



**THE RELATIONSHIP BETWEEN CLINICIAN COMPLIANCE WITH NATIONAL
DRUG SENSITIVE TUBERCULOSIS (DS-TB) MANAGEMENT GUIDELINES AND
TREATMENT OUTCOMES AT MDANTSANE CORRECTIONAL CENTRE,
EASTERN CAPE**

BY

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FACULTY OF HEALTH SCIENCES

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DATE: 07 AUGUST 2023

DECLARATION

I, Vuyolwethu Mjijelwa, hereby declare that the research study '**THE RELATIONSHIP BETWEEN CLINICIAN COMPLIANCE WITH NATIONAL DRUG SENSITIVE TB (DS-TB) MANAGEMENT GUIDELINES AND TREATMENT OUTCOME AT MDANTSANE CORRECTIONAL CENTRE, EASTERN CAPE**' is entirely my work, and all references to outside materials used have been properly cited. It is being submitted to the University of Fort Hare for consideration for the Master of Public Health degree. It has not been submitted to this institution or any other for the purpose of a degree or examination.

Vuyolwethu Mjijelwa

Signature:



Date signed: 07 August 2023



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CERTIFICATION

This mini dissertation entitled '**THE RELATIONSHIP BETWEEN CLINICIAN COMPLIANCE WITH NATIONAL DRUG SENSITIVE TB (DS-TB) MANAGEMENT GUIDELINES AND TREATMENT OUTCOME AT MDANTSANE CORRECTIONAL CENTRE, EASTERN CAPE**' satisfies the requirements for the University of Fort Hare's MASTER OF PUBLIC HEALTH postgraduate degree, contributes sufficiently to the field's corpus of scientific knowledge, and exhibits adequate literacy presentation.

SUPERVISOR: Mrs P. Giyose

SIGNATURE: 

DATE: 26/01/2024



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DEDICATION

I dedicate this dissertation to the late Johnson, Nobubele, Xolisile and Ayanna, memories of whom kept me motivated; to my mother Ellen for the support and to my sisters Hombisa, Zandi and Issa for their motivation throughout the course of my studies.



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ABSTRACT

Tuberculosis (TB) is an inflammatory infectious disease caused by *Mycobacterium tuberculosis* which affects any tissue of the body. The most common site of disease is the lungs (World Health Organisation, 2023). WHO developed guidelines for managing this disease and South Africa developed its own context specific guidelines. However, compliance with these guidelines is not always possible for various reasons, especially in sub-Saharan Africa. This study was conceptualised with the intention of assessing TB management practices in correctional centres and determining how those practices may be related to treatment outcomes.

The main objectives were to determine the compliance of correctional centre clinicians with TB management guidelines and to see if there is a relationship between compliance with guidelines and treatment outcomes.

A cross sectional study design was used and data was extracted from 106 patient files. Frequency distributions were used to determine the extent of compliance and the chi-square test was used to test for relationships between different compliance aspects and treatment outcomes. Odds ratios and 95% confidence intervals were used to measure the strength and direction of detected relationships.

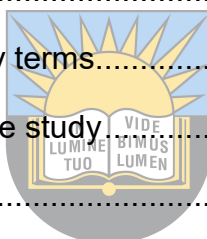
While there was high compliance in most of the aspects of TB management as per the guidelines, there was lack of justification of deviations, whenever they occurred. The patients who were more likely to have positive treatment outcomes were those whose baseline smear results were known (OR=4.8; 95%CI (1.22;22.59)), whose weight was monitored (OR=1.5; 95%CI (1.27;1.71)) and whose treatment duration was known (OR=6.1; 95%CI (1.39;26.81)).

The Department of Correctional Services health management should develop a comprehensive capacitation plan that will include mentoring and monitoring of compliance with TB guidelines. An effective linkage to the care system within correctional services and DOH facilities must be developed to ensure continuity of care and improve treatment outcomes. Tuberculosis case-finding and contact tracing require more research to understand the trends of infection and inform comprehensive infection control policies.

Keywords: Correctional centre, TB management guidelines, clinicians, compliance

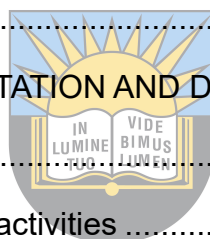
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List of acronyms	
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral treatment
ATTN	Appraisal Tool for Tier.Net
BCM	Buffalo city municipality
CD4	Clusters of differentiation 4
DCS	Department of Correctional Services
DOTS	Directly observed treatment short-course
DR-TB	Drug resistant tuberculosis
DS-TB	Drug sensitive tuberculosis
ESTC	European Union Standards for TB Care
EU	European Union
HIV	Human immunodeficiency virus
NDOH	National Department of Health
NIDS	National indicator data set
NTP	National Tuberculosis Programme
PFP	Private for profit
PHC	Primary health care
SA	South Africa
SAS	Statistical Analysis Systems
SSA	sub-Saharan African
TB	Tuberculosis
UFH	University of Fort Hare
UIC	Unique identification code
WHO	World Health Organisation

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CHAPTER 1: INTRODUCTION

1.1 Introduction and background

Tuberculosis (TB) is an inflammatory infectious disease caused by *Mycobacterium tuberculosis* which affects any tissue of the body. The most common site of the disease is the lungs (World Health Organisation, 2023). In South Africa, it is the main cause of death. South Africa was one of the eight nations responsible for two-thirds of the world's TB burden in 2020, responsible for 3.3% of global TB cases (Global Fund, 2022). Countries in sub-Saharan Africa (SSA) with results from several correctional facilities report that TB prevalence ranges from 457 to 888 per 100 000 population (Melese & Demelash, 2017). TB is a public health threat in SSA national TB programmes because of inadequate clinical management and poor treatment outcomes.

In SSA TB remains a public health threat. This region has the largest burden of TB disease relative to other WHO regions (WHO,2018). For this reason, in-service mentorships and trainings on TB management guidelines are critical and recommended to enhance clinician competence in TB management to improve TB treatment outcomes (Ahmed, Fatmi, Ali, Ahmed, & Ara, 2009). Varying rates of treatment success have been reported in SSA, South Africa is between 82.2% and 80%; Ethiopia 90.1% and 86.8%, Uganda 39%, Zimbabwe 70% and Nigeria 57.7% (WHO,2018). Despite the observed variations, SSA currently lacks reliable pooled data on the treatment success rate of TB patients. This data issue may hinder TB programmes from designing effective strategies for reducing TB morbidity and mortality and improving TB treatment outcomes (Izudi, Semakula, Sennono, Tamwesigire, & Bajunirwe, 2019). Disease surveillance and reporting of TB in correctional centres are often poor, and the problem of TB remains inappropriately defined (WHO, 2010).

Due to inmates' constant contact with the outside world, correctional facilities are environments with a high risk of disease. This poses complex and difficult challenges for public health, particularly in relation to the human immunodeficiency virus (HIV) and tuberculosis (TB) (World Health Organisation, 2013). The volume of air dispersed among inmates, the number of inmates in each cell, and the length of the lock-up time all affect the transmission of TB in correctional facilities (Witbooi & Vyambwera, 2017).

Therefore, health services in correctional centres should be of equivalent professional, ethical, and technical standards as public health services in the community (World Health Organisation, 2013).

In order to improve the quality of life for inmates, the Department of Correctional Services (DCS) is required by Chapter 2 of the Correctional Services Act No. 111 of 1998, as amended, to offer adequate health care services that are based on primary health care principles. Compliance with policies as a statutory obligation for guaranteeing quality services is one of the characteristics of strong clinical governance (Berg & Black, 2014). Therefore, it is important to incorporate correctional centre health services into national health policies and systems (World Health Organisation, 2013).

The year 2014 saw the release of revised guidelines by the South African National Department of Health (NDOH) that included new quick diagnostic tests for the detection and treatment of drug-sensitive tuberculosis (DS-TB). The recommendations urge screening for TB and starting TB treatment before beginning antiretroviral medication (ART) and include a diagnostic algorithm and its interpretation (National Department of Health, 2014). Following these recommendations can decrease TB-related mortality (Auld et al., 2016).

Clinician compliance with disease management guidelines is one of the basic practices by which clinicians can ensure successful management of TB. Guidelines are developed for use by clinicians and are principally based on high quality research evidence (Mavoko et al., 2015).

1.2 Research problem

There is a total of 7.58 million inmates in developing nations. This represents 71% of the estimated global prison population. However, settings of correctional facilities in these countries are still notably underrepresented in health studies that could affect health recommendations and policies (Fair & Walmsley, 2019) (Fair & Walmsley, 2019).

Within two years, approximately 10,000 inmates at Pollsmoor Correctional Centre were tested, and 701 were diagnosed with DS-TB. However, DCS has not addressed contributing factors including health care dysfunction, shortage of clinicians, and treatment disruptions (Skosana, 2015).

Since the introduction and dissemination of guidelines in 2013 by NDOH, adherence to these guidelines in management of drug resistant TB is unknown (Van de Water, et al., 2018). Similarly, there are no studies assessing clinician compliance to DS-TB management guidelines at Mdantsane Correctional Centre.

