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Implementation fidelity of management guidelines for hearing loss resulting from treatment of drug-resistant tuberculosis in Kano state, Nigeria

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2019
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IMPLEMENTATION FIDELITY OF MANAGEMENT GUIDELINES FOR HEARING LOSS RESULTING FROM TREATMENT OF DRUG-RESISTANT TUBERCULOSIS IN KANO STATE, NIGERIA



UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

BY:

Dr. Sani Ibrahim Muhammad

A research report submitted to the faculty of Health Science, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirement for the degree of Master of Science in Epidemiology in the field of Implementation science

July 2019

DECLARATION

I Dr. Sani Muhammad, declare that this research Report is my own unaided work. It is being submitted for the degree of Master of Science in Epidemiology in the field of implementation science at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



(Signature of Candidate)

16th day of July 2019

DEDICATION

In memory of my Mentor

Muhammad Bn Abdullah

(Abu Al-Qasim)

570 CE

PREFACE

This Research Report is submitted to the Division of Epidemiology and Biostatistics, School of Public Health, Faculty of Health Sciences, University of the Witwatersrand for the fulfilment of the requirement for the Master of Science degree in Epidemiology in the Field of Implementation Science. This MSc work was performed at the School of Public Health, with Professor Latifat Ibisomi as the main supervisor and with co-supervisor Professor Zubairu Iliyasu of the Department of Community Medicine, Bayero University Kano, Nigeria. Financial assistance was received from TDR fellowship awarded by the World Health Organization, Tropical Disease Research (WHO/TDR) from 2017 to 2018.

LIST OF PRESENTATIONS FROM THE STUDY

1. Muhammad SI**,** Ibisomi L, Iliyasu Z. Implementation fidelity of management guidelines for hearing loss resulting from treatment of Drug-resistant Tuberculosis in Kano, Nigeria. In: Skills Building Workshop: Overview of Implementation Science and its application to TB care. Proceedings in the conference programme of the 5th South Africa Tuberculosis Conference, Durban, South Africa, 12–15 June 2018. Available at: http://www.tbconference.co.za/css/images/TB%20Programme.pdf [Accessed 23.06.2018]

2. Muhammad SI, Ibisomi L, Iliyasu Z. Implementation fidelity of management guidelines for hearing loss resulting from treatment of Drug-resistant Tuberculosis. In: Education, Policy and Systems. Proceedings of the 2018 Faculty of Health Sciences Research Day & Postgraduate EXPO, University of the Witwatersrand, Johannesburg, South Africa, 6–7 September 2018

3. Muhammad SI, Ibisomi L, Iliyasu Z. Implementation fidelity of management guidelines for hearing loss resulting from treatment of Drug-resistant Tuberculosis. In: Addressing the Burden of disease: Communicable Disease. Proceedings of the 14th Annual Conference of the Public Health Association of South Africa (PHASA) 2018, Khaya iBhubesi, Parys, South Africa, 10-12 September 2018.

4. Muhammad SI, Ibisomi L, Iliyasu Z, Ramawasmy R. Preventing Ototoxicity through the application of Implementation Research Methods. In: Otology. Proceedings and Book of abstract of the 26th Annual meeting and scientific conference of the Otorhinolaryngological Society of Nigeria (ORLSON) 2018, Beverly Hill Hotel, Port Hacourt, Nigeria, 14-17 November 2018.

5. Muhammad SI, Ibisomi L, Iliyasu Z, Ramawasmy R. Prevention of Ototoxicity by application of Implementation Research Methods. In: Ensuring universal access to surgical services. Proceedings and Book of abstract of the 59th Annual meeting and scientific conference of the West African College of Surgeons (WACS), Dakar, Senegal, 21-24 January 2019.

ABSTRACT

Background: Nigeria has a high burden of Tuberculosis (TB) including Drug-resistant Tuberculosis (DR-TB). Hearing loss is a potential consequence of TB treatment, which has negatively affected the success of TB control and prevention. The aim of this study was to assess the Implementation fidelity of management guidelines for hearing loss resulting from DR-TB treatment and to find factors associated with the Implementation fidelity

Methods: A cross-sectional study, involving health care providers at Infectious Disease Hospital, Kano was conducted. It was a questionnaire-based assessment of implementation fidelity as defined by the four domains of content, coverage, duration and frequency of the Programmatic Management guidelines for treatment of Drug-resistant Tuberculosis. The data were statistically analyzed in Stata 14.2 (Inc. USA) and regression models were fitted.

Results: The Implementation fidelity was low, which ranged from 40 - 60% ($p < 0.001$). The core determinants of Implementation fidelity identified based on the conceptual framework were the facilitation strategies, quality of delivery, intervention complexity, participants' responsiveness and sociodemographic characteristics. Facilitation strategy, quality of delivery, intervention complexity, participants' responsiveness, age, sex, professional cadre and work experience were individually associated with implementation fidelity among the health care providers. Among all the determinants, quality of delivery, intervention complexity, participants' responsiveness, sex and professional cadre exerted a positive effect on implementation fidelity ($p<0.001$) while facilitation strategy, age and work experience exerted a negative effect on implementation fidelity ($p<0.001$).

Conclusion: The implementation fidelity of management guideline for hearing loss resulting from Drug-resistant Tuberculosis treatment was low among health care providers at the infectious disease hospital, Kano, Nigeria. The study serves as an empirical research in testing the conceptual framework for assessment of implementation fidelity that was developed theoretically. Implementation fidelity should be assessed early and at intervals in the course of implementing the PMDT guideline and indeed, in the course of implementing any intervention.

Keywords: Implementation fidelity, Determinants, Drug-resistant Tuberculosis, PMDT guidelines, Hearing loss, Nigeria.

ACKNOWLEDGEMENTS

Firstly, I would like to give all glories and thanks to Almighty Allah who gave me the health and wisdom to conceptualize and execute this work. I want to thank my supervisors who guided me through the journey of thinking and refining my ideas to arrive at a title for my study. Particularly, Professor Latifat Ibisomi has been more than a supervisor but also a prudent mentor to me. I really appreciate her guidance and insightful comments. As for my second supervisor, Professor Zubairu Iliyasu gladly gave me part of his time in understanding the larger picture of the need to participate actively in research.

I am very grateful to Professor Jonathan Levin who comforted me with clarification of my challenges on statistical analyses. He literally squeezed his many years of experience in scientific research in to those sessions we had. I really appreciate his time as he always grants me audience whenever I needed such. My appreciation goes to Dr. Innocent Maposa as well for demystifying aspects of Statistical analysis for me.

I am grateful to the Kano State Ministry of health and the IDH team of Dr. Farouk and Matron Hindatu Mahmoud for their assistance, useful advice, comments and support during data collection.

I acknowledge Professor Rohit Ramaswamy from the "Gilling's School of Global Public Health, University of North Carolina, Chapel Hill" with the entire Tropical Disease Research team hosted at the World Health Organization for their generous financial and academic support and the opportunity to be part of their research network.

My profound gratitude to the entire members of staff in the division of Epidemiology & Biostatistics, Wits School of Public Health, especially Professor Latifat Ibisomi, coordinating the course and doubling as my supervisor, the course administrator, Mrs. Busi Mamabolo and scholarship administrator, Mrs. Gloria Bowes for making my stay in the School a great experience that I will live to remember. A big thank you to Professor Tobias Chirwa, the head of School of Public Heath for the opportunity I had to present my research work at the 5th South Africa Tuberculosis conference in Durban (June 2018). I received very constructive feedback which has improved my report.

I would like to express special regards for Ms. Gila Carter of the office of student support who helped to proof read the work at its earliest form and offer suggestions on how to improve the work. I also thank Professor Shehu Mohammad of Dermatology and Prof. Habeeb AbdurRazaq of Infectious Disease for their continuous advice on my career. My thanks go to all my classmates for being wonderful and memorable companions.

I am also profoundly grateful to my father, Alhaji Ibrahim Muhammad and my mother, Mallama Maimunatu Muhammad, my uncles, my siblings and my parents' in-law Alhaji Idris Sulaiman Kuta and Hajiya Ruqayyatu Idris. They were very helpful and are the source of inspiration for my struggle. I will indeed remain indebted to them as they kept me going till the end of my studies.

My special thanks to my beloved wife, the mother of our children Mallama Aishatu. She has prudently maintained the home, allowing me to get focused on the study. To my lovely kids, Fatimatu, Maimunatu, Ruqayyatu and Ahmad, I really appreciate your sacrifice of coping with my absence for that long. I am glad to know that you still love me. I love you all.

I was fortunate to have a chance to work with some of my senior colleagues particularly Dr Abdu Adamu, his inspirational role in my research work was great. I thank Dr Gbenga Olorunfemi whom I greatly learned from his thorough scientific insight and his ability to think outside the box. Mr. Wellington Maruma was very helpful in putting a good look to my final documents.

Finally, I appreciate the great company I enjoyed from the Vistaero Jama'a group particularly Dr. Abdullahi Mudi, Dr. Kassim Muhideen Mahinde and Dr. Zahra Omary Muya for their various roles in my good stay at Johannesburg.

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NOMENCLATURE

Implementation fidelity	this can be defined as the degree to which an intervention is delivered according to the original plan.
Adherence	This describes how well those health care providers responsible for implementing the management guideline adhere to the original protocol as intended by the designers. It is comprised of coverage, content, frequency and duration as subcategories of adherence.
Dosage	Refers to the amount of an intervention, here management guideline received by the respondents among Doctors, Nurses and Principal clinical assistants.
Coverage	This is a component of dosage that clarifies if all the intended recipients of an intervention actually did participate or receive the benefits of such a program.
Duration	This defines the length of time which an intervention is required to run, for the essential and/or core parts of the program to be delivered to the recipients.
Frequency	This adds another dimension to duration. It defines in absolute number how many times should the program run in a particular predefined periodicity for the intervention's ingredient to be delivered and expect a favorable outcome.
Content	This refers to the active ingredient of a skills, knowledge or guideline that an intervention tries to impact on the participants.
Facilitation strategies	this refers to provision of supportive measures towards effective implementation of an intervention. These include training, provision of protocols, guidelines, monitoring the implementers and giving constructive feedback to those deriving and executing the intervention.

Quality of delivery	this typically describes the way health care providers deliver the intervention (PMDT management guideline). It also relates to the manner in which the program was delivered, if it was commensurate to the expectation of the desired outcome. That is also how badly or how well the implementation was done.
Intervention complexity	this describes the sophistication of an interventions, as simple, detailed interventions are very much more likely to be delivered with high adherence (implementation fidelity) as compared to a complex and vague interventions.
Participants' responsiveness	this refers to the extent of participants' response to the program or their level of engagement (with PMDT management guideline). This often could be inferred from both the recipient of the intervention and the personnel responsible for delivering the intervention.
Program differentiation	Refers to the process of identifying the unique forms of different part of the intervention and establishing which components are essential and unique.
Hearing loss	this is defined as partial or total inability to hear conversational speech. Depending on the severity, it could be mild, moderate, moderate-severe, severe, profound and total. It can also be temporary or permanent based on the duration.

ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
AE	Adverse Event
Am	Amikacin
Amx/Clv	Amoxicillin/Clavulanate
ANOVA	Analysis of Variance
AIDS	Acquired Immune Deficiency Syndrome
CI	Confidence interval
Cm	Capreomycin
Cs	Cycloserine
DR-TB	Drug-resistant Tuberculosis
dB	Decibel
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short course
DST	Drug Sensitivity Testing
DS-TB	Drug Susceptible Tuberculosis
E	Ethambutol
FDA	Food and Drug Administration
FLD	First Line Drugs
FMOH	Federal Ministry of Health
H	Isoniazid
HCP	Health Care Provider
HIV	Human Immunodeficiency Virus
Km	Kanamycin
MDR-TB	Multi-Drug Resistant Tuberculosis
MTB	Mycobacterium Tuberculosis
NDR-TBC	National DR-TB Committee
NRL	National TB reference Laboratory
NTBLCP	National Tuberculosis and Leprosy Control Program
OLS	Ordinary Least Squares
PMDT	Programmatic Management of Drug-resistant Tuberculosis
R	Rifampicin

RR	Rifampicin Resistance
RR-TB	Rifampicin Resistant Tuberculosis
SAE	Serious Adverse Effect
SLD	Second Line Drugs
SLI	Second Line Injectable
TB	Tuberculosis
XDR-TB	Extensively Drug Resistant Tuberculosis
WHO	World Health Organization
Z	Pyrazinamide
ZRL	Zonal Reference Laboratory

DEFINITION OF TERMS

Anti-Tuberculosis (Anti-TB) drugs	these are drugs used to treat Tuberculosis. These have currently been grouped in to five groups: **Group 1:** First-line oral anti-TB drugs - Isoniazid(H), Rifampicin (R), Ethambutol (E), Pyrazinamide (Z) and Rifabutin (Rfb). **Group 2:** Injectable anti-TB drugs - Kanamycin (Km), Amikacin (Am), Capreomycin (Cm), Streptomycin (S) **Group 3:** Fluoroquinolones - Levofloxacin (Lfx), Moxifloxacin (Mfx) and Gatifloxacin Gfx **Group 4:** Oral bacteriostatic second-line anti-TB drugs - Cycloserine (Cs), Terizidone (Trd), P-aminosalicylic acid (PAS) and P-aminosalicylic-Na **Group 5:** Anti-TB drugs with uncertain efficacy - Clofazimine (Cfz), Linezolid (Lzd), Amoxicillin/ Clavulanate (Amx/Clv), Thiacetazone (Th), Clarithromycin (Clr), Imipenem/Cilastatin(Ipm/Cln), Bedaquiline (Bdq), Delamanid (Dlm) and High dose isoniazid (High dose H)
Drug-resistant Tuberculosis	a situation when there is failure of patient's response to the anti-TB treatment as a result of resistance to any of the drugs used in treating Tuberculosis. These include mono resistant TB, poly resistant TB, multi drug resistant TB, pre-extensively drug resistant TB, extensively drug resistant TB and Rifampicin resistant TB
Mono resistance	Strains that are resistant only to one of the five first line drugs (Rifampicin, Isoniazide, Streptomycin, Ethambutol or Pyraziamide)
Poly resistance	Strains that are resistant to two or more drugs, but not to both Isonazid & Rifampicin

Multi Drug Resistance TB (MDR-TB)

MDR-TB is TB that is resistant to at least the two most important anti-TB drugs, isoniazid (H) and rifampicin. This means those two drugs do not effectively treat the TB disease.

Pre-Extensively Drug Resistance TB (Pre–XDR TB)

Pre–XDR TB is defined as TB with resistance to isoniazid and rifampicin and either a fluoroquinolone or second-line injectable agent but not both.

Extensively Drug Resistance TB (XDR-TB)

XDR-TB is a rare type of MDR-TB that is resistant to isoniazid and rifampicin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

Rifampicin Resistance (RR-TB)	Resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, in the form of mono-resistance, multidrug resistance, poly-drug resistance or extensively drug resistance.
Second-line Anti-TB drugs (SLD)	these are anti-TB drugs used for the treatment of Drug-resistant Tuberculosis. They are considered the "second-line drugs" because the "first-line drugs" are no longer effective due to drug resistance. Some of which are given parenterally as injectables. Example includes Streptomycin, Amikacin, Capreomycin and Kanamycin.
Sputum conversion	This describes a clinical stage when a newly diagnosed Tuberculosis patient by smear positive test result become smear negative after a period of taking anti-TB drugs. Hence, patient is not able to transmit the infection. This usually requires two or more sputum smear tests.

