MODELING THE IMPACT OF RISK FACTORS AFFECTING TB TREATMENT

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DECLARATION

I, URGENT TSURO, wish to declare that this dissertation emanates from my own work and that as far as I am aware; all direct quotes have been specifically acknowledged.

I also affirm that I have never submitted this thesis, in part or in full, for an award of any other academic qualification at any other institution apart from the University of Fort Hare in the Republic of South Africa for the Master of Science Degree in Biostatistics and Epidemiology. My dissertation has not been previously published.

SIGNATURE : ……..

DATE: 30 NOVEMBER 2013.

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ABSTRACT

The Tuberculosis infection rate has been generally escalating due to poor health conditions in the Gweru district of Zimbabwe. The study therefore seeks to identify the risk factors that affect TB treatment in the Gweru district. A cross sectional study was carried out in which a questionnaire was employed for data collection on 113 respondents. A binary logistic regression model was employed for data analysis. A total of 98 TB patients were interviewed: [50 respondents (44.0%) had Multi-drug resistant Tuberculosis and 63 respondents (56.0%) had general Tuberculosis). Before being enrolled into the study, an informed consent form was given to each of the participants. The data was then put into excel and later transferred to SPSS for analysis. Out of the 14 potential risk factors of TB treatment, only 6 variables (: side effects, gender, alcohol use, HIV status, smoking during the treatment period and having been pre-exposed to TB drugs) were statistically significant in their association with treatment failure.

Key Words: Tuberculosis, risk factor.

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ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centre for Disease Control.
CI	Confidence Interval
CNR	Case Notification Rate
CSS	Cross Sectional Studies
DOTS	Directly Observed Treatment Short course
DR-TB	Drug-Resistant Tuberculosis
FDC	Fixed Dose Combination
HIV	Human Immunodeficiency Virus
MDR-TB	Multi-Drug Resistant Tuberculosis
MTB	Mycobacterium Tuberculosis
OR	Odds Ratio
PLWHIV	People Living With HIV
RR	Relative Risk
TB	Tuberculosis
WHO	World Health Organization

XDR-TB	Extensive Drug Resistance Tuberculosis
SPSS	Statistical Package for the Social Sciences
RN	Registered Nurse
HAART	Highly Active Antiretroviral Therapy
ZCS	Zimbabwe Central Statistics

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CHAPTER ONE

1.1. INTRODUCTION

Tuberculosis (TB) is a disease that is caused by Mycobacterium Tuberculosis (MTB), which is a pathogenic bacteria species. Because of its low density, MTB can move from one person to another through the air. This transfer can happen when an infected person coughs, sneezes or talks (World Health Organisation 2006). Research has proved that it is much easier for a person who has Human Immuno-deficiency Virus (HIV) to be infected by TB than for a person without HIV (Caminero 2003).

TB infection rate is at an increase with approximately 9 million new cases of infected and about 1.8 million deaths every year (World Health Organisation 2009). Although TB is such a deadly disease, it is curable if its presence is diagnosed at an early stage of the disease and assigned the correct medication in the right way (Rieder 2002).

The World Health Organisation (WHO) reported that wrong and discontinuous consumption of TB medication will make the MTB develop into strains that are resistant to the ordinary way of treatment. The emergence of these strains gives rise to Multi-drug Resistant Tuberculosis (MDR-TB) which is harder, painful and expensive to cure (WHO 2006).

This dissertation reports on the analysis of the results of a cross survey carried out on TB patients in Gweru, Zimbabwe. The purpose of the study is to identify key individual factors that affect TB treatment. This first chapter of the dissertation gives the background of the study, problem statement, outlines the purpose of the study and provides information on the research question.

1.2. BACKGROUND OF THE STUDY

Africa has a disproportionate burden of TB. Of the 11.0% of the world's population that is infected with TB, the continent reports more than a quarter. Research was carried out on sub-regional differences in the burden of TB in Africa. Southern and

eastern Africa had the highest per capita burden with seven southern African countries reporting between 400-700 cases per 100 000 population. In the Central African countries, six out of seven countries reported between 100-200 cases per 100 000 while North Africa has comparatively the lowest TB burden of less than 65 cases per 100 000 population. More than 6 of western African countries registered fewer than 100 cases per 100 000 population. Most African countries are far worse off now, than they were in 1990, with the 15 reporting TB incidences above 100 cases per 100 000 population annually (WHO 2002). Of the 114 countries that provided information between 1994 and 2009 on resistance to first-line anti-TB drugs, 109 countries reported data on resistance occurring among new TB cases. Of these 109 countries, 102 also provided data for previously treated cases (Bhagat et al 2010). Presently, the WHO estimated that one-third of the world's population is infected with MTB and 9 million new cases of active TB and 2-3 million deaths occur annually of which 95.0% are in developing countries. However the probability of developing TB is much higher for people who are HIV positive (WHO 2009).

TB is the major cause of mortality in people living with HIV/AIDS (PLHIV) and also HIV negative people worldwide. Zimbabwe is ranked number 17 worldwide among the 22 countries that are highly affected by TB pandemic (WHO 2008). Case detection in 2006 was estimated at 37.0% (for all cases), and treatment success at 60.0% (for new cases). Less than one third of pulmonary TB cases had positive sputum smear microscopy in 2007 and 27.0% of all patients received TB treatment without smear examination having been performed [49].

Zimbabwe has good infrastructure in terms of the clinics and hospital as well as laboratories for the testing and treatment of patients. However the country's health system has been grossly challenged by the weak economy which led to the migration of health professionals to greener pastures. This emigration was greatly caused by the insufficient salaries which they were being paid. There are an estimated 180 TB diagnostic centres within the public health system. The diagnosis and treatment of TB is done by the public health sector without any charge. Fixed-dose combination (FDC) anti-TB drugs were introduced in 2007, and 6 month regimens are used for treatment of new cases. The proportion of multidrug resistant TB (MDR-TB) among new and previously treated cases is estimated at 1.8% and 8.3%, respectively (WHO 2007), though a national prevalence survey has not been

carried out since 1995. There is currently no systematic monitoring of TB drug resistance (ZCS 2012).

Although HIV status is said to be the major risk factor of MDR-TB in Zimbabwe, there are other risk factors that also contribute to the development of the pandemic, these include, alcoholism, marital status, gender, literacy, smoking, distance from the clinic, waiting time before treatment, pre-exposure to TB drugs and employment status.

Poverty was also identified as one of the contributing factors because while on a TB treatment course, the patient should be eating nutritious food, as well as live in a well-ventilated room that is not overcrowded, since TB can be spread through the air (Namibia 2006).

1.3. PROBLEM STATEMENT

Worldwide the introduction of Directly Observed Treatment Short course (DOTS) has helped in mitigating treatment failure and the occurrence of MDR-TB cases. DOTS has proved to be an effective programme, though some negative response is observed in clinics as patients do not arrive at the clinic for treatment (Tessema et al 2009). In most countries where DOTS has failed, self-administered treatment is common which is a potential cause of treatment failure (Sanou et al 2004).

After being diagnosed of TB a patient is put on DOTS treatment for six months, under normal circumstances and if the patient completes the treatment period, is supposed to be TB free. Now a problem emanates if the infection is not completely cleared after the six months period. TB treatment failure is of great concern not only because it leads to the breaking down of the TB programs. It can also lead to the development of MDR-TB and XDR-TB which are harder to diagnose, harder and more expensive to treat, require drugs with greater toxicity than those used to treat TB and have greater mortality rates (WHO 2011). These complications have a negative impact on the economy. This is because production would have been reduced because some of these TB patients will be forced to leave their jobs, since it is not allowed to work while on TB treatment (WHO 2006).

TB treatment failure can be caused by a number of factors which in the current study are called the risk factors. These risk factors include HIV status, pre-exposure to TB drugs, gender, age, employment status, literacy, marital status, alcoholism, smoking ability and distance from the clinic. It is of primary concern for medical practitioners to know how much influence each risk factor impacts on TB treatment, therefore an analysis of the risk factors that affect the treatment of TB is necessary. These factors need to be modelled so that we achieve useful treatment strategies that can be used to totally eradicate this pandemic.

1.4. PURPOSE OF THE STUDY

The rate of TB infection has been increasing at an alarming rate all over the world. Many measures were chosen to control the pandemic, but as yet, there has been no noticeable change.

This study sought to identify and report on the key risk factors that contribute to the growth of the TB epidemic in Zimbabwe. A survey was conducted and quantitative research methods were used. Some clinical trials were performed at the time of the survey to find out how many people were directly affected by the problem at hand. The survey was carried out on TB patients who visited Isolation clinic for TB treatment.

Modelling the risk factors of tuberculosis in the Gweru district helps to give insight into the high treatment default rate and also the treatment failure. The study reviews how the infection occurs and how it is treated. In some cases it is hard to treat TB because of some risk factors of the treatment. This study serves to identify the most important risk factors of TB treatment and how they affect the treatment in the Gweru district. For the MDR-TB cases to decreases these factors need to be identified and taken into consideration in the treatment of TB.

The survey might assist the health department as well as the policy makers with a model that can be used to identify the risk factor that has great impact on TB treatment. The research will be carried out at Isolation clinic in Gweru, Zimbabwe.

1.5. NATURE OF THE STUDY

This study sought to identify the factors that affect the treatment of TB and achieve a model that explains the impact that each of the factors has on TB treatment. Questionnaires were used to get the data from the TB patients. The data is summarised and analysed using quantitative methods.

1.6. AIMS AND OBJECTIVES OF THE STUDY

TB has some of the world's mortality rates and the pandemic is increasing at an alarming rate. Measures were selected for its eradication but appear unsuccessful. This outcome is due to a number of factors negatively affecting TB treatment, leading to the development of MDR-TB. It is of primary concern to know which of the factors appear most important. The study was conducted with the following aim:

- To identify factors affecting TB treatment in Gweru, Zimbabwe and to make recommendations, according to the findings, on how TB treatment success might be improved.

The specific objectives are:

- To determine the risk factors of TB treatment.
- To explain the statistical relationships between the risk factors.
- To have a statistical analysis of the impact of the factors on TB treatment outcomes.
- To build a statistical model of the association of TB treatment and the risk factors. (Using a binary logistic regression model).

1.7. DEFINITION OF KEY CONCEPTS

Risk factor - a characteristic, condition or behaviour that increases the possibility of a disease (Oxford University Press 2006).

Tuberculosis - a disease caused by mycobacterium tuberculosis infection (Caminero 2003).

1.8. RESEARCH DESIGN AND METHODOLOGY

Methodology comprised of the research design, definition of population and sample, study instrument and data analysis.

1.8.1. RESEARCH DESIGN

A quantitative, cross-sectional, descriptive and comparative study of TB patients who were being treated at Isolation clinic.

1.8.2. POPULATION

A target population is the full set of individuals who could be included in the study and around which the researcher would like to generalize the findings (Burns et al 2005).

The population of interest were the TB patients under treatment. The study population was a subset of Isolation clinic patients at the facility and from the surrounding areas. The sample consisted of 113 persons satisfying these criteria.

1.8.3. STUDY INSTRUMENT

A structured questionnaire is a list of organised questions which respondents are asked to make choices among fixed response categories. The administration of the instrument is standardized as far as possible, including a predetermined sequence of asking the questions (Joubert et al 2011). These questions were used to obtain the relevant information from the participants. The questionnaires were administered by a Registered Nurse (RN).

1.8.4. DATA ANALYSIS

Statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) in order to summarise the data and identify any discernable differences between the variables. Chi-square tests of association were conducted to assess dependence relationships among potential factors.

1.8.5. LIMITATIONS

Limitations are weaknesses or challenges in a study that may compromise the findings to be generalized to other settings (Burns et al 2005). This study had the following limitations.

Since the study was restricted to Gweru we may not generalise the findings to be of the whole country without other supportive and linking evidence.

