

**RISK FACTORS INFLUENCING THE EPIDEMIOLOGY OF DRUG RESISTANT
TUBERCULOSIS PATIENTS ENROLLED FOR TREATMENT AT THE NATIONAL
TUBERCULOSIS REFERRAL HOSPITAL, SWAZILAND**

by

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submitted in accordance with the requirements

for the degree of

MASTER OF PUBLIC HEALTH

at the

UNIVERSITY OF SOUTH AFRICA

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NOVEMBER 2015

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DECLARATION

I declare that **RISK FACTORS INFLUENCING THE EPIDEMIOLOGY OF DRUG RESISTANT TUBERCULOSIS PATIENTS ENROLLED FOR TREATMENT AT THE NATIONAL TUBERCULOSIS REFERRAL HOSPITAL, SWAZILAND** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

08 February 2016

.....

Ntombifuthi Shongwe

.....

Date

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ABSTRACT

The purpose of this study was to establish empirical evidence on risk factors influencing drug-resistant tuberculosis (DR-TB) in Swaziland. Globally factors have been identified and specific programmatic interventions were implemented to counter the emergence of DR-TB, but the case still remains with Swaziland. The research question was “What are the risk factors influencing the epidemiology of DR-TB patients enrolled for treatment at the National Tuberculosis Referral Hospital? The research objectives were to investigate factors that influence the emergence of DR-TB in Swaziland, to establish the relationship between DR-TB and HIV and to develop a poster that will exhibit the findings on the study on risk factors influencing the epidemiology of DR-TB. A mixed method was used. A qualitative study of participants using the in-depth one on one interview with a grand tour question “ What are the risk factors that resulted in you having DR-TB” and probing questions. The quantitative retrospective part was utilised to review medical records. Convenience sampling was utilised to recruit participants using an interview guide to collect data and random sampling for the quantitative aspect using a checklist to collect data.

Risk factors influencing the development of DR-TB were identified to be previous treatment with anti-tuberculosis drugs, human immunodeficiency virus (HIV). The findings showed that the prevalence of HIV in DR-TB was 61% for HIV positive and 39% for negative and the quantitative data showed 77% HIV positive and 23% negative to HIV. Lack of education for patients and their families on precautionary measures to take when caring for a family member, and what to do in cases of developing side effects.

This study concludes that both the need to ensure that bacteriologically confirmed patients are initiated to treatment, adhere to their treatment and complete treatment and due to the number of direct cases being infected with DR-TB ensuring that infection control strategies are put in place at work and at home settings.

KEY CONCEPTS

Drug resistance tuberculosis, epidemiology, patient, risk factors influencing, and treatment

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Dedication

This study is dedicated to my mom Margaret Ntombentsha Ndlangamandla-Shongwe who has been a pillar of my strength and ensured I am where I am today ... she would say:

“Education is the husband that will never leave you”.

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LIST OF ACRONYMS

DRS	Drug resistant survey
DR-TB	Drug-resistant tuberculosis
HIV	Human immunodeficiency virus
MDR-TB	Multidrug resistant tuberculosis
NTCP	National TB Control Program
SA	South Africa
SADC	Southern African Developing Countries
TB	Tuberculosis
US	United States
VCT	Voluntary counselling and testing
XDR	Extensive drug resistance

GLOSSARY

GenXpert: Is a new diagnostic machine that has made the testing of both TB and DR-TB easier through ensuring early diagnosis within four hours and enables early treatment of patients (The National Tuberculosis Manual 2013:14).

Strength of association: The association or relationship between cause and effect must be clear.

CHAPTER 1

ORIENTATION OF THE STUDY

“Every sickness has an alien quality, a feeling of invasion and loss of control that is evident in the language we use about it.”

Siri Hustvedt

1.1 INTRODUCTION

The epidemic of drug-resistant tuberculosis (DR-TB) is a public health emergency that threatens to destabilise global TB control. Although TB incidence and mortality are decreasing in several parts of the world, the overall prevalence of multidrug-resistant tuberculosis (MDR-TB) is increasing in many high-burden countries, particularly in Africa. In 2008, the World Health Organization (WHO) estimated that more than 440,000 individuals had multidrug resistant tuberculosis (MDR-TB) worldwide. Such patients are resistant to at least isoniazid and rifampicin, the most effective anti-TB drugs (WHO 2008:59).

Calligaro and Dheda (2013:9) state that TB is the second most common cause of death from infectious diseases in the world. The absolute number of tuberculosis cases has been decreasing since 2005 and new cases since 2002. In 2007, the country with the highest estimated incidence rate of TB in Southern African Developing Countries (SADC) was Swaziland, with 1200 cases per 100,000 people, from a total population of +1,100,000. India had the largest total incidence, with an estimated 2.0 million new cases (Calligaro & Dheda 2013:9). The incidence of TB varies with age, as in Africa, TB primarily affects adolescents and young adults. However, in countries where TB has gone from high to low incidence, such as the United States (US) where national data shows a steady decline, and currently TB is mainly a disease of older people, or of the immune compromised (Epidemiology of Tuberculosis 2013:1).

An understanding of the epidemiology of Mycobacterium TB which is critical for effective control of TB is essential. It is also useful for all TB program staff motivated by the Ministry of health, ranging from health care workers and public health representatives to

TB program managers in analysing and making practical use of data, assessing current and evolving trends in TB morbidity, identifying risk groups and associated risk factors, and determining where to allocate staff and resources. Conducting research to identify risk factors that exposes TB patients to DR-TB seem imperative in order to add to the current studies done especially by medical doctors to minimise its effect on the quality of life for patients suffering from TB (Epidemiology of Tuberculosis 2013:1).

Therefore this study envisages investigating what risk factors are there which influences prevalence and the incidence of DR-TB especially on patients already enrolled on treatment.

1.2 PHASES OF THE STUDY

The study was conducted in three phases as exhibited in figure 1.1. These phases included firstly conceptualisation and planning through comprehensive literature review. The second phase involved design and planning and the third phase involved empirical implementation of the research process.

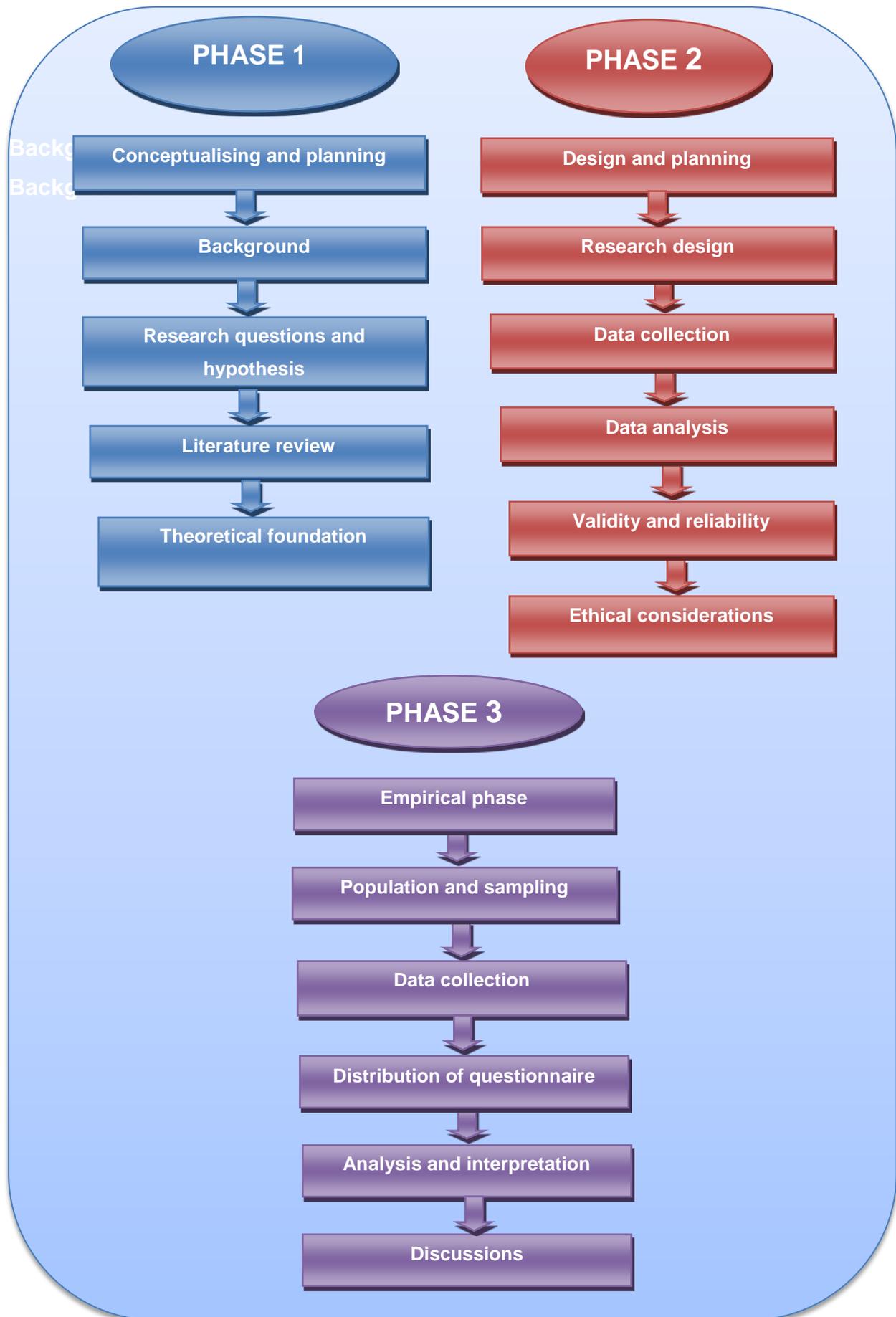


Figure 1.1 Phases of the study

All three of these phases demonstrated the pathway in which the research was followed from the beginning to the end of the study process.

The *first phase* was a very brief phase of the study and it involved conceptualising and planning. A comprehensive review of the literature using sources such as journals, articles, research and discipline books, and the internet was undertaken for contextual understanding of risk factors associated with DR-TB. The literature review included studies that were conducted internationally, sub-Saharan countries, Africa, and Swaziland

The *second phase* involved constructing the research methodology, which focused on both quantitative and qualitative non-experimental, contextual research design, theoretical framework and the research methods to be used, which included study population and sampling, data collection and data analysis. In this phase the researcher gained the privilege of entering the DR-TB hospitals and developing a rapport with the facility management and staff.

During the *third phase*, the researcher engaged in discussion, devising conclusions and recommendations based on the study findings.

1.3 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

Multidrug resistant tuberculosis (MDR-TB) is caused by the transmission of multidrug resistant *Mycobacterium tuberculosis* strains in new cases, or by the selection of single drug resistant strains induced by previous treatment (Faustini 2005:1-2). The resurgence of TB has been attributed to the human immunodeficiency virus (HIV) epidemic, immigration, and DR Emergence of DR-TB is a global threat that poses a threat to human kind. Drug resistant tuberculosis has caused the treatment of TB to be more complicated resulting in poor treatment outcomes leading to patients staying longer on treatment and longer exposure to toxic drugs that cause countless side effects to the patients such as hearing loss (Faustini 2005:1).

According to the Swaziland National Tuberculosis Manual (2013:14), Swaziland has reported an increase in TB incidence, with new cases rising from 1458 in 1995 to 11057

in 2010. Tuberculosis remains a major public health challenge in the kingdom of Swaziland with an estimated 20% of institutional deaths attributable to the disease. With an estimated TB incidence of 1,287 per every 100,000 of its population, Swaziland is one of the countries with the highest TB incidence in the world. Compared to a 1990 level of 267 new cases of all forms per 100,000 populations per year, TB incidence had increased six-fold, by 2010, while incidence of the infectious cases (sputum smear positive pulmonary TB cases) tripled in the same period which could be due to improved diagnostic measures such as the GenXpert. The GenXpert is a new diagnostic machine that has made the testing of both TB and DR-TB easier through ensuring early diagnosis within four hours and enables early treatment of patients (The National Tuberculosis Manual 2013:14).

The country's co-infection rate also does not assist as it is reportedly at 80%. Susceptible TB treatment takes a minimum of six months duration and DR-TB treatment takes at least 18 months of treatment which includes three to eight months of an injectable.

The Global response to TB was the STOP TB Strategy that Swaziland also adopted. This strategy puts in measures that encourage TB patients to adhere to TB treatment throughout their therapy. This included among others the introduction of community treatment supporters who were linked to a patient to ensure that the supporter motivates the patient to reach the treatment end line. (Stop TB Strategy 2011:5).

In the Manzini region in 2011, Swaziland declared TB a national emergency. The Prime Minister's declaration of TB as a national catastrophe resulted in escalated efforts against the pandemic, the NTCP put in place measures including placing adherence officers at different TB diagnostic facilities that were responsible for tracing treatment interrupters and defaulters. Integration of HTS (HIV Testing Services) in TB Clinics to minimise loss of patients through departmental referrals. The introduction of screening of all HIV positive patients at all voluntary counselling and Testing (VCT's) centres and introduction of TB screening at all facility entry points. This was to ensure early identification, early diagnosis and early treatment to prevent transmission and graduation from TB to DR-TB. Treatment for DR TB is more toxic, lengthy, and expensive than for drug susceptible TB and treatment success rates which is cure plus treatment completion are usually lower. Failure to adhere to susceptible TB treatment

may cause an increased incidence rate as a result of primary infection in the households and community. Poor adherence to TB treatment may lead to development of DR-TB as a result of exposure to drugs without completion of course duration.

The emergence and spread of MDR TB, extensively drug-resistant (XDR) TB, and more recently, totally drug-resistant TB poses a threat to global TB control (WHO 2013:1).

Tuberculosis remains one of the leading causes of morbidity and mortality worldwide, and resistance to commonly used anti-TB drugs is increasing. As a result DR-TB has become a major public health challenge confronting the population in Swaziland. In Swaziland about 40-50 cases of DR-TB are diagnosed on monthly basis. According to the DRS in 2009 done by the NTCP, drug resistant TB is associated with unfavorable treatment outcomes which are high morbidity and mortality, making Swaziland among the first highest burden of DR-TB globally. In comparison with other neighboring countries especially SA, which has the fifth highest burden of DR-TB globally, with an incidence of ~2% of new patients and ~7% of retreatment cases; of these, 5-10% have Extensive Drug Resistance (XDR-TB).

The World Health Organization (WHO 2013) statistics show that almost half a million new cases of MDR-TB develop every year, of which approximately 40 000 in more than 80 countries globally are thought to be extensively DR-TB. Limited laboratory capacity and lack of widespread drug susceptibility in resource-poor settings mean that only a fraction of that number are correctly diagnosed and started on treatment (WHO 2013). This reservoir of undiagnosed and/or untreated DR-TB is largely responsible for driving ongoing person-to-person transmission. Treatment defaulters, delays in initiating treatment, inadequate bed capacity, and poor infection control in healthcare facilities are also important contributors. According to Calligaro and Dheda (2013:9), identifying and dealing with the threat of DR-TB is critical.

Firstly, DR-TB has poorer treatment outcomes when compared to drug-sensitive TB. Of the estimated half a million MDR-TB patients started globally on treatment in 2009, only 48% were treated successfully. Outcomes for XDR-TB are even worse. Although the overall success rate for XDR-TB in a recent meta-analysis was reported as 44%, a retrospective study from SA by Ghandi et al showed that fewer than 20% of patients with XDR-TB culture converted within six months of initiation of treatment. This poor

outcome was independent of HIV status. Secondly, DR-TB involves a longer duration of treatment with less potent but more toxic medications, and higher relapse rates occur. Lastly, DR-TB treatment is considerably more expensive than standard TB treatment. Despite only comprising 2.2% of the case burden of TB in SA, DR-TB consumes a third of the total estimated national TB budget for the country (Calligaro & Dheda 2013:9).

Porwal, Kaushik, Makkar, Banavaliker, Hanif, Singla (2013:6) state that among the risk factors associated with progression of TB to drug resistance is chest x-ray cavitation's, with highest cavitation being associated with XDR-TB. Four factors showed significant associations with worsening drug resistant which are family history of TB, socio-economic status, comorbidities and previous intake of second line injectable drugs. According to Libo, Wu Qunhong, Gao Lijun, Hao et al (2011:12), a conclusion made was that inappropriate treatment is the most important influencing factor of DR-TB. The authors further contend that increasing people's awareness of TB, early detection and appropriate treatment of patients with TB should become a priority, which requires strong commitment and collaboration among health organisations and greater compliance with TB treatment guidelines by service providers and patients.

According to Espinal, Laserson, Camacho, Fusheng, Kim, Tlali et al (2001:22), patient characteristics including age and HIV infection are also believed to influence the dynamics of transmission of DR organisms.

1.3.1 Source of the research problem

The researcher, working as a coordinator of DR-TB facilities, observed that there is a notable increase in the number of patients confirmed with DR-TB in Swaziland. The development of DR-TB may result due to various reasons which could be inappropriate treatment, patients not taking the correct dosage or poor adherence to prescribed TB treatment. However, the high incidence of DR-TB seems to be associated with some risk factors which expose patients to infection with drug-resistant TB. More so TB is a high health challenge in the country because DR-TB has poorer treatment outcomes, takes longer period to treat, thereby expensive to treat, more toxic drugs, and uses a majority of the national health budget for TB prevention and treatment (Porwal et al 2013:6). It makes it crucial to empirically investigate what these factors are and how they can therefore be identified, addressed and minimised.

1.3.2 Research problem

A research problem is “a situation or condition that is enigmatic, perplexing or troubling that can be investigated through disciplined enquiry” (Polit & Beck 2012:34).

Espinal et al (2001:23) state that global statistics on the determinants of drug-resistant tuberculosis (TB) based on representative data seem to be inadequate.

Although Swaziland, is a country with a population of about 1,100,000 people in coverage of 17,300 square kilometers of land square meters, has reported a high incidence rate over the years. Swaziland prior to mid-1980 the country appeared to be winning the battle against TB but with emergence of other diseases such as HIV the tables turned around and TB became more prevalent in the country. Health facilities were burdened by more 11057 new TB patients in 2010 according to the National TB Control Program National Strategic Plan (2014). According to the last DR-TB survey done in the country, Swaziland had 3.3% of these new cases resulting in DR-TB and 33.9% of re-treatment cases ending up being DR-TB cases.

Swaziland has been putting different measures in the fight against TB and DR-TB. However, there is currently not enough scientific evidence in the country to assist in taking programmatic decisions and in the development of policies that are country specific to deal with risk factors that patients are exposed to. The measures currently in place are based on what the global experts concluded based on different studies done in various countries that may not have similar characteristics as Swaziland.

The NTCP, health care workers and the patients are truly not aware of what risk factors in Swaziland fuel the emergence of drug resistance TB. Studies on the construct under investigation such as this one are needed to actually validate assumptions by Global bodies such as the WHO which will in turn result in country specific interventions that are effective in a country such as Swaziland. Though the country has between 2011 and 2015 shown a gradual decline in TB patients, the same cannot be said for DR-TB which has shown a gradual increase. This is a major concern because a resistant infection results in high mortality, can spread to others and ultimately imposes huge costs to individuals and society.

A study conducted by Frieden, Sterling, Pablos-Mendez, Kilburn, Cauthen and Dooley (1993:2) in New York conclude that “DR-TB patients are rapidly increasing, as a result of previous TB treatment history, HIV infection and drug use”. Therefore empirical measures to identify high risk factors in order to control and reduce DR-TB are urgently needed.

1.4 PURPOSE OF RESEARCH

The purpose of this study was to determine the risk factors influencing epidemiology of DR-TB patients enrolled for treatment at the hospital.

The researcher also aimed to conduct qualitative discussions with individuals to investigate the risk factors associated with the development of drug resistant TB and retrospective review of drug resistant patient’s records.

1.5 OBJECTIVES OF THE STUDY

The objectives of this study were to

- explore and describe the risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB
- identify risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB treatment
- develop a poster that will exhibit the research process undertaken and the findings

1.6 RESEARCH QUESTION

The research question of this study was formulated based on the PICO approach which is discussed in detail in chapter 3.

The research question for this study was:

“What are the risk factors that influence DR-TB occurrence among patients enrolled on DR-TB treatment?”

1.7 HYPOTHESIS OF THE STUDY

A research hypothesis (H_1 or H_a) is the alternative to the null and is according to Creswell (2013:143), the prediction that a researcher makes about the expected outcomes of the relationship among study variables. These hypotheses are numeric estimates of the values within populations which are based on the data collected from the given samples. Testing of hypotheses employs statistical procedures in which the researcher draws inferences about the population which is used in the study sample (Creswell 2013:143).

A null hypothesis of this study was that there is no association between the independent and dependent variables. That there will be no increased awareness of risk factors influencing DR-TB, no interventions put in place and no reduction of DR-TB.

The research hypothesis of this study was that 'There are increased high risk factors influencing development of DR-TB among patients enrolled on DR-TB than among those with susceptible TB.

1.8 SIGNIFICANCE OF THE STUDY

Different assumptions have been made on multiple risk factors that contribute to the existing DR-TB prevalence globally. The findings of this study will assist clinicians, policy makers and researchers to gain insight on the major factors contributing to the high prevalence of DR-TB in the country. The findings of this study will also be used as a learning process on the risk factors resulting in the high prevalence of Drug resistant TB patients of the country in the region. It will increase awareness to stakeholders and decision makers on the risks predisposing the public to infection with DR-TB and in turn inform the staff that runs the National TB control program to set up systems that will minimise the rate of exposure to these risks, in turn less transmission will occur amongst those healthy/without clinical symptoms.

