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TITLE: TREATMENT ADHERENCE AMONG TUBERCULOSIS PATIENTS IN NELSON MANDELA DISTRICT, EASTERN CAPE PROVINCE

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Treatment Adherence among Tuberculosis Patients in

Nelson Mandela District, Eastern Cape Province

By

Ntombifikile Sohuma

The mini-dissertation is submitted in partial fulfilment of the requirements for the Master's degree in Public Health



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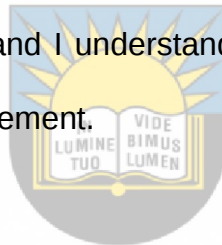
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September 2019

DECLARATION

I, Ntombifikile Sohuma, declare that this dissertation is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements. I understand that the University reserves the right to use plagiarism detection systems, and, to the best of my knowledge, the work does not breach any copyright law. I solemnly declare that to the best of my knowledge, no part of this report or in full has been previously submitted to this University or any other institution in South Africa for the award of a degree. I give consent for my dissertation, if accepted, to be lodged with the library system and I understand that any reference or quotation of my work will receive an acknowledgement.



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CERTIFICATION

This dissertation entitled 'Treatment adherence among tuberculosis patients in Qgebera Clinic, Nelson Mandela District, Eastern Cape, South Africa' meets the regulations governing the award of the degree of Masters of Public Health at the University of Fort Hare and is approved for its contribution to scientific knowledge.



Prof M.G. Pinkoane
Research Supervisor

28/1/2020
Date

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DEDICATION

I dedicate my work to my late father and my mother, who are my source of inspiration. They saw the potential in me, believed in me and helped me continue my academic pursuits. Above all, I thank God for bringing me this far.



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I thank God, the Almighty, for being with me and for invigorating me from start to completion of this mini-thesis. I would like to express my deepest gratitude to my supervisor, Professor Pinkoane. Her wide knowledge and logical way of thinking have been of great value for me. Her understanding, dedication, encouraging and personal guidance have provided me with a good basis for this thesis.

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LIST OF ACRONYMS

ART Antiretroviral therapy

ARV Antiretroviral

ANOVA Analysis of variance

DOTS Directly-observed therapy short-course/directly-observed therapy

TB Tuberculosis

UFHREC University of Fort Hare Research Ethics Committee

WHO World Health Organisation



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ABSTRACT

Background

Tuberculosis (TB) morbidity and mortality rates remain high globally and are even higher in Africa. The key factor that continues to drive the burden of disease is poor compliance / adherence to treatment regimens. This study aimed to identify determinants that continue to drive poor treatment adherence among low-income communities in South Africa.

Methods

A cross-sectional survey was conducted, drawing on TB patients who were defaulting on treatment. An assessment tool with several socio-economic and disease-related determinants was administered to participants. Data was entered into MS Excel and analysed in SPSS version 24.

Results

Regarding health services factors generally, all participants agreed that health service delivery was conducted in a conducive environment and that facilities were reasonably close to their places of residence. Participants demonstrated that health workers do not provide adequate information regarding medications that patients receive. Of patients cited, 11% indicated that they stopped medications owing to health services. When questioned, participants reported that health workers shouted at them for coming late (e.g. after lunch) and that waiting times were very long.

Approximately 85% of the study participants were more likely to adhere poorly to TB medication owing to various factors such as comorbidities and personal perceptions of wellbeing / health status. Comorbidities are high among patients, with 58% taking other medication while on TB treatment. Self-prognosis on wellbeing is significantly high, and 44% reported a tendency to stop medication when they were seemingly in recovery. The unemployment rate among respondents was 78%, with limited education: 69% had below matric. Of the respondents, 40% showed an unsatisfactory perception of their social and

economic life, 55% were somewhat satisfied and only 5% were very satisfied. These indicators constitute a highly vulnerable community that depends heavily on subsidised healthcare from the state. Adherence to TB treatment is mainly influenced by poverty, the health service provider–patient relationship and perceived stigma. Limited family support was noted towards the treatment of patients.

Keywords

TB treatment; adherence; health services; TB patients



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1 CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 Introduction

This chapter presents all the pertinent background facts and information about tuberculosis (TB) and its treatment in South Africa. The chapter highlights key issues that necessitate the significance of this TB treatment adherence study in the interest of public health from the context of preventing the development of drug resistance. The scope and outline of the study are described within the chapter.

1.2 Background

Tuberculosis (TB) is one of the world's deadliest communicable diseases. Globally, 10 million people are estimated to have fallen ill with TB in 2018. TB affects both sexes in all ages, but the highest burden is on men who are 15 years of age and older, who accounted for 57% of all TB cases in 2018. Women accounted for 32% and children for 11%. Among all TB cases, 8.6% were people living with HIV. World Health Organization (WHO, 2018). In 2019, an estimated 10 million people fell ill with TB worldwide, of whom approximately 5.6 million were men, 3.2 million were women and 1.2 million were children. A total number of 1.4 million people died of TB in 2019 (WHO, 2019).

In 2019, the high TB-burden countries accounted for 87% of new cases. Eight countries account for two thirds of the cases with the leading count followed by Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa. TB continues to be the leading cause of death in South Africa. In 2018 a total of 63,000 people died of TB, of these, it is estimated that 42,000 were HIV positive (WHO, 2019). South Africa notified a total number of 438,000 TB cases in 2019, which is a challenge in South Africa and especially in the Eastern Cape Province. Furthermore, South Africa has the third highest number of new infections of all types of TB and ranks the second highest in drug-resistant TB (DR-TB) in the world. The Eastern Cape Province has had a very high number of all new types of TB

cases since 2012 in comparison to the national average. A closer look at district segregation indicates that Eastern Cape districts are hotspots for TB in the country. Sarah Baartman district had the highest TB incidence of 11498 cases per 100, 000 in the country, followed by Nelson Mandela district with 1009 per 100,000 individuals (Health Systems Trust, 2018).

Non-compliance with TB treatment is one of the major barriers in achieving global TB control targets in most parts of the world regardless of strategies put in place globally to control TB. About half of the patients diagnosed with TB do not complete their treatment and this results in negative treatment outcomes such as prolonged infectiousness, drug resistance, relapse and death (WHO, 2011). This study examines TB treatment adherence in Nelson Mandela district.

1.3 Statement of the Problem

To date the Nelson Mandela district has recorded the highest mortality rate in the country, though the case detection and implementation of DOTS has increased substantially to enhance patient adherence, however, the cure rate has remained low and the defaulter and mortality rate remains high. The national target for the tuberculosis defaulter rate is below 5%. (National Department of Health, 2016). In 2019, the Nelson Mandela Bay health district lost to follow-up rate was at 9.8%, the success rate for MDR was 50.9, and the death rate was 6% (NDH, 2019). Therefore, it is clear that TB is a major challenge in the Nelson Mandela district, previous interventions were largely biomedical. That approach does not focus on other socio economic variables that have shaped the lived experience of TB patients, which can demote or promote their healing. Research indicates that changes in socio-economic status, and improvement in knowledge and attitudes can strengthen TB prevention control (WHO, 2019).

There is therefore a gap between the provision of TB health services, other medical conditions, socio-economic variables, and the utilization of successful treatment and healing. There is, consequently, a need to describe and understand these health services, socio-economic and medical conditions that influence the TB adherence in Nelson Mandela district. The research will assist in the

implementation of strategies that will improve the TB defaulter rate and, therefore, decrease the morbidity and mortality rate.

1.4 Aims of the Study

The aim of the study is to identify factors which affect medication adherence among TB patients in Nelson Mandela district, between April 2018 and September 2019, and to make recommendations, according to the findings.

1.5 Research Objectives

1. Investigate the service delivery factors that influence TB adherence in Nelson Mandel district.
2. Describe the socio-economic factors that influence TB adherence in Nelson Mandela district.
3. Examine the disease-related aspects which influence TB medication adherence in Nelson Mandel district.



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1.6 Research Questions

1. Which factors in service delivery influence TB medication adherence in Nelson Mandela district?
2. How do the socio-economic factors influence TB medication adherence in Nelson Mandela district?
3. What are the disease-related aspects that influence TB medication adherence in Nelson Mandela district?

1.7 Significance of the Study

The district health office in the Nelson Mandela Bay had limited evidence on TB treatment adherence and barriers or enabling factors to treatment optimisation. The results of the study contribute key information towards the design of a comprehensive approach to effective interventions, which is necessary to measure practically a level of medication adherence, and to explore barriers and enabling factors associated with treatment adherence (WHO, 2008a).

The study aimed to provide in-depth evidence on the social, contextual and structural constraints and enabling factors on TB care programmes. The knowledge is crucial to TB programme management, especially for District Managers and service planners in developing targeted strategies to increase compliance and improve treatment outcomes. Moreover, those strategies are crucial to improving and increasing TB treatment success (cure and treatment completion) in the district through the promotion of compliance with TB treatment by TB patients in order to prevent TB defaulting, treatment failure, resistance and TB mortality.



1.8 Theoretical Framework

The self-efficacy model (Figure 2) of Shortridge-Baggett and Van der Bijl (1996) is the foundation of this study and it is the belief that one is capable of performing at a certain level to achieve certain goals. It is further defined by Lenz and Shortridge-Baggett (2002) as people's judgments of their capabilities to organise and execute courses of action is required to attain designated types of performances. It is concerned not with the skills one has but with judgements of what one can do with whatever skills one possesses. It is a person's perception of their ability to achieve certain goals or outcomes.

The basis of this model recognises that a person's behaviour, characteristics and environment interact so that change in one component has implications for the others. According to Lenz and Shortridge-Baggett (2002), there is increasing evidence that self-efficacy influences the possibility of an individual to change

behaviour. The self-efficacy model is a set of assumptions that can determine whether health behaviour change will be started, how much effort one will put in and for how long one can sustain such efforts in the face of hindrances and potential failures.

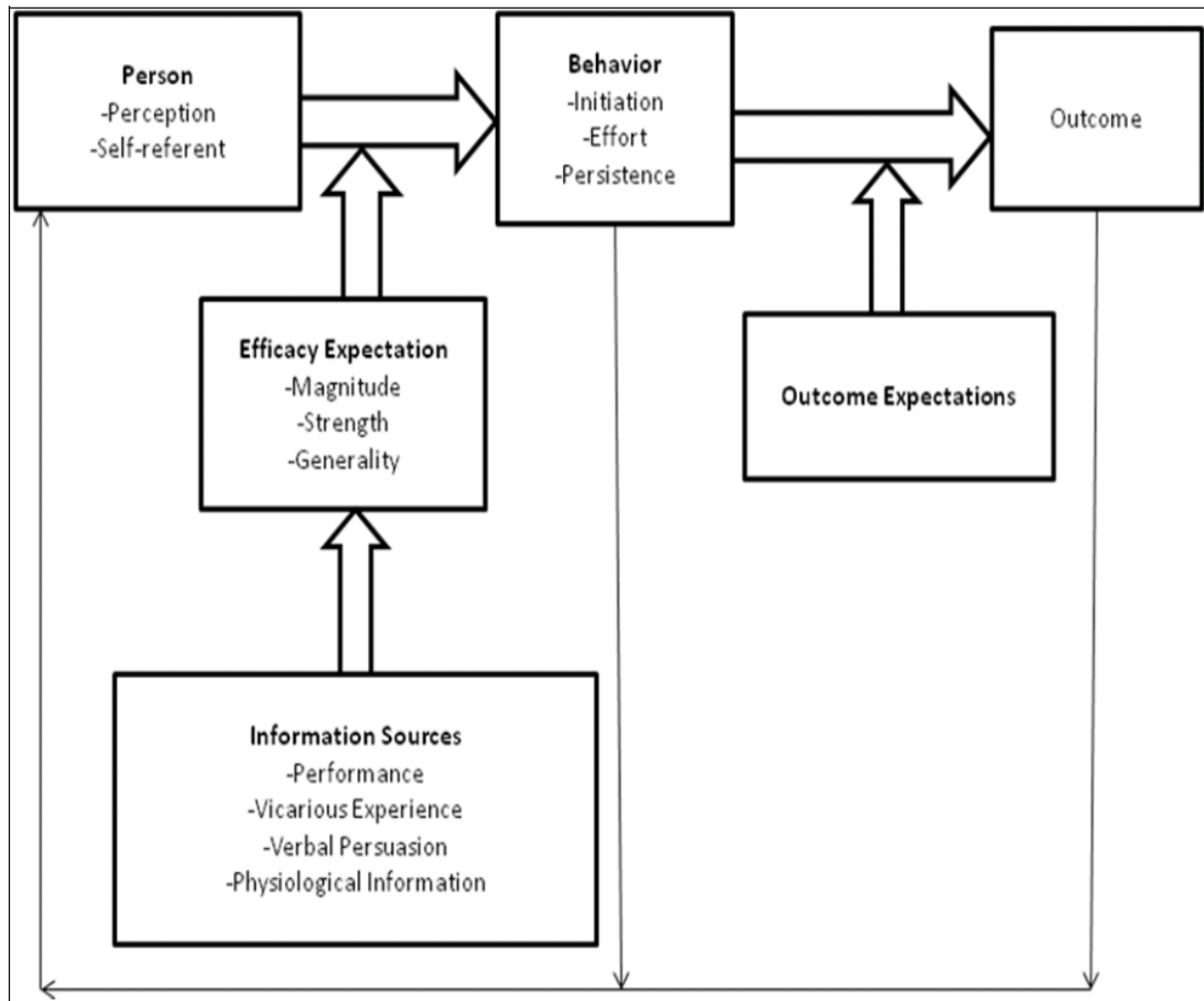


Figure 1 Theory and measurement of self-efficacy construct (Adapted from Shortridge-Baggett & Van Der Bijl, 1996).