Ambulatory phase of TB therapy	Patient discharged from the hospital to the community center.
Directly Observed Treatment Short.	This is a practice whereby a Tuberculosis patient is observed to swallow the anti-TB drug in the presence of a health worker in assigned treatment centers or by a community volunteer or dedicated family member.

CHAPTER ONE: INTRODUCTION

1.1 Background

Tuberculosis has remained a public health concern in Nigeria. According to the Global Tuberculosis report of the World Health Organization in 2016, Nigeria was rated to have the tenth highest prevalence (323 per 100,000 people) of Tuberculosis (TB) globally.(1)

While a lot of efforts have been geared toward effective control of the burden of Tuberculosis,(2) it has been observed that in the course of treating patients with Tuberculosis, the majority of them respond to the treatment while some fail to respond by developing resistance to the drugs used for treatment. This failure of a patient to respond to any of the drugs used to treat Tuberculosis (anti-TB drugs) leads to another condition called "Drug-resistant Tuberculosis (DR-TB)". DR-TB refers to a situation when the patient fails to respond to treatment by developing resistance to at least one of the anti-TB drugs(3,4)

The proliferation of Drug-resistant Tuberculosis has placed Nigeria in the category of one of the four nations in Africa with the highest prevalence of drug-resistant Tuberculosis.(1) A subset of drug resistance is when a patient develops resistance to both isoniazid and rifampicin, in a condition called "Multidrug-resistant Tuberculosis (MDR-TB)"(3,5) The World Health Organization (WHO) earlier in its report of 2011,(6) estimated the Multidrug-resistant Tuberculosis rate in Nigeria to be 2.2% and 9.4%, for new and retreated cases of Tuberculosis respectively, giving a crude prevalence rate of 4.8%.(7) Hence, Nigeria ranks third in the 22 top nations with a high MDR-TB burden (6).

Evidence from a systematic review on the burden of Drug-resistant Tuberculosis in Nigeria, that was conducted in 2017 indicated that the situation has worsened over the years, with the prevalence rate of DR-TB in Nigeria increasing from 4.3% to 32% and from 25% to 53% for newly diagnosed and previously treated cases respectively,(8) and MDR-TB rate increased from 2.2% to 6% and from 9.4% to 32% for new and retreatment cases respectively.(8)

The worsening levels of both DR-TB and MDR-TB has negatively affected the success of the Nigerian TB control and prevention programs, that was geared towards providing "access to DR-TB diagnosis to all presumptive DR-TB cases between 2015 and 2020 in line with the

national diagnostic algorithm, to enroll 100% of diagnosed DR-TB patients on appropriate treatment between 2015 and 2020 and eventually ending Tuberculosis in Nigeria by 2035".(6,9)

To curb the menace of rising prevalence of DR-TB, the World Health Organization recommended a new and revised protocol for managing DR-TB called "Programmatic Management of Drug-resistant Tuberculosis (PMDT)". This guideline places emphasis on monitoring for and management of adverse effects resulting from the TB treatment regimen.(10) Since then, Nigeria has established a Working Committee as well as policy guidelines for Drug-resistant Tuberculosis and how it can be ameliorated by implementing the Programmatic Management of Drug-resistant Tuberculosis.(11)

This new program requires that all DR-TB patients are to be admitted in some specially allocated sections of designated hospitals for their treatment with anti-tuberculous drugs. The first-line oral anti-TB drugs are usually not effective on DR-TB patients due to the resistance.(5,12,13) they receive anti-TB drugs that are considered the second line drugs (SLD). Some of these second line drugs are invariably administered by deep intramuscular injection (parenteral route of administration) which causes hearing loss.(14,15)

The intramuscular injection will continue with monthly sputum smear testing going on hand-in-hand until sputum conversion is achieved, a situation when no single mycobacterial organism is isolated from the sputum.(9,16) Then after sputum conversion, the patient is discharged to the community centre to be followed up in the ambulatory phase of the therapy, where a patient is allowed to come daily for his medications at a "Directly Observed Treatment Short-Course (DOTS)" centre in the community usually closest to the patient's residence.(11)

In the DOTS centre, patients take their anti-TB drug under strict observation by a health care worker, community volunteer or family member and this information is entered into the patient's Tuberculosis card.(9,11,16) the card is reviewed periodically, to determine the progress of the patient's treatment. This card record also helps to detect defaulting patients for prompt necessary action.

In the course of treatment with the injectable second-line anti-TB drugs, DR-TB patients were noticed to have experienced a high burden of hearing loss.(17) Hence, hearing loss management strategy is a component of the National TB Guideline.(11,18)

So far, there has been insufficient objective information that could explain the reason behind the rising prevalence of hearing loss among DR-TB patients from 15.6% in 2004 to 61% in 2016 in Nigeria.(19) In trying to understand the mystery behind the rise in hearing loss among these patients, a number of factors have been identified, ranging from limited qualified personnel to implement the management guidelines, financial pressure on the Nigerian healthcare system with no audiological equipment that is appropriate for screening the patients on injectable second line anti-TB drugs for hearing loss, health care personnel's negative attitude towards patients with hearing loss before and during DR-TB treatment, lack of adherence to the recommended guidelines and improper implementation of the DR-TB guideline may be possible factors accounting for the continued increase in the prevalence of hearing loss.(20)

Therefore, in Nigeria, nine special centres were designed to carry out hearing assessment during the treatment for drug-resistant TB.(21) By this, all DR-TB patients that present to any of these facilities should have their hearing assessment done by audiometry as a routine service according to the PMDT guideline.(22)

Depending on the audiology test outcome, clinically hearing test finding was classified by the WHO as; "Normal hearing: from -10–15 dB, slight hearing loss 16–25 dB, mild hearing loss: 26–40 dB, moderate hearing loss: 41–55 dB, moderately severe hearing loss: 56–70 dB, severe hearing loss: 71–90 dB and profound hearing loss: >91 dB(decibels)"(23,24)

1.1.1 Burden of Hearing loss in "Drug-resistant Tuberculosis (DR-TB)" patients

Managing Drug-resistant Tuberculosis involves the use of injectable second line anti-tuberculous drugs (SLD), associated with debilitating side effects, such as hearing loss among others.(10) A study in South Africa among patients with Drug-resistant Tuberculosis taking anti-TB medications found the prevalence of hearing loss at 28.7% when treated with injectable second line anti-TB drugs, particularly aminoglycosides.(25)

Aminoglycosides are one of the SLDs that are administered by deep intramuscular injection and have been noted to damage the hearing and balance systems of humans.(15) This damage tends to be permanently sustained for longer period after cessation of therapy with the offending agent.(26) The study tried to verify the common SLDs used that account for the high prevalence of hearing loss and find ways of minimising these side effects. Presumably hearing loss in these patients resulted solely from the use of SLDs.

1.1.2 The WHO-recommended management Guidelines for Hearing loss in DR-TB

The documented high burden of hearing loss resulting from injectable second line anti-TB drugs in DR-TB treatment is both a global(1,16) and regional concern.(26,27) The devastating psychological and socioeconomic consequences,(28) have prompted World Health Organization (WHO) to publish recommended guidelines in 2011 (also called suggested management strategies) for managing hearing loss in PMDT. This was subsequently revised in 2016. The guidelines state in sequential order:(29)

"*1. Develop a management protocol and train all staff responsible for delivering treatment of DR-TB and its implementation.*
2. Inform patient about the early symptoms of ototoxicity, such as tinnitus and dizziness.
3. Perform a monthly audiometry of every patient on injectables, starting with a baseline at the time of enrolment on treatment.
4. If the patient is experiencing clinically significant ototoxicity, decrease the dosing frequency of the injectable to two to three times a week. Then, consider switching to capreomycin.
5. Stop the injectable if symptoms worsen despite dose adjustment, and add additional anti-TB drugs to reinforce the regimen"(10,29)

The above guidelines have been widely adopted when advocated by the WHO in many countries including Nigeria.(30) If implemented as intended, it should minimise the burden of hearing loss.

However, it was not detailed enough to guide its full implementation with fidelity (adherence) by all health care providers. Because there was no predefined minimum professional level of skills in the health care providers implementing the guidelines, it gave room to some practitioners to misinterpret and make some assumptions about the guidelines.

The guidelines did not differentiate the core elements of the intervention from the supplementary part. In addition, WHO recommends proper adaptation of the guidelines and contextualising them to suit each country's unique practice settings. This study aims to scrutinise its implementation in Nigeria with the hope of understanding the rising prevalence of hearing loss among patients with drug-resistant TB treated with injectable SLDs, despite its wide scale implementation across the country since 2012.

1.1.3 Programmatic Management of Drug-resistant TB (PMDT)

The Programmatic Management of Drug-resistant Tuberculosis is a major component of the National TB control programme (NTP) established in conformity to global TB control practice and to execute National TB control plan with high implementation fidelity according to the Nigeria's strategic plan.(29) Because of diverse contextual differences of health care settings in different countries, the WHO recommends that PMDT even though are global guidelines, should be country specific and should be adapted to local needs (1,29).

The Nigerian Federal Ministry of Health in collaboration with WHO, has initiated and recently expanded its Programmatic Management of Drug-resistant TB (PMDT)(16) to reflect current WHO terminologies and DR-TB management plans.(16) The PMDT is within the central unit of National TB and Leprosy Control Program (NTBLCP) in Nigeria, to coordinate and formulate policies on DR-TB management and control.(31)

The framework has been based on the five essential components of DOTS (16) namely sustained political commitment, effective case finding strategy, comprehensive treatment strategy, continuous supply of quality-assured second line anti-TB drugs and standardized drug-resistant record keeping with prompt reporting avenues which involves monitoring and management of side effects particularly hearing loss among others.(29)

Theoretically these guidelines should lead to reduction in the incidence of hearing loss following full implementation of the guidelines. This was not the case in Nigeria as evidenced by the rising incidence of hearing loss from 15.6% in 2004 to 61% in 2016. Therefore, this research was set to evaluate how the intervention was implemented and to study the factors possibly affecting the delivery of this intervention in Nigeria.

1.1.4 Contextual Problems with Hearing Loss Assessment in DR-TB patients

People on drugs likely to cause ototoxicity (chemical damage to the inner ear that leads to hearing impairment) are monitored for hearing loss, by assessing their drug serum level and/or audiometry.(32) While it is the standard practiced in developed countries, this is not the case in many developing countries. A South African study(32) reported that only one out of the five designated hospitals treating patients with Tuberculosis does audiological hearing assessment during DR-TB treatment, and in this hospital, only 60% of the patients were covered by audiometry.(32)

In Nigeria, while some researchers reported total lack of hearing assessment services during DR-TB treatment in some centres,(33) others reported some level of audiological testing in other centres.(19) The challenges affecting hearing assessment have been studied fairly well by some researchers with the hope of providing potential solutions.(34) WHO report identified the distance of the treatment facility as being associated with a lack of audiological assessment; if the facility was located far away from the community this reduced compliance with medication and follow-up to the health facility.(34)

Fagan et al. found that most Sub-Saharan African countries have no audiological services in their clinics and hospitals managing DR-TB patients.(35) In like fashion, Harris et al.(32) Observed that the inadequate services were due to financial pressure and competing budgets within the healthcare systems of the developing countries. Another study found limited qualified health care personnel carrying out audiology test to be a potential problem affecting hearing assessment in the continent of Africa,(36) and also having many primary health care settings with no audiological services at all.(21)

The noncompliance with medication and follow-up were worsened by the absence of transport incentives to patients attending clinics as well as to staff reaching remote areas to perform audiological assessment in clinics with limited facilities for testing.(36) In addition, negative attitude of healthcare workers towards patients with hearing loss was identified as a barrier to audiological assessment.

Despite this development, a lot of questions still remained unanswered. Is the availability of audiometry likely to change the course of these adverse events? Would there be a noticeable

difference in the course of clinical outcome among those who had audiometry test done during treatment and those who did not? How does the situation differ between the hospitals adhering to audiometry guidelines compared to those that did not?

While it is reasonable to think that overcoming these problems will reduce the prevalence of hearing loss, there is also the need to look deeper at how these guidelines are being implemented to achieve the desired goal and objectives. Taking an evidence-based guideline (intervention) that has been proven to work somewhere and expect it to work everywhere without contextualising it to the local environment is a common flaw in the implementation process of many interventions. This study tries to understand how these guidelines were implemented and the factors that affected adherence to the adapted guidelines.

1.2 Problem Statement

The position of Nigeria as one of the top ten nations having the "highest burden" of Tuberculosis and the fact that it is among the four African nations with the highest prevalence of drug-resistant Tuberculosis, already highlights the magnitude of DR-TB in the country. The situation has progressively worsened over the years to the current state where 32% and 53% of newly diagnosed and previously treated cases of Tuberculosis are drug-resistant Tuberculosis,(8) and MDR-TB rate has increased to 6% and 32% for new and retreatment cases respectively.(8) In response to this, there has been continued use of the injectable second-line anti-TB drugs which is a cause of hearing loss.(15,17,19,21,25,26,37–39)

Consequently, the incidence of hearing loss among DR-TB patients has risen from 15.6% in 2004 to 61% in 2016.(19) This has increased the average cost of treatment in these patients, causing more economic loss from wasted productivity. In addition the psychological effects of the side effect of these drugs and the resultant social and family related problems may culminate in reduced compliance to the medication, and this allows for the spread of further DR-TB cases.

This state of affairs was despite nationwide implementation of the WHO-recommended PMDT management guidelines for hearing loss in DR-TB treatment in the country. The level of adherence to the recommended guidelines in implementation may be a rate-determining

step in achieving the national goal to control DR-TB and may explain this rising prevalence of hearing loss among DR-TB patients.

There is neither enough information on how well the guidelines were implemented nor on the factors (determinants) affecting the implementation process of the management guidelines. Specifically, there has been little or no research carried out to assess implementation fidelity of the management guidelines for hearing loss resulting from DR-TB treatment in Nigeria. Therefore, this study aims to assess implementation fidelity of management guidelines for hearing loss with a view to providing baseline data and a road map in proposing possible solutions to the noted negative outcomes.

1.3 Research Question aim and objectives

1.3.1 Research question

What is the implementation fidelity of management guidelines for hearing loss resulting from DR-TB treatment among health care providers in Kano State, Nigeria in 2017 and the determinants (factors) affecting implementation fidelity?

1.3.2 Aim

The aim of this study was to assess the implementation fidelity of management guidelines for hearing loss resulting from DR-TB treatment among health care providers of the DR-TB Centre in Kano State, Nigeria in 2017 and to find factors associated with the implementation fidelity.

1.3.3 Objectives

1. To measure the implementation fidelity of management guidelines for hearing loss among health care providers in the DR-TB Centre of Infectious Diseases Hospital in Kano State, Nigeria in 2017.
2. To describe determinants of implementation fidelity of management guidelines for hearing loss in the DR-TB Centre of Infectious Diseases Hospital in Kano State, Nigeria in 2017
3. To determine the relationship between identified determinants and implementation fidelity of management guidelines for hearing loss in the DR-TB Centre of Infectious Diseases Hospital in Kano State in 2017.

1.4 Justification

There is a dearth of information on the rising incidence of hearing loss resulting from the treatment of Drug-resistant tuberculosis. This hearing loss leads to non-compliance in completing the treatment regimen for DR-TB, which results in a reservoir of further resistance which jeopardizes Nigeria's plan and policy to end TB by 2035. Thus, this study is expected to provide a road map in obtaining baseline data and reference for subsequent studies on this subject matter. This research will also advance the understanding of implementation fidelity of management guidelines for hearing loss during DR-TB treatment, the recommended measures for reducing hearing loss' burden, and may lead to improved adherence to the management guidelines. Findings from this research may help to guide further planning and policy decisions on DR-TB control and prevention.

