 23%) and in the number of low birth weight babies (23% to 10%) (7). It also found that 75% of all pregnant women took advantage of IPTp when offered.

1.2 PROBLEM STATEMENT

Since 2006 the use of Artemether-Lumefanntrine (AL) has been recommended as a first line drug for treatment of uncomplicated malaria in Tanzania due to increased resistance of malaria parasites to SP (2).

AL is not used for treatment of malaria in pregnant women due to risk of teratogenicity especially in the first trimester. The drug has been proven to cause fetal resoption, malformation and even abortion in rats. For this reason it is not recommended for the use on intermittent preventive treatment against malaria in pregnancy (6). By contrast SP is relatively safe in pregnancy and is only drug for IPTp. In order to delay development and spread of resistance due to high drug pressure National treatment guideline (Tanzania) recommend AL for treatment of uncomplicated malaria and SP is the only drug used for IPTp. Unfortunately, this is not the case in the community, the drug is still available in private health facility and it is used against national policy for treatment of malaria.

For example in a situational analysis done in Dar es Salaam by the author ten private pharmacies and three dispensaries were visited and all had SP as one of their ant malaria in stock**.** This may continue to spread parasite resistance. Increased use of SP by pregnant women for IPTp, though to smaller extent also contribute to increased drug pressure on parasite and may contribute to increased resistance.

The use of IPTp-SP in Tanzania was adopted about ten years ago after some studies conducted in other countries with similar malaria burden and recommendation from WHO. It is wise to do formal study to evaluate the situation in Tanzania by finding the current efficacy of SP for IPTp.

1.3 STUDY RATIONALE

Given the likelihood of increased development and spread of resistance of SP by *P falciparum,* decrease in efficacy of SP in the intermittent preventive treatment of malaria during pregnancy is a real possibility.

For example, in a systematic review done by Chico and Chandramohan from London School of hygiene and Tropical Medicine in July 2011, it was found that, two doses of SP-IPTp showed decreased protective effect against low birth weight (8). Furthermore, presence of quintuple mutant (dhfr N51I/C59R/S108N and dhps A437G/K540E) combined genotype, which was found to increase from 7% from the year 2000 to 84% in the year 2009 in western Kenya has contributed much to failure of SP in combating *P. falciparam* malaria and might have worsened the outcome of pregnancy (9).

In Tanzania, two doses of SP-IPTp are recommended according to the national policy, therefore it is important to determine the current efficacy of SP for IPTp and see if the current practice continues to offer benefit to pregnant women in our country. Determining the current efficacy of SP in pregnant women could help National Malaria Control Program decide whether to continue using with the drug or switch to another drug with more safety and efficacy.

1.4. RESEARCH QUESTION

We wanted to find out whether there has been a decrease in the proportions of low birth weight infants born to women on IPTp-SP, proportion of severe maternal anemia at delivery of women on IPTp-SP and peripheral parasitemia at delivery of women on IPTp-SP as compared to previous studies.

1.5 HYPOTHESIS

Due to current trend of resistance of *Plasmodium falciparum* to SP, the drug is no longer effective in intermittent preventive treatment of malaria during pregnancy.

1.6. OBJECTIVES

1.6.1. Broad objective

To Estimate current efficacy of SP for intermittent preventive treatment of malaria in pregnant women in Dar es salaam.

1.6.2 Specific objectives

1.6.2.1 To determine the proportion of low birth weight (body weight < 2500 g) infants born to SP-treated pregnant women

1.6.2.2 To determine the proportion of SP-treated pregnant women with severe anemia (hemoglobin < 7 g/dL) at delivery

1.6.2.3 To determine proportion SP-treated pregnant women with peripheral parasitemia at delivery

1.6.2.4 To determine incidence of clinical malaria in SP-treated pregnant women

1.6.2.5 To determine the proportion of SP-treated pregnant women who develop adverse events after IPTp-SP.

CHAPTER TWO

2.0 LITERATURE REVIEW

Intermittent preventive treatment of malaria during pregnancy with sulphadoxine-pyrimethamine (IPTp-SP) helps to improve the outcome of pregnancy. The benefit occurs to both pregnant mother and her unborn child (6). A study which was carried out in central Mozambique to check effectiveness of the intermittent preventive treatment of malaria during pregnancy with SP revealed that the prevalence of severe anaemia (haemoglobin <7.0 g/dL) was 3.4% in women who had not received SP and 0.8% in women who had received 2 doses or more of SP (4). Maternal peripheral malaria parasitemia was present in 39.3% of women who had not received SP, and 7.5% in women who had received two doses. Therefore SP use is associated with significantly higher haemoglobin levels and lower parasitaemia (4), and thus better pregnancy outcome.

There has been a long time concern that malaria parasite resistance towards SP is on the increase, for example, in North-eastern Tanzania resistance was noted in the early nineteen nineties (10). Emergence and spread of Plasmodium falciparum parasite resistant to sulfadoxine and pyrimethamine (SP) poses a serious public health problem. Resistance is mainly caused by point mutations in dihydrofolate reductase (pfdhfr) and dihydropteroate synthase (pfdhps), the two key enzymes in the folate biosynthetic pathway. The use of microsatellite markers flanking pfdhfr has recently shown that the invasion of limited resistant lineages may explain the widespread SP resistance in many endemic regions. In Africa, however, multiple indigenous origins of pfdhfr triple mutants have been demonstrated. The increased and possible spread of SP resistance by *P. falciparum* is likely to affect the benefit which pregnant women are likely to have after the use of IPTp-SP.

Number of doses of SP given for IPTp differs between countries, for example in Tanzania two doses are given during the whole period of pregnancy (11). Other country

like Mozambique two to three doses are given and monthly IPTp was practiced in central Kenya (9, 11).

A study was carried out in Zambia to find out the effect of dosing frequency in intermittent preventive treatment against malaria during pregnancy using SP and results were different from those of two the previous studies carried out in Kenya and Malawi. Studies in Kenya and Malawi demonstrated that monthly IPTp-SP was more effective than two-dose IPTp-SP in HIV–infected and HIV-seronegative pregnant women (12). In the Zambian study it was revealed that there were no differences between monthly IPTp and standard two-doses of IPTp-SP in placental malaria by histopathology or placental parasitemia. There also were no differences in maternal anemia, stillbirths, preterm delivery, LBW, or all-cause mortality of infants at six weeks of age (12).

In Tanzania two doses of IPTp-SP are given to align with WHO recommendation where it is believed that there is no significant difference between two doses as compared to three doses and monthly IPTp-SP. (2)

SP remains to be the drug of choice for IPTp because it is relatively safe and affordable, therefore easier for health systems in many sub Saharan countries to afford buying and subsidize the drug for pregnant women so that they can take them free of charge. Apart from being of affordable cost SP also has tolerable side effects to pregnant woman and her un-born child. Serious side effects like Steven Johnson syndrome occurs in very rare situation and no other serious side effects are known to occur to the pregnant woman and unborn baby after second trimester. (13)

Apart from improving pregnancy outcome IPTp SP also reduces malaria burden during pregnancy and therefore save the limited budget of health services in many sub-Saharan countries. For example in Gabon, a study was done in order to see the burden of malaria during pregnancy at the time of IPTp-SP implementation and indeed, in the IPTpSP plus bed net group, parasitaemia and prevalence of maternal and placental *P. falciparum* infection were lower in multigravidae women. (6) This could be explained by the level

of parasite-specific immunity that is known to be stronger in multigravidae compared with primigravidae.

