Faculty of Health Sciences | School of Public Health

IMPLEMENTATION FIDELITY OF THE GUIDELINES OF INTERMITTENT PREVENTIVE TREATMENT OF MALARIA IN PREGNANCY AND ITS DETERMINANTS IN SOKOTO STATE, NIGERIA.

By

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DECLARATION

I, *Bilkisu Abdullahi Yar'adua*, declare that this research report is my own unaided work. It is being submitted in partial fulfilment of the requirement for the degree of Master of Science (MSc) in Epidemiology (field of Implementation Science) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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(Signature of candidate)

Date: 14th of October 2020

ABSTRACT

Background

Intermittent preventive treatment of malaria in pregnancy using sulphadoxine-pyrimethamine (IPTp-SP) is an evidence-based intervention for the prevention of malaria in pregnancy, but healthcare providers' adherence to IPTp-SP guidelines and its determinants in Sokoto State have not been fully explored. This quantitative study, therefore, measured implementation fidelity of IPTp-SP guidelines and its determinants. The relationship between implementation fidelity of IPTp-SP guidelines and its determinants was also examined.

Methodology

In this cross-sectional study, 91 healthcare providers from government healthcare facilities supported by the US President Malaria Initiative (PMI), government healthcare facilities not supported by the US President Malaria Initiative (nPMI), and private healthcare facilities were interviewed using an interviewer-administered questionnaire. The quantitative data were analysed using descriptive statistical analysis and chi-square test. General linear regression models were fitted to determine the relationship between implementation fidelity of IPTp-SP guidelines and the determinants.

Results

The mean score of implementation fidelity for all the participants was 60%, and the median interquartile range (IQR) was 60% (55 – 70). The minimum score of implementation fidelity of IPTp-SP guidelines was 25%, and the maximum was 95%. The highest mean fidelity (63%) was from healthcare facilities supported by PMI, followed by (60%) from nPMI and the lowest (49%)

was from private healthcare facilities. All the scores of determinants, except for facilitation strategy, were above 60%. The score of facilitation strategy was 39% with a standard deviation of 37, and the scores ranged from 0 to 100%. The level of knowledge of healthcare providers on IPTp-SP, educational qualification, cadre of healthcare providers, and type of healthcare facility were significant determinants of implementation fidelity of IPTp-SP guidelines ($p<0.05$). Content of IPTp-SP guidelines was significantly influenced by facilitation strategies in addition to the above determinants ($p<0.05$).

Conclusion

This study has shown that adherence to all the components of IPTp-SP guidelines can be improved by improving the level of knowledge of healthcare providers on IPTp-SP. And this can be achieved by training of healthcare providers on IPTp-SP, receiving of supervisory visits after training and making IPTp-SP guidelines available to them. Therefore, findings from this research can help to guide further planning and policy decisions on prevention of malaria in pregnancy.

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DEFINITION OF TERMS

Implementation fidelity	The extent to which an intervention or a programme is implemented as intended.
Dose	Dose (frequency and duration) refers to whether the active components of an intervention were implemented as frequently and as long as they were planned.
Content	The active ingredients or components of an intervention.
Coverage	The intervention's reach and whether eligible participants received the intervention or not.
Determinants of implementation fidelity	Factors that influence the degree of adherence to an intervention.
Facilitation strategies	Supports that may be used to improve and standardise implementation fidelity.
Intervention complexity	The description of an intervention.
Quality of delivery	The manner at which implementers deliver an intervention to achieve what was intended
Participant's responsiveness	The participants' engagement or reaction to an intervention

LIST OF ABBREVIATIONS

IPTp-SP Intermittent preventive treatment of malaria in pregnancy using sulphadoxine-pyrimethamine.

DOT Directly observed therapy

WHO World Health Organisation

PMI US president malaria initiative

CHAPTER 1: INTRODUCTION

1.0 INTRODUCTION OF CHAPTER

This chapter gives an overview of malaria in Nigeria and how intermittent preventive treatment of malaria in pregnancy using sulphadoxine-pyrimethamine (IPTp-SP) is conducted in the country. The factors that affect IPTp-SP implementation across many settings are discussed. The concept of implementation fidelity and its conceptual framework are also discussed. The chapter includes the following sub-sections: background, problem statement, research question, aim, objectives, justification and literature review.

1.1 BACKGROUND

Malaria is an important public health problem in Nigeria. According to the 2018 world malaria report, the country accounted for 25% of global malaria cases and 53% of global malaria deaths in the year 2017 (1). The number of malaria cases increased from 214 million in 2015 to 219 million in 2017 worldwide; 92% of the cases were from the World Health Organisation (WHO) African region. Nigeria is among the three countries that had the highest estimated increases of malaria cases in that year (1). The prevalence of malaria is higher in some parts of Nigeria than others; some isolated parts of northwestern Nigeria are among those with an over 70% prevalence of malaria (2). A 2015 Nigerian Malaria Indicator Survey reported that malaria contributes to approximately one in four infant and under-five deaths in Nigeria, and one in ten maternal mortalities making up about 11% of maternal deaths (3). Pregnancy makes women more susceptible to malaria due to the low immune system associated with pregnancy (4). Malaria

causes serious public health issues in pregnancy such as stillbirth, abortion, congenital malaria, low birth weight, neonate anaemia, intrauterine growth restriction and premature birth (5).

To prevent and control malaria in Nigeria, the National Malaria Elimination Programme of the Federal Ministry of Health, in collaboration with key international partners including US President Malaria Initiative (PMI), Global Fund, United Kingdom Department for International Development, World Health Organisation and the United Nations International Children's Emergency Fund, have been working hard to implement key malaria control interventions. These include intermittent preventive treatment of malaria in pregnancy using sulphadoxine-pyrimethamine (IPTp-SP), targeted indoor residual spraying, distribution of insecticide-treated nets and effective case management of malaria. Sokoto State, a state in the northwest part of Nigeria, is among the 11 states supported by PMI, one of the largest funding partners of malaria interventions in Nigeria. The government healthcare facilities supported by the US President Malaria Initiative (PMI) in Sokoto have shown a better performance than government healthcare facilities not supported by the US President Malaria Initiative (nPMI) in the state in terms of greater availability of malaria commodities, trained healthcare providers, higher quality of care, national malaria treatment guidelines, laboratories and microscopes and generally better data quality (6).

For the intermittent preventive treatment of malaria in pregnancy, the WHO IPTp-SP policy, an evidence-based intervention that has been proven to be effective in preventing malaria in pregnancy was adopted (7). The WHO recommends that sulphadoxine-pyrimethamine be provided to all pregnant women early in their second trimester of pregnancy at each scheduled antenatal care visit until delivery, as long as the doses of sulphadoxine-pyrimethamine are given at monthly intervals to ensure high coverage of pregnant women who receive at least three doses of the drug. Furthermore, sulphadoxine-pyrimethamine should be given to pregnant women as a directly

observed therapy (DOT) of three tablets to ensure that women take the full dosage. Folic acid at a dose of 5mg or greater daily should not be administered together with sulphadoxine-pyrimethamine, as it can counteract the efficacy of the drug. Therefore, 0.4mg folic acid is the recommended dose. Pregnant women can take sulphadoxine-pyrimethamine either with food or on an empty stomach. Sulphadoxine-pyrimethamine should not be given to women receiving co-trimoxazole prophylaxis due to the higher risk of adverse effects (7). However, effective scale-up of WHO IPTp-SP policy continues to face challenges in Nigeria (8) and other parts of Africa. These challenges include poor leadership and governance, low budgetary allocation towards policy implementation, prevailing service delivery barriers, including long-distance to healthcare facilities, long waiting times at healthcare facilities and poor service healthcare provider/client relations, low healthcare provider motivation levels, lack of inadequate healthcare providers, sulphadoxine-pyrimethamine stock-outs, poor supply chain management and management of information (9). A study carried out in Sokoto State reported a lack of adherence to the DOT component of the IPTp-SP guidelines by healthcare providers (10), this may contribute to why only 22.5% per cent of pregnant women in the state received three or more doses of sulphadoxine-pyrimethamine in 2018 (11).

The extent to which an intervention is implemented according to protocol or guidelines affects its success (12). The more an intervention is implemented with fidelity, the higher the intended outcome (13). Measuring the degree of adherence (implementation fidelity) of an intervention will help in understanding how and why an intervention works or fails and the degree to which the intended outcome may be enhanced. This is because implementation fidelity moderates the relationship between interventions and their outcomes (14). Implementation fidelity is one of the eight indicators of the success of an intervention, the other seven being acceptability, adoption,

appropriateness, feasibility, fidelity, implementation cost, coverage and sustainability (15). This study measured implementation fidelity of the IPTp-SP guidelines among healthcare providers in government healthcare facilities not supported by PMI, government healthcare facilities supported by PMI and private healthcare facilities in Sokoto State, Nigeria.

1.2 PROBLEM STATEMENT

Despite significant technical support from the government and supporting partners, and an enabling environment to implement the national malaria treatment guidelines in Sokoto, only 22.5% of pregnant women received three or more doses of sulphadoxine-pyrimethamine in 2018 (11). Even though there was an increase in the percentage of women who received more than three doses of sulphadoxine-pyrimethamine from 0.7% in 2013 to 22.5% in 2018 (11), the percentage increase is unacceptable due to malaria's harmful effects on pregnancy and for the goal of eliminating malaria by 2020. Furthermore, the percentage of persons (all ages) with confirmed malaria was significantly high (80%) between 2015 and 2016 in the state (6). A 2017 study carried out in the state found a lack of adherence to one of the components IPTp-SP guidelines (DOT) by healthcare providers (10). However, no research has been done among healthcare providers to measure their adherence to the IPTp-SP guidelines and the determinants affecting adherence in Sokoto. Therefore, this research measured the implementation fidelity of the IPTp guidelines and its determinants among healthcare providers in Sokoto.

1.3 RESEARCH QUESTION, AIM AND OBJECTIVES

1.3.1 Research Question

i. What is the implementation fidelity of the IPTp-SP guidelines and its determinants in Sokoto State, Nigeria, in 2019?

ii. What is the relationship between implementation fidelity of IPTp-SP guidelines and the identified determinants of implementation fidelity among healthcare providers in Sokoto State, Nigeria, in 2019?

1.3.2 Aim

To measure the implementation fidelity of IPTp guidelines among healthcare providers in government healthcare facilities not supported by PMI, government healthcare facilities supported by PMI and private healthcare facilities in Sokoto State, in 2019 and to determine the relationship between the identified determinants and implementation fidelity.

1.3.3 Objectives

1. To measure implementation fidelity of IPTp guidelines among healthcare providers in Sokoto State, Nigeria, in 2019.

2. To describe the determinants of implementation fidelity, of IPTp guidelines among healthcare providers in Sokoto State, Nigeria, in 2019.