1.9. SUMMARY

This chapter provided an introduction and background to the problem, as well as the research purpose, objectives, nature of the study and its significance. The next chapter will provide a detailed literature review.

CHAPTER TWO: REVIEW OF THE LITERATURES

2.1. INTRODUCTION

TB is rated as one of the world's worst killer diseases especially after developing into MDR-TB or XDR-TB (Extensive Drug Resistance Tuberculosis) (WHO 2008). This section will give a brief medical background of TB and the factors that affect TB treatment. This chapter will therefore give evidence from published work to support a selection of risk factors by which we model TB treatment.

2.2. PURPOSE OF THE LITERATURE REVIEW

The literature review makes the researcher more aware of some previous work so as to avoid unnecessary replication and waste of resources (Burns et al 2005). Various sources were consulted including the internet, medical text books and journals. Medical professionals were visited to obtain more specific information.

2.3. TUBERCULOSIS AND RELATED CONDITIONS

Overcrowding, living in a room with insufficient ventilation and being close to a person who has TB are some of the most common causes of TB. For a TB infected person, failure to medicate on the scheduled times, malnutrition and suppression of the immune system are also some of the causes of the progression from TB to MDR-TB (WHO 1999).

2.4. DRUG RESISTANT TUBERCULOSIS

The emergence of Drug resistant tuberculosis (DR-TB) presents significant challenges to global TB control with an increase in incident cases reaching 489,000 MDR-TB cases by 2006, representing a 65.0% increase since 2000 (WHO 2008). Failure to follow the correct procedures of TB control causes the development of almost all the DR-TB, and non-compliance to TB treatment is the main pre-disposing factor for an individual to develop DR-TB. This new condition leads to treatment failure and subsequently may lead to death and further spread of DR-TB (Bonilla et al 2008).

With such information at hand more focus should seek to minimise the emergence of new DR-TB cases. This aim can be achieved by proper management of drugs and employing the DOTS strategy. Being infected with HIV is one of the factors that make one vulnerable to being infected by MDR-TB (Lalloo 2010).

2.5. FACTORS AFFECTING TUBERCULOSIS TREATMENT

2.5.1. DEMOGRAPHIC FACTORS

Previous studies relating to the risk factors affecting TB treatment have identified the following factors.

2.5.1.1. ALCOHOL USE AND SMOKING

According to the WHO 2008, when patients are under the influence of alcohol they tend to forget to take their medication. They may also have side effects as some of the drugs react with alcohol in a negative way. According to a study in Russia, the authors identified substance abuse as a barrier to TB treatment and care, as it leads to non-compliance to TB treatment, default and acquisition of MDR-TB. In Uzbekistan, alcoholism and homelessness were associated with TB treatment default (Chani 2010). According to Sasone also the use of cigarettes during in the treatment period also has negative effects.

2.5.1.2. TREATMENT LITERACY

Treatment literacy is provision of accurate information about the science behind the disease and treatment, so that the patients may be more responsible for their own care and be able to demand their rights if proper care is not provided (De Walt 2010). Smart (2010) supported the findings arguing that knowledge and attitude towards TB treatment affects the rate at which they are cured.

A great percentage of patients who are infected by TB are ignorant to seek medication. Most of these TB victims do not even know the symptoms of the disease so they delay to seek professional help.

2.5.1.3. PRE-EXPOSURE TO TB DRUGS

Prior exposure to anti-TB drugs is a well-established risk factor for drug resistance, as shown from surveys and surveillance systems worldwide (WHO 2010). Often, when patients start treatment they will be very sick and may be inactive. However, as the treatment progresses and their condition improves, and symptoms start to regress, the improvement in itself may become a barrier to continuation of treatment. The patient might not see the need to continue with treatment when they are feeling so much better or well than previously, despite still being actively infected (Williams et al 2004).

Some research that was carried out in Malaysia showed that incorrect taking of TB drugs was associated with feeling better (Boyle 2002). TB treatment can be made successful by educating the patients and their relatives on how to take the medication.

2.5.2. SOCIO-ECONOMIC FACTORS

Socio economic factors affecting treatment include employment status, socio-economic status, and cost of transport.

2.5.2.1. EMPLOYMENT STATUS

According to the WHO, when TB patients are on treatment, they are supposed to be eating nutritious food. This requirement may only be possible if a patient is employed or has an alternative source of funds. In some cases the patient might be staying far from the clinic and on DOTS program at the same time. Transportation to treatment sites has to be paid by each TB patient.

2.5.2.2. ACCESS TO CLINIC

Studies in Nepal (Bam 2006) indicated that cost of transport accounts for non-compliance to TB treatment, especially once the patient feels better. In Malaysia a study was carried out and established that, both cost and time of travelling to the treatment centre were major contributory factors associated with TB treatment, because non-compliant patients paid significantly more for transport than those compliant (Boyle 2002).

2.5.2.3. AVAILABILITY OF MEDICATION

According to the WHO (2010) most of the people who are affected by MDR-TB do not have access to anti-TB drugs. Research done in Somalia established that most clinics with insufficient drugs have a high rate of MDR-TB positive cases.

2.6. PREVIOUS RELATED RESEARCH

The researcher will be revealing the similarities and differences in the past and the current research. Some study addressing similar cases to this study are briefly reviewed.

2.6.1. FACTORS AFFECTING TUBERCULOSIS RETREATMENT DEFAULTS IN NANDED, INDIA

A study was carried out by Bhagat et al (2010) in the Department of Community Medicine, Raichur Institute of Medical Science, India; Department of PSM, Government Medical College, Aurangabad, Aurangabad (Maharashtra) India. The purpose was to determine factors affecting tuberculosis retreatment defaults in Nanded, India. In all, 112 patients were interviewed; this count excludes those who died during treatment. Their socio-demographic characteristics and treatment history were recorded and later compared with their retreatment outcomes. The relevance of this study includes the fact that the modern DOTS was pioneered in India (WHO 2001).

This study was carried out from January 2005 to March 2007. Data were entered into Microsoft Excel and further analysed with Epi Info (Version 3.5.1) and SPSS (15.0 Windows Evaluation Version September 2006). Proportions, the chi-square test, and the Fisher exact test were utilized as tools for bivariate analysis. Independent risk was evaluated by logistic regression. Differences in subgroups were expressed as 95.0% confidence intervals.

Sex, religion, marital status, literacy, employment, alcohol use, type of family, overcrowding and history of TB were identified as the factors affecting TB retreatment. Table 1 shows the results obtained after their analysis. The researcher explained literacy status, employment and alcoholism as the factor that had much

impact on TB retreatment, based on his results, although other researchers had got different results before.

20.0% of the patients defaulted the retreatment which is higher than the national retreatment rate of 16.5%. After analysis, three factors, illiteracy (p=0.001), alcoholic addiction (p=0.003) and employment (p=0.009) were significantly associated with TB retreatment. These three factors were further confirmed to be somewhat strongly independently associated with defaulting, by multiple logistic regressions.

2.6.2. FACTORS AFFECTING COMPLIANCE TO TUBERCULOSIS TREATMENT IN ANDARA KAVANGO REGION, NAMIBIA.

A study carried out by Chani (2010) in Andara district Kavango region Namibia. The objective was to identify the factors affecting compliance to TB treatment in Andara district of Kavango region, in Namibia. Insight into non-compliance will give insight into the reasons behind high defaulter rates and low treatment success rates.
A quantitative, cross-sectional, descriptive and comparative study of TB patients who started TB treatment between April 2008 and March 2009 in Andara District was conducted. The target population consisted of all TB patients (Pulmonary and Extra-Pulmonary), adults and children, new and re-treated, defaulted and whose treatment is completed, and all those transferred in and out. A structured questionnaire was designed which was completed by the TB patients in hospitals, at home, and in clinics.

The sample consisted of 56 study participants; all the 26 defaulters (non-compliant) and 30 who completed treatment (compliant). After the sample was drawn, a list of the study participants with all their contact details was developed and each study participant followed up by the RN at their homes and villages. Of the 26 non-compliant participants, 22 were already being retreated for TB. Four patients from the non-compliant group were located during the period of study and were eventually restarted on TB treatment. The compliant study participants were more difficult to locate as some had left the area to return to work or look for employment in other regions of the country. Only 23 of the 30 compliant participants could be located and were eventually included in the study. Six of the study participants were reported to

have left the district, and one had died after completing TB treatment. None of the participants refused to participate in the study.

After the data was run in SPSS and excel, a relationship between TB treatment and its factors was established. Chi-square tests of association were conducted to assess dependence relationships among potential factors.

2.6.3. ANTI-TUBERCULOSIS DRUG RESISTANCE AND ASSOCIATED RISK FACTORS IN THE EUROPEAN SECTION OF TURKEY

A study was carried out by Karabay et al (2003) in the Departments of Clinical Bacteriology and Infectious Diseases and Chest Disease, Medical Faculty of Trakya University, Edirne, 22030, Turkey. The purpose was to establish the prevalence of anti-tuberculosis drug resistance in Mycobacterium tuberculosis strains and to determine risk factors for the development of resistance in Trakya region of Turkey.

The size of the sample was calculated using the formula $n = \frac{Nt^2 pq}{d^2(N-1)+t^2 pq}$ where n=the required sample size. N=population size, p=prevalence of tuberculosis, q=(1– p), t=values to be present in the 't' table at specified level of confidence interval (95.0% CI), d=deviation amount according to the prevalence of tuberculosis.

The data concerning the participants was collected using a questionnaire that was designed to cater for age, gender, marital status, occupations of the patients, their residence in a village or city, symptoms concerning the disease (sputum, coughing, sweating at night), presence of another tuberculosis case in the family, previous treatment for tuberculosis, number of persons in contact, screening status of persons in contact, presence of cavity lesion, presence of diabetes mellitus were recorded for all the patients.

The 12 factors that were found to be of statistical significance were included in logistics regression model. In order to identify the risk factors that play a dominant role in the development of resistance, "stepwise logistic regression", was performed using SPSS. Development of resistance was examined as the dependent variable while 12 potential risk factors were examined as explanatory variables. The author

concluded by stating that, the implementation of DOTS needs to be strengthened and further research needs to be carried out.

2.6.4. PREDICTORS OF TREATMENT FAILURE AMONG PULMONARY TB PATIENTS IN MULAGO HOSPITAL, UGANDA.

A study was conducted by Namukwaya et al (2011) in the Department of Medicine, College of Health Sciences, Makerere University Kampala, Uganda. The study was carried out in the TB clinic of Mulago hospital Kampala. The main purpose was to determine the predictors of treatment failure among patients with sputum smear positive pulmonary TB at Mulago hospital.

Some 156 patients were recruited into the study. The minimum age was thirteen years of age. The sample size was calculated based on persons with poor adherence. Poor adherence is one of the most significant predictors of treatment failure from the previous studies. Data was taken from the patients' medical files as well as some interviews. All data were recorded on a structured questionnaire and the data set included, age, gender, marital status, highest education level attained, approximate distance to the TB clinic, alcohol or substance abuse, fever persisting after 2 weeks of TB treatment, weight loss despite treatment or no weight gain, sputum smear microscopy results at baseline, 2 months and 5 months or later during treatment, drugs doses given and the presence of other medical conditions including HIV and Diabetes Mellitus. Data obtained was entered into SPSS for analysis. None of the socio-demographic factors was associated with TB treatment failure in this study though previous studies had found otherwise (Shargie et al 2003). It was found that poor adherence leads to development of drug resistance which may explain the treatment failure. The author concluded by stating that, program interventions like Directly Observed Therapy short course (DOTS), which enhance adherence, should be emphasized.

2.7. CONCLUSIONS

There are numerous factors that affect TB treatment, they include alcohol, smoking, HIV status, gender, age, environment, wrongly taking drugs, pre-exposure to drugs, marital status and literacy among others. From the literature review the most

common or significant factor is not taking the drugs in a right manner or even not taking the drugs themselves.