2.1 Malaria in pregnancy, situation in Tanzania

The MoHSW's stand on Malaria in Pregnancy is that pregnant women with symptomatic acute malaria are a high-risk group, and they promptly receive effective anti-malarial treatment. The drug of choice for IPTp in Tanzania is SP (11). In addition, the guideline recommend that pregnant women should get IPTp with two doses of SP from second trimester and the specified period is between 20-24 weeks of gestation for first dose and a second dose between 28-32 weeks of gestation. It is mandatory to give those two doses of SP any time after 20^{th} week of gestation as long they are more than one month apart.

Two doses SP are the recommended practice in Tanzania, however the recommended time differ with WHO recommendations due to safety concern. WHO recommendation state that all pregnant women in areas of stable malaria transmission should receive at least two doses of IPTp-SP after quickening (at the beginning of fetal movement usually four months) and at least one month apart (1). National guidelines recommend IPTp-SP to be delivered between 20-24 weeks and again between 28-32 weeks of gestation (11)
Implementation of the program of IPTp in Tanzania is not without a challenge, there are problems in distribution which make the drug out of stock when needed. This may make it difficult to see the direct benefit of implementation of IPTp-SP program because some time a woman may take the first dose and miss the second one or take them very late due to their absence(out of stock). There are also a concern among some pregnant women that SP is harmful to their un born baby therefore do resist the drug when offered to them (15). Despite the mentioned challenged most pregnant women in Tanzania do take IPTp-SP when offered.
It is about ten years since SP started being used for IPTp in Tanzania, the time is long enough to justify re- evaluation of its efficacy is important taking into consideration results from studies in other countries and practice on the ground where the drug is still used for treatment of malaria in non-pregnant patients.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design and study sites

This was an observational study involving pregnant women attending antenatal clinic at Buguruni health centre and Mnazi mmoja hospital in Dar es Salaam who were eligible to IPTp-SP. Enrolled women were given two standard doses of SP according to national standard treatment guideline for IPTp-SP. The first dose was given in the period between 20 to 24th weeks of gestation and the second dose was given at any time four weeks after the first dose. Participants were followed up until delivery. Evaluation for IPTp-SP was done at visits and at delivery. The primary end point was birth weight of infants and the secondary end points were severe maternal anemia and peripheral parasitemia at delivery.

The study was conducted at antenatal clinics of Buguruni health center and Mnazi mmoja hospital. The facilities are located in Ilala district Dar es Salaam region, close to the city centre. The two facilities were staffed with qualified doctors and nurses and have good infrastructure and equipments for antenatal and post natal care.

3.2 Ethical consideration

The study protocol was reviewed by Muhimbili University of Health and Allied Sciences Institution Review Board (IRB) for ethical clearance. All study participants were informed in Kiswahili about the study objectives and procedures (appendix iii). For each study participant, written informed consent was obtained and the participant was free to withdraw consent at any time of the study without influencing their access to health services.

3.3 Study population

All pregnant women attending Mnazi Mmoja Hospital and Buguruni Health Centre for antenatal care were invited to participate into the study.

Inclusion criteria:-

a) 15 years old or above
b) Living in Dar es salaam
c) Availability for follow-up during the pregnancy and willingness to deliver at the study site,
d) A pregnancy of less than 24 weeks duration
e) Willingness to come back for a planned visit and be visited by a field worker during pregnancy whenever necessary.
f) Willingness to comply with study procedures.

Exclusion criteria:-

a) Women who live outside Dar es Salaam region.
b) Women who were severely ill at the time of enrolment.
c) Women suspected to have hypersensitivity to sulfa-containing medications through history
d) Women who were known to be HIV positive

3.4 Study procedures

3.4.1 Selection and sampling

District Medical Officers of Dar es Salaam region were visited to obtain information regarding health centers and hospitals which have ANC clinics with high attendancy. Six facilities were identified and after visiting them, two facilities, Mnazi Mmoja Hospital and Buguruni Health Centre were selected. These two facilities had the highiest attendance ANC Clinic. On average, about 70 pregnant women visited Mnazi Mmoja Hospital and about 30 visited Buguruni Health Centre daily. The facilities are also located in areas where they could be reached easily, this might explain why most women

in Dar es Salaam chose them for their reproductive health services. They are also located in the same district which made administrative logistics for the conduct of the study easy.

Pregnant women were screened consecutively during recruitment days, every pregnant woman who was at the section of 'FIRST VISIT' was screened. After consenting, those with all the inclusion criteria and none of the exclusion criteria were included into the study.

3.4. 2 Data collection, follow up and data analysis

Case report forms (CRF) for every participant were bound together and put in a clear plastic office file were each stayed as a unit document for the whole period of study.

Every morning the ANC staff took maximum of 20 unfilled case report forms from the store to the working room. Potentially eligible subjects were identified during routine clinic visit screening and were referred to the working room for consenting. For those who consented, code numbers were assigned, CRF (See appendix iv) was opened and corresponding data for visit one were collected and recorded.

All participants were checked for malaria parasite using mRDT and axillary temperature was measured using digital thermometer. Sample of blood for Hb was examined using Hemo Cue 2.0 and the results were recorded on the appropriate form. Anemia was categorized according to WHO classification where Hb >11g/dl is categorized as non anemia, Hb of 10g/dl to 10.9g/dl is Mild anemia, Hb 7.0 to 9.9g/dl is Moderate anemia and Hb below 7g/dl is Severe anemia (16). All participants found to have malaria, anemia or other illness were sent to the clinician for further investigation and treatment but continued with the study. The first dose of SP was finally given to each participant on DOT and a remainder card which contained the date for second dose of SP was given.

All filled CRF of a particular day were packed in one envelope which was then taken to the store room where all were collected in one box. Code numbers and names of all participants were written on the site study participant log and for the purpose of easy

follow up MTUHA (Mfumo wa Taarifa za Utoaji Huduma za Afya) numbers which were unique to every individual were also included.

The IPTp regimen consisted of a single curative dose of 1.5 g/0.075 g Sulfadoxine Pyrimethamine (sulfadar^{R}) an SP brand from Shellys Pharmaceuticals, supplied by Medical Store Department (MSD). The first dose was given at the day of enrollment. On visit for second dose of SP, information on previous illnesses and treatments was collected. Each participant had her blood for malaria and Hb test taken and then auxiliary temperature was measured. The researcher or research assistant then examined her for side effects and all information gathered was recorded on unique form (Appendix 4)

During labor, blood samples were collected for checking Hb concentration and malaria parasite. Immediately after delivery, babies were weighed using hanging scale at the clinic.

Data regarding newborn characteristics and status of the mother were collected using unique form (appendix 4)

All participants were asked about any unusual effects they felt after taking the first dose and were examined for rashes; any rashes which develop after the use of SP were considered as side effect and were recorded as such (11).

All data collected from sites were entered in a specially designed database in the computer, cleaned and analyzed using the Statistical Package for Social Sciences (SPSS) version 20

Various characteristics of the research subjects were summarized using frequency distribution tables and the data were described by percentage. The variables were classified as categorical data.

Dependent variables were birth weight of an infant born to SP treated pregnant women, severe maternal anemia and peripheral parasitemia at delivery while independent variables were socio-demographic characteristics, gravidity, parasitemia during follow up, anemia during follow up, adverse event and other medicines used during the period

of pregnancy. Infant was categorized as under weigh when weighed below 2.5Kg while parasitemia was either positive or negative depending on the results from malaria Rapid Diagnostic Test (mRDT).