3. To determine the relationship between implementation fidelity and its determinants.

1.4 JUSTIFICATION

To reduce the burden of malaria in pregnancy, to achieve the pre-elimination status by 2020 and to reduce malaria-related mortality to zero in Nigeria, healthcare providers must adhere to IPTp guidelines with high fidelity. Therefore, it is necessary to assess implementation fidelity of IPTp-SP guidelines and its determinants. This would enable the National Malaria Elimination Programme of the Federal Ministry of Health and international partners to identify implementation bottlenecks of IPTp-SP and solutions to overcoming them in Sokoto.

This research examined the implementation fidelity of the guidelines of intermittent preventive treatment of malaria in pregnancy and its determinants in Sokoto. This study assisted in identifying health system barriers that get in the way of successful implementation of IPTp-SP. Furthermore, the study provides an opportunity to identify implementation bottlenecks that must be addressed to stay aligned with the 2020 malaria pre-elimination status. The study also adds to the existing literature on factors influencing implementation fidelity of IPTp-SP. Findings from this research can help to guide further planning and policy decisions on prevention of malaria in pregnancy.

1.5 LITERATURE REVIEW

The literature review was conducted through searching malaria in pregnancy library, PubMed, Google Scholar and Scopus using the search terms “malaria in pregnancy” “IPTp-SP,” “implementation fidelity” or “intervention adherence” or “intervention integrity” or “intervention fidelity”.

1.5.1 Intermittent Preventive Treatment in Pregnancy Using Sulphadoxine-pyrimethamine (IPTp-SP)

To prevent malaria among pregnant women in areas where malaria is constantly present, the WHO recommends a package of efficacious interventions which comprises promotion and use of insecticide-treated nets, appropriate case management of malaria and intermittent preventive treatment in pregnancy using sulphadoxine-pyrimethamine (IPTp-SP) (16).

IPTp-SP is an integral part of the WHO-recommended measures of preventing malaria in pregnancy, which should be started very early in the second trimester. The WHO recommends that pregnant women should be provided with sulphadoxine-pyrimethamine at every scheduled antenatal care visit starting early in the second trimester of pregnancy until delivery, with at least

one month between the doses, to be certain that the high percentage of pregnant women receive at least three doses of sulphadoxine-pyrimethamine. Sulphadoxine-pyrimethamine is administered to pregnant women as a DOT of three tablets, to ensure that women take the full dosage. Sulphadoxine-pyrimethamine can be taken with food or on an empty stomach. Due to the higher risk of adverse effects, sulphadoxine-pyrimethamine should not be given to women taking co-trimoxazole prophylaxis. Folic acid at a dose of 5 mg or greater daily should not be administered together with sulphadoxine-pyrimethamine, as it can counteract the efficacy of the drug; therefore, 0.4mg folic acid is the recommended dose (7).

1.5.2 Factors Affecting Implementation of IPTp-SP Guidelines for the Prevention of Malaria in Pregnancy.

Several factors have been identified to affect the successful implementation of the WHO recommended IPTp-SP guidelines (17–21,21–25). Some of the factors affect the administration of sulphadoxine-pyrimethamine as a directly observed therapy while some affect the duration, frequency and coverage of sulphadoxine-pyrimethamine, the antimalarial drug for IPTp, but no research reported on the level of implementation fidelity of all the components of IPTp-SP guidelines as a whole. Barriers that relate to the healthcare provider's knowledge and perception of IPTp using sulphadoxine-pyrimethamine were commonly cited, and these barriers are at the individual level. Healthcare provider's knowledge of IPTp strategy was considered to be poor by many researchers (19–22,26). In addition to this, barriers to implementation of IPTp-SP also exist at the organisational, healthcare system and non-healthcare system level (25). Barriers to implementation of IPTp-Sp emanating from pregnant women have also been identified (25).

1.5.2.1 Barriers to the administration of sulphadoxine-pyrimethamine as a directly observed therapy

Barriers to the administration of sulphadoxine-pyrimethamine as a DOT from healthcare providers were due to individual and organisational-level factors at healthcare facilities. Many researchers reported that DOT, one of the main components of IPTp-SP intervention, was poorly implemented by healthcare providers (10,17,27–29). Only one study from Ghana had a different finding and DOT strategy was reported to be satisfactory by these researchers (30).

A research carried out in the southeast part of Nigeria has reported reasons for lack of adherence to DOT component of IPTp-SP guidelines from the pregnant women and the healthcare facilities. Some of the pregnant women said that they were not told to take sulphadoxine-pyrimethamine as a DOT while 15% were not able to purchase it at the hospital due to financial problems. Eighteen percent of the women complained of long waiting times, and 3% had no reason. The healthcare facilities reported an inability to provide clean drinking water for DOT (20%), no healthcare providers to supervise DOT (10%) and too many patients to attend to (6%) (17).

Other researchers also reported that it was common for pregnant women to have to buy water and sulphadoxine-pyrimethamine for DOT, resulting in an economic barrier to the successful implementation of IPTp (18,19,31–35). Stock-outs of the antimalarial drug is another factor that affects the administration of sulphadoxine-pyrimethamine as a DOT (36). Other barriers to receiving sulphadoxine-pyrimethamine as a directly observed therapy were that pregnant women had to purchase the antimalarial drug outside the clinic, or took it home to eat first, or because they were told to take it home by nurses (20) or that they were requested to share cups (31). Unavailability of water (19,37) and cups to give sulphadoxine-pyrimethamine to pregnant women (19,38–40) are also known barriers to administering the drug as a DOT.

Azizi and colleagues (2018) found that women not taking sulphadoxine-pyrimethamine as a DOT are less likely to receive at least three doses of the drug as are pregnant women in the rural areas and those with very few anti-natal care visits (41). Researchers reported that pregnant women received a dosage of sulphadoxine-pyrimethamine under the recommended dosage (42,43). Even though there is strong evidence for the importance of at least three doses of sulphadoxine-pyrimethamine for the prevention of malaria in pregnancy. Kayentao and colleagues (2013) reported that three or more doses of sulphadoxine-pyrimethamine were associated with a lower risk of low birth weight and higher birth weight compared to two doses of the drug (44). It has been shown that less placental malaria is associated with three or more doses of sulphadoxine-pyrimethamine (45). Two doses of sulphadoxine-pyrimethamine may also not be effective in preventing malaria during the last 4 to 10 weeks of pregnancy (44); this is similar to what Onyebuchi and colleagues (2014) (46) found. They reported that malaria occurred more in pregnant women who failed to take the subsequent doses of sulphadoxine-pyrimethamine than those who did. The percentage of pregnant women who received three or more doses of sulphadoxine-pyrimethamine in Sokoto was found to be very low (22.5 %) (11).

1.5.2.2 Administering sulphadoxine-pyrimethamine with the recommended dose of folic acid

It has been shown that a high dose of folic acid (equal $\geqslant$ 5 mg) counteracts the efficacy of sulphadoxine-pyrimethamine as an antimalarial drug (7,47). However, to the best of my knowledge, no data is available on adherence of healthcare providers to the recommended dose of folic acid (0.4mg) that is given with sulphadoxine-pyrimethamine and the factors that affect its adherence.

1.5.2.3 Barriers to the WHO recommended frequency, duration and coverage of IPTp-SP

Factors affecting frequency, duration and coverage of IPTp-SP were found at the individual, organisational, healthcare system and non-healthcare system level. At an individual level, barriers to the successful implementation of IPTp-SP centred around the knowledge and perception of healthcare providers on IPTp using sulphadoxine-pyrimethamine (25).

Individual-level factors: Several researchers reported confusion in health professionals over the dosing and timing of sulphadoxine-pyrimethamine in relation to the stage of pregnancy (19,20,38), as well as failing to administer sulphadoxine-pyrimethamine to women in the second and third trimester when they present for antenatal care (48). Some administer sulphadoxine-pyrimethamine to pregnant women not at the recommended stage of the pregnancy, deviating from WHO IPTp-SP guidelines (19,37,49). While some had uncertainty over the actual stage of the pregnancy, leading to missed sulphadoxine-pyrimethamine administration (39). Healthcare providers in the southwest local government area of Nigeria were reported to administer different types of antimalarial drugs for IPTp to pregnant women, instead of using only Sulphadoxine-pyrimethamine (20). Healthcare providers in Nigeria and Ghana were not able to list the major side effects or contraindications of sulphadoxine-pyrimethamine (20,35,50,51). They were often found to give sulphadoxine-pyrimethamine to pregnant women without explanation or instruction or instruction not provided in a language the pregnant women understood (52). Unfriendly supervision (37) and poor quality of service by healthcare providers (19,27) have also been reported. Healthcare providers were found to attribute poor uptake of IPTp to the behaviour of pregnant women. For instance, according to healthcare providers from Nigeria and Malawi, the behaviour of pregnant women contributed to the low uptake of IPTp-SP. They stated that pregnant women dislike taking sulphadoxine-pyrimethamine on an empty stomach (19,53) and either did

not come back for subsequent antenatal care visits (21,54) or showed up late, leading to low coverage of IPTp-SP (21,38,53).

Healthcare system-related factors: Pregnant women reported that they were denied antenatal care services in some healthcare facilities if they could not pay for the services (34) or were charged for the second dose of Sulphadoxine-pyrimethamine (53), constituting an economic barrier to accessing the required doses. The main reason for pregnant women not receiving IPTp-SP at antenatal care clinics was that it was not offered by the antenatal care clinic staff (18,19,55–59). Healthcare providers in Tanzania were reported by pregnant women to impose penalties or fines on them for starting antenatal care clinic visits late in pregnancy (34). Other reasons for not giving pregnant women sulphadoxine-pyrimethamine was because they were taking iron supplements and folic acid (57), or because they needed a test done at the laboratory (57).

Other barriers at the organisational level, healthcare system and policy level include healthcare providers been too busy to prescribe sulphadoxine pyrimethamine, complicated IPTp-SP guidelines (23) or conflicting guidelines (23,24,38), unavailable IPTp-SP guidelines in healthcare facilities (23,25) aggravated by absence of quality checks on IPTp-SP delivery, inadequate training and supervision of health professionals, (25,37,38) and periodic stock-outs of the drug sometimes for an extended period of time (19,37,38).

It has been reported that private healthcare facilities were less likely to adhere to national IPTp-SP guidelines (22) or to provide pregnant women with other antimalarial drugs as per their request (40). A study carried out in Tanzania identified lack of basic facilities, inadequate training and poor remuneration as constraints to the delivery of intermittent preventive treatment of malaria in pregnancy (37).