1.5 Literature Review.

1.5.1 The Concept of Implementation Research and its Application today.

Implementation science research typically addresses implementation bottlenecks, identifies optimal approaches for a particular setting, and promotes the uptake of research findings: ultimately, leading to improved health care and its delivery.(40)

Implementation research is a relatively new field of research that is still evolving; however it has been widely applied to different settings. These include the application of an evidence based behavioural change intervention to promote physical activity in preventing various diseases of lifestyle by using health promotion strategies of translational research,(41) its application in obesity management among adults,(42) its application in public health program evaluations,(43) its application in the evaluation of school-based nutrition curriculum,(44) and in evaluating the weight management program of the Veteran's health administration in selected American institutions.(45)

The Product of this type of research is termed the Implementation outcome. The Implementation outcome is commonly assessed based on the heath care providers' perspective of the system and processes. This differentiates the Implementation outcome from the service outcome in conventional research such as Efficiency, Safety, Effectiveness, Equity, Patient centeredness and Timeliness. This is also different from research outcome

assessing client-oriented satisfaction, function or symptomatology. Thus, the Implementation outcome has been inaccurately measured as the health service outcome, which is based on the patients' perspective of the system and processes.(46)

A widely accepted definition of implementation outcomes was proposed by Proctor et al. He identified eight different forms of implementation outcomes namely: Implementation fidelity, Acceptability, Adoption, Appropriateness, Implementation cost, Feasibility, Penetration and Sustainability.(46)

The concept of implementation fidelity was theoretically based on the RE-AIM framework.(46) Implementation fidelity was traditionally referred to and measured by adherence(46) and it has been defined as "the degree to which programs are implemented as intended by the program developers".(47) Implementation fidelity was also termed quality of intervention delivery, integrity and delivery as intended in some literature.

Implementation fidelity is measured typically from the perspective of health care providers in assessing program implementation.(46) Because adherence has captured the implementation outcome reasonably well, it has been adapted in this study to assess implementation fidelity by measuring adherence to the management guidelines for hearing loss resulting from DR-TB treatment among the health care workers.

1.5.2 Conceptual framework for this study.

Theories and frameworks have become more and more relevant than ever in understanding the concept of fidelity in implementation processes.(48) Just like any field of knowledge, there have been reiterative heuristic attempts to define the concepts of implementation research.

After a thorough systematic review, Carroll et al. developed another conceptual framework for measuring implementation fidelity by measuring adherence.(49) This framework was adapted for this study, thus implementation fidelity was measured through adherence.

Adherence has four domains of duration, frequency, coverage and content. The four core determinants (moderators) affecting implementation fidelity that were identified are

"intervention complexity, facilitation strategies, quality of delivery and participant responsiveness".(24)

In addition, Socio-Demographic characteristics of the respondents were added as a determinant to the conceptual framework. These include Age, Sex, Professional cadre and Work experience. Figure 1.1 shows the adapted conceptual model depicting the relationship between the determinants (explanatory variables) and Implementation fidelity (outcome variable) of management guidelines for hearing loss where the hearing loss was a result of drug-resistant Tuberculosis treatment at the Infectious Diseases Hospital, Kano.

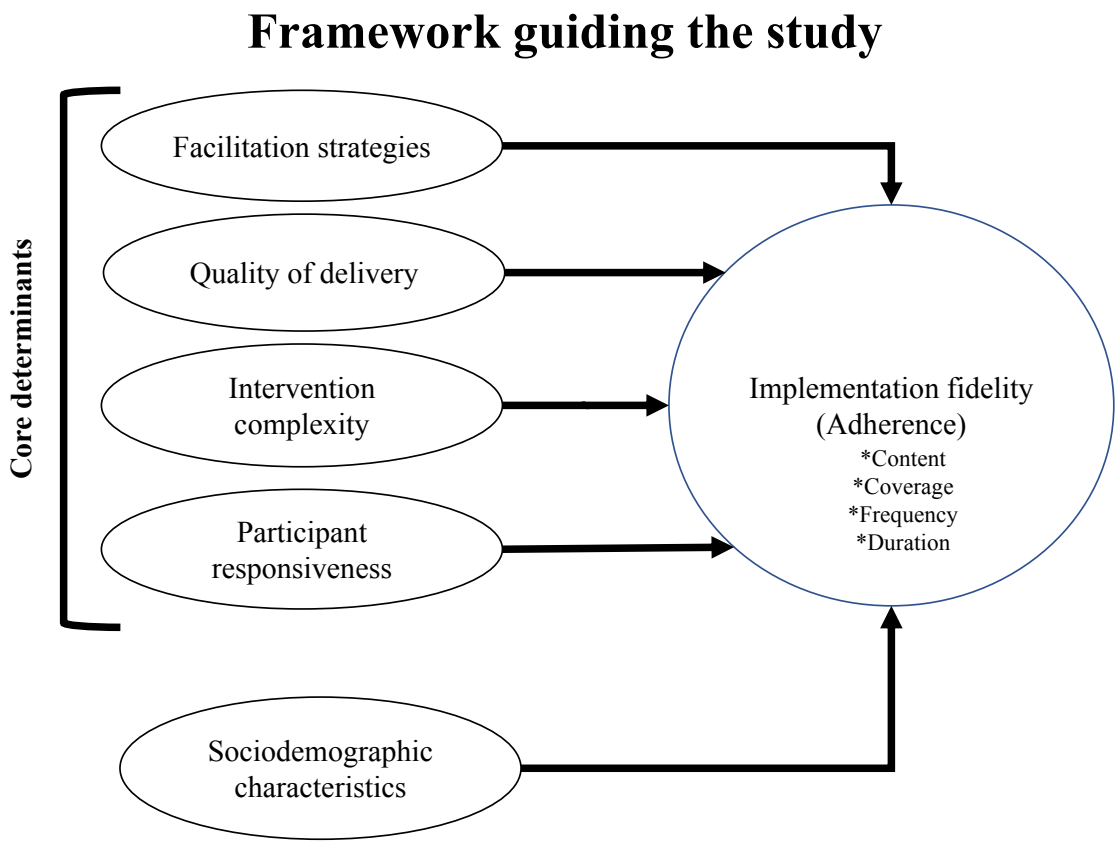


Figure 1.1: Adapted Conceptual Framework for Implementation fidelity derived from Carroll et al. (35)

1.5.3 Management of DR-TB and Hearing loss

The modality of treatment in Drug-resistant Tuberculosis form a strong aetiologic evidence for the subsequent adverse effects manifested by the DR-TB patients. Second line injectables (SLIs) are integral part of DR-TB treatment strategy.(50) Therefore the WHO recommends a

five-drug treatment regime (one fluoroquinolone, one SLI, two second line agent and pyrazinamide) for a period of nine to twenty-seven months in which the SLI treatment ranges from four to nine months based on the WHO regimen chosen.(51) The SLIs' use is often limited by the adverse effects during treatment in the form of nephrotoxicity, ototoxicity (hearing loss) and vestibular toxicity (vertigo, ataxia, dizziness).(51) The incidence of ototoxicity varies with the duration and dose of the SLIs.(21,52,53)

There have been a wide variation (3-100%) of indices used for determining ototoxicity.(54,55) These includes subjective and objective methods of diagnosis. The most widely used subjective method is clinical assessment during history taking of DR-TB patients. The commonest objective method is pure tone audiometry(32) in which the service is largely absent in many DR-TB centers in developing countries like Nigeria. Where the services are available, they are poorly utilized.(56) The PMDT guidelines recommend assessing hearing loss at baseline and at every clinic visit to prevent permanent hearing loss.(29) However there has not been documented evidence of adherence to this guideline or report on adherence assessment in Nigeria. Hence the need for this research that have assessed the adherence (implementation fidelity) of the health care providers to the PMDT guidelines in Nigeria.

1.6 Overview of the Research

This research work investigated the implementation fidelity as well as associated factors and determinants of implementation fidelity for management guidelines of hearing loss resulting from the treatment of drug-resistant Tuberculosis in Nigeria using Infectious Disease Hospital as a case study. The approach to the inquiry was based on Carroll's conceptual framework of implementation fidelity measured by adherence.

CHAPTER TWO: METHODOLOGY

2.1 Chapter Overview

This chapter describes the study setting, its design, study population and the sampling techniques adopted for this research. It also elucidates the research instrument designed in the study, the data collection procedure as well as the data analysis. Finally the testing of the validity and reliability of the instruments and the ethical issues involved in the study are presented.

2.2 The Study Design

This was a cross-sectional study. It took a snapshot of the health care providers involved with the administration and treatment of Drug-resistant Tuberculosis at the Infectious Disease Hospital, Kano. Quantitative data was collected through an interviewer administered questionnaire. The primary data collection was carried out during the period December 2017 to January 2018. Data was collected using REDCap mobile application.

2.3 The Study Site

This research work was carried out at the Infectious Disease Hospital (IDH), Kano. North-Western Nigeria. Kano state had a population of 9,410,288 in 2006,(57) and projected to have 11,215,688 by 2012 on a growth rate of 3.1 percent.(58) Kano state is among the six states with the highest burden of TB in Nigeria with TB incidence of 23,231 in 2017.(58) The state capital is located on latitude 12.000N and longitude 8.300E, within the semi-arid Sudan savannah zone of West Africa about 840 kilometres from the edge of the Sahara Desert. Kano has a mean height of about 472.45m above sea level.(59)

The Infectious Diseases Hospital, Kano is a public specialized secondary health care facility serving a population of about 1.5 million and having a patronage of about 300/day. The hospital is the only infectious diseases hospital in the whole of Northern Nigeria and serves as a referral centre for Tuberculosis (TB) and HIV/AIDS management which are provided to the patients at no cost.(60) It also serves the thematic component of the National TB & Leprosy Control Program that deals with issues concerning management of Tuberculosis. This Northern regional hospital handles the treatment of patient with Drug-resistant Tuberculosis. The hospital has been chosen and equipped with a sophisticated drug

sensitivity (DST) laboratory to cater for DR-TB patients. Hearing loss assessment for DR-TB patients has been going on as part of Programmatic Management of Drug-resistant Tuberculosis guidelines' implementation, following the national declaration in 2012.

2.4 Study Population

The target population for this research work consisted of all front-line health care providers implementing PMDT management guidelines for hearing loss resulting from DR-TB treatment at IDH, Kano. These personnel have been highly trained in order to deliver these unique management guidelines. The group was comprised of medical doctors, nurses and principal clinical assistants. A total of 73 respondents were available. This sample size will provide 80% power to detect as statistically significant a relationship between Implementation fidelity and a single regressor, provided the true value of R-squared for the regression is at least 0.10 In addition, the sample size will be sufficient to fit a multiple regression model with up to 7 regressors using the heuristic requirement of at least 10 observations per regressor. (See appendix II for Stata output on the sample size calculation).

2.4.1 Inclusion criteria

Front-line health care providers (HCP) that have participated in the implementation of PMDT guidelines for at least the last six months before the enquiry in the facility.

2.4.2 Exclusion criteria

Staff that have met the inclusion criteria but were unavailable for whatever reason during the period of the study.

2.5 Selection and Sampling Procedure

A convenient sampling was done. The entire health care personnel were selected as participants. This was deemed appropriate for this study because, it seeks to utilize the experienced and knowledgeable staff implementing the guidelines. These are few highly trained and customized staff involved with the process of PMDT implementation.(31)

2.6 Data Collection tool and techniques

2.6.1 Design of the Instrument

A questionnaire was designed to collect information on implementation fidelity for hearing loss management guidelines during DR-TB treatment, as well as factors associated with implementation fidelity among health care providers. A validated instrument (questionnaire) was not found after thorough search of the existing literature, hence a research tool in the form of a structured questionnaire was developed based on domains and constructs of the adopted implementation fidelity framework by Carroll et al.(49)

The constructs conformed to the theoretical overview of implementation fidelity in the current literature, the conceptual frameworks capturing implementation fidelity from previous research and the research objectives in this study. Attached to each questionnaire was an information sheet enlightening the respondents about the study as well as a consent form to be signed by the respondents.

The face validity of the questionnaire was assessed from the responses of a different group of health care providers with the same job categories as the study participants. Appropriate corrections were made after pre-testing the data collection instrument. The questionnaire comprised of three sections (see Appendix V). A 5-point Likert scale was used to define most domains.

Likert technique uses statements which are responded to using a scale of possible answers. “5-Strongly agree, 4-agree, 3-neutral, 2-disagree and 1-strongly disagree”. A Yes/No option was used for the domains of facilitation strategies. The questionnaire was tested for content validity and reliability in a pilot study with five participants from the general Tuberculosis treatment unit under the Kano State ministry of health.

2.6.2 Key Constructs

Sociodemographic Variables: Section A comprised of socio-demographic characteristics. This includes age and duration of work experience in DR-TB treatment unit as health care provider. Both were open-ended questions while sex was categorised as either male or female, professional cadre was categorized as doctor, nurse or principal clinical assistant. These variables were captured as questions 1-4 of the research instrument (Appendix V).

Implementation fidelity Domains: Section B comprised of domain and constructs for implementation fidelity. Four items namely content, coverage, frequency and duration were employed to capture domains of implementation fidelity. These variables were captured in Items 5-14 of the research instrument (Appendix V).

Determinants of implementation fidelity domains: Section C comprised of constructs for determinants of implementation fidelity. Four items, facilitation strategies, quality of delivery, intervention complexity & participants' responsiveness were employed to capture sub-components of determinants of implementation fidelity. These variables were captured in Items 15-33 of the research instrument. (See Appendix V)

2.6.3 Pre-Testing of the Instrument

The questionnaire was pre-tested. Five health care providers received the questionnaire for assessment of clarity of items listed. Refinement came in the form of incorporating the propositions of the practitioners. Most of their propositions related to linguistics and explanation of some vague terms. In addition a statistician evaluated the questionnaire during protocol development in order to detect any defect that could hinder subsequent data-analysis. No major changes were recommended.

2.6.3.1 Validity of the Instrument

In this study, both face and content validity were tested. The content validity in this study was carried out using the adapted constructs developed by Carroll et al. In addition, face validity was assessed when five different practitioners with experience on the research subject screened the questionnaire and declared that it captures the constructs and domains of interest. Each item in the questionnaire was examined thoroughly with the intent to evaluate whether each of the measuring items corresponds to and with the given conceptual domain of the framework. The questionnaire was approved as a suitable measure for the study's objectives.

2.6.3.2 Reliability of the Instrument

The instrument was subjected to an internal consistency test to establish the reliability of the instrument. In this study, the internal consistency of results was measured across variables

within the questionnaire (i.e. how closely related the set of questions are as a group capturing the intended domain) with the Cronbach alpha.

The Cronbach alpha is the average of all probable split-half coefficients, and it was regarded to be the measure of scale reliability. For all the constructs in the tool based on the adopted conceptual framework by Carroll et al. the alpha values ranged from 0.50 to 0.86, indicating that the instrument had a moderate to high internal consistency.

2.6.4 Design in REDCap

The data collection forms were designed in Research Electronic Data Capture (REDCap) software, which is a safe, web-based application for designing and handling online databases. The data from REDCap was exported, saved, cleaned and analysed using Stata 14.2 (StataCorp, 2017).