Pearson Chi-square Test, Cox regression and Fischer's Exact Test were used in the univariate and multvariete analysis between dependent and independent variables where applicable. Independent variables which showed a statistical significant difference with the outcome variable by univariate analysis were subjected to multivariate logistic regression to determine the predictors of the outcome.

P-value of < 0.05 was considered significant to provide evidence of significant difference or associations.

3.5 Sample size calculation

This was an observational study involving pregnant women attending antenatal clinic at Buguruni health centre and Mnazi mmoja hospital in Dar es Salaam who were eligible to IPTp-SP. The proportion of low birth weight infant was the primary outcome on which the sample size estimate was based. The proportions of LBW infants with IPTp SP and without IPTp SP were assumed to be 12.5%, and 7.3%, based on previous data **(4).** Since this study aimed at estimating single proportion, the fappropriate formula for calculating study size was used:

$[Z_{(1-\alpha_2)}*\pi_1(1-\pi_1)+Z_(1-0_)*\pi_2(1-\pi_2)]^2$

Where:

Z = 1.96

π_1 = The proportions of LBW infants without IPTp SP

π_2 = The proportions of LBW infants with IPTp SP

α = Type one error

With Type one error at 0.05% and type two error at 0.2%, the minimum sample size was calculated to be 279. A 10% lost to follow up was assumed and the final study sample was 310

CHAPTER FOUR

4.0 RESULTS

A total of 818 pregnant women who were attending ANC between April and May 2013 at Buguruni health centre and Mnazi Mmoja hospital were screened for eligibility. Among 818 pregnant women screened, 310 of them were enrolled in to the study and their data were included in the final analysis. See Figure 1.

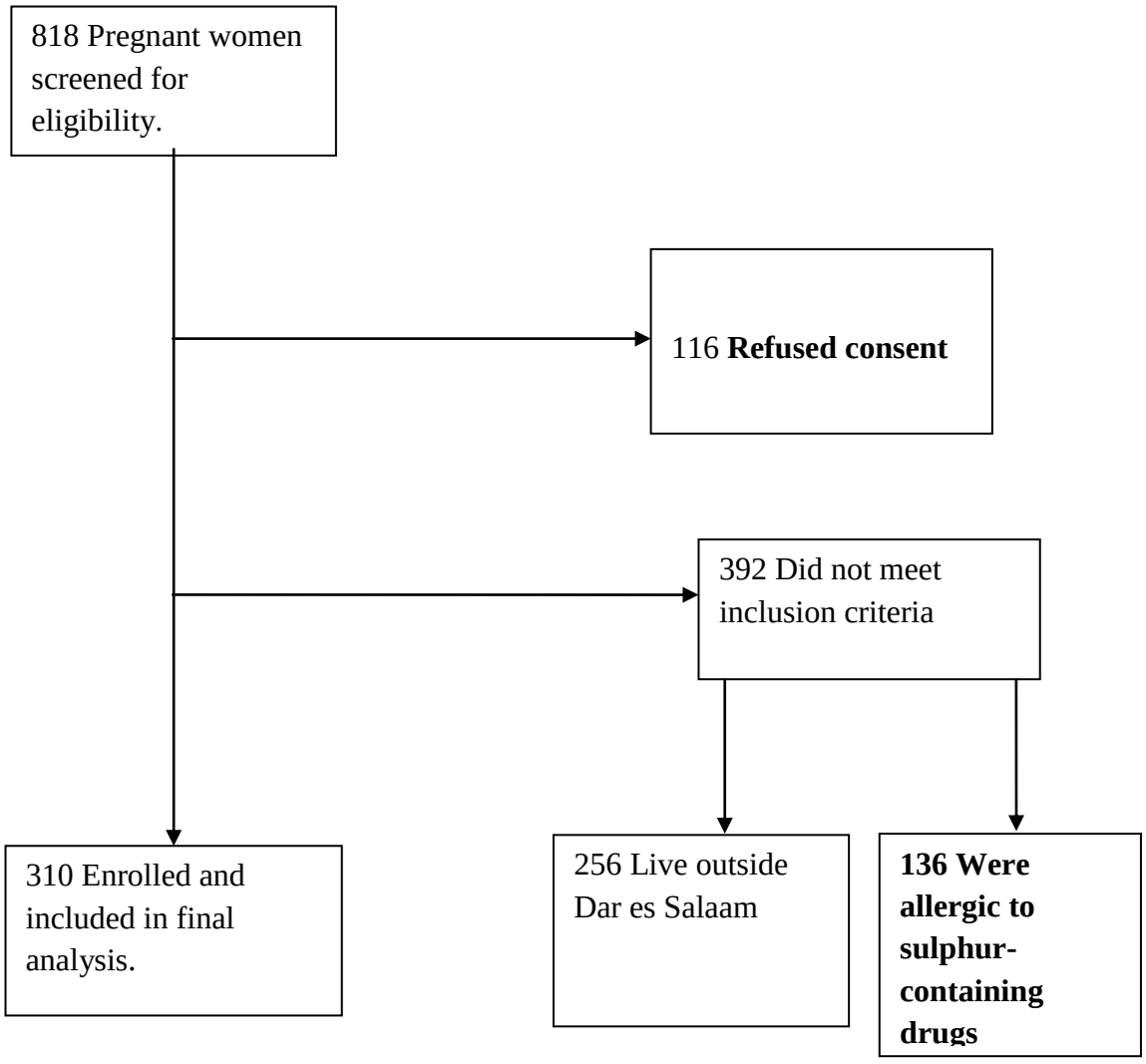


Figure 4.1: Flow chart indicating recruitment of study participants

4.1 Study Population

On average majority of women included in this study were young, mean age (SD) of the study population was 26.4(± 0.3) years. There was no significant difference in gravidity among the study population, 36.5 % among 310 respondents were prime gravida, 30.3% secundigravida and 30.3% were multigravida (p == 0.1655). Majority (58%) of enrolled women had attained primary education and 76.5% were married (Table 4.1).

Table 4.1: Socio-demographic characteristics of the study participants (N=310)

	n	%	P-VALUE
Education			
Informal	4	1.3	P<0.001
Primary	181	58.3	
Secondary school	106	34.8	
High school	9	2.9	
College	8	2.5	
Marital status			
Married	237	76.5	P<0.001
Single	73	23.5	
Gravida			
Prime gravida	116	37.5	0.1655
Secundigravida	97	31.2	
Multigravida	97	31.2	
Occupation			
Employed	57	18.4	P<0.001
House wife	130	42.0	
Self employment	123	39.6	

4.2 Pregnancy outcome

All participants were requested to deliver at the clinic where they were enrolled. Of 310 enrolled pregnant women 95.5% delivered at recruitment site where 197 pregnant women delivered at Mnazi mmoja hospital and the remaining 99 delivered at Buguruni health centre. Low birth weight (<2500g) rate was less than 10%, mean birth weight (SD) was 3.14 ±0.43 Kg. None of the participant had severe anemia at delivery and very few (2%) were malaria positive at delivery according to mRDT results.

4.2.1 Birth weight

Nineteen new born babies (6.5%) were underweight at delivery (<2500g). The distribution of birth weight among children born to SP-treated pregnant women is indicated in figure 4.2. Although the number of women who were mRDT positive was very small, there was no significant difference in birth weight between babies born to mothers with malaria infection at delivery and those born to mothers without malaria infection.