1.5.3 Implementation fidelity

The concept of implementation fidelity, also known as adherence or integrity (60), is the degree to which a programme or intervention is consistently implemented according to the protocol or as intended (14,61–64). Implementation fidelity moderates the relationship between an intervention and its outcome (14). The degree or extent to which interventions are implemented (implementation fidelity) affects how well they succeed (12,60,65,66). The higher the implementation fidelity, the better the outcomes and vice versa (67–70). For instance, in a programme testing for correctional interventions for chronically violent young offenders, the sites with the stronger implementation of most of the core components of the programme fared better than the sites that had not implemented most of the core components of the programme. The programmes implemented with high fidelity achieved significant reductions in the number and severity of arrests and greater time until rearrests (71).

1.5.4 Conceptual Framework of Implementation Fidelity

In this study, the conceptual framework for implementation fidelity developed by Carroll and colleagues (2007) (14) was adapted to guide our analysis. All the four constructs of adherence (content, coverage, frequency and dose) in Carroll's conceptual framework were used in this study to measure implementation fidelity of IPTp-SP guidelines. To examine their influence on implementation fidelity of IPTp-SP guidelines in Sokoto, all the determinants in Carroll's conceptual framework, in addition to characteristics of healthcare providers (level of knowledge of healthcare providers on IPTp-SP, work experience, cadre of healthcare providers, educational qualification, age and sex) were included in our adapted conceptual framework.

1.5.4.1 Constructs of implementation fidelity

In this study, implementation fidelity is measured by adherence. Adherence is the extent to which specified components of the intervention were delivered as prescribed in the intervention manuals (65). Adherence has four sub-categories, namely content, frequency, duration and coverage. Implementation fidelity is said to be high when there is complete adherence to these four sub-categories as prescribed by its designers (14).

Content of an intervention is the active ingredient of the intervention that is delivered to the recipients (14). The active ingredient of IPTp-SP is sulphadoxine-pyrimethamine, given as a DOT and together with not more than 0.4 mg of folic acid (7).

Coverage is the intervention's reach, and it refers to whether eligible participants who should be participating in or benefitting from an intervention actually do so (14), and whether the participants in the intervention arm of a randomised control trial received the intervention or not (72). Coverage in this research is the percentage of eligible women who received the required doses of IPTp-SP during ANC visits.

Frequency and duration are more broadly referred to as the dose of an intervention. Dose refers to whether or not the active ingredients of the intervention were implemented as frequently and for as long as they were planned (14,72). The dose of IPTp-SP is the required dosage of sulphadoxine-pyrimethamine received by pregnant women starting early in the second trimester of pregnancy until delivery (7).

1.5.4.2 Determinants of implementation fidelity

As illustrated in Figure 1.1, the adapted conceptual framework of implementation fidelity includes five determinants in two broad categories; (1) key determinants from Carroll's framework (14)

(facilitation strategy, intervention complexity, quality of delivery, participant responsiveness and (2) characteristics of healthcare providers (level of knowledge of healthcare providers on IPTp-SP, work experience, cadre of healthcare providers, educational qualification, age and sex).

Facilitation strategies: These are a form of supports that may be used to standardise and improve implementation fidelity (73). These supports can be training, provision of manuals or guidelines, monitoring and feedback for the implementers (14). The more that is done to support the implementation process, the better the potential implantation fidelity achieved. However, more of these supports do not necessarily mean better implementation, as facilitation strategies may depend on the complexity of the intervention. Facilitation strategies reflected factors at the healthcare system and policy level. Facilitation strategies were found by several researchers to affect the delivery of IPTp-SP (19,23,25,37,38,74).

Intervention complexity: This refers to the real nature and description of the intervention (72). It may be simple or complex, detailed or unclear (14). It has been shown that interventions that are simple and also specific are more likely to be delivered to its recipients with fidelity than interventions that are vague or overly complex (14). These also reflected factors at the healthcare system and policy level. Complicated or conflicting IPTp-SP guidelines were reported to affect the effective delivery of IPTp-SP (23).

Quality of delivery: The manner in which implementers deliver an intervention to its recipients. This can be their attitude, enthusiasm, preparedness, skills in using the techniques or the methods prescribed by the programme (60). All factors under quality of delivery are individual level factors.

Participant responsiveness: Participant responsiveness is defined as an essential moderator of implementation fidelity; non-engagement of participants when they perceived an intervention not

to be relevant to them could be a significant reason of failure, poor fidelity, or coverage (14). Implementation fidelity is negatively affected when patients intentionally fail to conform to their prescribed regimens (75,75,76). In this research, participant responsiveness is the perception of pregnant women on the importance of IPTp-SP in preventing malaria in pregnancy, compliance in taking sulphadoxine-pyrimethamine as a DOT and attending antenatal care clinic. These are also at the individual level.

Other determinants: These include the level of knowledge of healthcare providers on IPTp-SP, working experience, cadre of healthcare providers, educational qualification, sex and age. Other determinants reflected factors at the individual level. The level of knowledge of healthcare providers on IPTp-SP was included in the adapted conceptual framework of implementation fidelity based on findings from previous literature that it affects the implementation of IPTp-SP (20,25) because it centred around individual level factors affecting the delivery of IPTp-SP (25). Characteristics of healthcare providers were included for conceptual reasons.

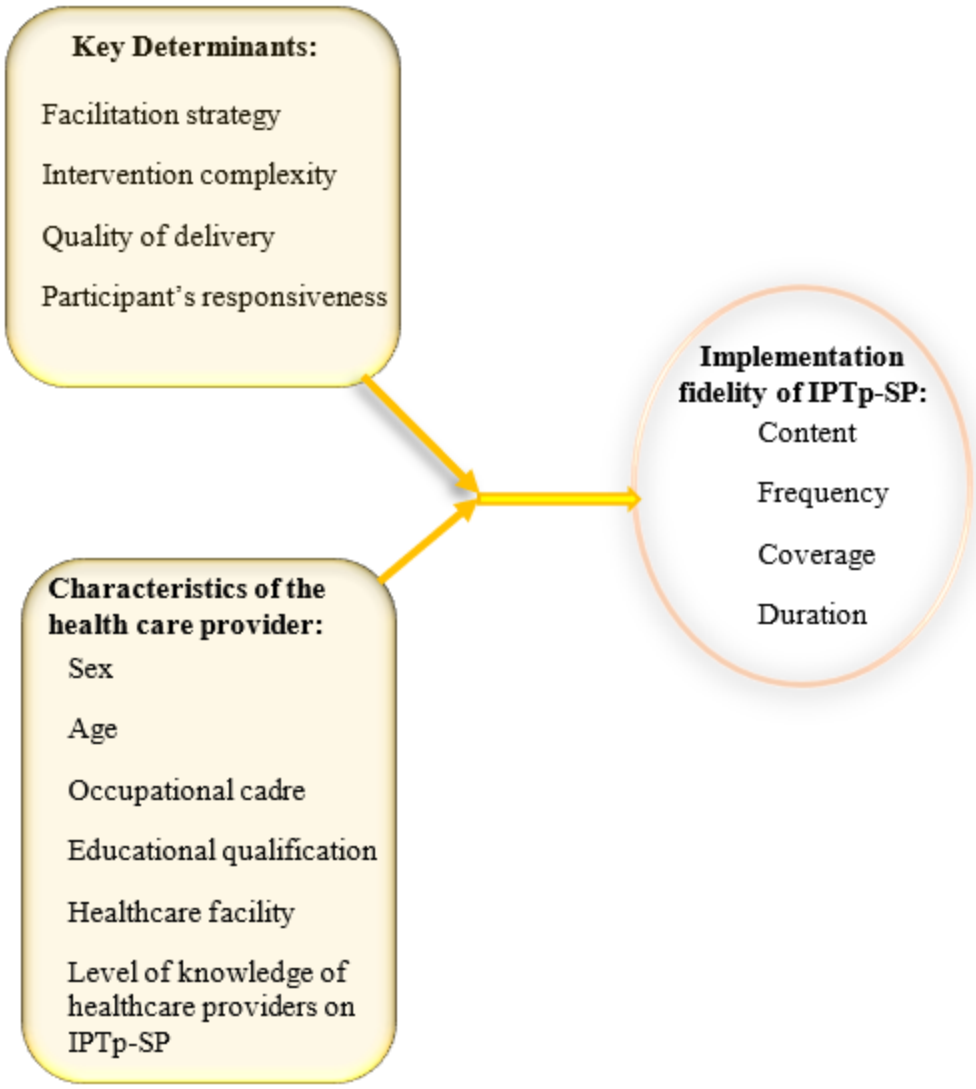

Figure 1.1: Conceptual framework of implementation fidelity adapted from Carroll's Conceptual framework (14)

CHAPTER 2: METHODOLOGY

2.0 INTRODUCTION

This chapter describes the study site, study design, study population, sample size, the sampling technique used, data collection and capture, data management, analysis plan, limitations and ethical considerations for the study.

2.1 STUDY SITE

The study was conducted in Sokoto State, a state in the northwest part of Nigeria. It is one of the states with the highest prevalence of malaria in Nigeria (46.6%) (3) and has malaria as one of the leading causes of morbidity and mortality (6). Sokoto is one of the 11 states in Nigeria receiving support from the PMI for control of malaria (6). The PMI supported 66% of healthcare facilities in Sokoto in the year 2019; the remaining healthcare facilities (44%) were government healthcare facilities not supported by the PMI and private healthcare facilities (8). Sokoto State was among the four PMI-supported states selected by PMI for documenting the progress of malaria control interventions between 2008 and 2016. Sokoto had the lowest percentage of women who received two or more doses of sulphadoxine-pyrimethamine of the 4 States assessed (6).

Sokoto State has an area of 25 973 km^2 (10 028 m^2) and consists of 23 local government areas (77). According to the 2006 Nigerian population census, the population was 4 998 090 (78). Limited rainfall starts from mid-May to mid-September and Harmattan is from November to March (79).

2.2 STUDY DESIGN

A cross-sectional design was used to measure implementation fidelity and its determinants, as well as the relationship between them.

2.3 STUDY APPROACH

Quantitative research method was the approach used to gather and analyze data on implementation fidelity and its determinants.

2.4 STUDY POPULATION

The study population consisted of healthcare providers working in the antenatal care section of the selected government healthcare facilities, government healthcare facilities supported by PMI and private healthcare facilities.

2.4.1 Inclusion Criteria

All healthcare providers attending to pregnant women in the antenatal care section of the selected healthcare facilities were included, irrespective of their sex, age, experience, cadre and educational qualification.

2. 5 SAMPLING

2.5.1 Sample size

PASS Power Analysis and Sample Size Software was used to get a sample size of 91 healthcare providers using a power of 0.9 and an alpha of 0.05.