In the cited research logistic regression is the most common mathematical tool used. More research needs to be carried out on the relationship between TB treatment and HIV infection. The next chapter describes the methodologies of data collection and the way the research was carried out and also reviews the steps and structure of statistical analysis.

CHAPTER THREE: METHODOLOGY

3.1. INTRODUCTION

This chapter focuses on the research design and the methodological procedures used to collect data on TB treatment factors of participants. It begins with a discussion of the study design followed by a full description of research instruments, variables investigated and respondents, sampling procedures, research sites and interviews. A review is also presented of the statistical methodology for analysis of categorical response variables. This chapter also presents an assessment of data quality, limitations and ethical issues involved in the research study.

3.2. RESEARCH DESIGN

A quantitative, cross-sectional, descriptive, contextual and comparative design was adopted in which a group of medical professionals were consulted on data collection. A questionnaire was designed to elicit easy and understandable data, statistical methods and techniques to be used for analysis.

3.3. RESEARCH QUESTIONS

The driving factor of this research is the research question.

- How much impact does each risk factor have on TB treatment?

3.4. POPULATION

Gweru is an industrial and mining town in the Midlands province of Zimbabwe. It is divided into two parts which are Gweru urban district which has a population of approximately 140 806 people and Gweru rural which has a population of 84 333 people (ZCS 2012). All the TB patients are serviced by the Gweru general hospital which is the largest hospital in the city, providing approximately 250 beds. It is a hospital with many departments that specialise on various diseases.

The TB notification rate for the province was 412 per 100 000 population in 2001, 66.7 % were pulmonary TB (PTB), and of these 51.5 % had a positive smear (Chihota 2011). After patients have been diagnosed with TB they are first admitted in the Gweru general hospital. All identified cases of MDR or XDR are then transferred to the Gweru TB Isolation clinic. This research was carried out in the Isolation clinic as a suitable place to target TB special cases.

This small clinic is located in the outskirts of Ascot, a high density residential suburb in Gweru, at an isolated geographical point.

3.5. SAMPLING

Sampling is the act of selecting individuals for study from a population. In this study the sample frame comprises of all the TB patients in Gweru. The information that would be relevant to this study includes the patient's name, registration number, date of starting and completion of treatment or outcome, HIV status, demographic details and address and classification or diagnosis. The researcher listed all the TB patients which were the possible research participants. All their data and their addresses were listed so that they would be followed up. The sampling frame consisted of 113 patients. This count also included all of the 15 defaulters.

3.6. DATA COLLECTION

According to Burns et al (2005) a systematic process of gathering information relevant to the study, should be used to address the research purpose and objectives, and answer the research questions.

After the sampling process was completed, a list of prospective study participants was made using the names and their contact details. A registered nurse (RN) then visited them at their homes. Prospective participants on second line treatment were interviewed at the TB clinic when they came for the medicines. The RN would introduce himself to the prospective participant. He read through the individual participant consent form that detailed the title and purpose of the study as well as the rights of the participant and details of the person to be contacted for future questions. The participant was interviewed after agreeing to sign the written consent form or finger print. The interview did not proceed if a person refused to participate. After obtaining the written consent, the RN entered the questionnaire serial number and date of interview and preceded from the first through to the last question using a language understood by the participant. The nurse entered responses given by the participant by circling the appropriate response option number and entering the same number into the coding box. This duplication was done to ensure data quality as the response number circled was supposed to be confirmed by the number entered in the coding box. If the numbers were different, the second would be valid. The researcher reviewed the questionnaires on a weekly basis to ensure they were

being completed correctly. Any errors were discussed with the RN to avoid them being repeated. The process of data collection continued until every prospective participant was serviced. All completed questionnaires were kept by the RN in a safe, lockable cupboard until the researcher collected them.

3.7. ETHICAL CONSIDERATIONS FOR THE RESEARCH STUDY

The "Principle of Respect for Persons", sometimes referred to as "Respect for Human Dignity", holds that persons have the right to determine whether they wish to participate in a study or not (Burns et al 2005). Accordingly an informed consent form was issued to every participant in the study, in their own local language. The details within the informed consent form included the purpose of the study, the expected benefits of the study, and the process of data collection. The participants were informed they had a right to refuse to take part in the study. The phone numbers of the researchers were made available to all participants. Approval of the study was granted by the University of Fort Hare Ethics Committee.

3.8. RESEARCH PARTICIPANTS AND ELIGIBILITY CRITERIA

The inclusion and exclusion criteria used for assessing eligibility of participants, for this research is presented below. The full set of inclusion criteria was a basis for recruitment of participants into the study, after they had given a written informed consent voluntarily. A single exclusion criterion implied a person was not recruited into the study.

ELIGIBILITY CRITERIA USED IN DRAWING RESEARCH PARTICIPANTS INTO THE STUDY

INCLUSION CRITERIA	EXCLUSION CRITERIA
• Zimbabwean.	• Non Zimbabwean.
• TB positive.	• TB negative.
• Aged 15 years or above.	• Aged below 15 years.
• Resident in Gweru district.	• Non Gweru district resident.
• Able to understand clearly about the research.	• Does not understand about the research.
• Agreeable to answer	• Does not agree to answer

general health questions and questions pertaining to TB treatment.

the research questions.

- Meeting the inclusion criteria but refused to consent to participate.

The research participants were met at Isolation clinic where they were briefed about the study before they were asked to agree to take part.

3.9. INTERVIEW PROCEDURE

A structured questionnaire consisting of both closed and open-ended questions was designed and administered to households for primary data collection. The advantage of the structured interview is that it takes place over a short period of time (Yin 1994). The questionnaire was designed in order to collect both qualitative and quantitative data. The questionnaire was administered to respondents through face-to-face interviews. There are other ways in which questionnaires can be administered, such as self-administered questionnaires and telephone surveys (Leedy et al 2004), but these methods were not suitable in this study.

Upon arrival at the clinic, a potential research participant was first approached by a research assistant and introduced to the research study. An assessment was made regarding whether or not the person satisfied the study criteria. If assessed to be eligible for the study, the person was taken into a private room. The research assistant thoroughly read the information sheet and explained to the participant. The sheet included all information about the research, covering purpose of the research study, participation process, time required for participation, risks, benefits, confidentiality, review of the research study and the emphasis on voluntary participation. The patient was given time to think about whether or not to participate. An affirmative answer prompted the research assistant to request signing the informed consent form. A provision was made to use inkpad for a signature in form of a fingerprint. After providing written informed consent voluntarily, a participant was taken through the questionnaire in a face-to-face interview in a vernacular language. Then he was thanked for participation.

As the participant proceeded to an HIV test, he was given a card bearing a secret number, identifying the questionnaire and the consent form, to present to the

counsellor performing the test. Every precaution was taken to ensure that no names were used to preserve the confidentiality of both the responses as well as impending the results. After performing the test using a finger prick blood sample, the counsellor recorded the results at the back of the card bearing the secret code. At the end of each day, this test result was recorded again on the questionnaire bearing the same code under the section 'HIV test result'. This record was made to ensure consistency in identification among a set of answers provided through the questionnaire, the HIV test result and the signed consent form.

Data collection started on 31st January 2012 and ended on 20st May 2012. The duration was shorter than initially thought, mainly due to cooperation from the participants, continued availability of HIV test kits as well as dedication by research assistants and counsellors. The entire interview process took approximately 45 minutes covering briefing a participant about the research study, decision regarding whether to take part in the study or not, providing written informed consent, answering a set of questions (the questionnaire) and undergoing HIV testing and counselling.

3.10. HIV TESTING PROCESS AT RESEARCH SITES

HIV testing and counselling is performed by a counsellor in three stages as part of routine service: pre-test counselling, HIV testing and post-test counselling. Covered under this section is the HIV testing process.

The HIV test follows a specified procedure. The first step is to determine the status. For a non-reactive outcome, the testing process is halted and the patient is informed about the non-reactive outcome status. Otherwise, the second line HIV reagent called uni-gold is engaged. If the result is reactive, the testing process is halted and the client is informed about the reactive status. Otherwise, the third line HIV reagent known as Bio line, which is more sensitive than the first two and treated as a tie-breaker, is engaged to determine a patient's HIV status. The result of this third line and final HIV reagent is taken as the real status of that particular client. A participant's test result usually shows after 15 minutes particularly for the determine and uni-gold HIV reagents (Kankuwe 2010).

3.11. DATA ANALYSIS

De Vos et al (2007) described data analysis as the process of categorizing, putting into order, manipulating and ultimately summarizing data in order to be able to answer the original research questions. The purpose is to reduce data collected to a format that can provide meaningful conclusions (Burns et al 2005).

After all the participants had been interviewed, the researcher reviewed all the questionnaires for completeness and performed appropriate data cleaning. Data was then entered on spread sheets within MS Excel and later transported to SPSS for further analysis.

3.12. THEORY AND METHODS FOR ANALYSIS OF CATEGORICAL RESPONSES

As documented by Agresti (1996), a categorical variable is fundamentally a grouping variable that can be dichotomous (having two response levels) or polytomous (having more than two response levels) and can be either ordinal (having levels with a natural ordering) or nominal (having membership groups without a natural ordering). Stokes et al (2000) noted that frequently, categorical data are presented in tabular form, known as contingency tables. Categorical data analysis is concerned with the analysis of categorical response measures regardless of whether or not any accompanying explanatory variables are also categorical or continuous. Categorical data analysis strategies are those that are concerned with either hypothesis testing or modelling. A discussion of selected methods designed for analysing categorical data follows.

3.13. TYPES OF STUDIES

3.13.1. QUANTITATIVE STUDIES

Quantitative studies follow a systematic process to describe and test associations or relationships, and may also be used to examine and determine causality, though not in cross-sectional studies alone (Burns et al 2005). According to Stommel et al (2004), quantitative researchers study phenomena that can be counted or measured and described in standardized numerical scales and allow for statistical analysis. The research is a deliberate attempt to control (experimental or statistical) variables and to use statistical and numerical summaries to report results (Stommel et al 2004).

This study will examine any associations between compliance and non-compliance to TB treatment and variables in numerical terms.

3.13.2. CROSS-SECTIONAL STUDIES

According to Burns et al (2005), cross-sectional study designs examine participants simultaneously, irrespective of their stage of development, but possibly with an aim to describe differences in phenomena across stages. Data is collected at a point in time but with different study participants, as opposed to different points in time for the same participant (Brink 2007). Thus the study is conducted in the present to determine what already exists and exposure and disease status are observed simultaneously (Joubert et al 2008). Data was collected from the TB patients using a structured questionnaire at a single point in time for each of the patients, until all efforts to access the sampled patients were exhausted. While the data collection was at different times for the different patients it was only collected once for each of them.

3.13.2.1. ADVANTAGES OF USING CROSS SECTIONAL STUDIES

Cross-sectional studies (CSS) have several advantages. Firstly, they are relatively easy and not very expensive to conduct, since they involve data collection at one point in time only (Hungler et al 2001). This study involved collection of data over a short period of time and was affordable.

CSS are useful for evaluating the relationship between exposures and outcomes (Gordis 2004). Associations were tested for various exposures, such as sex, educational level, distance from facility and cost of transport, socio-economic status, alcohol and substance abuse, DOT status, co-morbidities and health system factors with the two outcomes (compliance and non-compliance).

CSS are an important step in first assessing the possibility of a relationship between an exposure and a disease, before more difficult or expensive studies are undertaken, such as case-control and cohort (Gordis et al 2004). Identifying the factors associated with TB treatment compliance and non-compliance in Gweru district would pave a way for other studies that could identify the actual causes of treatment non-compliance.

Attrition is limited in CSS only to non-response by sampled patients who may refuse to give consent to participate, as opposed to attrition longitudinal studies which may be exposed to high dropout of study participants due to death, being lost to follow-up, or changing their minds at a later stage (Stommel et al 2004). However in this study, there were four non-responses due to death or to respondents having left the district and therefore not being identified.