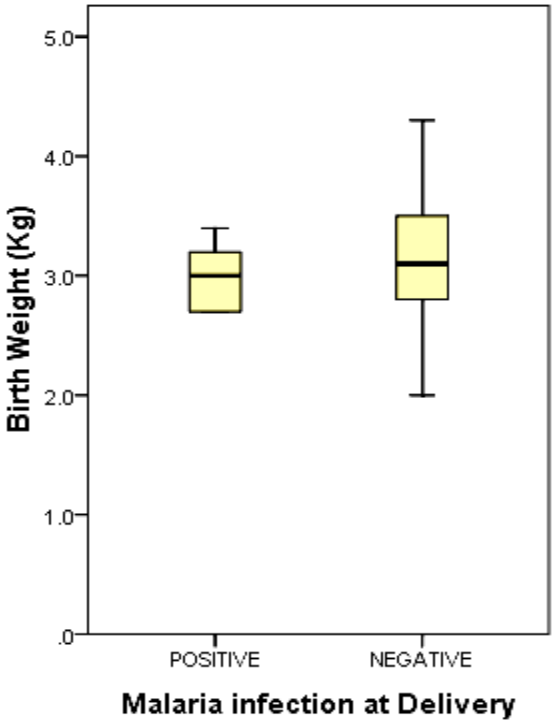


Figure 4.2: Distribution of birth weight by malaria infection status at delivery

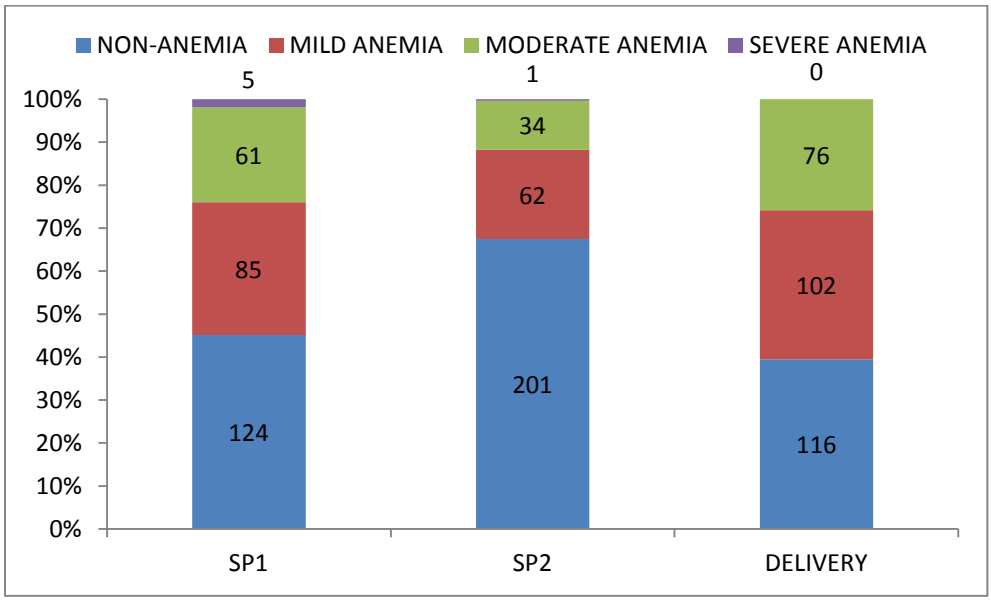
Although this study was not designed to investigate predictors of low birth weight an exploration of such factors was carried out. However none of explored factors (Gravidity Education, Marital status and Occupation) seemed to predict low birth weight, see table 4.2.

Table 4.2: Possible predictors of low birth weight

Pregnancy outcome	**Predictor**	**UNIVARIATE**		**MULTIVARIATE**	
Underweight at birth		OR	P-VALUE	OR	p-value
	Age	0.9	0.248	0.9	0.128
	Parasitemia at first SP dose	3.4	0.068	5.8	0.02
	Parasitemia at second SP dose	3.1	0.165	2.9	0.19
	Moderate anemia	5.8	0.009	6.1	0.009
	Mild anemia	2.3	0.235	1.9	0.352

4.2.2 Hemoglobin concentration at delivery and during follow up

Severe anemia was rarely observed throughout the follow up period and, no participant was found to have severe anemia at delivery. Moderate anemia varied throughout follow up period and was relatively high at delivery (25.8%), 22.1% during the first dose of SP and (11.4%) during the second dose of SP. Incidences of mild anemia was 31%, 21% and 34% during the first dose of SP, second dose and at delivery respectively (Figure 4.3).



Key: SP1= First dose of SP, SP2= Second dose of SP

Figure 4.3: Proportions of anemia at different follow-up periods

On average mean hemoglobin concentration was high during the second dose of SP compared to the first dose (Figure 4.4).

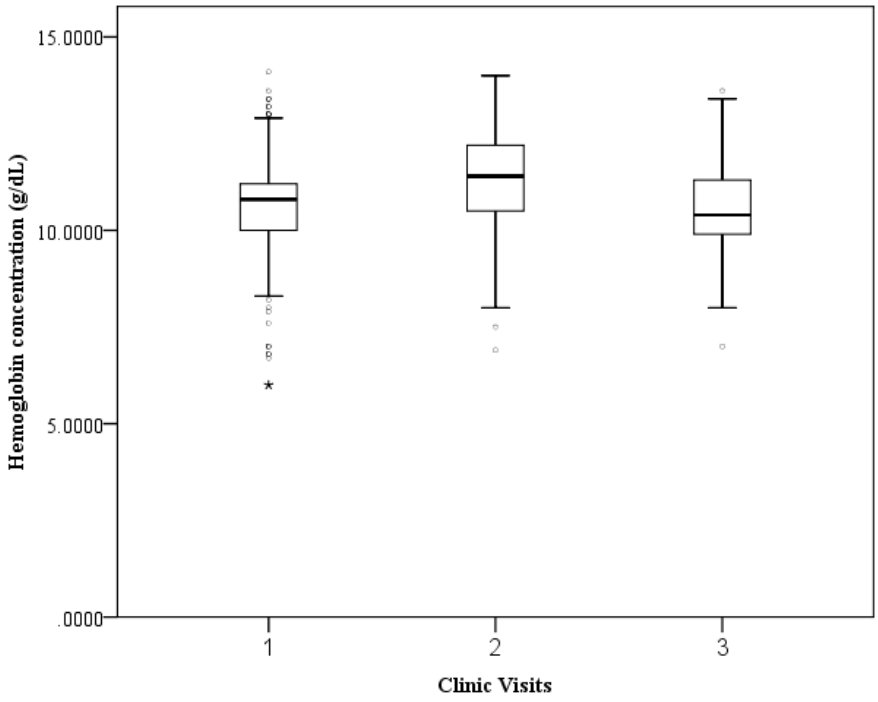


Figure 4.4: Maternal hemoglobin levels among pregnant women as assessed during clinic visits for IPTp-SP and at delivery 1=SP1, 2=SP2, 3=Delivery

4.2.3 Clinical malaria.

Clinical malaria was defined as mRDT positive and fever or history of fever in **the** previous 48 hours. Only few participants (1.3% at SP1 and 0.65% at SP2) had clinical malaria during the period between enrolment and delivery (Figure 4.5). Although six participants (2.0%) had positive mRDT at delivery, none of the participant, however, had clinical malaria.

None of the social demographic characteristics (marital status, education, gravidity and occupations) was associated with malaria parasitemia at the time of delivery.