1.9 DEFINITION OF KEY CONCEPTS

Drug resistance tuberculosis

The WHO (2013:12) defines drug-resistant TB as resistance to Antimicrobial – also known as drug resistance that occurs when microorganisms such as bacteria, viruses, fungi and parasites that render the medications used to cure the infections they cause ineffective. Faustini, Hall and Perruci (2006:159) define drug-resistant TB as a disease that is resistant to isoniazid (H) and rifampicin (R). Resistance to one drug may become resistance to two or more drugs.

In this study, drug resistance refers to resistance of the TB bacilli to anti TB drugs due to mutation of the bacteria as evidenced by lack of improvement even if the patient is on treatment.

Epidemiology

Epidemiology according to Stanhope and Lancaster (2011:G-11), is defined as the study determining and influencing the frequency and distribution of disease, injury and other health related events and their causes in a defined human population.

In this study epidemiology refers to the distribution of new infections, and current infections with DR-TB identified on patients who come monthly for treatment at the referral hospital.

Enrolment

The *Oxford Advanced Learner's Dictionary* (2010:349) defines enrolment as an act of officially joining or a state of being enrolled, recorded or listed.

In this study enrolment refers to initiation of a patient on DR-TB treatment.

Influence

The *Oxford Advanced Learner's Dictionary* (2010:450) defines influence as a positive or negative effect that somebody or something has on the way a person thinks or behaves or on the way that something works or develops. Influence can be good or bad (on someone or something).

In this study influence means either the positive or negative factors that predispose patients to DR-TB infection.

Patient

Patient is defined by Freshwater and Maslin-Prothero (2005:440) as a person who is physically or mentally ill and is undergoing nursing and medical treatments for healing. The term 'patient' is further referred to a person who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement or protection of health or lessening of illness, disability or pain (US Centers for Medicare and Medicaid services)

In this study, patient refers to the person who has been infected with TB and has been initiated on drug-resistant TB treatment.

Risk factors

According to Stanhope and Lancaster (2011:G27), 'risk factors' refers to the disease precursor, the presence of which is associated with higher than average mortality. Disease precursors include demographic variables, certain everyday health practices, family history of disease and some physiologic changes.

In this study, 'risk factors' refers to the situations or health practices and behaviors that predisposes one to infection resulting in the TB disease leading to drug resistance.

Treatment

‘Treatment’ according to Freshwater & Maslin-Prothero (2005:622), is any medical, surgical or psychological care of a person aimed at relieving symptoms of a disease or injury or curing the condition.

In this study, ‘treatment’ refers to the treatment given to DR-TB patients at the National DR-TB Hospital.

1.10 CONTEXT OF THE STUDY.

In Swaziland there are seven DR-TB initiating sites that offer DR-TB treatment to patients diagnosed with DR-TB. This study was conducted at one of these sites which is a central DR-TB site where complicated cases are referred to. It is a National TB Referral Hospital setting in Swaziland, that initiates and provide monthly reviews and follow ups of DR-TB patients The staff in the facility includes medical officers, professional nurses, nursing assistants, data clerks, and support staff. It has bed capacity of 100 patients per zone and has a turnover of about 30 patients daily.



Figure 1.2 The drug resistant facilities in Swaziland

1.11 METATHEORETICAL ASSUMPTIONS

Assumptions are basic principles that are assumed to be true, based on logic and reason, without proof or verification (Polit & Beck 2008:14). Sources of assumptions include: universally accepted truths; established theories and research findings; and verified medical practice. In research studies, assumptions are embedded in the philosophical base of the researcher, as well as in the study design and the interpretation of findings conducted by the researcher (Burns & Grove 2007:39). The recognition of these assumptions by the researcher is able to be strength and not a weakness. In this study, ontological, epistemological and methodological assumptions were reflected upon, which informed the way in which the study was framed.

Ontological assumptions

According to Mouton and Marais (1994:11, 12), ontological assumptions refer to the study of the state of being, or of concepts of reality. The ontological assumptions regarding reality which underpin this study have been that:

- DR-TB epidemiology is influenced by certain health related and social factors
- Human beings are diverse in how they think, act or behave in response especially to chronic illnesses
- Multiple realities exist with regard to the risk factors that influence DR-TB occurrence among patients and this can be captured by means of asking questions from people experiencing a particular phenomenon as how it is real to them

Epistemological assumptions

Epistemological assumptions are statements that embody the ideal of science, namely the quest for truth and knowledge (Mouton & Marais 1994:14-15). In this regard, the epistemological assumptions are as follows:

- Narrative data can elicit an understanding of the meanings that TB patients attach to what it means to default on treatment or be exposed to risks factors.

- Although it is difficult to ascertain when the truth has been attained, it is, however, necessary to strive for reality as close as possible.
- Theories inductively generated from data are likely to offer insight, knowledge, enhance understanding and provide a meaningful guide to action, including nursing practice.

Methodological assumptions

Methodological assumptions, according to Mouton and Marais (1994:15-16), provide the 'how' of research. In other words, how should research be planned, structured and executed to comply with the criteria of science. It refers to the logic of implementing scientific methods in the study of reality. Methodological assumptions regarding this study are as follows:

- Human beings use language to attach meaning to phenomena and communicate the meanings to others.
- Qualitative research supports naturalistic inquiry to collect narrative data on reality, which is constructed by people.
- Deductive reasoning is helpful to draw conclusions from the general premise of phenomena to specific situations.

Burns and Grove (2007:37) conclude that assumptions are embedded (unrecognised) in thinking and behavior, and uncovering these assumptions requires introspection and a strong knowledge base in the particular field of study.

1.12 RESEARCH DESIGN AND METHOD

The study was a mixed method study conducted based on both the quantitative and qualitative paradigms. A retrospective cohort study was conducted to review the DR-TB register for all DR-TB patients initiated on treatment during the time period January-December 2013. A mixed method of both quantitative and qualitative paradigms, explorative and descriptive design was used and quantitative was utilized. For the purpose of the quantitative part of the study where documents and registers were analysed and the elements of the Health Belief Model were also used as a theoretical foundation.

1.12.1 Method

The research methods as described by Polit and Beck (2012:12) are techniques or procedures that researchers use for the structure and implementation of a study such as gathering and analysis of data relevant to the research question, problem statement and the study objectives. Therefore, in this section population, sample and sample technique, data collection process and analysis as well as measures to ensure validity and reliability, trustworthiness and ethical considerations were described.

1.12.2 Population and sample selection

Population refers to the entire group of persons or objects that is of interest to the researcher, in other words, that meets the criteria which the researcher is interested in studying (Brink, Van der Walt & Van Rensburg 2006:123). In this study population refers to all DR-TB patients on treatment in Swaziland.

According to Polit and Beck (2008:338), the target population is the aggregate of cases about which the researcher would like to generalise the results or findings. The target population is formed by patients infected with DR-TB who are treated at the National Referral TB Hospital. A sample of informants was obtained from the accessible population. According to Brink et al (2006:123), an accessible population is the population that the researcher has access to and actually differs from the entire population in one or more aspects. Polit and Beck (2008:338) state that the accessible population is the aggregate of cases that conform to designate criteria and that are accessible as subjects for a study. In this study the accessible population were the DR-TB patients who visited the health facility on the day of data collection.

Within the accessible population the researcher considers the following inclusion and exclusion characteristics:

Inclusion criteria

Patients who are:

- DR-TB Confirmed

- Initiated on DR-TB treatment during time period of study
- >18 years old
- Both males and females

Exclusion criteria

- <18 years
- Drug resistant patients initiated before or after the study period

1.12.3 Sample and sample techniques

Following the mixed method approach, the researcher conducted both probability and nonprobability sampling methods. Nonprobability sampling means that not every element of the population has an opportunity for selection in the sample (Burns & Grove 2009:744). Probability sampling in form of random sampling was used to randomly select the respondents from the DR-TB register as guided by Morgan (2008). Convenience sampling was used to recruit informants for the in-depth individual interviews.

1.12.4 Sample size

The sample size in the qualitative study was not pre-determined as data was collected until saturation occurred. Saturation occurred by the 18th individual interview where the researcher noticed that similar information was being shared by the patients. Fifty six cases were randomly selected from the register for the quantitative aspect of document analysis.

1.12.5 Data collection

Data was collected through individual interviews through use of an interview guide. Document interview was conducted through use of a checklist as a data collection tool. The qualitative interviews were audio recorded and transcribed verbatim.

1.12.6 Data analysis

Data analysis occurred simultaneously with data collection. The eight steps provided by Tesch (1990) in Creswell (2013:184-187) to analyse data were mainly utilised to do the analysis of the qualitative data.

The quantitative data from the DR-TB register was analysed through document analysis using content analysis approach with consultation with the statistician.

1.12.7 Validity

The validity of the checklist tool was ensured through face, content validity and consultation with experts in the field. The tool was also pre-tested.

1.13 MEASURES TO ENSURE TRUSTWORTHINESS

Measures to ensure trustworthiness in qualitative research refer to the accuracy of the findings by employing certain procedures (Creswell 2013:250). The following measures were taken into account: confirmability, dependability, transferability and credibility (Brink et al 2006:118, 119).

1.14 ETHICAL CONSIDERATIONS

In this study considerations were taken to ensure protection of the rights of the research institution, of participants, and ensuring scientific integrity. The ethical protection of respondents was maintained throughout the study.

Protecting the rights of the institution

This research falls under the authority of the Department of Health Studies of UNISA, since it is conducted in order to obtain a Master's degree in Public Health from this institute. Therefore, the researcher sought official ethical approval from the Department's Research Ethics Committee (Annexure A). In addition ethical clearance by the Swaziland's Health Research Committee was also sought for (Annexure A). Moreover this research took place under the authority of the management of National

DR-TB Referral Hospital. Therefore, after obtaining ethical approval of the Ethics Committee of the Department of Health Studies a letter of application for permission to conduct this research was requested and obtained from the National Tuberculosis Control Program and the management of the respective facility (Annexure B and C).

1.15 SCIENTIFIC INTEGRITY OF THE RESEARCH

The researcher adhered to the principles of scientific integrity by avoiding plagiarism. These included: honesty in reporting, referencing and communicating the findings.

Privacy and confidentiality was maintained by keeping all data obtained under lock and key.

Anonymity may be difficult to maintain but all measures to protect the participants were ensured. Participants were informed that they may withdraw from the study at any time without victimisation.

Scientific integrity was ensured through avoiding plagiarism, acknowledging all sources used and writing the correct list of sources.

1.16 DISSEMINATION OF FINDINGS

The findings will be published in an accredited journal for wider readability; a poster will be developed and presented through in-service education to patients and staff.

1.17 SCOPE AND LIMITATIONS OF THE STUDY

The scope of this study was limited because of the small sample size of the qualitative part and it is not easy to generalise or transfer results to a wider community. Although some information will be obtained from the register it may have variables that are inaccurate or incomplete.

1.18 ORGANISATION OF THE DISSERTATION

The dissertation is divided in the following chapters.

Table 1.1: Organisation of the dissertation

Chapter	Logic and structure of the thesis
Chapter 1	Introduction and background information. This chapter introduced an overview and introduction on tuberculosis and MDR-TB; it briefly described the background of the research phenomena.
Chapter 2	Literature review In this chapter the different scholarly articles on risk factors related to drug resistant TB were discussed in-depth.
Chapter 3	Research methods and research design
Chapter 4	Findings and literature control
Chapter 5	Discussions of findings
Chapter 6	Conclusions, limitations and recommendations.

1.19 CONCLUSION

Chapter 1 gives introductory information of the entire study which utilised a mixed method approach. In the chapter, the background information to the research problem that existed has been discussed and the purpose, research question and objectives have been outlined. The significance of the study and definition of key concepts have been presented. The research design and method have been outlined to indicate how the study was conducted, such as research context, population, sample and sampling method, data collection methods and analysis. Methods of how validity and reliability, and trustworthiness were ensured are outlined. Ethical consideration of the research has also been outlined. Scope and limitations of the study is introduced.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

A literature review provides you with the current theoretical and scientific knowledge about a particular problem, and resulting in a synthesis of what is known and unknown. Such reviews include: a description of the current knowledge of a practice problem, the identification of the gaps in this knowledge base, and the contribution of the present study to the building of knowledge in this area (Burns & Grove 2007:135).

In this chapter the literature review was conducted to contribute to already available current knowledge and information that could lead to a better understanding of risk factors that influence the epidemiology for consistency and the golden thread of DR-TB among patients.

The primary rationale for reviewing literature relevant to this study was to gain an understanding of the information available on risk factors influencing the epidemiology of DR-TB on patients among patients that are already on DR-TB treatment. It was the researcher's intent to determine whether there are certain risk factors that are more likely than others that have a direct link with the development of DR-TB amongst patients already on DR-TB treatment. For this purpose the researcher reviewed mostly international journal publications and sources from a number of data bases on risk factors, such as Google Scholar, eBooks and other relevant clinical online data bases. However, it was discovered that most of the scientific knowledge was done outside Africa, in places such as China, United States of America, India with a few studies conducted in South Africa and none in Swaziland.

Many factors propagate the spread of drug-resistant TB, and lead to widespread emergence of XDR TB. These factors include:

Diagnostic factors: lack of rapid, cheap, and accessible point-of-care diagnostic methods to rapidly diagnose drug-resistant TB as early as possible

Limited drug regimen: insufficient second-line drug options

Patient treatment adherence and retention: poor patient adherence to prolonged treatment; inadequate case holding; poor treatment strategies.

Social issues: social stigma; deprivation and poverty; absence of community engagement.

Political will: insufficient political support

Equipment and supplies: inadequate resources for quality services.

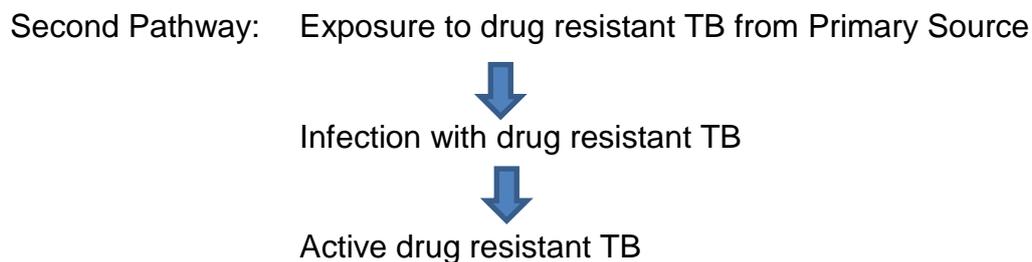
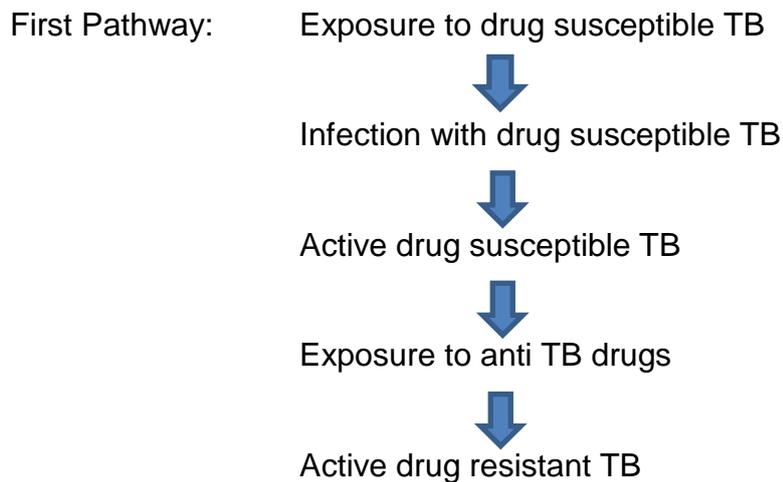
(Abubakar, Signol, Falson, Raviglione, Ditiu et al 2013:4)

The complex interaction between the host and M TB, affected by concomitant infections and wider social determinants, compound these structural factors. The genetic makeup of some M TB strains could increase risk of drug resistance. In several countries, primary transmission of MDR and XDR TB have been well documented, and have drawn attention to the crucial need to implement infection control precautions in congregate settings, according to Abubakar, Signol, Falson, Raviglione, Ditiu et al (2013:4). Concurring to this construct Shenoj, Escombe and Friedland (2010:256) acknowledged that the dramatic occurrence of 2 seemingly unrelated events, finally brought the issue of transmission of drug-resistant TB, its relationship to the HIV epidemic, and the global absence of adequate TB infection control into glaring public, medical, and scientific view.

Therefore, the risk factors influencing DR-TB was explored as the context that shapes and influences the current disease DR-TB trends in Swaziland and the awareness of these will assist in the control of the disease transmission amongst the public.

2.2 DRUG RESISTANT TB PATHWAYS

According to the WHO (2015:1), the reasons why multidrug resistance continues to emerge and spread are mismanagement of TB treatment and person-to-person transmission. These two are shown below.



Understanding the pathway of how people are exposed to DR-TB will help clinicians to manage and treat the diseases effectively.

2.3 GLOBAL DRUG RESISTANT TB PICTURE

Globally TB is the second most common cause of death from infectious disease (after HIV). The absolute number of TB cases has been decreasing since 2005 and new cases since 2002. China has achieved particularly dramatic progress, with an 80 percent decline in its TB mortality rate. The distribution of TB is not uniform across the globe; about 80% of the population in many Asian and African countries test positive in tuberculin tests, while only 5–10% of the US population test positive (Epidemiology of TB 2013:1).

Generally the prevalence of both drug-susceptible (DS-TB) and DR-TB appeared to decrease again in industrialized countries and recede from public and professional interest as highly active antiretroviral therapy (HAART) became available and TB programs strengthened airborne infection control. In many resource-limited settings, however, particularly in Africa, Asia, and the countries of the former Soviet Union, rates of DS-TB and DR-TB continued to increase, and TB re-emerged as a serious global

public health threat. World Health Organization (WHO) surveillance revealed high and increasing rates of drug resistance in retreatment cases and, shockingly, also in new, previously untreated TB cases. More than half of the estimated 500,000 global MDR-TB cases diagnosed in 2007 were believed to have resulted from primary transmission of drug-resistant organisms (Abubakar, Signal, Falson, Raviglione, Ditiu et al (2013:4-12; Shenoj et al 2010:251).

Roughly one-third of the world's population has been infected with M. TB, and new infections occur at a rate of one per second. However, not all infections with M. TB cause TB disease and many infections are asymptomatic. In 2007 there were an estimated 13.7 million chronic active cases, and in 2010 there were 8.8 million new cases, and 1.45 million deaths, mostly in developing countries. 0.35 Million of these deaths occur in those co-infected with HIV (Epidemiology of TB 2013:1).

According to the WHO Report (2014:14), China, India and Soviet Union has over 50% of the DR-TB cases primarily due to the high population density of these countries. Globally the treatment success rate for DR-TB is 48%. In 2007, the country with the highest estimated incidence rate of TB was Swaziland, with 1 200 cases per 100 000 people. As of 2014, India has the largest total incidence, with an estimated 2.2 million new cases. India has more than 0.3 million deaths and economic losses of \$23 billion every year. TB caused the second highest number of deaths in India with 63 265 casualties in 2011, 61887 in 2012 and 57 095 in 2013. Shenoj et al (2010:251) state that the lack of treatment options could endanger already diminished resources for TB control and potentially result in another disastrous surge of both drug-resistant and drug-susceptible TB globally.

In the United Kingdom, the national average was 15 per 100 000 in 2007, and the highest incidence rates in Western Europe were 30 per 100 000 in Portugal and Spain. These rates compared with 98 per 100 000 in China and 48 per 100 000 in Brazil. In the United States, the overall TB case rate was 4 per 100 000 persons in 2007. In Canada, TB is still endemic in some rural areas. Generally in developed countries, TB is less common and is mainly an urban disease.

2.4 SUB-SAHARAN AFRICA DR-TB PICTURE

A 2010 report by the WHO reported on new cases of XDR-TB, defined as MDR-TB plus resistance to any fluoroquinolone and any of the injectable second-line agents found in the region at KwaZulu-Natal Province, South Africa. This discovery called for attention to the dangers of nosocomial TB transmission in the presence of HIV infection and AIDS and the consequences of limited or no attention to infection control. XDR-TB was reported in 53 patients from a setting with a high prevalence of TB and HIV infection and a hospital with large congregate TB wards similar to those in most resource-limited settings. Reminiscent of the earlier outbreaks, all patients tested were HIV infected, and there was almost complete and rapid mortality. Nosocomial transmission was apparent because most patients had not previously been treated for TB and two-thirds had been hospitalised in the preceding 2 years. In addition, 85% of tested XDR *Mycobacterium TB* isolates were of a similar genetic family, and several HCWs were among the persons who were infected and died. (Ghandi et al 2006:24)

To support these findings where DR-TB was linked to HIV, Gandhi, Moll, Sturm, Pawinski, Govender, Lalloo, Zeller, Andrews and Friedland (2006:1) state that the number of TB cases in sub-Saharan Africa has increased substantially in the past decade, fueled by the HIV epidemic, making it difficult for TB programmes to improve outcomes. In South Africa, the national DOTS treatment success rate has been reported to be only 67%, well below the WHO standard of 85%. Low rates of treatment completion place patients at risk for relapse of TB disease as well as for development of drug resistance. The incidence of TB varies with age. In Africa, TB primarily affects adolescents and young adults who happen to be also the highly infected with HIV.