In this model, 'efficacy' denotes the capacity or mastery to produce a desired effect (Lenz & Shortridge-Baggett, 2002:10). This study will look at efficacy as the capacity of the patient to comply with taking TB treatment and the behaviour expected. According to Lenz and Shortridge-Baggett (2002:10), 'efficacy expectation' refers to a person's belief or confidence that they perceive that they are capable of performing the required behaviour. Self-efficacy is situational and task-related (Van der Bijl, & Shortridge-Baggett, 2001). An expression of personal

efficacy is an assertion of confidence in one's capability to manage the difficulties inherent in a specified level of behavioural change. The judgement about a specified task or behaviour is based on past experiences, successes and failures, and will vary according to how the following three factors interact: magnitude, strength and generality of the efficacy belief.

Generality relates to how experiences of self-efficacy can either be specific to one task in one situation or generalizable to new or other challenging situations (Shortridge-Baggett & Van der Bijl, 1996). Once a person has high self-efficacy, usually from repeated successes, they tend to generalise that they are able to perform the next task, which might be very different from the former. Therefore, behavioural, cognitive and social skills must be integrated for a person to perform a specified task. Lenz and Shortridge-Baggett (2002), assert that, while people who have high levels of self-efficacy are more persistent when faced with difficulties than those with lower levels, they also suffer from other negative factors such as stress and anxiety. The difference between the two groups is that those with high self-efficacy are able to mediate the relationship between stress and anxiety or any adverse situation (Lenz & Shortridge-Baggett, 2002).

Efficacy expectation refers to a person's confidence in their capability to behave in a certain way, and people are motivated to perform tasks they believe will produce desired outcomes or results. Outcome expectations depend on efficacy expectations; thus, the latter predict performance much better than the former. According to Lenz & Shortridge-Baggett (2002), self-efficacy is influenced by four sources of information, namely performance accomplishments, vicarious experience, verbal persuasion, and physiological information. These all influence a person's self-efficacy in different situations and affect expectations about the magnitude and strength of one's self-efficacy (Shortridge-Baggett & Van der Bijl, 1996). The four information sources are elaborated upon below:

1.8.1 Performance accomplishments

Performance accomplishments involve practising and experiencing success in achieving goals and are a composite of prior experiences in carrying out the task

(Lenz & Shortridge-Baggett, 2002). Successful achievements will enhance self-efficacy about the ability to perform a particular task and generalise to other tasks, while frequent failure, especially if it occurs early in the learning process, decreases self-efficacy (Shortridge-Baggett., 2001:183). Successful direct performance of a task results in a higher self-efficacy belief than vicarious experience or any other source; therefore, performance accomplishments are the most effective in developing one's perception of self-efficacy (Shortridge-Baggett & Van der Bijl, 1996).

1.8.2 Vicarious experience

Vicarious experience occurs when a person gets experience through observing others (who become role models) performing tasks, and thus enables judgements to be made based on those observations. Usually, the observed person has to be perceived to be at a similar level of performance, and the greater the perceived similarity to oneself the greater the impact of the modelled success or failure. Vicarious learning should be able to convince the observer that the barrier can be overcome and a clear outcome is necessary to convince them that if others can do it, they can do it too (Lenz & Shortridge-Baggett, 2002)

1.8.3 Verbal persuasion

Verbal persuasion is commonly used by healthcare workers when they try to convince patients to take certain treatments. The credibility or perceived credibility of the person doing the persuasion is important. The credibility is usually derived from expertise and trustworthiness. If the person is convinced of their capabilities, they will be more motivated to persevere and not to give up easily. However, the weakness of verbal persuasion lies in its not being related to one's own experience or that of others, but when used in conjunction with other sources it can be effective. It can also be useful when people have reverted to old behaviours after succeeding in new tasks ((Van der Bijl & Shortridge-Baggett, 2001).

1.8.4 Physiological information

Self-evaluation of the physiological and emotional effects of sources, particularly when it happens in the early learning phase, provides feedback to the person on how well they are performing the task (Van der Bijl & Shortridge-Baggett, 2001). People use information about their physiological and emotional status to judge their own capabilities. Emotions such as stress, anxiety and depression may negatively influence self-efficacy, especially for those with low levels of it (Lenz & Shortridge-Baggett, 2002).

1.9 Delimitations of the Study

The cross-sectional design of the study has inherent limitations in that causality cannot be established; rather, only associations. The study will only be carried out in one district, therefore it will not be easy to generalise it to other areas. In this study, the researcher will include only TB patients registered in Nelson Mandela district at Ggebera Clinic from April 2018 to September 2019.

1.10 Conclusion

In this chapter, pertinent information relating to the research topic (background facts, goals, objectives, and theoretical grounding) were presented to ensure a better understanding of the chapters that follow. Chapter 2 presents an in-depth analysis of literature relating to factors that underpin and influence treatment adherence.

1.11 Chapter Outline

Chapter 2 – Literature Review

This chapter presents an in-depth and concise description of literature relating to determinants of TB treatment adherence.

Chapter 3 – Research Methods

A thorough presentation of the methodology of sample, data, collection and data analysis.

Chapter 4 – Discussion of Results and Findings

Study findings are thematically presented in this chapter and starts by presenting data analysis, results and findings.

Chapter 5 – Conclusion and Recommendations

This chapter starts by presenting a concise summary of key findings. It then draws conclusions from the study findings and closes with key recommendations on ways to improve TB treatment adherence.



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2 CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

The previous chapter highlighted the magnitude of the TB burden both globally and in the South African context. In addition, the dire implications of poor TB treatment adherence on the emergence of drug-resistant TB strains is a sufficient threat to warrant research into strategies that could prevent this major setback to curative services. In this drive for strategies to improve treatment adherence, this chapter presents a thorough analysis of TB-related literature to shed light on the various factors that may play a role in driving or mediating treatment adherence. This literature review was conducted by using various sources of information which include government websites such as South African and Eastern Cape Departments of Health (SA DOH and EC DOH). The peer-reviewed journals, search engines such as PubMed and EBSCOhost on the University of Cape Town database, as well as other websites pertaining to health policies worldwide and WHO were also accessed.

Terms and phrases used in this search include: TB prevention, treatment adherence, TB in South Africa, missed opportunities, and TB control.

2.2 Service Delivery Factors

The service delivery factors identified are, TB treatment adherence, compliance with Direct Observed Treatment Strategy (DOTS), TB treatment and determinants on suboptimal adherence which are discussed below.

2.2.1 Tuberculosis Treatment Adherence

It has been reported that without treatment, TB mortality rates remain high as proven by studies of the history of the disease among sputum smear-positive/HIV-negative cases of pulmonary TB. An estimate of 70% died within 10 years, and among culture-positive but smear-negative cases, 20% died within 10 years (Tiemersma, van der Walt, Borgdorff, Williams & Nagelkerk, 2011).

The overall goal for TB treatments is to cure the individual patient and to minimise the transmission of mycobacterium tuberculosis to other persons. Hence, the successful treatment of TB has benefits both for the individual patient and for the community in which the patient resides (WHO, 2008a).

A literature review on adherence to TB care in a Canadian Aboriginal population found that poor adherence to TB treatment was the most common cause of initial treatment failure and disease relapse (Orr, 2011). Consequently, such failure contributed to higher levels of transmission of the disease and higher chances of developing multi-drug resistance. TB adherence is a general concern worldwide (Baylan, 2011).

Compliance with prescribed anti-TB treatment has many beneficial roles to play in TB-control programmes especially programmes that fall under the DOTS strategy. In many TB programmes, treatment compliance has been associated with high TB cure rates and reduction in the emergence of drug resistance (Adane, Alene, Koye & Zeleke, 2013). Therefore, correct and consistent compliance among TB patients receiving treatment through DOTS is required throughout the treatment period in order to achieve good treatment outcomes, which is key to achieving high cure rates (Naidoo, Peltzer, Louw, Matseke, McHunu & Tushana, 2013).

Compliance requires patients to take their TB treatment in a regular and consistent way in order to reduce the risk of treatment failure, relapse and the development of drug-resistant strains. According to Afns and Ji (2010), interruptions that occur especially in the early stages of treatment can cause an increase in the TB transmission rate. This is because the initial stage of treatment is regarded as the most infectious stage with many TB bacilli. This is also the stage where resistant bacilli survive if not properly treated, therefore, it requires correct and consistent administration of medication in order to ensure that the majority of TB bacilli are killed and that resistant bacilli have no chance of surviving. To prevent the increase in TB cases and the emergence of drug-resistant TB, patients need to be encouraged to comply with their TB medication (Adane et al., 2013).

Non-compliance with TB treatment still poses a challenge in most TB control programmes. In Uganda and Ethiopia, as in other sub-Saharan Africa countries, poor compliance with TB treatment among patients with TB was reported to be a

major problem (Adane et al., 2013). In a cross-sectional study undertaken in South Africa by Naidoo et al., (2013) on predictors of TB and ARV-adherence, it is argued that poor adherence to treatment was strongly associated with low cure rates of TB. Studies further indicate that poor and inconsistent adherence, non-adherence, has negative effects on TB control, and in most instances led to drug resistance and further spread of TB in the community leading to increases in morbidity and mortality (Adane et al., 2013). Many TB programmes have reported an increase in the healthcare costs related to these negative effects.

2.2.2 Compliance with DOTS TB Treatment

According to Ministry of Health and Social Services (MoHSS, 2012), the Global Plan to Stop TB was launched at the World Economic Forum which was held in Switzerland in 2006. This plan was aimed at treating 50 million people against TB and enrolling three million patients who have both TB and HIV infection on antiretroviral treatment. The foundation of this strategy was launched in 2006 by WHO, and is laid on elements to approach the care and control of TB patients as 'The Stop TB Strategy'.

This strategy was aimed at:

- achieving universal access to high-quality care for all people with TB;
- reducing human suffering and the socio-economic burden associated with TB;
- protecting vulnerable populations from TB, TB/HIV and drug resistant TB;
- supporting the development of new tools and enable their timely and effective use, and lastly;
- protecting and promoting human rights in TB prevention, care and control.

The WHO has reported a treatment success of 85% (MoHSS 2012).

Directly Observed Treatment Strategy (DOTS) is an international treatment protocol with a strategy comprising of five components such as, political commitment by national governments, improved laboratory facilities with quality sputum smear microscopy capabilities, regular supply of anti-TB drugs, direct

observation of each patient swallowing their medications by a health care worker, and a standardised recording and reporting system for patient and programme (Pasipanodya & Gumbo, 2013).

Duwell, Knowlton, Nachega, Efron, Goliath, Morroni and Chaisson (2013) noted that directly observed therapy differs from the traditional use of self-administered therapies in that the patient is given the medication, or observed in its administration, to ensure that the patients receive the proper dosage at the proper intervals with compliance concerns being restricted to the utilisation of this service. The self-administered therapies rely on the ability of the patient to administer the medication and the willingness of the patient to adhere to the schedule without the accountability entailed in the directly observed therapies. Duwell et al., (2013) found that the outcomes for patients were significantly improved by utilising directly observed therapy in comparison to the use of self-administered therapies.

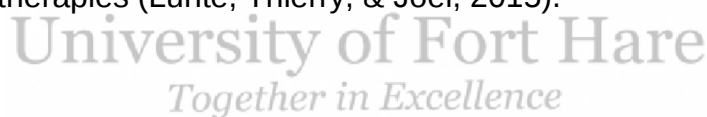
Khogali, Zachariah, Reid, Alipon, Zimble, Mahama and Hassan (2014) discussed the use of self-administered therapies for the purpose of treating tuberculosis in rural Ethiopia. The researchers explained that the participants were given adherence training and communication in order to promote compliance with the medical treatment protocol. Utilising patient follow-up and communication techniques, Khogali et al., (2014) referred to this protocol as a modified direct observation therapy with an adaptation for a self-administered therapy. This was found to be more effective in rural areas, whereas access to a more sustained direct observation therapy facility was more limited than the rigid direct observation therapy since patients were not limited to their transportation access but were granted the added support that would not be present in a traditional self-administered therapy. This was a significantly beneficial study as many of the patients in Ethiopia live in rural areas, and the compliance in these regions has been reported as being less than adequate for treating tuberculosis (Khogali et al., 2014).