2.7 Data Management

The data were explored, reviewed and checked for missing values, inconsistencies due to faulty logic and out of range or extreme values. The resultant queries were all resolved. REDCap used the metadata defined in the data dictionary to create syntax files for Stata. The Data Export tool was employed as it contains instructions for linking the exported syntax and data files. The data was cleaned and stored appropriately. To secure the data, it was stored in excel, .csv files, Stata files, SPSS format and protected by encryption.

2.7.1 Shaping Data Set

The data saved in the Excel spreadsheet was imported into Stata 14.2 It was reshaped "wide to long". String and numeric variables were clearly identified. No missing observation was found. The recode and encode commands in Stata were employed to create new variables without modifying the original data. A do-file was generated to store Stata syntax and was essential for replication and modification purposes.

2.7.2 Creation of new variables

The creation of new variables was carried out as follows:

1. Ordinal categorical data was converted to a continuous scale and to generate composite scores and percentages
2. Some of the data that are on a continuous scale were converted to categorical data.

Table 2.2 shows summaries of the variables, their scale of measurement and conversion. After obtaining acceptably high Cronbach alpha scores, scores were generated for implementation fidelity and the determinants, which were subsequently converted to their corresponding percentages from the scores. These scores were used for the entire statistical analysis

Table 2.1: Creation and Categorization of new variables

Variable	Type of Variable	Initial level of Measurement	New Scale of Measurement
Implementation fidelity	Main Outcome	Ordinal	Continuous, Categorical
Facilitation strategy	Explanatory	Ordinal	Continuous
Quality of delivery	Explanatory	Ordinal	Continuous
Intervention complexity	Explanatory	Ordinal	Continuous
Participants' responsiveness	Explanatory	Ordinal	Continuous
Age	Explanatory	Continuous	Continuous, Categorical
Sex	Explanatory	Binary	Binary
Professional cadre	Explanatory	Ordinal	Categorical
Work experience	Explanatory	Continuous	Continuous, Categorical

2.7.3 Variables and Data Analysis per Objective

2.7.3.1 The First objective.

Objective One: To measure Implementation fidelity of the management guidelines.

Variable creation: Implementation fidelity was measured by a total of ten constructs (questions) under four domains of the conceptual framework. These domains were content, coverage, frequency and duration. These constructs were captured as items 5-14 of the research instrument. A score was developed using the Likert scale for each item. The ten constructs had a maximum expected score of fifty. The Cronbach-alpha reliability test was used to confirm internal consistency of the constructs.

Implementation fidelity had Cronbach's alpha value of 0.81 (Appendix VIII), indicating high internal consistency between the ten questions capturing the outcome of implementation fidelity. Thus, all the ten constructs were summed up to give the overall composite score for implementation fidelity. Each respondent had an observed score for implementation fidelity. The composite score was subsequently converted to a percentage by dividing the observed fidelity score "X" by the expected fidelity score "Y" and all multiplied by 100 (X/Y x 100%). Implementation fidelity was further divided in to three equal parts called tertiles, namely tertile number one to three.

2.7.3.2 The Second Objective

Objective Two: To describe the determinants of implementation fidelity.

Variables: Facilitation strategies, quality of delivery, intervention complexity, participants' responsiveness and covariates of sociodemographic characteristics (Age, Sex, Professional cadre and duration of work experience). The four core determinants of Implementation fidelity based on the conceptual framework were facilitation strategies, quality of delivery, intervention complexity and participants' responsiveness. Other determinants found were age, sex, professional cadre and work experience grouped as Sociodemographic characteristics.

The facilitation strategy domain was measured by a total of six constructs (questions). These constructs were captured as items 15-20 of the research instrument. A score was developed using a Yes/No scale. The six constructs had a maximum expected score of six. The Cronbach-alpha reliability test was used to check the internal consistency of the six constructs.

The facilitation strategy had Cronbach's alpha value of 0.86 (Appendix IX), indicating high internal consistency between the six questions capturing facilitation strategy. Thus, all the six constructs were summed up to give the overall composite score for facilitation strategy. Each respondent had an observed score for facilitation strategy "X". The composite score was subsequently converted to a percentage by dividing the observed facilitation strategy score "X" by the expected facilitation strategy score "Y" and all multiplied by 100 (X/Y x 100%).

The quality of delivery domain was measured by a total of six constructs (questions). These constructs were captured as items 21-26 of the research instrument. A score was developed using Likert scale. The six constructs had a maximum expected score of thirty. The Cronbach-alpha reliability test was used to check the internal consistency of the six constructs

The quality of delivery had Cronbach's alpha value of 0.65 (Appendix X), indicating high internal consistency between the six questions capturing quality of delivery. Thus, all the six constructs were summed up to give the overall composite score for quality of delivery. Each respondent had an observed score for quality of delivery "X". The composite score was subsequently converted to a percentage by dividing the observed quality of delivery score "X" by the expected quality of delivery score "Y" and all multiplied by 100 (X/Y x 100%).

The intervention complexity domain was measured by a total of three constructs (questions). These constructs were captured as items 27-29 of the research instrument. A score was developed using Likert scale. The three constructs had a maximum expected score of fifteen. The Cronbach-alpha reliability test was used to check the internal consistency of the three constructs.

The intervention complexity had Cronbach's alpha value of 0.50 (Appendix XI), indicating moderate internal consistency between the three questions capturing intervention complexity. Thus, all the three constructs were summed up to give the overall composite score for Intervention complexity. Each respondent had an observed score for intervention complexity "X". The composite score was subsequently converted to a percentage by dividing the observed intervention complexity score "X" by the expected intervention complexity score "Y" and all multiplied by 100 (X/Y x 100%).

Participants' responsiveness domain was measured by a total of four constructs (questions). These constructs were captured as items 30-33 of the research instrument. A score was developed using Likert scale. The four constructs had a maximum expected score of twenty. The Cronbach-alpha reliability test was used to check the internal consistency of the four constructs.

The participants' responsiveness had Cronbach's alpha value of 0.50 (Appendix XII), indicating moderate internal consistency between the four questions capturing participants'

responsiveness. Thus, all the four constructs were summed up to give the overall composite score for participants' responsiveness. Each respondent had an observed score for participants' responsiveness "X". The composite score was subsequently converted to a percentage by dividing the observed participants' responsiveness score "X" by the expected participants' responsiveness score "Y" and all multiplied by 100 (X/Y x 100%).

2.7.3.3 The Third Objective

Objective Three: To determine the relationship between implementation fidelity and the identified determinants.

Variables: Implementation fidelity, facilitation strategies, quality of delivery, intervention complexity, participants' responsiveness and covariates of sociodemographic characteristics (Age, Sex, Professional cadre and duration of work experience)

Method of analysis:

1. Univariable analysis (linear regression) to establish significance level
2. Multivariable analysis (linear regression) to establish direct relationship.
3. Regression diagnostics: normality test (Shapiro-Wilk test, histogram, box and dot plots), homoscedasticity ("White's test and the Breusch-Pagan test") and relevant transformation tests.

2.8 Description and Justification of the Analytical tools used in the study

2.8.1 Multiple Linear Regressions (MLR)

This statistical technique employs a number of explanatory variables in predicting effect of a response variable.(61) MLR aims to create a prototype for an association between the outcome and explanatory variables. Given in **n** observations, MLR is modelled as:

$$y_i = B_0 + B_1xi_1 + B_2xi_2 + ... + B_pxi_p + E_i, \text{ where } i = 1,2, ..., n.$$

Multiple Linear Regressions uses set of variables randomly generated to attempt to get a mathematical relationship that links the explanatory to response variables. This relationship (known as the model) creates a linear relationship to estimates the meaningful inference in the datasets as best as possible. However, they are based on some assumptions, namely:

1. The residuals of regression follow a normal distribution.

2. The dependent variable and the independent variables are assumed to have a linear relationship.

3. The residuals are homoscedastic.

4. It is assumed that there is no multicollinearity in the model (i.e., no high correlation among independent variables).

A major task in MLR analysis is the attempt in fitting a single line across a scatter plot, or a multi-dimensional space of data points. Commonly, this analysis has one outcome variable and at least one explanatory variable. The former is called the regressand (outcome variable) while the latter variables are called the regressors (predictor variables).

MLR provide few advantages over certain models. Firstly, it identifies the strength of the influence of predictor variables on the outcome variable.(36) Secondly, MLR is used to predict the effects of changes, to understand the extent to which the dependent variable changes when the independent variables change.(61) Thirdly, it is used to predict future values and trends. MLR analysis can thus be employed to get point estimates.(61) In model fitting, many independent variables can be added to the MLR model, which raises R^2 (i.e., the amount of explained variance in the dependent variable). Thus, the outcome is simply an over-fit model.

For the regression analysis, the outcome was bootstrapped using seed 242 and replicates of 10,000. Both explanatory variables and determinants were rescaled by a factor of ten in order to assist with the interpretation of the beta coefficients, for example a variable “ageten” was generated to represent age in 10-year intervals. All six continuous explanatory variables were similarly scaled.

2.8.2 Regression diagnostics of the residuals

Inferential statistics are based on a normally distributed population. Therefore, before drawing conclusions, it is pertinent to examine the data for agreement or departure from the assumptions.

2.8.2.1 Normality

The assumption of normality states that, a mean's sampling distribution is regular and that the distribution of means across samples is regular. kurtosis and skewness test, the Kolmogorov-Smirnov (K-S) test and the Shapiro-Wilk test are used to determine the normality of a data distribution(62–64). The kernel density, dot plots (Appendix XIII) and Normal probability histogram boxes (Appendix XIV) were used to check the distribution. The residuals of implementation fidelity score showed evidence of non-normality in the distribution. The Shapiro-Wilk test was used in corroborating results of the histogram (Appendix XV).

2.8.2.2 Homoscedasticity

Homoscedasticity is a reference to the estimation of variation required for the outcome variables. It is assumed in multiple regression analysis that the variation of outcome variable should be constant.(62) Hair et al. stated that homoscedasticity assumes that dependent variable(s) show identical levels of variance across the range of predictor variable(s).(62,63) Graphical and statistical methods are used to measure homoscedasticity particularly the Cook-Weisberg test.(62,64) A commonly-used graphical method is plotting the residuals against the predicted values.(65) The Stata-plot command was used to draw a plot that gives the pictorial inspection of homoscedasticity. When inspected, the plot reveals the data points have different scatter, an indication of non-homoscedasticity (Appendix XVI).
Skewness was still considerably observed post data transformation. Therefore, by resampling techniques, the robustness of normal parametric methods like chi^2 and linear regression were explored, as reported in a study by McGuinness.(66) Results were analyzed using generalized linear regression in bootstrapping of 10,000 iterations as was reported in a study by Elliot et al.(67) Confidence intervals and regression coefficients have been examined.(67,68)

2.9 Ethical Considerations

2.9.1 Protection of the Rights of the Institutions Involved

Ethics approval was applied for to the Wits Human Research Ethics Committee (HREC) and Health Research Ethics Committee of the Kano State Ministry of Health in Nigeria. As a result, Wits HREC (Medical) gave a provisional approval on 27 November 2017, with a clearance certificate, **M171038**, subject to obtaining written approval from the study site.

Then ethical consent from the Ethics Review Board of Kano State Ministry of Health in Nigeria was obtained on the 12th December 2017, with reference number **MOH/Off/797/T.I/620** (Appendix VI). Finally, full ethical clearance was obtained from Wits HREC (Medical) on the 23rd of December 2018, certificate number **M171038** (Appendix VII).

2.9.2 Protection of the Respondents

The participants were informed about the aims of the research before commencing the interviews using the participant information sheet (see Appendix III). An informed consent was obtained from the study respondents, and they were assured of their confidentiality before conducting the interviews. The respondents who consented to be part of the study were made to sign the consent form (Appendix IV). These forms were returned to the principal investigator. The respondents were given a signed and dated copy of same form to keep for future reference.

2.10 Research translation and dissemination

A summary of the study findings will be presented to the Infectious Disease Hospital and Ministry of Health in Nigeria so as to guide further implementation with fidelity of the PMDT management guideline in Nigeria.

Furthermore, key findings of this report will be produced to help public campaigns on the prevention of hearing loss in Nigeria. Manuscripts for peer reviewed publication in scientific journals and conference abstracts are already being developed from this report to further disseminate the results of this study in a wider scientific community, to aid public health interventions and implementation of our research findings.

CHAPTER THREE: RESULTS

3.1 Chapter overview

This chapter presents the sociodemographic characteristics of the health care providers implementing the management guidelines for hearing loss during treatment of Drug-resistant Tuberculosis at the Infectious Disease Hospital, Kano between December 2017 and March 2018; a description of the implementation fidelity scores and of the potential determinants of implementation fidelity of the respondents. Lastly, univariable and multivariable regression analysis results of the relationship between the implementation fidelity and its determinants were reported.

Table 3.1: Demographic characteristics of study participants.

Age category	**N (%)**
≤35	28 (38.4)
>35	45 (61.6)
Sex	
Male	14 (19.2)
Female	59 (80.8)
Professional cadre	
Doctors	13 (17.8)
Nurses	49 (67.1)
Principal Clinical Assistant	11 (15.1)
Work experience	
≤12 months	10 (13.7)
13 - 36 months	17 (23.3)
>36 months	46 (63.0)

3.2. Characteristics of the respondents

Table 3.1 shows that about two-fifths of the respondent were 35 years or younger. Four-fifths (80.8%) were females and more than two-thirds (67.1%) were nurses. Almost two-thirds (63.0%) of the respondents had more than three years of work experience.

3.3 Objective 1: Implementation fidelity.

Implementation fidelity was measured by a total of ten constructs (questions) under four domains. These domains were content, coverage, frequency and duration based on the conceptual framework. Implementation fidelity had Cronbach's alpha value of 0.81 (Appendix VIII), indicating high internal consistency and allowing summation of the constructs to derive a composite score. The histogram in Figure 3.1 shows that the distribution of the implementation fidelity scores was skewed to the right (not normally distributed). Most of the respondents were on the left part of the distribution and below the fifty percent of implementation fidelity score.