A study on missed pulmonary TB screening opportunities at primary health care facilities was carried out in Buffalo City Metropolitan Municipality (BCM) (Kweza, Abraham, Claassense, & Schalkwyk, 2016). The study suggested that universal TB screening within the South African primary health care system must be conducted according to the national guidelines (Kweza, Abraham, Claassense, & Schalkwyk, 2016). However, correctional centre clinics in BCM were excluded from the study so much that it may not be possible to comfortably extrapolate the results to correctional centres. Consideration of the implementation context and setting is important in measuring competence and compliance to standard practices (Grant & Osanloo, 2014). Therefore, this study was conceptualised with the intention of assessing TB management practices in correctional centres and determining the association between these practices and treatment outcomes to inform future interventions.

1.3 Purpose of the study

The purpose of this study was to evaluate the relationship between clinician compliance with drug sensitive tuberculosis (DS-TB) management guidelines and treatment outcomes at Mdantsane Correctional Centre, Eastern Cape.

1.4 Objectives of the study

The objectives of the study were to:

- Assess alignment between DS-TB clinical management and DS-TB management guidelines at Mdantsane Correctional Centre.
- Determine the TB treatment success rate among DS-TB patients treated at the Mdantsane Correctional Centre.
- Determine the relationship between clinician compliance with DS-TB management guidelines and treatment outcomes at Mdantsane Correctional Centre.

1.5 Research questions

The objectives stated above were addressed through providing answers to the following research questions.

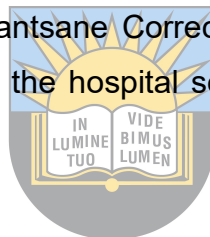
- To what extent does the clinical management of TB at Mdantsane correctional centre comply with established DS-TB guidelines?
- What is the treatment success rate among DS-TB patients at Mdantsane Correctional Centre?
- Is there any relationship between clinician compliance with DS-TB management guidelines and treatment outcomes among patients at Mdantsane Correctional Centre?

1.6 Significance of the study

This study might contribute towards identification of factors that enhance or compromise compliance to TB management guidelines by clinicians in the correctional centres. Furthermore, this study may influence policy development by the National Department of Correctional Services.

1.7 Delimitations of the study

The study was carried out at Mdantsane Correctional Centre among patients who received DS-TB clinical care from the hospital section from 01 January 2016 to 31 December 2021.



1.8 Limitations of the study

It may not be possible to comfortably extrapolate findings from this study to other correctional centres because it focusses on only one out of four correctional centres in Buffalo City Metropolitan Municipality.

1.9 Operational definitions of key terms

A detailed explanation of the key and technical terms is provided below to standardise meaning and context in this study.

Correctional centre: Is an institution established under the Correctional Services Act of 1998, as a place for the reception, detention and confinement of persons liable for detention in custody (DCS, 2019).

Inmate: A person who is being held in a correctional facility or remand detention facility, whether they have been found guilty or not, is said to be an inmate (DCS, 2019).

Compliance: This is upholding ethical values and abiding by policies and procedures, during clinical practice (Eisai, 2021).

Tuberculosis: According to WHO (2014), active tuberculosis refers to a disease that occurs in someone infected with mycobacterium tuberculosis.

Guidelines: This is a formal statement about a defined task or function in clinical practice such as an optimal treatment regimen for a specific diagnosis based on best available evidence (Williams & Wilkins, 2023).

Direct clinical observations: This is where a trained observer records clinical information during a clinical visit, typically using a checklist (Arsenault et al., 2019).

Standardised-patient method: Standardised patient method is a process of training individuals to portray a patient with symptoms of TB, and having clinicians record the clinical decisions while blinded to the assessment (Arsenault et al., 2019).

Clinician: A nurse or doctor in a correctional centre clinic whose primary role is to manage sick inmates with the purpose of alleviating the effects of illness (Philip & Tumulty, 2014).

Inappropriate treatment: This includes ineffective recommendations, noncompliance with guidelines or no guidelines, inadequate training, and a poorly run TB programme. (WHO, 2014).

MDR TB (NDOH, 2014): This is tuberculosis that is resistant to isoniazid and rifampicin.

Patient: A patient is considered to be cured if baseline testing (smear or culture) was positive at the start of treatment and negative results were obtained during the final month of treatment and on at least one prior occasion that occurred at least 30 days earlier (NDOH, 2014).

Treatment complete: A patient whose initial baseline examination (smear or culture) was positive has finished TB therapy but has not had a negative result in the past month or on at least one occasion more than 30 days earlier (NDOH, 2014).

Treatment failure: Client whose baseline investigation is positive and remains positive or becomes positive again at five months or later during the treatment period (NDOH, 2014).

Died: Client who dies for any reason during the course of TB treatment (NDOH, 2014).



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Clients lost to follow-up: These are clients whose treatment was interrupted for two months or longer during the treatment period (NDOH, 2014).

Transfer out: Patient who was referred to another health facility to continue with TB treatment and for whom the treatment outcome is unknown (NDOH, 2014).

Unknown treatment outcome: Client who has been actively on TB treatment for a minimum of six months with no recorded treatment outcome (NDOH, 2014).

Smear microscopy: it is an investigation for TB diagnosis based on identification of acid-fast bacilli through microscopic examination of stained sputum smears (NDOH, 2014).

GeneXpert: It is an automated molecular platform to diagnose TB and rifampicin resistance by targeting specific mutations (NDOH, 2014).

1.10 Theoretical framework of the study

Carroll et al.'s conceptual framework for implementation fidelity is the theoretical framework of the study. The implementation fidelity theory served as a guide for the researcher based on existing studies (Grant & Osanloo, 2014) to define variables to explain the phenomenon of compliance to guidelines (Farley et al., 2013). Fidelity is the degree to which a guideline of an intervention is implemented as intended to ensure that outcomes are achieved (Pérez, et al., 2016). Adaptation is the process of changes to the original guideline of an intervention; potentially it could be positive or carry the risk of resulting in a negative effect on expected outcomes (Pérez et al., 2016).

Fidelity coexists with adaptation in deferent settings (Pérez, Van der Stuyft, Zabala, Castro, & Lefèvre, 2016). Depending on the application of guidelines, adaptation could either be potentially positive or lead to non-compliance, resulting in a negative effect on expected outcomes (Dusenbury, Brannigan, Falco, & Hansen, 2003). The concept, methodology, and analysis of the study will all be connected to this theory. Implementation fidelity can be measured using either adherence or Relationships between moderators or quality of delivery (Mihalic, 2004).

Adherence: Integrity in implementation is measured by adherence to guidelines. When developers' instructions are followed to the letter and the material is applied as directed, fidelity can be considered high (Mihalic, 2004).

Fidelity in relation to the independent variable (compliance with guidelines) is one strategy to reduce implementation variability to ensure that clinicians deliver the service as per the guidelines (Livet et al., 2020). In South Africa, the constitution supports several guiding documents, including policies like the National Strategic Plan (NSP) on HIV, TB/STIs 2017–2022, and DOH TB management recommendations to promote health outcomes (Keehn & Nevin, 2018).

Moderators: A high level of adherence or fidelity to guideline as an essential component is not achieved easily. Several factors may influence or moderate the degree of fidelity with which an intervention is implemented (Mihalic, 2004). In practice there may be relationships between two or more variables that may affect outcomes and quality of service (Mihalic, 2004).

Implementation fidelity theory is intended to understand and explain what influences implementation outcomes (Nilsen, 2020). This framework also informs the determinants, processes and evaluation of implementation efforts (Moore et al., 2015). Therefore, the TB relationship between treatment outcome with clinician's compliance can be measured through the determined theoretical framework.

Quality of delivery: This is a potential moderator of the relationship between a guideline and the fidelity with which it is implemented. It concerns whether an intervention is delivered in a way appropriate to achieving what was intended. If the content of the guideline is poorly applied, then this may affect the degree to which full adherence to guidelines is realised (Mihalic, 2004). The theory validates the importance of key terms of the research problem, that is, guidelines, compliance and treatment outcomes and the need to acknowledge changes needed to improve outcomes intended. According to the study done in China it is evident that scientific evidence-based reviews must be conducted to improve adaptability of the guidelines for different settings (Mala, Moser, Dinant & Spigt, 2014). Through the guidance of this theory relevance and applicability of guidelines for innovations in DCS health care will be determined (May et al., 2016).

1.11 Outline of ethics

The operational manager of the Mdantsane Correctional Centre, and the National and Regional Management of Correctional Services Department were consulted for

permission to conduct the study after the proposal was submitted to the University of Fort Hare Ethics Committee for review and approval.

The permission from the Correctional Services Department was considered as consent from patients since historical records are used as the main source of data and patient records are the property of correctional services.

Data will not be shared or released for any other purpose than this study and will be utilised only in this context.

1.12 Summary

The researcher has stated the title of the study based on the research problem that denotes uncertainty of TB management guideline-based clinical management. Statistics confirm evidence that TB remains a major health problem in correctional centres. It is unknown how compliance or lack thereof affect treatment outcomes. All the operational terms have been explained to give context. The researcher has applied the research process to acknowledge limitations and delimitations of the study. Through the process of comparison two theories have been studied, namely:

- Conceptual Framework for Implementation Fidelity
- The Consolidated Framework for Implementation: a useful theoretical framework for guiding and evaluating a guideline implementation process.