According to Bruce, Eiserman, Acosta, Gote, Lin & Altice (2012) the directly observed therapies are superior to the self-administered therapies, added that the former keeps many of the factors that are associated with non-compliance and

avoidance of medical services from surfacing in a manner that prevents the best possible outcome for the patient.

In fact, Bruce et al., (2012) found that the experience level of the individual in relation to how to administer the medication, the socioeconomic status of the individual patient, and the demographic background of the patients did not significantly influence compliance to TB treatment when utilizing the directly observed therapy method of administering necessary medication. This shows that, when patients are given the scenario to be held accountable for their compliance with the medication treatment protocol, they can actually move beyond the barriers to their health. The disparities between race, gender, and socioeconomic status can therefore be discovered in a clinical setting (Gärden, Samarina, Stachanskaya, Alserlund, Ovregaard, Tanganovanova & Larsson 2013).

Using a study related to self-administered therapies, these are identified as more cost effective when considering the personnel required to administer the DOTS treatments. It is noted that if health care costs are taken into consideration, it is the directly observed therapies that are much more expensive than the self-administered therapies (Lunte, Thierry, & Joel, 2015).



2.2.3 Determinants on Sub-Optimal Adherence

The successful completion of tuberculosis treatment is not only dependent on the implementation of a TB treatment programme, but on multiple other factors. These factors include patient age, time of presentation for diagnosis, prevalence of HIV, socio-economic status, poor compliance, access to health care services, substance abuse and drug resistance (Demeke, Legesse & Bati, 2013).

The WHO (2015) has grouped these factors into structural and economic factors, patient-related factors, and regimen complexity, supportive relationships between the health providers and patients, and the patterns of health care delivery. The structure of categories involved in this study's framework was drawn from the ecological framework and the WHO's grouping. However, this study focuses on literature that specifically addresses factors associated with TB adherence that are divided into three categories (Figure 2).

The first level involves factors related to health service delivery, including accessibility and availability of services, delivery settings, availability of equipment and accessibility of health facilities, the patient–provider relationship and regimen complexity. The second level involves the social and economic factors, which include socio-demographic characteristics of individuals, such as gender, age, education, occupation, marital status and socio-economic status. The third category comprises the individual and disease-related factors, such as illness characteristics and severity, treatment duration, intensive and continuation phase, treatment progress over time, risk behaviours (tobacco smoking, illicit drug and alcohol use), individual knowledge, beliefs and attitudes, and mental health problems (Dick, Lewin, Rose, Zwarenstein & Van Der Walt, 2003).

The demographic characteristics and individual disease-related factors directly affect the level of medication adherence, while service factors and social supports directly or indirectly influence the adherence behaviours of patients through individual-related factors.

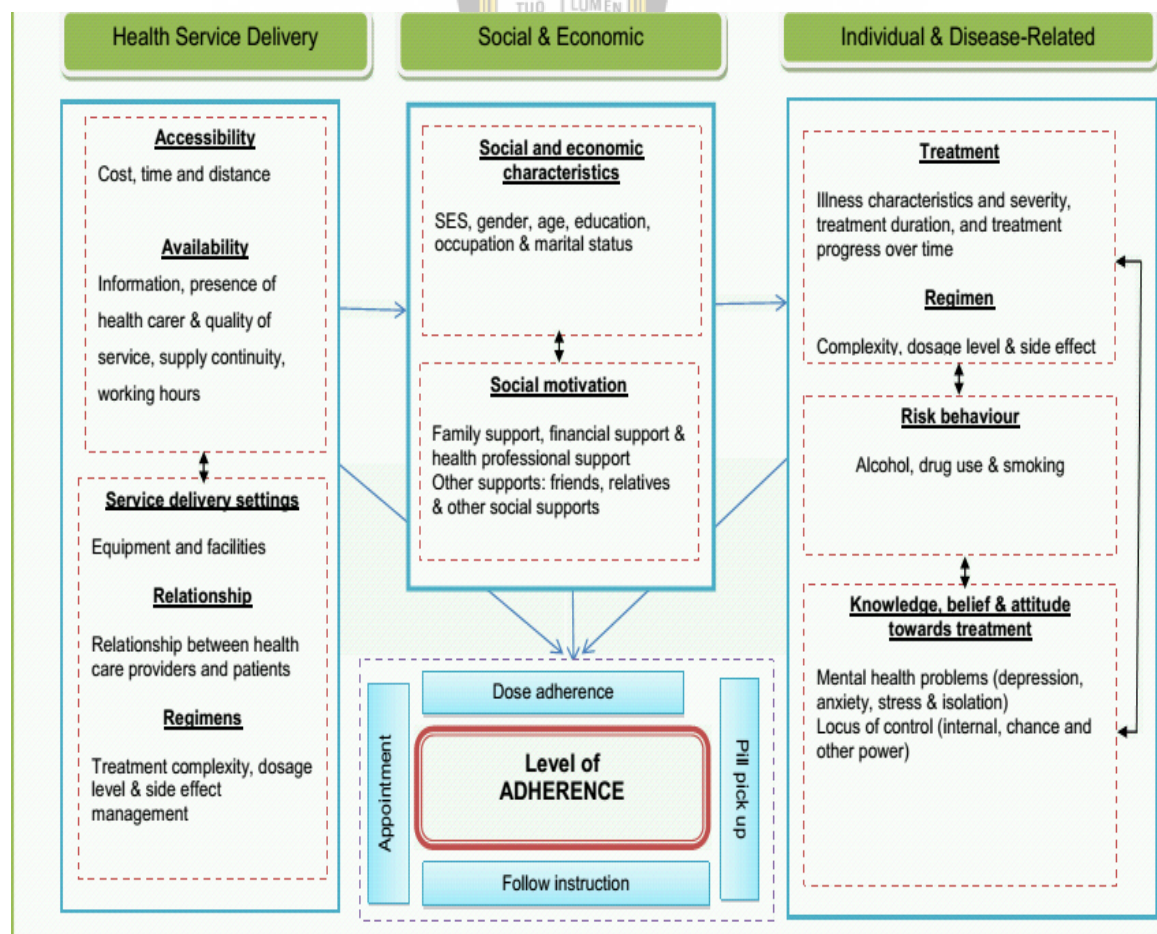


Figure 2: Literature mapping of TB treatment adherence. (Dick, Lewin, Rose Zwarenstein & Van Der Walt, 2003)

2.3 Health System-Related Factors

The healthcare delivery system has the potential to affect the adherence behaviour of patients. A good patient–provider relationship is one of the factors most likely to improve adherence within the health system (Rose, Hallbauer, Seddon, Hesselning, & Schaaf, 2012). Factors with negative effects include poorly developed health services with inadequate or non-existent reimbursement by health insurance plans, and poor medication distribution systems leading to shortage of medicines or commodities required for treatment. Factors related to the health provider that may lead to poor adherence include lack of knowledge about managing chronic diseases, overworked healthcare providers, lack of incentives or feedback on performance, and short consultations.

According to Orr (2011), health workers or systems which fail to provide services according to the recommended guidelines or standards cannot expect adherent behaviour from their patients. Long waiting times for care would most likely discourage patients from adhering to treatment. So too would healthcare facilities or mechanisms which actively or passively promote feelings of physical insecurity or rejection. Another factor is care that is apparently available, yet in reality not accessible owing to an operational culture. The operational culture that does not serve patient needs, like limited service availability and hours of operation, and transportation barriers (Podwils, Gler, Quelapio, & Chen, 2013). Lack of trust, respect and dignity in the relationship between patients and health workers, as well as staff having a lack of knowledge and skills in the diagnosis and management of the side effects are also discouraging. Poor TB programme management system results in drop-outs and losses from treatment and follow-up appointments. Care that focuses only on TB, yet fails to acknowledge and assist patients to overcome barriers, or assist patients with counselling, concerns, homelessness, food, and other individual associated factors faced by TB patients, are deterrents (Pasipandoya & Gumbo, 2013).

Patient-centred approaches that allowed TB patients to choose the treatment option that was convenient and flexible to them was found to have improved the treatment outcomes for patients treated under both community- and facility-based DOTS. The approach further improved treatment success rates for patients who opted for community DOTS rather than patients who chose facility-based DOTS (Van den Boogaard, Lyimo, Boeree, Kibiki, & Aarnoutse, 2011). Studies have identified the problems that are related to health facility DOTS, such as, availability and accessibility of health care facilities especially at the community level, and the availability of health workers were identified as influencing TB treatment compliance (Adane et al., 2013).

In some African studies and studies done elsewhere, health workers felt that daily DOTS increased their workload. Health workers attributed this workload to the treatment requirements where patients are seen and observed on a daily basis. For the proper implementation of the primary elements of DOTS, which is the monitoring of progress, patients are also seen on regular basis for follow-ups and sputum reviews (Afns & Ji, 2010).

Health care professionals play a vital role in TB treatment adherence. A lack of communication and support from healthcare workers discourages patients from adhering to treatment, while positive experiences and competent support creates meaningful connections and relationships with patients (Naidoo, Peltzer, Louw, Matseke, McHunu & Tutshana, 2013). The relationship between the healthcare provider and the individual patient is indicative of a good therapeutic alliance, a process of collaboration between provider and patient, in which the practitioner effectively communicates with the patients about their problems and formulates a management plan that is conducive to patient compliance. A therapeutic alliance is underpinned with values of empathy, trust and positive support. This is evident in a systematic mental health review, which found that the clinician–patient alliance and communication were associated with favourable outcomes of adherence (Thompson & McCabe, 2012).

2.4 Socio-economic Factors

There are many socio-economic factors that influence TB treatment adherence directly. According to Dick et al., (2003) supported by the WHO (2008b) evidence for action, lack of social support network, culture, beliefs and treatment, ethnicity, gender and age, and the high cost of transport affect adherence directly or indirectly.

Research indicates that TB rates are often higher in urban areas compared to rural locations. One reasonable explanation is that TB transmission increases owing to population density. Crowded living conditions and poor nutritional status increase the risk of infection, especially in urban areas (Afns & Ji,2010).

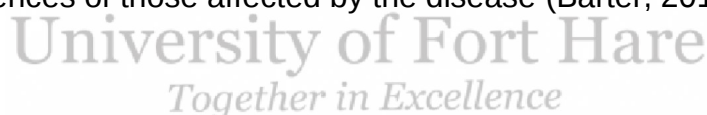
One other factor that directly or indirectly influences treatment adherence is the living conditions of patients. Those who live in remote areas with poor conditions and a lack of access to services are more likely to be non-adherent to treatment. This is evident in research which found that poor resource settings pose barriers to TB treatment adherence (Adane et al., 2013). The challenges faced by TB patients undergoing treatment are beyond their control when they are associated with poverty and inadequate health services. It is well established that poor living conditions contribute to the spread of TB, often referred to as a disease of poverty, and it is certainly a barrier to treatment adherence. As a result of living in a poorly resourced setting. The study by Naidoo et al., (2013) found that the majority of participants had to endure the experience of being poor and living with the consequences of poverty, including crowded, dangerous living conditions, unemployment, and limited formal education.

Many structural factors have been identified in previous research as factors influencing treatment compliance. An international systematic review by Kebede and Wabe (2012) identified financial burdens as a structural factor mentioned in most of the reviewed studies influencing TB treatment compliance. In a study undertaken in Gambia by Afns and Ji (2010), patients indicated that health facility-based daily medication increased their family expenditure, especially money spent on transport to and from the hospital. In other studies, treatment interruption was associated with treatment costs either directly paying for medications or indirectly, hospital stays, transportation and change in a diet. Other studies further indicated

that having TB had consequences for work, and that some patients hide their disease for fear of dismissal from their employment, thus compromising their compliance with treatment (Barter, 2012).

One of the enabling factors to treatment adherence is family and social support. These have been found to affect adherence behaviours both directly such as through positive encouragement and reinforcement. Indirectly through stress relief, reduced anxiety and depression. Although medical regimens for care of people with HIV and TB are different, the influences of family and social support on individuals undergoing treatment may be similar. The disclosure of information to others regarding treatment status is an important facilitator for medication adherence, while not being able to share treatment status was reported to be a major constraint. Sharing of information with relatives and friends had the potential to improve adherence (DOH EC, 2013).

Social stigma has been reported as an important factor that directly contributes to treatment non-adherence. Discrimination related to TB, in most societies, has been identified as one of the most important socio-cultural aspects that influences the illness experiences of those affected by the disease (Barter, 2012).



2.5 Individual and Disease Related Factors

There are a number of factors involved in the individual disease-related factors, including the level of education and knowledge of patients about TB, health locus of control, one's belief that his or her health outcome is determined by chance or luck, risk behaviours such as alcohol consumption and / or cigarette smoking and mental health problems.

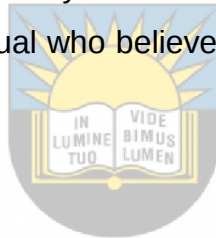
2.5.1 Level of education

Numerous studies have found that the higher the education level of an individual, the more successful treatment adherence seems to be (Ayisi, Van't Hoog, Agaya, Mchembere, Nyamthimba, Muhenje & Marston, 2011). Lack of key knowledge could adversely affect early diagnosis, treatment, adherence to treatment and a further spread of the disease. It was also highlighted that education was the most important predictor of knowledge, beliefs, perception and attitudes. It has been

demonstrated by research that patients might decide to interrupt TB treatment if they had a lack of knowledge about the duration of the course and they were unsure of the importance of completing treatment (Ayisi et al., 2011).