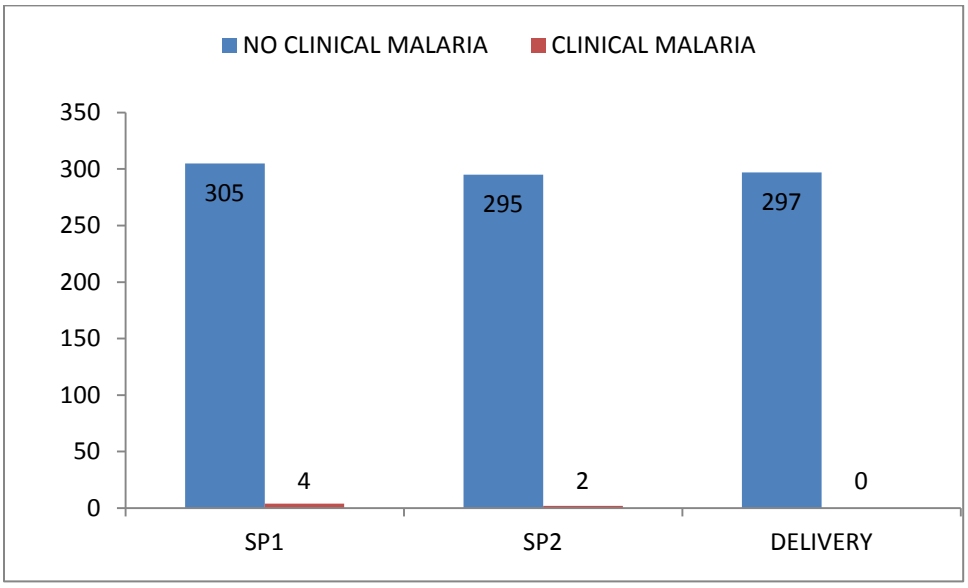


Figure4.5: Proportions of pregnant women with clinical malaria at different stages of follow-up period

4.2.4 Asymptomatic parasitemia

Most participants with MRDT positive did not have clinical malaria. This can be explained by the difference in number of those who were MRDT positive (Figure 4.6) those with clinical malaria (Figure 4.5)

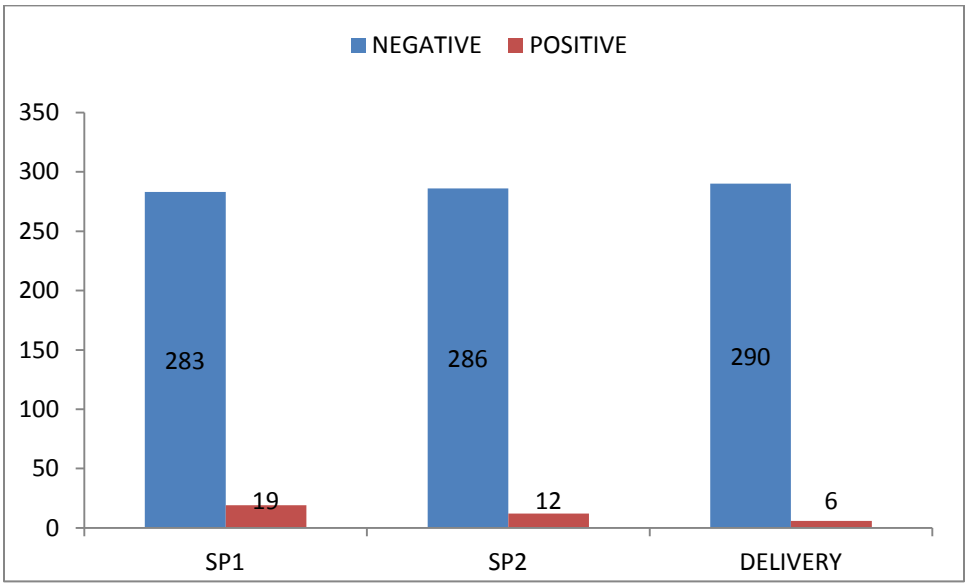


Figure 4.6: Trend pregnant women who were mRDT positive during follow up

CHAPTER FIVE

5.0 DISCUSSION

Low Birth Weight (LBW) is closely associated with fetal and Perinatal mortality and Morbidity, inhibited growth and cognitive development, and chronic diseases later in life.

LBW is responsible for 60-80% of the infant mortality rate in developing countries (6). Infant mortality due to LBW is usually a direct cause stemming from other medical complications such as malaria infection during pregnancy, other maternal sickness during pregnancy, preterm birth, poor maternal nutritional status, lack of prenatal care, and an unhygienic home environment.

On an individual basis, LBW is an important predictor of newborn health and survival and is associated with higher risk of infant and childhood mortality.

At the population level, the proportion of babies with a LBW is an indicator of a multifaceted public-health problem that includes long-term maternal malnutrition, ill health, hard work and poor health care in pregnancy (17). LBW is also associated with reduced brain volume in infants (18).

In sub Saharan Africa the main cause of low LBW is malaria infection (2). Malaria infection usually causes anemia and poor eating habit which contribute to poor fetal nutrition.

Percentage of low birth weight of infants born to SP treated pregnant women in Dar es salaam is 6.5%. These results are similar to those reported in Mozambique about ten years ago.

There has been a concern that continuing use of SP for treatment of malaria by individuals other than pregnant women could lead to increased drug pressure on malaria parasite and cause increased parasite resistance to SP. That does not seem to be the case at the moment, SP seems to be working very well: keeping proportion of low birth weight reasonably low, avoiding severe maternal anemia and keeping prevalence of maternal peripheral parasitemia low. However continued monitoring of how IPTp-SP

performs is essential for timely corrective measures when SP fails to provide required protection.

We believe our findings may justify the continuing use of SP for IPTp. It is good for the ministry of health and social well fare, through national malaria control program to continue promoting use of SP for IPTp because its impact on improving pregnancy outcome is still acceptable. However what we have observed may be attributable to other factors such as the use of ITNs and other mosquito control measure that may have been in place during the study.

No adverse event was reported among all 310 participants involved in our study from the first dose of SP to the time of delivery. This suggests that the drug is reasonably safe and tolerable to most individual in our population. Indeed SP have been reported to be well tolerated even when four doses are given within six months (19).

In our study we found out that 6.5% of infants born to SP-treated pregnant women had low birth weight. This seems to be similar to other previous studies conducted in different African countries. In the study done in central Mozambique the proportion of low birth weight of infants born to SP-treated pregnant women was 7.3% (4). In another study which was done in Côte d'Ivoire, 212 pregnant women were given two doses SP for IPTp and followed up to delivery. In the final analysis it was shown that 10.9% of infants were shown under weight (20). This finding in Côte d'Ivoire does not differ from what is observed in Tanzania and Mozambique. This similarity suggests SP efficacy for IPTp in Tanzania has not significantly changed over time. In similar **a** study conducted in Tororo district hospital in Uganda, 320 women were given two doses of SP and were followed up to delivery. The proportion of low birth weight of infants born by these women was found to be 7.9 (21). This result does not differ much from those of Tanzania, Mozambique and Côte d'Ivoire, although the area is closer to North East Kenya where there is high prevalence of dhfr/dhps mutant strain of *P. falciparam* which is strongly associated with treatment failure (9). This may mean that the resistance

associated with treatment using SP is not necessarily reflected when the drug is used for prevention.

Average hemoglobin concentration in SP 2 observed to be high while that of delivery is a bit lower, this difference may be contributed by efficacy of SP and lower Hemoglobin concentration at delivery may be contributed by high metabolic requirement in last trimester (1). However, this may be unlikely because the number of mothers with clinical malaria during follow up was small. In our study, there was no participant with severe anemia at delivery. This may have contributed to the observed low proportion of low birth weight. This finding does not differ much from that of Mozambique study where proportion of SP treated pregnant women who had severe anemia at delivery was 0.8% (4).