The researcher was able to identify a suitable framework that covers all elements of the study and the aim. The blueprint of Fidelity for implementation of interventions framework guided the researcher in conducting the study and review of relevant literature.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In order to evaluate and contrast the results of earlier studies on the research topic, identify research gaps, and explore potential future research directions, it is necessary to discover and synthesise pertinent literature and articles (Pau & Criado, 2020). For the purposes of this study the researcher developed search strategies. The researcher was using search engines such as Google scholar and PubMed to search for papers from the updated top ten list of TB journals by Omics international. Thereafter the researcher conducted searches using key terms of the study and prioritised recent

literature from these sources. In the process, other relevant and recent studies from other credible sources were not excluded. Key words from the research topic were used to search for relevant sources. In this chapter the researcher has referenced articles that were cited for the purpose of the study. Elements that were relevant to address the objectives of the study are explored from different perspectives and settings. These include burden of disease, importance of guidelines, compliance, non-compliance and TB data reporting in correctional centres.

2.2 Burden of TB disease

TB is a major public health problem that challenges professionals, especially in developing states, where over 80% of the total TB burden is identified (Moreira et al., 2022). Based on data from 202 countries, the WHO Global TB Report concluded that TB is present in all regions of the world (WHO, 2014). More than ten million new cases of TB are estimated to arise annually, despite the availability of very effective treatment recommendations and trustworthy fast diagnostics (WHO, 2022).

Internationally, the prevalence of TB in correctional centres can reach up to 100 times greater than those in the overall population, especially in Southern Africa due to high prevalence rate of human immunodeficiency virus (HIV) (Hatwiinda, Topp, Siyambango et al., 2018). In developing countries the estimated fraction of TB in the general population attributable to correctional centre-based transmission is 6.3% (IQR: 1.9–17.9%) (Hatwiinda et al., 2018).

According to the Global Tuberculosis Report 2020, in 2023, new TB cases in South Africa were predicted to be 615 cases per 100,000 people in 2019, ranging from 427 to 835 cases per 100,000, and with an anticipated 360,000 people developing TB (WHO, 2020).

According to the Eastern Cape Health Annual Report 2018/19, the TB incident rate of the province was at 206 per 100 000 in 2016.

The national and provincial status quo is also evident at the local government level. In 2018 TB was number two among leading underlying natural cause of death at 12.7% among males between ages 15 to 44 years (SA, 2019). In Buffalo City Metropolitan Municipality, the leading cause of death amongst the 25-64 age group is TB at 18.4% (BCMM, 2021).

TB prevalence among incarcerated populations is as much as 1,000 times higher than in the general population in South Africa (Sharp et al., 2018). Correctional facilities in South Africa may be a significant TB reservoir due to the country's high TB incidence and large population of detainees (Baird, Said, Koornhof, & Duse, 2022). A study conducted in twelve South African correctional centres estimates prevalence of TB at 2100 per 100 000 (Jordan et al., 2019). In 2015, 61 of the 90 correctional centres in South Africa were inspected, and it was established that they were overcrowded with lock-up of more than 100% (Witbooi & Vyambwera, 2017).

Subsequently, inmates have a high risk of infectious diseases, including TB, due to overcrowding, poor ventilation, poor nutrition, and limited access to health care (Walter et al., 2022). To effectively address the TB problem, guidelines on how to combine various components of health systems and services are required (NDOH, 2014).

Early and accurate diagnosis, and treatment initiation according to international standards prevents deaths and illness among people who develop TB (WHO, 2022).

2.3 TB management guidelines at a global scale

The World Health Organization (WHO) has a mandate to develop and disseminate evidence-based policy, guidelines, and standards for TB prevention, diagnosis, treatment, and care (WHO, 2022).

WHO member countries demanded clear policy guidance on the management of TB and guidelines were developed (Getahun, et al., 2015). These guidelines were developed to make it easier to reach the goals outlined in the WHO End TB Strategy, which call for a 90% decrease in TB incidence and a 95% decrease in TB mortality by 2035 (Grant & Osanloo, 2014).

The WHO guide offers recommendations on how to implement each component of the End TB Strategy in accordance with global standards for TB care (WHO, 2014). Specific suggestions on best practices and unique strategies on TB infection control are provided by the WHO guidelines on TB diagnosis and treatment. Clinicians working in health care facilities should follow these recommendations (WHO, 2013).

The purpose of the guidelines is to provide evidence-based principles for planning and implementation of TB programmes among high-risk groups that include inmates (WHO, 2013). Details of implementation in a health setting are provided by guidelines

including recommendations on eligibility for investigation and treatment regimen for TB (Getahun, 2015).

Clinicians and all care providers were acknowledged as essential in universal access to care for TB patients in the 62nd World Health Assembly held in Geneva in 2009 (WHO, 2014).

WHO guideline reviews on TB management are periodical and recommendations follow the Grading, Recommendations, Assessment, Development and Evaluation (GRADE) (WHO, 2016). The GRADE approach is a method for creating clinical practice recommendations that provide systematic and transparent advice from scientific evidence to recommendations (Neumann, et al., 2016). WHO newly revised recommendations include a shorter treatment regimen as first choice for patients with multidrug or rifampicin resistant TB strains (WHO, 2016). WHO reinforces the End TB Strategy in its most recent guideline for TB control (Evenblij, Vernon, & Van, 2016).

2.4 Compliance with TB management guidelines

Measurements of compliance focus on the quantity or presence of prescribed behaviours as defined in the guidelines or by the intervention protocol (Grant & Osanloo, 2014). The following recommendations can lower TB-related morbidity and mortality (Auld, et al., 2016). Clinical guidelines encourage ethical practice among professionals in South Africa. Compliance with these guidelines is mandated by the National Health Act 61 of 2003 that intends to provide a framework for a standardised health system considering the Constitution and other spheres of government regarding health services (SA, Government, 1995).

In addition to monitoring treatment coverage and availability of tools, governments should consider indicators of clinical compliance (Arsenault, Roder-DeWan, & Kruk, 2019). Such indicators include ability of clinicians to correctly diagnose TB and adhere to treatment guidelines as well as provide timely, continuous and integrated patient-centred care (Arsenault, Roder-DeWan, & Kruk, 2019).

The International Standards for TB Care outline the essential level of care for managing patients who have TB or are at increased risk of developing the disease (Migliori et al., 2018). The resources and capacity in the European Union (EU) and the European Economic Area permit higher standards of care, secure quality and timely TB diagnosis, prevention and treatment. The European Union Standards for TB Care

(ESTC) were published in 2012 as standards specifically tailored to the EU settings. Since the publication of the ESTC, new scientific evidence has become available and, therefore, the standards have since been reviewed and updated (Migliori, et al., 2018).

In Ethiopia, TB treatment programmes are integrated within the national TB control programme and treatment is provided based on the national guidelines (Adane, Spigt, & Dinant, 2018). The proportion of patients managed in full adherence with the national guidelines at the public and private Directly Observed Treatment Short-course (DOTS) facilities in Nigeria was low at 79% and 75%, respectively (Adejumo, et al., 2016). Particularly striking in Lagos was the fact that none of the patients managed at the Private for Profit (PFP) facilities was managed in full adherence with the national guidelines (Adejumo et al., 2016).

With implementation of DOTS strategy guidelines and other TB control projects, the prevalence of TB in China dropped from 611 per 100,000 in 1990 to 442 per 100,000 in 2010 (Wang, Zhu, Wei Chen, & Wei-Bing, 2021).

Studies from Nigeria and other high TB burden countries found that private and public health care workers did not comply fully with the National Tuberculosis Programme (NTP) (Adejumo et al., 2016). Non-compliance with the standardised guidelines for management of diseases by clinicians is a possibility (Adejumo et al., 2016).

According to Kweza, Abraham and Claassens (2016) missed TB screening opportunities within health facilities contribute to the 3.3 million missing cases of TB globally. Therefore, it is recommended that universal TB screening within South African Primary Health Care (PHC) must be conducted as mandated by national guidelines (Kweza, Abraham, Claassense, & Schalkwyk, 2016). Evaluation of TB guidelines compliance is a crucial part of programme evaluation and can provide areas for programme improvement (Auld, et al., 2016).

2.5 Noncompliance with TB management guidelines

Multiple guidelines were created by WHO and adopted by its member nations. However, when these guidelines were established, it was questioned if the content was appropriate for the local context and implementation (Zinatsa, Engelbrecht, van Rensburg, & Kigozi, 2018).

Major reasons for non-compliance include insufficient diagnostic modalities, ambiguity in guideline recommendations, poor documentation, health service situation and professional social context. Depending on the specific challenges and setting, clinicians will develop strategies and practices that are not always aligned with national guidelines (Mala, Moser, Dinant, & Spigt, 2014).

In India, poor quality of the sputum smear microscopy tests was considered to be the reason for non-compliance with diagnostic guidelines (Mala, Moser, Dinant, & Spigt, 2014).

According to Islam, Chughta, Banu, and Seale (2020), guidelines were frequently created without data from developing nations with high TB burdens and instead they relied heavily on expert opinions. However, they agree that implementation of these guidelines can improve TB outcomes.

In a study in China, it was found that doctors' compliance with National TB Control Program (NTP) on newly diagnosed TB patients needed improvement to promote quality medical care (Zheng, Zhong, & Xinping, 2014).