2.5.2 Health Locus of Control

Locus of control refers to the extent to which individuals believe they can control events affecting them, regardless of their actions being desirable or undesirable. The causal attributions that individuals assign to their illness condition will affect their way of coping with it. If a treatment regimen recommended by a health practitioner is consistent with an individual's understanding of what caused his or her illness, then the individual is more likely to adhere to treatment (Demeke et al., 2013). An individual, who ascribes external factors that are out of his or her control as causing the illness, is less likely to be self-motivated to improve their health status, compared to an individual who believes they can control what happens to them (Do, 2011).



2.5.3 Disease related factors

The other factors associated with either compliance or non-compliance were co-morbid conditions, such as cardiovascular diseases, diabetes and HIV. These conditions require patients to take additional medications in addition to TB treatment. Studies from sub-Saharan Africa and elsewhere have indicated that patients may either comply because they want to get better, or they may decide not to comply because they feel worthless, or they may become tired of taking a lot of medication (Kebede & Wabe, 2012).

2.5.4 Risk behaviours

In this study risk behaviours describes specific behaviours such as alcohol consumption, cigarette smoking and / or illicit drug use that direct or indirectly impacts or causes significant harms to the health of individuals. Clinical experience suggests that drug use and alcohol problems are associated with treatment non-adherence and poor treatment outcomes. Similarly, in Hong Kong, a study of TB

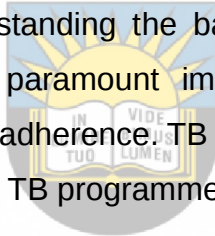
defaulters found that tobacco smoking was one of many factors that contributed towards treatment default, or poor adherence (DoH, 2011).

Depression is another potentially significant impediment to effective treatment. Within the treatment context, negative thoughts, anxiety, hopelessness and depression are often associated with low adherence to healthcare instructions (Do, 2011). It is considered that mental health need to be critically observed in individuals infected with TB because they are likely to cease trying to achieve a positive outcome when they are unable to control events in their lives. The psychological wellbeing of an individual is important to the overall management of the disease. Conversely, high self-efficacy has also been found to be associated with better disease management, such as adhering to prescribed medicines, managing stress, and following a recommended nutrition programme (Afns,2010). It can also be surmised that these individuals do not believe that adhering to the recommended treatment of the local health authorities will cure their condition, and they possibly view the treatment methods with scepticism and mistrust. Optimistic bias refers to 'the belief that other people but not oneself will develop a disease, have an accident, or experience other negative events (Naidoo et al., 2013).

Other social determinants associated with psychological stress include continued anxiety, low self-esteem, social isolation and control over one's home and working life. Alyssa, Lancaster and van der Walt (2012) summarised feelings of isolation and loneliness in 44%, and sadness in 42% of participants. Overall, 78% of the participants indicated that they had suffered significant psychological and emotional trauma after learning that they had to be tested for possible TB and had to receive treatment. Therefore, fighting to eliminate TB is not a simple task. It is an approach of all involved stakeholders, including international donors that provide sustainable funding, committed local government, the cooperation of health workers and communities, and the awareness among patients to take their treatment seriously (WHO, 2008b).

2.6 Conclusion

Treatment adherence has been recognised as a pivotal aspect of the fight against TB, as poor adherence has a negative influence at both individual and population levels. A major public health problem that threatens the progress made in TB care and control worldwide is the development of multi-drug resistant TB (MDR-TB). It has been documented in many different settings around the world that drug resistance arises as a result of improper treatment and failure to ensure that patients complete the whole course of their treatment regimen successfully. There are a number of ways in which adherence to TB treatment can be measured. A common measure is the self-report of the estimated percentage of prescribed doses taken over a given period of time. Yet, the self-report method sometimes leads to social desirability bias, which may influence the overestimation of medication adherence. Understanding the barriers and enabling factors to TB medication adherence is of paramount importance, especially in designing effective strategies to optimise adherence. TB is a key public health issue in South Africa and key stakeholders for TB programmes have limited data available on the level of treatment adherence.

The logo of the University of Fort Hare, featuring a shield with a sunburst at the top, a book in the center, and the motto 'IN TUIS LUMEN' on a banner below. The shield is flanked by two figures.
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3. CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

Chapter 2 presented the key pertinent and recent literature relating to TB treatment adherence. This chapter describes the study design, methodology used, sampling, population, data collection tools, data quality checks and analysis, trustworthiness and ethical considerations.

3.2 Research Design

Beck and Polit (2017) defined research design as an overall plan to obtain answers for research questions. A cross-sectional study design was used to assess the determinants of TB treatment defaulting among patients at Gqeberha Clinic in Nelson Mandela District, Eastern Cape, South Africa, retrospectively. According to Burns and Grove (2017), cross-sectional study designs examine participants simultaneously, irrespective of their stage of development but with an aim to describe differences in phenomena across stages.

3.3 Research Method

The study used quantitative method to describe life experiences and to give meaning so as to understand human experiences regarding their health (Burns and Grove, 2017).

3.4 Sampling and Population

The convenience sampling technique was used to select the patients who had been diagnosed with TB, started treatment and defaulted between April 2018 and September 2019 at Gqeberha Clinic. The technique involves recruiting all the people from the accessible population who meet the eligibility criteria over a specific time interval (Beck & Polit, 2017). This technique is considered easiest,

cheapest and least time consuming. The sample size for the study was calculated by the Epi Info version 7.2, and a minimum sample of 127 participants was needed for significant results at 95% CI, but the number was increased to 144 to ensure data saturation.

3.4.1 Population

In this study, the study population was selected from TB treatment defaulters at Gqeberha Clinic in Nelson Mandela district.

3.4 .1.1 Recruitment of study participants

The names of the defaulters were identified from the TB register at the Gqeberha clinic. The data collection was undertaken through door-to-door visits, for the convenience of the participants.

3.4.1.2 Inclusion criteria

The inclusion criteria used to recruit participants were TB patients who had been diagnosed with TB and registered on the TB register (ETR.net) between April 2018 and September 2019.

3.4.1.3 Exclusion criteria

The exclusion criteria used excluded any patient with final treatment outcomes recorded as either moved out or transferred, and children younger than 18 years of age.

3.5 Data Collection

A data collection was undertaken through the use of a questionnaire. The study was conducted in the Nelson Mandela district. Geographically, the district is in the Eastern Cape and has the second highest population of 1 184 988, with a

population density of 604.9 persons per km², and falls among the wealthiest districts (DHO EC, 2014/15:332). The percentage of the population living below the poverty line was 35.2%. The district unemployment rate was reported at 36.6% and the illiteracy rate at 31% (IDP, 2014/15). Of the 60 clinics in the District, Gqeberha Clinic in Walmer Township was chosen owing to the fact that it has the highest incidence of TB defaulters.

Door-to-door visits were conducted at the residences of defaulting TB patients who had been identified by the researcher and the two research assistants from the health facility database. The questionnaires were administered by the researcher with the assistance of two research assistants. The research assistants were two health promoters who were recruited and trained to support data collection (Polit & Beck, 2017). The tasks of the health promoters were to supervise, check understanding and completion of the survey questionnaire, read and translate the items to the participants.

3.6 The study instrument

A structured questionnaire was developed and used. The questionnaire was divided into four sections covering demographic information, socio-economic variables, healthcare system-related factors, default factors, and disease- and medicine-related factors. There were a total of 38 questions in the instrument, 10 on demographics, 3 related to TB status, and 25 related to determinants of non-adherence. Of the 25 questions, 17 used a 5-point Likert scale, 7 were dichotomous (yes/no) and 1 was an open-ended question.

3.6.1 Translation process

The translation process was carried out by adapting methods from the WHO (2011) as well as a number of guidelines for translational validity, including the Census Bureau Guideline for the Translation of Data Collection Instruments and Supporting Material. The questionnaire was from the original language – English– to Xhosa and Afrikaans which are languages used in Nelson Mandela district, and then translated back into English. The translation to Xhosa and Afrikaans from English was carried out by a qualified translator with a health background. Figure 3

describes the process of the questionnaire being-translated from Xhosa and Afrikaans into English by a different translator. The guidelines for translation validity were closely followed (Beck & Polit, 2017).

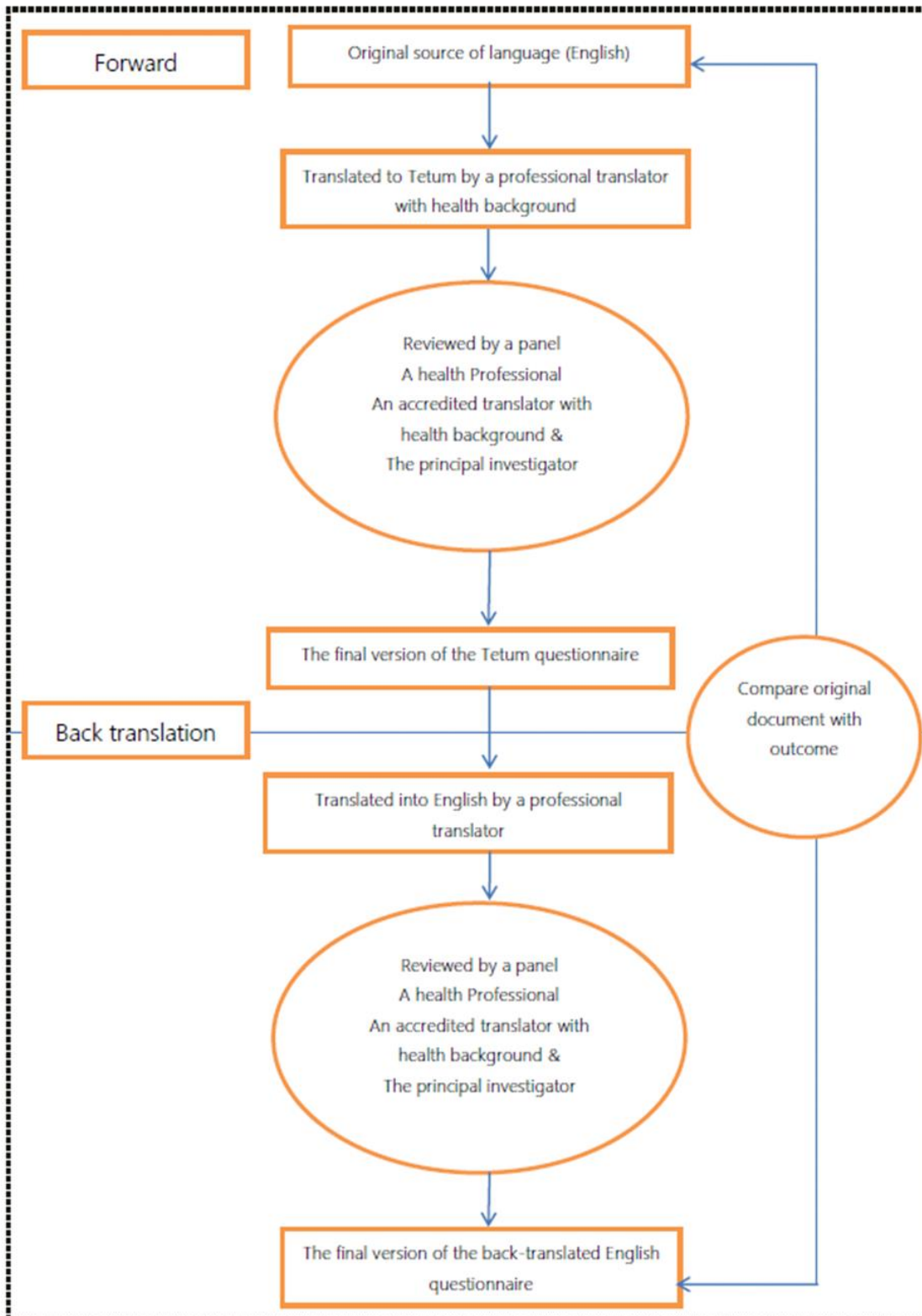


Figure 3: The translation process for the study instrument- (WHO, 2011)

3.6.2 Pre-testing of study instrument

Pre-testing of the instrument was conducted using 12 patients to test validity and reliability of the instrument. Findings were used to further adapt and refine the study instrument, according to the findings of the pre-test (Polit & Beck, 2017).

3.7 Data Analysis

According to Beck and Polit (2017) researchers use statistical analysis to organise, interpret and communicate numeric information. Statistical tests were used to address the research questions and a statistician analysed the data, entry was done in Microsoft Excel, and then exported to SPSS for analysis. Data quality checks were put in place in Excel to minimise errors, and data verifications were done for randomly selected completed questionnaires. Descriptive statistics were generated to paint picture of the features and variables found in the sample. Bivariate analyses were performed to determine the association between the outcome variables and independent factors. Categorical independent variables were analysed using chi-square and analysis of variance (ANOVA) for continuous independent variables. The study used the probability level of 95% for all statistical tests at the significant level of $p \leq 0.05$ and all prevalence estimates will be calculated with 95% confidence intervals.