2.5.2 Sampling technique

The sampling technique used was stratified random sampling where healthcare facilities were divided into three strata (government healthcare facilities not supported by the PMI, government healthcare facilities supported by the PMI and private healthcare facilities), healthcare facilities were then selected randomly from each stratum. The stratification assumes that the level of adherence may be different among the three types of healthcare facilities. The government healthcare facilities supported by the PMI have an enabling environment in support of malaria in pregnancy and the general perception that private healthcare facilities provide better care than government healthcare facilities (public system). Healthcare facilities were selected randomly across the state using the Sokoto State list of healthcare facilities. Six healthcare facilities not supported by PMI, 12 government healthcare facilities supported by PMI, and seven private healthcare facilities were selected for the study. The selection ensured that all the types of healthcare facilities (primary, secondary, and tertiary) under nPMI and PMI, as well as private healthcare facilities, were included in the study. The government healthcare facilities (both PMI and non-PMI supported) consisted of 11 primary, six secondary and one tertiary healthcare facility. All healthcare providers working in the antenatal care section of the selected healthcare facilities were invited to participate in the study.

2.6 DATA COLLECTION

2.6.1 Questionnaire

Data on implementation fidelity of IPTp guidelines as well as its determinants were collected using an interviewer-administered questionnaire, which was designed using Research Electronic Data Capture (REDCap). The structure of the survey was based on the adapted framework of

implementation fidelity. The domains of implementation fidelity in the framework are content, duration, frequency and coverage and its four key determinants are facilitation strategy, intervention complexity, quality of delivery and participants' responsiveness. Characteristics of healthcare providers were added as the fifth group of determinants in the framework as they are critical to adherence to guidelines. Characteristics of healthcare providers include age, sex, cadre of healthcare providers, working experience, educational qualification and level of knowledge on IPTp guidelines. The content of the questionnaire was guided by the WHO IPTp policy (the guideline adopted by Nigeria for the prevention of malaria in pregnancy). The guideline stipulates the provision of at least three or more doses of sulphadoxine-pyrimethamine to pregnant women starting as early as possible in the second trimester of pregnancy and continuing to the time of delivery, provided that there is a one-month interval between two doses of the antimalarial drug (7). The collection tool consisted of four parts. The first and second part captured information on characteristics of healthcare providers. Level of knowledge of healthcare providers on IPTp-SP is based on the activities that healthcare providers are expected to carry out in the guidelines. Parts three and four captured information on implementation fidelity and its four key determinants, respectively. To ensure the validity of responses, some of the questions were negatively worded. Pre-testing of the collection tool was done in Kano, a state in the northwest part of Nigeria. The questionnaire was pre-tested in five healthcare facilities to identify and resolve any problems with the collection tool. The questionnaire was translated into the dominant local language (Hausa) in Sokoto for healthcare providers that preferred the local language. See a copy of the questionnaire in Appendix B.

2.6.2 Field Work

Data were collected from 19 March to 10 April 2019 by the principal investigator and two research assistants. Data were collected either in the morning, before the working hours of the healthcare providers, after working hours or by appointment, due to their busy schedule. The research assistants were trained in essential data collection techniques, research ethics and the use of a mobile device before the commencement of data collection. The recruited research assistants were university graduates and had experience using mobile devices. Data were captured using the REDCap mobile application on android tablets.

The data file was exported from REDCap after executing data quality checks. Data was then transported from REDCap to STATA 15 for data cleaning, coding and analysis.

2.7 DATA MANAGEMENT

Data was collected using REDCap mobile application by the Principal Investigator and two other data collectors. The information collected from healthcare providers was treated with confidentiality and anonymity, as no name or any identifying information was asked. Branching logic was used for some questions so that their appearance would only be based on participants's responses. The data file was exported from REDCap to STATA 15 for data cleaning, coding and analysis. After analysis, data was securely stored in a database by the Principal investigator where only the principal investigator and the supervisor have access to it.

2.8 VARIABLES

Outcome variable: Implementation fidelity is the outcome variable; it was derived from four constructs and as a continuous variable. The constructs were estimated from the responses to the

questions that were asked on content (six items), duration (two items), frequency and coverage (three questions). Each question was scored on a Likert scale of 0 - never, 1 - occasionally and 2 - every time.

Composite reliability also known as McDonald's coefficient, was used to estimate the reliability of the instrument used in measuring implementation fidelity and its determinants, because it is a less biased measure of internal consistency (80) as it allows factor loadings to vary (81). The recommended value of composite reliability is 0.6 (82).

Composite reliability was computed after conducting a factor analysis. The factor loadings from factor analysis were used to calculate composite reliability using the following formula:

$$CR = \frac{\left(\sum_{i=1}^{n} \lambda_{y_i}\right)^2}{\left(\sum_{i-1}^{n} \lambda_{yi}\right)^2 + \left(\sum_{i=1}^{p} Var(\varepsilon)\right)} (83)$$

where;

CR = composite reliability

λ_y = standardised factor loading

Var (ε_i) = variance due to measurement error

The composite reliability for the items measuring implementation fidelity was 0.79. Since the value was high, the scores of all the four constructs of implementation fidelity were summed up to obtain the total score of implementation fidelity for each healthcare provider. The scores were converted to percentages for analysis and ease of interpretation.

Independent Variables: Each of the four key determinants was constructed from a number of questions. Intervention complexity was constructed from two questions on a Likert scale of 1 - very complex, 2 - somewhat complex, 3 - somewhat simple and 4 - very simple); facilitation strategies (three questions on a dichotomous scale of 0 - no and 1 - yes); quality of delivery (four questions on a Likert scale of 0 - never, 1 - occasionally and 2 - every time); and participant responsiveness (four questions on a Likert scale of 1 - strongly agree, 2 - agree, 3 - disagree and 4 - strongly disagree). The composite reliability measure for facilitation strategy, quality of delivery and participants responsiveness were 0.78, 0.67, and 0.79, respectively. The composite reliability of intervention complexity was not calculated as it is a two-item variable. A total score for each of the key determinants for each healthcare provider was computed and converted to percentages. Level of knowledge of healthcare providers on IPTp-SP was measured by 13 questions on the dichotomous scale of 0 - no and 1 - yes. Knowledge score for each healthcare provider was computed by summing the scores and converting to percentages. All negatively worded questions were reverse coded before data analysis.

Table 2.1: Characteristics of healthcare providers

Variables	Type	Coding
Age group in years	Categorical variable	1 = less than 30, 2 = 30 – 39, 3 = 40 – 49 and 4 = 50 and above.
Sex	Categorical variable	1 = female, 2 = male
Cadre of healthcare providers	Categorical variable	1 = Doctor, 2 = Midwife, 3 = Nurse and 4 = Community health worker.
Work experience in years	Categorical variable	1 = less than 1, 2 = 1 –5, 3 = 6 and above
Educational qualification	Categorical variable	1 = Nigerian national diploma 2 = first degree, 3 = post graduate
Type of healthcare facility	Categorical variable	1 = private, 2 = nPMI, 3 = PMI

2.8 DATA ANALYSIS

Objective 1: **To measure the implementation fidelity of IPTp guidelines among healthcare providers in government healthcare facilities, government healthcare facilities supported by the President Malaria Initiative and private healthcare facilities in Sokoto State, Nigeria in 2019.**

Skewness/Kurtosis tests for normality was first conducted and a histogram drawn to check whether data on implementation fidelity was normally distributed or not. Then summary statistics of the implementation fidelity score for all the healthcare providers were computed. This included the means with standard deviation and median with interquartile range as well as the mean implementation fidelity score by the three groups of healthcare facilities.. One-way analysis of variance was conducted to determine whether implementation fidelity scores of IPTp-SP guidelines differ in PMI, nPMI and private healthcare facilities.

Objective 2: To describe the determinants of implementation fidelity of IPTp guidelines among healthcare providers in government healthcare facilities, government healthcare facilities supported by the President Malaria Initiative and private healthcare facilities in 2019 in Sokoto State, Nigeria.

The mean of the computed scores for each of the four key determinants (quality of delivery, intervention complexity, participants' responsiveness and level of knowledge of healthcare providers on IPTp-SP) are presented. The description of the other determinants (work experience, cadre of healthcare providers, educational qualification, age and sex) are also presented.

Percentage distribution of the categorical determinants and their associated mean implementation scores was also done.

Objective 3: To determine the relationship between the identified determinants and implementation fidelity of IPTp-SP guidelines among healthcare providers in government healthcare facilities, government healthcare facilities supported by the President Malaria Initiative and private clinics in Sokoto State in 2019.

The unadjusted and adjusted multiple linear regression models were fitted to determine the relationship between implementation fidelity and all the determinants.

$y = \beta_0 + \beta_1 x_i + \beta_2 x_2 + \ldots + \beta_p x_p + \varepsilon_i$ (β_0, β_1 ……β_p were model parameters, and ε_i is the error term) was used as the linear regression equation and statistical significance was at $p < 0.05$.

The unadjusted model (Model 1) examined the relationship between each independent variable and implementation fidelity, while Model 2 (adjusted model) included all the set of determinants.

2.9 LIMITATIONS OF THIS STUDY

The sample size for this study was small, but healthcare providers from all the types of healthcare facilities across Sokoto participated in this research. The healthcare providers interviewed from private healthcare facilities were few compared to those in PMI and nPMI and this is because, it is not common to find more than two healthcare workers at the antenatal care section of a private healthcare facility.

There is a limit to the extent to which the findings of this study can be generalised to the entire country as the data was collected from only one of the 36 states in Nigeria. However this was minimized to a minimal level; participants in this research, though drawn from only one of the 36

states of Nigeria, comprises of all the cadre of healthcare providers (Doctors, Nurses, Midwives and Community health workers) and from all the types of healthcare facilities (primary, secondary and tertiary) in Nigeria.

2.10 ETHICAL CONSIDERATIONS

The following research ethical committees provided ethical approval for the study:

- The University of the Witwatersrand Human Research Ethics Committee (attached as Appendix C),
- Ethics Committee of the Sokoto state Ministry of Health (attached as Appendix D),
- Usmanu Danfodiyo University Teaching Hospital Research Ethics Committee (attached as Appendix E)
- Sokoto state Specialist Hospital Ethics and Research Committee (attached as Appendix F).

Permission was also obtained from healthcare facilities before the commencement of data collection. The research was explained to the study participants, and an information sheet (attached as Appendix G) detailing the purpose of the study and issues around freedom of participation and confidentiality was provided to all participants. All the participants signed an informed consent form (attached as Appendix H). All information collected is stored safely in a database.

CHAPTER 3: RESULTS

This section of the research report presents the results of the statistical analysis conducted on implementation fidelity and its determinants. Using tables and graphs, the findings of the three objectives of this study are illustrated, highlighting and summarizing the main findings in the text.