3.13.2.2. DISADVANTAGES OF USING CROSS SECTIONAL STUDIES

The main disadvantage of cross-sectional studies, however, is their failure to establish causation and the temporal relationship between exposure and disease or outcome as the two are measured simultaneously (Gordis et al 2004). This limitation was not a major problem as this study aimed to identify associated factors and not necessarily the causes.

3.14. CONTIGENCY TABLES

Suppose there are two categorical variables, denoted by X and Y. Let I denote the number of categories of X and J the number of categories of Y. A rectangular table having I rows for the categories of X and J columns for the categories of Y has cells that display the I times J possible combinations of outcomes. Such a table is called a contingency table (Agresti 2002).

A table that cross classifies two variables is called a two-way contingency table; one that cross classifies three variables is called a three-way contingency table, and so forth. A two-way table with I rows and J columns is called an I × J (read I times J) table (Agresti 2002).

Probabilities for contingency tables can be of three types – joint, marginal, or conditional. Suppose first that a randomly chosen subject from the population of interest is classified on X and Y. Let $\pi_{ij} = P(X = i,\ Y = j)$ denote the probability that (X, Y) falls in the cell in row i and column j . The probabilities $\{\pi_{ij}\}$ form the joint distribution of X and Y. They satisfy $\sum_{i,j} \pi_{ij} = 1$.

The marginal distributions are the row and column totals of the joint probabilities.

We denote these marginal totals by $\{\pi_{i+}\}$ for the row variable and $\{\pi_{+j}\}$ for the column variable, where the subscript "+" denotes the sum over the index it replaces. For 2 × 2 tables, $\pi_{1+} = \pi_{11} + \pi_{12}$ and $\pi_{+1} = \pi_{11} + \pi_{21}$

Each marginal distribution refers to a single variable. We use similar notation for sample proportions, with Roman p in place of Greek π and we define marginal proportions p_{i+} and p_{+j} simultaneously.

We denote the cell counts by $\{n_{ij}\}$. The marginal frequencies are the row totals $\{n_{i+}\}$ and the column totals $\{n_{+j}\}$, and $n = \sum_{i,j} n_{ij}$ denotes the total sample size for example $\{p_{ij}\}$ are cell proportions in the sample joint distribution. The sample has marginal proportions $p_{i+} = n_{i+}/n$ and $p_{+j} = n_{+j}/n$. The sample cell proportions relate to the cell counts by $\pi_{j/i} = \pi_{ij} / \pi_{i+}, \forall i, j \; p_{ij} = n_{ij}/n$.

In many contingency tables, one variable (say, the column variable, Y) is a response variable and the other (the row variable, X) is an explanatory variable. These rows of variables are consequences of the research questions. Then, it is informative to construct a separate probability distribution for Y at each level of X. Such a distribution consists of conditional probabilities for Y, given the level of X.
It is called a conditional distribution (Agresti 2002). We define conditional probabilities e.g. for a given row i by $\pi_{j/i} = \pi_{ij} / \pi_{i+}, \forall i, j$ and $p_{i/j} = n_{ij}/n_{i+}$.

3.15. DETERMINATION OF STATISTICAL INDEPENDENCE

As pointed out by Agresti (1996), two variables are said to be statistically independent if there is no association between them, that is, the known occurrence of one category in a variable does not affect the occurrence of any category of the other variable. When both variables are response variables, association can be described using their joint distribution, the conditional distribution of Y|X or X|Y . The conditional distribution of Y|X is related to the joint distribution by $\pi_{j/i} = \pi_{ij} / \pi_{i+}, \forall i, j \; \pi_{j/i} = \pi_{ij} / \pi_{i+}, \forall i, j$. The variables are statistically independent if all joint probabilities equal the product of their marginal probabilities, that is, if

$\pi_{i,j} = \pi_{i+}\pi_{+j}, \forall i = 1,....., I$ and $j = 1,....., J$. When X and Y are independent, $\pi_{j/i} = \pi_{ij} \Big/ \pi_{i+} = (\pi_{i+}\pi_{ij}) \Big/ \pi_{i+} = \pi_{ij}$ for $j = 1,....., J \; i = 1,....., I$. Equivalently, each conditional distribution of Y (given X) is identical to the marginal distribution of Y. Thus, two variables are independent when the probability of column response category is the same in each row, for $j = 1,....., J$.

3.15. MEASUREMENT OF ASSOCIATION

3.15.1. ODDS FOR A BINARY RESPONSE

For a probability of success, π , the odds of success are defined to be $odds = \frac{\pi}{1-\pi}$ For instance, if $\pi = 0.75$, then the odds of success equal $\frac{0.75}{0.25} = 3$. These odds are often stated as 3" to 1".

The odds are non-negative, with value greater than 1.0 when a success is more likely than a failure. When odds = 4.0, a success is four times as likely as a failure. When the probability of success is 0.8, the probability of failure is 0.2, the odds equal 0.8/0.2 = 4.0. We then expect in the long run to observe four successes for every one failure. When odds = 1/4, a failure is four times as likely as a success. We then expect in the long run to observe one success for every four failures. The success probability itself is the function of the odds, $\pi = \frac{odds}{odds+1}$ For instance, when $odds = 4$, then $\pi = \frac{4}{4+1} = 0.8$.

3.15.2. ODDS RATIO

An odds ratio (OR) is a measure of association between an exposure and an outcome. The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. OR are most commonly used in case control studies, however they can also be used in cross-sectional and cohort study designs as well.

The odds ratio can equal any nonnegative number. When X and Y are independent,

$\pi_1 = \pi_2$, so $odds_1 = odds_2$ and $\theta = \frac{odds_1}{odds_2}$. The independence value $\theta = 1$ is a baseline for comparison. Odds ratios on each side of 1 reflect particular types of associations. When $\theta > 1$, the odds of success are higher in row 1 than in row 2. For instance, when θ = 4, the odds of success in row 1 are four times the odds of success in row 2. Thus, subjects in row 1 are more likely to have successes than are subjects in row 2; that is, $\pi_1 > \pi_2$. When $\theta < 1$, a success is less likely in row 1 than in row 2; that is, $\pi_1 < \pi_2$.

Values of θ farther from 1.0 in a given direction represent stronger association. An odds ratio of 4 is farther from independence than an odds ratio of 2, and an odds ratio of 0.25 is farther from independence than an odds ratio of 0.50.

Two values for θ represent the same strength of association, but in opposite directions, when one value is the inverse of the other. When θ = 0.25, for example, the odds of success in row 1 are 0.25 times the odds of success in row 2, or equivalently $\frac{1}{0.25} = 4.0$ times as high in row 2 as in row 1. When the order of the rows is reversed or the order of the columns is reversed, the new value of θ is the inverse of the original value. This ordering is usually arbitrary, so whether we get 4.0 or 0.25 for the odds ratio is merely a matter of how we label the rows and columns. The odds ratio does not change in value when the table orientation reverses so that the rows become the columns and the columns become the rows. The same odds ratio value occurs when we treat the columns as the response variable and the rows as the explanatory variable, or the rows as the response variable and the columns as the explanatory variable. Thus, it is unnecessary to identify one classification as a response variable in order to estimate θ. The odds ratio can be defined using joint probabilities as

$$\theta = \frac{\pi_{11}/\pi_{12}}{\pi_{21}/\pi_{22}} = \frac{\pi_{11}\pi_{22}}{\pi_{12}\pi_{21}}$$

The odds ratio is also called the cross-product ratio, because it equals the ratio of the products $\pi_{11}\pi_{22}$ and $\pi_{12}\pi_{21}$ of cell probabilities from diagonally opposite cells. The sample odds ratio equals the ratio of the sample odds in the two rows,

$$\hat{\theta} = \frac{p_1/(1-p_1)}{p_2/(1-p_2)} = \frac{n_{11}/n_{12}}{n_{21}/n_{22}} = \frac{n_{11}n_{22}}{n_{12}n_{21}}$$

For a multinomial distribution over the four cells or for independent binomial distributions for the two rows, this $\hat{\theta}$ is the ML estimator of θ (Agresti 1996).

3.16. LOGISTIC REGRESSION MODELLING

Stokes et al (2000) posits that statistical modelling methods are aimed at describing the nature of association in terms of a parsimonious number of parameters but also addressing questions about association based on hypotheses concerning model parameters. Agresti (1996) is of the view that logistic regression is a form of statistical modeling that is often appropriate for categorical outcome variables. It describes the relationship between a categorical response variable and a set of explanatory variables which can be continuous or categorical. The response variable is usually dichotomous, but it may also be polytomous. These multi-level response variables can be nominally or ordinal scaled.

Logistic regression has the advantage that model interpretation is possible through odds ratios which are functions of model parameters. Stokes et al (2000) observes that one of the benefits of logistic regression is that estimates, of odds ratios can be obtained from the parameter estimates of logistic regression are computed through maximum likelihood estimation.

Consider a binary response Bernoulli random variable and explanatory variable and a probability denoted by $\pi(x)$. The regression model $E(Y) = \pi(x) = \alpha + \beta x$ is called a linear probability model. A logistic regression model uses a binary dependent or response variable, e.g. 0/1, 1/2 or yes/no and models its probabilities. However, the linear model has a major structural defect for probability. Since $0 \le \pi(x) \le 1$ and $-\infty < (\alpha + \beta x) < +\infty$, there surely exists a contradiction of some kind. Consequently, it is expected that a nonlinear relationship exists between $\pi(x)$ and x to overcome this contradiction (Agresti 1996).

Because of the structural problems with the linear probability model, Agresti (1996) reasons that it is more fruitful to study models implying a curvilinear relationship

between x and $\pi(x)$. This invokes the natural S-shape for regression curves with the logistic regression function given by $\pi(x)=\frac{\exp(\alpha+\beta x)}{1+\exp(\alpha+\beta x)}$. It behaves in a way that as $x\to\infty$, $\pi(x)\to 0$ when $\beta<0$, and $\pi(x)\to 1$ when $\beta>0$. However, as $\beta\to 0$, the curve flattens to a horizontal straight line. When the model holds with $\beta=0$, the binary response is independent of x. For this model, the odds of making response 1 are $\pi(x)/((1-\pi(x)))=\exp(\alpha+\beta x)=e^{\alpha}(e^{\beta})^{x}$. This formula provides a basic interpretation for β.The odds increase multiplicatively by e^{β} for every unit increase in x. The log odds has the linear relationship $\log\left[\frac{\pi(x)}{1-\pi(x)}\right]=\alpha+\beta x$. Thus, the appropriate link between the response y and the explanatory x is the log odds transformation, the logit. By defining the logit for general π as $\log it(\pi)=\log\{\pi/(1-\pi)\}$, taking the log of the odds ratio gives $\log\theta=\log\left\{\frac{\pi_{11}\pi_{22}}{\pi_{12}\pi_{21}}\right\}=\log\left\{\frac{\pi_{11}/\pi_{12}}{\pi_{12}/\pi_{21}}\right\}=\log\left\{\frac{\pi_{11}/(1-\pi_{11})}{\pi_{21}/(1-\pi_{21})}\right\}$ this equation reduces to $\log\theta=\log\{\pi_{11}/(1-\pi_{11})\}-\log\{\pi_{21}/(1-\pi_{21})\}$. This result indicates that the OR can be written in terms of the difference between two logits. Effects in the logistic model refer to odds, and the estimated odds at one value of x divided by the estimated odds at another value of x is an odds ratio (Agresti 2002).