3.8 Trustworthiness

Research has to be trustworthy to ensure that findings contribute towards social change. Therefore, several internal consistency checks have to be included for a study to be trustworthy. This study focused primarily on data validity and reliability as key to the generation of acceptable study findings, given the nature of the study topic (Beck & Polit, 2017).

3.8.1 Validity: For the validity of the study, conceptual and operational definitions of terms were highlighted in Chapter 1 and were used according to the objective of the study.

3.8.1.1 Construct validity focused on the questionnaires designed to address the wording and appearance of the questions.

3.8.1.2 Internal validity, the research remained objective throughout the study and was achieved by the use of the data collection tool.

3.8.1.3 External Validity was ensured by the questionnaire that asked the respondents demographic questions and gender neutral words for the purpose of determining whether the results can be generalized back to the population from which the sample was obtained. The use of statistician and health experts also ensures external validity. Bougie and Sekaran (2013) points out that all three are important issues in the questionnaire design and are there to minimise bias in research.

3.8.2 Reliability: To maintain the reliability of the study, pre-testing was done of the research instrument and consulting experts in the field. Only the researcher was responsible for cleaning abstracted data and, by so doing, increasing the chances of consistency in data collection (Burns & Grove, 2017).

3.9 Ethical considerations

3.9.1 Ethical clearance and permission

The study proposal was reviewed and approved by the School of Health Sciences (University of Fort Hare) Research and Senior Degrees Committee. Ethical clearance was granted by the University of Fort Hare Research Ethics Committee (UFHREC). In addition, approval for the study and permission to access the ETR.net data was obtained from Eastern Cape Provincial Research Committee.

3.9.2 Informed consent

The participants who met the inclusion criteria were fully informed about the study purpose, methods, benefits, risks to participants and how the collected data would be handled to ensure confidentiality and privacy. Each prospective participant had the right to refuse to participate without negative consequences. They were reassured that no treatment due would be withheld from them if they refused to participate in the study. They were made aware of the fact that they had the right to withdraw at any time without repercussion or penalty (Burns & Grove, 2017). After they understood the study and had agreed to participate, a written consent form was provided to each study participant to sign.

3.9.3 Anticipated benefits

Study participants were informed that there was no compensation for participation, and agreeing to participate should be voluntary. However, it was impressed upon them that this research study would generate evidence that could improve health services to ensure that TB patients may have a more conducive environment that supports compliance to treatment regimens. (Burns & Grove, 2017).

3.9.4 Anticipated risks and precautions

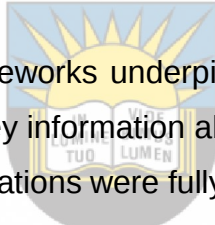
The study had no invasive procedures that could pose any potential health risks to participants. However, participants were encouraged to be open about any discomfort they may feel with the research questions, and a break would be taken to allow them to rest. In addition, should the interview become too uncomfortable, participants were free to terminate the interview, and in these instances, the researcher had a counsellor on standby who would be called upon to support the patient in getting through any emotional trauma (Beck & Polit, 2017).

3.9.5 Anonymity, privacy and confidentiality

To respect privacy, patient information was captured anonymously and all the data obtained were delinked from personal identifiers. The designed data collection instrument did not contain any personal identifiers to ensure that participant privacy was respected. Access to the ETR.net for the identification of potential study participants was done under the direct control of the responsible supervisors, i.e. the District Department TB programme officers. Personal information obtained from the database was only used to contact the potential participants for recruitment into the study, and this data was kept separate from the data collected for the study (Burns & Grove, 2017).

3.10 Conclusion

The details of theoretical frameworks underpinning the study methodology have been presented. In addition, key information about the study site, population, data collection, and ethical considerations were fully discussed. Chapter 4 presents the findings from the data collected for the study.



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CHAPTER FOUR: RESULTS, DISCUSSIONS AND FINDINGS

4.1 Introduction

Key findings from data collection and analysis are presented in this chapter. For ease of navigation and coherence, the findings are presented in a thematic manner that focuses on social, economic and health-related factors affecting TB treatment adherence.

4.2 Results

4.2.1 Demographic characteristics

As presented in Table 1 below, all the participants in the study were of one ethnicity, that is Black; 66% of whom were male and 34% female. Almost all of the participants were South African (99%). The majority of the participants were unemployed (80%). Education achievement was low among participants: 70.1% had below matric, 17.4% had matric; only 11.1% had at least a certificate, and 1.4% had a degree.

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Table 1: Demographic characteristics of study participants

Demographic indicator		N	Frequency	Percent
Ethnicity	Black	144	144	100.0
Gender	Male	144	95	66.0
	Female		49	34.0
Dwelling Type	Formal	144	107	73.8
	Informal		38	26.2
Employment status	Unemployed	144	112	77.8
	Employed		32	22.2

Demographic indicator		N	Frequency	Percent
Nationality	South African	144	142	98.6
	Non-South African		2	1.4
Marital Status	Divorced	144	6	4.2
	Married		30	20.8
	Single		105	72.9
	Widowed		3	2.1
Highest Education	Below Matric	144	101	70.1
	Matric		25	17.4
	Certificate		16	11.1
	Diploma		2	1.4

The age of study participants ranged from 22–72 years, with a mean of 33.40 and a standard deviation of 12.67 age of 33 years. Mean family size was noted at 4.22 with a standard deviation of 1.633, and the largest families having 9 members. As 78% of participants reported to be unemployed, average monthly income was negatively skewed with a mean income of R1,013 and the highest income of R7,600.

Table 2: Demographic characteristics (continued)

Demographic Characteristic	N	Min.	Max.	Mean	Std. Deviation
Age	144	22	72	33.40	12.267
Number of people in household	143	1	9	4.22	1.633
Average monthly income	144	0	7600	1013.79	1869.106

4.2.2 Service delivery factors

From the 5-point Likert scale, a categorical scoring system was developed to evaluate overall satisfaction with health services delivery among respondents. Generally, all participants were in agreement that health services delivery was conducted in a conducive environment and that facilities were reasonably close to their places of residence. On average scores, not one of the mean service delivery related responses was below 50%, with a lower score showing disagreement.

Table 3: Overall perceptions on health services-related factors

Aggregated service delivery responses	Frequency	Per cent
Very satisfied	133	92.4
Moderately satisfied	11	7.6
Total	144	100.0

To understand fully the possible issues relating to health services, an analysis of each question was conducted and is presented in Table 4 below. As noted earlier, participants were mostly in agreement with health services accessibility and quality. The lowest scoring question (mean=2.93 and a standard deviation of 1.022) related to the treatment of patients by health workers. This highlights that a significant proportion of patients hold reservations and negative perceptions about the level of respect and dignity extended to them by health workers. In the same manner, participants demonstrated that health workers do not provide adequate information regarding the medications that patients receive (mean=2.99 with a standard deviation of 0.964).

Table 4: Perceptions on health services-related questions

Health services-related question (1 = strongly disagree and 5 = strongly agree)	N	Mean	SD
I would prefer picking up my TB medication outside clinic hours (8am–5pm)	144	4.93	0.255
The waiting time to pick up medication is always less than two hours	144	3.36	1.015
I stay less than five km from this clinic	144	3.83	0.885
It cost me less than R50 to pick up my medication per visit	144	4.49	0.646
Health workers treat me with respect and dignity	144	2.93	1.022
Health workers provide all health information about my medication	144	2.99	0.964
Medication pick-ups are done in clean areas	144	4	0.205
Medication pick-ups are done in safe areas	144	3.88	0.624
Medication pick-ups are accessible to the disabled	144	3.92	0.749
My medication is always available	144	4.06	0.628

4.2.3 Socio-economic factors

From the 5-point Likert scale, a categorical scoring system was developed to evaluate the overall satisfaction of respondents with their socioeconomic status regarding their illness. Of the respondents, 40% showed an unsatisfactory perception towards their social and economic life, 55% were somewhat satisfied, while only 5% were very satisfied.

Table 5: Overall participant responses to socio-economic questions

Aggregated responses on socio-economic factors	Frequency	Per cent
Very satisfied	7	4.9
Moderately satisfied	79	54.9
Dissatisfied	58	40.3
Total	144	100.0

On analysis of individual social questions, it can be generalised that family support is somewhat limited for most participants. Family-related questions elicited responses that were at the lower end of the scoring system, and ranged from a mean of 1.9–2.9. However, the social clubs / support groups were perceived to have a positive impact (mean=3.4) on health services utilisation. Economic questions were at the lower end of the scale, with food security relatively poor (mean= 2.8) and income even lower (mean= 2.4).

Table 6: Perceptions towards socio-economic questions

Socioeconomic questions (1 = strongly disagree and 5 = strongly agree)	N	Mean	SD
My family encourages me to attend clinic visit	144	2.72	0.927
My family encourages me to adhere to medication	144	2.92	0.990
My family ensures that I have taken my medication	144	2.52	0.987
My family accompanies me to the clinic meetings	144	1.89	0.739
Clubs encourage couple counselling and testing	144	3.43	1.068
I always have adequate food to eat while taking medication	144	2.8	0.549
My income can cover my basic needs	144	2.4	0.855

4.2.4 Disease-related factors

From an aggregated score of responses to the disease-related questions, only 15% of participants demonstrated a resilience to these factors, with a majority (51%) being moderately affected, and 33% being severely affected. Therefore, approximately 85% of the study participants were more likely to adhere poorly to TB medications owing to various factors such as comorbidities and personal perceptions of wellbeing / health status.

Table 7: Overall participant responses to disease-related questions

Aggregated responses on disease-related factors	Frequency	Per cent
Minimal effects	22	15.6
Moderate effects	72	51.1
High effects	47	33.3
Total	141	100.0

Almost all of the participants (99%) reported that they sometimes forget to take medications, and they had forgotten to take their medications at least once in the previous two weeks. Comorbidities are high among patients, with 58% taking other medications while on TB treatment. Self-prognosis on wellbeing is significantly high, and 44% reported a tendency to stop medications when they were seemingly in recovery. About 10% feel that they are forced to remain compliant with treatment regimens when they are feeling better.

Table 8: Summary of responses on disease-related factors

Disease-related questions		N	Frequency	Per cent
Do you sometimes forget to take your pills?	No	144	2	1.4
	Yes		142	98.6

Disease-related questions		N	Frequency	Per cent
People sometimes miss taking their medication for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?	No	144	1	0.7
	Yes		143	99.3
Have you ever cut back or stopped taking your medication without telling your doctor/nurse, because you felt worse when you took it?	No	144	138	95.8
	Yes		6	4.2
When you travel or leave home, do you sometimes forget to bring along your medication?	No	141	125	88.7
	Yes		16	11.3
Were you taking other medication while taking TB medication?	No	144	60	41.7
	Yes		84	58.3
When you feel that your health is under control, do you sometimes stop taking medication?	No	144	81	56.3
	Yes		63	43.8
Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	No	144	129	89.6
	Yes		15	10.4

None of the participants reported never forgetting to take medications, and the majority (90%) highlighted that they forget taking medication on a few occasions. However, 2% of the participants reported that that forget to take their medications all the time.

Table 9: Frequency of forgetting to take medications

How often do you have difficulty remembering to take your medication?	Frequency	Per cent
All the time	3	2.1
Once in a while	129	89.6
Sometimes	10	6.9
Usually	2	1.4
Total	144	100.0

The highest reasons for defaulting on medications were the high number of pills (22%), stigma (21%), and transport challenges (19%), i.e. failing to afford transport. Of the respondents, 11% reported concerns with health services, particularly in terms of the treatment they receive from health workers, and 10% cited that the opening and closing times of the clinics conflicted with their working hours and that they could not collect their medications.


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Table 10: Reasons for defaulting on TB medications

Reasons for stopping medication	Frequency	Per cent
Valid Alcohol	4	2.8
Health services	16	11.1
Job	15	10.4
Moved	4	2.8
Pill numbers	31	21.5
Recovery	10	6.9
Side effects	3	2.1
Stigma	30	20.8

Stress	3	2.1
Transport	28	19.4
Total	144	100.0

4.2.5 Association tests

ANOVA was used to assess the difference between independent (demographic indicators) and dependent (health services delivery, socioeconomic and diseases related) factors. Significant differences were noted between an individual's employment status and their socioeconomic factors ($F_{8.975}$, $p < 0.003$), household size and health services-related factors ($F_{3.245}$, $p < 0.002$). The relationship between household size and socioeconomic factors ($F_{2.923}$, $p < 0.005$) resulted in a p-value exactly equal to 0.005.