3.1 MEASUREMENT OF IMPLEMENTATION FIDELITY

Overall implementation fidelity score

Descriptive statistics of the implementation fidelity score of the healthcare providers surveyed are presented in Table 3.1. The mean score for all the participants was 60% with a standard deviation of 14.25. The minimum implementation fidelity score was 25%, and the maximum was 95%. The implementation fidelity scores were normally distributed as shown by the probability of skewness and kurtosis (see Table 3.2) and histogram of implementation fidelity scores (see Figure 3.1).

The mean implementation fidelity score by the three groups of healthcare facilities are also presented in Table 3.1. The highest implementation fidelity score (63%) was from healthcare facilities supported by PMI, followed by (60%) from government healthcare facilities not supported by PMI and the lowest (49%) was from private healthcare facilities. There was a statistically significant difference in mean implementation fidelity among the three types of healthcare facilities as determined by one-way analysis of variance (F= 4.08, p = 0.015).

Descriptive statistics of the implementation fidelity score for each of the four constructs of implementation fidelity is presented in Table 3.3. Content of IPTp-SP guidelines had the lowest mean implementation fidelity score (37%) while frequency, coverage and duration had mean implementation fidelity scores above 78%. Only one of the variables measured under content was

high (79%), adherence to DOT and the required dose of folic that can be given with sulphadoxine-pyrimethamine were found to be low (21% and 41%).

Table 3.1: Descriptive statistics of the implementation fidelity score of IPTp-SP guidelines in Sokoto, Nigeria.

Healthcare facility	Number of observations	Mean IF (SD)	Min-Max	Median (IQR)	*p*-value
Overall IF	91	60.05 (14.25)	25-95	60 (55 – 70)	
Healthcare F					0.015
PMI	45	62.78 (11.31)	40-90	65 (55 – 70)	
nPMI	35	60.00 (15.29)	25-95	60 (55 – 70)	
Private	11	49.09 (17.44)	25-75	50 (35 – 65)	

IF = implementation fidelity, SD = standard deviation, IQR = interquartile range

Table 3.2: Skewness/kurtosis tests for normality

Variable	Number of observations	Pr (skewness)	Pr (kurtosis)	------ joint ------	
				adj chi2(2)	Prob>chi2
Implementation fidelity	91	0.0807	0.6566	3.35	0.1875

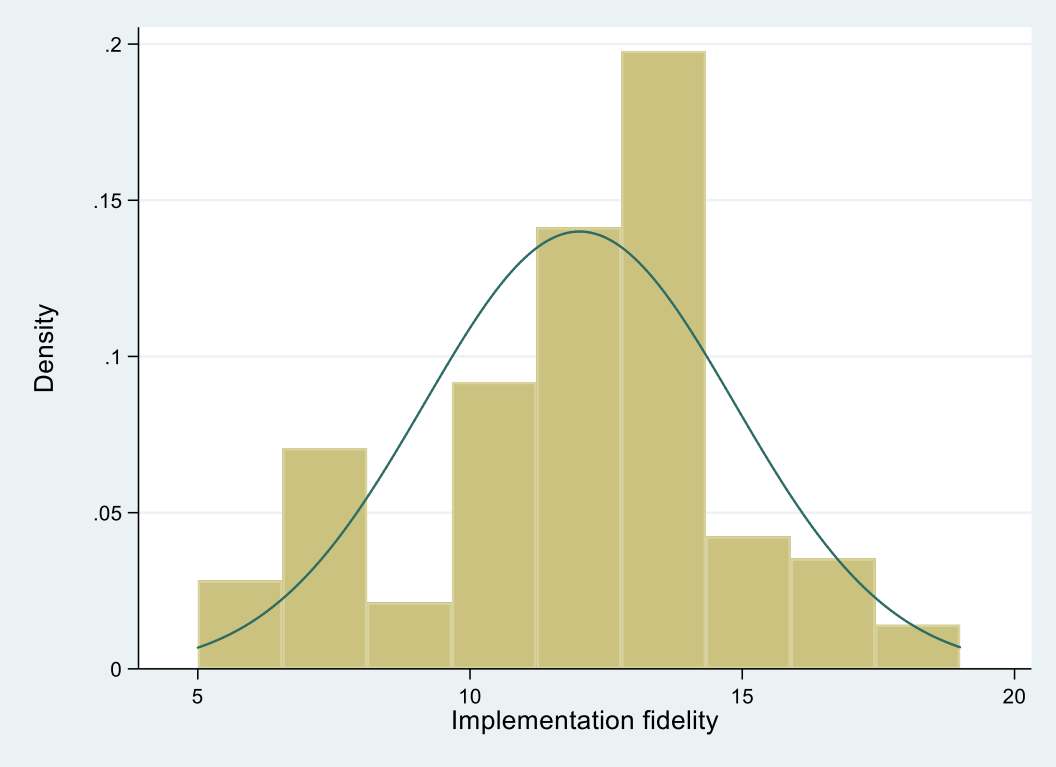

Figure 3.1 Histogram showing normal distribution of data on implementation fidelity

Table 3.3: Descriptive statistics of the implementation fidelity score for each of the four constructs of implementation fidelity.

Implementation fidelity	Number of observations	Mean IF
Content	91	37.14 (18.34)
• Use of the right antimalarial drug for IPTp-SP		79.12 (38.05)
• sulphadoxine-pyrimethamine given as a DOT		21.43 (26.33)
• sulphadoxine-pyrimethamine given with the recommended dose of folic acid		42.31 (45.90)
Frequency and coverage	91	85.35 (20.91)
Duration	91	79.40 (31.97)

IF = implementation fidelity, SD = standard deviation

3.2 DESCRIPTION OF DETERMINANTS OF IMPLEMENTATION FIDELITY OF IPTP-SP GUIDELINES

Descriptive scores of key determinants of implementation fidelity of IPTp-SP guidelines and level of knowledge of healthcare providers on IPTp-SP are described in Table 3.4. All the mean scores of the key determinants and level of knowledge of healthcare providers on IPTp-SP, except for facilitation strategy, were above 61%. The score of the facilitation strategy was 39% with a standard deviation of 37, and the scores ranged from 0 to 100%.

Table 3.4: Descriptive statistics of the key determinants of implementation fidelity of IPTp-SP guidelines and level of knowledge of healthcare providers on IPTp-SP

Determinants	Observations	Mean (SD)
Facilitation strategy	91	39.19 (37.05)
Quality of delivery	91	92.86 (10.40)
Participants responsiveness	91	75.27 (13.33)
Intervention complexity	91	61.95 (22.74)
Level of knowledge of healthcare providers on IPTp-SP.	91	86.64 (9.58)

SD = standard deviation

The mean implementation fidelity scores by the healthcare provider characteristics are presented in Table 3.5. The participants included 37 doctors, 24 midwives, nine nurses and 21 community health workers. Only 41% of the healthcare providers were doctors; the remaining 59% were midwives, nurses and community health workers. The majority of the participants were females (74%), had the Nigerian national diploma (59%), and work experience ranged from 1-10 years. More than half of the healthcare providers were between the ages of 30-39 (53%), very few were at the age of 50 and above (9%). Community health workers, females, healthcare providers with a

post-graduate degree, those with a working experience of less than one year and those between the age of 30-39 had the highest mean implementation fidelity scores.

Table 3.5: Descriptive statistics of implementation fidelity score by healthcare providers characteristics

Category	Variable	Number of observations	Percentage	Mean IF (SD)
Cadre of healthcare providers	Doctor	37	40.66	57.03 (16.77)
	Midwife	24	26.37	58.75 (12.45)
	Nurse	9	9.89	62.78 (10.03)
	Community health Worker	21	23.08	65.71 (11.54)
Sex	Female	67	73.63	61.34 (12.99)
	Male	24	26.37	56.46 (17.10)
Educational qualification	Nigerian national diploma	54	59.34	62.13 (11.96)
	First degree	17	18.68	50.59 (18.86)
	Post-graduate degree	20	21.98	62.50 (12.82)
Working experience in years	<1	11	12.09	63.64 (14.85)
	1 - 5	32	35.16	57.81 (13.32)
	6 and above	48	52.75	60.73 (14.77)
Age	less than 30	22	24.18	58.64 (11.57)
	30-39	49	53.85	62.04 (15.31)
	40-49	12	13.19	60.00 (14.92)
	50 and above	8	8.79	51.88 (11.93)

IF = implementation fidelity, SD = standard deviation,

3.3 DETERMINANTS OF IMPLEMENTATION FIDELITY OF IPTP-SP GUIDELINES

Model 1

In the unadjusted linear regression model (second column of Table 3.6), the level of knowledge of healthcare providers on IPTp-SP, type of health care facility, being a community healthcare provider and educational qualification were the significant determinants of implementation fidelity of IPTp-SP guidelines. For every unit increase in the level of knowledge of healthcare providers on IPTp-SP, the implementation fidelity score increased by 0.58 (95% CI: 0.11 - 1.04). The mean implementation fidelity score was higher by 2.74 among healthcare providers in PMI healthcare facilities compared to those in private healthcare facilities (95% CI: 0.90 - 4.57). In nPMI healthcare providers, the mean implementation fidelity was higher by 2.18 compared to healthcare providers in private healthcare facilities (95% CI:0.29 - 4.07). The mean implementation fidelity score was higher by 1.74 among community healthcare providers compared to doctors (95% CI: 0.21 - 3.26). In healthcare providers with a first degree, it was lower by 2.31 compared to healthcare providers with a Nigerian national diploma (95% CI: -3.81 – (- 0.80).

Model 2

In the adjusted model (third column of Table 3.6) that has all the determinants of IPTp-SP, the association between implementation fidelity and level of knowledge of healthcare providers on IPTp-SP became stronger in the adjusted model. For every unit increase in the level of knowledge of healthcare providers on IPTp-SP, the implementation fidelity score increased by 0.76 (95% CI: 0.25 - 1.27). The mean implementation fidelity score was higher by 3.21 among nurses compared to doctors (95% CI: 0.23 - 6.20).