In Côte d'Ivoire the situation is different, proportion of severe anemia in women who used two doses of SP was 9.8%, (17). The relatively high proportion of severe anemia may be explained by the way in which anemia was categorized and other minor differences in study design. In this study, hemoglobin concentration from < 8g/dL was categorized as severe anemia. This is different from our study and that of Mozambique where Hb < 7g/dL was classified as severe anemia (4).
The study in Tororo district, Uganda, the WHO category of anemia was not used rather anemia was classified as anemic (Hb<11gm/dl) or non anemic. The result showed that 45.7% of participants were anemic at delivery (18). This result somehow was misleading because the impact of severe anemia in pregnancy outcome is different mild and moderate anemia.

Six (2%) out of 296 pregnant women who came to deliver at the facilities had peripheral parasitemia. The finding seems to be significantly lower when compared to that of central Mozambique where proportion of pregnant women who had peripheral parasitemia at delivery was 7.5%, Tororo district Uganda 17.5% and Anonkoua-Kouté district in Côte d'Ivoire 13.9%. The difference may be attributed to other factors such as

use of ITN. In Tanzania, ITNs were distributed to all households in 2012 and we expect that up to now they are in good condition and that all pregnant women may at least have one each. There is also the existing program of ITN voucher offered by ministry of health to all pregnant women also known as 'HATI PUNGUZO' where all pregnant women are given ITN at reduced price. This practice has been shown to protect women from mosquito bite and hence associated with low level of parasitemia.

The difference observed from the study in Tororo district can be explained by high entomological inoculation rate (EIR), which can be up to 125 (21) . This is high when is compared to Dar es salaam where the EIR is 47 (22).

High EIR is usually above 10 infectious bites per person per year cause increased immunity in to individuals and make them resistant to clinical malaria at low level of parasitemia (2). This reason may explain why most pregnant women who tested positive in Dar es Salaam did not have clinical malaria (Figure 4.5, 4). It is possible that some women in Tororo district got infected after they have taken their second dose of SP and they did not develop clinical malaria.

In Côte d'Ivoire the proportion of peripheral parasitemia of SP treated pregnant women at delivery was 13.9% (20). The difference between Côte d'Ivoire and Tanzania may be contributed by high prevalence of dihydrofolate reductase and dihydroptoriate synthethase (dhfr and dhps respectively) mutant resistant gene in *P. falciparam* in Côte d'Ivoire. These resistant genes make the parasite none responsive to SP (23).

CHAPTER SIX

6.1 CONCLUSION

Efficacy of SP for IPTp seems to be at a level similar to what it was about ten years ago. Our data are reassuring that the efficacy of IPTP-SP is still high and very beneficial to pregnant women because it improves the outcome of pregnancy tremendously despite the challenges surrounding the practice.

In our study we found proportion of low birth weight to be significantly low, peripheral parasitemia at delivery was not common and there was no case severe maternal anemia at delivery. The good pregnancy outcome is unlikely by chance; it was contributed by IPTp-SP. We believe that local *Plasmodium falciparum* resistance to SP has not yet rendered SP- IPTp ineffective.

We believe that the on-going campaign by ministry of health and social welfare through various media about issues related to safe pregnancy, through mobile phone messages where any individual can get information regarding safe pregnancy and use of IPTp via any mobile phone company have contributed to higher compliance during the study period. Example if anybody send the word ‘mtoto to 15001’ the person will be receiving daily information on how to take care of pregnancy and all messages are free of charge.

The Ministry of Health and Social Welfare may not need to change the policy for treatment of malaria in pregnancy at the moment. However, regular monitoring is essential for timely corrective measures when the need arises

6.2 RECOMMENDATION

Our finding show that the efficacy of IPTp-SP is still acceptably high and recommend the continued use of SP for IPTp by all pregnant women in accordance with national guidelines. Although these results may be reassuring, SP resistance to *P faciparam* is likely increase if SP continues to be widely used and thus regular monitoring of performance of IPTp-SP is recommended.

At present, several studies show that IPTp-SP using three doses gives better protection than two doses. We recommend that similar study be conducted in Tanzania to evaluate the performance of three-dose IPTp-SP.

6.3 STUDY LIMITATIONS

The study did not take in to consideration the use of ITN. We think that since most pregnant women are given ITN through 'Hati punguzo' scheme mentioned earlier the effect of malaria in pregnancy may also be influenced by the said scheme. It was difficult to ascertain the actual use of mosquito net because having one does not mean that the owner will always sleep under it.

In this study one can not quantify the effects of IPTP-SP alone because of likely contribution of other factors such as residual spray and ITNs. In addition, it was not possible to have a control group for ethical reasons. However, similarity of the proportion of low birth weight infants born to SP treated pregnant women in previous studies with similar settings suggests that the efficacy of SP for IPTp has not significantly decreased.

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APPENDICES

Appendix I: Case report form in English

IPTp-SP 2013	**AMIRI**

VISIT 1. RECRUITMENT

Name (Initials) …… **Phone No ……**

Date ……..

CONSENT	**YES**	**NO**
Subject agreed to participate in to the study.	☐	☐

Date……,Time……

Reasons for no consent……

SOCIAL DERMOGRAPHIC CHARACTERISTIC

Marital status: Married ☐ Single ☐

Number of children:…….

Occupation: Work ☐ Business ☐ House wife ☐

HISTORY

- District of residence……
- Education Background

  - Std vii ☐
  - Form iv ☐
  - Form vi ☐
  - Diploma and above ☐

- Last Mestural Period (LMP)…Date……./……./…….

- Any treatment during current pregnancy: Yes ☐ No ☐

If yes,

No.	Drug	Indication	Start (date)	Finish(date)	On going
1					
2					
3					
4					
5					

- Current symptoms and signs

SYMPTOMS AND SIGNS	PRESENT	ABSENT
Rashes		
Insomnia		
Severe blistering		
Feeling of dizziness		
Hallucinations and seizure		
Urinating less than usual		
Jaundice		

Others symptoms and signs ……
……

LAB INVESTIGATION

- Slide for malaria taken YES ☐ NO ☐

- Parasite Density ……/200WBC

- Body Temperature (Axillary Temp.)……^{0}C

- Hb level……g/dl

Clinic staff……..signature…….

INCLUSION CRITERIA	**YES**	**NO**
• Age: Above 15 years	☐	☐
• Gestational age: Below 24 weeks	☐	☐
• Place of residence: DSM	☐	☐
• Previous use of sulphur containing drug	☐	☐

EXCLUSION CRITERIA	YES	NO
• Residing outside DSM	☐	☐
• Presence of severe illness (unconciousness, mentally ill, seizure)	☐	☐
• Previous reaction to sulphur drugs	☐	☐
• H.I.V positive	☐	☐

SELECTION IN TO THE STUDY

- Was the subject selected in to the study YES ☐ NO ☐

- Date ……., Time……

- Reasons for non selection…….

TREATMENT

ANC 1 given YES ☐ NO ☐

- Number of tablets …….. ……
- Date …….. Time…….

Clinic staff…… ….Signature…….

IPTp-SP: 2013	**AMIRI**

VISIT 2. FOLLOW UP VISIT

ID Number……..

Date……

HISTORY

- Gestational age……
- Any current illness: Yes ☐ No ☐
- If yes explain

  ……

  ……

  ……

- Any drug used or being used since last visit; Yes ☐ No ☐
- If yes.