Table 11: Summary of regression and ANOVA results between demographics and TB-related adherence factors

ANOVA and simple linear regression analysis

Independent variables	Dependent variables	Regression R value	ANOVA statistic	F	ANOVA Significance
Gender	Service delivery	0.094	1.258		0.264
	Socio-economic	0.023	0.073		0.787
	Disease related	0.035	0.168		0.683
Education	Service delivery	0.030	0.126		0.724
	Socio-economic	0.164	3.909		0.050
	Disease related	0.025	0.083		0.773
Employment	Service delivery	0.098	1.372		0.243
	Socio-economic	0.244	8.975		0.003*

	Disease related	0.126	2.241	0.137
Residence type	Service delivery	0.054	0.408	0.524
	Socio-economic	0.040	0.230	0.632
	Disease related	0.085	1.007	0.317
Household size	Service delivery	0.104	3.245	0.002*
	Socio-economic	0.110	2.923	0.005*
	Disease related	0.085	1.251	0.275

The strength of the relationships between the independent and dependent variables was assessed using simple linear regression. The results of the regression analysis (R value) are presented in Table 11 above.

4.3 Discussion and Findings

The present study has been one of the very few research endeavours to identify factors associated with compliance to TB treatment in Nelson Mandela District. The patients reported that a lack of financial support, limited access to transport, poverty, lack of treatment knowledge, lack of access to health services and stigma were the major constraints affecting their goal to achieve optimal treatment adherence. This section focuses on discussions and the results of the research under the following themes: health related factors, social support and knowledge regarding tuberculosis.

4.3 .1 Factors influence TB medication adherence

A number of important themes were identified from the analysis of the insights from patients in the qualitative study. These themes included service factors, discrimination, low social and family support, disease-related factors, medication side-effects, age, risk behaviours, knowledge, and illness severity.

Most of the findings in this study where the critical barriers to adherence were identified as those with low family income, alcohol use, high levels of psychological distress, perception of stigmatization, lack of treatment knowledge and an external health locus of control. The facilitating adherent factors included the no support of care providers, and patients who had no caregivers or somebody to remind them of medication time.

4.3.1.1 Service delivery factors

Health worker attitudes, clinic opening times, availability of medicines, and accessibility issues (distance and cost of getting to the health facility) have been shown in other studies to be important factors affecting TB treatment compliance. This is because health worker attitudes, such as being unfriendly to patients, tend to deter patients from seeking treatment or coming to collect medicines once they are finished. The findings regarding service delivery factors, all participants were generally satisfied with the quality of health services. However, poor provider–patient relationships impact negatively on care-seeking behaviour and health services utilization (Kebede & Wabe, 2012). From the respondents, the lowest scoring health services question related to the treatment of patients by health workers (mean=2.93 with a standard deviation of 1.022), and limited information regarding the medications that patients receive (mean=2.99 with a standard deviation of 0.964).

TB patients were likely to receive a short duration of individualized service with insufficient information, and no proper counselling services, which means they were less likely to adhere to treatment after enrolment (Orr, 2011). The findings from these probing questions were validated by the open-ended question where 11% of patients cited that they stopped medications owing to health services. To this question, participants reported that health workers shouted at them for coming late after lunch) and that there were long waiting times. Such poor services to meet patients' needs also result in patients extending their treatment duration, delaying seeking treatment, and/or being more likely to consider alternative treatments such as seeing a traditional healer (Finnie, Khoza, van den Borne, Mabunda, Abotchie, & Mullen, 2011).

Clinic opening times may be inconvenient, particularly to patients who are also employed, as the clinic times are often the same working hours of the patients. More than 60% of the respondents would prefer the clinic to have flexible opening hours, that is opening before 08h00 and closing after 17h00. Therefore, flexible hours may be necessary to cater for the employed patients.

Distance and cost of travelling to the clinic were not significant factors affecting treatment compliance and it was interesting to note a significant proportion (80%) of patients who did not complete treatment were staying within five kilometres of the TB clinic and did not have to pay any money to travel there. This could mean that while distance and medicine availability may not be deterring factors for patients to come to pick up their medicines on time, other healthcare system factors such as health worker attitudes, clinic opening times and waiting times at the clinic could be influencing compliance to treatment. Similarly, clinic opening times were not a significant factor affecting TB treatment compliance. This finding may be due to most of the patients being unemployed and therefore the usual clinic opening times being adequate for them. The time patients had to wait at the clinic before being attended to was however a significant factor contributing to treatment compliance, as the patients who waited longer than an hour were more likely to be non-compliant with treatment.

family support in treatment and adherence for most of the respondents was generally limited

Other barriers to effective TB treatment compliance and adherence were stigma (20%) and the perceived high number of pills (21%). In addition, the findings from the study are consistent with previous TB-related studies in South African communities that noted that perceptions have a stronger influence on health seeking behaviour and treatment adherence as opposed to health knowledge (Cramm, Finkenflugel, Moller & Niboer, 2010). Based on the previously discussed demographics that suggest poverty and related limited access to health services owing to transport, the demographics and social findings are consistent with another recent study in South Africa by Skinner & Claassens (2016).

4.3.2 Socio-economic factors

The findings regarding socio economic factors, the mean age for respondents was 33 years (Std. Dev = 12), making the majority of them part of the economically active population. However, unemployment rates among respondents was at 78% and with limited education achievement, 69% had below matric. These indicators constitute a highly vulnerable community that heavily depends on subsidised healthcare from the state, and with few who can afford medical aid. Studies in the African context on HIV and TB have highlighted the strong interlinkages between access to care and socio-economic status (Kebede & Wabe, 2012; Skinner & Claassens, 2016). The results of a KAP survey also supported the finding that financial constraints are a major issue when it comes to TB treatment (Ministry of Health Timor Leste, 2011). Therefore, government being their primary and presumably only access to health services, it is imperative that the services be accessible and with a high quality of care to ensure universal health coverage and reduced health disparities.

Social and economic factors contributed to overall TB treatment adherence. If individual patients were socially connected and economically stable, it was more likely that these factors influenced their treatment adherence in a positive way. However, those who experienced social isolation and economic instability would likely to find it difficult to meet the expectations of medication adherence throughout the treatment process. This was likely to be due to patients who underwent treatment being absent from their jobs or lacking the ability to earn, and, therefore, being less likely to sustain an income. This may affect their psychological well-being, knowing that it would be six to eight months before the treatment could be completed.

Financial security for a patient undergoing treatment has been identified as one of the most important factors in adherence. Although TB drugs are free for patients in some countries, inaccessibility of services, which requires commitments to travel and transport can cost more than purchasing the drugs. A report from the WHO on the evidence for action to sustain long-term therapies also identified finance as a contributing factor to adherence (WHO, 2018). Furthermore, a synthesis of cross-

sectional survey and qualitative research in China found that cost was the most cited reason for treatment default. It has been found to be worse in cases where providers utilize patients as a way of generating revenues. Cost associated with treatment forced patients to give up due to conflicts between work and treatment, treatment-related costs, expenses exceeding available resources (Qian, Smith, Tuohong, Shenglan & Garner, 2011).

Studies have also reported that social connectedness is crucial in encouraging patients to successfully follow the treatment regimens (Do, Dunne, Kato, Pham, & Nguyen, 2013). Additionally, those who lacked support are expected to have a poor treatment outcome. This is evident in the findings of the current study in which patients who lacked caregivers and people to remind them of medication times were associated with non-adherence. These findings are consistent with the results of a study which investigated TB/HIV co-infected patients in Ethiopia (Eticha & EKassa, 2014).

Along with financial problems, stigma related to TB has been identified as an important element that influences those affected by TB (Kipp et al., 2011a). Stigma is a socially constructed phenomenon which reflects prevailing attitudes and behaviours of others towards individuals affected by a disease or disability. The experience of stigma can cause people to socially isolate themselves from family, health professionals and other people to avoid becoming a subject of gossip. Consequently, patients who encountered stigmatization have severe suffering, which, in turn, results in non-compliance. Several studies have described the impact of stigma on tuberculosis medication adherence. Research has shown that patients may not want others to know of their regimen intake, as they often encounter stigmatization, and negative reactions and/or responses related to their treatment status (Kipp, Pungrassami, Nilmanat, Sengupta, Poole, Strauss, & Van Rie., 2011a; Yang, Wonpat-Borja, Opler, & Corcoran, 2010). Potential stigma associated with inclusion of the psychosis risk syndrome in the DSM-V: An empirical question. *Schizophrenia Research*, 120(1–3), 42-48. 2010). Studies of TB stigma and factors associated with adherence, such as level of education, gender and religion (Dodor & Kelly, 2010; Johansson et al., 2000; Kipp et al., 2011a), incorrect knowledge of its cause, mode of transmission and treatment

(Dodor & Kelly, 2010), and contagiousness of TB transmission (Mavhu , Dauya, Bandason, Munyati, Cowan, Hart & Chikovore , 2010) have also been conducted in other countries.

4.3.1.3 Disease-related factors

The findings regarding health-related diseases, 54,3 % were taking other medications while taking TB medication. TB compliance remains an issue in South Africa mainly owing to the close association between TB and HIV, and South Africa has one of the highest HIV rates in the world (Cramm et al, 2010). Latest reports show no significant progress and a stagnation in coverage of TB services. In South Africa many people, even the very poor, first seek care in the non-NTP private sector. The current care gap of approximately 160 000 missing TB cases requires a shift in the current management approach, if the target of ending TB is to be achieved. The Stop TB partnership has adopted the 90 90 90 strategy, and has also advocated for the involvement of the private sector (Skinner & Claassens, 2016).

This finding also highlighted that 6.9% did stop taking their medication after feeling better due to a lack of knowledge about the treatment process. It was also likely that the health professionals had provided limited information relating to the treatment process at the time of the treatment enrolment. This finding could be attributable to lack of health education and counselling that would inform the patient to continue until the treatment period is completed and until they are discharged by the health worker. Moreover, there were also a number of important factors that directly influenced the treatment outcomes, such as knowledge and understanding of the treatment process, in terms of side-effects, and consequences of not completing the treatment successfully (i.e. death, development of MDR-TB, further spread of the disease).

Individual risk behaviours, such as alcohol use and cigarette smoking were found to influence the overall outcome of TB treatment. Alcohol consumption has been reported from other settings to be directly associated with non-adherence. According to an HIV/AIDS study in Vietnam that investigated factors associated

with optimal antiretroviral medication adherence, alcohol use was found to be significantly associated with medication non-adherence (Do, et al., 2013). The findings of the present study were consistent with the previous study, suggesting that alcohol consumption was significantly associated with suboptimal medication adherence.

People with TB who are depressed may also experience impaired ability to follow treatment (Do, 2011). This may be because within the treatment context, patients have negative thoughts, anxiety and feelings of hopelessness associated with their treatment. Therefore, such feelings may impact on their ability to cope with the illness, thereby increasing the likelihood of ceasing treatment because they feel they are unable to control events in their lives (Do et al., 2013). The present study indicates that people with stress are among of those who stopped taking treatment. Some of these findings are consistent with the qualitative component of a HIV/AIDS adherence study in Vietnam (Do, 2011) and a study in Ethiopia that investigated the pattern of depression in patients with TB (Adem, Tesfaye, & Mohammed, 2014).

Findings, from the ANOVA, significant differences were noted between an individual's employment status and their socio-economic factors ($F_{8,975}$, $p < 0.003$); household size and health services-related factors ($F_{3,245}$, $p < 0.002$). The relationship between household size and socio-economic factors ($F_{2,923}$, $p < 0.005$) resulted in a p-value exactly equal to 0.005. However, post-hoc analysis of the data was not conducted to assess the exact groups that were different. In addition, the strength of the relationships between these factors were assessed using simple linear regression. From the regression analysis, weak associations were noted between demographic characteristics employment status and household size and the service delivery, socio-economic and disease-related factors, as shown in Table 11. While simple linear regression was used, these social, socio-cultural, and socio-economic factors are interwoven, and multinomial regression modelling may be needed from larger-scale studies to generate accurate predictive models for TB adherence in the South African context (Skinner & Claassens, 2016).

4.3.2 Self-efficacy

The discussion draws on the conceptual framework which is based on the self efficacy model. Self-efficacy influences the possibility of an individual patient being motivated to comply with treatment. Patients can be verbally persuaded to take their treatments by either health worker through health education at the start of the treatment and reinforcement throughout treatment period and follow-up, or the treatment or DOT supporters. In this study lack of knowledge of TB and treatment was a significant factor contributing to non-compliance to treatment. The treatment supporter role could also be improved by ensuring treatment supporters do observe the actual swallowing of medicines by the patients, and where a patient has missed their doses the supporter can encourage the patient to resume and continue taking their medicines. Verbal persuasion however does not provide the strongest self-efficacy as the motivation is derived externally. Health workers who have seen other patients complying with and completing their TB treatment could include these success stories in health education sessions, thus motivating TB patients (vicarious experience). Performance accomplishments through taking treatment correctly and getting better on treatment should provide the strongest self-efficacy, as the patient will be internally motivated. However, feeling better had the opposite effects, probably more due to lack of education or information on why they need to complete treatment than to lack of belief in the TB treatment efficacy.