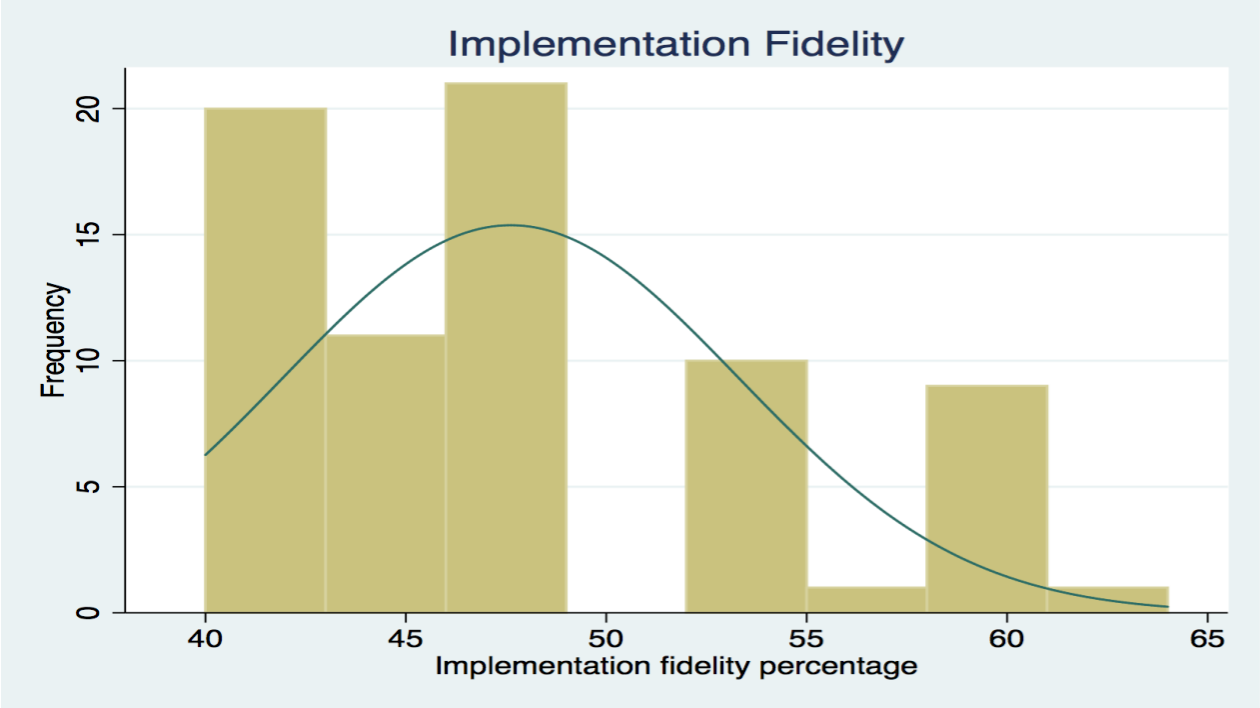


Figure 3.1: Distribution of the implementation fidelity percentage scores

Table 3.2 presents the implementation fidelity score ranged from 40 - 64%, with the first tertile including scores between 40 – 44%, the second tertile having scores from 46 – 48% and the third tertile scores from 52 – 64% (Table 3.2)

Table 3.2: Descriptive characteristics of Implementation fidelity

Fidelity	Observation, N	Range	Mean (SD)	Median (IQR)
Implementation Fidelity	73	40 - 64	47.62 (5.7)	46 (42 - 52)
Tertile 1	31	40 - 44		
Tertile 2	21	46 - 48		
Tertile 3	21	52 - 64		

Figure 3.2 presents percentage implementation fidelity. One quarter of the respondents had implementation fidelity score of about 42%, half of the respondents had implementation fidelity score of 46%, three quarter of the respondents had implementation fidelity of 52% and only one quarter of the respondents had implementation fidelity of 64%.

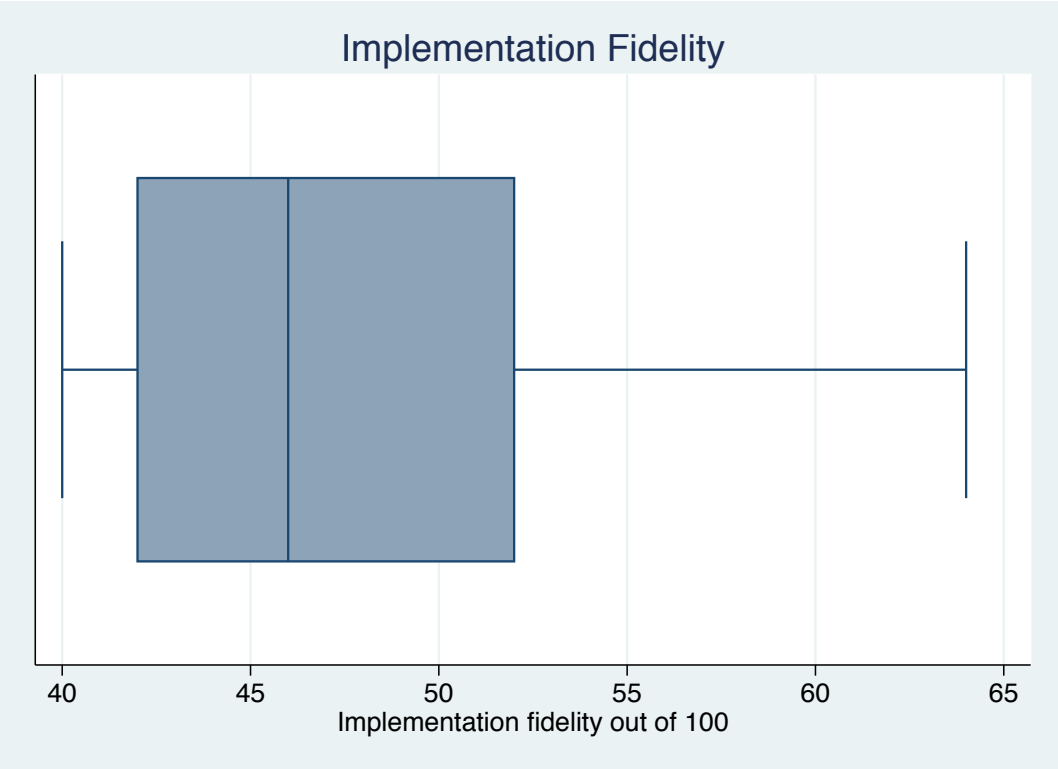


Figure 3.2: Box plot of Implementation fidelity

3.4 Objectives 2: Determinants of Implementation fidelity

The scores for the four core determinants were obtained as explained in Section 2.7.3.2 using the same methodology as used in deriving the scores of the outcome variable – implementation fidelity. Table 3.3 presents the reliability measures of implementation fidelity and the potential core determinants

Table 3.3: Reliability measures of the Implementation fidelity and its determinants.

Variables	Cronbach alpha
Implementation fidelity	0.81
Facilitation strategy	0.86
Quality of delivery	0.65
Intervention complexity	0.50
Participants' responsiveness	0.50

Facilitation strategy had a Cronbach's alpha value of 0.86, Quality of delivery had a Cronbach's alpha value of 0.65, Intervention complexity had a Cronbach's alpha value of 0.50 and Participants' responsiveness had Cronbach's alpha value of 0.50. These Cronbach alpha values indicated moderate to high internal consistency for each of the four determinants, hence allowing for summation of the variables' scores to give a composite score for each determinant.

Table 3.4 also shows that facilitation strategy ranged from 17 - 100%, quality of delivery ranged from 6 - 20%, intervention complexity ranged from 20 - 60% and participants' responsiveness ranged from 25 – 45%. Age, a component of the sociodemographic determinants ranged from 30 – 55 years and duration of work experience ranged from 7 – 72 months. The other socio-demographic determinants have been presented in Table 3.1.

Table 3.4: Determinants of Implementation fidelity

Determinants	N	Range	Mean (SD)	Median (IQR)
Facilitation strategy	73	17 - 100	78 (27.1)	83 (83 -100)
Quality of delivery	73	06 - 20	15 (04.3)	17 (13 - 19)
Intervention complexity	73	20 - 60	41 (13.8)	47 (27 - 53)
Participants' responsiveness	73	25 - 45	36 (06.8)	40 (30 - 40)
Age (years)	73	30 - 55	40 (06.4)	40 (34 - 45)
Work experience (months)	73	07 - 72	39 (17.7)	48 (24 - 48)

3.5 Objective 3: Relationship between Implementation fidelity and determinants.

3.5.1 Univariable analysis (Unadjusted model)

Table 3.5 shows that only quality of delivery, participants' responsiveness, sex and professional cadre were significantly associated with implementation fidelity at the 5%

significance level while facilitation strategies, intervention complexity, age and work experience did not attain statistical significance at the 5% level.

Table 3.5: Regression outputs of implementation fidelity and the potential determinants

Factors	Unadjusted Model		Model A (R^2 = 35.6)		Model B (R^2 = 76.64)	
	β	**95% CI**	**β**	**95% CI**	**β**	**95% CI**
Facilitation strategies	0.18	-0.31 – 0.68	-0.91*	-1.52– -0.28	-0.64*	-1.23– -0.05
Quality of delivery	1.91*	1.11 – 2.71	0.63	-0.57 – 1.84	1.15*	0 .17 – 2.12
Intervention complexity	-0.69	-1.65 - 0.27	-1.02*	-1.89– -0.13	1.24*	0.53 – 1.95
Participants responsiveness	3.82*	2.07 – 5.56	4.92*	1.63 – 8.21	0.57	-1.88 – 3.01
Age	0 .32	-1.76 – 2.41			-1.13	-1.13
Work experience	0.45	-0.29 – 1.21			-0.14	-0.14
Sex						
Female (Ref)	1.00	Ref			1.00	1.00
Male	10.37*	8.03 - 12.71			0.67	0.67
Professional Cadre						
Doctors (Ref)	1.00	Ref			1.00	1.00
Nurses	-11.31*	-13.67- -8.95			-12.80*	-12.80*
PCA	-9.34*	-12.45- -6.24			-13.25*	-13.25*

***** = Statistical significance at the 5% level.
β _= regression coefficient
R^2 = the value accounting for the internal variation of implementation fidelity

3.5.2 Multivariable Analysis (Adjusted models)

In looking at the relationship between implementation fidelity and its determinants, analysis was divided in to two stages. Firstly, regression of the potential core determinants against implementation fidelity (Model A) and secondly regression of both the core and other determinants against the outcome variable (Model B)

For model A, Table 3.5 reports the Ordinary Least Square (OLS) estimates of the core determinants predicting implementation fidelity for management guidelines of hearing loss. The four predictors in the model accounted for 36% of the internal variation of implementation fidelity, F (4, 39) = 9.39, $p < 0.001$, R^2 = 35.6 and the association did attain statistical significance. Compared to the unadjusted model, facilitation strategies have attained statistical significance exerting negative effect on the implementation fidelity.

In Model B (the full model), Table 3.5 revealed that the facilitation strategy, quality of delivery, intervention complexity and professional cadre have exerted a significant effect on implementation fidelity (P-values <0.001). This means that, for each unit increase in facilitation strategy, the implementation fidelity decreases by 0.64% adjusting for other variables in the model. This relationship was statistically significant (p<0.001).
Similarly, for each unit increase in quality of delivery, the implementation fidelity increases by 1.15% adjusting for other variables in the model. This relationship was statistically significant (p<0.001).

Correspondingly, for each unit increase in intervention complexity, the implementation fidelity increases by 1.24% adjusting for other variables in the model. The relationship was statistically significant (p<0.001).

In contrast, participants' responsiveness and age did not have significant statistical impact on implementation fidelity. However, for each unit increase in participants' responsiveness, the implementation fidelity increases by 0.56% adjusting for other variables in the model. Even though this relationship did not reach statistical significance (p=0.645).
In like fashion, for each unit increase in age, the implementation fidelity decreases by 1.13% adjusting for other variables in the model. But the relationship did not reach statistical significance (p=0.129).
For each unit increase in work experience, the implementation fidelity decreases by 0.14% adjusting for other variables in the model. However, this relationship did not reach statistical significance (p=0.650).

By sex of the health care providers, compared to the baseline females, implementation fidelity was 0.67% higher in males, adjusting for other variables in the model. The relationship did not reach statistical significance (p=0.833).

In terms of professional cadre of the health care providers, compared to the baseline Doctors, implementation fidelity was 12.8% lower in nurses and 13.3% lower in principal clinical assistants, adjusting for all other variables in the model. These had significant negative effects on the implementation fidelity (p<0.001).

The eight predictors in the model accounted for about 77% of the internal variation of implementation fidelity, F (9, 63) = 22.97, $p < 0.001$, R^2 = 76.64 and the association was statistically significant.

In comparing the three models, from the unadjusted to the adjusted in Table 3.5, we observed that the facilitation strategy that was not significant in the unadjusted Model became significant in the two adjusted Models in a negative direction. Quality of delivery was significant in the unadjusted model, was no longer significant in Model A, but remained significant in a positive direction at the full adjusted Model B. Intervention complexity was not significant in the unadjusted Model, became significant in the same negative direction at the adjusted Model A and remained significant but, in the positive direction in the full adjusted Model. Participants' responsiveness was significant in the unadjusted and adjusted Model A, but was not significant in the adjusted Model B. Age and work experiences were not significant in any of the models. Sex was significant before adjustment but was no longer statistically significant after adjustment. In contrast, professional cadre was significant and has remained significant before and after adjustment.

Considering the proportion of variability in implementation fidelity as explained by the fitted models according to the R^2 values, the full model was a better model because it had the highest R^2 value of 76.6%. Therefore, the core determinants accounted for 37% of the variability in the predictive model for Implementation fidelity while other characteristics added 40%, leaving 23% still unexplained. Thus, the characteristics measured in the model explained a good proportion of implementation fidelity in this context of management guidelines implementation and the factors affecting the outcome of the implementation.

3.6 Regression diagnostics

This study confirmed these relationships by scrutinising the assumptions of normality, linearity and homoscedasticity of the data before making inferences. The kernel density dot plots (Appendix XIII) and Normal probability histogram boxes (Appendix XIV) were used to visually inspect and evaluate the normality of the distribution. The residuals of the implementation fidelity score revealed no evidence of normality in the distribution. The Shapiro-Wilk test reported in Appendix XV, showed that there was overwhelming evidence of non-normality ($p<0.001$). Visual inspection of the residual plot to check for

homoscedasticity shows that the data points have variable scatter, an indication of non-homoscedasticity. The results of the IM test and the Breusch-Pagan test confirmed non-homoscedasticity of the data (Appendix XVI). Further diagnostics were carried out for possible options in transformation using ladder (Appendix XVI), gladder (Appendix XVII) and qladder (Appendix XVIII) commands. While there was strong evidence that the untransformed Implementation fidelity score was not normally distributed, none of the standard transformations was able to produce a variable that was normally distributed. We therefor decided not to carry out a transformation, but instead to use bootstrapping to find the standard errors in the fitted models.

CHAPTER FOUR: DISCUSSION

4.1 Introduction

This section discusses the results obtained from the research work on implementation fidelity in relation to other studies. Strength and limitations of the study are described as well. The study investigated the implementation fidelity for management guidelines of hearing loss resulting from the treatment of drug-resistant Tuberculosis in Nigeria and the potential determinant factors affecting implementation fidelity.

This study found the implementation fidelity to range from 40 - 64% among the 73 respondents suggesting that the implementation fidelity was low. The implementation fidelity was influenced by facilitation strategies, quality of delivery, intervention complexity, sex and professional cadre of the health care providers. Low implementation fidelity may account for the rise in the prevalence of drug-resistant Tuberculosis and consequently the hearing loss resulting from treatment in Nigeria.

The finding resonates with the concept that the degree to which the management guidelines are implemented affects the outcome.(47) Therefore programs and interventions implemented with low fidelity will lead to a poor outcome.(69). This might explain why the prevalence of hearing loss has been high and is still rising in Nigeria despite the adoption and implementation of the recommended management guidelines. The implementation fidelity was affected by a number of determinants with a significant relationship between them.

4.2 The implementation fidelity of the PMDT management guidelines

The low implementation fidelity may have resulted from the fact that emphasis has always been on the guideline implementation, without scrutinizing how well these guidelines are being implemented. There are other factors affecting the level of implementation fidelity called determinants.

The finding of low fidelity could explain the rising burden of hearing loss among patients with drug-resistant tuberculosis in Nigeria. Since there was no previous research that assessed implementation fidelity for management guidelines in Drug-resistant Tuberculosis in Kano, Nigeria or Sub-Saharan Africa for comparison, it can be suggested with certainty that the low

fidelity was a result of reaching a threshold in implementation fidelity or the implementation fidelity has been low since the time the implementation commenced.

Studies have indicated the possibility of reaching a fidelity threshold beyond which no higher implementation fidelity would improve the outcome, or alternatively that there would be a diminishing return on further improvement to the implementation fidelity. Then, instead of improvement in the outcome, there will be a steady decline, and, in some cases, there will be a steady flattening and subsequent decline in implementation fidelity.