Table 3.6: Unadjusted and adjusted coefficients of determinants of implementation fidelity of IPTp-SP guidelines in Sokoto, Nigeria

Variables	MODEL 1 Unadjusted coef. Coefficient(95%CI)	MODEL 2 Adjusted coef. Coefficient(95%CI)
Key Determinants of Implementation Fidelity		
Participants responsiveness	0.08 (-0.20 - 0.36)	-0.11 (-0.50 - 0.28)
Facilitation strategy	0.07 (-0.47- 0.61)	0.30 (-0.38 - 0.978)
Intervention complexity	0.15 (-0.18 - 0.48)	0.22 (-0.23 - 0.68)
Quality of delivery	0.02 (-0.52 - 0.9)	0 .01(-0.72 - 0 .75)
Characteristics of healthcare providers		
Level of knowledge of health workers on IPTp-SP	0.58 (0.11 - 1.04) *	0.76 (0.25 - 1.27) *
Healthcare facility		
Private	Ref	Ref
nPMI	2.18 (0.29 - 4.07) *	1.46 (-0.47 - 3.39)
PMI	2.74 (0.90 - 4.57) *	1.87 (-0.83 - 4.56)
Working experience		
<1	Ref	Ref
1-5	-1.16 (-3.15 - 0 .82)	-1.93 (-3.92 - 0.06)
6 and above	-0.58 (-2.48 - 1.32)	-1.17 (-3.62 - 1.29)
Age group		
less than 30	Ref	Ref
30-39	0.68 (-0.77 - 2.13)	1.05 (-0.83 - 2.93)
40-49	0.27 (-1.75 - 2.30)	0.94 (-1.61 - 3.38)
50 and above	-1.35 (-3.68 - 0.98)	-2.36 (-5.4 - 0.687)
Sex		
Female	Ref	Ref
Male	-0.98 (-2.32 - 0.36)	0.60 (-1.13 - 2.33)
Cadre of healthcare providers		
Doctor	Ref	Ref
Midwife	0.34 (-1.12 - 1.81)	2.09 (-1.11- 5.30)
Nurse	1.15 (-0.92 - 3.22)	3.21(0.23 - 6.20) *
Community health worker	1.74 (0.21 - 3.26) *	2.67 (-0.45 - 0.80)
Educational qualification		
Nigerian national diploma	Ref	Ref
First degree	-2.31 (-3.81 – (- 0.80) *	-1.50 (-3.37 - 0 .37)
Post graduate degree	0 .07 (-1.35 - 1.49)	Omitted

*significant at P<0.05, **significant at p<0.0001 R^2 for model 2 = 43%

CHAPTER 4: DISCUSSION

This research aimed to measure the implementation fidelity of IPTp-SP guidelines as well as its determinants among healthcare providers in government healthcare facilities supported by the US President Malaria Initiative (PMI), government healthcare facilities not supported by the US President Malaria Initiative (nPMI), and private healthcare facilities in Sokoto State and to determine the relationship between the identified determinants and implementation fidelity.

An interviewer-administered questionnaire to measure implementation fidelity and its determinants and Carrol's conceptual framework of implementation fidelity was used to guide the study. Results showed that overall implementation fidelity of IPTp-SP guidelines in Sokoto was moderate (60%). Implementation fidelity was higher in PMI supported healthcare facilities than in nPMI and private healthcare facilities. Level of knowledge of healthcare providers on IPTp-SP, facilitation strategies, cadre of healthcare providers and educational qualification was found to influence adherence to IPTp-SP guidelines significantly.

4.1 STRENGTH AND LIMITATIONS OF THIS STUDY OF THIS STUDY

All the types of healthcare facilities in Sokoto State (primary, secondary, and tertiary) under nPMI and PMI, as well as private healthcare facilities, were included in this study. Likewise, the participants interviewed in this research comprises of all the cadre of healthcare providers working in the antenatal care section of Sokoto State healthcare facilities.

Self-reporting was the method used to collect data on implementation fidelity and its determinants. Biases associated with self-reporting such as social desirability, exaggeration or over-reporting of adherence to IPTp-SP were minimized by informing the participants that their answers were

anonymous and confidential, this was also guaranteed by giving them informed consent form to sign before the commencement of data collection.

No prior research on healthcare workers' adherence to the recommended dose of folic acid that can be given with sulphadoxine-pyrimethamine was found, therefore this limited the depth at which this research's finding on adherence to the recommended dose of folic acid was discussed.

4.2 IMPLEMENTATION FIDELITY

The overall implementation fidelity score in this study was found to be moderate. The score of 60% implies that some prescribed components of IPTp-SP guidelines were not implemented as indicated. Low adherence to the content of IPTp-SP guidelines (one of the constructs of implementation fidelity) significantly lowered the overall implementation fidelity score. In particular, the administration of sulphadoxine-pyrimethamine as a directly observed therapy (DOT) and with a dose of folic acid (0.4mg) that does not affect its efficacy as an antimalarial drug. The other constructs of implementation fidelity (coverage, frequency, duration) were consistently high among healthcare providers. This research found that many healthcare providers used the right antimalarial drug for IPTp-SP at the recommended age of pregnancy and duration but failed to administer it as a DOT. The above finding is in contrast to what researchers found in other parts of Africa, where confusion over IPTp-SP guidelines among healthcare providers (29,84,85), and failure to administer sulphadoxine-pyrimethamine at the recommended stage of pregnancy (48,49) was reported. However, the lack of adherence to DOT is consistent with what other researchers reported (10,17,27,29). The World Health Organisation (WHO) recommendation on DOT was to ensure that pregnant women take the full dosage of the antimalarial drug (7). A study by Azizi and colleagues (2018) found that pregnant women not taking sulphadoxine-

pyrimethamine as a DOT are less likely to receive the recommended dosage of the drug (41). There is strong evidence that three or more doses of sulphadoxine-pyrimethamine are more effective in preventing malaria in pregnancy as well as reducing its burden (44,46). Low adherence to DOT could lead to failure of IPTp-SP, the evidence-based intervention to prevent malaria in pregnancy.

To the best of my knowledge, healthcare workers' adherence to the recommended dose of folic acid that can be given with sulphadoxine-pyrimethamine has not been reported in the literature unlike adherence to DOT, the component of IPTp-SP guidelines that was reported by many researchers (10,17,27–29). The importance of implementing all the core components of an intervention to achieve the desired health outcome was demonstrated by Fagan and colleagues (1990). These researchers reported that the sites with the stronger implementation of most of the core components of a programme testing for correctional interventions for chronically violent young offenders fared much better than the sites that had not implemented most of the core components of the programme. The programmes implemented with high fidelity achieved significant reductions in the number and severity of arrests and greater time until rearrests (71). Adherence to the other important component of IPTp-SP guidelines was found to be low. Some healthcare providers administer sulphadoxine-pyrimethamine with a high dose of folic acid (equal to or greater than 5 mg). It has been shown that a high dose of folic acid (equal to or greater than 5 mg) counteracts the antimalarial effect of sulphadoxine-pyrimethamine (7,47). Even though three out of the four constructs of implementation fidelity were found to be high among the healthcare providers, low adherence to the DOT component of the intervention and giving it together with a high dose of folic acid could render the whole intervention ineffective in preventing malaria in pregnancy.

Implementation fidelity of IPTp-SP guidelines varied among the three types of healthcare facilities. Healthcare providers in PMI healthcare facilities adhered to IPTp-SP guidelines with higher fidelity than those in the nPMI and private healthcare facilities. Implementation fidelity in PMI and nPMI was moderate while in private healthcare facilities, it was sub-optimal. It is not surprising that those in PMI adhered more than those in nPMI. PMI healthcare facilities in Sokoto have better performances over nPMI in terms of greater availability of malaria commodities, trained healthcare providers, higher quality of care, national malaria treatment guidelines, laboratories and microscopes and generally better data quality (6). Research has shown inadequate supplies of sulphadoxine-pyrimethamine and poor knowledge of IPTp-SP to be barriers to healthcare providers delivering IPTp-SP (25). Our results show that the level of knowledge of healthcare providers on IPTp-SP, availability of IPTp-SP guidelines, training of healthcare providers on IPTp-SP guidelines and supervisory visits after training influence adherence to IPTp-SP. The other factors shown by PMI healthcare facilities, such as better availability of laboratories and microscopes, higher quality of care and generally better data quality could be possible moderators of implementation fidelity of IPTp-SP. However, it is surprising that implementation fidelity was sub-optimal in private healthcare facilities. This is contrary to what was assumed before the research, that private healthcare facilities provide better health care than government healthcare facilities. Our finding corroborates the findings of Mubyazi and colleagues (2008) who reported that private healthcare facilities are more likely to fail to implement IPTp-SP with fidelity (38) or to administer other antimalarial drugs demanded by pregnant women (40). A systematic review found that healthcare providers in private healthcare facilities often fail to comply with the medical standard of care and had poor patient's outcomes, but they were better than healthcare providers in the public sector in terms of hospitality to their patients and timeliness (86). A study

carried out in Enugu, a state in the southeast of Nigeria also reported low levels of knowledge of healthcare providers on IPTp-SP by all the healthcare professionals, especially those in the private healthcare facilities and attributed this to lack of adherence to DOT (27).

4.3 DETERMINANTS OF IMPLEMENTATION FIDELITY OF IPTP-SP GUIDELINES

Determinants of implementation fidelity of IPTp-SP guidelines were measured in this research and their relationships with implementation fidelity determined. Four of these determinants—quality of delivery, intervention complexity, participant's responsiveness and level of knowledge of healthcare providers on IPTp-SP—were quite high among the healthcare providers. However, only level of knowledge was found to be a significant determinant of the overall implementation fidelity of IPTp-Sp. Facilitation strategies measured in this study, which include training of healthcare providers on IPTp-SP, receiving of supervisory visits after training and possession of IPTp-SP guidelines, were poor among all the healthcare providers and was found to significantly influence the construct of implementation fidelity that contributed to the lowering of the overall implementation score. Cadre of healthcare providers and educational qualification were also found to be significant determinants of overall implementation fidelity of IPTp-SP guidelines.

Contrary to the findings of other studies, that pregnant women did not like to take sulphadoxine-pyrimethamine on an empty stomach (19,53), and do not come back for subsequent antenatal care visits (21,54) or show up late for antenatal care visit (21,38,53), this research found that pregnant women comply with taking sulphadoxine-pyrimethamine as a DOT. They also come back for the next dose of sulphadoxine-pyrimethamine when properly advised to do so. Overall, participant responsiveness was found to be good, and this indicates that healthcare providers did not have problems with pregnant women when providing IPTp-SP to them.

The level of knowledge of healthcare providers on IPTp-SP was found to be a significant determinant of implementation fidelity of IPTp-SP guidelines. This finding is similar to the finding of research carried out in Ibadan, a southwestern part of Nigeria. The researchers reported that healthcare providers knowledge of IPTp-SP was a significant moderator of the practice of IPTp-SP (20). Another study carried out in southeast Nigeria, found adherence to the DOT component of IPTp-SP guidelines to be influenced by the healthcare providers level of knowledge on IPTp-SP (27).

A significant association between facilitation strategy and adherence to the content of IPTp-SP guidelines found in this study provided more evidence of the moderating effect of the level of knowledge of healthcare providers on IPTp-SP on implementation fidelity. Providing the right antimalarial drug to pregnant women as a DOT and with a dose of folic acid (0.4mg) that can safely be given with it were found to be significantly moderated by training of healthcare providers on IPTp-SP, receiving of supervisory visits after training and possession of IPTp-SP guidelines. Improving facilitation strategies could boost the level of knowledge of healthcare providers on IPTp-SP, thereby improving the whole implementation process and consequently successful prevention of malaria in pregnancy in Sokoto.