3.17. GOODNESS OF FIT TEST

Agresti (1996) postulates that for a given logit model, model parameter estimates can be used to calculate predicted logits, and hence predicted probabilities and estimated expected frequencies $\left\{\hat{m}_{ij}=n_{i+}\pi_{j/i}\right\}$. When expected frequencies are relatively large, goodness-of-fit can be tested with a Pearson's or likelihood-ratio chi-square statistic. For a model symbolized by M , these statistics are denoted by $X^2(M)$ and $G^2(M)$, respectively. For instance, $G^2(M)=2\sum_i\sum_j n_{ij}\log(n_{ij}/\hat{m}_{ij})$. The likelihood-ratio principle is used to construct a statistic $-2(l_2-l_1)$ that tests whether specified model parameters are zero, by comparing the fitted model M_1, also called

a full model, with a simpler model M_2, also called a restricted model. Denoting l_s as the maximized log likelihood for the saturated model, the likelihood-ratio statistic for comparing models M_1 and M_2 is:

$G^2(M_2 / M_1) = -2(l_2 - l_1) = -2(l_2 - l_S) - [-2(l_1 - l_S)] = G^2(M_2) - G^2(M_1)$. This identity means that the test statistic for comparing two models is identical to the difference in G^2 goodness-of-fit statistics for the two models. Here the set of hypotheses is:

H_0 : The restricted model fits the data better than the expanded model

H_1 : The expanded model fits the data better than the restricted model

As observed by Agresti (1996), goodness-of-fit statistics such as G^2 and X^2 are summary indicators of the overall quality of fit. Additional diagnostic analysis are necessary to describe the nature of any lack of fit. Consequently, residuals comparing observed and fitted counts can be useful. Such diagnostic analysis help show whether lack of fit is due to an inappropriate choice of the link function or perhaps due to non-linearity in effects of explanatory variables. Hosmer (2000) used the term covariate pattern to describe a single set of values for the covariate in a model. For example, in a dataset including values of age, race, sex and weight for each subject, the combination of these factors may result in as many different covariate patterns as there are subjects. On the other hand, if a model includes only race and sex, each coded at two levels, there are only four possible covariate patterns. Goodness-of-fit is assessed over the constellation of fitted values determined by the covariates currently in the model, not on the total collection of covariates. In selecting the 'best' model, Abraham (2006) argued that the deviance and Pearson's chi-square are two commonly used criteria. One prefers models with low values on these statistics. Pearson's chi-square is a similar statistic for evaluating model adequacy. For m distinct covariate patterns, $n_i \hat{\pi}_i$ successes and $n_i(1-\hat{\pi}_i)$ failures, the Person's chi-square statistic is given by:

$$\chi^2 = \sum_{i=1}^{m}\left[\frac{[y_i - n_i\hat{\pi}_i]^2}{n_i\hat{\pi}_i} + \frac{[(n_i - y_i) - n_i(1-\hat{\pi}_i)]^2}{n_i(1-\hat{\pi}_i)}\right] = \sum_{i=1}^{m}\frac{[y_i - n_i\hat{\pi}_i]^2}{n_i\hat{\pi}_i(1-\hat{\pi}_i)}, i = 1, 2, ..., m$$ for a $2 \times m$ contingency table where the rows correspond to the two outcomes 1 (success) and 0 (failure), and the columns correspond to the m distinct covariate patterns. This statistic can be compared with the percentile of a chi-square distribution with

$m-p-1$ degrees of freedom, with large values of the test statistic suggesting that the logistic regression model is inadequate. Abraham (2006) point out that goodness-of-fit measures also extend to analysis of residuals, most common of which are labelled Pearson and deviance. These residuals are given by:

$$e_i = \frac{y_i - n_i \hat{\pi}_i}{\sqrt{n_i \hat{\pi}_i (1-\hat{\pi}_i)}} \text{ and } d_i = \pm \left\{ 2 \left[y_i \ln \left(\frac{y_i}{n_i \hat{\pi}_i} \right) + (n_i - y_i) \ln \left(\frac{n_i - y_i}{n_i (1-\hat{\pi}_i)} \right) \right] \right\}^{1/2}$$, respectively,

where the sign of d_i is determined by the sign of $y_i - n_i \hat{\pi}_i$. Stokes et al (2000) observe that Pearson's residuals compare the differences between observed counts and their predicted values, scaled by the standard deviation of the observed count. By examining the e_i , one can determine how well the model fits the covariate patterns. Often, the e_i values are considered to be indicative of lack of fit if $|e_i| > 2$.

3.18. CHI-SQUARE TEST FOR INDEPENDENCE

According to Pallant (p 24) Chi-square test for independence is used when you wish to explore the relationship between two categorical variables. Each of these variables can have two or more categories. This test compares the observed frequencies or proportions of cases that occur in each of the categories, with the values that would be expected if there was no association between the two variables observed. It is based on a cross tabulation table, with cases classified according to the categories in each variable (e.g. male/female; smoker/non-smoker).
When a 2 by 2 table (two categories in each variable) is encountered by SPSS, the output from chi-square includes an additional correction value (Yates' Correction for Continuity). This correction is designed to compensate for what some writers feel is an overestimate of the chi-square value when used with a 2 by 2 table.

After the test statistic has been developed the data is run into SPSS to test for independence. The first thing to be checked is whether one of the assumptions of chi-square concerning the 'minimum expected cell frequency', has been violated which should be 5 or greater (or at least 80 per cent of cells have expected frequencies of 5 or more). This information is given in a footnote below the Chi-Square Tests table (Pallant 2011).

3.19. DATA PREPARATION: CODING OF RESPONSES

Pallant (p 188), In order to make sense of the results of logistic regression, it is important that we set up the coding of responses to each of your variables carefully. For the dichotomous dependent variable, the responses are coded 0 and 1. The value of 0 should be assigned to whichever response indicates an absence of the characteristic of interest. For example, 0 can be used to code the answer No to the question 'Do you have a problem with your sleep?' while the value of 1 is used to indicate a Yes answer.

3.20. CHI-SQUARE TEST FOR GOODNESS OF FIT

According to Pallant (p 212) the Chi-square test for goodness of fit test, which is also referred to as the one-sample chi-square, is often used to compare the proportion of cases from a sample with hypothesised values or those obtained previously from a comparison population. All that is needed in the data file is one categorical variable and a specific proportion against which you wish to test the observed frequencies. This structure may test that there is no difference in the proportion in each category (50%/50%) or a specific proportion obtained from a previous study.

3.21. RELIABILITY AND VALIDITY

Reliability and validity of a preference or observation instrument are very important (De Vos et al 2007). To obtain valid and reliable data from the preference or observation instrument it is important to ensure before administering the instrument that it can be replicated and provide accurate information for the researcher to make acceptable conclusions (Stommel & Wills 2004).

3.21.1. RELIABILITY

Reliability arises from the stability and consistency of the preference or observation and provides an indication of the random error in the measurement (Burns et al 2005). In order to assure reliability of the measuring instrument, one strategy is the use of closed-ended questions. Thus, if the same questions are administered to the same study participant at different times, the chances are very high that the same or a similar response is obtained.

3.21.2. VALIDITY

Validity is a “measure of the truth or accuracy of a claim” (Burns and Grove, 2005) and, according to Babbie (2004), it refers to how far a data collection instrument actually measures what it is supposed to measure. Validity has two aspects: firstly that the instrument does in fact reflect the concept it is intended to address and is fit for purpose.

3.21.3. CONTENT VALIDITY

The extent to which the questionnaire or instrument method of observation includes all major and important elements is labelled content validity (De Vos et al 2004). Content validity is achieved when all the important constructs that are identified in the literature are included in the instrument.

3.21.4. THREATS TO EXTERNAL VALIDITY

External validity is concerned with the generalizability of the study findings and depends largely on the research design (Burns et al 2005). It is necessary to have an indication of the sampling adequacy. Random sampling is a means to ensure external validity or generalisation of the study to the wider population. In this cross-sectional study, reducing the possibility of attrition of study participants is a necessary condition for external validity.

3.22. CONCLUSIONS

This chapter gave the methods that were used to carry out the study. The chapter started by giving a brief explanation of the study design, research questions, the type of population, the sample, data collection methods, the ethical considerations and also statistical techniques to be used, namely contingency tables, testing for dependences within the data, designing and testing a logistic regression model. The following chapter reports and explains the results.

CHAPTER FOUR:

4.1. DATA PRESENTATION RESULTS AND ANALYSIS

In this chapter the research findings are presented as data analysis and interpretation, including the demographic data of the research participants.

The specific objectives for this study were to:

- To determine the risk factors of TB treatment.
- To explain the statistical relationships between the risk factors.
- To have a statistical analysis of the impact of the factors on TB treatment outcomes.
- To build a statistical model of the association of TB treatment and the risk factors. (Using a logistic regression model).

The main purpose of this chapter is to realise these objectives in a series of statistical steps. All the results and finding will be stated in this chapter. The determination of the relationship between MDR-TB progression and its risk factors involved some contingency table analysis. Some odds ratios were used to check the strength and direction of the association. A logistic model was designed so that the association between HIV and MDR-TB will be explored as well as its relationship with other factors. The model was then diagnosed for the goodness of fit using Pearson's goodness of fit test.

4.2. DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS (n=113)

TABLE 4.1 shows the demographic characteristics of the research participants by MDR-TB status.

MDR-TB POSITIVE?		YES	NO
GENDER	FEMALE	14 (40.0%)	21 (60.0%)
	MALE	49 (62.8%)	29 (37.2%)
MARITAL STATUS	DIVORCED	3 (60.0%)	2 (40.0%)
	MARRIED	32 (53.3%)	28 (46.7%)
	SINGLE	14 (50.0%)	14 (50.0%)
	WIDOWED	14 (70.0%)	6 (30.0%)
LITERACY	LITERATE	39 (43.8%)	50 (56.2%)
	ILLITERATE	24 (100%)	0 (0.00%)
EMPLOYMENT STATUS	EMPLOYED	50 (54.3%)	42 (45.7%)
	UNEMPLOYED	13 (61.9%)	8 (38.1%)
ALCOHOL USE	NO	17 (73.9%)	6 (26.1%)
	YES	46 (51.1%)	44 (48.9%)
HIV STATUS	POSITIVE	38 (52.1%)	35 (47.9%)
	NEGATIVE	25 (62.5%)	15 (37.5%)
AGE	15-24	0 (0.00%)	4 (100%)
	25-34	20 (57.1%)	15 (42.9%)
	35-44	26 (66.7%)	13 (33.3%)
	45-54	11 (55.0%)	9 (45.0%)
	55-64	6 (46.2%)	7 (53.8%)
	>65	0 (0.00%)	2 (100%)
OVERCROWDING	ABSENT	13 (81.2%)	3 (18.8%)
	PRESENT	50 (51.5%)	47 (48.5%)
SMOKING IN 6 MONTHS	YES	46 (59.7%)	31 (40.1%)
	NO	17 (47.2%)	19 (52.8%)
ALCOHOL USE	YES	46 (51.1%)	44 (48.9%)
	NO	17 (73.9%)	6 (26.1%)

It was a pre-requisite that for a potential participant to be accepted into the study the patient should be TB positive. From table 4.1, of the participants who were involved in the study 31.0% were female and 69.0% were male. Of the 35 study females, 14(40.0%) were MDR-TB positive while 21(60.0%) were MDR-TB negative. Some 49(62.8%) of the 78 study males were MDR-TB positive while 29(37.2%) were MDR-TB negative. From the above findings even the frequency of men who were TB positive was more than that of the females.

The majority of the participants were married, with 53.3% being MDR-TB positive. There were few literate participants who were enrolled in the study but the illiterate had the greatest percentage of MDR-TB. Most of the participants in the study were employed and they appear most likely to be infected by MDR-TB.

A smaller portion of the participants who took alcohol were also MDR-TB positive. The greatest MDR – TB infection proportion is in the ranges 15 – 24 and > 65. Most of the participants who were staying in overcrowded places were not infected by MDR-TB.