2.5 SWAZILAND DR-TB PICTURE

In 2007, the country with the highest estimated incidence rate of TB was Swaziland, with 1 200 cases per 100 000 people. The TB/HIV co-infection rate in the country remains high at 79.6%. The country due to the high TB incidence then declared TB as a national emergency. The country has been faced with various issues related to DR-TB such as:

- Inadequate follow up and support mechanisms for patients on MDR-TB treatment

- Inadequate contact tracing mechanisms for contacts of MDRTB patients
- Lack of capacity (human resource capacity)
- Human resource: Numbers and skills and knowledge on XDRTB
- No operational surveillance system in place
- Pill burden creates high default rates and increase occurrence of side effects
- Referral system between the two programmes is weak (collaborative TB/HIV at facility level still a challenge)
- Health workers not utilizing IPC protective supplies such as N95

In response to these issues a number of targeted efforts were implemented including Conducting a rapid survey of drug-resistant TB to establish whether Swaziland has cases of Extreme Multi drug Resistant TB. The health workers to manage DR-TB at national level including clinicians, nurses and TB programme staff to effectively respond to M(X) DR-TB have been regularly capacitated. Strengthening and expanding current national TB laboratory capacity to deal with diagnosis for drug resistant TB through fast diagnostic measures such as GeneXpert and the development of comprehensive DR-TB guidelines that incorporate collaborative TB/HIV activities.

To declaration of tuberculosis a national disaster has aided in the positive direction in TB management.

According to Abubakar et al (2013:3), factors driving MDR and XDR TB arise because of inadequate or interrupted administration of first line treatment. If patients are given too few drugs, for too short a period, or drugs to which the infecting strain is partly resistant, the resistant strains are favoured and will eventually dominate in the body. However once the drug resistant strains have been selected and occur in a community, they are directly transmitted to others. This cycle shows the first pathway caused by exposure to anti TB drugs that eventually leads to the second pathway where there is direct infection with drug resistant TB.

According to Espinal, Laserson, Camacho, Fusheng, Kim, Tlali et al (2001:1) prior but ineffective treatment is a strong predictor of drug resistance, and that HIV is not an independent risk factor for MDR-TB. The association between length of treatment and drug resistance may reflect longer treatment as a result of treatment failure in patients

with drug resistance; it may also reflect irregular prior treatment for TB, leading to drug resistance.

WHO (2015:1) recommend these solutions to control drug-resistant TB:

- Cure the TB patient the first time around.
- Provide access to diagnosis.
- Ensure adequate infection control in facilities where patients are treated
- Ensure the appropriate use of recommended second-line drugs.

In 2014, an estimated 480 000 people worldwide developed MDR-TB. It is estimated that about 9.7% of these cases were XDR-TB.

2.6 RISK FACTORS FOR TB AND DR-TB

TB drug resistance is said to be present if growth of M. TB isolates is observed in spite of the presence of anti-TB drugs. Although its causes could be microbial, clinical or programmatic, DR-TB is essentially a man-made phenomenon. From a microbiological perspective, resistance is caused by a genetic mutation that makes a drug ineffective against the mutant bacilli. From a clinical and programmatic perspective, it is an inadequate or poorly administered treatment regimen that allows a drug-resistant strain to become the dominant strain in a patient infected with TB.

Short-course chemotherapy (SCC) for patients infected with drug-resistant strains may create even more resistance to the drugs in use. This has been termed the “amplifier effect” of SCC. Ongoing transmission of established drug-resistant strains in a population is also a significant source of new DR cases. Swaziland Drug Resistant TB Manual (2014:18).

2.6.1 Institutional related risk factors

These factors result in inadequate treatment regimens, it basically refers to those factors that the health care worker has direct influence over, resulting in inadequacy of the drug regimens. These factors include the following:

Inappropriate guidelines or noncompliance with guidelines

The WHO (2010:3) states that the mainstay of TB control is organising and administering standardised treatment across the country for all adult and paediatric TB cases on aspects such as sputum smear-positive or smear-negative. For standardisation the WHO recommends the adoption of its guideline on patient categorisation and management to be followed. These guidelines emphasise use of the most effective standardised, short-course regimens, and of fixed-dose drug combinations (FDCs) to facilitate adherence to treatment and to reduce the risk of the development of drug resistance.

Absence of guidelines

Absence of guidelines or in-availability of guidelines in health facilities to provide reference for the health care worker may result in health care workers providing different treatments as there is no guide.

Poor training

Poor training will result in poor knowledge transfer to the health care worker on the implementation ground. The health care worker may also lack confidence in following the set standards as she may lack proper training. The case may be the same in all the hospital departments even in the laboratories. According to WHO a wide network of properly equipped laboratories with trained personnel is necessary to ensure access to quality-assured sputum smear microscopy for early detection, initiation of TB treatment and prevention of DR-TB.

Poor monitoring of treatment

TB and DR-TB like all other health ailments require constant monitoring of progress. In DR-TB and TB the dosages of the medications are based on the weight of the patient. When a patient's weight increases the dosage should also increase once the monitoring of such determinants is poor the patient will end up with low dosage resulting in resistance.

The WHO (2010:2) recommended method of TB case detection, first using sputum smear microscopy and then culture and drug susceptibility testing (DST), as indicated below. Strengthened laboratory network.

Poorly organised or funded TB control programmes

The TB Control Program is the backbone of every country's health prevention and control of the TB disease. If the program is poorly organised or lacks funding it cannot function optimally as most activities and intervention cannot take off due to lack of funds or proper coordination.

Drugs: Inadequate supply or regimen

According to WHO (2010:3), an uninterrupted and sustained supply of quality-assured anti-TB drugs is fundamental to TB control. For this purpose, an effective drug supply and management system is essential. A reliable system of procurement and distribution of all essential anti-TB drugs to all relevant health facilities should be in place. The TB recording and reporting system is designed to provide the information needed to plan, procure, distribute and maintain adequate stocks of drugs.

Anti-TB drugs should be available free of charge to all TB patients, both because many patients are poor and may find them difficult to afford, and because treatment has benefits that extend to society as a whole (cure prevents transmission to others). Legislation related to drug regulation should be in place, and use of anti-TB drugs by all providers should be strictly monitored. The use of FDCs of proven bioavailability and of innovative packaging such as patient kits can help to improve drug supply logistics as well as drug administration, promote adherence to treatment and prevent development of drug resistance.

Poor quality

This is a result of governments purchasing drugs that are not accredited, favouring costs to quality. In the long run this can cost the very government that was maximising its purchasing power.

Unavailability of certain drugs (stock-outs or delivery disruptions)

This can be a result of poor forecasting by the supply chain experts. It may start from implementation level where the health care worker fails to account for the drugs used and constantly have stock outs resulting in patients' treatment being interrupted.

Poor storage conditions

Poor storage conditions result in drugs losing their potency and as a result drugs with poor potency will be given to the unsuspecting patient. Poor storage conditions include too much sunlight, warmth, placing of drugs on the floor, storing drugs without following a system to assist in using the drugs that were received first.

Wrong dose or combination of drugs

Wrong doses can be given to patients during their refills due to not following the weight dosage standards and wrong combination of the drugs can be another factor.

2.6.2 Patient factors

These factors result in inadequate drug intake by the patient. Poor adherence (or poor DOT): DOTS is defined as directly observed treatment, short-course, and is the name given to the **TB** control strategy recommended by the World Health Organisation. According to the (WHO 2008:53), "the most cost-effective way to stop the spread of **TB** in communities with a high incidence is by curing it.

Identifying and addressing patient factors such as physical, financial, social and cultural barriers and the health care workers as well as health system-barriers to accessing TB treatment services should be done. Particular attention should be given to the poorest and most vulnerable population groups. Examples of actions that may be appropriate include expanding treatment outlets in the poorest rural and urban settings, involving providers who practise close to where patients live, ensuring that services are free or heavily subsidised, offering psychological and legal support, addressing gender issues, improving staff attitudes, and undertaking advocacy and communication activities (WHO 2010:5).

Adverse effects of treatment and lack of information on treatment

The main objectives of TB therapy are to cure the patients and to minimise the possibility of transmission of the bacillus to healthy subjects. Adverse effects of anti-TB drugs or drug interactions (among anti-TB drugs or between anti-TB drugs and other drugs) can make it necessary to modify or discontinue treatment. The major side effects from TB include psychosis, convulsive seizures, mental confusion, and coma: Peripheral neuropathy: Peripheral neuropathy occurs in approximately 20% of patients on TB treatment, Clinical hepatitis: Hepatotoxicity: Transitory and asymptomatic increases in the serum levels of bilirubin and hepatic enzymes occur in 5% of patients. These reactions can lead patients to interrupt or abandon treatment, resulting in higher rates of treatment failure and acquired resistance, as well as an increase in the number of TB cases and, more rarely, in the number deaths (Arbex, Varella, Siqueira & Fiúsa de Mello 2010:627). With development of these side effects and lack of proper information to the patient the patient may decide to stop treatment on her own.

Although the therapeutic regimens are extremely effective, studies have shown that undesirable drug interactions (among the anti-TB drugs or between the anti-TB drugs and other drugs used by patients) can occur, as can adverse reactions of varying degrees of severity. Adverse reactions that are more severe contribute to changes in the therapeutic regimen and lead to the use of drugs that are less active and occasionally more toxic, substantially increasing treatment costs, as well as the number of home visits, outpatient visits, and hospitalisations. These reactions can lead patients to interrupt or abandon treatment, resulting in higher rates of treatment failure and acquired resistance, as well as an increase in the number of TB cases and, more rarely, in the number of deaths.

2.6.3 Social barriers

The institutional and community norms that lead to the stigmatization of TB are thought to hinder TB control. Several themes emerged: fear of infection is the most common cause of TB stigma; TB stigma has serious socioeconomic consequences, particularly for women; TB stigma is perceived to increase TB diagnostic delay and treatment noncompliance, although attempts to quantify its impact have produced mixed results; and interventions exist that may reduce TB stigma (Courtwright & Turner 2010:125).

Mental disorder

TB and mental illness share common risk factors including homelessness, HIV positive serology, alcohol/substance abuse and migrant status leading to frequent comorbidity. Rates of mental illness of up to 70% have been identified in TB patients. Medications used in the treatment of common mental illnesses, such as depression, may have significant interactions with anti-TB agents, especially isoniazid and increasingly linezolid. Many medications used in the treatment of TB can have significant adverse psychiatric effects and some medications such as rifampicin may reduce the effective doses of anti-psychotics by their enzyme induction actions. Treatment with agents such as cycloserine has been associated with depression, and there have been reported cases of psychosis with most anti-tuberculous agents. Mental illness and substance abuse may also affect compliance with treatment, with attendant public health concerns. (Doherty, Kelly, McDonald, O'Dywer, Keane & Cooney 2013:396).

Poverty and stigma

Tuberculosis can drive entire countries, not just the people within them, into ever deeper poverty. It is no coincidence that the countries with the highest rates of TB are also some of the poorest and/or most unequal societies. TB is more common in countries where many people live in absolute poverty because people are more likely to:

- live and work in poorly ventilated and overcrowded conditions, which provide ideal conditions for TB bacteria to spread
- suffer from malnutrition and disease – particularly HIV – which reduces resistance to TB
- have limited access to healthcare – and just one person with untreated infectious TB can pass the illness on to 10-15 people annually

TB affects the vulnerable

In any society, rich or poor, TB tends to impact heavily on the poorest and most marginalised groups:

- Migrant communities
- People with drink, drug or mental health issues
- Homeless people and those in poor quality housing
- People with weak immune systems, due to HIV, other illnesses or age
- People with a history of prison

People with TB can find themselves in a downward spiral of poverty. This is because: They are often unable to work or attend school – for 3-4 months on average. Carers, if needed, may be expected to give up work or school themselves. This can result in a significant loss of earnings and/or reduce a child's future earning potential. If a patient dies, a family loses about 15 years of potential income. People may not be aware of, or able to access, free treatment and may end up paying traditional healers or private doctors. Even where TB treatment and drugs are free there is often a cost of travelling to clinics and additional heating or nutrition needs.

People can lose their jobs, or be excluded from future employment, because of fears surrounding TB. Women may be divorced, or considered unworthy of marriage, if they are known to have been affected by TB, making them more likely to experience extreme poverty.

2.6.4 The 5 elements of DOTS

These five elements are the basics needed for the control of TB as recommended by the WHO Stop TB Strategy.

Political commitment with increased and sustained financing

Clear and sustained political commitment by national governments is crucial if basic DOTS and the Stop TB Strategy are to be effectively implemented. Political commitment is needed to foster national and international partnerships, which should be linked to long-term strategic action plans prepared by NTPs. Strategic action plans should address technical and financial requirements and promote accountability for results at all levels of the health system, political commitment should be backed up by national legislation.

The WHO acknowledged that currently resources are inadequate, and there was need to urgently mobilise additional resources from within the country, as well as international sources. The global financing and partnership resources now available for poverty reduction, health systems improvement and disease control offer new opportunities for TB control programmes. Even with adequate financing, critical deficiencies in human resources in the health sector will impede progress in many low- and middle-income countries, especially in Africa (WHO 2010:1).

Case detection through quality-assured bacteriology

Culture and DST services should be introduced, in a phased manner, at appropriate referral levels of the health system. Their functions should include diagnosis of sputum smear-negative TB, diagnosis of TB among HIV-positive adults and children, diagnosis and monitoring of response to treatment of MDR-TB, and testing related to periodic surveys of the prevalence of drug resistance. Maintaining the quality of the laboratory network depends on regular training, supervision and support, and motivation of laboratory staff. Best use should be made of existing public and private laboratories.

Standardised treatment, with supervision and patient support

Treatment services

The mainstay of TB control is organising and administering standardised treatment across the country for all adult and paediatric TB cases – sputum smear-positive, smear-negative, and extra pulmonary. For standardisation the WHO recommends the adoption of its guideline on patient categorisation and management to be followed. These guidelines emphasise use of the most effective standardised, short-course regimens, and of fixed-dose drug combinations (FDCs) to facilitate adherence to treatment and to reduce the risk of the development of drug resistance.

Supervision and patient support

According to WHO factors resulting in patients interrupting or stopping treatment should be identified and addressed. Supervised treatment, which may have to include direct observation of therapy (DOT), helps patients to take their drugs regularly and complete

treatment, thus achieving cure and preventing the development of drug resistance (WHO 2010:3).

Supervision must be carried out in a context-specific and patient-sensitive manner, and is meant to ensure adherence on the part both of providers (in giving proper care and support) and of patients (in taking regular treatment). Treatment monitoring can be at a health facility, workplace, in the community or at home. It should be provided by a treatment supporter who is acceptable to the patient and is trained and supervised by health services. Patient and peer support groups can help to promote adherence to treatment.

Improving access to treatment

An effective drug supply and management system

An uninterrupted and sustained supply of quality-assured anti-TB drugs is fundamental to TB control. For this purpose, an effective drug supply and management system is essential. The Global Drug Facility and the Green Light Committee offer countries with limited capacity the benefit of access to quality-assured TB drugs at reduced prices and also facilitate access to training on drug management:

Monitoring and evaluation system, and impact measurement

Recording and reporting system

Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital. This requires standardised recording of individual patient data, including information on treatment outcomes, which are then used to compile quarterly treatment outcomes in cohorts of patients. These data, when compiled and analysed, can be used at the facility level to monitor treatment outcomes, at the district level to identify local problems as they arise, at provincial or national level to ensure consistently high-quality TB control across geographical areas, and nationally and internationally to evaluate the performance of each country. Regular programme supervision should be carried out to verify the quality of information and to address performance problems.

Making the best use of data at all levels will mean many countries having to train staff in the analysis and interpretation of data, as well as in the use of the computer software that can greatly facilitate this work. As electronic recording systems become more widely available, consideration should be given to storing individual patient data, which will make more detailed analyses of aggregated data possible.

2.7 THEORETICAL FOUNDATION

The Health Belief Model (HBM) is by far the most commonly used theory in health education and health promotion (Glans, Rimer & Lewis 2002). It was developed in the 1950's as a way to explain why medical screening programs offered by the United States Public health service, particularly for TB, were not very successful (Hochbaum 1958). The underlying concept of the original HBM is that behaviour is determined by personal beliefs or perceptions about a disease and the strategies available to decrease its occurrence (Hochbaum 1958).

There are four perceptions that serve as the main constructs of the model: perceived seriousness, perceived susceptibility, perceived benefits, and perceived barriers. Each of these perceptions, either individually or in combination can be used to explain health behaviour. Recently, some other constructs have been added to the HBM; the model has therefore been expanded to include cues to action, motivating factors and self-efficacy as exhibited in figure 2.1.

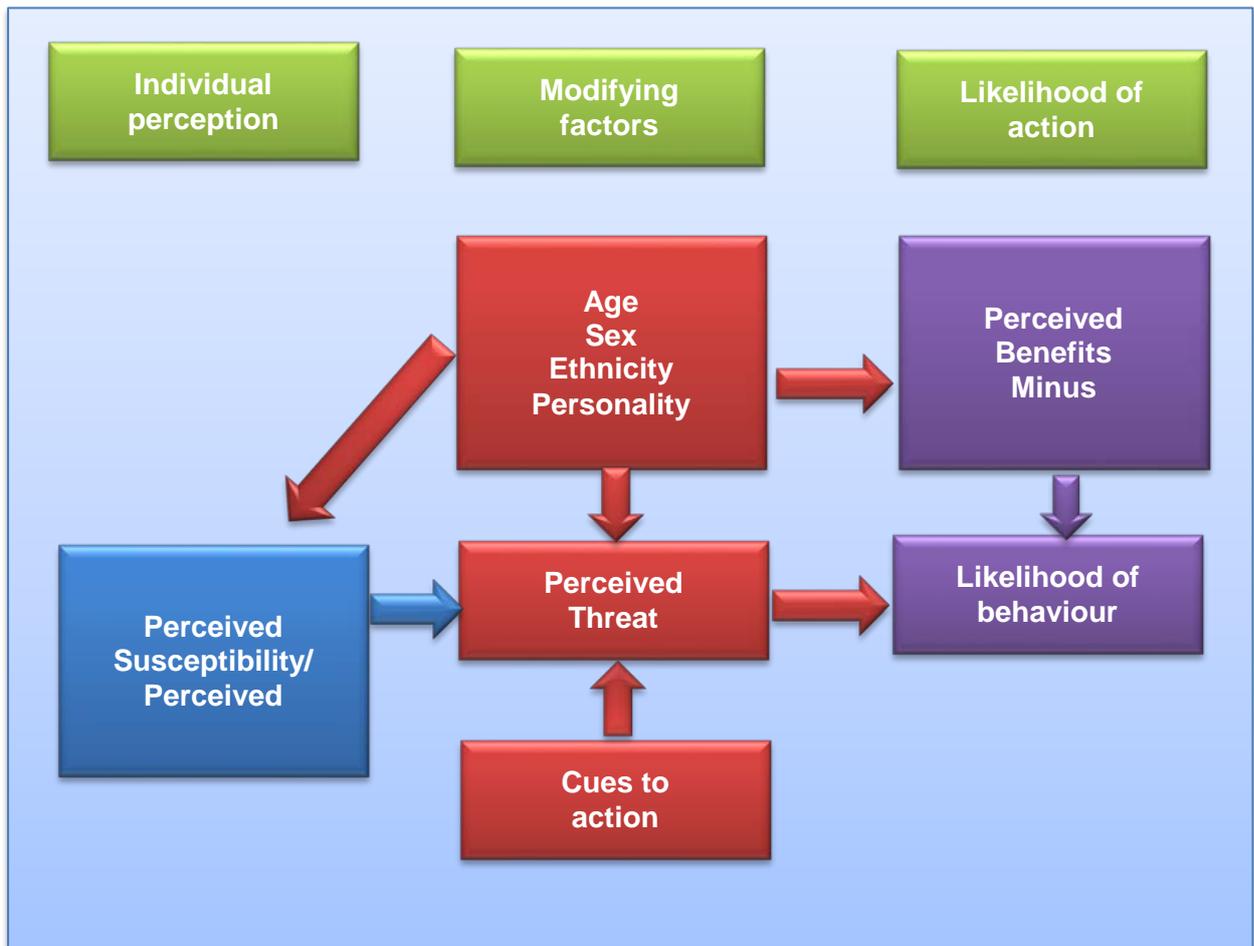


Figure 2.1 Health Belief Model

(Adapted from: Hayden, Hollmeyer, Poland & Buchholz 2009:34)

The model includes three constructs that ought to be combined to predict health-related behaviours, as applied in the context of the study. These are the individual perception, modifying factors and likelihood of action.

Individual perception

Individual perceptions refer to the way in which TB patients may reflect valuing their health, when compared to the other aspects of life. These perceptions include the following variables:

Perceived seriousness

This construct speaks to an individual's belief about the seriousness or severity of a disease. This is often based on medical information or knowledge but may also come from the beliefs a person has about the difficulties a disease would create or the effects it would have on his or her life in general (Hayden et al 2009:31).