Among the characteristics of healthcare providers studied, cadre of healthcare providers and educational qualification were found to have a significant association with implementation fidelity of IPTp-SP. Nurses were found to adhere to IPTp-SP guidelines with higher implementation fidelity than doctors. Doctors without a postgraduate degree were less likely to adhere to IPTp-SP guidelines compared to healthcare providers with a Nigerian national diploma. This is in contrast to research by Laurant and colleagues (2005) who found insignificant differences between doctors and nurses in terms of patients' health outcomes, the process of care and utilisation of resources

(87). Horrocks and colleagues (2002), however, reported that nurses had longer consultations and were more likely to do more investigations than doctors (88).

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSION

The findings of this research demonstrated that the overall implementation fidelity of IPTp-SP guidelines was moderate because some of the important components of the intervention were not implemented with high fidelity. In addition to this, adherence to IPTp-SP guidelines was also not uniform between the types of healthcare facilities, the four cadre of healthcare providers and the three levels of educational qualification studied in this research.

Adherence to all the components of IPTp-SP guidelines can be improved by improving the level of knowledge of healthcare providers on IPTp-SP. This can be achieved by the training of healthcare providers on IPTp-SP, receiving of supervisory visits after training and making IPTp-SP guidelines available to them. Also, it can be achieved by finding the reason and the solution to why nurses adhere more to IPTp-SP guidelines than doctors and why those with Nigerian national diploma adhere more to IPTp-SP guidelines than doctors with only a first degree. Therefore, findings from this research can help to guide further planning and policy decisions on prevention of malaria in pregnancy.

5.2 RECOMMENDATIONS

Based on the findings from this research, the following recommendations are made for the successful implementation of IPTp-SP:

1. There is a need for re-training of healthcare providers especially those in the private sector on WHO IPTp-SP guidelines, putting more emphasis on the recommended dosage of folic acid that can be giving with sulphadoxine-pyrimethamine and giving the drug as a DOT. Providing supervisory visits after the training and availability of IPTp-SP guidelines to all healthcare providers should be well in place. Poor availability of these facilitation strategies resulted in the reduction of implementation fidelity scores in this study.
2. Healthcare providers in the private sector should not be left on their own, they should be provided with all the necessary support for proper implementation of IPTp-SP.
3. The National Malaria Elimination Programme of the Federal Ministry of Health and international partners involved with prevention, control and eradication of malaria should consider assessment of implementation fidelity of IPTp-SP guidelines as part of monitoring and evaluation in both government and private healthcare facilities. This assessment can provide information on the level of healthcare providers adherence and suggest issues that need to be resolved to achieve the desired outcomes.
4. Further research is needed to investigate why nurses adhere more to IPTp-SP guidelines than doctors and why those with the Nigerian national diploma adhere more to IPTp-SP guidelines than doctors with only a first degree. The results could be used to develop strategies that can ensure uniform high adherence of IPTp-SP guidelines among all the healthcare providers.

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APPENDICES

APPENDIX A: PLAGIARISM DECLARATION

Plagiarism declaration for written work: Master of Science in Epidemiology

I Bilkisu Abdullahi Yar'adua (Student number: 1893792) am a postgraduate student registered

for degree / Programme MSc. Epidemiology (Implementation Science) in the Wits School of Public Health.

I am submitting my written work for assessment for the module:

Research Report (COMH7175) (course name and code).

I hereby declare the following:

- I am aware that plagiarism is the use of someone else's work without their permission and/or without acknowledging the original source).
- I am aware that plagiarism is wrong.
- I confirm that the work submitted for assessment for the above course is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature:  Date: 10/08/2019

APPENDIX B: QUESTIONNAIRE

QUESTIONNAIRE ID……

A1: CHARACTERISTICS OF HEALTHCARE PROVIDERS.

1. Age _____ (in years)

2. Sex: Male ☐Female ☐others, please specify ……

3. Cadre of healthcare providers: Doctor ☐Midwife☐ Nurse ☐ Community health worker ☐ others, please specify ……

4. How long have you been working as a healthcare provider in antenatal care section (working experience) ……

5. Educational qualification: Nigerian national diploma☐ First degree ☐ Post-graduate degree ☐ others, please specify ……

SECTION A2: LEVEL OF KNOWLEDGE OF HEALTHCARE PROVIDERS ON IPTp-SP

6. Malaria in pregnancy can be prevented successfully

Yes ☐ No ☐

7. IPTp-SP is the most effective way of preventing malaria in pregnancy

Yes ☐ No ☐

8. IPTp-SP is the use of sulphadoxine-pyrimethamine given in treatment doses at least two months apart between doses immediately after the second trimester

Yes ☐ No ☐

9. IPTp is based on the assumption that all pregnant women living in malaria endemic areas have malaria parasites in their blood or placenta, whether or not they have symptoms of malaria

Yes ☐ No ☐

10. Sulphadoxine-pyrimethamine is a safe drug for preventing malaria in pregnancy

Yes ☐ No ☐

11. Three or more doses of sulphadoxine-pyrimethamine are effective in protecting both baby and mother against malaria.

Yes ☐ No ☐

12. The full meaning of DOT is Directly Observed Treatment

Yes ☐ No ☐

13. Pregnant women should be screened for history of allergy tha drugs before administering sulphadoxine-pyrimethamine to them

Yes ☐ No ☐

14. History of allergy to sulpha drugs should not be recorded in maternal health record book.

Yes ☐ No ☐

15. A pregnant woman at her second trimester should be asked whether she has received sulphadoxine-pyrimethamine in the last month for whatever reason before administering sulphadoxine-pyrimethamine to her

Yes ☐ No ☐

16. A pregnant woman after her first trimester of pregnancy who has received sulphadoxine-pyrimethamine outside the antenatal care clinic should be advice to return to the hospital for Sulphadoxine-pyrimethamine one month after the last dose

Yes ☐ No ☐

17. Pregnant women with symptoms of malaria and who test positive for malaria should be treated accordingly.

Yes ☐No ☐

18. Pregnant women with symptoms of malaria and who test negative should receive sulphadoxine-pyrimethamine

Yes ☐ No ☐

SECTION B: INPLEMENTATION FIDELITY

I. CONTENT

19. I give sulphadoxine-pyrimethamine to pregnant women at least one month between doses as early as possible in the first trimester.

Never ☐ Occasionally ☐ Every time ☐

20. I give a daily dose of folic acid equal or above 5mg with sulphadoxine-pyrimethamine.

Never ☐ Occasionally ☐ Every time ☐

21.I administer sulphadoxine-pyrimethamine as a Directly Observed Treatment (DOT)

Never ☐ Occasionally ☐ Every time ☐

22. I give sulphadoxine-pyrimethamine to pregnant women to take at home

Never ☐ Occasionally ☐ Every time ☐

23. I give sulphadoxine-pyrimethamine to pregnant women as a DOT irrespective of whether they have eaten or not.

Never ☐ Occasionally ☐ Every time ☐

II. FREQUENCY AND COVERAGE

24. I provide IPTp-SP to pregnant women at every scheduled antenatal care visit starting early in the second trimester of pregnancy.

Never ☐ Occasionally ☐ Every time ☐

25.I give all the three tablets of sulphadoxine-pyrimethamine as a single dose at every scheduled antenatal care visit

Never ☐ Occasionally ☐ Every time ☐

26. I give a two months interval between two doses of sulphadoxine-pyrimethamine

Never ☐ Occasionally ☐ Every time ☐

III. DURATION

27. I start IPTp-SP as early as possible in the second trimester until the pregnant woman delivers.

Never ☐ Occasionally ☐ Every time ☐

28. I provide sulphadoxine-pyrimethamine to pregnant women even if she missed it in the second trimester with a monthly interval between doses until she delivers.

Never ☐ Occasionally ☐ Every time ☐

SECTION C: DETERMINANTS OF IMPLEMENTATION FIDELITY.

I. FACILITATION STRATEGIES

29. I have been trained on WHO-recommended IPTp guidelines

Yes ☐ No ☐

30. I have WHO-recommended IPTp guidelines

Yes ☐ No ☐

31. I received supervisory visits after training on WHO-recommended IPTp guidelines

Yes ☐ No ☐

II. QUALITY OF DELIVERY

32. I inform pregnant women to come back for next scheduled antenatal care visit

Never ☐ Occasionally ☐ Every time ☐

33. I encourage early and frequent antenatal care visit

Never ☐ Occasionally ☐ Every time ☐

34. I explain the purpose and benefits of IPTp-SP to pregnant women.

Never ☐ Occasionally ☐ Every time ☐

35. I advise pregnant women to report any side effects after taking sulphadoxine-pyrimethamine

Never ☐ Occasionally ☐ Every time ☐

III. INTERVENTION COMPLEXITY

36. How would you describe the process of conducting IPTp-SP as recommended by WHO.

Very complex ☐ Somewhat complex ☐ Somewhat simple ☐ Very Simple ☐

37. How would you describe the information provided in the guideline?

Very vague ☐ Somewhat vague ☐ Detailed ☐ Very Detailed ☐

.

IV. PARTICIPANTS' RESPONSIVENESS

38. Pregnant women attend antenatal care early in their first trimester of pregnancy and every month thereafter.

Strongly Agree ☐Agree☐ Disagree ☐ Strongly disagree ☐

39. Pregnant women are cooperative and feel comfortable with taking sulphadoxine-pyrimethamine as a DOT

Strongly disagree ☐Disagree☐ Agree ☐ Strongly Agree ☐

40. Pregnant women come back for next dose of sulphadoxine-pyrimethamine when properly advised to come for it?

Strongly Agree ☐Agree☐ Disagree ☐ Strongly disagree ☐

41. Pregnant women perceive sulphadoxine-pyrimethamine to be safe and effective in preventing malaria in pregnancy

Strongly Agree ☐Agree☐ Disagree ☐ Strongly disagree ☐

APPENDIX C: WITS HUMAN RESEARCH ETHICS COMMITTEE (HREC) CLEARANCE CERTIFICATE

R14/49 Ms B Yar'adua

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M181147

NAME: (Principal Investigator)	Ms B Yar'adua
DEPARTMENT:	School of Public Health Medical School University
PROJECT TITLE:	Implementation fidelity of the guidelines of intermittent preventive treatment of malaria in pregnancy and its determinants in Sokoto State, Nigeria
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professors L Ibisomi and Z Iliyasu
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	27/02/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore reports and re-certification will be due early in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature — Date: 3/1/2019

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX D: ETHICS APPROVAL LETTER FROM THE SOKOTO STATE MINISTRY OF HEALTH

MINISTRY OF HEALTH

Block 16, Shehu Kangiwa Secretariat
P.M.B. 2113, Sokoto State – Nigeria
Tel: 060-232856, 232425,2321

SMH/1580/V.IV 27/11/2018

Dr. Bilkisu Abdullahi Yar'Adua
University of the WITWATERSRAND,
Johannesburg, South Africa.