Implementation of the national HIV-TB guidelines in the Netherlands was hampered by the disconnection between clinical practice and evidence-based recommendations in the guidelines (Evenblij, Verbon, & van Leth, 2016).

Poor compliance with guidelines can reduce the quality of TB care and increase the incidence of drug resistant TB cases (Zheng, Zhong, & Xinping, 2014). Inadequate dosages due to non-compliance with guidelines may trigger dose-dependent adverse reactions (Zheng et al., 2014). Poor treatment outcomes, including acquired drug-resistant TB, are caused by inappropriate treatment, inadequate drug quality and patient factors hampering adherence and treatment responses (WHO, 2014).

Islam, Chughta, and Seale (2020) assert that the suggestions given in the guidelines should give high TB burden countries priority due to their high TB occurrence rates.

Compliance with national TB guidelines is necessary in ensuring that TB patients get quality service irrespective of where they receive the services (Adejumo et al., 2016).

The South African National Department of Health published a Data Quality Assessment Strategy to assess compliance with policies, guidelines, completeness of

clinical records and data quality management (DOH, Data Quality Assessment Strategy, 2019).

2.6 TB management in South African correctional centres

Considering the difference in dynamics and population, guidelines outlining TB research priorities need to be developed specifically for correctional institutions (Dara, et al., 2015). A combination of policies that emphasise prevention, early case finding, fast treatment initiation, and an efficient referral system should be put into place for effective infectious disease control in correctional facilities (DOH, 2013). In order to diagnose cases quickly and begin treatment, TB management guidelines should be expanded to include regular active screenings and preventive treatments both during and after incarceration (Walter et al., 2022).

National laboratory services are expected to provide 24-hour turnaround time for confirmation of diagnosis of DR-TB for the client to be transported to a DR-TB centralised site for initiation on treatment (DOH, 2019).

The NDOH and DCS collaborated to create guidelines for care of TB, HIV, and sexually transmitted illnesses in correctional centres in 2013. Undiagnosed TB among inmates, overcrowding and unhygienic conditions led to the development of TB management guidelines for correctional centres (DOH & DCS, 2013).

2.7 Correctional centre specific TB management guidelines in South Africa

Due to the crowded and confined circumstances in correctional centres, the potential for the spread of airborne infections is real. Targeted interventions that are specific to correctional environments need to be implemented to mitigate risk of infection (DOH & DCS, 2013). This culminated in the development of TB management guidelines that are specific for correctional centres. The distinctions between the general and correctional environment, TB management guidelines are in the duration of preventive treatment, choice of service and outbreak definition (DOH & DCS, 2013). Patients in correctional centres take the isoniazid and vitamin B TB preventive therapy for the duration of their incarceration while in the general population it can be discontinued after 12 months (DOH, 2019). With respect to the referral system, patients in correctional centres do not have the option of outpatient treatment. In the correctional environment, a TB outbreak is declared when more than two inmates from the same cell are infected (DOH & DCS, 2013), while in the general population an outbreak is

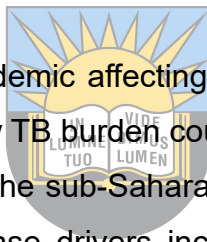
declared when more than the expected number of cases, in time and place, is observed (DOH, 2014).

2.8 Reporting of TB treatment outcomes

For a comprehensive understanding of the scale of the issue and the detection of potential gaps, data on TB diagnosis, treatment initiation, and completion from South African correctional facilities is essential (Baird, Said, Koornhof, & Duse, 2022). According to NDOH (2021) the National Indicator Data Set should cascade to draw reliable conclusions. Subbaraman et al. 2019, state that reporting TB indicators in a cascade of care is a useful model for evaluating patient management across stages of care to identify areas of improvement and achieve successful outcomes. However, the DCS 2020/21 annual report solely focuses on pulmonary TB cure rate, excluding other TB indicators. Therefore, representative data regarding TB prevalence in South African prisons has gaps (Keehn & Nevin, 2018).

2.9 Summary

Evidence shows that TB is a pandemic affecting all countries worldwide. WHO has classified countries from high to low TB burden countries depending on the prevalence rate. African countries, especially the sub-Saharan region, is among high TB burden areas. This depends on TB disease drivers including poverty, low socioeconomic status and poor health care systems and poor health seeking behaviours. Correctional centres in this region that includes South Africa are no exception. Scientific evidence-based guidelines were developed by WHO to curb the spread of TB and improve management. Furthermore, strategies based on new evidence and technologies are introduced to South Africa and other WHO member countries. It is argued that compliance with these guidelines is more important to improve outcomes than the lack thereof. DOH and DCS have jointly introduced guidelines specific to the correctional centre setting because high TB prevalence and TB infection friendly environment is known. Clinicians are pivotal in guideline-based TB management as per the set standards.



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CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter seeks to detail the methodology followed in collecting the data. It justifies the research methods used in the study based on the nature of the research problem and researcher's perspective.

3.2 Research design

Research design is a plan and the procedure for research that span the decisions from broad assumptions to detailed methods of data collection and analysis (Creswell, 2009).

This study is a quantitative observational study that involves measuring and quantifying characteristics of a phenomenon, upon gathering numerical data (George, 2023).

In this study, the data was collected at a specific point in time, thus, at the same time, which makes it a cross sectional design. Study participants were clients managed for DS-TB at Mdantsane Correctional Centre from 01 July 2016 to 31 December 2021. Data on the specific variables was extracted from their files.

3.3 Research setting

It is the physical, social, or experimental context within which research is conducted, accurately describing it is critical as the interpretation of the results may depend on it. In a research paper, describing this setting accurately is crucial since the results and their interpretation may depend heavily on it.

The study was conducted at Mdantsane Correctional Centre, Eastern Cape. The institution is divided into six sections (A, B, C, D, E (Hospital) & F). Within the sections, there are general and single holding cells. The E Section is the hospital section and has two general cells, four single cells, two primary health care consulting rooms and a dentist consulting room.

As of 31 July 2019, there were 1372 inmates registered on the lockup register in a 550-capacity centre. Critically ill, clinically unstable and TB patients are admitted in the hospital section. The hospital section staff complement consists of four professional nurses, one sessional doctor and one dentist. Guidelines, registers, patient files, screening tools and electronic patient management systems are used to monitor the

TB programme. There is a TB focal nurse who oversees TB management in the Mdantsane Correctional Centre.

3.4 Population

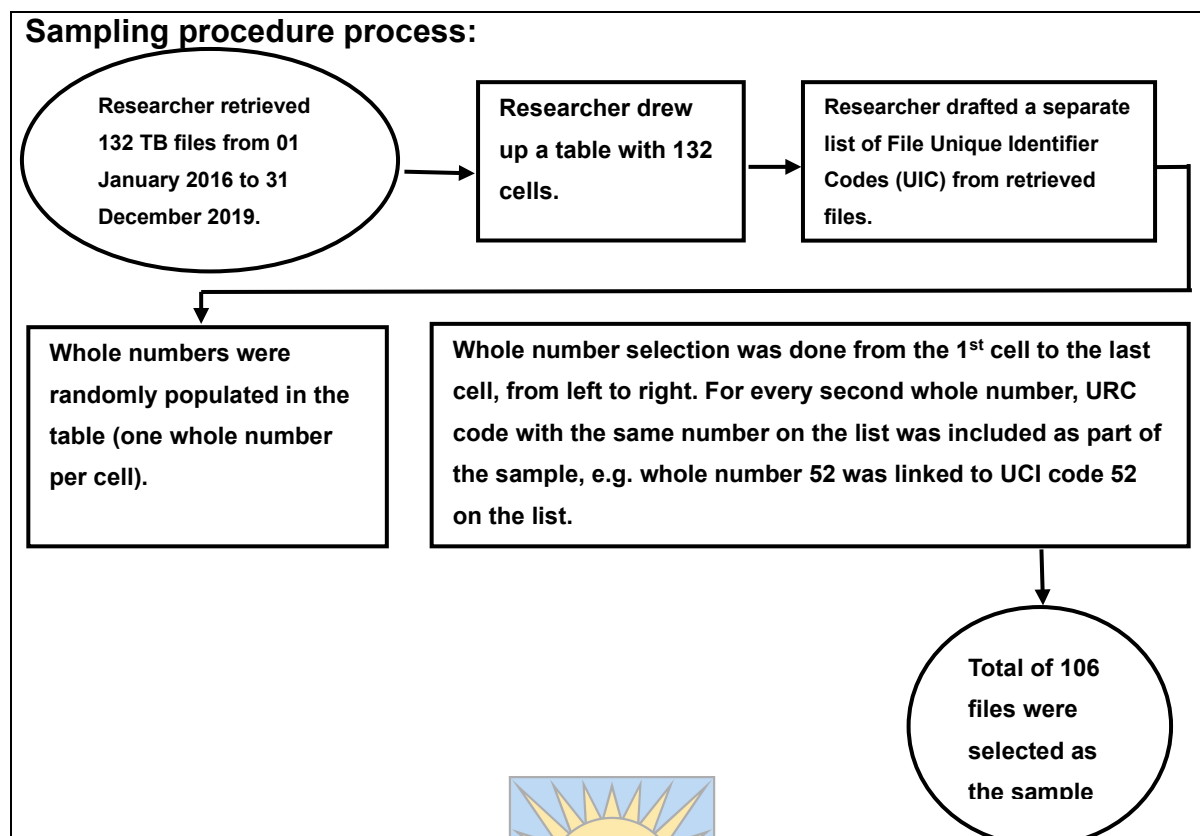
A population is the total group of persons that is of interest to the researcher, and which meet the criteria they are interested in studying (Burns & Grove, 2011; (Brink, Van Der, & Van Rensburg, 2018).