Perceived susceptibility

Personal risk or susceptibility is one of the more powerful perceptions in prompting people to adopt healthier behaviours. The greater the perceived risk, the greater the likelihood of engaging in behaviours to decrease the risk. This is what prompts homosexual men to be vaccinated against hepatitis B (De Wit et al 2005) and to use condoms in an effort to decrease susceptibility to HIV infection (Belcher et al 2005). When the perception of susceptibility is combined with seriousness, it results in perceived threat (Stretcher & Rosenstock 1997). If the perception of threat is to a serious disease for which there is a real risk, behaviour often changes.

Modifying factors

The four constructs described above are modified by other variables such as culture, past experience, educational level, skill, motivation etc. These are individual characteristics that influence personal perceptions. For example, if one is diagnosed with breast cancer and successfully treated, she may have a heightened perception of susceptibility because of this past experience and be more conscious of breast self-examination because of past experience. Conversely, this past experience could diminish the person's perception of seriousness because the cancer was easily treated and cured (Hayden et al 2009:33).

Cues to action

In addition to the four perceptions and modifying variables, the HBM suggests that behaviour is also influenced by cues to action. Cues to action are events, people or things that move people to change their behaviour e.g. illness of a family member

(Graham 2002), advice from others or reminder post cards from health care provider (Ali 2002).

Likelihood to take action

According to the HBM, modifying variables, cues to action and self-efficacy affect people's perception of susceptibility, seriousness, benefits and barriers and therefore own behaviour (see figure 2.1).

Likelihood to take action is influenced by perceptions of the benefits of the action to be taken if dealing with risk factors about DR-TB infection is perceived to have been able to make a difference in their quality of life, as well as in reducing high mortality rates amongst them.

Perceived benefits

This is a person's opinion of the value or usefulness of a new behaviour in decreasing the risk of developing a disease. People tend to adopt healthier behaviours when they believe the new behaviour will decrease their chances of developing a disease (Hayden et al 2009:32).

Perceived barriers

This is a person's evaluation of the obstacles in the way of him or her adopting a new behaviour. Of all the constructs, perceived barriers are the most significant in determining behaviour change (Janz & Becker 1984). In order for a new behaviour to be adopted, a person needs to believe the benefits of the new behaviour outweigh the consequences of continuing the old behaviour (Center of Disease Control and Prevention 2004). This enables barriers to be overcome and the new behaviour to be adopted.

Self-efficacy

Self-efficacy was added to the original 4 beliefs of the HBM in 1988 (Rosenstock, Stretcher & Becker 1988). It is the belief in one's own ability to do something (Bandura

1977). People generally do not try to do something new unless they think they can do it. If someone believes a new behaviour is useful (perceived benefit), but does not think he or she is capable of doing it (perceived barrier), chances are that it will not be tried (Hayden et al 2009:31).

This model adapted from the behavioural sciences (Stretcher & Rosenstock 1997) is one of the most widely recognised frameworks of health behaviour and may be applied to health-seeking behaviour for glaucoma. The model explains how a person perceives the threat of glaucoma, and consequent loss of vision from glaucoma, and how the need for early consultation is viewed. The three constructs of the model are individual perceptions about susceptibility to disease, modifying factors and variables affecting the likelihood that a person will take action to change behaviour based on perceived benefits and barriers.

2.8 CONCLUSION

This chapter has discussed the literature review conducted for the study. Varied literature was consulted, which covered different topics, such as the DR pathways, the picture of risk factors related to DR-TB globally, at Sub-Saharan, and in Swaziland, The HBM, which was the conceptual framework of the study, was highlighted and developed to act as a guide for the study especially in data collection and analysis.

Chapter 3 discusses the research design and method.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

The research methodology is the study of the theoretical, philosophical and epistemological assumptions as well as the social processes through which research is conducted (Powers & Knapp 2006:112-113; Rapport 2004:166). It has philosophical meaning and typically refers to the approach or the paradigm that forms the basis of the research (Blaxter, Hughes & Tight 2010:59) which is most commonly based on the quantitative or qualitative approaches. In this study the research methodology refers to the context of the study, research design and research method. However, the research objectives, question and hypothesis are discussed first.

3.2 OBJECTIVES OF THE STUDY:

The objectives of this study were to

- explore and describe the risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB
- Identify risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB treatment
- Develop a poster that will exhibit the research process undertaken and the findings

3.3 RESEARCH QUESTION

The research question of this study was formulated based on the PICO approach. The acronym stands for the following:

- P – Population which in this study is the DR-TB Patients who are enrolled for the DR-TB treatment.

- I – Intervention which is the reduction of risk factors predisposing patients to DR-TB.
- C – Comparison with global incidences and prevalence of DR-TB.
- O – Outcomes reduced transmission of DR-TB.

Therefore, the research question for this study was:

“What are the risk factors that influence DR-TB occurrence among patients enrolled on DR-TB treatment?”

3.4 HYPOTHESIS OF THE STUDY

A research hypothesis (H_1 or H_a) is the alternative to the null and is according to Creswell (2013:143), the prediction that a researcher makes about the expected outcomes of the relationship among study variables. These hypotheses are numeric estimates of the values within populations which are based on the data collected from the given samples. Testing of hypotheses employs statistical procedures in which the researcher draws inferences about the population which is used in the study sample (Creswell 2013:143).

Hypothesis is defined as the formal statement of the expected relationship between two or more variables in a specified population (Burns & Grove 2007:542).

LoBiondo-Wood and Haber (2010:39) define a hypothesis as a statement which involves the relationship between two or more variables that suggests an answer to the research question. The hypothesis is a declarative statement that predicts an expected outcome of a particular study. A hypothesis or hypotheses are formulated before a study is commenced as they provide the direction for the collection of data, the analysis and the interpretation of data.

Hypotheses, which identify different types of relationships and the number of variables in a particular study, are divided into four categories namely:

- Associative versus causal hypothesis. An associative hypothesis identifies variables that occur and exist together in a study, as one variable changes so

does the other. A causal hypothesis identifies a cause-and effect interaction among two or more variables, called independent and dependent variables (Burns & Grove 2009:171). Simple versus complex hypothesis. A simple hypothesis predicts the type of relationship that will occur between two variables. Complex hypotheses predict the relationship between three or more variables (Burns & Grove 2009:172).

- Non-directional versus directional hypotheses. A null directional hypothesis states there is an existence of a relationship between variables, but cannot predict the nature of the relationship. A directional hypothesis does state the nature of the relationship between two or more variables (Burns & Grove 2009:173).
- Null versus research hypothesis. The null hypothesis which is also called the statistical hypothesis is utilised for statistical testing and interpretation of statistical outcomes. The research hypothesis is an alternative to the null hypothesis, and predicts a relationship between two or more variables. A null hypothesis can be simple or complex as well associative or causal. An associative null hypothesis states that there is no relationship between the variable of the study. A casual null hypothesis may be stated as there being no effect of the independent variable on the dependent variable (Burns & Grove 2009:173-174).

The independent variable with regards to this study is the DR-TB among patients. The dependent variable is the reduction of the occurrence of risk factors leading to DR-TB development (Creswell 2013:144). A hypothesis may therefore be formulated: There will be a simple causal relationship between the independent and independent variable with regards to this study. If the level of awareness regarding risk factors influencing DR-TB among patients is increased, it will influence programmatic interventions and in turn decrease the development of DR-TB.

There will be a directional hypothesis between the dependent and dependent variable of this study. The researcher will be able to predict the direction of the relationship. The increase of awareness of DR-TB risk factors and putting in place targeted interventions will decrease the occurrence of DR-TB and reduce the incidence and prevalence of DR-TB.

A null hypothesis of this study may be that there will be no association between the independent and dependent variables. That there will be no increased awareness of risk factors influencing DR-TB, no interventions put in place and no reduction of DR-TB Research hypothesis on figure 3.1

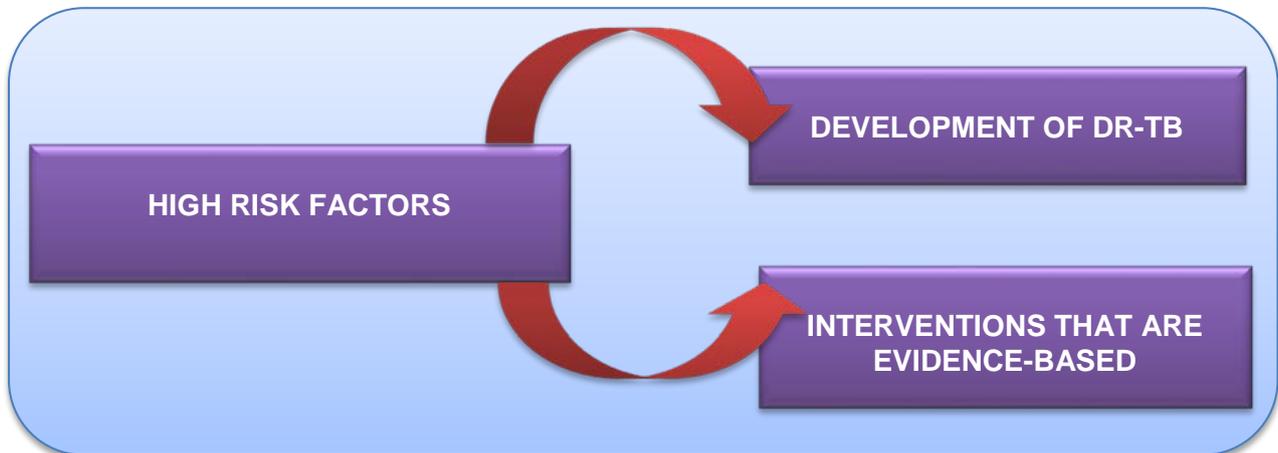


Figure 3.1 Research hypothesis

The research hypothesis of this study as exhibited in Figure 3.1 is that 'There are increased high risk factors influencing development of DR-TB among patients enrolled on DR-TB than among those with susceptible TB.'

3.5 RESEARCH CONTEXT/SETTING

The research setting is the specific place where the research study is conducted whereas the site is the overall location of the research context (Polit & Beck 2012:62). The research setting for this study is one of the hospitals in Manzini Swaziland. The Manzini region is the most densely populated region in the country with an average of +- 350,000 people. There are about 250 health facilities in the country that identify, diagnose and refer patients for treatment. However, there are seven DR-TB initiating sites that offer DR-TB treatment to patients diagnosed with DR-TB. However, this study was conducted at one of these sites which are a central DR-TB site where complicated and difficult cases are referred to. All facilities refer DR-TB patients diagnosed in their catchment area with the exception of the other DR-TB treatment initiating sites.

This facility serves a population of 1,018,449 but mainly 809,995 from the 3 regions Manzini, Hhohho, Lubombo. It has been for a long time been the central treatment site for DR-TB until recently in 2010 when decentralisation was done to other facilities (shown in the map). Shiselweni the remaining region has a total of 3 DR-TB sites which caters for its own population.

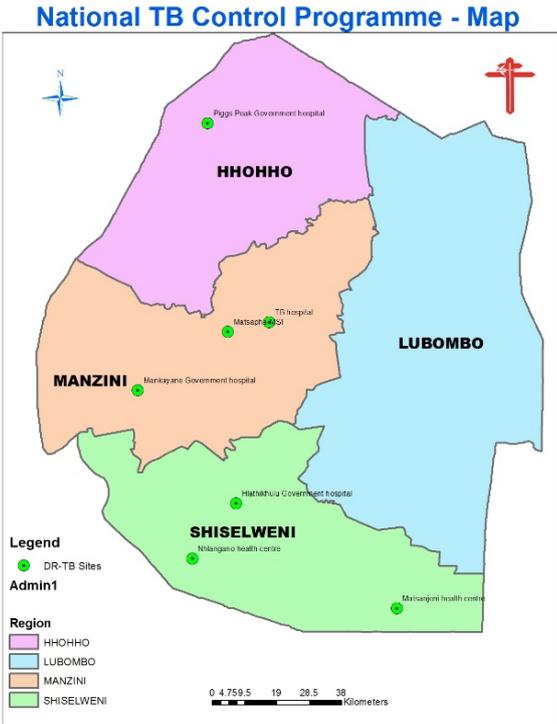


Figure 3.2 TB patient populations by region
(Source: National Strategic Plan 2014)

It is a facility that initiates and provides monthly reviews and follow-ups of DR-TB patients. It has a turnover of about 30 patients daily, with an admission capacity of 100 *inpatients* and also caters for ambulant patients who are initiated on DR-TB treatment, monitored monthly and given monthly refills by the medical officer. Those patients that require hospitalisation are also admitted at the same outpatient department.

The facility *out patient* load, on a monthly basis on average there is patient load of 525-600 (6600 visits per year), giving out a nurse-patient ratio of 1:13 monthly and the medical officer-patient ratio of 1:120. The services in this facility are available 24 hours a day, 7 days a week. The staff members are exhibited on table 3.1.

Table 3.1 Staffing at the hospital

Doctors	Matrons	Professional nurses	Nurses	Radiographers	Laboratory Technologist	Microscopist	Pharmacists	Pharm techs	Audiologist	Data clerks
5	2	6	48	2	2	3	1	2	1	2

The picture of staffing at the study context is further well clarified on figure 3.3.

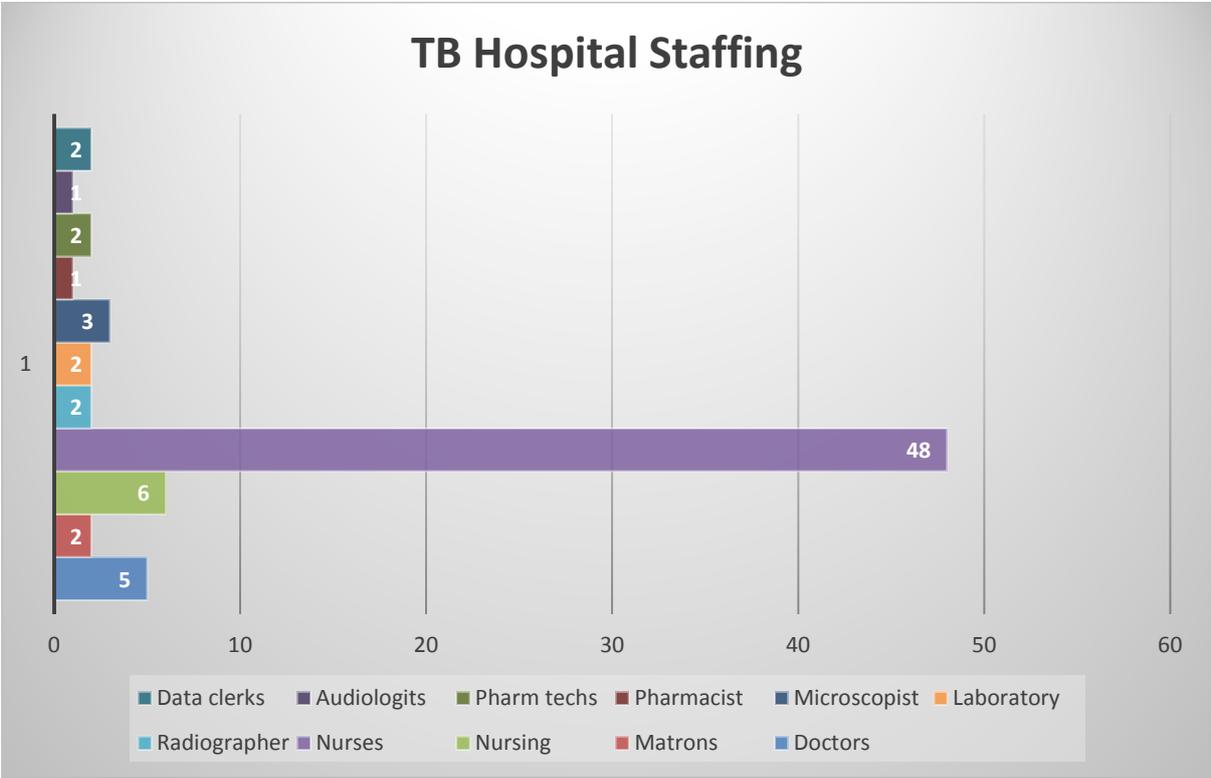


Figure 3.3 Staffing at the hospital

The staff compliment at the facility as exhibited in table 3.1 and figure 3.3 is reflected as 5 Doctors, 2 Matrons, 6 Professional nurses, 48 Nurses of other categories, 2 radiographers, 2 Lab technologists, 3 Micro-scopists, 1 Pharmacist, 2 Pharmacy techs, 2 Data clerks, (1 IT personnel), 1 Audiologist (refer to table 3.1) The majority of the personnel in the facility are the nurses.

The services offered by the hospital in view of the study context include:

- Out-patient services
- Health Education on MDR-TB, TB/HIV co-infection
- Screening for DR-TB and HIV
- Provision of DR-TB treatment initiation and follow-up
- Management of TB drug side effects
- Provision of DOTS plus where a treatment supporter is linked to the patient for treatment monitoring throughout the treatment duration
- In-patient admission services
- Initiation and provision of ART to DR-TB patients
- DR-TB treatment program through data management
- Community DR-TB services, home assessment, mapping, screening of DR-TB contacts, tracing of DR-TB treatment defaulters
- Audiology services
- Physiotherapy and occupational therapy

A research design appropriate to address the research problem is presented.

3.6 RESEARCH DESIGN

According to Polit and Beck (2008:766, 757), research design is a plan or a blue print of how you intend conducting the research, it focuses on the end product: what kind of a study is being planned and what kind of result is being aimed. The implementation of a good research study requires a clear research design to guide the data collection and analysis (Streubert & Carpenter 2011:33). In this study, a qualitative, quantitative, explorative and descriptive design was used.

3.6.1 Qualitative

Qualitative research is a systematic, interactive, subjective approach used to describe people's life experiences and give them meaning. It is conducted to describe and promote understanding of human experiences such as pain, caring and comfort (Burns & Grove 2007:22). Creswell (2011:34) describes qualitative research as "an inquiry

process of understanding human experiences based on a distinct methodological tradition of inquiry that explores a social or human problem". Qualitative research involves looking at characteristics or qualities that cannot easily be reduced to numerical values (Leedy & Ormrod 2010:94).

Qualitative research is a way of gaining insight through discovering meanings. In qualitative studies, researchers begin by talking with or observing people who have first-hand experience of the phenomenon under study (Polit & Beck 2012:532). This approach results in information that has the potential to elucidate varied dimensions of complicated phenomena, including caring for patients with TB or DR-TB. The researcher selected a qualitative design in order to investigate the experiences of DR-TB patients enrolled on treatment concerning risks they are exposed to.

In this study, a qualitative approach had the following advantages:

- Qualitative methods are useful for exploring the full nature of a little understood phenomenon (Polit & Beck 2012:20).
- Qualitative methods enable researchers to search for explanations about how or why a phenomenon exists or what a phenomenon means as a basis for developing a substantive theory that is grounded in rich, in-depth, experiential and empirical evidence. This mode of enquiry aims to examine the nuances and complexities of a particular phenomenon (Leedy & Ormrod 2010:94).
- The kind of data obtained and the people selected as participants become focused and purposeful as the conceptualisation is developed and refined (Polit & Beck 2008:70). The focus of qualitative research is usually broad and the intent is to give meaning to the whole as the qualitative researcher has an active part in the study (Burns & Grove 2007:23).
- The participants who participated in this study were knowledgeable informants on the subject of being sufferers of the DR-TB disease.

This approach assisted the researcher to construct representations based on the participants' detailed knowledge and experiences about the condition (Polit & Beck 2008:70). Furthermore, the design was suitable for gaining insight on what reality they attach to their world.

Quantitative

A quantitative approach had the following advantages:

- A *scientific method*, with a set of orderly, systematic, disciplined procedures were used to acquire information, in which the researcher progressed logically to access the data collecting documents, according to a specified plan of action and rule of science (Polit & Beck 2012:12).
- Various *control strategies* were used such as controlling the selection of subjects by using a specific sampling criteria, which imposed conditions on the research situation, and minimised bias, as well as reducing the influence or confounding effects of extraneous variables (Burns & Grove 2009:35; Polit & Beck 2012:13; 14). This was ensured by use of the inclusion and exclusion criteria.
- Quantitative researchers gather *empirical evidence*; where results are grounded in objective reality rather than the researchers' personal beliefs, opinions or assumptions (Polit & Beck 2012:14).
- The information gathered in the study was partly quantitative and numeric information obtained from the records using a checklist was analysed statistically (Polit & Beck 2012:14).

Disadvantages of a quantitative approach include:

- The context of the study may be ignored, as it would not allow studying the phenomena in the natural setting, and therefore tight controls could not be ensured (Polit & Beck 2012:13, 14).
- Requires large representative sample of the populations studied, which may not always be feasible, as in this study only records of the participants were included which was a small sample and not representative (Polit & Beck 2012:13).

A quantitative approach was necessary for this study because the researcher aimed to conduct a retrospective analysis of existing records to establish the disease profile of the participants which may have an indication of risk factors for patients from 2012-2015.

Explorative

Explorative research investigates “the full nature of a phenomenon, the manner in which it is manifested and other factor with which it is related” (Polit & Beck 2012:540). Explorative research begins with some phenomenon of interest and explores the full nature of that phenomenon (Polit & Beck 2012:548). The design was used to obtain basic information about the experiences of the DR-TB patients on their perception of risk factors that influence the epidemiology of DR-TB. LoBiondo-Wood and Haber (2010:198) state that research is exploratory when the researcher “searches for accurate information about the characteristics of particular subjects, groups, institutions or about the frequency of a phenomenon’s occurrence, particularly when little is known about the phenomenon”. An exploratory design was selected as the researcher intended to assess and understand the experiences of these patients in a new light, ask questions during the in-depth interviews, and search for new insights (Polit & Beck 2012:239).