NO.	Drug	Indication	Start (date)	Finish(date)	On going
1					
2					
3					
4					
5					

EXAMINATION

- Signs and symptoms of adverse drug reaction

SIGNS AND SYMPTOMS	PRESENT	ABSENT
Rashes		
Insomnia		
Severe blistering		
Feeling of dizziness		
Hallucinations and seizure		
Urinating less than usual		
Jaundice		

- Any other symptoms and signs: Yes ☐ No ☐

- If yes explain……

  ……

  ……

LAB INVESTIGATION

- Slide for malaria taken YES ☐ NO ☐

- Parasite Density ……/200WBC

- Body Temperature (Axillary Temp.)……^{0}C

- Hb……g/dl

Clinic staff……signature……

TREATMENT

- ANC 2 given YES ☐ NO ☐

- Number of tablets …….

- Date …….. Time……

Clinic staff…….Sig……..

IPTp-SP: 2013	**AMIRI**

VISIT 3. UNPLANNED VISIT

ID number…….

Date……

HISTORY

- Gestational age……

- Reason for the visit (illness)

  ……

  ……

  ……

- Any drug used or being used since last visit; Yes ☐ No ☐

NO.	Drug	Indication	Start (date)	Finish(date)	On going
1					
2					
3					
4					
5					

EXAMINATION

- Signs and symptoms of adverse drug reaction

SIGNS AND SYMPTOMS	PRESENT	ABSENT
Rashes		
Insomnia		
Severe blistering		
Feeling of dizziness		
Hallucinations and seizure		
Urinating less than usual		
Jaundice		

- Any other symptoms and signs Yes ☐ No ☐

If yes explain……

……

LAB INVESTIGATION

- Slide for malaria taken YES ☐ NO ☐
- Parasite Density ……/200WBC
- Body Temperature (Axillary Temp.)……^{0}C
- Hb……g/dl

Clinic staff……Sig……

IPTp-SP: 2013	**AMIRI**

VISIT4. DELIVERY DAY:

ID number……

Date……

PARTICULARS

PART A- MOTHER

- Hb……
- Bs; slide for malaria taken, Yes ☐ No ☐
- Parasite density……./200WBC
- Axillary temperature……^{0}C
- Type of pregnancy: Single ☐ Multiple ☐
- Pregnancy outcome: Live ☐ Dead ☐

Staff clinic……,Signature……

PART B- CHILD

- Birth weight of infant ……Kg
- Gestational age assessment : Premature ☐ term ☐
- Sex: Male ☐ Female ☐
- Presence of gross malformation: Yes ☐ No ☐

- If yes describe ……
  Staff clinic……..,Signature…….

Appendix II: Participant information and informed consent in English

Purpose of the study.

Malaria have been common and life threatening disease to pregnant women, it goes further by threatening the health of un-born baby because intra uterine death may occur leading to abortion.

Luckily we can avoid this threat by taking two planned courses of SP during pregnancy and hopeful avoid the problem. However some challenges come on our way. Periodical increase in resistance of malaria parasite towards SP worries a lot and some measures need to be taken to make sure that pregnant women and their un-born babies are protected.

This study will evaluate current effectiveness of SP in IPTp and suggest a way forward, whether to continue use it or not. The findings will benefit pregnant women, scientific community and health workers.

What does it involve

If you are interested in participating in this study, we will request you to answer a questionnaire regarding your situation, we will ask you few questions which you can answer but you have always an opportunity to withdraw.

Confidentiality

No information from this study will be available to un-authorized individuals. The information we obtain from you will be entered in to computer using your unique identification number known only to principle investigator. No one other than principle investigator and responsible ANC health worker will access the information you provide.

Risks

We do not expect that any harm will happen to you as a result of joining this study. The only risk that may occur during the study would be loss of confidentiality, which we will meet by rendering our data anonymous

Benefits

Regarding the benefit we offer patients to talk about their pregnancy and if anything unusual is noted, the official referral process will be initiated.

Right to withdraw

Taking part in this study is completely voluntary. You can withdraw any time without giving reasons even if you have already given consent. There will be no repercussion to your medical treatment.

Contact

If you have any problem or question concerning the study you are free to contact the investigator Mr RAJABU IDDI AMIRI P.O. BOX 65005 DAR ES SALAAM

Tel. 0713 296561

Informed consent

…….

I have read the information. My questions have been answered to my satisfaction. I consent to participate in this study.

Signature of participant……. Date ……...

Signature of investigator……Date ……..

Signature of witness…….Date ……..

Appendix III: Participant information and informed consent in Kiswahili

Taarifa kwa Mshiriki na Ridhaa ya Kushiriki.

Kichwa cha habari.

Kuangalia uwezo wa SP kama tiba ya kuzuia Malaria katika kipindi cha ujauzito kwa wakati huu.

Sababu ya utafiti.

Ni miaka karibia kumi imepita tangu serikali yetu iamue kusitisha matumizi ya SP kama tiba ya malaria katika nchi yetu kutokana na kuongezeka kwa usugu wa vimelea vya malaria thidi ya dawa hiyo. Hata hivyo dawa hiyo bado inatumika katika matibabu ya wajawazito kwani ndiyo dawa salama kupita nyingine. Kutokana na kwamba kuna watu ambao sio wajawazito wanaotumia dawa hiyo katika jamii zetu tuna wasiwasi kwamba usugu umeongezeka zaidi na kuifanya dawa hiyo isiwe na uwezo wa kuwakinga wajawazito thidi ya malaria. Utafiti huu utatusaidia kuthibitisha uwezo wa dawa hii kwa sasa na kutuwezesha kutoa mapendekezo kama iendelee kutumika au ibadilishwe na nyingine ambayo itaweza kumlinda mama mjamzito na mtoto aliye tumboni.

Unachotakiwa kufanya.

Ukiwa na nia ya kushiriki katika utafiti huu utatakiwa kujibu maswali yaliyo kwenye karatasi maalumu na kuruhusu vipimo vyako vya afya kila unapokuja cliniki vitumike katika utafiti. Kipimo cha ziada utakachofanyiwa zaidi ya vile watakavyofanyiwa wenzako ni kupima malaria ana wingi wa damu wakati wa kujifungua. Hii itakua ni faida pia kwani utajua hali ya afya yako.

Usiri.

Hakuna taarifa kutoka katika utafiti huu itakayotolewa kwa mtu asiyehusika. Taarifa zitakazokusanywa zitaingizwa katika compyuta kwa kutumia namba maaluum ya utambulisho wako. Hakuna mtu mwingine zaidi ya mtafiti ataweza kuona jina lako na

mahali unapokaa. Taarifa zote zinazohusu afya yako zitatunzwa sehemu maalumu ambayo haiwezi kufikiwa na mtu asiyehusika.

Madhara.

Hatutegemei mtu kupata madhara yeyote kwa kushiriki katika utafiti huu

Uwezo wa kujitoa.

Kushiriki katika utafiti huu ni hiari, unaweza kujitoa wakati wowote bila kutoa sababu hata kama ulisharidhia kushiriki. Kujitoa kwako hakuingiliani wala hakutaathiri huduma zako za kliniki na matibabu unayopata. Utatendewa sawasawa na mjamzito yeyote aliyeshiriki katika utafiti huu.

Mawasiliano.

Kama una chochote unataka kujua zaidi kuhusiana na utafiti huu, uko huru kuwasiliana na mtafiti, ambaye ni ndugu RAJABU I AMIRI SLP 65005 DAR ES SALAAM. SIMU 0713 296561.

Maswali.

Kama una maswali kuhusiana na wewe kushiriki katika utafiti huru unaweza kuuliza kuanzia sasa na wakati wowote katika utafiti.

Ridhaa ya kushiriki.