4.4 Conclusion

This chapter presented concisely the findings from data collected from TB patients who had defaulted on treatment. From the participant responses, most patients were satisfied with the infrastructure and general management of the health facility with regard to the availability of medications and general accessibility of the facility for various groups, like the disabled. Family support towards TB patients for health facility visits and adherence to medication was very limited for most respondents.

Health education for patients on their treatment regimen was noted to be poor. In addition to this, relationships between health workers and patients seemed poor and therefore affected health-seeking behaviour and treatment adherence. The next chapter presents all the key findings of the study, and makes key conclusions and recommendations from the study.



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5 CHAPTER FIVE: RESULTS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

The preceding chapter presented, in full detail, all the pertinent results from the study. The study aimed to identify the factors that influence adherence to TB treatment among TB patients in a low-income community. In this chapter, a summary of key results is presented and then the chapter draws conclusions from the study findings. The chapter closes by making recommendations that are levelled at improved TB treatment adherence.

5.2 Results

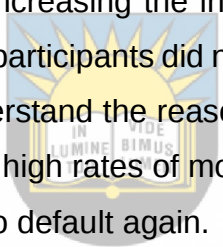
The study showed that defaulting on TB treatment occurred regardless of key demographics such as age, gender and income. In addition, occasionally forgetting to take medication was common among all study participants. The key barrier to services utilization and treatment adherence was the perceived stigma associated with TB. Lastly, self-diagnosing and stopping medication when one feels one's health has improved is significantly high among patients. This is of grave concern to public health as it poses risks of the development of drug resistance.

Of socio-economic factors, poverty was a key determinant of treatment adherence. As it is a low-income community, some patients fail to secure transport money for trips to the health facility, resulting in defaulting on treatment. In addition, limited family support in treatment adherence and health facility visits was associated with poor treatment adherence and outcomes. Membership of other social groups for patients was linked to improved motivation for treatment adherence among TB patients.

5.3 Conclusions

According to the self-efficacy model used in this study, a person's belief about his/her ability and confidence in performing at a certain level to achieve certain goals under difficult circumstances was confirmed. The findings of this study revealed that clients did not have confidence in taking the TB treatment because they lacked knowledge regarding the side effects of the drugs, and to report when they have missed the pills, lack of confidence leads to inability to reach the goal of adhering to treatment.

The most important unresolved challenge in tuberculosis control is the treatment completion. Treatment will only be effective if the patient completes the regimen which includes a combination of drugs. Poor compliance contributes to the worsening of tuberculosis by increasing the incidence of it and by initiating drug resistance. In this study all the participants did not finish their treatment for different reasons. It is important to understand the reasons behind defaulting so that it can be minimized as it may lead to high rates of mortality. It has also been shown that defaulters have the tendency to default again.



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Behavioural factors broadly affect TB program in two ways; first, they influence patient's health-seeking behaviour. Second, they impact medication adherence and completion rates. Participants fear stigmatization, the attitude of health staff, peers and community members lead to stop taking TB treatment.

5.4 Recommendations

South Africa has made impressive progress in addressing the issues of universal health access, and more importantly, in the treatment of communicable diseases such as TB and HIV. In this regard, and to continue upholding public health, the following recommendations would further improve health services access and utilisation among TB patients:

5.4.1 Recommendations for health practice

- Education strategies need to prioritise dispelling community perceptions and the stigma associated with TB, especially by delinking TB and HIV as separate diseases.
- Health workers need to be sensitised about the importance of provider–patient relationships and how this relationship influences both health-seeking behaviours and service utilisation. This entails training about courtesy, full disclosure of information to patients, and managing personal stigma and biases towards certain patients or medical conditions.
- Health promotion strategies have to be priorities in the prevention and management of TB.

5.4.2 Recommendations for policy makers

- There is a need for strategies to integrate aspects of quality health services into public health services, e.g. client satisfaction surveys to improve service utilisation.
- The current care gap of approximately 160 000 missing TB cases requires a shift in the current management approach, if the target of ending TB is to be achieved. The approach has to be more focused on enabling people to take care of their health.

5.4.3 Recommendations for further research

- Further research, particularly large-scale nationally representative studies, is needed to fully elucidate the key determinants of poor TB adherence.
- Innovative strategies are needed for the resupply of medications for both chronic and stigmatised conditions to motivate patients to continue adhering to treatment, e.g. eliminating multiple human contacts in the continuum of care, or the use of new technologies for drug collections, e.g. Pelebox smart lockers.



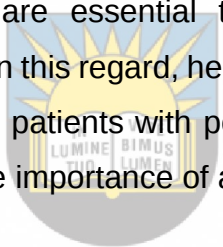
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5.5 Conclusion

There are several determinants that affect compliance with TB treatment programmes in South Africa. Access to health services and adherence to treatment are greatly influenced by poverty, employment status, family size, provider–patient relationships, TB-related stigma perceptions, and the treatment regimen.

Government services have bridged an essential gap in universal health access for poor communities, and the communities appreciate the essential role of these services. Satisfaction with the physical / structural amenities is high among the community members. However, there remain concerns about the provider–patient relationships to ensure that health-seeking behaviours are encouraged and that patients feel comfortable opening up to providers.

Health promotion strategies are essential to ensure health literacy among vulnerable population groups. In this regard, health workers at local health facilities can support them by providing patients with pertinent information regarding their medications and reinforcing the importance of adherence.

The logo of the University of Fort Hare is a circular emblem. It features a central shield with a sunburst at the top. Inside the shield, the Latin motto "LUMINE BINOUS TIO LUMEN" is written. The shield is flanked by two vertical bars. The entire emblem is set against a light blue background.

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University of Fort Hare
Together in Excellence

APPENDICES

Appendix A: Ethical clearance certificate



University of Fort Hare Together in Excellence

ETHICAL CLEARANCE CERTIFICATE REC-270710-028-RA LEVEL 01

Certificate Reference Number: PINOISSOHOI

Project title: Treatment adherence among tuberculosis patients in Nelson Mandela District, Eastern Cape Province

Nature of Project: Masters of Public Health

Principal Researcher: Sohuma N

Supervisor: Prof M Pinkoane

Co-supervisor: N/A

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

Please note that the UREC 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 UREC in the prescribed format, where applicable, annually, and at the end of the project, in respect of ethical compliance.

Special conditions: Research that includes children as per the official regulations of the act must take the following into account:

Note: The UREC is aware of the provisions of 71 0 the National Health Act of 2003 and that matters pertaining to obtaining the Minister's consent under discussion and remain unresolved. Nonetheless, as was decided at a meeting between the National Health Research Ethics Committee and stakeholders on 6 June 2003, university ethics committees may continue to grant ethical clearance for research involving children without the Minister's consent, provided that the prescripts of the previous rules have been met. This certificate is granted in terms of this agreement.

The UREC retains the right to

- Withdraw or amend this Ethical Clearance Certificate if o Any unethical principal or practices are revealed or suspected relevant information has been withheld or misrepresented or regulatory changes of whatsoever nature so require to 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.
- 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 the Dean of Research's office.

The Ethics Committee wished you well in your research.

Yours sincerely



Professor Eunice Seekoe
Dean of Faculty of Health Science
30th November 2018



Professor Pumla Dineo Gqola: Dean of Research
30th November 2018

Appendix B: Authorization letter from the Department of Health



Enquires: Zorwabele Merile

Tel no: 083 378 1202

Email: zorwabele.merile@echealth.gov.za

Fax no: 043 642 1409

Date: 10 April 2019

RE: Treatment adherence among Tuberculosis patients in Qgebera clinic at Nelson Mandela District, Eastern Cape, South Africa. (EC_201904_009)

Dear Ms Ntombifikile Sohuma

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE

Appendix C: Authorisation letter from the Nelson Mandela Bay Health District

 Province of the EASTERN CAPE HEALTH	Office of the Clinical Governance Manager Nelson Mandela Bay Health District Private Bag 228000, Greenacres, Port Elizabeth, 6057, REPUBLIC OF SOUTH AFRICA
	Enquiries : Dr L P MAYERISO Telephone : 041-391-8173 Facsimile : 041-391-8133 E-mail : mbasa.mayeriso@gmail.com

Our Reference: Your Reference: Date: 15 April 2019

Ms N. Sohumu
Nelson Mandela Bay Health District

**REQUEST FOR PERMISSION TO CONDUCT RESEARCH ON THE TREATMENT
ADHERENCE AMONG TUBERCULOSIS PATIENTS IN GQEBERA CLINIC AT NELSON
MANDELA DISTRICT, EASTERN CAPE, SOUTH AFRICA (EC-201904-009)**

In response to your application for permission to conduct the above research, permission is hereby granted with the following proviso:

- Health service delivery should not be disrupted under any circumstances.
- Timeous appointments must be made with the relevant persons prior to commencement of interviews/visits.
- All required data should be collected by the Researcher or a designated fieldworker (whose name should be forwarded to the relevant Sub District Coordinators prior to data collection). The Sub District Coordinators Messrs. Msutu – 083 378 1942, Koli – 060 563 1225 and Reuters – 060 557 9732 should be contacted **before** your visit and this letter is to be presented **when** visiting the facilities

The Nelson Mandela Bay Health District, as the research site, will expect a copy of the final research report when the study is completed. If the duration of the research period is required to be extended, the District Office (District Manager) should be informed accordingly.

This Office would like to wish you well in your research study.

Yours faithfully


DR L P MAYERISO
CLINICAL GOVERNANCE MANAGER – NMBHD

Appendix D: Information and Consent Form



Ethics Research Confidentiality and Informed Consent Form

Please note:

This form is to be completed by the researcher as well as the participant before the commencement of the research. Copies of the signed form must be filed and kept on record

I Ntombifikile Sohumu will be asking people from Nelson Mandela Metro to answer some questions, which we hope will benefit your community and possibly other communities in the future.

I am conducting research regarding treatment adherence among Tuberculosis in patients at Qgebera clinic in Nelson Mandela District, Eastern Cape, South Africa. I am interested in finding out more about the reasons given by patients who default in taking treatment. I am carrying out this research to help both the community and the department to improve treatment adherence among TB patients.

Please understand that you are not being forced to take part in this study and the choice whether to participate or not is yours alone. However, I would really appreciate it you do share your thoughts with me. If you choose not take part in answering these questions, you will not be affected in any way. If you agree to participate, you may stop me at any time and tell me that you don't want to go on with the interview. If you do this there will also be no penalties and you will NOT be prejudiced in ANY way. Confidentiality will be observed professionally.

I will not be recording your name anywhere on the questionnaire and no one will be able to link you to the answers you give. Only the researchers will have access to the unlinked information. The information will remain confidential and there will be no "come-backs" from the answers you give.

INFORMED CONSENT

I hereby agree to participate in research regarding Treatment adherence among tuberculosis patients in Qgebera clinic at Nelson Mandela District, Eastern Cape, South Africa. I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop this interview at any point should I not want to continue and that decision will not in any way affect me negatively.

I understand that this is a research project whose purpose is not necessarily to benefit me personally.

I have received the telephone number of a person to contact should I need to speak about any issues which may arise in this interview.

I understand that this consent form will not be linked to the questionnaire, and that my answers will remain confidential.

I understand that if at all possible, feedback will be given to my community on the results of the completed research.

.....
Signature of participant

date.....

I hereby agree to the interview of my participation in the study

.....
Signature of participant

date.....

Appendix E: Questionnaire schedule

OFFICE USE ONLY

Questionnaire #

District

Health Facility

Adherence Questionnaire

Section 1: Demographic Measures

- 1 Ethnicity Black 1 White 2 Asian 3 Coloured 4
- 2 Gender Male 0 Female 1
- 3 Type of dwelling Formal 1 Informal 2
- 4 Employment status Unemployed 1 Employed 2
- 5 Nationality South African 1 Non-South African 2
- 6 Average monthly income
- 7 Age
- 8 Marital Status Single 1 Married 2 Divorced 3 Cohabiting 4
Widowed 5
- 9 Highest Education below Matric 1 Matric 2 Certificate 3 Diploma 4
Degree
- 10 Number of people in household

Section 2: Health status

- 11 Date tested TB positive month/ year
- 12 Date started TB Treatment month/ year
- 13 Number of tablets taken daily 2 3 4 4

Section 3: Measurement of immediate outcome

Indicate the extent to which you agree or disagree to the following statements where 1= Strongly Disagree, 2= Disagree, 3= Neutral/ Don't know, 4= Agree, 5= Strongly Agree

- 14 I would prefer picking up my TB medication outside clinic hours (8am–5pm)
1 2 3 4 5
- 15 The waiting time to pick up medication is always less than two hours
1 2 3 4 5
- 16 I stay less than five km from this clinic 1 2 3 4 5
- 17 It cost me less that R50 to pick up my medication per visit
1 2 3 4 5
- 18 Health workers treat me with respect and dignity
1 2 3 4 5
- 19 Health workers provide all health information about my medication
1 2 3 4 5
- 20 Medication pick-ups are done in clean areas
1 2 3 4 5
- 21 medication pick-ups are done in safe areas
1 2 3 4 5
- 22 Medication pick-ups are accessible to the disabled
1 2 3 4 5
- 23 My medication is always available
1 2 3 4 5

Section 3:2 Socio-economic factors

- 24 My family encourages me to attend clinic visit
1 2 3 4 5
- 25 My family encourages me to adhere to medication
1 2 3 4 5
- 26 My family ensures that I have taken my medication
1 2 3 4 5
- 27 My family accompanies me to the clinic meetings
1 2 3 4 5

- 28 Clubs encourage couple counselling and testing
1 2 3 4 5
- 29 I always have adequate food to eat while taking medication
1 2 3 4 5
- 30 My income can cover my basic needs
1 2 3 4 5
- 31 Do you sometimes forget to take your pills?
Yes No
- 32 People sometimes miss taking their medication for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?
Yes No
- 33 Have you ever cut back or stopped taking your medication without telling your doctor/nurse, because you felt worse when you took it?
Yes No
- 34 When you travel or leave home, do you sometimes forget to bring along your medication?
Yes No
- 35 Were you taking other medication while taking TB medication?
Yes No
- 36 When you feel like your health is under control, do you sometimes stop taking medication?
Yes No
- 36 Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?
Yes No
- 37 How often do you have difficulties to remember to take your medications?
Once in a while Sometimes Usually All the time Never
- 38 Why did you stop taking your medication?