Researchers in exploratory studies must be creative, open minded, flexible and explore all sources of information to gather new data (Neuman 2006:34). However, exploratory designs are not intended for generalisation to large populations, they are designed to increase knowledge of the field of study (Burns & Grove 2007:359). Neuman (2006:34) adds that exploratory studies may be incorporated into a more systemic research that is published later.

Descriptive

The purpose of descriptive research is to “describe phenomena in real-life situations. Through descriptive research, concepts are described and relationships identified” (Burns & Grove 2007:52). Descriptive designs are commonly used in nursing research and are crafted to gain more information about characteristics. Their purpose is to provide a picture of situations as they naturally occur (Brink et al 2006:102, Burns & Grove 2007:237; Polit & Beck 2012:254).

The research design approach utilised in this study was chosen to be relevant to the research questions, the theoretical statement and the research objectives.

The mixed methods used to answer the research question and objectives are described.

3.6.2 Research method

The research methods, as described by Polit and Beck (2012:12), are techniques or procedures that researchers use for the structure and implementation of a study such as gathering and analysis of data relevant to the research question, problem statement and the study objectives. In this study the research methods included discussions on the population and sample selection, sample and sample techniques, sample size, data collection and data analysis, as well as measures to ensure validity and reliability, trustworthiness and ethical considerations

Population and sample selection

Population refers to the entire group of persons or objects that is of interest to the researcher, in other words, that meets the criteria which the researcher is interested in studying (Brink et al 2006:123). In this study, universal population referred to all DR-TB patients enrolled on treatment in Swaziland.

According to Polit and Beck (2012:78), the target population is the aggregate of cases about which the researcher would like to generalise the results or findings. In this study, the target population is formed by patients infected with DR-TB who are treated at the hospital in Manzini. A sample of informants was obtained from the accessible population.

According to Brink et al (2006:123), an accessible population is the population that the researcher has access to. Polit and Beck (2012:79) state that the accessible population is the aggregate of cases that conform to the designated criteria and that are accessible as subjects for a study. In this study the accessible population was the DR-TB patients who visited the health facility on the day of data collection and were eligible for inclusion to participate in the study.

Inclusion and exclusion criteria

When researchers prepare to recruit study subjects they begin by formulating a set of inclusion and exclusion criteria. This is used to define who is eligible and who is not to be a participant. For this study, the inclusion and exclusion criteria were developed to ensure that participants are within legal consenting age. Within the accessible population the researcher considered the following inclusion and exclusion characteristics:

Inclusion criteria

For patients who will participate in the *interviews* should be:

- DR-TB confirmed
- Initiated and enrolled on the DR-TB treatment during time period of study
- Either males and females
- 18 years old and above

Exclusion criteria

- Drug resistant patients initiated before or after the study period

Inclusion criteria

For written document analysis worksheets to be selected:

- DR-TB confirmed
- Initiated on DR-TB treatment retrospectively
- Either males and females

Exclusion criteria

- Documents of patients currently enrolled on treatment

Sample

A sample is a subset of the population which is selected to participate in a study (Polit & Beck 2010:307). In this study, the non-probability approach was used to recruit participants for the individual interviews and probability sampling method was used to identify the records to be included in the study. Using non-probability sampling, the researcher had no way of knowing whether each element of the population would be included or then represented in the sample and some members may have little to no chance of being included in the sample (Leedy & Ormrod 2005:206), however, the recruiting

Sampling methods

The recruitment method of choice was convenience sampling which fell under non probability sampling which by definition is when not all elements of the population has an opportunity for selection in the sample (Burns & Grove 2009:170). Convenience sampling was a method of choice to recruit participants for this study. According to Burns and Grove (2009:535), convenience sampling includes subjects in the study who happen to be at the right place at the right time, with addition of available subjects until the desired sample size is reached. There were a number of disadvantages experienced when using this sample approach:

- The approach decreased the sample representativeness of the population.
- Provided little control for biases.
- However, serious biases were not present in convenience sampling in this study.

The major advantage of the approach was that it was inexpensive, accessible and less time consuming.

However a sample that would be representative of the population was not sought for since generalisation was considered irrelevant in the qualitative setting because of the small sample size (Burns & Grove 2007:535).

Random sampling

Random sampling is a probability sampling technique that gives each element in a population the equal opportunity to be included in the study (Grove, Burns & Gray 2013:705). The files to study were arranged according to the patient's surnames and a Kth of 7 was used to select records to be analysed for this study — the records were arranged alphabetically in a group of 50 files. There were approximately 400 patient's files and of these every seventh of the files beneath was taken for inclusion in the study until total of 56 files were included.

Sample size

The sample size in the qualitative study was not pre-determined as data was collected until saturation occurred. The sample size of fifty (56) written document analysis worksheets was randomly selected (explained in section 1.12.3).

3.6.3 Data collection

Data collection, according to Burns and Grove (2007:378), begins with identifying the participants and the precise, systemic gathering of information relevant to the research purpose, study objective, study questions or study hypothesis (Burns & Grove 2007:536). Data collection process for the qualitative aspect of the study was through the individual technique. Individuals were encouraged to express and clarify in a way that is less likely to occur in a focus group interview (Burns & Grove 2007:379).

Data collection process

In this study, the individual qualitative interviews were audio recorded and transcribed verbatim by the researcher.

Individual interviews

The venues were easily accessible and supported the establishment of a non-threatening climate. The supervisors' offices were utilised and were prepared before the participants arrived. These provided privacy, comfort and were free from distractions such as noise or other interruptions. Telephone calls were diverted for the duration of the interview. The interviews were conducted on different days and times. The process followed was as follows:

- An office in a quiet place was provided for the purpose with a table and a chair around it for the convenience of the conversation and possible eye contact with one another.
- A 'do not disturb' notice was placed on the door to avoid distractions or interruptions.
- The sessions were held during lunch times as agreed upon with the unit managers and the participants. Refreshments were served thereafter.
- Participants were requested to switch off their cell phones to avoid interruptions
- The audio recorder was placed at the centre of the table after the methods of how information was recorded were explained, and permission to audiotape the interview was obtained from the participants.
- The letter of permission to conduct the study was read to the participants and each participant was requested to sign an informed consent form.
- The participants completed the demographic questionnaire.
- To commence the interview, the researcher asked an open ended question, designed to introduce the topic and to encourage the participants to be free and open.

The following questions were asked:

What do you understand by risk factors related to DR-TB?

Probing questions were directed based on the discussion generated from the opening questions. Some of these were as follows:

What do you understand by risks that influence your sickness of TB and drugs that seem not to help you get well?

What difficulties or barriers do you experience as you care for yourself?

How do you handle the identified risks?

What information do you need about your condition related to risks of DR-TB?

- The posing of questions and interview skills yielded better responses than experienced in the pre-test interview.
- The researcher listened attentively, showed interest in individuals and put in an effort to understand the meaning of their basic psychological and social experiences as they provided information about risk factors from their point of view. The interview was however terminated when all the major areas were covered. Participants were given an opportunity to ask questions. The researcher thanked them for sharing the valuable information and for their time. The interviews were terminated when the 18th participant could not provide more new information, themes or categories.

Data collection for the quantitative study

Document interview was conducted through use of a checklist as a data collection tool.

Pre-testing of the data collection instrument (checklist)

According to Polit and Beck (2012:738), a pre-test is the trial administration of a newly developed data collection instrument.

The purpose of a pre-test included the following:

- Identifying problems on the research instrument such as parts of the items that may be difficult to be completed.
- Evaluating and refining the data collection instrument.

- Assessing whether the sequencing of questions was sensible and answering the research question (Polit & Beck 2012:296).

The data collection instrument was pretested with 5 documents that had inclusion criteria but were not part of the main study and the modifications were done accordingly, especially in terms of the sequencing of questions.

The participants documents provided information such as the distribution of the participants by age and sex, by region, the type of drug resistance, previous treatment history, site of disease, HIV status, exposure to ARV's, other comorbid conditions, treatment support to patients and any development of side effects or adverse reactions during treatment.

3.6.4 Data analysis

Data analysis occurred simultaneously with data collection. The eight steps provided by Tesch (1990) in Creswell (2013:184-187) to analyse data were mainly utilised to do the analysis of the qualitative data and developed themes and categories.

The quantitative data from the DR-TB register were analysed through document analysis using content analysis approach with consultation with the statistician. Descriptive and inferential statistics were used to describe and summarise data, and the results were presented in the form of percentages, histograms, pie charts, frequencies, and tables

3.6.5 Validity and reliability

Validity

The validity of the checklist tool was ensured through face and content validity through consultation with experts in the field who are working with the researcher at the study context. They made some input and some of the items on the checklist were modified.

Validity is a term used to describe a measure that accurately reflects the concept it is intended to measure. It is the extent to which an empirical measure adequately reflects

the real meaning of the concept under consideration. It is a quality criterion, referring to the degree to which inferences made in a study are accurate and well-founded; in measurement, it refers to the degree to which an instrument measures what it is intended to or is supposed to measure (Babbie & Mouton 2001:648, 123; Polit & Beck 2012:745). Validity varies from one sample to another and from one situation to another; therefore validity testing actually validates the use of an instrument for a specific group or purpose, rather than the instrument itself (Grove, Burns & Gray 2013:393).

Face validity

Face validity refers to whether or not the instrument appears to reasonably measure the target construct. In this study, it was an important aspect of the usefulness of the instrument, because the willingness of subjects to complete the instruments related to their perception that the instrument measured what they agreed to provide (Grove et al 2013:394; Polit & Beck 2012:336). It was based on intuitive judgement of experts in the field who were the experienced medical personnel with regards to the study phenomena. They therefore verified that the checklist measured what was desired. Their input assisted the researcher to add some essential items on the checklist or modify some items about the study phenomena.

Content validity

Content validity examines the extent to which the method of measurement includes all the major elements relevant to the construct being measured. This evidence was obtained from the literature, from representatives of the relevant populations, and from content experts. Among the dimensions often used are the following: clarity of wording, relevance of the item to the construct, or to one of its dimensions, and appropriateness for the target population (Grove et al 2013:394-395).

To ensure content validity, the researcher conducted an extensive literature review comprising previous studies published in research journals, as well as WHO publications on the study phenomena.

Reliability

Reliability of the check list was ensured by use of the interrater reliability as the tool was tested by the researcher and the clerks who work with the patient's register.

3.6.6 Measures to ensure trustworthiness

Measures to ensure trustworthiness in qualitative research refer to the accuracy of the findings by employing certain procedures (Creswell 2013:250). The following measures were taken into account which was credibility, dependability, transferability and confirmability (Brink et al 2010:118, 119).

Credibility refers to confidence in the truth and interpretation of the data. The truth of the findings was established as the participants were accurately identified and described and the data obtained from participants who had personal experience of DR-TB (Polit & Beck 2012:539). The researcher's credibility has to do with the faith that can be put in the researcher (Polit & Beck 2008:538). The researcher has several years' experience working with researchers on DR-TB at the referral hospital. The researcher ensured the credibility of the study through prolonged engagement and use of mixed study methods. Prolonged engagement was through much time spent with the participants during the interviews and day to day contact during consultations (Polit & Beck 2008:545).

Dependability

Dependability refers to the stability of data over time and conditions (Polit & Beck 2012:539). In this study, the audio-taped and transcribed information served as evidence that is consistent and stable.

Transferability

Transferability refers to the extent to which findings can be transferred or applied to other similar settings or groups (Polit & Beck 2012:539). The findings of this study cannot be generalised as it was conducted with a small size of participants who were identified and recruited from one hospital, although the descriptions and results or

findings should assist researchers to consider transfer as a possibility (Polit & Beck 2012:541).

Confirmability

Confirmability refers to objectivity that is the potential congruence between two or more independent people about the accuracy, relevance and meaning of the data. In this study data collection and analysis represent the information provided by participants and not manipulated data by the researcher. The audio-taped information serves as evidence to reflect the participants' responses (Polit & Beck 2008:541).

3.7 ETHICAL CONSIDERATIONS

In this study considerations were taken to ensure protection of the rights of the research institution, of participants, and ensuring scientific integrity.

3.7.1 Protecting the rights of the research institution

This research fell under the authority of the Department of Health Studies of UNISA, since it is conducted in order to obtain a Master's degree in Public Health from this institution. Therefore, the researcher sought for official ethical approval from the Department's Research Ethics Committee. Ethical clearance was obtained (Annexure A). Permission by the Swaziland's Health Research Committee was also sought for. Moreover this research took place under the authority of the management of National DR-TB Referral Hospital. Therefore, after obtaining ethical approval by the Ethics Committee of the Department of Health Studies a letter of application for permission (Annexure B) to conduct this research was sent to the National Tuberculosis Control Program and the management of the respective facility.

3.7.2 Protecting the rights of the participants

Polit and Beck (2012:152) describe principles and procedures that researchers ought to adopt to protect the rights of participants. The Belmont report articulated three broad principles upon which standards of ethical conduct in research are based; which include beneficence, respect for human dignity and justice (Joubert & Ehrlich 2007:31). The

rights of the participants were also protected by obtaining informed consent (see Annexure D), protecting their right to withdraw from the study at any given time if they feel uncomfortable, respecting their right to confidentiality and anonymity, as well as maintaining privacy and dignity.

Beneficence

Human research should be intended to produce benefits for the participants, by avoiding, preventing and minimising harm and maximising benefits. In research with humans, harm and discomfort can be: physical such as stress, fear, loss of social support or financial loss of wages (Polit & Beck 2012:152). Since this research concerns identifying risk factors related DR-TB which may be a sensitive subject, and may bring about emotional discomfort.

A counsellor based at the hospital was arranged to be available during data collection for participants who may be emotionally affected by the interview. However, in this study none of the participants suffered emotional discomfort but rather most of them were amused by the questions.

The researcher ensured that all involved in the study respected the views of the participants and ensured that participants were not exposed to any emotional stress as a result of the study itself. The study involved minimal risk, which is defined as risks no greater than those ordinarily encountered in daily life, or during routine tests and procedures (Polit & Beck 2012:733). Participants were informed about the benefits for the advancement of knowledge that may improve the reproductive quality of life for women.

Respect for human dignity

The cardinal principle of respect for human dignity includes the right to self-determination and the right to full disclosure. Self-determination means that prospective participants are able to voluntarily decide whether or not they want to take part in the study without the risk of prejudicial treatment. Participants have the right to ask questions, to refuse to give information, and to withdraw from the study. With regards to full disclosure in this study, the researcher fully described the nature of the study, the

persons' right to refuse participation without victimisation, as well as likely risks and benefits (Polit & Beck 2012:154).

To ensure respect for human dignity in this study, participants were briefed about the benefits and risks and their right to refuse and /or withdraw from the study, before they signed the consent form, and without any form of coercion. They were further able to ask questions without encountering judgement or intimidation of any kind.

Justice

The cardinal principle of justice includes the participants' right to fair treatment and the right to privacy. Participants' selection should be based on study requirements, and not on a group's vulnerability. The right to fair treatment means that researchers must treat people who decline to participate or who withdraw from the study after initial agreement in a non-prejudicial manner; that they must honour all agreements made with participants and demonstrate respect for the beliefs, habits and lifestyles of people (Polit & Beck 2012:155).

In this study, all participants were selected by convenience sampling, as long as they fulfilled the inclusion criteria in a fair manner, and without coercion.

Informed consent

Informed consent meant that participants have access to adequate information about the research, that they comprehend that information and that they have the ability to consent to or decline participation voluntarily (Polit & Beck 2012:159). In this research, in order to satisfy this ethical requirement, a written informed consent explaining the objectives and potential risks, as well as assuring confidentiality of the study, was presented to each respondent. It was also explained that the respondent could withdraw from the study at any time. The participants signed the consent form in order to show that they voluntarily accept the right to participate in the study (Polit & Beck 2012:156).

Right to withdraw from the study

Participants were informed about the option to withdraw or discontinue participation in the study at any time, without any penalty or loss of benefit or intimidation as a regular patient in the health facility

Confidentiality and anonymity

Confidentiality involves the researchers' management of private information shared by a subject, which must not be shared with others without the subject's expressed consent (Burns & Grove 2005:196).

Anonymity exists if the subject's identity cannot be linked, even by the researcher, with individual responses (Burns & Grove 2005:196). Polit and Beck (2012:720) further clarified that it involves the protection of respondent's confidentiality, such that even the researcher cannot link individuals with the information provided).

In this study, to ensure confidentiality and anonymity, the participants were assured that all their responses and information obtained from them during the study would neither be disclosed nor publicly divulged.

Maintaining privacy

Privacy is an individual's right to determine the time, extent, and the general circumstances under which personal information will be shared with or withheld from others. This information consists of one's attitudes, behaviours, opinions and records (Burns & Grove 2005:195).

The researcher ensured that the research was no more intrusive than it needed to be, and that the participants' privacy was maintained and the data kept with strict confidence. Questionnaires were completed in a private venue designated for that purpose. A "do not disturb" sign was hung at the door to reduce the impact of external noise and distractions.

3.7.3 Scientific integrity of the research

The researcher will adhere to the principles of scientific integrity by avoiding plagiarism. These will include: honesty in reporting, referencing and communicating the findings.

Privacy and confidentiality will be maintained by keeping all data obtained under lock and key.

Anonymity may be difficult to maintain but all measures to protect the participants will be ensured. They will be informed that they may withdraw from the study at any time without victimisation.

Scientific integrity will be ensured through avoiding plagiarism, acknowledging all sources used and writing the correct list of sources.

3.7.4 Dissemination of findings

The findings will be published in an accredited journal for wider readability; a poster will be developed and presented through in-service education to patients and staff.

3.7.5 Scope and limitations of the study

The scope of this study was limited because of the small sample size of the qualitative part and it was not easy to generalise or transfer results or findings to a wider community. Although some information was obtained from the register it could have variables that were inaccurate or incomplete. Some of the participants had a challenge with the English language and the researcher mostly translated the questions into Swazi language.

3.8 CONCLUSION

This chapter described the research design and methodology used in conducting this study as a mixed method approach. The researcher used a quantitative, explorative and descriptive study design, and a check list was used to collect data from documents. Qualitative data was collected through use of an interview guide and 18 individuals were

interviewed. The chapter included discussions on the research setting, population, sample and sampling technique, data collection approach and method, data analysis, measures to ensure validity and reliability, trustworthiness and ethical considerations.

Chapter 4 discusses the data analysis and interpretation of the research findings.

CHAPTER 4

ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH RESULTS

4.1 INTRODUCTION

Data analysis is the systematic examination of data to discover conceptual patterns and in some cases, cause-and-effect associations within the broader social context in which the research question and objectives are directed (Ulin, Robinson & Trolley 2005:139).

The purpose of this study was to identify risk factors influencing epidemiology of drug resistant tuberculosis (DR-TB) in a drug resistant hospital setting. This was done by considering analysed information obtained from the questionnaire items. This was to determine whether the participants that had eventually developed DR-TB had similar occurrences or events leading to them finally being diagnosed with this type of TB resistance. The quantitative (Section A) employed document analysis using content analysis approach, and was done with consultation with the statistician. The qualitative (Section B) data analysis was done through thematic analysis. Quantitative data was obtained from patient files and registers and qualitative data through individual interviews.

Research question

“What are the risk factors that influence DR-TB occurrence among patients enrolled on DR-TB treatment?”

The objectives of this study were to:

- explore and describe the risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB
- identify risk factors influencing the epidemiology of DR-TB amongst patients enrolled on DR-TB treatment

- develop a poster that will exhibit the research process undertaken and the findings

SECTION A: Quantitative analysis of data

4.2 RESEARCH RESULTS BASED ON DEMOGRAPHICS

Most of the demographics in figures are of the live patients. Some aspects of analysis are alluding to information from the retrospective patient files that were randomly selected for analysis of 49 patients that had been treated and completed Drug resistant treatment. Initially 56 files were identified but 7 were incomplete and spoiled and were therefore not included.

Data management and analysis

Eighteen (18) participants participated in the study on face to face interviews and collected data was analysed through thematic analysis. The checklist was administered to 49 respondents identified on the register. Data were coded and analysed using the SPSS version 13.0 statistical software packages and excel in consultation with a statistician. Descriptive statistics such as frequency distributions, medians, contingency tables and percentages were obtained. A 95% confidence interval of proportions was constructed.

4.2.1 Demographics

The researcher did own analysis based on vast experience of use of the SPSS computer program with the help and validation of a statistician. Analysis was basically related to the demographic variables such the participant's age and sex, region where they are staying, level of education, employment, job loss due to illness, total cost per facility visit, previous treatment history and perception by patients for risk factors for developing DR-TB.

Age and sex are important determinants of people's likelihood to take health actions as guided by the HBM.