FIGURE 4.1 PREVALENCE OF MDR – TB WITHIN AGE

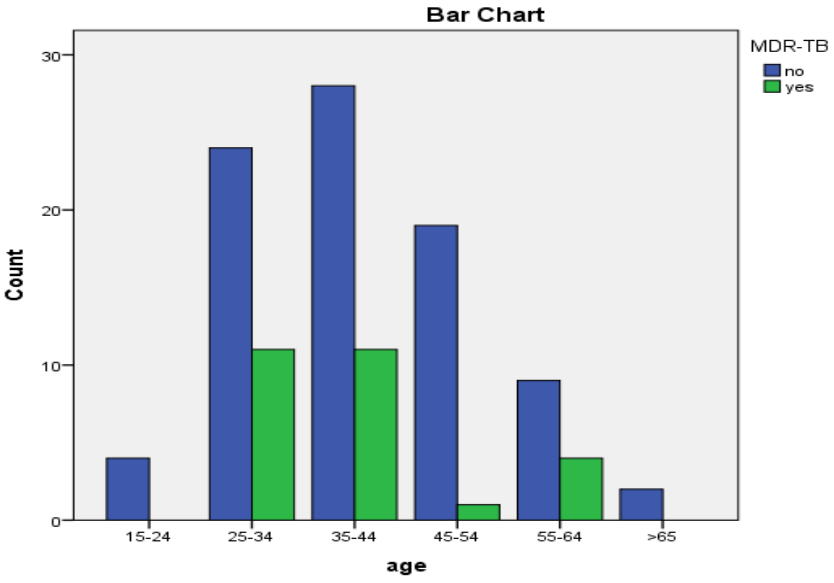

FIGURE 4.2 PREVALENCE OF HIV WITHIN AGE

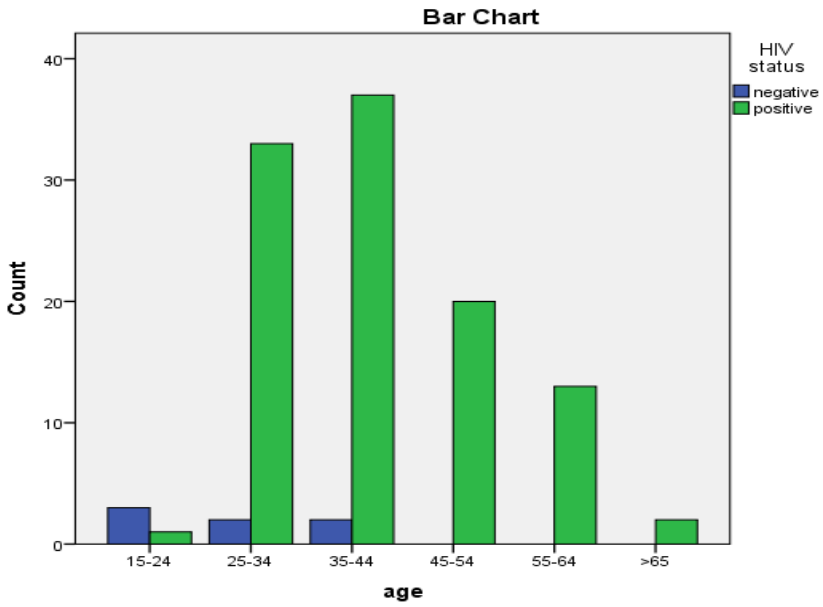

Figure 4.1 shows the prevalence of MDR-TB with age. The graph displays the relationship stated by table 4.1.

Figure 4.2 shows the prevalence of HIV within age.

TABLE 4.2: TREATMENT CHARACTERISTICS OF THE PARTICIPANTS (n=113)

MDR-TB POSITIVE?		NO	YES
PRE EXPOSURE	YES	29 (48.3%)	31 (51.7%)
	NO	21 (39.6%)	32 (60.4%)
WAITING TIME	1HR	16 (48.5%)	17 (51.5%)
	1HR – 2HRS	20 (42.6%)	27 (57.4%)
	>3HRS	14 (42.4%)	19 (57.6%)
DISTANCE TO CLINIC	<5KM	15 (50.0%)	15 (50.0%)
	5KM – 10KM	15 (42.9%)	20 (57.1%)
	11KM – 15KM	7 (33.3%)	14 (66.7%)
	16KM – 20KM	9 (52.9%)	8 (47.1%)
	>20KM	4 (40.0%)	6 (60.0%)
AVAILABILITY OF MEDICATION	ALWAYS	42 (46.2%)	49 (53.8%)
	SOMETIMES	8 (36.4%)	14 (63.6%)
SIDE EFFECTS	NO	34 (69.4%)	15 (30.6%)
`	YES	16 (25.0%)	48 (75.0%)

Table 4.2 outlines the treatment related characteristics of the participants. The proportion of participants that were pre – exposed to TB medication and also had MDR-TB was 51.7% which shows that they had a greater proportion than those who were MDR-TB negative. The participants reported most frequently that the time that they wait for medication at the clinic is between 1hr – 2hrs. Only a few waited for more than 3hrs. Many of the patients stayed between 5km - 10km from the site. 14 of the MDR-TB patients gave the response that they sometimes get the medication at the clinic. While 49 said they always get the medication at the clinic.

All the 48 MDR-TB positive patients reported that they had some side effects caused by the TB medication and non-reported otherwise.

TABLE 4.3 ASSOCIATIONS BETWEEN MDR-TB STATUS AND EXPLANATORY VARIABLES

VARIABLES	P – values
MDR - TB*GENDER	0.040*
MDR - TB*MARITAL STATUS	0.532
MDR - TB*LITERACY	0.000*
MDR - TB*EMPLOYMENT	0.700
MDR - TB*ALCOHOL USE	0.084
MDR - TB*HIV	0.384
MDR - TB*OVERCROWDING	0.121*
MDR - TB*PREEXPOSURE TO DRUGS	0.459
MDR - TB*SMOKING IN PAST 6 MONTHS	0.296
MDR - TB*WAITING TIME	0.844
MDR - TB*DISTANCE TO CLINIC	0.729
MDR - TB*AVAILABILTY OF MEDICATION	0.555
MDR - TB*SIDE EFFECTS	0.000*
MDR - TB*AGE	0.076

Table 4.3 shows association between MDR-TB status and the other variables. The information in the above mentioned table was extracted from the Chi-square test tables (appendix D) and compiled into a single table. The results reveal that there were significant associations between MDR-TB status and each of the following: the participant's gender (p=0.040), literacy (p=0.000) and whether the participant had some side effects (0.000). These variables were retained for more analysis because their p-values were less than 0.05 as per chi-square acceptance rules. This retention meant that all these variables were statistically significant to MDR-TB. The other variables had p-values that were greater than 0.05. This meant that they had no significant difference to MDR-TB.

4.3. LOGISTIC REGRESSION OF MDR-TB STATUS ON EXPLANATORY VARIABLES

After some univariate analysis were performed on the variables more analysis was done using a logistic regression model. In this the variables were entered into SPSS to perform a logistic regression model, the tables below explain the results.

TABLE 4.4 Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
gender(1)	1.572	0.638	5.297	1	0.021	4.815	1.263	18.358
mari			2.406	3	0.492			
mari(1)	-1.158	1.240	0.872	1	0.350	0.314	0.028	3.570
mari(2)	0.360	0.899	0.161	1	0.689	1.434	0.246	8.354
mari(3)	0.653	1.564	0.174	1	0.676	1.921	0.090	41.174
literacy(1)	-20.934	7306.303	0.000	1	0.998	0.000	0.000	.
empl(1)	1.381	0.897	2.372	1	0.124	3.980	0.686	23.082
alcuse(1)	-0.120	0.981	3.632	1	0.047	0.887	0.023	1.055
HIVstatus(1)	1.419	0.608	5.444	1	0.020	4.134	1.255	13.618
ovcrow(1)	-0.690	1.163	0.352	1	0.553	0.501	0.051	4.900
predrugs(1)	2.091	0.638	10.761	1	0.001	8.096	2.321	28.248
SM6(1)	1.905	0.743	6.572	1	0.010	6.722	1.566	28.852
wb4trt			0.684	2	0.710			
wb4trt(1)	0.509	0.861	0.349	1	0.554	1.664	0.308	8.992
wb4trt(2)	0.667	0.843	0.626	1	0.429	1.947	0.373	10.158
D2CLI			3.053	4	0.549			
D2CLI(1)	0.174	0.821	0.045	1	0.832	1.190	0.238	5.944
D2CLI(2)	1.368	1.239	1.219	1	0.270	3.927	0.346	44.519
D2CLI(3)	-0.690	0.951	0.526	1	0.468	0.502	0.078	3.236
D2CLI(4)	0.596	1.084	0.302	1	0.582	1.815	0.217	15.183
availmed(1)	0.038	0.737	0.003	1	0.958	1.039	0.245	4.405
syde(1)	2.043	0.737	7.682	1	0.006	7.716	1.819	32.728
Constant	-0.639	19467.577	0.000	1	1.000	0.528		

Table 4.4 gives information about the contribution or importance of each of MDR-TB predictor variables. The test that was used here is known as the Wald test, and all the value of the statistic for each predictor are shown in the column labelled Wald. Scanning down the column labelled Sig for values less than 0.05, we identify the variables that contribute significantly to the predictive ability of the model. In this case, we have six significant variables (side effects p=0.006, male gender p=0.021, pre-exposure to TB drugs p=0.001, smoking in the past 6 months p=0.010, alcohol

use p=0.047 and HIV status p=0.020). These are the only factors that contributed significantly to this MDR-TB model.

Considering the B values (side effects B=2.043, male gender B=1.572, pre-exposure to TB drugs B=2.091, smoking in the past 6 months B=1.905, alcohol use B=-0.120 and HIV status B=1.419) the table explains about the direction of the relationship (which factors increases the likelihood of a yes answer and which factors decreases it). Negative B values indicate that an increase in the explanatory variable indicator will result in a decreased probability of the case recording a score of yes in the response variable (indicating the presence of MDR-TB in this case). Alcohol use has a negative B value (B=-0.120) this means that there is a small probability of getting a patient who drinks alcohol yet on TB treatment. The positive B values (side effects B=2.043, male gender B=1.572, pre-exposure to TB drugs B=2.091, smoking in the past 6 months B=1.905, alcohol use B=-0.120 and HIV status B=1.419) show that there is great probability of a person being MDR-TB positive if they have indicated a yes to any of the 5 variables.

The other useful piece of information in table 4.4 is provided in the Exp(B) column. These values are the odds ratios (OR) for each of the independent variables. According to Tabachnick and Fidell (2007), the odds ratio represents ‘the change in odds of being in one of the categories of outcome when the value of a predictor increases by one unit’ (p. 461). All the odds that are greater than one are actually a positive increase in the probabilities of yes for MDR-TB. A negative odds shows a more likely no for MDR-TB.

TABLE 4.5 Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	9.544	8	0.298

Chi square goodness of fit was used to check the reliability of the model. Table 4.5 shows the results of the test, if a model has a significance value (less than 0.05) it is said to be a poor model. In this model the chi square value is 9.544 with 0.298 significance which is greater than 0.05 thus showing that the model has a high

predictive ability. Appendix K also supports the strength of the predictive ability of the model.

However no statistical significance was found between MDR-TB and the other remaining factors. Though not significant, the involvement of availability of medication would give credible results, so availability of medication will not be eliminated from the model.

Hosmer (2000) argued that Epidemiologic methodologists suggest including all clinically and intuitively relevant variables in the model, regardless of their statistical significance. Stokes et al (2000) stated that while some analysts might delete any effects that do not meet their designated 0.05 significance level, it is sometimes reasonable to keep modestly suggestive effects in the model to avoid potential bias of estimates.
Based on the explanation the final model can be summarised as

$$\log\left(\frac{\pi_{MDR\,positive}}{\pi_{MDR\,negative}}\right) = -0.639 + 1.572\,gender(1) - 0.120\,alcuse(1) + 1.419\,HIVstatus(1) + 2.091\,predrugs(1) + 1.905\,SM\,6(1) + 2.043\,syde(1)$$

The model proved to have a stronger predictive ability. Appendix G shows that initially the model had an overall predictive ability of 55.8% having a 0.00% for the no MDR-TB cases and 100% yes MDR-TB cases. Appendix L shows that the final model predicted much better with an overall of 84.1 predicting over 80.0% of both no and yes to MDR-TB which is much better than that shown in appendix G. Appendix I shows the amount of variation that is predicted of 65.5%.