The population for this study was files of clients who were actively on DS-TB treatment in the Mdantsane Correctional Centre from 01 July 2016 to 31 December 2021. The primary data source was the TB patient files. These files contain a variety of information, personal and general medical history, diagnosis and treatment and outcomes. Such information can be used to assess patient management throughout the period of treatment.

3.5 Sample and sampling procedure

Sampling method is a selection process of a sample that is representative of the whole population (McCombes, 2019).

Simple random sampling was used in this study. This sampling method was easily applied since the population was readily available and already listed. This method ensured equal chance of the elements to be selected. TB files of clients who were on DS-TB treatment for six months or more from 01 January 2016 to 31 December 2019 were selected and included as the sample. Pulmonary DS -TB is managed for at least six months and extra pulmonary DS-TB takes a maximum of nine of months for outcomes. Therefore, the study focused on 132 DS-TB patient files from 01 January 2016 to 31 December 2021. The researcher drew up a table of random numbers as a sampling technique. Files were randomly listed using a unique identification code (UIC) of the patient's file. The UIC code list from 01 to 132 quantity was equal to the number of cells in the random number table that was created by the researcher. The set of whole numbers on the table was randomised. For every second whole number selected from the table it was linked to a UIC that is at any place on the list. File aligned to the random number through UIC was then included in the sample.



The size calculation formula below was used for calculating the sample size for this study (Naing, Winn, & Nordin, 2006):

$$n = \frac{N z_{\alpha/2}^2 P(1 - P)}{d^2(N - 1) + z_{\alpha/2}^2 P(1 - P)}$$

Over the period under study, the facility treated 132 eligible cases. According to TB statistics in the Eastern Cape, the treatment success rate for TB is between 65% and 70%. Based on a total patient population of N=132, a hypothesised success rate of P=65%, a significance level of $\alpha=5\%$ and a margin of error $d=0.05$, the estimated minimum sample size for this study was calculated and found to be 100. To account for possible incomplete patient files, the effective sample size used in this study was 106 patient files.

3.7 Inclusion criteria

Inclusion criteria explain the attributes that prospective research participants must have in order to be included in the study (Nikolopoulou, 2022).

The study participants were clients who were treated for both pulmonary and extrapulmonary DS-TB from 01 January 2016 to 31 December 2021 in Mdantsane Correctional Centre.

3.8 Exclusion criteria

Exclusion criteria are the distinguishing characteristics used to identify potential study participants who are unfavourable to be included in the research. (Nikolopoulou, 2022).

Clients who were diagnosed with or who developed drug resistant TB while on DS-TB treatment from 01 January 2016 to 31 December 2021 were excluded. Clients who appear on the TB register as managed for DS-TB in the same period but whose medical files could not be retrieved were excluded.

3.9 Research instrument

According to Yin (2011), a research instrument is a tool for collecting the data.

In the context of this study a data collection tool was derived from Appraisal Tool for Tier.Net (ATTN) by DOH. ATTN is aimed at certifying clinical management of clients according to guidelines and observed recording processes in DOH facilities. The research instrument has been utilised from 2017 in a data triangulation process with TB register and tier.Net during DOH facility assessments on TB management. The researcher used the ATTN to capture demographic characteristics, medical history, clinical conditions, clinical and physical examinations, laboratory investigations and treatment outcomes. Compliance is determined based on the clinical condition of the patient and the respective clinical and physical examinations and laboratory investigations performed on the patient.

According to the management guidelines, given a patient's medical history and clinical condition, clinicians must carry out specific examinations of the patients and/or order specific laboratory investigations. Depending on whether the appropriate examinations and/or laboratory investigations were carried out or not, the clinician would be considered to have been compliant or non-compliant, respectively. Treatment outcome will be defined as successful or not depending on whether the patient recovered or not.

All the variables on the data capturing sheet were measured on a categorical scale, except for age, CD4 count, viral load, weight, and duration variables which are measured on an interval scale.

The tool enabled the researcher to evaluate the actual clinical practices implemented against the requirements and recommendations of TB management guidelines.

3.10 Validity

Validity seeks to ascertain whether an instrument provides accurate measures given the context in which it is applied (Brink, Van Der Walt, Rensburg, 2018).

Construct validity is about ensuring that the method of measurement matches the construct you want to measure (Middleton, 2019). The research instrument captured the objectives of the study because all components of the measured variables were included. Designation of professionals who provided clinical management for each patient was recorded in a section on the tool.

Content validity assesses whether a test is representative of all aspects of the construct (Middleton, 2019). Instructions and all concepts were clearly defined for greater understanding of the content on the tool to minimise ambiguity and confusion. The researcher adopted the research instrument from DOH that has been used to measure TB management variables. Applicability and analysis in the instrument is relevant in addressing the research questions.

3.11 Reliability

Reliability cogitates consistency and replicability over time. Furthermore, reliability is defined as the degree to which a tool is free from measurement errors; evidently, when more measurement errors occur the less reliable is the tool (Fraenkel & Wallen, 2003).

A data collection tool was derived from Appraisal Tool for Tier.Net (ATTN) by DOH based on the information contained in patient files. The tool was adapted to the context of this study in reference to the existing ATTN tool used in different Eastern Cape health facilities by the Department of Health and non-profit organisations with similar objectives.

Presentations to the supervisor and the Correctional Services Health management team were made for their inputs and approval for the tool. These inputs were informed by assessment of what is and what is not measured by the tool based on professional

expert knowledge. Scoring of performance and method of assessment were described on the research instrument.

3.12 Ethical considerations

The University of Fort Hare ethics committee was consulted for approval and issue of an ethical clearance, after which permission to carry out the study in the correctional centre was sought from the National and Regional management of Correctional Services, as well as the Mdantsane Correctional Centre manager.

Data collection was done using a data collection tool against information recorded by clinicians on patient files. There was no recording of identifying personal information to ensure confidentiality and anonymity.

The permission from the Correctional Services Department was considered as consent from patients since historical records are used as the main source of data and patient records are the property of correctional services.

Data collected will be used only for the purpose of this study and will not be shared or published for any other reason. This will be maintained according to the University of Fort Hare (UFH) policy.



Both the Correctional Services Department and UFH will be consulted in the development of a data dissemination plan. The plan will include but will not be limited to publishing reports and external official presentations in public platforms (conferences, seminars and congress).

3.13 Data collection procedure

Data collection is an integral part of any research effort, especially to decide on a research design, strategy and data-collection methods in conducting the research (Maxwell, 2012).

A study done by the Lancet Global Health Commission in 2016 identified direct clinical observation and standardised patient care as appropriate methods for monitoring compliance with clinical guidelines.

Data that was collected will determine the compliance of clinicians to national DS-TB management guidelines and treatment outcomes.

TB files of clients who were on DS-TB treatment for six months or more from 01 July 2016 to 31 December 2019 were selected. Data was captured from the sample to a customized data recording spreadsheet. An official Department of Correctional Services identification file code was recorded on the data collection tool to limit capturing errors. Data collection was done at the hospital section in Mdantsane Correctional Centre from folders of patients who received DS-TB management. After completion of the data collection activity, all patient folders were returned to the department's file archiving system. The researcher ensured limited and controlled access to data recording spreadsheet through a password electronic system.

All COVID-19 nonpharmaceutical precautionary measures were observed according to NDOH guidelines. The researcher used personal alcohol-based hand sanitizer, wore a mask and observed social distance during data collection.

3.14 Data analysis

According to Ary (2010) data analysis is a process whereby researchers systematically search and arrange the data in order to increase their understanding of the data and to enable them to describe what they learned.

The data analysis was carried out in two parts, namely, descriptive analysis and inferential analysis. For the descriptive analysis, variables measured on a categorical scale were summarised using frequency distribution tables and for the interval scale measured variables, the range, mean and standard deviations as descriptive summary statistics. This descriptive analysis provided the answers to the first two research questions. Treatment outcome was the dependent variable and compliance together with demographic characteristics, medical history and clinical condition were dependent variables. To test for associations between treatment outcome and each of the dependent variables, the chi-squared test for independence was used. Where significant associations were found, the corresponding odds ratios were used to determine the direction and strength of associations.

All tests for statistical significance were carried out at a 5% level of significance using the SAS (Statistical Analysis Systems) software (SAS for Academics version).

3.15 Summary

This chapter has defined the steps that were taken in conducting the research, observing the qualitative observational study, cross sectional design. The researcher

explained the procedures for conducting the study step by step and discussed the characteristics of the research design. Definitions and evidence were discussed in relation to the methodology which sought to address the research questions. The chapter has addressed the role of the researcher and sensitive ethical issues. Discussion of population, sample and sampling method were explained in relation to the data to be collected. Data analysis methods and tools using computer programmes and statistical software were clarified. Finally, the validity and reliability of the study were demonstrated to ensure quality of findings and recommendations thereof.