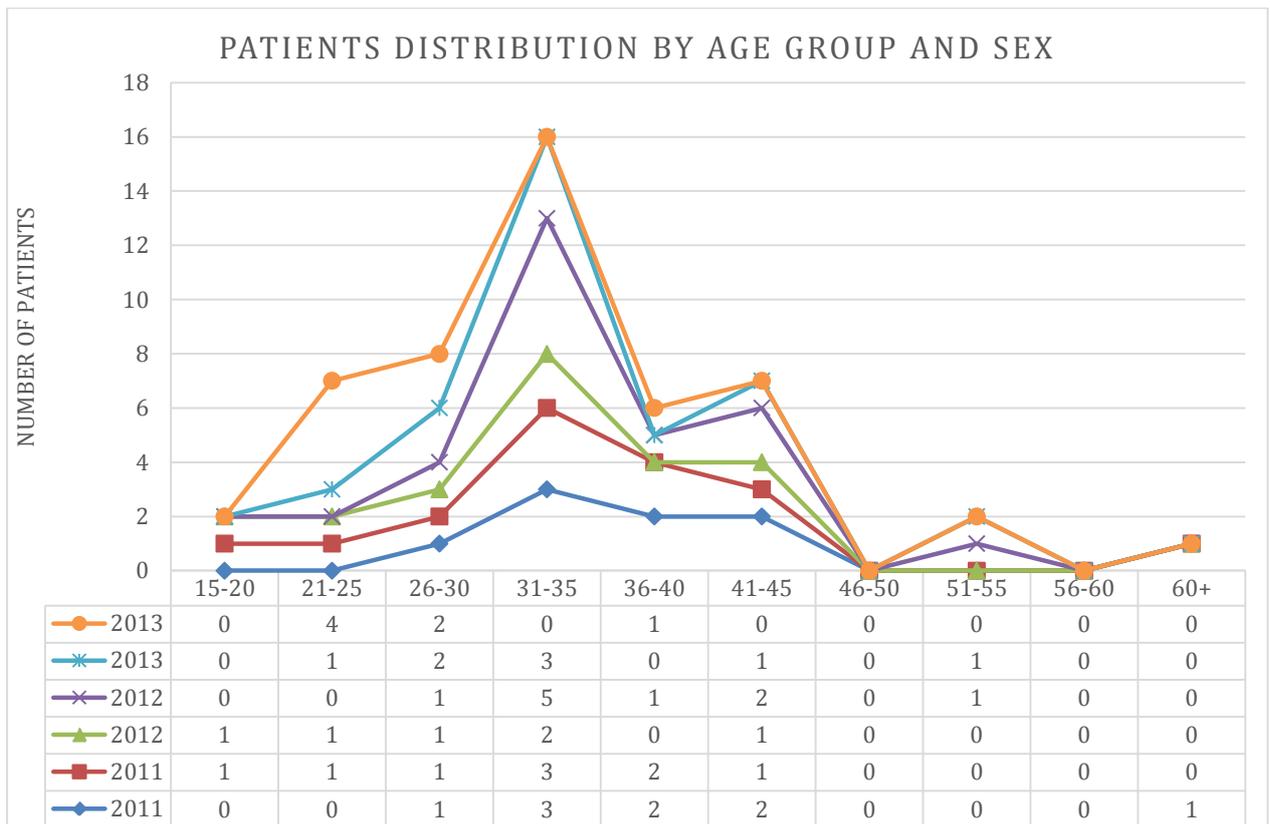


Figure 4.1: Age and sex (n=49)

Majority of the active patients who were interviewed were falling in the 20-29 age group, followed by the 30-39 age group, 40-39 and lastly 10-19. This trend suggests that the mostly highly likely to develop drug resistant TB are those falling between the reproductive age group and this can be validated using the secondary data collected from the 49 patients where it shows the same trend in age. The reason for the reproductive age group to be most affected is that this is the same group that is highly affected by HIV and Holland K also stated that HIV positive have a weakened immune system as a result are prone to opportunistic infections such as tuberculosis.

The following figures (4.2, 4.3 and 4.4) of age and sex and are displayed to portray a picture of affected patients as deduced from the files for the years 2011, 2012, 2013.

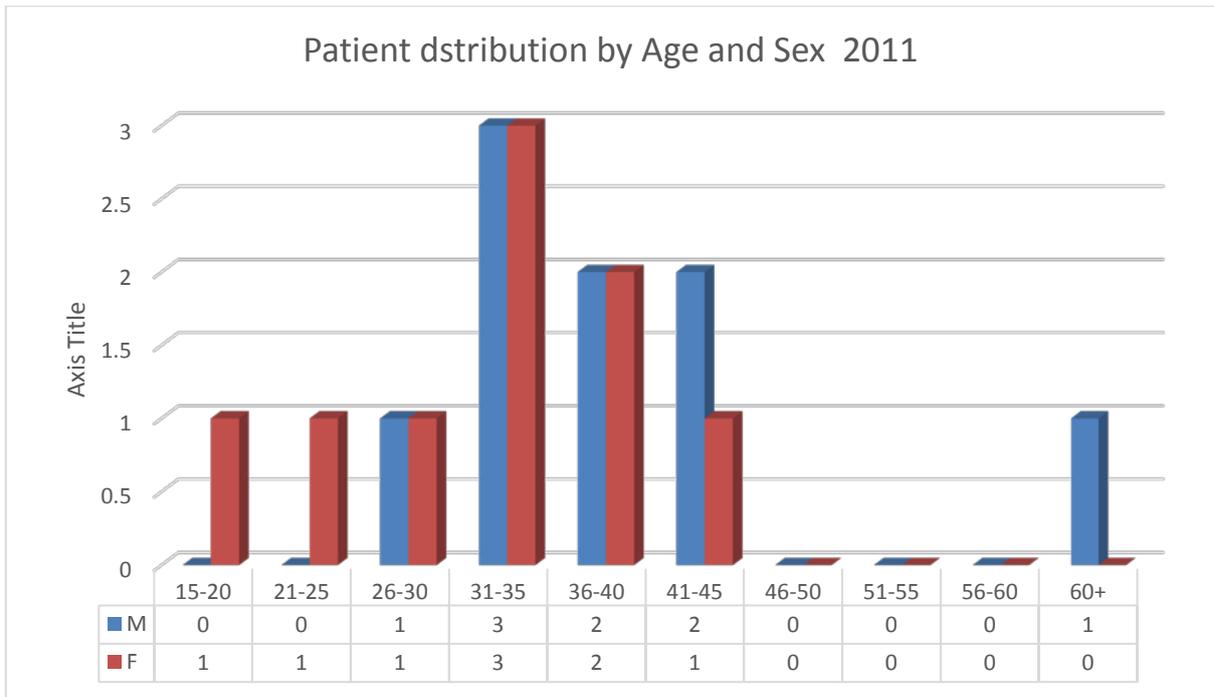


Figure 4.2: Age and sex 2011 (from files) (n=49)

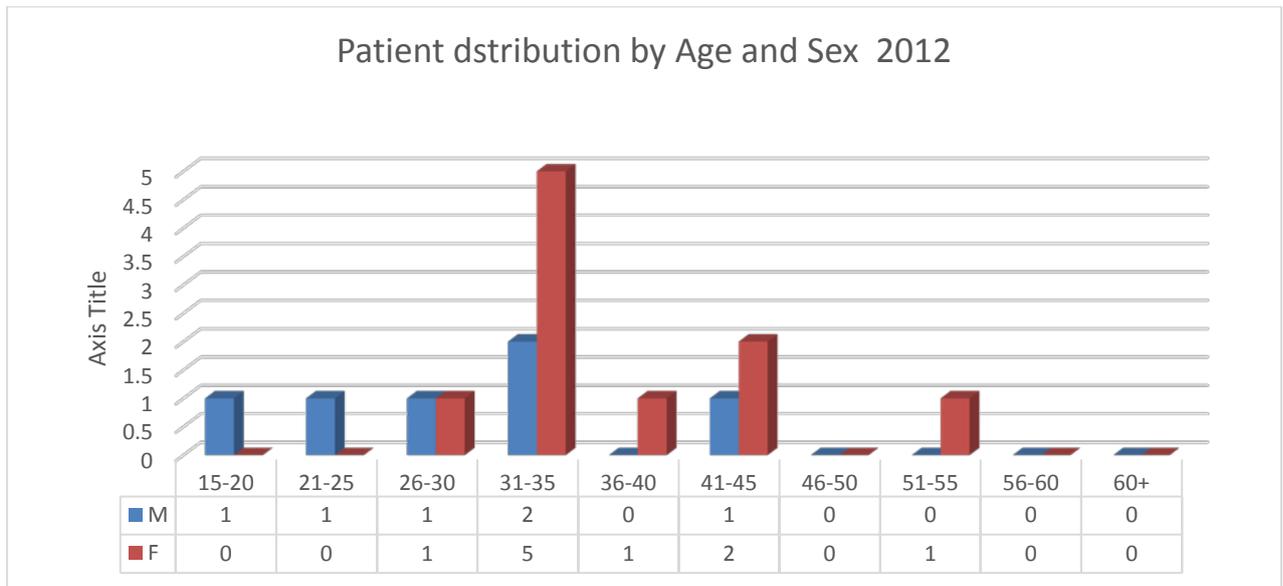


Figure 4.3: Age and sex 2012 (from files) (n=49)

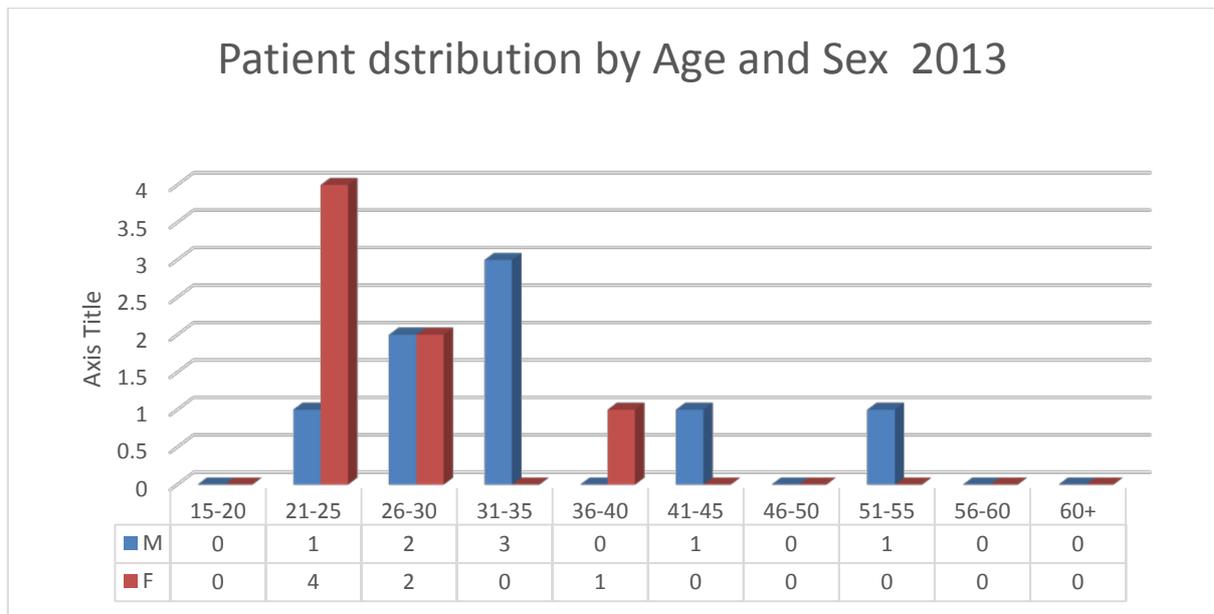


Figure 4.4: Age and sex 2013 (from files) (n=49)

The graphs above shows the distribution by age and sex of the patients from the files and registers, the results shows that at ages 20 and below the number of infection from DR-TB is low then the number gradually increases from ages 25-45 being at peak at ages 31-35. This shows that the most affected group is the reproductive age group which is also the highly infected by the HIV virus which could be the reason for this trend.

Another trend that can be identified from the graph is that the prevalence in 2011 has been gradually increasing in 2012 and is even higher in 2013 amongst all the sexes e.g. the males in 2013 are higher than the ones in 2012 which are also higher than the male in 2011, this is the similar case for the females as well. This suggests that DR-TB trend is continuously increasing even though in the country TB is gradually going down.

Understanding a population's age and sex composition yields insights into changing phenomena and highlights future social and economic challenges. (United States Census Bureau 2015:11).

The population's age was assessed from the years 2011-2013 to understand the concentration of DR-TB in relation to age and sex.

Table 4.1: Age groups

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	21.778 ^a	28	.791
Likelihood Ratio	25.261	28	.614
Linear-by-Linear Association	.064	1	.800
N of Valid Cases	50		

a. 38 cells (95.0%) have expected count less than 5. The minimum expected count is .04.

Table 4.1 shows that Pearson Chi-square statistic, $X^2 = 21.778$ and $p > 0.05$. The data does not support the claim that age influences the chances of developing DR-TB. There is not enough evidence to say age is a predictor of drug resistance.

4.2.2 Distribution of patients by region

The DR-TB patients were coming from different regions in the country Hhohho, Manzini, Lubombo and Shiselweni.

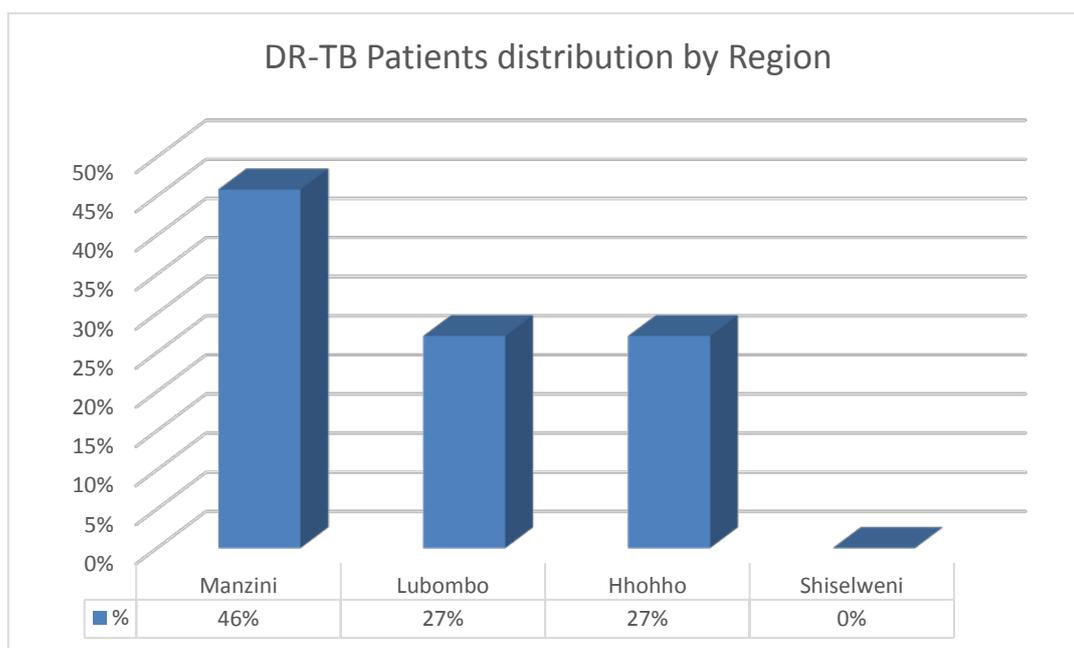


Figure 4.5: Distribution of patients by region (from files) (n=49)

Figure 4.5 shows that 46% of the respondents were from the Manzini region; these were then followed by Hhohho and Lubombo both with 27%. None of the respondents were from Shiselweni region and this is probably due to that Shiselweni offers DR-TB treatment in 3 health facilities in their region where patients prefer to access their care from mainly due to easier access.

4.2.2.1 Level of education

The majority (56%) of the participants had not completed their high school education.

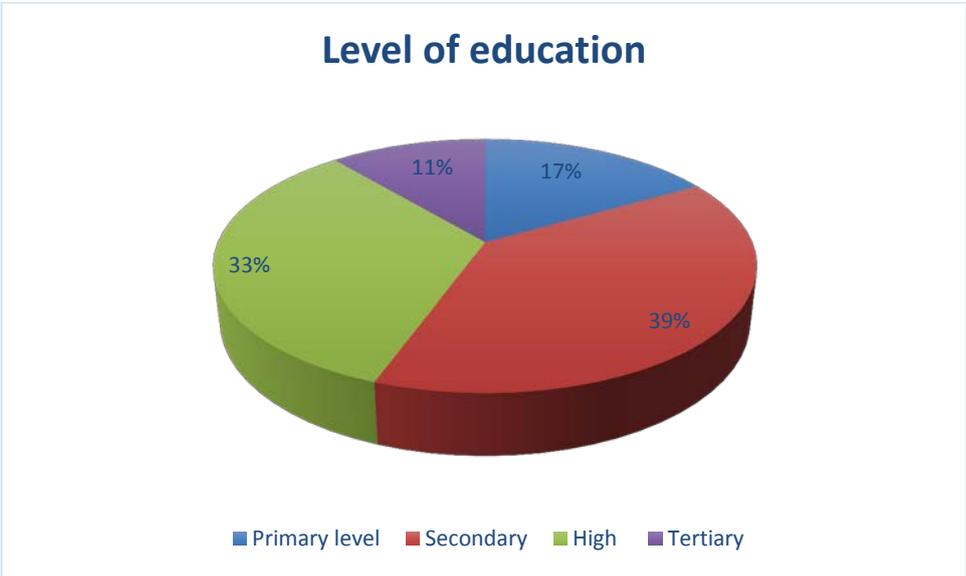


Figure 4.6: Level of education (n=18)

Figure 4.2 shows that there is little association between low education and development of DR-TB as 56% of the respondents were educated and 44% had not completed their O’level/IGCSE education. According to Desalu, Adeoti, Fadeyi, Salami, Fawibe and Oyedopo (2012:1), the association of higher family income and education with awareness of TB signs may be attributed to higher literacy. Higher level of educational attainment is often a factor for better family income. Families that have high income are able to purchase household assets like television, radio and Hi fi internet, and other communication appliances that increase their knowledge of health-related matters which are of public concern (Desalu, Adeoti, Fadeyi, Salami, Fawibe and Oyedopo (2012:1).

4.2.2.2 Employment history

Employments as a means to financial viability play a vital role to positively deal with risk factors related to DR-TB disease. Figure 4.3 exhibits the employment history of the participants.

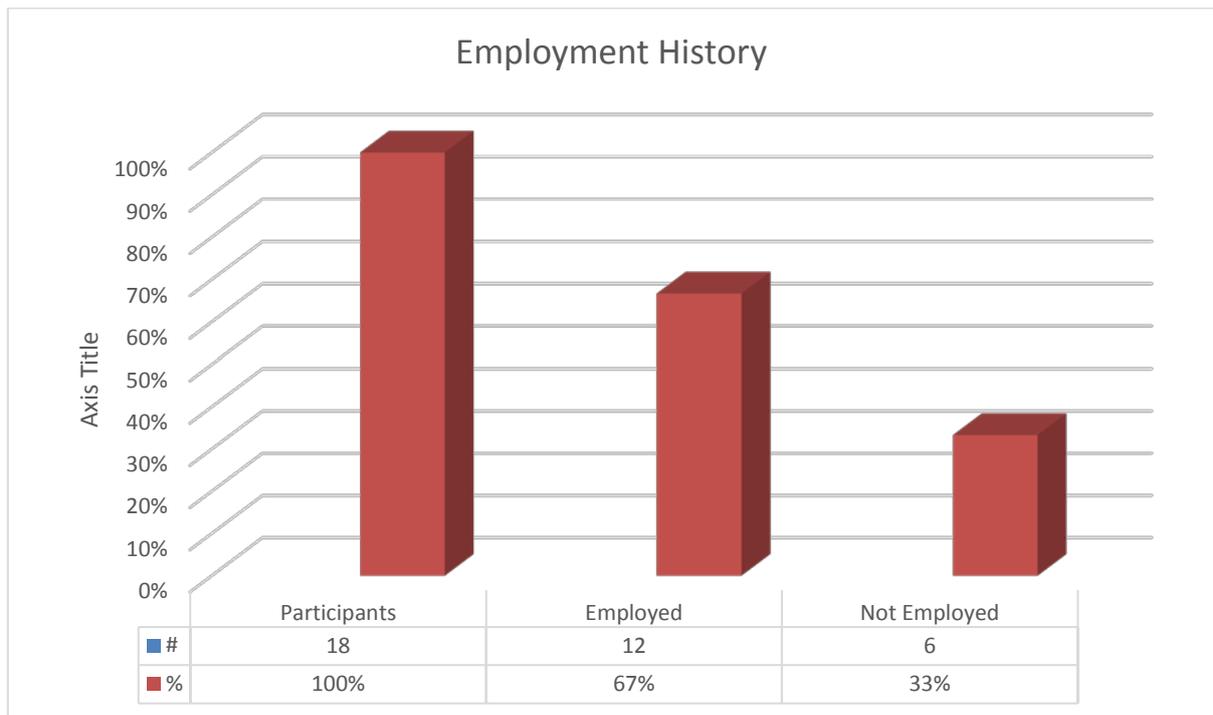


Figure 4.7: Employment history (n=18)

Twelve (67%) of the participants were employed at diagnosis with TB, 6 (33%) were not employed, of the 12 only 4 (33%) were able to keep their jobs which means 8/12 (67%) lost their jobs due to tuberculosis. Some of the participants stated that they would leave the jobs with an agreement that once they get better they will be re-instated in their previous positions and only 1 was. Some would just stop going to work due to ill health. According to Phelamei (2013:13), HIV and TB are also intricately linked to social situations such as malnutrition, unemployment, alcoholism, drug abuse, poverty and homelessness that reduce people to being vulnerable groups to diseases.

4.2.2.3 Job loss due to illness

Illness' compromises one's ability to seek for a job or be sustained in a job due to demands for doctors' appointments or consultations.