Thank you for participating

Appendix F1: Section of a Completed Questionnaire

OFFICE USE ONLY	
Questionnaire #	
District	
Health Facility	

Adherence Questionnaire

Section 1: Demographic Measures

1 Ethnicity: ☒ Black 1 ☐ White 2 ☐ Asian 3 ☐ Coloured 4 2 Gender: ☒ Male 1 ☐ Female 2

3 Type of dwelling: ☒ Formal 1 ☐ Informal 2 4 Employment status: ☒ Unemployed 1 ☐ Employed 2

5 Nationality: ☒ South African / Non South African 2 6 Average monthly income: _____ 7 Age: 44

8 Marital Status: ☒ Single 1 ☐ Married 2 ☐ Divorced 3 ☐ Cohabiting 4 ☐ Widowed 5

9 Highest Education: ☒ Below High School 1 ☐ Matric 2 ☐ Certificate / Diploma 3 ☐ Degree 4 10 Number of people in household: 5

Section 2: Health status 11 Date tested TB pos: 15.06.18 12 Date started TB Treat: month/year: _____ 13 Number of tablets taken daily: 2 3 4

Section 3: Measurement of immediate outcome

Indicate the extent to which you agree or disagree to the following statements where:
1= Strongly Disagree, 2= Disagree, 3= Neutral / Don't know, 4= Agree, 5= Strongly Agree

Section 3.1 Health Related Factors

14 I would prefer picking my TB medication outside clinic hours (Even-Open)	1	2	☒ 3	4	5
15 The waiting time to pick up medication is always less than 2 hours	1	2	☒ 3	4	5
16 I stay less than 5 km from the clinic	1	2	☒ 3	4	5
17 It cost me less than \$50 to pick up my medication per visit	1	2	☒ 3	4	5
18 Health workers treat me with respect and dignity	1	2	☒ 3	4	5
19 Health workers provide all health information about my medication	1	2	☒ 3	4	5
20 Medication pick ups are done in clean areas	1	2	☒ 3	4	5
21 Medication pick ups are done in safe areas	1	2	☒ 3	4	5
22 Medication pick up are accessible to the disabled	1	2	☒ 3	4	5
23 My medication is always available	1	2	☒ 3	4	5

Section 3.2 Socio-economic factors

24 My family encourages me to attend clinic visit	1	2	☒ 3	4	5
25 My family encourages me to adhere to medication	1	2	☒ 3	4	5
26 My family ensures that I have taken my medication	1	2	☒ 3	4	5
27 My family accompanies me to the clinic meetings	☒ 1	2	3	4	5
28 Clinic encourages couple counselling and testing	1	2	☒ 3	4	5
29 I always have adequate food to eat while taking medication	1	2	3	☒ 4	5
30 My income can cover my basic needs	1	2	3	4	☒ 5

Section 3.3 Disease related aspect

31 Do you sometimes forget to take your pills?	Yes ☒	No			
32 People sometimes miss taking their medication for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your pills? Have you ever cut back or stopped taking your medication without telling your doctor/nurse. Because you felt worse when you took it?	Yes ☒	No			
33 When you travel or leave home, do you sometimes forget to bring along your medication?	Yes ☒	No			
34 Were you taking other medication while taking TB medication?	Yes ☒	No			
35 When you feel like your health is under control, do you sometimes stop taking medication?	Yes ☒	No			
36 Taking medication everyday is a real inconvenience for some people. Do you ever feel frustrated about sticking to your treatment plan?	Yes ☒	No			
37 How often do you have difficulties to remember to take your medications?	Once a while	Sometimes	Usually	Always	Never
38 Why did you stop taking your medication?	<u>alcoholic</u>				

Thank you for participating

Appendix F2: Section of a Completed Questionnaire

OFFICE USE ONLY	
Questionnaire #	
District	
Health Facility	

Adherence Questionnaire

Section 1: Demographic Measures

1 Ethnicity: ☒ Black 1 ☐ White 2 ☐ Asian 3 ☐ Coloured 4 2 Gender: ☐ Male 3 ☐ Female 1

3 Type of dwelling: ☐ Formal 1 ☒ Informal 2 4 Employment status: ☐ Unemployed 1 ☐ Employed 2

5 Nationality: ☒ South African ☐ Non South African 2 6 Average monthly income: 3 500 7 Age: 35

8 Marital Status: ☒ Single 1 ☐ Married 2 ☐ Divorced 3 ☐ Cohabiting 4 ☐ Widowed 5

9 Highest Education: ☐ none matric 1 ☒ Matric 2 ☐ Certificate/Diploma 3 ☐ Degree 4 10 Number of people in household: 3

Section 2: Health status 12-01-18 3-23-18

11 Date tested TB (yy-mm-dd) 12 Date started TB Treatment (yy-mm-dd) 13 Number of tablets taken daily: 3 ☒ 4

Section 3: Measurement of immediate outcomes

Indicate the extent to which you agree or disagree to the following statements where
1= Strongly Disagree, 2= Disagree, 3= Neutral/Don't know, 4= Agree, 5= Strongly Agree

Section 3.1 Health Related Factors

14 I would prefer picking my TB medication outside clinic hours (8am-4pm)	1	2	3	4	5
15 The waiting time to pick up medication is always less than 2 hours	1	2	3	4	5
16 I stay less than 5 km from this clinic	1	2	3	4	5
17 It cost me less than R50 to pick up my medication per visit	1	2	3	4	5
18 Health workers treat me with respect and dignity	1	2	3	4	5
19 Health workers provide all health information about my medication	1	2	3	4	5
20 medication pick ups are done in clean areas	1	2	3	4	5
21 medication pick ups are done in safe areas	1	2	3	4	5
22 Medication pick up are accessible to the disabled	1	2	3	4	5
23 My medication is always available	1	2	3	4	5

Section 3.2 Socio-economic factors

24 My family encourages me to attend clinic visit	1	2	3	4	5
25 My family encourages me to adhere to medication	1	2	3	4	5
26 My family ensures that I have taken my medication	1	2	3	4	5
27 My family accompanies me to the clinic meetings	1	2	3	4	5
28 Clinics encourage couple counselling and testing	1	2	3	4	5
29 I always have adequate food to eat while taking medication	1	2	3	4	5
30 My income can cover my basic needs	1	2	3	4	5

Section 3.3 Disease related aspect

31 Do you sometimes forget to take your pills?	Yes ☒	No ☐
32 People sometimes miss taking their medication for reasons other than forgetting.	Yes ☒	No ☐
33 Thinking over the past two weeks, were there any days when you did not take your pills?	Yes ☒	No ☐
34 Have you ever not been or stopped taking your medication without talking your doctor/nurse, because you felt worse when you took it?	Yes ☒	No ☐
35 When you travel or leave home, do you sometimes forget to bring along your medication?	Yes ☒	No ☐
36 Were you taking other medication while taking TB medication?	Yes ☒	No ☐
37 When you feel like your health is under control, do you sometimes stop taking medication?	Yes ☒	No ☐
38 Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	Yes ☒	No ☐
39 How often do you have difficulties to remember to take your medications?	Once a while	Sometimes
40 Why did you stop taking your medication?	Usually	All the time

I am taking the drug 4 times a day and 950 on weekends!

Thank you for participating

Appendix G: Data Co-Coder Letter

Date: 23/12/2019

LETTER OF CLEARANCE FROM THE BIOSTATISTICIAN

This letter is to confirm that the student, with the Name(s)

SOHUMA NTOMBIFIKILE

Studying at the University of FORT HARE

submitted the Project with the title:

“Treatment adherence among Tuberculosis patients in Qgebera Clinic at Nelson Mandela District, Eastern Cape, South Africa”

to me for statistical review. I hereby confirm that the statistical methods used in the analysis are appropriate to answer the objectives of the study. A qualitative cross-sectional survey was conducted using thematic content analysis to determine determinants that drive poor treatment adherence among TB patients residing in low income communities in South Africa.

Name: Dr Alfred Musekiwa

Date: 23/12/2019

Signature



Tel: 012 356 3253

Department or Unit: SCHOOL OF HEALTH SYSTEMS AND PUBLIC HEALTH

*Letter compiled by:
Dr Alfred Musekiwa
University of Pretoria
SHSPH
Biostatistics section
December 23, 2019*

Appendix H: Letter from the Biostatistician

The Best Health Solutions



107 Louis Botha Avenue, Orange Grove, Johannesburg, South Africa • Phone: +27 (0) 057 6661 • Fax: +27 (0) 86 598 5221 E-Mail: info@besthealthsolutions.co.za Web: www.besthealthsolutions.co.za

The University of Fort Hare
Ring Road, Alice, 5700
Eastern Cape, ZA

Dear Sir/Madam,

RE: REPORT EDITING AND WRITING INTEGRITY ASSURANCE FOR SOHUMA NTOMBIFIKILE

This letter serves to inform you that the research project by the above-mentioned student, titled *"Treatment adherence among Tuberculosis patients in Qgebera Clinic at Nelson Mandela District, Eastern Cape, South Africa"* was supported independently by our organization with myself overseeing the process. Specifically, the support was focused on professional report writing.

In this regard, the document was edited for proper outline and English (United Kingdom) grammar, punctuation and spelling. From the editing, it is my opinion that the writing quality in the research report meets the university expectations for dissertations as well as conforms to the writing guidelines provided by the university.

Sincerely,

Antony K. Chiromba (BS, M.P.H, M.B.A)
Research Officer
The Best Health Solutions
107 Louis Botha Avenue
Orange Grove
Johannesburg, 2192
Tel: +27 (0) 11 057 6661
Email: antony@best-health.co.za

APPENDIX I: EDITING CERTIFICATE

The Best Health Solutions



107 Louis Botha Avenue, Orange Grove, Johannesburg, South Africa • Phone: +27 (0) 057 6661 • Fax: +27 (0) 86 598 5221 E-Mail: info@besthealthsolutions.co.za Web: www.besthealthsolutions.co.za

The University of Fort Hare
Ring Road, Alice, 5700
Eastern Cape, ZA

Dear Sir/Madam,

RE: REPORT EDITING AND WRITING INTEGRITY ASSURANCE FOR SOHUMA NTOMBIFIKILE

This letter serves to inform you that the research project by the above-mentioned student, titled *"Treatment adherence among Tuberculosis patients in Qgebera Clinic at Nelson Mandela District, Eastern Cape, South Africa"* was supported independently by our organization with myself overseeing the process. Specifically, the support was focused on professional report writing.

In this regard, the document was edited for proper outline and English (United Kingdom) grammar, punctuation and spelling. From the editing, it is my opinion that the writing quality in the research report meets the university expectations for dissertations as well as conforms to the writing guidelines provided by the university.

Sincerely,

Antony K. Chiromba (BS, M.P.H, M.B.A)
Research Officer
The Best Health Solutions
107 Louis Botha Avenue
Orange Grove
Johannesburg, 2192
Tel: +27 (0) 11 057 6661
Email: antony@best-health.co.za

APPENDIX J: EDITING CERTIFICATE

Prof M.G. Pinkoane
University of Fort Hare
East London Campus

Editing of Master's Thesis

I, Marietjie Alfreda Woods, hereby certify that I have completed the editing and correction of the mini thesis, **Treatment Adherence Among Tuberculosis Patients at Gqebera Clinic, Nelson Mandela District, Eastern Cape, South Africa** by **Ntombifikile Sohuma**, in partial fulfilment of the requirements for the Master's degree in Public Health in the Faculty of Health at the University of Fort Hare.

I believe that the thesis meets with the grammatical and linguistic requirements for a document of this nature.

Name of Editor: Marietjie Alfreda Woods

Qualifications: BA (Hons) (Wits)

Copy-editing and Proofreading (UCT)

Signature:

Contact Number: 083 312 6310

Email address: rickywoods604@gmail.com

Date Issued: 10 November 2020



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