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CHAPTER 4: RESULTS PRESENTATION AND DISCUSSION

4.1 Introduction

This chapter presents the results of the data analysis carried out on 106 patient files. Information on patient management was derived from patient files based on the TB patient management guidelines. Different areas of patient management were considered in this study. The results of the analysis are presented and followed by a discussion of the results.

4.2 TB management guidelines activities

Table 4.1 below expresses in frequencies and percentages the different TB management guidelines activities that were done (complied to) compared to those that were not done (not complied to) in the managing of TB patients.

Table 1: Distribution of TB management guidelines compliance

Activity	Done		Not done	
	<i>n</i>	%	<i>n</i>	%
<i>Diagnosis</i>				
<i>Baseline weight in kilograms</i>	103	97.2	3	2.8
<i>Diagnostic results recorded</i>	101	95.3	5	4.7
<i>Smear baseline results recorded</i>	83	78.3	23	21.7
<i>Site of disease recorded</i>	95	89.6	11	10.4
<i>Type of TB disease recorded</i>	100	94.3	6	5.7
<i>TB patient category shown</i>	106	100.0	0	0.0
<i>HIV co-infection</i>				
<i>HIV status during treatment</i>	84	79.3	22	20.7
<i>Initiated on antiretroviral treatment (ART)/Already on ART</i>	9	52.9	8	47.1
<i>Clinical management</i>				
<i>Treatment starts within two weeks</i>	74	69.8	32	30.2

<i>TB Treatment regimen</i>	101	95.3	5	4.7
<i>Pyridoxine prescribed monthly</i>	0	0.0	106	100.0
<i>Body weight measured monthly</i>	11	10.4	95	89.6
<i>First conversion smear taken at seven weeks</i>	86	81.1	20	18.8
<i>Conversion within two to three months</i>	86	81.1	20	18.8
<i>Date treatment outcome smear taken</i>	80	75.5	26	24.5
<i>Treatment outcome recorded</i>	86	81.1	20	18.8
<i>Duration of treatment</i>	77	72.6	29	27.4

The extent of clinician compliance was assessed based on the activities listed in the table above. These activities were classified as belonging to one of three groups, namely, diagnosis, HIV co-infection and clinical management. The results are presented according to these groups below.

4.2.1 Diagnosis

At the diagnosis stage, clinicians are expected to record the weight, diagnostic test results (GeneXpert or other) and smear baseline results. The results show that the clinicians were 97.2% compliant with respect to baseline weight, 95.3% compliant in recording of diagnostic results, 78.3% in baseline smear results, 89.6% in disease site, 94.3% in disease type and 100% in patient category. Clinician compliance with respect to diagnosis was assessed based on these aspects of TB management guidelines. The average clinician compliance at diagnosis stage, calculated as the mean compliance of the six diagnosis activities, was found to be 92.5%.

4.2.2 HIV co-infection

HIV co-infection was assessed based on whether the HIV status of the patient was confirmed during treatment of the patient and whether all HIV positive patients were initiated on treatment. The results of the analysis show that 22 (20.8%) of the patients did not have their HIV status recorded in the patient files. The ART initiation records

showed that eight of the 17 patients recorded as being HIV positive were not initiated on ART.

4.2.3 Clinical management

Compliance at clinical management stage was assessed based clinician indication of the TB treatment start within two weeks, the TB treatment regimen, monthly pyridoxine prescription, clinical notes on side effect monitoring, conversion within two to three months, date outcome smear taken, treatment outcome and duration of treatment. For these activities, there was 100% non-prescription of pyridoxine, 101 (95.3%) had indicated treatment regime, 95 (89.6%) did not have a record of monthly body weight monitoring and 77 (72.6%) had a recorded treatment duration. For the rest of the activities, the compliance rates were at least 80.0%.

4.3 Associations between compliance and treatment outcome

The chi-squared test for independence was used to determine the significance of associations between clinician compliance and treatment outcome. Where significant associations were detected, odds ratios and their 95% confidence intervals were determined as measures of the strength and direction of associations. The table below shows the cross tabulations treatment outcome and each of the TB management activities. The numbers in the tables are the frequency and the percentages within each category of compliance.

Table 2 : Cross tabulation of clinician compliance and treatment outcome

Activity	Clinician Compliance		Treatment outcome				Chisq	p-value
		Cured		Not cured				
		<i>n</i>	%	<i>n</i>	%			
Baseline weight	Compliant	25	29.4	60	70.6	0.4147	0.7093	
	Noncompliant	0	0.0	1	100.0			
Diagnostic results	Compliant	25	30.5	57	69.5	1.7193	0.3178	
	Noncompliant	0	0.0	4	100.0			

<i>Baseline smear results</i>	<i>Compliant</i>	23	34.9	43	65.2	4.60	0.0320 ^s
	<i>Noncompliant</i>	2	10.0	18	90.0		
<i>HIV status recording</i>	<i>Compliant</i>	4	21.1	15	78.9	0.76	0.3833
	<i>Noncompliant</i>	21	31.3	46	68.7		
<i>Site</i>	<i>Compliant</i>	21	28.0	54	72.0	0.33	0.5684
	<i>Noncompliant</i>	4	36.4	7	63.6		
<i>Treatment in two weeks</i>	<i>Compliant</i>	16	27.6	42	72.4	0.19	0.6628
	<i>Noncompliant</i>	9	32.1	19	67.9		
<i>Weight monitoring</i>	<i>Compliant</i>	0	0.0	10	100.0	4.64	0.0313 ^s
	<i>Noncompliant</i>	25	32.9	51	67.1		
<i>Conversion smear</i>	<i>Compliant</i>	23	31.9	49	68.1	1.78	0.1831
	<i>Noncompliant</i>	2	14.3	12	85.7		
<i>Treatment conversion two-three months</i>	<i>Compliant</i>	25	34.3	48	65.7	6.23	0.0122 ^s
	<i>Noncompliant</i>	0	0.0	13	100.0		
<i>Duration recording</i>	<i>Compliant</i>	19	24.7	58	75.3	6.89	0.0089 ^s
	<i>Noncompliant</i>	6	66.7	3	33.3		

<i>Date of smear</i>	<i>Compliant</i>	22	29.3	53	70.7	0.02	0.8882
	<i>Noncompliant</i>	3	27.3	8	72.7		
<i>Outcome recording</i>	<i>Compliant</i>	25	29.8	59	70.2	0.84	0.3596
	<i>Noncompliant</i>	0	0.0	2	100.0		

^s statistically significant at 5% significance level

The associations are presented according to the activity groups defined above, namely, diagnosis, HIV co-infection and clinical management. Treatment outcome was recorded in the files as cured, treatment complicated, transferred out or it was not recorded. Of the 106 patients, 86 (81.1%) had a recorded treatment outcome and the remaining 20 (18.9%) had no recorded treatment outcome. Of the 86 files whose treatment outcome was recorded, 25 (29.1%) were cured.

4.3.1 Associations with diagnosis activities

To determine if the compliance at diagnosis stage is associated with treatment outcome, only those whose treatment outcome was recorded were included in the analysis and treatment outcome was defined as cured or not cured (treatment complicated, transferred out). The chi-squared test was used to test for significance of the association between clinician compliance at diagnosis stage and patient treatment outcome. Tests for associations were tested for each diagnosis activity and treatment outcome and the results are shown in the table above.

The analysis found that compliance with respect to recording weight and the diagnostic results has no association with treatment outcome. Of the diagnosis activities, only compliance with respect to baseline smear results was significantly associated with treatment outcome (Chisq=4.6; p=0.0320). The corresponding odds ratio was found to be 4.8 with a 95% confidence interval of (1.22; 22.59).

This means compliance with respect to baseline smear results at diagnosis significantly increases the chances of recovery. Specifically, patients whose baseline smear results are known during diagnosis are 4.8 times as likely to recover than not recover compared to those whose baseline smear results are unknown.

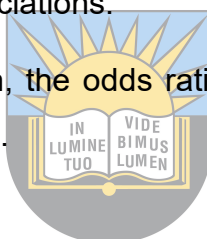
4.3.2 Associations with HIV co-infection activities

The chi-squared test was used to test for significance of association between clinician compliance with HIV co-infection activities and treatment outcome. The analysis findings showed that there is no significant association between compliance with HIV management and treatment outcome ($\text{Chisq}=0.8$; $p=0.3933$).

4.3.3 Associations with clinical management activities

Each of the clinical management activities were tested for associations with treatment outcome. The results show that treatment outcome is associated with weight monitoring ($\text{Chisq}=4.6$; $p=0.0313$), two-three months conversion ($\text{Chisq}=6.2$; $p=0.0122$) and treatment duration ($\text{Chisq}=6.9$; $p=0.0089$). The results, in Table 2 above, show that there was 100% non-recovery among the ten patients whose weight was monitored and among the 13 patients whose conversion status was unknown. Since some cells had 0% representation, it was not possible to determine the odds ratios corresponding to those associations.

With respect to treatment duration, the odds ratio was found to be 6.1 with a 95% confidence interval of (1.40; 26.81).



4.4 Discussion of findings

In this section, the results presented above will be discussed according to the way they have been presented above.