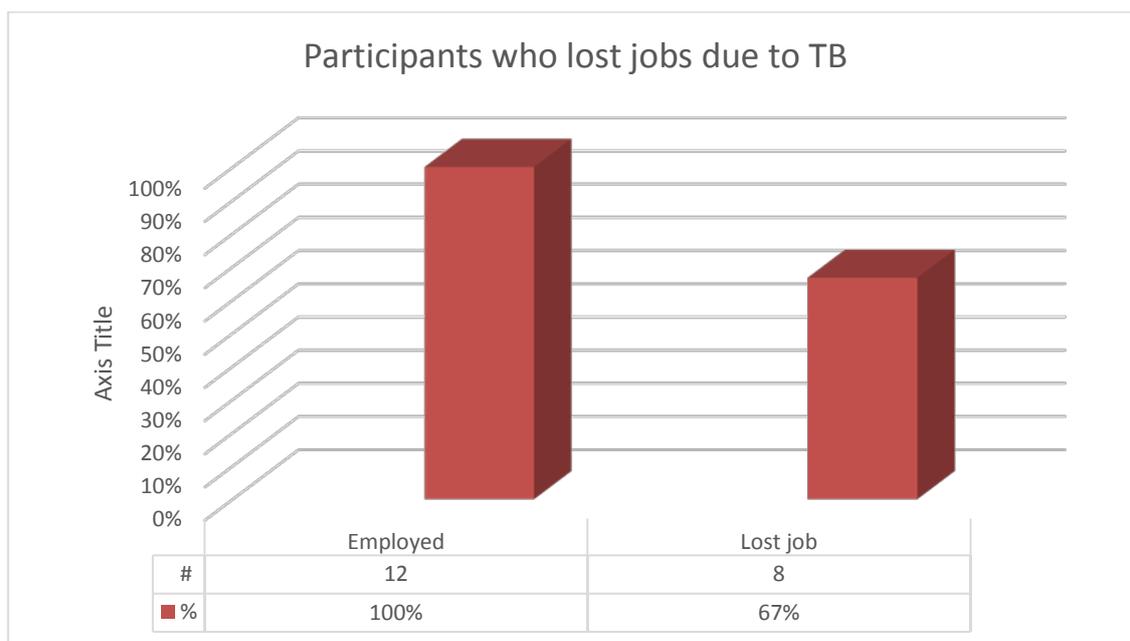


Figure 4.8: Job loss (n=18)

Twelve of the participants were employed at diagnosis with TB, 6 were not employed, of the 12 only 4 were able to keep their jobs which means 8/12 (67%) lost their jobs due to tuberculosis. Some of the participants stated that they would leave the jobs with an agreement that once they get better they will be re-instated in their previous positions and only 1 was. Some would just stop going to work due to ill health.

4.2.2.4 Total cost per facility visit

Visit to the health care facilities have escalating cost that lead to some patients defaulting treatment.



Figure 4.9: Total cost per facility visit (n=18)

Cost of seeking DR-TB care for the participants was another factor that was closely related to access. The researcher noted that participants that were accessing their tuberculosis medication previously before being started on DR-TB treatment that on average a patient would spend R90 for a facility visit and 78% of the participants were without a job (8 had lost their source of income, and 6 were without jobs at diagnosis).

According to WHO (2015:3: Figure 4.10) falling ill with TB often carries a devastating financial burden with social repercussions. On average, TB patients in low-and middle-income countries face medical expenses, costs of seeking/staying in care, and income loss equivalent to more than 50% of his or her annual income. The financial burden varies between settings, with total cost in relation to income ranging from 2% to over 300% across countries with different TB care models, general health systems and social protection schemes. The financial burden is on average greater for persons ill with MDR-TB and for the poorest (WHO 2015:3)

Income loss represents on average about 60% of the total costs faced by patients, whereas about 25% is for direct medical costs such as tests, medicines and hospitalisation, and the rest is for other care-related costs, such as transport (see

figure). On average, half of the costs are incurred before TB treatment has begun – in seeking diagnosis (see figure).

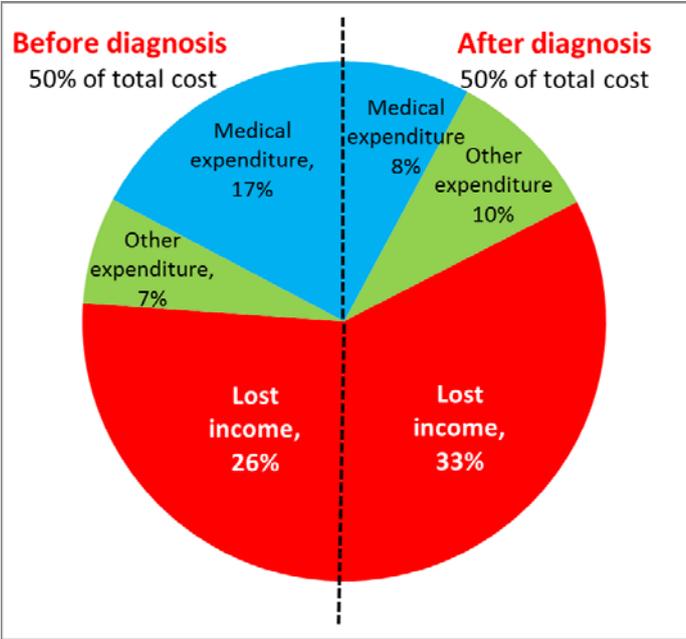


Figure 4.10: Cost of TB
(Adapted from WHO 2015:3)

Patients often have to resort to survival means to cope with their situation: up to 75% of TB patients must take out a loan; up to 50% sell household items; and up to 66% rely on financial support from relatives. In Swaziland the patients identified more with relying on relatives for support which meant that whether the patient adheres to treatment appointments heavily depends on the relatives.

4.2.2.5 Previous treatment history

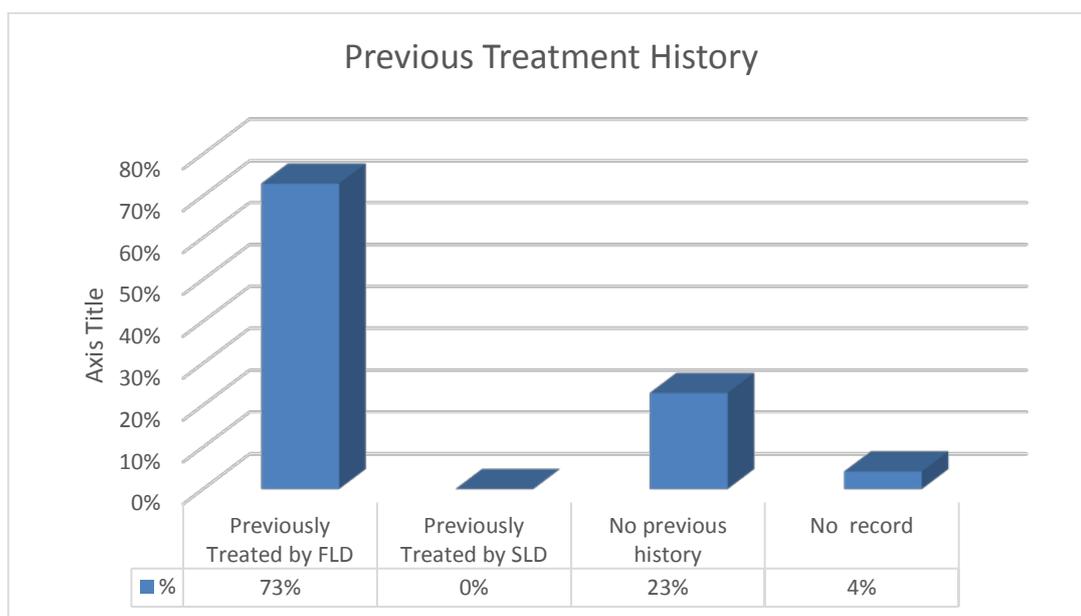


Figure 4.11: Previous treatment history (n=49)

The trend in both secondary and primary cohorts shows that the majority of patients have been exposed to first line drugs (FLD's) prior to developing DR-TB, with the current findings from patients who are still taking the drug resistant medication showing that 50% have been exposed to FLD's, and 44% had no prior exposure.

The secondary data finding (the cohort of patients (n=49) who were treated and have treatment outcomes shows that 73% were exposed to FLD's prior to developing drug resistant TB, 23% had no prior exposure to TB drugs. The researcher interpretation to this change in the trend is that in previous years 2011, 2012 and 2013 majority of those infected with drug resistant tuberculosis it was mainly from prior exposure to the TB drugs. The current findings suggest an increase in direct transmission of drug resistant TB in our communities as more and more drug resistant cases report that they have never been treated for TB before.

This would then bring the question why is there increase in direct contact infection over the years? The researcher would conclude that previously the number of DR-TB patients was mainly from poor treatment adherence or poor compliance which meant it was a result of poor treatment outcomes but this number of DR-TB patients resides in

the communities and workplaces and is directly transmitting the already resistant TB to people who have never been exposed to TB medication.

The chi-square test rejected the null hypothesis that previous treatment history is associated with progression to DR-TB. The data suggests that there is not enough evidence to support the claim, therefore there is no significant association between previous treatment history and DR-TB.

Side effects during TB treatment and DR-TB

In this example, since the p-value is .040 (which is less than .05), we can say that there is a significant association between development of side effects during TB treatment and progression to DR-TB. According to Luetkemeyer (2013:1), the risk of developing adverse reactions to TB treatment is higher in HIV-infected individuals than in HIV-uninfected individuals, occurring in approximately 25% and 13%, respectively. Hepatotoxicity is common in the treatment of TB in HIV-infected patients. The adverse reactions may be made worse by use of both tuberculosis and antiretroviral (ARV) drugs. Other drug to drug interactions which may be fatal with TB treatment include antibiotic medications such as fluconazole and trimethoprim-sulfamethoxazole, by coinfection with viral hepatitis, or by pre-existing liver disease.

4.2.2.6 Perception by patients for risk factors for developing DR-TB

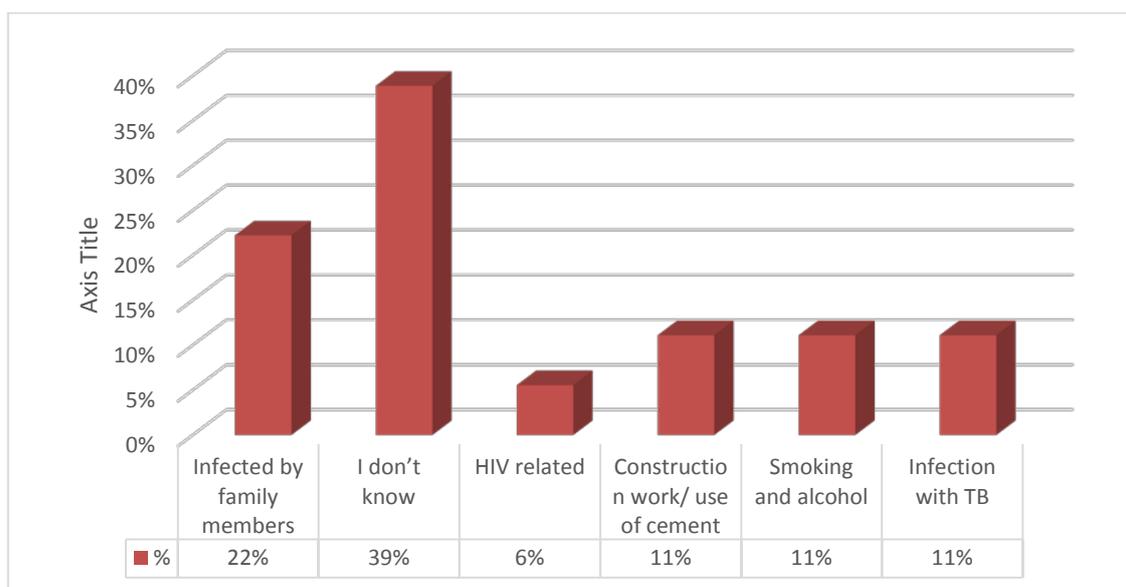


Figure 4.12: Perception by patients on reasons for developing drug resistant tuberculosis (n=18)

The majority (39%) of the patients did not know how they got to develop drug resistant TB and a majority of those infected didn't know as they were never treated for TB before. The next group 22% stated infection from family members, 11% said it was working with cement, 11% said it was due to smoking and alcohol, 11% said it was because they had TB that caused them to develop DR TB and 6% related drug resistant TB to HIV.

SECTION B: Qualitative data analysis

4.3 PARTICIPANT DEMOGRAPHICS

The participants comprised of eighteen Swazi patients who were all currently undergoing DR-TB treatment. There were more single young adults than those that are married among the participants. Drug resistant TB seemingly affects more females than males as the trend showed that 11/18 females and 7/18 were males. This could be due to the higher population ratio of female to male ratio in the general population.

Eighteen individuals were interviewed until saturation of data occurred. Demographic information was collected at the beginning of each interview using a questionnaire with predetermined fields based on the variables that would contribute to the analysis of the study phenomenon. The use of the concept 'participant' as referring to the patients who were the target population for this study was used interchangeably.

An interview guide was administered to collect data which had section A for the demographic questionnaire, Section B for the grand tour question. Participants were required to respond to the main question and probing questions about their experiences prior to being diagnosed with drug resistant TB. They were also encouraged to reflect on any occurrences that may have led to their eventual DR-TB diagnosis during TB treatment or otherwise.

The individual interview method as suggested by Polit and Beck (2012:341) was followed wherein a grand tour question open-ended question was asked and was supported with probing questions to ensure all thematic areas are covered.

The interview remained flexible and allowed the participants to engage in storytelling as they were encouraged to openly and freely respond to all the questions listed below.

Participants that were interviewed were 18 in total and the following thematic areas were used to present the analysis: History of TB in the family and previous treatment history, attitude of the health care workers, healthcare worker patient education, accessibility to medication and pill dosing , knowledge of general factors resulting to TB, geographic location to facility, employer attitude to TB patients, treatment supporter responsibilities, Adherence and counselling, patient side effects, co-infection and opportunistic infections, IPC issues, and stigma. These were categorised as follows:

4.4 THEMES AND CATEGORIES ON RISK FACTORS FOR DR-TB

4.4.1 Theme 1: History of TB in the family and previous treatment

The trend in both secondary and primary cohorts shows that the majority of patients have been exposed to first line drugs (FLD's) prior to developing DR-TB with the current findings from patients who are still taking the drug resistant medication showing that 50% have been exposed to FLD's, and 44% had no prior exposure.

The secondary data finding (the cohort of patients (n=-49) who were treated and have treatment outcomes shows that 73% were exposed to FLD's prior to developing drug resistant TB, 23% had no prior exposure to TB drugs. The researcher interpretation to this change in the trend is that in previous years 2011, 2012 and 2013 majority of those infected with drug resistant tuberculosis it was mainly from prior exposure to the TB drugs but of late the trend shows that there is increase in direct transmission of drug resistant TB in our communities and more and more drug resistant cases report that they have never been treated for TB before.

This would then bring the question why is there increase in direct contact infection over the years? The researcher would conclude that previously the number of DR-TB patients was mainly from poor treatment adherence or poor compliance which meant it was a result of poor treatment outcomes. These DR-TB patients reside in the communities and workplaces and are directly transmitting the already resistant TB to people who have never been exposed to TB medication. One of the participants said:

“I was staying with someone who had drug resistant TB without being aware that she had resistant TB.”

Another patient when asked what she thinks caused her to have DR-TB she responded:

“I started TB medication then stopped the medication. I was very angry and eventually stopped working too.”

Infection prevention and control in addition to treatment completion should form a vital part in tuberculosis control so as to minimise direct transmission to others.

4.4.2 Theme 2: Attitude of the health care worker

The majority of the patients said the relationship with the health care workers was good 13/18, those who said it was okay were 2/18 and 3 said it was bad. One of those saying it was bad was 44 year old single Dudu who when asked about side effects mentioned weakness, hallucinations and dreams, skin problems and when asked how she managed them she stated:

“... it got better with time without reporting because nurse never did anything, I think they didn't like me.”

“... there was bad language especially from gossips by the cleaners as they became friends with other patients.”

If a patient feels that the relationship is not good with the health care worker she may keep whatever problems she has and solve them her own most likely wrong way.

Other responses were positive:

“ it was good they still recognise me.”

4.4.2.1 Category 2.1: Health care worker patient education

The participants showed that there was a gap in tuberculosis education, this was evident when the participants were asked what they perceived to be the cause of them developing DR-TB and if they thought TB was curable. The participants stated various reasons some of which were not relevant to TB such as use of cement.

4.4.2.1.1 Subcategory 2.1.1: Knowledge of general risk factors resulting to TB

The majority 7/18 (38.8%) of the participants interviewed stated poor adherence to treatment/ not completing treatment and direct infection by contact as the major factors resulting to development of drug resistant tuberculosis. These were followed by smoking, dust, and poor diet. Other factors mentioned included HIV, by poor education and counselling, public transport, sex, working in mines, stress, unemployment, mismanagement and being emotional.

Another risk factor is that patients that are HIV/TB co-infected, these diseases do not normally get the same attention where even the structure of care shows the discrepancy. During adherence counselling HIV is provided with 3 sessions before the patient is started on the treatment, yet TB is only given a few minutes session and the patient is initiated on treatment.

4.4.2.2 Category 2.2: Accessibility to medication

The cost for the participants was another factor that was closely related to access. The researcher noted that participants that were accessing their tuberculosis medication previously before being started on DR-TB treatment that on average a patient would spend R90 for a facility visit and 78% of the participants were without a job (8 had lost their source of income, and 6 were without jobs at diagnosis). One of the participants said:

“To go for review at the facility a car was hired to take me because I was too ill, it cost R400 each trip and I was not employed my sister paid it for me.”

Geographic access proved to be another risk factor as 11/18 majority of the patients were from the rural health settings. In the country health care facilities are closer at the urban areas meeting the recommended 8 km radius by WHO. In rural areas the facilities are fewer and further apart making it cumbersome for patients to reach the facilities. Another factor is that TB services are not provided in all these facilities. This not only makes the facilities to be inaccessible to the patients but if accessible the TB service itself not being accessible as it is not provided in that facilities.

4.4.2.3 Category 2.3: Adherence counselling and education

In tuberculosis and HIV care adherence counselling is done by the health care workers. Looking at the structure of adherence counselling in other chronic diseases like HIV where there are 3 sessions of counselling done for the patient before initiating treatment, TB does not have such an intense structure to ensure importance of adherence to treatment. When asked on adherence counselling being done at the beginning of treatment 12 agreed they were counselled, though some in the 12 said they were too sick to understand what was being said. Six said they were not well counselled and a majority was those that were diagnosed with DR-TB without previous history of TB. One participant said:

“I was diagnosed at X facility in Manzini where they told me I had DR-TB and had to go to Moneni hospital, when I got here I was told I am being admitted to the ward for TB, it was when in the ward that i heard from the other patients that I will stay here for a long time since I was highly infectious until I complete my injections- I ended up staying in hospital for 8 months.”

Nineteen year old Mandisa asked after the interview:

“How long will I be taking the medication.”

The response given was that it will be 8 months of injections and at least 2 years medication. She was also informed that side effects may crop up but she should report these to the facility as soon as possible she broke down and cried. This is the same day she was to start the 2 year long DR-TB medication and she was emotionally not ready, and the information was new to her.

The majority (39%) of the patients did not know how they got to develop drug resistant TB and a majority of those that didn't know were never treated for TB before. The next group 22% stated infection from family members, 11% said it was working with cement, 11% said it was due to smoking and alcohol, 11% said it was because they had TB that caused them to develop DR TB and 6% related drug resistant TB to HIV.

4.4.2.4 Category 2.3: Treatment supporter responsibilities

Table 4.1: Treatment supporter

Yes	7	70%
No	3	30%
Never treated for TB (N/A)	8	

The participants who were interviewed were 18 in total, of these 10 were treated for tuberculosis before, of the 10, 7 had treatment supporters linked to their care, 3 did not have a treatment supporter and 8 were never treated for TB before. The researcher identified that the greater majority 70% of those previously treated were linked to a treatment supporter and mostly it was family treatment supporters. There are 3 types of treatment support structures in the country the family treatment supporter, the community treatment supporter and the facility treatment supporter. The treatment supporter responsibilities are to assist the patient in the taking of the medication, including reminding the patient when it is time to take medications, to remind patient of hospital visits, to monitor the patient when taking the medication and remind on the correct dosing of the drugs etc. These responsibilities require the treatment supporter to be close to the patient which is not usually the case so this results in some of the treatment supporters not being able to fulfil their responsibilities and in turn affect the patient intake of their medication (Swaziland National Drug-Resistant Tuberculosis Management Guidelines 2012).

During diagnosis twelve of the participants were employed, a total of 8 lost their jobs with only 4 being able to maintain their jobs. One participant stated that:

"We had an agreement with the employer to stop work and once my health improves I will be re-instated, when I got better someone had already taken my position, I was jobless."

The support and understanding of employers is crucial to for patients with DR-TB for their quality of life.

4.4.3 Theme 3: Stigma

The participants when asked about disclosure to community for support raised issues of fear of stigma as a reason why they are not disclosing their TB status. Eleven (11/18) stated that they did not have any community support, of the eleven, 9 stated fear of discrimination and isolation from community. One participant stated:

"I did not disclose because the community I stay in is not a good community."