Mimi……..
Nimesoma taarifa kuhusu utafiti, maswali yangu yamejibiwa yote. Ninaridhia kushiriki katika utafiti huu

Sahihi ya mshiriki ……. Tarehe ……...

Sahihi ya mtafiti …… Tarehe ……..

Sahihi ya shahidi …… Tarehe ……..

Appendix IV: Case Report form in Kiswahili

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FOMU NAMBA MOJA

SIKU YA DOZI YA KWANZA YA SP (VISIT 1.)

Jina (kifupi) …… Namba ya simu **……**

Tarehe ……..

Ridhaa ya kushiriki	**NDIYO**	**HAPANA**
Ameridhia kushiriki.	☐	☐

Tarehe……,Muda……

Sababu za kukataa kushiriki (kwa waliokataa)……

MAELEZO BINAFSI

NDOA: Ameolewa ☐ Hajaolewa ☐

Mimba hii ni ya ngapi :…… ☐

KAZI: kuajiriwa ☐ Biashara ☐ Mama wa nyumbani

HISTORIA YA MAMA

- Wilaya anayoishi……

- Kiwango cha elimu

  - Darasa la saba ☐
  - Kidato cha nne ☐
  - Kidato cha sita ☐
  - Diploma au zaidi ☐

- Ukomo wa hedhi (LMP)…Tarehe……./……/…….

- Ameshatumia dawa akiwa na ujauzito huu ambayo sio SP: NDIYO ☐ HAPANA ☐

Kama ndio ijazwe kwenye jedwali hapo chini,

No.	Aina ya Dawa	Ugonjwa	Kuanza (tarehe)	Kumaliza (tarehe)	Inaendelea kutumika
1					
2					
3					
4					
5					

- Adhari inayotokana na dawa aliyotumia

AINA YA ATHARI	IPO	HAIPO
Vipele		
Kukosa usingizi		
Malengelenge		
Kizunguzungu		
Maruerue na kifa		
Upungufu wa mkojo		
Manjano		

Athari nyingine kama ipo:

……..……

VIPIMO VYA MAABARA

- Vimelea vya Malaria VIPO ☐ HAKUNA ☐
- Joto la mwili ……..……^{0}C
- Wingi wa damu (Hb) ……g/dl

Imejazwa na ……..Sahihi…….

VIGEZO VYA KUSHIRIKI	**NDIYO**	**HAPANA**
• UMRI: Miaka zaidi ya 15	☐	☐
• UMRI WA MIMBA: Zaidi ya wiki 20	☐	☐
• SEHEMU ANAYOISHI: DSM	☐	☐
• AMESHAWAHI KUTUMIA DAWA YENYE SALFA	☐	☐

VIGEZO VYA KUTOSHIRIKI	**NDIYO**	**HAPANA**
• KUISHI NJE YA DSM	☐	☐
• KUWA NJONJWA SANA (kupoteza fahamu, kifafa n.k.)	☐	☐
• KUWAHI KUDHURIWA NA DAWA YA SALFA	☐	☐
• KUISHI NA VIRUSI VYA UKIMWI (VVU)	☐	☐

KUSHIRIKISHWA KWENYE UTAFITI

- Mama amechaguliwa kushiriki: NDIYO ☐ HAPANA ☐
- Tarehe ……., Muda……
- Sababu ya kutochaguliwa (kwa walioachwa tu)…….

MATIBABU

Amepewa SP **mara ya kwanza** NDIYO ☐ HAPANA ☐

- Idadi ya vidonge ……. ……
- Tarehe …….. Muda…….

Amepewa dawa na…… ….sahihi……

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FOMU NAMBA MBILI

SIKU YA DOZI YA PILI YA SP (VISIT 2.)

Namba ya utambulisho……

Tarehe……

HISTORIA

- Umri wa mimba……
- Anaumwa ugonjwa wowote: NDIYO ☐ HAPANA ☐

- Kama ndio elezea ……
  ……
  ……
- Kuna dawa aliyotumia nyumbani; NDIYO ☐ HAPANA ☐

- Kama ndio ijazwe kwenye jedwali hapo chini.

No.	Aina ya Dawa	Ugonjwa	Kuanza (tarehe)	kumaliza (tarehe)	Inaendelea kutumika
1					
2					
3					
4					
5					

UCHUNGUZI

- Dalili za madhara yatokanayo na dawa (jaza jedwali hapo chini kama zipo)

AINA YA ATHARI	IPO	HAIPO
Vipele		
Kukosa usingizi		
Malengelenge		
Kizunguzungu		
Maruerue na kifafa		
Upungufu wa mkojo		
Manjano		

- Kuna adhari nyingine: NDIYO ☐ HAPANA ☐

- Kama ipo elezea……
  ……
  ……

VIPIMO VYA MAABARA

- Vimelea vya Malaria VIPO ☐ HAKUNA ☐

- Joto la mwili ……^{0}C

- Wingi wa damu (Hb) ……g/dl

Imejazwa na ……..Sahihi…….

MATIBABU

Amepewa SP **mara ya pili**: NDIYO ☐ HAPANA ☐

- Idadi ya vidonge ……. ……
- Tarehe …….. Muda…….

Amepewa na…… ….sahihi…….

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FOMU NAMBA TATU

WATAKAOKUJA KLINIKI KWA DHARURA (VISIT 3)

Namba ya utambulisho…….

Tarehe……

HISTORIA

- Umri wa mimba……
- Sababu ya kuja Kliniki kwa dharura
  ……
  ……
- Kuna dawa aliyotumia nyumbani; NDIYO ☐ HAPANA ☐
- Kama ndio ijazwe kwenye jedwali hapo chini.

No.	Aina ya Dawa	Ugonjwa	Kuanza (tarehe)	kumaliza (tarehe)	Inaendelea kutumika
1					
2					
3					
4					
5					

UCHUNGUZI

- Dalili za madhara yatokanayo na dawa (jaza jedwali hapo chini kama zipo)

AINA YA ATHARI	IPO	HAIPO
Vipele		
Kukosa usingizi		
Malengelenge		
Kizunguzungu		
Maruerue na kifafa		
Upungufu wa mkojo		
Manjano		

- Kuna athari nyingine: NDIYO ☐ HAPANA ☐

- Kama ipo elezea……

……

……..……

VIPIMO VYA MAABARA

- Vimelea vya Malaria VIPO ☐ HAKUNA ☐

- Joto la mwili …….^{0}C

- Wingi wa damu (Hb) ……g/dl

Imejazwa na …… Sahihi……

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FOMU NAMBA NNE

SIKU YA KUJIFUNGUA (VISIT 4.)

Namba ya utambulisho ……

Tarehe……

TAARIFA YA UZAZI

SEHEMU YA KWANZA (MAMA)

- Wingi wa damu (Hb)……
- Uwepo wa vimelea vya malaria: NDIYO ☐ HAPANA ☐
- Joto la mwili (Kwapani) ……^{0}C
- Idadi ya watoto aliyojifungua: Mmoja ☐ Zaidi ya mmoja ☐
- Uhai: Yupo/wapo hai ☐ Amekufa/wamekufa ☐

Imejazwa na ……..,Sahihi……

SEHEMU YA PILI (MTOTO)

- Uzito wa mtoto wakati wa kuzaliwa……Kg
- Umri wa kuzaliwa : Kabla ya wakati ☐ Kwa wakati ☐
- Jinsia: Kike ☐ Kiume ☐
- Mtoto ana kasoro za kimaumbile: NDIYO ☐ HAPANA ☐

- Kama zipo elezea

  ……

  Imejazwa na ……..,Sahihi……