4.4. CONCLUSIONS

The chapter showed the results from the analysis of the data using SPSS. This was done by checking the contingency tables for different tests like variable independence, testing for strength and direction and also some binary logistic model was used to develop the statistical model. More information will be explained in chapter 5.

CHAPTER FIVE: CONCLUSIONS AND RECOMMENDATIONS

5.1. INTRODUCTION

This chapter discusses the main findings of the research study, assesses accomplishment of research objectives, questions and hypotheses, and presents a conclusion.

5.2. DISCUSSION

The present study has been one of the very few research endeavours to identify factors and modelling the factors affecting TB treatment in Zimbabwe. The researcher set out to identify factors affecting compliance to TB treatment in the Gweru district of Zimbabwe. Based on the findings, recommendations are then made to the Gweru district management to improve TB treatment compliance.

Data was collected from respondents through structured questionnaires, all of which were then checked for completeness and appropriate cleaning performed. Data was entered into MS Excel spread sheets and later exported to SPSS for analysis. SPSS was used to describe the data and identify significant differences between the compliant and non-compliant groups. Both SPSS and MS Excel were utilized to provide descriptive and graphical summary statistics in the form of bar graphs and cross-tabulations. Chi-square tests of association were conducted to assess dependence relationships among potential factors. The following is a discussion of the findings in line with the study objectives.

The main objectives of this research study were to:

- To determine the risk factors of TB treatment.
- To explain the statistical relationships between the risk factors.
- To have a statistical analysis of the impact of the factors on TB treatment outcomes.
- To build a statistical model of the association of TB treatment and the risk factors. (Using a logistic regression model).

5.2.1. FACTORS AFFECTING COMPLIANCE TO TB TREATMENT

TB treatment non-compliance is recognized as one of the major challenges in achieving TB control. Some of the most often cited factors contributing to non-

compliance in developing countries include TB treatment illiteracy; the impression of being cured once medicines begin to take effect and the patient feeling better; medicinal side effects; economic problems; and transport challenges (Boyle et al 2002). The factors discussed include those that are socio-demographic and economic, as well as those related to the patient (including knowledge of TB disease and treatment), to the health system.

The following factors were found to be statistically significant to MDR-TB. Having some side effects, male gender, pre-exposure to TB drugs, smoking during the treatment period, consumption of alcohol during the treatment period and being HIV positive.

Of the 78 study males 69.0% were MDR-TB positive whereas 31.0% of the study female were positive. These findings show that the TB treatment failure is more in males than in females. Married people had a greater percentage of TB infection over the divorced, the single and widowed. The literate patients (24) were fewer than the illiterate (89) and also the illiterate had high TB treatment failure. The employed had high treatment failure than the unemployed patients. Patients that were taking alcohol were much affected by MDR-TB compared to those who did not take alcohol. HIV positives had their majority being MDR-TB positive, this could be because their immune system got weakened by the HIV virus. All the age groups were affected by MDR-TB but most cases that were register were in the 35-44 group. The patients that lived in overcrowded places were infected by MDR-TB the most. Those who were once pre-exposed to the TB drugs had less MDR-TB cases than those who had not been exposed before.

The more the distance is from the clinic the more likely it is for the patient to be affected by MDR-TB meaning that those who stay far from the clinic could have problems with turning up for medication. Those who had some side effects had a high rate of MDR infection which is evident to say that if a patient has side effects it will be hard for the patient to take the medication.

Statistically significant bivariate associations were revealed between MDR-TB infection and each of the following: side effects p=0.006, male gender p=0.021, pre-exposure to TB drugs p=0.001, smoking in the past 6 months p=0.010, alcohol use

p=0.047 and HIV status p=0.020. The remaining variables showed a statistically non-significant relationship with MDR-TB.

A binary logistic model was built based on the above mentioned factors. The model was tested for the goodness of it and it showed a much stronger predictive power of 84.1%.

5.3. CONCLUSIONS

TB treatment success in Gweru District, of Zimbabwe is associated with side effects that the patient has due to the use of the anti-TB drugs, the male gender, the use of alcohol during the treatment period and the patient's HIV status. One of the important areas for TB control programmes is to improve or enhance TB treatment compliance. This study suggests that more information should be given to the TB patients about the eating of food before they take anti-TB drugs and also they should be discouraged to take alcohol during the treatment period. More focus should be put on the male patients and the HIV positive patients since the study has shown that they are the ones who are more vulnerable.

5.4. LIMITATIONS

The limitations of this study were that it was hard for the RN to make follow up on the patients to monitor their health state. This was because the RN opted voluntarily and did not expect any funding though a token of appreciation was later granted to her.

5.5. RECOMMENDATIONS

Based on the findings from the study, the following recommendations are made:

- Further research is needed to identify more risk factors of TB that diminish TB treatment in Gweru district.

- Further research on non-compliance by respondents on HAART treatment should be conducted on the patients that are TB positive and HIV positive at the same time.

- Both the patients and the community should be educated more about TB treatment in their local languages.

- The initiation of some income generating projects so that some nutritious food will be provided to the TB patients.

- TB clinics should be opened for more hours than usual to cater for the patients' needs.

- More support should be put on the DOTS program for all patients, enabling more patients to be observed by a health worker when taking their medicines.

- Strengthen follow-up of patients who interrupt TB treatment with the consumption of alcohol and smoking as well as those who default the treatment.

- More Nurses should be employed to improve the efficiency of the service delivery at the clinics.

- The involvement of patients in planning strategies that may be used to mitigate TB infection rate.

5.6. SUMMARY

This chapter has discussed the research findings, drawing on the research objectives and the conceptual framework. Some recommendations were highlighted in this section as to how the pandemic in the study can be curbed. To conclude more emphasis should be put on the DOTS program and TB education.

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APPENDIX A: INFORMED CONSENT FORM

Title:

MODELING THE IMPACT OF THE RISK FACTORS AFFECTING TB TREATMENT

Investigator(s) : Professor J.TYLER (040 602 2171)

: Professor Y.QIN (040 602 2162)

: Mr. U. Tsuro (073 956 5963)

PURPOSE OF THE STUDY

The main objective of the study is to explore the statistical methods that can be used to infer the influence of the risk factors on TB treatment. The purpose of the study is to contribute to the monitoring of MDR – TB by selecting appropriate methods.

DESCRIPTION OF THE STUDY

Participants will be provided with a questionnaire and they will be asked to respond to each of the questions in the questionnaire by choosing a preferred response. There is no actual or potential harm on the participants by completing the questionnaire. The only impact of the questionnaire will be using 20 minutes of the participants' time. You may refuse to participate or may withdraw at any time.

POTENTIAL BENEFITS:

The TB research community will be the principal beneficiary

CONFIDENTIALITY:

Confidentiality will be respected and no information that discloses the identity of the participant will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, infectious disease, and expression of suicidal ideas, where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities.

PARTICIPATION:

Participation in research is voluntary. If you choose to participate in this study you may withdraw at any time.

Contact:

If you have any questions about this study, please contact:

Mr Urgent Tsuro

Room 12 Beda Ferguson

Alice 5700

University of Fort Hare
(0027)+27727534672
Email:tsurourg82@gmail.com

CONSENT:

By signing this form, I agree that:

- The study has been explained to me.

  Yes No

- All my questions were answered.

  Yes No

- Possible harm and discomforts and possible benefits (if any) of this study have been explained to me.

  Yes No

- I understand that I have the right not to participate and the right to stop at any time.

  Yes No

- I understand that I may refuse to participate without consequence.

Yes No

- I have a choice of not answering any specific questions.

Yes No

- I am free now, and in the future, to ask any questions about the study.

Yes No

- I have been told that my personal information will be kept confidential.

Yes No

- I understand that no information that would identify me will be released or printed without asking me first.

Yes No

- I understand that I will receive a signed copy of this consent form.

Yes No

I hereby consent to participate in this study:

Name of Participant:

Signature:

Date:

APPENDIX B: Approval letter from University of Fort Hare Ethics Committee

Ethical Clearance Form

OFFICE OF THE DEPUTY VICE-CHANCELLOR:
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University of Fort Hare
Together in Excellence

REC-270510-038

Application for clearance from the University of Fort Hare's Ethics Committee

Project title: MODELING THE IMPACT OF THE RISK FACTORS AFFECTING TB TREATMENT CASE OF GWERU DISTRICT, ISOLATION CLINIC, ZIMBABWE.

Chief Researcher: Tsuro Urgent

Supervisor: Professor Y Qin

Date of application: 09 April 2012

Having consulted the Dean of Research, I hereby grant permission to conduct the research.

Professor J R Midgley
Deputy Vice-Chancellor
Chairperson of the interim Ethics Committee

25 June 2012

APPENDIX C: QUESTIONNAIRE

Individual patient's Questionnaire Number:_____

Date of Interview:_____

Instructions:

ENTER THE OPTION IN THE BOX FOR ALL THE QUESTIONS USING FIGURES FOR THE OPTIONS PROVIDED.

SECTION A: DEMOGRAPHIC INFORMATION

QUE 1 Age in years?	1. (15-24),	
	2. (25-34),	
	3. (35-44),	
	4. (45-54),	
	5. (55-64),	
	6. (> 65)	☐
QUE 2 Gender?	0. Female	
	1. Male	☐
QUE 3 Marital status?	0. Widowed	
	1. Devorced	
	2. Married	
	3. Single	☐
QUE 4 Literacy?	0. Illiterate	
	1. Literate	☐
QUE 5 Overcrowding?	0. Absent	
	1. Present	☐

SOCIO-ECONOMIC FACTORS

QUE 6 What is your employment status?

0. Employed

1. Unemployed ☐

QUE 7 How far do you stay from the clinic?

1. < 5KM

2. 5KM-10KM

3. 11KM-15KM

4. 16KM-20KM

5. > 20KM ☐

PATIENT TREATMENT FACTORS

QUE 8 Do you consume alcohol? 0. No

1. Yes ☐

QUE 9 MTB status? 0. No

1. Yes ☐

QUE 10 HIV status? 0. Negative

1. Positive ☐

QUE 11 Have you defaulted from TB treatment before?

0. No

1. Yes ☐

QUE 12 For how long do you wait at the clinic before you receive treatment?

1. 1HR
2. 1HR-2HRS
3. > 3HRS ☐

QUE 13 Availability of medication?

1. Always
2. Sometimes ☐

QUE 14 Do you have any side effects?

0. No
1. Yes ☐

QUE 15 Do you eat before taking medication?