McHugo et al. described a curvilinear pattern for implementation fidelity in improving research output. They showed a “linear improvement” in the implementation fidelity in the early period of implementation but reach a “plateau” on subsequent stages of implementation toward year one ending, which got sustained through year two.(70) On further investigation, the researchers found that the outcomes remained good even when implementation fidelity was lower than the previous year and the implementation was still on going.(70) It can be seen that other factors apart from implementation fidelity play a significant role in achieving good outcome after program implementation. This underscore the need to study the determinants of implementation fidelity like the facilitation strategy and quality of delivery among others.

In a study by Elliot et al.(71) On violence prevention program using surveys and interviews found that the implementation fidelity was low in two-third of the participants and that was only observed towards the end of the implementation process. Similarly, in a substance abuse prevention program, the implementation fidelity was low, when only half of the implementation time was spent in implementing the designed intervention.(72) This therefore calls for early assessment of implementation fidelity as well as assessment at regular intervals to accurately predict the trend of the implementation fidelity as the implementation progresses.

The low implementation fidelity might be because the management guidelines were implemented without much adaptation to the local context. The adaptation through the Nigerian federal ministry of health appeared to be shallow and somewhat vague in defining clearly the role of the implementers. Studies that reported high implementation fidelity attempted to adapt the program to the local context prior to implementation.(72) Some

researchers have exaggerated this concept of contextualizing interventions before implementation,(71) however it should be acceptable to adapt the intervention without affecting the essential and core components of the intervention.(49)

Having mentioned the significance of implementing an intervention with good and high implementation fidelity, a program could have a low implementation fidelity but good quality of the implementation process thereby yielding a good outcome.(72)

Another challenge to the concept of implementation fidelity assessment is the lack of consensus on what constitute an "acceptable level" of implementation fidelity.(73) However, according to Durlak et al.(69) If a programme is executed with high implementation fidelity this would lead to better outcome.

It has been proposed that implementation fidelity should be defined as a percentage score. (57) This grades implementation fidelity on a scale of zero to hundred percent. For example, a study on educational programmes reported high implementation fidelity of performance between 60–80%.(42,69) and this was considered good implementation fidelity for an implementation outcome.

4.3 Determinants of Implementation fidelity to the management guideline

This study explored factors affecting implementation fidelity. The finding that facilitation strategies, quality of delivery, intervention complexity, participants' responsiveness, age, sex, professional cadre and work experience to influence implementation fidelity was crucial to understanding the success or failure of the guideline's implementation process.

The Sociodemographic characteristics gave an insight in to how implementation fidelity was influenced by this determinant. For example, age, duration of work experience and not being a medical doctor were negatively associated with implementation fidelity.
This may explain the finding of low implementation fidelity in the Nigerian setting where a lot of efforts by the government were to increase the number of health care providers implementing the guideline. This may also suggest that younger health care providers are likely to implement the management guideline with higher implementation fidelity than older ones perhaps approaching their retirement age.

Being a female implementer in this setting has improved the fidelity of implementation compared to their male counterparts, particularly in regard to implementing the management guidelines of hearing loss during Drug-resistant Tuberculosis treatment. In like fashion, carrying out implementation by the medical doctors yielded higher implementation fidelity than the nurses and/or principal clinical assistants. This was arguably because of the different professional training received by the health care providers based on their professional cadres.

The medical degree in Nigeria is ranked higher than the two certificates in health care and academic settings. However, this should have no impact on the implementation. Prior to commencing implementation, they were all expected to be trained on the management guidelines, so that they are all on the same page during implementation. This finding alludes to either absence of the training before commencement of implementation or lack of periodic refresher training to the health care providers implementing the management guidelines.

Our demonstration that sociodemographic characteristics of the health care providers is an important determinant in understanding the concept of implementation fidelity supports the addition of this determinant to the existing repertoire of moderators and determinants in designing theoretical and conceptual frameworks.

Facilitation strategy was found to have negatively affected the implementation fidelity in this study. Here facilitation strategies refer to having adequate copies of the management guidelines, training and retraining of staff implementing the management guidelines, having access to an audiometer (machine used for hearing assessment) and being able to refer a patient to a specialist as or when necessary. This is contrary to what has been theoretically proposed by some researchers who documented facilitation strategies exerting a positive influence on implementation fidelity (49). Thus, higher facilitation strategies should lead to higher implementation fidelity.

Our finding on facilitation strategies differs from those in the established literature particularly the large series from Roen et al. that showed higher facilitation strategies leading to higher implementation fidelity. In our study this determinant was deconstructed into the four components of training, access to a copy of PMDT guidelines, availability of audiometry services and ability to refer a patient to an Ear, Nose and Throat specialist when necessary.

We found that having good access to PMDT guidelines had the significant and desired effect of improving the implementation fidelity while training had an undesired effect on the implementation fidelity. The availability of audiometry services and being able to refer a patient to the specialist did not have an effect on the implementation fidelity.

Although some workers reported availability of facilitation strategies to have impacted positively on the outcome of interventions, the reports were still at theoretical level and need to be proved by practical studies.(74) In addition the predictive influence of facilitation strategies on the level of implementation fidelity is as yet unmeasured in clear terms. Therefore increasing facilitation strategies may not always guarantee superior outcome of implementation.

A fairly simple program or intervention does need minimal input from training to yield high implementation fidelity, whereas a more complex program or intervention would need favorable strategies to produce a quality outcome with high implementation fidelity.(49) Hence adequacy is a very important factor in this context, which can be clarified from understanding the relationship between facilitation strategies and the complexity of a program's details.

Empirical research did not fully elaborate if facilitation strategies affect how well or badly an intervention is executed. In our study, the previous finding of implementation fidelity to be negatively affected by older health care providers, being a male implementer, having longer duration on the implementation process and not being a medical doctor, all could explain why an increase in facilitation strategies would yield lower implementation fidelity. This also clarifies the point that more and more training is not always the solution to the problem of achieving poor outcome in some implemented programs.

The quality of delivery which positively affects implementation fidelity was found to be very low. This gives an insight as to why the implementation fidelity was also low. The quality of delivery here refers to the availability of supportive supervision from superior officers during implementation, adequate drugs to be dispensed at the point of care, proper sensitization of staff before embarking on implementation and provision of channels to resolve ototoxicity related issues.

Studies that quoted higher rate for quality of delivery reported higher implementation fidelity of implemented interventions, establishing a moderating effect of quality of delivery on implementation fidelity.(75) Other studies viewed Quality of delivery as another dimension to implementation fidelity and did not considered it an independent determinant, hence it was assessed as a component of implementation fidelity.(76,77) Thus, this alludes to the fact that assessing implementation fidelity without paying attention to the determinants would perhaps be a futile effort or at least an intellectual exercise without meaningful contribution to the body of evidence that will influence the standard of practice in the real world.

The intervention complexity which also positively affects implementation fidelity was found to be low. In this context, intervention complexity tried to find out if the health care providers would rate the clarity of the management guidelines as complex, simple, detailed or vague. It also assessed what they felt about how clearly their roles were specified in the guidelines and how easy it was to implement these guidelines. The low scores may indicate that the management guidelines were complex to the implementers.

A study on guidelines made for general practitioners to control take home medication among psychiatric patients were shown to be twice as likely to be executed well with high implementation fidelity when they are clear and detailed than when they are vague and non-specific.(78,79) There is already existing evidence that simple interventions are implemented with high implementation fidelity.(47)

Participants' responsiveness also positively affected implementation fidelity and was found to be low. Contextually, this refers to health care providers' opinion about compliance of DR-TB patients to medications, their acceptability of the hearing loss assessment and willingness to seek clarification on their treatment from the health care providers. This may predict why the overall implementation fidelity with which the guidelines were implemented was low.
Studies reported higher implementation fidelity of intervention when the program was acceptable to the participants responsible for the implementation(80–82) and recipients of the intervention.(82) The low score obtained may suggest that the program is not acceptable to either the health care providers or the receiving DR-TB patients or to both groups.

In a similar school intervention program, the implementation fidelity was low because the teachers failed to implement a part of the curriculum because they thought the students'

interest was not on that section.(83) In another school program, reports showed a higher implementation fidelity when the teachers had good belief and were very much interested in the program. Thus, the implementer acceptance is central to implementation with high implementation fidelity.

So far, participants' responsiveness affecting the level of implementation fidelity has been assessed at the level of the health care providers who are directly responsible for the implementation of the management guidelines. Perhaps things will be different if the organizational support through the heads and senior managers were assessed and cross-examined for its influence on the staff and how it will eventually affect the overall implementation fidelity. This approach has been shown to depict a major organizational influence on the outcome.(84) This approach may be considered in a subsequent phase of this study and is a suggestion for other researchers in the future.

Another reason for the low implementation fidelity and low participants' response score could be that the response was captured by self-reported interview which is often understood and reported differently by different health care providers, often times with some level of bias. Even though several studies have assessed these scores by self-reporting (80–86) many other researchers have shown that their responses indicated varying levels of agreement, as some respondents perceived the questions to be assessing their level of responsibility to their patients,(87) some perceived the questions to be assessing how far they think the guideline were useful,(88) and some understood it to be assessing how responsive the environment and patients were to the implemented guidelines.(72) This indicates great level of subjectivity and has the potential of influencing the results in different directions.

These determinants were all assessed individually without much correlation to one another. That might account for the reason why we are seeing low scores for each one of the determinants and the overall implementation fidelity. There is possibility of a complex relationship and interactions at some levels, either among each individual determinant and/or between the determinants and the overall implementation fidelity

Improving facilitation strategies can lead to an improvement in the quality of delivery and eventually achieving an implementation with high implementation fidelity. Thus, the interactions between these determinants themselves influence the picture of the association

regarding the implemented management guidelines and the implementation fidelity of how they were implemented. This is an aspect that has not been explored by the current conceptual models of implementation fidelity.

The conceptual framework of implementation fidelity developed by Carroll has elaborated on the main outcome of implementation fidelity and the effect of the moderators on the outcome. However, the individual versus collective effect of these moderators was not considered in his model. The synergistic interplay between effect of one or two of these determinants and how they affect the overall implementation fidelity are yet to be described.

Other frameworks,(47,78) have attempted to assess implementation fidelity more holistically by looking at all the five elements of implementation fidelity; namely adherence, exposure or dose, quality of delivery, participants' responsiveness and program differentiation. However, reasonable overlaps between these constructs were observed and were a great flaw to the frameworks in this format. There is general lack of consistency on how each construct was assessed and how the dividing line was to be defined and agreed upon as to what constitutes high or low or good or bad implementation fidelity.

4.4 Strengths and limitations of the study

4.4.1 Limitations

In considering the findings from this research work, it is pertinent to consider the following limitations;

S**ocial desirability**: The participants reported their activities regarding the implemented management guidelines from their own perspective. This might not be free of reporting bias as they responded to the question during interview. Their response was cross validated using an objective method. However this limitation was ameliorated by pilot testing the questionnaire before starting the research work. The questionnaire was considered to capture the true situation.

The **sample size** was small because the respondents are highly trained and skilful health care providers. However, it was sufficient enough to power the study and allow for statistical analysis and inferences as evidenced from the sample size calculation.

The **cross-sectional study** design used for this study allows data capturing from the respondents once. This limits inference on temporal association between the determinants and implementation fidelity. However, this will not affect the findings of the study since only an association was required to achieve the defined objectives of this study and not causality.

The absence of **qualitative research component** has limited the participants' response in giving a more comprehensive and detailed picture of the phenomenon being investigated. The use of quantitative approach was to provide baseline data on when, where and on what subsequent qualitative research should be carried out

4.4.2 Strength of the study

With the advantage of primary data collection, this study will provide the baseline data on implementation fidelity of the management guideline for hearing loss resulting from Drug-resistant Tuberculosis treatment in Kano, Nigeria upon which further studies can be built on.

The study also serves as an empirical research in testing one of the conceptual frameworks for assessing implementation fidelity, which have been developed theoretically. This study has put forward one of the ways to measure implementation fidelity in terms of scoring and analysis.

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

In summary, our study found that Implementation fidelity was vital in understanding the success and failures of implemented interventions. It was found to range from 40-60% for implemented management guidelines of hearing loss resulting from Drug-resistant Tuberculosis treatment in Kano. This was low implementation fidelity.

Our study further described four core determinants of implementation fidelity, while sociodemographic factors were also associated with implementation fidelity. The fact that the relationship between implementation fidelity and the determinants was found to be significant in determining the outcome of management guideline implementation, provides strong evidence that Implementation fidelity can influence successful control of DR-TB and hearing loss resulting from the treatment of DR-TB.

Therefore, failure in combating DR-TB and hearing loss may be dependent on the low implementation fidelity with which the management guidelines were implemented. Further we established the fact that Implementation fidelity is also affected by certain sociodemographic factors, which need to be taken into account. A paradigm shift in focusing on both implementation fidelity and its determinants for a successful implementation of the management guideline is important.

5.2 Recommendations

Based on the finding of this research work, the followings are recommended:

1. There is the need to improve implementation fidelity by addressing facilitation strategies through recruiting younger, female health care providers particularly doctors.
2. The content and modality of training need to be studied carefully to understand the negative effect of facilitation strategies on the implementation fidelity.

3. There is the need for further empirical research in order to better understand how to measure implementation fidelity and to develop a precise definition of what constitutes good and acceptable implementation fidelity.
4. There is the need to explore some of the findings through qualitative research as an added armamentarium to assessing implementation fidelity.
5. This study has provided an insight in to the implementation fidelity with which the management guidelines were implemented after six years of PMDT implementation. However, future research should consider assessing implementation fidelity early enough to inform appropriate adaptation. Implementation fidelity should actually be assessed at intervals within the program implementation. This allows for better adjustment in subsequent phases of the program.
6. The conceptual framework of implementation fidelity by Carroll assessed adherence and four moderators of implementation fidelity. However, we recommend adding Sociodemographic characteristics as another moderator, which consist of age, sex, professional cadre and work experience. This will allow a robust analysis of true relationships between the constructs.
7. Nigeria should consider implementing the use of Bedaquiline, a new WHO recommended drug for treating Drug-resistant Tuberculosis.(89) This drug is given orally to minimise the burden of hearing loss resulting from the injectable anti-TB drugs.

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APPENDICES

Appendix I: Plagiarism Declaration Report



PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE SSTUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Dr. Sani Muhammad **(Student number:** 1702889 **) am a postgraduate student registered for the MSc Epidemiology in the Field of Implementation Science in the School of Public Health for academic year 2017-2018.**

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 degree 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:** 16 / 07 / 2019

Appendix II: Stata output for sample size calculation

```
. power rsquared 0.10, ntested(1)

Performing iteration ...

Estimated sample size for multiple linear regression
F test for R2 testing all coefficients
Ho: R2_T = 0  versus  Ha: R2_T != 0

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    0.1111
         R2_T =    0.1000
      ntested =         1

Estimated sample size:

            N =        73
```

Appendix III: Participants' Information Sheet (Questionnaire Cover Letter)

Study title:

IMPLEMENTATION FIDELITY OF MANAGEMENT GUIDELINES FOR HEARING LOSS RESULTING FROM TREATMENT OF DRUG-RESISTANT TUBERCULOSIS IN KANO STATE, NIGERIA

Introduction:

Dear potential participant. My name is Dr. Sani Muhammad, a Masters' student in the "Division of Epidemiology and Biostatistics, School of Public Health at the University of the Witwatersrand, Johannesburg, South Africa". I am conducting a study to know how well, hearing loss management guidelines are implemented during drug-resistant tuberculosis treatment in IDH, Kano State.