4.4.1 Diagnosis

With GeneXpert clinicians can diagnose TB and determine its resistance to rifampicin (DR-TB) sooner (Trajman, Durovni, Saraceni, Menezes, & Cordeiro-Santos, 2015). GeneXpert has the potential to decrease TB morbidity, mortality, and transmission, ultimately leading to better outcomes because of its ability to diagnose TB and rifampicin resistance quickly and correctly. In a study done on the impact of GeneXpert on treatment outcomes in 2017, it was found that in patients diagnosed by GeneXpert, TB-related deaths declined by 35% and delayed referral for drug-resistant TB management was reduced by 2.5 months (Pillay & Magula, 2021).

This is aligned to the logic of TB management guidelines, which is based on improving outcomes through proper diagnosis and management. Logically, proper management should follow from proper diagnosis and compliance at diagnosis stage is central to the consequent disease management. This analysis shows that there is sufficient

evidence that improper management at diagnosis stage is associated with negative treatment outcomes. The odds ratio shows that patients who were not properly managed at diagnosis were five times as likely to have a negative treatment outcome as those who were properly managed.

These results show that clinicians did not fully comply with diagnostic elements that were assessed. Baseline weight is critical for prescription of TB treatment management. In this study, three out of 106 patients did not have their baseline weight measured and this could lead to under-dose or over-dose with TB drugs. TB diagnostic results is the only method of confirmation before treatment starts. In this study, TB diagnostic results for five patients were not recorded which could lead to wrong prescription of treatment.

GeneXpert is the preferred investigation to diagnose TB patients followed by a baseline smear before treatment initiation as per the TB management guidelines. However, TB culture and X-ray were observed with few patients as diagnostic investigations in Mdantsane Correctional Centre. Although TB culture is more sensitive than AFB, it is an expensive and slow diagnostic technique (NDOH; 2014). The X-ray has a number of limitations, such as not being able to detect lung fibrosis or lung damage brought on by previous TB, which leads to an over diagnosis of pulmonary TB; therefore, it is unreliable as the only diagnostic investigation.

It is possible not to reach successful outcomes when false-positive clinical TB diagnosis is made in patients with other diseases or late detection of resistance to TB drugs. False-positive clinical diagnosis in people with other illnesses or the late identification of drug resistance to TB treatment can lead to unfavourable outcomes (Trajman, Durovni, Valeria et al., 2015). Acid-fast bacilli test (AFB) baseline smear is effective in detecting infectious levels and disease progression following a GeneXpert positive result before treatment initiation at baseline (DOH, 2014).

Even though a baseline smear is not recommended as a diagnostic investigation due to low sensitivity, it is critical in TB management because it reflects the patient's infectivity (DOH,2014). Furthermore, a baseline smear is a point of reference to determine TB outcomes. According to TB guidelines a negative baseline smear will determine that treatment is complete and a positive baseline smear will determine cured outcome. Site and type of disease are vital at diagnosis for all clients because

they determine the duration of treatment based on extra or pulmonary TB diagnosis. In this study, these critical elements were not completely complied with by clinicians.

4.4.2 Clinical management

Monitoring of the patients plays a crucial role in patient management because it informs the consequent course of action based on observations during monitoring. Clinician compliance in that regard has been found to significantly increase the chances of positive outcomes among TB patients.

At Mdantsane Correctional Centre, 32 clients were started on treatment late. Delays in treatment start can be attributed to factors other than clinician compliance, such as poor laboratory services leading to long turnaround time for results (Bhatt, Shrestha, & Risal, 2019). Delayed start TB therapy and clinical management can exacerbate the condition, increase the risk of death, and may be the cause of the fact that TB incidence has not significantly decreased despite global TB control efforts being scaled up (Sreeramareddy, Qin, Satyanarayana, Subbaraman, & Pai, 2014).

According to National TB guidelines, due to common peripheral neuropathy to patients on TB treatment, it is compulsory to prescribe pyridoxine 25mg each visit as a preventive measure. Other side effects are not as common as peripheral neuropathy, but they must be monitored especially during the first month of treatment. Based on good clinical practice, clinicians are expected to record such assessments and prescriptions on each visit, but in this study it was found that there was poor recording of these elements. Weight loss is one of the symptoms of TB and is critical in determination of the patient's clinical status. Monitoring of this variable informs clinicians about treatment responses.

Adherence to TB treatment and correct regimen and dose lead to positive clinical progress that is conversion from initial phase to continuation phase guided by negative smear results. Conversion investigations were conducted late (after three months) to 18.8% of patients in Mdantsane Correctional Centre, leading to delayed conversion to second phase of treatment. Therefore, the guidelines were not followed in this regard. According to TB guidelines 100% recording of TB treatment outcomes is a requirement because outcomes determine the treatment success rate. Compliance of clinicians on recording outcomes was at 86%.

Unsurprisingly, it was discovered that correctional centres with bigger inmate populations also have higher rates of transfers between other correctional and general community facilities (Trajman, Durovni, Valeria et al., 2015). Therefore, it is possible that some of those who were transferred out sought care and continued their treatment.

Given the extremely high rates of transfers and releases in the Mdantsane Correctional Centre, it is difficult to interpret other TB treatment outcomes. Unsurprisingly, the cure rate in Mdantsane Correctional Centre is lower than the DOH set target of 95%.

However, outcomes cannot be compared to those of the general population until there is improved tracking of released and transferred inmates.

It is challenging to track inmate-patients. Most of the time, the clinicians in charge of the patients are unaware of the impending transfers and are therefore unable to take the required precautions to enhance linkage to care.

Baseline smear results, treatment conversion two-three months, weight monitoring and duration of treatment have a P value that is less than 0.05 implying their significance to TB treatment outcomes. Baseline smear is critical on diagnosis compliance because it determines the progression of disease and prescription of TB medication. Weight monitoring, duration of treatment and conversion in two to three months relate to clinical management that essential monitoring clinical improvement. The results show that compliance with clinical management plays a significant role in TB outcomes.

4.4.3 HIV co-infection

The clinical pattern of TB correlates with the patient's immunological status, per National Consolidated Guidelines of the DOH. The symptoms are more reminiscent of post-primary TB (similar to TB in non-HIV infected individuals) in the early stages of HIV infection, when immunity is only partially weakened. HIV-infected patients may present with extra-pulmonary TB, disseminated disease, or an unusual pulmonary disease that resembles primary TB when immune weakness progresses. The most significant risk factor for developing active TB is co-infection with HIV, which also worsens the immune response to HIV and speeds up the progression from HIV infection to AIDS. HIV co-infection also raises the risk of TB reactivation in patients

with latent TB infection and makes them more susceptible to primary infection or reinfection (Bruchfeld, Correia-Neves, & Källenius, 2015).

Evidence from this study suggests that treatment outcome is not significantly related to HIV status. In this study eight out of 17 co-infected HIV/TB co-infected clients have transfer out outcomes, which is a high risk of negative outcome (treatment failure, lost to follow up, died). Correctional facilities typically do not allow transferred inmates to travel with their paper-based medical records. Therefore, receiving facilities are unable to identify if incoming inmates are currently on treatment for TB. It is up to the patient-inmates to see to it that their treatment regimen is continued (Hatwiinda, Topp & Siyambango, 2018).

Evidently, studies on risk association find strong correlation between HIV and TB. Nevertheless, it is important to note that TB is an opportunistic infection especially where there is low immunity, unlike HIV that needs a point of exit and point of entry to cause direct infection (sexually transmitted) irrespective of the immunity state. These results suggest that differences in treatment outcome can be explained by factors other than HIV management.



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CHAPTER 5: SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter provides a summary of the study's findings and recommendations. Future suggestions are made in light of those findings.

5.2 Major findings of the study

This study found that:

- There was no complete clinician compliance with guidelines for TB management, that is, there were some aspects of the guidelines which were not complied with.
- Compliance with diagnostic aspects of TB management increases the chances of positive treatment outcomes. The most important aspect in the diagnosis stage was found to be knowledge of the baseline smear results.
- No significant associations were detected for HIV/TB co-infection.
- Weight monitoring, duration of treatment and conversion in two to three months fall under clinical management and were found to have a significant association with TB outcomes.



5.3 Conclusion

Based on these results, the following conclusions can be drawn:

- While the compliance levels on individual aspects might be high, the principle should be that guidelines be followed as they are. In the event of a deviation, justification should be provided, and this was found to be lacking.
- The treatment success rate in the correctional facility was lower than that of the general public. This suggests a weak linkage between correctional services and public facilities.
- Patients whose baseline smear results are known and monitored for conversion have a high chance of experiencing positive treatment outcomes.

5.4 Limitations

This study was conducted in one correctional facility and, as such, the results may not be generalizable to other centres and the general population.

Some patients had no baseline smear results and it was clear from the records why this was the case. Probably these were cases that were diagnosed using the X-ray,

especially, in the cases of extra pulmonary TB where it might not be possible to get sputum samples after diagnosis.

It was not possible to establish treatment outcome from some records and this resulted in reduction of the sample size when testing for associations with treatment outcome. Movement of patients after completion of sentence or parole or between prisons could have resulted in some treatment outcomes being recorded as 'transfer out' which does not give an indication of whether the patients recovered or not.