ETHICAL CLEARANCE FOR RESEARCH ON "IMPLEMENTATION FIDELITY OF THE GUIDELINES OF INTERMITTENT PREVENTIVE TREATMENT OF MALARIA IN PREGNANCY AND ITS DETERMNANTS IN SOKOTO STATE, NGIERIA" SKHREC/117/018)

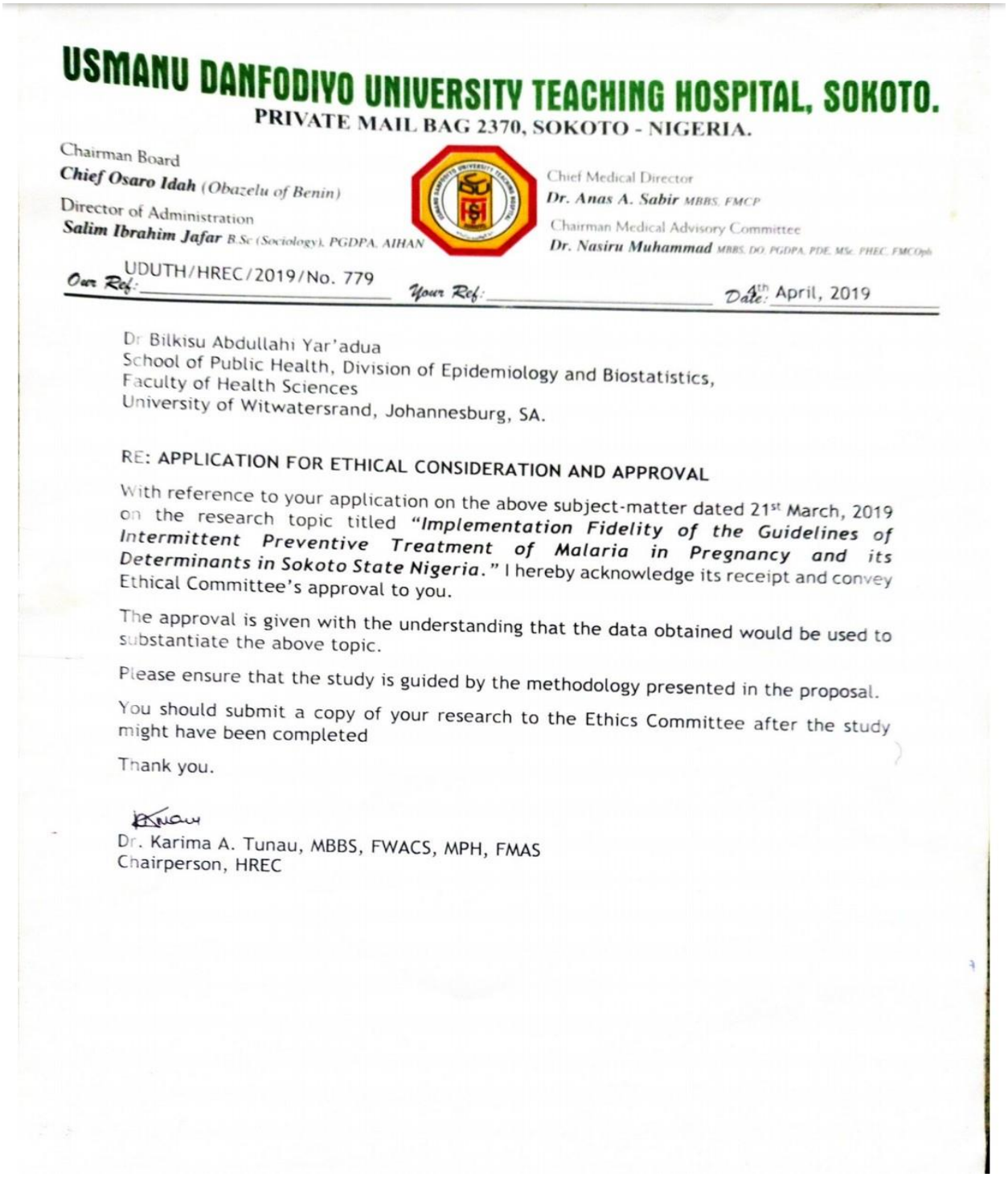
I am directed to refer to your application on the above and to inform you that, the protocol submitted was reviewed by State Health Research Ethics Committee and found the protocol and other documents related to the survey to be satisfactory.

In the light of the above, I am further directed to convey the approval of the committee for the conduct of the said survey. It is however, expected that, the results of the survey will be sent to the committee for documentation and further necessary action as soon as it is concluded.

Accept the best wishes of the Honourable Commissioner, please.

MUHAMMAD LADAN
Director, Health Planning, Research& Statistics,
For: Honourable Commissioner

APPENDIX E: ETHICS APPROVAL LETTER FROM USMANU DANFODIYO UNIVERSITY TEACHING HOSPITAL, SOKOTO



USMANU DANFODIYO UNIVERSITY TEACHING HOSPITAL, SOKOTO.

PRIVATE MAIL BAG 2370, SOKOTO - NIGERIA.

Chairman Board
Chief Osaro Idah *(Obazelu of Benin)*
Director of Administration
Salim Ibrahim Jafar *B.Sc (Sociology), PGDPA, AIHAN*

Chief Medical Director
Dr. Anas A. Sabir *MBBS, FMCP*
Chairman Medical Advisory Committee
Dr. Nasiru Muhammad *MBBS, DO, PGDPA, PDE, MSc, FHEC, FMCOph*

Our Ref: UDUTH/HREC/2019/No. 779 Your Ref: _____ Date: 4th April, 2019

Dr Bilkisu Abdullahi Yar'adua
School of Public Health, Division of Epidemiology and Biostatistics,
Faculty of Health Sciences
University of Witwatersrand, Johannesburg, SA.

RE: APPLICATION FOR ETHICAL CONSIDERATION AND APPROVAL

With reference to your application on the above subject-matter dated 21st March, 2019 on the research topic titled ***"Implementation Fidelity of the Guidelines of Intermittent Preventive Treatment of Malaria in Pregnancy and its Determinants in Sokoto State Nigeria."*** I hereby acknowledge its receipt and convey Ethical Committee's approval to you.

The approval is given with the understanding that the data obtained would be used to substantiate the above topic.

Please ensure that the study is guided by the methodology presented in the proposal.

You should submit a copy of your research to the Ethics Committee after the study might have been completed

Thank you.

Dr. Karima A. Tunau, MBBS, FWACS, MPH, FMAS
Chairperson, HREC

APPENDIX F: ETHICS APPROVAL LETTER FROM SPECIALIST HOSPITAL SOKOTO

SPECIALIST HOSPITAL SOKOTO

SULTAN ABUBAKAR ROAD
P.M.B 2133, Sokoto, Nigeria

HOSPITAL ETHICS AND RESEARCH COMMITTEE

CHAIRMAN
DR. BELLO U. TAMBUWAL
Chairman Medical Advisory Committee

MEMBER
DR. NASIRU ABDULLAHI
HOD Obs & Gyn.

MEMBER
DR. ALI A. YAROKO
Deputy CMAC/HOD ENT.

MEMBER
BELLO I. LADAN
HOD Health Record

MEMBER
BALA SAIDU
HOD Operating Theater

SECRETARY
USMAN M. MUH'D
Secretary Clinical Services

SHS/SUB/133/VOL.I

25th March, 2019

DR BILKISU ABDULLAYI YAR'ADUA,
School of Public Health,
Division of Epidemiology and Biostatistics
Faculty of Health Science,,
University of the Witwatersrand,
Johannesburg, S/Africa.

Re: Ethical Clearance

I am directed to refer to your topic proposal dated 18th March 2019 and to inform you that, the Hospital Ethics Committee has approved your request to carry out a research on **"IMPLEMENTATION FIDELITY OF THE GUIDELINES OF INTERMITTANT PREVENTIVE TREATMENT OF MALARIA IN PREGNANCY AND ITS DETERMINANTS IN SPECIALIST HOSPITAL, SOKOTO".**

2. All research programs should be carried out in line with the Hospital regulations.

3. The Hospital should have the copy of the research work upon completion.

4. Thanks.

CMAC OFFICE SPECIALIST HOSPITAL SOKOTO

USMAN M. MUH'D
Secretary Hospital Ethics Committee
For: Chairman Hospital Ethics Committee
Specialist Hospital, Sokoto.

APPENDIX G: INFORMATION SHEET

Good day

My name is Dr. Bilkisu Abdullahi Yar'adua and I am a Masters student of Epidemiology field of Implementation science, School of Public Health, University of the Witwatersrand, Johannesburg, South Africa. As part of my studies, I have to undertake a research project, the purpose of this research is to know how intermittent preventive treatment guidelines are being implemented in antenatal care section of private, government and PMI supported government healthcare facilities in Sokoto State.

As part of this project I would like to invite you to take part in answering an interviewer administered questionnaire. This activity will involve an interviewer asking you questions and you as a healthcare provider providing answers to the questions and it will take around forty minutes.

You will not receive any direct benefits from participating in this study, and there are no disadvantages or penalties for not participating. You may withdraw at any time or not answer any question if you do not want to. The interviewer administered questionnaire will be completely

confidential and anonymous as I will not be asking for your name or any identifying information, and the information you give to me will be held securely and not disclosed to anyone else. If you experience any distress or discomfort, the questionnaire will be stopped or resume another time.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Yours sincerely

Dr. Bilkisu Abdullahi Yar'adua, aybilkisu@gmail.com, (+234) 8037866346

Prof. Latifat Ibisomi, latifat.Ibisomi@wits.ac.za , +27780872521

APPENDIX H: INFORMED CONSENT FORM

IMPLEMENTATION FIDELITY OF THE GUIDELINES OF INTERMITTENT PREVENTIVE TREATMENT OF MALARIA IN PREGNANCY AND ITS DETERMINANTS IN SOKOTO STATE, NIGERIA

BILKISU ABDULLAHI YAR'ADUA

I …….. agree to participate in this research project. The research has been explained to me and I understand what my participation will involve.

I agree that my participation in this research is voluntary YES NO (please circle)

I agree that my participation will remain anonymous YES NO

I agree that information from this research may be used for a thesis report, publications or presentations YES NO

…… (signature)

…… (name of participant)

…… (date)