0. No
1. Yes ☐

APPENDIX D: CROSS TABULATIONS

Gender * MDR-TB

		MDR-TB	
		no	yes
Gender	female	21(60%)	14(40%)
	male	29(37.2%)	49(62.8%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	5.100[a]	1	.024		
Continuity Correction[b]	4.217	1	.040		
Likelihood Ratio	5.097	1	.024		
Fisher's Exact Test				.040	.020
N of Valid Cases	113				

Marital status * MDR-TB

		MDR-TB	
		no	yes
Marital status	widowe	6(30%)	14(70%)
	single	14(50%)	14(50%)
	married	28(46.7%)	32(53.3%)
	divorce	2(40%)	3(60%)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.200[a]	3	.532
Likelihood Ratio	2.261	3	.520
N of Valid Cases	113		

Literacy * MDR-TB

		MDR-TB	
		no	yes
literacy	illiterate	0(0%)	24(100%)
	literate	50(56.2%)	39(43.8%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	24.184[a]	1	.000		
Continuity Correction[b]	21.960	1	.000		
Likelihood Ratio	33.135	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	113				

Employment Status * MDR-TB

		MDR-TB	
		no	yes
employment status	employed	42(45.7%)	50(54.3%)
	unemployed	8(38.1%)	13(61.9%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.396[a]	1	.529		
Continuity Correction[b]	.149	1	.700		
Likelihood Ratio	.400	1	.527		
Fisher's Exact Test				.629	.352
N of Valid Cases	113				

Alcohol use * MDR-TB

		MDR-TB	
		no	yes
alcohol use	no	6(26.1%	17(73.9%)
	yes	44(48.9%)	46(51.8%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.861[a]	1	.049		
Continuity Correction[b]	2.992	1	.084		
Likelihood Ratio	4.028	1	.045		
Fisher's Exact Test				.061	.040
N of Valid Cases	113				

HIV status * MDR-TB

		MDR-TB	
		no	yes
HIV status	negative	15(37.5%)	25(62.5%)
	positive	35(47.9%)	38(52.1%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.143[a]	1	.285		
Continuity Correction[b]	.759	1	.384		
Likelihood Ratio	1.151	1	.283		
Fisher's Exact Test				.326	.192
N of Valid Cases	113				

Overcrowding * MDR-TB

		MDR-TB	
		no	yes
overcrowding	absent	3(21.4%)	11(78.6%)
	present	47(47.5%)	52(52.5%)

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.373[a]	1	.066		
Continuity Correction[b]	2.400	1	.121		
Likelihood Ratio	3.614	1	.057		
Fisher's Exact Test				.087	.058
N of Valid Cases	113				

Pre-exposure to drugs * MDR-TB

		MDR-TB	
		no	yes
pre-exposure	no	21(39.6%)	32(60.4%)
	yes	29(48.3%)	31(51.7%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.866[a]	1	.352		
Continuity Correction[b]	.548	1	.459		
Likelihood Ratio	.867	1	.352		
Fisher's Exact Test				.448	.230
N of Valid Cases	113				

Smoking in 6 months * MDR-TB

		MDR-TB	
		no	yes
smok in 6	no	19(52.8%	17(47.2%)
	yes	31(40.3%)	46(59.7%)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.558[a]	1	.212		
Continuity Correction[b]	1.092	1	.296		
Likelihood Ratio	1.553	1	.213		
Fisher's Exact Test				.229	.148
N of Valid Cases	113				

Waiting time * MDR-TB

		MDR-TB	
		no	yes
waiting time	<1hr	16(48.5%)	17(51.5%)
	1-2hrs	20(42.6%)	27(57.4%)
	>2hrs	14(42.4%)	19(57.6%)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	.339[a]	2	.844
Likelihood Ratio	.338	2	.844
N of Valid Cases	113		

Distance to clinic * MDR-TB

		MDR-TB	
		no	yes
Distance to the clinic	<5Km	15(50%)	15(50%)
	5-10Km	15(42.9%)	20(57.1%)
	11-15Km	7(33.3%)	14(66.7%)
	16-20Km	9(52.9%)	8(47.1%)
	>20Km	4(40%)	6(60%)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.038[a]	4	.729
Likelihood Ratio	2.058	4	.725
N of Valid Cases	113		

Availability of med * MDR-TB

		MDR-TB	
		no	yes
availability of med	always	42(46.2%)	49(53.8%)
	sometimes	8(36.4%)	14(63.6%)

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.688[a]	1	.407		
Continuity Correction[b]	.349	1	.555		
Likelihood Ratio	.697	1	.404		
Fisher's Exact Test				.478	.279
N of Valid Cases	113				

Side effects * MDR-TB

		MDR-TB	
		no	yes
side effects	no	34(69.4%)	15(30.6%)
	yes	16(25%)	48(75%)

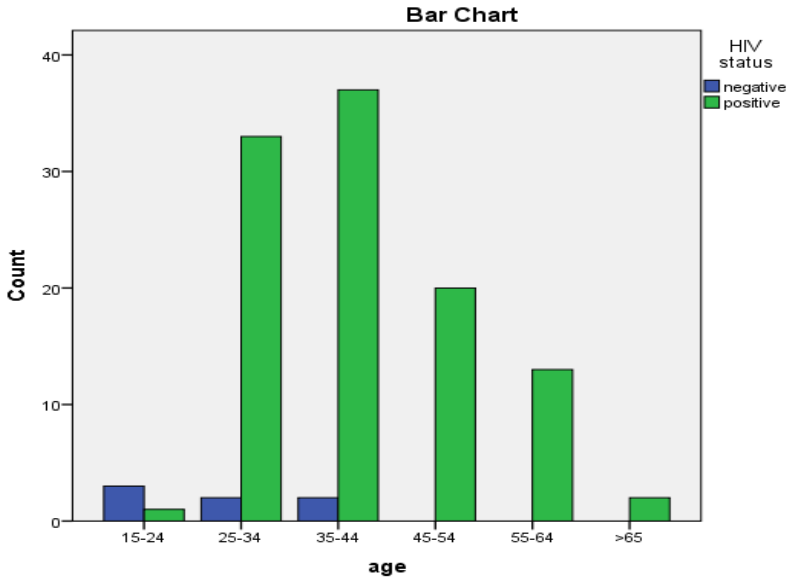
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	22.165[a]	1	.000		
Continuity Correction[b]	20.402	1	.000		
Likelihood Ratio	22.809	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	113				

Age * MDR-TB

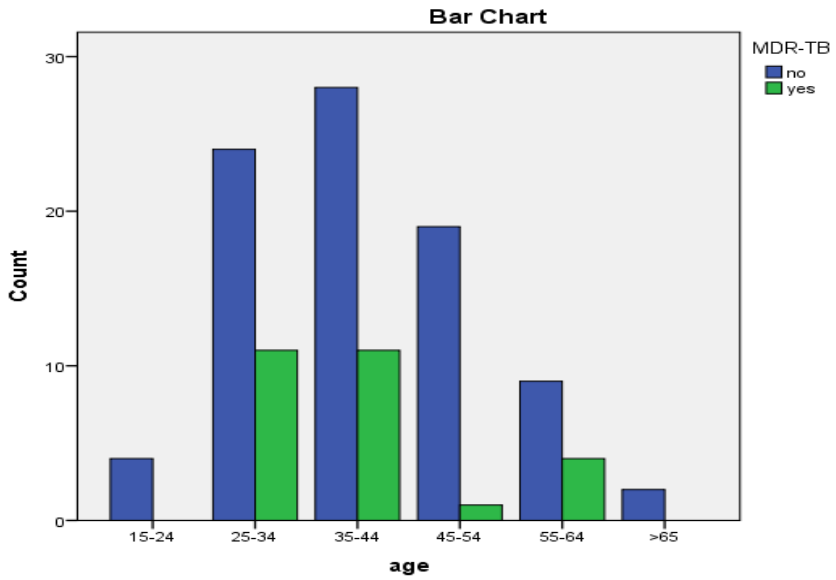
		MDR-TB	
		no	yes
age	15-24	4(100%)	0(0%)
	24-34	15(42.9%)	20(57.1%)
	35-44	13(33.3%)	26(66.7%)
	45-54	9(45%)	11(55%)
	55-64	7(53.8%)	6(46.2%)
	>65	2(100%)	0(0%)

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	9.961[a]	5	.076
Likelihood Ratio	12.230	5	.032
N of Valid Cases	113		

APPENDIX E: PREVALENCE OF MDR – TB WITHIN AGE



APPENDIX F: PREVALENCE OF HIV WITHIN AGE



APPENDIX G: Beginning Block

		Observed	Predicted		
			MDR-TB		Percentage Correct
			0	1	
Step 0	MDR-TB	0	0	50	.0
		1	0	63	100.0
	Overall Percentage				55.8

APPENDIX H: Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	75.919	24	.000
	Block	75.919	24	.000
	Model	75.919	24	.000

APPENDIX I: Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	79.233[a]	.489	.655

APPENDIX J: Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	9.544	8	.298

APPENDIX K:Contingency Table for Hosmer and Lemeshow Test

		MDR-TB = 0		MDR-TB = 1		Total
		Observed	Expected	Observed	Expected	
Step 1	1	10	10.867	1	.133	11
	2	11	10.078	0	.922	11
	3	9	8.808	2	2.192	11
	4	7	7.385	4	3.615	11
	5	6	5.389	5	5.611	11
	6	3	4.127	8	6.873	11
	7	4	2.499	7	8.501	11
	8	0	.821	11	10.179	11
	9	0	.027	11	10.973	11
	10	0	.000	14	14.000	14

APPENDIX L:Classification Table

	Observed		Predicted		
			MDR-TB		Percentage Correct
			0	1	
Step 1	MDR-TB	0	40	10	80.0
		1	8	55	87.3
	Overall Percentage				84.1

APPENDIX M: Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
gender(1)	1.572	0.638	5.297	1	0.021	4.815	1.263	18.358
mari			2.406	3	0.492			
mari(1)	-1.158	1.240	0.872	1	0.350	0.314	0.028	3.570
mari(2)	0.360	0.899	0.161	1	0.689	1.434	0.246	8.354
mari(3)	0.653	1.564	0.174	1	0.676	1.921	0.090	41.174
literacy(1)	-20.934	7306.303	0.000	1	0.998	0.000	0.000	.
empl(1)	1.381	0.897	2.372	1	0.124	3.980	0.686	23.082
alcuse(1)	-0.120	0.981	3.632	1	0.047	0.887	0.023	1.055
HIVstatus(1)	1.419	0.608	5.444	1	0.020	4.134	1.255	13.618
ovcrow(1)	-0.690	1.163	0.352	1	0.553	0.501	0.051	4.900
predrugs(1)	2.091	0.638	10.761	1	0.001	8.096	2.321	28.248
SM6(1)	1.905	0.743	6.572	1	0.010	6.722	1.566	28.852
wb4trt			0.684	2	0.710			
wb4trt(1)	0.509	0.861	0.349	1	0.554	1.664	0.308	8.992
wb4trt(2)	0.667	0.843	0.626	1	0.429	1.947	0.373	10.158
D2CLI			3.053	4	0.549			
D2CLI(1)	0.174	0.821	0.045	1	0.832	1.190	0.238	5.944
D2CLI(2)	1.368	1.239	1.219	1	0.270	3.927	0.346	44.519
D2CLI(3)	-0.690	0.951	0.526	1	0.468	0.502	0.078	3.236
D2CLI(4)	0.596	1.084	0.302	1	0.582	1.815	0.217	15.183
availmed(1)	0.038	0.737	0.003	1	0.958	1.039	0.245	4.405
syde(1)	2.043	0.737	7.682	1	0.006	7.716	1.819	32.728
Constant	-0.639	19467.577	0.000	1	1.000	0.528		

APPENDIX N:CODE BOOK

VARIABLE NAME	VARIABLE DISCRIPTION AND CODING
Gender	Gender (0=Female; 1=Male).
Mari	Marital status (0=Widowed; 1= Single; 2=Married; 3= Divorced).
Literacy	Literacy (0= illiterate; 1= Literate).
Empl	Employment status (0= employed; 1= unemployed).
Alcuse	Alcohol use (0=no; 1= yes).
HIV status	HIV status (0= negative; 1= positive).
Ovcrow	Overcrowding (0= absent; 1= present).
Predrugs	Pre-exposure to TB drugs (0= no; 1= yes).
SM6	Smoking in six months (0= no; 1= yes).
Wb4trt	Waiting time (in hours) before treatment (1= <1hr; 2= 1-2hrs; 3=>2hrs).
D2CLI	Distance (in Km) to the clinic (1<5Km; 2=5-10Km; 3=11-15Km; 4=16-20Km; 5=>20Km).
Availmed	Availability of medication (0= Always; 1= Sometimes)
Syde	Side effects (0=no; 1= yes).

Age	Age in years (1=15-24; 2=25-34; 3=35-44; 4=45-54; 5=55-64; 6=>65).
MDRTB	Multi-Drug Resistant TB status (0=no; 1= yes).