5.5 Recommendations

The following suggestions are offered based on the study findings:

- The health management of the Department of Correctional Services should develop a capacitation plan that will include mentoring and monitoring of compliance to TB guidelines.
- An effective linkage to care system within correctional services and public health facilities must be developed to ensure continuity of care and accurate recording of treatment outcomes.
- A national electronic and web-based data system for the Department of Correctional Services health services should be established to improve data management and quality of care.
- More research needs to be done on aspects under clinical management and their impact on patient physical health especially in relation to TB drugs.
- TB case findings and contact tracing need more research to understand trends of infection and inform comprehensive infection control policies.

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ANNEXURES



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ANNEXURE 1: UFH DEPARTMENTAL APPROVAL



Departmental Approval Form for Proposals

Recommendation of the Departmental Research Higher Degrees Committee (DRHDC) to the Research Ethics Committee for Research Using Human Participants

Title of the study:	The relationship between clinician compliance with national drug sensitive tuberculosis (DS-TB) management guidelines and treatment outcomes at Mdantsane Correctional Centre, Eastern Cape	
Researcher/s involved in the study:	Mr V. Mjijelwa	
Promoters/supervisors (if for qualification)	Mr A. Mandeya	
Potential risk level for human participants: (Tick the box and motivate)	☐ No risk ☐ Minimal risk ☐ Medium risk ☐ High risk	X Motivate: There are no clinical or medical procedures involved in human subjects. In addition, the study does not involve measuring instruments and questionnaires that need psychometric interpretation
Potential risk level for vulnerable group: (If applicable, tick the box and motivate)	☐ No risk ☐ No more than minimal risk of harm ☐ Greater than minimal risk with the prospect of direct benefit ☐ Greater than minimal risk with no direct benefit	Motivate: The study does not involve the vulnerable population X
Recommendation for the ethics committee: (Tick the box and motivate)	☐ Expedited review ☐ Full review ☐ Review exemption	Motivate: The protocol has never been submitted before for review by the ethical committee, hence it needs a full review.
Any additional comments:		

Departmental Higher Degrees Committee members present during the review:	Higher Degrees Committee members present	Signatures
	Department:	
	Prof DT Goon	DTG
	Dr B-F Mayeye	BFM
	Dr N Nkutu	NN

Critical Reviewers assigned:	All faculty members reviewed the proposal
-------------------------------------	---

Date of review: 30 October 2019

The committee approved this proposal and it can now be submitted to the HREC for Ethical Clearance Review.



Signature of the Chairperson

10/11/2021

Date



Signature of the HOD

10/11/2021

Date

The HREC decision for this application:

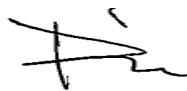
Expedited review

Motivate:

Full review

X

Review Exemption



10/11/2021

Signature of the Chairperson of the Research Ethics Committee

Date



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ANNEXURE 2: DCS PERMISSION LETTER



correctional services

Department:
Correctional Services
REPUBLIC OF SOUTH AFRICA

Private Bag X136, PRETORIA, 0001 Poyntons Building, C/O WF Nkomo and Sophie De Bruyn Street, PRETORIA
Tel (012) 307 2770, Fax 086 539 2693

Dear Mr V Mjijelwa

RE: APPLICATION TO CONDUCT RESEARCH IN THE DEPARTMENT OF CORRECTIONAL SERVICES ON: THE RELATIONSHIP BETWEEN CLINICIAN COMPLIANCE WITH NATIONAL DRUG SENSITIVE TUBERCULOSIS (DS-TB) MANAGEMENT GUIDELINES AND TREATMENT OUTCOMES AT MDANTSANE CORRECTIONAL CENTRE, EASTERN CAPE

I wish to inform you that your request to conduct research in the Department of Correctional Services has been approved

- This ethical approval is valid from **22th July 2022 to 22th December 2023**
- The Area Commissioner where the research will be conducted will be informed of your proposed research project.
- You are requested to contact him at -043-7114107 before the commencement of your research
- Your internal guide is the Health Operational Manager-Mdantsane Correctional Centre
- It is your responsibility to make arrangements for your interviewing times
- Your identity document/passport and this letter should be in your possession when visiting the Correctional Centres
- You are required to use the terminology used in the White Paper on Corrections in South Africa (February 2005) and Correctional Services Act (No.111 of 1998) e.g. "Offenders" not "Prisoners" and "Correctional Centres" not "Prisons".
- Comply with COVID-19 safety and hygiene procedures during data collection processes
- Ensure that all participants have been duly screened for Covid19 according to DCS screening protocols
- You are required to submit your final report to the Department for approval by the Commissioner of Correctional Services before publication (including presentation at

- screening processes
- You are required to submit your final report to the Department for approval by the Commissioner of Correctional Services before publication (including presentation at workshops, conferences, seminars, etc) of the report.
- Should you have any enquiries regarding this process, please contact the REC Administration for assistance at telephone number (012) 3072894/95/0723271937

Thank you for your application and interest to conduct research in the Department of Correctional Services.

Yours faithfully

ND MBULI
Chair: DCS REC
DATE: 22 /07/2022

ANNEXURE 3: CONFIRMATION FROM LANGUAGE EDITOR

8 Nahoon Valley Place

Nahoon Valley

East London

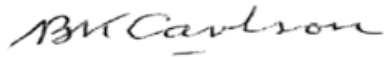
5241

14 January 2024

TO WHOM IT MAY CONCERN

I hereby confirm that I have proofread and edited the following mini-thesis using the Windows 'Tracking' system to reflect my comments and suggested corrections for the student to action and produce a clean copy:

The relationship between clinician compliance with national drug sensitive tuberculosis (DS-TB) management guidelines and treatment outcomes at Mdantsane Correctional Centre, Eastern Cape by VUYOLWETHU MJIJELWA, a mini-dissertation submitted in partial fulfilment of the requirements for the degree of Master of Public Health at the University of Fort Hare.



Brian Carlson (B.A., M.Ed.)

Professional Editor

Email: bcarlson521@gmail.com

Cell: 0834596647

Disclaimer: Although I have made comments and suggested corrections, the responsibility for the quality of the final document lies with the **student** in the first instance and not with myself as the editor.

ANNEXURE 4: DATA COLLECTION TOOL



Categorised TB Data
Mdantsane CC -.xlsx



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HEALTH RESEARCH ETHICS COMMITTEE

P.O Box 1054
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ETHICAL CLEARANCE CERTIFICATE REG100118054

Certificate Reference Number ~~Ref #2022-0206~~ **Ref #2022-0206-MjijelwaV**

Project title: Relationship between clinician compliance with national drug sensitive tuberculosis management guidelines and treatment outcomes A case of Mdantsane Correctional Centre, Eastern Cape

Nature of Project: Masters of Public Health

Principal Researcher: V Mjijelwa

Student Number: 201927761

Supervisor: Mr A Mandeya

On behalf of the University of Fort Hare Health Research Ethics Committee (HREC), I hereby give ethical approval in respect of the undertakings contained in the mentioned project and research instruments(s). Should any other instruments be used, these require separate authorization. The Researcher may therefore commence the research as from the date of this certificate, using the reference number indicated above.

Please note that the HREC must be informed immediately of

- ☐ Any material change in the conditions or undertakings mentioned in the document
- ☐ Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research

The Principal Researcher must report to the HREC in the prescribed format, where applicable, annually, and at the end of the project, in respect of ethical compliance.

The HREC retains the right to

- ☐ Withdraw or amend this Ethical Clearance Certificate if
 - ☐ Any unethical principles or practices are revealed or suspected
 - ☐ relevant information has been withheld or misrepresented
 - ☐ regulatory changes of whatsoever nature so require
 - ☐ the conditions contained in the Certificate have not been adhered to
- ☐ Request access to any information or data at any time during the course or after completion of the project.



University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

P.O Box 1054
East London 5200
Tel: +27 (0) 43 704 7368
E-mail: dgoon@ufh.ac.za

- In addition to the need to comply with the highest level of ethical conduct principal investigators must report back annually as an evaluation and monitoring mechanism on the progress being made by the research. Such a report must be sent to HREC_monitoring@ufh.ac.za.

The Ethics Committee wishes you well in your research endeavours.

Yours sincerely

Professor DT Goon
Chairperson: HREC
18th February 2022

ANNEXURE 6: STATISTICAL ANALYSIS CONFIRMATION

 5 Boqwana Place, Lolo Park, Bisho 5605 Tel: +27-40-635 0278 Cell: +27-78-966 6219	
To whom it may concern	
<u>RE: Confirmation of Statistical Analysis Services</u>	
This serves to confirm that <u>_Vuyolwetu Mjijelwa_UFH Student No: 201927761_</u> received the following research services from us.	
Services:	Statistical Analysis
Statistician:	RT. Chirukha (BSc CompSc, MSc Biostatistics)
Project:	<i>Relationship between Clinician Compliance with National Drug Sensitive TB Management Guidelines and Treatment Outcomes at Mdantsane Correctional Centre, Eastern Cape.</i>
In the event that you need further details of the services, feel free to contact the Statistician on the contact details provided above.	
Regards 	 2023 -01- 05 Statistician Cell: 078966 6219, Tel: 040 635 0278 Fax: 086 568 0434