Another participant who is the fourth TB case in the family where both parents and a sister died of TB said:

"No but the community is aware that I am from a family of TB affected people."

This statement gave the impression that the community has labelled the homestead to be the "TB stricken family".

On a more positive note one of the patients felt like this about stigma:

"No by the way what I have realised by stigmatisation is that it usually starts with you, I never blamed anyone for my status."

In areas of high HIV prevalence, where HIV and TB co-infection is common, the link between the two diseases has contributed to the stigmatisation of TB. TB is perceived as a marker for HIV positivity; therefore, HIV-associated stigma is transferred to TB-infected individuals. Other causes of TB stigma include the perceived associations of TB with malnutrition, poverty, being foreign-born, and low social class. As with HIV, TB is stigmatized in this context because it is linked to other disvalued characteristics,

which themselves are also social determinants of health. Finally, TB stigma may occur because an affected individual's community believes he or she must have done something to deserve to be infected. This judgment may reflect the belief that TB is divine punishment for a moral or personal failing, which then licenses stigmatisation.

TB-infected individuals perceive themselves to be at risk for a number of stigma-related social and economic consequences. Because the most common result of TB stigma is isolation from other members of the community, TB infection can substantially impact economic opportunities. (Courtwright et al 2010).

According to Courtwright et al (2010), in areas of high HIV prevalence, where HIV and TB co-infection is common, the link between the two diseases has contributed to the stigmatization of TB. TB is perceived as a marker for HIV positivity; therefore, HIV-associated stigma is transferred to TB-infected individuals. Other causes of TB stigma include the perceived associations of TB with malnutrition, poverty, being foreign-born, and low social class. As with HIV, TB is stigmatized in this context because it is linked to other disvalued characteristics, which themselves are also social determinants of health. Finally, TB stigma may occur because an affected individual's community believes he or she must have done something to deserve to be infected. This judgment may reflect the belief that TB is divine punishment for a moral or personal failing, which then licenses stigmatisation.

TB-infected individuals perceive themselves to be at risk for a number of stigma-related social and economic consequences. Because the most common result of TB stigma is isolation from other members of the community, TB infection can substantially impact economic opportunities.

4.5 CONCLUSION

A mixed method approach was undertaken in this study to identify risk factors related to DR-TB from patients who were enrolled for treatment. Data analysis of both documents and active patients (these are the patients who were currently undergoing DR-TB treatment) provided a picture that assisted to make deductive conclusions on the study phenomena.

The results and findings of this study helped to formulate conclusions and recommendations made in chapter 5.

CHAPTER 5

DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

“Prevention is better than cure”

5.1 INTRODUCTION

In this chapter the findings and results of the study on risk factors influencing the epidemiology of DR-TB in TB Hospital are discussed and concluded.

The study findings were discussed in relation to literature and conclusions were drawn. The limitations, recommendations and implications relating to nursing practice, education, further research and how a poster will be structured were presented.

5.2 RESEARCH QUESTION

The main and probing questions asked were: What are the prime risk factors of drug resistance TB? The control measures currently in place, are they effective in eliminating any form of TB in Swaziland. Does the TB treatment success rate reflect the prevailing status of TB in Swaziland in light of drug resistance TB? Does previous treatment with other anti-tuberculosis fuel the progression to DR-TB?

5.2.1 Research objectives

- To investigate the factors that influences the emergence of DR-TB in Swaziland.
- To establish the relationship between DR-TB and HIV.
- To develop a poster that will portray the findings on risk factors influencing the epidemiology of DR-TB.

5.3 DISCUSSIONS AND CONCLUSIONS ON THE MAJOR FINDINGS

The findings of this study were based on the purpose and objectives of the study. They are discussed in this section as an integrated summary of results derived from the data and related to literature.

To investigate the factors that influences the emergence of DR-TB in Swaziland

Previous treatment history

The researcher arrived at the conclusion that the major factors contributing to the emergence of DR-TB are previous treatment with anti-tuberculosis drugs, human immune virus, and lack of education for patients especially during transfer between facilities, where referring facility assumes education will be done in receiving facility and vice versa and education of the patient's families on precautionary measures to take when caring for a family member, and what to do in cases of developing side effects, which other studies validate.

In a study conducted in Portugal, Gomes, Correia, Mendonca and Duarte (2014:12) concluded that DM, previous treatment history and intravenous drug use were the major risk factors identified in the study. Pinto and Menzies (2011:18) suggest that poor management of susceptible tuberculosis (previously treated TB) propagates the emergence of DR-TB. During treatment three possible mechanisms can result in the selection of drug-resistant mutant strains: treatment with an inadequate number of effective drugs, sub-therapeutic dosing or absorption, or treatment interruption (Pinto & Menzies 2011:18). Patient consumption of all doses of an appropriate drug regimen with the correct dosages is essential to prevent resistance. The value of evidence-based adequate drug regimens cannot be over-emphasized; unfortunately, these seem to be flouted in countries where drug regulatory systems are lax, and private physicians and pharmacies are allowed to prescribe drugs in an unregulated manner. They further state that when treated with a single drug, the population of TB bacilli initially shrinks due to the killing of susceptible organisms in the population, often rendering a person smear-negative (as a result of fewer organisms being present). However, the organisms that survive the initial phase are the drug-resistant mutants, and the proliferation of these mutants eventually causes the entire population of bacilli to be replaced by drug-

resistant forms that continue to proliferate until they are numerous enough to cause recurrence of symptoms, and smear positivity; this is termed “the fall and rise phenomenon.

Unemployment and job losses due to TB: Socio-economic factors were also identified as strong determinants of patients seeking health related care which may also affect the actual access of care due to unemployment and having to travel long distances to facilities. This can also affect reporting of side effects on time at facilities as patients would rather wait until they return to the facility for review to bring up issues related to medication. The patient health care worker relationship also plays a major role when it comes to reporting side effects and four of the participants reported vomiting as a side effect which could result in sub optimal drugs in their system for cure.

Another risk factor identified to be related was the number of patients who reported having lost their jobs due to diagnosis with TB, as 8 out 12 reported some form of interruption of financial gain as a result of TB. Only one was able to regain her job after being cleared by the medical officers, during this time the patients need the income to take care of themselves and their families rely on their income. Job loss means the patients will have to rely on others to travel to the facility to get treatment though the TB treatment is free in all public facilities and this renders the patients helpless on financing for their own health care.

To establish the relationship between DR-TB and HIV

The relationship between DR-TB and HIV was identified in both cohorts. The qualitative findings show that the prevalence of HIV in DR-TB was 61% for HIV positive and 39% for negative and the quantitative data showed 77% HIV positive and 23% negative to HIV. Both these data sets show that there is a close link between DRTB and HIV.

A classical research study by Goble, Iseman, Madsen, Waite, Ackerson and Horsburgh (1993:527) although old but came out with critical findings that confirmed that many patients who contracted drug resistant TB have HIV infection, their response to treatment appears to be very poor with high rates of treatment failure and mortality.

5.3.1 Recommendations

- Intensification of active case finding strategies among HIV positive population: measures that will allow early identification of DR-TB such as the universal use of the TB screening tool in all HIV care settings.
- Strengthening health education in facilities even if the patient is from another facility to ensure that the important information is communicated to both the client and the family.
- The integration of Infection, Prevention and control measures in all health care planning. This should start with the planning structures in facilities, ensuring health education of the patients and their families to avoid feelings of discrimination and bring understanding on need for some of the precautionary measures in the control of TB.
- Regimens for drug-susceptible TB have a strong evidence base and, when employed in the right dosages for the right duration with close monitoring of adherence, lead to high cure rates without the development of drug-resistant strains. Getting treatment right the first time should therefore be the primary focus of TB control programs worldwide.
- Infection prevention and control in addition to treatment completion should form a vital part in tuberculosis control so as to minimise direct transmission to others.

According to Pinto and Menzies (2011:30), the occurrence of rare, spontaneous mutations during replication of the TB bacillus is a natural phenomenon, but the preferential selection and propagation of such resistant mutants is man-made, and largely preventable.

Development of a poster

A poster will be developed for presentation of the study and its findings to interest groups. The poster will cover the content of research purpose, research question, objectives, data collection, data analysis, presentation of the findings and recommendations.

5.3.2 Implications relating to nursing practice

The implications of these findings to nursing practice are as follows:

Emphasise should be on ensuring that TB patients are properly treated and adherence counselling for patients at every contact with patient should be ensured during the initial treatment. It is important that the adherence counselling of TB patients be as aggressive as the one in HIV care, where the patients are provided 3 counselling sessions prior to treatment initiation, and during follow up visits to have a one on one counselling session prior to refill of medication and in case of suspicion of default the patient is provided stepped up intensified counselling and potential risks discussed with patient. This system has worked quite well for HIV care and may need to be adopted for the TB programme.

The study showed a significant association between development of side effects during TB treatment and progression to DR TB, which brings up the need for the health care workers to stay alert of patients who have been initiated on TB treatment presenting to their facilities. Patient empowerment on not waiting at home with any side effect or adverse reaction to the medication but to report it immediately without waiting for the next scheduled appointment or visit. This would greatly minimize the side effects and patients would adhere to the medication better with reduced side effects.

Infection prevention and control measures need to be strengthened in health care facilities, this includes the all the 3 measures: administrative (policies and procedures), environmental (opening of windows, doors, designing patient flow) and personal protection (use of masks, gloves).

Implications relating to education

The education of health care workers and health care students should include Tuberculosis as a module at the nursing and medical schools. Currently the nursing curriculum does not have tuberculosis as a standing module and as a result students complete their education with little knowledge on the TB management subject. Pre service training on TB has already been identified as lacking in the country's nursing

curriculum and equipping the students with knowledge on management on tuberculosis will address a lot of issues.

Implications relation to research

Research needs to be continued to understand the extent that the TB bacteria has evolved over the coming years through constant mutations and exposure to the TB drugs. The results in this study has already shown that over the years drug resistant TB has become more a direct infection than due to previous exposure to TB drugs, the factors contributing to this have to be further investigate, could this be due to TB bacteria evolving over the years as a result TB is becoming more resistant or is due to the increased pool of patients with poor adherence resulting in the resistant bacteria increasing, another possibility could be that as a result of the introduction of Expert testing as a first diagnostic test in the country more yield of patients is identified which before microscopy was only identifying as positive to TB but unable to categorise as resistant.

Implications to public health

The results from the study showed that infection mostly happens through transmission from an infected individual to an uninfected individual. This suggests as recommended above that infection prevention and control measures in the health facility and also in the community is very important. TB has been seen to affect one family member to the next and this has been due to poor IPC measures at the family and community settings. The need for the government to ensure that the rights of the people infected by TB are protected cannot be overly emphasized as stigma was seen to play a large role and fear of losing jobs which majority of the patients infected with TB eventually lost may be another factor that results in continued TB spread at work settings. The country also has no bill protecting the public from a patient that refuses to take his TB medication and the individual can continue working without treatment and continue transmitting the TB to unsuspecting work colleagues.

5.4 CONCLUSION

Based on the findings of this study into factors influencing the trend of DR-TB, we are able to conclude the following:

Previous treatment history has influence in the development of DR-TB as shown in the study results from comparison of the 2 cohorts. In cohorts, the participants and the reviewed records it shows that prior exposure to FLD's was a common denominator and this confirms that patients that have been previously treated for TB once have an increased probability of developing drug resistant tuberculosis. The results of the retrospective data (2012-2015) shows that in the past years the main cause for DR-TB was previous treatment with FLD's (these were patients that had completed treatment) but the analysis of current patients on DR-TB showed that there was evolution in the transmission of DR-TB where direct transmission is increasing showing that the DR-TB patients in the communities are now directly passing the disease to others (close contacts).

The researcher's interpretation was that there was an increase in direct transmission of drug resistant TB in our communities over the years almost to the same level as previous treatment. This was suggested by that there was an increase in drug resistant cases reporting that they have never been treated for TB before from the interviewed participants.

As much a previous treatment is a factor for DR-TB, but direct transmission is on the rise and may eventually be the major transmitter of DR-TB surpassing prior treatment. This leads recommending strengthening of IPC measures including development of policies, IPC work-plans and personal protection to curb the evident gradual increase in direct transmission of DR-TB.

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ANNEXURES

ANNEXURE A

ETHICAL CLEARANCE CERTIFICATE:

DEPARTMENT OF HEALTH STUDIES, UNISA
SWAZILAND'S HEALTH RESEARCH COMMITTEE

SWAZILAND'S HEALTH RESEARCH COMMITTEE

ANNEXURE B

LETTER OF REQUEST FOR PERMISSION TO
CONDUCT THE STUDY

LETTER OF REQUEST FOR PERMISSION TO CONDUCT THE STUDY

ANNEXURE C

PERMISSION GRANTED TO CONDUCT THE STUDY

PERMISSION GRANTED TO CONDUCT THE STUDY

ANNEXURE D

CONSENT FORM

CONSENT FORM

ANNEXURE E

DATA COLLECTION TOOLS

DATA COLLECTION TOOLS: QUESTIONNAIRE

Risk Factors influencing the epidemiology of drug resistant tuberculosis patients enrolled for treatment at the National Tuberculosis Referral Hospital, Swaziland

All information herewith provided will be treated confidentially. It is not necessary to indicate your name on this questionnaire

INSTRUCTIONS

1. Answer all questions by providing an "X" in the box corresponding to the chosen alternative
2. Answer all questions as honestly, frankly and objectively as possible
3. Answer according to your own personal opinion, knowledge and experience

Answer the question by placing an "X" in the box corresponding to the alternative which is applicable to you

SECTION A: BIOGRAPHICAL DATA

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1.	<p>In which age category do you fall?</p> <table border="1" style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 20px; text-align: center;">1</td> <td style="width: 300px;">10-19</td> <td style="width: 50px;"></td> </tr> <tr> <td style="text-align: center;">2</td> <td>20-29</td> <td></td> </tr> <tr> <td style="text-align: center;">3</td> <td>30-39</td> <td></td> </tr> <tr> <td style="text-align: center;">4</td> <td>40-49</td> <td></td> </tr> <tr> <td style="text-align: center;">5</td> <td>50-59</td> <td></td> </tr> <tr> <td style="text-align: center;">6</td> <td>60+</td> <td></td> </tr> </table>	1	10-19		2	20-29		3	30-39		4	40-49		5	50-59		6	60+		<table border="1" style="width: 100%; text-align: center; margin-top: 20px;"> <tr> <td style="width: 100px; height: 20px;"></td> </tr> </table> <p style="text-align: right; margin: 0;">10</p>	
1	10-19																				
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2.	<p>What is your marital status?</p> <table border="1" data-bbox="475 286 986 479"> <tr><td>1</td><td>Single</td><td></td></tr> <tr><td>2</td><td>Married</td><td></td></tr> <tr><td>3</td><td>Cohabiting</td><td></td></tr> <tr><td>4</td><td>Other</td><td></td></tr> </table>	1	Single		2	Married		3	Cohabiting		4	Other		<input data-bbox="1305 405 1481 456" type="text"/> 11			
1	Single																
2	Married																
3	Cohabiting																
4	Other																
3	<p>What is your gender?</p> <table border="1" data-bbox="320 801 432 952"> <tr><td></td></tr> <tr><td>Male</td></tr> </table> <table border="1" data-bbox="735 790 858 947"> <tr><td></td></tr> <tr><td>Female</td></tr> </table>		Male		Female	<input data-bbox="1305 714 1505 766" type="text"/> 12											
Male																	
Female																	
4	<p>Indicate the highest grade passed</p> <table border="1" data-bbox="475 1048 1007 1238"> <tr><td>1</td><td>Grade 7</td><td></td></tr> <tr><td>2</td><td>Grade 10</td><td></td></tr> <tr><td>3</td><td>Grade 12</td><td></td></tr> <tr><td>4</td><td>Other (specify)</td><td></td></tr> </table>	1	Grade 7		2	Grade 10		3	Grade 12		4	Other (specify)		<input data-bbox="1305 1077 1481 1128" type="text"/> 13			
1	Grade 7																
2	Grade 10																
3	Grade 12																
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5	<p>Indicate who you live with</p> <table border="1" data-bbox="475 1384 986 1619"> <tr><td>1</td><td>Family with both parents</td><td></td></tr> <tr><td>2</td><td>Single parent family</td><td></td></tr> <tr><td>3</td><td>Sibling-headed family</td><td></td></tr> <tr><td>4</td><td>Alone</td><td></td></tr> <tr><td>5</td><td>Other (specify)</td><td></td></tr> </table>	1	Family with both parents		2	Single parent family		3	Sibling-headed family		4	Alone		5	Other (specify)		<input data-bbox="1326 1417 1493 1469" type="text"/> 14
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6	<p>What is your position in the family?</p> <table border="1" data-bbox="475 1709 986 1944"> <tr><td>1</td><td>First born</td><td></td></tr> <tr><td>2</td><td>Second born</td><td></td></tr> <tr><td>3</td><td>Third born</td><td></td></tr> <tr><td>3</td><td>Last born</td><td></td></tr> <tr><td>4</td><td>Other (specify0</td><td></td></tr> </table>	1	First born		2	Second born		3	Third born		3	Last born		4	Other (specify0		<input data-bbox="1318 1787 1493 1839" type="text"/> 15
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2	Second born																
3	Third born																
3	Last born																
4	Other (specify0																

7	Which region are you from?			16
	1	Manzini		
	2	Hhohho		
	3	Shiselweni		
	4	Lubombo		

1-16

Please comment on the following aspects from B-F by placing an “X” on the choice that best reflects your opinion about the **topic under discussion**

SECTION B: GRAND TOUR QUESTION

“What could be the risk factors that resulted in you having DR-TB?”

THANK YOU FOR YOUR PARTICIPATION

ANNEXURE F

TRANSCRIPTION

TRANSCRIPTION

ANNEXURE G

LETTER FROM STATISTICIAN

LETTER FROM STATISTICAIN

ANNEXURE H

CHECKLIST TO COLLECT DATA FROM DOCUMENTS

CHECKLIST TO COLLECT DATA FROM DOCUMENTS

	Type of document (check one) <ul style="list-style-type: none"> <input type="radio"/> Newspaper <input type="radio"/> Letter <input type="radio"/> Memorandum <input type="radio"/> Report <input type="radio"/> register 																																							
2.	Unique physical characteristics of the document (check at least one or more) <ul style="list-style-type: none"> <input type="radio"/> handwritten <input type="radio"/> typed <input type="radio"/> interestingly letter-headed <input type="radio"/> other 																																							
3.	Dates of document																																							
4.	Author Position																																							
5.	For what audience was the document written?																																							
6.	List key areas touched by the document. List from the document, Why do you think the document was written?																																							
7.	<p style="text-align: center;"><i>Fill in information captured by the document</i></p> <p style="text-align: center;">Patient Distribution by Age and Sex</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: left;">SEX</th> <th style="text-align: center;">0-4</th> <th style="text-align: center;">5-14</th> <th style="text-align: center;">15-20</th> <th style="text-align: center;">21-25</th> <th style="text-align: center;">26-30</th> <th style="text-align: center;">31-35</th> <th style="text-align: center;">36-40</th> <th style="text-align: center;">41-45</th> <th style="text-align: center;">46-50</th> <th style="text-align: center;">51-55</th> <th style="text-align: center;">56-60</th> <th style="text-align: center;">60+</th> </tr> </thead> <tbody> <tr> <td>Male</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>Female</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table>	SEX	0-4	5-14	15-20	21-25	26-30	31-35	36-40	41-45	46-50	51-55	56-60	60+	Male													Female												
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8.

Resistance Pattern by Age and Sex

SEX	0-4	5-14	15+	0-4	5-14	15+
	Male			Female		
Mono Resistance						
Poly resistance						
Rif only						
MDR						
XDR						

9.

Patient Distribution by Region

Region	Male	Female
Hhohho		
Manzini		
Lubombo		
Shiselweni		

10.

Patient distribution by disease type

Disease Type	SEX	
	Male	Female
Mono Resistance		
Poly resistance		
Rif only		
MDR		
XDR		

11.

Previous Treatment History by Site (at initiation)

Disease by Site	SEX	
	Male	Female
Pulmonary		
Extra Pulmonary		

12.

Previous Treatment History by Sex

History of Treatment	Male	Female
Previously treated for TB (FLD)		
Previously treated for TB (SLD)		
No previous history of TB (New)		

13.

If previously treated

Risk Category	Male	Female
New: smear + (HIV)		
Failure to convert at 2/3 mths of treatment		
Treatment Failure category 1		
Treatment Failure Category 2		
Relapse		
Default		
Contact to DR patient		
Mine worker		
Health Worker		
Prisoner		

14.	<p style="text-align: center;">Resistance by HIV Status</p> <table border="1" data-bbox="336 371 1093 768"> <thead> <tr> <th rowspan="2">Disease Type</th> <th colspan="3">HIV STATUS</th> </tr> <tr> <th>Positive</th> <th>Negative</th> <th>Unknown</th> </tr> </thead> <tbody> <tr> <td>Mono Resistance</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poly resistance</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Rif only</td> <td></td> <td></td> <td></td> </tr> <tr> <td>MDR</td> <td></td> <td></td> <td></td> </tr> <tr> <td>XDR</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Disease Type	HIV STATUS			Positive	Negative	Unknown	Mono Resistance				Poly resistance				Rif only				MDR				XDR																														
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