Purpose of Study:

The reason why I am conducting this study is because there is increasing rate of hearing loss seen in patients receiving treatment for drug-resistant tuberculosis, with resultant high socioeconomic consequences. Data collected will be compiled in a thesis report and may be shared in publications or presentations.

Invitation to participate:

As a health care provider that has been involved in carrying out hearing assessment, I would like to invite you to participate in this study because your response is important. Before you decide to take part, you need to understand why the research is being conducted and what would be required of you. Therefore, take your time to read this information sheet carefully. Please ask any question, if anything that you have read is not clear to you or would like to have further information.

Description of the Study Procedures:

The entire survey will take about 20 - 30 minutes and it will be conducted in Hausa Language. This survey will be carried out at the Infectious Disease Hospital, Kano. The principal investigator will be populating the survey sheet on the Samsung mobile tablet.

Confidentiality

The survey is confidential and anonymous. Research records will be kept in a locked file, and all electronic information will be coded and secured using a password-protected file. We will not include any information in any report we may publish that would make it possible to identify you.

Right to Refuse or Withdraw

If you decide to take part in this study, be assured that your participation is voluntary, and you are free to withdraw at any time without giving any reason.

Risks/Discomforts of Being in this Study

There are no reasonable foreseeable (or expected) risks. There may be unknown risks.

Benefits of Being in the Study

There are no direct benefits to participants for taking part in the study.

Payments: There will be no payment for participation in this study.

Right to Ask Questions and Report Concerns

You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, at any time feel free to contact me, Dr. Sani Muhammad at 1702889@students.wits.ac.za or by telephone at +234 803 595 3169. If you like, a summary of the results of the study will be sent to you.

Contact details of REC administrator and chair.

If you have any problems or concerns that occur because of your participation, you can report them to the administrators of the Research Ethics Committee Office at the University of the Witwatersrand.

- Chairperson: Professor Peter Cleaton-Jones.
  Email: peter.cleaton-jones1@wits.ac.za
- Administrators - Ms Zanele Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng
  Tel 011 717 2700/2656/1234/1252
  Email: HREC-Medical.ResearchOffice@wits.ac.za

Consent

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Appendix IV: Informed Consent form

I, _____ consent and volunteer to participate in a research looking at how well hearing loss management guidelines are implemented during drug-resistant tuberculosis treatment in IDH, Kano State. The study is being conducted by Dr. Sani Muhammad; a master's student from University of the Witwatersrand, Johannesburg.

I confirm that:

1. I was provided with an information sheet that explained what the study is about, I have read and understood the information about the study as provided in the information sheet.
2. I have been given the opportunity to ask questions about the project and my participation.
3. I understand that I will not be paid for participating in this study.
4. I understand that I can withdraw at any time without giving reasons and there is/will be no risks or penalty for withdrawing"
5. It has been clearly explained to me that the research is confidential and anonymous, and what I say will not be linked to me as a person and that, the information will only be used for this research purpose and not shared with other people that are not part of this research team.
6. It has been clearly explained to me that information from this research may be used in a thesis report, publications or presentations.

Participant's Name (print): _____

Participant 's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Appendix V: Questionnaire

Questionnaire ID: …….…….

"SECTION A: SOCIO-DEMOGRAPHICS OF HEALTH CARE PROVIDERS.

1. Age _____ (in years)
2. Sex 1] Male 2] Female
3. Professional cadre: 1] Doctor 2] Nurse 3] Other, please specify ----------
4. Years working on DR-TB as Health Care Provider (in months if <1 year) ……

SECTION B: IMPLEMENTATION FIDELITY OF HEARING LOSS MANAGEMENT GUIDELINE.

I. CONTENT AND COVERAGE:

5. I always inform patients about the early symptoms of hearing loss.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

6. I reduce the dosing frequency of the injectable to two to three times a week in patients experiencing hearing loss.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

7. If patients are experiencing hearing loss, I consider switching to capreomycin (or its equivalence). 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

8. In patients whose hearing got worse, I stop injectables if reducing dosing frequency or switching medications does not work.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

9. When injectables are stopped in patients whose hearing got worse, I add additional anti-TB drugs to reinforce the regimen. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

10. When additional anti-TB drugs are not available, and a patient wants to maintain their hearing, I would continue the injectables. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

II. FREQUENCY

11. For patient on injectables, I start with a baseline audiometry at the time of enrolment.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

12. I perform monthly audiometry for patients on injectables after the baseline at enrolment. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

III. DURATION

13. The minimum number of audiometry test in four months is five.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

14. The maximum number of audiometry in eight months is nine.

   1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

   5) Strongly agree

SECTION C: DETERMINANTS OF IMPLEMENTATION FIDELITY.

I. FACILITATION STRATEGIES

15. I was trained on the Programmatic Management of Drug-Resistant TB (PMDT) guidelines? 0) No 1) Yes
16. I received refresher training on PMDT? 0) No 1) Yes
17. I have access to a copy of the PMDT guidelines. 0) No 1) Yes
18. I have access to an audiometer. 0) No 1) Yes
19. I can get my patient to do their audiometry test on time. 0) No 1) Yes
20. I can refer my patient to see a specialist (if required) on time 0) No 1) Yes

II. QUALITY OF DELIVERY

21. There was good supportive supervision from my superiors during PMDT implementation.1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree
22. The injectable drugs were available to me for administration to the patient at the scheduled time. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree
23. I have an effective linkage system to an audiometer when required 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree
24. Staffs were adequately sensitized through mobilization and training activities before the commencement of PMDT implementation. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

25. I can easily resolve ototoxicity related problems of my patients following the PMDT guidelines. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

26. Adequate copies of the PMDT guidelines on managing hearing loss are available during PMDT implementation. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

III. INTERVENTION COMPLEXITY

27. How would you rate the clarity of information provided in the PMDT guidelines?

    1] Very vague 2] Somewhat vague 3] Neither 4] Detailed 5] Very detailed

28. How would you rate the ease of the current process of implementing PMDT guidelines?

    1] Very complex 2] Somewhat complex 3] Neither

    4] Somewhat simple 5] Very simple

29. How would you rate the different roles among health care providers in the PMDT guidelines?

    1] Very complex 2] Somewhat complex 3] Neither 4] Somewhat simple

    5] Very simple

IV. PARTICIPANTS' RESPONSIVENESS

30. Most DR-TB patients know their treatment process. 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

31. Is hearing loss assessment acceptable to DR-TB patients? 1) Strongly disagree 2) Disagree 3) Neutral 4) Agree 5) Strongly agree

32. Are DR-TB patients compliant with their treatment regimen?

1) Strongly disagree 2) Disagree 3) Neutral 4) Agree

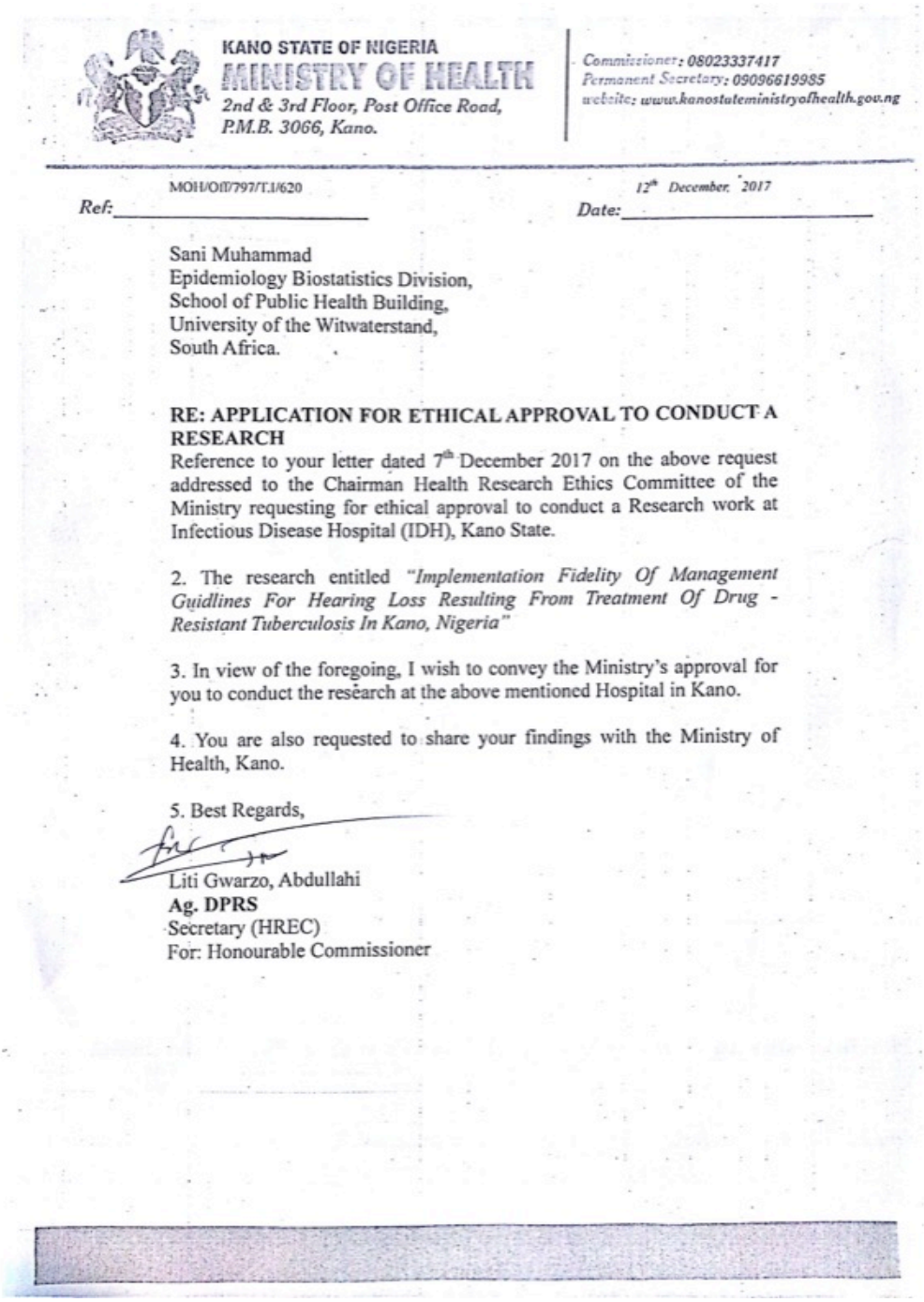
5) Strongly agree

33. Over the last six months, I have been asked questions for clarifications by DR-TB patients. 1) Strongly disagree 2) Disagree 3) Neutral

4) Agree 5) Strongly agree

Thank you so much for your time.

Appendix VI: Local Ethics/Permission to Conduct Research



KANO STATE OF NIGERIA
MINISTRY OF HEALTH
2nd & 3rd Floor, Post Office Road,
P.M.B. 3066, Kano.

Commissioner: 08023337417
Permanent Secretary: 09096619985
website: www.kanostateministryofhealth.gov.ng

Ref: MOH/Off/797/T.I/620

Date: 12th December, 2017

Sani Muhammad
Epidemiology Biostatistics Division,
School of Public Health Building,
University of the Witwaterstand,
South Africa.

RE: APPLICATION FOR ETHICAL APPROVAL TO CONDUCT A RESEARCH

Reference to your letter dated 7th December 2017 on the above request addressed to the Chairman Health Research Ethics Committee of the Ministry requesting for ethical approval to conduct a Research work at Infectious Disease Hospital (IDH), Kano State.

2. The research entitled *"Implementation Fidelity Of Management Guidlines For Hearing Loss Resulting From Treatment Of Drug - Resistant Tuberculosis In Kano, Nigeria"*

3. In view of the foregoing, I wish to convey the Ministry's approval for you to conduct the research at the above mentioned Hospital in Kano.

4. You are also requested to share your findings with the Ministry of Health, Kano.

5. Best Regards,

Liti Gwarzo, Abdullahi
Ag. DPRS
Secretary (HREC)
For: Honourable Commissioner

Appendix VII: Final Wits Certificate of Ethics

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr S Muhammad

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M171038

NAME: (Principal Investigator)	Dr S Muhammad
DEPARTMENT:	School of Public Health Medical School University
PROJECT TITLE:	Implementation fidelity of management guidelines for hearing loss resulting from treatment of drug-resistant tuberculosis in Kano, Nigeria
DATE CONSIDERED:	27/10/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr L Ibisomi and Professor Z Iliyasu
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/01/2018

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**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially reviewed in **October** and will therefore be due in the month of **October** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix VIII: Implementation Fidelity (Cronbach alpha outputs)

A Cronbach alpha of 0.81 was obtained for Implementation Fidelity

```
. alpha if1 if2 if3 if4 if5 if6 if7 if8 if9 if10, item

Test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem covariance	alpha
if1	73	-	0.4556	0.3558	.3675271	0.8036
if2	73	-	0.8354	0.7571	.2689783	0.7539
if3	73	+	0.8301	0.7574	.2779575	0.7560
if4	73	-	0.5868	0.4891	.3440512	0.7919
if5	73	+	0.6361	0.4849	.3113532	0.7934
if6	73	+	0.5267	0.4246	.354489	0.7977
if7	73	+	0.8483	0.8212	.337741	0.7782
if8	73	+	0.5201	0.4472	.3672945	0.7991
if9	73	+	0.6444	0.5050	.3124313	0.7896
if10	73	-	0.4409	0.2266	.3574328	0.8349
Test scale					.3299256	0.8080

Appendix IX: Facilitation strategy (Cronbach alpha output)

Facilitation strategy with c-alpha of 0.86

```
. alpha fs1 fs2 fs3 fs4 fs5 fs6, item

Test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem covariance	alpha
fs1	73	+	0.9515	0.9232	.0534817	0.7896
fs2	73	+	0.9301	0.8879	.0535578	0.7947
fs3	73	+	0.3589	0.2274	.0869482	0.8945
fs4	73	+	0.4916	0.2401	.0793379	0.9318
fs5	73	+	0.9515	0.9232	.0534817	0.7896
fs6	73	+	0.9515	0.9232	.0534817	0.7896
Test scale					.0633815	0.8627

Appendix X: Quality of delivery (Cronbach alpha output)

Quality of delivery with c-alpha of 0.65

```
. alpha qod1 qod2 qod3 qod4 qod5 qod6, item

Test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem covariance	alpha
qod1	73	+	0.7270	0.5000	.2594178	0.5363
qod2	73	+	0.7418	0.5543	.2579148	0.5163
qod3	73	+	0.4325	0.1854	.4256279	0.6571
qod4	73	+	0.7666	0.6285	.2642694	0.5039
qod5	73	+	0.3750	0.1581	.4468037	0.6588
qod6	73	+	0.5073	0.2335	.391933	0.6485
Test scale					.3409944	0.6382

Appendix XI: Intervention complexity (Cronbach alpha output)

Intervention complexity with c-alpha of 0.50

```
. alpha ic1 ic2 ic3, item

Test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem covariance	alpha
ic1	73	+	0.8078	0.2859	.2363014	0.5842
ic2	73	+	0.6644	0.4924	.2747336	0.3485
ic3	73	+	0.7188	0.3516	.2005327	0.3401
Test scale					.2371892	0.4992

Appendix XII: Participants` responsiveness (Cronbach alpha output)

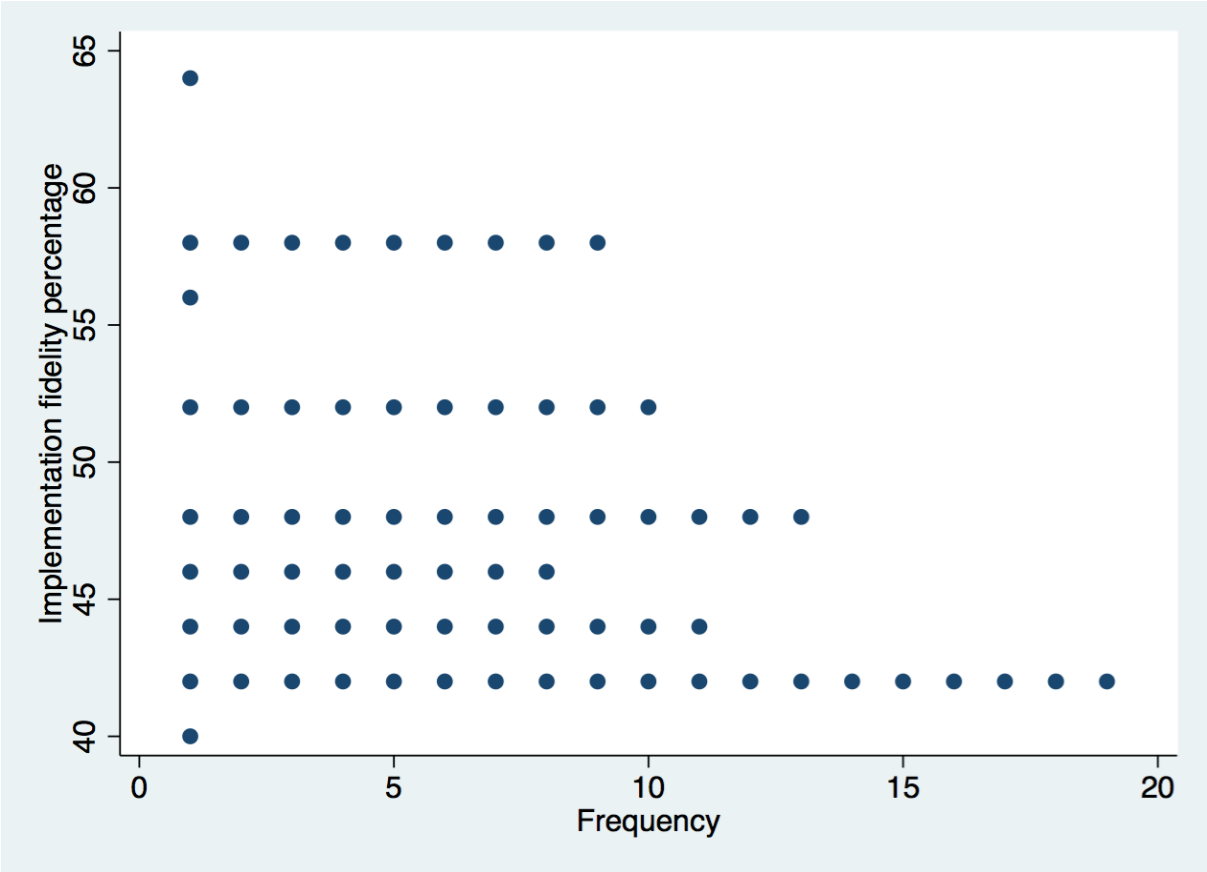
Participants' responsiveness with c-alpha of 0.50

```
. alpha pr1 pr2 pr3 pr4, item

Test scale = mean(unstandardized items)
```

Item	Obs	Sign	item-test correlation	item-rest correlation	average interitem covariance	alpha
pr1	73	-	0.6263	0.4412	.0931634	0.3727
pr2	73	+	0.8191	0.5721	.0191527	0.1182
pr3	73	+	0.1695	-0.0023	.1861365	0.5784
pr4	73	+	0.7902	0.2939	.0730594	0.5365
Test scale					.092878	0.4984

Appendix XIII: Dot plot for normality test



Dot plot for normality test for the distribution of the implementation fidelity scores

Appendix XIV: Pnorm Implementation fidelity

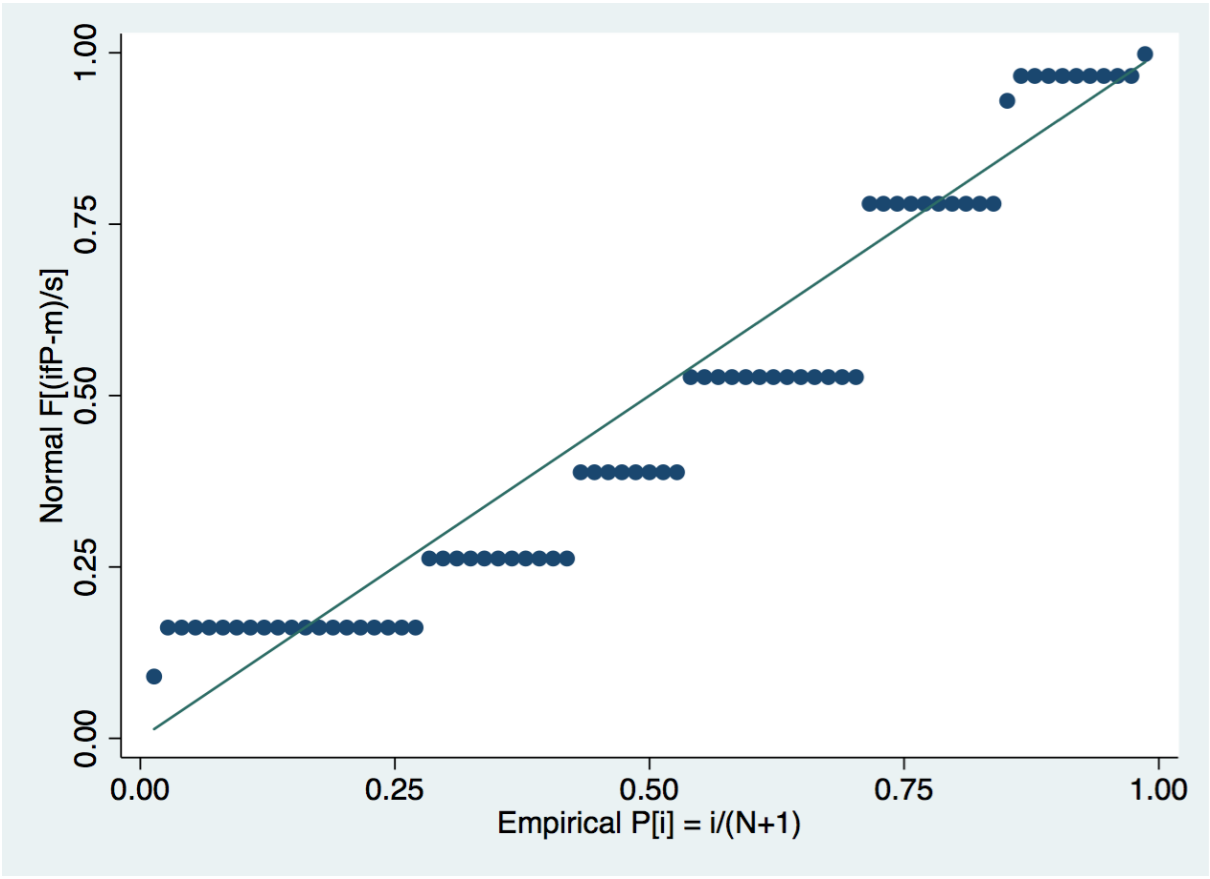


Figure of Normal probability plots of Implementation fidelity

Appendix XV: Shapiro-Wilk Test for Normality

. swilk ifP

Shapiro-Wilk W test for normal data

VARIABLE	OBS	W	V	Z	PROB>Z
IFP	73	0.92441	4.814	3.426	0.0031

NB: The p-value of 0.00031 is significant indicating the strength of evidence of non-normality of the residuals for the implementation fidelity score distribution.

Appendix XVI: Test for Homoscedasticity of Variance

Cameron & Trivedi's decomposition of IM-test

Source	Chi2	df	p
Heteroskedasticity	6.91	61	0.0086
Skewness	0.0030	10	0.0199
Kurtosis	0.9921	2	0.0199

Breusch-Pagan / Cook-Weisberg test for heteroscedasticity

Ho: Constant variance

Variables: fitted values of ifP

Chi2 (1) = 6.91

Prob > chi2 = 0.0086

Appendix XVII: Ladder result with significant p-values

. ladder ifP

Transformation	Formula	Chi2(2)	P(Chi2)
Cubic	ifP^3	14.40	0.001
Square	ifP^2	10.60	0.005
Identity	ifP	7.83	0.020
Square root	Sqrt(ifP)	6.94	0.031
Log	Log(ifP)	6.45	0.040
1/ (square root)	1/sqrt(ifP)	6.40	0.041
Inverse	1/ifP	6.80	0.033
1/square	1/(ifP^2)	8.85	0.012
1/cubic	1/(ifP^3)	11.97	0.003

Appendix XVIII: gladder result with probability curves of possible transformations

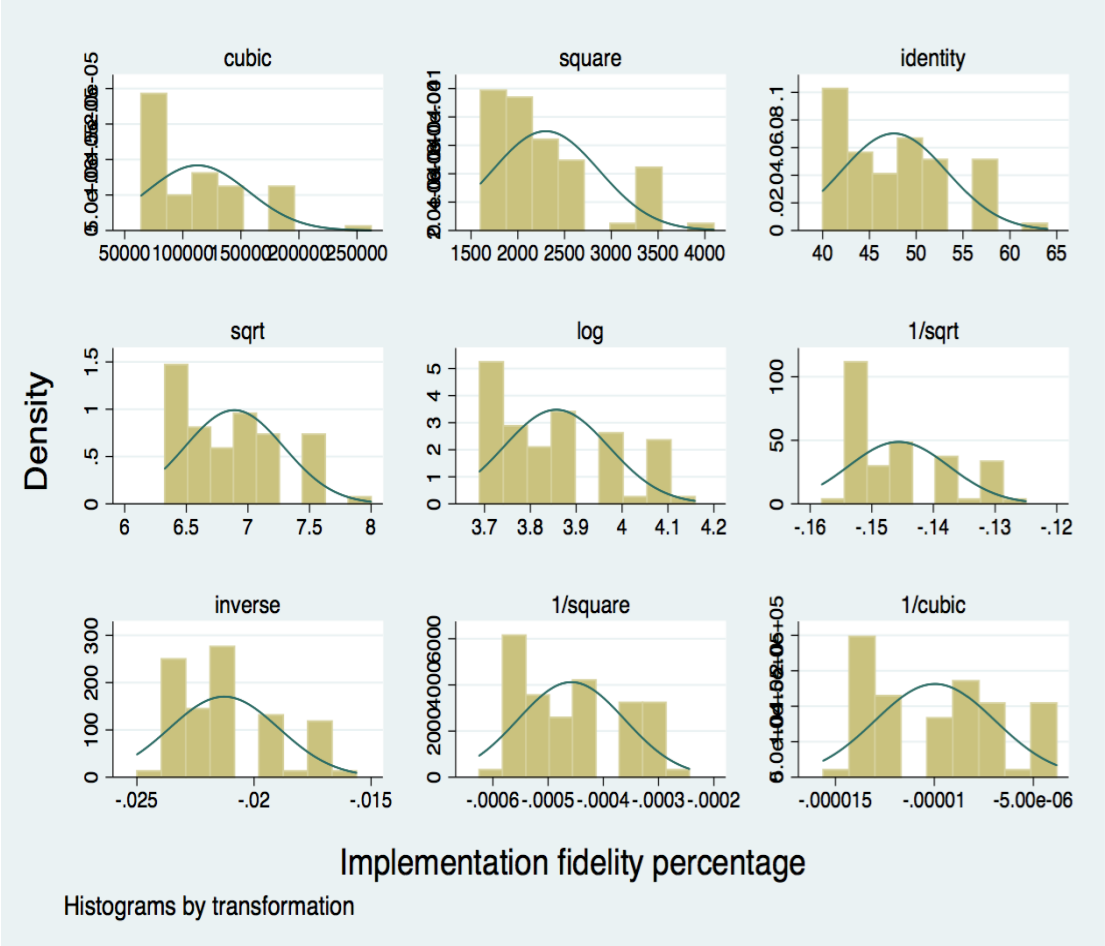


Figure of Histogram plots by transformation of Implementation fidelity

Appendix XIX: qladder result with correlation curves of possible transformations

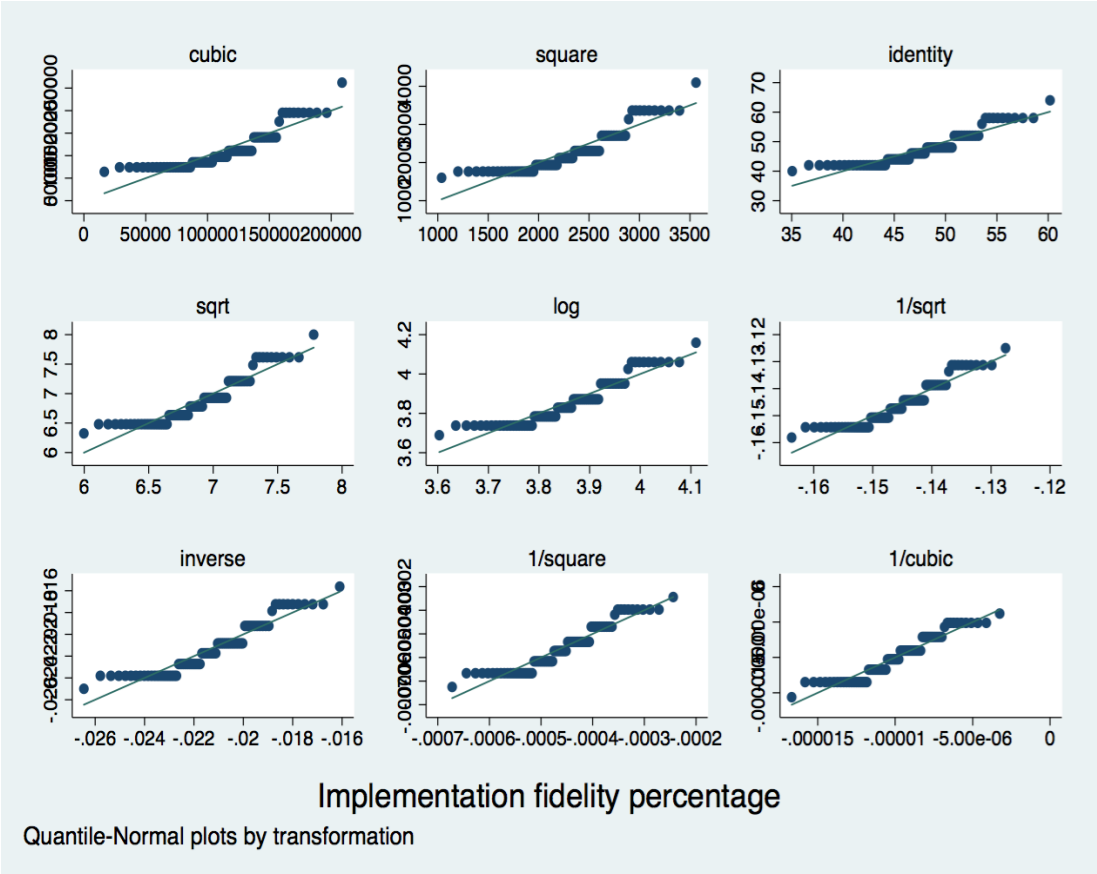


Figure of Quantile-Normal plots by transformation of Implementation fidelity